

REGISTRATION REPORT
Part B
Section 3
Efficacy Data and Information
Concise summary

Product code: CA3301
Product name(s): JOUST
Chemical active substance:
Prothioconazole, 250 g/L

Central Zone
Zonal Rapporteur Member State: Poland

CORE ASSESSMENT (New Authorization)

Applicant: Nufarm Polska Sp. z o. o.
Submission date: 23/12/2021, updated 02/2024
MS Finalisation date: September 2022 (initial Core Assessment)
December 2022, updated May 2023 (final Core Assessment)
April 2024 (extension of use), June 2024 (final Core Assessment)

Version history

When	What
December 2021	First submission
July 2022	Update on the GAP following the request from German BVL (country specific)
September 2022	Submission of 5 additional efficacy trials to support the registration of product in Poland
September 2022	Initial zRMS assessment The report in the dRR format has prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency.
December 2022	Final report (Core Assessment updated following the commenting period). Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Information no longer relevant is struck through and shaded.
May 2023	Update resulting from re-analysis of submitted data for Poland (all changes are highlighted in blue).
February 2023	Major uses extension art. 45 by Applicant (highlighted in green).
April 2024	zRMS assessment after extension of use (USE No. 37 <i>Oculimacula acuformis</i> (PSDCHA) in winter wheat in Poland) Additional information/assessments included by the zRMS in the report are highlighted in pink. Not agreed or not relevant information are struck through and shaded for transparency.
June 2024	Final report (Core Assessment updated following the commenting period) No additional information or assessments after the commenting period.

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3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)

Transformation of the dRR (applicant version) into the RR (zRMS version)

Comments of zRMS:

Conclusions from the assessment were prepared using grey commenting boxes placed at the end of each chapter. Textual changes were done using grey highlights in the text. The parts of the text amended or added by the zRMS evaluator are highlighted in grey, whereas the parts struck off are ~~visibly marked with the grey font.~~

3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

Abstract of the evaluation, by the cMS PL:

This application has been submitted for the authorization of new product CA3301/JOUST in Poland, Austria, Belgium, Czech Republic, Germany, Hungary, Ireland, Netherlands, Luxemburg, Romania and Slovakia. CA3301 contains one active substance: prothioconazole (250 g/l). This product is intended to use as a fungicide for protection of wheat, durum wheat, spelt, triticale, rye, oat, barley, oilseed rape and minor crops against disease pathogens.

MED

The trial results submitted for determine minimum effective dose to control of disease pathogens showed that CA3301 at 0,6 l/ha is justified as MED in winter wheat, durum wheat, winter triticale, winter and spring barley, winter rye and winter oilseed rape. However, it should be noted that the higher dose rate of 0,7 l/ha (in case of winter oilseed rape) or 0,8 l/ha (wheat, durum, triticale, rye) will be justified in more challenging conditions (i.a. high disease pressure). A detailed assessment is included in the chapter 3.2.2.

Efficacy

Based on the submitted trial results, it can be concluded that CA3301 used twice per vegetative season is effective to control of SEPTTR, PUCCRT, PUC CST, ERYSGR, FUSASP, PYRNTR, PSDCHA in winter wheat, ERYSGT in durum wheat, RHYNSE, PUCCRE/PUCRR in winter rye, SEPTTR, ERYSGR, FUSASP, PUCCRE, PUC CST in winter triticale, SCLESC, ALTEBA, LEPTMA, ERYSCR in winter oilseed rape, RAMUCC, PUCCHD, RHYNSE, PYRNTE in winter and spring barley, respectively to the EPPO climatic zones. Furthermore, effectiveness of single application was assessed only for several pathogens in winter wheat and winter oilseed rape. According to the applicant explanation, trials were designed to test applications as preventative usage as well as some with curative applications. The infestation before first application was very low (<5%) and only some trials demonstrated that a single application significantly reduced disease severity and provided control generally comparable to authorised reference products. In the zRMS opinion, the limited assessment of the effectiveness of a single application results in uncertainty as its intervention use. Taking into account submitted trial results, only preventive use of single application is proposed in this situation. This solution has been accepted in Poland. However, the cMSs are kindly asked to consider this propose on the national level. A detailed assessment is included in the chapter 3.2.3.

Selectivity

No negative symptoms were observed after application of CA3301 in winter barley, spring barley, spring oat, winter wheat, durum wheat, winter tritical and winter rye in all EPPO zones. The minor stunting and discoloration was noted on winter oilseed rape after twice application (autumn/spring) at dose rate of 0,7 l/ha in the Maritime EPPO climatic zone. All symptoms were transient and disappeared at later assessment. Furthermore, the trial results showed volume reduction after twice spring application at dose rate of 0,6 l/ha in the North-East EPPO zone. Overall, it can be considered that CA3301 is safe for cereal crops but it should be

noted that can cause some transient phytotoxicity symptoms (stunting, discoloration, volume reduction) on winter oilseed rape.

Resistance risk

To reduce the risk of resistance to DMI-fungicides (FRAC Group 3), resistance management strategy is necessary including: limited number and appropriate time of applications, recommended dose rate and alternating use of different MoA's. A detailed assessment is included in the chapter 3.3.

Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)

		GAP rev. 2 December 2022 <small>↓, date:</small> 2022-09	
PPP (product name/code):	JOUST / CA3301	Formulation type:	EC ^(a, b)
Active substance 1:	Prothioconazole	Conc. of as 1:	250 g/L ^(c)
Active substance.....:	NA	Conc. of as:	NA ^(c)
Safener:	NA	Conc. of safener:	NA ^(c)
Synergist:	NA	Conc. of synergist:	NA ^(c)
Applicant:	Nufarm	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	Central	Non professional use:	<input type="checkbox"/>
Verified by MS:	Yes		
Field of use:	Fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1.	BE	Barley winter	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6 b) 1.2	a) 150 b) 300	100- 400	35		<div>A RAMUCC PUCCHD RHYNSE PYRNTE</div> <div>C PSDCHA ERYSGR FUSASP</div> <div>Single application for all pathogens</div>
2.	CZ	Barley winter	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Brown Rust <i>Puccinia hordei</i> (PUCCHD)	foliar spray	BBCH 30 – 61 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6 b) 1.2	a) 150 b) 300	100- 400	35		<div>A RAMUCC PUCCHD RHYNSE PYRNTE</div>

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
				Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)										C PSDCHA ERYSGR FUSASP Single application for all pathogens
3.	DE	Barley winter Barley spring	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Oculimacula acutiformis</i> (PSDCHA) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) <i>Fusarium ear blight</i> <i>Fusarium spp.</i> (FUSASP) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6 b) 1.2	a) 150 b) 300	150- 400	35		A RAMUCC PUCCHD RHYNSE PYRNTE ERYSGR
														C PSDCHA ERYSGR Single application for all pathogens
113.	DE	Barley winter	F	Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)	Foliar spray	BBCH 61	a) 1 b) 2		a) 0.6 b) 1.2	a) 150 b) 300	150- 400	35		C
114.	DE	Barley win- ter, Barley sprng	F	<i>Pseudocercospora herpotrich- oides</i> (PSDCHE)	Foliar spray	BBCH 30-32	a) 1 b) 2		a) 0.6 b) 1.2	a) 150 b) 300	150- 400	35		C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
4.	HU	Barley winter	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6 b) 1.2	a) 150 b) 300	100- 400	35		<div>A RAMUCC PUCCHD RHYNSE PYRNTE</div> <div>C PSDCHA ERYSGR FUSASP</div> <div>Single application for all pathogens</div>
5.	IE	Barley winter	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6 b) 1.2	a) 150 b) 300	100- 400	35		<div>A RAMUCC PUCCHD RHYNSE PYRNTE</div> <div>C PSDCHA ERYSGR FUSASP</div> <div>Single application for all pathogens</div>

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
6.	LU	Barley winter	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6 b) 1.2	a) 150 b) 300	100- 400	35		<div>A RAMUCC PUCCHD RHYNSE PYRNTE</div> <div>C PSDCHA ERYSGR FUSASP</div> <div>Single application for all pathogens</div>
7.	NL	Barley winter	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6 b) 1.2	a) 150 b) 300	100- 400	35		<div>A RAMUCC PUCCHD RHYNSE PYRNTE</div> <div>C PSDCHA ERYSGR FUSASP</div> <div>Single application for all pathogens</div>

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
8.	PL	Barley winter	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6 b) 1.2	a) 150 b) 300	100- 400	35		<div>A RAMUCC PUCCHD ERYSGR RHYNSE PYRNTE</div> <div>N PSDCHA FUSASP</div>
9.	RO	Barley winter	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6 b) 1.2	a) 150 b) 300	100- 400	35		<div>A RAMUCC PUCCHD RHYNSE PYRNTE</div> <div>C PSDCHA ERYSGR FUSASP Single application for all pathogens</div>

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
10.	SK	Barley winter	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6 b) 1.2	a) 150 b) 300	100- 400	35		<div>A RAMUCC PUCCHD RHYNSE PYRNTE</div> <div>C PSDCHA ERYSGR FUSASP</div> <div>Single application for all pathogens</div>
11.	BE	Barley spring	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61	a) 1-2 b) 1-2	14 - 21	a) 0.6 b) 1.2	a) 150 b) 300	100- 400	35		<div>A RAMUCC PYRNTE</div> <div>C PSDCHA PUCCHD ERYSGR RHYNSE</div> <div>Single application for all pathogens</div>

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
12.	CZ	Barley spring	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61	a) 1-2 b) 1-2	14 - 21	a) 0.6 b) 1.2	a) 150 b) 300	100- 400	35		A RAMUCC PYRNTE
														C PSDCHA PUCCHD ERYSGR RHYNSE Single application for all pathogens
13.	HU	Barley spring	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61	a) 1-2 b) 1-2	14 - 21	a) 0.6 b) 1.2	a) 150 b) 300	100- 400	35		A RHYNSE PYRNTE
														C RAMUCC PSDCHA PUCCHD ERYSGR Single application for all pathogens

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
14.	IE	Barley spring	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61	a) 1-2 b) 1-2	14 - 21	a) 0.6 b) 1.2	a) 150 b) 300	100- 400	35		<div>A RAMUCC PYRNTE</div> <div>C PSDCHA PUCCHD ERYSGR RHYNSE</div> <div>Single application for all pathogens</div>
15.	LU	Barley spring	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61	a) 1-2 b) 1-2	14 - 21	a) 0.6 b) 1.2	a) 150 b) 300	100- 400	35		<div>A RAMUCC PYRNTE</div> <div>C PSDCHA PUCCHD ERYSGR RHYNSE</div> <div>Single application for all pathogens</div>

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
16.	NL	Barley spring	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61	a) 1-2 b) 1-2	14 - 21	a) 0.6 b) 1.2	a) 150 b) 300	100- 400	35		<div>A RAMUCC PYRNTE</div> <div>C PSDCHA PUCCHD ERYSGR RHYNSE</div> <div>Single application for all pathogens</div>
17.	PL	Barley spring	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61	a) 1-2 b) 1-2	14 - 21	a) 0.6 b) 1.2	a) 150 b) 300	100- 400	35		<div>A RAMUCC PUCCHD ERYSGR RHYNSE PYRNTE</div> <div>N PSDCHA possible authorization based on the art. 51 - minor uses</div>

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
18.	RO	Barley spring	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61	a) 1-2 b) 1-2	14 - 21	a) 0.6 b) 1.2	a) 150 b) 300	100- 400	35		A RHYNSE PYRNTE
														C RAMUCC PSDCHA PUCCHD ERYSGR Single application for all pathogens
19.	SK	Barley spring	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61	a) 1-2 b) 1-2	14 - 21	a) 0.6 b) 1.2	a) 150 b) 300	100- 400	35		A RHYNSE PYRNTE
														C RAMUCC PSDCHA PUCCHD ERYSGR Single application for all pathogens

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
20.	BE	Oat (winter & spring)	F	Crown Rust <i>Puccinia coronata</i> (PUCCCO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Oculimacula acuformis</i> (PSDCHA)	foliar spray	BBCH 30 – 61 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6 b) 1.2	a) 150 b) 300	100- 400	35		C
21.	CZ	Oat (winter & spring)	F	Crown Rust <i>Puccinia coronata</i> (PUCCCO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Oculimacula acuformis</i> (PSDCHA)	foliar spray	BBCH 30 – 61 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6 b) 1.2	a) 150 b) 300	100- 400	35		C
22.	DE	Oat (winter & spring)	F	Crown Rust <i>Puccinia coronata</i> (PUCCCO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR)	foliar spray	BBCH 30 – 61 (Spring)	a) 2 b) 2	14 - 21	a) 0.6 b) 1.2	a) 150 b) 300	150- 400	35		C
115.	DE	Oat (winter & spring)	F	<i>Pseudocercospora herpotrich- oides</i> (PSDCHE)	Foliar spray	BBCH 30-32 (spring)	a) 1 b) 2		a) 0.6 b) 1.2	a) 150 b) 300	150- 400	35		C
23.	HU	Oat (winter & spring)	F	Crown Rust <i>Puccinia coronata</i> (PUCCCO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Oculimacula acuformis</i> (PSDCHA)	foliar spray	BBCH 30 – 61 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6 b) 1.2	a) 150 b) 300	100- 400	35		C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
24.	IE	Oat (winter & spring)	F	Crown Rust <i>Puccinia coronata</i> (PUCCCO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Oculimacula acuformis</i> (PSDCHA)	foliar spray	BBCH 30 – 61 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6 b) 1.2	a) 150 b) 300	100- 400	35		C
25.	LU	Oat (winter & spring)	F	Crown Rust <i>Puccinia coronata</i> (PUCCCO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Oculimacula acuformis</i> (PSDCHA)	foliar spray	BBCH 30 – 61 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6 b) 1.2	a) 150 b) 300	100- 400	35		C
26.	NL	Oat (winter & spring)	F	Crown Rust <i>Puccinia coronata</i> (PUCCCO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Oculimacula acuformis</i> (PSDCHA)	foliar spray	BBCH 30 – 61 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6 b) 1.2	a) 150 b) 300	100- 400	35		C
27.	PL	Oat (winter & spring)	F	Crown Rust <i>Puccinia coronata</i> (PUCCCO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Oculimacula acuformis</i> (PSDCHA)	foliar spray	BBCH 30 – 61 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6 b) 1.2	a) 150 b) 300	100- 400	35		N

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
28.	RO	Oat (winter & spring)	F	Crown Rust <i>Puccinia coronata</i> (PUCCCO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Oculimacula acuformis</i> (PSDCHA)	foliar spray	BBCH 30 – 61 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6 b) 1.2	a) 150 b) 300	100- 400	35		C
29.	SK	Oat (winter & spring)	F	Crown Rust <i>Puccinia coronata</i> (PUCCCO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Oculimacula acuformis</i> (PSDCHA)	foliar spray	BBCH 30 – 61 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6 b) 1.2	a) 150 b) 300	100- 400	35		C
30.	BE	Wheat (win- ter & spring) Spelt Einkorn wheat Emmer Wheat	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		A SEPTTR PUCCRT PUCST ERYSGR

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
		Tritordeum		Yellow Rust <i>Puccinia striiformis</i> (PUCST) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Tan Spot <i>Pyrenophora tritici-repentis</i> (PYRNTR) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)										C LEPTNO PSDCHA PYRNTR FUSASP All pathogens in Wheat spring, Spelt, Einkorn, Emmer and Tritordeum Single application for all pathogens
31.	CZ	Wheat (win- ter & spring) Spelt Einkorn wheat Emmer Wheat	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		A SEPTTR PUCCRT PUCST ERYSGR

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
		Tritordeum		Yellow Rust <i>Puccinia striiformis</i> (PUCST) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Tan Spot <i>Pyrenophora tritici-repentis</i> (PYRNTR) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)										C LEPTNO PSDCHA PYRNTR FUSASP All pathogens in Wheat spring, Spelt, Einkorn, Emmer and Tritordeum Single application for all uses
32.	DE	Wheat (win- ter & spring) (within the group of wheat in- cluded: spelt, einkorn wheat, em- mer wheat, durum wheat) Tritordeum	F	Septoria leaf spot <i>Septoria tritici</i> (SEPTTR) Glume blotch <i>Septoria nodorum</i> (LEPTNO) Brown Rust <i>Puccinia recondite f. sp. tritici</i> (PUCCRT) Yellow Rust <i>Puccinia striiformis</i> (PUCST) Powdery mildew <i>Erysiphe graminis</i> (ERYSGR) Tan Spot <i>Drechslera tritici-repentis</i> (PYRNTR)	foliar spray	BBCH 30 – 69 (Spring)	a) 2 b) 2	14 - 21	a) 0.8 b) 1.6	a) 200 b) 400	150- 400	35		A SEPTTR PUCCRT PUCST ERYSGR C LEPTNO PYRNTR All pathogens in Wheat spring, Spelt, Einkorn, Emmer and Tritordeum Single application for all uses
116.	DE	Wheat (win- ter & spring) Tritordeum	F	Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)	Foliar spray	BBCH 61-69	a) 1 b) 2		a) 0.8 b) 1.6	a) 200 b) 400	150- 400	35		A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
117.	DE	Wheat (win- ter & spring) Tritordeum	F	<i>Pseudocercospora herpotrich- oides</i> (PSDCHE)	Foliar spray	BBCH 30-32	a) 1 b) 2		a) 0.8 b) 1.6	a) 200 b) 400	150- 400	35		C
33.	HU	Wheat (win- ter & spring) Spelt Einkorn wheat Emmer Wheat Tritordeum	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Yellow Rust <i>Puccinia striiformis</i> (PUC CST) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Tan Spot <i>Pyrenophora tritici-repentis</i> (PYRNTR) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		<div>A SEPTTR PUC CRT ERYSGR FUSASP</div> <div>C LEPTNO PUC CST PSDCHA PYRNTR</div> <div>All pathogens in Wheat spring, Spelt, Einkorn, Emmer and Tritordeum</div> <div>Single application for all uses</div>

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
34.	IE	Wheat (win- ter & spring) Spelt Einkorn wheat Emmer Wheat Tritordeum	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Yellow Rust <i>Puccinia striiformis</i> (PUCGST) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Oculimacula acufiformis</i> (PSDCHA) Tan Spot <i>Pyrenophora tritici-repentis</i> (PYRNTR) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		<div>A</div> <div>SEPTTR PUCCRT PUCGST ERYSGR</div> <div>C</div> <div>LEPTNO PSDCHA PYRNTR FUSASP</div> <div>All pathogens in Wheat spring, Spelt, Einkorn, Emmer and Tritordeum</div> <div>Single application for all uses</div>

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
35.	LU	Wheat (win- ter & spring) Spelt Einkorn wheat Emmer Wheat Tritordeum	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Yellow Rust <i>Puccinia striiformis</i> (PUCGST) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Oculimacula acufiformis</i> (PSDCHA) Tan Spot <i>Pyrenophora tritici-repentis</i> (PYRNTR) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		<div>A</div> <div>SEPTTR PUCCRT PUCGST ERYSGR</div> <div>C</div> <div>LEPTNO PSDCHA PYRNTR FUSASP</div> <div>All pathogens in Wheat spring, Spelt, Einkorn, Emmer and Tritordeum</div> <div>Single application for all uses</div>
36.	NL	Wheat (win- ter & spring) Spelt Einkorn wheat Emmer Wheat	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		<div>A</div> <div>SEPTTR PUCCRT PUCGST ERYSGR</div>

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
		Tritordeum		Yellow Rust <i>Puccinia striiformis</i> (PUCST) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Tan Spot <i>Pyrenophora tritici-repentis</i> (PYRNTR) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)										C LEPTNO PSDCHA PYRNTR FUSASP All pathogens in Wheat spring, Spelt, Einkorn, Emmer and Tritordeum Single application for all uses
37.	PL	Wheat (win- ter & spring) Spelt Einkorn wheat Emmer Wheat	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35	Only for PSDCHA: BBCH 30-32 Recommended dose rate: 0,8 l/ha	A SEPTTR PUCCRT ERYSGR PYRNTR FUSASP PSDCHA (winter wheat)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
		Tritordeum		Yellow Rust <i>Puccinia striiformis</i> (PUCST) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Oculimacula acufiformis</i> (PSDCHA) Tan Spot <i>Pyrenophora tritici-repentis</i> (PYRNTR) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)										N LEPTNO PUCST PSDCHA All pathogens in Wheat spring, Spelt, Einkorn, Emmer and Tritordeum possible authorization based on the art. 51 - minor uses for spelt, einkorn, emmer and tri- tordeum
38.	RO	Wheat (win- ter & spring) Spelt Einkorn wheat Emmer Wheat	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		A SEPTTR PUCCRT ERYSGR FUSASP

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fn, G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
		Tritordeum		Yellow Rust <i>Puccinia striiformis</i> (PUCST) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Tan Spot <i>Pyrenophora tritici-repentis</i> (PYRNTR) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)										C LEPTNO PUCST PSDCHA PYRNTR All pathogens in Wheat spring, Spelt, Einkorn, Emmer and Tritordeum Single application for all uses
39.	SK	Wheat (win- ter & spring) Spelt Einkorn wheat Emmer Wheat	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		A SEPTTR PUCCRT ERYSGR FUSASP

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
		Tritordeum		Yellow Rust <i>Puccinia striiformis</i> (PUCST) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Tan Spot <i>Pyrenophora tritici-repentis</i> (PYRNTR) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)										C LEPTNO PUCST PSDCHA PYRNTR All pathogens in Wheat spring, Spelt, Einkorn, Emmer and Tritordeum Single application for all uses
40.	BE	Durum Wheat	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		C
41.	CZ	Durum Wheat	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
42.	HU	Durum Wheat	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		C
43.	IE	Durum Wheat	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		C
44.	LU	Durum Wheat	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
45.	NL	Durum Wheat	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		C
46.	PL	Durum Wheat	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		<div>A ERYSGR</div> <div>N SEPTTR, PUCCRT, FUSASP possible authorization based on the art. 51 - minor uses</div>
47.	RO	Durum Wheat	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
48.	SK	Durum Wheat	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		C
49.	BE	Triticale (winter & spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondite</i> <i>Puccinia tritici</i> (PUCCRT) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Yellow Rust <i>Puccinia striiformis</i> (PUCGST) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
50.	CZ	Triticale & (winter spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondite</i> <i>Puccinia tritici</i> (PUCCRT) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Yellow Rust <i>Puccinia striiformis</i> (PUCCST) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		C
51.	DE	Triticale & (winter spring)	F	Septoria leaf spot <i>Septoria tritici</i> (SEPTTR) Brown Rust <i>Puccinia recondite f. sp. tritici</i> (PUCCRT) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Yellow Rust <i>Puccinia striiformis</i> (PUCCST) Glume blotch <i>Septoria nodorum</i> (LEPTNO) Powdery mildew <i>Erysiphe graminis</i> (ERYSGR)	foliar spray	BBCH 30 – 69 (Spring)	a) 2 b) 2	14 - 21	a) 0.8 b) 1.6	a) 200 b) 400	150- 400	35		<div>A PUCCRT, ERYSGR</div> <div>C SEPTTR, RHYNSE, PUCCST, LEPTNO</div>

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
118.	DE	Triticale (winter & spring)	F	Fusarium ear blight <i>Fusarium</i> spp. (FUSASP)	Foliar spray	BBCH 61-69 (spring)	a) 1 b) 2		a) 0.8 b) 1.6	a) 200 b) 400	150- 400	35		A
52.	HU	Triticale (winter & spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondite</i> <i>Puccinia tritici</i> (PUCCRT) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Yellow Rust <i>Puccinia striiformis</i> (PUC CST) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Fusarium ear blight <i>Fusarium</i> spp. (FUSASP)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
53.	IE	Triticale (winter & spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondite</i> <i>Puccinia tritici</i> (PUCCRT) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Yellow Rust <i>Puccinia striiformis</i> (PUCST) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
54.	LU	Triticale (winter & spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondite</i> <i>Puccinia tritici</i> (PUCCRT) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Yellow Rust <i>Puccinia striiformis</i> (PUCST) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
55.	NL	Triticale & (winter spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondite</i> <i>Puccinia tritici</i> (PUCCRT) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Yellow Rust <i>Puccinia striiformis</i> (PUCGST) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		C
56.	PL	Triticale & (winter spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondite</i> <i>Puccinia tritici</i> (PUCCRT) Leaf blotch	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		A SEPTTR PUCCRT ERYSGR FUSASP

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
				<i>Rhynchosporium secalis</i> (RHYNSE) Yellow Rust <i>Puccinia striiformis</i> (PUCCST) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)										N RHYNSE PUCCST LEPTNO All pathogens in spring triticale possible authorization based on the art. 51 - minor uses for PUCCST
57.	RO	Triticale & (winter spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondite</i> <i>Puccinia tritici</i> (PUCCRT) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Yellow Rust <i>Puccinia striiformis</i> (PUCCST) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fn, G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
58.	SK	Triticale (winter & spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondite</i> <i>Puccinia tritici</i> (PUCCRT) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Yellow Rust <i>Puccinia striiformis</i> (PUCST) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		C
59.	BE	Rye (winter & spring),	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Crown Rust <i>Puccinia coronata</i> (PUCCCO) <i>Puccinia recondita</i> (PUCCRE/PUCCRR) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Powdery mildew <i>Blumeria graminis</i> (ERYSGR)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		<div>A PUCCRE/PUCCRR</div> <div>C SEPTTR, RHYNSE, PSDCHA, ERYSGR</div>

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
60.	CZ	Rye (winter & spring),	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Crown Rust <i>Puccinia coronata</i> (PUCCCO) <i>Puccinia recondita</i> (PUCCRE/PUCCRR) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Powdery mildew <i>Blumeria graminis</i> (ERYSGR)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		A PUCCRE/PUCCRR
														C SEPTTR, RHYNSE, PSDCHA, ERYSGR
61.	DE	Rye (winter & spring),	F	Septoria leaf spot <i>Septoria tritici</i> (SEPTTR) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Crown Rust <i>Puccinia coronata</i> (PUCCCO) <i>Puccinia recondita</i> (PUCCRE/PUCCRR) Powdery mildew <i>Erysiphe graminis</i> (ERYSGR)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.8 b) 1.6	a) 200 b) 400	150- 400	35		A PUCCRE/PUCCRR RHYNSE
														C SEPTTR, ERYSGR
119.	DE	Rye (winter & spring)	F	<i>Pseudocercospora herpotrich- oides</i> (PSDCHE	Foliar spray	BBCH 30-32	a) 1 b) 2		a) 0.8 b) 1.6	a) 200 b) 400	150- 400	35		C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
62.	HU	Rye (winter & spring),	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Crown Rust <i>Puccinia coronata</i> (PUCCCO) <i>Puccinia recondita</i> (PUCCRE/PUCCRR) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Powdery mildew <i>Blumeria graminis</i> (ERYSGR)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		C
63.	IE	Rye (winter & spring),	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Crown Rust <i>Puccinia coronata</i> (PUCCCO) <i>Puccinia recondita</i> (PUCCRE/PUCCRR) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Powdery mildew <i>Blumeria graminis</i> (ERYSGR)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		<div>A PUCCRE/PUCCRR</div> <div>C SEPTTR, RHYNSE, PSDCHA, ERYSGR</div>

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
64.	LU	Rye (winter & spring),	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Crown Rust <i>Puccinia coronata</i> (PUCCCO) <i>Puccinia recondita</i> (PUCCRE/PUCCRR) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Powdery mildew <i>Blumeria graminis</i> (ERYSGR)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		A PUCCRE/PUCCRR
														C SEPTTR, RHYNSE, PSDCHA, ERYSGR
65.	NL	Rye (winter & spring),	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Crown Rust <i>Puccinia coronata</i> (PUCCCO) <i>Puccinia recondita</i> (PUCCRE/PUCCRR) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Powdery mildew <i>Blumeria graminis</i> (ERYSGR)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		A PUCCRE/PUCCRR
														C SEPTTR, RHYNSE, PSDCHA, ERYSGR

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
66.	PL	Rye (winter & spring),	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Crown Rust <i>Puccinia coronata</i> (PUCCCO) <i>Puccinia recondita</i> (PUCCRE/PUCCRR) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Powdery mildew <i>Blumeria graminis</i> (ERYSGR)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		<div>A</div> <div>RHYNSE</div> <div>PUCCRE/PUCCRR</div> <div>SEPTTR</div> <div>N</div> <div>SEPTTR</div> <div>PUCCCO</div> <div>PSDCHA</div> <div>ERYSGR</div> <div>All pathogens in spring rye possible authorization based on the art. 51 - minor uses</div>
67.	RO	Rye (winter & spring),	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Crown Rust <i>Puccinia coronata</i> (PUCCCO) <i>Puccinia recondita</i> (PUCCRE/PUCCRR) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Powdery mildew <i>Blumeria graminis</i> (ERYSGR)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
68.	SK	Rye (winter & spring),	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Crown Rust <i>Puccinia coronata</i> (PUCCCO) <i>Puccinia recondita</i> (PUCCRE/PUCCRR) Eyespot <i>Oculimacula acuformis</i> (PSDCHA) Powdery mildew <i>Blumeria graminis</i> (ERYSGR)	foliar spray	BBCH 30 – 69 (Spring)	a) 1-2 b) 1-2	14 - 21	a) 0.6-0.8 b) 1.2-1.6	a) 150-200 b) 300-400	100- 400	35		C
69.	BE	Oilseed Rape (winter)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 14-18 (Autumn) BBCH 20 – 69 (Spring)	a) 1-2 b) 1-2	90	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100- 400	56	First application in Autumn; Second ap- plication in Spring	<div>A LEPTMA SCLESC</div> <div>C ERYSCR ALTEBA PYRPBR</div> <div>Single application for all pathogens</div>

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
70.	CZ	Oilseed Rape (winter)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 14-18 (Autumn) BBCH 20 – 69 (Spring)	a) 1-2 b) 1-2	90	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100- 400	56	First application in Autumn; Second ap- plication in Spring	<div>A</div> <div>LEPTMA</div> <div>SCLESC</div> <div>C</div> <div>ERYSCR</div> <div>ALTEBA</div> <div>PYRPBR</div> <div>Single application for all pathogens</div>
71.	DE	Oilseed Rape (winter)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Light leaf spot <i>Cylindrosporium concentricum</i> (PYRPBR)	foliar spray	BBCH 14-18 (Autumn) BBCH 20 – 69 (Spring)	a) 1-2 b) 1-2	90	a) 0.7 b) 1.4	a) 175 b) 350	150- 400	56	First application in Autumn; Second ap- plication in Spring	
72.	HU	Oilseed Rape (winter)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew	foliar spray	BBCH 14-18 (Autumn) BBCH 20 – 69 (Spring)	a) 1-2 b) 1-2	90	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100- 400	56	First application in Autumn; Second ap- plication in Spring	<div>A</div> <div>LEPTMA</div> <div>SCLESC</div> <div>ERYSCR</div> <div>ALTEBA</div>

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group) <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
														C SCLESC ERYSCR ALTEBA PYRPBR Single application for all pathogens
73.	IE	Oilseed Rape (winter)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 14-18 (Autumn) BBCH 20 – 69 (Spring)	a) 1-2 b) 1-2	90	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100- 400	56	First application in Autumn; Second ap- plication in Spring	A LEPTMA SCLESC
														C ERYSCR ALTEBA PYRPBR Single application for all pathogens
74.	LU	Oilseed Rape (winter)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew	foliar spray	BBCH 14-18 (Autumn) BBCH 20 – 69 (Spring)	a) 1-2 b) 1-2	90	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100- 400	56	First application in Autumn; Second ap- plication in Spring	A LEPTMA SCLESC

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group) <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
75.	NL	Oilseed Rape (winter)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 14-18 (Autumn) BBCH 20 – 69 (Spring)	a) 1-2 b) 1-2	90	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100- 400	56	First application in Autumn; Second ap- plication in Spring	<div>A LEPTMA SCLESC</div> <div>C ERYSCR ALTEBA PYRPBR Single application for all pathogens</div>
76.	PL	Oilseed Rape (winter)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew	foliar spray	BBCH 14-18 (Autumn) BBCH 20 30 – 69 (Spring)	a) 1-2 b) 1-2	90	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100- 400	56	First application in Autumn; Second ap- plication in Spring	<div>A LEPTMA SCLESC</div>

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group) <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
77.	RO	Oilseed Rape (winter)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 14-18 (Autumn) BBCH 20 – 69 (Spring)	a) 1-2 b) 1-2	90	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100- 400	56	First application in Autumn; Second ap- plication in Spring	<div>A LEPTMA</div> <div>C SCLESC ERYSCR ALTEBA PYRPBR Single application for all pathogens</div>
78.	SK	Oilseed Rape (winter)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew	foliar spray	BBCH 14-18 (Autumn) BBCH 20 – 69 (Spring)	a) 1-2 b) 1-2	90	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100- 400	56	First application in Autumn; Second ap- plication in Spring	A LEPTMA

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group) <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
														C SCLESC ERYSCR ALTEBA PYRPBR Single application for all pathogens
79.	BE	Oilseed Rape (winter)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 20 – 69 (Spring)	a) 1-2 b) 1-2	14-28	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100- 400	56		A SCLESC ALTEBA C LEPTMA ERYSCR PYRPBR Single application for all pathogens
80.	CZ	Oilseed Rape (winter)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew	foliar spray	BBCH 20 – 69 (Spring)	a) 1-2 b) 1-2	14-28	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100- 400	56		A SCLESC ALTEBA

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group) <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
														C LEPTMA ERYSCR PYRPBR Single application for all pathogens
81.	DE	Oilseed Rape (winter)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Light leaf spot <i>Pyrenopeziza brassicae</i> <i>Cylindrosporium concentricum</i> (PYRPBR)	foliar spray	BBCH 20 – 69 (Spring)	a) 2 b) 2	14-28	a) 0.7 b) 1.4	a) 175 b) 350	150- 400	56		A LEPTMA (with only 1 application)
														C ERYSCR, PYRPBR
120.	DE	Oilseed Rape (winter)	F	Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA)	Foliar spray	BBCH 61-69	a) 1 b) 2	14-28	a) 0.7 b) 1.4	a) 175 b) 350	150- 400	56		C
82.	HU	Oilseed Rape (winter)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew	foliar spray	BBCH 20 – 69 (Spring)	a) 1-2 b) 1-2	14-28	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100- 400	56		A SCLESC ERYSCR ALTEBA LEPTMA

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group) <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
83.	IE	Oilseed Rape (winter)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 20 – 69 (Spring)	a) 1-2 b) 1-2	14-28	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100- 400	56		<div>C LEPTMA PYRPBR</div> <div>Single application for all pathogens</div>
84.	LU	Oilseed Rape (winter)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew	foliar spray	BBCH 20 – 69 (Spring)	a) 1-2 b) 1-2	14-28	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100- 400	56		<div>A SCLESC ALTEBA</div>

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group) <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
85.	NL	Oilseed Rape (winter)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 20 – 69 (Spring)	a) 1-2 b) 1-2	14-28	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100- 400	56		A SCLESC ALTEBA C LEPTMA ERYSCR PYRPBR Single application for all pathogens
86.	PL	Oilseed Rape (winter)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew	foliar spray	BBCH 20 30 – 69 (Spring)	a) 1-2 b) 1-2	14-28	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100- 400	56		A LEPTMA SCLESC ALTEBA ERYSCR

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group) <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
87.	RO	Oilseed Rape (winter)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 20 – 69 (Spring)	a) 1-2 b) 1-2	14-28	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100- 400	56		<div>N ERYSCR PYRPBR</div> <div>A SCLESC ERYSCR ALTEBA</div> <div>C LEPTMA PYRPBR</div> <div>Single application for all pathogens</div>
88.	SK	Oilseed Rape (winter)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew	foliar spray	BBCH 20 – 69 (Spring)	a) 1-2 b) 1-2	14-28	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100- 400	56		<div>A SCLESC ERYSCR ALTEBA</div>

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No.	Regulatory region	Crop and/or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group) <i>Erysiphe cruciferarum</i> (ER-YSCR) <i>Alternaria</i> leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Minor uses according to Article 51 (zonal uses)														

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fn, G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
89.	BE	Oilseed Rape (spring)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 20 – 69	a) 1 b) 1	n/a	a) 0.6-0.7 b) 0.6-0.7	a) 150-175 b) 150-175	100- 400	56	Minor Use	n.r.
90.	CZ	Oilseed Rape (spring)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 20 – 69	a) 1 b) 1	n/a	a) 0.6-0.7 b) 0.6-0.7	a) 150-175 b) 150-175	100- 400	56	Minor Use	n.r.
91.	DE	Oilseed Rape (spring)	F	Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Light leaf spot <i>Cylindrosporium concentricum</i> (PYRPBR)	foliar spray	BBCH 20 – 69	a) 1 b) 1	n/a	a) 0.7 b) 0.7	a) 175 b) 175	150- 400	56	Minor Use applied in a separate applica- tion	n.r.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
92.	HU	Oilseed Rape (spring)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 20 – 69	a) 1 b) 1	n/a	a) 0.6-0.7 b) 0.6-0.7	a) 150-175 b) 150-175	100- 400	56	Minor Use	n.r.
93.	IE	Oilseed Rape (spring)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 20 – 69	a) 1 b) 1	n/a	a) 0.6-0.7 b) 0.6-0.7	a) 150-175 b) 150-175	100- 400	56	Minor Use	n.r.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
94.	LU	Oilseed Rape (spring)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 20 – 69	a) 1 b) 1	n/a	a) 0.6-0.7 b) 0.6-0.7	a) 150-175 b) 150-175	100- 400	56	Minor Use	n.r.
95.	NL	Oilseed Rape (spring)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 20 – 69	a) 1 b) 1	n/a	a) 0.6-0.7 b) 0.6-0.7	a) 150-175 b) 150-175	100- 400	56	Minor Use	n.r.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
96.	PL	Oilseed Rape (spring)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 20 – 69	a) 1 b) 1	n/a	a) 0.6-0.7 b) 0.6-0.7	a) 150-175 b) 150-175	100- 400	56	Minor Use	n.r.
97.	RO	Oilseed Rape (spring)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 20 – 69	a) 1 b) 1	n/a	a) 0.6-0.7 b) 0.6-0.7	a) 150-175 b) 150-175	100- 400	56	Minor Use	n.r.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
98.	SK	Oilseed Rape (spring)	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 20 – 69	a) 1 b) 1	n/a	a) 0.6-0.7 b) 0.6-0.7	a) 150-175 b) 150-175	100- 400	56	Minor Use	n.r.
99.	FR	Flax (for fi- ber produc- tion only)	F	Powdery mildew flax <i>Erysiphe spp</i> (ERYSPP)	Foliar spray	BBCH 33 – 51	a) 1-2 b) 1-2	14-28	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100- 400	NA	Minor Use, linked to OSR	n.r.
100.	BE	Flax (for fi- ber produc- tion only)	F	Powdery mildew flax <i>Erysiphe spp</i> (ERYSPP)	Foliar spray	BBCH 33 – 51	a) 1-2 b) 1-2	14-28	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100- 400	NA	Minor Use, linked to OSR	n.r.
101.	BE	Mustard, Cameline and other seed-produc- ing Brassica- ceae	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	Foliar spray	BBCH 14-18 (Autumn) BBCH 20 – 69 (Spring)	a) 1-2 b) 1-2	14-28	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100- 400	56	Minor Use, linked to OSR	n.r.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
102.	CZ	Mustard, Cameline and other seed-produc- ing Brassica- ceae	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	Foliar spray	BBCH 14-18 (Autumn) BBCH 20 – 69 (Spring)	a) 1-2 b) 1-2	14-28	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100- 400	56	Minor Use, linked to OSR	n.r.
103.	DE,	Mustard, Cameline and other seed-produc- ing Brassica- ceae for seed production / use of seeds only	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	Foliar spray	BBCH 14-18 (Autumn) BBCH 20 – 69 (Spring)	a) 1-2 b) 1-2	14-28	a) 0.7 b) 1.4	a) 175 b) 350	150- 400	56	Minor Use, linked to OSR, applied in a separate application	n.r.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
104.	HU	Mustard, Cameline and other seed-produc- ing Brassica- ceae	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	Foliar spray	BBCH 14-18 (Autumn) BBCH 20 – 69 (Spring)	a) 1-2 b) 1-2	14-28	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100- 400	56	Minor Use, linked to OSR	n.r.
105.	IE	Mustard, Cameline and other seed-produc- ing Brassica- ceae	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	Foliar spray	BBCH 14-18 (Autumn) BBCH 20 – 69 (Spring)	a) 1-2 b) 1-2	14-28	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100- 400	56	Minor Use, linked to OSR	n.r.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fn, G, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
106.	LU	Mustard, Cameline and other seed-produc- ing Brassica- ceae	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	Foliar spray	BBCH 14-18 (Autumn) BBCH 20 – 69 (Spring)	a) 1-2 b) 1-2	14-28	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100- 400	56	Minor Use, linked to OSR	n.r.
107.	NL	Mustard, Cameline and other seed-produc- ing Brassica- ceae	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	Foliar spray	BBCH 14-18 (Autumn) BBCH 20 – 69 (Spring)	a) 1-2 b) 1-2	14-28	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100- 400	56	Minor Use, linked to OSR	n.r.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
108.	PL	Mustard, Cameline and other seed-produc- ing Brassica- ceae	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	Foliar spray	BBCH 14-18 (Autumn) BBCH 20 – 69 (Spring)	a) 1-2 b) 1-2	14-28	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100- 400	56	Minor Use, linked to OSR	n.r.
109.	RO	Mustard, Cameline and other seed-produc- ing Brassica- ceae	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	Foliar spray	BBCH 14-18 (Autumn) BBCH 20 – 69 (Spring)	a) 1-2 b) 1-2	14-28	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100- 400	56	Minor Use, linked to OSR	n.r.

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No.	Regula- tory re- gion	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F, Fpn G, Gn, Gpn or I	Pests or Group of pests con- trolled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/syner- gist per ha	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa- ter L/ha min / max			
110.	SK	Mustard, Cameline and other seed-produc- ing Brassica- ceae	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEP- TMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ER- YSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	Foliar spray	BBCH 14-18 (Autumn) BBCH 20 – 69 (Spring)	a) 1-2 b) 1-2	14-28	a) 0.6-0.7 b) 1.2-1.4	a) 150-175 b) 300-350	100- 400	56	Minor Use, linked to OSR	n.r.

**Remarks
table
heading:**

- (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife Interna-
tional Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l

- (d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in col-
umn 1
(f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the
notifier no longer supports this use.

- | | | | | |
|-------------------------|---|--|----|--|
| Remarks columns: | 1 | Numeration necessary to allow references | 7 | Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application |
| | 2 | Use official codes/nomenclatures of EU Member States | 8 | The maximum number of application possible under practical conditions of use must be provided. |
| | 3 | For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure) | 9 | Minimum interval (in days) between applications of the same product |
| | 4 | F: professional field use, Fn: non-professional field use, Fpn: professional and non- professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application | 10 | For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products. |
| | 5 | Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named. | 11 | The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha). |
| | 6 | Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants -type of equipment used must be indicated. | 12 | If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind". |
| | | | 13 | PHI - minimum pre-harvest interval |
| | | | 14 | Remarks may include: Extent of use/economic importance/restrictions |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |

Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable/ evaluation not possible
n.r.	Not relevant for section 3

3.2 Efficacy data (KCP 6)

Introduction

This document summarises the information related to the efficacy of the plant protection product **CA3301** (commercial name JOUST) containing 250 g/L of Prothioconazole. Prothioconazole was included into Annex I of Regulation (EC) no 1107/2009 (Commission Implementing Regulation (EU) No 540/2011 and Commission Implementing Regulation (EU) 2020/869). The SANCO report for active substance (SANCO/3923/07 – 10/12/2007) is considered to provide the relevant review information or a reference to where such information can be founded.

The Annex I of the Commission Implementing Regulation (EU) No 540/2011 provides specific provisions for the active substance prothioconazole under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

This document is submitted in view to a first authorization of the product.

Central zone: This document will be evaluated by Poland as Zonal Rapporteur Member State (zRMS). Member States concerned by the authorization are Austria, Belgium, Czech Republic, Germany, Hungary, Ireland, Luxemburg, the Netherlands, Romania, Slovakia and Northern Ireland.

Additional information and studies have been submitted for the label extension acc. to art. 45.

Description of active substances

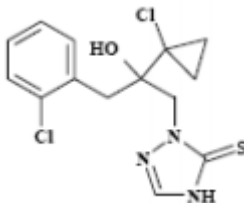
CA3301 is an emulsifiable concentrate (EC) containing 250 g/l of prothioconazole for use on crops for use as a fungicide on winter wheat, durum wheat, triticale, rye, oat, barley, oilseed rape and relevant minor crops (flax, minor seed-producing Brassicaceae). Prothioconazole belongs to the triazolinthiones group.

Mode of action

Prothioconazole is a systemic fungicide molecule from the chemical group of triazolinthiones. It is very polyvalent on the cereals pathogens. It acts on the endoplasmic reticulum of the cell. Its mode of action is interference with the synthesis of ergosterol in the target fungi by inhibition of CYP51, which catalyses demethylation at C14 of lanosterol or 24-methylene dihydrolanosterol, leading to morphological and functional changes in the fungal cell membrane (FAO; BAYER).

Table 3.2-1: Details of the active substance

Active substance	Prothioconazole
Concentration (Unit: g/kg or g/L...)	250 g/L
Systematic name	2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione
Chemical group	Triazolinthiones
Mode of action	Interference with sterol biosynthesis in membranes
Biological action	Systemic fungicide
Molecular formula	C ₁₄ H ₁₃ C ₁₂ N ₃ OS
Molecular mass	344.26 g/mol

Active substance	Prothioconazole
Molecular formula	

Description of the plant protection product

CA3301 is an emulsifiable concentrate (EC) containing 250 g/L of Prothioconazole.

CA3301 is a fungicide developed for use in cereals and oil seed rape. CA3301 is a DeMethylation Inhibitor fungicide, which inhibits the sterol biosynthesis in the membranes of target fungi to control the disease.

Table 3.2-2: Simplified table of currently registered uses and requested uses for CA3301.

Uses		Member State	Currently registered rate(s)	Requested rate(s) a) Per use b) Per season	Comments / Other relevant details on GAPs
Crop(s)	Target(s)				
Barley winter	<i>Ramularia collo-cygni</i> <i>Oculimacula acuformis</i> <i>Puccinia hordei</i> <i>Blumeria graminis</i> <i>Rhynchosporium secalis</i> <i>Fusarium spp.</i> <i>Pyrenophora teres</i>	PL, AT, BE, CZ, DE, HU, IE, LU, NL, RO, SK and Northern IE.	-	a) 0.6 l/ha b) 1.2 l/ha	
Barley spring	<i>Ramularia collo-cygni</i> <i>Oculimacula acuformis</i> <i>Puccinia hordei</i> <i>Blumeria graminis</i> <i>Rhynchosporium secalis</i> <i>Pyrenophora teres</i>	PL, AT, BE, CZ, DE, HU, IE, LU, NL, RO, SK and Northern IE.	-	a) 0.6 l/ha b) 1.2 l/ha	
Oat (winter & spring)	<i>Puccinia coronata</i> <i>Blumeria graminis</i> <i>Oculimacula acuformis</i>	PL, AT, BE, CZ, DE, HU, IE, LU, NL, RO, SK and Northern IE.	-	a) 0.6 l/ha b) 1.2 l/ha	
Wheat winter	<i>Oculimacula acuformis</i>	PL	-	a) 0.6-0.8 l/ha b) 0.6-0.8 l/ha	
Wheat (winter & spring) Spelt + Minor cereals	<i>Zymoseptoria tritici</i> / <i>Mycosphaerella graminicola</i> <i>Stagnospora nodorum</i> <i>Puccinia recondita/tritici</i> <i>Puccinia striiformis</i> <i>Blumeria graminis</i> <i>Oculimacula acuformis</i>	PL, AT, BE, CZ, DE, HU, IE, LU, NL, RO, SK and Northern IE.	-	a) 0.6-0.8 l/ha b) 1.2-1.6 l/ha	

Uses		Member State	Currently registered rate(s)	Requested rate(s) a)Per use b)Per season	Comments / Other relevant details on GAPs
Crop(s)	Target(s)				
	<i>Pyrenophora tritici-repentis</i> <i>Fusarium spp.</i>				
Durum wheat	<i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> <i>Puccinia recondita/tritici</i> <i>Blumeria graminis</i> <i>Fusarium spp.</i>	PL, AT, BE, CZ, DE, HU, IE, LU, NL, RO, SK and Northern IE.	-	a) 0.6-0.8 l/ha b) 1.2-1.6 l/ha	
Triticale (winter & spring)	<i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> <i>Puccinia recondita/tritici</i> <i>Blumeria graminis</i> <i>Rhynchosporium secalis</i> <i>Puccinia striiformis</i> <i>Stagnospora nodorum</i> <i>Fusarium spp.</i>	PL, AT, BE, CZ, DE, HU, IE, LU, NL, RO, SK and Northern IE.	-	a) 0.6-0.8 l/ha b) 1.2-1.6 l/ha	
Rye (winter & spring)	<i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> <i>Rhynchosporium secalis</i> <i>Puccinia coronata</i> <i>Oculimacula acutiformis</i> <i>Blumeria graminis</i>	PL, AT, BE, CZ, DE, HU, IE, LU, NL, RO, SK and Northern IE.	-	a) 0.6-0.8 l/ha b) 1.2-1.6 l/ha	
Oilseed rape (winter)	<i>Leptosphaeria maculans</i> <i>Sclerotinia sclerotiorum</i> <i>Erysiphe crucifearum</i> <i>Alternaria brassicae</i> <i>Pyrenopeziza brassicae</i>	PL, AT, BE, CZ, DE, HU, IE, LU, NL, RO, SK and Northern IE.	-	a) 0.6-0.7 l/ha b) 1.2-1.4 l/ha	
Oilseed rape (spring)	<i>Leptosphaeria maculans</i> <i>Sclerotinia sclerotiorum</i> <i>Erysiphe crucifearum</i> <i>Alternaria brassicae</i> <i>Pyrenopeziza brassicae</i>	PL, AT, BE, CZ, DE, HU, IE, LU, NL, RO, SK and Northern IE.	-	a) 0.6-0.7 l/ha b) 0.6-0.7 l/ha	
Mustard, Cameline and other seed-producing Brassicaceae	<i>Leptosphaeria maculans</i> <i>Sclerotinia sclerotiorum</i> <i>Erysiphe crucifearum</i> <i>Alternaria</i>	PL, AT, BE, CZ, DE, HU, IE, LU, NL, RO, SK and Northern IE.	-	a) 0.6-0.7 l/ha b) 1.2-1.4l/ha	

Uses		Member State	Currently registered rate(s)	Requested rate(s) a)Per use b)Per season	Comments / Other relevant details on GAPs
Crop(s)	Target(s)				
	<i>brassicae</i> <i>Pyrenopeziza</i> <i>brassicae</i>				
Flax (for fiber production only)	<i>Golovinomyces orontii</i>	PL, AT, BE, CZ, DE, HU, IE, LU, NL, RO, SK and Northern IE.	-	a) 0.6-0.7 l/ha b) 1.2-1.4 l/ha	

Further details are in the table “All intended uses” in Part B - Section 0.

Description of the target diseases

Table 3.2-3: Glossary of pests mentioned in the dossier.

EPPO code	Scientific name	Common name
ALTEBA	<i>Alternaria brassicae</i>	Dark leaf spot
ERYSCR	<i>Erysiphe cruciferarum</i>	Powdery mildew of crucifers
ERYSGH	<i>Blumeria graminis f. sp. hordei</i>	Powdery mildew of barley
ERYSGR	<i>Blumeria graminis</i>	Powdery mildew of cereals
ERYSGT	<i>Blumeria graminis f. sp. tritici</i>	Powdery mildew of wheat
FUSACU	<i>Fusarium culmorum</i>	Ear blight
FUSASP	<i>Fusarium sp.</i>	Ear blight
GIBBZE	<i>Fusarium graminearum</i>	Ear blight
LEPTMA	<i>Plenodomus lingam</i>	Black leg
LEPTNO	<i>Parastagonospora nodorum</i>	Glume blotch of wheat
PSDCHA	<i>Oculimacula acuformis</i>	Eye spot disease
PUCCCA/PUCCCO	<i>Puccinia coronata var. avenae</i>	Crown rust of oats
PUCCHD	<i>Puccinia hordei</i>	Brown Rust of barley
PUCCRE	<i>Puccinia recondita</i>	Brown Rust
PUCCRT	<i>Puccinia triticina</i>	Brown Rust of wheat
PUCCSI	<i>Puccinia striiformis f. sp. tritici</i>	Yellow rust (or stripe rust) of wheat
PUC CST	<i>Puccinia striiformis</i>	Yellow rust (or stripe rust)
PYRNGR	<i>Pyrenophora graminea</i>	Leaf stripe
PYRNTE	<i>Pyrenophora teres</i>	Tan spot
PYRNTR	<i>Pyrenophora tritici-repentis</i>	Net blotch
PYRPBR	<i>Pyrenopeziza brassicae</i>	Light leaf spot
RAMUCC	<i>Ramularia collo-cygni</i>	Ramularia leaf spot
RHYNSE	<i>Rhynchosporium secalis</i>	Leaf scald
SCLESC	<i>Sclerotinia sclerotiorum</i>	Cottony rot
SEPTTR	<i>Zymoseptoria tritici</i>	<i>Septoria tritici</i> blotch

Description of the target cereals diseases:

- **Powdery mildew of cereals – *Blumeria graminis* (ERYSGR) / *Blumeria graminis* f. sp. *tritici* (ERYSGT) / *Blumeria graminis* f. sp. *hordei* (ERYSGH)**

(Pietrusinska A. and Tratwal A, Characteristics of powdery mildew and its importance for wheat grown in Poland, *Plant Protection Science*, 2020)

(Agriculture and Horticulture Development Board AHDB – The encyclopedia of cereal diseases, 2018)

Generalities:

Powdery mildew is widespread and affects various plant species in different climatic zones. The disease is common in cereals and many species of grasses. This is one of the most dangerous fungal disease of wheat and barley, every year causing losses in yield volume and quality. It is less damaging to oats and rye, and until recently did not affect triticale. Powdery mildew of cereals and grasses is becoming more and more important in the times of climate change. The causal agent is *Blumeria graminis*, an *Ascomycota* that belongs to the *Erysiphaceae* family.

Late-sown winter wheat crops are often particularly prone to attack, especially when growing rapidly in the spring. High levels of nitrogen fertiliser encourage the disease and mildew can be particularly severe in dense crops. In susceptible varieties, yield losses can be high, up to 20%. However, the disease generally causes much smaller yield losses and late attacks (after flowering) on the flag-leaf and ear rarely cause significant losses.

Symptoms:

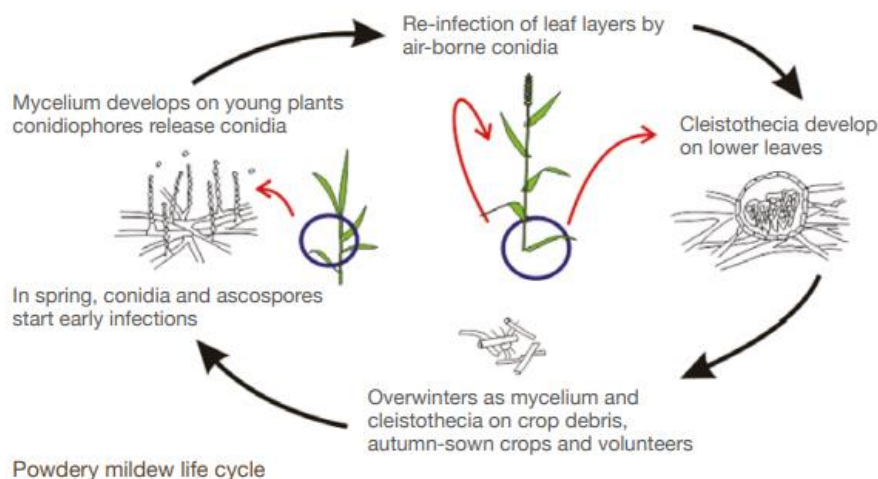
The first symptoms of powdery mildew of cereals and grasses develop on winter cereals in late autumn or early spring. These symptoms are characterized by a powdery fungal growth, white to grey, on leaves, stems and heads. As the plant matures, the white powdery growth changes to a grey-brown colour.

Infection spreads gradually from the lower leaves to higher parts of the stem and the most severe symptoms of powdery mildew are observed on the lower leaves. Initially, small, fluffy white-grey pustules develop on the surface of leaves or underneath leaves. The leaf tissue on the opposite side of the leaf from the white mold growth becomes yellow, later turning tan or brown. Small, black fruiting bodies (cleistothecia) develop on leaves as plants mature. Cleistothecia, recognized as distinct round, black dots within older, grey colonies of powdery mildew, contain ascospores that will serve to infect then.

Over time, the disease progresses, and under favourable weather conditions, white fluffy pustules cover increasingly larger area of leaves, sheaths, stems and ears. The scurf on infected parts of plants is white, later turning grey and farinose. Severely infected leaves become chlorotic and gradually die back. In a darkening scurf, small dark brown or black chasmothecia can be seen.

Life cycle & Epidemiology:

Figure 3.2-4: *Blumeria graminis* life cycle



The *B. graminis* life cycle has two stages – ascospore and conidial. In the ascospore stage the fungus produces dark brown or black ascocarps (perithecia or cleistothecia or chasmothecia) 135 to 224 µm in diameter. Chasmothecia are covered with filamentous appendages and contain 8–25 asci 70–100 × 25–40 µm in size. Ascospores formed in asci in late summer or early autumn are ovoid, single-celled and 20–23 × 10–13 µm in size. After rainfall, ripe ascocarps break open and release ascospores that infect grass, volunteer cereal plants and germinating winter crops. A white scurf on the infected plant is formed by mycelium, conidiophores and conidia. The pathogen overwinters as mycelium on winter cereals, volunteer plants and wild grasses and can survive until the next growing season. In the spring, the growing mycelium produces conidiophores and conidia that spread infection to new plants. Conidia are colourless, ellipsoid, 24–35 × 12–17 µm in size and arranged in chains on conidiophores formed by hyphae growing on the surface of leaves. The dense mycelium of greyish colour is gradually formed.

B. graminis is an ectoparasite and its sporulation is favoured by dry and warm weather. The fungus assimilates nutrients necessary for its growth and development using haustoria penetrating epithelial cells of the host plant. Plants are infected in a wide temperature range of 5 to 30 °C and air humidity of 50–100%, but the optimal conditions are 12–20 °C and high humidity. Powdery mildew produces conidia as often as every 7 to 10 days.

In regions where chasmothecium are an important source of infection (e.g. southern Europe), asci are released from the perithecia under favourable weather conditions and give rise to primary infections. Fungal spores can be dispersed by wind for several hundred kilometres, initiating many successive cycles of secondary infections during the growing season.

- **Ear blight – *Fusarium* spp. (FUSASP) / *Fusarium culmorum* (FUSACU) / *Fusarium graminearum* (GIBBZE)**

(Agriculture and Horticulture Development Board AHDB – The encyclopedia of cereal diseases, 2018)

Generalities:

Fusarium spp. including *F. culmorum* and *F. graminearum* belong to the *Ascomycota* phylum. These fungi are highly destructive pathogens affecting many cereal species with small grains such as wheat, barley, triticale and oats. The greatest economic losses occur when the floral tissues become infected and lead to reductions in grain yield and quality.

Upon infection of the inflorescences, several *Fusarium* species produce mycotoxins, jeopardizing food and feed safety. The most toxicologically important mycotoxins produced by *F. graminearum* are deoxynivalenol (DON) and zearalenone (ZEN). The European Union and many other countries around the globe have established maximum levels in human food and guidance levels in animal feed (European Commission, 2006). During the post-harvest period, if infected cereal grain is stored or transported at too high a moisture content, post-harvest growth of the fungus occurs and mycotoxin levels increase.

Symptoms:

Fusarium species cause a range of symptoms on the ear. Bleached ears often show above the point of infection around the milky ripe stage. Later infections may result in infection of the grain without obvious bleaching of the ears. The presence of orange/pink fusarium spores may also be visible on infected spikelets.

Diseased spikelets turn light-straw coloured and have a bleached appearance due to premature death of tissues. Healthy spikelets on the same head retain their normal green colour. One or more spikelets may be bleached, or the entire head may be diseased.

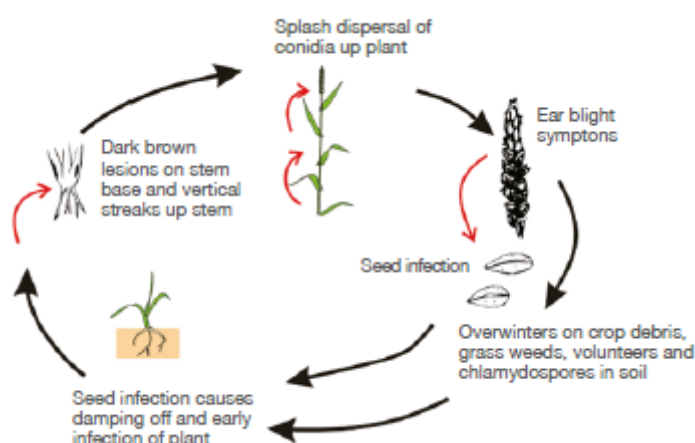
Within 7 to 10 days after symptom development pinkish to salmon-coloured spore masses and mycelium (called sporodochia) may form on the margin of the glumes of individual spikelets, especially near the base of the spikelet. The pink spore masses are easiest to see early in the morning before the dew dries. As the crop ripens, symptoms become less visible.

At harvest, fusarium ear blight can result in shrivelled grains with a chalky white or pink appearance, although this is not always the case. Infected kernels are generally shrunken, wrinkled, and light-weight, with a rough, scabby appearance. These kernels range in colour from light-brown to pink to greyish white. The extent of shriveling and discoloration of the kernels depends on when and where infections occur and the weather conditions following infection. If the fungus invades and kills the rachis or main

axis of the spike, the spikelets above that point die, even if they are not colonized by the fungus. The result is no grain at all or small, shriveled kernels that are lost during the threshing process. Towards the end of the season, heads with diseased spikelets may become speckled with dark purplish-black fruiting bodies (perithecia) of the fungus if the weather remains cool and moist. These perithecia are signs of the sexual stage and the overwintering structures of the fungus.

Life cycle & Epidemiology:

Figure 3.2-5: *Fusarium* spp. life cycle



Fusarium spp. overwinter and survive between crops in infected grain and grass stubble, chaff, and cornstalk residue left on the soil surface. They survive as asexual spores (conidia), mycelium, and perithecia within which are borne the sexual spores (ascospores). These fungi continue to grow and produce spores from harvest until the residues decompose in the soil.

Primary infection is from infected seed, soil, crop debris and volunteers or host weed species. Environmental conditions affect disease development and *Fusarium* species have different temperature requirements. For example, *F. graminearum* seedling blight is most severe under warmer, drier soil conditions. Warm, wet, humid conditions during flowering favours ear blights and seed-borne infection. Further rainfall and humid conditions allow secondary infection to occur, allowing further fungal growth and mycotoxin production.

Conidia are produced profusely during warm, moist weather on corn and small grain residues. Ascospores produced within perithecia are forcibly discharged and carried by air currents to the flowering spikelets where infections occur. Ascospores and conidia may also be splash dispersed to spike from in-field crop residue. Both spore types germinate in free water on the surface of the spikelet and invade the flower. Infections are most serious when the anthers are exposed during flowering, leading to a grain infection.

Early symptoms may develop in as little as three days after infection when temperatures range from 25-30°C and humidity is high. Conidia from sporodochia on diseased spikes can be blown by wind to flowering heads in neighbouring fields or splash dispersed to heads on late-developing tillers in the same field where new (secondary) infections occur.

This process may continue as long as the spikelets are susceptible and moist weather conditions prevail, leading to secondary spread within and across fields. Primary and secondary infections may all result from long distance spread of air borne conidia and ascospores.

- **Glume blotch - *Parastagonospora nodorum* (LEPTNO)**

(Mehra L.K., et al, Septoria nodorum blotch of wheat. *PeerJ*, 2018)

(Solomon, P.S., *Stagonospora nodorum*: cause of stagonospora nodorum blotch of wheat. *Molecular Plant pathology*, 2006)

Generalities

Parastagonospora nodorum is the causal agent of glume blotch of wheat. It belongs to the Ascomycota

phylum and Phaeosphaeriaceae family. In wheat, the disease is called glume blotch or *Septoria nodorum* blotch (SNB). Although most closely associated with wheat, *P. nodorum* is also pathogenic on barley, and isolates from each of these hosts are able to infect the other.

P. nodorum causes a necrotic leaf blotch as well as discoloration of the head in the symptom known as glume blotch.

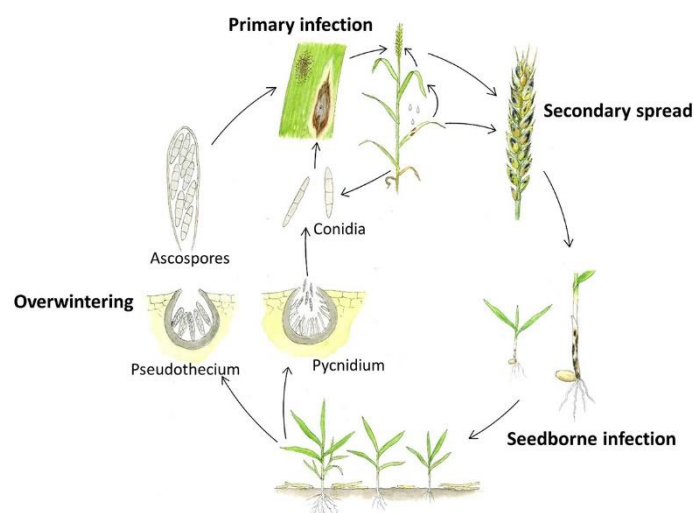
This fungus is a major pathogen on cereals in major wheat-growing regions of the world and can cause up to 31% loss of yield in wheat, with heavier losses in areas of high rainfall.

Symptoms:

P. nodorum produces symptoms on all aboveground parts of the plant; i.e. leaves, leaf sheaths, stems, glumes, and awns. On leaves, initial symptoms of SNB appear as small dark-brown to chocolate-coloured lesions, usually on the mid-rib of older leaves that are close to the soil surface. These lesions typically have a yellow halo as a result of diffusible toxins produced by the pathogen. The lesions expand and become oval (lens-shaped) or elliptical with dark-brown centers. A mature lesion has a greyish-white center with a dark-brown periphery. In severe epidemics, lesions can coalesce to cover the whole leaf, resulting in the death of the leaf tissue. On the glumes and awns, symptoms appear as tan to brown-coloured lesions. The lesion on a glume typically starts at the tip of the glume and progresses downward. The pathogen can also result in dark-brown lesions on stems and nodes of wheat plant. Infected glumes lead to shriveled kernels that reduce the quality and quantity of the produce.

Life cycle & Epidemiology:

Figure 3.2-6: *Parastagonospora nodorum* life cycle



The pathogen overwinters on wheat residue in the form of pseudothecia and pycnidia. The fungus is also known to survive on seed as dormant mycelium and colonized seed can be a source of primary infection. Rain-splashed conidia or windborne ascospores from infected wheat debris can also be a primary inoculum in the field.

Ascospores released from pseudothecia are usually the source of primary inoculum; however, conidia splashed from wheat debris to the young seedlings can also initiate the disease. Release of ascospores from pseudothecia is highly dependent on weather variables (rainfall >1 mm, temperature above 0°C, and high (75–95%) relative humidity). Transmission of the pathogen from seed to coleoptile and the first leaf decreases with increase in temperature. It is likely that seed infection plays a relatively bigger role in regions where mean temperature is lower (around 9°C). Severity of *Septoria nodorum* blotch is known to increase with increasing amounts of wheat residue on the ground.

Mature lesions on plant leaves contain pinhead sized pycnidia that are the source of secondary inoculum. The secondary spread of the pathogen within the season occurs when rain-splashed conidia are spread from lower leaves to upper leaves and to glumes. Disease symptoms appear first on the oldest leaves in early spring. Lesions can expand and coalesce, leading to necrosis of the entire leaf. Small (160–210 µm

in diameter) fruiting bodies (pycnidia) are formed at the center of mature lesions one to two weeks after infection under high relative humidity. Both conidia and ascospores can germinate and cause infection between 5 and 35°C (optimum 15 to 25°C), and penetration can happen directly through the cuticle or opportunistically through stomata. The optimum temperature for the development of disease symptoms and pycnidia formation is 20°C.

This pathogen also produces multiple host selective toxins that aid in infection by killing the cells before hyphal colonization. Susceptibility in the host is influenced by the interaction between necrotrophic effectors produced by the pathogen and sensitivity genes present in the host, and likely by other interacting gene products as well. Infected wheat residue left in the field and infected grain (if used for seed) serve as the source of inoculum in the following year, and the disease cycle continues.

The rate at which an epidemic spreads is dependent upon the latent period, which is defined as the period between inoculation of host tissue and sporulation. The latent period of *P. nodorum* varies greatly and is dependent on temperature, moisture, and cultivar. Glume blotch development is also favoured by rainstorms, which can cause sudden outbreaks and fast vertical spread from lower leaves to upper leaves.

- **Eye spot disease - *Oculimacula acufiformis* (PSDCHA)**

(Peraldi A, et al., *Brachypodium distachyon* exhibits compatible interactions with *Oculimacula* spp. and *Ramularia collo-cygni*, providing the first pathosystem model to study eyespot and ramularia leaf spot diseases. *Plant Pathology*, 2014)
(Agriculture and Horticulture Development Board AHDB – The encyclopedia of cereal diseases, 2018)

Generalities:

Eyespot is a stem base disease of wheat and other small-grain cereals caused by two closely related fungal species: *Oculimacula yallundae* and *Oculimacula acufiformis*. Eyespot is more prevalent in cool and wet regions of the world and can lead to significant yield reduction due to reduced nutrient transport at the stem base and predisposition to lodging.

Eyespot is a common disease in intensive cereal rotations. The disease most seriously affects autumn-sown crops, especially when inoculum builds up across the rotation. Spring cereals can also suffer from infection.

The disease tends to damage yield only when the lesion penetrates the leaf sheath. This restricts water and nutrient flow to the ear, reduces grain number and size and causes whiteheads. Associated lodging can also delay harvest, increase grain moisture, reduce grain quality and encourage other diseases. Moderate or severe eyespot infections can cause yield loss in the order of 10–30%, even in the absence of lodging.

Symptoms:

Visual symptoms are characterized by elliptical shaped lesions with dark centres forming on the leaf sheaths and culms near ground level. One of the most distinctive microscopic infection structures produced by the eyespot-causing fungi is the formation of multicellular aggregates on the host leaf sheath, termed infection plaques. Branching and aggregation of hyphae provide the source of subsequent infection hyphae, which penetrate the host cuticle and epidermal cell wall.

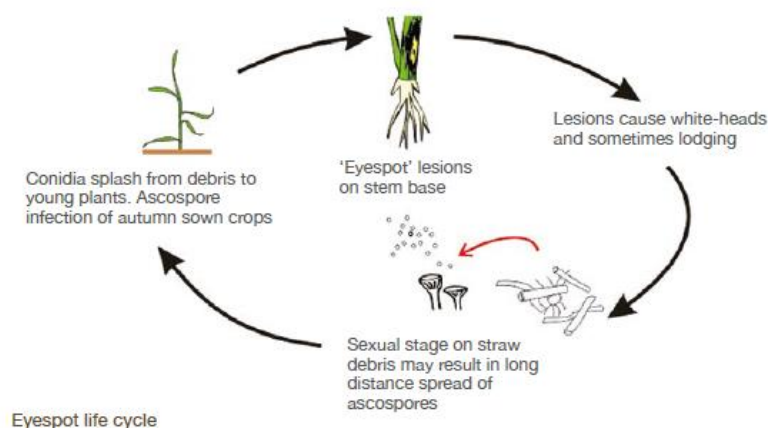
Although severe and early attacks of eyespot can kill seedlings outright, eyespot symptoms typically first become visible in early spring. Symptoms appear as a brown smudge at the stem base. They have a diffuse margin and appear on one side of the outer leaf sheath.

As the season progresses, symptoms become more distinct with an eye-shaped lesion with a dark, diffuse margin, usually below the first node. A central black 'pupil' may be visible: this is a mass of compacted hyphae and is difficult to remove by rubbing. Eyespot lesions then penetrate through the leaf layers. As leaf sheaths die off during spring growth, eyespot symptoms may disappear but can reappear later.

Severe eyespot infections can weaken stems around the lesion and cause lodging – stems can fall in all directions, as opposed to lodging caused by wind.

Life cycle & Epidemiology:

Figure 3.2-7: *Oculimacula acuformis* life cycle



The fungus over-winters on infected stubble, volunteers and grass weeds acting as sources of inoculum. It can survive on stubble for up to three years, so a break from cereals will not necessarily reduce eyespot risk in following crops. Grass weeds also act as sources of inoculum. Spores are produced throughout autumn and winter, posing a threat to early sown crops. Infection occurs at temperatures above 5°C with a daytime optimum temperature of 15°C and a night-time optimum temperature of 10°C. High temperatures inhibit infection. Prolonged humid conditions are conducive to infection. Spores are rain splashed short distances from infected stubble. The development of symptoms following infection takes 6–8 weeks, depending upon environmental conditions. Eyespot can be a serious problem in continuous cereals, where inoculum may build up from year to year.

The sexual stage of both eyespot fungi may play an important part in the pathogen life cycle. This stage of the fungus is produced on stubble at the end of the season and after harvest, ascospores may travel long distances and infect emerging or young plants. Ascospores are produced on stubble after harvest. Dispersed by wind across long distances, these spores infect emerging or young plants throughout the autumn and winter.

The infection is heaviest on early drilled, lush crops particularly on compacted, cold wet soils. Excess nitrogen and susceptible varieties increase the risk.

- **Crown rust of oats – *Puccinia coronata* var. *avenae* (PUCCCA)**

(Nazareno E.S., et al, *Puccinia coronata* f. sp. *Avenae*: a threat to global oat production. *Molecular plant Pathology*, 2018).
(Agriculture and Horticulture Development Board AHDB – The encyclopedia of cereal diseases, 2018)

Generalities:

Puccinia coronata var. *avenae* is the causal agent of crown rust disease in cultivated and wild oat. *P. coronata* is a basidiomycete fungus with an obligate biotrophic lifestyle and is classified as a typical macrocyclic and heteroecious fungus. This fungus affects only oats.

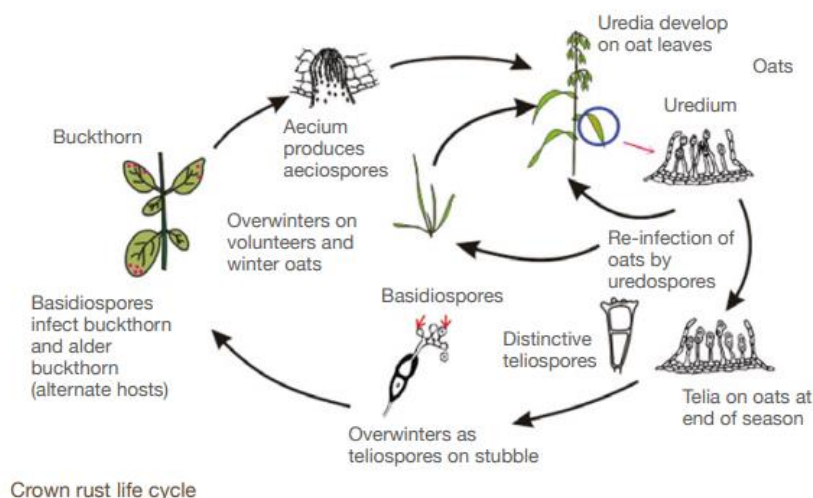
Epidemics of crown rust happens in areas with warm temperatures (20–25°C) and high humidity. Infection by the pathogen leads to plant lodging and shrivelled grain of poor quality. Severe attacks can reduce yield by 10–20%. The significant yield losses inflicted by this pathogen make crown rust the most devastating disease in the oat industry.

Symptoms:

Infection of susceptible oat varieties gives rise to orange–yellow round to oblong uredinia (pustules) containing newly formed urediniospores. Pustules vary in size and can be larger than 5 mm in length. Infection occurs primarily on the surfaces of leaves, although occasional symptoms develop in the oat leaf sheaths and/or floral structures, such as awns. Symptoms in resistant oat varieties vary from flecks to small pustules, typically accompanied by chlorotic halos and/or necrosis. The pycnial and aecial stages are mostly present in the leaves, but occasionally symptoms can also be observed in petioles, young stems and floral structures. Aecial structures display a characteristic hypertrophy and can differ in size, occasionally reaching more than 5 mm in diameter.

Life cycle & Epidemiology:

Figure 3.2-8: *Puccinia coronata* var. *avenae* life cycle



P. coronata possesses five infectious stages that are associated with either sexual or asexual reproductive phases in its life cycle. In Europe, where alternative hosts grow in close association with oat, both sexual and asexual stages exist. The asexual infection phase occurs entirely in oat, whereas sexual reproduction takes place in alternative hosts. The asexual phase involves repeated cycles of infection and sporulation mediated by urediniospores that can repeat as quickly as every 2 weeks. The urediniospores germinate on the leaf surfaces under suitable conditions (i.e. mild temperatures, adequate moisture and short exposure to light). Once germinated, these spores form appressoria and, subsequently, a penetration peg, which allows the fungus to penetrate the stoma and gain access to the mesophyll space of the leaf. The intercellular branching of the infection hyphae proceeds until a fungal colony is formed in the surrounding leaf tissue, which, after 7–10 days, gives rise to sporulating uredinia that produce a new set of urediniospores. The uredinia emerge as bright orange–yellow oblong pustules that constitute the characteristic symptom of infection.

The sexual phase of the disease involves both oat and the alternative host. Late in the cropping season, as the plant starts to senesce, rust infection sites differentiate teliospores. These structures germinate in the spring and basidiospores, which subsequently infect growing buckthorn leaves. At this stage, pycnidia are formed on the surface of the leaf and produce pycniospores. Then, aeciospores are produced and re-infect the grass host.

Urediniospores and aeciospores are wind transmitted and can travel long distances. During autumn, the wind may carry urediniospores south to infect winter oat. Moreover, migrating birds have been shown to play a role in both the northward and southward dispersal of spores during spring and autumn, respectively, and even across continents. Teliospores survive the winter in temperate regions or the hot dry summers in regions with Mediterranean climates. Mild, wet weather stimulates dormant teliospores to germinate and produce basidiospores that infect newly formed leaves of the alternate host.

- **Brown rust – *Puccinia recondita* (PUCCRE) / *Puccinia triticina* (PUCCRT) / *Puccinia hordei* (PUCCHD)**

(Jorge David Salgado, Elizabeth Roche and Pierce A. Paul*, Department of Plant Pathology)
(Agriculture and Horticulture Development Board AHDB – The encyclopedia of cereal diseases, 2018)

Generalities:

Brown rust is a foliar disease caused by *Puccinia recondita* or *P. triticina* on wheat and *P. hordei* on barley.

There is large seasonal and geographic variation in brown rust severity.

In wheat, brown rust in wheat is common in regions with high summer temperatures. Brown rust tends to develop late in the summer and results in a significant loss of green leaf area and, hence, yield and specific weight.

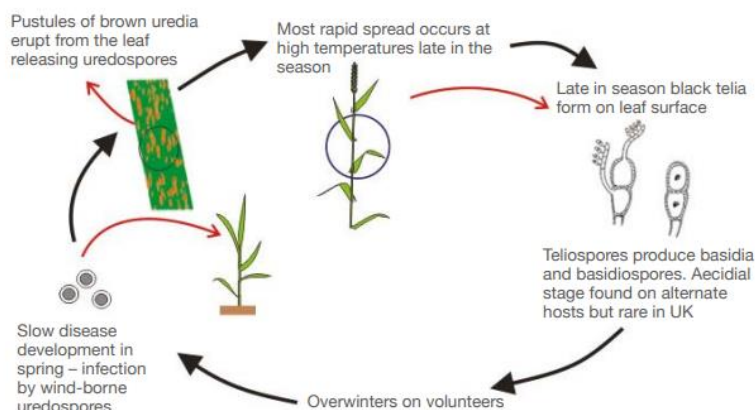
In barley, brown rust can be widespread, if conditions are conducive and there is dense cropping of barley. Brown rust epidemics on barley tend to start earlier in the spring than for wheat. Brown rust is usually more of an issue in winter barley than in spring barley, especially in early sown crops when the winter is mild. A severe attack of brown rust early in the season affects final yield, through reduced green leaf area and tiller retention.

Symptoms:

Pustules (about 0.5–1.0 mm in diameter) often develop on leaves in the autumn on early-sown crops. These pustules contain orange-brown, rusty coloured spores. Later in the season, dark brown to black spores are produced which are not easily rubbed off the leaf surface. Pustules first develop on lower leaves and progress up the plant. Symptoms can be present from seedling stages through ripening. Often seen on the leaves, symptoms can occur on the stem, leaf sheaths, and ears when infection is severe.

Life cycle & Epidemiology:

Figure 3.2-9: Brown rust life cycle



The fungus can only grow and survive on live leaf tissue.

Urediniospores initiate germination 30 minutes after contact with free water and temperatures between 15°C and 22°C are optimal for sporulation and germination. Surface moisture on leaves (i.e. 100% relative humidity) is essential for spore germination. Therefore, windy days disperse spores and cool nights with dew favour the build-up of the disease. The germ tube grows along the leaf surface until it reaches a stoma; an appressorium is then formed, followed immediately by the development of a penetration peg and a sub-stomatal vesicle from which primary hyphae develop. A haustorial mother cell develops against the meso-phyll cell, and direct penetration occurs. The haustorium is formed inside the living host cell. Secondary hyphae develop resulting in additional haustorial mother cells and haustoria. When the host cell dies, the fungus haustorium dies too..

Symptoms can occur 5–6 days after infection at optimum temperatures. Cold weather slows disease development but does not kill the pathogen (unless the leaf dies).

Brown rust has a complex life cycle that include two hosts (primary host and alternate host) and several different spore stages. Urediospores overwinter on infected wheat and are carried by the wind. Under favourable temperature and moisture conditions, urediospores germinate and infect leaves within 6 to 8 hours after landing on the plant surface. Once established, a new crop of urediospores may be produced every 7 to 14 days if environmental conditions are favourable.

The earlier rust develops, the more spore and disease cycles are likely to occur during the season and the greater the risk of severe epidemics and yield loss. Frequent heavy dew, light rain, or high humidity are ideal for leaf rust development.

As the plant matures, black, submerged pustules develop on the leaves. These pustules (telia) contain the winter spores (teliospores). Teliospores do not infect wheat but may develop on diseased plant tissue, indicating a second developmental stage of the fungus.

Telia may not develop when plants become infected very late in the season (close to maturity). In the fall, urediospores are blown southward, infect wheat, and overwinter as urediospores or mycelium on volunteer wheat plants.

- **Yellow rust (or stripe rust) – *Puccinia striiformis* (PuccST) / *Puccinia striiformis* f. sp. *tritici* (PUCCSI)**

(Agriculture and Horticulture Development Board AHDB – The encyclopedia of cereal diseases, 2018)

Generalities:

Puccinia striiformis, causal agent of stripe or yellow rust, is an agronomically important obligate biotrophic fungal pathogen of wheat, barley, and other domesticated crops, as well as many non-domesticated grasses.

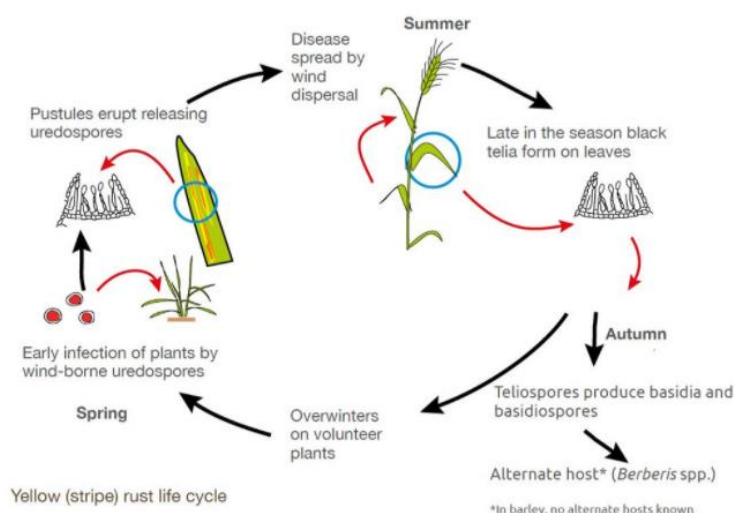
Severe epidemics are usually associated with susceptible varieties, mild winters and cool moist summers. Yield losses of 40–50% can be recorded in susceptible varieties.

Symptoms:

Yellow rust symptoms appear as parallel rows of yellowish orange coloured pustules on the leaves of adult plants. Epidemics often start on individual plants, usually in the autumn. Symptoms develop slowly over winter and are often missed until the early spring when small patches or foci of infected plants can be seen in fields. Yellow rust lesions tend to spread as a yellow band on young leaves moving ahead of the sporulating lesion. On older leaves pustules occur in obvious stripes hence it sometimes being referred to as stripe rust. Severe infections quickly give rise to chlorosis, and later necrosis, of leaves resulting in desiccation in May/June if the weather conditions are warm and dry. In severe attacks, yellow rust infection of the ears can occur with the formation of masses of spores between the grain and the glumes. At the end of the season, secondary black spores (teliospores) are sometimes produced amongst the stripes of pustules.

Life cycle & Epidemiology:

Figure 3.2-10: *Puccinia striiformis* life cycle



Yellow rust requires living green plant material to survive. In the winter, the fungus survives as dormant mycelium or active sporulating pustules on volunteers and autumn-sown crops. Although, low temperatures kill pustules, mycelium within plant tissue can survive temperatures of -5°C .

The epidemic takes off as temperatures warm. The primary inoculum to cause epidemics on cereal crops is mainly from cereal crops, volunteer plants and grasses. The fungus produces bright yellow to orange

urediniospores 20 to 30 µm in diameter. These spores have thick and echinulated walls and are contained in sori or pustules on the plant. Urediniospores can be disseminated by wind for long distance and also can be carried on clothes and shoes for unintended introduction.

Urediniospore production usually is followed by teliospore production late in the growing season. Temperatures of 10–15°C and a relative humidity of 100% are optimal for spore germination, penetration and production of new spores. These are spread by wind or leaf-to-leaf contact. Cool, damp weather in the spring, with overnight dew or rain, provides optimum conditions for disease development. At the end of the season, secondary black spores (teliospores) may be produced as part of the sexual stage.

The complete cycle from infection to the production of new spores can take as little as 10 days during ideal conditions, so leaf tips may show symptoms before leaves fully emerge. The disease cycle may repeat many times in one season.

In wheat, the basidiospores produced from these teliospores have an alternative host. This means sexual recombination can take place, forming new races. In barley, there is no known alternate host, meaning sexual recombination cannot take place.

The fungus can survive summer and/or winter as mycelium in host tissue for months and/or as viable urediniospores in the air or host surface for different length of time in different regions depending upon environmental conditions. Temperatures over 20°C slow the fungus, although there are strains tolerant to high temperatures. A prolonged spell of warm, dry weather often stops an epidemic. This is due to the direct effect on the fungus and increasing host resistance at higher temperatures. Stripe rust epidemics are affected by various crop and environmental factors, especially host factors such as cultivar susceptibility and cropping systems, and weather factors such as moisture and temperature.

- **Tan spot – *Pyrenophora tritici-repentis* (PYRNTE)**

(Moreno V, et al, *Pyrenophora tritici-repentis*, Causal agent of tan spot: a review of intraspecific genetic diversity. *The Molecular Basis of Plant Genetic Diversity*, 2012)
(Agriculture and Horticulture Development Board AHDB – The encyclopedia of cereal diseases, 2018)

Generalities:

Pyrenophora tritici-repentis is the causal agent of tan spot of wheat leaf. It is a facultative parasite fungus that belongs to the *Ascomycota* Phylum and the class of *Hyphomycetes*. The tan spot disease is able to induce losses that reached from 20 % to 70% of yield and it is very destructive on durum, winter and spring wheat. Tan spot reduces total yield, kernel weight, number of grains per head, total biomass, and/or grain quality because of red-smudge symptoms.

The disease affects wheat but can also attack barley, rye and some grasses.

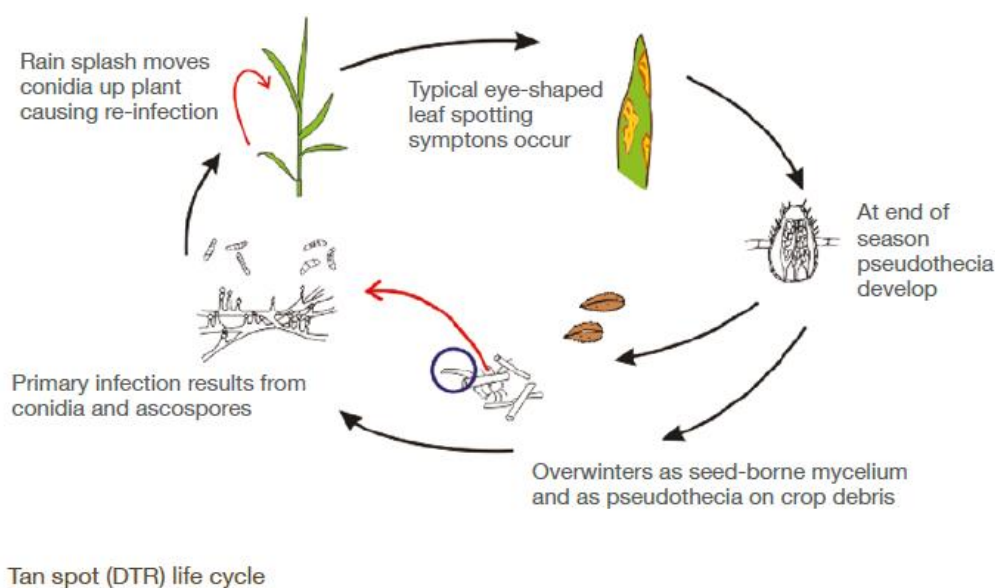
Symptoms:

P. tritici-repentis can be seed-borne and infect seedlings, resulting in small tan to light brown flecks on young leaves. However, symptoms are generally seen later in the season on the middle and upper canopy.

Early symptoms appear as small tan to light brown flecks, with a chlorotic halo, often with a dark spot at the centre. Later these develop into light brown oval lesions with slightly darker margins and a light coloured spot at the centre. Under wet conditions, the lesions produce spores, which can make lesions darker in colour. Under ideal conditions, these lesions coalesce to produce large areas of dead tissue.

Life cycle & Epidemiology:

Figure 3.2-11: *Pyrenophora tritici-repentis* life cycle



P. tritici-repentis survives mainly as dormant mycelium on stubble and crop debris. Pseudothecia are produced on stubble, which in turn produce ascospores for long distance spread. Under warm, wet conditions, leaf spots produce dark conidia, which are spread up the plant. In severe infections, and when conditions during flowering are conducive to the disease, it can infect the ear, cause discoloration of the glumes and the grain, and infect seed. The disease develops over a wide range of temperatures but has quite a high optimum (20–28°C). It is also favoured by long periods (18 hours or more) of dew or rain. Leaf lesions appear in 7–14 days.

The seeds, straw and collateral hosts are the principal source of inoculum of tan spot.

The primary inoculum wade through the wheat areas for long distances and it is introduced in new areas by seeds. In the seed, the pathogen is located in the pericarpio as mycelium. Another source of primary inoculum is the straw of wheat.

Infested residue usually results in significant disease severity at flag leaf emergence and later growth stages due to secondary infections. Collateral hosts could be inoculum source between growing seasons.

- **Net blotch – *Pyrenophora teres* (PYRNTR)**

(Liu, Z, et al. *Pyrenophora teres*: profile of an increasingly damaging barley pathogen, *Molecular Plant Pathology*, 2011)
(Agriculture and Horticulture Development Board AHDB – The encyclopedia of cereal diseases, 2018)

Generalities:

The fungus *Pyrenophora teres* is the causal agent of net blotch of barley. Similar to other stubble-borne diseases, net blotch has become economically important and has emerged as a major disease in many barley-growing areas worldwide.

Reduced or no-till agricultural practices have probably contributed to the increase in importance of both net form and spot form of net blotch disease. However, the susceptibility of current cultivars and trends in environmental conditions cannot be ruled out as contributing factors to the increased importance of the disease. Net blotch can cause typical yield losses of 10%–40%, with the potential for total loss if susceptible cultivars are planted under extreme environmental conditions. Furthermore, infection leads to a reduction in kernel size, plumpness and bulk density, and negatively affects the malting and feed quality of barley.

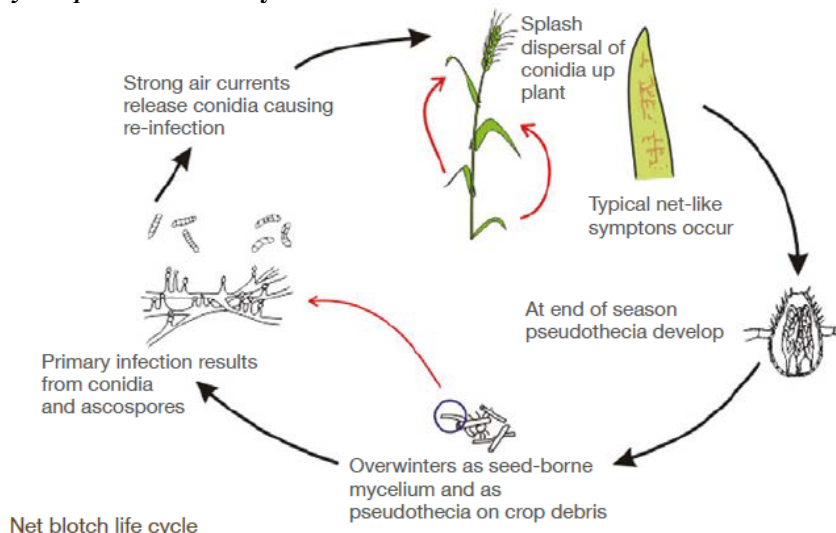
Symptoms:

Netblotch occurs in two forms, one producing a network of necrosis on leaves extending mostly along the veins and partly across the veins of the leaf (termed the net form) and the other causing smaller discrete dark spots (termed the spot form). Both also produce chlorosis around infected areas as the infection matures.

On juvenile plants, particularly emerging crops, the disease may also appear as a brown stripe extending from the leaf base to the tip, similar to leaf stripe.

Life cycle & Epidemiology:

Figure 3.2-12: *Pyrenophora teres* life cycle



The pseudothecia are spherical structures seen as many dark dots on the surface of barley straw. Club-shaped and bitunicate asci, develop within the mature and fertile pseudothecia. Each ascus generally contains eight ascospores that are light-brown and often have three or four transverse septa and one or two longitudinal septa only in the median cells. Mature ascospores are actively discharged, dispersed by wind and serve as primary inoculum early in the growing season. In some cases, seed-borne mycelium and conidia released from the stubble of barley or an alternative host can also serve as primary inoculum for early season infection.

After initial colonization, the fungus produces a large number of conidia, which serve as secondary inocula. Conidia are borne on top of conidiophores that are slightly swollen at the base and usually arise singly or in groups of two or three. Conidia are smooth, cylindrical and straight, round at both ends, subhyaline to yellowish brown, and often with four to six. Conidia are produced throughout the growing season and are dispersed by strong wind or rain to cause new infections on plants locally, or can be carried longer distances potentially to new barley fields.

P. teres also produces pycnidia and pycnidiospores on the host and in culture. These structures are yellow to brown and produce hyaline, nonseptate, spherical, and ellipsoidal pycnidiospores. Pycnidia can develop on infected straw, leaf fragments and seed.

Seed-borne mycelium infects the coleoptile and the first leaf becomes infected as it emerges. Spores produced on this first leaf serve to spread the disease to other leaves and to surrounding plants. Seed-borne inoculum is usually much less important than infected stubble and trash which allows the pathogen to over-winter.

The dispersion, germination and successful infection of conidia are greatly influenced by the relative humidity, temperature, leaf wetness and other environmental factors. During the growing season, several secondary cycles can occur, causing high disease severity on susceptible plants if environmental conditions are favourable. At the end of the growing season, the fungus colonizes the senescent tissue, ultimately producing pseudothecia, the protective teleomorph structure used for overseasoning.

Infection occurs during periods of prolonged high humidity and temperatures of 10–25°C. Higher temperatures and dry weather inhibit infection. The disease cycle can complete in 14 days in optimal conditions.

- **Ramularia Leaf Spot – *Ramularia collo-cygni* (RAMUCC)**

Generalities:

Ramularia collo-cygni, which belongs to the Ascomycota phylum, Dothideomycete class, is the causal agent of ramularia leaf spot (RLS) disease of barley. RLS has emerged as a serious threat to barley production across temperate regions of Europe and can cause extensive losses in yield and quality.

The fungus produces phytotoxins called rubellins in the plant, which cause foliar necrosis and reduce photosynthetic area. With this reduction in green leaf area, RLS can affect yields by as much as 70%, but losses are more usually in the region of 5–10%. Importantly, RLS can also increase the proportion of small grains by as much as 4% consequently lowering the quality of the grain.

Although RLS is primarily a disease of barley *R. collo-cygni* is also able to infect other cereal crops such as wheat and oats as well as some grasses including weed species. Typical RLS lesions can be observed on some nonbarley host species but infection is often asymptomatic.

Symptoms:

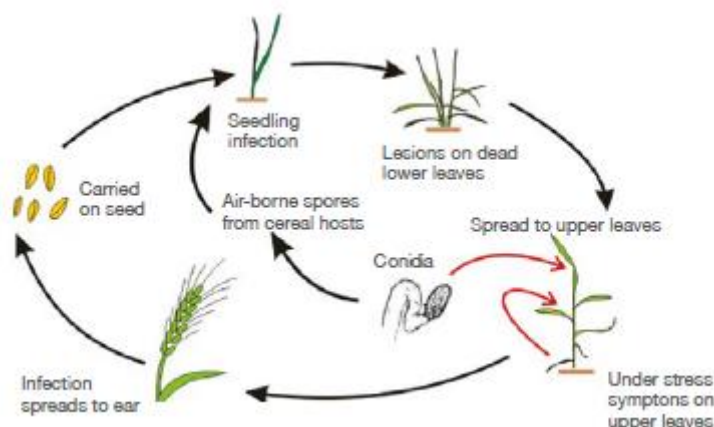
Symptoms appear on the upper leaves after flowering. Initial damage is a fine pepper spot, which darkens to a square spot, bounded by leaf veins and surrounded by a chlorotic halo. Mature ramularia lesions can be distinguished from other foliar symptoms by applying the ‘5Rs’:

- **R**inged with yellow margin of chlorosis
- **R**ectangular shape
- **R**estricted by the leaf veins
- **R**eddish-brown colouration
- **R**ight through the leaf

Physiological leaf spots, caused by oxidative stress, tend to be caused by superficial browning on upper leaf surfaces, while the undersides remain unaffected. These cause less yield loss but can trigger the production of ramularia leaf spots.

Life cycle & Epidemiology:

Figure 3.2-13: *Ramularia collo-cygni* life cycle



R. collo-cygni grows from infected seed and moves systemically within new plant growth. Airborne spores produced on trash and crop debris can also infect plants. Infected crops do not display visible symptoms initially. Senescing leaves may show signs of infection early in the season but the main damage occurs on the top leaves after flowering. Later in the season, rows of white spores can be seen with a hand lens on the undersides of affected leaves. As leaves senesce, these structures can be seen with the naked eye. Stressed crops are thought to be more likely to show symptoms, including those exposed to high light levels, waterlogging and rainfall after flowering. However, even stress associated with flowering may be sufficient to initiate symptoms.

R. collo-cygni can also be spread by wind-dispersed spores. On the leaf surface, the fungus forms a hyphal network whilst infectious hyphae invade the host through open stomata. Upon penetration, the

fungus forms substomatal aggregates, which remain connected to the epiphytic network on the leaf surface. As *R. collo-cygni* colonises the plant, fungal growth is intercellular and host epidermal cells remain intact. Disease symptoms tend to appear following collapse of the mesophyll tissue, which has been associated with fungus sporulation events. However, detectable levels of spore release tend to occur mainly post-flowering in both winter and spring barley crops.

The toxin rubellin D is also thought to be produced by the fungus when the barley host is stressed. Under certain light conditions, this toxin causes oxidative stress, leading to plant cell damage and causing typical leaf symptoms.

- **Leaf Scald – *Rhynchosporium secalis* (RHYNSE)**

(Avrova A. & Knogge W., *Rhynchosporium commune*: a persistent threat to barley cultivation. *Molecular Plant Pathology*, 2012)
(Agriculture and Horticulture Development Board AHDB – The encyclopedia of cereal diseases, 2018)

Generalities:

Rhynchosporium secalis (or *R. commune*) is the causal agent of leaf scald on barley. The fungus belongs to the *Ascomycota* phylum and is a globally important pathogen of barley crops, especially in cool temperate regions, which favour disease development. Leaf scald affects barley, rye, triticale and a number of grasses, particularly ryegrasses. There are specialised forms of the pathogen, which are generally restricted in their host range.

In winter barley, yield losses can exceed 1.5 t/ha and grain quality can be reduced. The most serious effect on yield, in both winter and spring barley, results from attacks that develop between first node detectable and boot-swollen growth stages. Yield losses of up to 40% have been reported in the field, although losses of 1 – 10% are more typical.

Symptoms:

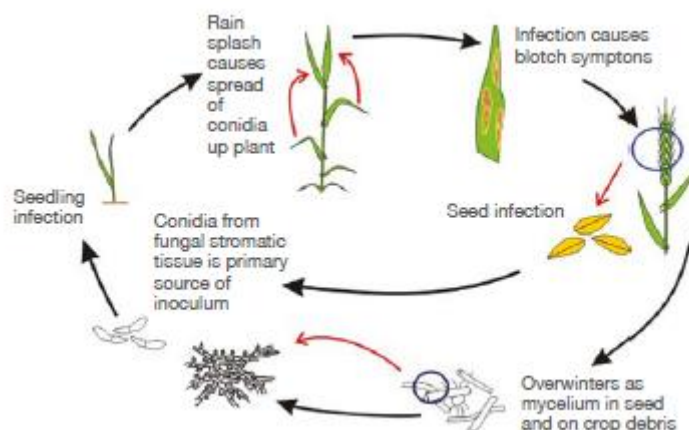
Initial symptoms often appear in random patches soon after sowing winter barley. Symptoms due to the seedborne phase of the disease do not appear until January/February, as the disease initially develops inside the leaves and roots without symptoms showing.

Typical, early symptoms are oval or irregular, pale green-grey, water-soaked lesions. Infection often occurs in the leaf axil. Symptoms often first appear at the base of the leaf close to the stem. Symptoms then spread to the rest of the leaf, leaf sheaths, ears and grain, particularly in wet conditions. As the lesions age, they acquire a dark-brown margin (the centre remains pale green or turns pale brown). Lesions often coalesce and form large areas, around which leaf yellowing is common. These can cause chlorosis and eventual death of the rest of the leaf.

In winter barley, symptom expression can be high during tillering in early spring. In spring barley, it is rare to see symptoms until after tillering, except in very early sown crops. In both crops, symptoms can build up rapidly after emergence of the flag leaf under favourable conditions.

Life cycle & Epidemiology:

Figure 3.2-14: *Rhynchosporium secalis* life cycle



Rhynchosporium is a polycyclic pathogen with several generations of spores developing during the crop growing season. The disease cycle can repeat every 14 days. The ideal temperature range is 18–20°C but temperatures over 20°C slow disease development. Cool, moist conditions favour the disease.

Primary inoculum probably originates from crop debris or infected seeds. Secondary spread occurs through splash-dispersed conidia from infected leaves. Rainfall, at the growth stage of stem extension, is the major environmental factor in epidemic development. *R. secalis* can infect any part of the leaf and produce spots or blotches of irregular shape. Because of the tendency for water retention between the auricle and the stem, lesions are also often found there.

Infection of barley ears can result in severe grain infection. *R. secalis* can be transmitted by seeds, and seed dust remaining on the soil surface. Infection in seeds can be seen as a typical lesion at the base of the awn and show a dark brown margin with a light centre. However, seed infection can remain symptomless, which implies that visible analysis of the seeds may not always be accurate when determining seed quality. Seedlings grown from infected seeds have symptoms at the tip of the coleoptile 4–6 days after emergence, or remained symptomless. Although splash dispersal of *R. secalis* conidia contributes to the short-distance spread in the field, transport of infected seeds may be responsible for the long-distance dispersal of inoculum.

In humid conditions, conidia germinate on the leaf surface, producing hyphae that penetrate the cuticle directly above epidermal cells. Subsequent fungal growth is confined to the subcuticular region of the epidermis. New conidia are produced on conidiophores, which erupt through the leaf cuticle in apparently healthy leaf regions. In addition, sporulation occurs in the lesion areas.

The development of the disease is characterised by a long phase of asymptomatic growth between penetration and occurrence of the typical disease symptoms, necrotic lesions with dark brown margins. Indeed, several generations of the pathogen may occur before symptoms appear. Although the disease is spread from the lower to upper leaves by rain splash, severe symptoms can appear on the upper leaves of the crop, which previously exhibited little visible signs of disease.

During the asymptomatic phase, collapsing epidermal cells represent the earliest microscopically visible evidence of disease. This phase ends with the appearance of the typical scald lesions, which are caused by the collapse of mesophyll cells beneath extensive fungal mycelia. The greyish colour in the middle of the blotch is caused by the formation of spores on the surface. The size of the lesion can vary as a function of environmental conditions and cultivar resistance. The lesions may merge and destroy the entire leaf.

Disease symptoms mainly occur in late summer / autumn (although can occur at other times of year as well). The fungus overwinters via infected barley stubble / volunteers and infected seed (also possibly by some infected grass species) – these then infect the developing seedlings. Autumn-sown crops can become infected very soon after sowing.

- **Septoria tritici blotch – *Zymoseptoria tritici* (SEPTTR)**

(Ponomarenko A., S.B. Goodwin, and G.H.J. Kema. 2011. Septoria tritici blotch (STB) of wheat. *Plant Health Instructor*).
(Agriculture and Horticulture Development Board AHDB – The encyclopedia of cereal diseases, 2018)

Generalities:

Septoria Tritici Blotch (STB) is caused by the ascomycete fungus *Zymoseptoria tritici*, (sexual stage: *Mycosphaarella graminicola*), which belongs to the order Dothideales. This disease constitutes one of the most important foliar diseases of wheat. This is a major economic constraint on wheat productivity, particularly in temperate growth regions.

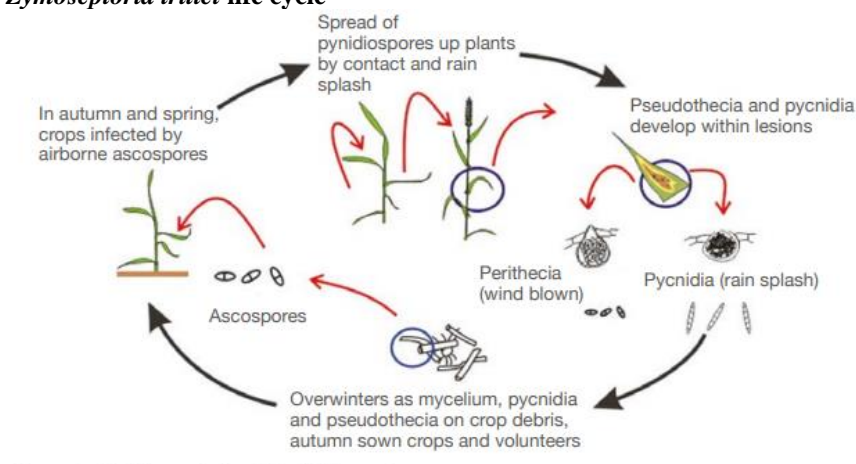
Zymoseptoria tritici blotch is found commonly in the same fields and on the same plants as *Parastagonospora nodorum* (sexual stage: *Phaeosphaeria nodorum*), the causal agent of glum blotch of wheat. When both pathogens occur together, they are referred to collectively as the Septoria blotch complex or Septoria complex. Only *P. nodorum* causes symptoms on ears.

Symptoms:

Symptoms of septoria can be seen very early in the growing season. On young autumn-sown wheat, water-soaked patches, which quickly turn brown and necrotic, may be evident by early December and throughout the winter on the lowest leaves. These contain the visible black pycnidia, which are the most characteristic feature of *Z. tritici*. Pycnidia are particularly common on dead over-wintering leaves of winter wheat. Lesions on the mature plant are brown and sometimes restricted by veins giving a rectangular appearance. The black pycnidia become more visible in the lesions as the symptoms develop. Lesions may coalesce leading to large areas of necrotic brown tissue.

Life cycle & Epidemiology:

Figure 3.2-15: *Zymoseptoria tritici* life cycle



Primary infection by *Z. tritici* occurs soon after seedlings emerge in fall (for winter wheat) or spring. Ascospore germ tubes are attracted either to the stomata, through which they gain entry into the substomatal cavity directly or after production of an appressorium-like structure (infection cushion). For several days the hyphae grow intercellularly with little increase in biomass. After the switch from biotrophic to necrotrophic growth, cells collapse and lesions appeared. The lesions expand, primarily in the direction of the leaf veins to form long, narrow, necrotic blotches. Pycnidia develop around stomata within the necrotic areas of the lesions and exude conidia.

Conidia constitute the secondary inoculum and are disseminated by rain splash to leaves of the same or nearby plants. Secondary spread of the disease also can be by ascospores. Pycnidia with conidia are produced roughly 14 to 40 days after infection, depending on the host and seasonal conditions. These spores disperse through rain wash and splashing, causing local spread of the disease to uninfected leaves of the same and nearby plants. Conidia and ascospores contribute to the epidemic but the asexual cycle seems to dominate during the growing season. Ascospores can be airborne over large distances, while conidia are unlikely to travel far from their site of origin by rain-splash dispersal. Conidia help to spread the disease upwards through the canopy.

Infection of flag leaves (last leaf to emerge on a wheat stalk) is common and leads to greatly reduced yields and poor quality of harvested grain.

Debris from heavily infected leaves and stems remains in fields after harvest to produce inoculum for

the next growing season. The pathogen survives crop-free periods primarily as pseudothecia but also in pycnidia on crop debris. Autumn-sown crops and volunteer plants can aid survival over winter.

Description of the target oilseed rape diseases:

- **Dark Leaf Spot – *Alternaria brassicae* (ALTEBA)**

(Agriculture and Horticulture Development Board AHDB – Brassica diseases, 2020)
(Encyclopedia of oilseed rape diseases, ADAS & BASF, 2009)

Generalities:

Alternaria brassicae is the causal agent of dark leaf spot disease in oilseed rape. The fungus belongs to the phylum Ascomycota and to the class Dothideomycetes. *A. brassicae* is characterized by formation of polymorphous conidia either singly or in short or longer chains with longitudinal and transverse septa with long or short beaks.

In European countries involved in oilseed rape production, this disease is very common. Weather conditions, especially air temperature and precipitation, have a great effect on *Alternaria* blight severity in different years. When the air temperature varies within optimal range (15–23°C), precipitation rate and relative air humidity during the silique ripening period have a decisive effect.

Alternaria blight is especially dangerous if it spreads early and affects young siliques and seed. The yield loss is related to the severity of pod symptoms.

Symptoms:

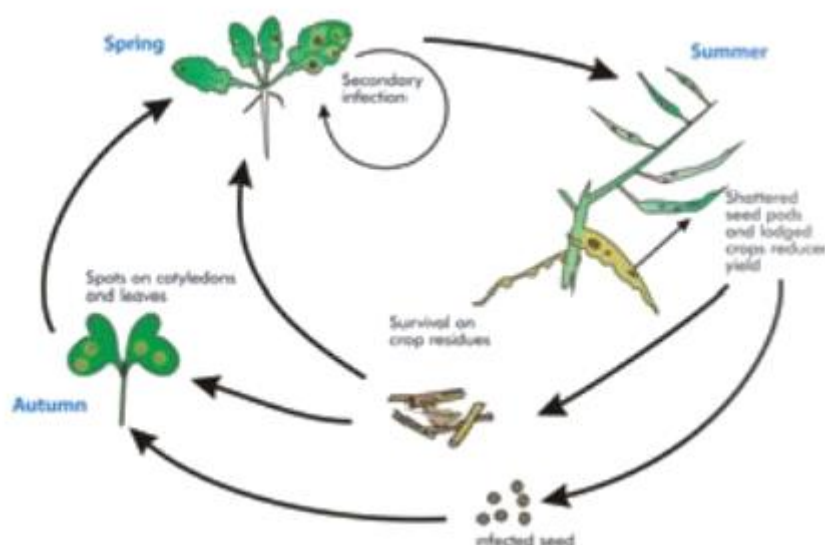
Small black spots (1-2 mm diameter) are the first symptoms. These gradually increase in size and become brown ‘target’ spots with concentric light and dark brown rings. Secondary spotting often occurs around the target spot and is useful for showing the range of lesion sizes. Leaf spotting can be very extensive and lead to early leaf loss.

During flowering, leaf symptoms may develop in the upper leaves and bracts and it is often easier to identify them by examining the underside of the leaf where there is less floral debris occurring the leaf surface.

Black spots develop on the stem and pods. As pod symptoms develop, they become brown in colour and lead to premature ripening and pod splitting when severe. Dark pod spot is more prevalent where the crop is lodged and remains damp for long periods. However, even in a standing crop, pod symptoms become severe and often occur in distinct patches or foci. The disease increases as plant senesce and continues to increase after swathing.

Life cycle & Epidemiology:

Figure 3.2-16: *Alternaria brassicae* life cycle



A. brassicae is commonly seedborne but there are numerous sources of infection including crop residues, neighbouring brassica crops, volunteers and weed hosts. Air-borne spores introduce the pathogen into new crops then secondary spread occurs within the crop. Early sown crops tend to be more heavily infected than later sown crops. There is usually slow spread during the autumn and winter followed by spread to upper leaves, stem and pods from flowering onwards. Problems occur mainly in untreated crops and in periods of wet weather from flowering onwards. Only 6-8 hours of surface wetness are required for infection to take place and symptoms appear in 4-5 days at temperatures above 20°C. Thunderstorms provide good conditions for epidemic development.

During harvesting operations, large numbers of air-borne spores of *A. brassicae* are dispersed and can cause problems in spring oilseed rape. The fungus can be also disseminated from infected host tissue by means of spores produced on mature fungal lesions. Spore dispersal can occur by a number of mechanisms, including air currents, rain splash or dew droplets. Dispersal in the air is potentially over much greater distances than by rain splash. Spores of dark leaf spot have been shown to travel at least 1.8 km from their source.

The fungus requires at least 12–14 hours with a relative humidity of greater than 90% for sporulation to occur. The sporulation rate is optimal between 18°C and 24°C. Sporulation is inconsistent at 26°C and spores formed at this temperature are often not viable. Sporulation by *A. brassicicola* is observed over a greater temperature range, from 18°C up to 30°C. However, time to 50% spore production is greater over the lower temperature ranges, indicating a higher temperature optima for this species. No sporulation by either pathogen is observed below 5°C.

Viable spores landing on healthy plant tissue germinate on and penetrate the host surface through the stomata.

- **Powdery mildew of crucifers - *Erysiphe cruciferarum* (ERYSCR)**

(Mehta NK., Development of prediction models for the management of rapeseed-mustard diseases- Current scenario. *Plant Disease Research*, 2020).

(Encyclopedia of oilseed rape diseases, ADAS & BASF, 2009)

Generalities:

Powdery mildew disease of oilseed brassicas, caused by *Erysiphe cruciferarum*, an obligate pathogen. The disease is a widespread, although sometimes sporadic, problem affecting Brassica crops in Europe. Yield losses as high as 25–30% can occur, particularly when seed pods are attacked, reducing both the number and size of seeds.

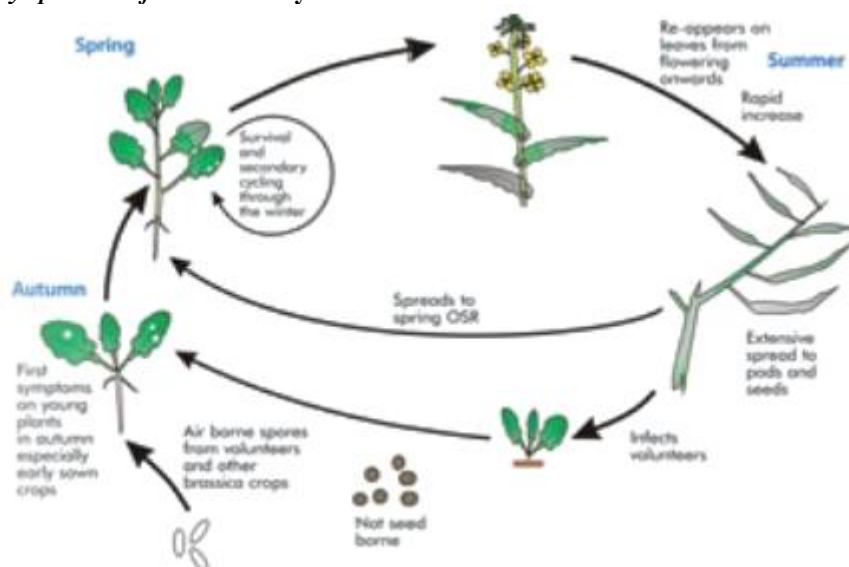
The disease does not cause much damage except during epidemic outbreak on late sown crop especially when it appears at early stage of the crop growth. The pods heavily covered with powdery mass remained empty or produced few seeds at base with twisted sterile tips.

Symptoms:

Discrete off-white patches appear on the leaves, and often the stems and buds. These patches join up and a powdery white coating develops. Leaves can curl at the margins, becoming distorted, or turn yellow or purple and fall early. Infected parts may wither and die back.

Life cycle & Epidemiology:

Figure 3.2-17: *Erysiphe cruciferarum* life cycle



The off season host plants of Brassica species and other weed may carry the fungal mycelium and conidia as source of primary inoculum. This pathogen is an obligate parasite and produces abundant number of cleistothecia on diseased plant tissues at the maturity stage of the crop. The secondary spread of the pathogen takes place through air borne conidia. Long distance dissemination of the pathogen is rapid through wind currents under low humid conditions. Conidia fallen on the host tissues germinate, grow and spread in the form of mycelium, later producing conidiophores and conidia in the form of white mildew growth. It is likely to carry over from season to season through cleistothecia or as mycelium on volunteer plants.

The optimum temperature for the germination of conidia, germ-tube growth and appressorium formation is 20-25°C. Conidia could not germinate below 15°C and above 30°C. Maximum conidia germinate at 40 to 50% of moisture. To initiate the spore germination, at-least 30% of relative humidity is essential and there is no conidial germination above 60% RH. Conidial germination is not influenced by light and darkness. For onset and epidemic development of disease under field conditions, moderate temperature, low humidity, minimum rainfall or dry season are more favourable. The cleistothecial formation is favoured by alternating low and moderate temperature. Heavy sporulation took place with low nutrition of the host, low relative humidity, dry soil and aging of the host.

There are number of environmental factors which are very crucial to influence the powdery mildew development of crucifers in to epidemic form after host-pathogen interaction. These factors determine the progress of powdery mildew on host plants with their influence, and effects on interacting partners, host, and pathogen.

Infection, and disease development is faster with the influence of mean temperature (16-22°C), minimum temperature (>7°C), maximum temperature (25-28°C), relative humidity (27-65%), sunshine hours (>9h/day) and wind velocity (2km/h). Infection rate increases with ageing host tissues. There is no infection on younger than 37 days host, and freshly emerging new leaves. Disease develops at fast rate if host, and pathogen interact coinciding with favourable host age, plant growth stages, and environmental factors. Stem infection is maximum with the increase in length of time they are exposed to the pathogen, and maturity level of the host.

Symptoms are visible at asexual stage with the development of pathogens mycelium, conidiophores, and conidia on host surface. Date of crop planting has significant bearing on disease epidemiology under

late sown conditions coinciding with congenial, and critical factors at 40-120 days after sowing. Sexual stage appears in the form of dark brown spherical bodies of cleistothecia or chasmothecia embedded in powdery mass of host leaf, stem, and pods at maturity stage of crop when temperature is 11- 27°C (19°C), alternate moderate temperature, heavy sporulation, low host nutrition, low relative humidity, dry soil, and ageing host tissues.

- **Black leg - *Plenodomus lingam* (LEPTMA)**

(Howlett BJ, *et al.* *Leptosphaeria maculans*, the causal agent of blackleg disease of brassicas. *Fungal Genetics & Biology*, 2001).
(Ash, G. Blackleg of oilseed rape. *The Plant Health Instructor*, 2000)

Generalities:

Plenodomus lingam or *Leptosphaeria maculans* is able to cause phoma stem canker (or black leg) on different winter and spring cultivars of oilseed rape grown under a wide range of climates and despite different agricultural practices.

The disease is of major economic importance in the main oilseed rape growing areas in Europe and the severity of epidemics differs greatly between seasons, between regions and between crops. Where the disease occurs, total destruction of the crop due to seedling death is rare and usually yield losses at harvest are 10%, although they can reach 30-50%.

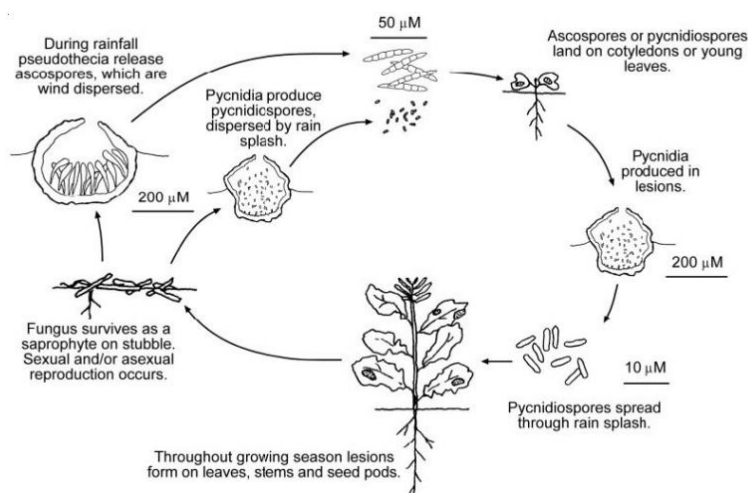
Symptoms:

In oilseed rape, the first obvious symptom of blackleg is the appearance of grey-green to ash-grey lesions on the lower leaves. The disease is characterized by the presence of small, black pycnidia at the edge or scattered across the blackleg lesions. Tissue in a lesion may dry, crack, and fall out, making identification difficult. Blackleg lesions from multiple infections may coalesce and these lesions often expand down leaf veins towards the base of the leaf. In severe epidemics, lesions also can be found on the stems and pods of oilseed rape plants.

Basal stem lesions are the most damaging. When these occur in the seedling or rosette phases of growth, symptoms resemble damping-off or cut-worm damage. In older plants, the more typical canker symptom leads to premature ripening or lodging of the crop.

Life cycle & Epidemiology:

Figure 3.2-18: *Plenodomus lingam*. life cycle



L. maculans has a complex life cycle compared to most other fungal phytopathogens attacking annual plants. It can infect different plant tissues, undergo multiple switches from biotrophy to necrotrophy in plant tissues, and can also live as a saprophyte on plant residues.

The epidemiological cycle begins with the hemibiotrophic colonisation of young leaves by spores generated by sexual reproduction (ascospores) in early autumn (October-November). Ascospores are released after rainfall when temperatures are between 8-12°C. These spores can be wind-dispersed for hundreds of meters and germinate in the presence of free water from 4-28°C. Penetration is through stomates.

The fungus first colonises the leaf tissues as a biotroph, for a few days or weeks, depending on the climatic conditions, without causing any symptoms. The fungus invades the intercellular spaces between the epidermal layers of the leaf. This symptomless biotrophic phase is followed by invasion of the mesophyll with the resultant death of cells and the appearance of grey-green lesions. The hyphae continue to ramify through the leaf tissue until they reach a leaf vein. The fungus then colonises the cortex and/or xylem parenchyma of the petiole. At the junction of the petiole and the stem, the fungus invades the stem cortex where it causes a canker.

It then induces the development of necrotrophic leaf lesions in which its asexual spores (conidia) are produced. The fungus then migrates, without causing symptoms, from the petiole to the stem, where it lives in the plant tissues, as an endophyte, for several months. Finally, at the end of the growing season, it switches back to necrotrophic behaviour, inducing the formation of a damaging stem canker that may result in plant lodging. Stem cankers develop most quickly at 20-24°C and are most severe under stress conditions such as mechanical, insect, or herbicide injury.

The pycnidiospores are dispersed to new infection sites by rain splash. Pycnidia can and do overwinter readily in stubble, but because pycnidiospores are not airborne to any significant extent, they are of minor importance in initiating the first cycle of disease. Pycnidiospores germinate more slowly than ascospores and require more than 16 hr of continuous wetness at the optimal temperature range of 20-25°C. The minimum latent period (the time from infection to the production of new inoculum) following infection by pycnidiospores is 13 days. Although secondary infections by pycnidiospores do occur, most losses are due to primary infections of leaves by ascospores that lead to basal stem cankers and eventual lodging of the plants.

Having completed all these stages of infection on living plant tissues, *L. maculans* then switches to a saprotrophic lifestyle, living on crop residues for up to three years. It develops structures for sexual reproduction to create the new inoculum (ascospores) for subsequent seasons on these residues.

The pathogen also may be seedborne and infected seeds can give rise to infected seedlings, but levels of seed contamination are always very low. Primary infections usually occur on the cotyledons or basal rosette leaves of the plant. Wet weather favours these primary infections.

- **Light Leaf Spot - *Pyrenopeziza brassicae* (PYRPBR)**

(Encyclopedia of oilseed rape diseases, ADAS & BASF, 2009)

Generalities:

Light leaf spot is a foliar disease caused by the ascomycete fungus *Pyrenopeziza brassicae*. The disease is widely distributed in Europe and particularly in the UK, where weather conditions are favourable to the fungus.

The disease appears, after a long period of symptomless growth, as speckles of white spore pustules on leaves, stems and pods. These spore pustules are only visible after a period of dry weather. As infections mature, the fungus can also cause bleaching and stunting of leaves in affected positions causing leaf distortion and by spreading to the growing point, can cause stunting of the whole plant. The disease typically reduces yield by a third of the incidence (90% plants affected at early stem extension causes 30% yield loss) and on average.

Light leaf spot is a polycyclic disease, which infects oilseed rape leaves, stems, flowers and pods during the course of the season, between sowing in autumn and harvest in summer. The disease remains active at far lower temperatures than other pathogens of vegetable brassicas, down to 4°C, so continues to cause outbreaks right through the winter.

Symptoms:

A light leaf spot lesion can be recognised as groups of small black spots on the underside of leaves, clustered in to a 'thumbprint' (Figure 19). Small white spore droplets are produced on and around these

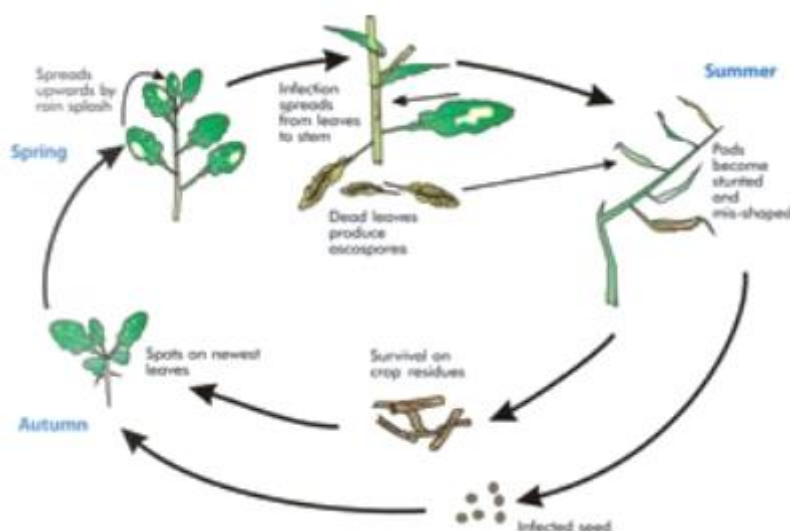
lesions. On very susceptible varieties, large areas of individual leaves may be affected and large pale blotches develop. Lesions on the older yellowing leaves often have a 'watermark' appearance, confined to one side of the leaf and developing a pinkish or red colour.

Leaf lesions are not very numerous in summer but become easier to find on the upper leaves in autumn and winter. The white spore droplets are usually found around the edges of the lesions but are less likely to be found when buttons have been wetted by rain. Lesions on buttons induce considerable yellowing of the outer leaves and advanced symptoms may be confused with overmaturity and soft rots.

Symptoms of light leaf spot can appear as early as July, but disease symptoms become most prevalent during autumn and winter. A feature of the disease is its rapid development on buttons in autumn, despite little evidence of earlier leaf infection. This is probably due to the spread of airborne spores from debris in nearby fields, rather than secondary spread within the crop itself. Because light leaf spot is one of several diseases which cause black spots in brassicas, reliable identification may require laboratory diagnosis.

Life cycle & Epidemiology:

Figure 3.2-19: *Pyrenopeziza brassicae* life cycle



Light leaf spot is a polycyclic disease in that it switches spore type throughout its life cycle within the crop. This ability to switch allows further spread by rain splash, with symptoms often appearing patchy in the crop. Light leaf spot produces ascospores on dead tissue and conidia are formed in acervuli on living tissue. Ascospores and conidia are morphologically similar when observed under a light microscope. Ascospores are hyaline, cylindrical, septate and roughly $15.0\ \mu\text{m} \times 2.5\ \mu\text{m}$ in size, while conidia are hyaline, cylindrical, aseptate and roughly $10\text{--}16\ \mu\text{m} \times 3\text{--}4\ \mu\text{m}$. Ascospores play an important role in initiating epidemics in the autumn, when they are released from infected oilseed rape debris as it dries after overnight dew or rainfall, and are dispersed by wind. Conidia only travel short distances by splash dispersal and are responsible for secondary spread of the disease during autumn and winter. These later infections by secondary spores will not be picked up by spore trapping. Dry conditions delay spore maturation and release but do not prevent it.

The winddispersed ascospores of light leaf spot are likely to be responsible for transmitting the disease to crops. These ascospores are produced on leaf debris underneath oilseed rape crops in spring/early summer when horticultural brassica crops are transplanted to the field, and on stem and pod debris after oilseed rape harvest during late summer/autumn when horticultural brassica crops have been fully established. Once infected, leaves and buttons can remain symptomless for long periods of time (3–4 weeks), especially during cold weather. Volunteer oilseed rape plants may also act as a 'green bridge' between crops and thus provide another inoculum source.

Infection is influenced by environmental factors, including temperature and leaf wetness duration.

During the past decade, there has been a considerable increase in the severity of light leaf spot epidemics in northern Europe, perhaps due to changes in *P. brassicae* populations, to render ineffective some sources of resistance and some previously effective fungicides.

Isolates from oilseed rape can cause light leaf spot on cabbage or Brussels sprouts, and vice versa.

The amount of stem and pod infection determines the amount of inoculum for winter oilseed rape crops in the next season and along with weather records, is the basis for a forecast of disease severity the following season.

- **Cottony rot - *Sclerotinia sclerotium* (SCLESC)**

(Leyronas C. et al, Assessing the phenotypic and genotypic diversity of *Sclerotinia sclerotium* in France. *European Journal of Plant Pathology*, 2018)

(Bolton MD. Et al, *Sclerotinia sclerotium* (Lib.) de Bary: biology and molecular traits of a cosmopolitan pathogen. *Molecular Plant Pathology*, 2006)

(Encyclopedia of oilseed rape diseases, ADAS & BASF, 2009)

Generalities:

Sclerotinia sclerotium, an Ascomycete fungus, is one of the most devastating and cosmopolitan of plant pathogens. The fungus infects over 400 species of plants worldwide including important crops and numerous weeds. *S. sclerotium* poses a threat to dicotyledonous crops such as sunflower, soybean, oilseed rape, edible dry bean, chickpea, peanut, dry pea, lentils and various vegetables, but also monocotyledonous species such as onion and tulip.

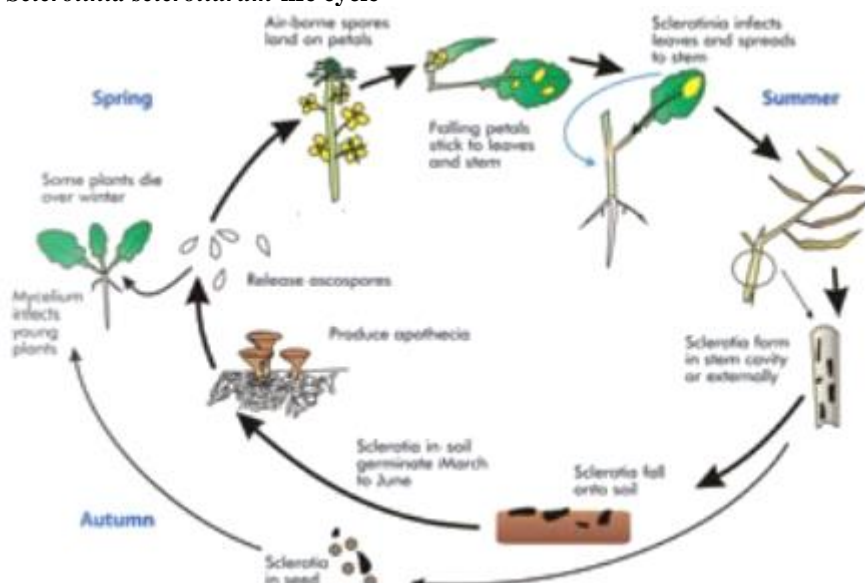
Symptoms:

S. sclerotium is a necrotrophic pathogen. Leaves usually have water-soaked lesions that expand rapidly and move down the petiole into the stem. Lesions usually develop into necrotic tissues that subsequently develop patches of fluffy white mycelium, which are the most obvious sign of infected plants. Early in lesion development, plants may not appear affected by the disease. However, as the fungus progresses into the main stems, wilting typically occurs. As lesions age, infected tissues appear bleached and are often shredded, leaving only vascular tissues.

Sclerotia are formed inside infected tissue, often in the stem pith, but may form on the surface of tissues during high humidity conditions. Sclerotia will commonly form on or in flowering and seed-producing portions of the plant and, therefore, are often found in harvest samples. Once the disease has been initiated in the host, infection can spread to adjacent plants through plant-to-plant contact.

Life cycle & Epidemiology:

Figure 3.2-20: *Sclerotinia sclerotium* life cycle



Sclerotia are central components of the disease thanks to the massive reproductive potential along with capability for long-term survival. Sclerotia can germinate carpogenically or myceliogenically, depending on environmental conditions, resulting in two distinct categories of diseases. Sclerotia that germinate myceliogenically produce hyphae that can directly attack plant tissues. Sclerotia that germinate carpogenically produce apothecia and subsequently ascospores that infect aboveground portions of host plants. Hyphae resulting from either germination type are hyaline, septate, branched and multinucleate with mycelium appearing white to tan in culture and in planta. Microconidia are produced on hyphae or the apothecial hymenium, but these structures do not germinate.

Most diseases caused by this pathogen are initiated by ascospores. The apothecium or fruiting body that produces ascospores is formed following carpogenic germination of a sclerotium at or near the soil surface under certain environmental conditions. Environmental factors conditioning carpogenic germination include soil temperature and moisture, but also the temperature at which the sclerotia were produced. In temperate zones, conditioning appears to be a combination of wetting and drying events, low temperatures, and time. Soil moisture is a critical factor in apothecia production and is one of the principal reasons that ascospore-initiated diseases are associated with irrigation events or periods of high rainfall.

An apothecium consists of a stipe originating from a sclerotium and a receptacle with a flat to concave hymenial layer (2–10 mm diameter), which is ochre to light tan in colour. One or more apothecia may arise from a sclerotium. Ascospores are forcibly discharged from each ascus. It can occur continuously under optimum conditions for greater than 10 days in the field at a rate of 1600 spores/h. *S. sclerotiorum* frequently releases ascospores by ‘puffing’ of the apothecium, a state at which vast quantities of asci simultaneously release their ascospores, triggered by changes in relative humidity or physical disturbance of the apothecium. Most ascospores are deposited within the field where they are produced although some can be carried several kilometre in air currents. Ascospores are covered by sticky mucilage, which aids in adhesion to the substrate they land on. They can survive on plant tissue for about 2 weeks depending on environmental conditions; high relative humidity and ultraviolet light are detrimental to their survival.

Ascospores can germinate on the surface of healthy tissue but cannot infect the plant without an exogenous nutrient source and a film of water. Therefore, senescent or necrotic tissues generally serve as the nutrient source to initiate ascospore germination, giving rise to mycelial infection of the host plant. Flowering is considered a critical host factor associated with most ascospore-initiated diseases because senescing flower parts serve as the primary nutrient source as they fall on to the leaves, petioles or stems. As flowering of crops occurs about the time canopies close, the nutrient sources are available during a time when environmental conditions are more favourable for growth of the pathogen.

Information on the target crops

Table 3.2-21: Major / minor status of intended uses in Central EU Regulatory zone (for all cMS and zRMS).

(source: EUMUDA database for EU Minor Uses database, <https://www.eumuda.eu/>)

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	minor
Durum wheat (TRZDU)	AT, DE, HU, RO, SK	PL, BE, CZ, IE, NL, LU	SEPTTR, PUCCRE, ERYSGR, FUSASP	AT, DE, HU, RO, SK, PL, BE, CZ, IE, NL, LU	-
Winter wheat (TRZAW)	AT, DE, HU, RO, SK, PL, BE, CZ, IE, NL	LU	SEPTTR, PUCCRE/PUCCRT, PUCCSI/PUCCST, ERYSGR/ERYSGT, FUSASP, PYRNTE, LEPTNO	AT, DE, HU, RO, SK, PL, BE, CZ, IE, NL, LU	-
Triticale (TTLWI)	AT, DE, HU, SK,	IE, NL, RO, LU	SEPTTR, PUCCRE,	AT, DE, HU,	-

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	minor
	PL, BE, CZ		ERYSGR, FUSASP	RO, SK, PL, BE, CZ, IE, NL, LU	
Rye (SECCW)	AT, DE, HU, SK, PL, BE, CZ	IE, NL, RO, LU	SEPTTR, PUCCRE, ERYSGR, RHYNSE	AT, DE, HU, RO, SK, PL, BE, CZ, IE, NL, LU	-
Oats (AVESS)	AT, DE, HU, RO, SK, PL, BE, CZ, IE	NL, LU, HU	PUCCCA, ERYSGR, PSDCHA, PYRNAV	AT, DE, HU, RO, SK, PL, BE, CZ, IE, NL, LU	-
Spring barley (HORVS)	AT, DE, HU, RO, SK, PL, BE, CZ, IE, NL	LU	RAMUCC, PUCCHD, ERYSGH, RHYNSE, PYRNNGR, PYRNTE	AT, DE, HU, RO, SK, PL, BE, CZ, IE, NL, LU	-
Winter barley (HORW)	AT, DE, HU, RO, SK, PL, BE, CZ, IE	NL, LU	RAMUCC, PUCCHD, ERYSGH, RHYNSE, PYRNTE	AT, DE, HU, RO, SK, PL, BE, CZ, IE, NL, LU	-
Oilseed rape (BRNSW)	AT, DE, HU, RO, SK, PL, BE, CZ, IE	NL, LU	LEPTMA, SCLESC, ERYSCR, ALTEBA, PYRPBR	AT, DE, HU, RO, SK, PL, BE, CZ, IE, NL, LU	-
Mustard, Cameline and other seed-producing Brassicaceae	-	AT, DE, HU, RO, SK, PL, BE, CZ, IE, NL, LU	LEPTMA, SCLESC, ERYSCR, ALTEBA, PYRPBR	AT, DE, HU, RO, SK, PL, BE, CZ, IE, NL, LU	-
Flax (for fiber production only)	-	PL, AT, BE, CZ, DE, HU, IE, LU, NL, RO, SK and Northern IE.	ERYSSP	-	AT, DE, HU, RO, SK, PL, BE, CZ, IE, NL, LU

Cereal production in Europe

With a production area of more than 56 million ha and 324 million tons in the European Union in 2019 (Eurostat, 2021), cereal production can be regarded as major part of agricultural plant production in Europe. Compared to the worldwide production, this area makes approx. 13% of the world's cereal production. The major cereal crop for countries of the European Union is wheat, followed by barley.

The production (surface in ha, production in tons) of the major target cereals in each cMS is summarized in the following table.

Table 3.2-22: Production (per 1000 t) and cultivated areas (per 1000 ha) of the target crops in the European Union and in some countries of the Central EU regulatory zone in 2019 (Eurostat 26/05/2021)

CROP	Winter wheat & Spelt		Durum wheat		Rye		Winter barley		Spring barley	
	1000 ha	1000 t	1000 ha	1000 t	1000 ha	1000 t	1000 ha	1000 t	1000 ha	1000 t
European Union	23 882,10	147 860,09	2 143,98	7 635,33	2 220,45	8 377,19	5 335,85	33 164,24	6 962,90	30 360,46
Poland	2 511,33	10 807,49	0,00	0,00	903,80	2 415,64	224,76	949,12	750,53	2 362,45
Austria	261,64	1 516,63	16,70	80,24	43,68	199,67	101,57	680,17	35,67	147,96

Belgium	203,76	1 902,38	0,00	0,00	0,77	3,36	43,80	384,41	2,95	16,62
Czech Republic	839,45	4 812,16	0,00	0,00	31,13	157,56	107,71	644,11	211,88	1 073,95
Germany	3 086,70	22 907,90	31,50	154,70	-	-	1 351,90	9 762,80	356,90	1 828,70
Hungary	978,72	5 215,24	36,92	162,47	25,94	90,54	222,13	1 268,69	25,23	114,57
Ireland	63,48	595,36	0,00	0,00	0,00	0,00	82,85	740,18	96,52	739,43
Luxembourg	13,36	82,26	0,00	0,00	1,14	6,44	4,46	28,16	1,60	7,86
The Netherlands	120,55	1 130,53	0,00	0,00	1,49	5,30	11,09	97,96	22,30	114,41
Romania	2 162,64	10 280,58	5,73	16,53	9,36	26,18	348,79	1 597,55	100,10	282,39
Slovakia	363,21	1 751,33	43,61	187,80	13,90	48,69	41,26	216,74	85,12	382,82

CROP	Oat		Triticale		Oilseed rape	
Area/Production	1000 ha	1000 t	1000 ha	1000 t	1000 ha	1000 t
European Union	2 571,70	8 023,77	2 766,03	11 179,26	5 648,42	17 040,68
Poland	495,50	1 209,58	1 314,79	4 498,20	875,21	2 268,85
Austria	20,60	77,35	59,82	326,34	35,97	107,17
Belgium	3086	20,17	6,06	40,07	9,26	33,43
Czech Republic	42,53	134,41	39,67	195,41	379,78	1 156,97
Germany	126,30	519,30	358,20	2 194,90	856,80	2 830,20
Hungary	21,77	70,31	83,91	338,34	300,60	912,12
Ireland	23,82	193,03	0,00	0,00	9,24	37,49
Luxembourg	1,40	7,23	4,91	28,96	2,88	10,06
The Netherlands	1,43	8,36	1,33	7,05	1,78	6,01
Romania	161,19	361,57	78,77	314,00	352,62	798,22
Slovakia	12,09	31,90	10,03	34,69	147,02	422,23

Compliance with the Uniform Principles

The overall assessment was performed according to the uniform principles, by officially recognized organizations.

Information on trials submitted (3.1 Efficacy data)

Between 2017 and 2020, a total of 534 trials were conducted on cereals and 146 on oilseed rape in several countries of the 4 EPPO zones to evaluate the fungicidal activity of the formulation CA3301 against several target diseases. The trials were carried out by certified testing institutes. Mediterranean trials were included in this dossier at the suggestion of zRMS Poland since cMS Slovakia may consider these as supportive data.

Detail on available trials for each use is on the following table:

Table 3.2-23: Presentation of trials (efficacy trials, preliminary trials...)

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					Mari-time zone	Mediterranean zone	North-Eastern zone	South-Eastern zone		
Winter	RAMUCC	Denmark	2018	MED +	1 (0)	-	-	-	GEP	

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					Mari-time zone	Mediterranean zone	North-Eastern zone	South-Eastern zone		
barley				E						
		France (N)	2019-2020	MED + E	6 (4)	-	-	-	GEP	
		Germany	2019-20120	MED + E	7 (6)	-	-	-	GEP	
		United Kingdom	2019-2020	MED + E	3 (2)	-	-	-	GEP	
Winter barley	RAMUCC	France (S)	2019-2020	MED + E	-	15 (11)	-	-	GEP	
		Spain	2019-2020	MED + E	-	4 (3)	-	-	GEP	
Winter barley	RAMUCC	Latvia	2020	MED + E	-	-	2 (2)	-	GEP	
		Poland	2017-2020	MED + E	-	-	5 (1)	-	GEP	
Winter barley	RAMUCC	Hungary	2017	MED + E	-	-	-	2 (2)	GEP	
		Romania	2020	MED + E	-	-	-	2 (2)	GEP	
		Slovakia	2020	MED + E				5 (5)	GEP	
TOTAL	-	-	2017 - 2020	MED + E	17 (12)	19 (14)	7 (3)	9 (9)	GEP	
Winter barley	PUCCHD	Czech Republic	2020	MED + E	1 (0)	-	-	-	GEP	
		Denmark	2018	MED + E	2 (0)	-	-	-	GEP	
		France (N)	2019-2020	MED + E	5 (3)	-	-	-	GEP	
		Germany	2019-2020	MED + E	7 (4)	-	-	-	GEP	
		United Kingdom	2019-2020	MED + E	2 (2)	-	-	-	GEP	
Winter barley	PUCCHD	France (S)	2019-2020	MED + E	-	3 (0)	-	-	GEP	
		Spain	2019-2020	MED + E	-	4 (3)	-	-	GEP	
Winter barley	PUCCHD	Latvia	2019-2020	MED + E	-	-	7 (3)	-	GEP	
		Lithuania	2019	MED + E	-	-	1 (1)	-	GEP	
		Poland	2019-2020	MED + E	-	-	14 (4)	-	GEP	

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					Mari-time zone	Mediterranean zone	North-Eastern zone	South-Eastern zone		
Winter barley	PUCCHD	Bulgaria	2018-2019	MED + E	-	-	-	2 (1)	GEP	
		Hungary	2019-2020	MED + E	-	-	-	8 (6)	GEP	
		Romania	2020	MED + E	-	-	-	2 (2)	GEP	
		Slovakia	2020	MED + E				1 (1)	GEP	
TOTAL	-	-	2018-2020	MED + E	17 (9)	7 (3)	22 (8)	13 (10)	GEP	
Winter barley	RHYNSE	Czech Republic	2018-2019	MED + E	3 (1)	-	-	-		
		Denmark	2018	MED + E	2 (0)	-	-	-	GEP	
		France (N)	2019-2020	MED + E	4 (2)	-	-	-	GEP	
		Germany	2019-2020	MED + E	8 (3)	-	-	-	GEP	
		United Kingdom	2019-2020	MED + E	3 (2)	-	-	-	GEP	
Winter barley Winter barley	RHYNSE RHYNSE	France (S)	2019-2020	MED + E	-	6 (0)	-	-	GEP	
		Portugal	2018-2020	MED + E		5 (5)			GEP	
		Spain	2019-2020	MED + E	-	6 (2)	-	-	GEP	
		Latvia	2019-2020	MED + E	-	-	7 (1)	-	GEP	
		Poland	2017-2020	MED + E	-	-	6 (4)	-	GEP	
Winter barley	RHYNSE	Bulgaria	2019	MED + E	-	-	-	1 (1)	GEP	
		Hungary	2017	MED + E	-	-	-	1 (1)	GEP	
		Slovakia	2020	MED + E				2 (2)	GEP	
		Romania	2020	MED + E	-	-	-	3 (0)	GEP	
TOTAL	-	-	2018-2020	MED + E	20 (8)	17 (7)	13 (5)	7 (4)	GEP	
Winter barley	PYRNTE	Czech Republic	2018-2020	MED + E	4 (3)	-	-	-	GEP	
		Denmark	2018	MED + E	2 (0)	-	-	-	GEP	

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					Mari-time zone	Mediterranean zone	North-Eastern zone	South-Eastern zone		
		France (N)	2019-2020	MED + E	2 (2)	-	-	-	GEP	
		Germany	2019-2020	MED + E	10 (5)	-	-	-	GEP	
		United Kingdom	2019	MED + E	2 (2)	-	-	-	GEP	
Winter barley	PYRNTE	France (S)	2019-2020	MED + E	-	9 (7)	-	-	GEP	
		Italy	2019	MED + E	-	4 (4)	-	-	GEP	
		Portugal	2019	MED + E	-	1 (1)	-	-	GEP	
		Spain	2019-2020	MED + E	-	7 (7)	-	-	GEP	
Winter barley	PYRNTE	Latvia	2019	MED + E	-	-	3 (2)	-	GEP	
		Lithuania	2019	MED + E	-	-	1 (0)	-	GEP	
		Poland	2017-2020	MED + E	-	-	26 (20)	-	GEP	
Winter barley	PYRNTE	Bulgaria	2018-2019	MED + E	-	-	-	10 (9)	GEP	
		Hungary	2018-2020	MED + E	-	-	-	6 (5)	GEP	
		Romania	2019	MED + E	-	-	-	2 (2)	GEP	
TOTAL	-	-	2017-2020	MED + E	20 (12)	21 (19)	30 (22)	18 (16)	GEP	
Winter barley	ERYSGH	Czech Republic	2018-2020	MED + E	3 (0)	-	-	-	GEP	
		Denmark	2018	MED + E	2 (0)	-	-	-	GEP	
		France (N)	2019	MED + E	2 (2)	-	-	-	GEP	
		Germany	2019	MED + E	3 (0)	-	-	-	GEP	
Winter barley	ERYSGH	France (S)	2019	MED + E	-	1 (0)	-	-	GEP	
		Spain	2020	MED + E	-	1 (0)	-	-	GEP	
Winter barley	ERYSGH	Latvia	2019	MED + E	-	-	5 (1)	-	GEP	
			2021	E	-	-	2 (2)	-	GEP	
		Lithuania	2019	MED +	-	-	2 (1)	-		

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					Mari-time zone	Mediterranean zone	North-Eastern zone	South-Eastern zone		
		Poland		E						
			2021	E	-	-	1 (1)	-	GEP	
			2017-2020	MED + E	-	-	11 (1)	-	GEP	
			2021	E	-	-	1 (0)	-	GEP	
Winter barley	ERYSGH	Hungary	2019-2020	MED + E	-	-	-	5 (2)	GEP	
TOTAL	-	-	2017-2020	MED + E	10 (2)	2 (0)	18 (3)	5 (2)	GEP	
Spring barley	RAMUCC	Czech Republic	2018	MED + E	1 (1)	-	-	-	GEP	
		Denmark	2019	MED + E	1 (0)	-	-	-	GEP	
		Germany	2019	MED + E	2 (2)	-	-	-	GEP	
		United Kingdom	2019	MED + E	4 (3)	-	-	-	GEP	
Spring barley	RAMUCC	France (S)	2019	MED + E	-	1 (0)	-	-	GEP	
		Italy	2019-2020	MED + E	-	6 (5)	-	-	GEP	
		Spain	2019-2020	MED + E	-	5 (3)	-	-	GEP	
Spring barley	RAMUCC	Poland	2019	MED + E	-	-	2 (0)	-	GEP	
Spring barley	RAMUCC	Hungary	2020	MED + E	-	-	-	1 (0)	GEP	
		Romania	2020	MED + E	-	-	-	2 (2)	GEP	
		Slovakia	2019-2020	MED + E	-	-	-	3 (3)	GEP	
TOTAL	-	-		MED + E	8 (6)	12 (8)	2 (0)	6 (5)	GEP	
Spring barley	PUCCHD	Czech Republic	2018	MED + E	1 (1)	-	-	-	GEP	
		Germany	2019-2020	MED + E	4 (2)	-	-	-	GEP	
		Denmark	2018	MED + E	2 (1)	-	-	-	GEP	
		United Kingdom	2019	MED + E	1 (1)	-	-	-	GEP	
Spring barley	PUCCHD	Italy	2019	MED + E	-	1 (1)	-	-	GEP	
		Spain	2019-	MED +	-	3 (0)	-	-	GEP	

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					Mari-time zone	Mediterranean zone	North-Eastern zone	South-Eastern zone		
			2020	E						
Spring barley	PUCCHD	Poland	2018-2020	MED + E	-	-	5 (2)	-	GEP	
		Lithuania	2019	MED + E	-	-	1 (0)	-	GEP	
		Latvia	2020	MED + E	-	-	3 (2)	-	GEP	
Spring barley	PUCCHD	Hungary	2019-2020	MED + E	-	-	-	3 (2)	GEP	
		Slovakia	2019	MED + E	-	-	-	3 (3)	GEP	
TOTAL	-	-	2018-2020	MED + E	8 (5)	4 (1)	9 (4)	6 (5)	GEP	
Spring barley	PYRNTE	Czech Republic	2018-2019	MED + E	2 (1)	-	-	-	GEP	
		Germany	2019-2020	MED + E	3 (2)	-	-	-	GEP	
		Denmark	2018-2019	MED + E	3 (1)	-	-	-	GEP	
		United Kingdom	2019-2020	MED + E	5 (4)	-	-	-	GEP	
Spring barley	PYRNTE	Italy	2020	MED + E	-	4 (4)	-	-	GEP	
		Spain	2019-2020	MED + E	-	7 (4)	-	-	GEP	
		France	2019	MED + E	-	1 (1)	-	-	GEP	
Spring barley	PYRNTE	Poland	2018-2020	MED + E	-	-	22 (16)	-	GEP	
		Lithuania	2019	MED + E	-	-	1 (0)	-	GEP	
		Latvia	2019-2020	MED + E	-	-	7 (4)	-	GEP	
Spring barley	PYRNTE	Hungary	2018-2020	MED + E	-	-	-	5 (5)	GEP	
		Bulgaria	2018	MED + E	-	-	-	1 (1)	GEP	
		Romania	2018-2019	MED + E	-	-	-	3 (3)	GEP	
		Slovakia	2019-2020	MED + E	-	-	-	2 (2)	GEP	
TOTAL	-	-	2018-2020	MED + E	13 (8)	12 (9)	30 (20)	11 (11)	GEP	
Spring	ERYSGR /	Czech	2019	MED +	2 (2)	-	-	-	GEP	

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					Mari-time zone	Mediterranean zone	North-Eastern zone	South-Eastern zone		
barley	ERYSGH	Republic		E						
		Germany	2019	MED + E	2 (1)	-	-	-	GEP	
Spring barley	ERYSGR / ERYSGH	Italy	2019	MED + E	-	2 (1)	-	-	GEP	
Spring barley	ERYSGR / ERYSGH	Latvia	2019-2020	MED + E	-	-	3 (1)	-	GEP	
Spring barley	ERYSGR / ERYSGH	Hungary	2020	MED + E	-	-	-	1 (0)	GEP	
		Slovakia	2019	MED + E	-	-	-	3 (0)	GEP	
TOTAL	-	-	2018-2020	MED + E	4 (3)	2 (1)	3 (1)	4 (0)	GEP	
Spring barley	RHYNSE	United Kingdom	2019-2020	MED + E	7 (3)	-	-	-	GEP	
		Germany	2019-2020	MED + E	3 (2)	-	-	-	GEP	
		Denmark	2018	MED + E	2 (0)	-	-	-	GEP	
Spring barley	RHYNSE	Italy	2020	MED + E	-	1 (0)	-	-	GEP	
		Spain	2019-2020	MED + E	-	3 (1)	-	-	GEP	
		Portugal	2018	MED + E	-	1 (1)	-	-	GEP	
Spring barley	RHYNSE	Poland	2019-2020	MED + E	-	-	2 (1)	-	GEP	
Spring barley	RHYNSE	Hungary	2020	MED + E	-	-	-	1 (0)	GEP	
		Slovakia	2019	MED + E	-	-	-	1 (1)	GEP	
		Romania	2019-2020	MED + E	-	-	-	5 (5)		
TOTAL	-	-	2018-2020	MED + E	12 (5)	5 (2)	2 (1)	7 (6)	GEP	
Oat	PUCCCA PUCCCO	Czech Republic	2018	MED + E	2 (1)	-	-	-	GEP	
		Germany	2019-2020	MED + E	3 (2)	-	-	-	GEP	
Oat	PUCCCA PUCCCO	Italy	2019-2020	MED + E	-	2 (0)	-	-	GEP	
		Portugal	2020	MED + E		1 (1)	-	-	GEP	
		Spain	2019-	MED +	-	3 (1)	-	-	GEP	

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					Mari-time zone	Mediterranean zone	North-Eastern zone	South-Eastern zone		
			2020	E						
Oat	PUCCCA PUCCCO	Latvia	2019	MED + E	-	-	1 (0)	-	GEP	
		Poland	2018-2019	MED + E	-	-	3 (1)	-	GEP	
			2021	E	-	-	1 (1)	-	GEP	
Oat	PUCCCA PUCCCO	Hungary	2018	MED + E	-	-	-	2 (2)	GEP	
		Romania	2019	MED + E	-	-	-	2 (1)	GEP	
TOTAL	-	-	2018 - 2020	MED + E	5 (3)	6 (2)	4 (1)	4 (3)	GEP	
Oat	ERYSGA	Czech Republic	2017-2018	MED + E	2 (0)	-	-	-	GEP	
		Germany	2020	MED + E	2 (1)	-	-	-	GEP	
Oat	ERYSGA	Poland	2020	MED + E	-	-	3 (2)	-	GEP	
TOTAL	-	-	2017-2020	MED + E	4 (1)	-	3 (2)	-	GEP	
Winter wheat	SEPTTR	Czech Republic	2017-2018	MED + E	3 (0)	-	-	-	GEP	
		Denmark	2018	MED + E	3 (0)	-	-	-	GEP	
		France (N)	2019-2020	MED + E	8 (6)	-	-	-	GEP	
		Germany	2019-20120	MED + E	10 (6)	-	-	-	GEP	
		United Kingdom	2019-2020	MED + E	13 (10)	-	-	-	GEP	
Winter wheat	SEPTTR	France (S)	2018-2020	MED + E	-	11 (9)	-	-	GEP	
		Greece	2019	MED + E	-	2 (2)	-	-	GEP	
		Italy	2020	MED + E	-	3 (3)	-	-	GEP	
		Portugal	2018-2020	MED + E	-	4 (4)	-	-	GEP	
		Spain	2019-2020	MED + E	-	3 (2)	-	-	GEP	
Winter wheat	SEPTTR	Latvia	2019-2020	MED + E	-	-	5 (3)	-	GEP	
		Lithuania	2019-	MED +	-	-	3 (1)	-	GEP	

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					Mari-time zone	Mediterranean zone	North-Eastern zone	South-Eastern zone		
			2020	E						
		Poland	2017-2020	MED + E	-	-	21 (18)	-	GEP	
Winter wheat	SEPTTR	Bulgaria	2018	MED + E	-	-	-	1 (1)	GEP	
		Hungary	2018-2020	MED + E	-	-	-	15 (13)	GEP	
		Romania	2019-2020	MED + E	-	-	-	7 (4)	GEP	
TOTAL	-	-	2017 - 2020	MED + E	37 (22)	23 (20)	29 (22)	23 (18)	GEP	
Winter wheat	PUCCRE/PUCCRT	Czech Republic	2018-2020	MED + E	5 (2)	-	-	-	GEP	
		Germany	2019-2020	MED + E	5 (2)	-	-	-	GEP	
		France	2019-2020	MED + E	7 (4)	-	-	-	GEP	
		United Kingdom	2020	MED + E	1 (1)	-	-	-	GEP	
Winter wheat	PUCCRE/PUCCRT	France	2019-2020	MED + E	-	13 (11)	-	-	GEP	
		Spain	2019-2020	MED + E	-	5 (5)	-	-	GEP	
		Italy	2020	MED + E	-	1 (1)	-	-	GEP	
Winter wheat	PUCCRE/PUCCRT	Poland	2018-2020	MED + E	-	-	13 (13)	-	GEP	
		Latvia	2019	MED + E	-	-	3 (3)	-	GEP	
Winter wheat	PUCCRE/PUCCRT	Hungary	2018-2019	MED + E	-	-	-	5 (4)	GEP	
		Romania	2019-2020	MED + E	-	-	-	2 (2)	GEP	
		Bulgaria	2019	MED + E	-	-	-	1 (1)	GEP	
TOTAL	-	-	2018-2020	MED + E	18 (9)	19 (7)	16 (16)	8 (7)	GEP	
Winter wheat	PUCCST/PUCCSI	Czech Republic	2018-2020	MED + E	1 (1)	-	-	-	GEP	
		Germany	2019-2020	MED + E	2 (1)	-	-	-	GEP	
		United Kingdom	2020	MED + E	15 (11)	-	-	-	GEP	

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					Mari-time zone	Mediterranean zone	North-Eastern zone	South-Eastern zone		
Winter wheat	PUCCST/PUCCSI	Greece	2020	MED + E	-	1 (1)	-	-	GEP	
		Spain	2020	MED + E	-	1 (1)	-	-	GEP	
Winter wheat	PUCCST/PUCCSI	Poland	2020	MED + E	-	-	1 (1)	-	GEP	
Winter wheat	PUCCST/PUCCSI	Hungary	2018	MED + E	-	-	-	1 (1)	GEP	
		Romania	2019	MED + E	-	-	-	2 (2)	GEP	
TOTAL	-	-	2018-2020	MED + E	18 (13)	2 (2)	1 (1)	3 (3)	GEP	
Winter wheat	ERYSGR / ERYSGT	Czech Republic	2017-2019	MED + E	7 (7)	-	-	-	GEP	
		Germany	2019-2020	MED + E	3 (3)	-	-	-	GEP	
		United Kingdom	2019-2020	MED + E	3 (2)	-	-	-	GEP	
		France	2019	MED + E	2 (2)					
Winter wheat	ERYSGR / ERYSGT	France	2019-2020	MED + E	-	4 (2)	-	-	GEP	
		Spain	2019	MED + E	-	2 (2)	-	-	GEP	
		Portugal	2019	MED + E	-	1 (1)	-	-	GEP	
Winter wheat	ERYSGR / ERYSGT	Poland	2017-2020	MED + E	-	-	11 (11)	-	GEP	
		Lithuania	2019-2020	MED + E	-	-	5 (5)	-	GEP	
		Latvia	2019	MED + E	-	-	2 (0)	-	GEP	
Winter wheat	ERYSGR / ERYSGT	Hungary	2019-2020	MED + E	-	-	-	4 (4)	GEP	
		Romania	2019-2020	MED + E	-	-	-	4 (4)	GEP	
		Slovakia	2020	MED + E	-	-	-	2 (2)	GEP	
TOTAL	-	-	2019-2020	MED + E	15 (14)	7 (5)	19 (17)	10 (10)	GEP	
Winter wheat	FUSACU	Denmark	2018	MED + E	1 (0)	-	-	-	GEP	
		Germany	2019-2020	MED + E	3 (1)	-	-	-	GEP	

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					Mari-time zone	Mediterranean zone	North-Eastern zone	South-Eastern zone		
		Czech Republic	2018	MED + E	2 (2)	-	-	-	GEP	
Winter wheat	FUSACU	Portugal	2018	MED + E	-	2 (2)	-	-	GEP	
Winter wheat	FUSACU	Poland	2017-2020	MED + E	-	-	9 (7)		GEP	
Winter wheat	FUSACU	Hungary	2018	MED + E	-	-	-	2 (2)	GEP	
		Romania	2019	MED + E	-	-	-	1 (1)	GEP	
TOTAL	-	-	2017 - 2020	MED + E	6 (3)	2 (2)	9 (7)	3 (3)	GEP	
Winter wheat	GIBBZE	Czech Republic	2019	MED + E	1 (1)	-	-	-	GEP	
		Germany	2019-2020	MED + E	2 (1)	-	-	-	GEP	
		United Kingdom	2019-2020	MED + E	3 (3)	-	-	-	GEP	
Winter wheat	GIBBZE	France	2020	MED + E	-	1 (1)	-	-	GEP	
		Italy	2019-2020	MED + E	-	3 (3)	-	-	GEP	
		Spain	2019-2020	MED + E	-	2 (2)	-	-	GEP	
		Portugal	2018-2020	MED + E	-	4 (4)	-	-	GEP	
Winter wheat	GIBBZE	Latvia	2019	MED + E	-	-	2 (2)	-	GEP	
		Poland	2019	MED + E	-	-	1 (1)	-	GEP	
Winter wheat	GIBBZE	Hungary	2019-2020	MED + E	-	-	-	3 (3)	GEP	
		Romania	2019-2020	MED + E	-	-	-	3 (3)	GEP	
TOTAL	-	-	2018 - 2020	MED + E	6 (5)	10 (10)	3 (3)	6 (6)	GEP	
Winter wheat	FUSASP	Czech Republic	2017	MED + E	1 (0)	-	-	-	GEP	
		France (N)	2019	MED + E	1 (0)	-	-	-	GEP	
Winter wheat	FUSASP	Italy	2020	MED + E	-	1 (1)	-		GEP	
Winter	FUSASP	Hungary	2018-	MED +	-	-	-	3 (3)	GEP	

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					Mari-time zone	Mediterranean zone	North-Eastern zone	South-Eastern zone		
wheat			2019	E						
TOTAL	-	-	2017 - 2020	MED + E	1 (1)	1 (1)	0	3 (3)	GEP	
Winter wheat	PYRNTR	Czech Republic	2018-2019	MED + E	2 (1)	-	-	-	GEP	
Winter wheat	PYRNTR	Lithuania	2019-2020	MED + E	-	-	5 (1)	-	GEP	
		Latvia	2019-2020	MED + E	-	-	6 (6)	-	GEP	
		Poland	2017	MED + E	-	-	1 (0)	-	GEP	
Winter wheat	PYRNTR	Romania	2018	MED + E	-	-	-	1 (1)	GEP	
		Slovakia	2020	MED + E	-	-	-	1 (1)	GEP	
TOTAL	-	-	2018-2020	MED + E	2 (1)	0	12 (7)	2 (2)	GEP	
Winter wheat	LEPTNO	Czech Republic	2017-2028	MED + E	2 (1)	-	-	-	GEP	
Winter wheat	LEPTNO	Spain	2019	MED + E	-	1 (0)	-	-	GEP	
		Italy	2020	MED + E	-	1 (1)	-	-	GEP	
TOTAL	-	-	2019-2020	MED + E	2 (1)	2 (1)	0	0	GEP	
Winter wheat	PSDCHA	Poland	2023	MED + E	-	-	7 (7)	-	GEP	
TOTAL	-	-	2023	MED + E	-	-	7 (7)	-	GEP	
Durum wheat	SEPTTR	France (N)	2019	MED + E	2 (2)	-	-	-	GEP	
		Germany	2019-2020	MED + E	2 (0)	-	-	-	GEP	
Durum wheat	SEPTTR	France (S)	2019	MED + E	-	1 (0)			GEP	
		Italy	2019-2020	MED + E	-	4 (3)	-	-	GEP	
		Portugal	2017-2018	MED + E	-	2 (2)	-	-	GEP	
Durum wheat	SEPTTR	Hungary	2017-2019	MED + E	-	-	-	4 (3)	GEP	
		Romania	2020	MED + E			-	1 (1)	GEP	

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					Mari-time zone	Mediterranean zone	North-Eastern zone	South-Eastern zone		
TOTAL	-	-	2017 – 2020	MED + E	4 (2)	7 (5)	0	5 (4)	GEP	
Durum wheat	PUCCRE/PUCCRT	France (S)	2019	MED + E	-	1 (0)-	-	-	GEP	
Durum wheat	PUCCRE/PUCCRT	Hungary	2017-2018	MED + E	-	-	-	2 (1)	GEP	
TOTAL	-	-	2017-2019	MED + E	0	1 (0)	0	2 (1)	GEP	
Durum wheat	GIBBZE	Italy	2020	MED + E		1 (1)	-	-	GEP	
Durum wheat	GIBBZE	Hungary	2018	MED + E	-	-	-	1 (1)-	GEP	
TOTAL	-	-	2018 -2020	MED + E	0	1 (1)	0	1 (1)	GEP	
Durum wheat	FUSASP	Poland	2018	MED + E	-	-	1 (0)-	-	GEP	
TOTAL	-	-	2018	MED + E	-	-	1 (0)	-	GEP	
Durum wheat	ERYSGT	Germany	2019-2020	MED + E	2 (2)		-	-	GEP	
Durum wheat	ERYSGR	Italy	2019	MED + E	-	1 (1)	-	-	GEP	
Durum wheat	ERYSGR	Hungary	2019	MED + E				2 (2)	GEP	
TOTAL	-	-	2018 -2020	MED + E	2 (2)	1 (1)	0	2 (2)	GEP	
Triticale	SEPTTR	France (N)	2019-2020	MED + E	2 (1)	-	-	-	GEP	
		Germany	2019-2020	MED + E	5 (3)	-	-	-	GEP	
		Czech Republic	2017	MED + E	1 (0)				GEP	
		Denmark	2018	MED + E	1 (0)				GEP	
Triticale	SEPTTR	France (S)	2020	MED + E	-	1 (0)			GEP	
		Portugal	2018-2020	MED + E	-	2 (2)	-	-	GEP	
Triticale	SEPTTR	Poland	2017-2019	MED + E	-	-	5 (4)		GEP	
Triticale	SEPTTR	Hungary	2020	MED + E				1 (1)	GEP	
		Romania	2019-2020	MED + E			-	3 (2)	GEP	

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					Mari-time zone	Mediterranean zone	North-Eastern zone	South-Eastern zone		
TOTAL	-	-	2017-2020	MED + E	9 (4)	3 (2)	5 (4)	4 (3)	GEP	
Triticale	ERYSGR	France	2019	MED + E	1 (1)	-	-	-	GEP	
		Germany	2019-2020	MED + E	3 (1)	-	-	-	GEP	
		Czech Republic	2017-2018	MED + E	2 (1)	-	-	-	GEP	
Triticale	ERYSGR	Poland	2017-2018	MED + E	-	-	3 (1)	-	GEP	
Triticale	ERYSGR	Hungary	2018-2020	MED + E	-	-	-	2 (2)-	GEP	
TOTAL	-	-	2017-2020	MED + E	6 (3)	-	3 (1)	2 (2)	GEP	
Triticale	FUSASP	Denmark	2018	MED + E	1 (1)	-	-	-	GEP	
Triticale	FUSASP	Poland	2018	MED + E			1 (1)		GEP	
Triticale	FUSASP	Hungary	2018	MED + E				1 (1)	GEP	
TOTAL	-	-	2018	MED + E	1 (1)	-	1 (1)	1 (1)	GEP	
Triticale	FUSACU	Czech Republic	2018	MED + E	1(1)				GEP	
Triticale	FUSACU	Portugal	2018	MED + E	-	1 (0)	-	-	GEP	
Triticale	FUSACU	Poland	2017	MED + E				1 (1)	GEP	
TOTAL	-	-	2018-2020	MED + E	1 (1)	1 (0)	-	1 (1)	GEP	
Triticale	PUCCRE	Czech Republic	2018	MED + E	1 (1)	-	-	-	GEP	
		Denmark	2018	MED + E	1 (1)	-	-	-	GEP	
Triticale	PUCCRE	Poland	2018		-	-	1 (0)		GEP	
Triticale	PUCCRE	Hungary	2017-2018	MED + E	-	-	-	2 (1)	GEP	
TOTAL	-	-	2017-2018	MED + E	2 (2)	-	1 (0)	2 (0)	GEP	
Triticale	PUCCSI	Czech Republic	2018	mED + E	1 (1)				GEP	
	PUCCST	Germany	2020	MED + E	1 (0)	-		-	GEP	
Triticale	PUCCST	Portugal	2018	MED +		1 (1)			GEP	

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					Mari-time zone	Mediterranean zone	North-Eastern zone	South-Eastern zone		
				E						
TOTAL	-	-	2018-2020	MED + E	2 (1)	1 (1)	-	-	GEP	
Rye	SEPTTR	Czech Republic	2017-2018	MED + E	2 (1)	-	-	-	GEP	
		Denmark	2019	MED + E	1 (0)	-	-	-	GEP	
		United Kingdom	2019	MED + E	1 (1)	-	-	-	GEP	
Rye	SEPTTR	Portugal	2018	MED + E	-	2 (0)	-	-	GEP	
		Greece	2020	MED + E	-	1 (1)	-	-	GEP	
Rye	SEPTTR	Poland	2017-2020	MED + E	-	-	6 (3)	-	GEP	
Rye	SEPTTR	Hungary	2018-2019	MED + E	-	-	-	3 (2)	GEP	
		Romania	2019	MED + E	-	-	-	1 (1)	GEP	
TOTAL	-	-	2017 - 2020	MED + E	4 (2)	3 (1)	6 (3)	4 (3)	GEP	
Rye	PUCCRE/PUCCRR	Czech Republic	2017-2018	MED + E	3 (3)	-	-	-	GEP	
		Denmark	2018-2019	MED + E	3 (0)				GEP	
		Germany	2020	MED + E	2 (2)	-	-	-	GEP	
Rye	PUCCRE/PUCCRR	Poland	2017-2019	MED + E	-	-	5 (3)	-	GEP	
		Latvia	2020	MED + E	-	-	1 (0)	-	GEP	
Rye	PUCCRE/PUCCRR	Hungary	2018-2019	MED + E	-	-	-	2 (1)	GEP	
TOTAL	-	-	2017-2020	MED + E	8 (5)	-	6 (3)	2 (1)	GEP	
Rye	RHYNSE	Denmark	2018-2019	MED + E	3 (1)	-	-	-	GEP	
		Germany	2020	MED + E	2 (1)					
Rye	RHYNSE	Latvia	2020				1 (1)			
TOTAL	-	-	2018-2020	MED + E	5 (2)	0	1 (1)	0	GEP	

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					Mari-time zone	Mediterranean zone	North-Eastern zone	South-Eastern zone		
Rye	ERYSGR	Czech Republic	2018	MED + E	1 (1)	-	-	-	GEP	
		Denmark	2019	MED + E	1 (0)	-	-	-	GEP	
Rye	ERYSGR	Latvia	2020	MED + E	-	-	1 (0)	-	GEP	
TOTAL	-	-	2018-2020	MED + E	2 (1)	0	1 (0)	0	GEP	
BRSNW	SCLESC	Czech Republic	2017-2019	MED + E	11 (7)	-	-	-	GEP	
		Germany	2019-2020	MED + E	9 (9)	-	-	-	GEP	
		France	2020	MED + E	3 (3)	-	-	-	GEP	
		Denmark	2018	MED + E	1 (0)	-	-	-	GEP	
BRSNW	SCLESC	France	2019	MED + E	-	2 (0)	-	-	GEP	
		Spain	2020	MED + E	-	3 (2)	-	-	GEP	
BRSNW	SCLESC	Poland	2017-2020	MED + E	-	-	21 (14)	-	GEP	
		Lithuania	2019-2020	MED + E	-	-	3 (0)	-	GEP	
		Latvia	2019-2020	MED + E	-	-	5 (2)	-	GEP	
BRSNW	SCLESC	Hungary	2017-2019	MED + E	-	-	-	6 (5)	GEP	
		Romania	2019-2020	MED + E	-	-	-	4 (3)	GEP	
		Slovakia	2020	MED + E	-	-	-	2 (2)	GEP	
TOTAL	-	-	2017-2020	MED + E	24 (19)	5 (2)	28 (16)	12 (10)	GEP	
BRSNW	ALTEBA	Czech Republic	2018-2019	MED + E	2 (2)	-	-	-	GEP	
		Germany	2020	MED + E	4 (4)	-	-	-	GEP	
		France	2020	MED + E	3 (0)	-	-	-	GEP	
		Denmark	2018	MED + E	1 (0)	-	-	-	GEP	
		United Kingdom	2020	MED + E	2 (1)	-	-	-	GEP	

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					Mari-time zone	Mediterranean zone	North-Eastern zone	South-Eastern zone		
BRSNW	ALTEBA	France	2019-2020	MED + E	-	5 (0)	-	-	GEP	
		Spain	2020	MED + E	-	3 (3)	-	-	GEP	
		Italy	2020	MED + E	-	2 (2)	-	-		
BRSNW	ALTEBA	Poland	2017-2020	MED + E	-	-	14 (7)	-	GEP	
		Lithuania	2019-2020	MED + E	-	-	3 (0)	-	GEP	
		Latvia	2019-2020	MED + E	-	-	5 (2)	-	GEP	
BRSNW	ALTEBA	Hungary	2019-2020	MED + E	-	-	-	4 (3)	GEP	
		Romania	2018-2020	MED + E	-	-	-	4 (3)	GEP	
		Slovakia	2009-2020	MED + E	-	-	-	2 (2)	GEP	
TOTAL	-	-	2018-2020	MED + E	12 (7)	10 (5)	22 (9)	10 (8)	GEP	
BRSNW	LEPTMA	Czech Republic	2018-2020	MED + E	8 (6)	-	-	-	GEP	
		Germany	2019-2020	MED + E	5 (5)	-	-	-	GEP	
		France	2020	MED + E	3 (2)	-	-	-	GEP	
		Denmark	2018	MED + E	1 (0)	-	-	-	GEP	
		United Kingdom	2020	MED + E	2 (1)	-	-	-	GEP	
BRSNW	LEPTMA	France	2020	MED + E	-	4 (1)	-	-	GEP	
BRSNW	LEPTMA	Poland	2018-2020	MED + E	-	-	22 (5)	-	GEP	
		Lithuania	2019-2020	MED + E	-	-	3 (0)	-	GEP	
		Latvia	2019-2020	MED + E	-	-	2 (1)	-	GEP	
BRSNW	LEPTMA	Hungary	2018-2020	MED + E	-	-	-	10 (9)	GEP	
		Romania	2020	MED + E	-	-	-	4 (3)	GEP	
TOTAL	-	-	2018-2020	MED + E	19 (14)	4 (1)	27 (6)	14 (12)	GEP	

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					Mari-time zone	Mediterranean zone	North-Eastern zone	South-Eastern zone		
BRSNW	ERYSCR	Czech Republic	2019	MED + E	1 (1)	-	-	-	GEP	
		France	2020	MED + E	1 (1)	-	-	-	GEP	
BRSNW	ERYSCR	France	2019-2020	MED + E	-	8 (0)	-	-	GEP	
		Spain	2020	MED + E	-	2 (1)	-	-	GEP	
		Italy	2020	MED + E	-	1 (1)	-	-	GEP	
BRSNW	ERYSCR	Lithuania	2019	MED + E	-	-	3 (0)	-	GEP	
BRSNW	ERYSCR	Hungary	2020	MED + E	-	-	-	7 (7)	GEP	
		Romania	2019-2020	MED + E	-	-	-	5 (5)	GEP	
		Slovakia	2019-2020	MED + E	-	-	-	3 (3)	GEP	
TOTAL	-	-	2018-2020	MED + E	2 (2)	11 (2)	3 (0)	15 (15)	GEP	
BRSNW	PYRPBR	United kingdom	2020	MED + E	1 (0)	-	-	-	GEP	
		France	2020	MED + E	3 (3)	-	-	-	GEP	
		Denmark	2020	MED + E	1 (0)	-	-	-	GEP	
TOTAL	-	-	2018-2020	MED + E	5 (3)	0	0	0	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

3.2.1 Preliminary tests (KCP 6.1)

No preliminary tests are presented in this dossier.

Considering that prothioconazole has been widely used since many years and is now very well known; implementing preliminary tests was considered unnecessary.

Comments of zRMS:

Accepted.

3.2.2 Minimum effective dose tests (KCP 6.2)

In accordance with the EPPO standard PP 1/225 ‘*Minimum effective dose*’.

3.2.2.1 Winter barley (HORVW) / *Ramularia collo-cygni* (RAMUCC)

Between 2017 and 2020, a series of 52 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the minimum effective dose of CA3301 against *Ramularia collo-cygni* on winter barley (see Table 3.2-331). The trials were carried out by certified testing institutes. The proposed rate is 0.6 l/ha.

In the Maritime EPPO zone, a total of 17 trials were performed in Denmark (1), France (6), Germany (7) and the United Kingdom (3).

In the Mediterranean EPPO zone, a total of 19 trials were performed in France (15) and Spain (4).

In the North-eastern East EPPO zone, a total of 7 trials were performed in Latvia (2) and Poland (5).

In the South-eastern East EPPO zone, a total of 9 trials were performed in Hungary (2), Romania (2) and Slovakia (5).

Data groupings were also made specifically for Poland evaluation and trials involved (19) were performed in the North-Eastern East EPPO zone (7), in Germany (7) and in Slovakia (5).

Out of the 52 trials performed on winter wheat against *Ramularia collo-cygni*, 38 were considered valid.

Min. Eff. Dose evaluation of CA3301 - Maritime EPPO zone

In the Maritime EPPO zone, a total of 17 trials evaluated the efficacy of CA3301 on winter barley against *Ramularia collo-cygni*. 12 trials out of 17 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 30-37 and the 2nd application was at BBCH 39-61. The analysis was conducted on foliar levels 1 and 2.

Summary results are presented in Table 3.2-24.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6 l/ha compared to the lower dose rate of 0.48 l/ha for the reduction of disease severity on winter barley against *Ramularia collo-cygni*. On foliar level 2, CA3301 at 0.6 l/ha showed 68.67% mean efficacy against *Ramularia collo-cygni* over 12 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 70.16% efficacy on reduction of disease severity over 11 trials before harvest.

An overall trend of decreasing disease severity with the 0.6 l/ha dose rate compared to the 0.48 l/ha dose rate was observed in the dataset, although differences were not always statistically significant. In the majority of the assessments there were no significant increases in efficacy at 0.8 l/ha compared to the proposed rate of 0.6 l/ha.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Ramularia collo-cygni* on winter barley in the Maritime EPPO zone.

Table 3.2-24: Summary table – Minimum effective dose evaluation – Winter barley – RAMUCC - Maritime EPPO zone

Treatment name	UNTREATED	CA3301	CA3301	CA3301	No of trials where CA3301		
Rate	CHECK	0,48	0,6	0,8	at 0,6 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB	compared to		
% Disease severity L2 - 24-51 DA-B							
Number of values	12	12	12	12	UTC	CA3301	CA3301
Minimum value	6.80	2.30	2.46	0.93		0.48 l/ha	0.8 l/ha

Maximum value	100,00	29,18	24,11	11,39	12 >	0 >	0 >
Mean disease severity (%)	37,91	10,83	9,16	5,68	0 =	12 =	11 =
Abbott efficacy (%)	0,00%	63,79%	68,67%	80,72%	0 <	0 <	1 <
% Disease severity L1 - 25-51 DA-B							
Number of values	11	11	11	11	UTC	CA2445	CA2445
Minimum value	5,70	1,40	0,71	0,49		0,48 l/ha	0,8 l/ha
Maximum value	100,00	22,19	22,63	12,19	10 >	3 >	0 >
Mean disease severity (%)	29,52	9,11	7,21	4,04	1 =	8 =	10 =
Abbott efficacy (%)	0,00%	61,88%	70,16%	80,76%	0 <	0 <	1 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - Mediterranean EPPO zone

In the Mediterranean EPPO zone, a total of 19 trials evaluated the efficacy of CA3301 on winter barley against *Ramularia collo-cygni*. 15 trials out of 19 were considered valid and 14 enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). One trial was valid but tested CA3301 applied only once. CA3301 was first applied at crop stages BBCH 32-39 and the 2nd application was at BBCH 45-61. The analysis was conducted on foliar levels 1 and 2.

Summary results are presented in Table 3.2-25.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6 l/ha compared to the lower dose rate of 0.48 l/ha for the reduction of disease severity on winter barley against *Ramularia collo-cygni*. On foliar level 2, CA3301 at 0.6 l/ha showed 90.95% efficacy over 5 trials against *Ramularia collo-cygni* two weeks after the 2nd application and 69.14% over 12 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 96.23% efficacy over 3 trials on reduction of disease severity around two weeks after the 2nd application and 62.17% over 13 trials before harvest.

An overall trend of decreasing disease severity with the 0.6 l/ha dose rate compared to the 0.48 l/ha dose rate was observed in the dataset, although differences were not always significant. In many instances the rate of 0.6 l/ha gave acceptable control of *Ramularia collo-cygni* very comparable to that of 0.8 l/ha and even a numerically slightly higher mean efficacy was observed 2 weeks after the 2nd application on L1 and L2. Despite the high disease pressure of the last assessment timing, the 0.6 l/ha dose rate still provided an acceptable level of disease control even if in some instances 0.8 l/ha provided higher disease control in this condition.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Ramularia collo-cygni* on winter barley in the Mediterranean EPPO zone.

Table 3.2-25: Summary table – Minimum effective dose evaluation – Winter barley – RAMUCC - Mediterranean EPPO zone

Treatment name	UNTREATED	CA3301	CA3301	CA3301	No of trials where CA3301		
Rate	CHECK	0,48	0,6	0,8	at 0,6 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB	compared to		
% Disease severity L2 - 13-18 DA-B							
Number of values	5	5	5	5	UTC	CA3301	CA3301
Minimum value	15,40	0,56	0,44	0,50		0,48 l/ha	0,8 l/ha
Maximum value	44,13	7,90	5,88	9,25	5 >	0 >	0 >
Mean disease severity (%)	31,49	3,67	2,79	2,97	0 =	5 =	4 =
Abbott efficacy (%)	0,00%	88,17%	90,95%	90,71%	0 <	0 <	1 <
% Disease severity L1 - 17-18 DA-B							
Number of values	3	3	3	3	UTC	CA3301	CA3301
Minimum value	12,78	0,06	0,06	0,13		0,48 l/ha	0,8 l/ha

Maximum value	29,19	3,44	1,06	2,44	3 >	0 >	0 >
Mean disease severity (%)	21,07	1,59	0,63	1,05	0 =	3 =	3 =
Abbott efficacy (%)	0,00%	91,20%	96,23%	94,49%	0 <	0 <	0 <
% Disease severity L2 - 26-36 DA-B							
Number of values	12	12	12	12	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	8,09	0,75	0,35	0,19			
Maximum value	100,00	77,09	78,35	93,91	11 >	4 >	0 >
Mean disease severity (%)	69,1	31,45	26,31	21,66	1 =	8 =	8 =
Abbott efficacy (%)	0,00%	61,02%	69,14%	74,12%	0 <	0 <	4 <
% Disease severity L1 - 23-36 DA-B							
Number of values	13	13	13	13	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	5,28	0,91	0,41	0,13			
Maximum value	100,00	66,10	72,00	82,58	12 >	5 >	0 >
Mean disease severity (%)	63,07	30,17	26,32	20,88	1 =	8 =	7 =
Abbott efficacy (%)	0,00%	58,49%	62,17%	71,69%	0 <	0 <	6 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 7 trials evaluated the efficacy of CA3301 on winter barley against *Ramularia collo-cygni*. 3 trials out of 7 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 31-39 and the 2nd application was at BBCH 45-61. The analysis was conducted on foliar levels 1 and 2.

Summary results are presented in Table 3.2-26.

On foliar level 2, CA3301 at 0.6 l/ha showed 34.79% efficacy over 2 trials against *Ramularia collo-cygni* before harvest and 54.74% on foliar level 1.

In the North-Eastern East EPPO zone, a limited dataset was available to support the evaluation of CA3301 against *Ramularia collo-cygni*. Disease severity was low to medium, and although the 0.6 l/ha dose rate gave significantly higher disease control than the 0.48 l/ha dose rate on L1 in a single trial, no significant differences were observed on L2 between the 3 dose rates in this limited dataset. Still, the rate of 0.6 l/ha is considered to be appropriate to obtain an acceptable level of disease control and when some level of resistance is suspected, in particular as the efficacy section demonstrates comparability with the authorised reference product against this pathogen in this zone

Considering all elements presented above, CA3301 at 0.6 l/ha is proposed as the minimum effective dose to control *Ramularia collo-cygni* on winter barley in the North-Eastern East EPPO zone.

Table 3.2-26: Summary table – Minimum effective dose evaluation – Winter barley – RAMUCC – North-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
Rate							
Rate unit							
Appl. Code							
% Disease severity L2 - 22-29 DA-B							
Number of values	2	2	2	2	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	14,00	7,88	10,13	7,63			
Maximum value	23,25	15,75	13,50	15,25	2 >	0 >	0 >
Mean disease severity (%)	18,63	11,81	11,81	11,44	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	37,99%	34,79%	39,95%	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

In the South-Eastern EPPO zone, a total of 9 trials evaluated the efficacy of CA3301 on winter barley against *Ramularia collo-cygni*. All 9 trials were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 31-39 and the 2nd application was at BBCH 49-63. The analysis was conducted on foliar levels 1 and 2.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6 l/ha compared to lower dose rate of 0.48 l/ha for the reduction of disease severity on winter barley against *Ramularia collo-cygni*. On foliar level 2, CA3301 at 0.6 l/ha showed 85.78% efficacy over 3 trials against *Ramularia collo-cygni* two weeks after the 2nd application and 82.48% over 9 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 82.31% efficacy over 6 trials on reduction of disease severity before harvest.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Ramularia collo-cygni* on winter barley in the South-Eastern East EPPO zone.

– South-Eastern East EPPO zone

Treatment name	UNTREATED	CA3301	CA3301	CA3301	No of trials where CA3301		
Rate	CHECK	0,48	0,6	0,8	at 0,6 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB	compared to		
% Disease severity L2 - 15 DA-B							
Number of values	3	3	3	3	UTC	CA3301	CA3301
Minimum value	7,76	1,68	0,93	0,55		0,48 l/ha	0,8 l/ha
Maximum value	9,36	2,18	1,34	1,01	3 >	3 >	0 >
Mean disease severity (%)	8,38	1,98	1,19	0,77	0 =	0 =	0 =
Abbott efficacy (%)	0,00%	76,39%	85,78%	90,93%	0 <	0 <	3 <
% Disease severity L2 - 25-34 DA-B							
Number of values	9	9	9	9	UTC	CA3301	CA3301
Minimum value	6,49	0,30	0,06	0,03		0,48 l/ha	0,8 l/ha
Maximum value	65,81	32,13	23,55	15,23	9 >	5 >	0 >
Mean disease severity (%)	27,51	9,16	6,65	4,80	0 =	4 =	4 =
Abbott efficacy (%)	0,00%	74,59%	82,48%	87,02%	0 <	0 <	5 <
% Disease severity L1 - 25-34 DA-B							

Number of values	6	6	6	6	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	7,64	0,60	0,31	0,24	6 >	5 >	0 >
Maximum value	47,50	21,25	15,93	10,30	0 =	1 =	1 =
Mean disease severity (%)	21,66	6,81	4,97	3,37	0 <	0 <	5 <
Abbott efficacy (%)	0,00%	74,96%	82,31%	88,00%			

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301- Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this condition, a total of 19 trials from the North-Eastern EPPO zone and the neighbouring countries Germany and Slovakia evaluated the efficacy of CA3301 on winter barley against *Ramularia collo-cygni*. 14 trials were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 31-39 and the 2nd application was at BBCH 45-61. The analysis was conducted on foliar levels 1 and 2.

Summary results are presented in Table 3.2-28.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6 l/ha compared to lower dose rate of 0.48 l/ha for the reduction of disease severity on winter barley against *Ramularia collo-cygni*. On foliar level 2, CA3301 at 0.6 l/ha showed 85.78% efficacy over 3 trials two weeks after the 2nd application and 64.21% over 13 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 72.63% efficacy over 12 trials on reduction of disease severity before harvest.

CA3301 at 0.6 l/ha showed medium to high efficacy in reducing the severity of *Ramularia collo-cygni* on winter barley. A trend of decreasing disease severity with increasing dose rates was observed in the dataset, particularly between the 0.6 l/ha and 0.48 l/ha dose rates. In many instances the rate of 0.6 l/ha gave acceptable control of *Ramularia collo-cygni* very comparable to that of 0.8 l/ha but not always statistically equivalent. Overall the 0.6 l/ha rate was sufficient to obtain an acceptable level of disease control.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Ramularia collo-cygni* on winter barley in Poland.

Table 3.2-28: Summary table – Minimum effective dose evaluation – Winter barley – RAMUCC – Data relevant for Poland

Treatment name	UNTREATED	CA3301	CA3301	CA3301	No of trials where CA3301		
Rate	CHECK	0,48	0,6	0,8	at 0,6 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB	compared to		
% Disease severity L2 - 15 DA-B							
Number of values	3	3	3	3	UTC	CA3301	CA3301
Minimum value	7,76	1,68	0,93	0,55		0,48 l/ha	0,8 l/ha
Maximum value	9,36	2,18	1,34	1,01	3 >	3 >	0 >
Mean disease severity (%)	8,38	1,98	1,19	0,77	0 =	0 =	0 =
Abbott efficacy (%)	0,00%	76,39%	85,78%	90,93%	0 <	0 <	3 <
% Disease severity L2 - 22-51 DA-B							
Number of values	13	13	13	13	UTC	CA3301	CA3301
Minimum value	6,80	2,30	2,46	0,93		0,48 l/ha	0,8 l/ha
Maximum value	100,00	32,13	23,55	15,25	13 >	5 >	0 >

Mean disease severity (%)	31,78	10,77	8,93	6,68	0 =	8 =	7 =
Abbott efficacy (%)	0,00%	58,41%	64,21%	74,24%	0 <	0 <	6 <
% Disease severity L1 - 27-51 DA-B							
Number of values	12	12	12	12	UTC	CA3301	CA3301
Minimum value	5,70	1,76	1,23	0,71		0,48 l/ha	0,8 l/ha
Maximum value	100,00	22,19	19,83	12,19	12 >	8 >	0 >
Mean disease severity (%)	28,67	9,23	6,37	4,28	0 =	4 =	5 =
Abbott efficacy (%)	0,00%	61,42%	72,63%	80,37%	0 <	0 <	7 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

12 valid trials have been submitted to determine minimum efficacy dose in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,6 l/ha achieved significant better results compared to the lower dose of 0,48 l/ha. The effectiveness amounted >70% on L1 in 11 out of 12 trials. The test product at 0,6 l/ha is effective on medium level.

3 valid trials were presented to determine MED in **the North-East EPPO zone**. The limited number of trials showed very low efficacy after application of CA3301, either at 0,48 l/ha and 0,6 l/ha. Also results from the trials conducted in the neighbouring countries have been included to the overall calculation to support of Polish registration. Taking into account all trials, the use of dose rate of 0,6 l/ha caused increase of efficacy about 10% compared to lower dose. The test product at 0,6 l/ha is effective on medium level.

9 valid trials were available to determine MED in **the South-East EPPO zone**. CA3301 applied at dose rate of 0,6 l/ha achieved high efficacy in control of RAMUCC. A significant lower results were noted after application of dose rate of 0,48 l/ha, however on medium level. An increase of effectiveness amounted near to 10%. The test product at 0,6 l/ha is effective on high level. Moreover, 14 trials from the Mediterranean zone have been submitted to support of product registration in the other zones. The dose rate of 0,48 l/ha was insufficient in control of disease pathogen and this trend was visible in 13 out of 14 trials on L1.

Taking into account all EPPO zones, the dose rate of 0,6 l/ha can be considered minimum effective dose to control of *Ramularia collo-cygni* in winter barley.

3.2.2.2 Winter barley (HORVW) / *Puccinia hordei* (PUCCHD)

Between 2018 and 2020, a series of 59 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the minimum effective dose of CA3301 against *Puccinia hordei* on winter barley (see Table 3.2-229). The trials were carried out by certified testing institutes. The proposed rate is 0.6 l/ha.

In the Maritime EPPO zone, a total of 17 trials were performed in the Czech Republic (1), Denmark (2), France (5), Germany (7) and the United Kingdom (2).

In the Mediterranean EPPO zone, a total of 7 trials were performed in France (3) and Spain (4).

In the North-eastern East EPPO zone, a total of 22 trials were performed in Latvia (7), Lithuania (1) and Poland (14).

In the South-eastern East EPPO zone, a total of 13 trials were performed in Bulgaria (2), Hungary (8), Romania (2) and Slovakia (1).

Out of the 59 trials performed on winter wheat against *Puccinia hordei*, 30 were considered valid.

Min. Eff. Dose evaluation of CA3301 - Maritime EPPO zone

In the Maritime EPPO zone, a total of 17 trials evaluated the efficacy of CA3301 on winter barley against *Puccinia hordei*. 9 trials out of 17 were considered valid and enabled to compare the efficacy of several

dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 30-53 and the 2nd application was at BBCH 39-65. The analysis was conducted on foliar levels 1 and 2.

Summary results are presented in Table 3.2-29.

Over the available dataset, CA3301 at 0.6 l/ha provided high efficacy in reducing the severity of *Puccinia hordei* on winter barley. On foliar level 2, CA3301 at 0.6 l/ha showed 94.78% efficacy over 6 trials against *Puccinia hordei* two weeks after the 2nd application and 87.35% over 8 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 85.53% efficacy over 6 trials on reduction of disease severity before harvest.

In the Maritime EPPO zone, the trials displayed a relatively low to medium mean infestation (15.85-47.50%). An overall trend of decreasing disease severity with the 0.6 l/ha dose rate compared to the 0.48 l/ha dose rate was observed in the dataset, although differences were not always significant. In the majority of the assessments there were no significant increase of efficacy at 0.8 l/ha compared to the proposed rate of 0.6 l/ha. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for the control of brown rust, with a high level of control.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Puccinia hordei* on winter barley in the Maritime EPPO zone.

Table 3.2-29: Summary table – Minimum effective dose evaluation – Winter barley – PUCCHD - Maritime EPPO zone

Maritime LTPO zone							
Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
% Disease severity L2 - 14-17 DA-B							
Number of values	6	6	6	6	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	4,99	0,00	0,00	0,00			
Maximum value	57,28	4,28	3,93	3,28	6 >	0 >	0 >
Mean disease severity (%)	15,85	1,09	1,00	0,73	0 =	6 =	5 =
Abbott efficacy (%)	0,00%	94,49%	94,78%	97,02%	0 <	0 <	1 <
% Disease severity L2 - 27-40 DA-B							
Number of values	8	8	8	8	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	6,38	0,20	0,00	0,00			
Maximum value	95,50	63,38	61,50	53,38	8 >	0 >	0 >
Mean disease severity (%)	47,50	10,14	9,69	7,97	0 =	8 =	7 =
Abbott efficacy (%)	0,00%	84,94%	87,35%	89,07%	0 <	0 <	1 <
% Disease severity L1 - 28-40 DA-B							
Number of values	6	6	6	6	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	12,10	0,05	0,00	0,08			
Maximum value	70,00	45,88	47,88	35,25	6 >	0 >	0 >
Mean disease severity (%)	28,33	8,96	8,60	6,13	0 =	6 =	5 =
Abbott efficacy (%)	0,00%	82,04%	85,53%	90,23%	0 <	0 <	1 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - Mediterranean EPPO zone

In the Mediterranean EPPO zone, a total of 7 trials evaluated the efficacy of CA3301 on winter barley against *Puccinia hordei*. 3 trials out of 7 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on

disease severity (%). CA3301 was first applied at crop stages BBCH 32-47 and the 2nd application was at BBCH 39-59. The analysis was conducted on foliar levels 1 and 2.

Summary results are presented in Table 3.2-30.

In the available dataset, CA3301 at 0.6 l/ha showed low to high efficacy in reducing the severity of *Puccinia hordei* on winter barley (see Table 3.2-236). On foliar level 2, CA3301 at 0.6 l/ha showed 74.12% efficacy over 3 trials two weeks after the 2nd application and 6.31% on a single trial before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 85.80% efficacy on a single trial on reduction of disease severity around two weeks after the 2nd application and 17.07% on 1 trial before harvest.

In the Mediterranean EPPO zone, a limited dataset was available to support the evaluation of CA3301 against *Puccinia hordei*. However, this situation is representative of heavy infestation (mean disease pressure ranging from 34.58% to 100.00%) and allow us to show the performance of CA3301 in challenging conditions. Two weeks after the 2nd application, when the pressure reached medium level, applications of CA3301 provided high disease control statistically equivalent between the three dose rates. At the last assessment before harvest, a single trial was available and disease pressure reached 99.94%-100.00%. Although efficacy was medium to high in this trial at the earlier assessment, conditions highly conducive to this pathogen lead to further infection which the earlier applications were not able to fully control. It is likely that in these conditions of continued high disease pressure further applications of other fungicides would be required. Nevertheless, it is envisaged that in most instances with less extreme conditions, applications of 0.6 l/ha will be sufficient for the control of brown rust, in particular since early assessments indicated medium to high efficacy at this dose rate.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Puccinia hordei* on winter barley in the Mediterranean EPPO zone.

Table 3.2-30: Summary table – Minimum effective dose evaluation – Winter barley – PUCCHD - Mediterranean EPPO zone

Mediterranean L170 Zone							
Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
% Disease severity L2 - 17 DA-B							
Number of values	3	3	3	3	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	5,51	1,09	1,24	0,58			
Maximum value	92,50	16,65	18,61	13,10	3 >	0 >	0 >
Mean disease severity (%)	34,58	6,85	7,29	5,05	0 =	3 =	3 =
Abbott efficacy (%)	0,00%	70,97%	74,12%	83,12%	0 <	0 <	0 <
% Disease severity L1 - 17 DA-B							
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	64,31	8,89	9,13	6,06			
Maximum value	64,31	8,89	9,13	6,06	1 >	0 >	0 >
Mean disease severity (%)	64,31	8,89	9,13	6,06	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	86,18%	85,80%	90,58%	0 <	0 <	0 <
% Disease severity L2 - 34 DA-B							
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	100,00	96,31	93,69	84,38			
Maximum value	100,00	96,31	93,69	84,38	0 >	0 >	0 >
Mean disease severity (%)	100,00	96,31	93,69	84,38	1 =	1 =	0 =
Abbott efficacy (%)	0,00%	3,69%	6,31%	15,62%	0 <	0 <	1 <
% Disease severity L1 - 34 DA-B							
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	99,94	87,88	82,88	61,81			
Maximum value	99,94	87,88	82,88	61,81	1 >	0 >	0 >
Mean disease severity (%)	99,94	87,88	82,88	61,81	0 =	1 =	0 =
Abbott efficacy (%)	0,00%	12,07%	17,07%	38,15%	0 <	0 <	1 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 22 trials evaluated the efficacy of CA3301 on winter barley against *Puccinia hordei*. 8 trials out of 22 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 31-37 and the 2nd application was at BBCH 43-61. The analysis was conducted on foliar levels 1 and 2.

Summary results are presented in Table 3.2-31.

In this dataset, CA3301 at 0.6 l/ha provided high efficacy in reducing the severity of *Puccinia hordei* on winter barley. On foliar level 2, CA3301 at 0.6 l/ha showed 92.38% efficacy over 2 trials two weeks after the 2nd application and 97.49% over 6 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 94.29% efficacy on a single trial on reduction of disease severity around two weeks after the 2nd application and 87.51% over 4 trials before harvest.

In the North-Eastern East EPPO zone, all trials displayed relatively low disease pressure (6.30-15.93%) and in most of assessments CA3301 at 0.48 l/ha, 0.6 l/ha or 0.8 l/ha gave similar levels of disease control. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for the control of brown rust and when conditions are conducive to heavy disease infestation the rate of 0.6 l/ha may be beneficial to further reduce disease pressure.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Puccinia hordei* on winter barley in the North-Eastern East EPPO zone.

Table 3.2-31: Summary table – Minimum effective dose evaluation – Winter barley – PUCCHD – North-Eastern East EPPO zone

Treatment name	UNTREATED	CA3301	CA3301	CA3301	No of trials where CA3301		
Rate	CHECK	0,48	0,6	0,8	at 0,6 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB	compared to		
% Disease severity L2 - 15 DA-B							
Number of values	2	2	2	2	UTC	CA3301	CA3301
Minimum value	10,13	1,13	0,81	0,06		0,48 l/ha	0,8 l/ha
Maximum value	10,63	1,73	0,88	0,54	2 >	0 >	0 >
Mean disease severity (%)	10,38	1,43	0,84	0,30	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	89,37%	92,38%	99,44%	0 <	0 <	0 <
% Disease severity L1 - 15 DA-B							
Number of values	1	1	1	1	UTC	CA3301	CA3301
Minimum value	6,30	0,78	0,36	0,16		0,48 l/ha	0,8 l/ha
Maximum value	6,30	0,78	0,36	0,16	1 >	0 >	0 >
Mean disease severity (%)	6,30	0,78	0,36	0,16	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	87,62%	94,29%	97,46%	0 <	0 <	0 <
% Disease severity L2 - 22-36 DA-B							
Number of values	6	6	6	6	UTC	CA3301	CA3301
Minimum value	10,13	0,05	0,00	0,00		0,48 l/ha	0,8 l/ha
Maximum value	24,00	1,44	1,60	0,85	6 >	0 >	0 >
Mean disease severity (%)	15,93	0,50	0,42	0,25	0 =	6 =	6 =
Abbott efficacy (%)	0,00%	97,23%	97,49%	98,53%	0 <	0 <	0 <
% Disease severity L1 - 24-33 DA-B							
Number of values	4	4	4	4	UTC	CA3301	CA3301

Minimum value	5,84	0,03	0,06	0,00		0,48 l/ha	0,8 l/ha
Maximum value	28,19	2,13	2,20	1,46	4 >	0 >	0 >
Mean disease severity (%)	14,18	0,78	0,90	0,52	0 =	4 =	3 =
Abbott efficacy (%)	0,00%	88,97%	87,51%	92,09%	0 <	0 <	1 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 13 trials evaluated the efficacy of CA3301 on winter barley against *Puccinia hordei*. 10 trials out of 13 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 31-39 and the 2nd application was at BBCH 41-61. The analysis was conducted on foliar levels 1 and 2.

Summary results are presented in Table 3.2-32.

Over this dataset, CA3301 at 0.6 l/ha showed medium to high efficacy in reducing the severity of *Puccinia hordei* on winter barley. On foliar level 2, CA3301 at 0.6 l/ha showed 76.38% efficacy over 2 trials two weeks after the 2nd application and 97.03% over 9 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 89.60% efficacy on a single trial on reduction of disease severity around two weeks after the 2nd application and 95.67% over 7 trials before harvest.

In the South-Eastern East EPPO zone, the trials displayed a relatively low disease pressure (7.50-18.47%) and in most of instances the three dose rates of CA3301 gave equivalent disease control with in some cases significant benefits observed in favour of the 0.6 l/ha dose rate compared to the 0.48 l/ha dose rate. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient to provide an acceptable control of the brown rust, particularly when conditions are more conducive to heavy disease infestation.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Puccinia hordei* on winter barley in the South-Eastern East EPPO zone.

Table 3.2-32: Summary table – Minimum effective dose evaluation – Winter barley – PUCCHD – South-Eastern East EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
% Disease severity L2 - 15 DA-B							
Number of values	2	2	2	2	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	8,50	1,23	0,59	0,49		2 >	1 >
Maximum value	8,86	2,90	3,45	3,30	0 =	1 =	2 =
Mean disease severity (%)	8,68	2,06	2,02	1,89	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	76,00%	76,38%	77,82%			
% Disease severity L1 - 15 DA-B							
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	7,50	0,75	0,78	0,40		1 >	0 >
Maximum value	7,50	0,75	0,78	0,40	0 =	1 =	1 =
Mean disease severity (%)	7,50	0,75	0,78	0,40	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	90,00%	89,60%	94,67%			
% Disease severity L2 - 24-45 DA-B							
Number of values	9	9	9	9	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	11,18	0,00	0,00	0,00			

Maximum value	41,81	4,18	3,35	3,05	9 >	1 >	0 >
Mean disease severity (%)	18,47	0,91	0,61	0,47	0 =	8 =	8 =
Abbott efficacy (%)	0,00%	95,44%	97,03%	97,72%	0 <	0 <	1 <
% Disease severity L1 - 28-45 DA-B							
Number of values	7	7	7	7	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	5,80	0,00	0,00	0,00			
Maximum value	46,38	2,99	2,45	2,39	7 >	2 >	0 >
Mean disease severity (%)	13,83	1,01	0,74	0,55	0 =	5 =	5 =
Abbott efficacy (%)	0,00%	93,63%	95,67%	97,35%	0 <	0 <	2 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

9 trials have been submitted to determine minimum effective dose to control of PUCCHD in **the Maritime EPPO climatic zone**. No significant differences between dose rates were observed. CA3301 at 0,48-0,8 l/ha achieved high efficacy. However, the dose rate of 0,6 l/ha can be more sufficient in case of high disease pressure. 8 trials were presented to determine MED in **the North-East EPPO zone**. Similar to the above conclusions, the dose rate of 0,6 l/ha can be recommended to control of *Puccinia hordei* in winter barley. 10 trials were available to determine MED in **the South-East EPPO zone**. CA3301 applied at dose rate of 0,48-0,8 l/ha achieved high level of control in most of trials. The medium efficacy were noted in 2 out of 10 trials. Taking into account low disease pressure in submitted trials, the dose rate of 0,6 l/ha can give more benefits compared to dose of 0,48 l/ha in more unfavorable conditions.

Tking into account all EPPO zones, the dose rate of 0,6 l/ha can be considered minimum effective dose to control of *Puccinia hordei* in winter barley.

3.2.2.3 Winter barley (HORVW) / *Rhynchosporium secalis* (RHYNSE/RHYNSP)

Between 2017 and 2020, a series of 57 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the minimum effective dose of CA3301 against *Rhynchosporium secalis* on **winter barley** (see Table 3.2-343). The trials were carried out by certified testing institutes. The proposed rate is 0.6 l/ha.

In the Maritime EPPO zone, a total of 20 trials were performed in the Czech Republic (3), Denmark (2), France (4), Germany (8) and the United Kingdom (3).

In the Mediterranean EPPO zone, a total of 17 trials were performed in France (6), Portugal (5) and Spain (6).

In the North-Eastern East EPPO zone, a total of 13 trials were performed in Latvia (7) and Poland (6).

In the South-Eastern East EPPO zone, a total of 7 trials were performed in Bulgaria (1), Hungary (1), Romania (3) and Slovakia (2).

Data groupings were also made specifically for Poland evaluation and trials involved (26) were performed in the North-Eastern East EPPO zone (13), in the Czech Republic (3), in Germany (8) and in Slovakia (2).

Out of the 57 trials performed on winter wheat against *Rhynchosporium secalis*, 24 were considered valid.

Min. Eff. Dose evaluation of CA3301 - Maritime EPPO zone

In the Maritime EPPO zone, a total of 20 trials evaluated the efficacy of CA3301 on winter barley against *Rhynchosporium secalis* 8 trials out of 20 were considered valid and enabled to compare the efficacy of

several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 30-53 and the 2nd application was at BBCH 39-65. The analysis was conducted on foliar levels 1 and 2.

Summary results are presented in Table 3.2-33.

Over this dataset, CA3301 at 0.6 l/ha showed medium to high efficacy in reducing the severity of *Rhynchosporium secalis* on winter barley. On foliar level 2, CA3301 at 0.6 l/ha showed 84.70% efficacy over 4 trials two weeks after the 2nd application and 82.00% over 6 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 80.80% efficacy over 2 trials on reduction of disease severity two weeks after the 2nd application and 79.65% over 4 trials before harvest.

An overall trend of decreasing disease severity with the 0.6 l/ha dose rate compared to the 0.48 l/ha dose rate was observed in the dataset, although differences were not always significant the level of efficacy was overall increased. In the majority of the assessments there were no significant increase in efficacy at 0.8 l/ha compared to the proposed rate of 0.6 l/ha, except in a couple of trials.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Rhynchosporium secalis* on winter barley in the Maritime EPPO zone.

Table 3.2-33: Summary table – Minimum effective dose evaluation – Winter barley – RHYNSE - Maritime EPPO zone

Maritime EPPO zone							
Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
% Disease severity L2 - 15 DA-B							
Number of values	4	4	4	4	UTC	CA3301	CA3301
Minimum value	7,09	1,65	0,00	0,00		0,48 l/ha	0,8 l/ha
Maximum value	14,06	5,63	2,84	3,53	4 >	1 >	0 >
Mean disease severity (%)	10,55	3,27	1,68	1,30	0 =	3 =	4 =
Abbott efficacy (%)	0,00%	69,56%	84,70%	89,22%	0 <	0 <	0 <
% Disease severity L1 - 15 DA-B							
Number of values	2	2	2	2	UTC	CA3301	CA3301
Minimum value	5,11	1,26	0,98	0,10		0,48 l/ha	0,8 l/ha
Maximum value	11,11	2,50	2,63	0,46	2 >	0 >	0 >
Mean disease severity (%)	8,11	1,88	1,80	0,28	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	75,34%	80,82%	91,00%	0 <	0 <	0 <
% Disease severity L2 - 37-49 DA-B							
Number of values	6	6	6	6	UTC	CA3301	CA3301
Minimum value	7,05	0,19	0,38	0,20		0,48 l/ha	0,8 l/ha
Maximum value	51,50	15,04	10,35	8,51	6 >	1 >	0 >
Mean disease severity (%)	19,81	5,70	4,36	3,68	0 =	5 =	4 =
Abbott efficacy (%)	0,00%	75,80%	82,00%	83,83%	0 <	0 <	2 <
% Disease severity L1 - 37-49 DA-B							
Number of values	4	4	4	4	UTC	CA3301	CA3301
Minimum value	8,41	1,31	1,14	0,91		0,48 l/ha	0,8 l/ha
Maximum value	29,35	7,96	5,41	3,64	4 >	2 >	0 >
Mean disease severity (%)	16,17	4,74	3,36	2,46	0 =	2 =	3 =
Abbott efficacy (%)	0,00%	71,79%	79,65%	84,64%	0 <	0 <	1 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - Mediterranean EPPO zone

In the Mediterranean EPPO zone, a total of 17 trials evaluated the efficacy of CA3301 on winter barley against *Rhynchosporium secalis*. 7 trials out of 17 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice). CA3301 was first applied at crop stages BBCH 32-37 and the 2nd application was at BBCH 39-69. The analysis was conducted on foliar levels 1 and 2.

Summary results are presented in Table 3.2-34.

Data demonstrated a higher effect of 2 applications of CA3301 at 0.6 l/ha compared to the lower dose rate of 0.48 l/ha for the reduction of disease severity on winter barley against *Rhynchosporium secalis* on winter barley. On foliar level 2, CA3301 at 0.6 l/ha showed 82.57% efficacy over 4 trials two weeks after the 2nd application and 58.58% over 7 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 85.22% efficacy over 4 trials on reduction of disease severity two weeks after the 2nd application and 58.94% over 6 trials before harvest.

An overall trend of decreasing disease severity with the 0.6 l/ha dose rate compared to the 0.48 l/ha dose rate was observed in the dataset, although differences were not always significant. Moreover, in this dataset CA3301 at 0.6 l/ha gave always comparable disease control than 0.8 l/ha.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Rhynchosporium secalis* on winter barley in the Mediterranean EPPO zone.

Table 3.2-34: Summary table – Minimum effective dose evaluation – Winter barley – RHYNSE - Mediterranean EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
% Disease severity L2 - 14-15 DA-B							
Number of values	4	4	4	4	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	14,25	0,38	0,00	0,00		4 >	1 >
Maximum value	63,73	29,65	28,20	24,90	0 =	3 =	4 =
Mean disease severity (%)	32,40	9,59	8,10	7,11	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	74,45%	82,57%	84,82%			
% Disease severity L1 - 14-15 DA-B							
Number of values	4	4	4	4	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	9,38	0,00	0,00	0,00		4 >	0 >
Maximum value	44,95	11,75	15,00	14,20	0 =	4 =	4 =
Mean disease severity (%)	22,31	4,63	5,01	4,64	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	84,86%	85,22%	86,55%			
% Disease severity L2 - 26-43 DA-B							
Number of values	7	7	7	7	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	7,53	0,00	0,00	1,35		7 >	1 >
Maximum value	75,00	61,88	59,75	55,75	0 =	6 =	7 =
Mean disease severity (%)	40,08	23,28	20,98	20,11	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	52,10%	58,58%	62,05%			
% Disease severity L1 - 26-43 DA-B							
Number of values	6	6	6	6	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	19,60	0,00	0,00	0,00		5 >	1 >
Maximum value	75,25	61,50	51,25	50,75	1 =	5 =	6 =
Mean disease severity (%)	41,30	25,25	20,95	19,30	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	53,41%	58,94%	61,96%			

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 13 trials evaluated the efficacy of CA3301 on winter barley against *Rhynchosporium secalis*. 5 trials out of 13 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice). CA3301 was first applied at crop stages BBCH 31-37 and the 2nd application was at BBCH 51-61. The analysis was conducted on foliar levels 1 and 2.

Summary results are presented in Table 3.2-35.

Over this dataset, CA3301 at 0.6 l/ha showed medium to high efficacy in reducing the severity of *Rhynchosporium secalis* on winter barley. On foliar level 2, CA3301 at 0.6 l/ha showed 95.52% efficacy over 2 trials two weeks after the 2nd application and 76.22% over 4 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 92.96% efficacy over 3 trials on reduction of disease severity before harvest.

In the North-Eastern East EPPO zone, a limited dataset was available to support the evaluation of CA3301 against *Rhynchosporium secalis*. However, this situation highlights the performance of the tested product in conditions of low disease pressure (around 8-10%). In overall, CA3301 at 0.6 l/ha gave comparable disease control than 0.8 l/ha, however on L2 before harvest a single trial provided a decrease of the efficacy compared to the two other dose rates. In conditions of higher disease pressure, additional disease reduction obtained from the rate of 0.6 l/ha may be more appropriate than the 0.48 l/ha dose rate, in particular where some level of resistance is suspected.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Rhynchosporium secalis* on winter barley in the North-Eastern East EPPO zone.

Table 3.2-35: Summary table – Minimum effective dose evaluation – Winter barley – RHYNSE – North-Eastern East EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
% Disease severity L2 - 13-15 DA-B							
Number of values	2	2	2	2	UTC	CA3301	CA3301
Minimum value	7,63	0,51	0,20	0,09		0,48 l/ha	0,8 l/ha
Maximum value	8,30	0,56	0,50	0,13	2 >	0 >	0 >
Mean disease severity (%)	7,96	0,54	0,35	0,11	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	93,26%	95,52%	98,61%	0 <	0 <	0 <
% Disease severity L2 - 24-33 DA-B							
Number of values	4	4	4	4	UTC	CA3301	CA3301
Minimum value	6,94	0,39	0,38	0,19		0,48 l/ha	0,8 l/ha
Maximum value	14,06	3,99	6,09	2,65	4 >	0 >	0 >
Mean disease severity (%)	9,53	1,63	2,46	0,86	0 =	3 =	3 =
Abbott efficacy (%)	0,00%	79,71%	76,22%	88,51%	0 <	1 <	1 <
% Disease severity L1 - 24-35 DA-B							
Number of values	3	3	3	3	UTC	CA3301	CA3301
Minimum value	5,76	0,19	0,18	0,03		0,48 l/ha	0,8 l/ha
Maximum value	13,75	1,50	1,14	0,86	3 >	0 >	0 >
Mean disease severity (%)	9,15	1,02	0,60	0,34	0 =	3 =	3 =
Abbott efficacy (%)	0,00%	89,26%	92,96%	95,90%	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 7 trials evaluated the efficacy of CA3301 on winter barley against *Rhynchosporium secalis*. 4 trials out of 7 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice). CA3301 was first applied at crop stages BBCH 32-37 and the 2nd application was at BBCH 49-59. The analysis was conducted on foliar levels 1 and 2.

Summary results are presented in Table 3.2-36.

Over this dataset, CA3301 at 0.6 l/ha showed high efficacy in reducing the severity of *Rhynchosporium secalis* on winter barley. On foliar level 2, CA3301 at 0.6 l/ha showed 89.36% efficacy over 2 trials two weeks after the 2nd application and 79.75% over 3 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 100.00% efficacy over 1 trial on reduction of disease severity two weeks after the 2nd application and 85.67% over 3 trials before harvest.

In the South-Eastern East EPPO zone, a limited dataset was available to support the evaluation of CA3301 against *Rhynchosporium secalis*. However, this situation highlights the performance of the tested product in conditions of relatively low disease pressure (around 8 to 16%) and CA3301 at 0.6 l/ha provided high efficacy in controlling *Rhynchosporium secalis*. Over this dataset, the 0.6 l/ha dose rate gave higher or equivalent disease control than the 0.48 l/ha dose rate. At times, the 0.8 l/ha dose rate provided significantly higher efficacy, but the numerical difference in mean efficacy never exceeded 5% compared to the 0.6 l/ha dose rate. Therefore, 0.6 l/ha may be more appropriate than 0.48 l/ha and it is envisaged that in most instances applications of 0.6 l/ha will be sufficient to provide acceptable of control against *Rhynchosporium secalis*.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Rhynchosporium secalis* on winter barley in the South-Eastern East EPPO zone.

Table 3.2-36: Summary table – Minimum effective dose evaluation – Winter barley – RHYNSE – South-Eastern East EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
% Disease severity L2 - 14-15 DA-B							
Number of values	2	2	2	2	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	12,83	1,66	1,30	1,26			
Maximum value	14,13	1,81	1,55	1,51	2 >	0 >	0 >
Mean disease severity (%)	13,48	1,74	1,43	1,39	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	87,13%	89,36%	89,66%	0 <	0 <	0 <
% Disease severity L1 - 15 DA-B							
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	9,41	0,00	0,00	0,00			
Maximum value	9,41	0,00	0,00	0,00	1 >	0 >	0 >
Mean disease severity (%)	9,41	0,00	0,00	0,00	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	100,00%	100,00%	100,00%	0 <	0 <	0 <
% Disease severity L2 - 24-31 DA-B							
Number of values	3	3	3	3	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	13,23	3,63	2,34	1,53			
Maximum value	17,61	4,83	4,05	4,04	3 >	2 >	0 >
Mean disease severity (%)	15,78	4,23	3,22	2,63	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	73,17%	79,75%	83,61%	0 <	0 <	2 <
% Disease severity L1 - 24-31 DA-B							
Number of values	3	3	3	3	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	5,99	1,28	0,75	0,46			
Maximum value	10,30	2,35	1,34	0,90	3 >	3 >	0 >
Mean disease severity (%)	7,94	1,92	1,10	0,65	0 =	0 =	1 =
Abbott efficacy (%)	0,00%	74,36%	85,67%	91,71%	0 <	0 <	2 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301- Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this condition, a total of 26 trials from the North-East EPPO zone and the neighbouring countries Czech Republic, Germany and Slovakia evaluated the efficacy of CA3301 on winter barley against *Rhynchosporium secalis*. 11 trials out of 26 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice). CA3301 was first applied at crop stages BBCH 31-37 and the 2nd application was at BBCH 45-61. The analysis was conducted on foliar levels 1 and 2.

Summary results are presented in Table 3.2-37.

Over this dataset, CA3301 at 0.6 l/ha provided high efficacy in reducing the severity of *Rhynchosporium secalis* on winter barley. On foliar level 2, CA3301 at 0.6 l/ha showed 87.63% efficacy over 4 trials two weeks after the 2nd application and 77.50% over 9 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 80.82% efficacy over 1 trial on reduction of disease severity two weeks after the 2nd application and 86.62% over 8 trials before harvest.

CA3301 at 0.6 l/ha provided medium to high efficacy in reducing the severity of *Rhynchosporium secalis* on winter barley. A trend of decreasing disease severity with increasing dose rates was observed in the dataset, particularly compared to the 0.48 l/ha dose rate. In many instances the rate of 0.6 l/ha gave acceptable control of *Rhynchosporium secalis* very comparable to that of 0.8 l/ha around two weeks after application B but not always statistically equivalent at the last assessment timing. However in overall, the 0.6 l/ha rate was sufficient to obtain an acceptable level of disease control.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Rhynchosporium secalis* on winter barley in Poland.

Table 3.2-37: Summary table – Minimum effective dose evaluation – Winter barley – RHYNSE – Data relevant for Poland

Data Relevant for Poland							
Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
% Disease severity L2 - 13-15 DA-B							
Number of values	4	4	4	4	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	7,09	0,51	0,20	0,09			
Maximum value	14,06	5,63	2,84	3,53	4 >	1 >	0 >
Mean disease severity (%)	9,27	2,09	1,24	1,10	0 =	3 =	4 =
Abbott efficacy (%)	0,00%	80,80%	87,63%	90,73%	0 <	0 <	0 <
% Disease severity L1 - 15 DA-B							
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	5,11	1,26	0,98	0,46			
Maximum value	5,11	1,26	0,98	0,46	1 >	0 >	0 >
Mean disease severity (%)	5,11	1,26	0,98	0,46	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	75,34%	80,82%	91,00%	0 <	0 <	0 <
% Disease severity L2 - 24-49 DA-B							
Number of values	9	9	9	9	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	6,94	0,39	0,38	0,19			

Maximum value	26,70	11,06	10,35	8,51	9 >	2 >	0 >
Mean disease severity (%)	12,83	3,43	3,28	2,18	0 =	6 =	5 =
Abbott efficacy (%)	0,00%	75,35%	77,50%	84,69%	0 <	1 <	4 <
% Disease severity L1 - 24-49 DA-B							
Number of values	8	8	8	8	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	5,76	0,19	0,18	0,03			
Maximum value	14,83	6,60	5,01	3,58	8 >	3 >	0 >
Mean disease severity (%)	10,08	2,18	1,49	1,07	0 =	5 =	6 =
Abbott efficacy (%)	0,00%	80,55%	86,62%	90,48%	0 <	0 <	2 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

8 trials have been submitted to determine minimum effective dose to control of RHYNSE in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,6 l/ha achieved significant better results compared to lower dose. The visible increase of effectiveness was noted in 4 out of 8 trials on L2. The dose rate of 0,6 l/ha was effective on a level of 84,70% and a dose rate of 0,48 l/ha achieved 69,56%.

5 trials were available to determine MED in **the North-East EPPO zone**. The comparable results were observed after application of CA3301 at dose rate of 0,48-0,8 l/ha. Also results from neighbouring countries have been included to the overall calculation to support of Polish registration. Based on all trial results, the dose rate of 0,6 l/ha achieved high level control in most trials.

4 trials were presented to determine MED in **the South-East EPPO zone**. The dose rate of 0,6 l/ha caused increase of effectiveness about 10% compared to the lower dose in 3 out of 4 trials on L1 before harvest. Moreover, 7 trials from the Mediterranean zone have been submitted to support of product registration in other zones. CA3301 at 0,6 l/ha was more effective in control of RHYNSE and it was visible na L2 after 14-15 days after seconf application.

Taking into account all EPPO zones, the dose rate of 0,6 l/ha can be considered minimum effective dose to control of *Rhynchosporium secalis* in winter barley.

3.2.2.4 Winter barley (HORVW) / *Pyrenophora teres* (PYRNTE)

Between 2017 and 2020, a series of 89 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern and South-Eastern EPPO zones to evaluate the minimum effective dose of CA3301 against *Pyrenophora teres* on **winter barley** (see Table 3.2-256). The trials were carried out by certified testing institutes. The proposed rate is 0.6 l/ha.

In the Maritime EPPO zone, a total of 20 trials were performed in the Czech Republic (4), Denmark (2), France (2), Germany (10) and the United Kingdom (2).

In the Mediterranean EPPO zone, a total of 21 trials were performed in France (9), Italy (4), Portugal (1) and Spain (7).

In the North-~~eastern~~ **East** EPPO zone, a total of 30 trials were performed in Latvia (3), Lithuania (1) and Poland (26).

In the South-~~eastern~~ **East** EPPO zone, a total of 18 trials were performed in Bulgaria (10), Hungary (6) and Romania (2).

Out of the 89 trials performed on winter wheat against *Pyrenophora teres*, 69 were considered valid.

Min. Eff. Dose evaluation of CA3301 - Maritime EPPO zone

In the Maritime EPPO zone, a total of 20 trials evaluated the efficacy of CA3301 on winter barley against *Pyrenophora teres*. 12 trials out of 20 were considered valid and enabled to compare the efficacy of

several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 31-53 and the 2nd application was at BBCH 39-65. The analysis was conducted on foliar levels 1 and 2.

Summary results are presented in Table 3.2-38.

Over this dataset, CA3301 at 0.6 l/ha provided high efficacy in reducing the severity of *Pyrenophora teres* on winter barley. On foliar level 2, CA3301 at 0.6 l/ha showed 83.40% efficacy over 4 trials two weeks after the 2nd application and 78.60% over 10 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 81.21% efficacy over 2 trials on reduction of disease severity two weeks after the 2nd application and 72.85% over 9 trials before harvest.

An overall trend of decreasing disease severity with the 0.6 l/ha dose rate compared to the 0.48 l/ha dose rate was observed in the dataset, although differences were not always significant. In most instances, CA3301 at 0.6 l/ha gave comparable disease control than 0.8 l/ha, except in a couple of trials at the last assessment before harvest.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Pyrenophora teres* on winter barley in the Maritime EPPO zone.

Table 3.2-38: Summary table – Minimum effective dose evaluation – Winter barley – PYRNTE – Maritime EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
% Disease severity L2 - 14-15 DA-B							
Number of values	4	4	4	4	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	5,29	0,00	0,00	0,00			
Maximum value	20,00	5,76	7,36	2,66	4 >	0 >	0 >
Mean disease severity (%)	10,05	2,07	2,43	0,94	0 =	4 =	4 =
Abbott efficacy (%)	0,00%	85,64%	83,40%	93,25%	0 <	0 <	0 <
% Disease severity L1 - 15 DA-B							
Number of values	2	2	2	2	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	5,21	1,34	1,09	0,48			
Maximum value	22,80	5,63	3,80	3,21	2 >	0 >	0 >
Mean disease severity (%)	14,01	3,48	2,44	1,84	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	74,79%	81,21%	88,35%	0 <	0 <	0 <
% Disease severity L2 - 25-46 DA-B							
Number of values	10	10	10	10	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	10,25	0,30	0,31	0,63			
Maximum value	83,19	22,00	30,38	13,69	10 >	2 >	0 >
Mean disease severity (%)	28,57	7,25	6,58	4,51	0 =	7 =	8 =
Abbott efficacy (%)	0,00%	71,68%	78,60%	84,34%	0 <	1 <	2 <
% Disease severity L1 - 25-46 DA-B							
Number of values	9	9	9	9	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	5,51	0,75	1,20	0,63			
Maximum value	86,88	27,66	39,69	13,15	9 >	1 >	0 >
Mean disease severity (%)	19,26	5,86	6,29	3,03	0 =	8 =	7 =
Abbott efficacy (%)	0,00%	65,44%	72,85%	80,16%	0 <	0 <	2 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - Mediterranean EPPO zone

In the Mediterranean EPPO zone, a total of 21 trials evaluated the efficacy of CA3301 on winter barley against *Pyrenophora teres*. 19 trials out of 21 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 31-47 and the 2nd application was at BBCH 39-65. The analysis was conducted on foliar levels 1 and 2.

Summary results are presented in Table 3.2-39.

Over this dataset, CA3301 at 0.6 l/ha provided high to medium efficacy in reducing the severity of *Pyrenophora teres* on winter barley. On foliar level 2, CA3301 at 0.6 l/ha showed 81.63% efficacy over 11 trials two weeks after the 2nd application and 81.06% over 10 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 78.20% efficacy over 9 trials on reduction of disease severity two weeks after the 2nd application and 72.69% over 10 trials before harvest.

An overall trend of decreasing disease severity with the 0.6 l/ha dose rate compared to the 0.48 l/ha dose rate was observed in the dataset, although differences were not always significant. In most instances, CA3301 at 0.6 l/ha gave comparable disease control than 0.8 l/ha, except in 1 trial on L1.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Pyrenophora teres* on winter barley in the Mediterranean EPPO zone.

Table 3.2-39: Summary table – Minimum effective dose evaluation – Winter barley – PYRNTE – Mediterranean EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
% Disease severity L2 - 13-20 DA-B							
Number of values	11	11	11	11	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	5,20	1,44	0,44	0,30		11 >	2 >
Maximum value	64,56	14,16	10,26	12,09	0 =	9 =	11 =
Mean disease severity (%)	28,68	6,56	4,69	4,52	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	73,73%	81,63%	80,82%			
% Disease severity L1 - 13-20 DA-B							
Number of values	9	9	9	9	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	5,71	0,81	0,25	1,18		9 >	1 >
Maximum value	99,10	85,78	76,55	84,88	0 =	8 =	8 =
Mean disease severity (%)	32,83	13,50	11,07	11,55	0 <	0 <	1 <
Abbott efficacy (%)	0,00%	71,17%	78,20%	75,44%			
% Disease severity L2 - 25-37 DA-B							
Number of values	10	10	10	10	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	9,38	0,78	0,60	0,23		10 >	1 >
Maximum value	38,06	8,54	7,90	8,08	0 =	9 =	10 =
Mean disease severity (%)	25,73	5,29	4,79	3,70	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	80,21%	81,06%	86,35%			
% Disease severity L1 - 25-37 DA-B							
Number of values	10	10	10	10	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	5,13	1,39	0,28	0,56		10 >	2 >
Maximum value	92,13	48,03	47,71	19,04	0 =	8 =	9 =
Mean disease severity (%)	26,66	10,99	10,05	6,21	0 <	0 <	1 <
Abbott efficacy (%)	0,00%	66,98%	72,69%	81,01%			

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 30 trials evaluated the efficacy of CA3301 on winter barley against *Pyrenophora teres*. 22 trials out of 30 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 30-39 and the 2nd application was at BBCH 45-61. The analysis was conducted on foliar levels 1 and 2.

Summary results are presented in Table 3.2-40.

Over this dataset, CA3301 at 0.6 l/ha showed generally high efficacy in reducing the severity of *Pyrenophora teres* on winter barley. On foliar level 2, CA3301 at 0.6 l/ha showed 72.29% efficacy over 7 trials two weeks after the 2nd application and 85.67% over 16 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 83.28% efficacy over 3 trials on reduction of disease severity two weeks after the 2nd application and 81.70% over 9 trials before harvest.

An overall trend of decreasing disease severity with the 0.6 l/ha dose rate compared to the 0.48 l/ha dose rate was observed in the dataset, although differences were not always significant. Applied at 0.6 l/ha CA3301 demonstrated overall high efficacy, in particular at later assessments, whereas efficacy from 0.48 l/ha was medium. In most instances, CA3301 at 0.6 l/ha gave comparable disease control than 0.8 l/ha, except in a few trials.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Pyrenophora teres* on winter barley in the North-Eastern East EPPO zone.

Table 3.2-40: Summary table – Minimum effective dose evaluation – Winter barley – PYRNTE – North-Eastern East EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
% Disease severity L2 - 13-15 DA-B							
Number of values	7	7	7	7	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	5,44	0,73	0,44	0,25			
Maximum value	37,63	14,24	16,53	9,06	7 >	1 >	0 >
Mean disease severity (%)	15,59	5,30	5,24	3,46	0 =	6 =	6 =
Abbott efficacy (%)	0,00%	71,45%	72,29%	80,55%	0 <	0 <	1 <
% Disease severity L1 - 14-15 DA-B							
Number of values	3	3	3	3	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	6,50	1,65	1,26	0,88			
Maximum value	28,56	6,30	5,16	3,51	3 >	0 >	0 >
Mean disease severity (%)	15,20	3,28	2,58	1,75	0 =	3 =	3 =
Abbott efficacy (%)	0,00%	78,18%	83,28%	88,61%	0 <	0 <	0 <
% Disease severity L2 - 24-38 DA-B							
Number of values	16	16	16	16	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	5,40	0,15	0,06	0,10			
Maximum value	28,25	9,13	7,63	6,28	16 >	0 >	0 >
Mean disease severity (%)	11,39	2,44	1,79	1,10	0 =	16 =	14 =
Abbott efficacy (%)	0,00%	79,68%	85,67%	91,29%	0 <	0 <	2 <
% Disease severity L1 - 24-37 DA-B							
Number of values	9	9	9	9	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	5,06	0,14	0,16	0,06			
Maximum value	29,19	7,10	5,44	4,03	9 >	0 >	0 >
Mean disease severity (%)	10,99	2,38	1,86	1,40	0 =	9 =	8 =
Abbott efficacy (%)	0,00%	76,78%	81,70%	85,65%	0 <	0 <	1 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy

<60% Low efficacy

Min. Eff. Dose evaluation of CA3301 - South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 18 trials evaluated the efficacy of CA3301 on winter barley against *Pyrenophora teres*. 16 trials out of 18 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 31-39 and the 2nd application was at BBCH 41-61. The analysis was conducted on foliar levels 1 and 2.

Summary results are presented in Table 3.2-41.

Over this dataset, CA3301 at 0.6 l/ha provided medium to high efficacy in reducing the severity of *Pyrenophora teres* on winter barley. On foliar level 2, CA3301 at 0.6 l/ha showed 70.28% efficacy over 4 trials two weeks after the 2nd application and 77.37% over 13 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 57.02% efficacy over 1 trial on reduction of disease severity two weeks after the 2nd application and 83.10% over 11 trials before harvest.

An overall trend of decreasing disease severity with the 0.6 l/ha dose rate compared to the 0.48 l/ha dose rate was observed in the dataset, with statistical differences being observed in many assessments. In most instances, CA3301 at 0.6 l/ha gave comparable disease control than 0.8 l/ha, except in a few trials.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Pyrenophora teres* on winter barley in the South-Eastern East EPPO zone.

Table 3.2-41: Summary table – Minimum effective dose evaluation – Winter barley – PYRNTE – South-Eastern East EPPO zone

Treatment name	UNTREATED D CHECK	CA3301	CA3301	CA3301	No of trials where CA3301		
Rate		0,48	0,6	0,8	at 0,6 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB	compared to		
% Disease severity L2 - 15-19 DA-B							
Number of values	4	4	4	4	UTC	CA3301	CA3301
Minimum value	7,25	2,28	1,48	0,35	4 > 0 = 0 <	0,48 l/ha	0,8 l/ha
Maximum value	26,61	8,29	7,16	6,93		2 > 2 = 0 <	0 > 1 = 3 <
Mean disease severity (%)	15,17	4,45	4,33	3,47			
Abbott efficacy (%)	0,00%	68,32%	70,28%	81,77%			
% Disease severity L1 - 19 DA-B							
Number of values	1	1	1	1	UTC	CA3301	CA3301
Minimum value	7,19	3,43	3,09	1,60	1 > 0 = 0 <	0,48 l/ha	0,8 l/ha
Maximum value	7,19	3,43	3,09	1,60		1 > 0 = 0 <	0 > 0 = 1 <
Mean disease severity (%)	7,19	3,43	3,09	1,60			
Abbott efficacy (%)	0,00%	52,29%	57,02%	77,75%			
% Disease severity L2 - 21-45 DA-B							
Number of values	13	13	13	13	UTC	CA3301	CA3301
Minimum value	6,50	0,00	0,00	0,00	13 > 0 = 0 <	0,48 l/ha	0,8 l/ha
Maximum value	100,00	9,81	8,56	8,50		6 > 7 = 0 <	0 > 9 = 4 <
Mean disease severity (%)	23,85	4,20	3,45	2,76			
Abbott efficacy (%)	0,00%	70,92%	77,37%	82,35%			
% Disease severity L1 - 21-45 DA-B							
Number of values	11	11	11	11	UTC	CA3301	CA3301
Minimum value	5,56	0,00	0,00	0,00	11 >	0,48 l/ha	0,8 l/ha
Maximum value	29,31	6,88	6,25	5,38		4 >	0 >

Mean disease severity (%)	11,38	2,16	1,71	1,08	0 =	7 =	8 =
Abbott efficacy (%)	0,00%	78,61%	83,10%	89,98%	0 <	0 <	3 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

12 trials have been submitted to determine minimum effective dose to control of PYRNT in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,6 l/ha achieved better results compared to dose of 0,48 l/ha on L1, either after second application and before harvest. The similar efficacy was observed between dose rate of 0,8 l/ha and lower.

22 trials were presented to determine MED in **the North-East EPPO zone**. The test product at dose rate of 0,6-0,8 l/ha achieved high level of control in most trials. The dose of 0,48 l/ha was effective on medium level, however the disease pressure was low in submitted trials. The dose of 0,6 l/ha can be justification in unfavourable conditions.

16 trials were available to determine MED in **the South-East EPPO zone**. The comparability results after application of 0,6 l/ha and 0,8 l/ha were achieved in 11 out of 16 trials on L1. An instability in the level of control was obtained in case of dose rate of 0,48 l/ha. The similar trend was visible in the additional 19 trials from the Mediterranean zone. The test product at 0,6 l/ha achieved high efficacy in most trials with different level of disease pressure.

Taking into account all EPPO zones, the dose rate of 0,6 l/ha can be considered minimum effective dose to control of *Pyrenophora teres* in winter barley.

3.2.2.5 Winter barley (HORVW) / *Blumeria graminis f. sp. hordei* (ERYSGH / ERYSGR)

Between 2017 and 2020, a series of 35 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the minimum effective dose of CA3301 against *Blumeria graminis f. sp. hordei* on winter barley (see Table 3.2-260). The trials were carried out by certified testing institutes. The proposed rate is 0.6 l/ha.

In the Maritime EPPO zone, a total of 10 trials were performed in the Czech Republic (3), Denmark (2), France (2) and Germany (3).

In the Mediterranean EPPO zone, a total of 2 trials were performed in France (1) and Spain (1).

In the North-eastern East EPPO zone, a total of 18 trials were performed in Latvia (5), Lithuania (2) and Poland (11).

In the South-eastern East EPPO zone, a total of 5 trials were performed in Hungary (5).

Out of the 35 trials performed on winter wheat against *Blumeria graminis f. sp. hordei*, 7 were considered valid.

Min. Eff. Dose evaluation of CA3301 - Maritime EPPO zone

In the Maritime EPPO zone, a total of 10 trials evaluated the efficacy of CA3301 on winter barley against *Blumeria graminis f. sp. hordei*. 2 trials out of 10 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 31-53 and the 2nd application was at BBCH 39-65. The analysis was conducted on foliar level 2 only.

Summary results are presented in Table 3.2-42

CA3301 at 0.6 l/ha provided high efficacy in reducing the severity of *Blumeria graminis f. sp. hordei* on winter barley. On foliar level 2, CA3301 at 0.6 l/ha showed 87.18% efficacy over 2 trials before harvest.

In the Maritime EPPO zone, a limited dataset was available to support the evaluation of CA3301 against *Blumeria graminis f. sp. hordei*. However, this situation highlights the performance of the tested product in conditions of relatively low disease pressure (around 6 to 12%) and CA3301 provided high efficacy whatever the dose rate considered. In addition, 3 supportive trials carried out on spring barley demonstrated that even if statistical dose response was not always observed, it appears that CA3301 at 0.6 l/ha provided higher control of disease severity than 0.48 l/ha dose rate. Over these 2 datasets, CA3301 at the proposed dose rate provided very comparable efficacy to the 0.8 l/ha dose rate. Therefore, 0.6 l/ha may be appropriate to obtain an acceptable level of disease control.

The same conclusions were also observed on winter wheat in which 10 trials enabled to compare the efficacy of CA3301 and the minimum effective dose evaluation was conducted considering the disease incidence on leaves. Following 2 applications, the fungicidal performance of CA3301 enabled to significantly decrease the disease incidence on leaves in most of trials, compared to the untreated control and whatever the dose rate considered. The data demonstrated that in conditions of low to medium disease pressure, the 0.6 l/ha provided an acceptable disease control.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Blumeria graminis f. sp. hordei* on winter barley in the Maritime EPPO zone.

Table 3.2-42: Summary table – Minimum effective dose evaluation – Winter barley – ERYSGH/ERYSGR – Maritime EPPO zone

Treatment name	UNTREATED	CA3301	CA3301	CA3301	No of trials where CA3301		
Rate	CHECK	0,48	0,6	0,8	at 0,6 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB	compared to		
% Disease severity L2 - 32-39 DA-B							
Number of values	2	2	2	2	UTC	CA3301	CA3301
Minimum value	6,76	0,00	0,00	0,00		0,48 l/ha	0,8 l/ha
Maximum value	12,25	3,86	3,14	3,48	2 >	0 >	0 >
Mean disease severity (%)	9,51	1,93	1,57	1,74	0 =	2 =	2 =
Abbott efficacy (%)	0.00%	84.24%	87.18%	85.80%	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - Mediterranean EPPO zone

In the Mediterranean EPPO zone no valid data were available to support the minimum effective dose evaluation of CA3301 applied at several dose rates (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). However, spring and winter sown barley are the same species *Hordeum vulgare* and the proposed applications are the same (dose rate, application timing etc), therefore reference is made to the data presented on spring barley in support of the proposed minimum effective dose. The validity of this argumentation is supported by the fact that existing authorisations of similar prothioconazole products also have the same dose rates registered for both spring and winter barley, hence the pathogens are controlled similarly in each crop at the same dose rate.

In the Mediterranean EPPO zone, 2 supportive trials carried out on spring barley (see **Spring barley (HORVS) / *Blumeria graminis f. sp. hordei* (ERYSGH/ERYSGR)**) demonstrated that in trials with

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Blumeria graminis* f. sp. *hordei* on winter barley in the Mediterranean EPPO zone.

In the North-Eastern East EPPO zone, a total of 18 trials evaluated the efficacy of CA3301 on winter barley against *Blumeria graminis* f. sp. *hordei*. 3 trials out of 18 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 30-39 and the 2nd application was at BBCH 43-61. The analysis was conducted on foliar levels 1 and 2.

CA3301 at 0.6 l/ha provided low to high efficacy in reducing the severity of *Blumeria graminis* f. *sp. hordei* on winter barley. On foliar level 2, CA3301 at 0.6 l/ha showed 58.97% efficacy over 2 trials two weeks after the 2nd application and 78.24% over 1 trial before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 82.26% efficacy over 1 trial on reduction of disease severity two weeks after the 2nd application. In one trial (EU18-041-13) efficacy was lower on L2 for all 3 dose rates compared to other trials.

The same trend was observed in a supportive trial carried out on spring barley.

Therefore 0.6 l/ha may be more appropriate to obtain an acceptable level of disease control.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Blumeria graminis* f. sp. *hordei* on winter barley in the North-Eastern East EPPO zone.

Treatment name	UNTREATED	CA3301	CA3301	CA3301	No of trials where CA3301		
Rate	CHECK	0,48	0,6	0,8	at 0,6 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB	compared to		
% Disease severity L2 - 14-15 DA-B							
Number of values	2	2	2	2	UTC	CA3301	CA3301
Minimum value	21,95	14,60	11,69	7,91		0,48 l/ha	0,8 l/ha
Maximum value	54,31	15,44	15,64	11,19	2 >	0 >	0 >
Mean disease severity (%)	38,13	15,02	13,66	9,55	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	52,53%	58,97%	71,68%	0 <	0 <	0 <
% Disease severity L1 - 15 DA-B							

Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	9,30	2,10	1,65	1,55	1 >	0 >	0 >
Maximum value	9,30	2,10	1,65	1,55	0 =	1 =	1 =
Mean disease severity (%)	9,30	2,10	1,65	1,55	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	77,42%	82,26%	83,33%			
% Disease severity L2 - 33 DA-B							
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	5,33	0,96	1,16	0,90	1 >	0 >	0 >
Maximum value	5,33	0,96	1,16	0,90	0 =	1 =	1 =
Mean disease severity (%)	5,33	0,96	1,16	0,90	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	81,99%	78,24%	83,11%			

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 5 trials evaluated the efficacy of CA3301 on winter barley against *Blumeria graminis f. sp. hordei*. 2 trials out of 5 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 31-39 and the 2nd application was at BBCH 43-61. The analysis was conducted on foliar level 1 and foliar level 2.

Summary results are presented in Table 3.2-44.

CA3301 at 0.6 l/ha provided high efficacy in reducing the severity of *Blumeria graminis f. sp. hordei* on winter barley. On foliar level 2, CA3301 at 0.6 l/ha showed 99.11% efficacy over 1 trial two weeks after the 2nd application and 94.23% over 2 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 94.78% efficacy over 1 trial on reduction of disease severity before harvest.

In the South-Eastern East zone, a limited dataset was available to support the evaluation of CA3301 against *Blumeria graminis f. sp. hordei*. However, this situation highlights the performance of the tested product in conditions of relatively low to medium disease pressure and the three dose rates of CA3301 provided high efficacy. The three dose rates gave comparable disease control although a numerical trend in decreasing disease severity with increasing dose rates was observed. Therefore, in case of higher infestation the rate of 0.6 l/ha may be appropriate to obtain an acceptable level of disease control.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Blumeria graminis f. sp. hordei* on winter barley in the South-Eastern East EPPO zone.

Table 3.2-44: Summary table – Minimum effective dose evaluation – Winter barley – ER-YSGH/ERYSGR – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
Rate							
Rate unit							
Appl. Code							
% Disease severity L2 - 15 DA-B							
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	5,61	0,09	0,05	0,44	1 >	0 >	0 >
Maximum value	5,61	0,09	0,05	0,44	0 =	1 =	1 =
Mean disease severity (%)	5,61	0,09	0,05	0,44	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	98,40%	99,11%	92,16%			
% Disease severity L2 - 21-37 DA-B							
Number of values	2	2	2	2	UTC	CA3301	CA3301

Minimum value	6,96	0,04	0,00	0,00		0,48 l/ha	0,8 l/ha
Maximum value	54,63	7,35	6,30	2,45	2 >	0 >	0 >
Mean disease severity (%)	30,79	3,69	3,15	1,23	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	92,99%	94,23%	97,76%	0 <	0 <	0 <
% Disease severity L1 - 37 DA-B							
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	37,13	1,48	1,94	0,29	1 >	0 >	0 >
Maximum value	37,13	1,48	1,94	0,29	0 =	1 =	1 =
Mean disease severity (%)	37,13	1,48	1,94	0,29	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	96,01%	94,78%	99,22%			

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

Very limited number of trials has been submitted to determine minimum effective dose to control of ERYSGR in all EPPO climatic zone (Maritime-2 trials, North-East-3 trials, South-East-2 trials). However, CA3301 applied at dose rate of 0,6 l/ha achieved consistently high effectiveness in most trials, comparable to the dose rate of 0,8 l/ha. Due to the limited number of trials, the cMSs are kindly asked to consider MED for this use on the national level.

3.2.2.6 Winter barley (HORVW) / *Oculimacula acufiformis* (PSDCHA)

(Ramanauskiene *et al.*, Effects of fungicides on the occurrence of winter wheat eyespot caused by fungi *Oculimacula acufiformis* and *O. yalundae*, Crop protection, 2016)

No data were available for assessment of minimum effective dose of eyespot of cereals *Oculimacula acufiformis* on any crop. Although early symptoms can be confused with *Fusarium spp.*, the diseases are not related and therefore it is impossible to extrapolate from these data.

However, Ramanauskiene *et al.*, showed that 2, 3 and 4 years of prothioconazole treatments allowed to reduce the population of *O. acufiformis* assessed from 2009 to 2011 on winter wheat. This positive effect was observed as early as 10 days after treatment. This pathogen infecting both winter wheat and barley, it is therefore possible to transpose these results to winter barley.

Moreover, prothioconazole is one of the active substances the most used as fungicide in commercial practices (*Forecasting eyespot development and yield losses in winter wheat*, HGCA, 2012). Standard reference products containing prothioconazole, such as Proline 275 are registered to control eyespot on cereals, at the same application rates as for the other authorised pathogens, which indicates that prothioconazole controls eyespot at dose rates which are demonstrated to control the other major disease pathogens in cereals. Since the proposed dose rate for CA3301 against this pathogen is comparable to the rates demonstrated against other pathogens, and data shows overall equivalence of efficacy between Proline 275 and CA3301 in other pathogens, it is considered that the minimum effective dose rate for CA3301 to control eyespot will be the same as that demonstrated for other pathogens.

Moreover, since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6 l/ha generally gave significantly better disease control compared to the rate of 0.48 l/ha, it is supposed that the same dose range will be acceptable to control eyespot on winter barley.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Oculimacula acufiformis* on winter barley in all EPPO zones.

Comments of zRMS:

No valid efficacy trials for PSDCHA on winter barley have been submitted in any EPPO zones. The cMSs are kindly asked to consider MED for this use on the national level.

3.2.2.7 Winter barley (HORVW) / *Fusarium* spp. (FUSASP)

No data were available for assessment of minimum effective dose of *Fusarium* spp. on barley. Since *Fusarium* spp. including *F. culmorum* and *F. graminearum* are highly destructive pathogens affecting many cereal species with small grains such as wheat, barley, triticale and oats, the extrapolation of the data presented on winter wheat for the same disease is possible.

Over the supportive dataset available on winter wheat, data demonstrated an overall trend of decreasing disease severity of *Fusarium* spp. with increasing dose rates was observed in particular for CA3301 applied at 0.6 & 0.8 l/ha compared to 0.48 l/ha. The same trend was also observed against *F. culmorum* and *F. graminearum* on winter wheat and differences between the 0.6 l/ha dose rate and the 0.8 l/ha dose rate were not always significant. Therefore, it was envisaged that in most instances a dose rate of 0.6 l/ha may be sufficient to control *Fusarium* spp. on winter barley.

Considering all elements presented above, 0.6 l/ha is the minimum effective dose to control *Fusarium* sp. on winter barley in all EPPO zones.

Comments of zRMS:

No efficacy trials for FUSASP on winter barley have been submitted in any EPPO zones. The cMSs are kindly asked to consider MED for this use on the national level.

3.2.2.8 Winter barley (HORVW) / Green leaf area

Min. Eff. Dose evaluation of CA3301 - Maritime EPPO zone

Green leaf area was recorded at 15-56 DA-B in 33 valid trials on winter barley after two applications of CA3301 at 0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N). In 31 trials, green leaf area was assessed on the whole plant while in 2 trials it was assessed by foliar levels. For those 2 trials, green leaf area will be presented separately and on foliar levels 2 to 1.

Summary results are presented in Table 3.2-45.

Data demonstrated a higher effect of 2 applications of CA3301 at 0.6 l/ha compared to lower dose rate for the increase of green leaf area on winter barley infected by foliar and ears diseases. In the 31 trials assessing green leaf area on the whole plant, an increase of 255.88%, 214.77% and 187.85% was recorded with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check on winter barley. In the 2 trials assessing green leaf area by foliar level, an increase of 3748.73%, 3038.67% and 35662.26% was recorded on foliar level 2 and an increase of 2130.81%, 1191.58% and 1686.79% was recorded on foliar level 1 with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check.

A dose effect was observed over the dataset whereby the green leaf area increased with higher dose rates, although differences were not always significant. Therefore, the 0.6 l/ha dose rate was sufficient to induce a positive effect on the green leaf area on winter barley.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on winter barley infected by a range of diseases in the Maritime EPPO zone.

Table 3.2-45: Summary table – Minimum effective dose evaluation – Winter barley – Green leaf area - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
Green leaf area Plant - 15-56 DA-B							
Number of values	31	31	31	31	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	0,00	1,25	4,00	2,50			
Maximum value	71,25	83,75	82,50	90,00	25 >	4 >	0 >
Mean green leaf area (%)	25,10	40,89	44,58	47,87	6 =	26 =	24 =
Mean %UTC*	100,00%	287,85%	314,77%	355,88%	0 <	1 <	7 <
Green leaf area L2 - 41-46 DA-B							
Number of values	2	2	2	2	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	0,94	60,33	49,58	62,54			
Maximum value	8,38	75,96	84,04	87,51	2 >	1 >	0 >
Mean green leaf area (%)	4,66	68,14	66,81	75,03	0 =	1 =	1 =
Mean %UTC	100,00%	3662,26%	3138,67%	3848,73%	0 <	0 <	1 <
Green leaf area L1 - 41-46 DA-B							
Number of values	2	2	2	2	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	1,69	56,55	39,73	71,34			
Maximum value	39,84	90,61	92,54	95,74	2 >	1 >	0 >
Mean green leaf area (%)	20,76	73,58	66,13	83,54	0 =	1 =	0 =
Mean %UTC	100,00%	1786,79%	1291,58%	2230,81%	0 <	0 <	2 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

* Calculated on 27 trials because 4 trials were excluded from the calculation

Min. Eff. Dose evaluation of CA3301 - Mediterranean EPPO zone

Green leaf area was recorded at 15-43 DA-B in 42 valid trials on winter barley after two applications of CA3301 at 0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N). In all 42 trials, green leaf area was assessed on the whole plant.

Summary results are presented in Table 3.2-46.

Data demonstrated a higher effect of 2 applications of CA3301 at 0.6 l/ha compared to lower dose rate for the increase of green leaf area on winter barley infected by foliar and ears diseases. In the 42 trials assessing green leaf area on the whole plant, an increase of 166.94%, 182.00% and 129.67% was recorded with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check on winter barley.

A dose effect was observed from the whole dataset whereby the green leaf area increases with higher dose rates, although differences were not always significant. Therefore, the 0.6 l/ha dose rate was sufficient to induce a positive effect on the green leaf area on winter barley.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on winter barley infected by a range of diseases in the Mediterranean EPPO zone.

Table 3.2-46: Summary table – Minimum effective dose evaluation – Winter barley – Green leaf area - Mediterranean EPPO zone

Treatment name	UNTREATED	CA3301	CA3301	CA3301	No of trials where CA3301		
Rate	CHECK	0,48	0,6	0,8	at 0,6 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB	compared to		
Green leaf area - 15-43 DA-B							
Number of values	42	42	42	42	UTC	CA3301	CA3301
Minimum value	0,50	5,00	3,50	4,00		0,48 l/ha	0,8 l/ha
Maximum value	90,00	100,00	100,00	100,00	23 >	5 >	0 >
Mean green leaf area (%)	33,62	49,85	52,62	55,60	19 =	37 =	38 =
Mean %UTC	100,00%	229.67%	282,00%	266,94%	0 <	0 <	4 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Min. Eff. Dose evaluation of CA3301 - North-Eastern East EPPO zone

Green leaf area was recorded at 14-62 DA-B in 38 valid trials on winter barley after two applications of CA3301 at 0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N). In all 38 trials, green leaf area was assessed on the whole plant.

Summary results are presented in Table 3.2-47.

Data demonstrated a higher effect of 2 applications of CA3301 at 0.6 l/ha compared to lower dose rate for the increase of green leaf area on winter barley infected by foliar and ears diseases. In the 42 trials assessing green leaf area on the whole plant, an increase of 115.48%, 102.26% and 82.12% was recorded with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check on winter barley.

A dose effect was observed from the whole dataset whereby the green leaf area increases with higher dose rates, although differences were not always significant. Therefore, the 0.6 l/ha dose rate was sufficient to induce a positive effect on the green leaf area on winter barley.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on winter barley infected by a range of diseases in the North-Eastern East EPPO zone.

Table 3.2-47: Summary table – Minimum effective dose evaluation – Winter barley – Green leaf area – North-Eastern East EPPO zone

Treatment name	UNTREATED	CA3301	CA3301	CA3301	No of trials where CA3301		
Rate	CHECK	0,48	0,6	0,8	at 0,6 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB	compared to		
Green leaf area - 14-62 DA-B							
Number of values	38	38	38	38	UTC	CA3301	CA3301
Minimum value	1,50	5,25	7,25	8,00		0,48 l/ha	0,8 l/ha
Maximum value	75,00	87,50	95,00	95,00	20 >	3 >	1 >
Mean green leaf area (%)	31,19	39,39	42,46	42,61	17 =	35 =	34 =
Mean %UTC	100,00%	182,12%	202,26%	215,48%	1 <	0 <	3 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Min. Eff. Dose evaluation of CA3301 - South-Eastern East EPPO zone

Green leaf area was recorded at 15-45 DA-B in 34 valid trials on winter barley after two applications of CA3301 at 0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N). In 31 trials, green leaf area was assessed on the whole plant while in 3 trials it was assessed by foliar levels. For those 3 trials, green leaf area will be presented separately and on foliar levels 2 to 1.

Summary results are presented in Table 3.2-48

Data demonstrated a higher effect of 2 applications of CA3301 at 0.6 l/ha compared to lower dose rate for the increase of green leaf area on winter barley infected by foliar and ears diseases. In the 31 trials assessing green leaf area on the whole plant, an augmentation of 259.13%, 242.53% and 201.40% was recorded with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check on winter barley. In the 3 trials assessing green leaf area by foliar level, an increase of 5347.37%, 5250.88% and 2970.18% was recorded on foliar level 2 and an increase of 522.44%, 505.66% and 289.75% was recorded on foliar level 1 with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check.

A dose effect was observed from the whole dataset whereby the green leaf area increases with higher dose rates, although differences were not always significant. Therefore, the 0.6 l/ha dose rate was sufficient to induce a positive effect on the green leaf area on winter barley.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on winter barley infected by a range of diseases in the South-Eastern East EPPO zone.

Table 3.2-48: Summary table – Minimum effective dose evaluation – Winter barley – Green leaf area – South-Eastern East EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
Green leaf area Plant - 15-45 DA-B							
Number of values	31	31	31	31	UTC	CA3301	CA3301
Minimum value	1,68	3,50	3,75	4,00		0,48 l/ha	0,8 l/ha
Maximum value	90,00	90,00	92,00	94,00	23 >	10 >	0 >
Mean green leaf area (%)	31,06	52,04	55,19	57,95	8 =	21 =	23 =
Mean %UTC	100,00%	301,40%	342,53%	359,13%	0 <	0 <	8 <
Green leaf area L2 - 24-29 DA-B							
Number of values	3	3	3	3	UTC	CA3301	CA3301
Minimum value	0,25	19,00	30,00	32,50		0,48 l/ha	0,8 l/ha
Maximum value	4,75	38,50	50,00	54,25	3 >	3 >	0 >
Mean green leaf area (%)	2,50	25,83	38,17	40,50	0 =	0 =	1 =
Mean %UTC	100,00%	3070,18%	5350,88%	5447,37%	0 <	0 <	2 <
Green leaf area L1 - 24-29 DA-B							
Number of values	3	3	3	3	UTC	CA3301	CA3301
Minimum value	2,50	15,00	29,00	30,00		0,48 l/ha	0,8 l/ha
Maximum value	17,75	51,50	58,50	60,00	3 >	3 >	0 >
Mean green leaf area (%)	11,58	34,83	44,17	45,00	0 =	0 =	2 =
Mean %UTC	100,00%	389,75%	605,66%	622,44%	0 <	0 <	1 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Comments of zRMS:

Very positive effect after application of CA3301 at dose rate of 0,6-0,8 l/ha were observed. An augmentation of green leaf area was visible on high level in all EPPO climatic zones. It can be concluded that CA3301 at 0,6 l/ha is justified as minimum effective dose in winter barley.

3.2.2.9 Winter barley (HORVW) / Conclusion

On winter barley, 5 foliar diseases and several crop quality parameters were assessed in 156 trials across 4 EPPO zones. Disease severity was assessed and analysed on the main foliar levels 1 and 2. Although a comprehensive trials programme was undertaken for this dossier, in some instances, due to the absence of appropriate level of diseases or other agronomic or climatic limitations, the proposed number of valid trials was not fully achieved. Hence, depending on the EPPO zone, the disease, the assessment timing and the

crop part assessed, the dataset available was sometimes limited and so not fully representative of the efficacy of CA3301. Therefore, to get an overview of the efficacy of CA3301 at 0.6 l/ha, summary tables are presented in “Winter barley (HORVW) / Conclusion”, on foliar levels 1&2 (see Table 3.2-273 and Table 3.2-274).

Overall, across the 4 EPPO zones and all diseases, a consistent dose rate trend was observed for higher disease control with higher dose rates. In particular, the rate of 0.6 l/ha generally gave significantly better control compared to the rate of 0.48 l/ha. In much of the dataset there were no statistical differences between the dose rates of 0.6 l/ha (100% dose rate) and 0.8 l/ha (133% dose rate), even if in some assessments a numerical increase was observed with CA3301 at 0.8 l/ha. Moreover, in circumstances of high disease pressure the rate of 0.6 l/ha showed sufficient efficacy to control the disease and maintain good crop growth conditions until harvest.

In addition, the data demonstrates overall similar effects for the targeted diseases regardless of EPPO zone. Similarly, the same dose rate trends were observed for improving green leaf area in situations of infection from a single pathogen or in cases of disease complexes. Green leaf area not only indicates the area free of infection but also the ability of the plant to continue effective growth and develop to productive stages, enabling a longer duration of grain filling and therefore improved yield quantity and quality. After all, the proposed dose rate of 0.6 l/ha did not involve negative effects on the crop quality parameters observed at harvest. Finally, the same observations were made in the sections assessing the efficacy of CA3301 against the same pathogens on spring barley and are supportive of the proposed dose rate of 0.6 l/ha. Therefore, a minimum effective dose rate of 0.6 l/ha is proposed for CA3301 on winter barley in each of the EPPO zones, in order to allow optimum efficacy in relation to disease occurrence.

In this dossier data presented for minimum effective dose is primarily from assessments where 2 applications of the test product were made. However, according to disease development conditions, a single application may provide sufficient disease control, therefore users should not be restricted to always applying twice, hence in the GAP the proposed use is for 1-2 applications. In addition, crop pathogens are commonly controlled using a programme of different fungicides with varied modes of action, therefore the choice should be available to growers to make a single application of CA3301, followed by application of a different appropriate fungicide. Prothioconazole is well established over a number of years in providing good broad spectrum efficacy across a range of common crop pathogens, with either 1 or more applications appropriate according to disease development conditions, risk of resistance development and local conditions. Current authorisations for similar products containing prothioconazole including Proline 275 and Proline/Praktis/Joao (CA2445) are for 1-2 applications at comparative rates of prothioconazole to the requested use for CA3301. Considering these elements, and that data in the efficacy section shows comparability of CA3301 to these authorised products, registration of CA3301 at the proposed minimum effective dose rate and with a number of applications of 1- 2, is requested.

Considering all elements presented in the previous sections of each disease and on spring barley, CA3301 applied at 0.6 l/ha is the minimum effective dose to control a range of foliar diseases on winter barley.

3.2.2.10 Spring barley (HORVS) / *Ramularia collo-cygni* (RAMUCC)

Between 2018 and 2020, a series of 28 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the minimum effective dose of CA3301 against *Ramularia collo-cygni* on **spring barley** (see Table 3.2-275). The trials were carried out by certified testing institutes. The proposed dose rate is 0.6 l/ha.

In the Maritime EPPO zone, a total of 8 trials were performed in the Czech Republic (1), Denmark (1), Germany (2) and the United Kingdom (4).

In the Mediterranean EPPO zone, a total of 12 trials were performed in France (1), Italy (6) and Spain (5).

In the North-Eastern East EPPO zone, a total of 2 trials were performed in Poland (2). These two trials were not valid. Therefore, this EPPO zone is not presented in the results below.

In the South-Eastern East EPPO zone, a total of 6 trials were performed in Slovakia (3), Hungary (1), Romania (2) .

Data groupings were also made specifically for Poland evaluation and trials involved (8) were performed in the North-Eastern East EPPO zone (2), in Czech Republic (1), in Germany (2) and in Slovakia (3).

Out of the 28 trials performed on spring barley against *Ramularia collo-cygni*, 19 were considered valid.

Min. Eff. Dose evaluation of CA3301 - Maritime EPPO zone

In the Maritime EPPO zone, a total of 8 trials evaluated the efficacy of CA3301 on spring barley against *Ramularia collo-cygni*. 6 trials out of 8 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33 N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 31-37 and the 2nd application was at BBCH 42-65. Two main assessment timings were selected: around two weeks after the 2nd application (15 DA-B) and the last timing close to harvest (25-34 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-49.

An overall trend can be observed from the whole dataset whereby the rate of 0.6 l/ha improved efficacy compared to the rate of 0.48 l/ha. In the majority of assessments (9 of 13) there were no significant increase in efficacy at 0.8 l/h compared to the proposed rate of 0.6 l/ha.

When evaluating the reduction of disease severity, the data demonstrated a better effect of 2 applications of CA3301 at 0.6 l/ha compared to the lower dose rate of 0.48 l/ha on spring barley against *Ramularia collo-cygni*. In 7 assessments a statistically significant increase in efficacy was obtained from the proposed rate of 0.6 l/ha compared to 0.48 l/ha.

On foliar level 2, when applied at 0.6 l/ha, CA3301 showed 76.71% of efficacy against *Ramularia collo-cygni* two weeks after the 2nd application and 60.12% before harvest. On foliar level 1, CA3301 showed 62.99% efficacy on reduction of disease severity around two weeks after the 2nd application and 58.25% before harvest. At the proposed dose rate therefore, medium efficacy was obtained in 3 of 4 assessment timings, whereas the reduced dose rate of 0.48 l/ha provided only low efficacy in 3 of 4 assessment timings. Hence for satisfactory control of *Ramularia collo-cygni* the minimum effective dose of CA3301 is 0.6 l/ha.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Ramularia collo-cygni* on spring barley in the Maritime EPPO zone.

Table 3.2-49: Summary table – Minimum effective dose evaluation – Spring barley – RAMUCC - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301		
Rate		0,48	0,6	0,8	at 0,6 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB	compared to		
% Disease severity L2 - 15 DA-B							
Number of values	2	2	2	2	UTC	CA3301	CA3301
Minimum value	38,59	10,04	8,59	7,86		0,48 l/ha	0,8 l/ha
Maximum value	60,31	22,55	12,48	8,83	2 >	1 >	0 >
Mean disease severity (%)	49,45	16,29	10,53	8,34	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	62,48%	76,71%	82,04%	0 <	0 <	1 <
% Disease severity L1 - 15 DA-B							
Number of values	1	1	1	1	UTC	CA3301	CA3301
Minimum value	21,05	11,80	7,79	4,40		0,48 l/ha	0,8 l/ha
Maximum value	21,05	11,00	7,79	4,40	1 >	1 >	0 >
Mean disease severity (%)	21,05	11,80	7,79	4,40	0 =	0 =	0 =
Abbott efficacy (%)	0,00%	43,94%	62,99%	79,10%	0 <	0 <	1 <

% Disease severity L2 - 25-34 DA-B							
Number of values	4	4	4	4	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	20,19	5,56	4,39	3,31	4 >	2 >	0 >
Maximum value	100,00	89,44	82,01	79,64	0 =	2 =	2 =
Mean disease severity (%)	41,63	27,63	24,83	22,96	0 <	0 <	2 <
Abbott efficacy (%)	0,00%	54,17%	60,12%	66,46%			
% Disease severity L1 - 28-34 DA-B							
Number of values	6	6	6	6	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	11,30	1,11	0,69	0,35	6 >	3 >	0 >
Maximum value	100,00	91,63	86,25	89,13	0 =	3 =	6 =
Mean disease severity (%)	44,50	27,71	25,66	24,88	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	54,00%	58,25%	63,84%			

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - Mediterranean EPPO zone

In the Mediterranean EPPO zone, a total of 12 trials evaluated the efficacy of CA3301 on spring barley against *Ramularia collo-cygni*. 8 trials out of 12 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33 N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 30-37 and the 2nd application was at BBCH 55-61. Two main assessment timings were selected: around two weeks after the 2nd application (13-14 DA-B) and the last timing close to harvest (26-32 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-50

Data demonstrated a better effect of 2 applications of CA3301 at 0.6 l/ha compared to lower dose rate for the reduction of disease severity on spring barley against *Ramularia collo-cygni*. An overall trend of decreasing disease severity with increasing dose rates from 0.48 to 0.6 l/ha was observed in the dataset, although differences were not always statistically significant. In the majority of assessments there were no significant increase in efficacy at 0.8 l/h compared to the proposed rate of 0.6 l/ha.

On foliar level 2, CA3301 at 0.6 l/ha showed 60.75% efficacy against *Ramularia collo-cygni* two weeks after the 2nd application and 68.88% before harvest. On foliar level 1, when applied at 0.6 l/ha, CA3301 showed 69.16% efficacy on reduction of disease severity around two weeks after the 2nd application and 63.57% before harvest. At all 4 assessment timings therefore, the proposed dose rate demonstrated medium efficacy, whereas at the reduced dose rate of 0.48 l/ha efficacy was low at 2 of the 4 assessment timings. No benefit was derived from increasing the dose rate to 0.8 l/ha which also provided medium efficacy. Therefore 0.6 l/ha o CA3301 is the minimum effective dose for control of *Ramularia collo-cygni*.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Ramularia collo-cygni* on spring barley in the Mediterranean EPPO zone.

Table 3.2-50: Summary table – Minimum effective dose evaluation – Spring barley – RAMUCC - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
% Disease severity L2 - 13-14 DA-B					
Number of values	3	3	3	3	UTC
Minimum value	5,63	0,63	0,45	0,43	CA3301 0,48 l/ha
Maximum value	100,00	99,94	80,56	45,69	CA3301 0,8 l/ha
					3 >

Mean disease severity (%)	47,15	39,06	30,49	19,50	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	47,50%	60,75%	70,70%	0 <	0 <	1 <
% Disease severity L1 - 13-14 DA-B							
Number of values	2	2	2	2	UTC	CA3301	CA3301
Minimum value	30,50	7,30	5,00	8,01		0,48 l/ha	0,8 l/ha
Maximum value	84,75	59,69	38,38	20,81	2 >	1 >	0 >
Mean disease severity (%)	57,62	33,50	21,69	14,41	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	52,82%	69,16%	74,59%	0 <	0 <	1 <
% Disease severity L2 - 26-32 DA-B							
Number of values	6	6	6	6	UTC	CA3301	CA3301
Minimum value	6,44	0,00	0,00	0,00		0,48 l/ha	0,8 l/ha
Maximum value	16,15	9,04	11,78	8,84	6 >	0 >	0 >
Mean disease severity (%)	11,98	3,84	4,06	2,97	0 =	6 =	6 =
Abbott efficacy (%)	0,00%	69,06%	68,88%	77,54%	0 <	0 <	0 <
% Disease severity L1 - 28 DA-B							
Number of values	1	1	1	1	UTC	CA3301	CA3301
Minimum value	6,45	2,58	2,35	1,96		0,48 l/ha	0,8 l/ha
Maximum value	6,45	2,58	2,35	1,96	1 >	0 >	0 >
Mean disease severity (%)	6,45	2,58	2,35	1,96	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	60,00%	63,57%	69,61%	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - North-Eastern East EPPO zone

No data were available from the North-eastern East EPPO zone for *Ramularia collo-cygni* in spring-sown barley. However, data collected in winter-sown barley for the same pathogen is considered supportive for this use as Poland is the only cMS for this zone in the CEU regulatory area and Poland guidance document (extrapolation table, June 2016) indicates that this is possible.

Over the dataset presented for the same crop sown in winter disease severity was low to medium, and even if the 0.6 l/ha dose rate gave significant higher disease control than the 0.48 l/ha dose rate on L1 in a single trial, no significant differences were observed on L2 between the 3 dose rate of CA3301. In many instances the rate of 0.6 l/ha gave acceptable control of *Ramularia collo-cygni* comparable to that of 0.8 l/ha but not always statistically equivalent. Overall the 0.6 l/ha rate was sufficient to obtain an acceptable level of disease control.

Considering all elements presented above, CA3301 at 0.6 l/ha is proposed as the minimum effective dose to control *Ramularia collo-cygni* on spring barley in the North-Eastern East EPPO zone.

Min. Eff. Dose evaluation of CA3301 - South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 6 trials evaluated the efficacy of CA3301 on spring barley against *Ramularia collo-cygni*. 5 trials out of 6 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33 N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 32-37 and the 2nd application was at BBCH 55-61. Two main assessment timings were selected: around two weeks after the 2nd application (15-16 DA-B) and the last timing close to harvest (20-23 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-51.

An overall trend of decreasing disease severity with increasing dose rates from 0.48 to 0.6 l/ha was observed in the dataset, although differences were not always statistically significant. Whilst a significant increase in

efficacy at 0.8 l/h compared to the proposed rate of 0.6 l/ha was sometimes observed the rate of 0.6 l/ha nevertheless provided high efficacy. Data demonstrated a better effect of 2 applications of CA3301 at 0.6 l/ha compared to lower dose rate for the reduction of disease severity on spring barley against *Ramularia collo-cygni*. In 9 of 12 assessments disease control was statistically significantly better from the proposed dose rate of 0.6 l/ha compared to the lower dose rate of 0.48 l/ha.

On foliar level 2, CA3301 at 0.6 l/ha showed 92.92% efficacy against *Ramularia collo-cygni* two weeks after the 2nd application and 80.64% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 86.64% efficacy on reduction of disease severity two weeks after the 2nd application and 83.00% before harvest. The proposed dose rate therefore provided high efficacy at all 4 assessment timings, whereas efficacy was lower (medium) from the reduced rate of 0.48 l/ha in 3 of 4 assessment timings. There was no benefit derived from increasing the dose rate to 0.8 l/ha. The minimum effective dose for CA3301 to control *Ramularia collo-cygni* is therefore 0.6 l/ha.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Ramularia collo-cygni* on spring barley in the South-Eastern East EPPO zone.

Table 3.2-51: Summary table – Minimum effective dose evaluation – Spring barley – RAMUCC – South-Eastern East EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
% Disease severity L2 - 15-16 DA-B							
Number of values	3	3	3	3	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	5,09	0,19	0,00	0,00			
Maximum value	76,88	20,68	16,34	14,01	3 >	2 >	0 >
Mean disease severity (%)	29,11	7,04	5,45	4,67	0 =	1 =	2 =
Abbott efficacy (%)	0,00%	88,22%	92,92%	93,93%	0 <	0 <	1 <
% Disease severity L1 - 16 DA-B							
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	54,88	11,66	7,33	4,66			
Maximum value	54,88	11,66	7,33	4,66	1 >	1 >	0 >
Mean disease severity (%)	54,88	11,66	7,33	4,66	0 =	0 =	0 =
Abbott efficacy (%)	0,00%	78,75%	86,64%	91,51%	0 <	0 <	1 <
% Disease severity L2 - 20-23 DA-B							
Number of values	4	4	4	4	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	15,38	3,79	2,98	1,91			
Maximum value	45,13	9,83	8,35	6,45	4 >	3 >	0 >
Mean disease severity (%)	28,64	6,76	5,52	4,08	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	76,06%	80,64%	86,29%	0 <	0 <	3 <
% Disease severity L1 - 20-23 DA-B							
Number of values	4	4	4	4	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	8,23	2,21	1,30	1,05			
Maximum value	2,05	5,14	4,10	3,11	4 >	3 >	0 >
Mean disease severity (%)	17,19	3,67	2,82	2,09	0 =	1 =	2 =
Abbott efficacy (%)	0,00%	77,29%	83,00%	87,73%	0 <	0 <	2 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, a total of 6 valid trials from the neighbouring countries Czech Republic, Germany and Slovakia evaluated the efficacy of CA3301 on spring barley

Treatment name	UNTREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
Rate		0,48	0,6	0,8			
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB			
% Disease severity L2 - 16 DA-B							
Number of values	1	1	1	1	UTC	CA3301 1 0,48 l/ha	CA3301 1 0,8 l/ha
Minimum value	76,88	20,68	16,34	14,01		1 >	1 >
Maximum value	76,88	20,68	16,34	14,01	0 =	0 =	0 =
Mean disease severity (%)	76,88	20,68	16,34	14,01	0 <	0 <	1 <
Abbott efficacy (%)	0,00%	73,10%	78,75%	81,78%			
% Disease severity L1 - 16 DA-B							
Number of values	1	1	1	1	UTC	CA3301 1 0,48 l/ha	CA3301 1 0,8 l/ha
Minimum value	54,88	11,66	7,33	4,66		1 >	1 >
Maximum value	54,88	11,66	7,33	4,66	0 =	0 =	0 =
Mean disease severity (%)	54,88	11,66	7,33	4,66	0 <	0 <	1 <
Abbott efficacy (%)	0,00%	78,75%	86,64%	91,51%			
% Disease severity L2 - 23-34 DA-B							

Treatment name	UNTREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
Rate		0,48	0,6	0,8			
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB			
Number of values	5	5	5	5	UTC	CA3301 1 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	20,19	5,56	4,39	3,31			
Maximum value	45,13	9,83	8,35	6,45	5 >	3 >	0 >
Mean disease severity (%)	30,02	8,11	6,68	4,94	0 =	2 =	1 =
Abbott efficacy (%)	0,00%	71,85%	76,72%	83,10%	0 <	0 <	4 <
% Disease severity L1 - 23-34 DA-B							
Number of values	5	5	5	5	UTC	CA3301 1 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	11,30	3,03	2,63	1,78			
Maximum value	27,05	10,99	9,31	6,14	5 >	2 >	0 >
Mean disease severity (%)	19,36	6,12	5,23	3,75	0 =	3 =	3 =
Abbott efficacy (%)	0,00%	66,78%	71,19%	79,36%	0 <	0 <	2 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

6 trials have been submitted to determine minimum effective dose in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,48 l/ha was insufficient to control of RAMUCC in spring barley. The higher dose rate of 0,6 l/ha caused increase of effectiveness about 10%. The results achieved after application of 0,6 l/ha and 0,8 l/ha was comparable. However, it should be noted that CA3301 at 0,6-0,8 l/ha is effective on a medium level. No efficacy trials were presented to determine MED in **the North-East EPPO zone**. The results from the neighbouring countries have been submitted to support of Polish registration. 6 efficacy trials showed that CA3301 applied at dose rate of 0,6 l/ha is sufficient to control of RAMUCC. The dose rate of 0,48 l/ha achieved lower efficacy in situation of high disease pressure. The test product at 0,6 l/ha is more effective in unfavorable condition. 5 trials were available to determine MED in **the South-East EPPO zone**. CA3301 applied at dose rate of 0,6-0,8 l/ha achieved consistently high level of control. The lower dose rate was also effective but on the medium level in most trials. Also results in 8 additional trials from the Mediterranean zone showed significant differences between the lowest and higher dose rates. The test product at 0,48 l/ha was not effective to control of RAMUCC. The medium level of control was noted in case of 0,6-0,8 l/ha.

Taking into account all EPPO zones, the dose rate of 0,6 l/ha can be considered minimum effective dose to control of *Ramularia collo-cygni* in spring barley.

3.2.2.11 Spring barley (HORVS) / *Puccinia hordei* (PUCCHD)

Between 2018 and 2020, a series of 27 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the minimum effective dose of CA3301 against *Puccinia hordei* on **spring barley** (see Table 3.2-285). The trials were carried out by certified testing institutes. The proposed dose rate is 0.6 l/ha.

In the Maritime EPPO zone, 8 trials were performed in Czech Republic (1), Germany (4), Denmark (2) and United Kingdom (1).

In the Mediterranean EPPO zone, 4 trials were performed in Spain (3) and Italy (1).

In the North-Eastern East EPPO zone, 9 trials were performed in Poland (5), Lithuania (1) and Latvia (3).

In the South-Eastern East EPPO zone, 6 trials were performed in Hungary (3) and Slovakia (3).

Out of the 27 trials performed on spring barley against *Puccinia hordei*, 15 were considered valid.

Min. Eff. Dose evaluation of CA3301 - Maritime EPPO zone

In the Maritime EPPO zone, a total of 8 trials evaluated the efficacy of CA3301 on spring barley against *Puccinia hordei*. 5 trials out of 8 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33 N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 32-39 and the 2nd application was at BBCH 52-69. Two main assessment timings were selected: around two weeks after the 2nd application (14-17 DA-B) and the last timing close to harvest (19-39 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-53.

When evaluating the reduction of disease severity, the data demonstrated a better effect of 2 applications of CA3301 at 0.6 l/ha compared to lower dose rate for the reduction of disease severity on spring barley against *Puccinia hordei*. At 3 assessments the differences were statistically significant. In many of the trials disease severity was relatively low and both rates provided high control although disease severity was lower at the proposed dose rate compared to 0.48 l/ha. However, where disease severity was higher, significant differences were observed.

On foliar level 2, when applied at 0.6 l/ha, CA3301 showed 97.72% of efficacy against *Puccinia hordei* two weeks after the 2nd application and 81.49% before harvest. On foliar level 1, when applied at 0.6 l/ha, CA3301 showed 92.99% of efficacy against *Puccinia hordei* two weeks after the 2nd application and 86.50% before harvest. Hence, the proposed dose rate of 0.6 l/ha provided high efficacy at all assessment timings, whereas the reduced rate of 0.48 l/ha provided medium efficacy on L2 close to harvest. There was no benefit derived from increasing the dose rate to 0.8 l/ha.

An overall trend can be observed from the whole dataset whereby efficacy increases with an increased dose rate from 0.6 l/ha to 0.48 l/ha. Also, this trend appears stronger as the disease pressure increases and the closer the observation is to harvest. For the rates of 0.6 and 0.8 l/ha it was often observed that the performance of the product was statistically equivalent or very comparable. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for the control of *Puccinia hordei* on spring barley. The same trend was observed on winter barley in which the dataset was larger and can be supportive to this current dataset.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Puccinia hordei* on spring barley in the Maritime EPPO zone.

Table 3.2-53 Summary table – Minimum effective dose evaluation – Spring barley – PUCCHD - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
Rate							
Rate unit							
Appl. Code							
% Disease severity L2 - 14-17 DA-B							
Number of values	2	2	2	2	UT C	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	7,28	0,16	0,03	0,08	2 >	1 >	0 >
Maximum value	27,70	2,95	1,15	0,51			
Mean disease severity (%)	17,49	1,56	0,59	0,29	0 =	1 =	1 =

Treatment name	UNTREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
Rate Rate unit Appl. Code Abbott efficacy (%)	0,00%	0,48 L/ha AB	0,6 L/ha AB	0,8 L/ha AB	0 <	0 <	1 <
% Disease severity L1 - 17 DA-B							
Number of values	1	1	1	1	UT C	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	9,84	0,93	0,69	0,13	1 >	0 >	0 >
Maximum value	9,84	0,93	0,69	0,13	0 =	1 =	1 =
Mean disease severity (%)	9,84	0,93	0,69	0,13	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	90,55%	92,99%	98,68%			
% Disease severity L2 - 19-39 DA-B							
Number of values	3	3	3	3	UT C	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	8,51	1,90	1,43	0,33	2 >	1 >	0 >
Maximum value	12,94	3,03	2,20	1,78	0 =	2 =	2 =
Mean disease severity (%)	10,96	2,30	1,92	1,21	0 <	0 <	1 <
Abbott efficacy (%)	0,00%	78,60%	81,49%	88,01%			
% Disease severity L1 - 19-39 DA-B							
Number of values	3	3	3	3	UT C	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	6,37	0,93	1,03	0,10	2 >	1 >	0 >
Maximum value	10,06	2,78	1,40	1,08	0 =	2 =	3 =
Mean disease severity (%)	8,79	1,64	1,15	0,64	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	81,80%	86,50%	92,07%			

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (con-
versely for '<')

* at 19-39 DA-B, UTC was excluded from statistical analysis in
1 trial out of 3

Levels of efficacy (% Abbott effi-
cacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - Mediterranean EPPO zone

In the Mediterranean EPPO zone, a total of 4 trials evaluated the efficacy of CA3301 on spring barley against *Puccinia hordei*. 1 trial out of 4 was considered valid and enabled to compare the efficacy of several dose rates of (0.8 l/ha (1.33 N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 30 and the 2nd application was at BBCH 55. One main assessment timing was available: close to harvest (33 DA-B), and the analysis was conducted on main foliar level 2 (L2).

Summary results are presented in Table 3.2-54.

In the Mediterranean EPPO zone, the data demonstrated high efficacy of 2 applications of CA3301 at 0.6 l/ha for the reduction of disease severity on spring barley against *Puccinia hordei*. The efficacy was statistically equivalent for the 2 dose rates but a numerical difference of +12%, and of 48% for disease severity was observed for 0.6 compared to 0.48 l/ha. The reduced dose rate of 0.48 l/ha provided medium efficacy, compared to high efficacy for the proposed dose rate.

Although this dataset for the Mediterranean zone is limited, a larger dataset was presented for the closely related crop winter barley (see **Winter barley (HORVW) / *Puccinia hordei* (PUCCHD)**) in which rust

Puccinia hordei is from a different strain but with a very similar biology. The dataset demonstrated a very similar behaviour of the test product and can be supportive for the spring barley species. Whereas the differences were not always significant, the dataset for rust on winter barley showed an overall trend where 0.6 l/ha dose rate provide a better control of *Puccinia hordei* than lower rate (0.48 l/ha) and very comparable to upper rate (0.8 l/ha). Consequently, it is highly probable that the slight increase in control of rust of winter barley provided by 0.6 l/ha dose rate seen in this dataset would be very comparable on spring barley.

Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for the control of *Puccinia hordei* on spring barley.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Puccinia hordei* on spring barley in the Mediterranean EPPO zone

Table 3.2-54 Summary table – Minimum effective dose evaluation – Spring barley – PUCCHD - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
Rate							
Rate unit							
Appl. Code							
% Disease severity L2 - 33 DA-B							
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	5,28	1,21	0,63	0,19			
Maximum value	5,28	1,21	0,63	0,19	1 >	0 >	0 >
Mean disease severity (%)	5,28	1,21	0,63	0,19	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	77,08%	88,07%	96,40%	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 9 trials evaluated the efficacy of CA3301 on spring barley against *Puccinia hordei*. 4 trials out of 9 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33 N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 31-38 and the 2nd application was at BBCH 53-59. Two main assessment timings were selected: around two weeks after the 2nd application (14-15 DA-B) and the last timing close to harvest (17-21 DA-B). The analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-55

On foliar level 2, when applied at 0.6 l/ha, CA3301 showed 91.14% of efficacy against *Puccinia hordei* two weeks after the 2nd application and 96.61% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 88.61% of efficacy before harvest. Therefore, the proposed dose rate provided high efficacy against *Puccinia hordei* in the North-Eastern EPPO zone.

In these trials all dose rates provided high efficacy however, the positive effects to control *Puccinia hordei* of CA3301 at 0.6 l/ha were overall superior than at 0.48 l/ha dose rate and especially in assessments close to harvest.

An overall trend of decreasing disease severity with increasing dose rates was observed in the dataset, although differences were not statistically significant. In many instances the rate of 0.6 l/ha gave control of *Puccinia hordei* very comparable to that of 0.8 l/ha. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for the control of *Puccinia hordei* on spring barley. The same trend was observed on winter barley in which the dataset was larger and can be supportive to this current dataset.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Puccinia hordei* on spring barley in the North-Eastern East EPPO zone

Table 3.2-55 Summary table – Minimum effective dose evaluation – Spring barley – PUCCHD – North-Eastern East EPPO zone

Treatment name		CA3301	CA3301	CA3301	No of trials where CA3301		
Rate	UNTREATED CHECK	0,48	0,6	0,8	at 0,6 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB	compared to		
% Disease severity L2 - 14-15 DA-B							
Number of values	3	3	3	3	UTC	CA3301	CA3301
Minimum value	8,48	0,56	0,75	0,19		0,48 l/ha	0,8 l/ha
Maximum value	46,88	1,73	1,53	1,21	3 >	0 >	0 >
Mean disease severity (%)	22,89	1,30	1,21	0,75	0 =	3 =	3 =
Abbott efficacy (%)	0,00%	90,64%	91,14%	94,16%	0 <	0 <	0 <
% Disease severity L2 - 17-21 DA-B							
Number of values	2	2	2	2	UTC	CA3301	CA3301
Minimum value	7,74	0,36	0,19	0,08		0,48 l/ha	0,8 l/ha
Maximum value	14,56	1,50	0,63	0,31	2 >	0 >	0 >
Mean disease severity (%)	11,15	0,93	0,41	0,19	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	92,52%	96,61%	98,42%	0 <	0 <	0 <
% Disease severity L1 - 17-21 DA-B							
Number of values	2	2	2	2	UTC	CA3301	CA3301
Minimum value	6,14	1,34	0,69	0,13		0,48 l/ha	0,8 l/ha
Maximum value	20,25	1,63	1,19	1,06	2 >	0 >	0 >
Mean disease severity (%)	13,19	1,48	0,94	0,59	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	85,06%	88,61%	91,05%	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 6 trials evaluated the efficacy of CA3301 on spring barley against *Puccinia hordei*. 5 trials out of 6 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33 N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 32-37 and the 2nd application was at BBCH 51-61. Two main assessment timings were selected: around two weeks after the 2nd application (15 DA-B) and the last timing close to harvest (20-27 DA-B). The analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-56

Data demonstrated a better effect of 2 applications of CA3301 at the proposed dose rate of 0.6 l/ha compared to lower dose rate of 0.48 l/ha for the reduction of disease severity on spring barley against *Puccinia hordei* (see

Table 3.2-56). In 6 of 7 assessments the differences were statistically significant.

On foliar level 2, CA3301 at 0.6 l/ha showed 81.12% efficacy against *Puccinia hordei* two weeks after the 2nd application and 86.34% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 88.44% efficacy on reduction of disease severity before harvest. Hence, at the proposed dose rate CA3301 provided high efficacy against *Puccinia hordei* at all assessment timings, whereas the reduced dose rate provided medium efficacy at all assessment timings. Therefore 0.6 l/ha is the minimum effective dose of CA3301 for control of *Puccinia hordei*.

An overall trend can be observed from the whole dataset whereby the rate of 0.6 l/ha improved efficacy compared to the rate of 0.48 l/ha. In all instances the rate of 0.6 l/ha gave high control of *Puccinia hordei* usually very comparable to that of 0.8 l/ha. The same trend was observed on winter barley (see **Winter barley (HORVW) / *Puccinia hordei* (PUCCHD)** in which the dataset was larger and can be supportive to this current dataset.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Puccinia hordei* on spring barley in the South-Eastern East EPPO zone.

Table 3.2-56: Summary table – Minimum effective dose evaluation – Spring barley – PUCCHD – South-Eastern East EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
% Disease severity L2 - 15 DA-B							
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	5,56	2,44	1,05	0,59	1 > 0 = 0 <	1 > 0 = 0 <	0 > 0 = 1 <
Maximum value	5,56	2,44	1,05	0,59			
Mean disease severity (%)	5,56	2,44	1,05	0,59			
Abbott efficacy (%)	0,00%	56,12%	81,12%	89,39%			
% Disease severity L2 - 20-27 DA-B							
Number of values	5	5	5	5	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	5,80	0,24	0,28	0,00	5 < 0 = 0 <	4 > 1 = 0 <	0 > 1 = 4 <
Maximum value	28,25	3,56	2,93	2,75			
Mean disease severity (%)	11,75	2,57	1,46	0,99			
Abbott efficacy (%)	0,00%	72,48%	86,34%	92,22%			
% Disease severity L1 - 24 DA-B							
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	21,88	2,95	2,53	2,05	1 > 0 = 0 <	1 > 0 = 0 <	0 > 0 = 1 <
Maximum value	21,88	2,95	2,53	2,05			
Mean disease severity (%)	21,88	2,95	2,53	2,05			
Abbott efficacy (%)	0,00%	86,52%	88,44%	90,63%			

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

5 trials have been submitted to determine minimum effective dose in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,48-0,8 l/ha achieved high efficacy. However, the dose rate of 0,6-0,8 l/ha was consistently effective in all assessments and the dose rate of 0,48 l/ha was on medium level before harvest. Overall, the low

disease pressure was in submitted trials and increase of dose rate to 0,6 l/ha would be more beneficial to control of pathogens in spring barley in the MAR zone.

4 trials were available to determine MED in **the North-East EPPO zone**. CA3301 applied at 0,48-0,8 l/ha achieved high efficacy in all assessments. Due to the limited number of trials, also results from the neighbouring countries can supported of Polish registration. Overall, the low disease pressure was in submitted trials and increase of dose rate to 0,6 l/ha would be more beneficial to control of pathogens in spring barley in the NE zone.

5 trials were presented to determine MED in **the South-East EPPO zone**. The high level of control was visible after application of dose rate of 0,6-0,8 l/ha. CA3301 at 0,48 l/ha achieved varied results from low efficacy after second application to high level before harvest. In 1 additional trial fro the Mediterranean zone, the test product at 0,6 l/ha was better compare to lower dose about 10% (88,07% vs 77,08%).

Taking into account all EPPO zones, the dose rate of 0,6 l/ha can be considered minimum effective dose to control of *Puccinia hordei* in spring barley.

3.2.2.12 Spring barley (HORVS) / *Pyrenophora teres* (PYRNTE)

Between 2018 and 2020, a series of 66 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the minimum effective dose of CA3301 against *Pyrenophora teres* on **spring barley** (see Table 3.2-295). The trials were carried out by certified testing institutes. The proposed dose rate is 0.6 l/ha.

In the Maritime EPPO zone, 13 trials were performed in Czech Republic (2), Germany (3), Denmark (3) and United Kingdom (5).

In the Mediterranean EPPO zone, 12 trials were performed in Spain (7), France (1) and Italy (4).

In the North-eastern East EPPO zone, 30 trials were performed in Poland (22), Lithuania (1) and Latvia (7).

In the South-eastern East EPPO zone, 11 trials were performed in Hungary (5), Bulgaria (1), Romania (3) and Slovakia (2).

Out of the 66 trials performed on spring barley against *Pyrenophora teres*, 48 were considered valid.

Min. Eff. Dose evaluation of CA3301 - Maritime EPPO zone

In the Maritime EPPO zone, a total of 13 trials evaluated the efficacy of CA3301 on spring barley against *Pyrenophora teres*. 8 trials out of 13 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33 N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 31-39 and the 2nd application was at BBCH 42-69. Two main assessment timings were selected: around two weeks after the 2nd application (14-21 DA-B) and the last timing close to harvest (29-39 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-57.

When evaluating the reduction of disease severity, the data demonstrated a better effect of 2 applications of CA3301 at 0.6 l/ha compared to 0.48 l/ha for the reduction of disease severity on spring barley against *Pyrenophora teres*. Differences between the rates were statistically significant in 3 assessments.

On foliar level 2, when applied at 0.6 l/ha, CA3301 showed 77.81% of efficacy against *Pyrenophora teres* two weeks after the 2nd application and 51.69% before harvest. On foliar level 1, CA3301 showed 69.41% efficacy on reduction of disease severity around two weeks after the 2nd application and 77.00% before harvest. Hence the proposed dose rate provided medium efficacy at 3 assessment timings and low efficacy on L2 at the last assessment timing. For applications at 0.48 l/ha efficacy was low on L1 and also on L2 at the last assessment timing. Net blotch is one of the most economically important diseases of barley, causing significant grain yield loss and reduction in grain quality, therefore the additional efficacy provided by 0.6 l/ha is the minimum effective dose.

An overall trend can be observed from the whole dataset whereby efficacy increases with higher dose rates, in particular for 0.6 l/ha compared to 0.48 l/ha. This trend was clearer as we get closer to the harvest. For the rates of 0.6 and 0.8 l/ha it was often observed that the performance of the product was statistically equivalent. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for the control of *Pyrenophora teres* on spring barley.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Pyrenophora teres* on spring barley in the Maritime EPPO zone.

Table 3.2-57 Summary table – Minimum effective dose evaluation – Spring barley – PYRNT - Maritime EPPO zone

Treatment name		CA3301	CA3301	CA3301	No of trials where CA3301		
Rate		0,48	0,6	0,8	at 0,6 l/ha is >, = or <		
Rate unit	UNTREATED CHECK	L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB	compared to		
% Disease severity L2 - 14-21 DA-B							
Number of values	5	5	5	5	UTC	CA3301	CA3301
Minimum value	12,50	1,35	1,41	1,38		0,48 l/ha	0,8 l/ha
Maximum value	54,19	20,70	19,59	12,54	4 >	0 >	0 >
Mean disease severity (%)	34,56	8,74	9,13	5,53	0 =	5 =	4 =
Abbott efficacy (%)	0,00%	78,23%	77,81%	85,70%	0 <	0 <	1 <
% Disease severity L1 - 15-21 DA-B							
Number of values	5	5	5	5	UTC	CA3301	CA3301
Minimum value	5,49	0,00	0,00	0,00		0,48 l/ha	0,8 l/ha
Maximum value	27,31	10,46	10,53	9,41	4 >	1 >	0 >
Mean disease severity (%)	14,09	4,56	4,40	3,55	0 =	4 =	5 =
Abbott efficacy (%)	0,00%	65,73%	69,41%	74,83%	0 <	0 <	0 <
% Disease severity L2 - 29-39 DA-B							
Number of values	4	4	4	4	UTC	CA3301	CA3301
Minimum value	5,03	2,48	1,96	0,71		0,48 l/ha	0,8 l/ha
Maximum value	91,81	30,75	29,48	27,46	4 >	0 >	0 >
Mean disease severity (%)	34,83	15,38	13,41	12,02	0 =	4 =	3 =
Abbott efficacy (%)	0,00%	46,55%	51,69%	63,95%	0 <	0 <	1 <
% Disease severity L1 - 29-37 DA-B							
Number of values	3	3	3	3	UTC	CA3301	CA3301
Minimum value	15,33	11,75	4,19	4,20		0,48 l/ha	0,8 l/ha
Maximum value	100,00	22,81	27,15	31,28	4 >	2 >	1 >
Mean disease severity (%)	60,28	17,36	13,62	14,41	0 =	0 =	2 =
Abbott efficacy (%)	0.00%	57.93%	77.00%	76.49%	0 <	1 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - Mediterranean EPPO zone

In the Mediterranean EPPO zone, a total of 12 trials evaluated the efficacy of CA3301 on spring barley against *Pyrenophora teres*. 9 trials out of 12 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33 N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 30-37 and the 2nd application was at BBCH 55-61. Two main assessment timings were selected: around two weeks after the 2nd application (12-19 DA-B) and the last timing close to harvest (23-40 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-58.

Data demonstrated a numerically better effect of 2 applications of CA3301 at 0.6 l/ha compared to lower dose rate for the reduction of disease severity on spring barley against *Pyrenophora teres*.

On foliar level 2, CA3301 at 0.6 l/ha showed 74.11% efficacy against *Pyrenophora teres* two weeks after the 2nd application and 63.63% before harvest. On foliar level 1, when applied at 0.6 l/ha, CA3301 showed 96.18% efficacy on reduction of disease severity around two weeks after the 2nd application and 94.69% before harvest. Hence, CA3301 at the proposed dose rate provided medium to high efficacy at all assessment timings.

Whereas the differences were not significant, these positive effects to control *Pyrenophora teres* of CA3301 at 0.6 l/ha were overall superior than at 0.48 l/ha dose rate, and more comparable to the efficacy obtained from applications at 0.8 l/ha. In particular, on L1 at 2 weeks after application 0.6 l/ha provided 10% more efficacy compared to 0.48 l/ha. Net blotch is one of the most economically important diseases of barley, causing significant grain yield loss and reduction in grain quality, therefore the additional efficacy provided by 0.6 l/ha is the minimum effective dose.

Furthermore, in the dataset presented for winter-sown barley (see **Winter barley (HORVW) / *Pyrenophora teres* (PYRNTE)**), a more clear benefit was demonstrated from increasing the dose rate from 0.48 l/ha to 0.6 l/ha for control of this pathogen.

An overall trend of decreasing disease severity with increasing dose rates was observed in the dataset, although differences were not always statistically significant. In most instances the rate of 0.6 l/ha gave good control of *Pyrenophora teres* and was always statistically equivalent to that of 0.8 l/ha. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for the control of *Pyrenophora teres*.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Pyrenophora teres* on spring barley in the Mediterranean EPPO zone.

Table 3.2-58 Summary table – Minimum effective dose evaluation – Spring barley – PYRNTE - Mediterranean EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
% Disease severity L2 - 12-19 DA-B							
Number of values	5	5	5	5	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	5,18	2,01	1,19	0,83	5 >	0 >	0 >
Maximum value	14,20	4,46	4,71	4,69	0 =	5 =	5 =
Mean disease severity (%)	10,04	3,13	2,63	2,24	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	67,03%	74,11%	76,85%			
% Disease severity L1 - 14-19 DA-B							
Number of values	2	2	2	2	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	5,05	0,30	0,05	0,00	2 >	0 >	0 >
Maximum value	8,11	1,73	0,54	0,81	0 =	2 =	2 =
Mean disease severity (%)	6,58	1,01	0,29	0,41	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	86,36%	96,18%	95,01%			
% Disease severity L2 - 23-40 DA-B							
Number of values	7	7	7	7	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	6,25	1,44	0,85	0,40	6 >	0 >	0 >
Maximum value	40,19	7,88	9,88	8,51	1 =	7 =	7 =
Mean disease severity (%)	14,06	4,35	4,71	3,68	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	63,02%	63,63%	68,84%			
% Disease severity L1 - 40 DA-B							
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	17,69	1,36	0,94	0,95	1 >	0 >	0 >
Maximum value	17,69	1,36	0,94	0,95	0 =	1 =	1 =
Mean disease severity (%)	17,69	1,36	0,94	0,95	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	92,31%	94,69%	94,63%			

>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

Treatment name	UNTREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301
Rate		0,48	0,6	0,8	at 0,6 l/ha is >, = or <
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	compared to
>80%	High efficacy				
60-80%	Medium efficacy				
<60%	Low efficacy				

Min. Eff. Dose evaluation of CA3301 - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 30 trials evaluated the efficacy of CA3301 on spring barley against *Pyrenophora teres*. 20 trials out of 30 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33 N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 31-38 and the 2nd application was at BBCH 49-61. Two main assessment timings were selected: around two weeks after the 2nd application (14-18 DA-B) and the last timing close to harvest (21-36 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-59.

Data demonstrated an overall better effect of 2 applications of CA3301 at 0.6 l/ha compared to lower dose rates for the reduction of disease severity on spring barley against *Pyrenophora teres*, with statistically significant differences in 3 assessments.

On foliar level 2, CA3301 at 0.6 l/ha showed 84.07% efficacy against *Pyrenophora teres* two weeks after the 2nd application and 75.76% before harvest. On foliar level 1, when applied at 0.6 l/ha, CA3301 showed 81.65% efficacy on reduction of disease severity around two weeks after the 2nd application and 75.81% before harvest. Hence at the proposed dose rate CA3301 gave high efficacy at both early assessments and medium efficacy at both later assessments, whereas for 0.48 l/ha efficacy was medium at 3 of the 4 assessment timings. Net blotch is one of the most economically important diseases of barley, causing significant grain yield loss and reduction in grain quality, therefore the additional efficacy provided by 0.6 l/ha is the minimum effective dose.

An overall trend of decreasing disease severity with increasing dose rates was observed in the dataset, although differences were not always statistically significant. In most instances the rate of 0.6 l/ha gave reliable control of *Pyrenophora teres* very comparable to that of 0.8 l/ha. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for the control of *Pyrenophora teres*.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Pyrenophora teres* on spring barley in the North-Eastern East EPPO zone.

Table 3.2-59 Summary table – Minimum effective dose evaluation – Spring barley – PYRNTE – North-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301
Rate		0,48	0,6	0,8	at 0,6 l/ha is >, = or <
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	compared to
% Disease severity L2 - 14-18 DA-B					
Number of values	10	10	10	10	UTC
Minimum value	6,96	0,13	0,13	0,00	CA3301 0,48 l/ha
Maximum value	68,75	30,00	28,75	20,50	CA3301 0,8 l/ha
Mean disease severity (%)	26,68	6,76	6,01	4,06	10 > 0 < 0 >
Abbott efficacy (%)	0,00%	81,04%	84,07%	87,75%	0 = 10 = 9 =
% Disease severity L1 - 14-18 DA-B					
Number of values	5	5	5	5	UTC
Minimum value	8,94	1,00	1,50	1,25	CA3301 0,48 l/ha
Maximum value	48,13	17,50	13,75	8,88	CA3301 0,8 l/ha
Mean disease severity (%)	29,51	7,76	5,77	3,20	5 > 0 > 0 >
					0 = 5 = 5 =

Abbott efficacy (%)	0,00%	76,92%	81,65%	86,95%	0 <	0 <	0 <
% Disease severity L2 - 21-36 DA-B							
Number of values	14	14	14	14	UTC	CA3301	CA3301
Minimum value	5,81	0,65	0,31	0,00		0,48 l/ha	0,8 l/ha
Maximum value	80,31	38,81	32,94	31,56	14 >	2 >	0 >
Mean disease severity (%)	19,56	8,36	6,65	5,40	0 =	12 =	11 =
Abbott efficacy (%)	0,00%	69,13%	75,76%	80,62%	0 <	0 <	3 <
% Disease severity L1 - 21-36 DA-B							
Number of values	12	12	12	12	UTC	CA3301	CA3301
Minimum value	6,75	0,58	0,84	0,34		0,48 l/ha	0,8 l/ha
Maximum value	59,00	16,26	12,70	8,38	12 >	1 >	0 >
Mean disease severity (%)	14,00	3,92	3,36	2,45	0 =	11 =	9 =
Abbott efficacy (%)	0,00%	71,77%	75,81%	82,03%	0 <	0 <	3 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 11 trials evaluated the efficacy of CA3301 on spring barley against *Pyrenophora teres*. All 11 trials were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33 N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 31-39 and the 2nd application was at BBCH 51-61. Two main assessment timings were selected: around two weeks after the 2nd application (15-16 DA-B) and the last timing close to harvest (21-34 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-60.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6 l/ha compared to lower dose rate for the reduction of disease severity on spring barley against *Pyrenophora teres*. Statistically significant differences were observed in 10 assessments, whereby 0.6 l/ha reduced disease severity more than 0.48 l/ha.

On foliar level 2, CA3301 at 0.6 l/ha showed 80.15% efficacy against *Pyrenophora teres* two weeks after the 2nd application and 69.22% before harvest. On foliar level 1, when applied at 0.6 l/ha, CA3301 showed 90.84% efficacy on reduction of disease severity around two weeks after the 2nd application and 75.77% before harvest.

These positive effects to control *Pyrenophora teres* of CA3301 at 0.6 l/ha were overall superior than the 0.48 l/ha dose rate, as efficacy across the datasets was medium to high for the proposed dose rate and medium for the lower rate. Net blotch is one of the most economically important diseases of barley, causing significant grain yield loss and reduction in grain quality, therefore the additional efficacy provided by 0.6 l/ha is the minimum effective dose.

An overall trend of decreasing disease severity with increasing dose rates was observed in the dataset, although differences were not always statistically significant. In most instances the rate of 0.6 l/ha gave reliable control of *Pyrenophora teres* more comparable to that of 0.8 l/ha. Therefore, it is envisaged that in most instances, applications of 0.6 l/ha will be sufficient for the control of *Pyrenophora teres* on spring barley.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Pyrenophora teres* on spring barley in the South-Eastern East EPPO zone.

Table 3.2-60 Summary table – Minimum effective dose evaluation – Spring barley – PYRNT – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301
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Rate Rate unit Appl. Code		0,48 L/ha AB	0,6 L/ha AB	0,8 L/ha AB	at 0,6 l/ha is >, = or < compared to		
% Disease severity L2 - 15-16 DA-B							
Number of values	7	7	7	7	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	6,10	1,06	0,58	0,16			
Maximum value	24,19	4,76	4,01	3,60	7 >	4 >	0 >
Mean disease severity (%)	12,67	2,73	1,86	1,33	0 =	3 =	3 =
Abbott efficacy (%)	0,00%	73,61%	80,15%	85,03%	0 <	0 <	4 <
% Disease severity L1 – 15 DA-B							
Number of values	2	2	2	2	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	9,00	2,06	0,63	0,38			
Maximum value	9,81	2,24	1,11	0,60	2 >	2 >	0 >
Mean disease severity (%)	9,41	2,15	0,87	0,49	0 =	0 =	1 =
Abbott efficacy (%)	0,00%	77,06%	90,84%	94,83%	0 <	0 <	1 <
% Disease severity L2 - 21-29 DA-B							
Number of values	6	6	6	6	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	5,94	2,01	1,63	0,76			
Maximum value	68,88	28,25	22,00	14,81	6 >	2 >	0 <
Mean disease severity (%)	25,37	9,36	7,50	4,95	0 =	4 =	4 =
Abbott efficacy (%)	0,00%	62,81%	69,22%	79,34%	0 <	0 <	2 <
% Disease severity L1 - 24-34 DA-B							
Number of values	5	5	5	5	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	5,01	0,65	0,43	0,40			
Maximum value	41,94	16,25	12,50	6,75	5 >	2 >	0 >
Mean disease severity (%)	16,63	5,20	3,77	2,38	0 =	3 =	3 =
Abbott efficacy (%)	0,00%	65,15%	75,77%	80,69%	0 <	0 <	2 <

> means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

8 trials have been submitted to determine minimum effective dose in the **Matritime EPPO climatic zone**. CA3301 applied at dose rate of 0,48 l/ha was not effective in assessments before harvest. The dose rate of 0,6 l/ha achieved medium level of control. The results of 0,6 and 0,8 l/ha were comparable.

20 trials were presented to determine MED in the **North-East EPPO zone**. The test product applied at 0,8 l/ha achieved consistantly high level of control, while the dose rate of 0,6 l/ha was medium to high effective. The dose rate of 0,48 l/ha showed significant lower effectiveness compare to the dose rate of 0,6 l/ha on L2 before harvest in 14 out of 20 trials.

11 trials were available to determine MED in the **South-East EPPO zone**. CA3301 applied at dose rate of 0,6-0,8 l/ha achieved consistantly high level of control, while the dose rate of 0,48 l/ha showed visible lower effectiveness in assessments before harvest. In 9 additional trials from the Mediterranean zone, a decrease of dose rate to 0,48 l/ha caused lower results about 7-10% after second application. The comparable effectiveness was noted for 0,6 and 0,8 l/ha.

Taking into account all EPPO zones, the dose rate of 0,6 l/ha can be considered minimum effective dose to control of *Pyrenophora teres* in spring barley.

3.2.2.13 Spring barley (HORVS) / *Blumeria graminis* (ERYSGR-ERYSGH)

Between 2019 and 2020, a series of 13 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the minimum effective dose of CA3301 against *Blumeria graminis* or *Blumeria graminis f. sp. hordei* on **spring barley** (see Table 3.2-305). The trials were carried out by certified testing institutes. The proposed dose rate is 0.6 l/ha.

In the Maritime EPPO zone, 4 trials were performed in Czech Republic (2) and Germany (2).

In the Mediterranean EPPO zone, 2 trials were performed in Italy (2).

In the North-Eastern East EPPO zone, 3 trials were performed in Latvia (3).

In the South-Eastern East EPPO zone, a total of 4 trials were performed in Hungary (1) and Slovakia (3).

Data groupings were also made specifically for Poland evaluation and trials involved (10) were performed in North-Eastern EPPO zone (3), in Germany (2), Czech Republic (2) and Slovakia (3).

Out of the 13 trials performed on spring barley against *Blumeria graminis* or *Blumeria graminis* f. sp. *hordei*, 5 were considered valid.

Min. Eff. Dose evaluation of CA3301 - Maritime EPPO zone

In the Maritime EPPO zone, a total of 4 trials evaluated the efficacy of CA3301 on spring barley against *Blumeria graminis*. 3 trials out of 4 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33 N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 33-37 and the 2nd application was at BBCH 55-59. Two main assessment timings were selected: around two weeks after the 2nd application (13-15 DA-B) and the last timing close to harvest (19 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-61.

The dataset for *Blumeria graminis* in the Maritime zone is somewhat limited, nevertheless a dose rate effect is discernible from the earlier assessment. CA3301 applied at the proposed dose rate of 0.6 l/ha provided significantly better disease control compare to the rate of 0.48 l/ha in 1 assessment and a numerical trend was observed in the other assessments at this timing.

On foliar level 2, when applied at 0.6 l/ha, CA3301 showed 80.50% of efficacy against *Blumeria graminis* two weeks after the 2nd application and 94.74% before harvest. Hence the proposed dose rate provided high efficacy at both assessment timings, compared to the reduced rate of 0.48 l/ha which gave medium efficacy at the earlier timing. Therefore 0.6 l/ha is the minimum effective dose for control of *Blumeria graminis* in spring barley.

Even if statistical dose response was not always observed, it appears that CA3301 at 0.6 l/ha provided better control of disease severity than 0.48 l/ha dose rate. Moreover, at the proposed dose rate CA3301 provided very comparable efficacy to the 0.8 l/ha dose rate.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Blumeria graminis* on spring barley in the Maritime EPPO zone.

Table 3.2-61 Summary table – Minimum effective dose evaluation – Spring barley – ERYSGR-ER-YSGH - Maritime EPPO zone

Treatment name		CA3301	CA3301	CA3301	No of trials where CA3301		
Rate	UNTREATED CHECK	0,48	0,6	0,8	at 0,6 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB	compared to		
% Disease severity L2 - 13-15 DA-B							
Number of values	3	3	3	3	UTC	CA3301	CA3301
Minimum value	7,00	0,19	0,06	0,13		0,48 l/ha	0,8 l/ha
Maximum value	23,94	8,19	6,63	7,06	3 >	1 >	0 >
Mean disease severity (%)	15,47	5,21	3,77	3,13	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	72,04%	80,50%	84,83%	0 <	0 <	1 <
% Disease severity L2 - 19 DA-B							
Number of values	1	1	1	1	UTC	CA3301	CA3301
Minimum value	8,74	0,40	0,46	0,46		0,48 l/ha	0,8 l/ha
Maximum value	8,74	0,40	0,46	0,46	1 >	0 >	0 >
Mean disease severity (%)	8,74	0,40	0,46	0,46	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	95,42%	94,74%	94,74%	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - Mediterranean EPPO zone

In the Mediterranean EPPO zone, a total of 2 trials evaluated the efficacy of CA3301 on spring barley against *Blumeria graminis*. 1 trial out of 2 was considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33 N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 30-32 and the 2nd application was at BBCH 55-59. One main assessment timings was selected: close to harvest (24 DA-B), and the analysis was conducted on main foliar levels 2 (L2).

Summary results are presented in Table 3.2-62.

The reduced size of the dataset for this disease in the Mediterranean zone is partially explained by the low frequency of occurrence of powdery mildew on barley and all the more in this zone where climatic conditions are less conducive to its development. On foliar level 2, when applied at 0.6 l/ha, CA3301 showed 83.94% of efficacy against *Blumeria graminis* before harvest. Hence, the proposed dose rate provided high efficacy, whereas medium efficacy was obtained from the reduced rate of 0.48 l/ha.

Even if statistical dose response was not observed, it appears that CA3301 at 0.6 l/ha provided better control of disease severity than 0.48 l/ha dose rate. Moreover, at the proposed dose rate CA3301 provided comparable level of efficacy to the 0.8 l/ha dose rate.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Blumeria graminis* on spring barley in the Mediterranean EPPO zone.

Table 3.2-62 Summary table – Minimum effective dose evaluation – Spring barley – ERYSGR-ERYSGH - Mediterranean EPPO zone

Treatment name		CA3301	CA3301	CA3301	No of trials where CA3301		
Rate	UNTREATED CHECK	0,48	0,6	0,8	at 0,6 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB	compared to		
% Disease severity L2 - 24 DA-B							
Number of values	1	1	1	1	UTC	CA3301	CA3301
Minimum value	11,75	3,36	1,94	0,49		0,48 l/ha	0,8 l/ha
Maximum value	11,75	3,36	1,94	0,49	1 >	0 >	0 >
Mean disease severity (%)	11,75	3,36	1,94	0,49	0 =	1 =	1 =
Abbott efficacy (%)	0.00%	71.40%	83.94%	95.83%	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - South-Eastern East EPPO zone

No data were available from the South-eastern East EPPO zone for *Blumeria graminis* in spring-sown barley, however data collected in winter-sown barley (see **Winter barley (HORVW) / *Blumeria graminis* f. sp. hordei (ERYSGR / ERYSGH)**) for the same pathogen is considered supportive for this use.

Over the dataset presented for the same crop sown in winter disease severity was low to medium, and even if no significant differences were observed on between the 3 dose rates of CA3301 a numerical trend in decreasing disease severity with increasing dose rates was observed. Therefore, in case of higher infestation the rate of 0.6 l/ha may be appropriate to obtain an acceptable level of disease control.

Considering all elements presented above, CA3301 at 0.6 l/ha is proposed as the minimum effective dose to control *Blumeria graminis* on spring barley in the South-Eastern East EPPO zone.

Min. Eff. Dose evaluation of CA3301 - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 3 trials evaluated the efficacy of CA3301 on spring barley against *Blumeria graminis*. 1 trial out of 3 was considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33 N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 31-37 and the 2nd application was at BBCH 55. One main assessment timings was selected: close to harvest (26 DA-B), and the analysis was conducted on main foliar levels 2 (L2).

Summary results are presented in Table 3.2-63.

A limited dataset is available for this pathogen in the North-Eastern East EPPO zone, however a larger dataset is presented for winter-sown barley (see **Winter barley (HORVW) / *Blumeria graminis* f. sp. hordei (ERYSGR / ERYSGH)**) which is supportive of the proposed dose rate of 0.6 l/ha.

On foliar level 2, when applied at 0.6 l/ha, CA3301 showed 65.00% of efficacy against *Blumeria graminis* before harvest, providing medium efficacy. In the single trial, with relatively low disease severity, there was no difference in control between the proposed dose rate and the reduced dose rate. However, in the larger dataset in winter-sown barley a benefit was observed from increasing the dose rate from 0.48 l/ha to 0.6 l/ha.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Blumeria graminis* on spring barley in the North-Eastern East EPPO zone.

Table 3.2-63 Summary table – Minimum effective dose evaluation – Spring barley – ERYSGR-ERYSGH – North-Eastern East EPPO zone

North - South East EPTC zone							
Treatment name		CA3301	CA3301	CA3301	No of trials where CA3301		
Rate	UNTREATED CHECK	0,48	0,6	0,8	at 0,6 l/ha is >, = or < compared to		
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB			
% Disease severity L2 - 26 DA-B							
Number of values	1	1	1	1	UTC	CA3301	CA3301
Minimum value	10,00	3,50	3,50	2,80		0,48 l/ha	0,8 l/ha
Maximum value	10,00	3,50	3,50	2,80		1 >	0 >
Mean disease severity (%)	10,00	3,50	3,50	2,80	0 =	1 =	1 =
Abbott efficacy (%)	0.00%	65.00%	65.00%	72.00%	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, a total of 10 trials from the North-Eastern East

EPPO zone and the neighbouring countries Czech Republic, Germany and Slovakia evaluated the efficacy of CA3301 on spring barley against *Blumeria graminis*. 4 trials were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 33-37 and the 2nd application was at BBCH 55-59. Two main assessments were selected: around two weeks after the 2nd application (13-15 DA-B) and close to harvest (19-26 DA-B). The analysis was conducted on main foliar level 2.

Summary results are presented in Table 3.2-64.

Following 2 applications, the fungicidal performance of CA3301 enabled to significantly decrease the disease severity on leaves in the single trial, compared to the untreated control and whatever the dose rate considered. On foliar level 2, when applied at 0.6 l/ha, CA3301 showed 80.50% of efficacy against *Blumeria graminis* two weeks after the 2nd application and 79.87% before harvest, providing high to medium efficacy at the proposed dose rate

Even if statistical dose response was not observed, it appears that CA3301 at 0.6 l/ha provided better control of disease severity than 0.48 l/ha dose rate two weeks after the 2nd application. Moreover, at the proposed dose rate of 0.6 l/ha, CA3301 provided an efficacy level very comparable to the 0.8 l/ha dose rate at the two assessment timings.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Blumeria graminis* on spring barley in Poland.

Table 3.2-64: Summary table – Minimum effective dose evaluation – Spring barley – ERYSGR-ERYSGH – Data relevant for Poland

Treatment name	UNTREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301		
Rate		0,48	0,6	0,8	at 0,6 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB	compared to		
% Disease severity L2 - 13-15 DA-B							
Number of values	3	3	3	3	UTC	CA3301	CA3301
Minimum value	7,00	0,19	0,06	0,13		0,48 l/ha	0,8 l/ha
Maximum value	23,94	8,19	6,63	7,06	3 >	1 >	0 >
Mean disease severity (%)	15,47	5,21	3,77	3,13	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	72,04%	80,50%	84,83%	0 <	0 <	1 <
% Disease severity L2 - 19-26 DA-B							
Number of values	2	2	2	2	UTC	CA3301	CA3301
Minimum value	8,74	0,40	0,46	0,46		0,48 l/ha	0,8 l/ha
Maximum value	10,00	3,45	3,50	2,80	2 >	0 >	0 >
Mean disease severity (%)	9,37	1,93	1,98	1,63	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	80,46%	79,87%	83,37%	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

The limited number of trials has been submitted to determine minimum effective dose to control of ERYSGR in spring barley. 3 trials conducted in the **Maritime EPPO climatic zone** show consistantly high efficacy after application of CA3301 at 0,6-0,8 l/ha. The dose rate of 0,48 l/ha achieved medium efficacy after 13-15 DA-B in all submitted trials. 1 trial conducted in the **North-East EPPO zone** presented medium efficacy after application of CA3301 at 0,48-0,8 l/ha. However, an increase of dose rate to 0,8 l/ha caused increase of effectiveness about 7%. No efficacy trials were available in the **South-East EPPO zone**. 1 additional trial from the Mediterranean zone showed high efficacy after application of CA3301 at 0,6-0,8 l/ha.

Due to the limited number of trials, the cMSs are kindly asked to consider MED for this use on the national level.

3.2.2.14 Spring barley (HORVS) / *Rhynchosporium secalis* (RHYNSE)

Between 2018 and 2020, a series of 26 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the minimum effective dose of CA3301 against *Rhynchosporium secalis* on spring barley (see Table 3.2-314). The trials were carried out by certified testing institutes. The proposed dose rate is 0.6 l/ha.

In the Maritime EPPO zone, 12 trials were performed in United Kingdom (7), Denmark (2) and Germany (3).

In the Mediterranean EPPO zone, 5 trials were performed in Italy (1), Portugal (1) and Spain (3).

In the North-Eastern East EPPO zone, 2 trials were performed in Poland (2).

In the South-Eastern East EPPO zone, a total of 7 trials were performed in Hungary (1), Romania (5) and Slovakia (1).

Data groupings were also made specifically for Poland evaluation and trials involved (6) were performed in Germany (3), Poland (2) and Slovakia (1).

Out of the 26 trials performed on spring barley against *Rhynchosporium secalis*, 13 were considered valid.

Min. Eff. Dose evaluation of CA3301 - Maritime EPPO zone

In the Maritime EPPO zone, a total of 12 trials evaluated the efficacy of CA3301 on spring barley against *Rhynchosporium secalis*. 5 trials out of 12 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33 N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 31-37 and the 2nd application was at BBCH 43-61. Two main assessment timings were selected: around two weeks after the 2nd application (14-17 DA-B) and the last timing close to harvest (25-34 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-65.

When evaluating the reduction of disease severity, the data demonstrated a better effect of 2 applications of CA3301 at 0.6 l/ha compared to 0.48 l/ha for the reduction of disease severity on spring barley against *Rhynchosporium secalis*. The differences were statistically significant in 4 assessments.

On foliar level 2, when applied at 0.6 l/ha, CA3301 showed 88.96% of efficacy against *Rhynchosporium secalis* two weeks after the 2nd application and 68.61% before harvest. On foliar level 1, when applied at 0.6 l/ha, CA3301 showed 85.25% of efficacy against *Rhynchosporium secalis* before harvest. Hence, the proposed dose rate provided high efficacy at 2 assessment timings and medium efficacy at the other assessment timing. The reduced rate of 0.48 l/ha provided medium efficacy at 2 timings and high efficacy at 1 timing, therefore the rate of 0.6 l/ha is the minimum effective dose for control of *Rhynchosporium secalis*.

An overall trend can be observed from the whole dataset whereby efficacy increases with an increased dose rate from 0.48 l/ha to 0.6 l/ha. Also, this trend appears stronger as the disease pressure increases and the closer the observation is to harvest. For the rates of 0.6 and 0.8 l/ha it was often observed that the performance of the product was statistically equivalent or very comparable. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for the control of *Rhynchosporium secalis* on spring barley.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Rhynchosporium secalis* on spring barley in the Maritime EPPO zone.

Table 3.2-65 Summary table – Minimum effective dose evaluation – Spring barley – RHYNSE - Maritime EPPO zone

Treatment name		CA3301	CA3301	CA3301	No of trials where CA3301		
Rate	UNTREATED CHECK	0,48	0,6	0,8	at 0,6 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB	compared to		
% Disease severity L2 - 14-17 DA-B							
Number of values	5	5	5	5	UTC	CA3301	CA3301
Minimum value	5,56	0,16	0,00	0,00		0,48 l/ha	0,8 l/ha
Maximum value	21,14	6,68	5,00	4,55	5 >	3 >	0 >
Mean disease severity (%)	9,52	2,13	1,39	1,00	0 =	2 =	4 =
Abbott efficacy (%)	0,00%	80,54%	88,96%	94,05%	0 <	0 <	1 <
% Disease severity L2 - 25-34 DA-B							
Number of values	3	3	3	3	UTC	CA3301	CA3301
Minimum value	7,56	4,28	3,61	2,74		0,48 l/ha	0,8 l/ha
Maximum value	51,96	6,53	5,63	3,60	3 >	1 >	0 >
Mean disease severity (%)	24,46	5,57	4,52	3,20	0 =	2 =	3 =
Abbott efficacy (%)	0,00%	59,50%	68,61%	77,18%	0 <	0 <	0 <
% Disease severity L1 - 29-34 DA-B							
Number of values	2	2	2	2	UTC	CA3301	CA3301
Minimum value	8,63	0,84	0,76	0,41		0,48 l/ha	0,8 l/ha
Maximum value	12,73	2,91	2,03	1,14	2 >	0 >	0 >
Mean disease severity (%)	10,68	1,88	1,39	0,78	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	79,84%	85,25%	91,78%	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - Mediterranean EPPO zone

In the Mediterranean EPPO zone, a total of 5 trials evaluated the efficacy of CA3301 on spring barley against *Rhynchosporium secalis*. 2 trials out of 5 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33 N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 32-37 and the 2nd application was at BBCH 59-61. Two main assessment timings were selected: around two weeks after the 2nd application (14-15 DA-B) and the last timing close to harvest (30 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-66.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6 l/ha compared to lower dose rate for the reduction of disease severity on spring barley against *Rhynchosporium secalis*. A statistically significant difference was observed in 1 assessment, and in all assessments a consistent reduction in disease severity was observed from applications of 0.6 l/ha compared to 0.48 l/ha.

On foliar level 2, CA3301 at 0.6 l/ha showed 65.98% efficacy against *Rhynchosporium secalis* two weeks after the 2nd application and 51.50% before harvest. On foliar level 1, when applied at 0.6 l/ha, CA3301 showed 69.32% efficacy on reduction of disease severity around two weeks after the 2nd application and 64.37% before harvest. Hence, at the proposed dose rate CA3301 provided medium efficacy at 3 assessment timings and low efficacy at 1 timing, whereas for the rate of 0.48 l/ha efficacy was low at 2 assessment timings. Therefore, the rate of 0.6 l/ha is the minimum effective dose for control of *Rhynchosporium secalis*.

Whilst the differences were not always significant, these positive effects to control *Rhynchosporium secalis* of CA3301 at 0.6 l/ha were overall superior than at 0.48 l/ha dose rate.

In most instances the rate of 0.6 l/ha gave acceptable control of *Rhynchosporium secalis* and was always statistically equivalent to that of 0.8 l/ha. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for the control of *Rhynchosporium secalis*.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Rhynchosporium secalis* on spring barley in the Mediterranean EPPO zone.

Table 3.2-66 Summary table – Minimum effective dose evaluation – Spring barley – RHYNSE - Mediterranean EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
% Disease severity L2 - 14-15 DA-B							
Number of values	2	2	2	2	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	6,64	2,64	1,64	0,99	2 > 0 = 0 <	1 > 1 = 0 <	0 > 2 = 0 <
Maximum value	21,00	9,92	9,10	8,20		1 >	0 >
Mean disease severity (%)	13,82	6,28	5,37	4,59		0 =	1 =
Abbott efficacy (%)	0,00%	56,50%	65,98%	73,02%	0 <	0 <	0 <
% Disease severity L1 - 15 DA-B							
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	18,25	6,85	5,60	6,10	1 > 0 = 0 <	0 > 1 = 0 <	0 > 1 = 0 <
Maximum value	18,25	6,85	5,60	6,10		0 >	0 >
Mean disease severity (%)	18,25	6,85	5,60	6,10		0 =	1 =
Abbott efficacy (%)	0,00%	62,47%	69,32%	66,58%	0 <	0 <	0 <
% Disease severity L2 - 30 DA-B							
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	23,30	13,72	11,30	10,20	1 > 0 = 0 <	0 > 1 = 0 <	0 > 1 = 0 <
Maximum value	23,30	13,72	11,30	10,20		0 >	0 >
Mean disease severity (%)	23,30	13,72	11,30	10,20		0 =	1 =
Abbott efficacy (%)	0,00%	41,12%	51,50%	56,22%	0 <	0 <	0 <
% Disease severity L1 - 30 DA-B							
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	21,05	9,45	7,50	7,30	1 > 0 = 0 <	0 > 1 = 0 <	0 > 1 = 0 <
Maximum value	21,05	9,45	7,50	7,30		0 >	0 >
Mean disease severity (%)	21,05	9,45	7,50	7,30		0 =	1 =
Abbott efficacy (%)	0,00%	55,11%	64,37%	65,32%	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 2 trials evaluated the efficacy of CA3301 on spring barley against *Rhynchosporium secalis*. 1 trial out of 2 was considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33 N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 37 and the 2nd application was at BBCH 59. One main assessment timings was available: around 2 weeks after the 2nd application (17 DA-B), and the analysis was conducted on main foliar level 1 (L1).

Summary results are presented in Table 3.2-67.

A limited dataset is available for this pathogen in the North-Eastern East EPPO zone, however a larger dataset is presented for winter-sown barley which is supportive of the proposed dose rate of 0.6 l/ha.

On foliar level 1, when applied at 0.6 l/ha, CA3301 showed 89.72% of efficacy against *Rhynchosporium secalis* two weeks after the 2nd application, providing high efficacy. In the single trial, with relatively low disease severity, differences were not significant but a clear numerical trend appears where disease control increases with the dose rate and particularly for 0.6 l/ha compared to lower dose rate. Moreover, in the larger dataset in winter-sown barley the same benefit was observed from increasing the dose rate from 0.48 l/ha to 0.6 l/ha.

Considering all elements presented above, 2 applications of CA3301 at 0.6 l/ha is the minimum effective dose to control *Rhynchosporium secalis* on spring barley in the North-Eastern East EPPO zone.

Table 3.2-67 Summary table – Minimum effective dose evaluation – Spring barley – RHYNSE – North-Eastern East EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
% Disease severity L1 - 17 DA-B							
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	6,13	1,63	0,63	0,19	1 >	0 >	0 >
Maximum value	6,13	1,63	0,63	0,19	0 =	1 =	1 =
Mean disease severity (%)	6,13	1,63	0,63	0,19	0 <	0 <	0 <
Abbott efficacy (%)	0.00%	73.41%	89.72%	96.90%			

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 7 trials evaluated the efficacy of CA3301 on spring barley against *Rhynchosporium secalis*. 6 trials out of 7 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33 N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 32-37 and the 2nd application was at BBCH 55-61. Two main assessment timings were selected: around two weeks after the 2nd application (15 DA-B) and the last timing close to harvest (22-23 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in

Table 3.2-68.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6 l/ha compared to lower dose rate for the reduction of disease severity on spring barley against *Rhynchosporium secalis*. At 0.6 l/ha CA3301 provided a statistically higher reduction in disease severity compared to applications at 0.48 l/ha at 13 of 14 assessments.

On foliar level 2, CA3301 at 0.6 l/ha showed 95.01% efficacy against *Rhynchosporium secalis* two weeks after the 2nd application and 81.49% before harvest. On foliar level 1, when applied at 0.6 l/ha, CA3301 showed 89.92% efficacy on reduction of disease severity around two weeks after the 2nd application and 86.85% before harvest. Therefore, at the proposed dose rate CA3301 provided high efficacy at 4 all assessment timings, whereas at 0.48 l/ha efficacy was medium at 3 assessment timings. Hence the rate of 0.6 l/ha is the minimum effective dose for control of *Rhynchosporium secalis*.

In all instances the rate of 0.6 l/ha gave good control of *Rhynchosporium secalis*, and efficacy was overall comparable to that of 0.8 l/ha. Therefore, it is envisaged that in most instances, applications of 0.6 l/ha will

be sufficient for the control of *Rhynchosporium secalis* on spring barley.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Rhynchosporium secalis* on spring barley in the South-Eastern East EPPO zone.

Table 3.2-68 Summary table – Minimum effective dose evaluation – Spring barley – RHYNSE – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
% Disease severity L2 - 15 DA-B							
Number of values	5	5	5	5	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	5,29	0,54	0,00	0,00			
Maximum value	18,00	4,61	2,55	1,55	5 >	5 >	0 >
Mean disease severity (%)	10,32	1,92	0,89	0,42	0 =	0 =	3 =
Abbott efficacy (%)	0,00%	84,92%	95,01%	97,64%	0 <	0 <	2 <
% Disease severity L1 - 15 DA-B							
Number of values	2	2	2	2	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	6,48	1,59	0,51	0,28			
Maximum value	7,76	1,79	0,88	0,58	2 >	2 >	0 >
Mean disease severity (%)	7,12	1,69	0,69	0,43	0 =	0 =	2 =
Abbott efficacy (%)	0,00%	75,94%	89,92%	93,72%	0 <	0 <	0 <
% Disease severity L2 - 22-23 DA-B							
Number of values	4	4	4	4	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	6,11	2,10	1,60	1,00			
Maximum value	20,69	4,44	3,53	2,44	4 >	3 >	0 >
Mean disease severity (%)	16,93	3,73	2,86	1,95	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	75,79%	81,49%	87,64%	0 <	0 <	3 <
% Disease severity L1 - 22-23 DA-B							
Number of values	3	3	3	3	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	9,30	1,95	0,30	0,61			
Maximum value	11,94	2,64	1,49	0,73	3 >	3 >	0 >
Mean disease severity (%)	10,90	2,20	1,41	0,66	0 =	0 =	0 =
Abbott efficacy (%)	0,00%	79,19%	86,85%	93,82%	0 <	0 <	3 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, a total of 6 trials from the North-Eastern East EPPO Zone (2) and the neighbouring countries Germany (3) and Slovakia (1) evaluated the efficacy of CA3301 on spring barley against *Rhynchosporium secalis*. 4 trials out of 6 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33 N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 32-37 and the 2nd application was at BBCH 55-61. Two main assessments were selected: around two weeks after the 2nd application (14-17 DA-B) and close to harvest (23-29 DA-B).

Summary results are presented in Table 3.2-69.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6 l/ha compared to lower dose rate for the reduction of disease severity on spring barley against *Rhynchosporium secalis*. At 0.6 l/ha CA3301 provided a statistically higher reduction in disease severity compared to applications at 0.48 l/ha at 4 of 5

assessments. On foliar level 2, when applied at 0.6 l/ha, CA3301 showed 87.57% of efficacy against *Rhynchosporium secalis* two weeks after the 2nd application and 58.27% before harvest. On foliar level 1, when applied at 0.6 l/ha, CA3301 showed 89.72% of efficacy against *Rhynchosporium secalis* two weeks after the 2nd application and 76.48% before harvest. Hence the proposed dose rate provided high efficacy at the early assessment timing and low to medium at the later assessment timings, whereas at 0.48 l/ha efficacy was low to medium at all assessment timings. Therefore, the rate of 0.6 l/ha is the minimum effective dose for control of *Rhynchosporium secalis*.

These positive effects to control *Rhynchosporium secalis* of CA3301 at 0.6 l/ha were overall superior than the 0.48 l/ha dose rate. At the proposed dose rate of 0.6 l/ha CA3301 provided more comparable efficacy to the 0.8 l/ha dose rate at the two assessment timing.

Furthermore, since according to Poland national guidance extrapolation can be made from winter barley for this pathogen, which indicates the same trends, is supportive of the proposed dose rate.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Rhynchosporium secalis* on spring barley in Poland.

Table 3.2-69: Summary table – Minimum effective dose evaluation – Spring barley – RHYNSE– Data relevant for Poland

Treatment name		CA3301	CA3301	CA3301	No of trials where CA3301		
Rate	UNTREATED CHECK	0,48	0,6	0,8	at 0,6 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB	compared to		
% Disease severity L2 - 14-17 DA-B							
Number of values	2	2	2	2	UTC	CA3301	CA3301
Minimum value	5,56	1,08	0,55	0,13		0,48 l/ha	0,8 l/ha
Maximum value	5,68	1,96	0,85	0,33	2 >	2 >	0 >
Mean disease severity (%)	5,62	1,52	0,70	0,23	0 =	0 =	1 =
Abbott efficacy (%)	0,00%	73,03%	87,57%	95,89%	0 <	0 <	1 <
% Disease severity L1 - 17 DA-B							
Number of values	1	1	1	1	UTC	CA3301	CA3301
Minimum value	6,13	1,63	0,63	0,19		0,48 l/ha	0,8 l/ha
Maximum value	6,13	1,63	0,63	0,19	1 >	0 >	0 >
Mean disease severity (%)	6,13	1,63	0,63	0,19	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	73,41%	89,72%	96,90%	0 <	0 <	0 <
% Disease severity L2 - 23-25 DA-B							
Number of values	2	2	2	2	UTC	CA3301	CA3301
Minimum value	6,11	2,10	1,60	1,00		0,48 l/ha	0,8 l/ha
Maximum value	7,56	5,90	4,33	2,74	2 >	2 >	0 >
Mean disease severity (%)	6,84	4,00	2,96	1,87	0 =	0 =	1 =
Abbott efficacy (%)	0,00%	43,79%	58,27%	73,70%	0 <	0 <	1 <
% Disease severity L1 - 29 DA-B							
Number of values	1	1	1	1	UTC	CA3301	CA3301
Minimum value	8,63	2,91	2,03	1,14		0,48 l/ha	0,8 l/ha
Maximum value	8,63	2,91	2,03	1,14	1 >	0 >	0 >
Mean disease severity (%)	8,63	2,91	2,03	1,14	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	66,28%	76,48%	86,79%	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

5 trials have been submitted to determine minimum effective dose in the **Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,6-0,8 l/ha achieved consistently high level of control. The significant differences between higher doses and the lowest dose of 0,48 l/ha was visible on leaves level 2 after 25-34 DA-B in 3 out of 5 trials. The

test product at 0,48 l/ha was insufficient in these trials.

Only 1 trial was available to determine MED in **the North-East EPPO zone**. The high level of control was achieved after application of CA3301 at 0,6-0,8 l/ha. The dose rate of 0,48 l/ha was effective on a medium level. Also results from the neighbouring countries have been included to the overall calculation to support of Polish registration. All trials showed that the dose rate of 0,6 l/ha is sufficient to control of RHYNSE in the NE zone.

6 trials were presented to determine MED in **the South-East EPPO zone**. CA3301 applied at dose rate rate of 0,6-0,8 l/ha achieved high efficacy in all assessments, either after second application and before harvest, The dose rate of 0,48 l/ha showed medium level, especially before harvest. The increase of dose rate to 0,6 l/ha caused higher effectiveness about 10%. Also 2 additional trials from the Mediterranean zone showed that the dose rate of 0,48 l/ha is insufficient to control of RHYNSE in spring barley. CA3301 at 0,6-0,8 l/ha achieved medium efficacy.

Taking into account all EPPO zones, the dose rate of 0,6 l/ha can be considered minimum effective dose to control of *Rhynchosporium secalis* in spring barley.

3.2.2.15 Spring barley (HORVS) / *Oculimacula acuformis* (PSDCHA)

Ramanauskiene *et al.*, Effects of fungicides on the occurrence of winter wheat eyespot caused by fungi *Oculimacula acuformis* and *O. yallundae*, *Crop protection*, 2016)

No data were available for assessment of minimum effective dose of eyespot of cereals *Oculimacula acuformis* on any crop. Although early symptoms can be confused with *Fusarium spp.*, the diseases are not related and therefore it is impossible to extrapolate from these data.

However, Ramanauskiene *et al.*, showed that 2, 3 and 4 years of prothioconazole treatments allowed to reduce the population of *O. acuformis* assessed from 2009 to 2011 on winter wheat. This positive effect was observed as early as 10 days after treatment. This pathogen infecting both winter wheat and barley, it is therefore possible to transpose these results to spring barley.

Moreover, prothioconazole is one of the active substances the most used as fungicide in commercial practices (*Forecasting eyespot development and yield losses in winter wheat, HGCA, 2012*). Standard reference products containing prothioconazole, such as Proline 275 are registered to control eyespot on cereals, at the same application rates as for the other authorised pathogens, which indicates that prothioconazole controls eyespot at dose rates which are demonstrated to control the other major disease pathogens in cereals. Since the proposed dose rate for CA3301 against this pathogen is comparable to the rates demonstrated against other pathogens, and data shows overall equivalence of efficacy between Proline 275 and CA3301 in other pathogens, it is considered that the minimum effective dose rate for CA3301 to control eyespot will be the same as that demonstrated for other pathogens it is considered that the minimum effective dose rate for CA3301 to control eyespot will be the same as that demonstrated for other pathogens.

Moreover, since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6 l/ha generally gave significantly better disease control compared to the rate of 0.48 l/ha, it is supposed that the same dose range will be acceptable to control eyespot on spring barley.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Oculimacula acuformis* on spring barley in all EPPO zones.

Comments of zRMS:

No efficacy trials for PSDCHA have been submitted in any EPPO climatic zones. The cMSs are kindly asked to consider minimum effective dose for this use on the national level.

3.2.2.16 Spring barley (HORVS) / Green leaf area

Min. Eff. Dose evaluation of CA3301 - Maritime EPPO zone

Green leaf area was recorded at 14-40 DA-B in 22 valid trials on spring barley after two applications of CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha. In 16 trials, green leaf area was assessed on the entire plant while it was assessed on foliar level 2 and 1 respectively in 2 and 6 trials.

Summary results are presented in Table 3.2-70.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6 l/ha (100% dose rate) compared to lower dose rate for the increase of green leaf area on spring barley infected by foliar diseases. In 4 assessments these differences were statistically significant.

In the 16 trials assessing green leaf area on the whole plant, an increase of 179.83%, 151.50% and 129.62% was recorded with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check on spring barley. In the trials assessing green leaf area by foliar level, and augmentation of 687.50%, 675.00% and 625.00% was recorded on foliar level 2 and an augmentation of 120.00%, 114.33% and 94.23% was recorded on foliar level 1 with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check.

Considering the whole dataset, the positive effects of CA3301 at 0.6 l/ha on green leaf area were overall equivalent to those of 0.8 l/ha dose rate. In addition, compared to 0.48 l/ha, these positive effects were either better or equivalent.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on spring barley infected by a range of diseases in the Maritime EPPO zone.

Table 3.2-70: Summary table – Minimum effective dose evaluation – Spring barley – Green leaf area - Maritime EPPO zone

Treatment name		CA3301	CA3301	CA3301	No of trials where CA3301		
Rate		0,48	0,6	0,8			
Rate unit	UNTREATED CHECK	L/ha	L/ha	L/ha	at 0,6 l/ha is >, = or <		
Appl. Code		AB	AB	AB	compared to		
% Green leaf area - 14-39 DA-B							
Number of values	16	16	16	16	UTC	CA3301	CA3301
Minimum value	0,00	3,50	4,50	6,25		0,48 l/ha	0,8 l/ha
Maximum value	85,00	90,75	93,00	94,00	14 >	1 >	0 >
Mean green leaf area (%)	32,88	48,27	51,17	53,20	2 =	15 =	14 =
Mean %UTC	100,00%	229,62%	251,50%	279,83%	0 <	0 <	2 <
% Green leaf area - L2 - 29-32 DA-B							
Number of values	2	2	2	2	UTC	CA3301	CA3301
Minimum value	0,00	10,56	17,99	20,36		0,48 l/ha	0,8 l/ha
Maximum value	10,00	72,50	77,50	78,75	2 >	1 >	0 >
Mean green leaf area (%)	5,00	41,53	47,74	49,56	0 =	1 =	2 =
Mean %UTC	100,00%	725,00%	775,00%	787,50%	0 <	0 <	0 <
% Green leaf area - L1 - 19-40 DA-B							
Number of values	6	6	6	6	UTC	CA3301	CA3301
Minimum value	0,00	46,89	51,01	52,75		0,48 l/ha	0,8 l/ha
Maximum value	71,25	87,00	87,50	87,50	6 <	2 >	1 >
Mean green leaf area (%)	30,83	68,72	72,85	72,95	0 =	3 =	5 =
Mean %UTC	100,00%	194,23%	214,33%	220,00%	0 <	1 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Min. Eff. Dose evaluation of CA3301 - Mediterranean EPPO zone

Green leaf area was recorded at 12-40 DA-B in 27 valid trials on spring barley after two applications of CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha. In 26 trials, green leaf area was assessed on the entire plant while in 1 additional trial it was assessed by foliar level.

Summary results are presented in Table 3.2-71.

Data on the whole demonstrated a better effect of 2 applications of CA3301 at 0.6 l/ha (100% dose rate) compared to lower dose rate for the augmentation of green leaf area on spring barley infected by foliar diseases.

In the 26 trials assessing green leaf area on the whole plant, an augmentation of 18.58%, 13.86 % and 11.30% was recorded with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check on spring barley. In the trial assessing green leaf area by foliar level, an augmentation of 105.95%, 89.40% and 84.55% was recorded on foliar level 2 and an augmentation of 70.84%, 45.40% and 48.35% was recorded on foliar level 1 with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check.

Considering the whole dataset, the positive effects of CA3301 at 0.6 l/ha on green leaf area were generally equivalent to those of 0.8 l/ha dose rate. In addition, compared to 0.48 l/ha, these positive effects were generally better or equivalent.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on spring barley infected by a range of diseases in the Mediterranean EPPO zone.

Table 3.2-71: Summary table – Minimum effective dose evaluation – Spring barley – Green leaf area - Mediterranean EPPO zone

Treatment name		CA3301	CA3301	CA3301	No of trials where CA3301		
Rate	UNTREATED CHECK	0,48	0,6	0,8	at 0,6 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB	compared to		
% Green leaf area - 12-40 DA-B							
Number of values	26	26	26	26	UTC	CA3301	CA3301
Minimum value	0,00	5,00	6,38	6,50		0,48 l/ha	0,8 l/ha
Maximum value	85,00	91,25	92,25	95,00	12 >	1 >	0 >
Mean green leaf area (%)	48,51	55,25	56,06	57,72	14 =	25 =	23 =
Mean % UTC	100,00%	111,30%	113,86%	118,58%	0 <	0 <	3 <
% Green leaf area - L2 - 13 DA-B							
Number of values	1	1	1	1	UTC	CA3301	CA3301
Minimum value	20,00	36,91	37,88	41,19		0,48 l/ha	0,8 l/ha
Maximum value	20,00	36,91	37,88	41,19	0 >	0 >	0 >
Mean green leaf area (%)	20,00	36,91	37,88	41,19	1 =	1 =	1 =
Mean % UTC	100,00%	184,55%	189,40%	205,95%	0 <	0 <	0 <
% Green leaf area - L1 - 13 DA-B							
Number of values	1	1	1	1	UTC	CA3301	CA3301
Minimum value	28,50	42,28	41,44	48,69		0,48 l/ha	0,8 l/ha
Maximum value	28,50	42,28	41,44	48,69	0 >	0 >	0 >
Mean green leaf area (%)	28,50	42,28	41,44	48,69	1 =	1 =	1 =
Mean % UTC	100,00%	148,35%	145,40%	170,84%	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Min. Eff. Dose evaluation of CA3301 - North-Eastern East EPPO zone

Green leaf area was recorded at 8-40 DA-B in 31 valid trials on spring barley after two applications of CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha. In all 31 trials, green leaf area was assessed on the entire plant.

Summary results are presented in Table 3.2-72.

Data generally demonstrated a better effect of 2 applications of CA3301 at 0.6 l/ha compared to lower dose rate for the augmentation of green leaf area on spring barley infected by foliar diseases.

In the 31 trials assessing green leaf area on the whole plant, an augmentation of 67.73%, 53.56% and 48.82% was recorded with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check on spring barley.

An overall trend of increasing the green leaf area with increasing dose rates was observed in the whole dataset, although differences were not always statistically significant.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on spring barley infected by a range of diseases in the North-Eastern East EPPO zone.

Table 3.2-72: Summary table – Minimum effective dose evaluation – Spring barley – Green leaf area – North-Eastern East EPPO zone

Treatment name		CA3301	CA3301	CA3301	No of trials where CA3301		
Rate	UNTREATED CHECK	0,48	0,6	0,8	at 0,6 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB	compared to		
% Green leaf area - 8-40 DA-B							
Number of values	31	31	31	31	UTC	CA3301	CA3301
Minimum value	1,75	3,75	4,50	7,25		0,48 l/ha	0,8 l/ha
Maximum value	73,75	81,25	83,75	87,50	21 >	0 >	0 >
Mean green leaf area (%)	26,94	36,53	37,70	40,11	10 =	31 =	29 =
Mean % UTC	100.00%	148.82%	153.56%	167.73%	0 <	0 <	2 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Min. Eff. Dose evaluation - CA3301 in South-Eastern East EPPO zone

Green leaf area was recorded at 15-34 DA-B in 25 valid trials on spring barley after two applications of CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha. In all 25 trials, green leaf area was assessed on the entire plant.

Summary results are presented in Table 3.2-73.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6 l/ha compared to lower dose rate for the augmentation of green leaf area on spring barley infected by foliar diseases, with statistical differences observed in 5 assessments.

In the 25 trials assessing green leaf area on the whole plant, an augmentation of 87.72%, 79.98% and 57.07% was recorded with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check on spring barley.

An overall trend of increasing the green leaf area with increasing dose rates was observed in the whole dataset, although the rate of 0.6 l/ha was more comparable to the higher rate of 0.8 l/ha.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on spring barley infected by a range of diseases in the South-Eastern East EPPO zone.

Table 3.2-73: Summary table – Minimum effective dose evaluation – Spring barley – Green leaf area – South-Eastern East EPPO zone

Treatment name		CA3301	CA3301	CA3301	No of trials where CA3301		
Rate	UNTREATED CHECK	0,48	0,6	0,8	at 0,6 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB	compared to		
% Green leaf area - 15-34 DA-B							
Number of values	25	25	25	25	UTC	CA3301	CA3301
Minimum value	10,00	27,50	30,00	30,00		0,48 l/ha	0,8 l/ha
Maximum value	100,00	100,00	100,00	100,00	13 >	5 >	0 >
Mean green leaf area (%)	47,25	65,83	70,82	73,70	12 =	20 =	22 =
Mean % UTC	100,00%	157,07%	179,98%	187,72%	0 <	0 <	3 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Comments of zRMS:

Very positive effect after application of CA3301 at dose rate of 0,6-0,8 l/ha were observed. An augmentation of green leaf area was visible on high level in all EPPO climatic zones. It can be concluded that CA3301 at 0,6 l/ha is justified as minimum effective dose in spring barley.

3.2.2.17 Spring barley (HORVS) / Conclusion - Minimum effective dose evaluation

On spring barley, 5 foliar diseases and several crop quality parameters were assessed in 106 trials across 4 EPPO zones. Disease severity was assessed and analysed on the main foliar levels 1 and 2. Although a comprehensive trials programme was undertaken for this dossier, in some instances, due to the absence of appropriate level of diseases or other agronomic or climatic limitations, the proposed number of valid trials was not fully achieved. Hence, depending on the EPPO zone, the disease, the assessment timing and the crop part assessed, the dataset available was sometimes limited and so not fully representative of the efficacy of CA3301. Therefore, to get an overview of the efficacy of CA3301 at 0.6 l/ha, summary tables are presented in “Spring barley (HORVS) / Conclusion”, on foliar levels 1&2 (see Table 3.2-329 & Table 3.2-330).

Overall, across the 4 EPPO zones and all diseases, a consistent dose rate trend was observed for higher disease control with higher dose rates. In particular, the rate of 0.6 l/ha generally gave significantly better control compared to the rate of 0.48 l/ha. In much of the dataset there were no statistical differences between the dose rates of 0.6 l/ha (100% dose rate) and 0.8 l/ha (133% dose rate), even if in some assessments a numerical increase was observed with CA3301 at 0.8 l/ha. Moreover, in circumstances of high disease pressure the rate of 0.6 l/ha showed sufficient efficacy to control the disease and maintain good crop growth conditions until harvest.

Where datasets were low for spring barley, extrapolation as additional support has been requested from the corresponding data generated on winter sown barley. These extrapolations are indicated to be acceptable according to Poland national guidance (Extrapolation table, June 2016) and are agronomically logical.

In addition, the data demonstrates overall similar effects for the targeted diseases regardless of EPPO zone. Similarly, the same dose rate trends were observed for improving green leaf area in situations of infection from a single pathogen or in cases of disease complexes. Green leaf area not only indicates the area free of infection but also the ability of the plant to continue effective growth and develop to productive stages, enabling a longer duration of grain filling and therefore improved yield quantity and quality. After all, the proposed dose rate of 0.6 l/ha did not involve negative effects on the crop quality parameters observed at harvest.

In this dossier data presented for minimum effective dose is primarily from assessments where 2 applications of the test product were made. However, according to disease development conditions, a single application may provide sufficient disease control, therefore users should not be restricted to always applying twice, hence in the GAP the proposed use is for 1-2 applications. In addition, crop pathogens are commonly controlled using a programme of different fungicides with varied modes of action, therefore the choice should be available to growers to make a single application of CA3301, followed by application of a different appropriate fungicide. Prothioconazole is well established over a number of years in providing good broad spectrum efficacy across a range of common crop pathogens, with either 1 or more applications appropriate according to disease development conditions, risk of resistance development and local conditions. Current authorisations for similar products containing prothioconazole including Proline 275 and Proline/Praktis/Joao (CA2445) are for 1-2 applications at comparative rates of prothioconazole to the requested use for CA3301. Considering these elements, and that data in the efficacy section shows comparability of CA3301 to these authorised products, registration of CA3301 at the proposed minimum effective dose rate and with a number of applications of 1- 2, is requested.

Therefore, a minimum effective dose rate of 0.6 l/ha is proposed for CA3301 on spring barley in each of the EPPO zones, in order to allow optimum efficacy in relation to disease occurrence.

Considering all elements presented in the previous sections of each disease, CA3301 applied at 0.6 l/ha is the minimum effective dose to control a range of foliar diseases on spring barley.

3.2.2.18 Oat (AVESS/AVESA) / *Puccinia coronata* (PUCCCA/PUCCCO)

Between 2018 and 2020, a total of 19 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the minimum effective dose of CA3301 against *Puccinia coronata* on oat (see Table 3.2-331). The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, a total of 5 trials were performed in the Czech Republic (2) and Germany (3). In the Mediterranean EPPO zone, a total of 6 trials were performed in Italy (2), Portugal (1) and Spain (3). In the North-Eastern East EPPO zone, a total of 4 trials were performed in Latvia (1) and Poland (3). In the South-Eastern East EPPO zone, a total of 4 trials were performed in Hungary (2) and Romania (2).

Data groupings were also made specifically for Poland evaluation and trials involved (9) were performed in the North-Eastern EPPO zone (4), in the Czech Republic (2) and in Germany (3).

Out of the 19 trials performed on oat against *Puccinia coronata*, 9 were considered valid.

Puccinia coronata var. *avenae* (PUCCCA) and *Puccinia coronata* (PUCCCO) are both the causal agents of the crown rust on oats and belong to the same specie of the genus *Puccinia*. Consequently, these two fungi were considered as the same target in this analysis.

Min. Eff. Dose evaluation of CA3301 - Maritime EPPO zone

In the Maritime EPPO zone, a total of 5 trials evaluated the efficacy of CA3301 on oat against *Puccinia coronata*. 3 trials out of 5 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 30-39 and the 2nd application was at BBCH 55-61.

Summary results are presented in Table 3.2-74.

Data demonstrated a higher effect of CA3301 at 0.6 l/ha compared to the lower dose rate of 0.48 l/ha for the reduction of disease severity on oat against *Puccinia coronata*. On foliar level 2, CA3301 at 0.6 l/ha showed 87.75% efficacy against *Puccinia coronata* in a single trial before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 100.00% efficacy in a single trial on reduction of disease severity around two weeks after the 2nd application and 94.65% efficacy over 2 trials before harvest.

In the Maritime EPPO zone, a limited dataset was available for assessment of control of *Puccinia coronata*, which is an inadequate data set for evaluation. However, the situation reflected the high efficacy of the tested product in conditions of low to high disease pressure. A clear numerical trend of decreasing disease severity with the 0.6 l/ha dose rate compared to the 0.48 l/ha dose rate was observed where disease severity was higher although differences were not significant.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Puccinia coronata* on oat in the Maritime EPPO zone.

Table 3.2-74: Summary table – Minimum effective dose evaluation – Oat – PUCCCA/PUCCCO - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301		
Rate		0,48	0,6	0,8	at 0,6 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB	compared to		
% Disease severity L1 - 15 DA-B							
Number of values	1	1	1	1	UTC	CA3301	CA3301
Minimum value	5,56	0,00	0,00	0,00		0,48 l/ha	0,8 l/ha
Maximum value	5,56	0,00	0,00	0,00	1 >	0 >	0 >
Mean disease severity (%)	5,56	0,00	0,00	0,00	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	100,00%	100,00%	100,00%	0 <	0 <	0 <
% Disease severity L2 - 47 DA-B							
Number of values	1	1	1	1	UTC	CA3301	CA3301
Minimum value	40,81	7,44	5,00	2,63		0,48 l/ha	0,8 l/ha
Maximum value	40,81	7,44	5,00	2,63	1 >	0 >	0 >
Mean disease severity (%)	40,81	7,44	5,00	2,63	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	81,77%	87,75%	93,56%	0 <	0 <	0 <
% Disease severity L1 - 25-47 DA-B							
Number of values	2	2	2	2	UTC	CA3301	CA3301
Minimum value	11,44	0,40	0,18	0,05		0,48 l/ha	0,8 l/ha
Maximum value	25,31	4,38	2,31	1,00	2 >	0 >	0 >
Mean disease severity (%)	18,38	2,39	1,24	0,53	0 =	2 =	2 =
Abbott efficacy (%)	0.00%	89.60%	94.65%	97.81%	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - Mediterranean EPPO zone

In the Mediterranean EPPO zone, a total of 6 trials evaluated the efficacy of CA3301 on oat against *Puccinia coronata*. 2 trials out of 6 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 30-37 and the 2nd application was at BBCH 39-58.

Summary results are presented in Table 3.2-75.

Data demonstrated a higher effect of CA3301 at 0.6 l/ha compared to the lower dose rate of 0.48 l/ha for the reduction of disease severity on oat against *Puccinia coronata*. On foliar level 2, CA3301 at 0.6 l/ha showed 100.00% efficacy two weeks after the 2nd application and 96.52% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 100% efficacy around two weeks after the 2nd application and 100% before harvest.

In the Mediterranean EPPO zone, disease pressure was relatively medium to high. In these conditions, CA3301 provided high efficacy (100% in many instances) in reducing the severity of *Puccinia coronata* on oat, whatever the dose rate considered. In addition, among this dataset relatively low, CA3301 at 0.6 l/ha gave significantly higher disease control than 0.48 l/ha in the dataset with the highest level of disease severity, and was always comparable to 0.8 l/ha.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Puccinia coronata* on oat in the Mediterranean EPPO zone.

Table 3.2-75: Summary table – Minimum effective dose evaluation – Oat – PUCCCA/PUCCCO - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301
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Rate		0,48 L/ha AB	0,6 L/ha AB	0,8 L/ha AB	at 0,6 l/ha is >, = or < compared to		
Rate unit							
Appl. Code							
% Disease severity L2 - 13-14 DA-B							
Number of values	2	2	2	2	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	26,56	0,00	0,00	0,00			
Maximum value	34,25	0,00	0,00	0,00	2 >	0 >	0 >
Mean disease severity (%)	30,41	0,00	0,00	0,00	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	100,00%	100,00%	100,00%	0 <	0 <	0 <
% Disease severity L1 - 13-14 DA-B							
Number of values	2	2	2	2	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	9,25	0,00	0,00	0,00			
Maximum value	17,66	0,00	0,00	0,00	2 >	0 >	0 >
Mean disease severity (%)	13,46	0,00	0,00	0,00	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	100,00%	100,00%	100,00%	0 <	0 <	0 <
% Disease severity L2 - 27-35 DA-B							
Number of values	2	2	2	2	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	22,56	0,00	0,00	0,00			
Maximum value	93,38	15,38	6,50	7,50	2 >	1 >	0 >
Mean disease severity (%)	57,97	7,69	3,25	3,75	0 =	1 =	2 =
Abbott efficacy (%)	0,00%	91,76%	96,52%	95,98%	0 <	0 <	0 <
% Disease severity L1 - 27-35 DA-B							
Number of values	2	2	2	2	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	26,50	0,00	0,00	0,00			
Maximum value	76,00	0,00	0,00	0,00	2 >	0 >	0 >
Mean disease severity (%)	51,25	0,00	0,00	0,00	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	100,00%	100,00%	100,00%	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 in North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 4 trials evaluated the efficacy of CA3301 on oat against *Puccinia coronata*. 1 trial out of 4 was considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 33-38 and the 2nd application was at BBCH 52-59.

Summary results are presented in Table 3.2-76.

Data demonstrated a higher effect of CA3301 at 0.6 l/ha compared to the lower dose rate of 0.48 l/ha for the reduction of disease severity on oat against *Puccinia coronata* and on foliar level 1, CA3301 at 0.6 l/ha showed 89.33% efficacy before harvest.

In the North-Eastern East zone, a limited dataset was available for assessment of control of *Puccinia coronata*. However, the situation reflected the high efficacy of the tested product in conditions of low disease pressure. A clear numerical trend of decreasing disease severity with the 0.6 l/ha dose rate compared to the 0.48 l/ha dose rate was observed although differences were not significant.

Considering all elements presented above, CA3301 at 0.6 l/ha is proposed as the minimum effective dose to control *Puccinia coronata* on oat in the North-Eastern East EPPO zone.

Table 3.2-76: Summary table – Minimum effective dose evaluation – Oat – PUCCCA/PUCCCO – North-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or <
Rate		0,48	0,6	0,8	

Rate unit Appl. Code		L/ha AB	L/ha AB	L/ha AB	compared to		
% Disease severity L1 - 26 DA-B							
Number of values	1	1	1	1	UTC	CA3301	CA3301
Minimum value	6,56	1,01	0,70	0,61		0,48 l/ha	0,8 l/ha
Maximum value	6,56	1,01	0,70	0,61	1 >	0 >	0 >
Mean disease severity (%)	6,56	1,01	0,70	0,61	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	84,60%	89,33%	90,70%	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 4 trials evaluated the efficacy of CA3301 on oat against *Puccinia coronata*. 3 trials out of 4 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 35-39 and the 2nd application was at BBCH 59-65.

Summary results are presented in Table 3.2-77.

Data demonstrated a higher effect of CA3301 at 0.6 l/ha compared to the lower dose rate of 0.48 l/ha for the reduction of disease severity on oat against *Puccinia coronata*. On foliar level 2, CA3301 at 0.6 l/ha showed 86.96% efficacy over 2 trials against *Puccinia coronata* two weeks after the 2nd application and 92.29% over 2 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 85.90% efficacy on a single trial on reduction of disease severity before harvest.

In the South-Eastern East zone, a limited dataset was available for assessment of control of *Puccinia coronata*. However, the situation reflected the high efficacy of the tested product in conditions of low disease pressure.

A trend of decreasing disease severity with increasing dose rates was observed in the dataset, particularly between the 0.6 l/ha and 0.48 l/ha dose rates although differences were not always significant. The rate of 0.6 l/ha gave acceptable control of *Puccinia coronata* which was always statistically equivalent to 0.8 l/ha. Therefore, the 0.6 l/ha rate is sufficient to control *Puccinia coronata* on oats.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Puccinia coronata* on oats in the South-Eastern East EPPO zone.

Table 3.2-77: Summary table – Minimum effective dose evaluation – Oat – PUCCCA/PUCCCO – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
Rate unit Appl. Code							
% Disease severity L2 - 14-15 DA-B							
Number of values	2	2	2	2	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	6,00	0,23	0,05	0,00	2 >	0 >	0 >
Maximum value	11,25	3,63	2,84	1,90	0 =	2 =	2 =
Mean disease severity (%)	8,63	1,93	1,44	0,95	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	81,95%	86,96%	91,56%			
% Disease severity L2 - 25-26 DA-B							
Number of values	2	2	2	2	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	9,17	0,07	0,02	0,03	2 >	1 >	0 >
Maximum value	11,90	2,88	1,81	1,29	0 =	1 =	2 =
Mean disease severity (%)	10,53	1,47	0,92	0,66	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	87,52%	92,29%	94,42%			

Treatment name	UNTREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
Rate		0,48	0,6	0,8			
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB			
% Disease severity L1 - 25 DA-B							
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	6,10	1,50	0,86	0,55	1 >	0 >	0 >
Maximum value	6,10	1,50	0,86	0,55	0 =	1 =	1 =
Mean disease severity (%)	6,10	1,50	0,86	0,55	0 <	0 <	0 <
Abbott efficavc (%)	0.00%	75.41%	85.90%	90.98%			

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-Eastern East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, a total of 9 trials from the North-Eastern East EPPO zone and the neighbouring countries Germany and Czech Republic evaluated the efficacy of CA3301 on oat against *Puccinia coronata*. 4 trials were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 30-39 and the 2nd application was at BBCH 52-61.

Summary results are presented in Table 3.2-78.

Data demonstrated a higher effect of CA3301 at 0.6 l/ha compared to the lower dose rate of 0.48 l/ha for the reduction of disease severity on oat against *Puccinia coronata*. On foliar level 2, CA3301 at 0.6 l/ha showed 87.75% efficacy against *Puccinia coronata* before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 100.00% efficacy two weeks after the 2nd application and 92.88% over 2 trials before harvest.

Over this dataset, disease pressure was low to medium and in these conditions CA3301 at 0.6 l/ha provided high efficacy in reducing the severity of *Puccinia coronata* on oat. A numerical trend of decreasing disease severity with increasing dose rates was observed in the dataset, particularly between the 0.6 l/ha and 0.48 l/ha dose rates, in the datasets with higher disease severity, although differences were not significant. The rate of 0.6 l/ha gave acceptable control of *Puccinia coronata* and was always comparable to 0.8 l/ha.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Puccinia coronata* on oat in Poland.

Table 3.2-78: Summary table – Minimum effective dose evaluation – Oat – PUCCCA/PUCCCO– Data relevant for Poland

Treatment name	UNTREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
Rate		0,48	0,6	0,8			
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB			
% Disease severity L1 - 15 DA-B							
Number of values	1	1	1	1	UTC	CA3301	CA3301
Minimum value	5,56	0,00	0,00	0,00		0,48 l/ha	0,8 l/ha
Maximum value	5,56	0,00	0,00	0,00	1 >	0 >	0 >
Mean disease severity (%)	5,56	0,00	0,00	0,00	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	100,00%	100,00%	100,00%	0 <	0 <	0 <
% Disease severity L2 - 47 DA-B							
Number of values	1	1	1	1	UTC	CA3301	CA3301

Treatment name	UNTREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
Rate		0,48	0,6	0,8			
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB			
Minimum value	40,81	7,44	5,00	2,63		0,48 l/ha	0,8 l/ha
Maximum value	40,81	7,44	5,00	2,63	1 >	0 >	0 >
Mean disease severity (%)	40,81	7,44	5,00	2,63	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	81,77%	87,75%	93,56%	0 <	0 <	0 <
% Disease severity L1 - 25-47 DA-B							
Number of values	3	3	3	3	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	6,56	0,40	0,18	0,05			
Maximum value	25,31	4,38	2,31	1,00	3 >	0 >	0 >
Mean disease severity (%)	14,44	1,93	1,06	0,55	0 =	3 =	3 =
Abbott efficacy (%)	0,00%	87,93%	92,88%	95,44%	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

The limited number of trials have been submitted to determine minimum effective dose against Puccinia in oat. 3 efficacy trials conducted in **the Maritime EPPO climatic zone** showed high efficacy after application of CA3301 at dose rate of 0,48-0,8 l/ha, either after second application and before harvest. Also 3 trials from **the South-East EPPO zone** and 2 trials from the Mediterranean zone presented very good results of all used dose rates. 1 trial from **the North-East EPPO zone** confirmed above conclusions. CA3301 applied at dose rate of 0,48-0,8 l/ha achieved high level of control. However, a disease pressure was low or very low in submitted trials. Taking into account unfavorable conditions, more benefits would come with use of dose rate of 0,6 l/ha. The cMSs are kindly asked to consider MED for this use on the national level.

3.2.2.19 Oat (AVESS/AVESA) / *Blumeria graminis f. sp. avenae* (ERYSGA)

Between 2017 and 2020, a series of 6 trials were conducted in several countries of the Maritime and North-Eastern East EPPO zones to evaluate the minimum effective dose of CA3301 against *Blumeria graminis f. sp. avenae* on oat (see Table 3.2-343). The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, a total of 4 trials were performed in the Czech Republic (2), and Germany (2). In the Mediterranean EPPO zone, no trials were performed.

In the North-Eastern East EPPO zone, a total of 2 trials were performed in Poland (2).

In the South-Eastern East EPPO zone, no trials were performed.

Data groupings were also made specifically for Poland evaluation and trials involved (6) were performed in the North-Eastern East EPPO zone (2), in the Czech Republic (2) and in Germany (2).

Out of the 6 trials performed on oat against *Blumeria graminis f. sp. avenae*, 3 were considered valid.

The argumentation on minimum effective dose of CA3301 for the control of *Blumeria graminis* on oat was based also on data presented on winter wheat in the same EPPO zones and for the same disease.

Min. Eff. Dose evaluation of CA3301 - Maritime EPPO zone

In the Maritime EPPO zone, a total of 4 trials evaluated the efficacy of CA3301 on oat against *Blumeria graminis f. sp. avenae*. 1 trial out of 4 was considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity

(%). CA3301 was first applied at crop stages BBCH 32-37 and the 2nd application was at BBCH 55-61. A single assessment timing was available before harvest and the analysis was conducted on foliar level 2.

Summary results are presented in Table 3.2-79.

Data demonstrated that CA3301 at 0.6 l/ha provided higher efficacy compared to the lower dose rate of 0.48 l/ha for the reduction of disease severity on oat against *Blumeria graminis f. sp. avenae*. A single trial showed that CA3301 at 0.6 l/ha provided 76.82% efficacy on foliar level 2 before harvest.

In the Maritime EPPO zone, a limited dataset was available for assessment of control of *Blumeria graminis f. sp. avenae*. However, the situation reflected the high efficacy of the tested product in conditions of low disease pressure. An overall trend of decreasing disease severity with the 0.6 l/ha dose rate compared to the 0.48 l/ha dose rate was observed, although differences were not significant. In the assessment, there was no statistical difference in efficacy at 0.8 l/ha compared to the proposed rate of 0.6 l/ha.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Blumeria graminis f. sp. avenae* on oat in the Maritime EPPO zone.

Table 3.2-79: Summary table – Minimum effective dose evaluation – Oat – ERYSGA - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
Rate							
Rate unit							
Appl. Code							
% Disease severity L2- 47 DA-B							
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	9,19	2,94	2,13	0,75			
Maximum value	9,19	2,94	2,13	0,75	1 >	0 >	0 >
Mean disease severity (%)	9,19	2,94	2,13	0,75	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	68,01%	76,82%	91,84%	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 2 trials evaluated the efficacy of CA3301 on oat against *Blumeria graminis f. sp. avenae*. 2 trials out of 2 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice). CA3301 was first applied at crop stages BBCH 32 and the 2nd application was at BBCH 57-58. Two assessment timings were available and the analysis was conducted on foliar level 2.

Summary results are presented in Table 3.2-80.

Data demonstrated that CA3301 at 0.6 l/ha provided higher efficacy compared to the lower dose rate of 0.48 l/ha for the reduction of disease severity on oat against *Blumeria graminis f. sp. avenae*. On foliar level 2, CA3301 at 0.6 l/ha showed 100.00% efficacy two weeks after the 2nd application and 93.64% before harvest.

In the North-Eastern East EPPO zone, a limited dataset was available for assessment of control of *Blumeria graminis f. sp. avenae*. However, the situation reflected the high efficacy of the tested product in conditions of low disease pressure. CA3301 at 0.6 l/ha gave always statistically equivalent disease control compared to the 0.48 l/ha and 0.8 l/ha dose rates. However, under circumstances of increased disease pressure the

additional disease reduction obtained from the rate of 0.6 l/ha may be more appropriate than the 0.48 l/ha dose rate.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Blumeria graminis* f. sp. *avenae* on oat in the North-Eastern East EPPO zone.

Table 3.2-80: Summary table – Minimum effective dose evaluation – Oat – ERYSGA – North-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
Rate		0,48	0,6	0,8			
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB			
% Disease severity L2- 14 DA-B							
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	7,44	0,00	0,00	0,00			
Maximum value	7,44	0,00	0,00	0,00	1 >	0 >	0 >
Mean disease severity (%)	7,44	0,00	0,00	0,00	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	100,00%	100,00%	100,00%	0 <	0 <	0 <
% Disease severity L2- 33-35 DA-B							
Number of values	2	2	2	2	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	6,60	0,19	0,00	0,00			
Maximum value	11,94	1,08	0,84	0,80	2 >	0 >	0 >
Mean disease severity (%)	9,27	0,63	0,42	0,40	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	91,02%	93,64%	93,94%	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – all EPPO zones

Considering that no data were available to support the evaluation of CA3301 in the Mediterranean and South-Eastern East EPPO zones, the argue regarding the minimum effective dose of CA3301 for the control of *Blumeria graminis* on oat was based on the extrapolation of the data presented on winter wheat for the same disease.

This argumentation is possible since *Avena* sp. or *Avena sativa* and *Triticum aestivum* have the same life cycle with the same exposure to *Blumeria graminis* infection.

Triticum aestivum and *Avena* sp. or *Avena sativa* belong to the same Order (Poales) and the same Family (Poaceae), are two crops with the same life cycle and are cultivated following the same agricultural practice. At the end the two crops are showing a very similar sensitivity to *Blumeria graminis* f. sp. *avenae* (ERYSGA) or *Blumeria graminis* f. sp. *tritici* (ERYSGT) infection.

Over the dataset available on winter wheat, the tested product demonstrated comparable efficacy from CA3301 dose rates on the related pathogen *Blumeria graminis* for which the higher rate of 0.8 l/ha is more appropriate in situations of high disease pressure, but in case of low disease pressure the 0.6 l/ha rate might be sufficient to obtain a suitable level of disease control.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Blumeria graminis* f. sp. *avenae* on oat in all EPPO zones

Min. Eff. Dose evaluation of CA3301 - Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-Eastern East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, a total of 6 trials from the North-

Eastern East EPPO zone and the neighbouring countries Czech Republic and Germany evaluated the efficacy of CA3301 on oat against *Blumeria graminis f. sp. avenae*. 3 trials out of 6 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice). CA3301 was first applied at crop stages BBCH 32-37 and the 2nd application was at BBCH 55-61. Two assessment timings were available and the analysis was conducted on foliar level 2.

Summary results are presented in Table 3.2-81.

Data demonstrated that CA3301 at 0.6 l/ha provided higher efficacy compared to the lower dose rate of 0.48 l/ha for the reduction of disease severity on oat against *Blumeria graminis f. sp. avenae*. On foliar level 2, CA3301 at 0.6 l/ha showed 100.00% efficacy two weeks after the 2nd application and 88.03% over 3 trials before harvest.

In this data grouping intended to Poland evaluation, the dataset was limited but reflected the high performance of CA3301 in conditions of low disease pressure. In these conditions, the tested product provided high efficacy to control *Blumeria graminis f. sp. avenae* and the 0.6 l/ha dose rate was always statistically equivalent to the 0.48 l/ha and 0.8 l/ha dose rates. However, in the trial with the highest disease pressure, CA3301 at 0.6 l/ha (and at 0.8 l/ha) gave full control of disease which was not observed for the rate of 0.48 l/ha. Therefore, when disease pressure increases, additional disease reduction obtained from the rate of 0.6 l/ha may be more appropriate than the 0.48 l/ha dose rate.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Blumeria graminis f. sp. avenae* on oat in Poland.

Table 3.2-81: Summary table – Minimum effective dose evaluation – Oat – ERYSGA – Data relevant for Poland

Treatment name	UNTREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
Rate		0,48	0,6	0,8			
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB			
% Disease severity L2- 14 DA-B							
Number of values	1	1	1	1	UTC	CA3301	CA3301
Minimum value	7,44	0,00	0,00	0,00		0,48 l/ha	0,8 l/ha
Maximum value	7,44	0,00	0,00	0,00	1 >	0 >	0 >
Mean disease severity (%)	7,44	0,00	0,00	0,00	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	100,00%	100,00%	100,00%	0 <	0 <	0 <
% Disease severity L2- 33-47 DA-B							
Number of values	3	3	3	3	UTC	CA3301	CA3301
Minimum value	6,60	0,19	0,00	0,00		0,48 l/ha	0,8 l/ha
Maximum value	11,94	2,94	2,13	0,80	3 >	0 >	0 >
Mean disease severity (%)	9,24	1,40	0,99	0,52	0 =	3 =	3 =
Abbott efficacy (%)	0,00%	83,35%	88,03%	93,24%	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

The limited number of trials have been submitted to determine minimum effective dose against ERYSGA in oat. Only 1 efficacy trial conducted in **the Maritime EPPO climatic zone** showed high efficacy after application of CA3301 at dose rate of 0,8 l/ha before harvest. The medium level of effectiveness was noted for dose rate of 0,48-0,6 l/ha. The increase of dose rate to 0,6 l/ha caused higher efficacy about 8%. Also 2 trials from **the North-East EPPO zone** presented very good results of all used dose rates. CA3301 applied at dose rate of 0,48-0,8 l/ha achieved high level of control. However, a disease pressure was low or very low in submitted trials. Taking into account unfavorable conditions, more benefits would come with use of dose rate of 0,6 l/ha. No efficacy trials were available

in the South-East EPPO zone and the Mediterranean zone.
The cMSs are kindly asked to consider MED for this use on the national level.

3.2.2.20 Oat (AVESS/AVESA) / *Oculimacula acufformis* (PSDCHA)

(Ramanauskiene *et al.*, Effects of fungicides on the occurrence of winter wheat eyespot caused by fungi *Oculimacula acufformis* and *O. yallundae*, Crop protection, 2016)

No data were available for assessment of minimum effective dose of eyespot of cereals *Oculimacula acufformis* on any crop. Although early symptoms can be confused with *Fusarium spp.*, the diseases are not related and therefore it is impossible to extrapolate from these data.

However, Ramanauskiene *et al.*, showed that 2, 3 and 4 years of prothioconazole treatments allowed to reduce the population of *O. acufformis* assessed from 2009 to 2011 on winter wheat. This positive effect was observed as early as 10 days after treatment. This pathogen infecting both winter wheat and several other cereals, it is therefore possible to transpose these results to oat.

Moreover, prothioconazole is one of the active substances the most used as fungicide in commercial practices (*Forecasting eyespot development and yield losses in winter wheat, HGCA, 2012*). Standard reference products containing prothioconazole, such as Proline 275 are registered to control eyespot on cereals, at the same application rates as for the other authorised pathogens, which indicates that prothioconazole controls eyespot at dose rates which are demonstrated to control the other major disease pathogens in cereals. Since data shows equivalence of efficacy between CA3301 at the proposed dose rate and the authorised product Proline 275 in other pathogens, it is considered that the minimum effective dose rate for CA3301 to control eyespot will be the same as that demonstrated for other pathogens.

Moreover, since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6 l/ha generally gave higher disease control compared to the rate of 0.48 l/ha, it is supposed that the same dose rate will be acceptable to control eyespot on oat.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose to control *Oculimacula acufformis* on oat in all EPPO zones.

Comments of zRMS:

No efficacy trials for PSDCHA in oat have been submitted in any EPPO climatiz zones. The cMSs are kindly asked to consider MED for this use on the national level.

3.2.2.21 Oat (AVESS/AVESA) / Green leaf area

Min. Eff. Dose evaluation of CA3301 - Maritime EPPO zone

Green leaf area was recorded at 15-47 DA-B in 5 valid trials on oat after two applications of CA3301 at 0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N). In all 5 trials, green leaf area was assessed on the whole plant.

Summary results are presented in Table 3.2-82.

Data demonstrated a higher increase of the green leaf area after application of CA3301 at 0.6 l/ha compared to lower dose rate on oat infected by foliar diseases. In the 5 trials assessing green leaf area on the whole plant, an increase of 168.37%, 154.36% and 134.29% was recorded with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check on oat.

A dose effect was observed over the dataset whereby the green leaf area increased with higher dose rates, although differences were not always significant. Therefore, the 0.6 l/ha dose rate was sufficient to induce a positive effect on the green leaf area on oat.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on oat infected by a range of diseases in the Maritime EPPO zone.

Table 3.2-82: Summary table – Minimum effective dose evaluation – Oat – Green leaf area - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
Rate		0,48	0,6	0,8			
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB			
Green leaf area Plant - 15-47 DA-B							
Number of values	5	5	5	5	UTC	CA3301	CA3301
Minimum value	1,50	4,00	4,00	4,50		0,48 l/ha	0,8 l/ha
Maximum value	50,00	53,50	57,50	60,00	5 >	1 >	0 >
Mean green leaf area (%)	19,75	28,00	30,65	32,40	0 =	4 =	4 =
% UTC	100.00%	234.29%	254.36%	268.37%	0 <	0 <	1 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Min. Eff. Dose evaluation of CA3301 - Mediterranean EPPO zone

Green leaf area was recorded at 25-36 DA-B in 8 valid trials on oat after two applications of CA3301 at 0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N). In all 8 trials, green leaf area was assessed on the whole plant.

Summary results are presented in Table 3.2-83.

Data demonstrated a higher increase of the green leaf area after application of CA3301 at 0.6 l/ha compared to lower dose rate on oat infected by foliar diseases. In the 8 trials assessing green leaf area on the whole plant, an increase of 59.84%, 62.04% and 46.17% was recorded with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check on oat.

A dose effect was observed over the dataset whereby the green leaf area increases with higher dose rates, although differences were not always significant. Therefore, the 0.6 l/ha dose rate was sufficient to induce a positive effect on the green leaf area on oat.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on oat infected by a range of diseases in the Mediterranean EPPO zone.

Table 3.2-83: Summary table – Minimum effective dose evaluation – Oat – Green leaf area - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
Rate		0,48	0,6	0,8			
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB			
Green leaf area Plant - 25-36 DA-B							
Number of values	8	8	8	8	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	8,00	8,63	9,13	9,38			
Maximum value	80,00	80,00	80,00	82,50	3 >	1 >	0 >
Mean green leaf area (%)	38,47	47,64	49,89	50,23	5 =	7 =	7 =
% UTC*	100.00%	146.17%	162.04%	159.84%	0 <	0 <	1 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Min. Eff. Dose evaluation of CA3301 - North-Eastern East EPPO zone

Green leaf area was recorded at 21-54 DA-B in 7 valid trials on oat after two applications of CA3301 at 0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N). In all 7 trials, green leaf area was assessed on the whole plant.

Summary results are presented in Table 3.2-84.

Data demonstrated a higher increase of the green leaf area after application of CA3301 at 0.6 l/ha compared to lower dose rate on oat infected by foliar diseases. In the 7 trials assessing green leaf area on the whole plant, an increase of 51.62%, 39.62% and 37.13% was recorded with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check on oat.

A numerical dose response was observed over the dataset whereby the green leaf area increased with higher dose rates although differences were not significant. Therefore, the 0.6 l/ha dose rate was sufficient to induce a positive effect on the green leaf area on oat.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on oat infected by a range of diseases in the North-Eastern East EPPO zone.

Table 3.2-84: Summary table – Minimum effective dose evaluation – Oat – Green leaf area – North-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
Rate							
Rate unit							
Appl. Code							
Green leaf area Plant - 15-47 DA-B							
Number of values	7	7	7	7	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	7,50	11,25	11,25	15,00			
Maximum value	86,25	93,75	87,50	93,75	2 >	0 >	0 >
Mean green leaf area (%)	32,68	42,68	42,86	45,18	5 =	7 =	7 =
%UTC	100,00%	137,13%	139,62%	151,62%	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Min. Eff. Dose evaluation of CA3301 - South-Eastern East EPPO zone

Green leaf area was recorded at 14-30 DA-B in 5 valid trials on oat after two applications of CA3301 at 0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N). In 4 trials, green leaf area was assessed on the whole plant while in 1 trial it was assessed by foliar levels. For these 3 trials, green leaf area will be presented separately and on foliar levels 2 to 1.

Summary results are presented in Table 3.2-85.

Data demonstrated a higher increase of the green leaf area after application of CA3301 at 0.6 l/ha compared to lower dose rate on oat infected by foliar diseases but differences were not always significant. In the 4 trials assessing green leaf area on the whole plant, an increase of 259.99%, 199.77% and 166.28% was recorded with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check on oat. In the trial assessing green leaf area by foliar level, a reduction of 6.47% with 0.8 l/ha and an increase of 12.07% and 7.33% were recorded on foliar level 2. A reduction of 18.10% and an increase of 3.81% and 2.38% were recorded on foliar level 1 with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check.

A dose effect was observed over the dataset whereby the green leaf area increases with higher dose rates, although differences were not always significant. In the trial where green leaf area was assessed by foliar levels, a reduction of the green leaf area was observed on L2 and L1 with the 0.8 l/ha dose rate compared

with the untreated check although it was not significant. Therefore, the 0.6 l/ha dose rate was sufficient to induce a positive effect on the green leaf area on oat.

Considering all elements presented above, CA3301 at 0.6 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on oat infected by a range of diseases in the South-Eastern East EPPO zone.

Table 3.2-85: Summary table – Minimum effective dose evaluation – Oat – Green leaf area – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
Rate		0,48	0,6	0,8			
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB			
Green leaf area Plant - 14-30 DA-B							
Number of values	4	4	4	4	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	8,75	40,00	38,75	52,50			
Maximum value	77,50	85,00	87,50	90,00	4 >	1 >	0 >
Mean green leaf area (%)	37,19	59,69	62,50	71,25	0 =	3 =	2 =
% UTC	100,00%	266,28%	299,77%	359,99%	0 <	0 <	2 <
Green leaf area L2 - 26 DA-B							
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	58,00	62,25	65,00	54,25			
Maximum value	58,00	62,25	65,00	54,25	0 >	0 >	0 >
Mean green leaf area (%)	58,00	62,25	65,00	54,25	1 =	1 =	1 =
% UTC	100,00%	107,33%	112,07%	93,53%	0 <	0 <	0 <
Green leaf area L1 - 26 DA-B							
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha
Minimum value	52,50	53,75	54,50	43,00			
Maximum value	52,50	53,75	54,50	43,00	0 >	0 >	0 >
Mean green leaf area (%)	52,50	53,75	54,50	43,00	1 =	1 =	1 =
% UTC	100,00%	102,38%	103,81%	81,90%	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment) (conversely for '<')

Comments of zRMS:

Very positive effect after application of CA3301 at dose rate of 0,6-0,8 l/ha were observed. An augmentation of green leaf area was visible on high level in all EPPO climatic zones. It can be concluded that CA3301 at 0,6 l/ha is justified as minimum effective dose in oat.

3.2.2.22 Oat (AVESS/AVESA) / Conclusion

On oat, 2 foliar diseases were assessed in 12 valid trials across 4 EPPO zones. Winter and spring oat were analysed together despite different climatic conditions due to the availability of a low dataset. Moreover, when observed separately the data demonstrated the same trend allowing to draw the same conclusions. Disease severity was assessed and analysed on the main foliar levels 1 and 2. Although a comprehensive trials programme was undertaken for this dossier, in some instances, due to the absence of appropriate level of diseases or other agronomic or climatic limitations, the proposed number of valid trials was not fully achieved. Hence, depending on the EPPO zone, the disease, the assessment timing and the crop part assessed, the dataset available was sometimes limited and so not fully representative of the efficacy of CA3301. Therefore, to get an overview of the efficacy of CA3301 at 0.6 l/ha, summary tables are presented in “Oat (AVESS/AVESA) / Conclusion”, on foliar levels 1&2 (see Table 3.2-353 and Table 3.2-354).

Overall, across the 4 EPPO zones and all diseases, a consistent dose rate trend was observed for higher disease control with higher dose rates. In particular, the rate of 0.6 l/ha generally gave higher disease control compared to the rate of 0.48 l/ha, although it was not always significant. This could be explained by the fact that in some instances all dose rates gave a full disease control, as observed against crown rust in conditions of relatively low disease pressure. In most instances, no statistical differences were observed

between the dose rates of 0.6 l/ha (100% dose rate) and 0.8 l/ha (133% dose rate), even if in some assessments a numerical increase was observed with CA3301 at 0.8 l/ha. Moreover, in circumstances of high disease pressure the rate of 0.6 l/ha provided sufficient efficacy to control the disease and maintain good crop growth conditions until harvest.

In addition, the data demonstrated overall comparable performance for the targeted diseases regardless of EPPO zone. Similarly, the same dose rate trends were observed for improving green leaf area in situations of infection from a single pathogen or in cases of disease complexes. Green leaf area not only indicates the area free of infection but also the ability of the plant to continue effective growth and develop to productive stages, enabling a longer duration of grain filling and therefore improved yield quantity and quality. After all, the proposed dose rate of 0.6 l/ha did not involve negative effects on the crop quality parameters observed at harvest.

In this dossier data presented for minimum effective dose is primarily from assessments where 2 applications of the test product were made. However, according to disease development conditions, a single application may provide sufficient disease control, therefore users should not be restricted to always applying twice, hence in the GAP the proposed use is for 1-2 applications. In addition, crop pathogens are commonly controlled using a programme of different fungicides with varied modes of action, therefore the choice should be available to growers to make a single application of CA3301, followed by application of a different appropriate fungicide. Prothioconazole is well established over a number of years in providing good broad-spectrum efficacy across a range of common crop pathogens, with either 1 or more applications appropriate according to disease development conditions, risk of resistance development and local conditions. Current authorisations for similar products containing prothioconazole including Proline 275 and Proline/Praktis/Joao (CA2445) are for 1-2 applications at comparative rates of prothioconazole to the requested use for CA3301. Considering these elements, and that data in the efficacy section shows comparability of CA3301 to these authorised products, registration of CA3301 at the proposed minimum effective dose rate and with a number of applications of 1- 2, is requested.

Considering all elements presented in the previous sections of each disease, CA3301 applied at 0.6 l/ha is the minimum effective dose to control a range of foliar diseases on oat.

3.2.2.23 Winter wheat (TRZAW) / *Zymoseptoria tritici* (SEPTTR)

Between 2017 and 2020, a series of 112 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the minimum effective dose of CA3301 against *Zymoseptoria tritici* on winter wheat. The trials were carried out by certified testing institutes. The proposed rate is the range of 0.6-0.8 l/ha.

In the Maritime EPPO zone, a total of 37 trials were performed in the Czech Republic (3), Denmark (3), France (8), Germany (10) and the United Kingdom (13)

In the Mediterranean EPPO zone, a total of 23 trials were performed in France (11), Greece (2), Italy (3), Portugal (4) and Spain (3)

In the North-eastern East EPPO zone, a total of 29 trials were performed in Latvia (5), Lithuania (3) and Poland (21)

In the South-eastern East EPPO zone, a total of 23 trials were performed in Bulgaria (1), Hungary (15), Romania (7).

Out of the 112 trials performed on winter wheat against *Zymoseptoria tritici*, 82 were considered valid.

Min. Eff. Dose evaluation of CA3301 – Maritime EPPO zone

In the Maritime EPPO zone, a total of 37 trials evaluated the efficacy of CA3301 on winter wheat against *Zymoseptoria tritici*. 23 trials out of 37 were considered valid and 22 trials enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). One trial was valid but tested CA3301 applied only once. CA3301 was first applied at crop

Summary results are presented in Table 3.2-86.

On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 68.28-67.67% efficacy against *Zymoseptoria tritici* two weeks after the 2nd application and 63.89-68.65% before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 35.85-37.45% efficacy on reduction of disease severity around two weeks after the 2nd application and 67.86-71.94% before harvest. The proposed dose rates of 0.8-0.6 l/ha provided medium to low efficacy whereas the reduced rate of 0.48 l/ha demonstrated low efficacy.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Zymoseptoria tritici* on winter wheat in the Maritime EPPO zone.

Table E11 O zone										
Treatment name	UNTREATED CHECK	CA330 1	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		0,48	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Disease severity L2 - 13-20 DA-B										
Number of values	9	9	9	9	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	5,19	0,00	0,00	0,00						
Maximum value	18,76	12,45	7,03	9,59	9 >	2 >	0 >	9 >	2 >	2 >
Mean disease severity (%)	11,32	5,22	3,67	3,94	0 =	7 =	7 =	0 =	7 =	7 =
Abbott efficacy (%)	0,00%	57,80%	68,28%	67,67%	0 <	0 <	2 <	0 <	0 <	0 <
% Disease severity L1 - 13-20 DA-B										
Number of values	1	1	1	1	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	8,09	4,86	5,19	5,06						
Maximum value	8,09	4,86	5,19	5,06	0 >	0 >	0 >	0 >	0 >	0 >
Mean disease severity (%)	8,09	4,86	5,19	5,06	1 =	1 =	1 =	1 =	1 =	1 =
Abbott efficacy (%)	0,00%	39,93%	35,85%	37,45%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 25-53 DA-B										
Number of values	19	19	19	19	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	6,90	1,11	0,69	0,40						
Maximum value	100,00	84,88	74,50	67,86	19 >	4 >	1 >	19 >	8 >	4 >
Mean disease severity (%)	34,98	19,05	15,22	13,62	0 =	15 =	14 =	0 =	10 =	14 =
Abbott efficacy (%)	0,00%	56,09%	63,89%	68,65%	0 <	0 <	4 <	0 <	1 <	1 <
% Disease severity L1 - 30-53 DA-B										

Number of values	17	17	17	17	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	6,26	0,92	0,56	0,00						
Maximum value	67,19	28,50	30,50	29,81	17 >	5 >	1 >	17 >	6 >	2 >
Mean disease severity (%)	21,51	8,99	7,36	6,35	0 =	12 =	14 =	0 =	11 =	14 =
Abbott efficacy (%)	0,00%	59,39%	67,86%	71,94%	0 <	0 <	2 <	0 <	0 <	1 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – Mediterranean EPPO zone

In the Mediterranean EPPO zone, a total of 23 trials evaluated the efficacy of CA3301 on winter wheat against *Zymoseptoria tritici*. 20 trials out of 23 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 30-51 and the 2nd application was at BBCH 39-69. Two main assessment timings were selected: around two weeks after the 2nd application (13-19 DA-B) and the last timing close to harvest (23-42 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-87.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rates for the reduction of disease severity on winter wheat against *Zymoseptoria tritici*.

On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 73.70-76.50% efficacy against *Zymoseptoria tritici* two weeks after the 2nd application and 57.01-64.73% before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 82.51-84.33% efficacy on reduction of disease severity around two weeks after the 2nd application and 70.64-77.08% before harvest. These positive effects to control *Zymoseptoria tritici* of CA3301 at 0.6-0.8 l/ha were overall superior than the 0.48 l/ha dose rate, as observed in the 9 or 5 assessments where the rates of 0.8 l/ha or 0.6 l/ha respectively gave significantly more disease reduction compared to 0.48 l/ha

An overall trend of decreasing disease severity with increasing dose rates was observed in the dataset, although differences were not always statistically significant. The trend is more apparent in the assessments with larger dataset. In many instances the rate of 0.6 l/ha gave acceptable control of *Zymoseptoria tritici* very comparable to that of 0.8 l/ha, nevertheless in conditions of high disease pressure the additional disease reduction obtained from the higher rate of 0.8 l/ha may be more appropriate, in particular where some level of resistance is suspected.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Zymoseptoria tritici* on winter wheat in the Mediterranean EPPO zone.

Table 3.2-87: Summary table – Minimum effective dose evaluation – Winter wheat – SEPTTR - Mediterranean EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREAT ED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity L2 - 14-19 DA-B										
Number of values	9	9	9	9	UTC	CA3 301	CA3301 0,8 l/ha	UTC	CA33 01	CA 330 1
Minimum value	6,75	0,24	0,23	0,13		0,48 l/ha			0,48 l/ha	0,6 l/ha

Maximum value	63,73	29,65	28,2	24,9	9 >	0 >	0 >	9 >	1 >	1 >
Mean disease severity (%)	27,72	11,46	9,39	8,23	0 =	9 =	8 =	0 =	8 =	8 =
Abbott efficacy (%)	0,00%	65,10%	73,70%	76,50 %	0 <	0 <	1 <	0 <	0 <	0 <
% Disease severity L1 - 14-19 DA-B										
Number of values	5	5	5	5	UTC	CA3 301 0,48 l/ha	CA3301 0,8 l/ha	UTC	CA33 01 0,48 l/ha	CA 330 1 0,6 l/ha
Minimum value	5,75	0,00	0,00	0,00						
Maximum value	44,96	11,75	15,00	14,20	5 >	0 >	0 >	5 >	0 >	0 >
Mean disease severity (%)	19,71	4,69	4,87	4,45	0 =	5 =	5 =	0 =	5 =	5 =
Abbott efficacy (%)	0,00%	82,20%	82,51%	84,33 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 23-42 DA-B										
Number of values	13	13	13	13	UTC	CA3 301 0,48 l/ha	CA3301 0,8 l/ha	UT C	CA3301 0,48 l/ha	CA 330 1 0,6 l/ha
Minimum value	11,93	0,48	0,34	0,15						
Maximum value	99,63	85,19	55,94	52,24	11 >	2 >	0 >	12 >	4 >	3 >
Mean disease severity (%)	49,66	27,39	22,46	18,57	2 =	11 =	10 =	1 =	9 =	10 =
Abbott efficacy (%)	0,00%	48,58%	57,01%	64,73 %	0 <	0 <	3 <	0 <	0 <	0 <
% Disease severity L1 - 23-42 DA-B										
Number of values	11	11	11	11	UTC	CA3 301 0,48 l/ha	CA3301 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	5,53	2,40	2,11	1,42						
Maximum value	59,31	50,63	39,88	18,88	11 >	3 >	0 >	11 >	4 >	3 >
Mean disease severity (%)	31,26	12,91	9,29	6,49	0 =	8 =	8 =	0 =	7 =	8 =
Abbott efficacy (%)	0,00%	60,12%	70,64%	77,08 %	0 <	0 <	3 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 29 trials evaluated the efficacy of CA3301 on winter wheat against *Zymoseptoria tritici*. 22 trials out of 29 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 30-39 and the 2nd application was at BBCH 37-65. Two main assessment timings were selected: around two weeks after the 2nd application (15-20 DA-B) and the last timing close to harvest (21-42 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-88.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rates for the reduction of disease severity on winter wheat against *Zymoseptoria tritici*.

On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 79.13-79.98% efficacy against *Zymoseptoria tritici* two weeks after the 2nd application and 68.35-76.96% before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 68.04-74.45% efficacy on reduction of disease severity before harvest. These positive effects to control *Zymoseptoria tritici* of CA3301 at 0.6-0.8 l/ha were overall superior than the 0.48 l/ha dose rate as a consistent numerical dose rate was observed on disease severity

Generally an overall trend of decreasing disease severity with increasing dose rates was observed in the dataset, although differences were not always statistically significant. The trend is more apparent in the assessments with larger dataset. In many instances the rate of 0.6 l/ha gave acceptable control of *Zymoseptoria tritici* very comparable to that of 0.8 l/ha, nevertheless in conditions of high disease pressure the additional disease reduction obtained from the higher rate of 0.8 l/ha may be more appropriate, in particular where some level of resistance is suspected.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Zymoseptoria tritici* on winter wheat in the North-Eastern East EPPO zone.

Table 3.2-88: Summary table – Minimum effective dose evaluation – Winter wheat – SEPTTR – North-Eastern East EPPO zone

North-Eastern East EFTO Zone										
Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA3301 1 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity L2 - 15-20 DA-B										
Number of values	6	6	6	6	UT		CA3301		CA3301	CA3301
Minimum value	5,05	0,83	0,25	0	C	CA3301	1 0,8	UTC	0,48	0,6
Maximum value	23,75	9,38	5,88	5,25	6 >	1 >	0 >	6 >	0 >	0 >
Mean disease severity (%)	10,91	3,11	1,97	1,88	0 =	5 =	6 =	0 =	6 =	6 =
Abbott efficacy (%)	0,00%	71,40%	79,13%	79,98%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 21-42 DA-B										
Number of values	16	16	16	16	UT		CA3301		CA3301	CA3301
Minimum value	5,25	0,44	0,44	0,04	C	CA3301	1 0,8	UTC	0,48	0,6
Maximum value	45,00	17,71	17,08	16,75	16 >	1 >	0 >	16 >	5 >	3 >
Mean disease severity (%)	16,77	6,35	5,6	4,48	0 =	15 =	13 =	0 =	11 =	13 =
Abbott efficacy (%)	0,00%	64,73%	68,35%	76,96%	0 <	0 <	3 <	0 <	0 <	0 <
% Disease severity L1 - 23-42 DA-B										
Number of values	14	14	14	14	UT		CA3301		CA3301	CA3301
Minimum value	5,01	0,13	0	0	C	CA3301	1 0,8	UTC	0,48	0,6
Maximum value	36,56	8,25	8,19	9,38	14 >	2 >	0 >	14 >	2 >	2 >
Mean disease severity (%)	12,62	4,1	3,57	3,17	0 =	12 =	12 =	0 =	12 =	12 =
Abbott efficacy (%)	0,00%	63,68%	68,04%	74,45%	0 <	0 <	2 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy

<60% Low efficacy

Min. Eff. Dose evaluation of CA3301 – South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 23 trials evaluated the efficacy of CA3301 on winter wheat against *Zymoseptoria tritici*. 18 trials out of 23 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 31-47 and the 2nd application was at BBCH 39-65. Two main assessment timings were selected: around two weeks after the 2nd application (14-17 DA-B) and the last timing close to harvest (21-48 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-89.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rate for the reduction of disease severity on winter wheat against *Zymoseptoria tritici*.

On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 66.05-79.15% efficacy against *Zymoseptoria tritici* two weeks after the 2nd application and 70.31-75.25% before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 81.49-86.25% efficacy on reduction of disease severity two weeks after the 2nd application and 75.39-77.82% before harvest. These positive effects to control *Zymoseptoria tritici* of CA3301 at 0.6-0.8 l/ha were overall superior than the 0.48 l/ha dose rate, in particular a strong dose effect was observed between the proposed rates and the lower rate at early assessments on foliar level 1

An overall trend of decreasing disease severity with increasing dose rates was observed in the dataset, although differences were not always statistically significant. In many instances the rate of 0.6 l/ha gave acceptable control of *Zymoseptoria tritici* very comparable to that of 0.8 l/ha, nevertheless in conditions of high disease pressure the additional disease reduction obtained from the higher rate of 0.8 l/ha may be more appropriate, in particular where some level of resistance is suspected.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Zymoseptoria tritici* on winter wheat in the South-Eastern East EPPO zone.

Table 3.2-89: Summary table – Minimum effective dose evaluation – Winter wheat – SEPTTR – South-Eastern East EPPO zone

South-Eastern East LFO zone										
Treatment name Rate Rate unit Appl. Code	UNTREAT ED CHECK	CA330 1 0,48 L/ha AB	CA330 1 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity L2 - 14-17 DA-B										
Number of values	4	4	4	4	UTC			UTC	CA33 01 0,48 l/ha	CA3301 0,6 l/ha
Minimum value	8,83	2,75	2,75	1,25		CA3301 0,48 l/ha	CA3301 0,8 l/ha			
Maximum value	24,56	10,44	9,50	8,00	4 >	1 >	0 >	4 >	2 >	2 >
Mean disease severity (%)	18,13	6,90	6,14	4,14	0 =	3 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	60,38%	66,05%	79,15 %	0 <	0 <	2 <	0 <	0 <	0 <
% Disease severity L1 - 14-17 DA-B										
Number of values	3	3	3	3	UTC			UTC	CA33 01 0,48 l/ha	CA3301 0,6 l/ha
Minimum value	12,11	3,55	0,18	0,00		CA3301 0,48 l/ha	CA3301 0,8 l/ha			

										0,6 l/h a
Maximum value	30,00	6,11	4,65	3,69	3 >	3 >	0 >	3 >	3 >	2 >
Mean disease severity (%)	18,85	5,18	2,53	1,86	0 =	0 =	1 =	0 =	0 =	1 =
Abbott efficacy (%)	0,00%	69,58%	81,49%	86,25 %	0 <	0 <	2 <	0 <	0 <	0 <
% Disease severity L2 - 21-45 DA-B										
Number of values	13	13	13	13	UTC					C A3 30 1 0,6 l/h a
Minimum value	5,96	0,22	0,00	0,00		CA3301 0,48 l/ha	CA3301 0,8 l/ha		CA33 01 0,48 l/ha	
Maximum value	100,00	18,06	13,98	17,36	11 >	5 >	0 >	11 >	4 >	2 >
Mean disease severity (%)	26,46	7,44	5,37	4,80	2 =	8 =	11 =	2 =	9 =	11 =
Abbott efficacy (%)	0,00%	62,02%	70,31%	75,25 %	0 <	0 <	2 <	0 <	0 <	0 <
% Disease severity L1 - 21-48 DA-B										
Number of values	7	7	7	7	UTC				CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	10,26	0,18	0,14	0,06		CA3301 0,48 l/ha	CA3301 0,8 l/ha	UTC		
Maximum value	33,75	13,46	12,16	14,38	5 >	0 >	0 >	5 >	0 >	0 >
Mean disease severity (%)	19,89	5,37	5,19	4,97	2 =	7 =	7 =	2 =	7 =	7 =
Abbott efficacy (%)	0,00%	75,39%	75,39%	77,82 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

23 trials have been submitted to determine minimum effective dose in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,48 l/ha was not effective in control of SEPTTR. The similar effectiveness was observed between dose rate of 0,6 and 0,8 l/ha. The test product used at higher doses achieved medium level of control in all assessments.

22 trials were available to determine MED in **the North-East EPPO zone**. CA3301 applied at dose rate of 0,48-0,8 l/ha achieved medium efficacy. However, the comparable results were noted between 0,6 l/ha and 0,8 l/ha after second application and significant differences between the dose rate of 0,48 l/ha and higher doses. It should be noted that the low disease pressure was observed in all trials. Overall, the dose rate of 0,6 l/ha would come more benefits in unfavorable conditions.

18 trials were presented to determine MED in **the South-East EPPO zone**. CA3301 applied at dose rate of 0,6-0,8 l/ha achieved medium to high efficacy in control of SEPTTR. The significant lower results were noted for dose rate of 0,48 l/ha after second application. A decrease of dose rate to 0,48 l/ha caused lower efficacy about 8% in 13 out of 18 trials. 20 additional trials from the Mediterranean zone showed differences between dose rates of CA3301. The test product at 0,48 l/ha was not effective before harvest. The dose rates of 0,6-0,8 l/ha achieved consistantly results with medium to high level.

Taking into account all EPPO zones, the dose rate of 0,6 l/ha can be considered minimum effective dose to control of *Zymoseptoria tritici* in winter wheat. It should be noted that the dose rate of 0,6 l/ha can be considered MED mainly in situation of low disease pressure. In more challenging conditions, the dose rate of 0,8 l/ha will be more justified.

3.2.2.24 Winter wheat (TRZAW) / *Puccinia recondita* – *Puccinia triticina* (PUCCRE-PUCCRT)

Puccinia recondita and *Puccinia triticina* are the causal agents of the brown rust on wheat and are considered as the same pathogen in this analysis.

Between 2017 and 2020, a series of 61 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the minimum effective dose of CA3301 against *Puccinia recondita* or *P. triticina* on winter wheat. The trials were carried out by certified testing institutes. The proposed rate is the range of 0.6-0.8 l/ha.

In the Maritime EPPO zone, 18 trials were performed in Czech Republic (5), Germany (5), France (7) and United Kingdom (1).

In the Mediterranean EPPO zone, 19 trials were performed in France (13), Spain (5) and Italy (1).

In the North-Eastern East EPPO zone, 16 trials were performed in Poland (13) and Latvia (3).

In the South-Eastern East EPPO zone, a total of 8 trials were performed in Hungary (5), Romania (2) and Bulgaria (1).

Out of the 61 trials carried out against *Puccinia recondita* (PUCCRE) or *Puccinia triticina* (PUCCRT) on winter wheat, 43 were considered valid.

Min. Eff. Dose evaluation of CA3301 – Maritime EPPO zone

In the Maritime EPPO zone, 9 trials had a level of disease severity higher than 5% and were included to support evaluation of CA3301. Several dose rates ((0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). CA3301 was first applied at crop stages BBCH 31-37 and the 2nd application was at BBCH 39-67. Two main assessment timings were selected: around two weeks after application B (16-18 DA-B) and the last timing close to harvest (27-49 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-90.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect on brown rust was provided after two applications of CA3301 at 0.6-0.8 l/ha.

On foliar level 2, when applied at 0.6 l/ha, CA3301 showed 87.93% of efficacy to control brown rust two weeks after the 2nd application and 63.06% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 83.61% of efficacy on reduction of disease severity around two weeks after the 2nd application and 63.99% before harvest.

When applied at 0.8 l/ha, on foliar level 2, CA3301 showed 93.83% of efficacy against to control brown rust two weeks after the 2nd application and 66.43% before harvest. On foliar level 1, CA3301 at 0.8 l/ha showed 88.03% of efficacy on reduction of disease severity around two weeks after the 2nd application and 70.58% before harvest.

These positive effects to control brown rust of CA3301 at 0.6-0.8 l/ha were overall superior than the 0.48 l/ha dose rate tested, as efficacy was high to medium, whereas for the lower rate efficacy was low at both assessments undertaken close to harvest

Among the data presented in this section in 3 trials out of 5, disease developed at around 4-6 weeks (37-42 DA-B) after both applications of the test products. The data from these trials demonstrate the later preventative effect of CA3301 with a mean of 69.99% of efficacy when applied at 0.6 l/ha and 76.31% at 0.8 l/ha

on foliar level 2. This performance contrasted with the trials presented at the earlier assessment where applications were made curatively or at earlier preventative timing.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Puccinia recondita* or *Puccinia triticina* on winter wheat in the Maritime EPPO zone. In case of early time of disease arrival, CA3301 at 0.6 l/ha can be sufficient to have a high level of efficacy but in case of late development of the disease it could be advised to use the 0.8 l/ha dose rate.

Table 3.2-90: Summary table – Minimum effective dose evaluation – Winter wheat – PUCCRE/PUCCRT - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA3 301	CA3301	CA3 301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		0,48	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Disease severity L2 - 16-18 DA-B										
Number of values	2	2	2	2	UTC	CA3301 0,48 l/ha	CA330 1 0,8 l/ha	UTC	CA330 1 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	7,84	1,05	0,74	0,19						
Maximum value	8,90	1,39	1,24	0,80	2 >	0 >	0 >	2 >	1 >	0 >
Mean disease severity (%)	8,37	1,22	0,99	0,49	0 =	2 =	2 =	0 =	1 =	2 =
Abbott efficacy (%)	0,00%	85,2 4%	87,93%	93,8 3%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 18 DA-B										
Number of values	1	1	1	1	UTC	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UTC	CA330 1 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	6,10	1,14	1,00	0,73						
Maximum value	6,10	1,14	1,00	0,73	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	6,10	1,14	1,00	0,73	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	81,3 1%	83,61%	88,0 3%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 27-42 DA-B										
Number of values	5	5	5	5	UTC	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UTC	CA330 1 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	5,75	0,68	0,00	0,00						
Maximum value	25,80	19,4 6	16,66	15,9 9	5 >	0 >	0 >	5 >	1 >	0 >
Mean disease severity (%)	11,41	6,22	5,36	5,11	0 =	5 =	5 =	0 =	4 =	5 =
Abbott efficacy (%)	0,00%	55,2 4%	63,06%	66,4 3%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 27-49 DA-B										
Number of values	8	8	8	8	UTC	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UTC	CA33 01 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	7,68	0,76	0,46	0,56						
Maximum value	26,16	14,3 4	13,58	13,5 4	8 >	0 >	0 >	8 >	2 >	1 >
Mean disease severity (%)	17,01	7,33	6,34	5,25	0 =	8 =	7 =	0 =	6 =	7 =
Abbott efficacy (%)	0,00%	57,8 5%	63,99%	70,5 8%	0 <	0 <	1 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – Mediterranean EPPO zone

In the Mediterranean EPPO zone, 17 valid trials had a level of disease severity higher than 5% and were included to support the minimum effective dose evaluation of CA3301. Several dose rates (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). CA3301 was first applied at crop stages BBCH 30-39 and the 2nd application was at BBCH 49-69. Two main assessment timings were selected: around two weeks after application B (12-16 DA-B) and the last timing close to harvest (20-43 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-91.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect to control brown rust was provided after two applications of CA3301 at 0.6-0.8 l/ha.

On foliar level 2, when applied at 0.6 l/ha, CA3301 showed 49.63% of efficacy to control brown rust two weeks after the 2nd application and 58.73% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 57.12% of efficacy on reduction of disease severity around two weeks after the 2nd application and 70.01% before harvest.

When applied at 0.8 l/ha, on foliar level 2, CA3301 showed 63.94% of efficacy to control brown rust two weeks after the 2nd application and 66.94% before harvest. On foliar level 1, CA3301 at 0.8 l/ha showed 69.15% of efficacy on reduction of disease severity around two weeks after the 2nd application and 76.46% before harvest.

These positive effects of CA3301 at 0.6-0.8 l/ha to control brown rust were overall superior than the 0.48 l/ha dose rate tested.

In trials with relatively high disease pressure a statistical benefit was observed in increasing the dose rate from 0.6 L/ha to 0.8 L/ha, for example in trials EU19-068-06 & EU19-068-07. Whereas in trials with lower disease pressure the levels of control between these 2 dose rates were more comparable. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for the control of *Puccinia recondita* or *Puccinia triticina* on winter wheat. Nevertheless in conditions of high disease pressure the additional disease reduction obtained from the higher rate of 0.8 l/ha may be more appropriate.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Puccinia recondita* or *Puccinia triticina* on winter wheat in the Mediterranean EPPO zone.

Table 3.2-91: Summary table – Minimum effective dose evaluation – Winter wheat – PUCCRE/PUCRT – Mediterranean EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
% Disease severity L2 - 12-16 DA-B						
Number of values	7	7	7	7	UTC	CA3301 0,48 l/ha
Minimum value	9,34	0,95	0,81	0,31	CA3301 0,6 l/ha	CA3301 0,8 l/ha
Maximum value	80,75	58,13	59,00	37,63	5 >	6 >
Mean disease severity (%)	30,66	20,09	20,76	13,35	2 =	7 =
Abbott efficacy (%)	0,00%	52,25%	49,63%	63,94%	0 <	3 <
% Disease severity L1 - 12-16 DA-B						
Number of values	7	7	7	7	UTC	CA3301 0,48 l/ha
Minimum value	5,76	0,01	0,05	0,01	CA3301 0,6 l/ha	CA3301 0,8 l/ha
Maximum value	58,63	50,13	49,75	29,63	6 >	7 >
Mean disease severity (%)	19,10	13,59	13,58	9,11	1 =	7 =

Abbott efficacy (%)	0,00%	54,67%	57,12%	69,15%	0 <	0 <	2 <	0 <	0 <	0 <
% Disease severity L2 - 20-43 DA-B										
Number of values	9	9	9	9	UTC	CA330 1 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	8,81	0,00	0,00	0,00						
Maximum value	91,94	87,56	84,44	46,19	7 >	0 >	0 >	9 >	2 >	2 >
Mean disease severity (%)	39,13	24,15	22,45	15,73	2 =	9 =	7 =	0 =	7 =	7 =
Abbott efficacy (%)	0,00%	52,18%	58,73%	66,94%	0 <	0 <	2 <	0 <	0 <	0 <
% Disease severity L1 - 20-43 DA-B										
Number of values	14	14	14	14	UTC	CA330 1 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	8,60	0,00	0,00	0,00						
Maximum value	66,13	35,88	36,88	24,38	13 >	2 >	0 >	14 >	4 >	2 >
Mean disease severity (%)	30,16	11,88	10,41	7,17	1 =	12 =	12 =	0 =	10 =	12 =
Abbott efficacy (%)	0,00%	61,90%	70,01%	76,46%	0 <	0 <	2 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, 10 trials had a level of disease severity higher than 5% and were included to support the minimum effective dose evaluation of CA3301. Several dose rates (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). CA3301 was first applied at crop stages BBCH 30-39 and the 2nd application was at BBCH 52-65. Two main assessment timings were selected: around two weeks after application B (15 DA-B) and the last timing close to harvest (20-35 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-92.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect to control brown rust was provided after two applications of CA3301 at 0.6-0.8 l/ha.

On foliar level 2, when applied at 0.6 l/ha, CA3301 showed 99.22% of efficacy to control brown rust two weeks after the 2nd application and 85.46% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 83.31% of efficacy on reduction of disease severity around two weeks after the 2nd application and 68.19% before harvest.

When applied at 0.8 l/ha, on foliar level 2, CA3301 showed 100% of efficacy to control brown rust two weeks after the 2nd application and 90.15% before harvest. On foliar level 1, CA3301 at 0.8 l/ha showed 88.27% of efficacy on reduction of disease severity around two weeks after the 2nd application and 75.86% before harvest.

These positive effects of CA3301 at 0.6-0.8 l/ha to control brown rust were overall superior than the 0.48 l/ha dose rate tested.

In these trials, the disease pressure was low to medium and in these conditions CA3301 applied at 0.6 l/ha gave comparable disease control than 0.8 l/ha in all trials. However, in most instances a numerical trend appeared to reduce the disease severity with increasing dose rates, particularly when the disease pressure increases. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for the control of *Puccinia recondita* or *Puccinia triticina* on winter wheat. Nevertheless in conditions of high

disease pressure the additional disease reduction obtained from the higher rate of 0.8 l/ha may be more appropriate.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Puccinia recondita* or *Puccinia triticina* on winter wheat in the North-Eastern East EPPO zone.

Table 3.2-92: Summary table – Minimum effective dose evaluation – Winter wheat – PUCCRE/PUCRT – North-Eastern East EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREAT ED CHECK	CA330 1 0,48 L/ha AB	CA33 01 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity L2 - 15 DA-B										
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha	UTC	CA330 1 0,48 l/ha	CA3301 0,6 l/ha
Minimum value	7,69	0,69	0,06	0,00						
Maximum value	7,69	0,69	0,06	0,00	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	7,69	0,69	0,06	0,00	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	91,03%	99,22 %	100,00%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 15 DA-B										
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha	UTC	CA330 1 0,48 l/ha	CA3301 0,6 l/ha
Minimum value	18,75	4,24	3,13	2,20						
Maximum value	18,75	4,24	3,13	2,20	1 >	1 >	0 >	1 >	1 >	0 >
Mean disease severity (%)	18,75	4,24	3,13	2,20	0 =	0 =	1 =	0 =	0 =	1 =
Abbott efficacy (%)	0,00%	77,39%	83,31 %	88,27%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 20-35 DA-B										
Number of values	6	6	6	6	UTC	CA3301 0,48 l/ha	CA330 1 0,8 l/ha	UTC	CA330 1 0,48 l/ha	CA3301 0,6 l/ha
Minimum value	5,00	1,06	0,13	0,06						
Maximum value	17,25	1,89	1,39	1,16	6 >	0 >	0 >	6 >	1 >	0 >
Mean disease severity (%)	8,48	1,49	1,03	0,68	0 =	6 =	6 =	0 =	5 =	6 =
Abbott efficacy (%)	0,00%	78,44%	85,46 %	90,15%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 20-35 DA-B										
Number of values	6	6	6	6	UTC	CA3301 0,48 l/ha	CA330 1 0,8 l/ha	UTC	CA330 1 0,48 l/ha	CA3301 1 0,6 l/ha
Minimum value	8,23	1,44	0,56	0,75						
Maximum value	16,44	16,88	9,65	10,69	5 >	1 >	0 >	6 >	2 >	0 >
Mean disease severity (%)	11,77	5,71	4,13	3,28	1 =	4 =	6 =	0 =	3 =	6 =
Abbott efficacy (%)	0,00%	55,56%	68,19 %	75,86%	0 <	1 <	0 <	0 <	1 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)
>80% High efficacy

60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, 7 valid trials had a level of disease severity higher than 5% and were included to support the minimum effective dose evaluation of CA3301.

Several dose rates (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). CA3301 was first applied at crop stages BBCH 31-39 and the 2nd application was at BBCH 47-65. Two main assessment timings were selected: around two weeks after application B (14-17 DA-B) and the last timing close to harvest (21-43 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-93.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect to control brown rust was provided after two applications of CA3301 at 0.6-0.8 l/ha.

On foliar level 2, when applied at 0.6 l/ha, CA3301 showed 92.31% of efficacy to control brown rust two weeks after the 2nd application and 77.91% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 88.64% of efficacy on reduction of disease severity around two weeks after the 2nd application and 74.15% before harvest.

When applied at 0.8 l/ha, on foliar level 2, CA3301 showed 93.85% of efficacy to control brown rust two weeks after the 2nd application and 89.27% before harvest. On foliar level 1, CA3301 at 0.8 l/ha showed 100% of efficacy on reduction of disease severity around two weeks after the 2nd application and 91.36% before harvest.

These positive effects of CA3301 at 0.6-0.8 l/ha to control brown rust were overall superior than the 0.48 l/ha dose rate tested.

Among the data presented in this section, the data demonstrated that in case of high level of disease pressure, a distinct difference can be seen between the dose rates, therefore, it is envisaged that a dose rate of 0.8 L/ha is appropriate for control of brown rust at this level of disease pressure (see EU19-067-70 trial). Moreover, in case of early time for disease development, the two higher dose rates 0.6 and 0.8 l/ha showed an equivalent performance.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Puccinia recondita* or *Puccinia tritricina* on winter wheat in the South-Eastern East EPPO zone.

Table 3.2-93: Summary table – Minimum effective dose evaluation – Winter wheat – PUCCRE/PUCRT – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA330	CA330	CA330	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		1	1	1						
Rate unit		0,48	0,6	0,8						
Appl. Code		L/ha	L/ha	L/ha						
		AB	AB	AB						
% Disease severity L2 - 15-17 DA-B										
Number of values	3	3	3	3	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UTC	CA330 1 0,48 l/ha	CA330 01 0,6 l/ha
Minimum value	5,85	0,00	0,00	0,00		3 >	1 >		0 >	3 >
Maximum value	15,00	1,78	1,35	1,08	0 =	2 =	3 =	0 =	2 =	3 =
Mean disease severity (%)	8,95	0,75	0,45	0,36	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	87,20 %	92,31 %	93,85 %						
% Disease severity L1 - 14-15 DA-B										
Number of values	2	2	2	2	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA3301 0,48 l/ha	CA330 01 0,6 l/ha
Minimum value	5,30	0,00	0,00	0,00						

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA330 1 0,48 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Maximum value	5,50	0,00	1,25	0,00	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	5,40	0,00	0,63	0,00	1 =	2 =	2 =	1 =	2 =	2 =
Abbott efficacy (%)	0,00%	100,00 %	88,64 %	100,00 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 21-43 DA-B										
Number of values	5	5	5	5	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA3301 0,48 l/ha	CA3301 0,6 l/ha
Minimum value	6,23	1,75	1,34	0,30						
Maximum value	56,75	14,43	13,51	4,95	5 >	3 >	0 >	5 >	4 >	2 >
Mean disease severity (%)	21,50	5,86	4,85	2,33	0 =	2 =	3 =	0 =	1 =	3 =
Abbott efficacy (%)	0,00%	71,56 %	77,91 %	89,27 %	0 <	0 <	2 <	0 <	0 <	0 <
% Disease severity L1 - 21-43 DA-B										
Number of values	4	4	4	4	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	7,43	0,88	0,55	0,00						
Maximum value	52,63	13,66	13,85	7,51	4 >	3 >	0 >	4 >	3 >	3 >
Mean disease severity (%)	19,83	5,21	4,70	2,37	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	74,15 %	80,13 %	91,36 %	0 <	0 <	3 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

9 trials have been submitted to determine minimum effective dose in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,48-0,8l/ha achieved high efficacy in 2 out of 9 trials after 16-18 days after second application. The significant differences between dose rates were noted before harvest. The test product at 0,48 l/ha was not effective in control of PUCCRE. The dose rate of 0,6-0,8 l/ha achieved medium efficacy in the same assessments. The dose rate of 0,6 l/ha showed consistently good results.

10 trials were presented to determine MED in **the North-East EPPO zone**. CA3301 applied at dose rate of 0,6-0,8 l/ha was effective on high level in most trials. The dose rate of 0,48 l/ha achieved significant lower results and was not effective after 20-35 DA-B in 6 out of 10 trials. The higher dose rates showed medium efficacy in the same assessments.

7 trials were available to determine MED in **the South-East EPPO zone**. CA3301 at 0,48-0,8 l/ha achieved high efficacy after 14-17 days after second application. The differences between doses were visible after 21-43 DA-B. The test product applied at 0,6-0,8 l/ha was effective on high level while lower dose rate of 0,48 l/ha showed medium level in 4 out of 7 trials on leaves level 1. 17 additional trials from the Mediterranean zone have been submitted to support of product registration in other zones. A very low results were observed in the assessments after second application. The significant differences were noted between doses before harvest. A decrease of dose rate to 0,48 l/ha caused lower efficacy about 9% after 20-43 DA-B.

Taking into account all EPPO zones, the dose rate of 0,6 l/ha can be considered minimum effective dose to control of *Puccinia recondita*/*P.triticina* in winter wheat. It should be noted that the dose rate of 0,6 l/ha can be considered MED mainly in situation of low disease pressure. In more challenging conditions, the dose rate of 0,8 l/ha will be more justified.

3.2.2.25 Winter wheat (TRZAW) / *Puccinia striiformis* - *Puccinia striiformis* f. sp. *tritici*

(PUCCST-PUCCSI)

Between 2018 and 2020, a series of 24 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the minimum effective dose of CA3301 against *Puccinia striiformis* or *Puccinia striiformis f. sp. tritici* on winter wheat. The trials were carried out by certified testing institutes. The proposed rate is the range of 0.6-0.8 l/ha.

In the Maritime EPPO zone, 18 trials were performed in Czech Republic (1), Germany (2) and United Kingdom (15).

In the Mediterranean EPPO zone, 2 trials were performed in Greece (1) and Spain (1).

In the North-Eastern East EPPO zone, a single trial was performed in Poland (1).

In the South-Eastern East EPPO zone, a total of 3 trials were performed in Hungary (1) and Romania (2).

Out of the 24 trials carried out against *Puccinia striiformis* (PUCCST) or *Puccinia striiformis f. sp. Tritici* (PUCCSI) on winter wheat, 18 were considered valid.

Min. Eff. Dose evaluation of CA3301 – Maritime EPPO zone

In the Maritime EPPO zone, 13 trials had a level of disease severity higher than 5% and were included to support evaluation of CA3301. Several dose rates CA3301 (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). CA3301 was first applied at crop stages BBCH 31-39 and the 2nd application was at BBCH 39-65. Two main assessment timings were selected: around two weeks after application B (14-19 DA-B) and the last timing close to harvest (27-46 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-94.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect on yellow rust was provided after two applications of CA3301 at 0.6-0.8 l/ha.

On foliar level 2, when applied at 0.6 l/ha, CA3301 showed 83.81% of efficacy to control yellow rust two weeks after the 2nd application and 79.27% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 93.63% of efficacy on reduction of disease severity around two weeks after the 2nd application and 83.22% before harvest.

When applied at 0.8 l/ha, on foliar level 2, CA3301 showed 90.85% of efficacy against to control yellow rust two weeks after the 2nd application and 83.49% before harvest. On foliar level 1, CA3301 at 0.8 l/ha showed 92.30% of efficacy on reduction of disease severity around two weeks after the 2nd application and 83.41% before harvest.

These positive effects to control yellow rust of CA3301 at 0.6-0.8 l/ha were overall superior than the 0.48 l/ha dose rate tested, as among the data groupings efficacy was more often high compared to medium for the lower rate. In a number of trials where disease pressure was high there was an observed statistical benefit from increasing the dose rate from 0.6 to 0.8 L/ha. Generally in trials with lower disease the control was more comparable between these 2 dose rates. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for the control of *Puccinia striiformis* or *Puccinia striiformis f. sp. tritici* on winter wheat. Nevertheless in conditions of high disease pressure the additional disease reduction obtained from the higher rate of 0.8 l/ha may be more appropriate.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Puccinia striiformis* or *Puccinia striiformis f. sp. tritici* on winter wheat in the Maritime EPPO zone.

Table 3.2-94: Summary table – Minimum effective dose evaluation – Winter wheat – PUCCST/PUCCSI - Maritime EPPO zone

Treatment name	UNTREATED	CA330	CA33	CA330	No of trials where	No of trials where
Rate	CHECK	1	01	1	CA3301 at 0,6 l/ha is	CA3301 at 0,8 l/ha is
Rate unit		0,48	0,6	0,8	>, = or < compared to	>, = or < compared to

Appl. Code		L/ha AB	L/ha AB	L/ha AB						
% Disease severity L2 - 14-19 DA-B										
Number of values	7	7	7	7	UTC	CA33 01	CA33 01	UT C	CA330 1	CA330 1
Minimum value	6,49	0,00	0,00	0,00		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	87,50	15,05	10,88	8,06	6 >	1 >	0 >	6 >	2 >	2 >
Mean disease severity (%)	41,69	6,13	4,86	2,49	1 =	5 =	5 =	1 =	5 =	5 =
Abbott efficacy (%)	0,00%	73,14 %	83,81 %	90,85 %	0 <	1 <	2 <	0 <	0 <	0 <
% Disease severity L1 - 14-19 DA-B										
Number of values	5	5	5	5	UTC	CA33 01	CA33 01	UT C	CA330 1	CA330 1
Minimum value	6,48	0,00	0,00	0,00		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	50,63	7,65	3,90	2,15	5 >	0 >	0 >	5 >	1 >	0 >
Mean disease severity (%)	24,98	2,27	1,35	0,99	0 =	5 =	5 =	0 =	4 =	5 =
Abbott efficacy (%)	0,00%	88,31 %	93,63 %	92,30 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 27-46 DA-B										
Number of values	11	11	11	11	UTC	CA33 01	CA33 01	UT C	CA330 1	CA330 1
Minimum value	5,24	0,00	0,00	0,00		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	100,00	79,50	48,88	30,38	11 >	4 >	1 >	11 >	4 >	3 >
Mean disease severity (%)	46,58	15,84	11,18	7,70	0 =	6 =	7 =	0 =	7 =	7 =
Abbott efficacy (%)	0,00%	72,67 %	79,27 %	83,49 %	0 <	1 <	3 <	0 <	0 <	1 <
% Disease severity L1 - 27-46 DA-B										
Number of values	10	10	10	10	UTC	CA33 01	CA33 01	UT C	CA330 1	CA330 1
Minimum value	5,58	0,00	0,00	0,00		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	88,94	42,88	17,18	19,68	9 >	5 >	1 >	10 >	5 >	1 >
Mean disease severity (%)	35,48	10,21	5,15	4,91	1 =	4 =	8 =	0 =	5 =	8 =
Abbott efficacy (%)	0,00%	72,61 %	83,22 %	83,41 %	0 <	1 <	1 <	0 <	0 <	1 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – Mediterranean EPPO zone

In the Mediterranean EPPO zone, all 2 trials available had a level of disease severity higher than 5% and were included to support evaluation of CA3301. Several dose rates of CA3301 (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). CA3301 was first applied at crop stages BBCH 37 and the 2nd application was at BBCH 58-65. Two main assessment timings were selected: around two weeks after application B (15-16 DA-B) and the last timing close to harvest (22 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-95.

On foliar level 2, when applied at 0.6 l/ha, CA3301 showed 70.64% of efficacy to control yellow rust two weeks after the 2nd application. On foliar level 1, CA3301 at 0.6 l/ha showed 89.08% of efficacy on reduction of disease severity around two weeks after the 2nd application and 89.83% before harvest. When applied at 0.8 l/ha, on foliar level 2, CA3301 showed 81.85% of efficacy against yellow rust two weeks after the 2nd application. On foliar level 1, CA3301 at 0.8 l/ha showed 89.35% of efficacy on reduction of disease severity around two weeks after the 2nd application and 89.60% before harvest.

These positive effects to control yellow rust of CA3301 at 0.6-0.8 l/ha were overall superior than the 0.48 l/ha dose rate tested, as disease severity was consistently higher from the latter treatments compared to the proposed dose rates. In all 2 trials available with focus on yellow rust, the disease pressure was moderate to high and the levels of control between 0.6 l/ha and 0.8 l/ha dose rates were comparable. These data are consistent with the data recorded against brown rust, in which it is envisaged, that a dose rate of 0.8 L/ha is appropriate for control of brown rust at high level of disease pressure. Therefore, we can conclude that the highest fungicidal effect on yellow rust was provided after two applications of CA3301 at 0.6-0.8 l/ha.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Puccinia striiformis* or *Puccinia striiformis* f. sp. *tritici* on winter wheat in the Mediterranean EPPO zone.

Table 3.2-95: Summary table – Minimum effective dose evaluation – Winter wheat – PUCGST/PUCCSI - Mediterranean EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA330 1 0,48 L/ha AB	CA330 1 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity L2 - 15-16 DA-B										
Number of values	2	2	2	2	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	16,94	3,60	2,35	1,86		2 >	0 >		0 >	2 >
Maximum value	33,18	25,65	14,88	8,40	0 =	2 =	2 =	0 =	1 =	2 =
Mean disease severity (%)	25,06	14,63	8,61	5,13	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	50,72 %	70,64 %	81,85 %						
% Disease severity L1 - 15-16 DA-B										
Number of values	2	2	2	2	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	15,20	3,65	1,75	1,53		2 >	0 >		0 >	2 >
Maximum value	26,53	4,45	2,74	2,98	0 =	2 =	2 =	0 =	2 =	2 =
Mean disease severity (%)	20,86	4,05	2,24	2,25	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	79,61 %	89,08 %	89,35 %						
% Disease severity L1 - 22 DA-B										
Number of values	1	1	1	1	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	51,94	9,56	5,28	5,40		1 >	0 >		0 >	1 >
Maximum value	51,94	9,56	5,28	5,40	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	51,94	9,56	5,28	5,40	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	81,59 %	89,83 %	89,60 %						

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80% High efficacy

60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, the single available trial had a level of disease severity higher than 5% and was included to support evaluation of CA3301. Several dose rates of CA3301 (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). CA3301 was first applied at crop stage BBCH 30 and the 2nd application was at BBCH 57. No data were available before the last assessment timing close to harvest (35 DA-B).

Summary results are presented in Table 3.2-96.

When evaluating the reduction of disease severity, the data was limited to a single trial. Yellow rust remains an unusual and opportunistic disease in North-Eastern zone and its distribution is higher in Maritime EPPO Zone. The 3 dose rates tested showed no statistical differences in performance against yellow rust. However, applications of 0.8 L/ha resulted in control of >90% compared to 79.04% from the 0.6 L/ha rate and 78.75% from the 0.48 L/ha rate.

These positive effects to control yellow rust of CA3301 at 0.6-0.8 l/ha were overall statistically equivalent to the 0.48 l/ha dose rate tested. Nevertheless, the dose rate of 0.8 L/ha provided high efficacy compared to the medium efficacy obtained from applications at the lower rates. The dataset presented in this section was limited for the evaluation but a larger supportive dataset was presented on brown rust in the North-Eastern East EPPO zone and the same trend of increasing efficacy with increasing dose rate was observed in these trials.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Puccinia striiformis* or *Puccinia striiformis f. sp. tritici* on winter wheat in the North-Eastern East EPPO zone.

Table 3.2-96: Summary table – Minimum effective dose evaluation – Winter wheat – PUCGST/PUCCSI – North-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA33	CA330	CA33	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		01	1	01						
Rate unit		0,48	0,6	0,8						
Appl. Code		L/ha	L/ha	L/ha						
		AB	AB	AB						
% Disease severity L1 - 35 DA-B										
Number of values	1	1	1	1	UT	CA330	CA33	UT	CA330	CA330
Minimum value	7,06	1,50	1,48	0,63	C	1	01	C	1	1
Maximum value	7,06	1,50	1,48	0,63		0,48	0,8		0,48	0,6 l/ha
						l/ha	l/ha			
Mean disease severity (%)	7,06	1,50	1,48	0,63	1 >	0 >	0 >	1 >	0 >	0 >
					0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	78,75 %	79,04%	91,08 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, 3 trials had a level of disease severity higher than 5% and were included to support evaluation of CA3301. Several dose rates of CA3301 (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). CA3301 was first applied at crop stages BBCH 33-47 and the 2nd application was at BBCH 59-65. Two main assessment timings were selected: around two weeks after application B (17 DA-B) and the last timing close to harvest (27-36 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-97.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect on yellow rust was provided after two applications of CA3301 at 0.6-0.8 l/ha.

On foliar level 2, when applied at 0.6 l/ha, CA3301 showed 63.83% of efficacy to control yellow rust two weeks after the 2nd application and 99.36% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 65.81% of efficacy on reduction of disease severity around two weeks after the 2nd application and 99.66% before harvest.

When applied at 0.8 l/ha, on foliar level 2, CA3301 showed 72.89% of efficacy against to control yellow rust two weeks after the 2nd application and 99.50% before harvest. On foliar level 1, CA3301 at 0.8 l/ha showed 73.03% of efficacy on reduction of disease severity around two weeks after the 2nd application and 99.62% before harvest.

These positive effects to control yellow rust of CA3301 at 0.6-0.8 l/ha were overall superior than the 0.48 l/ha dose rate tested, with significant differences observed in each dataset. A larger dataset of 7 supportive trials showed that in the same EPPO zone, in most instances the 0.6 and 0.8 l/ha dose rates gave comparable disease control of brown rust but in case of high level of disease pressure, a distinct difference can be seen between the dose rates. Therefore, it is envisaged that a dose rate of 0.6 l/ha may be sufficient in conditions of low to medium disease pressure but 0.8 l/ha is appropriate for control of yellow rust in conditions of high of disease pressure.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Puccinia striiformis* or *Puccinia striiformis* f. sp. *tritici* on winter wheat in the South-Eastern East EPPO zone.

Table 3.2-97: Summary table – Minimum effective dose evaluation – Winter wheat – PUCST/PUCCSI – South-Eastern East EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA330 1 0,48 L/ha AB	CA33 01 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity L2 - 17 DA-B										
Number of values	1	1	1	1	UT C	CA330 1 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	12,69	5,59	4,59	3,44	1 >	1 >	0 >	1 >	1 >	1 >
Maximum value	12,69	5,59	4,59	3,44	0 =	0 =	0 =	0 =	0 =	0 =
Mean disease severity (%)	12,69	5,59	4,59	3,44	0 <	0 <	1 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	55,95 %	63,83 %	72,89 %						
% Disease severity L1 - 17 DA-B										
Number of values	1	1	1	1	UT C	CA330 1 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	18,28	7,76	6,25	4,93	1 >	1 >	0 >	1 >	1 >	1 >
Maximum value	18,28	7,76	6,25	4,93	0 =	0 =	0 =	0 =	0 =	0 =
Mean disease severity (%)	18,28	7,76	6,25	4,93						

Abbott efficacy (%)	0,00%	57,55 %	65,81 %	73,03 %	0 <	0 <	1 <	0 <	0 <	0 <
% Disease severity L2 - 27-36 DA-B										
Number of values	2	2	2	2	UT C	CA330 1 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	5,16	0,08	0,04	0,02						
Maximum value	29,56	0,61	0,15	0,18	2 >	1 >	0 >	2 >	1 >	0 >
Mean disease severity (%)	17,36	0,34	0,09	0,10	0 =	1 =	2 =	0 =	1 =	2 =
Abbott efficacy (%)	0,00%	98,19 %	99,36 %	99,50 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 27 DA-B										
Number of values	1	1	1	1	UT C	CA330 1 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	20,88	0,22	0,07	0,08						
Maximum value	20,88	0,22	0,07	0,08	1 >	1 >	0 >	1 >	1 >	0 >
Mean disease severity (%)	20,88	0,22	0,07	0,08	0 =	0 =	1 =	0 =	0 =	1 =
Abbott efficacy (%)	0,00%	98,95 %	99,66 %	99,62 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-East Eppo zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this case, a total of 4 trials evaluated the efficacy of CA3301 on winter wheat against *Puccinia striiformis* (PUCCST) or *Puccinia striiformis* f. sp. *tritici* (PUCCSI). 3 trials out of 4 were considered valid. Several dose rates of CA3301 (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). CA3301 was first applied at crop stages BBCH 30-37 and the 2nd application was at BBCH 39-65. Two main assessment timings were selected: around two weeks after application B (19 DA-B) and the last timing close to harvest (35-46 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-98.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect on yellow rust was provided after two applications of CA3301 at 0.6-0.8 l/ha, except in one trial (EU20-035-16) that demonstrated higher control from 0.6 l/ha.

On foliar level 2, when applied at 0.6 l/ha, CA3301 showed 81.04% of efficacy to control yellow rust two weeks after the 2nd application and 79.15% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 83.95% of efficacy on reduction of disease severity around two weeks after the 2nd application and 85.25% before harvest.

When applied at 0.8 l/ha, on foliar level 2, CA3301 showed 85.71% of efficacy against to control yellow rust two weeks after the 2nd application and 49.05% before harvest. On foliar level 1, CA3301 at 0.8 l/ha showed 89.35% of efficacy on reduction of disease severity around two weeks after the 2nd application and 68.81% before harvest.

In this particular data grouping, a limited dataset was available and the disease severity of yellow rust on winter wheat relatively low (6.48-8.44%). Overall CA3301 at 0.6-0.8 l/ha provided a higher efficacy than the one provided by the 0.48 l/ha dose rate, except in 1 trial in which 0.8 l/ha dose rate showed a lower

disease pressure reduction than the one provided by the 0.6 l/ha dose rate. At the exception of this trial, the dataset demonstrates that CA3301 applied at 0.6 l/ha can be sufficient to provide a high efficacy against yellow rust, but that increasing the dose rate to 0.8 l/ha to provide fuller control close to harvest could be beneficial when disease pressure is high.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Puccinia striiformis* or *Puccinia striiformis* f. sp. *tritici* on winter wheat in Poland.

Table 3.2-98: Summary table - Minimum effective dose evaluation – Winter wheat – PUCST-PUCCSI – Data relevant for Poland

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA330 1 0,48 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity L2 - 19 DA-B										
Number of values	1	1	1	1	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	7,70	1,50	1,46	1,10		1 >	0 >		0 >	1 >
Maximum value	7,70	1,50	1,46	1,10	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	7,70	1,50	1,46	1,10	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	80,52 %	81,04 %	85,71 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 19 DA-B										
Number of values	1	1	1	1	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	6,48	1,21	1,04	0,69		1 >	0 >		0 >	1 >
Maximum value	6,48	1,21	1,04	0,69	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	6,48	1,21	1,04	0,69	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	81,33 %	83,95 %	89,35 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 46 DA-B										
Number of values	1	1	1	1	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	8,44	3,55	1,76	4,30		1 >	1 >		1 >	1 >
Maximum value	8,44	3,55	1,76	4,30	0 =	0 =	0 =	0 =	1 =	0 =
Mean disease severity (%)	8,44	3,55	1,76	4,30	0 <	0 <	0 <	0 <	0 <	1 <
Abbott efficacy (%)	0,00%	57,94 %	79,15 %	49,05 %	0 <	0 <	0 <	0 <	0 <	1 <
% Disease severity L1 - 35-46 DA-B										
Number of values	2	2	2	2	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	7,06	1,50	0,78	0,63		2 >	1 >		1 >	2 >
Maximum value	9,13	5,56	1,48	4,88	0 =	1 =	1 =	0 =	2 =	1 =
Mean disease severity (%)	8,09	3,53	1,13	2,75	0 <	0 <	0 <	0 <	0 <	1 <
Abbott efficacy (%)	0,00%	58,93 %	85,25 %	68,81 %	0 <	0 <	0 <	0 <	0 <	1 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

13 trials have been submitted to determine minimum effective dose in **the Maritime EPPO climatic zone**. The consistently high level of efficacy was observed after application of CA3301 at 0,6-0,8 l/ha. The dose rate of 0,48 l/ha achieved significant lower results but still on medium level. Overall, the trials with higher disease pressure showed better results for higher doses of 0,6-0,8 l/ha. The test product at 0,6 l/ha will come more benefits in unfavorable conditions.

Only 1 trial was available to determine MED in **the North-East EPPO zone**. The significant differences between dose rate of 0,8 l/ha and lower doses were visible. CA3301 at 0,48-0,6 l/ha achieved medium efficacy while the dose rate of 0,8 l/ha was high effective. The results from the neighbouring countries have been included to the overall calculations to support of Polish registration. CA3301 applied at dose rate of 0,48-0,8 l/ha achieved high efficacy after 19 days after second application. The significantly lower efficacy of dose rate of 0,48 l/ha compared to higher doses were noted before harvest.

3 trials were presented to determine MED in **the South-East EPPO zone**. CA3301 applied at dose rate of 0,48-0,8 l/ha achieved high efficacy after 27-36 DA-B. The significant differences were observed in assessments 17 after second application. The dose rate of 0,48 l/ha was insufficient to control of PuccST. The higher dose rate of 0,6-0,8 l/ha achieved medium efficacy in the same time. Also 2 additional trials from the Mediterranean zone confirmed this trend. CA3301 at 0,6-0,8 l/ha was effective on consistently good level while the dose of 0,48 l/ha achieved very low result on L2 after 15-16 days after second application.

Taking into account all EPPO zones, the dose rate of 0,6 l/ha can be considered minimum effective dose to control of *Puccinia striiformis* in winter wheat. It should be noted that the dose rate of 0,6 l/ha can be considered MED mainly in situation of low disease pressure. In more challenging conditions, the dose rate of 0,8 l/ha will be more justified.

3.2.2.26 Winter wheat (TRZAW) / *Blumeria graminis* (ERYSGR-ERYSGT)

Between 2017 and 2020, a series of 51 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the minimum effective dose of CA3301 against *Blumeria graminis* or *Blumeria graminis* f. sp. *tritici* on winter wheat. The trials were carried out by certified testing institutes. The proposed rate is the range of 0.6-0.8 l/ha.

In the Maritime EPPO zone, 15 trials were performed in Czech Republic (7), Germany (3), United Kingdom (3) and France (2).

In the Mediterranean EPPO zone, 7 trials were performed in Southern France (4), Spain (2) and Portugal (1).

In the North-Eastern East EPPO zone, 19 trials were performed in Poland (12), Lithuania (5) and Latvia (2).

In the South-Eastern East EPPO zone, a total of 10 trials were performed in Hungary (4), Romania (4) and Slovakia (2).

Over this dataset, due to the low disease severity occurring on the infected plants with *Blumeria graminis*, the parameter 'Disease severity %' could not be used. Considering the fact that treatment against *Blumeria graminis* is triggered when 20% of leaves (L1 to L4 considered together) are attacked by the fungus on sensitive varieties (source ARVALIS Institut du végétal), the analysis will be conducted on four foliar levels L1 to L4 with the parameter 'Disease incidence %'.

A trial was considered valid when the level of disease incidence was higher than 5% in the untreated control and if the reference product shows a significant difference compared to the untreated control. Therefore, out of the 51 trials performed on winter wheat against *Blumeria graminis* or *Blumeria graminis* f. sp. *tritici*, 46 were considered valid.

Min. Eff. Dose evaluation of CA3301 – Maritime EPPO zone

In the Maritime EPPO zone, a total of 15 trials evaluated the efficacy of CA3301 on winter wheat against *Blumeria graminis*. 14 trials out of 15 were considered valid and 10 trials enabled to compare the efficacy

of several dose rates of CA3301 (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease incidence (%). Therefore, the minimum effective dose evaluation will be conducted thanks to 10 trials considered as valid and assessing disease incidence on leaves.

CA3301 was first applied at crop stages BBCH 31-39 and the 2nd application was at BBCH 39-65. Two main assessment timings were selected: around two weeks after the 2nd application (13-16 DA-B) and the last timing close to harvest (30-46 DA-B). The analysis was conducted on the fourth main foliar levels L1, L2, L3 and L4.

Summary results are presented in Table 3.2-99 and Table 3.2-100.

Following 2 applications, the fungicidal performance of CA3301 enabled to significantly decrease the disease incidence on leaves in most of trials, compared to the untreated control and whatever the dose rate considered.

About 2 weeks after the second application or before harvest, CA3301 achieved its highest performance when sprayed at 0.8 l/ha. Even if statistical dose response was not always observed, it clearly appeared that CA3301 at 0.8 l/ha reduced the disease incidence on leaves. When disease pressure is high and due to the possibility of resistance in the Maritime EPPO zone, the 0.8 l/ha dose rate may be beneficial to maximise protection when lower dose rates might fail to provide a sufficient control. In addition, CA3301 at 0.6 l/ha appeared to provide a satisfactory level of protection, higher than the one provided by 0.48 l/ha.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Blumeria graminis* on winter wheat in the Maritime EPPO zone.

Table 3.2-99: Summary table – Minimum effective dose evaluation – Winter wheat – ERYSGR-ERYSGT - Maritime EPPO zone – 13-16 DA-B

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA330 1 0,48 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease incidence L4 - 14-15 DA-B										
Number of values	2	2	2	2	UT	CA330	CA330	UT	CA330	CA330
Minimum value	83,75	60,00	51,25	23,75	C	1 0,48 l/ha	1 0,8 l/ha	C	1 0,48 l/ha	1 0,6 l/ha
Maximum value	100,00	63,75	52,50	41,25	2 >	0 >	0 >	2 >	2 >	1 >
Mean disease incidence (%)	91,88	61,88	51,88	32,50	0 =	2 =	1 =	0 =	0 =	1 =
Abbott efficacy (%)	0,00%	32,30 %	43,03 %	63,50 %	0 <	0 <	1 <	0 <	0 <	0 <
% Disease incidence L3 - 14-15 DA-B										
Number of values	3	3	3	3	UT	CA330	CA330	UT	CA330	CA330
Minimum value	66,25	28,75	26,25	0,00	C	1 0,48 l/ha	1 0,8 l/ha	C	1 0,48 l/ha	1 0,6 l/ha
Maximum value	97,50	50,00	41,25	8,75	2 >	0 >	0 >	3 >	2 >	2 >
Mean disease incidence (%)	86,67	38,33	32,92	5,42	1 =	3 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	55,89 %	61,87 %	93,23 %	0 <	0 <	2 <	0 <	0 <	0 <
% Disease incidence L2 - 13-16 DA-B										
Number of values	4	4	4	4	UT	CA330	CA330	UT	CA330	CA330
Minimum value	76,25	0,00	0,00	0,00	C	1 0,48 l/ha	1 0,8 l/ha	C	1 0,48 l/ha	1 0,6 l/ha
Maximum value	100,00	62,50	70,00	55,00	2 >	0 >	0 >	3 >	0 >	0 >
Mean disease incidence (%)	91,25	32,19	33,75	26,56	2 =	4 =	4 =	1 =	4 =	4 =
Abbott efficacy (%)	0,00%	65,57 %	64,25 %	71,82 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Table 3.2-100: Summary table – Minimum effective dose evaluation – Winter wheat – ERYSGR-ER-YSGT - Maritime EPPO zone – 30-46 DA-B

Treatment name	UNTREATED CHECK	CA33 01	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		0,48	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Disease incidence L3 - 38 DA-B										
Number of values	1	1	1	1	UT C	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	26,25	0,00	0,00	0,00		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	26,25	0,00	0,00	0,00	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease incidence (%)	26,25	0,00	0,00	0,00	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	100,00 %	100,00 %	100,00 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease incidence L2 - 30-46 DA-B										
Number of values	3	3	3	3	UT C	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	42,50	36,25	28,75	16,25		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	80,00	62,50	62,50	58,75	1 >	1 >	0 >	1 >	1 >	0 >
Mean disease incidence (%)	67,50	46,25	40,42	33,75	2 =	2 =	3 =	2 =	2 =	3 =
Abbott efficacy (%)	0,00%	28.86 %	38.45 %	48.16 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease incidence L1 - 46 DA-B										
Number of values	2	2	2	2	UT C	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	45,00	0,00	0,00	0,00		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	62,50	43,75	30,00	32,50	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease incidence (%)	53,75	21,88	15,00	16,25	1 =	2 =	2 =	1 =	2 =	2 =
Abbott efficacy (%)	0,00%	51.39 %	66.67 %	63.89 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – Mediterranean EPPO zone

In the Mediterranean EPPO zone, a total of 7 trials evaluated the efficacy of CA3301 on winter wheat against *Blumeria graminis*. 5 trials out of 7 were considered valid and all trials enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease incidence (%). Therefore, the minimum effective dose evaluation will be conducted from 5 trials considered as valid and assessing disease incidence on leaves.

CA3301 was first applied at crop stages BBCH 30-39 and the 2nd application was at BBCH 39-61. Two main assessment timings were selected: around two weeks after the 2nd application (14 DA-B) and the last timing close to harvest (27-43 DA-B). The analysis was conducted on the fourth main foliar levels L1, L2, L3 and L4.

Summary results are presented in Table 3.2-101 and Table 3.2-102.

About 2 weeks after the 2nd application, the highest fungicidal performance of CA3301 was clearly achieved by 0.8 l/ha, whatever the foliar level considered:

- 82.39% efficacy on incidence on L4
- 85.54% efficacy on incidence on L3
- 96.05% efficacy on incidence on L2

When sprayed at 0.6 l/ha, CA3301 performance decreased but remained acceptable with 73.12% efficacy on L4, 74.96% efficacy on L3 and 81.80% efficacy on L2.

Before harvest (27-43 DA-B), the fungicidal performance of CA3301 against *Blumeria graminis* on wheat remained high whatever the leaf level considered.

As previously observed, 0.8 l/ha brought a significant gain of efficacy compared to 0.48 and 0.6 l/ha:

- 100,00% efficacy on incidence on L4
- 100,00% efficacy on incidence on L3
- 90.29% efficacy on incidence on L2
- 87.04% efficacy on incidence on L1

When sprayed at 0.6 l/ha, CA3301 performance decreased but remained still high with 77.27% efficacy on L4, 87.50% efficacy on L3, 76.88% efficacy on L2 and 82.06% efficacy on L1.

Compared to 0.48 l/ha the increased dose rates overall showed increased disease reduction, which was particularly noticeable close to harvest where efficacy levels were higher from the proposed dose rates compared to 0.48 l/ha.

Even if the dose response effect was not always significant, a numerical dose effect could be seen showing a higher reduction of the disease incidence with increasing dose rates, particularly 0.8 l/ha. In addition, due to the importance of this disease and the possibility of resistance of this pathogen, the higher rate with increased disease suppression may be considered more appropriate especially in case of high infestation.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Blumeria graminis* on winter wheat in the Mediterranean EPPO zone.

Table 3.2-101: Summary table – Minimum effective dose evaluation – Winter wheat – ERYSGR-ERYSGT - Mediterranean EPPO zone – 14 DA-B

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA330 1 0,48 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease incidence L4 - 14 DA-B										
Number of values	2	2	2	2	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	28,75	2,50	2,50	0,00	2 >	0 >	0 >	2 >	0 >	0 >
Maximum value	88,75	45,00	40,00	31,25	0 =	2 =	2 =	0 =	2 =	2 =
Mean disease incidence (%)	58,75	23,75	21,25	15,63	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	70,30 %	73,12 %	82,39 %						
% Disease incidence L3 - 14 DA-B										
Number of values	4	4	4	4	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	21,25	2,50	1,25	0,00	4 >	0 >	0 >	0 >	1 >	0 >
Maximum value	100,00	80,00	61,25	50,00	0 =	4 =	4 =	4 =	3 =	4 =
Mean disease incidence (%)	54,38	24,06	19,69	13,75						

Abbott efficacy (%)	0	65,90 %	74,96 %	85,54 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease incidence L2 - 14 DA-B										
Number of values	2	2	2	2	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	15,00	1,25	2,50	0,00						
Maximum value	95,00	30,00	18,75	7,50	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease incidence (%)	55,00	15,63	10,63	3,75	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	80,04 %	81,80 %	96,05 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Table 3.2-102: Summary table – Minimum effective dose evaluation – Winter wheat – ERYSGR-ER-YSGT - Mediterranean EPPO zone – 27-43 DA-B

Treatment name	UNTREATED CHECK	CA330 1 0,48 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
% Disease incidence L4 - 27 DA-B						
Number of values	1	1	1	1	UT C	CA330 1 0,48 l/ha
Minimum value	27,50	8,75	6,25	0,00		CA330 1 0,8 l/ha
Maximum value	27,50	8,75	6,25	0,00	1 >	0 >
Mean disease incidence (%)	27,50	8,75	6,25	0,00	0 =	1 =
Abbott efficacy (%)	0	68,18 %	77,27 %	100,00 %	0 <	0 <
% Disease incidence L3 - 27-28 DA-B						
Number of values	2	2	2	2	UT C	CA330 1 0,48 l/ha
Minimum value	30,00	10,00	0,00	0,00		CA330 1 0,8 l/ha
Maximum value	31,25	12,50	7,50	0,00	2 >	0 >
Mean disease incidence (%)	30,63	11,25	3,75	0,00	0 =	2 =
Abbott efficacy (%)	0,00%	63,17 %	87,50 %	100,00 %	0 <	0 <
% Disease incidence L2 - 27-43 DA-B						
Number of values	4	4	4	4	UT C	CA330 1 0,48 l/ha
Minimum value	17,50	2,50	0,00	0,00		CA330 1 0,8 l/ha
Maximum value	100,00	77,50	55,00	30,00	4 >	1 >
Mean disease incidence (%)	57,43	29,38	18,44	9,38	0 =	3 =
Abbott efficacy (%)	0,00%	58,31 %	76,88 %	90,29% %	0 <	1 <
% Disease incidence L1 - 27-39 DA-B						
Number of values	2	2	2	2	UT C	CA330 1 0,48 l/ha
Minimum value	20,00	1,25	1,25	0,00		CA330 1 0,8 l/ha
Maximum value	67,50	27,50	20,00	17,50	2 >	0 >
Mean disease incidence (%)	43,75	14,38	10,63	8,75	0 =	2 =

Abbott efficacy (%)	0,00%	76,50 %	82,06 %	87,04%	0 <	0 <	0 <	0 <	0 <	0 <
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'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 19 trials evaluated the efficacy of CA3301 on winter wheat against *Blumeria graminis*. 17 trials out of 19 were considered valid and 16 trials enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease incidence (%). One trial (EU17-056-01) was valid but tested CA3301 applied only once and was therefore excluded in this analysis.

Therefore, the minimum effective dose evaluation will be conducted from 16 trials considered as valid and assessing disease incidence on leaves. CA3301 was first applied at crop stages BBCH 30-39 and the 2nd application was at BBCH 37-65. Two main assessment timings were selected: around two weeks after the 2nd application (13-16 DA-B) and the last timing close to harvest (18-42 DA-B). The analysis was conducted on the fourth main foliar levels L1, L2, L3 and L4.

Summary results are presented in Table 3.2-103 and

Table 3.2-104.

Following 2 applications, the fungicidal performance of CA3301 enabled to significantly decrease the disease incidence on leaves in most instances, compared to the untreated control and whatever the dose rate considered. At 13-16 DA-B or before harvest, all doses of CA3301 were statistically equivalent except once where 0.48 l/ha appeared significantly less efficient than 0.6 or 0.8 l/ha. Nevertheless in the majority of datasets a numerical dose rate trend was observed and data clearly evidenced that 0.6 l/ha and 0.8 l/ha provided a strongest control of disease incidence on leaves compared to 0.48 l/ha. The maximum disease incidence decreases when the dose rate increases.

Therefore, and logically, the effectiveness of CA3301 tended to increase and be highest when sprayed at 0.8 l/ha. In addition, due to the importance of this disease and the possibility of resistance in this pathogen, the higher rate with increased disease suppression may be considered more appropriate especially in case of high infestation.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Blumeria graminis* on winter wheat in the North-Eastern East EPPO zone.

Table 3.2-103: Summary table – Minimum effective dose evaluation – Winter wheat – ERYSGR-ERYSGT – North-Eastern East EPPO zone – 13-16 DA-B

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA330 1 0,48 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease incidence L4 - 15 DA-B										
Number of values	1	1	1	1	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	26,25	7,50	16,25	11,25						
Maximum value	26,25	7,50	16,25	11,25	0 >	0 >	0 >	1 >	0 >	0 >
Mean disease incidence (%)	26,25	7,50	16,25	11,25	1 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	71,43 %	38,10 %	57,14 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease incidence L3 - 13-15 DA-B										
Number of values	7	7	7	7	UT C	CA330 1	CA330 1	UT C	CA330 1	CA330 1

Minimum value	12,50	0,00	0,00	0,00		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	100,00	60,00	58,75	31,25	6 >	1 >	0 >	6 >	2 >	0 >
Mean disease incidence (%)	61,25	25,36	20,71	13,57	1 =	6 =	7 =	1 =	5 =	7 =
Abbott efficacy (%)	0,00%	70,82 %	77,08 %	82,57 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease incidence L2 - 13-15 DA-B										
Number of values	7	7	7	7	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	5,00	0,00	0,00	0,00						
Maximum value	98,75	57,50	35,00	27,50	5 >	0 >	0 >	5 >	1 >	0 >
Mean disease incidence (%)	56,25	13,04	8,04	6,25	2 =	7 =	7 =	2 =	6 =	7 =
Abbott efficacy (%)	0,00%	85,24 %	90,77 %	93,15 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease incidence L1 - 14-15 DA-B										
Number of values	4	4	4	4	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	11,25	0,00	0,00	0,00						
Maximum value	96,25	51,25	47,50	35,00	4 >	0 >	0 >	4 >	0 >	0 >
Mean disease incidence (%)	57,50	14,38	17,50	11,88	0 =	4 =	4 =	0 =	4 =	4 =
Abbott efficacy (%)	0,00%	84,16 %	78,73 %	86,15 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Table 3.2-104: Summary table – Minimum effective dose evaluation – Winter wheat – ERYSGR-ER-YSGT – North-Eastern East EPPO zone – 18-42 DA-B

Treatment name	UNTREATED CHECK	CA330 1 0,48 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate										
Rate unit										
Appl. Code										
% Disease incidence L2 - 18-42 DA-B										
Number of values	4	4	4	4	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	13,75	0,00	0,00	0,00						
Maximum value	100,00	10,00	8,75	5,00	3 >	0 >	0 >	3 >	0 >	0 >
Mean disease incidence (%)	55,00	6,88	3,44	1,56	1 =	4 =	4 =	1 =	4 =	4 =
Abbott efficacy (%)	0,00%	69,02 %	80,70 %	89,59 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease incidence L1 - 23-33 DA-B										
Number of values	5	5	5	5	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	10,00	1,25	0,00	0,00						
Maximum value	70,00	25,00	17,50	12,50	3 >	0 >	0 >	4 >	0 >	0 >
Mean disease incidence (%)	38,25	7,75	5,25	4,75	2 =	5 =	5 =	1 =	5 =	5 =
Abbott efficacy (%)	0,00%	80,35 %	85,89 %	84,38 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
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60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – – South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 10 trials evaluated the efficacy of CA3301 on winter wheat against *Blumeria graminis*. All 10 trials were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease incidence (%). Therefore, the minimum effective dose evaluation will be conducted from 10 trials considered as valid and assessing disease incidence on leaves.

CA3301 was first applied at crop stages BBCH 31-35 and the 2nd application was at BBCH 41-57. Two main assessment timings were selected: around two weeks after the 2nd application (14-15 DA-B) and the last timing close to harvest (27-47 DA-B). The analysis was conducted on the fourth main foliar levels L1, L2, L3 and L4.

Summary results are presented in Table 3.2-105 and

Table 3.2-106.

The fungicidal performance of CA3301 is globally higher when sprayed at 0.6 or 0.8 l/ha about 2 weeks after the 2nd application (14-15 DA-B), reaching:

- 94.83% efficacy at 0.6 l/ha and 100% efficacy at 0.8 l/ha on L4
- 60.87% efficacy at 0.6 l/ha and 66.43% efficacy at 0.8 l/ha on L3
- 84.69% efficacy at 0.6 l/ha and 87.13% efficacy at 0.8 l/ha on L2
- 100% efficacy at 0.6 or 0.8 l/ha on L1.

When sprayed at 0.6-0.8 l/ha at 27-47 DA-B, CA3301 reached:

- 100% efficacy at 0.6 l/ha and 100% efficacy at 0.8 l/ha on L3
- 49.31% efficacy at 0.6 l/ha and 54.98% efficacy at 0.8 l/ha on L2
- 70.53% efficacy at 0.6 l/ha and 78.21% efficacy at 0.8 l/ha on L1

An overall trend of decreasing disease incidence with increasing dose rates was observed in the dataset, in particular for 0.6 & 0.8 l/ha compared to 0.48 l/ha, with significant differences in several trials especially on L2. In addition, due to the importance of this disease and also the possibility of resistance in this pathogen, the higher rate with increased disease suppression may be considered more appropriate.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Blumeria graminis* on winter wheat in the South-Eastern East EPPO zone.

Table 3.2-105: Summary table – Minimum effective dose evaluation – Winter wheat – ERYSGR-ERYSGT – South-Eastern East EPPO zone – 14-15 DA-B

Treatment name	UNTREATED CHECK	CA330	CA330	CA330	No of trials where CA3301			No of trials where CA3301		
Rate		1	1	1	at 0,6 l/ha is >, = or			at 0,8 l/ha is >, = or		
Rate unit		L/ha	L/ha	L/ha	< compared to			< compared to		
Appl. Code		AB	AB	AB						
% Disease incidence L4 - 14-15 DA-B										
Number of values	2	2	2	2	UT	CA330	CA330	UT	CA330	CA330
Minimum value	13,75	0,00	1,25	0,00	C	0,48 l/ha	0,8 l/ha	C	0,48 l/ha	0,6 l/ha
Maximum value	100,00	5,00	1,25	0,00	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease incidence (%)	56,88	2,50	1,25	0,00	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	97,50%	94,83%	100,00 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease incidence L3 - 14-15 DA-B										
Number of values	9	9	9	9	UT	CA330	CA330	UT	CA330	CA330
					C	1	1	C	1	1

Minimum value	16,25	0,00	0,00	0,00		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	100,00	100,00	98,75	82,50	8 >	1 >	0 >	9 >	2 >	2 >
Mean disease incidence (%)	82,08	45,14	37,22	32,78	1 =	8 =	7 =	0 =	7 =	7 =
Abbott efficacy (%)	0,00%	49,46%	60,87%	66,43%	0 <	0 <	2 <	0 <	0 <	0 <
% Disease incidence L2 - 14-15 DA-B										
Number of values	9	9	9	9	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	20,00	0,00	0,00	0,00						
Maximum value	100,00	73,75	63,75	56,25	9 >	4 >	0 >	9 >	4 >	1 >
Mean disease incidence (%)	73,06	29,86	14,86	12,50	0 =	5 =	8 =	0 =	5 =	8 =
Abbott efficacy (%)	0,00%	65,25%	84,69%	87,13%	0 <	0 <	1 <	0 <	0 <	0 <
% Disease incidence L1 - 15 DA-B										
Number of values	2	2	2	2	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	6,25	0,00	0,00	0,00						
Maximum value	53,75	0,00	0,00	0,00	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease incidence (%)	30,00	0,00	0,00	0,00	1 =	2 =	2 =	1 =	2 =	2 =
Abbott efficacy (%)	0,00%	100,00 %	100,00 %	100,00 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%

60-80%

<60%

High efficacy

Medium efficacy

Low efficacy

Table 3.2-106: Summary table – Minimum effective dose evaluation – Winter wheat – ERYSGR-ER-YSGT – South-Eastern East EPPO zone – 27-47 DA-B

Treatment name	UNTREATED CHECK	CA330 1 0,48 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Rate						
Rate unit						
Appl. Code						
% Disease incidence L3 - 27 DA-B						
Number of values	1	1	1	1	UT C	CA330 1 0,48 l/ha
Minimum value	22,50	3,75	0,00	0,00		CA330 1 0,8 l/ha
Maximum value	22,50	3,75	0,00	0,00	1 >	UT C
Mean disease incidence (%)	22,50	3,75	0,00	0,00	0 =	CA330 1 0,48 l/ha
Abbott efficacy (%)	0,00%	83,33 %	100,00 %	100,00 %	0 <	CA330 1 0,6 l/ha
% Disease incidence L2 - 27-47 DA-B						
Number of values	8	8	8	8	UT C	CA330 1 0,48 l/ha
Minimum value	21,25	0,00	0,00	0,00		CA330 1 0,8 l/ha
Maximum value	100,00	100,00	92,50	86,25	7 >	UT C
Mean disease incidence (%)	89,94	66,41	50,47	44,84	1 =	CA330 1 0,48 l/ha
Abbott efficacy (%)	0,00%	33,38 %	49,31%	54,98%	0 <	CA330 1 0,6 l/ha
% Disease incidence L1 - 27-47 DA-B						
Number of values	8	8	8	8	UT C	CA330 1 0,48 l/ha
Minimum value	5,00	0,00	0,00	0,00		CA330 1 0,8 l/ha
Maximum value	100,00	83,75	77,50	62,50	7 >	UT C

Mean disease incidence (%)	70,63	40,47	29,22	21,56	1 =	5 =	5 =	1 =	3 =	5 =
Abbott efficacy (%)	0,00%	52,57 %	70,53%	78,21%	0 <	0 <	3 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

10 trials have been submitted to determine minimum effective dose in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,6-0,8 l/ha achieved medium to high efficacy in all assessments. The significant lower results were noted in case of dose rate of 0,48 l/ha. The test product at 0,48 l/ha was not effective after second application in 3 out of 10 trials on L3 and before harvest in 2 trials on L1.

17 trials were available to determine MED in **the North-East EPPO zone**. CA3301 applied at dose rate of 0,8 l/ha achieved consistently high efficacy while the lower dose of 0,6 l/ha had medium results in 7 out of 17 trials after 13-15 DA-B. The dose rate of 0,48 l/ha was effective on medium level after 18-42 DA-B in 4 out of 17 trials but an increase of dose to 0,6 l/ha caused higher effectiveness about 10%. In case of high disease pressure, the dose rate of 0,8 l/ha will come more benefits in control of ERYSGR.

10 trials were presented in **the South-East EPPO zone**. CA3301 applied at dose rate of 0,6-0,8 l/ha achieved similar results after second application (14-15 DA-B). The significant lower efficacy was noted after application of 0,48 l/ha on L2 in 9 out of 10 trials. The lowest dose rate was not effective with result of 49,46% on L3 while the higher doses had medium level of control. The similar trend was observed in second period of assessments. The test product at 0,48 l/ha achieved low efficacy after 27-47 DA-B while the dose rate of 0,6-0,8 l/ha had medium level in the same time. In 5 additional trials from the Mediterranean zone, significant lower efficacy was noted after application of dose rate of 0,48 l/ha in 4 out of 5 trials. CA3301 applied at dose rate of 0,6-0,8 l/ha achieved medium to high level of control in these assessments.

Taking into account all EPPO zones, the dose rate of 0,6 l/ha can be considered minimum effective dose to control of *Blumeria graminis* in winter wheat. It should be noted that the dose rate of 0,6 l/ha can be considered MED mainly in situation of low disease pressure. In more challenging conditions, the dose rate of 0,8 l/ha will be more justified.

3.2.2.27 Winter wheat (TRZAW) / *Fusarium culmorum* (FUSACU)

Between 2017 and 2020, a series of 20 trials were conducted in several countries of the Maritime, Mediterranean North-~~Eastern~~ East and South-~~Eastern~~ East EPPO zones to evaluate the minimum effective dose of CA3301 against *Fusarium culmorum* on winter wheat. The trials were carried out by certified testing institutes. The proposed rate is the range of 0.6-0.8 l/ha.

In the Maritime EPPO zone, a total of 6 trials were performed in Denmark (1), Germany (3) and the Czech Republic (2)

In the Mediterranean EPPO zone, 2 trials were performed in Portugal (2)

In the North-~~eastern~~ East EPPO zone, a total of 9 trials were performed in Poland (9)

In the South-~~eastern~~ East EPPO zone, a total of 3 trials were performed in Hungary (2) and Romania (1).

Out of the 20 trials performed on winter wheat against *Fusarium culmorum*, 15 were considered valid.

Min. Eff. Dose evaluation of CA3301 – – Maritime EPPO zone

In the Maritime EPPO zone, a total of 6 trials evaluated the efficacy of CA3301 on winter wheat against *Fusarium culmorum*. 3 trials were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 37-39 and the 2nd application was at BBCH 65-69. The analysis was conducted on ears.

Summary results are presented in Table 3.2-107.

Data demonstrated a better effect of 2 applications of CA3301 at 0.8 l/ha compared to lower dose rates for the reduction of disease severity on winter wheat against *Fusarium culmorum*.

On inoculated ears, CA3301 at 0.6-0.8 l/ha showed 81.81-83.81% mean efficacy against *Fusarium culmorum* around two weeks after the 2nd application. On uninoculated ears, CA3301 at 0.6-0.8 l/ha showed 75.31-84.63% efficacy against *Fusarium culmorum* around two weeks after the 2nd application.

In the Maritime EPPO zone, CA3301 at 0.6-0.8 l/ha showed medium to high efficacy in reducing the severity of *Fusarium culmorum* on winter wheat, whereas at 0.48 l/ha efficacy was medium. An overall trend of decreasing disease severity with increasing dose rates was observed in the dataset, in particular for 0.6 & 0.8 l/ha compared to 0.48 l/ha, although differences were not always significant. However, due to the importance of this disease the higher rate with increased disease suppression may be considered more appropriate.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Fusarium culmorum* on winter wheat in the Maritime EPPO zone.

Table 3.2-107: Summary table - Minimum effective dose evaluation – Winter wheat – FUSACU - Maritime EPPO zone

EARS zone										
Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA330 1 0,48 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity Ears I - 15-19 DA-B										
Number of values	3	3	3	3	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	5,60	0,92	0,49	0,37		3 >	0 >		0 >	3 >
Maximum value	62,71	16,75	14,64	13,92	0 =	3 =	3 =	0 =	3 =	3 =
Mean disease severity (%)	24,73	6,37	5,48	5,15	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	77,50 %	81,81 %	83,81 %						
% Disease severity Ears NI - 15-18 DA-B										
Number of values	2	2	2	2	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	1,20	0,41	0,33	0,21		2 >	0 >		0 >	2 >
Maximum value	8,00	1,44	1,75	1,06	0 =	2 =	2 =	0 =	1 =	2 =
Mean disease severity (%)	4,60	0,93	1,04	0,64	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	73,92 %	75,31 %	84,63 %						

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – Mediterranean EPPO zone

In the Mediterranean EPPO zone, a total of 2 trials evaluated the efficacy of CA3301 on winter wheat against *Fusarium culmorum*. Both trials were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 37-51 and the 2nd application was at BBCH 65-67. The analysis was conducted on ears.

Summary results are presented in Table 3.2-108.

In this somewhat limited dataset, the data did not demonstrate a statistically better effect of 2 applications of CA3301 at 0.8 l/ha compared to lower dose rates for the reduction of disease severity on winter wheat against *Fusarium culmorum*. On ears I, CA3301 at 0.6-0.8 l/ha showed 76.65-78.30% mean efficacy against *Fusarium culmorum* around two weeks after the 2nd application and 72.67-73.26% before harvest.

In the Mediterranean EPPO zone, CA3301 at 0.6-0.8 l/ha showed medium efficacy in reducing the severity of *Fusarium culmorum* on winter wheat. These positive effects of CA3301 at 0.6-0.8 l/ha to control *Fusarium culmorum* were overall statistically equivalent to the 0.48 l/ha dose rate for the disease severity in the 2 trials assessed here. However, against *Fusarium graminearum* an overall trend of decreasing disease severity with increasing dose rates was observed in particular for 0.6 & 0.8 l/ha compared to 0.48 l/ha. In addition, due to the importance of this disease the higher rates may be considered more appropriate than the 0.48 l/ha dose rate.

Considering all elements presented above and the data available in other EPPO zones, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Fusarium culmorum* on winter wheat in the Mediterranean EPPO zone.

Table 3.2-108: Summary table - Minimum effective dose evaluation – Winter wheat – FUSACU - Mediterranean EPPO zone

mean EPTO zone										
Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA330 1 0,48 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared		
% Disease severity Ears I - 15 DA-B										
Number of values	2	2	2	2	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	14,13	0,58	1,00	0,48		0 >	0 >		0 >	0 >
Maximum value	26,50	9,90	10,50	10,60	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	20,31	5,24	5,75	5,54	1 =	2 =	2 =	1 =	2 =	2 =
Abbott efficacy (%)	0,00%	79,27 %	76,65 %	78,30 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity Ears I - 25-29 DA-B										
Number of values	2	2	2	2	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	22,98	2,10	2,00	0,80		0 >	0 >		0 >	0 >
Maximum value	32,20	15,10	14,80	16,10	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	27,59	8,60	8,40	8,45	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	71,98 %	72,67 %	73,26 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 9 trials evaluated the efficacy of CA3301 on winter wheat against *Fusarium culmorum*. 7 trials were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 37-39 and the 2nd application was at BBCH 61-65. The analysis was conducted on ears.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rates for the reduction of disease severity on winter wheat against *Fusarium culmorum*, with statistical differences observed in particular on inoculated ears. On inoculated ears, CA3301 at 0.6-0.8 l/ha showed 73.07-78.48% mean efficacy against *Fusarium culmorum* around two weeks after the 2nd application and 52.84-67.99% mean efficacy before harvest. On uninoculated ears, CA3301 at 0.6-0.8 l/ha showed 73.96-78.26% mean efficacy against *Fusarium culmorum* around 2 weeks after the 2nd application and 61.55-75.59% mean efficacy before harvest.

In the North-Eastern East EPPO zone, CA3301 at 0.6-0.8 l/ha showed medium to high efficacy in reducing the severity of *Fusarium culmorum* on winter wheat. These positive effects of CA3301 at 0.6-0.8 l/ha to control *Fusarium culmorum* were overall superior than the 0.48 l/ha dose rate for the disease severity. In trials with high disease pressure, for example trials EU20-036-17 and EU20-036-18, there was a statistical benefit in increasing the dose rate from 0.6 to 0.8 l/ha. Therefore, it is envisaged that a dose rate of 0.6 l/ha may be sufficient in conditions of low to medium disease pressure but 0.8 l/ha is appropriate in conditions of high of disease pressure.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Fusarium culmorum* on winter wheat in the North-Eastern East EPPO zone.

Table 3.2-109: Summary table - Minimum effective dose evaluation – Winter wheat – FUSACU – North-Eastern East EPPo zone

North-Eastern East LTFO Zone										
Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA330 1 0,48 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity Ears I - 14-20 DA-B										
Number of values	7	7	7	7	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	7,49	2,80	2,29	1,76		7 >	5 >		0 >	7 >
Maximum value	38,58	13,56	11,02	7,60	0 =	2 =	5 =	0 =	2 =	5 =
Mean disease severity (%)	23,10	7,89	6,01	4,86		0 <	0 <		2 <	0 <
Abbott efficacy (%)	0,00%	65,04 %	73,07 %	78,48 %						
% Disease severity Ears I - 21-31 DA-B										
Number of values	4	4	4	4	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	10,81	6,04	4,11	2,60		4 >	2 >		0 >	4 >
Maximum value	71,35	50,64	38,92	22,53	0 =	2 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	51,57	29,49	25,52	17,47		0 <	0 <		3 <	0 <
Abbott efficacy (%)	0,00%	43,55 %	52,84 %	67,99 %						
% Disease severity Ears NI - 14-20 DA-B										
Number of values	4	4	4	4	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	2,84	0,70	0,56	0,40		3 >	0 >		0 >	3 >
Maximum value	16,25	2,75	2,25	1,75	1 =	4 =	4 =	1 =	4 =	4 =
Mean disease severity (%)	7,43	1,75	1,53	1,25		0 <	0 <		0 <	0 <
Abbott efficacy (%)	0,00%	69,56 %	73,96 %	78,26 %						
% Disease severity Ears NI - 21-31 DA-B										

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

In the South-Eastern East EPPO zone, a total of 3 trials evaluated the efficacy of CA3301 on winter wheat against *Fusarium culmorum*. 3 trials were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stage BBCH 39 and the 2nd application was at BBCH 65. The analysis was conducted on ears.

Data demonstrated a better effect of 2 applications of CA3301 at 0.8 l/ha compared to lower dose rates for the reduction of disease severity on winter wheat against *Fusarium culmorum*. On inoculated ears, CA3301 at 0.6-0.8 l/ha showed 84.94-89.80% mean efficacy against *Fusarium culmorum* around two weeks after the 2nd application. On uninoculated ears, CA3301 at 0.6-0.8 l/ha showed 74.80-79.11% efficacy against *Fusarium culmorum* before harvest.

In the South-Eastern East EPPo zone, CA3301 at 0.6-0.8 l/ha showed medium to high efficacy in reducing the severity of *Fusarium culmorum* on winter wheat. These positive effects of CA3301 at 0.6-0.8 l/ha to control *Fusarium culmorum* were overall superior than the 0.48 l/ha dose rate for the disease severity. In addition, in the trial with the highest disease severity the rate of 0.8 L/ha was significantly more effective in reducing disease compared to the other dose rates. Therefore, it is envisaged that a dose rate of 0.6 l/ha may be sufficient in conditions of low to medium disease pressure but 0.8 l/ha is appropriate in conditions of high of disease pressure.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Fusarium culmorum* on winter wheat in the South-Eastern East EPPO zone.

Treatment name	UNTREATED CHECK	CA330	CA330	CA330	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		1	1	1						
Rate unit		0,48	0,6	0,8						
Appl. Code		L/ha	L/ha	L/ha						
		AB	AB	AB						
% Disease severity Ears I - 14-15 DA-B										
Number of values	2	2	2	2	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	21,68	1,61	1,34	1,16		1 >	0 >		2 >	1 >
Maximum value	64,31	20,47	15,39	9,68	2 >	1 >	0 >	2 >	1 >	1 >
Mean disease severity (%)	42,99	11,04	8,36	5,42	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	80,37 %	84,94 %	89,80 %	0 <	0 <	1 <	0 <	0 <	0 <
% Disease severity Ears NI - 21-25 DA-B										

Number of values	3	3	3	3	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	25,26	1,72	1,38	1,17						
Maximum value	66,22	21,73	16,53	12,70	3 >	1 >	0 >	3 >	1 >	1 >
Mean disease severity (%)	40,61	12,84	10,54	8,19	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	70,25 %	74,80 %	79,11 %	0 <	0 <	1 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – — Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this case, a total of 14 trials evaluated the efficacy of CA3301 on winter wheat against *Fusarium culmorum*. 10 trials out of 14 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 37-39 and the 2nd application was at BBCH 61-69. The analysis was conducted on ears.

Summary results are presented in Table 3.2-111.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rates for the reduction of disease severity on winter wheat against *Fusarium culmorum*. On inoculated ears, CA3301 at 0.6-0.8 l/ha showed 75.69-80.08% mean efficacy against *Fusarium culmorum* around two weeks after the 2nd application and 52.84-67.99% mean efficacy before harvest. On uninoculated ears, CA3301 at 0.6-0.8 l/ha showed 74.41-80.38% mean efficacy against *Fusarium culmorum* around 2 weeks after the 2nd application and 61.55-75.59% before harvest.

In Poland and neighbouring countries, CA3301 at 0.6-0.8 l/ha showed medium to high efficacy in reducing the severity of *Fusarium culmorum* on winter wheat. These positive effects of CA3301 at 0.6-0.8 l/ha to control *Fusarium culmorum* were overall superior than the 0.48 l/ha dose rate for the disease severity. In trials with high disease pressure for example trials EU20-036-17 and EU20-036-18 there was a statistical benefit in increasing the dose rate from 0.6 to 0.8 l/ha. Therefore, it is envisaged that a dose rate of 0.6 l/ha may be sufficient in conditions of low to medium disease pressure but 0.8 l/ha is appropriate in conditions of high of disease pressure.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Fusarium culmorum* on winter wheat in Poland.

Table 3.2-111: Summary table - Minimum effective dose evaluation – Winter wheat – FUSACU – Data relevant for Poland

Relevant for Poland										
Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA330 1 0,48 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity Ears I - 14-20 DA-B										
Number of values	10	10	10	10	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	5,60	0,92	0,49	0,37						
Maximum value	62,71	16,75	14,64	13,92	10 >	5 >	0 >	10 >	5 >	2 >

Mean disease severity (%)	23,59	7,43	5,85	4,94	0 =	5 =	8 =	0 =	5 =	8 =
Abbott efficacy (%)	0,00%	68,78 %	75,69 %	80,08 %	0 <	0 <	2 <	0 <	0 <	0 <
% Disease severity Ears I - 21-31 DA-B										
Number of values	4	4	4	4	UT	CA330 1	CA330 1	UT	CA330 1	CA330 1
Minimum value	10,81	6,04	4,11	2,60	C	0,48 l/ha	0,8 l/ha	C	0,48 l/ha	0,6 l/ha
Maximum value	71,35	50,64	38,92	22,53	4 >	2 >	0 >	4 >	3 >	3 >
Mean disease severity (%)	51,57	29,49	25,52	17,47	0 =	2 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	43,55 %	52,84 %	67,99 %	0 <	0 <	3 <	0 <	0 <	0 <
% Disease severity Ears NI - 15-20 DA-B										
Number of values	6	6	6	6	UT	CA330 1	CA330 1	UT	CA330 1	CA330 1
Minimum value	1,20	0,41	0,33	0,21	C	0,48 l/ha	0,8 l/ha	C	0,48 l/ha	0,6 l/ha
Maximum value	16,25	2,75	2,25	1,75	5 >	0 >	0 >	5 >	1 >	0 >
Mean disease severity (%)	6,48	1,48	1,36	1,04	1 =	6 =	6 =	1 =	5 =	6 =
Abbott efficacy (%)	0,00%	71,01 %	74,41 %	80,38 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity Ears NI - 21-31 DA-B										
Number of values	4	4	4	4	UT	CA330 1	CA330 1	UT	CA330 1	CA330 1
Minimum value	2,50	0,63	1,25	0,63	C	0,48 l/ha	0,8 l/ha	C	0,48 l/ha	0,6 l/ha
Maximum value	28,75	16,25	13,75	11,25	3 >	0 >	0 >	3 >	2 >	0 >
Mean disease severity (%)	13,98	6,30	5,52	4,06	1 =	4 =	4 =	1 =	2 =	4 =
Abbott efficacy (%)	0,00%	63,85 %	61,55 %	75,59 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

3 trials have been submitted to determine minimum effective dose in **the Maritime EPPO climatic zone**. In case of inoculated ears, CA3301 applied at dose rate of 0,6-0,8 l/ha achieved high efficacy while the dose rate of 0,48 l/ha had medium level of control in all trials. In case of uninoculated ears, the dose rate of 0,6 l/ha showed medium efficacy, comparable to result at 0,48 l/ha. The dose rate of 0,8 l/ha will come more benefits in unfavorable conditions.

7 trials were presented to determine MED in **the North-East EPPO zone**. CA3301 applied at dose rate of 0,48-0,8 l/ha achieved medium efficacy. The slight differences were visible on inoculated and uninoculated ears after 14-20 days after second application. The dose rate of 0,6-0,8 l/ha showed results of >70% while >60% was noted for 0,48 l/ha. The dose rate of 0,8 l/ha will come more benefits in unfavorable conditions.

3 trials were available to determine MED in **the South-East EPPO zone**. No significant differences between dose rates were noted. CA3301 applied at 0,48-0,8 l/ha achieved high efficacy in assessments on inoculated ears after 14-15 DA-B and medium level of control on uninoculated ears (21-25 DA-B). Also 2 additional trials from the Mediterranean zone showed medium efficacy of CA3301 at 0,48-0,8 l/ha, either on inoculated and uninoculated ears.

Taking into account all EPPO zones, the dose rate of 0,6 l/ha can be considered minimum effective dose to control of *Fusarium culmorum* in winter wheat. It should be noted that the dose rate of 0,6 l/ha can be considered MED mainly in situation of low disease pressure. In more challenging conditions, the dose rate of 0,8 l/ha will be more

justified.

3.2.2.28 Winter wheat (TRZAW) / *Fusarium graminearum* (GIBBZE)

Between 2017 and 2020, a series of 25 trials were conducted in several countries of the Maritime, Mediterranean North-Eastern East and South-Eastern East EPPO zones to evaluate the minimum effective dose of CA3301 against *Fusarium graminearum* on winter wheat. The trials were carried out by certified testing institutes. The proposed rate is the range of 0.6-0.8 l/ha.

In the Maritime EPPO zone, a total of 6 trials were performed in the Czech Republic (1), in Germany (2) and in the United Kingdom (3)

In the Mediterranean EPPO zone, 10 trials were performed in the south of France (1), in Italy (3) in Spain (2) and in Portugal (4)

In the North-Eastern East EPPO zone, a total of 4 trials were performed in Latvia (2) and in Poland (2)

In the South-Eastern East EPPO zone, a total of 6 trials were performed in Hungary (3) and in Romania (3).

Out of the 25 trials performed on winter wheat against *Fusarium graminearum*, 24 were considered valid.

Min. Eff. Dose evaluation of CA3301 – Maritime EPPO zone

In the Maritime EPPO zone, a total of 6 trials evaluated the efficacy of CA3301 on winter wheat against *Fusarium graminearum*. 5 trials were considered valid and enabled to determine the efficacy of several dose rates of CA3301 (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 37-41 and the 2nd application was at BBCH 61-65. The analysis was conducted on ears.

Summary results are presented in Table 3.2-112.

Data did not demonstrate a statistically better effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to the lower dose rate for the reduction of disease severity on winter wheat against *Fusarium graminearum*. However, in the dataset available regarding uninoculated ears, the rates of 0.6 & 0.8 l/ha gave higher numerical disease control than 0.48 l/ha.

On inoculated ears, CA3301 at 0.6-0.8 l/ha showed 67.88-69.00% mean efficacy against *Fusarium graminearum* around two weeks after the 2nd application and 55.00-60.48% mean efficacy at the last assessment timing. On uninoculated ears, CA3301 at 0.6-0.8 l/ha showed 71.69-67.15% mean efficacy against *Fusarium graminearum* around two weeks after the 2nd application and 71.66-71.15% mean efficacy at the last assessment timing.

In the Maritime EPPO zone, CA3301 at 0.6-0.8 l/ha showed medium efficacy in reducing the severity of *Fusarium graminearum* on winter wheat. These positive effects of CA3301 at 0.6-0.8 l/ha were overall statistically equivalent to the 0.48 l/ha dose rate. Over this dataset, the disease pressure was low to medium, therefore the performance of the tested product in conditions of relatively high pressure could not be assessed. However, in the supportive dataset available against *Fusarium culmorum*, an overall trend of decreasing disease severity with increasing dose rates was observed in particular for 0.6 & 0.8 l/ha compared to 0.48 l/ha. The same trend would be expected for *Fusarium graminearum* at higher disease levels. In addition, due to the importance of this disease the higher rates may be considered more appropriate than the 0.48 l/ha dose rate.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Fusarium graminearum* on winter wheat in the Maritime EPPO zone.

Table 3.2-112: Summary table - Minimum effective dose evaluation – Winter wheat – GIBBZE - Maritime EPPO zone

Treatment name Rate	UNTREATED CHECK	CA330 1	CA330 1	CA330 1	
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Rate unit		0,48 L/ha AB	0,6 L/ha AB	0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Appl. Code										
% Disease severity Ears I - 15-19 DA-B										
Number of values	4	4	4	4	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	1,51	0,32	0,17	0,20						
Maximum value	6,07	4,14	4,37	3,41	4 >	0 >	0 >	4 >	0 >	0 >
Mean disease severity (%)	3,28	1,39	1,42	1,21	0 =	4 =	4 =	0 =	4 =	4 =
Abbott efficacy (%)	0,00%	66,57 %	67,88 %	69,00 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity Ears I - 22-34 DA-B										
Number of values	5	5	5	5	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	4,19	2,36	2,20	1,22						
Maximum value	82,74	58,31	62,93	73,07	4 >	0 >	0 >	3 >	0 >	0 >
Mean disease severity (%)	38,32	21,79	20,73	22,47	1 =	5 =	5 =	2 =	4 =	5 =
Abbott efficacy (%)	0,00%	52,52 %	55,00 %	60,48 %	0 <	0 <	0 <	0 <	1 <	0 <
% Disease severity Ears NI - 15 DA-B										
Number of values	2	2	2	2	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	2,22	0,77	0,56	0,53						
Maximum value	2,36	0,84	0,73	0,96	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	2,29	0,80	0,65	0,74	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	64,86 %	71,69 %	67,15 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity Ears NI - 22-34 DA-B										
Number of values	3	3	3	3	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	2,56	0,00	0,00	0,00						
Maximum value	63,13	48,44	39,06	46,56	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	24,05	16,75	13,52	15,80	1 =	3 =	3 =	1 =	3 =	3 =
Abbott efficacy (%)	0,00%	65,01 %	71,66 %	71,15 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – Mediterranean EPPO zone

In the Mediterranean EPPO zone, a total of 10 trials evaluated the efficacy of CA3301 on winter wheat against *Fusarium graminearum*. All 10 trials were considered valid and enabled to determine the efficacy of several dose rates of CA3301 (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 37-39 and the 2nd application was at BBCH 59-69. The analysis was conducted on ears.

Summary results are presented in Table 3.2-113.

Data did not always demonstrate a statistically better effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to the lower dose rate for the reduction of disease severity on winter wheat against *Fusarium*

graminearum. On inoculated ears, CA3301 at 0.6-0.8 l/ha showed 56.17-64.15% mean efficacy against *Fusarium graminearum* around two weeks after the 2nd application and 49.83-61.70% mean efficacy at the last assessment timing. On ears non-inoculated, CA3301 at 0.6-0.8 l/ha showed 60.44-61.26% mean efficacy against *Fusarium graminearum* around two weeks after the 2nd application and 48.73-57.68% mean efficacy at the last assessment timing.

In the Mediterranean EPPO zone, CA3301 at 0.6-0.8 l/ha showed medium efficacy in reducing the severity of *Fusarium graminearum* on winter wheat. An overall trend of decreasing disease severity with increasing dose rates was observed in the dataset, in particular for 0.6 & 0.8 l/ha compared to 0.48 l/ha, although differences were not always significant. However, due to the importance of this the higher rate with increased disease suppression may be considered more appropriate.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Fusarium graminearum* on winter wheat in the Mediterranean EPPO zone.

Table 3.2-113: Summary table - Minimum effective dose evaluation – Winter wheat – GIBBZE - Mediterranean EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA330 1 0,48 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity Ears I - 14-19 DA-B										
Number of values	9	9	9	9	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	1,12	0,28	0,21	0,26	6 >	0 >	0 >	6 >	0 >	0 >
Maximum value	27,95	15,10	14,75	17,50	3 =	9 =	9 =	3 =	9 =	9 =
Mean disease severity (%)	11,87	5,86	5,13	4,49	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	53,38 %	56,17 %	64,15 %						
% Disease severity Ears I - 25-36 DA-B										
Number of values	9	9	9	9	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	4,44	0,66	1,05	0,99	5 >	0 >	0 >	7 >	2 >	2 >
Maximum value	44,36	41,74	40,18	32,97	4 =	9 =	7 =	2 =	7 =	7 =
Mean disease severity (%)	18,79	11,97	11,07	9,37	0 <	0 <	2 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	45,89 %	49,83 %	61,70 %						
% Disease severity Ears NI - 16 DA-B										
Number of values	3	3	3	3	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	4,06	2,50	1,56	1,56	3 >	2 >	0 >	3 >	2 >	0 >
Maximum value	41,88	28,94	17,50	18,63	0 =	1 =	3 =	0 =	1 =	3 =
Mean disease severity (%)	19,38	13,19	7,92	8,08	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	34,21 %	60,44 %	61,26 %						
% Disease severity Ears NI - 25-36 DA-B										
Number of values	5	5	5	5	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	4,06	0,00	0,00	0,00	2 >	0 >	0 >	3 >	0 >	1 >
Maximum value	38,13	24,78	18,44	17,56	3 =	4 =	4 =	2 =	5 =	4 =
Mean disease severity (%)	19,50	10,99	10,70	9,20	0 <	1 <	1 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	51,31 %	48,73 %	57,68 %						

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 4 trials evaluated the efficacy of CA3301 on winter wheat against *Fusarium graminearum*. All 4 trials were considered valid and enabled to determine the efficacy of several dose rates of CA3301 (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 39 and the 2nd application was at BBCH 61-65. The analysis was conducted on ears.

Summary results are presented in Table 3.2-114.

Data overall demonstrated higher control of *Fusarium graminearum* from 2 applications of CA3301 at 0.6-0.8 l/ha compared to the lower dose rate. On inoculated ears, CA3301 at 0.6-0.8 l/ha showed 51.50-63.45% mean efficacy around two weeks after the 2nd application and 41.60-47.93% mean efficacy at the last assessment timing. On uninoculated ears, CA3301 at 0.6-0.8 l/ha showed 69.12-79.05% mean efficacy against *Fusarium graminearum* around two weeks after the 2nd application and 67.12-71.73% mean efficacy at the last assessment timing.

In the North-Eastern East EPPO zone, CA3301 at 0.6-0.8 l/ha showed low to medium efficacy in reducing the severity of *Fusarium graminearum* on winter wheat. Applied at 0.48 l/ha efficacy was low across the data groupings. An overall trend of decreasing disease severity with increasing dose rates was observed in the dataset, in particular for 0.8 l/ha which was often statistically more efficient compared to 0.6 l/ha and 0.48 l/ha, although differences were not always significant especially between the 2 lower dose rates. Due to the importance of this disease the higher rate with increased disease suppression may be considered more appropriate, especially in trials with high disease pressure.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Fusarium graminearum* on winter wheat in the North-Eastern East EPPO zone.

Table 3.2-114: Summary table - Minimum effective dose evaluation – Winter wheat – GIBBZE – North-Eastern East EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA330 1 0,48 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity Ears I - 15 DA-B										
Number of values	4	4	4	4	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	5,70	2,64	2,06	1,52	4 >	1 >	0 >	4 >	3 >	1 >
Maximum value	19,78	15,49	13,25	9,56	0 =	3 =	3 =	0 =	1 =	3 =
Mean disease severity (%)	13,83	8,49	7,05	5,24	0 <	0 <	1 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	41,19 %	51,50 %	63,45 %						
% Disease severity Ears I - 29 DA-B										
Number of values	2	2	2	2	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	28,52	23,33	17,33	16,96	2 >	0 >	0 >	2 >	1 >	0 >
Maximum value	49,54	33,54	27,76	22,13						

Mean disease severity (%)	39,03	28,44	22,54	19,55	0 =	2 =	2 =	0 =	1 =	2 =
Abbott efficacy (%)	0,00%	25,25 %	41,60 %	47,93 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity Ears NI - 15 DA-B										
Number of values	3	3	3	3	UT	CA330 1	CA330 1	UT	CA330 1	CA330 1
Minimum value	2,29	1,35	0,83	0,46	C	0,48 l/ha	0,8 l/ha	C	0,48 l/ha	0,6 l/ha
Maximum value	5,56	1,71	1,69	1,51	3 >	0 >	0 >	3 >	0 >	0 >
Mean disease severity (%)	4,22	1,54	1,25	0,91	0 =	3 =	3 =	0 =	3 =	3 =
Abbott efficacy (%)	0,00%	59,29 %	69,12 %	79,05 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity Ears NI - 29 DA-B										
Number of values	2	2	2	2	UT	CA330 1	CA330 1	UT	CA330 1	CA330 1
Minimum value	6,20	2,94	2,13	1,95	C	0,48 l/ha	0,8 l/ha	C	0,48 l/ha	0,6 l/ha
Maximum value	9,19	3,08	2,64	2,19	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	7,69	3,01	2,38	2,07	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	59,17 %	67,12 %	71,73 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 6 trials evaluated the efficacy of CA3301 on winter wheat against *Fusarium graminearum*. All 6 trials were considered valid and enabled to determine the efficacy of several dose rates of CA3301 (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 37-39 and the 2nd application was at BBCH 59-65. The analysis was conducted on ears.

Summary results are presented in Table 3.2-115.

Data demonstrated a better effect of 2 applications of CA3301 at 0.8 l/ha compared to lower dose rates for the reduction of disease severity on winter wheat against *Fusarium graminearum*. On inoculated ears, CA3301 at 0.6-0.8 l/ha showed 73.77-80.97% mean efficacy around two weeks after the 2nd application and 63.66-75.21% mean efficacy at the last assessment timing. On uninoculated ears, CA3301 at 0.6-0.8 l/ha showed 80.00-91.30% efficacy against *Fusarium graminearum* around two weeks after the 2nd application and 47.53-71.14% efficacy at the last assessment timing.

In the South-Eastern East EPPO zone, CA3301 at 0.6-0.8 l/ha showed medium to high efficacy in reducing the severity of *Fusarium graminearum* on winter wheat. A clear dose effect was observed with CA3301 at 0.8 l/ha which gave in overall significantly higher disease control than the 2 lower dose rates and the 0.6 l/ha showed also a higher disease infection reduction than the 0.48 l/ha dose rate to control *Fusarium graminearum*. Therefore, the higher rate of 0.8 l/ha is more appropriate in situations of high disease pressure, but in case of low disease pressure the 0.6 l/ha rate might be sufficient to obtain an acceptable level of disease control.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Fusarium graminearum* on winter wheat in the South-Eastern East EPPO zone.

Table 3.2-115: Summary table - Minimum effective dose evaluation – Winter wheat – GIBBZE – South-Eastern East EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA330 1 0,48 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity Ears I - 15-17 DA-B										
Number of values	4	4	4	4	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	6,11	1,84	1,34	0,91	4 >	2 >	0 >	4 >	3 >	2 >
Maximum value	35,00	10,50	7,00	5,50	0 =	2 =	2 =	0 =	1 =	2 =
Mean disease severity (%)	13,83	4,54	3,21	2,43	0 <	0 <	2 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	64,15 %	73,77 %	80,97 %						
% Disease severity Ears I - 23-28 DA-B										
Number of values	5	5	5	5	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	6,72	3,40	2,71	1,75	5 >	3 >	0 >	5 >	5 >	4 >
Maximum value	17,61	14,02	9,54	5,72	0 =	2 =	1 =	0 =	0 =	1 =
Mean disease severity (%)	12,36	6,16	4,62	3,12	0 <	0 <	4 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	52,52 %	63,66 %	75,21 %						
% Disease severity Ears NI - 15 DA-B										
Number of values	1	1	1	1	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	28,75	13,75	5,75	2,50	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	28,75	13,75	5,75	2,50	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	28,75	13,75	5,75	2,50	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	52,17 %	80,00 %	91,30 %						
% Disease severity Ears NI - 24 DA-B										
Number of values	1	1	1	1	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	19,06	13,13	10,00	5,50	1 >	1 >	0 >	1 >	1 >	1 >
Maximum value	19,06	13,13	10,00	5,50	0 =	0 =	0 =	0 =	0 =	0 =
Mean disease severity (%)	19,06	13,13	10,00	5,50	0 <	0 <	1 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	31,11 %	47,53 %	71,14 %						

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

5 trials have been submitted to determine minimum effective dose in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,48-0,8 l/ha achieved medium efficacy. The slight differences between results were visible in case of uninoculated ears. The dose rate of 0,6-0,8 l/ha had level control of >70% while the dose of 0,48 l/ha had >60%. The test product at 0,48-0,6 l/ha was not effective after 22-34 DA-B (on inoculated ears).

4 trials were available to determine MED in **the North-East EPPO zone**. CA3301 applied at dose rate of 0,48 l/ha showed very low efficacy on uninoculated ears after 15-29 DA-B. The higher dose rate of 0,6-0,8 l/ha achieved

medium efficacy. In case of inoculated ears, the effectiveness was insufficient at dose rate of 0,48-0,6 l/ha after 15 DA-B in 4 trials. However, the results from neighbouring countries showed medium level of control at dose rate of 0,6 l/ha.

6 trials were presented to determine MED in the **South-East EPPO zone**. CA3301 applied at dose rate of 0,48 l/ha was not effective to control GIBBZE in some trials, either on inoculated and uninoculated ears. The dose rate of 0,6-0,8 l/ha showed medium to high level of control.

Taking into account all EPPO zones, the dose rate of 0,6 l/ha can be considered minimum effective dose to control of *Fusarium graminearum* in winter wheat. It should be noted that the dose rate of 0,6 l/ha can be considered MED mainly in situation of low disease pressure. In more challenging conditions, the dose rate of 0,8 l/ha will be more justified.

3.2.2.29 Winter wheat (TRZAW) / *Fusarium sp* (FUSASP)

Between 2017 and 2020, a series of 6 trials were conducted in several countries of the Maritime, Mediterranean and South-Eastern East EPPO zones to evaluate the minimum effective dose of CA3301 against *Fusarium sp.* on winter wheat. The trials were carried out by certified testing institutes.

Fusarium sp. trials were trials with an artificial inoculation of a mix of *Fusarium* species (*Fusarium culmorum* and *Fusarium graminearum*) or trials with a natural infestation where the species has not been identified. The proposed rate is the range of 0.6-0.8 l/ha.

In the Maritime EPPO zone, a total of 2 trials were performed in the Czech Republic (1) and France (1)

In the Mediterranean EPPO zone, 1 trial was performed in Italy (1)

In the South-eastern East EPPO zone, a total of 3 trials were performed in Hungary (3)

Out of the 6 trials performed on winter wheat against *Fusarium sp.*, 4 were considered valid.

Min. Eff. Dose evaluation of CA3301 – Maritime EPPO zone

In the Maritime EPPO zone no data were available to support the minimum effective dose evaluation several dose rates of CA3301 (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). However, since *Fusarium* spp. including *F. culmorum* and *F. graminearum* belong to the same *Ascomycota* phylum and since in the fields a complex of disease is often observed on ears for these three fungi instead of an individual disease, it is possible to extrapolate from the dataset presented in the *Fusarium graminearum* and *Fusarium culmorum* sections.

Against the related pathogen *Fusarium culmorum* an overall trend of decreasing disease severity with increasing dose rates was observed in particular for 0.6 & 0.8 l/ha compared to 0.48 l/ha. The same trend would be expected for *Fusarium sp.* and due to the importance of this disease the higher rates may be considered more appropriate than the 0.48 l/ha dose rate.

Considering all elements presented above and the dataset previously presented against *Fusarium culmorum*, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Fusarium sp.* on winter wheat in the Maritime EPPO zone.

Min. Eff. Dose evaluation of CA3301 – Mediterranean EPPO zone

In the Mediterranean EPPO zone, 1 trial evaluated the efficacy of CA3301 on winter wheat against *Fusarium sp.*. The trial was considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stage BBCH 30 and the 2nd application was at BBCH 49. The analysis was conducted on ears.

Summary results are presented in Table 3.2-116.

Data did not demonstrated a better effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rates for the reduction of disease severity on winter wheat against *Fusarium sp.* However the targeted disease of this trial was not *Fusarium sp.* initially, which explain the late infestation and the fact that the applications were not performed at an optimal timing to control this disease. On uninoculated ears, CA3301 at 0.6-0.8 l/ha showed 66.37-40.36% of efficacy against *Fusarium sp.* before harvest. These positive effects of CA3301 at 0.6-0.8 l/ha to control *Fusarium sp.* were equivalent to the 0.48 l/ha dose rate for the disease severity.

In the Mediterranean EPPO zone only a single trial was available for assessment of undetermined *Fusarium sp.* However, the reference product demonstrated an acceptable efficacy in this trial, therefore the data has been included. According to the statistical analysis, the three rates of CA3301 were comparable to each other. In this single trial, where infection occurred late and disease severity was low, CA3301 demonstrated medium to low efficacy. Whilst a single trial is insufficient to evaluate the minimum effective dose, the tested product nevertheless also demonstrated comparable efficacy from CA3301 dose rates on the related pathogen *Fusarium graminearum* but with a higher disease suppression from the rate of 0.8 l/ha compared to 0.6 l/ha.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Fusarium sp.* on winter wheat in the Mediterranean EPPO zone.

Table 3.2-116: Summary table – Minimum effective dose evaluation – Winter wheat – FUSASP – Mediterranean EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA33 01 0,48 L/ha AB	CA33 01 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity Ears NI - 35 DA-B										
Number of values	1	1	1	1	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	7,88	3,95	2,65	4,70	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	7,88	3,95	2,65	4,70	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	7,88	3,95	2,65	4,70	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	49,87 %	66,37 %	40,36%						

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – North-Eastern East EPPO zone

In the North-Eastern East EPPO zone no data were available to support the minimum effective dose evaluation several dose rates of CA3301 (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). However, since *Fusarium* spp. including *F. culmorum* and *F. graminearum* belong to the same *Ascomycota* phylum and since in the fields a complex of disease is often observed on ears for these three fungi instead of an individual disease, it is possible to extrapolate from the dataset presented in the *Fusarium graminearum* and *Fusarium culmorum* sections.

In the North-Eastern East EPPO zone, 9 supportive trials demonstrated that CA3301 at 0.6-0.8 l/ha showed medium to high efficacy in reducing the severity of *Fusarium culmorum* on winter wheat. Moreover, a statistical benefit to control the disease was observed with increasing the dose rate from 0.6 to 0.8 l/ha.

In addition, a supportive dataset of 4 trials showed that CA3301 at 0.6-0.8 l/ha showed low to medium efficacy in reducing the severity of *Fusarium graminearum* on winter wheat. An overall trend of decreasing disease severity with increasing dose rates was observed in the dataset, in particular for 0.8 l/ha, although differences were not always significant.

Therefore, it was envisaged that a dose rate of 0.6 l/ha may be sufficient in conditions of low to medium disease pressure but 0.8 l/ha is more appropriate in conditions of high of disease pressure due to the impact of this disease on seed quality.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Fusarium sp.* on winter wheat in the North-Eastern East EPPO zone.

Min. Eff. Dose evaluation of CA3301 – South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 3 trials evaluated the efficacy of CA3301 on winter wheat against *Fusarium sp.*. The trials were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0,8N) applied twice) on pest severity (%). CA3301 was first applied at crop stages BBCH 39-47 and the 2nd application was at BBCH 65. The analysis was conducted on ears.

Summary results are presented in Table 3.2-117.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rates for the reduction of disease severity on winter wheat against *Fusarium sp.* On inoculated ears, CA3301 at 0.6-0.8 l/ha showed 52.14-67.75% mean efficacy against *Fusarium sp.* around two weeks after the 2nd application. On uninoculated ears, CA3301 at 0.6-0.8 l/ha provided a full disease control before harvest.

In the South-East EPPO zone, CA3301 at 0.6-0.8 l/ha showed low to high efficacy in reducing the severity of *Fusarium sp.* on winter wheat. These positive effects of CA3301 at 0.6-0.8 l/ha to control *Fusarium sp.* were overall superior than the 0.48 l/ha dose rate for the disease severity but this dataset was low and consequently inadequate for the evaluation of CA3301. A supportive dataset of 6 trials targeting *F. graminearum* demonstrated that the higher rate of 0.8 l/ha is more appropriate in situations of high disease pressure, but in case of low disease pressure the 0.6 l/ha rate might be sufficient to obtain an acceptable level of disease control.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Fusarium sp.* on winter wheat in the South-Eastern East EPPO zone.

Table 3.2-117: Summary table – Minimum effective dose evaluation – Winter wheat – FUSASP – South-Eastern East EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < com- pared to		
% Disease severity Ears I - 17 DA-B										
Number of values	2	2	2	2	UTC	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	34,75	23,24	16,53	12,21		2 >	2 >	0 >	2 >	2 >
Maximum value	72,30	41,85	34,82	21,23	0 =	0 =	0 =	0 =	0 =	0 =
Mean disease severity (%)	53,53	32,55	25,67	16,72	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	37,62%	52,14%	67,75%						
% Disease severity Ears NI - 27 DA-B										
Number of values	1	1	1	1	UTC	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	1,11	0,00	0,00	0,00		1 >	0 >	0 >	1 >	0 >
Maximum value	1,11	0,00	0,00	0,00						

Mean disease severity (%)	1,11	0,00	0,00	0,00	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	100,00%	100,00%	100,00%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

The limited number of trials have been submitted to determine minimum effective dose to control of *Fusarium* sp. in winter wheat. Only 3 trials were available in **the South-East EPPO climatic zone**. CA3301 applied at dose rate of 0,48-0,6 l/ha achieved very low efficacy while higher dose of 0,8 l/ha had medium level of control of pathogen in 2 out of 3 trials. On uninoculated ears, the results showed an effectiveness of 100% for all dose rates. No trials have been submitted in other EPPO zones. However, the trials conducted on *Fusarium culmorum* and *Fusarium graminearum* can support of product registration for this use.

Taking into account all trials, the dose rate of 0,6 l/ha can be considered minimum effective dose to control of *Fusarium* sp. in winter wheat. It should be noted that the dose rate of 0,6 l/ha can be considered MED mainly in situation of low disease pressure. In more challenging conditions, the dose rate of 0,8 l/ha will be more justified.

3.2.2.30 Winter wheat (TRZAW) / *Pyrenophora tritici-repentis* (PYRNTR)

Between 2017 and 2020, a series of 16 trials were conducted in several countries of the Maritime, North-Eastern East and South-Eastern East EPPO zones to evaluate the minimum effective dose of CA3301 against *Pyrenophora tritici-repentis* on winter wheat. The trials were carried out by certified testing institutes. The proposed rate is the range of 0.6-0.8 l/ha.

In the Maritime EPPO zone, 2 trials were performed in Czech Republic.

In the North-Eastern East EPPO zone, a total of 12 trials were performed in Lithuania (5), Latvia (6) and Poland (1).

In the South-Eastern East EPPO zone, 2 trials were performed in Romania (1) and Slovakia (1).

Out of the 16 trials carried out against *Pyrenophora tritici-repentis* (PYRNTR) on winter wheat, 11 were considered valid.

Min. Eff. Dose evaluation of CA3301 – Maritime EPPO zone

In the Maritime EPPO zone, a single valid trial had a level of disease severity higher than 5% and was included to support evaluation of CA3301. Several dose rates (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). CA3301 was first applied at crop stages BBCH 32 and the 2nd application was at BBCH 41. A single assessment timing was available, at the last timing close to harvest (35 DA-B) and the analysis could be conducted only on foliar level 1 (L1).

Summary results are presented in Table 3.2-118.

When evaluating the reduction of disease severity, the analysis could be conducted only in one trial because data were statistically equivalent to the untreated control for all treatments in the other trial (EU18-039-02). However, the data demonstrated that the highest fungicidal effect on *Pyrenophora tritici-repentis* was provided after two applications of CA3301 at 0.6-0.8 l/ha, despite the high level of infestation on foliar level 1.

On foliar level 1, CA3301 at 0.6 l/ha showed 55.08% of efficacy on reduction of disease severity before harvest and 54.33% when applied at 0.8 l/ha.

These positive effects to control *Pyrenophora tritici-repentis* of CA3301 at 0.6-0.8 l/ha were overall statistically superior to the one provided by the 0.48 l/ha dose rate.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Pyrenophora tritici-repentis* on winter wheat in the Maritime EPPO zone.

Table 3.2-118: Summary table – Minimum effective dose evaluation – Winter wheat – PYRNTR - Maritime EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA330 1 0,48 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity L1 - 35 DA-B										
Number of values	1	1	1	1	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	58,44	36,06	26,25	26,69						
Maximum value	58,44	36,06	26,25	26,69	1 >	1 >	0 >	1 >	1 >	0 >
Mean disease severity (%)	58,44	36,06	26,25	26,69	0 =	0 =	1 =	0 =	0 =	1 =
Abbott efficacy (%)	0,00%	38,30 %	55,08%	54,33 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – Mediterranean EPPO zone

No data were available to support the minimum effective dose of CA3301 against *Pyrenophora tritici-repentis* on winter wheat. However, existing authorisations for prothioconazole products (Proline, Praktis, JOAO) to control *Pyrenophora tritici-repentis* have the same dose rate for this pathogen which indicates the performance of this active substance in this condition.

Nevertheless, since in the fields a complex of disease is often observed instead of a single disease, it is of interest to look at the efficacy of CA3301 across the diseases and to not focus on a single one. It has been shown in the previous sections that a trend of decreasing disease severity with increasing dose rate was observed with CA3301 at 0.6 l/ha providing a higher disease control than the lower rate of 0.48 l/ha although it was not always significant. The rate of 0.6 l/ha was in most instances statistically equivalent to the 0.8 l/ha rate. Moreover, in circumstances of high disease pressure the rate of 0.6 l/ha showed sufficient efficacy to maintain crop quality.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Pyrenophora tritici-repentis* on winter wheat in the Mediterranean EPPO zone.

Min. Eff. Dose evaluation of CA3301 – North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, 7 trials had a level of disease severity higher than 5% and were included to support evaluation of CA3301. Several dose rates (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). CA3301 was first applied at crop stages BBCH 32-39 and the 2nd application was at BBCH 39-61. Two main assessment timings were selected: around two weeks after application B (15 DA-B) and the last timing close to harvest (20-37 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-119.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect to control *Pyrenophora tritici-repentis* was provided after two applications of CA3301 at 0.6-0.8 l/ha. On foliar level 2, when applied at 0.6 l/ha, CA3301 showed 50.10% of efficacy to reduce the disease severity two weeks after the 2nd application and 49.60% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 68.07% of efficacy on reduction of disease severity before harvest.

When applied at 0.8 l/ha, on foliar level 2, CA3301 showed 77.25% of efficacy to control *Pyrenophora tritici-repentis* two weeks after the 2nd application and 57.69% before harvest. On foliar level 1, CA3301 at 0.8 l/ha showed 77.68% of efficacy on reduction of disease severity before harvest.

Overall a general trend was observed for reduced disease severity with increasing dose rates, although the differences between 0.6 and 0.8 L/ha were not generally statistically significant. However, in the trial with the greatest disease severity on L1 at the second assessment, a statistical benefit was observed for increasing the dose rate from 0.6 to 0.8 L/ha. These positive effects of CA3301 at 0.6-0.8 l/ha to control *Pyrenophora tritici-repentis* were overall superior than the 0.48 l/ha dose rate tested.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Pyrenophora tritici-repentis* on winter wheat in the North-Eastern East EPPO zone.

Table 3.2-119: Summary table – Minimum effective dose evaluation – Winter wheat – PYRNTR – North-Eastern East EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA330 1 0,48 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity L2 - 15 DA-B										
Number of values	1	1	1	1	UTC	CA330 1 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	5,01	2,45	2,50	1,14		1 >	0 >	0 >	1 >	0 >
Maximum value	5,01	2,45	2,50	1,14	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	5,01	2,45	2,50	1,14	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	51,10%	50,10 %	77,25 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 20-37 DA-B										
Number of values	5	5	5	5	UTC	CA330 1 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	10,63	5,25	4,25	3,75		5 >	1 >	0 >	5 >	1 >
Maximum value	34,38	24,25	17,50	18,25	0 =	4 =	5 =	0 =	4 =	5 =
Mean disease severity (%)	22,24	14,04	11,68	10,02	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	38,63%	49,60 %	57,96 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 20-37 DA-B										
Number of values	5	5	5	5	UTC	CA330 1 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	6,78	2,65	2,20	1,25		5 >	0 >	0 >	5 >	1 >
Maximum value	31,75	14,81	13,88	10,06	0 =	5 =	4 =	0 =	4 =	4 =
Mean disease severity (%)	14,94	5,74	4,93	3,64	0 <	0 <	1 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	62,34%	68,07 %	77,68 %	0 <	0 <	1 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – South ~~Eastern~~ East EPPO zone

In the South-~~Eastern~~ East EPPO zone, 2 trials had a level of disease severity higher than 5% and were included to support evaluation of CA3301. Several dose rates (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). CA3301 was first applied at crop stages BBCH 31-39 and the 2nd application was at BBCH 49-65. Two main assessment timings were selected: around two weeks after application B (15 DA-B) and the last timing close to harvest (36 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-120.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect on *Pyrenophora tritici-repentis* was provided after two applications of CA3301 at 0.6-0.8 l/ha. On foliar level 2, when applied at 0.6 l/ha, CA3301 showed 79.92% of efficacy to control *Pyrenophora tritici-repentis* two weeks after the 2nd application and 60.91% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 63.68% of efficacy on reduction of disease severity before harvest.

When applied at 0.8 l/ha, on foliar level 2, CA3301 showed 87.23% of efficacy against to control *Pyrenophora tritici-repentis* two weeks after the 2nd application and 71.33% before harvest. On foliar level 1, CA3301 at 0.8 l/ha showed 75.24% of efficacy on reduction of disease severity before harvest.

Despite the low number of valid trials used to perform this analysis, in one of the trial, the level of disease infection was high and therefore provided reliable data to give a true picture of CA3301 disease control. As disease pressure increased to relatively high levels in these trials a distinct dose rate effect was observed among the 3 tested dose rates. These positive effects to control *Pyrenophora tritici-repentis* of CA3301 at 0.6-0.8 l/ha were overall superior than the 0.48 l/ha dose rate tested.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Pyrenophora tritici-repentis* on winter wheat in the South-~~Eastern~~ East EPPO zone.

Table 3.2-120: Summary table – Minimum effective dose evaluation – Winter wheat – PYRNTR – South-~~Eastern~~ East EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA330 1 0,48 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity L2 - 14-15 DA-B										
Number of values	2	2	2	2	UTC	CA330 1 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	7,01	1,16	1,11	0,74		1 >	1 >	0 >	1 >	1 >
Maximum value	12,66	3,13	2,20	1,38	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	9,84	2,14	1,66	1,06	0 <	0 <	1 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	73,09%	79,92 %	87,23 %						
% Disease severity L2 - 36 DA-B										
Number of values	1	1	1	1	UTC	CA330 1 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	46,25	24,63	18,08	13,26		1 >	1 >	0>	1 >	1 >
Maximum value	46,25	24,63	18,08	13,26						

Mean disease severity (%)	46,25	24,63	18,08	13,26	0 =	0 =	0 =	0 =	0 =	0 =
Abbott efficacy (%)	0,00%	46,75%	60,91 %	71,33 %	0 <	0 <	1 <	0 <	0 <	0 <
% Disease severity L1 - 36 DA-B										
Number of values	1	1	1	1	UTC	CA330 1	CA33 01	UT C	CA330 1	CA330 1
Minimum value	25,00	12,93	9,08	6,19		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	25,00	12,93	9,08	6,19	1 >	1 >	0 >	1 >	1 >	1 >
Mean disease severity (%)	25,00	12,93	9,08	6,19	0 =	0 =	0 =	0 =	0 =	0 =
Abbott efficacy (%)	0,00%	48,28%	63,68 %	75,24 %	0 <	0 <	1 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. Consequently, a total of 15 trials evaluated the efficacy of CA3301 on winter wheat against *Pyrenophora tritici-repentis* and 9 trials out of 15 were considered valid. Several dose rates (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). CA3301 was first applied at crop stages BBCH 31-45 and the 2nd application was at BBCH 39-69. Two main assessment timings were selected: around two weeks after application B (15 DA-B) and the last timing close to harvest (20-37 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-121.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect to control *Pyrenophora tritici-repentis* was provided after two applications of CA3301 at 0.6-0.8 l/ha. On foliar level 2, when applied at 0.6 l/ha, CA3301 showed 59.36% of efficacy to reduce the disease severity two weeks after the 2nd application and 51.49% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 65.59% of efficacy on reduction of disease severity before harvest.

When applied at 0.8 l/ha, on foliar level 2, CA3301 showed 78.78% of efficacy to control *Pyrenophora tritici-repentis* two weeks after the 2nd application and 60.19% before harvest. On foliar level 1, CA3301 at 0.8 l/ha showed 74.00% of efficacy on reduction of disease severity before harvest.

An overall general trend was observed for reduced disease severity with increasing dose rates, although the differences between 0.6 and 0.8 L/ha were not always significant. However, statistical benefits were often observed when increasing the dose rate from 0.6 to 0.8 L/ha in the trials with the greatest disease severity. These positive effects of CA3301 at 0.6-0.8 l/ha to control *Pyrenophora tritici-repentis* were overall superior than the 0.48 l/ha dose rate tested.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Pyrenophora tritici-repentis* on winter wheat in Poland.

Table 3.2-121: Summary table - Minimum effective dose evaluation – Winter wheat – PYRNTR – Data relevant for Poland

Treatment name	UNTREATED CHECK	CA330 1	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Rate		0,48	0,6	0,8		
Rate unit		L/ha	L/ha	L/ha		
Appl. Code						

		AB	AB	AB						
% Disease severity L2 - 15 DA-B										
Number of values	2	2	2	2	UT	CA330	CA330	UT	CA330	CA330
Minimum value	5,01	2,45	2,20	1,14	C	1	1	C	1	1
Maximum value	7,01	3,13	2,50	1,38		0,48	0,8		0,48	0,6
Mean disease severity (%)	6,01	2,79	2,35	1,26	2 >	1 >	0 >	2 >	1 >	1 >
Abbott efficacy (%)	0,00%	53,22 %	59,36 %	78,78 %	0 =	1 =	1 =	0 =	1 =	1 =
					0 <	0 <	1 <	0 <	0 <	0 <
% Disease severity L2 - 20-37 DA-B										
Number of values	6	6	6	6	UT	CA330	CA330	UT	CA330	CA330
Minimum value	10,63	5,25	4,25	3,75	C	1	1	C	1	1
Maximum value	46,25	24,63	18,08	18,25		0,48	0,8		0,48	0,6
Mean disease severity (%)	26,24	15,80	12,74	10,56	6 >	2 >	0 >	6 >	2 >	1 >
Abbott efficacy (%)	0,00%	39,99 %	51,49 %	60,19 %	0 =	4 =	5 =	0 =	4 =	5 =
					0 <	0 <	1 <	0 <	0 <	0 <
% Disease severity L1 - 20-37 DA-B										
Number of values	7	7	7	7	UT	CA330	CA330	UT	CA330	CA330
Minimum value	6,78	2,65	2,20	1,25	C	1	1	C	1	1
Maximum value	58,44	36,06	26,25	26,69		0,48	0,8		0,48	0,6
Mean disease severity (%)	22,59	11,30	8,57	7,29	7 >	2 >	0 >	7 >	3 >	2 >
Abbott efficacy (%)	0,00%	56,90 %	65,59 %	74,00 %	0 =	5 =	5 =	0 =	4 =	5 =
					0 <	0 <	2 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

Only 1 trial has been submitted to determine minimum effective dose in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,48-0,8 l/ha achieved low efficacy after 35 days after second application. Due to the limited number of trials, the cMSs are kindly asked to consider MED for this use on the national level.

7 trials were available to determine MED in **the North-East EPPO zone**. CA3301 at dose rate of 0,8 l/ha achieved medium efficacy in most trials. The dose rate of 0,6 l/ha showed medium level of control in assessments with low disease pressure in 5 out of 7 trials. The test product at 0,48 l/ha was not effective in control of PYRNTR. This trend is also visible in supportive trial from Slovakia. The dose rate of 0,6 l/ha can be considered MED to control of *Pyrenophora tritici-repentis* in winter wheat in Poland, however on medium level. It should be noted that the dose rate of 0,6 l/ha can be considered MED mainly in situation of low disease pressure. In more challenging conditions, the dose rate of 0,8 l/ha will be more justified.

2 trials were presented to determine MED in **the South-East EPPO zone**. CA3301 applied at dose rate of 0,6-0,8 l/ha achieved medium efficacy while the lower dose rate of 0,48 l/ha was not effective before harvest. No additional trials from the Mediterranean zone have been submitted to support of product registration in other zones. Due to the limited number of trials, the cMSs are kindly asked to consider MED for this use on the national level.

3.2.2.31 Winter wheat (TRZAW) / *Parastagonospora nodorum* (LEPTNO)

Between 2017 and 2020, a series of 4 trials were conducted in several countries of the Maritime and Mediterranean EPPO zones to evaluate the minimum effective dose of CA3301 against *Parastagonospora nodorum* on winter wheat. The trials were carried out by certified testing institutes. The proposed rate is the range of 0.6-0.8 l/ha.

In the Maritime EPPO zone, 2 trials were performed in Czech Republic.
In the Mediterranean EPPO zone, 2 trials were performed in Spain (1) and Italy (1).

Out of the 4 trials carried out against *Parastagonospora nodorum* (LEPTNO) on winter wheat, 2 were considered valid.

Min. Eff. Dose evaluation of CA3301 – Maritime EPPO zone

In the Maritime EPPO zone, a single valid trial had a level of disease severity higher than 5% and was included to support evaluation of CA3301. Several dose rates (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). CA3301 was first applied at crop stage BBCH 32 and the 2nd application was at BBCH 67. Two main assessment timings were selected: two weeks after application B (15 DA-B) and the last timing close to harvest (27 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-122.

On foliar level 2, CA3301 at 0.6 l/ha showed 35.38% of efficacy on reduction of disease severity two weeks after the 2nd application and 16.35% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 37.66% of efficacy to reduce the disease severity before harvest.

When applied at 0.8 l/ha, CA3301 showed 42.37% of efficacy to reduce the disease severity two weeks after the 2nd application on foliar level 2 and 17.89% before harvest. On foliar level 1, CA3301 reduced the disease severity with 48.10% of efficacy before harvest.

In the Maritime zone EPPO zone, a limited dataset was available for assessment of control of glume blotch. This disease, one of the fungi responsible of leaf (and glume) blotch of cereals- also known as Septoria nodorum blotch - occurred in lesser proportion and more heterogeneous way than the Septoria species *Zymoseptoria tritici*, presented earlier in the dossier, which can also be supportive for this dataset. Overall a general trend was observed for reduced disease severity with increasing dose rates, although the differences between 0.6 and 0.8 L/ha were not generally statistically significant.

Considering all elements presented above, the other conditions occurring in this area and also the dataset previously presented against *Zymoseptoria tritici*, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Parastagonospora nodorum* on winter wheat in the Maritime EPPO zone.

Table 3.2-122: Summary table – Minimum effective dose evaluation – Winter wheat – LEPTNO - Maritime EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity L2 - 15 DA-B										
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha	UTC	CA3301 0,48 l/ha	CA3301 0,6 l/ha
Minimum value	25,44	18,50	16,44	14,66		1 >	0 >		0 >	1 >
Maximum value	25,44	18,50	16,44	14,66	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	25,44	18,50	16,44	14,66	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	27,28%	35,38 %	42,37 %						
% Disease severity L2 - 27 DA-B										
Number of values	1	1	1	1	UTC	CA3301	CA3301	UTC	CA3301	CA3301

Minimum value	73,38	64,94	61,38	60,25		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	73,38	64,94	61,38	60,25	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	73,38	64,94	61,38	60,25	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	11,50%	16,35 %	17,89 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 27 DA-B										
Number of values	1	1	1	1	UTC	CA330 1 0,48 l/ha	CA33 01 0,8 l/ha	UTC	CA330 1 0,48 l/ha	CA3 301 0,6 l/ha
Minimum value	30,06	20,21	18,74	15,60						
Maximum value	30,06	20,21	18,74	15,60	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	30,06	20,21	18,74	15,60	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	32,77%	37,66 %	48,10 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – Mediterranean EPPO zone

In the Mediterranean EPPO zone, a single valid trial had a level of disease severity higher than 5% and was included to support evaluation of CA3301. Several dose rates (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). CA3301 was first applied at crop stage BBCH 37 and the 2nd application was at BBCH 61. Two main assessment timings were selected: two weeks after application B (16 DA-B) and the last timing close to harvest (25 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-123.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect on glume blotch was provided after two applications of CA3301 at 0.6-0.8 l/ha. On foliar level 2, when applied at 0.6 l/ha, CA3301 showed 63.65% of efficacy to control the disease severity two weeks after the 2nd application and 59.05% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 100% of efficacy on reduction of disease severity around two weeks after the 2nd application and 91.41% before harvest. When applied at 0.8 l/ha, on foliar level 2, CA3301 showed 68.30% of efficacy to control glume blotch of wheat two weeks after the 2nd application and 60.51% before harvest. On foliar level 1, CA3301 at 0.8 l/ha showed 100% of efficacy on reduction of disease severity around two weeks after the 2nd application and 92.28% before harvest.

These positive effects to control the glume blotch of wheat disease of CA3301 at 0.6-0.8 l/ha were overall superior than the 0.48 l/ha dose rate tested. In the Mediterranean EPPO zone, a limited dataset was available for assessment of control of glume blotch. This disease, one of the fungi responsible of leaf (and glume) blotch of cereals- also known as *Septoria nodorum* blotch - occurred in lesser proportion and more heterogeneous way than the *Septoria* species *Zymoseptoria tritici*, presented earlier in the dossier, which can also be supportive for this dataset.

In overall a general trend was observed for reduced disease severity with increasing dose rates, although the differences between 0.6 and 0.8 L/ha were not generally statistically significant.

Considering all elements presented above, the other conditions occurring in this area and also the dataset previously presented against *Zymoseptoria tritici*, 2 applications of CA3301 at 0.6-0.8 l/ha is

the minimum effective dose to control *Parastagonospora nodorum* on winter wheat in the Mediterranean EPPO zone.

Table 3.2-123: Summary table – Minimum effective dose evaluation – Winter wheat – LEPTNO - Mediterranean EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA330 1 0,48 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity L2 - 16 DA-B										
Number of values	1	1	1	1	UTC	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UTC	CA330 1 0,48 l/ha	CA3 301 0,6 l/ha
Minimum value	47,13	19,63	17,13	14,94		1 >	1 >		0 >	1 >
Maximum value	47,13	19,63	17,13	14,94	0 =	0 =	0 =	0 =	0 =	0 =
Mean disease severity (%)	47,13	19,63	17,13	14,94	0 <	0 <	1 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	58,35 %	63,65%	68,30 %	0 <	0 <	1 <	0 <	0 <	0 <
% Disease severity L1 - 16 DA-B										
Number of values	1	1	1	1	UTC	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UTC	CA330 1 0,48 l/ha	CA3 301 0,6 l/ha
Minimum value	15,06	0,00	0,00	0,00		1 >	0 >		0 >	1 >
Maximum value	15,06	0,00	0,00	0,00	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	15,06	0,00	0,00	0,00	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	100,00 %	100,00 %	100,00 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 25 DA-B										
Number of values	1	1	1	1	UTC	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UTC	CA330 1 0,48 l/ha	CA3 301 0,6 l/ha
Minimum value	72,50	31,88	29,69	28,63		1 >	1 >		0 >	1 >
Maximum value	72,50	31,88	29,69	28,63	0 =	0 =	1 =	0 =	0 =	1 =
Mean disease severity (%)	72,50	31,88	29,69	28,63	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	56,03 %	59,05%	60,51 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 25 DA-B										
Number of values	1	1	1	1	UTC	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UTC	CA330 1 0,48 l/ha	CA3 301 0,6 l/ha
Minimum value	21,88	1,88	1,88	1,69		1 >	0 >		0 >	1 >
Maximum value	21,88	1,88	1,88	1,69	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	21,88	1,88	1,88	1,69	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	91,41 %	91,41%	92,28 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, no trials were available for assessment of control of glume blotch. *Zymoseptoria tritici* blotch is found commonly in the same fields and on the same plants as *Parastagonospora nodorum*, the fungi responsible of leaf (and glume) blotch of cereals, also known as *Septoria nodorum* blotch. When both pathogens occur together, they are referred to collectively as the Septoria blotch complex

or Septoria complex. Glume blotch occurred in lesser proportion and more heterogeneous way than the Septoria species *Zymoseptoria tritici*, presented earlier in the dossier, which can also be supportive for this dataset.

Therefore with Glume blotch it is also expected to observe an overall trend of decreasing disease severity with increasing dose rates, especially for 0.6 & 0.8 l/ha compared to 0.48 l/ha. In many instances the rate of 0.6 l/ha should give acceptable control of *Parastagonospora nodorum* very comparable to that of 0.8 l/ha, nevertheless in conditions of high disease pressure the additional disease reduction obtained from the higher rate of 0.8 l/ha may be more appropriate, in particular if some level of resistance is suspected.

Considering all elements presented above and the dataset previously presented against *Zymoseptoria tritici*, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Parastagonospora nodorum* on winter wheat in the North-Eastern East EPPO zone.

Min. Eff. Dose evaluation of CA3301 – South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, no trials were available for assessment of control of glume blotch. *Zymoseptoria tritici* blotch is found commonly in the same fields and on the same plants as *Parastagonospora nodorum*, the fungi responsible of leaf (and glume) blotch of cereals, also known as *Septoria nodorum* blotch. When both pathogens occur together, they are referred to collectively as the Septoria blotch complex or Septoria complex. Glume blotch occurred in lesser proportion and more heterogeneous way than the Septoria species *Zymoseptoria tritici*, presented earlier in the dossier, which can also be supportive for this dataset.

Therefore with Glume blotch it is also expected to observe an overall trend of decreasing disease severity with increasing dose rates, especially for 0.6 & 0.8 l/ha compared to 0.48 l/ha. In many instances the rate of 0.6 l/ha should give acceptable control of *Parastagonospora nodorum* very comparable to that of 0.8 l/ha, nevertheless in conditions of high disease pressure the additional disease reduction obtained from the higher rate of 0.8 l/ha may be more appropriate, in particular if some level of resistance is suspected.

Considering all elements presented above and the dataset previously presented against *Zymoseptoria tritici*, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Parastagonospora nodorum* on winter wheat in the South-Eastern East EPPO zone.

Comments of zRMS:

The limited number of trials have been submitted to determine minimum effective dose to control of *Parastagonospora nodorum* in winter wheat. Only 1 trial were available in the **Maritime EPPO climatic zone** and Mediterranean zone. CA3301 applied at dose rate of 0.48-0.8l/ha achieved very low efficacy in all assessments in the MAR zone. In one additional trial, the test product achieved varied results, from low efficacy observed on leaves level 2 to very high noted on leaves level 1. No efficacy trials were presented in the North-East and South East EPPO zones. The cMSs are kindly asked to consider MED for this use on the national level.

3.2.2.32 Winter wheat (TRZAW) / *Oculimacula acuformis* (PSDCHA)

(Ramanauskienė *et al.*, Effects of fungicides on the occurrence of winter wheat eyespot caused by fungi *Oculimacula acuformis* and *O. yallundae*. Crop protection, 2016)

No data were available for assessment of minimum effective dose of eyespot of cereals *Oculimacula acuformis* on any crop. Although early symptoms can be confused with *Fusarium spp.*, the diseases are not related and therefore it is impossible to extrapolate from these data.

However, Ramanauskienė *et al.*, showed that 2, 3 and 4 years of prothioconazole treatments allowed to reduce the population of *O. acuformis* assessed from 2009 to 2011 on winter wheat. This positive effect was observed as early as 10 days after treatment.

Moreover, prothioconazole is one of the active substances the most used as fungicide in commercial practices (*Forecasting eyespot development and yield losses in winter wheat, HGCA, 2012*). Standard reference products containing prothioconazole, such as Proline 275 are registered to control eyespot on cereals, at the same application rates as for the other authorised pathogens, which indicates that prothioconazole controls eyespot at dose rates which are demonstrated to control the other major disease pathogens in cereals. Since the proposed dose rate for CA3301 (200-150 g/ha prothioconazole) is comparable to that of the authorised product Proline 275 (275 g/ha prothioconazole), and data shows equivalence of efficacy between these products in other pathogens, it is considered that the minimum effective dose rate for CA3301 to control eyespot will be the same as that demonstrated for other pathogens.

Moreover, since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.8 l/ha generally gave significantly better disease control compared to the rate of 0.48 l/ha, it is supposed that the same dose range will be acceptable to control eyespot on winter wheat.

In North-East zone, 7 valid trials conducted in Poland on winter wheat against *Oculimacula acuformis* were included to support evaluation of CA3301. Conducted trials evaluated the efficacy of CA3301 and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha (N rates), 0.3 l/ha (0.5N) and 0.45 l/ha (0.75N) applied once) on eyespot of cereals severity. CA3301 was applied once at crop stage BBCH 30-32. Efficacy assessment was conducted between BBCH 71-77, on 25-ear-bearing tillers taken randomly.

Summary results are presented in Table 3.2-124.

Data demonstrated a better effect of application of CA3301 at 0.6-0.8 l/ha compared to lower dose rates for the reduction of eyespot disease severity on winter wheat.

The proposed dose rates of 0.6 and 0.8 l/ha CA3301 provided medium (69.1%) to high efficacy (81.3%), respectively whereas the reduced rate of 0.45 l/ha demonstrated low efficacy (57.1%). Efficacy at dose rate 0.3 l/ha was 24.6%.

Considering all elements presented above, one application of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Oculimacula acuformis* on winter wheat.

Table 3.2-124: Summary table – Minimum effective dose evaluation – Winter wheat – North-East EPPO zone

Treatment name	UNTREATED CHECK	CA3301	CA3301	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to				No of trials where CA3301 at 0,8 l/ha is >, = or < compared to			
Rate		0,3	0,45	0,6	0,8								
Rate unit		L/ha	L/ha	L/ha	L/ha								
Appl. Code		A	A	A	A								
Disease severity-52-75 DA-A													
Number of values	7	7	7	7	7	UTC	CA3301 0,3 l/ha	CA3301 0,45 l/ha	CA3301 0,6 l/ha	UTC	CA3301 0,3 l/ha	CA3301 0,45 l/ha	CA3301 0,6 l/ha
Minimum value	0,14	0,13	0,05	0,02	0,01								
Maximum value	0,4	0,29	0,16	0,17	0,11	7 >	6 >	1 >	0 >	7 >	7 >	3 >	2 >
Mean disease severity*	0,27	0,20	0,12	0,09	0,05	0 =	1 =	6 =	5 =	0 =	0 =	4 =	5 =
Abbott efficacy (%)	0,0%	24,6 %	57,1 %	69,1%	81,3%	0 <	0 <	0 <	2 <	0 <	0 <	0 <	0 <

> means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

*As total damage value

Levels of efficacy (% Abbott efficacy)	
>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Oculimacula acufiformis* on winter wheat in all EPPO zones.

Comments of zRMS:

No efficacy trials for PSDCHA have been submitted to determine minimum effective dose in any EPPO climatic zones. The eMSs are kindly asked to consider MED for this use on the national level.

The applicant has submitted 7 efficacy trials to determine minimum effective dose for control *Oculimacula acufiformis* (PSDCHA) in winter wheat. All trials were conducted in Poland (belonging to the North-East EPPO climatic zone) in 2023. CA3301 (Joust 250 EC) was applied at four dose rates of 0,3 L/ha (0,5N), 0,45 L/ha (0,75N), 0,6 L/ha (1N) and 0,8 L/ha (1N). Based on total damage value, it can be concluded that the dose rate of 0,8 L/ha is sufficient for control PSDCHA (with the mean result of 81,3% (67,4-91,2%)) in winter wheat in the North-East zone. The claimed dose rate of 0,6 l/ha achieved moderate effectiveness with the mean result of 69,1% (50,0-84,3%). Taking into account low disease pressure in the submitted trials, dose rate of 0,8 L/ha should be recommended MED for control PSDCHA in winter wheat in Poland in opinion of zRMS. The lower dose rate may be insufficient at higher pest severity.

3.2.2.33 Winter wheat (TRZAW) / Green leaf area

Min. Eff. Dose evaluation of CA3301 – Maritime EPPO zone

Green leaf area was recorded at 9-58 DA-B in 49 valid trials on winter wheat after two applications of CA3301 at several dose rates (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) In 44 trials, green leaf area was assessed on the entire plant while in 5 trials it was assessed by foliar levels. For those 5 trials, green leaf area will be presented separately and on foliar levels 2 to 1.

Summary results are presented in Table 3.2-125.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rate for the augmentation of green leaf area on winter wheat infected by foliar and ears diseases. In the 44 trials assessing green leaf area on the whole plant, an increase of 139.36%, 111.77% and 89.94% was recorded with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check on winter wheat. In the 5 trials assessing green leaf area by foliar level, an increase of 204.29%, 191.76% and 133.36% was recorded on foliar level 2 and an increase of 75.11%, 69.15% and 64.78% was recorded on foliar level 1 with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check.

A significant dose effect was observed over the dataset whereby the green leaf area increases with higher dose rates, in particular for 0.8 l/ha compared to 0.48 and 0.6 l/ha.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on winter wheat infected by a range of diseases in the Maritime EPPO zone.

Table 3.2-125: Summary table – Minimum effective dose evaluation – Winter wheat – Green leaf area - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA330	CA330	CA330	No of trials where			No of trials where		
Rate		1	1	1	CA3301 at 0,6 l/ha			CA3301 at 0,8 l/ha		
Rate unit		0,48	0,6	0,8	is >, = or < compared			is >, = or < compared		
Appl. Code		L/ha	L/ha	L/ha	to			to		
	AB	AB	AB							
% Green leaf area - 9-58 DA-B										
Number of values	44	44	44	44	UT	CA330	CA33	UT	CA330	CA33
Minimum value	0,00	3,75	6,25	6,25	C	1	01	C	1	01
						0,48	0,8		0,48	0,6
						l/ha	l/ha		l/ha	l/ha

Maximum value	88,75	94,25	97,25	97,75	30 > 14 =	8 >	2 >	30 > 14 =	12 >	7 >
Mean green leaf area (%)	37,48	52,69	55,45	59,26		35 =	35 =		30 =	35 =
%UTC	100,00%	189,94 %	211,77 %	239,36 %	0 <	1 <	7 <	0 <	2 <	2 <
% Green leaf area L2 - 32-47 DA-B										
Number of values	5	5	5	5	UT C	CA330 1 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	16,25	27,50	61,25	62,50						
Maximum value	42,50	78,75	87,50	87,50	5 >	2 >	0 >	5 >	3 >	1 >
Mean green leaf area (%)	26,30	56,75	69,25	71,50	0 =	3 =	4 =	0 =	2 =	4 =
%UTC	100,00%	233,36 %	291,76 %	304,29 %	0 <	0 <	1 <	0 <	0 <	0 <
% Green leaf area L1 - 32-47 DA-B										
Number of values	5	5	5	5	UT C	CA330 1 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	27,50	66,25	63,75	65,00						
Maximum value	66,25	83,75	92,50	94,25	5 >	2 >	0 >	5 >	2 >	0 >
Mean green leaf area (%)	50,50	77,25	80,25	83,10	0 =	3 =	5 =	0 =	3 =	5 =
%UTC	100,00%	164,78 %	169,15 %	175,11 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Min. Eff. Dose evaluation of CA3301 – Mediterranean EPPO zone

Green leaf area was recorded at 14-43 DA-B in 46 valid trials on winter wheat after two applications of CA3301 at several dose rates (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice). In all 46 trials, green leaf area was assessed on the whole plant.

Summary results are presented in Table 3.2-126.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rate for the augmentation of green leaf area on winter wheat infected by foliar and ears diseases. In the 46 trials assessing green leaf area on the whole plant, an increase of 104.62%, 82.16% and 64.98% was recorded with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check on winter wheat.

A significant dose effect was observed over the dataset whereby the green leaf area increases with higher dose rates, in particular for 0.8 l/ha compared to 0.48 and 0.6 l/ha.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on winter wheat infected by a range of diseases in the Mediterranean EPPO zone.

Table 3.2-126: Summary table – Minimum effective dose evaluation – Winter wheat – Green leaf area - Mediterranean EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA330 1 0,48 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
% Green leaf area - 14-43 DA-B						
Number of values	46	46	46	46	UT C	CA330 1 01 C

Minimum value	2,00	5,25	5,75	8,75		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	92,50	98,75	100,00	100,00	22 >	4 >	0 >	24 >	10 >	7 >
Mean green leaf area (%)	38,05	50,34	52,92	55,86	24 =	42 =	39 =	22 =	36 =	39 =
%UTC	100,00%	164,98 %	182,16 %	204,62 %	0 <	0 <	7 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Min. Eff. Dose evaluation of CA3301 – North-Eastern East EPPO zone

Green leaf area was recorded at 15-45 DA-B in 33 valid trials on winter wheat after two applications of CA3301 at several dose rates (0.8 l/ha (1N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice). In all 33 trials, green leaf area was assessed on the whole plant.

Summary results are presented in Table 3.2-127.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rate for the augmentation of green leaf area on winter wheat infected by foliar and ears diseases. In the 46 trials assessing green leaf area on the whole plant, an increase of 67.42%, 56.55% and 44.14% was recorded with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check on winter wheat.

An overall trend of increasing the green leaf area with increasing dose rates was observed in the whole dataset in particular for 0.6 and 0.8 l/ha compared to 0.48 l/ha, although differences were not always significant.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on winter wheat infected by a range of diseases in the North-Eastern East EPPO zone.

Table 3.2-127: Summary table – Minimum effective dose evaluation – Winter wheat – Green leaf area – North-Eastern East EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA330 1 0,48 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Green leaf area - 15-45 DA-B										
Number of values	33	33	33	33	UT C	CA330 1 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	9,00	13,75	13,75	13,75	18 >	2 >	0 >	20 >	6 >	3 >
Maximum value	86,25	90,00	92,50	95,00	15 =	31 =	30 =	13 =	27 =	30 =
Mean green leaf area (%)	35,64	45,30	47,98	50,76						
%UTC	100,00%	144,14 %	156,55 %	167,42 %	0 <	0 <	3 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Min. Eff. Dose evaluation of CA3301 – South-Eastern East EPPO zone

Green leaf area was recorded at 16-48 DA-B in 37 valid trials on winter wheat after two applications of CA3301 at several dose rates (0.8 l/ha (1.33N), 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice). In 36 trials, green leaf area was assessed on the whole plant while in 1 trial it was assessed by foliar levels. For this trial, green leaf area will be presented separately and on foliar levels 2 to 1.

Summary results are presented in Table 3.2-128.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rate for the augmentation of green leaf area on winter wheat infected by foliar and ears diseases. In the 36 trials assessing green leaf area on the whole plant, an increase of 246.57%, 207.77% and 192.33% was recorded with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check on winter wheat. In the trial assessing green leaf area by foliar level, an increase of 1169.2%, 1015.4% and 976.9% was recorded on foliar level 2 and an increase of 243.9%, 245.1% and 220.7% was recorded on foliar level 1 with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check.

A significant dose effect was observed over the dataset whereby the green leaf area increases with higher dose rates, in particular for 0.8 l/ha compared to 0.48 and 0.6 l/ha.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on winter wheat infected by a range of diseases in the South-Eastern East EPPO zone.

Table 3.2-128: Summary table – Minimum effective dose evaluation – Winter wheat – Green leaf area – South-Eastern East EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA330 1 0,48 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < com- pared to			No of trials where CA3301 at 0,8 l/ha is >, = or < com- pared to				
% Green leaf area - 16-48 DA-B												
Number of values	36	36	36	36	UTC	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UTC	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha		
Minimum value	0,00	11,25	15,00	18,75								
Maximum value	100,00	100,00	100,00	100,00		23 > 13 =	3 > 33 =		0 > 28 =	25 > 11 =	12 > 24 =	8 > 28 =
Mean green leaf area (%)	38,31	57,46	59,44	64,07								
%UTC	100,00%	292,33 %	307,77 %	346,57 %	0 <	0 <	8 <	0 <	0 <	0 <		
% Green leaf area L2 - 27 DA-B												
Number of values	1	1	1	1	UTC	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UTC	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha		
Minimum value	3,25	35,00	36,25	41,25								
Maximum value	3,25	35,00	36,25	41,25		1 > 0 =	0 > 1 =		0 > 1 =	1 > 0 =	0 > 1 =	0 > 1 =
Mean green leaf area (%)	3,25	35,00	36,25	41,25								
%UTC	100,00%	1076,90 %	1115,40 %	1269,20 %	0 <	0 <	0 <	0 <	0 <	0 <		
% Green leaf area L1 - 27 DA-B												
Number of values	1	1	1	1	UTC	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UTC	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha		
Minimum value	20,50	65,75	70,75	70,50								
Maximum value	20,50	65,75	70,75	70,50		1 > 0 =	0 > 1 =		0 > 1 =	1 > 0 =	0 > 1 =	0 > 1 =
Mean green leaf area (%)	20,50	65,75	70,75	70,50								
%UTC	100,00%	320,70 %	345,10 %	343,90 %	0 <	0 <	0 <	0 <	0 <	0 <		

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Comments of zRMS:

Very positive effect after application of CA3301 at dose rate of 0,6-0,8 l/ha were observed. An argumentation

of green leaf area was visible on high level in all EPPO climatic zones. It can be concluded that CA3301 at 0,6 l/ha is justified as minimum effective dose in winter wheat.

3.2.2.34 Winter wheat (TRZAW) / Conclusion - Minimum effective dose tests

On winter wheat, 6 foliar diseases and 3 ears diseases were assessed in 176 trials across 4 EPPO zones. Disease severity or incidence (for *Blumeria graminis*) was assessed and analysed on the main foliar levels 1 and 2 and on inoculated or non-inoculated ears. Although a comprehensive trials program was undertaken for this dossier, in some instances, due to the absence of appropriate level of diseases or other agronomic or climatic limitations, the proposed number of valid trials was not fully achieved for some of the uses. Hence, depending on the EPPO zone, the disease, the assessment timing and the crop part assessed, the dataset available was sometimes limited and so not fully representative of the efficacy of CA3301. Therefore, to get an overview of the efficacy of CA3301 at 0.6-0.8 l/ha, summary tables are presented in “KCP 6.2.2.1 Winter wheat (TRZAW) / Conclusion – Efficacy tests“, on foliar levels 1&2 and on ears inoculated or non-inoculated (see Table 3.2-459, Table 3.2-460, Table 3.2-461 and Table 3.2-462).

Overall, across the 4 EPPO zones and all diseases, a consistent dose rate trend was observed for higher disease control with higher dose rates. In particular, the rates of 0.6-0.8 l/ha generally gave significantly better control compared to the rate of 0.48 l/ha. In much of the dataset there was no statistical differences between the dose rates of 0.6 l/ha or 0.8 l/ha, however it was frequently observed that where disease incidence was higher a significant benefit was derived from increasing the dose rate from 0.6 to 0.8 l/ha while in circumstances of low disease pressure, the 0.6 l/ha dose rate was sufficient to give comparable disease control. Due to the importance of the diseases and given the possibility of resistance in some of the pathogens assessed, the higher rate may be deemed more appropriate and should be available for users according to disease development conditions, historical control and cultivar tolerance to the pathogens.

In addition, the data demonstrates overall similar effects for the targeted diseases regardless of EPPO zone. Similarly, the same dose rate trends were observed for improving green leaf area in situations of infection from a single pathogen or in cases of disease complexes. Green leaf area not only indicates the area free of infection but also the ability of the plant to continue effective growth and develop to productive stages, enabling a longer duration of grain filling and therefore improved yield quantity and quality.

Therefore, a minimum effective dose rate of 0.6-0.8 l/ha is proposed for CA3301 on winter wheat in each of the EPPO zones, in order to allow optimum efficacy in relation to disease occurrence.

In this dossier data presented for minimum effective dose is primarily from assessments where 2 applications of the test product were made. However, according to disease development conditions, a single application may provide sufficient disease control, therefore users should not be restricted to always applying twice, hence in the GAP the proposed use is for 1-2 applications. In addition, crop pathogens are commonly controlled using a programme of different fungicides with varied modes of action, therefore the choice should be available to growers to make a single application of CA3301, followed by application of a different appropriate fungicide. Prothioconazole is well established over a number of years in providing good broad spectrum efficacy across a range of common crop pathogens, with either 1 or more applications appropriate according to disease development conditions, risk of resistance development and local conditions. Current authorisations for similar products containing prothioconazole including Proline 275, Bumper 25 EC and Proline/Praktis/Joao (CA2445) are for 1-2 applications at comparative rates of prothioconazole to the requested use for CA3301. Considering these elements, and that data in the efficacy section shows comparability of CA3301 to these authorised products, registration of CA3301 at the proposed minimum effective dose rate and with a number of applications of 1- 2, is requested.

Considering all elements presented in the previous sections of each disease, 1-2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control a range of foliar and ears diseases on winter wheat.

3.2.2.35 Spring wheat (TRZAS) / Minimum Effective Dose

Spring wheat is planted in the early spring, grows quickly and is normally harvested in late summer or early autumn whereas winter wheat is planted in the autumn and harvested in late spring or early summer. In addition, spring sown wheat is susceptible to face the same pathogens than winter wheat, it therefore seems reasonable from an agronomic perspective to assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on spring wheat from the robust dataset proposed for winter wheat.

Over the dataset for winter wheat a consistent dose rate trend was observed for higher disease control with higher dose rates. In particular, the rates of 0.6-0.8 l/ha generally gave significantly higher control compared to the rate of 0.48 l/ha. In much of the dataset there was no statistical differences between the dose rates of 0.6 l/ha or 0.8 l/ha, however it was frequently observed that where disease pressure was higher a significant benefit was derived from increasing the dose rate from 0.6 to 0.8 l/ha while in circumstances of low disease pressure, the 0.6 l/ha dose rate was sufficient to give comparable disease control. Due to the importance of the diseases and given the possibility of resistance in some of the pathogens assessed, the higher rate may be deemed more appropriate and should be available for users according to disease development conditions, historical control and cultivar tolerance to the pathogens. Similarly, the same dose rate trends were observed for improving green leaf area in situations of infection from a single pathogen or in cases of disease complexes. Green leaf area not only indicates the area free of infection but also the ability of the plant to continue effective growth and develop to productive stages, enabling a longer duration of grain filling and therefore improved yield quantity and quality. Moreover, prothioconazole is well established over a number of years in providing good broad spectrum efficacy across a range of common crop pathogens in winter and spring-sown wheat, with either 1 or more applications appropriate according to disease development conditions, risk of resistance development and local conditions. In addition, the same dose rates are authorised in winter and spring wheat for numerous registered prothioconazole products, indicating that the same pathogens are controlled at the same rates in either crop. Therefore, a minimum effective dose rate of 0.6-0.8 l/ha is proposed for CA3301 on spring wheat for all EPPO zones, in order to allow optimum efficacy in relation to disease occurrence.

Considering all elements presented in the previous sections of each disease, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control a range of foliar and ears diseases on spring wheat.

Comments of zRMS:

No efficacy trials have been submitted to determine minimum effective dose in spring wheat in any EPPO climatic zones. The cMSs are kindly asked to consider MED in this crop on the national level.

3.2.2.36 Durum wheat (TRZDU) / *Zymoseptoria tritici* (SEPTTR)

Between 2017 and 2020, 16 trials were conducted in some countries of the Maritime, Mediterranean, and South-Eastern East EPPO zones to evaluate the minimum effective dose of CA3301 against *Zymoseptoria tritici* on durum wheat. The trials were carried out by certified testing institutes. The proposed dose rates are the range 0.6-0.8 l/ha.

In the Maritime EPPO zone, a total of 4 trials were performed in France (2) and in Germany (2).
In the Mediterranean EPPO zone, a total of 7 trials were performed in France (1), Portugal (2) and in

Italy (4).

In the South-Eastern East EPPO zone, a total of 5 trials were performed in Hungary (4), and in Romania (1).

No trials were available for the North-Eastern East EPPO zone.

Min. Eff. Dose evaluation of CA3301 - Maritime EPPO zone

In the Maritime EPPO zone, 4 trials evaluated the efficacy of CA3301 on durum wheat against *Zymoseptoria tritici*. Only two trials were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 31-37 and the 2nd application was at BBCH 49-55.

Summary results are presented in Table 3.2-129.

Data demonstrated a numerically better effect of 2 applications of CA3301 at 0.6 l/ha compared to lower dose rate for the reduction of disease severity on durum wheat against *Zymoseptoria tritici*.

CA3301 at 0.6 l/ha showed 65.38% of efficacy against *Zymoseptoria tritici* at 31-42 DA-B on foliar level 2 and 76% on foliar level 1 at 42 DA-B. When applied at 0.8 l/ha, the tested product provided 52.49% of efficacy to control the disease at 31 DA-B on foliar level 2 and 74.00% on foliar level 1 at 42 DA-B.

The number of valid trials for this use was very low, but in the previous chapters was demonstrated the minimum effective dose to control *Zymoseptoria tritici* on winter wheat for CA3301 at 0.6 and 0.8 l/ha. Since durum wheat and winter wheat belong to the same Order and Family, are two crops with the same life cycle, cultivated following the same agricultural practice and sensitive to *Zymoseptoria tritici* attack the data presented on winter wheat is supportive for this use.

Considering all elements presented above, it is possible to state that 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Zymoseptoria tritici* on durum wheat in the Maritime EPPO zone.

Table 3.2-129: Summary table – Minimum effective dose evaluation – Durum wheat – SEPTTR - Maritime EPPO zone

Maritime L1 O zone										
Treatment name	UNTREATED CHECK	CA33 01	CA33 01	CA330 1	No of trials where CA3301			No of trials where CA3301		
Rate		0,48	0,6	0,8	at 0,6 l/ha is >, = or <			at 0,8 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
% Disease severity L2 - 31-42 DA-B										
Number of values	2	2	2	2	UT C	CA33 01	CA330 1	UT C	CA330 1	CA330 1
Minimum value	14,08	5,09	4,70	6,69		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	34,00	21,00	12,19	19,31	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease sever- ity (%)	24,04	51,04	65,37	47,85	0 =	2 =	2 =	1 =	2 =	2 =
Abbott efficacy (%)	0,00%	51,04 %	65,38 %	47,85%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 42 DA-B										
Number of values	1	1	1	1	UT C	CA33 01	CA330 1	UT C	CA330 1	CA330 1
Minimum value	12,50	4,19	3,00	3,25		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	12,50	4,19	3,00	3,25	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease sever- ity (%)	12,50	4,19	3,00	3,25	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	66,48 %	76,00 %	74,00%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)
(conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - Mediterranean EPPO zone

In the Mediterranean EPPO zone, a total of 7 trials evaluated the efficacy of CA3301 on durum wheat against *Zymoseptoria tritici*. 5 trials were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 31-39 and the 2nd application was at BBCH 45-61. Two main assessment timings were selected: around two weeks after the 2nd application (14-16 DA-B) and the last timing close to harvest (32-37 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-130.

Data demonstrated a better effect (in one trial statistically better and in the second trial numerically better) of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rate for the reduction of disease severity on foliar level 2 and level 1 around two weeks after the 2nd application. In the assessments close to harvest 0.8 l/ha showed numerically better efficacy than 0.48 and 0.6 l/ha on leaf level 2 on durum wheat against *Zymoseptoria tritici*.

On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 68.20 – 68.95% efficacy against *Zymoseptoria tritici* two weeks after the 2nd application and 65.14 – 70.80% before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 82.92 – 86.86% efficacy on reduction of disease severity around two weeks after the 2nd application and 78.52- 76.99% before harvest. These positive effects to control *Zymoseptoria tritici* of CA3301 at 0.6-0.8 l/ha with high to medium efficacy were overall superior to the 0.48 l/ha dose rate which demonstrated medium to low efficacy.

An overall trend of decreasing disease severity with increasing dose rates was observed in the dataset, although differences were not always statistically significant. In all cases the rate of 0.6 l/ha gave acceptable control of *Zymoseptoria tritici* very comparable to that of 0.8 l/ha. Therefore, it is likely that in instances of low disease levels applications at 0.6 l/ha will provide sufficient control of *Zymoseptoria tritici*, however, when disease pressure is high, as highlighted in the trial EU17-028-05, the increased level of efficacy generally observed over the dataset from application of 0.8 l/ha may be beneficial.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Zymoseptoria tritici* on durum wheat in the Mediterranean EPPO zone.

Table 3.2-130: Summary table – Minimum effective dose evaluation – Durum wheat – SEPTTR - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301		No of trials where CA3301			
Rate		0,48	0,6	0,8	at 0,6 l/ha is >, = or <		at 0,8 l/ha is >, = or <			
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to		compared to			
% Disease severity L2 - 14-22 DA-B										
Number of values	4	4	4	4	UTC	CA33 01	CA33 01	UT	CA33 01	CA33 01
Minimum value	8,81	0,00	0,00	0,00		0,48 l/ha	0,8 l/ha	C	0,48 l/ha	0,6 l/ha
Maximum value	56,56	26,94	15,88	12,69	4 >	0 >	0 >	4 >	0 >	0 >
Mean disease se- verityv (%)	22,58	9,91	6,61	5,86	0 =	4 =	4 =	0 =	4 =	4 =

Treatment name	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate Rate unit Appl. Code Abbott efficacy (%)	0,00%	62,65%	71,90%	72,88%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 14-19 DA-B										
Number of values	2	2	2	2	UTC	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	7,31	2,25	1,38	1,13						
Maximum value	49,06	17,25	7,50	5,31	2 >	1 >	0 >	2 >	1 >	0 >
Mean disease severity (%)	28,19	9,75	4,44	3,22	0 =	1 =	2 =	0 =	1 =	2 =
Abbott efficacy (%)	0,00%	67,03%	82,92%	86,86%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 32-37 DA-B										
Number of values	3	3	3	3	UTC	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	29,88	6,28	5,64	4,19						
Maximum value	33,30	12,21	12,47	9,00	3 >	0 >	0 >	3 >	0 >	0 >
Mean disease severity (%)	24,97	9,68	8,76	6,96	0 =	3 =	3 =	0 =	3 =	3 =
Abbott efficacy (%)	0,00%	60,45%	65,14%	70,80%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 32-37 DA-B										
Number of values	4	4	4	4	UTC	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	10,50	3,00	1,86	1,01						
Maximum value	16,38	6,38	3,31	4,05	4 >	0 >	0 >	4 >	0 >	0 >
Mean disease severity (%)	13,84	4,47	2,84	3,06	0 =	4 =	4 =	0 =	4 =	4 =
Abbott efficacy (%)	0,00%	67,10%	78,52%	76,99%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)
(conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone no data were available to support the minimum effective dose evaluation several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha and 0.48 l/ha applied twice) on disease severity (%). However, durum wheat and winter wheat are comparable crops, both of the genus *Triticum* and the proposed applications are the same (dose rate, application timing etc), therefore reference is made to the data presented on winter wheat in support of the proposed minimum effective dose. The validity of this argumentation is supported by the fact that existing authorisations of similar prothioconazole products also have the same dose rates registered for both soft wheat and hard (durum) wheat, hence the pathogens are controlled similarly in each crop at the same dose rate.

In the North-Eastern East EPPO zone, 22 supportive trials carried out on winter wheat demonstrated that an overall trend of decreasing disease severity with increasing dose rates was observed in the dataset, although differences were not always statistically significant. The trend was more apparent in the

assessments with larger dataset. In many instances the rate of 0.6 l/ha gave acceptable control of *Zymoseptoria tritici* very comparable to that of 0.8 l/ha, nevertheless in conditions of high disease pressure the additional disease reduction obtained from the higher rate of 0.8 l/ha may be more appropriate, in particular where some level of resistance is suspected.

Therefore, it was envisaged that a dose rate of 0.6 l/ha may be sufficient in conditions of low to medium disease pressure but 0.8 l/ha is more appropriate in conditions of high of disease pressure.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Zymoseptoria tritici* on durum wheat in the North-Eastern East EPPO zone.

Min. Eff. Dose evaluation of CA3301 - South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 5 trials evaluated the efficacy of CA3301 on durum wheat against *Zymoseptoria tritici*. 4 trials out of 5 were considered valid to compare the efficacy of several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 31-37 and the 2nd application was at BBCH 49-61. Two main assessment timings were selected: around two weeks after the 2nd application (15 DA-B) and the last timing close to harvest (32-37 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-131.

The dataset available on the South-Eastern East EPPO zone did not consistently demonstrate a better effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rate for the reduction of disease severity on durum wheat against *Zymoseptoria tritici*, although a trend was observed in 4 of 5 trial assessments whereby the proposed dose rates gave lower disease severity compared to the rate of 0.48 l/ha. Since durum wheat and winter wheat belong to the same Order and Family, are two crops with the same life cycle, cultivated following the same agricultural practice and sensitive to *Zymoseptoria tritici* infection the data presented on winter wheat in South-Eastern East EPPO zone is supportive for this use.

In this EPPO zone on winter wheat, a total of 23 trials evaluated the efficacy of CA3301 on winter wheat against *Zymoseptoria tritici* (see **Winter wheat (TRZAW) / *Zymoseptoria tritici* (SEPTTR)**). 18 trials out of 23 were considered valid. Data demonstrated a better effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rate for the reduction of disease severity on winter wheat against *Zymoseptoria tritici*. An overall trend of decreasing disease severity with increasing dose rates was observed in the dataset, although differences were not always statistically significant. In many instances the rate of 0.6 l/ha gave acceptable control of *Zymoseptoria tritici* very comparable to that of 0.8 l/ha, nevertheless in conditions of high disease pressure the additional disease reduction obtained from the higher rate of 0.8 l/ha may be more appropriate, in particular where some level of resistance is suspected.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Zymoseptoria tritici* on durum wheat in the South-Eastern East EPPO zone.

Table 3.2-131: Summary table – Minimum effective dose evaluation – Durum wheat – SEPTTR – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA33 01 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3 301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
% Disease severity L2 - 15 DA-B						
Number of values	1	1	1	1	UTC CA330 1	CA33 01 UT C CA33 01 CA330 1

Minimum value	11,35	4,29	4,13	1,96		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	11,35	4,29	4,13	1,96	1 >	0 >	0 >	1 >	1 >	1 >
Mean disease severity (%)	11,35	4,29	4,13	1,96	0 =	1 =	0 =	0 =	0 =	0 =
Abbott efficacy (%)	0,00%	62,20 %	63,61%	82,73 %	0 <	0 <	1 <	0 <	0 <	0 <
% Disease severity L1 - 15 DA-B										
Number of values	1	1	1	1	UTC	CA330 1 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	10,46	4,14	3,56	1,76						
Maximum value	10,46	4,14	3,56	1,76	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	10,46	4,14	3,56	1,76	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	60,42 %	65,97%	83,17 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 32-37 DA-B										
Number of values	2	2	2	2	UT C	CA330 1 0,48 l/ha	CA3301 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	19,35	1,53	2,08	3,59						
Maximum value	22,10	5,74	3,33	4,63	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	20,73	3,63	2,70	4,44	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	83,06 %	87,09%	79,91 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 32 DA-B										
Number of values	1	1	1	1	UTC	CA330 1 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	6,87	0,14	0,09	0,06						
Maximum value	6,87	0,14	0,09	0,06	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	6,87	0,14	0,09	0,06	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	97,96 %	98,69%	99,13 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (con-
versely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

2 trials have been submitted to determine minimum effective dose in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,6-0,8 l/ha achieved medium efficacy while the lower dose of 0,48 l/ha was not effective. A decrease of dose rate to 0,48 l/ha caused lower effectiveness about 10%. Due to the limited number of trials, the cMSs are kindly asked to consider MED for this use on the national level.

No trials were available to determine MED in **the North-East EPPO zone**.

4 trials were presented to determine MED in **the South-East EPPO zone**. CA3301 at dose rate of 0,8 l/ha achieved high efficacy in all assessments. No significant differences between lower doses of 0,48 l/ha and 0,6 l/ha were visible after 15 days after second application with results of medium to high level of control. Taking into account the applicant explanation, more benefits will come an application of 0,6-0,8 l/ha compare to the lower dose in situation of high disease pressure.

3.2.2.37

Durum wheat (TRZDU) / *Puccinia recondita* – *Puccinia triticina*

(PUCCRE-PUCCRT)

Puccinia recondita and *Puccinia triticina* are the causal agents of the brown rust on wheat and are considered as the same pathogen in this analysis.

Between 2017 and 2019, a single trial was conducted in France for the Mediterranean EPPO zone and 2 trials in Hungary for the South-Eastern East EPPO zones to evaluate the minimum effective dose of CA3301 against *Puccinia recondita* or *P. triticina* on durum wheat. The trials were carried out by certified testing institutes. The proposed dose rates are the range 0.6-0.8 l/ha.

In the Mediterranean EPPO zone, a single trial was performed in France but this trial was not valid because the disease level was not acceptable.

In the South-Eastern East EPPO zone, 2 trials were performed in Hungary.

No trials were available in this Biological dossier for the Maritime EPPO zone and for the North-Eastern East EPPO zone.

Out of the 3 trials carried out against *Puccinia recondita* (PUCCRE) or *Puccinia triticina* (PUCCRT) on durum wheat, only one in Hungary was considered valid.

Considering the single valid trial available on this disease the argumentation will be only on South-Eastern East EPPO zone. The argumentation on minimum effective dose of CA3301 for the control of brown rust on durum wheat was based also on data presented on winter wheat in the same EPPO zone and for the same disease.

This argumentation is possible since *Triticum durum* and *Triticum aestivum* have the same life cycle with the same exposure at *Puccinia recondita* or *Puccinia triticina* infection.

Triticum aestivum and *Triticum durum* belong to the same Order (Poales) and the same Family (Poaceae), are two crops with the same life cycle and are cultivated following the same agricultural practice. At the end are two crops showing a very similar sensitivity to *Puccinia recondita* (PUCCRE) or *Puccinia triticina* (PUCCRT) infection.

For these reasons, due the lack of valid trials, it is possible to refer to the data presented on winter wheat for the evaluation of the minimum effective dose in each EPPO zone.

Min. Eff. Dose evaluation of CA3301 - Maritime EPPO zone

In the Maritime EPPO zone no data were available to support the minimum effective dose evaluation several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha and 0.48 l/ha applied twice) on disease severity (%). However, durum wheat and winter wheat are comparable crops, both of the genus *Triticum* and the proposed applications are the same (dose rate, application timing etc), therefore reference is made to the data presented on winter wheat in support of the proposed minimum effective dose. The validity of this argumentation is supported by the fact that existing authorisations of similar prothioconazole products also have the same dose rates registered for both soft wheat and hard (durum) wheat, hence the pathogens are controlled similarly in each crop at the same dose rate.

In the Maritime EPPO zone, 9 supportive trials carried out on winter wheat demonstrated the later preventative effect of CA3301 on foliar level 2 in trials in which disease developed later in contrast with the trials presented at the earlier assessment where applications were made curatively or at earlier preventative timing. Over this dataset, it was envisaged that in most instances applications of 0.6 l/ha will be sufficient for the control of *Puccinia recondita* or *Puccinia triticina* on winter wheat. Nevertheless in conditions of high disease pressure the additional disease reduction obtained from the higher rate of 0.8 l/ha may be more appropriate.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Puccinia recondita* or *Puccinia triticina* on durum wheat in the Maritime EPPO zone.

Min. Eff. Dose evaluation of CA3301 - Mediterranean EPPO zone

In the Mediterranean EPPO zone no data were available to support the minimum effective dose evaluation several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha and 0.48 l/ha applied twice) on disease severity (%). However, durum wheat and winter wheat are comparable crops, both of the genus *Triticum* and the proposed applications are the same (dose rate, application timing etc), therefore reference is made to the data presented on winter wheat in support of the proposed minimum effective dose. The validity of this argumentation is supported by the fact that existing authorisations of similar prothioconazole products also have the same dose rates registered for both soft wheat and hard (durum) wheat, hence the pathogens are controlled similarly in each crop at the same dose rate.

In the Mediterranean EPPO zone, 17 supportive trials carried out on winter wheat demonstrated that in trials with relatively high disease pressure a statistical benefit was observed in increasing the dose rate from 0.6 L/ha to 0.8 L/ha whereas in trials with lower disease pressure the levels of control between these 2 dose rates were more comparable. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for the control of *Puccinia recondita* or *Puccinia triticina* on winter wheat. Nevertheless in conditions of high disease pressure the additional disease reduction obtained from the higher rate of 0.8 l/ha may be more appropriate.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Puccinia recondita* or *Puccinia triticina* on durum wheat in the Mediterranean EPPO zone.

Min. Eff. Dose evaluation of CA3301 - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone no data were available to support the minimum effective dose evaluation several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha and 0.48 l/ha applied twice) on disease severity (%). However, durum wheat and winter wheat are comparable crops, both of the genus *Triticum* and the proposed applications are the same (dose rate, application timing etc), therefore reference is made to the data presented on winter wheat in support of the proposed minimum effective dose. The validity of this argumentation is supported by the fact that existing authorisations of similar prothioconazole products also have the same dose rates registered for both soft wheat and hard (durum) wheat, hence the pathogens are controlled similarly in each crop at the same dose rate.

In the North-Eastern East EPPO zone, 10 supportive trials carried out on winter wheat demonstrated that in conditions of low to medium disease pressure, CA3301 applied at 0.6 l/ha gave comparable disease control than 0.8 l/ha in all trials. However, in most instances a numerical trend appeared to reduce the disease severity with increasing dose rates, particularly when the disease pressure increases. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for the control of *Puccinia recondita* or *Puccinia triticina* on winter wheat. Nevertheless in conditions of high disease pressure the additional disease reduction obtained from the higher rate of 0.8 l/ha may be more appropriate.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Puccinia recondita* or *Puccinia triticina* on durum wheat in the North-Eastern East EPPO zone.

Min. Eff. Dose evaluation of CA3301 – South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a single valid trial on durum wheat was included to support the minimum effective dose evaluation of CA3301. Several dose rates (0.8 l/ha, 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). CA3301 was first applied at crop stages BBCH 34-37 and the 2nd application was at BBCH 58-61.

Summary results are presented in Table 3.2-132

When evaluating the reduction of disease severity, the data demonstrated the highest fungicidal effect to control brown rust was provided after two applications of CA3301 at 0.6-0.8 l/ha.

On foliar level 2, when applied at 0.6 l/ha, CA3301 showed 83.47% of efficacy to control brown rust 19 days after the 2nd application. On foliar level 1, CA3301 at 0.6 l/ha showed 74.07% of efficacy on reduction of disease severity 19 days after the 2nd application.

When applied at 0.8 l/ha, on foliar level 2, CA3301 showed 93.32% of efficacy to control brown rust and on foliar level 1, CA3301 at 0.8 l/ha showed 92.72% of efficacy on reduction of disease severity 19 days after the 2nd application.

These positive effects of CA3301 at 0.6-0.8 l/ha to control brown rust were significantly superior than the 0.48 l/ha dose rate tested and provided high to medium efficacy

In these trials, the disease pressure was low and the levels of disease control between 0.6 and 0.8 l/ha dose rates were comparable. Durum wheat is generally less susceptible to *Puccinia* pathogens, which may explain the low levels of disease. In addition to a single trial presented above, since durum wheat and winter wheat are comparable crops for several reasons, it is possible to demonstrate the minimum effective dose referring to the data presented on winter wheat. On winter wheat in the South-Eastern East EPPO zone, 7 valid trials were included to support the minimum effective dose evaluation of CA3301 and can be supportive to this section (see **Winter wheat (TRZAW) / Puccinia recondita – Puccinia triticina (PUCCRE-PUCCRT)**). The data demonstrated that in case of high level of disease pressure, a distinct difference can be seen between the 0.6 l/ha and 0.8 l/ha dose rates and moreover, in case of early time for disease development, the two higher dose rates 0.6 and 0.8 l/ha showed an equivalent performance.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Puccinia recondita* or *Puccinia triticina* on durum wheat in the South-Eastern East EPPO zone.

Table 3.2-132: Summary table – Minimum effective dose evaluation – Durum wheat – PUCCRE – South-Eastern East EPPO zone

South-Eastern East EPTO zone										
Treatment name	UNTREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		0,48	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Disease severity L2 - 19 DA-B										
Number of values	1	1	1	1	UT	CA330	CA33	UT	CA33	CA33
Minimum value	5,99	3,66	0,99	0,40	C	1 0,48 l/ha	01 0,8 l/ha	C	01 0,48 l/ha	01 0,6 l/ha
Maximum value	5,99	3,66	0,99	0,40	1 >	1 >	0 >	1 >	1 >	0 >
Mean disease severity (%)	5,99	3,66	0,99	0,40	0 =	0 =	1 =	0 =	0 =	1 =
Abbot efficacy (%)	0,00%	38,90%	83,47%	93,32%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 19 DA-B										
Number of values	1	1	1	1	UT	CA330	CA33	UT	CA33	CA33
Minimum value	5,36	3,83	1,39	0,39	C	1 0,48 l/ha	01 0,8 l/ha	C	01 0,48 l/ha	01 0,6 l/ha
Maximum value	5,36	3,83	1,39	0,39	1 >	1 >	0 >	1 >	1 >	0 >
Mean disease severity (%)	5,36	3,83	1,39	0,39	0 =	0 =	1 =	0 =	0 =	1 =
Abbot efficacy (%)	0,00%	28,54%	74,07%	92,72%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treat-
ment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy

<60% Low efficacy

Comments of zRMS:

No trials have been submitted to determine minimum effective dose to control of *Puccinia recondite* in durum wheat in the **Maritime** and **North-East EPPO climatic zones**. The cMSs are kindly asked to consider MED for this use on the national level.

Only 1 trial was available in the **South-East EPPO zone**. CA3301 applied at dose rate of 0,6 l/ha achieved medium to high level of control after 19 days after second application while the lower dose of 0,48 l/ha was not effective in this assessment. Due to the limited number of trials, the cMSs are kindly asked to consider MED for this use on the national level.

3.2.2.38 Durum wheat (TRZDU) / *Fusarium graminearum* (GIBBZE)

Between 2018 and 2020, 2 trials were conducted in several countries of the Mediterranean and South-Eastern ~~East~~ EPPO zones to evaluate the minimum effective dose of CA3301 against *Fusarium graminearum* on durum wheat. The trials were carried out by certified testing institutes. The proposed dose rates are the range 0.6-0.8 l/ha.

In the Mediterranean EPPO zone, a single trial was performed in Italy.

In the South-~~Eastern~~ **East** EPPO zone, a single trial was performed in Hungary.

All 2 trials were considered valid.

Since a single trial was available in the Mediterranean and South-~~Eastern~~ **East** EPPO zones for this use, the argumentation on minimum effective dose of CA3301 for the control on durum wheat was based also on data presented on winter wheat in the same EPPO zones and for the same disease.

This argumentation is possible since *Triticum durum* and *Triticum aestivum* have the same life cycle with the same exposure at *Fusarium graminearum* infection.

Triticum aestivum and *Triticum durum* belong to the same Order (Poales) and the same Family (Poaceae), are two crops with the same life cycle and are cultivated following the same agricultural practice. At the end are two crops showing a very similar sensitivity to *Fusarium graminearum* (GIBBZE).

For these reasons, due the lack of valid trials, it is possible to refer to the data presented on winter wheat for the evaluation of the minimum effective dose in all EPPO zones.

Min. Eff. Dose evaluation of CA3301 - Maritime EPPO zone

In the Maritime EPPO zone no data were available to support the minimum effective dose evaluation several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha and 0.48 l/ha applied twice) on disease severity (%). However, durum wheat and winter wheat are comparable crops, both of the genus *Triticum* and the proposed applications are the same (dose rate, application timing etc), therefore reference is made to the data presented on winter wheat in support of the proposed minimum effective dose. The validity of this argumentation is supported by the fact that existing authorisations of similar prothioconazole products also have the same dose rates registered for both soft wheat and hard (durum) wheat, hence the pathogens are controlled similarly in each crop at the same dose rate.

In the Maritime EPPO zone, 6 supportive trials demonstrated that CA3301 at 0.6-0.8 l/ha showed medium efficacy in reducing the severity of *Fusarium graminearum* on winter wheat. These positive effects of CA3301 at 0.6-0.8 l/ha were overall statistically equivalent to the 0.48 l/ha dose rate. Over this dataset, the disease pressure was low to medium, therefore the performance of the tested product in conditions of relatively high pressure could not be assessed. However, in the supportive dataset available against *Fusarium culmorum*, an overall trend of decreasing disease severity with increasing dose rates was observed in particular for 0.6 & 0.8 l/ha compared to 0.48 l/ha. The same trend would be expected for

Fusarium graminearum at higher disease levels. In addition, due to the importance of this disease the higher rates may be considered more appropriate than the 0.48 l/ha dose rate.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Fusarium graminearum* on durum wheat in the Maritime EPPO zone.

Min. Eff. Dose evaluation of CA3301 – Mediterranean EPPO zone

In the Mediterranean EPPO zone, a single valid trial on durum wheat was included to support the minimum effective dose evaluation of CA3301 against *Fusarium graminearum*. Several dose rates (0.8 l/ha, 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). In this trial the principal aim was the efficacy evaluation against foliar disease therefore CA3301 was first applied at crop stage BBCH 31 and the 2nd application was at BBCH 47-49.

Summary results are presented in Table 3.2-133.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect to control *Fusarium graminearum* on ears was provided by CA3301 0.8 l/ha. In addition to a single trial presented above, since a durum wheat and winter wheat are comparable crops, it is possible to demonstrate the minimum effective dose referring to the data presented on winter wheat.

On winter wheat in the Mediterranean EPPO zone, 10 valid trials were included to support the minimum effective dose evaluation of CA3301, and the data did not always demonstrate a statistically better effect of CA3301 at 0.6-0.8 l/ha versus 0.48 l/ha against *Fusarium graminearum*. CA3301 at 0.6-0.8 l/ha showed a medium efficacy in reducing the disease severity on ears on winter wheat. An overall trend of decreasing disease severity with increasing the dose rate was observed in the dataset, in particular for 0.6-0.8 l/ha compared to 0.48 l/ha, although differences were not always statistically significant.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Fusarium graminearum* on durum wheat in the Mediterranean EPPO zone.

Table 3.2-133: Summary table – Minimum effective dose evaluation – Durum wheat – GIBBZE – Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA330 1 0,48 L/ha AB	CA33 01 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate										
Rate unit										
Appl. Code										
% Disease severity EARS - 35 DA-B										
Number of values	1	1	1	1	UT C	CA33 01 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	14,83	10,00	8,03	5,85						
Maximum value	14,83	10,00	8,03	5,85	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	14,83	10,00	8,03	5,85	0 =	1 =	1 =	0 =	1 =	1 =
Abbot efficacy (%)	0,00%	32,57 %	45,85 %	60,55%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone no data were available to support the minimum effective dose evaluation several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha and 0.48 l/ha applied twice) on disease severity (%). However, durum wheat and winter wheat are comparable crops, both of the genus *Triticum* and the proposed applications are the same (dose rate, application timing etc), therefore reference is made to the data presented on winter wheat in support of the proposed minimum effective dose. The validity of this argumentation is supported by the fact that existing authorisations of similar prothioconazole products also have the same dose rates registered for both soft wheat and hard (durum) wheat, hence the pathogens are controlled similarly in each crop at the same dose rate.

In the North-Eastern East EPPO zone, 6 supportive trials demonstrated that CA3301 at 0.6-0.8 l/ha showed low to medium efficacy in reducing the severity of *Fusarium graminearum* on winter wheat. An overall trend of decreasing disease severity with increasing dose rates was observed in the dataset, in particular for 0.8 l/ha which was often statistically more efficient compared to 0.6 l/ha and 0.48 l/ha, although differences were not always significant especially between the 2 lower dose rates. Due to the importance of this disease the higher rate with increased disease suppression may be considered more appropriate, especially in trials with high disease pressure.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Fusarium graminearum* on durum wheat in the North-Eastern East EPPO zone.

Min. Eff. Dose evaluation of CA3301 – South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a single valid trial on durum wheat was included to support the minimum effective dose evaluation of CA3301. Several dose rates (0.8 l/ha, 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). As the aim of this trials was also the efficacy evaluation against *Fusarium culmorum* in the first durum wheat stage CA3301 was first applied at crop stage BBCH 39 and the 2nd application was at BBCH 65.

Summary results are presented in Table 3.2-134.

When evaluating the reduction of disease severity, the data demonstrated the highest fungicidal effect to control *Fusarium graminearum* on ears provided after the flowering applications of CA3301. In addition to a single trial presented above, since durum wheat and winter wheat are comparable crops, it is possible to demonstrate the minimum effective dose referring to the data presented on winter wheat.

In the South-Eastern East EPPO zone 6 valid trials evaluated the efficacy of CA3301 against *Fusarium graminearum* and can be supportive for this section. In the South-Eastern East EPPO zone, CA3301 at 0.6-0.8 l/ha showed medium to high efficacy in reducing the severity of *Fusarium graminearum* on winter wheat.

A clear dose effect was observed with CA3301 at 0.8 l/ha that was globally statistically more efficient than the 2 lower dose rates and the 0.6 l/ha that was also more efficient than the 0.48 l/ha dose rate to control *Fusarium graminearum*. Therefore, the higher rate of 0.8 l/ha is more appropriate in situations of high disease pressure, but in case of low to medium disease pressure the 0.6 l/ha rate might be sufficient to obtain a suitable level of disease control.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Fusarium graminearum* on durum wheat in the South-Eastern East EPPO zone.

Table 3.2-134: Summary table – Minimum effective dose evaluation – Durum wheat – GIBBZE – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA330 1	CA330 1	CA330 1	No of trials where CA3301	No of trials where CA3301
Rate		0,48	0,6	0,8	at 0,6 l/ha is >, = or <	at 0,8 l/ha is >, = or <
Rate unit		L/ha	L/ha	L/ha		

Appl. Code		AB	AB	AB		compared to			compared to	
% Disease severity Ear 14 DA-B										
Number of values	1	1	1	1	UT	CA330	CA330	UT	CA330	CA3301
Minimum value	44,00	3,55	0,48	0,43	C	0,48 l/ha	0,8 l/ha	C	0,48 l/ha	0,6 l/ha
Maximum value	44,00	3,55	0,48	0,43	1 >	1 >	0 >	1 >	1 >	0 >
Mean disease severity (%)	44,00	3,55	0,48	0,43	0 =	0 =	1 =	0 =	0 =	1 =
Abbot efficacy (%)	0,00%	91,93 %	98,91 %	99,02 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity Ear 21 DA-B										
Number of values	1	1	1	1	UT	CA330	CA330	UT	CA330	CA3301
Minimum value	59,15	2,82	0,57	0,53	C	0,48 l/ha	0,8 l/ha	C	0,48 l/ha	0,6 l/ha
Maximum value	59,15	2,82	0,57	0,53	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	59,15	2,82	0,57	0,53	0 =	1 =	1 =	0 =	1 =	1 =
Abbot efficacy (%)	0,00%	95,23 %	99,04 %	99,10 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

No trials have been submitted to determine minimum effective dose to control of *Fusarium graminearum* on durum wheat in the **Maritime** and **North-East EPPO climatic zones**. The cMSs are kindly asked to consider MED for this use on the national level.

Only 1 trial was available in the **South-East EPPO zone**. CA3301 applied at dose rate of 0,48-0,8 l/ha achieved very high level of control after 14-21 days after second application. Also 1 additional trial from the Mediterranean zone has been submitted to support of product registration in other zones. However, a very low effectiveness was observed after application of CA3301. Due to the limited number of trials, the cMSs are kindly asked to consider MED for this use on the national level.

3.2.2.1 Durum wheat (TRZDU) / *Fusarium spp.* (FUSASP)

In 2018, a single trial was conducted in the North-~~Eastern~~ **East EPPO** zone to evaluate the minimum effective dose of CA3301 against *Fusarium spp.* on **durum wheat**. The trial was carried out by certified testing institutes.

The proposed dose rates are the range 0.6-0.8 l/ha.

In the North-~~eastern~~ **East EPPO** zone, a single trial was performed in Poland but was not considered valid. Therefore no data were available to support the evaluation of CA3301 on this use.

Min. Eff. Dose evaluation of CA3301 – all EPPO zones

In the North-~~eastern~~ **East EPPO** zone, a single trial was performed in Poland but was not considered valid. Considering that no data were available to support the evaluation of CA3301 on this section, the argue regarding the minimum effective dose of CA3301 for the control of *Fusarium spp.* on durum wheat was based on the extrapolation of the data presented on winter wheat for the same disease.

This extrapolation is possible since *Triticum durum* and *Triticum aestivum* have the same life cycle with the same exposure at *Fusarium spp.* infection. Moreover, *Triticum aestivum* and *Triticum durum* belong to the same Order (Poales) and the same Family (Poaceae), are two crops with the same life cycle and

are cultivated following the same agricultural practice. At the end are two crops showing a very similar sensitivity to *Fusarium spp.* (FUSASP).

Over the dataset available on winter wheat, the tested product demonstrated comparable efficacy from CA3301 dose rates on the related pathogen *Fusarium graminearum* for which the higher rate of 0.8 l/ha is more appropriate in situations of high disease pressure, but in case of low disease pressure the 0.6 l/ha rate might be sufficient to obtain a suitable level of disease control.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Fusarium spp.* on durum wheat in all EPPO zones

Comments of zRMS:

No trials have been submitted to determine minimum effective dose to control of *Fusarium sp.* on durum wheat in any EPPO climatic zones. The cMSs are kindly asked to consider MED for this use on the national level.

3.2.2.2 Durum wheat (TRZDU) / *Blumeria graminis* – *Blumeria graminis f. sp. tritici* (ERYSGR – ERYSGT)

Between 2019 and 2020, 2 trials were conducted in Germany for the Maritime EPPO zone, 1 trial in Italy for the Mediterranean EPPO zone and 2 trials in Hungary for the South-Eastern East EPPO zone to evaluate the minimum effective dose of CA3301 against *Blumeria graminis* and *Blumeria graminis f. sp. tritici* on durum wheat. The trials were carried out by certified testing institutes. The proposed dose rates are the range 0.6-0.8 l/ha.

These 5 trials carried out against *Blumeria graminis* (ERYSGR) and *Blumeria graminis f. sp. tritici* (ERYSGT) on durum wheat were considered valid.

Treatment against *Blumeria graminis* is triggered when 20% of leaves (L1 to L4 considered together) are attacked by the fungus on sensitive varieties (source ARVALIS Institut du vegetal). As a consequence, the analysis will be conducted on four foliar levels L1 to L4 with the parameter 'Disease incidence %' and 'Disease severity %', when the disease pressure was sufficient in the untreated control. In addition, a trial was considered valid when the level of disease incidence or the disease severity was higher than 5% in the untreated control and if the reference product shows a significant difference compared to the untreated control.

No trials were available in this Biological dossier for the North-Eastern East EPPO zones.

Considering the low data package available on this disease on Maritime, Mediterranean and South-Eastern East EPPO zones the argumentation on minimum effective dose of CA3301 for the control against *Blumeria graminis* on durum wheat was also based on data presented on winter wheat in the same EPPO zones and for the same disease.

This argumentation is possible since *Triticum durum* and *Triticum aestivum* have the same life cycle with the same exposure at *Blumeria graminis* infection.

Triticum aestivum and *Triticum durum* belong to the same Order (Poales) and the same Family (Poaceae), are two crops with the same life cycle and are cultivated following the same agricultural practice. At the end *Triticum aestivum* and *Triticum durum* are two crops showing a very similar sensitivity to *Blumeria graminis* (ERYSGR/ERYSGT).

For these reasons, due to the lack of valid trials, it is possible to refer to the data presented on winter wheat for the evaluation of the minimum effective dose in Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones.

In the Maritime EPPO zone, two valid trials on durum wheat were included to support the minimum effective dose evaluation of CA3301 against *Blumeria graminis* f. sp. *tritici*. Several dose rates (0.8 l/ha, 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) were tested to compare the efficacy of CA3301 on disease incidence and severity (%). CA3301 was applied twice, the first application at crop stage BBCH 31 and the 2nd application was done at crop stage BBCH 53-55.

When evaluating the reduction of disease incidence, the data demonstrated that the highest fungicidal effect to control *Blumeria graminis* f. sp. *tritici* on leaves was provided by CA3301 0.8 l/ha even if not always statistically different from other dose rates. A consistent trend was observed across the data for lower disease with increasing dose rates. On disease incidence and disease severity the data confirmed the improved control (high to medium efficacy) provided by CA3301 at 0.8 l/ha and at 0.6 l/ha, even if these rates are not always statistically different from 0.48 l/ha (medium to low efficacy).

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Blumeria graminis* on durum wheat in the Maritime EPPo zone.

Multivariate LFC Zone										
Treatment name	UNTREATED CHECK	CA33 01	CA330 1	CA33 01	No of trials where CA3301			No of trials where CA3301		
Rate		0,48	0,6	0,8	at 0,6 l/ha is >, = or <			at 0,8 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
% Disease incidence L3 - 14 DA-B										
Number of values	1	1	1	1	UT	CA33 01	CA330 1	UT	CA330 1	CA330 1
Minimum value	95,00	30,00	25,00	16,25	C	0,48 l/ha	0,8 l/ha	C	0,48 l/ha	0,6 l/ha
Maximum value	95,00	30,00	25,00	16,25	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease incidence (%)	95,00	30,00	25,00	16,25	0 =	1 =	1 =	0 =	1 =	1 =
Abbot efficacy (%)	0,00%	68,42 %	73,68%	82,89 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease incidence L2 - 14-19 DA-B										
Number of values	2	2	2	2	UT	CA33 01	CA330 1	UTC	CA330 1	CA33 01
Minimum value	47,50	0,00	0,00	0,00	C	0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	87,50	40,00	35,00	20,00	2 >	0 >	0 >	2 >	1 >	0 >
Mean disease incidence (%)	67,50	20,00	17,50	10,00	0 =	2 =	2 =	0 =	1 =	2 =
Abbot efficacy (%)	0,00%	77,14 %	80,00%	88,57 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease incidence L2 - 39 DA-B										

Treatment name	UNTREATED CHECK	CA33 01 0,48 L/ha AB	CA330 1 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate					UT	CA33 01	CA330 1	UTC	CA330 1	CA33 01
Rate unit					C	0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Appl. Code										
Number of values	1	1	1	1						
Minimum value	71,25	35,00	25,00	15,00						
Maximum value	71,25	35,00	25,00	15,00	1 >	0 >	0 >	1 >	1 >	0 >
Mean disease incidence (%)	71,25	35,00	25,00	15,00	0 =	1 =	1 =	0 =	0 =	1 =
Abbot efficacy (%)	0,00%	50,88 %	64,91%	78,95 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease incidence L1 - 39 DA-B										
Number of values	1	1	1	1	UT	CA33 01	CA330 1	UTC	CA330 1	CA33 01
Minimum value	65,00	31,25	17,50	3,75	C	0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	65,00	31,25	17,50	3,75	1 >	0 >	0 >	1 >	1 >	0 >
Mean disease incidence (%)	65,00	31,25	17,50	3,75	0 =	1 =	1 =	0 =	0 =	1 =
Abbot efficacy (%)	0,00%	51,92 %	73,08%	94,23 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 39 DA-B										
Number of values	1	1	1	1	UT	CA33 01	CA330 1	UTC	CA330 1	CA33 01
Minimum value	9,06	2,96	1,94	0,56	C	0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	9,06	2,96	1,94	0,56	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	9,06	2,96	1,94	0,56	0 =	1 =	1 =	0 =	1 =	1 =
Abbot efficacy (%)	0,00%	67,33 %	78,59%	93,82 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 39 DA-B										
Number of values	1	1	1	1	UT	CA33 01	CA330 1	UTC	CA330 1	CA33 01
Minimum value	6,94	1,68	0,75	0,19	C	0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	6,94	1,68	0,75	0,19	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	6,94	1,68	0,75	0,19	0 =	1 =	1 =	0 =	1 =	1 =
Abbot efficacy (%)	0,00%	75,79 %	89,19%	97,26 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – Mediterranean EPPO zone

In the Mediterranean EPPO zone, a single valid trial on durum wheat was included to support the minimum effective dose evaluation of CA3301 against *Blumeria graminis*. Several dose rates (0.8 l/ha, 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) were tested to compare the efficacy of CA3301 on disease incidence and severity (%) on leaves and on ears.

Summary results are presented in Table 3.2-136 &

Table 3.2-137.

When evaluating the reduction of disease incidence, the data demonstrated the highest fungicidal effect on leaves to control *Blumeria graminis* provided by CA3301 at the proposed dose rates as high efficacy was obtained at each assessment timing.. On ears at the earlier assessment the rate of 0.6 l/ha was significantly more efficient than the reduced rate and comparable with 0.8 l/ha. On severity the data confirmed the high to medium efficacy provided by CA3301 at 0.8 l/ha and at 0.6 l/ha, even if these rates were not always statistically different from 0.48 l/ha, a consistent trend was nevertheless observed with overall higher efficacy.

In addition to this trial presented above, since durum wheat and winter wheat are comparable crops and the proposed applications are the same, it is possible to demonstrate the minimum effective dose referring to the data presented on winter wheat.

In the Mediterranean EPPO zone, 5 trials enabled to compare the efficacy of CA3301 only on disease incidence (%), since the disease severity was too low to evaluate the performance of the tested product. The analysis was conducted on the fourth main foliar levels L1, L2, L3 and L4 and the data can be supportive for this section. Even if statistical dose response was not always observed, a numerical dose effect could be seen with a better reduction of the disease incidence with CA3301 at 0.8 l/ha than with the 0.6 l/ha, which itself appeared more efficient than the 0.48 l/ha. In addition, due to the importance of this disease and the possibility of resistance of this pathogen, the higher rate with increased disease reduction may be considered more appropriate especially in case of high infestation.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Blumeria graminis* on durum wheat in the Mediterranean EPPO zone.

Table 3.2-136: Summary table – Minimum effective dose evaluation – Durum wheat – ERYSGR – Mediterranean EPPO zone – Disease incidence (%)

Treatment name	UNTREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		0,48	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Disease incidence L4 - 6 DA-B										
Number of values	1	1	1	1	UTC	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	100,00	33,75	6,25	16,25		1 >	0 >	0 >	1 >	0 >
Maximum value	100,00	33,75	6,25	16,25	0 =	1 =	1 =	0 =	1 =	
Mean disease inci- dence (%)	100,00	33,75	6,25	16,25	0 <	0 <	0 <	0 <	0 <	
Abbot efficacy (%)	0,00%	66,25%	93,75%	83,75%	0 <	0 <	0 <	0 <	0 <	
% Disease incidence L3 - 6 DA-B										
Number of values	1	1	1	1	UTC	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	85,00	16,25	0,00	6,25		1 >	0 >	0 >	1 >	0 >
Maximum value	85,00	16,25	0,00	6,25	0 =	1 =	1 =	0 =	1 =	
Mean disease inci- dence (%)	85,00	16,25	0,00	6,25	0 <	0 <	0 <	0 <	0 <	
Abbot efficacy (%)	0,00%	80,88%	100,00%	92,65%	0 <	0 <	0 <	0 <	0 <	
% Disease incidence L2 - 6 DA-B										
Number of values	1	1	1	1	UTC	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	35,00	0,00	0,00	3,75		1 >	0 >	0 >	1 >	0 >
Maximum value	35,00	0,00	0,00	3,75	0 =	1 =	1 =	0 =	1 =	
Mean disease inci- dence (%)	35,00	0,00	0,00	3,75						

Abbot efficacy (%)	0,00%	100,00%	100,00%	89,29%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease incidence Ear - 22 DA-B										
Number of values	1	1	1	1	UTC	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	100,00	60,00	38,80	48,80		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	100,00	60,00	38,80	48,80	1 >	1 >	0 >	1 >	0 >	0 >
Mean disease inci- dence (%)	100,00	60,00	38,80	48,80	0 =	0 =	1 =	0 =	1 =	1 =
Abbot efficacy (%)	0,00%	40,00%	61,20%	51,20%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease incidence Ear - 33 DA-B										
Number of values	1	1	1	1	UTC	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	100,00	60,80	60,00	52,50		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	100,00	60,80	60,00	52,50	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease inci- dence (%)	100,00	68,80	60,00	52,50	0 =	1 =	1 =	0 =	1 =	1 =
Abbot efficacy (%)	0,00%	31,20%	40,00%	47,50%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treat-
ment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

**Table 3.2-137: Summary table – Minimum effective dose evaluation – Durum wheat – ERYSGR – Medi-
terranean EPPO zone – Disease severity (%)**

Treatment name	UN-TREAT ED CHEC K	CA3301	CA3301	CA3301	No of trials where CA3301			No of trials where CA3301		
Rate		0,48	0,6	0,8	at 0,6 l/ha is >, = or			at 0,8 l/ha is >, = or		
Rate unit		L/ha	L/ha	L/ha	<			<		
Appl. Code		AB	AB	AB	compared to			compared to		
% Disease severity L4 - 6 DA-B										
Number of values	1	1	1	1	UT C	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	37,69	4,13	0,38	2,38		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	37,69	4,13	0,38	2,38	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease sever- ity (%)	37,69	4,13	0,38	2,38	0 =	1 =	1 =	0 =	1 =	1 =
Abbot efficacy (%)	0,00%	89,04%	98,99%	93,69%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L3 - 6 DA-B										
Number of values	1	1	1	1	UT C	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	15,31	1,13	0	0,63		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	15,31	1,13	0	0,63	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease sever- ity (%)	15,31	1,13	0	0,63	0 =	1 =	1 =	0 =	1 =	1 =
Abbot efficacy (%)	0,00%	92,62%	100,00%	95,89%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity Ear - 22 DA-B										
Number of values	1	1	1	1	UT C	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	20,4	5,7	3,6	2,7		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	20,4	5,7	3,6	2,7	1 >	1 >	0 >	1 >	1 >	0 >

Treatment name	UN-TREAT ED CHEC K	CA3301	CA3301	CA3301	No of trials where CA3301			No of trials where CA3301		
Rate		0,48	0,6	0,8	at 0,6 l/ha is >, = or			at 0,8 l/ha is >, = or		
Rate unit		L/ha	L/ha	L/ha	<			<		
Appl. Code		AB	AB	AB	compared to			compared to		
Mean disease severity (%)	20,4	5,7	3,6	2,7	0 =	0 =	1 =	0 =	0 =	1 =
Abbot efficacy (%)	0,00%	72,06%	82,35%	86,76%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease incidence Ear - 33 DA-B										
Number of values	1	1	1	1	UT	CA33 01	CA33 01	UT	CA33 01	CA33 01
Minimum value	43,8	12,9	10,6	5,9	C	0,48 l/ha	0,8 l/ha	C	0,48 l/ha	0,6 l/ha
Maximum value	43,8	12,9	10,6	5,9	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	43,8	12,9	10,6	5,9	0 =	1 =	1 =	0 =	1 =	1 =
Abbot efficacy (%)	0,00%	70,55%	75,80%	86,53%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone no data were available to support the minimum effective dose evaluation several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha and 0.48 l/ha applied twice) on disease severity (%). However, durum wheat and winter wheat are comparable crops, both of the genus *Triticum* and the proposed applications are the same (dose rate, application timing etc), therefore reference is made to the data presented on winter wheat in support of the proposed minimum effective dose. The validity of this argumentation is supported by the fact that existing authorisations of similar prothioconazole products also have the same dose rates registered for both soft wheat and hard (durum) wheat, hence the pathogens are controlled similarly in each crop at the same dose rate.

In the North-Eastern East EPPO zone, 19 supportive trials carried out on winter wheat demonstrated that following 2 applications, the fungicidal performance of CA3301 enabled to significantly decrease the disease incidence on leaves in most instances, compared to the untreated control and whatever the dose rate considered. At 13-16 DA-B or before harvest, all doses of CA3301 were statistically equivalent except once where 0.48 l/ha gave significant lower disease control than 0.6 or 0.8 l/ha. Nevertheless in the majority of datasets a numerical dose rate trend was observed and data clearly evidenced that 0.6 l/ha and 0.8 l/ha provided a strongest control of disease incidence on leaves compared to 0.48 l/ha. The maximum disease incidence decreases when the dose rate increases.

Therefore, and logically, the effectiveness of CA3301 tended to increase and be highest when sprayed at 0.8 l/ha. In addition, due to the importance of this disease, the higher rate with increased disease suppression may be considered more appropriate especially in case of high infestation.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Blumeria graminis* on durum wheat in the North-Eastern East EPPO zone.

Min. Eff. Dose evaluation of CA3301 – South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, two valid trials on durum wheat were included to support the minimum effective dose evaluation of CA3301 against *Blumeria graminis*. Several dose rates (0.8 l/ha,

0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%) on foliar levels L3 and L2.

Summary results are presented in Table 3.2-138.

When evaluating the reduction of disease severity on leaves, the data demonstrated the highest fungicidal effect to control *Blumeria graminis* provided by CA3301 0.6-0.8 l/ha even if not always statistically different from other dose rates appeared. High to medium efficacy was obtained from the proposed dose rates compared to medium to low efficacy for the reduced rate of 0.48 l/ha.

In addition to this trial presented above, since durum wheat and winter wheat are comparable crops, it is possible to demonstrate the minimum effective dose referring to the data presented on winter wheat. In the South-Eastern East EPPO zone, the minimum effective dose evaluation was conducted thanks to 10 trials considered as valid and assessing disease incidence on leaves. An overall trend of decreasing disease incidence with increasing dose rates was observed in the dataset, in particular for 0.6 & 0.8 l/ha compared to 0.48 l/ha, with differences that were statistically significant in a several trials especially on L2. In addition, due to the importance of this disease and also the possibility of resistance in this pathogen, the higher rate with increased disease reduction may be considered more appropriate.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Blumeria graminis* on durum wheat in the South-Eastern East EPPO zone.

Table 3.2-138: Summary table – Minimum effective dose evaluation – Durum wheat – ERYSGR – South-Eastern East EPPO zone (%)

Treatment name	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity L3 - 15 DA-B										
Number of values	2	2	2	2	UT C	CA3301 0,48 l/ha	CA3301 0,8 l/ha	UT C	CA3301 0,48 l/ha	CA3301 0,6 l/ha
Minimum value	49,50	23,96	12,76	10,18	2 >	0 >	0 >	2 >	1 >	1 >
Maximum value	54,75	33,50	24,50	24,69	0 =	2 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	52,13	28,73	18,63	17,43	0 <	0 <	1 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	45,20 %	64,74 %	67,17 %						
% Disease severity L2 - 15 DA-B										
Number of values	2	2	2	2	UT C	CA3301 0,48 l/ha	CA3301 0,8 l/ha	UT C	CA3301 0,48 l/ha	CA3301 0,6 l/ha
Minimum value	18,65	5,09	3,94	3,43	2 >	0 >	0 >	2 >	1 >	0 >
Maximum value	23,00	6,64	5,11	3,94	0 =	2 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	20,83	5,86	4,53	3,68	0 <	0 <	1 <	0 <	0 <	1 <
Abbot efficacy (%)	0,00%	71,92 %	77,74 %	82,24 %						

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

2 trials have been submitted to determine minimum effective dose in the Maritime EPPO climatic zone.

CA3301 applied at dose rate of 0,6-0,8 l/ha achieved consistently medium to high level of control of ERYSGR. The dose rate of 0,48 l/ha showed low efficacy in 1 out of 2 trials. A significant differences between higher and lower doses were observed, especially before harvest. Due to the limited number of trials, the cMSs are kindly asked to consider MED for this use on the national level.

No efficacy trials were available to determine MED in **the North-East EPPO zone**.

2 trials were presented to determine MED in **the South-East EPPO zone**. CA3301 at 0,6-0,8 l/ha achieved medium to high efficacy while the lower dose of 0,48 l/ha showed low to medium level. Also 1 additional trial from the Mediterranean zone has been submitted to support of product registration in other zones. Based on PESSEV parameter, the dose rate of 0,6-0,8 l/ha is not significant better compared to the lower dose in all assessments. The all doses achieved similar efficacy in observations provided on leaves (L4 and L3). Due to the limited number of trials, the cMSs are kindly asked to consider MED for this use on the national level.

3.2.2.1 Durum wheat (TRZDU) / Green leaf area

In all trials presented in this Biological dossier was assessed the green leaf area. The reduction of green leaf area in untreated check was a consequence of the disease infection. The green leaf area is a parameter to evaluate the CA3301 efficacy against foliar diseases.

Min. Eff. Dose evaluation of CA3301 – Maritime EPPO zone

Green leaf area was recorded at 31-42 DA-B in 4 trials on durum wheat in the Maritime EPPO zone after two applications of CA3301 at 0.8 l/ha (1), 0.6 l/ha (1N) and 0.48 l/ha (0.8N). In these trials, green leaf area was assessed on the whole plant.

Summary results are presented in Table 3.2-139.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rate for the augmentation of green leaf area on durum wheat infected by foliar diseases. In these trials assessing green leaf area on the whole plant, an augmentation of 49.82%, 38.87% and 20.34% averaged across each trial was recorded with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check on durum wheat.

A dose effect with statistical differences were observed in 1 trial, green leaf area statistically increases with higher dose rate, in particular for CA3301 at 0.8-0.6 l/ha compared to 0.48 l/ha.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on durum wheat infected by a range of diseases in the Maritime EPPO zone.

Table 3.2-139: Summary table – Minimum effective dose evaluation – Durum wheat – Green leaf area - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301			No of trials where CA3301		
Rate		0,48	0,6	0,8	at 0,6 l/ha is >, = or <			at 0,8 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
% Green leaf area plant 31-42 DA-B										
Number of values	4	4	4	4	UTC	CA3301	CA3301	UTC	CA3301	CA3301
Minimum value	5,00	7,50	8,75	10,00		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	68,75	72,50	70,00	71,25	1 >	1 >	0 >	2 >	1 >	1 >
Green Leaf Area (%)	39,38	42,50	46,88	48,13	3 =	3 =	3 =	2 =	3 =	3 =
%UTC	100,00%	120,34%	138,87%	149,82%	0 <	0 <	1 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Min. Eff. Dose evaluation of CA3301 – Mediterranean EPPO zone

Green leaf area was recorded at 16-35 DA-B in 7 trials on durum wheat after two applications of CA3301 at 0.8 l/ha, 0.6 l/ha (1N) and 0.48 l/ha (0.8N) applied twice. In 6 trials, green leaf area was assessed as a percentage on the entire plant while one trial was assessed with the NDVI instrument with a 0-1 scale.

Summary results are presented in Table 3.2-140

Data demonstrated a better effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rate for the preservation of green leaf area on durum wheat infected by foliar diseases in two trials. In the trials assessing green leaf area as a visual estimation in percentage, an augmentation of 57.85%, 72.76% and 48.11% was recorded with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check on durum wheat. In the trial where the green leaf area was assessed with NDVI instrument no differences appeared between treatments and untreated, with increment lower than 10% compared to untreated check.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on durum wheat infected by a range of diseases in the Mediterranean EPPO zone.

Table 3.2-140: Summary table – Minimum effective dose evaluation – Durum wheat – Green leaf area (%) - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate								
Rate unit								
Appl. Code								
% Green leaf area plant - 22-35 DA-B								
Number of values	6	6	6	6	UT	CA33 01	CA33 01	UT
Minimum value	1,25	5,00	6,25	5,00	C	0,48 l/ha	0,8 l/ha	C
Maximum value	80,00	85,00	85,00	86,25	2 >	0 >	0 >	2 >
Mean Green leaf area (%)	53,18	57,09	57,66	58,59	4 =	6 =	5 =	4 =
% UTC	100,00%	148,11%	172,76%	157,85%	0 <	0 <	1 <	0 <
Green leaf area (NDVI 0-1) plant - 16 DA-B								
Number of values	1	1	1	1	UT	CA33 01	CA33 01	UT
Minimum value	0,40	0,41	0,42	0,43	C	0,48 l/ha	0,8 l/ha	C
Maximum value	0,40	0,41	0,42	0,43	0 >	0 >	0 >	0 >
Green leaf area (NDVI 0-1)	0,40	0,41	0,42	0,43	1 =	1 =	1 =	1 =
%UTC	-	-	-	-	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Min. Eff. Dose evaluation of CA3301 – North-Eastern East EPPO zone

Green leaf area was recorded 15 DA-B in a single trial on durum wheat after two applications of CA3301 at 0.8 l/ha , 0.6 l/ha (1N) and 0.48 l/ha (0.8N). In this trial, green leaf area was assessed on the whole plant.

Summary results are presented in Table 3.2-141.

Data demonstrated a slightly better effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rate for the augmentation of green leaf area on durum wheat infected by foliar and ears diseases. In support to this single trial on durum wheat it is possible to considering the data presented in winter wheat in the same EPPO zone where in 33 trials assessing green leaf area on the whole plant, an augmentation of 50.76%, 47.98% and 45.3% was recorded with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check on winter wheat.

An overall trend of increasing the green leaf area with increasing dose rates was observed in the whole dataset in particular for 0.6 and 0.8 l/ha compared to 0.48 l/ha, although differences were not always statistically significant.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on durum wheat infected by a range of diseases in the North-Eastern East EPPO zone.

Table 3.2-141: Summary table – Minimum effective dose evaluation – Durum wheat – Greenleaf area – North-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		0,48	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Green leaf area plant 15 DA-B										
Number of values	1	1	1	1	UT	CA3301	CA3301	UT	CA3301	CA3301
Minimum value	67,50	70,00	71,25	75,00	C	0,48 l/ha	0,8 l/ha	C	0,48 l/ha	0,6 l/ha
Maximum value	67,50	70,00	71,25	75,00	0 >	0 >	0 >	0 >	0 >	0 >
Mean Green leaf area (%)	67,50	70,00	71,25	75,00	1 =	1 =	1 =	1 =	1 =	1 =
% UTC	100,00%	103,70 %	105,56 %	111,11 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Min. Eff. Dose evaluation of CA3301 –South-Eastern East EPPO zone

Green leaf area was recorded 15-37 DA-B in 6 trials on durum wheat after two applications of CA3301 at 0.8 l/ha, 0.6 l/ha (1N) and 0.48 l/ha (0.8N) in South-Eastern East EPPO zone. In 5 trials green leaf area was assessed on the whole plant and in one trial the green leaf area was assessed on foliar levels L1 and on L2.

Summary results are presented in Table 3.2-142.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rate for the preservation of green leaf area on durum wheat infected by foliar and ears diseases (see Table 3.2-142)

In 5 trials assessing green leaf area on the whole plant, an augmentation of 71.09%, 68.01% and 42.32% averaged across each trial was recorded with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check on durum wheat. In the trials where the green leaf area was assessed on L1 and L2 the green leaf area increased of about 20 times for CA3301 at 0.6 -0.8 l/ha and of 15 times for CA3301 at 0.48 l/ha .

An overall trend of increasing the green leaf area with increasing dose rates was observed in the whole dataset in particular for 0.6 and 0.8 l/ha compared to 0.48 l/ha, although differences were not always statistically significant.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on durum wheat infected by a range of diseases in the South-Eastern East EPPO zone.

Table 3.2-142: Summary table – Minimum effective dose evaluation – Durum wheat – Greenleaf area (%) – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Green leaf area plant - 15-37 DA-B										
Number of values	5	5	5	5	UT	CA33 01	CA33 01	UT	CA33 01	CA33 01
Minimum value	6,00	7,25	7,75	8,50	C	0,48 l/ha	0,8 l/ha	C	0,48 l/ha	0,6 l/ha
Maximum value	48,75	70,00	70,00	73,75	4 >	1 >	0 >	4 >	1 >	0 >
Mean Green leaf area (%)	30,95	49,45	52,80	53,70	1 =	4 =	5 =	1 =	4 =	5 =
%UTC	100,00%	142,32%	168,01%	171,09%	0 <	0 <	0 <	0 <	0 <	0 <
% Green leaf area L1 - 32 DA-B										
Number of values	1	1	1	1	UT	CA33 01	CA33 01	UT	CA33 01	CA33 01
Minimum value	17,50	44,50	55,00	55,50	C	0,48 l/ha	0,8 l/ha	C	0,48 l/ha	0,6 l/ha
Maximum value	17,50	44,50	55,00	55,50	1 >	1 >	0 >	1 >	1 >	0 >
Mean Green leaf area (%)	17,50	44,50	55,00	55,50	0 =	0 =	1 =	0 =	0 =	1 =
%UTC	100,00%	254,29%	314,29%	317,14%	0 <	0 <	0 <	0 <	0 <	0 <
% Green leaf area L2 - 32 DA-B										
Number of values	1	1	1	1	UT	CA33 01	CA33 01	UT	CA33 01	CA33 01
Minimum value	1,25	18,00	23,25	25,50	C	0,48 l/ha	0,8 l/ha	C	0,48 l/ha	0,6 l/ha
Maximum value	1,25	18,00	23,25	25,50	1 >	1 >	0 >	1 >	1 >	0 >
Mean Green leaf area (%)	1,25	18,00	23,25	25,50	0 =	0 =	1 =	0 =	0 =	1 =
%UTC	100,00%	1440,00%	1860,00%	2040,00 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)
(conversely for '<')

Comments of zRMS:

Very positive effect after application of CA3301 at dose rate of 0,6-0,8 l/ha were observed. An augmentation of green leaf area was visible on high level in all EPPO climatic zones. It can be concluded that CA3301 at 0,6 l/ha is justified as minimum effective dose in durum wheat.

3.2.2.1 Durum wheat (TRZDU) / Conclusion – Minimum Effective Dose

On durum wheat, 4 foliar diseases were assessed in 18 trials across 4 EPPO zones. Disease severity was assessed and analysed on the main foliar levels 1 and 2, whereas for *Blumeria graminis* were considered all leaf foliar levels 1, 2, 3 and 4. In some instances, due the absence of appropriate level of disease the proposed number of valid trials was not fully achieved. No valid trials were presented for North-Eastern EPPO zone, as the crop is rarely grown in those areas, and regarding the other EPPO zone depending on the disease, the assessment timing and the crop part assessed, the dataset available was sometimes limited and so not fully representative of the minimum effective dose of CA3301. However, durum wheat and winter wheat are comparable crops, both of the genus *Triticum* and the proposed applications are the same (dose rate, application timing etc), therefore reference is made to the data presented on

winter wheat in support of the proposed minimum effective dose. The validity of this argumentation is supported by the fact that existing authorisations of similar prothioconazole products also have the same dose rates registered for both soft wheat and hard (durum) wheat, hence the pathogens are controlled similarly in each crop at the same dose rate.

Globally, across the 3 EPPO zones and all diseases the efficacy, of CA3301 at 0.6-0.8 l/ha was acceptable to high, with some exceptions. Nevertheless, since in the fields a complex of disease is often observed instead of a single disease, it is of interest to present a summary of the efficacy of CA3301 across the diseases and EPPO zone, as well as considering the green leaf area presented above. Green leaf area not only indicates the area free of infection, but also the ability of the plant to continue effective growth and develop, enabling a longer duration of grain filling and therefore improved yield.

In many instances, a trend of decreasing disease severity when increasing the dose rates was observed with CA3301 applied at 0.6 l/ha or 0.8 l/ha. In fact, in overall the rate of 0.8 l/ha was not statistically different from 0.6 l/ha dose rate but both provided a better disease control than the lower rate of 0.48 l/ha. In circumstances of low disease pressure, the 0.6 l/ha rate may be sufficient to give comparable disease control, but due to the importance of the diseases and given the possibility of resistance in some pathogens assessed, the high rate of 0.8 l/ha may be deemed more appropriate and should be available for user according to disease development conditions, historical control and cultivar tolerance to the pathogen.

In this dossier data presented for minimum effective dose is primarily from assessments where 2 applications of the test product were made. However, according to disease development conditions, a single application may provide sufficient disease control, therefore users should not be restricted to always applying twice, hence in the GAP the proposed use is for 1-2 applications. In addition, crop pathogens are commonly controlled using a programme of different fungicides with varied modes of action, therefore the choice should be available to growers to make a single application of CA3301, followed by application of a different appropriate fungicide. Prothioconazole is well established over a number of years in providing good broad spectrum efficacy across a range of common crop pathogens, with either 1 or more applications appropriate according to disease development conditions, risk of resistance development and local conditions. Current authorisations for similar products containing prothioconazole including Proline 275 and Proline/Praktis/Joao (CA2445) are for 1-2 applications at comparative rates of prothioconazole to the requested use for CA3301. Considering these elements, and that data in the efficacy section shows comparability of CA3301 to these authorised products, registration of CA3301 at the proposed minimum effective dose rate and with a number of applications of 1- 2, is requested.

Considering all elements presented in the preceding sections of each disease, 1-2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control a range of foliar and ear diseases on durum wheat.

3.2.2.2 Triticale (TTLWI) / *Zymoseptoria tritici* (SEPTTR)

Between 2017 and 2020, 21 trials were conducted in some countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the minimum effective dose of CA3301 against *Zymoseptoria tritici* on triticale. The trials were carried out by certified testing institutes. The proposed dose rate is 0.6-0.8 l/ha.

In the Maritime EPPO zone, a total of 9 trials were performed in France (2), in Germany (5), in Czech Republic (1), in Denmark (1).

In the Mediterranean EPPO zone, a total of 3 trials were performed in France (1) and in Portugal (2).

In the North-Eastern East EPPO zone, a total of 5 trials were performed in Poland.

In the South-Eastern East EPPO zone, a total of 4 trials were performed in Hungary (1) and in Romania (3).

Data groupings were also made specifically for Poland evaluation and trials involved (11) were performed in the North-Eastern East EPPO zone (5), in the Czech Republic (1) and in Germany (5).

Min. Eff. Dose evaluation of CA3301 – Maritime EPPO zone

In the Maritime EPPO zone, 9 trials evaluated the minimum effective dose of CA3301 on triticale against *Zymoseptoria tritici*. Only four trials were considered valid to evaluate the efficacy of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on disease severity (%) on foliar level 2 and 1. CA3301 was first applied at crop stages BBCH 30-39 and the 2nd application was at BBCH 39-65. Two assessment timings were selected: 15 days after second application for trial EU19-067-22 and 31-42 days after second application for the other trials. In the first assessment timing the analysis was conducted on foliar level 2 and in the second assessment timing were analyzed both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-143.

On foliar level 2, CA3301 at 0.6-0.8 l/ha provided 61.36–44.08% efficacy against *Zymoseptoria tritici* two weeks after the 2nd application and 60.09-56.42% before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 44.29-38.81% efficacy on reduction of disease severity before harvest.

In this dataset with relatively low disease pressure, 0.48 l/ha, 0.6 l/ha and 0.8 l/ha were statistically equivalent but a numerical benefit was derived from increasing the dose rate from 0.48 to 0.6 l/ha. In addition a larger dataset was presented in Maritime EPPO zone for the related crop winter wheat in which leaf blotch caused by *Zymoseptoria tritici* shares the same biology. In this dataset, whereas differences were not always significant, a clear trend appears where 0.6 l/ha dose rate provide a higher control than 0.48 l/ha and very comparable to 0.8 l/ha. Consequently, this dataset can be supportive in order to validate the range of 0.6-0.8 as the minimum effective dose to control this disease on triticale. Finally, given the propensity of the pathogen to develop resistance, the increased efficacy observed from the higher rates of 0.6-0.8 l/ha, is considered most appropriate for control of this pathogen.

Considering all elements presented above, it is possible to state that CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Zymoseptoria tritici* on triticale in the Maritime EPPO zone.

Table 3.2-143: Summary table – Minimum effective dose evaluation – Triticale – SEPTTR – Maritime EPPO zone

Treatment name	UN-TREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301			No of trials where CA3301		
Rate		0,48	0,6	0,8	at 0,6 l/ha			at 0,8 l/ha		
Rate unit		L/ha	L/ha	L/ha	is >, = or <			is >, = or <		
Appl. Code		AB	AB	AB	compared to			compared to		
% Disease severity L2 – 15 DA-B										
Number of values	1	1	1	1	UTC	CA330 1	CA330 1	UT C	CA330 1	CA33 01
Minimum value	5,15	2,08	1,99	2,88		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	5,15	2,08	1,99	2,88	1 >	0 >	0 >	1 >	0 >	0 >
Mean Disease severity (%)	5,15	2,08	1,99	2,88	0 =	1 =	1 =	0 =	1 =	1 =
Mean Abbott efficacy (%)	0,00%	59,61%	61,36%	44,08%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 – 31-42 DA-B										
Number of values	4	4	4	4	UTC	CA330 1	CA330 1	UT C	CA330 1	CA33 01
Minimum value	5,61	2,46	1,98	1,80		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	18,09	10,41	11,89	10,74	3>	0 >	0 >	4 >	0 >	0 >

Mean disease severity (%)	10,72	4,85	4,84	4,94	1 =	4 =	4 =	0 =	4 =	4 =
Mean Abbott efficacy (%)	0,00%	57,57%	60,09%	56,42%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 – 35 DA-B										
Number of values	1	1	1	1	UTC	CA3301	CA3301	UT	CA3301	CA3301
Minimum value	8,76	6,23	4,88	5,36		0,48 l/ha	0,8 l/ha	C	0,48 l/ha	0,6 l/ha
Maximum value	8,76	6,23	4,88	5,36	1 >	0 >	0 >	1 >	0 >	0 >
Mean Disease severity (%)	8,76	6,23	4,88	5,36	0 =	1 =	1 =	0 =	1 =	1 =
Mean Abbott efficacy (%)	0,00%	28,88%	44,29%	38,81%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – Mediterranean EPPO zone

In the Mediterranean EPPO zone, three trials evaluated the minimum effective dose of CA3301 on triticale against *Zymoseptoria tritici*. Two trials were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 32-39 and the 2nd application was at BBCH 39-61. Two main assessment timings were selected: two weeks after the 2nd application (15 DA-B) on leaf level L2 and the last timing close to harvest (29-48 DA-B) on leaf level L2 and L1.

Summary results are presented in Table 3.2-144.

Data demonstrated a numerically higher effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rate for the reduction of disease severity on triticale against *Zymoseptoria tritici*. On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 82.00-86.33% efficacy two weeks after the 2nd application and 81.20-83.40% before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 45.80-51.15% efficacy on reduction of disease severity close to harvest.

An overall trend of decreasing disease severity with increasing dose rates was observed in the dataset, although differences were not significant. In all cases the rate of 0.6 l/ha gave a consistent control of *Zymoseptoria tritici* very comparable to that of 0.8 l/ha, and these dose rates demonstrated high efficacy on foliar level 2. Moreover, this limited dataset can be supplemented by the larger dataset provided on winter wheat which highlights a similar behaviour of the test item where depending on the disease development the range of 0.6-0.8 l/ha gave acceptable to high control of *Zymoseptoria tritici*. In addition, given the propensity of the pathogen to develop resistance, the increased efficacy observed from the higher rates of 0.6-0.8 l/ha, is considered the most appropriate for control of this pathogen.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Zymoseptoria tritici* on triticale in the Mediterranean EPPO zone.

Table 3.2-144: Summary table – Minimum effective dose evaluation – Triticale – SEPTTR – Mediterranean EPPO zone

Treatment name	UN-TREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Rate		0,48	0,6	0,8		
Rate unit		L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB		

% Disease severity L2 - 15 DA-B										
Number of values	2	2	2	2	UTC	CA3301	CA3301	UT	CA3301	CA3301
Minimum value	5,69	0,00	0,00	0,00		0,48 l/ha	0,8 l/ha	C	0,48 l/ha	0,6 l/ha
Maximum value	7,50	3,25	2,70	2,05	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	6,59	1,63	1,35	1,03	0 =	2 =	2 =	0 =	2 =	2 =
Mean Abbott efficacy (%)	0,00%	78,33%	82,00%	86,33%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 29-48 DA-B										
Number of values	2	2	2	2	UTC	CA3301	CA3301	UT	CA3301	CA3301
Minimum value	10,69	0,00	0,00	0,00		0,48 l/ha	0,8 l/ha	C	0,48 l/ha	0,6 l/ha
Maximum value	12,50	6,40	4,70	4,15	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	11,59	3,20	2,35	2,08	0 =	2 =	2 =	0 =	2 =	2 =
Mean Abbott efficacy (%)	0,00%	74,40%	81,20%	83,40%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 29 DA-B										
Number of values	1	1	1	1	UTC	CA3301	CA3301	UT	CA3301	CA3301
Minimum value	6,55	5,25	3,55	3,20		0,48 l/ha	0,8 l/ha	C	0,48 l/ha	0,6 l/ha
Maximum value	6,55	5,25	3,55	3,20	0 >	0 >	0 >	0 >	0 >	0 >
Mean disease severity (%)	6,55	5,25	3,55	3,20	1 =	1 =	1 =	1 =	1 =	1 =
Mean Abbott efficacy (%)	0,0n%	19,85%	45,80%	51,15%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)
(conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 5 trials evaluated the minimum effective dose of CA3301 on triticale against *Zymoseptoria tritici*. 4 trials out of 5 were considered valid to compare the efficacy of several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 30-37 and the 2nd application was at BBCH 55-61. Two main assessment timings were selected: two weeks after the 2nd application (15 DA-B) on L2 and the last timing close to harvest (31-44 DA-B) on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-145.

Data demonstrated a higher effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rate for the reduction of disease severity on triticale against *Zymoseptoria tritici*. On these trials on foliar level 2, CA3301 at 0.6-0.8 l/ha showed 56.70-74.46% efficacy two weeks after the 2nd application and 58.43-72.17% before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 67.62-75.65% efficacy on reduction of disease severity before harvest. These positive effects to control *Zymoseptoria tritici* of CA3301 at 0.6-0.8 l/ha were overall superior than the 0.48 l/ha dose rate.

An overall trend of decreasing disease severity with increasing dose rates was observed in the dataset, although differences were not always significant. The rate of 0.6 l/ha gave acceptable control of *Zymoseptoria tritici* comparable to 0.8 l/ha, nevertheless in conditions of high disease pressure the additional disease reduction obtained from the higher rate of 0.8 l/ha may be more appropriate, in particular where some level of resistance is suspected. Moreover, a larger dataset was presented on the related crop-disease pair winter wheat – *Zymoseptoria tritici*, which confirms and strengthens the numerical trend observed here. In many instances the rate of 0.6 l/ha gave acceptable control of *Zymoseptoria tritici* very comparable to that of 0.8 l/ha, nevertheless in conditions of high disease pressure the additional disease reduction obtained from the higher rate of 0.8 l/ha may be more appropriate, in particular where some level of resistance is suspected.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Zymoseptoria tritici* on triticale in the North-Eastern East EPPO zone.

Table 3.2-145: Summary table – Minimum effective dose evaluation – Triticale – SEPTTR – North-Eastern East EPPO zone

Treatment name	UN-TREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity L2 - 15 DA-B										
Number of values	2	2	2	2	UT C	CA3301 0,48 l/ha	CA3301 0,8 l/ha	UT C	CA3301 0,48 l/ha	CA3301 0,6 l/ha
Minimum value	5,53	2,89	2,75	1,31	2 >	1 >	0 >	2 >	2 >	1 >
Maximum value	10,55	5,23	3,89	2,89	0 =	1 =	1 =	0 =	0 =	1 =
Mean disease severity (%)	8,04	4,06	3,32	2,10	0 <	0 <	1 <	0 <	0 <	0 <
Mean Abbott efficacy (%)	0,00%	49,08%	56,70%	74,46%						
% Disease severity L2 - 31-41 DA-B										
Number of values	3	3	3	3	UT C	CA3301 0,48 l/ha	CA3301 0,8 l/ha	UT C	CA3301 0,48 l/ha	CA3301 0,6 l/ha
Minimum value	6,69	2,65	3,15	1,50	3 >	2 >	0 >	3 >	2 >	0 >
Maximum value	25,94	15,50	10,31	8,44	0 =	1 =	3 =	0 =	1 =	3 =
Mean disease severity (%)	16,23	8,84	6,51	4,84	0 <	0 <	0 <	0 <	0 <	0 <
Mean Abbott efficacy (%)	0,00%	49,52%	58,43%	72,17%						
% Disease severity L1 - 31-44 DA-B										
Number of values	3	3	3	3	UT C	CA3301 0,48 l/ha	CA3301 0,8 l/ha	UT C	CA3301 0,48 l/ha	CA3301 0,6 l/ha
Minimum value	11,48	3,84	3,53	2,83	3 >	1 >	0 >	3 >	2 >	1 >
Maximum value	16,69	6,68	5,08	3,50	0 =	2 =	2 =	0 =	1 =	2 =
Mean disease severity (%)	13,26	5,65	4,26	3,17	0 <	0 <	1 <	0 <	0 <	0 <
Mean Abbott efficacy (%)	0,00%	56,84%	67,62%	75,65%						

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%
60-80%
<60%

Min. Eff. Dose evaluation of CA3301 – South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 4 trials evaluated the minimum effective dose of CA3301 on triticale against *Zymoseptoria tritici*. 3 trials out of 4 were considered valid compare the efficacy of several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 32-37 and the 2nd application was at BBCH 39-61. Only one assessment timing was selected close to harvest (26-48 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-146.

In these trials CA3301 provided high disease control against *Zymoseptoria tritici* whatever the dose rates considered. In one trial, a dose rate effect was observed where CA3301 at 0.8-0.6 l/ha were more efficient than lower rate. CA3301 at 0.6-0.8 l/ha showed 96.00-96.74% efficacy on foliar level 2 and 96.60-97.11% efficacy on foliar level 1 before harvest.

In this limited dataset with low to medium disease pressure, all tested dose rates provided high efficacy level and no clear trend appeared in reduction of disease severity. However, a larger dataset was presented on the related crop-disease pair winter wheat – *Zymoseptoria tritici*, which highlights the trend of decreasing disease severity with increasing dose rates, although differences were not always significant. In many instances the rate of 0.6 l/ha gave acceptable control of *Zymoseptoria tritici* very comparable to that of 0.8 l/ha, nevertheless in conditions of high disease pressure the additional disease reduction obtained from the higher rate of 0.8 l/ha may be more appropriate, in particular where some level of resistance is suspected.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Zymoseptoria tritici* on triticale in the South-Eastern East EPPO zone.

Table 3.2-146: Summary table – Minimum effective dose evaluation – Triticale – SEPTTR – South-Eastern East EPPO zone

Treatment name	UN-TREATED CHECK	CA3301 1 0,48 L/ha AB	CA3301 1 0,6 L/ha AB	CA3301 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity L2 - 26-48 DA-B										
Number of values	3	3	3	3	UT C	CA3301 1 0,48 l/ha	CA3301 1 0,8 l/ha	UT C	CA3301 1 0,48 l/ha	CA3301 1 0,6 l/ha
Minimum value	19,50	0,23	0,19	0,15	3 >	1 >	0 >	3 >	1 >	0 >
Maximum value	33,00	5,66	3,43	2,80	0 =	2 =	3 =	0 =	2 =	3 =
Mean disease severity (%)	28,13	2,06	1,27	1,04	0 <	0 <	0 <	0 <	0 <	0 <
Mean Abbott efficacy (%)	0,00%	93,58%	96,00%	96,74%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 26-48 DA-B										
Number of values	3	3	3	3	UT C	CA3301 1 0,48 l/ha	CA3301 1 0,8 l/ha	UT C	CA3301 1 0,48 l/ha	CA3301 1 0,6 l/ha
Minimum value	10,00	0,13	0,11	0,05	3 >	0 >	0 >	3 >	0 >	0 >
Maximum value	19,19	0,83	0,90	0,81	0 =	3 =	3 =	0 =	3 =	3 =
Mean disease severity (%)	16,04	0,37	0,38	0,31	0 <	0 <	0 <	0 <	0 <	0 <
Mean Abbott efficacy (%)	0,00%	96,76%	96,60%	97,11%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%

60-80%

<60%

Min. Eff. Dose evaluation of CA3301 – Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-Eastern EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. Therefore, for Poland, a total of 11 trials evaluated the minimum effective dose of CA3301 on triticale against *Zymoseptoria tritici* 7 trials out of 9 were considered valid and enabled to determine the minimum effective dose of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 30-39 and the 2nd application was at BBCH 39-65. Two assessment timings were selected, one two weeks after 2nd application on leaf level 2 and one about four weeks after 2nd application (31-44 DA-B).

Summary results are presented in Table 3.2-147.

Data demonstrated a higher effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rates for the reduction of disease severity on triticale against *Zymoseptoria tritici*. On foliar level 2 CA3301 at 0.6-0.8 l/ha showed 57.63-64.04% mean efficacy two weeks after the 2nd application and 57.80-63.72% mean efficacy before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 61.79-66.44% mean efficacy before harvest.

In Poland and neighbouring countries, CA3301 at 0.6-0.8 l/ha provided medium efficacy in reducing the severity of *Zymoseptoria tritici* on triticale. These positive effects of CA3301 at 0.6-0.8 l/ha were overall superior than the 0.48 l/ha dose rate for the disease severity, and are recommended against this pathogen which has a propensity for resistance development. An overall trend of decreasing disease severity with increasing dose rates was observed in the dataset, although differences were not always significant. In most instances the rate of 0.6 l/ha gave acceptable control of *Zymoseptoria tritici* very comparable to that of 0.8 l/ha, nevertheless in conditions of high disease pressure the additional disease reduction obtained from the higher rate of 0.8 l/ha may be more appropriate, in particular where some level of resistance is suspected.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Zymoseptoria tritici* on triticale in Poland.

Table 3.2-147: Summary Table - Minimum effective dose evaluation – Triticale – SEPTTR – Data relevant for Poland – Disease severity (%)

Treatment name	UN-TREATED CHECK	CA330 1 0,48 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity L2 - 15 DA-B										
Number of values	3	3	3	3	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	5,15	2,08	1,99	1,31	3 >	1 >	0 >	3 >	2 >	1 >
Maximum value	10,55	5,23	3,89	2,89	0 =	2 =	2 =	0 =	1 =	2 =
Mean disease severity (%)	7,08	3,40	2,88	2,36	0 <	0 <	1 <	0 <	0 <	0 <
Mean Abbott efficacy (%)	0,00%	51,94%	57,63%	64,04%						
% Disease severity L2 - 31-42 DA-B										
Number of values	6	6	6	6	UT C	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	5,61	2,46	1,98	1,50						

Maximum value	25,94	15,50	11,89	10,74	5 >	2 >	0 >	6 >	2 >	0 >
Mean disease severity (%)	13,52	7,09	5,94	5,01	1 =	4 =	6 =	0 =	4 =	6 =
Mean Abbott efficacy (%)	0,00%	51,86%	57,80%	63,72%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 31-44 DA-B										
Number of values	4	4	4	4	UT	CA330 1	CA330 1	UT	CA330 1	CA330 1
Minimum value	8,76	3,84	3,53	2,83	C	0,48 l/ha	0,8 l/ha	C	0,48 l/ha	0,6 l/ha
Maximum value	16,69	6,68	5,08	5,36	4 >	1 >	0 >	4 >	2 >	1 >
Mean disease severity (%)	12,14	5,79	4,41	3,72	0 =	3 =	3 =	0 =	2 =	3 =
Mean Abbott efficacy (%)	0,00%	49,85%	61,79%	66,44%	0 <	0 <	1 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%
60-80%
<60%

Comments of zRMS:

4 trials have been submitted to determine minimum effective dose **in the Maritime EPPO climatic zone**. CA3301 applied at dose rate rate of 0,48 l/ha achieved insufficient level of control. Slight higher efficacy was noted after application of dose 0,6 l/ha, however the result was <62% after 15 days after second application. The limited effectiveness was observed also in case of dose rate of 0,8 l/ha. Due to the limited number of trials, the cMSs are kindly asked to consider MED for this use on the national level.

4 trials were presented to determine MED in **the North-East EPPO zone**. CA3301 at 0,6-0,8 l/ha achieved medium efficacy while the lower dose of 0,48 l/ha was not effective after 31-44 days after second application in 3 out 4 trials. Also results from the neighbouring countries showed similar trend of effectiveness. The dose rate of 0,6 l/ha can be considered MED to control of SEPTTR in winter triticale, however only on medium level. It should be noted that the dose rate of 0,6 l/ha can be considered MED mainly in situation of low disease pressure. In more challenging conditions, the dose rate of 0,8 l/ha will be more justified.

3 trials were available to determine MED in **the South-East EPPO zone**. No significant differences between dose rate of 0,48-0,8 l/ha were observed in all assessments. In 2 additional trials from the Mediterranean zone, more benefits of using of 0,6 l/ha were visible compared to the lower dose. The dose rate of 0,48 l/ha achieved medium efficacy while the higher dose had high level of control. Due to the limited number of trials, the cMSs are kindly asked to consider MED for this use on the national level.

3.2.2.3 Triticale (TTLWI) / *Blumeria graminis* - *Blumeria graminis* f. sp. *tritici* (ERYSGR – ERYSGT)

Between 2017 and 2020, 11 trials were conducted in different country for the of the Maritime, North-Eastern East and South-Eastern East EPPO zones to evaluate the minimum effective dose of CA3301 against *Blumeria graminis* and *Blumeria graminis* f. sp. *tritici* on **triticale**. The trials were carried out by certified testing institutes. The proposed dose rate is 0.6-0.8 l/ha.

Blumeria graminis and *Blumeria graminis* f. sp. *tritici* are the causal agents of the powdery mildew on cereals and are considered as the same pathogen in this analysis.

In the Maritime EPPO zone, 1 trial was performed in France, 3 trials were done in Germany and 2 trials in Czech Republic.

In the North-Eastern East EPPO zone, 3 trials were performed in in Poland.

In the South-Eastern East EPPO zone, 2 trials were performed in Hungary.

No trials were available in the Mediterranean EPPO zone.

Data groupings were also made specifically for Poland evaluation and trials involved (8) were performed in the North-Eastern East EPPO zone (3), in the Czech Republic (2) and in Germany (3).

Out of the 11 trials carried out against *Blumeria graminis* (ERYSGR) on triticale, 7 were considered valid.

Min. Eff. Dose evaluation of CA3301 – Maritime EPPO zone

In the Maritime EPPO zone, a total of 6 trials evaluated the minimum effective dose of CA3301 on triticale against *Blumeria graminis* and *Blumeria graminis* f. sp. *tritici*. Out of 6 trials, 3 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 30-37 and the 2nd application was at BBCH 39-61. The analysis was conducted on foliar level 1 and foliar level 2.

Summary results are presented in Table 3.2-148.

When evaluating the reduction of disease severity, CA3301 at all tested dose rates provided high disease control but on foliar level 1 two weeks after second application and close to harvest the data demonstrated that the best fungicidal effect to control powdery mildew of cereals was provided after two applications of CA3301 at 0.6-0.8 l/ha. On foliar level 1, when applied at 0.6-0.8 l/ha, CA3301 gave a full disease control around 2 weeks after the 2nd applications and 85.19-88.15% of efficacy before harvest. On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 96.67-97.65% efficacy on disease reduction before harvest.

In this limited dataset with low disease pressure, no significant differences were observed between the tested dose rates of CA3301. A numerical trend appeared at the last assessment timing on foliar level 1. On triticale, powdery mildew remains an occasional disease and depending on climatic conditions, will develop in a heterogeneous way in the crop. This explains the limited data set obtained despite the several trials implemented on triticale. In addition, powdery mildew on triticale and on wheat is caused by the same pathogen agent *Blumeria graminis* f. sp. *tritici*. It therefore seems reasonable from an agronomic perspective to assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on triticale from the robust dataset proposed for the closely related crop winter wheat. The dataset presented on winter wheat showed that CA3301 applied at 0.6-0.8 l/ha provided significant disease control in the two main assessment timings. Both dose rates provided frequently higher disease control than the lower rate of 0.48 l/ha. Moreover, the level of disease control observed was medium to high depending on the disease pressure. Indeed, whereas differences were not always significant, a numerical trend appeared where CA3301 at 0.8 l/ha provided higher efficacy than 0.6 l/ha dose in the most challenging conditions. Finally, since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.8 l/ha generally gave adequate disease control, it is supposed that the same dose range will be acceptable to control powdery mildew on triticale.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Blumeria graminis* on triticale in the Maritime EPPO zone.

Table 3.2-148: Summary table – Minimum effective dose evaluation – Triticale – ERYSGR – ERYSGT – Maritime EPPO zone

Treatment name	UN-TREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate								
Rate unit								
Appl. Code								
% Disease severity L1 - 19 DA-B								
Number of values	1	1	1	1	UTC	CA330 1	CA33 01	UT C
							CA33 01	CA33 01

Minimum value	12,19	0,31	0,00	0,00		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	12,19	0,31	0,00	0,00	1 >	0 >	0 >	1 >	0 >	0 >
Mean Disease severity (%)	12,19	0,31	0,00	0,00	0 =	1 =	1 =	0 =	1 =	1 =
Mean Abbott efficacy (%)	0,00%	97,46%	100,00%	100,00%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 31-42 DA-B										
Number of values	2	2	2	2	UTC	CA330 1 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	5,46	0,00	0,00	0,00						
Maximum value	11,26	0,99	0,75	0,53	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	8,36	0,49	0,38	0,26	0 =	2 =	2 =	0 =	2 =	2 =
Mean Abbott efficacy (%)	0,00%	95,60%	96,67%	97,65%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 42 DA-B										
Number of values	1	1	1	1	UTC	CA330 1 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	5,74	1,30	0,85	0,68						
Maximum value	5,74	1,30	0,85	0,68	1 >	0 >	0 >	1 >	0 >	0 >
Mean Disease severity (%)	5,74	1,30	0,85	0,68	0 =	1 =	1 =	0 =	1 =	1 =
Mean Abbott efficacy (%)	0,00%	77,35%	85,19%	88,15%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)
(conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - Mediterranean EPPO zone

In the Mediterranean, no data were available to support the minimum effective dose of CA3301 against *Blumeria graminis* on triticale due to lack of disease infestation in the trials. However, the specie *Blumeria graminis* is also a pathogen agent present on wheat. It therefore seems reasonable from an agronomic perspective to assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on triticale from the robust dataset proposed for the closely related crop winter wheat. Furthermore, existing authorisations for prothioconazole products have the same dose rate for this pathogen in both winter wheat and in triticale, which also indicates that performance is comparable between the pathogen/crop pairs.

In the Mediterranean EPPO zone, 5 trials enabled to compare the efficacy of CA3301 only on disease incidence (%), since the disease severity was too low to evaluate the performance of the tested product. The analysis was conducted on the fourth main foliar levels L1, L2, L3 and L4 and the data can be supportive for this section. Even if statistical dose response was not always observed, a numerical dose effect could be seen with a better reduction of the disease incidence with CA3301 at 0.8 l/ha than with the 0.6 l/ha, which itself appeared more efficient than the 0.48 l/ha. In addition, due to the importance of this disease and the possibility of resistance of this pathogen, the higher rate with increased disease reduction may be considered more appropriate especially in case of high infestation.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Blumeria graminis* on triticale in the Mediterranean EPPO zone.

In the North-Eastern East EPPO zone, three trials evaluated the minimum effective dose of CA3301 on triticale against *Blumeria graminis*. Out of 3 trials, only one was considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 37-39 and the 2nd application was at BBCH 59-67. The analysis was conducted on foliar level 1 and foliar level 2.

When evaluating the reduction of disease severity, CA3301 at 0.8-0.6 l/ha provided high disease control significantly better than 0.48 l/ha in all foliar levels. Around 3 weeks after the 2nd application, CA3301 at 0.6-0.8 l/ha provided 82.90-86.22% efficacy on foliar level 2 and 85.68-89.82% on foliar level 1.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Blumeria graminis* on triticale in the North-Eastern East EPPo zone.

Treatment name	UN-TREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity L2 23 DA-B										
Number of values	1	1	1	1	UTC	CA330 1 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	25,03	5,70	4,28	3,45		1 >	0 >	0 >	1 >	1 >
Maximum value	25,03	5,70	4,28	3,45	1 =	1 =	1 =	0 =	0 =	1 =
Mean Disease severity (%)	25,03	5,70	4,28	3,45	0 <	0 <	0 <	0 <	0 <	0 <
Mean Abbott efficacy (%)	0,00%	77,23%	82,90%	86,22%						
% Disease severity L1 23 DA-B										
Number of values	1	1	1	1	UTC	CA330 1 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	12,08	2,35	1,73	1,23		1 >	1 >	0 >	1 >	1 >
Maximum value	12,08	2,35	1,73	1,23	1 =	1 =	1 =	0 =	0 =	1 =
Mean Disease severity (%)	12,08	2,35	1,73	1,23						

Mean Abbott efficacy (%)	0,00%	80,55%	85,68%	89,82%	0 <	0 <	0 <	0 <	0 <	0 <
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'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, two trials, one in 2019 and one in 2020 evaluated the minimum effective dose of CA3301 on triticale against *Blumeria graminis*. These two were considered valid and were included to support the minimum effective dose evaluation of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice). CA3301 was first applied at crop stages BBCH 31-32 and the 2nd application was at BBCH 39-47. The analysis was conducted on foliar level 1 and foliar level 2.

Summary results are presented in Table 3.2-150.

Data demonstrated a positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on triticale against *Blumeria graminis*. At the assessment timing close to harvest, CA3301 at 0.6-0.8 l/ha provided 99.63-99.52% efficacy on foliar level 2 and 95.64-94.36% efficacy on foliar level 1. In this limited dataset, no significant differences were observed although overall CA3301 at 0.48 l/ha gave lower disease control compared to 0.6 l/ha and 0.8 l/ha.

However a larger dataset was presented on the closely related crop winter wheat. Indeed, the causal agent of powdery mildew on triticale and on wheat is *Blumeria graminis* f. sp. *tritici*. It therefore seems reasonable from an agronomic perspective to assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on triticale from the robust dataset proposed for winter wheat. The dataset presented on winter wheat showed that CA3301 applied at 0.6-0.8 l/ha provided significant disease control in the two main assessment timings. Both dose rates gave frequently higher disease control than the lower rate of 0.48 l/ha. Moreover, the level of disease control observed was medium to high depending on the disease pressure. Indeed, whereas differences were not always significant, a numerical trend appeared where CA3301 at 0.8 l/ha provided higher efficacy than 0.6 l/ha dose in the most challenging conditions. Finally, since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.8 l/ha generally gave adequate disease control, it is supposed that the same dose range will be acceptable to control powdery mildew on triticale in South-Eastern EPPO zone.

Considering all elements presented above, it is justified to claim the registration of CA3301 at 0.6-0.8 l/ha to control *Blumeria graminis* on triticale in the South-Eastern East EPPO zone.

Table 3.2-150: Summary table – Minimum effective dose evaluation – Triticale – ERYSGR– South-Eastern East EPPO zone

Treatment name	UN-TREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Rate	Rate unit	Rate unit	Rate unit	Rate unit	Rate unit	Rate unit
Appl. Code	Appl. Code	Appl. Code	Appl. Code	Appl. Code	Appl. Code	Appl. Code
% Disease severity L2 40-48 DA-B						
Number of values	2	2	2	2	UTC	CA3301 0,48 l/ha
Minimum value	11,88	0,00	0,00	0,00	CA3301 0,6 l/ha	CA3301 0,8 l/ha
Maximum value	27,00	0,65	0,20	0,26	UT	CA3301 0,48 l/ha
Mean disease severity (%)	19,44	0,33	0,10	0,13	0 >	0 >
					0 =	0 =
					0 <	0 <

Mean Abbott efficacy (%)	0,00%	98,80%	99,63%	99,52%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 47 DA-B										
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha	UTC	CA3301 0,48 l/ha	CA3301 0,6 l/ha
Minimum value	11,71	1,19	0,51	0,66						
Maximum value	11,71	1,19	0,51	0,66	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	11,71	1,19	0,51	0,66	0 =	1 =	1 =	0 =	1 =	1 =
Mean Abbott efficacy (%)	0,00%	89,84%	95,64%	94,36%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)	
>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-Eastern EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, a total of 8 trials from North-Eastern EPPO zone and the neighbouring countries Germany and Czech Republic evaluated the efficacy of CA3301 on triticale against *Blumeria graminis* and *Blumeria graminis* f. sp. *tritici*. 3 trials out of 8 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 30-39 and the 2nd application was at BBCH 45-67. Two assessment timings were available: around 2 weeks after the 2nd application (19 DA-B) and the last timing close to harvest (23-31 DA-B). The analysis was conducted on foliar level 1 and foliar level 2.

Summary results are presented in Table 3.2-151.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect to control *Blumeria graminis* was provided after two applications of CA3301 at 0.6-0.8 l/ha.. On foliar level 2, CA3301 showed 91.45-93.11% of efficacy to reduce the disease severity close to harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha gave a full disease control around 2 weeks after the 2nd application and 89.82-85.68% close to harvest.

In this limited dataset, a trend can be observed whereby efficacy increases with higher dose rates although differences were not always significant. The range of 0.6-0.8 l/ha of CA3301 provided significantly higher efficacies than 0.48 l/ha dose rate in some instances and a numerical increase appeared in the majority of assessments. Therefore, in most instances the rate of 0.6 l/ha will provide sufficient disease control and when conditions are more challenging or when some resistance is suspected the 0.8 l/ha dose rate may be more appropriate. In addition, according to Poland guidance extrapolation table June 2016, data from winter wheat can support the use against this pathogen in triticale.

Considering all elements presented above, it is justified to claim the registration of CA3301 at 0.6-0.8 l/ha to control *Blumeria graminis* on triticale in Poland.

Table 3.2-151: Summary table – Minimum effective dose evaluation – Triticale – ERYSGR– Data relevant for Poland

Treatment name	UN-TREATED CHECK	CA3301 0,48	CA3301 0,6	CA3301 0,8	No of trials where CA3301 at 0,6 l/ha is >, = or <	No of trials where CA3301
Rate						

Rate unit		L/ha	L/ha	L/ha							at 0,8 l/ha is >, = or <
Appl. Code		AB	AB	AB		compared to					compared to
% Disease severity L1 - 19 DA-B											
Number of values	1	1	1	1	UTC	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UTC	CA330 1 0,48 l/ha	CA3 301 0,6 l/ha	
Minimum value	12,19	0,31	0,00	0,00							
Maximum value	12,19	0,31	0,00	0,00	1 >	0 >	0 >	1 >	0 >	0 >	
Mean Disease severity (%)	12,19	0,31	0,00	0,00	0 =	1 =	1 =	0 =	1 =	1 =	
Mean Abbott efficacy (%)	0,00%	97,46%	100,00%	100,00%	0 <	0 <	0 <	0 <	0 <	0 <	
% Disease severity L2 - 23-31 DA-B											
Number of values	2	2	2	2	UTC	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UTC	CA330 1 0,48 l/ha	CA3 301 0,6 l/ha	
Minimum value	5,46	0,00	0,00	0,00							
Maximum value	25,03	5,70	4,28	3,45	2 >	0 >	0 >	2 >	1 >	0 >	
Mean Disease severity (%)	15,24	2,85	2,14	1,73	0 =	2 =	2 =	0 =	1 =	2 =	
Mean Abbott efficacy (%)	0,00%	88,61%	91,45%	93,11%	0 <	0 <	0 <	0 <	0 <	0 <	
% Disease severity L1 - 23 DA-B											
Number of values	1	1	1	1	UTC	CA330 1 0,48 l/ha	CA330 1 0,8 l/ha	UTC	CA330 1 0,48 l/ha	CA3 301 0,6 l/ha	
Minimum value	12,08	2,35	1,73	1,23							
Maximum value	12,08	2,35	1,73	1,23	1 >	1 >	0 >	1 >	1 >	0 >	
Mean Disease severity (%)	12,08	2,35	1,73	1,23	0 =	0 =	1 =	0 =	0 =	1 =	
Mean Abbott efficacy (%)	0,00%	80,55%	85,68%	89,82%	0 <	0 <	0 <	0 <	0 <	0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

3 trials have been submitted to determine minimum effective dose in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,6-0,8 l/ha achieved high efficacy in all assessments. The lower dose of 0,48 l/ha showed medium level of control in 1 out of 3 trials before harvest. However, the submitted trials were conducted in conditions of low disease pressure. Due to the limited number of trials, the cMSs are kindly asked to consider MED for this use on the national level.

Only 1 trial was available to determine MED in **the North-East EPPO zone**. Similar to above results, CA3301 at 0,6-0,8 l/ha achieved high efficacy while the lower dose of 0,48 l/ha showed medium to high level after second application. Moreover, data relevant for Poland demonstrated superior results at dose rate of 0,6-0,8 l/ha. The lower dose provided comparable efficacy, however the effectiveness has been decreasing with the increase of the disease pressure. The results from the trials conducted on winter wheat can be supportive to this use of CA3301. It can be concluded that more benefits will come with using of 0,6-0,8 l/ha. It should be noted that the dose rate of 0,6 l/ha can be considered MED mainly in situation of low disease pressure. In more challenging conditions, the dose rate of 0,8 l/ha will be more justified.

2 trials were presented to determine MED in **the South-East EPPO zone**. CA3301 applied at dose rate of 0,48-0,8 l/ha achieved high efficacy before harvest. No significant differences between results were visible, however the trials were carried out in conditions of low disease pressure. Based on the trials in winter wheat, it can be supposed that more benefits will come with using of dose rate of 0,6-0,8 l/ha in unfavorable conditions. Due to the limited number of trials, the cMSs are kindly asked to consider MED for this use on the national level.

3.2.2.4 Triticale (TTLWI) / *Fusarium spp.* (FUSASP)

In 2018, a single trial was conducted in Denmark for the Maritime EPPO zone, 1 trial in Poland for the North-Eastern East EPPO zone and 1 trial in Hungary for the South-Eastern East EPPO zone to evaluate the minimum effective dose of CA3301 against *Fusarium spp.* on **triticale**. The trials were carried out by certified testing institutes. The proposed dose rate is 0.6-0.8 l/ha.

These 3 trials carried out against *Fusarium spp.* (FUSASP) on triticale were considered valid.

Considering the limited dataset available on this disease in Maritime, North-Eastern East and South-Eastern East EPPO zones, the argumentation on minimum effective dose of CA3301 for the control against *Fusarium spp.* on triticale was based also on data presented on winter wheat.

Min. Eff. Dose evaluation of CA3301 – Maritime EPPO zone

In the Maritime EPPO zone, a single trial evaluated the minimum effective dose of CA3301 on triticale against *Fusarium spp.* and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on infected ears. This trial was inoculated with *Fusarium spp.* 2 days after each application the first one at crop stage BBCH 39 and the second one at BBCH 65. Due to the inoculation, it was possible to determine the efficacy on inoculated ears (Ears I) at 15 DA-B and 30 DA-B, and non-inoculated ears (Ears NI) close to harvest.

Summary results are presented in Table 3.2-152.

Data did not demonstrated a higher effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rates for the reduction of disease severity on triticale against *Fusarium sp.* On inoculated ears, CA3301 at 0.6-0.8 l/ha showed 94.54-90.30% efficacy on disease reduction around 2 weeks after the 2nd application and 85.39-67.34% around 4 weeks after the 2nd application. On non-inoculated ears, disease appeared lately and CA3301 at 0.6-0.8 l/ha provided 64.46-50.85% efficacy before harvest. A supportive dataset is available on winter wheat and the tested product demonstrated comparable efficacy from CA3301 dose rates on the related pathogen *Fusarium graminearum* for which the higher rate of 0.8 l/ha is more appropriate in situations of high disease pressure, but in case of low disease pressure the 0.6 l/ha rate might be sufficient to obtain a suitable level of disease control.

On triticale in the Maritime EPPO zone, a single trial was included to support the minimum effective dose evaluation of CA3301. According to statistical analysis the three rates of CA3301 were comparable to each other. However due to the importance of *Fusarium* species in the production of mycotoxins which is a critical quality parameter, the range of 0.6-0.8 l/ha will be more appropriate to actively lower disease severity and maintain crop quality.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Fusarium spp.* on triticale in the Maritime EPPO zone.

Table 3.2-152: Summary table – Minimum effective dose evaluation – Triticale – FUSASP – Maritime EPPO zone

Treatment name	UN-TREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity Ears I - 15 DA-B										
Number of values	1	1	1	1	UTC	CA330 1 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	26,19	1,88	1,43	2,54		1 >	0 >	0 >	1 >	0 >
Maximum value	26,19	1,88	1,43	2,54						

Mean Disease severity (%)	26,19	1,88	1,43	2,54	0 =	1 =	1 =	0 =	1 =	1 =
Mean Abbott efficacy (%)	0,00%	92,82%	94,54%	90,30%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity Ears I - 30 DA-B										
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha	UT C	CA3301 0,48 l/ha	CA3301 0,6 l/ha
Minimum value	80,00	15,38	11,69	26,13						
Maximum value	80,00	15,38	11,69	26,13	1 >	0 >	0 >	1 >	0 >	0 >
Mean Disease severity (%)	80,00	15,38	11,69	26,13	0 =	1 =	1 =	0 =	1 =	1 =
Mean Abbott efficacy (%)	0,00%	80,78%	85,39%	67,34%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity Ears NI - 63 DA-B										
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha	UT C	CA3301 0,48 l/ha	CA3301 0,6 l/ha
Minimum value	16,46	10,33	5,85	8,09						
Maximum value	16,46	10,33	5,85	8,09	1 >	0 >	0 >	1 >	0 >	0 >
Mean Disease severity (%)	16,46	10,33	5,85	8,09	0 =	1 =	1 =	0 =	1 =	1 =
Mean Abbott efficacy (%)	0,00%	37,24%	64,46%	50,85%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – Mediterranean EPPO zone

In the Mediterranean, no data were available to support the minimum effective dose of CA3301 against *Fusarium spp* on triticale due to lack of disease infestation in the trials. However, the specie *Fusarium spp* is also a pathogen agent present on wheat. It therefore seems reasonable from an agronomic perspective to assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on triticale from the robust dataset proposed for the closely related crop winter wheat. Furthermore, existing authorisations for prothioconazole products have the same dose rate for this pathogen in both winter wheat and in triticale, which also indicates that performance is comparable between the pathogen/crop pairs.

Over the dataset available on winter wheat, the tested product demonstrated comparable efficacy from CA3301 dose rates on the related pathogen *Fusarium spp* for which the higher rate of 0.8 l/ha is more appropriate in situations of high disease pressure, but in case of low disease pressure the 0.6 l/ha rate might be sufficient to obtain a suitable level of disease control.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Fusarium spp* on triticale in the Mediterranean EPPO zone.

Min. Eff. Dose evaluation of CA3301 – North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a single trial evaluated the minimum effective dose of CA3301 on triticale against *Fusarium spp*. and compared the efficacy of several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on disease severity (%) on inoculated ears. The inoculation was done two days after each application, the first one at crop stages BBCH 39 and the 2nd one at BBCH 67. Only one assessment was available on this trial on inoculated ears 23 days after 2nd application.

Summary results are presented in Table 3.2-153.

In this trial submitted for the North-Eastern East EPPO data demonstrated a higher effect of 2 applications of CA3301 at 0.8-0.6 l/ha compared to lower dose rate for the reduction of disease severity on triticale against *Fusarium spp.* On inoculated ears, CA3301 at 0.8-0.6 l/ha showed 82.38-77.22% efficacy against *Fusarium spp.* three weeks after the 2nd application. This positive effect was significantly higher than the 0.48 l/ha dose rate.

A supportive dataset is available on winter wheat and the tested product demonstrated comparable efficacy from CA3301 dose rates on the related pathogen *Fusarium graminearum* for which the higher rate of 0.8 l/ha is more appropriate in situations of high disease pressure, but in case of low disease pressure the 0.6 l/ha rate might be sufficient to obtain a suitable level of disease control.

Whilst a single trial is insufficient to evaluate the minimum effective dose, the tested product nevertheless also demonstrated comparable efficacy from CA3301 dose rates on the related pathogen *Fusarium culmorum* with the same numerical trend when increasing dose rates (see Triticale (TTLWI) / *Fusarium culmorum* (FUSACU)). Moreover, due to the importance of *Fusarium* species in the production of mycotoxins which is a critical quality parameter, the range of 0.6-0.8 l/ha is considered more appropriate to actively lower disease severity and maintain crop quality.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Fusarium spp.* on triticale in the North-Eastern East EPPO zone.

Table 3.2-153: Summary table – Minimum effective dose evaluation – Triticale – FUSASP – North-Eastern East EPPO zone

East ETPG zone										
Treatment name	UN-TREAT ED CHEC K	CA3301	CA3301	CA3301	No of trials where CA3301			No of trials where CA3301		
Rate		0,48	0,6	0,8	at 0,6 l/ha is >, = or <			at 0,8 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
% Disease severity Ear I - 23 DA-B										
Number of values	1	1	1	1	UTC	CA330 1	CA330 1	UTC	CA330 1	CA330 1
Minimum value	19,18	7,25	4,37	3,38		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	19,18	7,25	4,37	3,38	1 >	1 >	0 >	1 >	1 >	0 >
Mean Disease se- verity (%)	19,18	7,25	4,37	3,38	0 =	0 =	1 =	0 =	0 =	1 =
Mean Abbott effi- cacy (%)	0,00%	62,20%	77,22%	82,38%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a single valid trial on triticale was included to support the minimum effective dose evaluation of CA3301. CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) was tested on disease severity (%). CA3301 was first applied at crop stages BBCH 39 and the 2nd application was at BBCH 65.

Summary results are presented in Table 3.2-154.

When evaluating the reduction of disease severity on inoculated ears, the data demonstrated the positive fungicidal effect of CA3301 to control *Fusarium spp.* on ears. Indeed, on inoculated ears 14 days after 2nd application, CA3301 at 0.6-0.8 l/ha showed 72.24-54.23% efficacy against *Fusarium sp.* Although differences were not always significant, a clear trend appeared where disease control increases with the dose rate and particularly for 0.6-0.8 l/ha compared to 0.48 l/ha.

Moreover, a larger dataset was presented on the closely related crop winter wheat. In the South-Eastern East EPPO zone, a total of 3 trials evaluated the efficacy of CA3301 on winter wheat against *Fusarium sp.* On ears inoculated, CA3301 at 0.6-0.8 l/ha showed 52.05-68.77% mean efficacy against *Fusarium sp.* around two weeks after the 2nd application. On ears non-inoculated, CA3301 at 0.6-0.8 l/ha showed 100% efficacy against *Fusarium sp.* before harvest. These positive effects of CA3301 at 0.6-0.8 l/ha to control *Fusarium sp.* were overall superior than the 0.48 l/ha dose rate for the disease severity. Finally, since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.8 l/ha generally gave adequate disease control, it is supposed that the same dose range will be acceptable to control fusariosis on triticale in South-Eastern East EPPO zone.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Fusarium spp.* on triticale in the South-Eastern East EPPO zone.

Table 3.2-154: Summary table – Minimum effective dose evaluation – Triticale – FUSASP – South-Eastern East EPPO zone

Treatment name	UN-TREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
% Disease severity Ear I - 14 DA-B						
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha
Minimum value	19,27	10,60	8,82	5,35		CA3301 0,8 l/ha
Maximum value	19,27	10,60	8,82	5,35	1 >	UT C
Mean disease severity (%)	19,27	10,60	8,82	5,35	0 =	CA3301 0,48 l/ha
Mean Abbott efficacy (%)	0,00%	44,99%	54,23%	72,24%	0 <	CA3301 0,6 l/ha

'>' means CA3301 is significantly more efficient than plants treated with (treatment)
(conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

Only 1 trial has been submitted to determine minimum effective dose in the **Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,48-0,8 l/ha achieved high efficacy, based on the results from inoculated ears. Significant differences were visible on uninoculated ears in assessment before harvest. The dose rate of 0,48 l/ha was not effective to control of FUSASP while the higher doses showed medium efficacy. Due to the limited number of trials, the cMSs are kindly asked to consider MED for this use on the national level.

1 trial was presented to determine MED in the **North-East EPPO zone**. CA3301 at 0,48-0,6 l/ha achieved medium efficacy, however reduce of dose to 0,48 l/ha caused lower effectiveness about 15%. Taking into account more challenging conditions and results from trials conducted in winter wheat, it can be concluded that more benefits will come with using of 0,6-0,8 l/ha. It should be noted that the dose rate of 0,6 l/ha can be considered MED mainly in situation of low disease pressure. In more challenging conditions, the dose rate of

0,8 l/ha will be more justified.

1 trial was available to determine MED in the **South-East EPPO zone**. The test product applied at 0,48-0,6 l/ha achieved low efficacy while the higher dose rate of 0,8 l/ha showed medium level of control on inoculated ears after second application. Due to the limited number of trials, the cMSs are kindly asked to consider MED for this use on the national level.

3.2.2.5 Triticale (TTLWI) / *Fusarium culmorum* (FUSACU)

Between 2017 and 2018 were performed three trials, one in the Czech Republic for the Maritime EPPO zone, one in Portugal for the Mediterranean EPPO zone and one in Poland for the North-Eastern East EPPO zone to evaluate the minimum effective dose of CA3301 against *Fusarium culmorum* on **triticale**. The trials were carried out by certified testing institutes. The proposed dose rate is 0.6-0.8 l/ha.

Out of these three trials carried out against *Fusarium culmorum* (FUSACU) on triticale two were considered valid.

Min. Eff. Dose evaluation of CA3301 – Maritime EPPO zone

In the Maritime EPPO zone, one trial evaluated the minimum effective dose of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on triticale against *Fusarium culmorum* on inoculated ears. CA3301 was applied twice, the first application at crop stages BBCH 37 and the 2nd application was done at crop stage BBCH 65. The inoculated ears were evaluated at one valid timing: four weeks after the 2nd application.

Summary results are presented in Table 3.2-155.

Data demonstrated a numerically higher efficacy of CA3301 at 0.8-0.6 l/ha compared to the lower rate for the reduction of disease severity on triticale against *Fusarium culmorum*. On ears inoculated, CA3301 at 0.6-0.8 l/ha showed 68.09-80.14% efficacy around 4 weeks after the 2nd application.

In the limited dataset, CA3301 at 0.6-0.8 l/ha provided medium to high efficacy in reducing the severity of *Fusarium culmorum* on triticale. These positive effect were overall superior than that of the 0.48 l/ha dose rate. However, a larger dataset was presented on closely related crop winter wheat which demonstrates the same behaviour of the test item with a higher effect of CA3301 at 0.6-0.8 l/ha compared to lower dose rate for the reduction of disease severity. Finally, since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.8 l/ha generally gave adequate disease control, it is supposed that the same dose range will be acceptable to control fusariosis on triticale in Maritime EPPO zone.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Fusarium culmorum* on triticale in the Maritime EPPO zone.

Table 3.2-155: Summary table – Minimum effective dose evaluation – Triticale – FUSACU – Maritime EPPO zone

treatment EFFICACY										
Treatment name	UNTREATED CHECK	CA33 01	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		0,48	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Disease severity Ears I - 28 DA-B										
Number of values	1	1	1	1	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	14,10	4,80	4,50	2,80	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha

Maximum value	14,10	4,80	4,50	2,80	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	14,10	4,80	4,50	2,80	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	65,96 %	68,09 %	80,14 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, one trial evaluated the minimum effective dose of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on triticale against *Fusarium culmorum* on non-inoculated ears. CA3301 was applied twice, the first application at crop stages BBCH 37 and the 2nd application was done at crop stage BBCH 59. The non-inoculated ears were evaluated in two timings: three weeks after the 2nd application and close to harvest.

Summary results are presented in Table 3.2-156.

Data demonstrated a numerically higher efficacy of CA3301 at 0.8-0.6 l/ha compared to the lower rate for the reduction of disease severity on triticale against *Fusarium culmorum*. On ears, CA3301 at 0.6-0.8 l/ha showed 72.86-80.45% efficacy around 3 weeks after the 2nd application and 63.53-65.79% before harvest.

In the limited dataset, CA3301 at 0.6-0.8 l/ha provided medium to high efficacy in reducing the severity of *Fusarium culmorum* on triticale. These positive effect were overall superior than that of the 0.48 l/ha dose rate. However, a larger dataset was presented on closely related crop winter wheat which demonstrates the same behaviour of the test item with a higher effect of CA3301 at 0.6-0.8 l/ha compared to lower dose rate for the reduction of disease severity. Finally, since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.8 l/ha generally gave adequate disease control, it is supposed that the same dose range will be acceptable to control fusariosis on triticale in North-Eastern East EPPO zone.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Fusarium culmorum* on triticale in the North-Eastern East EPPO zone.

Table 3.2-156: Summary table – Minimum effective dose evaluation – Triticale – FUSACU – North-Eastern East EPPO zone

East of FC zone										
Treatment name	UN-TREATED CHECK	CA3301 1 0,48 L/ha AB	CA3301 1 0,6 L/ha AB	CA3301 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate	Rate unit	AB	AB	AB						
Appl. Code										
% Disease severity Ears NI- 25 DA-B										
Number of values	1	1	1	1	UT C	CA3301 1 0,48 l/ha	CA3301 0,8 l/ha	UT C	CA3301 1 0,48 l/ha	CA3301 0,6 l/ha
Minimum value	6,19	1,61	1,68	1,21	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	6,19	1,61	1,68	1,21	0 =	1 =	1 =	0 =	1 =	1 =
Mean Disease severity (%)	6,19	1,61	1,68	1,21	0 <	0 <	0 <	0 <	0 <	0 <
Mean Abbott efficacy (%)	0,00%	73,99%	72,86%	80,45%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity Ears NI - 44 DA-B										
Number of values	1	1	1	1	UT C	CA3301 1	CA3301	UT C	CA3301 1	CA3301 1

Minimum value	16,81	7,13	6,13	5,75		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	16,81	7,13	6,13	5,75	1 >	0 >	0 >	1 >	0 >	0 >
Mean Disease severity (%)	16,81	7,13	6,13	5,75	0 =	1 =	1 =	0 =	1 =	1 =
Mean Abbott efficacy (%)	0,00%	57,58%	63,53%	65,79%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%
60-80%
<60%

Min. Eff. Dose evaluation of CA3301 – All other EPPO zones

In the Mediterranean, and South-Eastern East EPPO zones, no data were available to support the minimum effective dose of CA3301 against *Fusarium culmorum* on triticale due to lack of disease infestation in the trials. However, the specie *Fusaium culmorum* is also a pathogen agent present on wheat. It therefore seems reasonable from an agronomic perspective to assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on triticale from the robust dataset proposed for the closely related crop winter wheat. Furthermore, existing authorisations for prothioconazole products have the same dose rate for this pathogen in both winter wheat and in triticale, which also indicates that performance is comparable between the pathogen/crop pairs.

The dataset presented in - Winter wheat (TRZAW) / *Fusarium culmorum* – showed that CA3301 applied at 0.6-0.8 l/ha provided significant disease control against this fusarium species. Both dose rates gave higher disease control than the lower rate of 0.48 l/ha. Moreover, the level of disease control observed was medium to high with differences that were sometimes significant. Overall, a numerical trend appeared where CA3301 at 0.8 l/ha provided higher efficacy than 0.6 l/ha, particularly in case of high disease pressure.

Finally, since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.8 l/ha generally gave adequate disease control, it is supposed that the same dose range will be acceptable to control *Fusarium culmorum* on triticale in all other EPPO zones.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Fusarium culmorum* on triticale in all EPPO zones.

Comments of zRMS:

The limited number of trials has been submitted to determine minimum effective dose to control of *Fusarium culmorum* in winter triticale. Only 1 trial conducted in the Maritime EPPO climatic zone presented medium efficacy after application of CA3301 at 0,48-0,6 l/ha while the higher dose of 0,8 l/ha achieved result of >80%. Also single trial was available in the North-East EPPO zone. The significant lower effectiveness was visible on uninoculated ears before harvest. The dose rate of 0,48 l/ha was not effective while the higher doses achieved medium level of control. No trials have been submitted in the South-East and Mediterranean EPPO zone.

3.2.2.6 Triticale (TTLWI) / *Puccinia recondita* (PUCCRE)

In 2018 five trials were performed, one in Czech Republic, one in the Denmark in the Maritime EPPO zone , one in Poland for the North-Eastern East EPPO zone, and two in Hungary for the South-Eastern

East EPPO zone to evaluate the minimum effective dose of CA3301 against *Puccinia recondita* on **triticale**. The trials were carried out by certified testing institutes. The proposed dose rate is 0.6-0.8 l/ha.

Out of these five trials, carried out to evaluate the CA3301 efficacy against *Puccinia recondita* (PUCCRE) on triticale, only two were considered valid.

Min. Eff. Dose evaluation of CA3301 – Maritime EPPO zone

In the Maritime EPPO zone, two trials were considered valid and enabled to determine the minimum effective dose of CA3301 on triticale against *Puccinia recondita*. CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) was applied at crop stage BBCH 32-39 and at crop stage BBCH 59-65. The analysis was conducted on foliar level 1 and foliar level 2, three weeks after 2nd application.

Summary results are presented in Table 3.2-157.

When evaluating the reduction of disease severity, the data demonstrated the high efficacy to control *Puccinia recondita* provided by CA3301 without statistical differences between tested dose rates. On foliar level 2, CA3301 at 0.6-0.8 l/ha provided 88.01-95.21% efficacy to control brown rust around 4 weeks after the 2nd application. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 89.67-92.43% efficacy to control brown rust around 4 weeks after the 2nd application.

Average across this limited dataset, whereas differences are not significant, a trend appeared where disease control increased with the dose rates. Moreover, for the closely related crop winter wheat a larger dataset was presented which demonstrated the same behaviour of the test item. Therefore, in most instances the rate of 0.6 l/ha will provide sufficient disease control and when conditions are more challenging or when some resistance is suspected the 0.8 l/ha dose rate may be more appropriate.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Puccinia recondita* on triticale in the Maritime EPPO zone.

Table 3.2-157: Summary table – Minimum effective dose evaluation – Triticale – PUCCRE – Maritime EPPO zone

Treatment name	UN-TREAT ED CHEC K	CA3301	CA3301	CA3301	No of trials where CA3301			No of trials where CA3301		
Rate		0,48	0,6	0,8	at 0,6 l/ha is >, = or <			at 0,8 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
% Disease severity L2 - 30-31 DA-B										
Number of values	2	2	2	2	UTC	CA330 1	CA330 1	UTC	CA330 1	CA330 1
Minimum value	8,96	0,44	0,13	0,19		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	10,69	2,53	2,04	0,70	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease se- verity (%)	9,83	1,48	1,08	0,44	0 =	2 =	2 =	0 =	2 =	2 =
Mean Abbott effi- cacy (%)	0,00%	83,82%	88,01%	95,21%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 30 DA-B										
Number of values	1	1	1	1	UTC	CA330 1	CA330 1	UTC	CA330 1	CA330 1
Minimum value	5,81	0,25	0,13	0,44		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	5,81	0,25	0,13	0,44	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease se- verity (%)	5,81	0,25	0,13	0,44	0 =	1 =	1 =	0 =	1 =	1 =
Mean Abbott effi- cacy (%)	0,00%	95,70%	89,67%	92,43%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)	
>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – All other EPPO zones

In the North-~~Eastern~~ East EPPO zone, a single trial was conducted to assess the control brown rust *Puccinia recondita* on triticale by CA3301 but it was not valid due to lack of disease infestation. In addition, no valid trials were available in the Mediterranean or South-East EPPO zones. However, the species *Puccinia recondita* is also the pathogen agent that causes brown rust on wheat. It therefore seems reasonable from an agronomic perspective to assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on triticale from the robust dataset proposed for the closely related crop winter wheat. Furthermore, existing authorisations for prothioconazole products have the same dose rate for this pathogen in both winter wheat and in triticale, which also indicates that performance is comparable between the pathogen/crop pairs.

The dataset presented in – Winter wheat (TRZAW) / *Puccinia recondita* – showed that CA3301 applied at 0.6-0.8 l/ha provided significant disease control in the two main assessment timing. Both dose rates gave frequently higher disease control than the lower rate of 0.48 l/ha. Moreover, the level of disease control observed was medium to high depending on the disease pressure. Indeed, whereas differences were not always significant, a numerical trend appeared where CA3301 at 0.8 l/ha provided better efficacy than 0.6 l/ha dose in the most challenging conditions.

On triticale, brown rust remains an occasional disease and depending on climatic conditions, will develop in a heterogeneous way in the crop. Finally, since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.8 l/ha generally gave adequate disease control, it is supposed that the same dose range will be acceptable to control brown rust on triticale in other EPPO zones.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Puccinia recondita* on triticale in all EPPO zones.

Comments of zRMS:

The limited number of trials has been submitted to determine minimum effective dose to control of *Puccinia recondita* in winter triticale. 2 trials from **the Maritime EPPO zone** presented high efficacy for all dose rates after 30-31 days after second application. However, the trials were conducted in conditions with low disease pressure. It can be supposed that more benefits will come with using of 0,6-0,8 l/ha in more challenging conditions. No trials were available in **the North-East and South-East EPPO zone**. Based on the results from the Czech Republic and the trials conducted on winter wheat, the dose rate of 0,6 l/ha can be considered MED in winter triticale in Poland. The cMSs from the MAR and SE zone are kindly asked to consider MED for this use on the national level.

3.2.2.7 Triticale (TTLWI) / *Puccinia striiformis* – *Puccinia striiformis* f. sp. *tritici* (PUCCST-PUCCSI)

Between 2018 and 2020, two trials were performed, one in the Czech Republic and one in Germany for the Maritime EPPO zone and one in Portugal for the Mediterranean EPPO zone to evaluate the minimum effective dose of CA3301 against *Puccinia striiformis* on **triticale**. The trials were carried out by certified testing institutes. The proposed dose rate is 0.6-0.8 l/ha.

Out of these three trials carried out against *Puccinia striiformis* (PUCCST) on triticale two were considered as valid.

Min. Eff. Dose evaluation of CA3301 – Maritime EPPO zone

In the Maritime EPPO zone, 2 trials evaluated the minimum effective dose of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on triticale against *Puccinia striiformis*. Out of 2 trials, 1 was considered valid. CA3301 was applied twice, the first application at crop stages BBCH 37 and the 2nd application was done at crop stage BBCH 65. One valid assessment timing was selected thus the analysis was done on foliar 1 and foliar level 2 four weeks after 2nd application.

Summary results are presented in Table 3.2-158.

In this limited dataset with low disease pressure, CA3301 at 0.6-0.8 provided a high disease control against *Puccinia striiformis*. Averaged across the dataset, these positive effects were superior than that provided by CA3301 at 0.48 l/ha. On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 82.48-84.67% efficacy on disease reduction around 4 weeks after the 2nd application. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 84.31-88.24% efficacy on disease reduction around 4 weeks after the 2nd application.

In the Maritime EPPO zone the dataset was limited, however a larger dataset was presented for the closely related crop winter wheat which demonstrate medium to high disease control of CA3301 at 0.6-0.8 l/ha. In this dataset, a clear trend appeared where disease control increased with the dose rate, sometimes statistically, particularly for 0.6-0.8 l/ha compared to 0.48 l/ha. Therefore, in most instances the rate of 0.6 l/ha will provide sufficient disease control and when conditions are more challenging the 0.8 l/ha dose rate may be more appropriate.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Puccinia striiformis* on triticale in the Maritime EPPO zone.

Table 3.2-158: Summary table – Minimum effective dose evaluation – Triticale – PUCCSI – Maritimez EPPO zone

Treatment name	UNTREATED CHECK	CA33 01 0,48 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity L2 - 28 DA-B										
Number of values	1	1	1	1	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	13,70	2,70	2,40	2,10	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	13,70	2,70	2,40	2,10		0 =	1 =	1 =	0 =	1 =
Mean disease severity (%)	13,70	2,70	2,40	2,10	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	80,29 %	82,48 %	84,67 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 28 DA-B										
Number of values	1	1	1	1	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	10,20	1,80	1,60	1,20	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	10,20	1,80	1,60	1,20		0 =	1 =	1 =	0 =	1 =
Mean disease severity (%)	10,20	1,80	1,60	1,20	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	82,35 %	84,31 %	88,24 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

In the Mediterranean EPPO zone, a single trial on triticale was included to support the minimum effective dose evaluation of CA3301 against *Puccinia striiformis*. CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) was tested on disease severity (%) on foliar levels 2 & 1 around two weeks and four weeks after the 2nd application. CA3301 was applied first at crop stage BBCH 39 and a second application was performed at crop stage BBCH 59.

Summary results are presented in Table 3.2-159.

In this limited dataset with high disease pressure, CA3301 at 0.6-0.8 provided overall low to medium disease control against *Puccinia striiformis*. Averaged across the dataset, these positive effects were superior than that provided by CA3301 at 0.48 l/ha. On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 35.00-35.00% efficacy on disease reduction 2 weeks after the 2nd application and 35.29-39.98% around 4 weeks after the 2nd application. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 56.76-59.08% efficacy on disease reduction 2 weeks after the 2nd application and 59.82-64.29% around 4 weeks after the 2nd application.

In the Mediterranean EPPO zone the dataset was limited, however a larger dataset was presented for the closely related crop winter wheat which demonstrate medium to high disease control of CA3301 at 0.6-0.8 l/ha. In this dataset, whereas differences were not always significant, a clear trend appeared where disease control increased with the dose rate and particularly for 0.6-0.8 l/ha compared to 0.48 l/ha. Therefore, in most instances the rate of 0.6 l/ha will provide sufficient disease control and when conditions are more challenging the 0.8 l/ha dose rate may be more appropriate.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Puccinia striiformis* on triticale in the Mediterranean EPPO zone.

Table 3.2-159: Summary table – Minimum effective dose evaluation – Triticale – Puccst – Mediterranean EPPO zone

Treatment name	UN-TREATED	CA3301	CA3301	CA3301	No of trials where CA3301			No of trials where CA3301		
Rate	CHECK	0,48	0,6	0,8	at 0,6 l/ha is >, = or <			at 0,8 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
% Disease severity L2 13 DA-B										
Number of values	1	1	1	1	UTC	CA3301	CA3301	UT	CA3301	CA3301
Minimum value	58,75	43,44	38,19	38,19		0,48 l/ha	0,8 l/ha	C	0,48 l/ha	0,6 l/ha
Maximum value	58,75	43,44	38,19	38,19	1 >	0 >	0 >	1 >	0 >	0 >
Mean Disease severity (%)	58,75	43,44	38,19	38,19	0 =	1 =	1 =	0 =	1 =	1 =
Mean Abbott efficacy (%)	0,00%	26,06%	35,00%	35,00%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 13 DA-B										
Number of values	1	1	1	1	UTC	CA3301	CA3301	UT	CA3301	CA3301
Minimum value	32,38	16,00	14,00	13,25		0,48 l/ha	0,8 l/ha	C	0,48 l/ha	0,6 l/ha
Maximum value	32,38	16,00	14,00	13,25	1 >	0 >	0 >	1 >	0 >	0 >
Mean Disease severity (%)	32,38	16,00	14,00	13,25	0 =	1 =	1 =	0 =	1 =	1 =

Treatment name	UN-TREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Mean Abbott efficacy (%)	0,00%	50,59%	56,76%	59,08%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 31 DA-B										
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha	UTC	CA3301 0,48 l/ha	CA3301 0,6 l/ha
Minimum value	79,88	51,81	51,69	47,94						
Maximum value	79,88	51,81	51,69	47,94	1 >	0 >	0 >	1 >	0 >	0 >
Mean Disease severity (%)	79,88	51,81	51,69	47,94	0 =	1 =	1 =	0 =	1 =	1 =
Mean Abbott efficacy (%)	0,00%	35,14%	35,29%	39,98%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 31 DA-B										
Number of values	1	1	1	1	UTC	CA3301 0,48 l/ha	CA3301 0,8 l/ha	UTC	CA3301 0,48 l/ha	CA3301 0,6 l/ha
Minimum value	40,44	18,44	16,25	14,44						
Maximum value	40,44	18,44	16,25	14,44	1 >	0 >	0 >	1 >	0 >	0 >
Mean Disease severity (%)	40,44	18,44	16,25	14,44	0 =	1 =	1 =	0 =	1 =	1 =
Mean Abbott efficacy (%)	0,00%	54,40%	59,82%	64,29%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - All other EPPO zones

In the North-Eastern East, and South-East EPPO zones, no data were available to support the minimum effective dose of CA3301 against *Puccinia striiformis* on triticale due to lack of disease infestation in the trials. However, the specie *Puccinia striiformis* is also the causal agent of yellow rust on wheat. It therefore seems reasonable from an agronomic perspective to assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on triticale from the robust dataset proposed for the closely related crop winter wheat. Furthermore, existing authorisations for prothioconazole products have the same dose rate for this pathogen in both winter wheat and in triticale, which also indicates that performance is comparable between the pathogen/crop pairs.

The dataset presented in - Winter wheat (TRZAW) / *Puccinia striiformis* and Winter wheat (TRZAW) / *Puccinia recondita* – showed that CA3301 applied at 0.6-0.8 l/ha provided significant disease control against the two different rusts. Both dose rates gave higher disease control than the lower rate of 0.48 l/ha. Moreover, the level of disease control observed was medium to high and whereas differences were not significant, a numerical trend appeared where CA3301 at 0.8 l/ha provided higher efficacy than 0.6 l/ha, particularly in case of high disease pressure.

On triticale, yellow rust remains an occasional disease and depending on climatic conditions, will develop in a heterogeneous way in the crop. Finally, since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.8 l/ha generally gave adequate disease control, it is supposed that the same dose range will be acceptable to control yellow rust on triticale in all other EPPO zones.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Puccinia striiformis* on triticale in all EPPO zones.

Comments of zRMS:

The limited number of trials has been submitted to determine minimum effective dose to control of *Puccinia striiformis* in winter triticale. Only 1 trial was available in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,48-0,8 l/ha achieved high efficacy after second application. No significant differences between dose rates were observed. However, the trial was conducted in conditions of low disease pressure. Also 1 trial from the Mediterranean EPPO zone was presented to support of product registration in other zones. A very low effectiveness was visible in all assessments for all applied doses. No trials have been submitted in **the North-East and South-East EPPO zone**. Based on the results from the Czech Republic and the trials conducted on winter wheat, the dose rate of 0,6 l/ha can be considered MED for PUCGST in winter triticale in Poland. The cMSs from the MAR and SE zone are kindly asked to consider MED for this use on the national level.

3.2.2.1 Triticale (TTLWI) / *Rhynchosporium secalis* (RHYNSE)

No data were available to support the minimum effective dose of CA3301 against *Rhynchosporium secalis* on triticale. However, the specie *Rhynchosporium secalis* is also the causal agent of leaf blotch on barley. It therefore seems reasonable from an agronomic perspective to assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on triticale from the robust dataset proposed for the closely related crops winter and spring barley. This extrapolation is supported by Poland national guidance extrapolation table. Furthermore, existing authorisations for prothioconazole products (Proline, Praktis, Joao) to control *Rhynchosporium secalis* have the same dose rate for this pathogen in both barley and in triticale, which also indicates that performance is comparable between the pathogen/crop pairs.

The dataset presented in – Winter barley (HORVW) / *Rhynchosporium secalis* (RHYNSE/RHYNSP) and Spring barley (HORVS) / *Rhynchosporium secalis* (RHYNSE)– showed that an overall trend can be observed whereby efficacy increases with an increased dose rate from 0.48 l/ha to 0.6 l/ha. Also, this trend appears stronger as the disease pressure increases and the closer the observation is to harvest. For the rates of 0.6 and 0.8 l/ha it was often observed that the performance of the product was statistically equivalent or very comparable. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for the control of *Rhynchosporium secalis* on barley but in case of heavy infestation, 0.8 l/ha may be more adequate to obtain higher disease control on triticale.

On triticale, leaf blotch remains more occasional than on barley crops and since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.8 l/ha generally gave adequate disease control, it is supposed that the same dose range will be acceptable to control *Rhynchosporium secalis* on triticale.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Rhynchosporium secalis* on triticale in all EPPO zones.

Comments of zRMS:

No trials have been submitted to determine minimum effective dose to control of *Rhynchosporium secalis* on winter triticale in any EPPO climatic zones. The cMSs are kindly asked to consider MED for this use on the national level.

3.2.2.1 Triticale (TTLWI) / *Parastagonospora nodorum* (LEPTNO)

In all EPPO zones, no data were available to support the minimum effective dose of CA3301 against *Parastagonospora nodorum* on triticale. *Parastagonospora nodorum* is the causal agent of glume blotch

on triticale although this disease is most closely associated with wheat. It therefore seems reasonable from an agronomic perspective to assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on triticale from the more robust dataset proposed for the closely related crop winter wheat. Furthermore, existing authorisations for prothioconazole products (Proline, Praktis) have the same dose rate for this pathogen in winter wheat, which also indicates that performance is comparable between the pathogen/crop pairs.

The dataset presented in – Winter wheat (TRZAW) / *Parastagonospora nodorum* (LEPTNO) - allowed to conclude that it is also expected to observe an overall trend of decreasing disease severity with increasing dose rates, especially for 0.6 and 0.8 l/ha compared to 0.48 l/ha. In many instances the rate of 0.6 l/ha should give acceptable control of *Parastagonospora nodorum* very comparable to that of 0.8 l/ha, nevertheless in conditions of high disease pressure the additional disease reduction obtained from the higher rate of 0.8 l/ha may be more appropriate, in particular if some level of resistance is suspected.

On triticale, glume blotch remains an occasional disease and depending on climatic conditions, will develop in a heterogeneous way in the crop. Finally, since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.8 l/ha generally gave adequate disease control, it is supposed that the same dose range will be acceptable to control *Parastagonospora nodorum* on triticale in all EPPO zones.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Parastagonospora nodorum* on triticale in all EPPO zones.

Comments of zRMS:

No trials have been submitted to determine minimum effective dose to control of *Parastagonospora nodorum* on winter triticale in any EPPO climatic zones. The cMSs are kindly asked to consider MED for this use on the national level.

3.2.2.2 Triticale (TTLWI) / Green leaf area

Min. Eff. Dose evaluation of CA3301 – Maritime EPPO zone

Green leaf area was recorded at 19-47 DA-B in 11 trials on triticale in the Maritime EPPO zone after two applications of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N)). In these trials, the green leaf area was assessed on the whole plant.

Summary results are presented in Table 3.2-160.

Data demonstrated a higher effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rate for the increase of green leaf area on triticale infected by foliar diseases. In these trials assessing green leaf area on the whole plant, an increase of 75.48%, 72.26% and 61.11% was recorded with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check on triticale.

A dose effect with statistical differences was observed in a single trial, and a general trend appeared where green leaf area increased with higher dose rate, in particular for 0.6-0.8 l/ha compared to 0.48.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on triticale infected by a range of diseases in the Maritime EPPO zone.

Table 3.2-160: Summary table – Minimum effective dose evaluation – Triticale – Green leaf area – Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA330 1 0,48 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Green leaf area plant 19-47 DA-B										
Number of val- ues	11	11	11	11	UT C	CA244 5 0,48 l/ha	CA330 1 0,8 l/ha	UT C	CA244 5 0,48 l/ha	CA330 1 0,6 l/ha
Minimum value	17,50	26,25	38,75	41,25	6 >	1 >	0 >	6 >	1 >	0 >
Maximum value	85,00	95,00	95,00	95,00	5 =	10 =	11 =	5 =	10 =	11 =
Green Leaf Area	46,98	63,82	68,25	68,07	5 =	10 =	11 =	5 =	10 =	11 =
Abbott efficacy (%)	100,0%	161,11 %	172,26 %	175,48 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Min. Eff. Dose evaluation of CA3301 – Mediterranean EPPO zone

Green leaf area was recorded at 29-48 DA-B in 4 trials on triticale after two applications of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N)). In these trials this parameter was assessed on the whole plant.

Summary results are presented in Table 3.2-161.

CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha respectively provided an increase of 18.95%, 11.47% and 5.85% in green leaf area compared to the untreated check on triticale. Even if no statistical differences were noticed in these trials between untreated check and treated modalities, data demonstrated anyway a numerical increase of the green leaf area after two applications of CA3301, whatever the dose rate considered. An overall trend of increasing the green leaf area with increasing dose rates was observed in the whole dataset, although differences were not significant.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on triticale infected by a range of diseases in the Mediterranean EPPO zone.

Table 3.2-161: Summary table – Minimum effective dose evaluation – Triticale – Green leaf area (%) – Mediterranean EPPO zone

Treatment name	UN-TREATED CHECK	CA3301 1 0,48 L/ha AB	CA3301 1 0,6 L/ha AB	CA3301 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Green leaf area plant 29-48 DA-B										
Number of values	4	4	4	4	UT C	CA3301 1 0,48 l/ha	CA3301 1 0,8 l/ha	UT C	CA3301 1 0,48 l/ha	CA3301 1 0,6 l/ha
Minimum value	13,75	13,75	15,00	15,00	0 >	0 >	0 >	0 >	0 >	0 >
Maximum value	46,50	50,00	50,00	50,00	4 =	4 =	4 =	4 =	4 =	4 =
Mean Green Leaf Area	28,81	31,13	32,25	32,75						
Mean %UTC	100,00%	105,85 %	111,47 %	118,95 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Min. Eff. Dose evaluation of CA3301 – North-Eastern East EPPO zone

In the North-Eastern East EPPO zone green leaf area was recorded 23-41 DA-B on triticale after two applications of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N)). Green leaf area was assessed on the whole plant in 4 trials.

Summary results are presented in Table 3.2-162.

Data demonstrated a higher effect of 2 applications of CA3301 at 0.8 l/ha compared to lower dose rates for the increase of green leaf area on triticale infected by foliar and ears diseases. The performance of CA3301 at 0.8 l/ha was significantly higher than other rates in one trial. The mean green leaf area augmentation of CA3301 at 0.8-0.6 and 0.48 l/ha in these trials was equal to 68.91-66.17% and 55.13% respectively and was significant compared to the untreated control in two trials.

An overall trend of increasing the green leaf area with increasing dose rates was observed in the whole dataset, although differences were not always significant.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on triticale wheat infected by a range of diseases in the North-Eastern East EPPO zone.

Table 3.2-162: Summary table – Minimum effective dose evaluation – Triticale – Green leaf area – North-Eastern East EPPO zone

Treatment name	UN-TREATED CHECK	CA3301 0,48 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Rate						
Rate unit						
Appl. Code						
% Green leaf area plant 23-41 DA-B						
Number of values	4	4	4	4	UTC	CA3301 1 0,48 l/ha
Minimum value	16,25	22,50	25,00	22,50	CA3301 1 0,8 l/ha	UT C
Maximum value	51,25	71,25	73,75	82,50	CA3301 2 >	CA3301 01 0,48 l/ha
Mean Green Leaf Area	32,81	48,13	51,25	52,50	CA3301 2 =	CA3301 01 0,6 l/ha
Mean % UTC	100,00%	155,13%	166,17%	168,91%	CA3301 0 <	CA3301 01 0,6 l/ha

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Min. Eff. Dose evaluation of CA3301 – South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, the green leaf area was recorded in 7 trials after two applications of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N)). Among these trials, green leaf area was assessed on the whole plant in 4 trials and by foliar levels in 3 trials. These trials are presented separately.

Summary results are presented in Table 3.2-163.

Data demonstrated a higher effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rate for the increase of green leaf area on triticale infected by foliar and ears diseases. An overall trend of increasing the green leaf area with increasing dose rates was observed in the whole dataset in particular for 0.6 and 0.8 l/ha compared to 0.48 l/ha, although differences were not always significant.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on triticale infected by a range of diseases in the South-Eastern East EPPO zone.

Table 3.2-163: Summary table – Minimum effective dose evaluation – Triticale – Green leaf area (%) - South-Eastern East EPPO zone

South-Eastern East LTPC zone										
Treatment name	UN-TREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301			No of trials where CA3301		
Rate		0,48	0,6	0,8	at 0,6 l/ha is >, = or <			at 0,8 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
% Green leaf area plant 19-48 DA-B										
Number of values	4	4	4	4	UT	CA330	CA330	UT	CA330	CA330
Minimum value	10,00	20,00	30,00	33,75	C	1	1	C	1	1
Maximum value	58,75	70,00	70,00	70,00		0,48	0,8 l/ha		0,48	0,6 l/ha
Mean Green Leaf Area	40,63	46,56	48,75	50,94	1 >	1 >	0 >	1 >	1 >	1 >
Mean %UTC	100,00%	133,07%	156,99%	169,04%	3 =	3 =	3 =	3 =	3 =	3 =
					0 <	0 <	1 <	0 <	0 <	0 <
% Green leaf area on L2 26-28 DA-B										
Number of values	3	3	3	3	UT	CA330	CA330	UT	CA330	CA330
Minimum value	0,00	1,25	16,25	20,75	C	1	1	C	1	1
Maximum value	2,25	24,50	30,00	33,50		0,48	0,8 l/ha		0,48	0,6 l/ha
Mean Green Leaf Area	0,75	18,83	23,25	25,17	3 >	1 >	2 >	3 >	2 >	2 >
Mean %UTC	100,00%	1061,30 %	1769,44 %	3356,00 %	0 =	2 =	1 =	0 =	1 =	1 =
					0 <	0 <	0 <	0 <	0 <	0 <
% Green leaf area on L1 26-28 DA-B										
Number of values	3	3	3	3	UT	CA330	CA330	UT	CA330	CA330
Minimum value	11,75	42,50	48,75	50,00	C	1	1	C	1	1
Maximum value	19,00	57,00	57,25	58,00		0,48	0,8 l/ha		0,48	0,6 l/ha
Mean Green Leaf Area	14,17	47,92	52,00	53,92	3 >	1 >	0 >	3 >	2 >	0 >
Mean %UTC	100,00%	90,96%	388,43%	404,74%	0 =	2 =	3 =	0 =	1 =	3 =
					0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Comments of zRMS:

Very positive effect after application of CA3301 at dose rate of 0,6-0,8 l/ha were observed. An augmentation of green leaf area was visible on high level in all EPPO climatic zones. It can be concluded that CA3301 at 0,6 l/ha is justified as minimum effective dose in winter triticale.

3.2.2.1 Triticale (TTLWI) / Conclusion – Minimum Effective Dose

On triticale, 4 foliar diseases were assessed in 21 trials across 4 EPPO zones on foliar levels 1 and 2. In some instances, due the absence of appropriate level of disease the proposed number of valid trials was not fully achieved. In all EPPO zones, depending on the disease, the assessment timing and the crop part assessed, the dataset available was sometimes limited and so not fully representative of the minimum effective dose of CA3301. All trials were carried out on winter triticale varieties but the same targets can attack also spring triticale varieties and consequently results can be transposables on both crops, since the dose rates and application timing in relation to the crops is the same. In addition, the same pathogens are assessed for minimum effective dose in wheat and rye with the same dose rates and timing and these results are also supportive for the proposed minimum effective dose rate range. To get an overview of the efficacy of CA3301 at 0.6-0.8 l/ha, summary tables are presented in “Triticale (TTLWI) / Conclusion – Efficacy test”, on foliar levels 1&2 (see Table 3.2-562 and Table 3.2-553) for SEPTTR – PUCCRE/ PUCCRT - PUCST, on all foliar levels for ERYSGT/ERYSGR (see Table 3.2-554) and on ears for FUSASP and FUSACU (see

Table 3.2-555).

Globally, across the 4 EPPO zones and all diseases the efficacy of CA3301 at 0.6-0.8 l/ha was medium to high, with some exceptions. Nevertheless, since in the fields a complex of disease is often observed instead of a single disease, it is of interest to present a summary of the efficacy of CA3301 across the diseases and EPPO zone, as well as considering the green leaf area presented above. Green leaf area not only indicates the area free of infection, but also the ability of the plant to continue effective growth and develop, enabling a longer duration of grain filling and therefore improved yield.

In many instances, a trend of decreasing disease severity when increasing the dose rates was observed with CA3301 applied at 0.6 l/ha or 0.8 l/ha. In fact, overall the rate of 0.8 l/ha was not statistically different from 0.6 l/ha dose rate but both provided a better disease control than the lower rate of 0.48 l/ha. In circumstances of low disease pressure, the 0.6 l/ha rate may be sufficient to give comparable disease control, but due the importance of the diseases and given the possibility of resistance in some pathogens assessed the high rate of 0.8 l/ha may be deemed more appropriate and should be available for user according to disease development conditions, historical control and cultivar tolerance to the pathogen.

In this dossier data presented for minimum effective dose is primarily from assessments where 2 applications of the test product were made. However, according to disease development conditions, a single application may provide sufficient disease control, therefore users should not be restricted to always applying twice, hence in the GAP the proposed use is for 1-2 applications. In addition, crop pathogens are commonly controlled using a programme of different fungicides with varied modes of action, therefore the choice should be available to growers to make a single application of CA3301, followed by application of a different appropriate fungicide. Prothioconazole is well established over a number of years in providing good broad spectrum efficacy across a range of common crop pathogens, with either 1 or more applications appropriate according to disease development conditions, risk of resistance development and local conditions. Current authorisations for similar products containing prothioconazole including Proline 275 and Proline/Praktis/Joao (CA2445) are for 1-2 applications at comparative rates of prothioconazole to the requested use for CA3301. Considering these elements, and that data in the efficacy section shows comparability of CA3301 to these authorised products, registration of CA3301 at the proposed minimum effective dose rate and with a number of applications of 1- 2, is requested.

Considering all elements presented in the previous sections of each disease, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control a range of foliar and ear diseases on triticale.

3.2.2.2 Rye (SECCW) / *Zymoseptoria tritici* (SEPTTR)

Between 2017 and 2020, a series of 17 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the minimum effective dose of CA3301 against *Zymoseptoria tritici* on rye. The trials were carried out by certified testing institutes. The proposed dose rate is 0.6-0.8 l/ha.

In the Maritime EPPO zone, a total of 4 trials were performed in the Czech Republic (2), Denmark (1) and the United Kingdom (1).

In the Mediterranean EPPO zone, a total of 3 trials were performed in Greece (1) and Portugal (2).

In the North-Eastern East EPPO zone, a total of 6 trials were performed in Poland (6).

In the South-Eastern East EPPO zone, a total of 4 trials were performed in Hungary (3) and Romania (1).

Data groupings were also made specifically for Poland evaluation and trials involved (8) were performed in the North-Eastern East EPPO zone (6) and in the Czech Republic (2).

Out of the 17 trials performed on rye against *Zymoseptoria tritici*, 10 were considered valid.

Min. Eff. Dose evaluation of CA3301 - Maritime EPPO zone

In the Maritime EPPO zone, a total of 4 trials evaluated the efficacy of CA3301 on rye against *Zymoseptoria tritici*. 3 trials out of 4 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 31-37 and the 2nd application was at BBCH 39-65. Two main assessment timings were selected: around two weeks after the 2nd application (12-15 DA-B) and the last timing close to harvest (28-49 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-164.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rate for the reduction of disease severity on rye against *Zymoseptoria tritici*.

On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 80.83-80.51% efficacy against *Zymoseptoria tritici* two weeks after the 2nd application and 44.45-50.82% before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 58.45-70.54% efficacy on reduction of disease severity around two weeks after the 2nd application and 76.42-65.50% before harvest.

Zymoseptoria tritici remains an occasional disease in rye and may occur less frequently than classical rye disease such as *Puccinia recondita* or *Rhynchosporium secalis*. In this limited dataset, disease pressure was relatively high and 0.48 l/ha, 0.6 l/ha and 0.8 l/ha were statistically equivalent except in 1 trial where 0.6 and 0.8 l/ha provided a higher disease reduction than 0.48 l/ha.

In addition a larger dataset was presented in Maritime EPPO zone for the related crop winter wheat in which leaf blotch caused by *Zymoseptoria tritici* shares the same biology. In this dataset, whereas differences were not always significant, a clear trend appears where 0.6 l/ha dose rate provide a better control than 0.48 l/ha and very comparable to 0.8 l/ha. Consequently, this dataset can be supportive in order to validate the range of 0.6-0.8 as the minimum effective dose to control this disease on rye.

In addition, given the propensity of the pathogen to develop resistance, the increased efficacy observed from the higher rates of 0.6-0.8 l/ha, is considered most appropriate for control of this pathogen.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Zymoseptoria tritici* on rye in the Maritime EPPO zone.

Table 3.2-164: Summary table – Minimum effective dose evaluation – Rye – SEPTTR - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA33 01 0,48 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate										
Rate unit										
Appl. Code										
% Disease severity L2 - 12-15 DA-B										
Number of values	2	2	2	2	UT	CA33 01	CA33 01	UT	CA33 01	CA33 01
					C	0,48 l/ha	0,8 l/ha	C	0,48 l/ha	0,6 l/ha
Minimum value	16,69	2,75	1,75	1,13						
Maximum value	57,06	15,55	15,89	17,24	2 >	1 >	0 >	2 >	1 >	0 >
Mean disease severity (%)	36,88	9,15	8,82	9,18	0 =	1 =	2 =	0 =	1 =	2 =
Abbott efficacy (%)	0,00%	78,14 %	80,83 %	81,51 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 15 DA-B										
Number of values	1	1	1	1	UT	CA33 01	CA33 01	UT	CA33 01	CA33 01
					C	0,48 l/ha	0,8 l/ha	C	0,48 l/ha	0,6 l/ha
Minimum value	14,56	6,15	6,05	4,29						

Maximum value	14,56	6,15	6,05	4,29	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	14,56	6,15	6,05	4,29	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	57,76 %	58,45 %	70,54 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 28-49 DA-B										
Number of values	2	2	2	2	UT	CA33 01	CA33 01	UT	CA33 01	CA33 01
Minimum value	14,44	7,28	9,50	6,73	C	0,48 l/ha	0,8 l/ha	C	0,48 l/ha	0,6 l/ha
Maximum value	100,00	49,50	45,31	51,75	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	57,22	28,39	27,41	29,24	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	50,04 %	44,45 %	50,82 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 49 DA-B										
Number of values	1	1	1	1	UT	CA33 01	CA33 01	UT	CA33 01	CA33 01
Minimum value	100,00	27,76	23,58	34,50	C	0,48 l/ha	0,8 l/ha	C	0,48 l/ha	0,6 l/ha
Maximum value	100,00	27,76	23,58	34,50	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	100,00	27,76	23,58	34,50	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	72,24 %	76,42 %	65,50 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - Mediterranean EPPO zone

In the Mediterranean EPPO zone, a total of 3 trials evaluated the efficacy of CA3301 on rye against *Zymoseptoria tritici*. 1 trial out of 3 was considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stage BBCH 37 and the 2nd application was at BBCH 54. Two main assessment timings were selected: around two weeks after the 2nd application (15 DA-B) and the last timing close to harvest (45 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-165.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rates for the reduction of disease severity on rye against *Zymoseptoria tritici*.

On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 54.16-72.72% efficacy against *Zymoseptoria tritici* two weeks after the 2nd application and 58.82-75.93% before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 54.02-76.11% efficacy on reduction of disease severity around two weeks after the 2nd application and 42.45-73.91% before harvest. These positive effects to control *Zymoseptoria tritici* of CA3301 at 0.6-0.8 l/ha were overall superior than the 0.48 l/ha dose rate.

An overall trend of decreasing disease severity with increasing dose rates was observed in the dataset, although differences were not always statistically significant. In many instances the rate of 0.6 l/ha gave low control of *Zymoseptoria tritici* but higher than 0.48 l/ha. In this single trial the higher rate of 0.8 l/ha provided medium control of the disease severity. *Zymoseptoria tritici* remains an occasional disease in rye and may occur less frequently than classical rye diseases such as *Puccinia recondita* or *Rhynchosporium secalis*. Rye crop in Mediterranean zone is less developed than in other EPPO zones, this is

also a reason of the low to medium occurrence of the diseases in rye crop in this area. In addition, this very limited dataset can be supplemented by the larger dataset provided on winter wheat which highlights a similar behaviour of the test item where depending on the disease development the range of 0.6-0.8 l/ha gives acceptable to high control of *Zymoseptoria tritici*.

In addition, given the propensity of the pathogen to develop resistance, the increased efficacy observed from the higher rates of 0.6-0.8 l/ha, is considered most appropriate for control of this pathogen.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Zymoseptoria tritici* on rye in the Mediterranean EPPO zone.

Table 3.2-165: Summary table – Minimum effective dose evaluation – Rye – SEPTTR - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA33 01 0,48 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity L2 - 15 DA-B										
Number of values	1	1	1	1	UT C	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	17,56	11,50	8,05	4,79		1 >	0 >		0 >	1 >
Maximum value	17,56	11,50	8,05	4,79	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease se- verity (%)	17,56	11,50	8,05	4,79	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	34,51 %	54,16 %	72,72 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 15 DA-B										
Number of values	1	1	1	1	UT C	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	8,33	6,28	3,83	1,99		1 >	1 >		0 >	1 >
Maximum value	8,33	6,28	3,83	1,99	0 =	0 =	1 =	0 =	0 =	1 =
Mean disease se- verity (%)	8,33	6,28	3,83	1,99	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	24,61 %	54,02 %	76,11 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 45 DA-B										
Number of values	1	1	1	1	UT C	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	24,89	17,48	10,25	5,99		1 >	1 >		0 >	1 >
Maximum value	24,89	17,48	10,25	5,99	0 =	0 =	1 =	0 =	0 =	1 =
Mean disease se- verity (%)	24,89	17,48	10,25	5,99	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	29,77 %	58,82 %	75,93 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 45 DA-B										
Number of values	1	1	1	1	UT C	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	8,74	6,44	5,03	2,28		1 >	0 >		0 >	1 >
Maximum value	8,74	6,44	5,03	2,28	0 =	1 =	0 =	0 =	0 =	0 =
Mean disease se- verity (%)	8,74	6,44	5,03	2,28	0 <	0 <	1 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	26,32 %	42,45 %	73,91 %	0 <	0 <	1 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80% High efficacy

60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 6 trials evaluated the efficacy of CA3301 on rye against *Zymoseptoria tritici*. 3 trials out of 6 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 31-37 and the 2nd application was at BBCH 37-65. Two main assessment timings were selected: around two weeks after the 2nd application (15 DA-B) and the last timing close to harvest (26-44 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-166.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rates for the reduction of disease severity on rye against *Zymoseptoria tritici*, with some statistical differences being observed between these proposed rates and the reduced rate of 0.48 l/ha.

On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 84.33-83.79% efficacy against *Zymoseptoria tritici* two weeks after the 2nd application and 75.33-82.96% before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 74.91-95.27% efficacy against *Zymoseptoria tritici* two weeks after the 2nd application and 83.03-91.92% before harvest.

These positive effects to control *Zymoseptoria tritici* of CA3301 at 0.6-0.8 l/ha were overall superior than the 0.48 l/ha dose rate, demonstrating medium to high efficacy at the 4 assessment timings compared to medium efficacy for the lower rate

In this limited dataset an overall trend of decreasing disease severity with increasing dose rates was observed, although differences were not always statistically significant. Moreover, a larger dataset was presented on the related crop-disease pair winter wheat – *Zymoseptoria tritici*, which confirms and strengthens the numerical trend observed here. In many instances the rate of 0.6 l/ha gave acceptable control of *Zymoseptoria tritici* very comparable to that of 0.8 l/ha, nevertheless in conditions of high disease pressure the additional disease reduction obtained from the higher rate of 0.8 l/ha may be more appropriate, in particular where some level of resistance is suspected.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Zymoseptoria tritici* on rye in the North-Eastern East EPPO zone.

Table 3.2-166: Summary table – Minimum effective dose evaluation – Rye – SEPTTR – North-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA33 01	CA33 01	CA33 01	No of trials where CA3301			No of trials where CA3301		
Rate		0,48	0,6	0,8	at 0,6 l/ha is >, = or			at 0,8 l/ha is >, = or		
Rate unit		L/ha	L/ha	L/ha	<			<		
Appl. Code		AB	AB	AB	compared to			compared to		
% Disease severity L2 - 15 DA-B										
Number of values	2	2	2	2	UT	CA33 01	CA33 01	UT	CA33 01	CA33 01
Minimum value	5,43	1,51	1,23	1,24	C	0,48 l/ha	0,8 l/ha	C	0,48 l/ha	0,6 l/ha
Maximum value	16,81	4,66	1,46	1,36	2 >	1 >	0 >	2 >	1 >	0 >
Mean disease se- verity (%)	11,12	3,09	1,34	1,30	0 =	1 =	2 =	0 =	1 =	2 =
Abbott efficacy (%)	0,00%	72,23 %	84,33 %	83,79 %	0 <	0 <	0 <	0 <	0 <	0 <

% Disease severity L1 - 15 DA-B										
Number of values	1	1	1	1	UT C	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	10,56	2,63	2,65	0,50						
Maximum value	10,56	2,63	2,65	0,50	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease se- verity (%)	10,56	2,63	2,65	0,50	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	75,09 %	74,91 %	95,27 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 26-44 DA-B										
Number of values	3	3	3	3	UT C	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	9,61	2,51	1,80	0,60						
Maximum value	24,40	4,94	5,98	3,24	3 >	0 >	0 >	3 >	1 >	0 >
Mean disease se- verity (%)	17,32	3,92	3,66	2,26	0 =	3 =	3 =	0 =	2 =	3 =
Abbott efficacy (%)	0,00%	72,44 %	75,33 %	82,96 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 26-44 DA-B										
Number of values	2	2	2	2	UT C	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	8,94	1,35	0,50	0,34						
Maximum value	15,63	7,39	4,43	1,93	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease se- verity (%)	12,28	4,37	2,46	1,13	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	68,81 %	83,03 %	91,92 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 4 trials evaluated the efficacy of CA3301 on rye against *Zymoseptoria tritici*. 3 trials out of 4 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 31-37 and the 2nd application was at BBCH 41-61. Two main assessment timings were selected: around two weeks after the 2nd application (14 DA-B) and the last timing close to harvest (25-38 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-167.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rate for the reduction of disease severity on rye against *Zymoseptoria tritici*, with a consistent trend.

On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 69.19-65.65% efficacy against *Zymoseptoria tritici* two weeks after the 2nd application and 83.99-91.03% before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 98.84-98.18% efficacy on reduction of disease before harvest. These positive effects to control *Zymoseptoria tritici* of CA3301 at 0.6-0.8 l/ha were overall superior than the 0.48 l/ha dose rate and specially on foliar level 2 at relatively high disease pressure which was infected earlier than foliar level 1.

An overall trend of decreasing disease severity with increasing dose rates was observed in this limited dataset, although differences were not always statistically significant. Moreover, a larger dataset was presented on the related crop-disease pair winter wheat – *Zymoseptoria tritici*, which confirms and strengthens the numerical trend observed here. *Zymoseptoria tritici* remains an occasional disease in rye and may occur less frequently than classical rye diseases such as *Puccinia recondita* or *Rhynchosporium secalis*. Therefore, in many instances the rate of 0.6 l/ha gave acceptable control of *Zymoseptoria tritici* very comparable to that of 0.8 l/ha. Nevertheless in conditions of high disease pressure the additional disease reduction obtained from the higher rate of 0.8 l/ha may be more appropriate, in particular where some level of resistance is suspected.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Zymoseptoria tritici* on rye in the South-Eastern East EPPO zone.

Table 3.2-167: Summary table – Minimum effective dose evaluation – Rye – SEPTTR – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA33 01 0,48 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity L2 - 15 DA-B										
Number of values	1	1	1	1	UT C	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	10,19	3,76	3,14	3,50		1 >	0 >		0 >	1 >
Maximum value	10,19	3,76	3,14	3,50	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease se- verity (%)	10,19	3,76	3,14	3,50	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	63,10 %	69,19 %	65,65 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 38 DA-B										
Number of values	1	1	1	1	UT C	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	34,66	8,05	5,55	3,11		1 >	0 >		0 >	1 >
Maximum value	34,66	8,05	5,55	3,11	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease se- verity (%)	34,66	8,05	5,55	3,11	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	76,77 %	83,99 %	91,03 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 25-38 DA-B										
Number of values	2	2	2	2	UT C	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	5,88	0,03	0,01	0,02		2 >	0 >		0 >	2 >
Maximum value	8,60	0,54	0,13	0,20	0 =	2 =	2 =	0 =	2 =	2 =
Mean disease se- verity (%)	7,24	0,29	0,07	0,11	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	95,23 %	98,84 %	98,18 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, a total of 8 trials from North-Eastern East EPPO zone and the neighbouring country Czech Republic evaluated the minimum effective dose of CA3301 on rye against *Zymoseptoria tritici*. 5 trials out of 8 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 31-37 and the 2nd application was at BBCH 39-65. Two main assessment timings were selected: around two weeks after the 2nd application (12-15 DA-B) and the last timing close to harvest (26-44 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-168.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rate for the reduction of disease severity on rye against *Zymoseptoria tritici*, with some statistical differences being observed.

On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 86.06-86.94% efficacy against *Zymoseptoria tritici* two weeks after the 2nd application and 65.05-75.57% before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 74.91-95.27% efficacy on reduction of disease two weeks after the 2nd application and 83.03-91.92% before harvest. Hence at the proposed dose rates CA3301 provided medium to high efficacy against *Zymoseptoria tritici*, whereas at 0.48 l/ha the efficacy was medium at each assessment timing. These positive effects to control *Zymoseptoria tritici* of CA3301 at 0.6-0.8 l/ha were therefore overall superior than the 0.48 l/ha dose rate, and are recommended against this pathogen which has a propensity for resistance development.

An overall trend of decreasing disease severity with increasing dose rates was observed in the dataset, although differences were not always statistically significant. In most instances the rate of 0.6 l/ha gave acceptable control of *Zymoseptoria tritici* very comparable to that of 0.8 l/ha, nevertheless in conditions of high disease pressure the additional disease reduction obtained from the higher rate of 0.8 l/ha may be more appropriate, in particular where some level of resistance is suspected.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Zymoseptoria tritici* on rye in Poland.

Table 3.2-168: Summary table – Minimum effective dose evaluation – Rye – SEPTTR – Data relevant for Poland

Treatment name	UNTREATED CHECK	CA33 01	CA33 01	CA33 01	No of trials where CA3301			No of trials where CA3301		
Rate		0,48	0,6	0,8	at 0,6 l/ha is >, = or			at 0,8 l/ha is >, = or		
Rate unit		L/ha	L/ha	L/ha	<			<		
Appl. Code		AB	AB	AB	compared to			compared to		
% Disease severity L2 - 12-15 DA-B										
Number of values	3	3	3	3	UT C	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	5,43	1,51	1,23	1,13		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	16,81	4,66	1,75	1,36	3 >	2 >	0 >	3 >	2 >	0 >
Mean disease se- verity (%)	12,98	2,98	1,48	1,24	0 =	1 =	3 =	0 =	1 =	3 =
Abbott efficacy (%)	0,00%	76,00 %	86,06 %	86,94 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 15 DA-B										
Number of values	1	1	1	1	UT C	CA33 01	CA33 01	UT C	CA33 01	CA33 01

Treatment name		CA33 01 0,48 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate										
Rate unit										
Appl. Code										
Minimum value	10,56	2,63	2,65	0,50		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	10,56	2,63	2,65	0,50	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease se- verity (%)	10,56	2,63	2,65	0,50	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	75,09 %	74,91 %	95,27 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 26-44 DA-B										
Number of values	4	4	4	3	UT C	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	9,61	2,51	1,80	0,60						
Maximum value	24,40	7,28	9,50	6,73	4 >	0 >	0 >	4 >	1 >	0 >
Mean disease se- verity (%)	16,60	4,76	5,12	3,38	0 =	4 =	4 =	0 =	3 =	4 =
Abbott efficacy (%)	0,00%	66,73 %	65,05 %	75,57 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 26-44 DA-B										
Number of values	2	2	2	2	UT C	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	8,94	1,35	0,50	0,34						
Maximum value	15,63	7,39	4,43	1,93	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease se- verity (%)	12,28	4,37	2,46	1,13	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	68,81 %	83,03 %	91,92 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

3 trials have been submitted to determine minimum effective dose in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,8 l/ha achieved medium to high efficacy. The level of control for lower doses was varied. The dose rate of 0,48 l/ha and 0,6 l/ha were not effective in 2 out of 3 trials, either after second application and before harvest. However, some trials showed also medium level of control for these doses. Due to the limited number of trials, the cMSs are kindly asked to consider MED for this use on the national level.

3 trials were available to determine MED in **the North-East EPPO zone**. The test product at 0,8 l/ha achieved consistently high efficacy in all assessments. The lower dose rate of 0,6 l/ha was effective on medium to high level. The reduce dose to 0,48 l/ha caused a decrease of effectiveness about 12% after second application and 14% before harvest. However, the lowest dose showed still medium level of control. The trials from the neighbouring countries confirm this trend. Taking into account low disease pressure in submitted trials, more benefits will come using of dose rate of 0,6 l/ha. It should be noted that the dose rate of 0,6 l/ha can be considered MED mainly in situation of low disease pressure. In more challenging conditions, the dose rate of 0,8 l/ha will be more justified.

3 trials were presented to determine MED in **the South-East EPPO zone**. CA3301 at 0,48-0,8 l/ha achieved medium to high efficacy. The significant differences between effectiveness of doses were visible in 1 out of 3 trials before harvest (38 DA-B). The lowest dose rate showed medium level of control while the higher doses had high efficacy. 1 additional trial from the Mediterranean zone has been submitted to support of product registration in other zone. However, the dose rate of 0,48-0,6 l/ha achieved very low results. The effectiveness of 0,8 l/ha was on medium level. Due to the limited number of trials, the cMSs are kindly asked to consider MED for this use on the national level.

3.2.2.3 Rye (SECCW) / *Puccinia recondita* – *Puccinia recondita* f. sp. *recondita* (PUCCRE-PUCCRR)

Puccinia recondita and *Puccinia recondita* f. sp. *recondita* are the causal agents of the brown rust on rye and are considered as the same pathogen in this analysis.

Between 2017 and 2020, a series of 17 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the minimum effective dose of CA3301 against *Puccinia recondita* or *Puccinia recondita* f. sp. *recondita* on rye. The trials were carried out by certified testing institutes. The proposed dose rate is 0.6-0.8 l/ha.

In the Maritime EPPO zone, 9 trials were performed in Czech Republic (3), Germany (2), United Kingdom (1) and Denmark (3).

In the North-Eastern East EPPO zone, 6 trials were performed in Poland (5) and Latvia (1).

In the South-Eastern East EPPO zone, a total of 2 trials were performed in Hungary (2).

Data groupings were also made specifically for Poland evaluation and trials involved (11) were performed in the North-Eastern East EPPO zone (6), in the Czech Republic (3) and in Germany (2).

Out of the 17 trials carried out against *Puccinia recondita* (PUCCRE) or *Puccinia recondita* f. sp. *recondita* (PUCCRR) on rye, 10 were considered valid:

Min. Eff. Dose evaluation of CA3301 - Maritime EPPO zone

In the Maritime EPPO zone, a total of 9 trials evaluated the efficacy of CA3301 on rye against *Puccinia recondita*. 6 trials out of 9 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 31-39 and the 2nd application was at BBCH 45-69. Two main assessment timings were selected: around two weeks after the 2nd application (12 DA-B) and the last timing close to harvest (28-55 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-169.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rate for the reduction of disease severity on rye against *Puccinia recondita*, with some statistical differences.

On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 71.48-82-92% efficacy against *Puccinia recondita* two weeks after the 2nd application and 76.70-84.81% before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 85.99-89.25% efficacy on reduction of disease severity before harvest. The proposed dose rates therefore provided high to medium efficacy whereas at the rate of 0.48 efficacy was low to high.

In this limited dataset, although differences were not always significant, a numerical trend appears whereby disease control increase when increasing CA3301 dose rate. In addition, a larger dataset was presented in Maritime EPPO zone for the related crop-disease pair winter wheat – *Puccinia recondita* which strengthen the trend where 0.6 l/ha dose rate provide a better control than 0.48 l/ha and very comparable to 0.8 l/ha. Also, this dataset suggests that 0.8 l/ha dose rate provides better disease control in conditions of high disease pressure. Consequently, this dataset can be supportive in order to validate the range of 0.6-0.8 as the minimum effective dose to control brown rust on rye.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Puccinia recondita* on rye in the Maritime EPPO zone.

Table 3.2-169: Summary table – Minimum effective dose evaluation – Rye – PUCCRE/PUCCRR - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA33 01 0,48 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate										
Rate unit										
Appl. Code										
% Disease severity L2 - 12 DA-B										
Number of values	1	1	1	1	UT C	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	12,06	5,25	3,44	2,06						
Maximum value	12,06	5,25	3,44	2,06	1 >	1 >	0 >	1 >	1 >	1 >
Mean disease severity (%)	12,06	5,25	3,44	2,06	0 =	0 =	0 =	0 =	0 =	0 =
Abbott efficacy (%)	0,00%	56,47 %	71,48 %	82,92 %	0 <	0 <	1 <	0 <	0 <	0 <
% Disease severity L2 - 28-55 DA-B										
Number of values	4	4	4	4	UT C	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	13,68	0,80	0,50	0,28						
Maximum value	100,00	10,00	16,19	20,13	4 >	0 >	0 >	4 >	0 >	1 >
Mean disease severity (%)	38,72	4,88	7,68	6,97	0 =	4 =	3 =	0 =	4 =	3 =
Abbott efficacy (%)	0,00%	84,30 %	76,70 %	84,81 %	0 <	0 <	1 <	0 <	0 <	0 <
% Disease severity L1 - 35-55 DA-B										
Number of values	4	4	4	4	UT C	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA330 1 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	5,38	0,41	0,20	0,13						
Maximum value	100,00	13,63	8,14	13,04	4 >	0 >	0 >	4 >	0 >	0 >
Mean disease severity (%)	31,98	4,64	3,18	4,06	0 =	4 =	4 =	0 =	4 =	4 =
Abbott efficacy (%)	0,00%	85,23 %	85,99 %	89,25 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 6 trials evaluated the efficacy of CA3301 on rye against *Puccinia recondita*. 3 trials out of 6 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 32-37 and the 2nd application was at BBCH 53-65. Two main assessment timings were selected: around two weeks after the 2nd application (15 DA-B) and the last timing close to harvest (26-29 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-170.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rate for the reduction of disease severity on rye against *Puccinia recondita*, with some statistical differences observed at each assessment timing.

On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 76.73-86.32% efficacy against *Puccinia recondita* two weeks after the 2nd application and 83.52-85.02% before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 73.81-92.65% efficacy on reduction of disease severity two weeks after the 2nd application and 79.79-88.22% before harvest. Hence at the proposed dose rates CA3301 provided high to medium efficacy against *Puccinia recondita*, whereas at 0.48 l/h efficacy was medium to low.

In this limited dataset, with medium to high disease pressure, an overall trend can be observed whereby efficacy increases with higher dose rates although differences were not always statistically significant.

Moreover, in trials where a high disease infection is observed, CA3301 at 0.8 l/ha offers a statistically higher control than CA3301 at 0.6 l/ha while for lower disease infection, the gap of efficacy between the two dose rates is lower.

In addition, a larger dataset was presented in North-Eastern East EPPO zone for the related crop-disease pair winter wheat – *Puccinia recondita* which strengthens the trend that 0.6 l/ha dose rate gave a higher disease control than 0.48 l/ha and was very comparable to 0.8 l/ha. Also, this dataset suggested that 0.8 l/ha dose rate provided better disease control in conditions of high disease pressure. Consequently, this dataset can be supportive in order to validate the range of 0.6-0.8 l/ha as the minimum effective dose to control brown rust on rye.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Puccinia recondita* on rye in the North-Eastern East EPPO zone.

Table 3.2-170: Summary table – Minimum effective dose evaluation – Rye – PUCCRE/PUCRR – North-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA33 01	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or <			No of trials where CA3301 at 0,8 l/ha is >, = or <		
Rate		0,48	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
% Disease severity L2 - 15 DA-B										
Number of values	1	1	1	1	UT C	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	42,25	18,96	9,83	5,78		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	42,25	18,96	9,83	5,78	1 >	1 >	0 >	1 >	1 >	1 >
Mean disease se- verity (%)	42,25	18,96	9,83	5,78	0 =	0 =	0 =	0 =	0 =	0 =
Abbott efficacy (%)	0,00%	55,12 %	76,73 %	86,32 %	0 <	0 <	1 <	0 <	0 <	0 <
% Disease severity L1 - 15 DA-B										
Number of values	1	1	1	1	UT C	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	16,19	6,55	4,24	1,19		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	16,19	6,55	4,24	1,19	1 >	1 >	0 >	1 >	1 >	1 >
Mean disease se- verity (%)	16,19	6,55	4,24	1,19	0 =	0 =	0 =	0 =	0 =	0 =
Abbott efficacy (%)	0,00%	59,54 %	73,81 %	92,65 %	0 <	0 <	1 <	0 <	0 <	0 <
% Disease severity L2 - 26 DA-B										
Number of values	2	2	2	2	UT C	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	5,34	0	0	0		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	16,45	2,25	1,76	1,6	2 >	1 >	0 >	2 >	1 >	0 >
Mean disease se- verity (%)	10,9	1,12	0,88	0,8	0 =	1 =	2 =	0 =	1 =	2 =
Abbott efficacy (%)	0,00%	78,93 %	83,52 %	85,02 %	0 <	0 <	0 <	0 <	0 <	0 <

% Disease severity L1 - 26-29 DA-B										
Number of values	2	2	2	2	UT	CA33	CA33	UT	CA33	CA33
					C	01	01	C	01	01
Minimum value	7,29	0	0	0		0,48	0,8		0,48	0,6
						l/ha	l/ha		l/ha	l/ha
Maximum value	53	22,81	12,19	7,1	2 >	1 >	0 >	2 >	1 >	1 >
Mean disease severity (%)	30,14	11,41	6,09	3,55	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	62,14 %	79,79 %	88,22 %	0 <	0 <	1 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 2 trials evaluated the efficacy of CA3301 on rye against *Puccinia recondita*. 1 trial out of 2 was considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stage BBCH 31 and the 2nd application was at BBCH 41. One main assessment timings was available: the last timing close to harvest (38 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-171.

Data demonstrated a very strong effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on rye against *Puccinia recondita*.

On both foliar levels, CA3301 at 0.6-0.8 l/ha showed 100.00% of efficacy against *Puccinia recondita* before harvest.

In this limited dataset, composed of 1 trial and 1 assessment timing before harvest, each tested dose rate gave a full disease control on both foliar levels 1 and 2. However, a larger dataset was presented in South-Eastern East EPPO zone on the related crop-disease pair winter wheat – *Puccinia recondita* which confirmed the high efficacy level of CA3301 applied at the range of 0.6-0.8 l/ha. This larger dataset also showed a numerical and statistical trend where disease control increases with the dose rate and all the more in case of high disease pressure and close to harvest.

Therefore, among the data presented in this section, it is envisaged that the range of 0.6-0.8 l/ha is appropriate for control of brown rust in rye depending on the disease pressure and its development timing on the crop.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Puccinia recondita* on rye in the South-Eastern East EPPO zone.

Table 3.2-171: Summary table – Minimum effective dose evaluation – Rye – PUCCRE/PUCCRR – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA33 01	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		0,48	0,6	0,8				
Rate unit		L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB				
% Disease severity L2 - 38 DA-B								
Number of values	1	1	1	1	UT	CA33	CA33	UT
					C	01	01	C
Minimum value	16,30	0,00	0,00	0,00		0,48	0,8	
						l/ha	l/ha	

Maximum value	16,30	0,00	0,00	0,00	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	16,30	0,00	0,00	0,00	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	100,00 %	100,00 %	100,00 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 38 DA-B										
Number of values	1	1	1	1	UT	CA33 01	CA33 01	UT	CA33 01	CA33 01
Minimum value	8,29	0,00	0,00	0,00	C	0,48 l/ha	0,8 l/ha	C	0,48 l/ha	0,6 l/ha
Maximum value	8,29	0,00	0,00	0,00	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	8,29	0,00	0,00	0,00	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	100,00 %	100,00 %	100,00 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, a total of 10 trials from North-East EPPO zone and the neighbouring countries Czech Republic and Germany evaluated the efficacy of CA3301 on rye against *Puccinia recondita*. 8 trials out of 10 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 31-39 and the 2nd application was at BBCH 37-65. Two main assessment timings were selected: around two weeks after the 2nd application (12-15 DA-B) and the last timing close to harvest (26-55 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-172

Data demonstrated a better effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rate for the reduction of disease severity on rye against *Puccinia recondita*, with statistical differences frequently being observed.

On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 74.10-84.62% efficacy against *Puccinia recondita* two weeks after the 2nd application and 78.00-85.88% before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 73.81-92.65% efficacy on reduction of disease two weeks after the 2nd application and 85.82-91.33% before harvest. Hence at the proposed dose rates CA3301 provided high to medium efficacy against *Puccinia recondita*, whereas at 0.48 l/ha efficacy was low to high. These positive effects to control *Puccinia recondita* of CA3301 at 0.6-0.8 l/ha were therefore superior to the 0.48 l/ha dose rate.

Furthermore, national guidance from Poland indicates that extrapolation is possible from winter wheat for this pathogen, and the corresponding dataset in winter wheat shows consistent results to those observed here.

An overall trend of decreasing disease severity with increasing dose rates was observed in the dataset, although differences were not always statistically significant. In most instances the rate of 0.6 l/ha gave acceptable control of *Puccinia recondita* and was often comparable to that of 0.8 l/ha, nevertheless in

conditions of high disease pressure the additional disease reduction obtained from the higher rate of 0.8 l/ha may be more appropriate.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Puccinia recondita* on rye in Poland.

Table 3.2-172: Summary table – Minimum effective dose evaluation – Rye – PUCCRE/PUCCRR – Data relevant for Poland

Data Relevant for Poland										
Treatment name	UNTREATED CHECK	CA33 01	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		0,48	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Disease severity L2 - 12-15 DA-B										
Number of values	2	2	2	2	UT C	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	12,06	5,25	3,44	2,06		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	42,25	18,96	9,83	5,78	2 >	2 >	0 >	2 >	2 >	2 >
Mean disease se- verity (%)	27,16	12,11	6,63	3,92	0 =	0 =	0 =	0 =	0 =	0 =
Abbott efficacy (%)	0,00%	55,80 %	74,10 %	84,62 %	0 <	0 <	2 <	0 <	0 <	0 <
% Disease severity L1 - 15 DA-B										
Number of values	1	1	1	1	UT C	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	16,19	6,55	4,24	1,19		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	16,19	6,55	4,24	1,19	1 >	1 >	0 >	1 >	1 >	1 >
Mean disease se- verity (%)	16,19	6,55	4,24	1,19	0 =	0 =	0 =	0 =	0 =	0 =
Abbott efficacy (%)	0,00%	59,54 %	73,81 %	92,65 %	0 <	0 <	1 <	0 <	0 <	0 <
% Disease severity L2 - 26-55 DA-B										
Number of values	5	5	5	5	UT C	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	5,34	0,00	0,00	0,00		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	21,63	5,59	10,40	5,73	5 >	1 >	0 >	5 >	1 >	1 >
Mean disease se- verity (%)	15,33	2,35	3,25	1,87	0 =	4 =	4 =	0 =	4 =	4 =
Abbott efficacy (%)	0,00%	81,01 %	78,00 %	85,88 %	0 <	0 <	1 <	0 <	0 <	0 <
% Disease severity L1 - 26-55 DA-B										
Number of values	5	5	5	5	UT C	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	5,38	0,00	0,00	0,00		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	53,00	22,81	12,19	7,10	5 >	1 >	0 >	5 >	1 >	1 >
Mean disease se- verity (%)	17,65	5,55	3,35	2,06	0 =	4 =	4 =	0 =	4 =	4 =
Abbott efficacy (%)	0,00%	82,30 %	85,82 %	91,33 %	0 <	0 <	1 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

6 trials have been submitted to determine minimum effective dose in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,8 l/ha achieved high efficacy in all assessments. The dose rate of 0,6 l/ha showed medium to high level of control. The significant differences between effectiveness of 0,48 l/ha and 0,6 l/ha were visible in 1 out of 6 trials after 12 days after second application. The lower dose rate had 56,47% and the higher dose had 71,48%. It should be noted that the dose rate of 0,6 l/ha can be considered MED mainly in situation of low disease pressure. In more challenging conditions, the dose rate of 0,8 l/ha will be more justified. 3 trials were presented to determine MED in **the North-East EPPO zone**. CA3301 at 0,48 l/ha achieved low to medium efficacy. The significant better results were noted in case of doses of 0,6-0,8 l/ha with effectiveness of medium to high. Also trials from the neighbouring countries confirmed this trend. The reduce dose rate to 0,48 l/ha caused a decrease of effectiveness about 20% compare to higher dose of 0,6 l/ha. It should be noted that the dose rate of 0,6 l/ha can be considered MED mainly in situation of low disease pressure. In more challenging conditions, the dose rate of 0,8 l/ha will be more justified. Only 1 trial was available to determine MED in **the South-East EPPO zone**. A full efficacy was observed after application of all dose rates on leaves level 1 and 2 before harvest. No additional trials from the Mediterranean zone have been submitted. Due to the limited number of trials, the cMSs are kindly asked to consider MED for this use on the national level.

3.2.2.4 Rye (SECCW) / *Rhynchosporium secalis* (RHYNSE)

Between 2018 and 2020, a series of 6 trials were conducted in several countries of the Maritime and North-Eastern East EPPO zones to evaluate the minimum effective dose of CA3301 against *Rhynchosporium secalis* on rye. The trials were carried out by certified testing institutes. The proposed dose rate is 0.6-0.8 l/ha.

In the Maritime EPPO zone, 5 trials were performed in Denmark (3) and Germany (2). In the North-Eastern East EPPO zone, a total of 1 trial was performed in Latvia (1).

Data groupings were also made specifically for Poland evaluation and trials involved (3) were performed in the North-Eastern East EPPO zone (1) and in the Czech Republic (2).

Out of the 6 trials carried out against *Rhynchosporium secalis* (RHYNSE) on rye, 3 were considered valid:

Min. Eff. Dose evaluation of CA3301 - Maritime EPPO zone

In the Maritime EPPO zone, a total of 5 trials evaluated the efficacy of CA3301 on rye against *Rhynchosporium secalis*. 2 trials out of 5 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 32-37 and the 2nd application was at BBCH 47-65. Two main assessment timings were selected: around two weeks after the 2nd application (13 DA-B) and the last timing close to harvest (55 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-173.

Data demonstrated a strong effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rate for the reduction of disease severity on rye against *Rhynchosporium secalis*. On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 100.00% efficacy against *Rhynchosporium secalis* two weeks after the 2nd application and 79.05-83.91% before harvest. Moreover, on foliar level 1, CA3301 at 0.6-0.8 l/ha showed 82.47-88.26% efficacy on reduction of disease severity before harvest. Hence, the proposed dose rates of CA3301 provided overall high efficacy against *Rhynchosporium secalis*. At the later assessments the reduced rate of 0.48 l/ha provided medium efficacy

In this limited dataset, an overall trend can be observed whereby efficacy increases with higher dose rates, although differences were not statistically significant, and particularly for 0.6-0.8 l/ha compared to 0.48 l/ha. In addition, larger datasets were presented in Maritime EPPO zone for the related crops-disease pairs winter and spring barley – *Rhynchosporium secalis* which strengthens the trend that 0.6 l/ha dose rate provides a better control than 0.48 l/ha and is very comparable to 0.8 l/ha. Also, these datasets suggest that 0.8 l/ha dose rate gave higher disease control in conditions of high disease pressure. Consequently, these data can be supportive in order to validate the range of 0.6-0.8 l/ha as the minimum effective dose to control rhynchosporiosis on rye.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Rhynchosporium secalis* on rye in the Maritime EPPO zone.

Table 3.2-173: Summary table – Minimum effective dose evaluation – Rye – RHYNSE - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA33 01 0,48 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate										
Rate unit										
Appl. Code										
% Disease severity L2 - 13 DA-B										
Number of values	1	1	1	1	UT C	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	5,00	0,00	0,00	0,00	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	5,00	0,00	0,00	0,00	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	5,00	0,00	0,00	0,00	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	100,00 %	100,00 %	100,00 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 55 DA-B										
Number of values	1	1	1	1	UT C	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	17,09	4,85	3,58	2,75	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	17,09	4,85	3,58	2,75	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	17,09	4,85	3,58	2,75	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	71,62 %	79,05 %	83,91 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 55 DA-B										
Number of values	1	1	1	1	UT C	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	6,73	1,81	1,18	0,79	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	6,73	1,81	1,18	0,79	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	6,73	1,81	1,18	0,79	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	73,11 %	82,47 %	88,26 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - Mediterranean EPPO zone

No data were available to support the minimum effective dose of CA3301 against *Rhynchosporium secalis* on rye. However, the specie *Rhynchosporium secalis* is also the causal agent of leaf blotch on

barley. It therefore seems reasonable from an agronomic perspective to assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on rye from the robust dataset proposed for the closely related crops winter and spring barley. Furthermore, existing authorisations for prothioconazole products (Proline, Praktis, Joao) to control *Rhynchosporium secalis* have the same dose rate for this pathogen in both barley and in rye, which also indicates that performance is comparable between the pathogen/crop pairs.

The dataset presented in – Winter barley (HORVW) / *Rhynchosporium secalis* (RHYNSE/RHYNSE) and Spring barley (HORVS) / *Rhynchosporium secalis* (RHYNSE)– showed that an overall trend can be observed whereby efficacy increases with an increased dose rate from 0.48 l/ha to 0.6 l/ha. Also, this trend appears stronger as the disease pressure increases and the closer the observation is to harvest. For the rates of 0.6 and 0.8 l/ha it was often observed that the performance of the product was statistically equivalent or very comparable. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for the control of *Rhynchosporium secalis* on barley but in case of heavy infestation, 0.8 l/ha may be more adequate to obtain higher disease control on rye.

On rye, leaf blotch remains more occasional than on barley crops and since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.8 l/ha generally gave adequate disease control, it is supposed that the same dose range will be acceptable to control *Rhynchosporium secalis* on rye.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Rhynchosporium secalis* on rye in the Mediterranean EPPO zone.

Min. Eff. Dose evaluation of CA3301 - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a single trial evaluated the efficacy of CA3301 on rye against *Rhynchosporium secalis*. This trial was considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stage BBCH 33 and the 2nd application was at BBCH 51. One main assessment timing was available: the last timing close to harvest (39 DA-B), and the analysis was conducted on main foliar levels 2 (L2).

Summary results are presented in Table 3.2-174.

On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 74.31-75.21% efficacy against *Rhynchosporium secalis* before harvest.

In this limited dataset, a trend can be observed whereby efficacy increases with higher dose rates although differences were not statistically significant. A larger dataset was presented in North-Eastern East EPPO zone for the related crop-disease pair winter barley – *Rhynchosporium secalis*. Except for 1 trial, this dataset showed the same trend that 0.6 l/ha dose rate gave a higher disease control than 0.48 l/ha and was very comparable to 0.8 l/ha. Also, this dataset suggests that 0.8 l/ha dose rate gave higher disease control in conditions of high disease pressure and can be supportive in order to validate the range of 0.6-0.8 as the minimum effective dose to control rhynchosporiosis on rye. Therefore, although CA3301 at 0.6 l/ha may provide sufficient reduction of the disease severity in most instances, the dose rate of 0.8 l/ha may be necessary in conditions of high disease pressure or when some level of resistance is suspected.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Rhynchosporium secalis* on rye in the North-Eastern East EPPO zone.

Table 3.2-174: Summary table – Minimum effective dose evaluation – Rye – RHYNSE – North-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA33 01	CA33 01	CA33 01	No of trials where CA3301	No of trials where CA3301
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Rate		0,48 L/ha AB	0,6 L/ha AB	0,8 L/ha AB	at 0,6 l/ha is >, = or < compared to			at 0,8 l/ha is >, = or < compared to		
Rate unit										
Appl. Code										
% Disease severity L2 - 39 DA-B										
Number of values	1	1	1	1	UT	CA33 01	CA33 01	UT	CA33 01	CA33 01
Minimum value	20,94	5,56	5,38	5,19	C	0,48 l/ha	0,8 l/ha	C	0,48 l/ha	0,6 l/ha
Maximum value	20,94	5,56	5,38	5,19	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	20,94	5,56	5,38	5,19	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	73,45 %	74,31 %	75,21 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – ~~Southern~~ South-East EPPO zone

No data were available to support the minimum effective dose of CA3301 against *Rhynchosporium secalis* on rye. However, the specie *Rhynchosporium secalis* is also the causal agent of leaf blotch on barley. It therefore seems reasonable from an agronomic perspective to assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on rye from the robust dataset proposed for the closely related crops winter and spring barley. Furthermore, existing authorisations for prothioconazole products (Proline, Praktis, Joao) to control *Rhynchosporium secalis* have the same dose rate for this pathogen in both barley and in rye, which also indicates that performance is comparable between the pathogen/crop pairs.

The dataset presented in – Winter barley (HORVW) / *Rhynchosporium secalis* (RHYNSE/RHYNSP) and Spring barley (HORVS) / *Rhynchosporium secalis* (RHYNSE)– showed that an overall trend can be observed whereby efficacy increases with an increased dose rate from 0.48 l/ha to 0.6 l/ha. Also, this trend appears stronger as the disease pressure increases and the closer the observation is to harvest. For the rates of 0.6 and 0.8 l/ha it was often observed that the performance of the product was statistically equivalent or very comparable. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for the control of *Rhynchosporium secalis* on barley but in case of heavy infestation, 0.8 l/ha may be more adequate to obtain higher disease control on rye.

On rye, leaf blotch remains more occasional than on barley crops and since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.8 l/ha generally gave adequate disease control, it is supposed that the same dose range will be acceptable to control *Rhynchosporium secalis* on rye.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Rhynchosporium secalis* on rye in the South-~~Eastern~~ East EPPO zone.

Min. Eff. Dose evaluation of CA3301 - Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, a total of 3 trials from North-~~Eastern~~ East EPPO zone and the neighbouring country Germany evaluated the efficacy of CA3301 on rye against *Rhynchosporium secalis*. 2 trials out of 3 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 32-33 and the 2nd application

was at BBCH 47-51. One main assessment timing was available: the last timing close to harvest (39-55 DA-B), and the analysis was conducted on both main foliar levels 1 (L1) and 2 (L2).

Summary results are presented in Table 3.2-175.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect to control *Rhynchosporium secalis* was provided after two applications of CA3301 at 0.6-0.8 l/ha. On foliar level 2, when applied at 0.6-0.8 l/ha, CA3301 showed 76.68-79.56% of efficacy to reduce the disease severity before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 82.47-88.26% of efficacy on reduction of disease severity before harvest. Hence, at the proposed dose rates CA3301 provided high to medium efficacy against *Rhynchosporium secalis*, whereas applied at 0.48 l/ha efficacy was medium.

In this limited dataset, composed of only two trials, a clear trend can be observed whereby efficacy increases with higher dose rates although differences were not statistically significant. According to the Poland national extrapolation table data from winter or spring barley can support this pest in rye. A larger dataset was presented for the closely related crop disease pair spring barley – *Rhynchosporium secalis* which supports this trend with significant results. The range of 0.6-0.8 l/ha of CA3301 provided significantly better efficacies than 0.48 l/ha dose rate.

Therefore, in most instances, the rate of 0.6 l/ha is sufficient to provide an acceptable disease control but the higher dose rate of 0.8 l/ha may be more appropriate in conditions of high disease pressure or where some level of resistance is suspected.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Rhynchosporium secalis* on rye in Poland.

Table 3.2-175: Summary table - Minimum effective dose evaluation – Rye – RHYNSE – Data relevant for Poland

Treatment name	UNTREATED CHECK	CA33 01 0,48 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity L2 - 39-55 DA-B										
Number of values	2	2	2	2	UT C	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	17,09	4,85	3,58	2,75		2 >	0 >		0 >	2 >
Maximum value	20,94	5,56	5,38	5,19	0 =	2 =	2 =	0 =	2 =	2 =
Mean disease se- verity (%)	19,01	5,21	4,48	3,97	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	72,53 %	76,68 %	79,56 %						
% Disease severity L1 - 55 DA-B										
Number of values	1	1	1	1	UT C	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	6,73	1,81	1,18	0,79		1 >	0 >		0 >	1 >
Maximum value	6,73	1,81	1,18	0,79	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease se- verity (%)	6,73	1,81	1,18	0,79	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	73,11 %	82,47 %	88,26 %						

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy

<60% Low efficacy

Comments of zRMS:

2 trials have been submitted to determine minimum effective dose in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,48-0,6 l/ha achieved medium to high efficacy while the dose of 0,8 l/ha had high level of control. Due to the limited number of trials, the cMSs are kindly asked to consider MED for this use on the national level.

Only 1 trial was available to determine MED in **the North-East EPPO zone**. No significant differences between effectiveness of all dose rates were visible. Also trials from the neighbouring countries showed similar results. Slight higher efficacy was noted in case of 0,6-0,8 l/ha compare to lower dose in 1 trial before harvest (82,47% and 88,26% vs 73,11%). Taking into extrapolation from winter barley, the dose rate of 0,6-0,8 l/ha are sufficient to control of RHYNSE in winter rye. It should be noted that the dose rate of 0,6 l/ha can be considered MED mainly in situation of low disease pressure. In more challenging conditions, the dose rate of 0,8 l/ha will be more justified.

No dataset was presented in the South-East and Mediterranean EPPO zone. The cMSs are kindly asked to consider MED for this on the national level.

3.2.2.5 Rye (SECCW) / *Blumeria graminis* (ERYSGR)

Between 2018 and 2020, a series of 3 trials were conducted in several countries of the Maritime and North-Eastern East EPPO zones to evaluate the efficacy of CA3301 against *Blumeria graminis* f. sp. *secalis* on rye (ERYSGS / ERYSGR). The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, 2 trials were performed in Denmark (1) and Czech Republic (1).

In the North-Eastern East EPPO zone, 1 trial was performed in Latvia (1).

Out of the 3 trials carried out against *Blumeria graminis* (ERYSGS / ERYSGR) on rye, 1 was considered valid.

Min. Eff. Dose evaluation of CA3301 - Maritime EPPO zone

In the Maritime EPPO zone, a total of 2 trials evaluated the efficacy of CA3301 on rye against *Blumeria graminis* 1 trials out of 2 was considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 37 and the 2nd application was at BBCH 65. One main assessment timing was available: the last timing close to harvest (28 DA-B), and the analysis was conducted on main foliar level 2 (L2).

Summary results are presented in Table 3.2-176.

Data demonstrated a positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on rye against *Blumeria graminis*. On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 60.76-81.25% efficacy against *Blumeria graminis* before harvest.

In this limited dataset, no significant differences were observed and the numerical trend is not clear between CA3301 at 0.48 l/ha, 0.6 l/ha and 0.8 l/ha.

On rye, powdery mildew remains an occasional disease and depending on climatic conditions, will develop in a heterogeneous way in the crop. This explains the limited data set obtained despite the several trials implemented on rye. In addition, the species *Blumeria graminis* f. sp. *secalis* is very comparable to other *Blumeria graminis* species as f. sp. *tritici*, which causes powdery mildew on wheat. It therefore seems reasonable from an agronomic perspective to assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on rye from the robust dataset proposed for the closely related crop winter wheat. Furthermore, existing authorisations for prothioconazole products in the Maritime zone (e.g. UK, DE) have the

same dose rate for this pathogen in both winter wheat and in rye, which also indicates that performance is comparable between the pathogen/crop pairs.

The dataset presented in – **Winter wheat (TRZAW) / *Blumeria graminis* (ERYSGR)** – showed that CA3301 applied at 0.6-0.8 l/ha provided significant disease control in the two main assessment timings. Both dose rates were frequently better than the lower rate of 0.48 l/ha. Moreover, the level of disease control observed was medium to high depending on the disease pressure. Indeed, whereas differences were not always significant, a numerical trend appeared where CA3301 at 0.8 l/ha provided better efficacy than 0.6 l/ha dose in the most challenging conditions.

Finally, since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.8 l/ha generally gave adequate disease control, it is supposed that the same dose range will be acceptable to control powdery mildew on rye.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Blumeria graminis* on rye in the Maritime EPPO zone.

Table 3.2-176: Summary table – Minimum effective dose evaluation – Rye – ERYSGR - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA330 1 0,48 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Rate						
Rate unit						
Appl. Code						
% Disease severity L2 - 28 DA-B						
Number of values	1	1	1	1	UT C	CA330 1 0,48 l/ha
Minimum value	6,88	1,74	2,7	1,29	CA330 1 0,8 l/ha	UT C
Maximum value	6,88	1,74	2,7	1,29	CA330 1 0,48 l/ha	CA330 1 0,6 l/ha
Mean disease severity (%)	6,88	1,74	2,7	1,29	0 >	0 >
Abbott efficacy (%)	0,00%	74,71 %	60,76 %	81,25 %	0 =	0 =
					0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 - Mediterranean EPPO zone

In the Mediterranean EPPO zone, no trial was conducted to assess the control of powdery mildew *Blumeria graminis* f. sp. *secalis* on rye by CA3301 due to lack of disease infestation. However, the species *Blumeria graminis* f. sp. *secalis* is very comparable to other *Blumeria graminis* species as f. sp. *tritici*, which causes powdery mildew on wheat. It therefore seems reasonable from an agronomic perspective to assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on rye from the robust dataset proposed for the closely related crop winter wheat. Furthermore, existing authorisations for prothioconazole products have the same dose rate for this pathogen in both winter wheat and in rye, which also indicates that performance is comparable between the pathogen/crop pairs.

The dataset presented in – **Winter wheat (TRZAW) / *Blumeria graminis* (ERYSGR)** – showed that CA3301 applied at 0.6-0.8 l/ha provided significant disease control in the two main assessment timing. Both dose rates were frequently better than the lower rate of 0.48 l/ha. Moreover, the level of disease control observed was medium to high depending on the disease pressure. Indeed, whereas differences were not always significant, a numerical trend appeared where CA3301 at 0.8 l/ha provided better efficacy than 0.6 l/ha dose in the most challenging conditions.

On rye, powdery mildew remains an occasional disease and depending on climatic conditions, will develop in a heterogeneous way in the crop. This explains the lack of data despite the trials implemented on rye. Finally, since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.8 l/ha generally gave adequate disease control, it is supposed that the same dose range will be acceptable to control powdery mildew on rye in the Mediterranean EPPO zone.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Blumeria graminis* on rye in the Mediterranean EPPO zone.

Min. Eff. Dose evaluation of CA3301 - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a single trial was conducted to assess the control of powdery mildew *Blumeria graminis* f. sp. *secalis* on rye by CA3301 but it was not valid due to lack of disease infestation. However, the species *Blumeria graminis* f. sp. *secalis* is very comparable to other *Blumeria graminis* species as f. sp. *tritici*, which causes powdery mildew on wheat. It therefore seems reasonable from an agronomic perspective to assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on rye from the robust dataset proposed for the closely related crop winter wheat. Furthermore, existing authorisations for prothioconazole products have the same dose rate for this pathogen in both winter wheat and in rye, which also indicates that performance is comparable between the pathogen/crop pairs.

The dataset presented in – **Winter wheat (TRZAW) / *Blumeria graminis* (ERYSGR)** – showed that CA3301 applied at 0.6-0.8 l/ha provided significant disease control in the two main assessment timing. Both dose rates were frequently better than the lower rate of 0.48 l/ha. Moreover, the level of disease control observed was medium to high depending on the disease pressure. Indeed, whereas differences were not always significant, a numerical trend appeared where CA3301 at 0.8 l/ha provided better efficacy than 0.6 l/ha dose in the most challenging conditions.

On rye, powdery mildew remains an occasional disease and depending on climatic conditions, will develop in a heterogeneous way in the crop. This explains the lack of data despite the several trials implemented on rye. Finally, since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.8 l/ha generally gave adequate disease control, it is supposed that the same dose range will be acceptable to control powdery mildew on rye in North-Eastern East EPPO zone.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Blumeria graminis* on rye in the North-Eastern East EPPO zone.

Min. Eff. Dose evaluation of CA3301 - South-Eastern EPPO zone

In the South-Eastern East EPPO zone, no trial was conducted to assess the control of powdery mildew *Blumeria graminis* f. sp. *secalis* on rye by CA3301 due to lack of disease infestation. However, the species *Blumeria graminis* f. sp. *secalis* is very comparable to other *Blumeria graminis* species as f. sp. *tritici*, which causes powdery mildew on wheat. It therefore seems reasonable from an agronomic perspective to assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on rye from the robust dataset proposed for the closely related crop winter wheat. Furthermore, existing authorisations for prothioconazole products (e.g. in Hungary) have the same dose rate for this pathogen in both winter wheat and in rye, which also indicates that performance is comparable between the pathogen/crop pairs

The dataset presented in – **Winter wheat (TRZAW) / *Blumeria graminis* (ERYSGR)** – showed that CA3301 applied at 0.6-0.8 l/ha provided significant disease control in the two main assessment timings. Both dose rates were frequently better than the lower rate of 0.48 l/ha. Moreover, the level of disease control observed was medium to high depending on the disease pressure. Indeed, whereas differences

were not always significant, a numerical trend appeared where C3301 at 0.8 l/ha provided better efficacy than 0.6 l/ha dose in the most challenging conditions.

On rye, powdery mildew remains an occasional disease and depending on climatic conditions, will develop in a heterogeneous way in the crop. This explains the lack of data despite the several trials implemented on rye. Finally, since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.8 l/ha generally gave adequate disease control, it is supposed that the same dose range will be acceptable to control powdery mildew on rye in South-Eastern EPPO zone.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Blumeria graminis* on rye in the South-Eastern East EPPO zone.

Comments of zRMS:

Only 1 trial has been submitted to determine minimum effective dose to control of ERYSGR in winter rye in the Maritime EPPO climatic zone. CA3301 at 0,48-0,8 l/ha achieved medium efficacy while the higher dose of 0,8 l/ha showed high level of control. No trials were available in the North-East and South-East EPPO zone. Due to the limited number of trials, the cMSs are kindly asked to consider MED for this use on the national level.

3.2.2.6 Rye (SECCW) / *Oculimacula acufiformis* (PSDCHA)

(Ramanauskiene *et al.*, Effects of fungicides on the occurrence of winter wheat eyespot caused by fungi *Oculimacula acufiformis* and *O. yallundae*, Crop protection, 2016)

No data were available for assessment of minimum effective dose of eyespot of cereals *Oculimacula acufiformis* on any crop. Although early symptoms can be confused with *Fusarium spp.*, the diseases are not related and therefore it is impossible to extrapolate from these data.

However, Ramanauskiene *et al.*, showed that 2, 3 and 4 years of prothioconazole treatments allowed to reduce the population of *O. acufiformis* assessed from 2009 to 2011 on winter wheat. This positive effect was observed as early as 10 days after treatment. This pathogen infecting both winter wheat and rye, it is therefore possible to transpose these results to rye.

Moreover, prothioconazole is one of the active substances the most used as fungicide in commercial practices (*Forecasting eyespot development and yield losses in winter wheat, HGCA, 2012*). Standard reference products containing prothioconazole, such as Proline 275 are registered to control eyespot on cereals, at the same application rates as for the other authorised pathogens, which indicates that prothioconazole controls eyespot at dose rates which are demonstrated to control the other major disease pathogens in cereals. Since the proposed dose rate for CA3301 (200-150 g/ha prothioconazole) is comparable to that of the authorised product Proline 275 (200 g/ha prothioconazole), and data shows equivalence of efficacy between these products in other pathogens, it is considered that the minimum effective dose rate for CA3301 to control eyespot will be the same as that demonstrated for other pathogens.

Finally, since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.8 l/ha generally gave significantly better disease control compared to the rate of 0.48 l/ha, it is supposed that the same dose range will be acceptable to control eyespot on rye.

Considering all elements presented above, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control *Oculimacula acufiformis* on rye in all EPPO zones.

Comments of zRMS:

No trials have been submitted to determine minimum effective dose to control of *Oculimacula acufiformis* on winter rye in any EPPO climatic zones. The cMSs are kindly asked to consider MED for this use on the national level.

3.2.2.7 Rye (SECCW) / Green leaf area

Min. Eff. Dose evaluation of CA3301 - Maritime EPPO zone

Green leaf area was recorded at 12-55 DA-B in 8 valid trials on rye after two applications of CA3301 at 0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N). In 8 trials, green leaf area was assessed on the entire plant.

Summary results are presented in Table 3.2-177.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rate for the increase of green leaf area on rye infected by foliar diseases, with some statistical differences

In the 8 trials assessing green leaf area on the whole plant, an augmentation of 99.28%, 72.42% and 56.69% was recorded with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check on rye.

Both dose rates induced a positive effect on green leaf area although differences were not always significant. However, a clear trend showed that mean green leaf area increases with increasing dose rates, in particular for 0.6-0.8 l/ha compared to 0.48 l/ha

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose to induce a strong positive effect on the green leaf area on rye infected by a range of diseases in the Maritime EPPO zone.

Table 3.2-177: Summary table – Minimum effective dose evaluation – Rye – Green leaf area - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA33 01	CA33 01	CA33 01	No of trials where CA3301			No of trials where CA3301		
Rate		0,48	0,6	0,8	at 0,6 l/ha is >, = or			at 0,8 l/ha is >, = or		
Rate unit		L/ha	L/ha	L/ha	<			<		
Appl. Code		AB	AB	AB	compared to			compared to		
% Green leaf area - 12-55 DA-B										
Number of values	8	8	8	8	UT C	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	0,00	17,50	21,25	35,00		0,48 l/ha	0,8 l/ha		0,48 l/ha	0,6 l/ha
Maximum value	53,75	58,75	66,25	70,00		1 >	0 >		2 >	1 >
Mean Green leaf area (%)	27,50	45,31	48,91	50,94	2 =	7 =	7 =	2 =	6 =	7 =
Mean %UTC	100,00%	156,6 9%	172,4 2%	199,2 8%	0 <	0 <	1 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Min. Eff. Dose evaluation of CA3301 - Mediterranean EPPO zone

Green leaf area was recorded at 16-45 DA-B in 3 valid trials on rye after two applications of CA3301 at 0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N). In all 3 trials, green leaf area was assessed on the whole plant.

Summary results are presented in Table 3.2-178.

In the 3 trials assessing green leaf area on the whole plant, an augmentation of 11.91%, 8.83% and 8.02% was recorded with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check on rye.

In this limited dataset, no differences were observed in 2 trials out of 3 in which green leaf area was assessed early (16-22 DA-B) possibly due to a warmer and dryer weather than average in the trials area. In the last trial, where GLA was assessed later (45 DA-B) a clear trend showed that CA3301 at 0.6 and 0.8 l/ha provided a statistically better increase in green leaf area compared to 0.48 l/ha dose rate.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on rye infected by a range of diseases in the Mediterranean EPPO zone.

Table 3.2-178: Summary table – Minimum effective dose evaluation – Rye – Green leaf area - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA33 01 0,48 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to			
Rate											
Rate unit											
Appl. Code											
% Green Leaf Area - 16-45 DA-B											
Number of values	3	3	3	3	UT C	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha	
Minimum value	49,50	55,00	50,00	52,50							
Maximum value	67,50	75,00	85,00	90,00	1 >	1 >	0 >	1 >	1 >	0 >	
Mean Green leaf area (%)	57,25	61,92	63,17	65,08	2 =	2 =	3 =	2 =	2 =	3 =	
Mean %UTC	100,00%	108,02 %	108,83 %	111,91 %	0 <	0 <	0 <	0 <	0 <	0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Min. Eff. Dose evaluation of CA3301 - North-Eastern East EPPO zone

Green leaf area was recorded at 23-44 DA-B in 7 valid trials on rye after two applications of CA3301 at 0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N). In all 7 trials, green leaf area was assessed on the whole plant.

Summary results are presented in Table 3.2-179.

Data demonstrated a better effect of 2 applications of CA3301 at 0.6-0.8 l/ha compared to lower dose rate for the augmentation of green leaf area on rye infected by foliar diseases, with some statistical differences.

In the 7 trials assessing green leaf area on the whole plant, an augmentation of 63.82%, 54.47% and 53.96% was recorded with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check on rye.

An overall numerical trend of increasing the green leaf area with increasing dose rates was observed in the whole dataset in particular for 0.6 and 0.8 l/ha compared to 0.48 l/ha.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.8 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on rye infected by a range of diseases in the North-Eastern East EPPO zone.

Table 3.2-179: Summary table – Minimum effective dose evaluation – Rye – Green leaf area – North-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA33 01	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to			
Rate		0,48	0,6	0,8							
Rate unit		L/ha	L/ha	L/ha							
Appl. Code		AB	AB	AB							
% Green leaf area - 23-44 DA-B											
Number of values	7	7	7	7	UT C	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha	
Minimum value	13,00	21,25	20,00	21,25		6>	0 >	0 >	5>	1 >	1 >
Maximum value	42,50	93,75	93,75	92,50		1 =	7 =	6 =	2 =	6 =	6 =
Mean Green leaf area (%)	31,93	48,04	49,07	50,79		0 <	0 <	1 <	0 <	0 <	0 <
Mean %UTC	100,00%	153,96 %	154,47 %	163,82 %							

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Min. Eff. Dose evaluation of CA3301 - South-Eastern East EPPO zone

Green leaf area was recorded at 14-38 DA-B in 4 valid trials on rye after two applications of CA3301 at 0.8 l/ha, 0.6 l/ha (N rates) and 0.48 l/ha (0.8N). In 4 trials, green leaf area was assessed on the whole plant.

Summary results are presented in Table 3.2-180.

Data demonstrated a positive effect of 2 applications of CA3301 for the increase of green leaf area on rye infected by foliar diseases.

In the 4 trials assessing green leaf area on the whole plant, an augmentation of 67.92%, 55.64% and 67.19% was recorded with CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha compared to the untreated check on rye.

In these 4 trials, no significant differences were observed between the 3 tested dose rates of CA3301 moreover, although the increase was not always significant both dose rates induced numerical positive effects on green leaf area.

Considering all elements presented above, 2 applications of CA3301 induces a positive effect on the green leaf area on rye infected by a range of diseases in the South-Eastern East EPPO zone.

Table 3.2-180: Summary table – Minimum effective dose evaluation – Rye – Green leaf area – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA33 01	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		0,48	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Green leaf area - 14-38 DA-B										
Number of values	4	4	4	4	UT C	CA33 01 0,48 l/ha	CA33 01 0,8 l/ha	UT C	CA33 01 0,48 l/ha	CA33 01 0,6 l/ha
Minimum value	21,25	49,50	41,50	53,75						
Maximum value	62,50	80,00	80,00	80,00	1 >	0 >	0 >	1 >	0 >	0 >
Mean Green leaf area (%)	44,69	66,75	63,50	65,31	3 =	4 =	4 =	3 =	4 =	4 =
Mean %UTC	100,00%	167,19 %	155,64 %	167,92 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Comments of zRMS:

Very positive effect after application of CA3301 at dose rate of 0,6-0,8 l/ha were observed. An augmentation of green leaf area was visible on high level in all EPPO climatic zones. It can be concluded that CA3301 at 0,6 l/ha is justified as minimum effective dose in winter rye.

3.2.2.8 Rye (SECCW) / Conclusion - Minimum effective dose tests

On rye, 4 foliar diseases were assessed in 23 trials across 4 EPPO zones. Disease severity was assessed and analysed on the main foliar levels 1 and 2. Although a comprehensive trials programme was undertaken for this dossier, in some instances, due to the absence of appropriate level of diseases or other agronomic or climatic limitations, the proposed number of valid trials was not fully achieved. Hence, depending on the EPPO zone, the disease, the assessment timing and the crop part assessed, the dataset available was sometimes limited and so not fully representative of the efficacy of CA3301. Therefore, to get an overview of the efficacy of CA3301 at 0.6-0.8 l/ha, summary tables are presented in “**3.2.3.8 Rye (SECCW) / Conclusion – Efficacy tests**”, on foliar levels 1&2 (see Table 3.2-592, Table 3.2-593).

Overall, across the 4 EPPO zones and all diseases, a consistent dose rate trend was observed for higher disease control with higher dose rates. In particular, the rates of 0.6-0.8 l/ha generally gave significantly better control compared to the rate of 0.48 l/ha. In much of the dataset there was no statistical differences between the dose rates of 0.6 l/ha or 0.8 l/ha, however it was frequently observed that where disease severity was higher, a significant benefit was derived from increasing the dose rate from 0.6 to 0.8 l/ha while in circumstances of low disease pressure, the 0.6 l/ha dose rate was sufficient to give comparable disease control. Due to the importance of the diseases and given the possibility of resistance in some of the pathogens assessed, the higher rate may be deemed more appropriate and should be available for users according to disease development conditions, historical control and cultivar tolerance to the pathogens.

In addition, the data demonstrates overall similar effects for the targeted diseases regardless of EPPO zone. Similarly, the same dose rate trends were observed for improving green leaf area in situations of infection from a single pathogen or in cases of disease complexes. Green leaf area not only indicates the area free of infection but also the ability of the plant to continue effective growth and develop to productive stages, enabling a longer duration of grain filling and therefore improved yield quantity and quality.

In this dossier data presented for minimum effective dose is primarily from assessments where 2 applications of the test product were made. However, according to disease development conditions, a single application may provide sufficient disease control, therefore users should not be restricted to always applying twice, hence in the GAP the proposed use is for 1-2 applications. In addition, crop pathogens are commonly controlled using a programme of different fungicides with varied modes of action, therefore the choice should be available to growers to make a single application of CA3301, followed by application of a different appropriate fungicide. Prothioconazole is well established over a number of years in providing good broad spectrum efficacy across a range of common crop pathogens, with either 1 or more applications appropriate according to disease development conditions, risk of resistance development and local conditions. Current authorisations for similar products containing prothioconazole including Proline 275 and Proline/Praktis/Joao (CA2445) are for 1-2 applications at comparative rates of prothioconazole to the requested use for CA3301. Considering these elements, and that data in the efficacy section shows comparability of CA3301 to these authorised products, registration of CA3301 at the proposed minimum effective dose rate and with a number of applications of 1- 2, is requested.

Therefore, a minimum effective dose rate of 0.6-0.8 l/ha is proposed for CA3301 on rye in each of the EPPO zones, in order to provide optimum efficacy in relation to disease occurrence.

Considering all elements presented in the previous sections of each disease, CA3301 at 0.6-0.8 l/ha is the minimum effective dose to control a range of foliar diseases on Rye.

3.2.2.9 Oilseed rape (BRSNW) / *Sclerotinia sclerotiorum* (SCLESC)

Between 2017 and 2020, a total of 69 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the minimum effective dose of CA3301 against *Sclerotinia sclerotiorum* on oilseed rape. The trials were carried out by certified testing institutes. The proposed dose rate is 0.6-0.7 l/ha.

In the Maritime EPPO zone, 24 trials were performed in Czech Republic (11), Germany (9), France (3) and Denmark (1).

In the Mediterranean EPPO zone, 5 trials were performed in France (2) and Spain (3).

In the North-Eastern East EPPO zone, 28 trials were performed in Poland (20), Lithuania (3) and Latvia (5).

In the South-Eastern East EPPO zone, a total of 12 trials were performed in Hungary (6), Romania (4) and Slovakia (2).

Out of the 69 trials carried out against *Sclerotinia sclerotiorum* (SCLESC) on oilseed rape, 47 were considered valid.

Min. Eff. Dose evaluation of CA3301 with one application in autumn and one application in spring - Maritime EPPO zone

In the Maritime EPPO zone, 24 trials were available against *Sclerotinia sclerotiorum* on oilseed rape. Among these trials, 19 valid trials had a level of disease severity higher than 5% on leaves, stem, pods or roots and were included to support the evaluation of CA3301. Several dose rates (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). Among the 19 valid trials, CA3301 was applied once in autumn and then once in spring in 7 trials, first at crop stages BBCH 14-19 and the 2nd application was at BBCH 65-67. A single assessment timing was available close to harvest and the analysis was conducted on stem.

Summary results are presented in Table 3.2-181.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect against *Sclerotinia sclerotiorum* was provided after two applications of CA3301 at 0.6-0.7 l/ha. On stems, when applied at 0.6 l/ha, CA3301 showed 73.79% of efficacy to control the disease before harvest and 79.54% when applied at 0.7 l/ha.

These positive effects to control the disease of CA3301 at 0.6-0.7 l/ha were overall superior than the 0.5 l/ha dose rate tested.

In all 7 trials presented in this section, disease developed late after both applications of the tested product. Indeed infection by *Sclerotinia sclerotiorum* mainly occurred at flowering stage of the crop. Therefore, the data demonstrated the later preventive effect of CA3301 to control *Sclerotinia sclerotiorum* on stems. In trials with relatively high disease pressure a statistically benefit was observed in increasing the dose rate from 0.6 l/ha to 0.7 l/ha. Whereas in trials with lower disease pressure, the levels of control between these 2 dose rates were more comparable. Therefore, it is envisaged that in situations of low to medium disease pressure, CA3301 applied at 0.6 l/ha would be sufficient to control disease, but in case of heavy infestation 0.7 l/ha is more appropriate.

Considering all elements presented above, CA3301 at 0.6-0.7 l/ha with one application in autumn and one application in spring, is the minimum effective dose to control *Sclerotinia sclerotiorum* on oilseed rape in the Maritime EPPO zone.

Table 3.2-181: Summary table – Minimum effective dose evaluation – Oil seed rape – SCLESC - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA33 01	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to		
Rate		0,5	0,6	0,7						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Disease severity STEM - 44-84 DA-B										
Number of values	7	7	7	7	UT	CA33 01	CA33 01	UT	CA33 01	CA33 01
Minimum value	6,37	0,25	0,63	0,44	C	0,5 l/ha	0,7 l/ha	C	0,5 l/ha	0,6 l/ha
Maximum value	34,00	22,06	22,25	14,13	7 >	1 >	0 >	7 >	3 >	0 >
Mean disease severity (%)	22,59	8,18	7,10	5,31	0 =	6 =	7 =	0 =	4 =	7 =
Abbott efficacy (%)	0,00%	69,60 %	73,79 %	79,54 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 with 2 applications in spring – Maritime EPPO zone

In the Maritime EPPO zone, 24 trials were available against *Sclerotinia sclerotiorum* on oilseed rape. Among these trials, 19 valid trials had a level of disease severity higher than 5% on leaves, stem, pods or roots and were included to support the evaluation of CA3301. Several dose rates (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). Among these 19 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis. Among the 19 valid trials, CA3301 was applied twice in spring in 12 trials, first at crop stages BBCH stage 34-55 and the 2nd application was at BBCH 63-65. A single assessment timing was available for each part rated and the analysis was conducted on leaves and on stem.

Summary results are presented in Table 3.2-182.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect on cottony rot was provided after two applications of CA3301 at 0.6-0.7 l/ha. On leaves, when applied at 0.6 l/ha, CA3301 showed 60.32% of efficacy to control the disease at 22-42 DA-B and 64.72% at 0.7 l/ha.

On stem, when applied at 0.6 l/ha, CA3301 showed 76.49% of efficacy to control the disease before harvest and 81.20% when applied at 0.7 l/ha.

These positive effects to control the disease of CA3301 at 0.6-0.7 l/ha were overall superior than the 0.5 l/ha dose rate tested. Applied at the proposed rates of 0.6-0.7 l/ha CA3301 gave medium to high efficacy whereas at the rate of 0.5 l/ha efficacy was low to medium.

Generally an overall trend of decreasing disease severity with increasing dose rates was observed in the datasets, although differences were not always significant. The trend is more apparent in the assessments on stem where the dataset is larger. In many instances the rate of 0.6 l/ha gave acceptable control of *Sclerotinia sclerotiorum* very comparable to that of 0.7 l/ha, nevertheless in conditions of high disease pressure the additional disease reduction obtained from the higher rate of 0.7 l/ha may be more appropriate.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.7 l/ha is the minimum

effective dose to control *Sclerotinia sclerotiorum* on oilseed rape in the Maritime EPPO zone.

Table 3.2-182: Summary table – Minimum effective dose evaluation – Oilseed rape – SCLESC - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to		
Rate		0,5	0,6	0,7						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Disease severity LEAF - 22-42 DA-B										
Number of values	5	5	5	5	UT C	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	7,68	2,30	1,73	1,88		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	18,00	11,00	9,20	7,63	5 >	2 >	0 >	5 >	2 >	0 >
Mean disease severity (%)	11,22	6,40	4,71	4,15	0 =	3 =	5 =	0 =	3 =	5 =
Abbott efficacy (%)	0,00%	44,56%	60,32%	64,72%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity STEM 36-77 DA-B										
Number of values	12	12	12	12	UT C	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	6,25	0,25	0,13	0,00		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	53,13	19,81	15,88	12,25	12 >	6 >	0 >	12 >	7 >	2 >
Mean disease severity (%)	18,52	6,68	4,44	3,56	0 =	6 =	10 =	0 =	5 =	10 =
Abbott efficacy (%)	0,00%	64,82%	76,49%	81,20%	0 <	0 <	2 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)
(conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 with 2 applications in spring – Mediterranean EPPO zone

In the Mediterranean EPPO zone, 5 trials were available against *Sclerotinia sclerotiorum* on oilseed rape. 2 trials out of 5 had a level of disease severity higher than 5% on leaves, stems, pods or roots and were included to support the minimum effective dose evaluation of CA3301. In all 2 trials, CA3301 was applied twice in spring and no data were available in the case where CA3301 was applied once in autumn and once in spring. CA3301 was applied first at crop stages BBCH 53-55 and the 2nd application was at BBCH 65. Two main assessment timings were selected: around two weeks after application B (20 DA-B) and the last timing close to harvest (41-50 DA-B), and the analysis was conducted on leaves, stems and on pods.

Summary results are presented in Table 3.2-183.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect to control *Sclerotinia sclerotiorum* was provided after two applications of CA3301 at 0.6-0.7 l/ha. On leaves, when applied at 0.6 l/ha, CA3301 showed 69.70% of efficacy to control the disease severity two weeks after the 2nd application and 61.43% before harvest. Moreover at this dose rate, the product showed 85.86% of efficacy on stems and 51.38% of efficacy on pods before harvest.

When applied at 0.7 l/ha, on leaves, CA3301 showed 78.84% of efficacy to control *S. sclerotiorum* two weeks after the 2nd application and 54.13% before harvest. Moreover at this dose rate, the product showed 93.00% of efficacy on stems and 61.28% of efficacy on pods before harvest.

These positive effects of CA3301 at 0.6-0.7 l/ha to control *Sclerotinia sclerotiorum* were overall superior than the 0.5 l/ha dose rate tested, particularly on pods where the reduced rate gave only 25% efficacy

In the Mediterranean EPPO zone, a limited dataset, mainly due to the lower presence of the crop compared to the other EPPO zones, was available for assessment of control of *Sclerotinia sclerotiorum*. Overall a general trend was observed for reduced disease severity when increasing dose rate from 0.5 l/ha to 0.6 or 0.7 l/ha. In most instances, the rates of 0.6 l/ha gave control of *Sclerotinia sclerotiorum* very comparable to that of 0.7 l/ha, nevertheless in conditions of high disease pressure the additional disease reduction obtained from the higher rate of 0.7 l/ha may be more appropriate.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.7 l/ha is the minimum effective dose to control *Sclerotinia sclerotiorum* on oilseed rape in the Mediterranean EPPO zone.

Table 3.2-183: Summary table – Minimum effective dose evaluation – Oilseed rape – SCLESC - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA3301 0,5 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to		
Rate										
Rate unit										
Appl. Code										
% Disease severity LEAF - 20 DA-B										
Number of values	2	2	2	2	UT	CA33 01	CA3 301	UT	CA33 01	CA33 01
Minimum value	6,36	1,37	1,43	0,8	C	0,5 l/ha	0,7 l/ha	C	0,5 l/ha	0,6 l/ha
Maximum value	6,69	2,36	2,55	1,99	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	6,52	1,87	1,99	1,40	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	71,59%	69,70%	78,84%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity LEAF - 41-50 DA-B										
Number of values	2	2	2	2	UT	CA33 01	CA3 301	UT	CA33 01	CA33 01
Minimum value	18,38	8,76	7,46	10,08	C	0,5 l/ha	0,7 l/ha	C	0,5 l/ha	0,6 l/ha
Maximum value	38,00	12,01	13,89	14,02	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	28,19	10,39	10,68	12,05	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	60,37%	61,43%	54,13%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity STEM - 50 DA-B										
Number of values	1	1	1	1	UT	CA33 01	CA3 301	UT	CA33 01	CA33 01
Minimum value	14,00	2,28	1,98	0,98	C	0,5 l/ha	0,7 l/ha	C	0,5 l/ha	0,6 l/ha
Maximum value	14,00	2,28	1,98	0,98	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	14,00	2,28	1,98	0,98	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	83,71%	85,86%	93,00%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity POD - 41 DA-B										
Number of values	1	1	1	1	UT	CA33 01	CA3 301	UT	CA33 01	CA33 01
Minimum value	5,45	4,05	2,65	2,11	C	0,5 l/ha	0,7 l/ha	C	0,5 l/ha	0,6 l/ha
Maximum value	5,45	4,05	2,65	2,11	1 >	0 >	0 >	1 >	1 >	0 >
Mean disease severity (%)	5,45	4,05	2,65	2,11	0 =	1 =	1 =	0 =	0 =	1 =
Abbott efficacy (%)	0,00%	25,69%	51,38%	61,28%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)
(conversely for '<')

Levels of efficacy (% Abbott efficacy)	
>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

In the North-Eastern **East** EPPO zone, 28 trials were available against *Sclerotinia sclerotiorum* on oilseed rape. 16 trials out of 28 had a level of disease severity higher than 5% on leaves, stem, pods or roots and were included to support the minimum effective dose evaluation of CA3301. Several dose rates (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). Among these 16 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis. Among the 16 valid trials, CA3301 was applied once in autumn and then once in spring in 9 trials, first at crop BBCH stage 15-20 and the 2nd application was at BBCH 63-69. Two main assessment timings were selected: around 2-4 weeks after application B (16-28 DA-B) and the last timing close to harvest (34-62 DA-B), and the analysis was conducted on stems and on roots.

Summary results are presented in Table 3.2-184.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect to control *Sclerotinia sclerotiorum* was provided after two applications of CA3301 at 0.6-0.7 l/ha. On stems, when applied at 0.6 l/ha, CA3301 showed 80.58% of efficacy to control the disease 2-4 weeks after the 2nd application and 64.95% before harvest. On roots, CA3301 at 0.6 l/ha showed 95.24% of efficacy on reduction of disease severity around 2-4 weeks after the 2nd application and 90.35% before harvest.

When applied at 0.7 l/ha, on stems, CA3301 showed 87.31% of efficacy 2-4 weeks after the 2nd application and 77.10% before harvest. On roots, CA3301 at 0.7 l/ha showed 95.24% of efficacy on reduction of disease severity around 2-4 weeks after the 2nd application and 90.35% before harvest.

These positive effects of CA3301 at 0.6-0.7 l/ha to the disease severity were overall superior than the 0.5 l/ha dose rate tested, as observed from the level of efficacy obtained for each dose rate.

At earlier assessment as well as on roots, a limited dataset was available for assessment of control of *S. sclerotiorum*. As disease progression occurred, and when the dataset increased the differences between the higher dose rates became more discernible. The data consistently shows that efficacy is increased for the 0.6 and 0.7 l/ha dose rates compared to 0.5 l/ha. For the severity on roots, there were no apparent differences in efficacy between the 0.6 and 0.7 l/ha rates. However, on stem, in particular where there was a larger dataset, a clear increase in efficacy was observed for the 0.7 l/ha dose rate compared to 0.6 l/ha. Therefore, although 0.6 l/ha generally gives acceptable control, in situations of high disease pressure it may be beneficial to increase the dose rate to 0.7 l/ha.

Considering all elements presented above, CA3301 applied once in autumn and once in spring, at 0.6-0.7 l/ha is the minimum effective dose to control *Sclerotinia sclerotiorum* on oilseed rape in the North-Eastern East EPPO zone.

Table 3.2-184: Summary table – Minimum effective dose evaluation – Oilseed rape – SCLESC – North-Eastern East EPPO zone

North East LAO zone						
Treatment name	UNTREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or <	No of trials where CA3301 at 0,7 l/ha is >, = or <
Rate		0,5	0,6	0,7		
Rate unit		L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	compared to	compared to
% Disease severity STEM - 16-28 DA-B						

Number of values	2	2	2	2	UT	CA33 01	CA33 01	UT	CA33 01	CA33 01
Minimum value	10,15	2,05	1,90	0,55	C	0,5 l/ha	0,7 l/ha	C	0,5 l/ha	0,6 l/ha
Maximum value	31,30	6,35	6,30	6,25	2 >	0 >	0 >	2 >	1 >	1 >
Mean disease severity (%)	20,73	4,20	4,10	3,40	0 =	2 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	79,76 %	80,58 %	87,31 %	0 <	0 <	1 <	0 <	0 <	0 <
Severity index - ROOT - 24 DA-B										
Number of values	1	1	1	1	UT	CA33 01	CA33 01	UT	CA33 01	CA33 01
Minimum value	15,75	2,25	0,75	0,75	C	0,5 l/ha	0,7 l/ha	C	0,5 l/ha	0,6 l/ha
Maximum value	15,75	2,25	0,75	0,75	1 >	0 >	0 >	1 >	0 >	0 >
Mean severity index	15,75	2,25	0,75	0,75	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	85,71 %	95,24 %	95,24 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity STEM - 34-62 DA-B										
Number of values	7	7	7	7	UT	CA33 01	CA33 01	UT	CA33 01	CA33 01
Minimum value	8,95	3,18	1,80	1,30	C	0,5 l/ha	0,7 l/ha	C	0,5 l/ha	0,6 l/ha
Maximum value	26,18	12,4	8,95	5,88	7 >	4 >	0 >	7 >	6 >	4 >
Mean disease severity (%)	16,42	7,70	5,34	3,32	0 =	3 =	3 =	0 =	1 =	3 =
Abbott efficacy (%)	0,00%	47,81 %	64,95 %	77,10 %	0 <	0 <	4 <	0 <	0 <	0 <
Severity index - ROOT - 38 DA-B										
Number of values	1	1	1	1	UT	CA33 01	CA33 01	UT	CA33 01	CA33 01
Minimum value	20,75	4,50	2,00	2,00	C	0,5 l/ha	0,7 l/ha	C	0,5 l/ha	0,6 l/ha
Maximum value	20,75	4,50	2,00	2,00	1 >	0 >	0 >	1 >	0 >	0 >
Mean severity index	20,75	4,50	2,00	2,00	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	78,29 %	90,35 %	90,35 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)
(conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 with 2 applications in spring – North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, 28 trials were available against *Sclerotinia sclerotiorum* on oilseed rape. 16 trials out of 28 had a level of disease severity higher than 5% on leaves, stem, pods or roots and were included to support the minimum effective dose evaluation of CA3301. Several dose rates (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). Among these 16 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis. Among the 16 valid trials, CA3301 was applied twice in spring in 7 trials, first at crop stages BBCH stage 33-55 and the 2nd application was at BBCH 65-69. Two main assessment timings were selected: around three weeks after application B (21 DA-B) and the last timing close to harvest (33-56DA-B), and the analysis was conducted on stems and on pods.

Summary results are presented in Table 3.2-185.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect to control *Sclerotinia sclerotiorum* was provided after two applications of CA3301 at 0.6-0.7 l/ha. On stems, when applied at 0.6 l/ha, CA3301 showed 83.73% of efficacy to control the disease 3 weeks after the 2nd application and 79.55% before harvest. On pods, CA3301 at 0.6 l/ha showed 92.99% of efficacy on reduction of disease severity before harvest.

When applied at 0.7 l/ha, on stems, CA3301 showed 88.21% of efficacy to control *S. sclerotiorum* 3 weeks after the 2nd application and 85.17% before harvest. On pods, CA3301 at 0.7 l/ha showed 92.61% of efficacy on reduction of disease severity before harvest.

These positive effects of CA3301 at 0.6-0.7 l/ha to the disease severity were overall superior than the 0.5 l/ha dose rate tested.

At earlier assessment as well as on pods, a limited dataset was available for assessment of control of *S. sclerotiorum*. However, in both cases, the situations are representative of an earliest disease infection (shortly after flowering period) or strong disease infection (visible on pods) and allows us to show the behaviour of CA3301 in these specific infection situations. As disease progression occurred, and when the dataset increased the differences between the higher dose rates became more discernible. An overall trend can be observed from the whole dataset whereby efficacy increases with higher dose rates, in particular for 0.6 & 0.7 l/ha compared to 0.5 l/ha. For the rates of 0.6 and 0.7 l/ha it was often observed in the trials that differences were not significant. Therefore, in case of low disease pressure the use of the 0.6 l/ha dose can be acceptable to control *S. sclerotiorum* but where disease pressure is high the increased efficacy derived from the 0.7 l/ha rate may be economically beneficial.

Considering all elements presented above, CA3301 applied twice in spring, at 0.6-0.7 l/ha is the minimum effective dose to control *Sclerotinia sclerotiorum* on oilseed rape in the North-Eastern East EPPO zone.

Table 3.2-185: Summary table – Minimum effective dose evaluation – Oilseed rape – SCLESC – North-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA330 1 0,5 L/ha AB	CA33 01 0,6 L/ha AB	CA3301 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to		
% Disease severity STEM - 21 DA-B										
Number of values	2	2	2	2	U T C	CA330 1 0,5 l/ha	CA33 01 0,7 l/ha	UT C	CA33 01 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	6,60	0,83	0,90	0,60	2 > 0 = 0 =<	0 >	0 >	2 >	1 >	1 >
Maximum value	7,83	1,75	1,48	1,05		2 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	7,21	1,29	1,19	0,83		0 <	1 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	82,54%	83,73 %	88,21%						
% Disease severity STEM - 33-56 DA-B										
Number of values	7	7	7	7	U T C	CA330 1 0,5 l/ha	CA33 01 0,7 l/ha	UT C	CA33 01 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	4,95	0,08	0,50	0,20	7 > 0 = 0 =<	1 >	0 >	7 >	2 >	0 >
Maximum value	23,08	9,95	6,90	5,40		6 =	7 =	0 =	5 =	7 =
Mean disease severity (%)	11,66	3,08	2,68	1,86		0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	74,80%	79,55 %	85,17%						
% Disease severity POD - 54 DA-B										
Number of values	1	1	1	1		CA330 1	CA33 01	UT C	CA33 01	CA33 01

Minimum value	7,85	1,48	0,55	0,58	U T C	0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	7,85	1,48	0,55	0,58	1 > 0 = 0 <	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	7,85	1,48	0,55	0,58		1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	81,15%	92,99 %	92,61%		0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)
(conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 with one application in autumn and one application in spring – South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, 12 trials were available against *Sclerotinia sclerotiorum* on oilseed rape. 10 trials out of 12 had a level of disease severity higher than 5% on leaves, stem, pods or on roots and were included to support the minimum effective dose evaluation of CA3301. Several dose rates (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). Among these 10 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis. Among the 10 trials, in 1 trial, CA3301 was first applied in autumn at crop BBCH stage 18 and once in spring at BBCH 65. One main assessment timing was available: close to harvest (47 DA-B), and the analysis was conducted on stems.

Summary results are presented in Table 3.2-186.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect to *Sclerotinia sclerotiorum* was provided after two applications of CA3301 at 0.6-0.7 l/ha.

On stems before harvest, CA3301 showed 91.60% of efficacy to control the disease when applied at 0.6 l/ha and 85.76% when applied at 0.7 l/ha.

In the South-Eastern East EPPO zone, a limited dataset was available for assessment of control of cottony rot when CA3301 was applied once in autumn and once in spring. A general trend was observed for reduced disease severity with increasing dose rates, but the differences between the three dose rates were not significant. However, these data are consistent with the data recorded in the case where CA3301 is applied twice in spring. Therefore, we can conclude that the highest fungicidal effect on *Sclerotinia sclerotiorum* was provided after two applications of CA3301 at 0.6-0.7 l/ha.

Considering all elements presented above, 2 applications of CA3301 (one in spring and one in autumn) at 0.6-0.7 l/ha is the minimum effective dose to control *Sclerotinia sclerotiorum* on oilseed rape in the South-Eastern East EPPO zone.

Table 3.2-186: Summary table – Minimum effective dose evaluation – Oilseed rape – SCLESC – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA3301 0,5 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,7 l/ha is >, = or < compared to
% Disease severity STEM - 47 DA-B						
Number of values	1	1	1	1	UTC CA330 1	CA3 301 CA3 301 CA3 301

Minimum value	33,35	5,80	2,80	4,75		0,5 l/ha	0,7 l/ha	U T C	0,5 l/ha	0,6 l/ha
Maximum value	33,35	5,80	2,80	4,75	1 >	0 >	0 >	1 > 0 =	0 >	0 >
Mean disease severity (%)	33,35	5,80	2,80	4,75	0 =	1 =	1 =	0	1 =	1 =
Abbott efficacy (%)	0,00%	82,61%	91,60%	85,76%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 with 2 applications in spring – South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, 12 trials were available against *Sclerotinia sclerotiorum* on oilseed rape. 10 trials out of 12 had a level of disease severity higher than 5% on leaves, stems, pods or on roots and were included to support the minimum effective dose evaluation of CA3301. Several dose rates (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). Among these 10 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis. Among the 10 valid trials, CA3301 was applied twice in spring in 9 trials, first at crop stages BBCH 51-55 and the 2nd application was at BBCH 65-69. Two main assessment timings were selected: around three weeks after application B (21 DA-B) and the last timing close to harvest (36-39 DA-B), and the analysis was conducted on leaves, stems, pods and roots.

Summary results are presented in Table 3.2-187.

When evaluating the reduction of disease severity on different part rated of oilseed rape, the data demonstrated that the highest fungicidal effect to control *Sclerotinia sclerotiorum* was provided after two applications of CA3301 at 0.6-0.7 l/ha.

When applied at 0.6 l/ha, CA3301 showed:

- On leaves: 82.87% of efficacy to control the disease 3 weeks after the 2nd application and 65.86% before harvest.
- On stem: 87.32% of efficacy 3 weeks after the 2nd application and 71.67% before harvest.
- On pods: 69.89% of efficacy on reduction of disease severity before harvest.
- On roots: 100% of efficacy before harvest.

When applied at 0.7 l/ha, CA3301 showed:

- On leaves: 87.96% of efficacy to control the disease 3 weeks after the 2nd application and 72.28% before harvest.
- On stem: 94.16% of efficacy 3 weeks after the 2nd application and 74.97% before harvest.
- On pods: 78.15% of efficacy on reduction of disease severity before harvest.
- On roots: 100% of efficacy before harvest.

These positive effects of CA3301 at 0.6-0.7 l/ha to the disease severity were overall superior than the 0.5 l/ha dose rate tested.

Apart from the assessment on roots, an overall trend of decreased disease severity when increasing dose rates above 0.5 l/ha was observed in the dataset, although differences were not always statistically significant. For disease on leaves and stems, the rates of 0.6 l/ha and 0.7 l/ha gave high to medium efficacy, whereas the rate of 0.5 l/ha only achieved low to medium efficacy. The trend is more apparent in the assessments with larger dataset. In many instances with a low-medium disease pressure, the rate of 0.6 l/ha gave acceptable control of *Sclerotinia sclerotiorum* very comparable to that of 0.7 l/ha. However, in situations of high disease pressure the numerical increase in efficacy of the 0.7 l/ha rate may be more appropriate.

Considering all elements presented above, CA3301 applied twice in spring, at 0.6-0.7 l/ha is the minimum effective dose to control *Sclerotinia sclerotiorum* on oilseed rape in the South-Eastern East EPPO zone.

Table 3.2-187: Summary table – Minimum effective dose evaluation – Oilseed rape – SCLESC – South-Eastern East EPPO zone

South-Eastern East LEAF Zone											
Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA3301 0,5 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to			
% Disease severity LEAF - 21 DA-B											
Number of values	3	3	3	3	UTC	CA3301 0,5 l/ha	CA3301 0,7 l/ha	UTC	CA3301 0,5 l/ha	CA3301 0,6 l/ha	
Minimum value	7,10	1,20	0,64	0,19							
Maximum value	19,36	5,25	4,11	3,47		3 >	0 >		0 >	3 >	1 >
Mean disease severity (%)	15,27	3,58	2,95	2,22		0 =	3 =		3 =	0 =	2 =
Abbott efficacy (%)	0,00%	77,90%	82,87%	87,96%	0 <	0 <	0 <	0 <	0 <	0 <	
% Disease severity STEM - 21 DA-B											
Number of values	3	3	3	3	UTC	CA3301 0,5 l/ha	CA3301 0,7 l/ha	UTC	CA3301 0,5 l/ha	CA3301 0,6 l/ha	
Minimum value	6,78	1,66	0,81	0,27							
Maximum value	12,87	2,74	1,41	0,62		3 >	1 >		0 >	3 >	2 >
Mean disease severity (%)	9,76	2,10	1,12	0,50		0 =	2 =		2 =	0 =	1 =
Abbott efficacy (%)	0,00%	78,17%	87,32%	94,16%	0 <	0 <	1 <	0 <	0 <	0 <	
% Disease severity LEAF - 36-69 DA-B											
Number of values	3	3	3	3	UTC	CA3301 0,5 l/ha	CA3301 0,7 l/ha	UTC	CA3301 0,5 l/ha	CA3301 0,6 l/ha	
Minimum value	13,26	5,37	5,53	4,75							
Maximum value	21,43	7,08	6,44	5,18		3 >	2 >		0 >	3 >	2 >
Mean disease severity (%)	18,70	6,36	5,99	4,96		0 =	1 =		3 =	0 =	1 =
Abbott efficacy (%)	0,00%	65,16%	65,86%	72,28%	0 <	0 <	0 <	0 <	0 <	0 <	
% Disease severity STEM - 38-57 DA-B											
Number of values	6	6	6	6	UTC	CA3301 0,5 l/ha	CA3301 0,7 l/ha	UTC	CA3301 0,5 l/ha	CA3301 0,6 l/ha	
Minimum value	5,55	2,30	1,40	0,70							
Maximum value	24,70	12,53	7,05	10,30		6 >	2 >		0 >	6 >	3 >
Mean disease severity (%)	14,12	6,96	3,85	4,17		0 =	4 =		4 =	0 =	3 =

Treatment name	UNTREATED CHECK	CA3301 0,5 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to		
Rate										
Rate unit										
Appl. Code										
Abbott efficacy (%)	0,00%	53,15%	71,6 7%	74,97 %	0 <	0 <	2 <	0 <	0 <	0 <
% Disease severity POD - 39-50 DA-B										
Number of values	5	5	5	5	UT C	CA3301 0,5 l/ha	CA3301 0,7 l/ha	UTC	CA3301 0,5 l/ha	CA3301 0,6 l/ha
Minimum value	5,33	0,21	0,15	0,09						
Maximum value	32,95	17,70	15,5 0	14,65	5 >	1 >	0 >	5 >	1 >	0 >
Mean disease severity (%)	14,52	6,58	6,41	5,13	0 =	4 =	5 =	0 =	4 =	5 =
Abbott efficacy (%)	0,00%	65,68%	69,8 9%	78,15 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity ROOT - 39 DA-B										
Number of values	2	2	2	2	UT C	CA3301 0,5 l/ha	CA3301 0,7 l/ha	UTC	CA3301 0,5 l/ha	CA3301 0,6 l/ha
Minimum value	5,07	0,00	0,00	0,00						
Maximum value	5,16	0,00	0,00	0,00	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	5,11	0,00	0,00	0,00	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	100,00%	100,00%	100,00%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)
(conversely for '<')

Levels of efficacy (% Abbott efficacy)	
>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

19 trials have been submitted to determine minimum effective dose in **the Maritime EPPO climatic zone**. 7 out of 19 trials were conducted with 2 application, in autumn and spring. CA3301 at 0,48-0,7 l/ha achieved medium efficacy before harvest. 2 application in spring were used in 12 trials. The dose rate of 0,48 l/ha was not effective in 5 trials while higher doses showed medium level of control. The significant better results were observed after application of 0,6-0,7 l/ha compare to lower dose rate in all trials based on the observations provided on stem.

16 trials were presented to determine MED in **the North-East EPPO zone**. 9 out of 16 trials were conducted with 2 application, autumn and spring. CA3301 at 0,6-0,7 l/ha achieved medium to high efficacy. The dose rate of 0,48 l/ha showed also good results, however very low effectiveness was noted in 7 out of 9 trials before harvest. 2 application in spring were used in 7 trials. The dose rate of 0,48-0,6 l/ha achieved medium to high efficacy, while the high level was observed at 0,7 l/ha. Taking into account all trials, the dose rate of 0,6-0,7 l/ha is sufficient to control of SCLESC in winter oilseed rape.

10 trials were available to determine MED in **the South-East EPPO zone**. 1 out of 10 trials was carried out with 2 application, autumn and spring. CA3301 at 0,48-0,7 l/ha achieved high efficacy before harvest. Due to the limited number of trials, the cMSs are kindly asked to consider MED for autumn/spring applications on the national level. 2 applications in spring were used in 9 trials. The test product at 0,6-0,7 l/ha showed medium to high level of control in all assessments. The dose rate of 0,48 l/ha was insufficient in 6 out of 9 trials before harvest. Moreover, 2 additional trials with spring applications from the Mediterranean zone have been submitted to support of product registration in other zones. The results were very varied, especially in assessments before harvest. CA3301 at 0,48-0,7 l/ha achieved medium level of control in both trials after second application (20 DA-B). The conclusions of these trials are not unequivocal.

Taking into account of all EPPO zones, the dose rate of 0,6 l/ha can be considered minimum effective dose to control of *Sclerotinia sclerotiorum* in winter oilseed rape. It should be noted that the dose rate of 0,6 l/ha can be considered MED mainly in situation of low disease pressure. In more challenging conditions, the dose rate of 0,7 l/ha will be more justified.

3.2.2.10 Oilseed rape (BRSNW) / *Alternaria brassicae* (ALTEBA)

Between 2017 and 2020, a total of 54 trials were conducted in several countries of the Maritime, Mediterranean, North-~~Eastern~~ East and South-~~Eastern~~ East EPPO zones to evaluate the minimum effective dose of CA3301 against *Alternaria brassicae* on oilseed rape. The trials were carried out by certified testing institutes. The proposed dose rate is 0.6-0.7 l/ha.

In the Maritime EPPO zone, 12 trials were performed in Czech Republic (2), Germany (4), France (3) and Denmark (1) and United Kingdom (2).

In the Mediterranean EPPO zone, 10 trials were performed in France (5), Italy (2) and Spain (3).

In the North-~~Eastern~~ East EPPO zone, 22 trials were performed in Poland (14), Lithuania (3) and Latvia (5).

In the South-~~Eastern~~ East EPPO zone, a total of 10 trials were performed in Hungary (4), Romania (4) and Slovakia (2).

Data groupings were also made specifically for Poland evaluation and trials involved (30) were performed in the North-~~Eastern~~ East EPPO zone (22), in Czech Republic (2), in Germany (4) and in Slovakia (2).

Out of the 54 trials carried out against *Alternaria brassicae* (ALTEBA) on oilseed rape, 30 were considered valid.

Min. Eff. Dose evaluation of CA3301 with one application in autumn and one application in spring – Maritime EPPO zone

In the Maritime EPPO zone, 12 trials were available against *Alternaria brassicae* on oilseed rape. Among these trials, 7 valid trials had a level of disease severity higher than 5% on leaves, stems or pods and were included to support the evaluation of CA3301. Several dose rates (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). Among the 7 valid trials, CA3301 was applied once in autumn and then once in spring in 1 trial, first at crop stage BBCH 19 and the 2nd application was at BBCH 67. A single assessment timing was available for each part rated and the analysis was conducted on leaves and on pods.

Summary results are presented in Table 3.2-188.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect against *Alternaria brassicae* was provided after two applications of CA3301 at 0.7 l/ha. When applied at 0.6 l/ha, CA3301 showed 64.99% of efficacy on leaves 4 weeks after the 2nd application and 63.04% on pods before harvest. At 0.7 l/ha, CA3301 showed 79.48% of efficacy on leaves 4 weeks after the 2nd application and 78.46% on pods before harvest.

In the Maritime EPPO zone, a limited dataset was available for assessment of control of *Alternaria brassicae* when CA3301 was applied once in autumn and once in spring. However, a larger dataset has been presented regarding to the case where CA3301 was applied twice in spring in the Maritime zone, which demonstrates that the efficacy of CA3301 at 0.6 l/ha was comparable to that of the dose rate of 0.7 l/ha. This dataset can be supportive for the case where the first application of the product is in autumn. Therefore, we can conclude that the highest fungicidal effect on *Alternaria brassicae* was provided after two applications of CA3301 at 0.6-0.7 l/ha.

Considering all elements presented above, CA3301 at 0.6-0.7 l/ha with one application in autumn and one application in spring, is the minimum effective dose to control *Alternaria brassicae* on oilseed rape in the Maritime EPPO zone.

Table 3.2-188: Summary table – Minimum effective dose evaluation – Oilseed rape – ALTEBA - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA33 01	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to		
Rate		0,5	0,6	0,7						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Disease severity LEAF - 28 DA-B										
Number of values	1	1	1	1	UT C	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	8,77	2,74	3,07	1,80		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	8,77	2,74	3,07	1,80	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	8,77	2,74	3,07	1,80	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	68,76 %	64,99 %	79,48 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity POD 56 DA-B										
Number of values	1	1	1	1	UT C	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	8,17	2,82	3,02	1,76		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	8,17	2,82	3,02	1,76	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	8,17	2,82	3,02	1,76	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	65,48 %	63,04 %	78,46 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 with 2 applications in spring – Maritime EPPO zone

In the Maritime EPPO zone, 12 trials were available against *Alternaria brassicae* on oilseed rape. Among these trials, 7 valid trials had a level of disease severity higher than 5% on leaves, stems or pods and were included to support the evaluation of CA3301. Several dose rates (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis. Among the 7 valid trials, CA3301 was applied twice in spring in 6 trials, first at crop stages BBCH stage 50-55 and the 2nd application was at BBCH 65. A single assessment timing was available for each part rated and the analysis was conducted on leaves, on stems and on pods.

Summary results are presented in Table 3.2-189.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect on *Alternaria brassicae* was provided after two applications of CA3301 at 0.6-0.7 l/ha. Before harvest, when applied at 0.6 l/ha, CA3301 showed 100% of efficacy to control the disease on total leaves, 44.83% on upper leaves, 28.26% on lower leaves, 74.56% on stem and 86.85% on pods.

At 0.7 l/ha, CA3301 showed 100% of efficacy to control the disease on total leaves, 44.75% on upper leaves, 30.39% on lower leaves, 76.45% on stem and 91.83% on pods.

These positive effects to control the disease of CA3301 at 0.6-0.7 l/ha were overall superior than the 0.5

Generally, an overall trend of decreasing disease severity with increasing dose rates was observed in the datasets, although differences were not always significant. The trend is more apparent in the assessments on stems and on pods where the dose response effect of CA3301 is more discernible and where a higher data package was present. The rate of 0.6 l/ha gave acceptable control of *Alternaria brassicae* very comparable to that of 0.7 l/ha, however under conditions of high disease pressure, particularly on pods where the risk of transmission to seeds is high, further disease reduction obtained from the higher rate of 0.7 l / ha may be greater appropriate.

Considering all elements presented above, 2 applications in spring of CA3301 at 0.6-0.7 l/ha is the minimum effective dose to control *Alternaria brassicae* on oilseed rape in the Maritime EPPO zone.

Treatment name	UNTREATED CHECK	CA33 01 0,5 L/ha AB	CA330 1 0,6 L/ha AB	CA33 01 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to		
% Disease severity LEAF - 76 DA-B										
Number of values	2	2	2	2	UT C	CA330 1 0,5 l/ha	CA330 1 0,7 l/ha	UT C	CA3 301 0,5 l/ha	CA3 301 0,6 l/ha
Minimum value	6,59	0,00	0,00	0,00	2 >	0 >	0 >	2 >	0 >	0 >
Maximum value	10,03	0,20	0,00	0,00	0 =	2 =	2 =	0 =	2 =	2 =
Mean disease severity (%)	8,31	0,10	0,00	0,00	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	98,48 %	100,00 %	100,0 0%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity LEAF UP - 72 DA-B										
Number of values	1	1	1	1	UTC	CA330 1 0,5 l/ha	CA33 01 0,7 l/ha	UT C	CA3 301 0,5 l/ha	CA3 301 0,6 l/ha
Minimum value	23,60	13,48	13,02	13,04	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	23,60	13,48	13,02	13,04	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	23,60	13,48	13,02	13,04	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	42,88 %	44,83 %	44,75 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity LEAF LOW - 72 DA-B										
Number of values	1	1	1	1	UTC	CA330 1 0,5 l/ha	CA33 01 0,7 l/ha	UT C	CA3 301 0,5 l/ha	CA3 301 0,6 l/ha
Minimum value	53,08	36,88	38,08	36,95	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	53,08	36,88	38,08	36,95	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	53,08	36,88	38,08	36,95	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	30,52 %	28,26 %	30,39 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity STEM - 73 DA-B										
Number of values	2	2	2	2	UTC	CA330 1 0,5 l/ha	CA33 01 0,7 l/ha	UT C	CA3 301 0,5 l/ha	CA3 301 0,6 l/ha
Minimum value	17,44	6,38	4,31	3,79	2 >	1 >	0 >	2 >	1 >	0 >
Maximum value	18,76	7,88	4,91	4,69	0 =	1 =	2 =	0 =	1 =	2 =
Mean disease severity (%)	18,10	7,13	4,61	4,24	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	60,71 %	74,56 %	76,45 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity POD 73-76 DA-B										

'>' means CA3301 is significantly more efficient than plants treated with (treatment)'
(conversely for '<')

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

In the Mediterranean EPPO zone, 10 trials were available against *Alternaria brassicae* on oilseed rape. Among these trials, 5 valid trials had a level of disease severity higher than 5% on leaves, stems or pods and were included to support the evaluation of CA3301. Several dose rates (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). In all these 5 trials, CA3301 was applied twice in spring, first at crop stages BBCH 51-55 and the 2nd application was at BBCH 65-69. In all 5 trials, CA3301 was applied twice in spring and no data were available in the case where CA3301 was applied once in autumn and once in spring.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect on *Alternaria brassicae* was provided after two applications of CA3301 at 0.6-0.7 l/ha. When applied at 0.6 l/ha, CA3301 showed 95.70% of efficacy to control the disease on total leaves around three weeks after the 2nd application and 73.91% of efficacy on leaves, 79.30% on stem and 70.70% on pods before harvest.

At 0.7 l/ha, CA3301 showed 94.15% of efficacy to control the disease on total leaves around three weeks after the 2nd application and 79.64% of efficacy on leaves, 81.99% on stem and 73.81% on pods before harvest.

In the Mediterranean EPPO zone, the dataset does not highlight significant differences between the 3 dose rates tested. However, a general trend was observed for reduced disease severity when increasing dose rate from 0.5 l/ha to 0.6 or 0.7 l/ha, particularly on pods (the most damaging organ for harvest purpose). The rate of 0.6 l/ha gave control of *Alternaria brassicae* very comparable to that of 0.7 l/ha, nevertheless in conditions of high pressure the additional disease reduction obtained from the higher rate of 0.7 l/ha may be more appropriate.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.7 l/ha is the minimum effective dose to control *Alternaria brassicae* on oilseed rape in the Mediterranean EPPO zone.

Mediterranean EPO zone						
Treatment name	UNTREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301	No of trials where CA3301
Rate		0,5	0,6	0,7	at 0,6 l/ha is >, = or <	at 0,7 l/ha is >, = or <
Rate unit		L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB		
% Disease severity LEAF - 19 DA-B						

Number of values	1	1	1	1	UTC	CA330 1 0,5 l/ha	CA3 301 0,7 l/ha	UT C	CA33 01 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	5,81	0,32	0,25	0,34						
Maximum value	5,81	0,32	0,25	0,34	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	5,81	0,32	0,25	0,34	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	94,49%	95,70%	94,15%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity LEAF - 39-49 DA-B										
Number of values	5	5	5	5	UTC	CA330 1 0,5 l/ha	CA3 301 0,7 l/ha	UT C	CA33 01 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	8,28	0,86	0,90	0,64						
Maximum value	62,70	18,47	22,43	11,97	5 >	0 >	0 >	5 >	0 >	0 >
Mean disease severity (%)	28,43	7,09	7,70	5,20	0 =	5 =	5 =	0 =	5 =	5 =
Abbott efficacy (%)	0,00%	73,25%	73,91%	79,64%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity STEM - 39-48 DA-B										
Number of values	2	2	2	2	UTC	CA330 1 0,5 l/ha	CA3 301 0,7 l/ha	UT C	CA33 01 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	5,91	1,07	0,78	1,18						
Maximum value	18,69	4,42	5,27	3,00	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	12,30	2,74	3,02	2,09	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	79,12%	79,30%	81,99%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity POD - 39-48 DA-B										
Number of values	3	3	3	3	UTC	CA330 1 0,5 l/ha	CA3 301 0,7 l/ha	UT C	CA33 01 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	7,42	2,77	2,27	1,62						
Maximum value	25,57	8,65	5,61	5,43	3 >	0 >	0 >	3 >	0 >	0 >
Mean disease severity (%)	13,82	5,33	3,62	3,35	0 =	3 =	3 =	0 =	3 =	3 =
Abbott efficacy (%)	0,00%	58,32%	70,70%	73,81%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (con-
versely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 with one application in autumn and one application in spring – North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, 22 trials were available against *Alternaria brassicae* on oilseed rape. Among these trials, 9 valid trials had a level of disease severity higher than 5% on leaves, stems or pods and were included to support the evaluation of CA3301. Several dose rates (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). Among the 9 valid trials, CA3301 was applied once in autumn and then once in spring in 2 trials, first at crop stage BBCH 15 and the 2nd application was at BBCH 67-69. For these 2 trials, data were available at a single assessment timing on pods.

Summary results are presented in Table 3.2-191.

When evaluating the reduction of disease severity, the data demonstrated the fungicidal effect against *Alternaria brassicae*, provided after two applications of CA3301 at 0.6-0.7 l/ha. When applied at 0.6 l/ha, CA3301 showed 74.02% of efficacy to control the disease on pods before harvest and 83.03% when applied at 0.7 l/ha.

In the North-~~Eastern~~ **East** EPPO zone, a limited dataset was available for assessment of control of *Alternaria brassicae* when CA330 was applied once in autumn and once in spring. These positive effects to control the disease of CA3301 at 0.6-0.7 l/ha were overall statistically equivalent to the 0.5 l/ha dose rate tested. Nevertheless, the dose rate of 0.7 l/ha provided high efficacy compared to the medium efficacy obtained from applications at the lower rates. Furthermore, these data are consistent with the data recorded in the case where CA3301 was applied twice in spring, in which the dataset was larger and an overall trend was observed whereby efficacy increases with higher dose rates. Therefore, we can conclude that the highest fungicidal effect on *Alternaria brassicae* was provided after two applications of CA3301 at 0.6-0.7 l/ha.

Considering all elements presented above, CA3301 at 0.6-0.7 l/ha with one application in autumn and one application in spring, is the minimum effective dose to control *Alternaria brassicae* on oilseed rape in the North-~~Eastern~~ **East EPPO zone.**

Table 3.2-191: Summary table – Minimum effective dose evaluation – Oilseed rape – ALTEBA – North-~~Eastern~~ **East EPPO zone**

Treatment name	UNTREATED CHECK	CA3301	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to		
Rate		0,5	0,6	0,7						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Disease severity POD - 38-50 DA-B										
Number of values	2	2	2	2	UT	CA3301	CA3301	UT	CA3301	CA3301
Minimum value	5,60	1,10	1,35	0,70	C	0,5 l/ha	0,7 l/ha	C	0,5 l/ha	0,6 l/ha
Maximum value	6,75	1,46	1,79	1,32	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	6,18	1,28	1,57	1,01	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	78,82%	74,02 %	83,03 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 with 2 applications in spring – North-~~Eastern~~ **East EPPO zone**

In the North-~~Eastern~~ **East** EPPO zone, 22 trials were available against *Alternaria brassicae* on oilseed rape. Among these trials, 9 valid trials had a level of disease severity higher than 5% on leaves, stems or pods and were included to support the evaluation of CA3301. Several dose rates (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). Among these 9 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis. Among the 9 valid trials, CA3301 was applied twice in spring in 7 trials, first at crop stages BBCH 33-55 and the 2nd application was at BBCH 65-67. The analysis was conducted on leaves, on stems and on pods. For one trial only, 2 assessments timings were available on leaves and for the other parts assessed (stems and pods), a single assessment timing was available.

Summary results are presented in Table 3.2-192.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal

effect on *Alternaria brassicae* was provided after two applications of CA3301 at 0.6-0.7 l/ha. On leaves, when applied at 0.6 l/ha, CA3301 showed 94.37% of efficacy to control the disease three weeks after the 2nd application and 73.47% before harvest. Moreover, at this dose rate CA3301 showed 82.68% of efficacy on stems and 80.33% on pods before harvest.

When applied at 0.7 l/ha, on leaves, CA3301 showed 97.42% of efficacy to control the disease three weeks after the 2nd application and 80.92% before harvest. Moreover, at this dose rate CA3301 showed 87.19% of efficacy on stems and 87.71% on pods before harvest.

Although differences were not statistically significant, a clear numerical dose rate effect on disease reduction was observed for CA3301 between the three dose rates and the positive effects to control the disease of CA3301 at 0.6-0.7 l/ha were overall superior than the 0.5 l/ha dose rate tested.

At earlier assessment, a limited dataset was available for assessment of control of *Alternaria brassicae*. However, the situation is representative of an earliest than usual disease infection and allows us to show the behaviour of CA3301 in these specific infection situation. As disease progression occurred, the disease pressure was low but reached to the pods. At the last assessment timing before harvest and when the dataset increased an overall trend can be observed from the whole dataset whereby efficacy increases with higher dose rates, in particular for 0.6 & 0.7 l/ha compared to 0.5 l/ha. Therefore, in case of low disease pressure the use of the 0.6 l/ha dose can be acceptable to control *Alternaria brassicae*, but where disease pressure is high the increased efficacy derived from the 0.7 l/ha rate may be economically beneficial.

Considering all elements presented above, 2 applications in spring of CA3301 at 0.6-0.7 l/ha is the minimum effective dose to control *Alternaria brassicae* on oilseed rape in the North-Eastern East EPPO zone.

Table 3.2-192: Summary table – Minimum effective dose evaluation – Oilseed rape – ALTEBA – North-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA33 01	CA33 01	CA33 01	No of trials where CA3301			No of trials where CA3301		
Rate		0,5	0,6	0,7	at 0,6 l/ha is >, = or			at 0,7 l/ha is >, = or		
Rate unit		L/ha	L/ha	L/ha	<			<		
Appl. Code		AB	AB	AB	compared to			compared to		
% Disease severity LEAF- 21 DA-B										
Number of values	1	1	1	1	UT C	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	14,73	0,9	0,83	0,38		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	14,73	0,9	0,83	0,38	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	14,73	0,9	0,83	0,38	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	93,89 %	94,37 %	97,42 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity LEAF - 36-50 DA-B										
Number of values	3	3	3	3	UT C	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	5,36	1,38	0,6	0,28		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	20,33	4,45	3,55	2,75	3 >	0 >	0 >	3 >	0 >	0 >
Mean disease severity (%)	11,08	3,06	1,75	1,16	0 =	3 =	3 =	0 =	3 =	3 =
Abbott efficacy (%)	0,00%	65,78 %	73,47 %	80,92 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity STEM - 48-54 DA-B										
Number of values	3	3	3	3	UT C	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	7,05	1,41	0,58	0,38		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	10,75	1,93	2,25	1,65	3 >	0 >	0 >	3 >	0 >	0 >
Mean disease severity (%)	8,8	1,69	1,57	1,17	0 =	3 =	3 =	0 =	3 =	3 =

Abbott efficacy (%)	0,00%	79,97 %	82,68 %	87,19 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity POD - 36-54 DA-B										
Number of values	3	3	3	3	UT C	CA33 01 0,5 l/ha	CA33 01 0,7 l/ha	UT C	CA33 01 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	5,2	1,23	0,8	0,3	3 >	0 >	0 >	3 >	0 >	0 >
Maximum value	21,25	1,85	2,06	1,53	0 =	3 =	3 =	0 =	3 =	3 =
Mean disease severity (%)	10,69	1,48	1,32	0,76	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	81,22 %	80,33 %	87,71 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 with one application in autumn and one application in spring – South-Eastern East

In the South-Eastern East EPPO zone, 10 trials were available against *Alternaria brassicae* on oilseed rape. Among these trials, 8 valid trials had a level of disease severity higher than 5% on leaves, stems or pods and were included to support the evaluation of CA3301. Several dose rates (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). Among the 8 valid trials, CA3301 was applied once in autumn and then once in spring in 2 trials, first at crop stage BBCH 16 and the 2nd application was at BBCH 65-67. For these 2 trials data were available at a single assessment timing on pods.

Summary results are presented in Table 3.2-193.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect against *Alternaria brassicae* was provided after two applications of CA3301 at 0.6-0.7 l/ha. When applied at 0.6 l/ha, CA3301 showed 78.62% of efficacy to control the disease on pods before harvest and 84.36% when applied at 0.7 l/ha.

In the South-Eastern East EPPO zone, a limited dataset was available for assessment of control of *Alternaria brassicae* at this application timing. The rate of 0.6 l/ha gave acceptable control of the disease fairly comparable to that of 0.7 l/ha. Nevertheless, the dose rate of 0.7 l/ha provided high efficacy compared to the medium efficacy obtained from applications at the lower rates. Furthermore, the data recorded when CA3301 was applied twice in spring, in which the dataset was larger showed an overall trend whereby efficacy increases with higher dose rates and which is consistent with the trend observed here. Therefore, in case of low disease pressure the use of the 0.6 l/ha dose can be acceptable to control *Alternaria brassicae*, but where disease pressure is high the increased efficacy derived from the 0.7 l/ha rate may be economically beneficial.

Considering all elements presented above, CA3301 at 0.6-0.7 l/ha with one application in autumn and one application in spring, is the minimum effective dose to control *Alternaria brassicae* on oilseed rape in the South-Eastern East EPPO zone.

Table 3.2-193: Summary table – Minimum effective dose evaluation – Oilseed rape – ALTEBA – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA330 1 0,5	CA330 1 0,6	CA330 1 0,7	No of trials where CA3301	No of trials where CA3301
Rate						

Rate unit		L/ha	L/ha	L/ha	at 0,6 l/ha is >, = or < compared to			at 0,7 l/ha is >, = or < compared to		
Appl. Code		AB	AB	AB						
% Disease severity POD - 37-54 DA-B										
Number of values	2	2	2	2	UT	CA330 1	CA330 1	UT	CA330 1	CA330 1
Minimum value	30,00	4,15	3,32	3,68	C	0,5 l/ha	0,7 l/ha	C	0,5 l/ha	0,6 l/ha
Maximum value	35,21	11,25	10,00	6,25	2 >	0 >	0 >	2 >	1 >	1 >
Mean disease severity (%)	32,61	7,70	6,66	4,97	0 =	2 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	75,36 %	78,62 %	84,36 %	0 <	0 <	1 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (con-
versely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 with 2 applications in spring – South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, 10 trials were available against *Alternaria brassicae* on oilseed rape. Among these trials, 8 valid trials had a level of disease severity higher than 5% on leaves, stems or pods and were included to support the evaluation of CA3301. Several dose rates (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). Among these 8 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis. Among the 8 valid trials, CA3301 was applied twice in spring in 6 trials, first at crop stages BBCH 35-55 and the 2nd application was at BBCH 65-67. The analysis was conducted on leaves, on stems and on pods. 2 assessment timings were available on leaves and stems, whereas a single assessment timing was available on pods.

Summary results are presented in Table 3.2-194.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect on *Alternaria brassicae* was provided after two applications of CA3301 at 0.6-0.7 l/ha. On leaves, when applied at 0.6 l/ha, CA3301 showed 85.86% of efficacy to control the disease 2-4 weeks after the 2nd application and 83.78% before harvest. On stem, CA3301 showed 94.41% of efficacy to control the disease at three weeks after the 2nd application and 80.48% before harvest. On pods, CA3301 showed 86.20% of efficacy on pods before harvest.

On leaves, CA3301 at 0.7 l/ha showed 90.47% of efficacy to control the disease 2-4 weeks after the 2nd application and 91.83% before harvest. On stem, the tested product showed 98.88% of efficacy to control the disease at three weeks after the 2nd application and 89.13% before harvest. On pods, CA3301 showed 87.19% of efficacy on pods before harvest.

These positive effects to control the disease of CA3301 at 0.6-0.7 l/ha were overall superior than the 0.5 l/ha dose rate tested, as high efficacy was provided from applications at the proposed dose rates.

Generally an overall trend of decreasing disease severity with increasing dose rates was observed in the datasets, although differences were not always significant. In many instances the rate of 0.6 l/ha gave acceptable control of *Alternaria brassicae* very comparable to that of 0.7 l/ha. In trials with relatively higher disease pressure a statistically benefit was observed in increasing the dose rate from 0.6 l/ha to 0.7 l/ha. Whereas in trials with lower disease pressure the levels of control between these 2 dose rates were more comparable. Therefore, in conditions of high disease pressure the additional disease reduction obtained from the higher rate of 0.7 l/ha may be more appropriate.

Considering all elements presented above, 2 applications in spring of CA3301 at 0.6-0.7 l/ha is the

minimum effective dose to control *Alternaria brassicae* on oilseed rape in the South-Eastern East EPPO zone.

Table 3.2-194: Summary table – Minimum effective dose evaluation – Oilseed rape – ALTEBA – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA3301 0,5 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to		
% Disease severity LEAF - 14-28 DA-B										
Number of values	4	4	4	4	UTC	CA330 1	CA33 01	UT	CA33 01	CA33 01
Minimum value	6,03	1,04	0,63	0,36		0,5 l/ha	0,7 l/ha	C	0,5 l/ha	0,6 l/ha
Maximum value	14,81	3,55	1,95	1,18	4 >	1 >	0 >	4 >	1 >	1 >
Mean disease severity (%)	9,83	2,71	1,26	0,75	0 =	3 =	3 =	0 =	3 =	3 =
Abbott efficacy (%)	0,00%	69,35%	85,86%	90,47%	0 <	0 <	1 <	0 <	0 <	0 <
% Disease severity STEM - 21 DA-B										
Number of values	1	1	1	1	UTC	CA330 1	CA33 01	UT	CA33 01	CA33 01
Minimum value	7,15	1,12	0,40	0,08		0,5 l/ha	0,7 l/ha	C	0,5 l/ha	0,6 l/ha
Maximum value	7,15	1,12	0,40	0,08	1 >	1 >	0 >	1 >	1 >	0 >
Mean disease severity (%)	7,15	1,12	0,40	0,08	0 =	0 =	1 =	0 =	0 =	1 =
Abbott efficacy (%)	0,00%	84,34%	94,41%	98,88%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity LEAF - 31-56 DA-B										
Number of values	5	5	5	5	UTC	CA330 1	CA33 01	UT	CA33 01	CA33 01
Minimum value	6,15	0,99	0,65	0,28		0,5 l/ha	0,7 l/ha	C	0,5 l/ha	0,6 l/ha
Maximum value	21,90	6,85	4,25	2,59	5 >	2 >	0 >	5 >	4 >	2 >
Mean disease severity (%)	13,15	3,62	2,30	1,21	0 =	3 =	3 =	0 =	1 =	3 =
Abbott efficacy (%)	0,00%	73,71%	83,78%	91,83%	0 <	0 <	2 <	0 <	0 <	0 <
% Disease severity STEM - 31-56 DA-B										
Number of values	3	3	3	3	UTC	CA330 1	CA33 01	UT	CA33 01	CA33 01
Minimum value	5,74	0,69	0,63	0,48		0,5 l/ha	0,7 l/ha	C	0,5 l/ha	0,6 l/ha
Maximum value	10,73	3,08	2,00	0,98	3 >	1 >	0 >	3 >	2 >	1 >
Mean disease severity (%)	7,64	2,16	1,47	0,81	0 =	2 =	2 =	0 =	1 =	2 =
Abbott efficacy (%)	0,00%	71,63%	80,48%	89,13%	0 <	0 <	1 <	0 <	0 <	0 <
% Disease severity POD - 37-56 DA-B										
Number of values	5	5	5	5	UTC	CA330 1	CA33 01	UT	CA33 01	CA33 01
Minimum value	5,84	0,08	0,00	0,00		0,5 l/ha	0,7 l/ha	C	0,5 l/ha	0,6 l/ha
Maximum value	32,00	5,70	6,26	12,79	5 >	1 >	0 >	5 >	1 >	1 >
Mean disease severity (%)	13,02	2,48	2,33	3,05	0 =	4 =	4 =	0 =	4 =	4 =
Abbott efficacy (%)	0,00%	81,30%	86,20%	87,19%	0 <	0 <	1 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (con-
versely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of Use of CA3301 with one application in autumn and one application in spring – Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, a total of 3 valid trials evaluated the minimum effective dose of CA3301 applied twice, first in autumn and secondly in spring, on oilseed rape against *Alternaria brassicae*. These trials enabled to compare the efficacy of several dose rates of CA3301 (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 (0.83N) l/ha applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 15-19 and the 2nd application was at BBCH 67-69. Two assessment timings were available and the analysis was conducted on leaves and on pods.

Summary results are presented in Table 3.2-195

When evaluating the reduction of disease severity, the data demonstrated the fungicidal effect against *Alternaria brassicae*, provided after two applications of CA3301 at 0.6-0.7 l/ha. When applied at 0.6 l/ha, CA3301 showed 64.99% of efficacy to control the disease on leaves four weeks after the 2nd application and 70.36% on pods before harvest.

CA3301 showed 79.48% of efficacy to control the disease on leaves four weeks after the 2nd application and 81.51% on pods before harvest.

In Poland and neighbouring countries, a limited dataset was available for assessment of control of *Alternaria brassicae* when CA3301 was applied once in autumn and once in spring. These positive effects to control the disease of CA3301 at 0.6-0.7 l/ha were overall statistically equivalent to the 0.5 l/ha dose rate tested. Nevertheless, the dose rate of 0.7 l/ha provided high efficacy compared to the medium efficacy obtained from applications at the lower rates, particularly on pods. Furthermore, these data are consistent with the data recorded in the case where CA3301 was applied twice in spring, in which the dataset was larger and an overall trend was observed whereby efficacy increases with higher dose rates. Moreover in this dataset, in most instances the rate of 0.6 l/ha gave acceptable control of *Alternaria brassicae* very comparable to that of 0.7 l/ha. Therefore, in case of low disease pressure the use of the 0.6 l/ha dose can be acceptable to control *Alternaria brassicae*, but where disease pressure is high the increased efficacy derived from the 0.7 l/ha rate may be economically beneficial.

Considering all elements presented above, CA3301 at 0.6-0.7 l/ha with one application in autumn and one application in spring, is the minimum effective dose to control *Alternaria brassicae* on oilseed rape in Poland.

Table 3.2-195: Summary table - Minimum effective dose evaluation – Oilseed rape – ALTEBA – Data relevant for Poland

Data Relevant for Podand										
Treatment name	UNTREATED CHECK	CA330 1	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to		
Rate		0,5	0,6	0,7						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Disease severity LEAF - 28 DA-B										
Number of values	1	1	1	1	UT C	CA330 1	CA330 1	UT C	CA330 1	CA330 01
Minimum value	8,77	2,74	3,07	1,80		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	8,77	2,74	3,07	1,80	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	8,77	2,74	3,07	1,80	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	68,76 %	64,99%	79,48%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity POD - 38-56 DA-B										
Number of values	3	3	3	3	UT C	CA330 1	CA330 1	UT C	CA330 1	CA330 01

Minimum value	5,6	1,1	1,35	0,70		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	8,17	2,82	3,02	1,76	3 >	0 >	0 >	3 >	0 >	0 >
Mean disease severity (%)	6,84	1,79	2,05	1,26	0 =	3 =	3 =	0 =	3 =	3 =
Abbott efficacy (%)	0,00%	74,37 %	70,36%	81,51, %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 with 2 applications in spring – Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, a total of 14 valid trials evaluated the efficacy of CA3301 applied twice in spring on oilseed rape against *Alternaria brassicae*. These trials enabled to compare the efficacy of several dose rates of CA3301 (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N) applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 33-55 and the 2nd application was at BBCH 65-67. 2 assessment timings were available and the analysis was conducted on leaves, on stem and on pods.

Summary results are presented in Table 3.2-196.

When evaluating the reduction of disease severity, the data demonstrated the fungicidal effect against *Alternaria brassicae*, provided after two applications of CA3301 at 0.6-0.7 l/ha. On leaves, when applied at 0.6 l/ha, CA3301 showed 86.29% of efficacy to control the disease 3-4 weeks after the 2nd application and 83.00% before harvest. Moreover, at this dose rate CA3301 showed 77.69% of efficacy on stems and 81.60% on pods before harvest.

When applied at 0.7 l/ha, on leaves, CA3301 showed 95.56% of efficacy to control the disease 3-4 weeks after the 2nd application and 89.16% before harvest. Moreover, at this dose rate CA3301 showed 83.21% of efficacy on stems and 89.34% on pods before harvest.

These positive effects to control the disease of CA3301 at 0.6-0.7 l/ha were overall superior than the 0.5 l/ha dose rate tested, with the proposed dose rates demonstrating overall high efficacy compared to medium efficacy from the lower dose rate.

In Poland and neighbouring countries, an overall trend of decreasing disease severity with increasing dose rates was observed in the datasets, although differences were not always significant. The trend is more apparent in the late assessments on leaves, stems and pods, when the disease infection is the most suitable for efficacy evaluation and where the dose response effect of CA3301 is more discernible. The rate of 0.6 l/ha gave acceptable control of *Alternaria brassicae* very comparable to that of 0.7 l/ha, however under conditions of high disease pressure further disease reduction obtained from the higher rate of 0.7 l/ha may be more appropriate.

Considering all elements presented above, 2 applications in spring of CA3301 at 0.6-0.7 l/ha is the minimum effective dose to control *Alternaria brassicae* on oilseed rape in Poland.

Table 3.2-196: Summary table - Minimum effective dose evaluation – Oilseed rape – ALTEBA – Data relevant for Poland

Treatment name		CA3301	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,7 l/ha is >, = or < compared to
Rate	UNTREATED	1	01	1		
Rate unit	CHECK	0,5	0,6	0,7		
Appl. Code		L/ha	L/ha	L/ha		
		AB	AB	AB		

% Disease severity LEAF - 21-28 DA-B										
Number of values	2	2	2	2	UT C	CA330 1 0,5 l/ha	CA330 1 0,7 l/ha	UT C	CA330 1 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	8,95	0,90	0,83	0,38						
Maximum value	14,73	3,55	1,95	1,10	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	11,84	2,23	1,39	0,74	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	77,11%	86,29 %	92,56 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity LEAF - 36-76 DA-B										
Number of values	7	7	7	7	UT C	CA330 1 0,5 l/ha	CA330 1 0,7 l/ha	UT C	CA330 1 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	5,36	0,00	0,00	0,00						
Maximum value	20,33	6,85	4,25	2,75	7 >	1 >	0 >	7 >	2 >	1 >
Mean disease severity (%)	11,03	2,78	1,56	0,89	0 =	6 =	6 =	0 =	5 =	6 =
Abbott efficacy (%)	0,00%	74,67%	83,00 %	89,16 %	0 <	0 <	1 <	0 <	0 <	0 <
% Disease severity STEM - 48-73 DA-B										
Number of values	6	6	6	6	UT C	CA330 1 0,5 l/ha	CA330 1 0,7 l/ha	UT C	CA330 1 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	6,45	1,41	0,58	0,38						
Maximum value	18,76	7,88	4,91	4,69	6 >	1 >	0 >	6 >	2 >	1 >
Mean disease severity (%)	11,51	3,73	2,66	2,16	0 =	5 =	5 =	0 =	4 =	5 =
Abbott efficacy (%)	0,00%	68,93%	77,69 %	83,21 %	0 <	0 <	1 <	0 <	0 <	0 <
% Disease severity POD - 36-76 DA-B										
Number of values	8	8	8	8	UT C	CA330 1 0,5 l/ha	CA330 1 0,7 l/ha	UT C	CA330 1 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	5,20	0,25	0,00	0,00						
Maximum value	39,78	20,03	15,43	9,65	8 >	2 >	0 >	8 >	4 >	1 >
Mean disease severity (%)	16,39	4,70	3,11	1,80	0 =	6 =	7 =	0 =	4 =	7 =
Abbott efficacy (%)	0,00%	74,28%	81,60 %	89,34 %	0 <	0 <	1 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (con-
versely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

7 trials have been submitted to determine minimum effective dose to control of ALTEBA in **the Maritime EPPO climatic zone**. Only 1 trial was provided with 2 application, in autumn and spring. CA3301 at 0,48-0,7 l/ha achieved medium efficacy. However, the results at 0,48 l/ha and 0,6 l/ha were comparable while the dose rate of 0,7 l/ha had slight higher effectiveness (near to 80%), either after second application and before harvest. Due to the limited number of trials, the cMSs are kindly asked to consider MED for this use on the national level. 2 spring applications were used in 6 out of 7 trials. The test product at 0,48-0,7 l/ha was effective on medium to high level before harvest. The visible differences were in 2 trials where observations were provided on stem. The reduce of dose rate to 0,48 l/ha caused lower efficacy about 14% with result of 60,71%.

9 trials were presented to determine MED in **the North-East EPPO zone**. 2 trials were provided with 2 applications, in autumn and spring. CA3301 at 0,48-0,6 l/ha achieved medium efficacy while the dose of 0,7 l/ha had high level of control. 1 additional trial showed similar trend of effectiveness. Also 2 spring applications were used in 7 out of 9 trials. The test product at 0,7 l/ha was effective on high level in all assessments. The lower

doses 0,48 l/ha and 0,6 l/ha achieved medium to high efficacy. The slight differences between dose rates were visible in 3 trials before harvest. The reduce of dose to 0,48 l/ha caused lower effectiveness about 8% with result of 65,78%. In additional trials from the neighbouring countries, the doses of 0,6 l/ha and 0,7 l/ha were comparable and achieved high level of control in most assessments.

8 trials were available to determine MED in **the South-East EPPO zone**. 2 trials were provided with 2 applications, autumn and spring. CA3301 at 0,48-0,6 l/ha achieved medium efficacy while the dose of 0,7 l/ha was effective on high level before harvest. Due to the limited number of trials, the cMSs are kindly asked to consider MED for this use on the national level. The test product was used in 2 spring applications in 6 trials. The dose rates of 0,6-0,7 l/ha achieved high level of control in all assessments. CA3301 at 0,48 l/ha showed medium to high efficacy and significant differences was visible in 4 out of 6 trials after second application. The reduce of dose to 0,48 l/ha caused lower effectiveness about 16% with result of 69,35%. Similar trend was observed in 5 additional trials from the Mediterranean zone. The test product at 0,48 l/ha was not effective in 3 trials while the higher doses achieved medium level of control.

Taking into account all EPPO zones, the dose rate of 0,6 l/ha can be considered minimum effective dose to control of *Alternaria brassicae* in winter oilseed rape. It should be noted that the dose rate of 0,6 l/ha can be considered MED mainly in situation of low disease pressure. In more challenging conditions, the dose rate of 0,7 l/ha will be more justified.

3.2.2.11 Oilseed rape (BRSNW) / *Plenodomus lingam* (LEPTMA)

Between 2018 and 2020, a total of 64 trials were conducted in several countries of the Maritime, Mediterranean, North-~~Eastern~~ East and South-~~Eastern~~ East EPPO zones to evaluate the minimum effective dose of CA3301 against *Plenodomus lingam* on oilseed rape. The trials were carried out by certified testing institutes. The proposed dose rate is 0.6-0.7 l/ha.

In the Maritime EPPO zone, 19 trials were performed in Czech Republic (8), Germany (5), France (3), Denmark (1) and United Kingdom (2).

In the Mediterranean EPPO zone, 4 trials were performed in France (4).

In the North-~~Eastern~~ East EPPO zone, 27 trials were performed in Poland (22), Lithuania (3) and Latvia (2).

In the South-~~Eastern~~ East EPPO zone, a total of 14 trials were performed in Hungary (10) and Romania (4).

Data groupings were also made specifically for Poland evaluation and trials involved (40) were performed Poland (22), Lithuania (3), Latvia (2), Czech Republic (8) and Germany (5).

Min. Eff. Dose evaluation of CA3301 with one application in autumn and one application in spring – Maritime EPPO zone

In the Maritime EPPO zone, 19 trials were available against *Plenodomus lingam* on oilseed rape. Among these trials, 11 valid trials had a level of disease severity higher than 5% on leaves, stems, pods or roots and were included to support the evaluation of CA3301. Several dose rates (0.7 l/ha, 0.6 l/ha (N rates), and 0.5 l/ha (0.83N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). Among these 11 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis. Among the 11 valid trials, CA3301 was applied once in autumn and once in spring in 8 trials, first at crop stages BBCH 14-19 and the 2nd application was at BBCH 65-67. A single assessment timing was available for each part rated and the analysis was conducted on leaves, on stems and on roots.

Summary results are presented in Table 3.2-197.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect on *Plenodomus lingam* was provided after two applications of CA3301 at 0.6-0.7 l/ha. When

applied at 0.6 l/ha, CA3301 showed 63.07% of efficacy to control the disease on leaves around 2-4 weeks after the 2nd application and 54.27% of efficacy on stems before harvest. Moreover, CA3301 allowed to reduce the severity index on roots from 3.20 to 2.22.

When applied at 0.7 l/ha, CA3301 showed 76.06% of efficacy to control the disease on leaves around 2-4 weeks after the 2nd application and 66.46% of efficacy on stem before harvest. Moreover, CA3301 allowed to reduce the severity index on roots from 3.20 to 2.13.

These positive effects to control the disease of CA3301 at 0.6-0.7 l/ha were overall superior than the 0.5 l/ha dose rate tested.


Generally, an overall trend of decreasing disease severity with increasing dose rates was observed in the datasets, although differences were not always significant. The trend is more apparent in the assessments on leaves and particularly on stems where the dataset is larger. In many instances the rate of 0.6 l/ha gave acceptable control of *Plenodomus lingam* very comparable to that of 0.7 l/ha. Nevertheless, in conditions of high disease pressure the additional disease reduction obtained from the higher rate of 0.7 l/ha may be more appropriate.

Considering all elements presented above, CA3301 at 0.6-0.7 l/ha with one application in autumn and one application in spring, is the minimum effective dose to control *Plenodomus lingam* on oilseed rape in the Maritime EPPO zone.

Table 3.2-197: Summary table – Minimum effective dose evaluation – Oilseed rape – LEPTMA - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA330 1	CA330 1	CA330 1	No of trials where CA3301			No of trials where CA3301		
Rate		0,5	0,6	0,7	at 0,6 l/ha is >, = or			at 0,7 l/ha is >, = or		
Rate unit		L/ha	L/ha	L/ha	<			<		
Appl. Code		AB	AB	AB	compared to			compared to		
% Disease severity LEAF- 18-28 DA-B										
Number of values	3	3	3	3	UT C	CA330 1	CA330 1	UT C	CA330 1	CA330 1
Minimum value	5,00	1,72	1,20	1,02		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	14,73	6,48	7,42	3,75	3 >	1 >	0 >	3 >	1 >	0 >
Mean disease severity (%)	11,06	4,68	4,51	2,75	0 =	2 =	3 =	0 =	2 =	3 =
Abbott efficacy (%)	0,00%	59,26 %	63,07%	76,06 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity STEM - 56-84 DA-B										
Number of values	6	6	6	6	UT C	CA330 1	CA330 1	UT C	CA330 1	CA330 1
Minimum value	17,52	6,25	8,69	4,99		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	63,25	38,63	30,75	24,13	6 >	2 >	0 >	6 >	2 >	1 >
Mean disease severity (%)	36,11	19,10	16,26	12,17	0 =	4 =	5 =	0 =	4 =	5 =
Abbott efficacy (%)	0,00%	50,48 %	54,27%	66,46 %	0 <	0 <	1 <	0 <	0 <	0 <
Severity index ROOT - 83 DA-B										
Number of values	1	1	1	1	UT C	CA330 1	CA330 1	UT C	CA330 1	CA330 1
Minimum value	3,20	2,20	2,22	2,13		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	3,20	2,20	2,22	2,13	1 >	0 >	0 >	1 >	0 >	0 >
Mean severity index (1-5)	3,20	2,20	2,22	2,13	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	-	-	-	-	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)
 >80% High efficacy

60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 – Mediterranean EPPO zone

In the Mediterranean EPPO zones, no trials were available against *Plenodomus lingam* on oilseed rape. However, other similar prothioconazole products such as Proline are authorised for use against *Plenodomus lingam* at the same dose rate of 0.7 l/ha, and since data across the various pathogens of oilseed rape has demonstrated comparability with this approved product it is anticipated that CA3301 applied at the proposed dose rates would also provide acceptable control of this pathogen. Furthermore, the data generated in the Maritime and South Eastern EPPO zones supports the minimum effective dose against *Plenodomus lingam*, and across the dataset on oilseed rape the efficacy against pathogens appears comparable regardless of the climatic zone.

Considering all elements presented above, CA3301 at 0.6-0.7 l/ha with two applications in spring or one application in autumn and one application in spring, is the minimum effective dose to control *Plenodomus lingam* on oilseed rape in the Mediterranean EPPO zone.

Min. Eff. Dose evaluation of CA3301 with 2 applications in spring – Maritime EPPO zone

In the Maritime EPPO zone, 19 trials were available against *Plenodomus lingam* on oilseed rape. Among these trials, 11 valid trials had a level of disease severity higher than 5% on leaves, stems, pods or roots and were included to support the evaluation of CA3301. Several dose rates (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). Among the 11 valid trials, CA3301 was applied twice in spring in 3 trials, first at crop stage BBCH 53-55 and the 2nd application was at BBCH 65-67. A single assessment timing was available for each part rated and the analysis was conducted on leaves and on stems.

Summary results are presented in Table 3.2-198.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect against *Plenodomus lingam* was provided after two applications of CA3301 at 0.6-0.7 l/ha. When applied at 0.6 l/ha, CA3301 showed 100,00% of efficacy to control the disease on leaves 39 days after the 2nd application and 55.58% on stems before harvest.

When applied at 0.7 l/ha, CA3301 showed 100% of efficacy to control the disease on leaves 39 days after the 2nd application and 59.49% on stems before harvest.

These positive effects to control the disease of CA3301 at 0.6-0.7 l/ha were overall superior than the 0.5 l/ha dose rate tested.

In the Maritime EPPO zone, a limited dataset was available at this application timing mainly due to the fact that fungicides are generally applied earlier to prevent the early infection of *Plenodomus lingam* in the young stages of oilseed rape plants. Overall a general trend was observed for reduced disease severity when increasing dose rate from 0.5 l/ha to 0.6 or 0.7 l/ha. In most instances, the rates of 0.6 l/ha gave control of *Plenodomus lingam* very comparable to that of 0.7 l/ha, nevertheless in conditions of high pressure the additional disease reduction obtained from the higher rate of 0.7 l/ha may be more appropriate. Furthermore, the data recorded when CA3301 was applied once in autumn and once in spring, in which the dataset was larger showed an overall trend whereby efficacy increases with higher dose rates and which is consistent with the trend observed here. Therefore, in case of low disease pressure the use of the 0.6 l/ha dose can be acceptable to control *Plenodomus lingam*, but where disease pressure is high the increased efficacy derived from the 0.7 l/ha rate may be economically beneficial.

Considering all elements presented above, CA3301 at 0.6-0.7 l/ha with two applications in spring, is the minimum effective dose to control *Plenodomus lingam* on oilseed rape in the Maritime EPPO zone.

Table 3.2-198: Summary table – Minimum effective dose evaluation – Oilseed rape – LEPTMA - Maritime EPPO zone

LEAF zone										
Treatment name	UNTREATED CHECK	CA3301 0,5 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to		
Rate	Rate unit	Appl. Code	% Disease severity LEAF - 39 DA-B							
Number of values	1	1	1	1	UTC	CA330 1	CA33 01	UT C	CA33 01	CA33 01
Minimum value	5,83	0,00	0,00	0,00		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	5,83	0,00	0,00	0,00	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	5,83	0,00	0,00	0,00	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	100,00%	100,00 %	100,00%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity STEM - 51-73 DA-B										
Number of values	2	2	2	2	UTC	CA330 1	CA33 01	UT C	CA33 01	CA33 01
Minimum value	11,00	7,56	4,75	3,19		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	24,70	10,95	11,28	12,85	2 >	1 >	0 >	2 >	1 >	0 >
Mean disease severity (%)	17,85	9,26	8,01	8,02	0 =	1 =	2 =	0 =	1 =	2 =
Abbott efficacy (%)	0,00%	43,47%	55,58%	59,49%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (con-
versely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 with one application in autumn and one application in spring – North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, 27 trials were available against *Plenodomus lingam* on oilseed rape. Among these trials, 7 valid trials had a level of disease severity higher than 5% on leaves, stems, pods or roots and were included to support the evaluation of CA3301. Several dose rates (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). Among these 7 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis. Among the 7 valid trials, CA3301 was applied once in autumn and once in spring in 4 trials, first at crop stages BBCH 15-17 and the 2nd application was at BBCH 63-69. Two assessment timings were available on leaves, whereas a single assessment timing was available for the other rated parts (stems, roots and pods).

Summary results are presented in Table 3.2-199.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect on *Plenodomus lingam* was provided after two applications of CA3301 at 0.6-0.7 l/ha. When applied at 0.6 l/ha, CA3301 showed 77.46% of efficacy to control the disease on leaves 4 weeks after the 2nd application and 74.59% 6 weeks after the 2nd application, 100% of efficacy on roots 5 weeks after the 2nd application, and 82.35% on stems and 85.03% on pods before harvest.

When applied at 0.7 l/ha, CA3301 showed 80.56% of efficacy to control the disease on leaves 4 weeks after the 2nd application and 82.70% 6 weeks after the 2nd application, a full disease control on roots 5 weeks after the 2nd application, and 93.68% on stems and 95.08% on pods before harvest.

These positive effects to control the disease of CA3301 at 0.6-0.7 l/ha were overall superior than the 0.5 l/ha dose rate tested.

Generally, an overall trend of decreasing disease severity with increasing dose rates was observed in the datasets for all plant parts rated, although differences were not significant. The rate of 0.6 l/ha gave acceptable control of *Plenodomus lingam* very comparable to that of 0.7 l/ha. Nevertheless, in conditions of high disease pressure the additional disease reduction obtained from the higher rate of 0.7 l/ha may be more appropriate.

Considering all elements presented above, CA3301 at 0.6-0.7 l/ha with one application in autumn and one application in spring, is the minimum effective dose to control *Plenodomus lingam* on oilseed rape in the North-Eastern East EPPO zone.

Table 3.2-199: Summary table – Minimum effective dose evaluation – Oilseed rape – LEPTMA – North-Eastern East EPPO zone

North-Eastern East EPPO zone										
Treatment name	UNTREATED CHECK	CA3301 0,5 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to		
Rate										
Rate unit										
Appl. Code										
% Disease severity LEAF- 28 DA-B										
Number of values	1	1	1	1	UTC	CA330 1	CA33 01	UT C	CA33 01	CA33 01
Minimum value	7,10	2,12	1,60	1,38		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	7,10	2,12	1,60	1,38	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	7,10	2,12	1,60	1,38	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	70,14%	77,46%	80,56%	0 <	0 <	0 <	0 <	0 <	0 <
Severity index ROOT - 35 DA-B										
Number of values	1	1	1	1	UTC	CA330 1	CA33 01	UT C	CA33 01	CA33 01
Minimum value	1,50	0,00	0,00	0,00		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	1,50	0,00	0,00	0,00	1 >	0 >	0 >	1 >	0 >	0 >
Mean Severity Index	1,50	0,00	0,00	0,00	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	-	-	-	-	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity LEAF - 42 DA-B										
Number of values	1	1	1	1	UTC	CA330 1	CA33 01	UT C	CA33 01	CA33 01
Minimum value	7,40	2,08	1,88	1,28		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	7,40	2,08	1,88	1,28	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	7,40	2,08	1,88	1,28	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	71,89%	74,59%	82,70%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity STEM - 50 DA-B										
Number of values	1	1	1	1	UTC	CA330 1	CA33 01	UT C	CA33 01	CA33 01
Minimum value	6,80	1,70	1,20	0,43		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	6,80	1,70	1,20	0,43	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	6,80	1,70	1,20	0,43	0 =	1 =	1 =	0 =	1 =	1 =

Abbott efficacy (%)	0,00%	75,00%	82,35%	93,68%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity POD - 50 DA-B										
Number of values	1	1	1	1	UTC	CA330 1 0,5 l/ha	CA33 01 0,7 l/ha	UT C	CA33 01 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	9,35	2,60	1,40	0,46						
Maximum value	9,35	2,60	1,40	0,46	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	9,35	2,60	1,40	0,46	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	72,19%	85,03%	95,08%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 with 2 applications in spring – North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, 27 trials were available against *Plenodomus lingam* on oilseed rape. Among these trials, 7 valid trials had a level of disease severity higher than 5% on leaves, stems, pods or roots and were included to support the evaluation of CA3301. Several dose rates (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). Among the 7 valid trials, CA3301 was applied twice in spring in 3 trials, first at crop stages BBCH 36-55 and the 2nd application was at BBCH 65-69. The analysis was conducted on leaves, stems and pods. Two assessment timings were available on leaves and stems, whereas a single assessment timing was available on pods.

Summary results are presented in Table 3.2-200.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect against *Plenodomus lingam* was provided after two applications of CA3301 at 0.6-0.7 l/ha. When applied at 0.6 l/ha, CA3301 showed 98.21% of efficacy to control the disease on leaves three weeks after the second application and 95.25% six weeks after the second application. Then the tested product showed 87.80% of efficacy on stems around three weeks after the 2nd application and 58.17% before harvest. Moreover, it showed 95.02% of efficacy to reduce the disease severity on pods around 6 weeks after the 2nd application.

CA3301 at 0.7 l/ha showed 98.81% of efficacy to control the disease on leaves three weeks after the second application and 98.38% six weeks after the second application. Then the tested product showed 93.22% of efficacy on stems around three weeks after the 2nd application and 79.83% before harvest. Moreover, it showed 97.84% of efficacy to reduce the disease severity on pods around 6 weeks after the 2nd application.

These positive effects to control the disease of CA3301 at 0.6-0.7 l/ha were superior to the one provided by the 0.5 l/ha dose rate in all the trials.

In the North-Eastern East EPPO zone, a limited dataset was available at this application timing mainly due to the fact that fungicides are generally applied earlier to prevent the early infection of *Plenodomus lingam* in the young stages of oilseed rape plants. Overall a general trend was observed for reduced disease severity when increasing dose rate from 0.5 l/ha to 0.6 or 0.7 l/ha. The rate of 0.6 l/ha gave control of *Plenodomus lingam* very comparable to that of 0.7 l/ha, nevertheless in conditions of high pressure the additional disease reduction obtained from the higher rate of 0.7 l/ha may be more appropriate, particularly on stems. Furthermore, the data recorded when CA3301 was applied once in autumn and once in spring, in which the dataset was larger showed an overall trend whereby efficacy increases with higher dose rates and which is consistent with the trend observed here. Therefore, in case of low

disease pressure the use of the 0.6 l/ha dose can be acceptable to control *Plenodomus lingam*, but where disease pressure is high the increased efficacy derived from the 0.7 l/ha rate may be economically beneficial.

Considering all elements presented above, CA3301 at 0.6-0.7 l/ha with two applications in spring, is the minimum effective dose to control *Plenodomus lingam* on oilseed rape in the North-Eastern East EPPO zone.

Table 3.2-200: Summary table – Minimum effective dose evaluation – Oilseed rape – LEPTMA – North-Eastern East EPPO zone

North - Subtropical East Africa zone										
Treatment name	UNTREATED CHECK	CA330 1	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to		
Rate		0,5	0,6	0,7						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Disease severity LEAF - 21 DA-B										
Number of values	1	1	1	1	UT C	CA330 1 0,5 l/ha	CA3 301 0,7 l/ha	UT C	CA33 01 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	8,40	0,40	0,15	0,10	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	8,40	0,40	0,15	0,10	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	8,40	0,40	0,15	0,10	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	95,24%	98,21 %	98,81 %						
% Disease severity STEM - 24 DA-B										
Number of values	1	1	1	1	UT C	CA330 1 0,5 l/ha	CA3 301 0,7 l/ha	UT C	CA33 01 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	8,85	1,83	1,08	0,60	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	8,85	1,83	1,08	0,60	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	8,85	1,83	1,08	0,60	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	79,32%	87,80 %	93,22 %						
% Disease severity LEAF - 36 DA-B										
Number of values	1	1	1	1	UT C	CA330 1 0,5 l/ha	CA3 301 0,7 l/ha	UT C	CA33 01 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	8,00	1,23	0,38	0,13	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	8,00	1,23	0,38	0,13	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	8,00	1,23	0,38	0,13	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	84,63%	95,25 %	98,38 %						
% Disease severity POD- 36 DA-B										
Number of values	1	1	1	1	UT C	CA330 1 0,5 l/ha	CA3 301 0,7 l/ha	UT C	CA33 01 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	10,65	0,98	0,53	0,23	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	10,65	0,98	0,53	0,23	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	10,65	0,98	0,53	0,23	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	90,80%	95,02 %	97,84 %						
% Disease severity STEM - 54 DA-B										
Number of values	1	1	1	1	UT C	CA330 1 0,5 l/ha	CA3 301 0,7 l/ha	UT C	CA33 01 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	9,42	4,50	3,94	1,90	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	9,42	4,50	3,94	1,90	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	9,42	4,50	3,94	1,90						

Abbott efficacy (%)	0,00%	52,23%	58,17 %	79,83 %	0 <	0 <	0 <	0 <	0 <	0 <
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'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 with one application in autumn and one application in spring – South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, 14 trials were available against *Plenodomus lingam* on oilseed rape. Among these trials, 12 valid trials had a level of disease severity higher than 5% on leaves, stems, pods or roots and were included to support the evaluation of CA3301. Several dose rates (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). Among these 12 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis. Among the 12 valid trials, CA3301 was applied once in autumn and once in spring in 9 trials, first at crop stages BBCH 14-18 and the 2nd application was at BBCH 65-67. The analysis was conducted on leaves, roots, stems and pods. Two assessment timings were available on leaves and stems, whereas a single assessment timing was available for the other rated parts (roots and pods).

Summary results are presented in Table 3.2-201.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect on *Plenodomus lingam* was provided after two applications of CA3301 at 0.6-0.7 l/ha. When applied at 0.6 l/ha, CA3301 showed 88.04% of efficacy to control the disease on leaves around 2 weeks after the 2nd application and 86.58% of efficacy before harvest. On stems, CA3301 at 0.6 l/ha provided 91.46% efficacy 2 weeks after the 2nd application and 60.11% before harvest. Finally the tested product provided 92.78% efficacy on pods before harvest and gave significant higher disease control on roots from 2.62 to 1.35.

When applied at 0.7 l/ha, CA3301 showed 90.48% of efficacy to control the disease on leaves around 2 weeks after the 2nd application and 92.28% of efficacy before harvest. On stems, CA3301 at 0.7 l/ha provided 95.44% efficacy 2 weeks after the 2nd application and 68.04% before harvest. Finally the tested product provided, 95.51% efficacy on pods before harvest and gave significant higher disease control on roots from 2.62 to 1.14.

These positive effects to control the disease of CA3301 at 0.6-0.7 l/ha were overall superior than the 0.5 l/ha dose rate tested.

Generally, an overall trend of decreasing disease severity with increasing dose rates was observed in the dataset, although differences were not always significant. The trend is more apparent in the assessments on stems and particularly close to harvest where the disease pressure is higher. In many instances the rate of 0.6 l/ha gave acceptable control of *Plenodomus lingam* very comparable to that of 0.7 l/ha. Nevertheless, in conditions of high disease pressure the additional disease reduction obtained from the higher rate of 0.7 l/ha may be more appropriate.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.7 l/ha is the minimum effective dose to control *Plenodomus lingam* on oilseed rape in the South-Eastern East EPPO zone.

Table 3.2-201: Summary table – Minimum effective dose evaluation – Oilseed rape – LEPTMA – South-East EPPO zone

Treatment name	UNTREATED CHECK	CA3301 0,5 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to		
Rate										
Rate unit										
Appl. Code										
% Disease severity LEAF- 15 DA-B										
Number of values	4	4	4	4	UT	CA33 01	CA33 01	UT	CA33 01	CA33 01
Minimum value	8,70	0,30	0,60	0,85	C	0,5 l/ha	0,7 l/ha	C	0,5 l/ha	0,6 l/ha
Maximum value	23,90	2,24	2,77	1,54	4 >	0 >	0 >	4 >	0 >	0 >
Mean disease severity (%)	14,36	1,64	1,76	1,26	0 =	4 =	4 =	0 =	4 =	4 =
Abbott efficacy (%)	0,00%	88,46%	88,04%	90,48%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity STEM - 15 DA-B										
Number of values	2	2	2	2	UT	CA33 01	CA33 01	UT	CA33 01	CA33 01
Minimum value	6,02	0,83	0,50	0,26	C	0,5 l/ha	0,7 l/ha	C	0,5 l/ha	0,6 l/ha
Maximum value	6,29	0,84	0,55	0,30	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	6,16	0,84	0,53	0,28	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	86,43%	91,46%	95,44%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity LEAF - 32-49 DA-B										
Number of values	2	2	2	2	UT	CA33 01	CA33 01	UT	CA33 01	CA33 01
Minimum value	5,62	1,38	0,83	0,61	C	0,5 l/ha	0,7 l/ha	C	0,5 l/ha	0,6 l/ha
Maximum value	42,00	2,68	5,07	1,93	2 >	1 >	0 >	2 >	1 >	0 >
Mean disease severity (%)	23,81	2,03	2,95	1,27	0 =	1 =	2 =	0 =	1 =	2 =
Abbott efficacy (%)	0,00%	84,53%	86,58%	92,28%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity STEM - 41-79 DA-B										
Number of values	6	6	6	6	UT	CA33 01	CA33 01	UT	CA33 01	CA33 01
Minimum value	7,46	1,39	1,00	0,62	C	0,5 l/ha	0,7 l/ha	C	0,5 l/ha	0,6 l/ha
Maximum value	76,40	54,15	43,10	33,60	6 >	2 >	0 >	6 >	5 >	1 >
Mean disease severity (%)	31,19	20,56	16,38	11,62	0 =	4 =	5 =	0 =	1 =	5 =
Abbott efficacy (%)	0,00%	51,28%	60,11%	68,04%	0 <	0 <	1 <	0 <	0 <	0 <
% Disease severity POD - 41 DA-B										
Number of values	2	2	2	2	UT	CA33 01	CA33 01	UT	CA33 01	CA33 01
Minimum value	6,20	0,49	0,37	0,25	C	0,5 l/ha	0,7 l/ha	C	0,5 l/ha	0,6 l/ha
Maximum value	6,29	0,66	0,53	0,31	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	6,25	0,58	0,45	0,28	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	90,78%	92,78%	95,51%	0 <	0 <	0 <	0 <	0 <	0 <
Severity index (1-5) ROOT- 41-62 DA-B										
Number of values	5	5	5	5	UT	CA33 01	CA33 01	UT	CA33 01	CA33 01
Minimum value	1,60	1,09	1,00	1,00	C	0,5 l/ha	0,7 l/ha	C	0,5 l/ha	0,6 l/ha
Maximum value	3,65	2,05	2,25	1,36	5 >	3 >	0 >	5 >	4 >	1 >
Mean severity index (1-5)	2,62	1,44	1,35	1,14	0 =	2 =	4 =	0 =	1 =	4 =
Abbott efficacy (%)	-	-	-	-	0 <	0 <	1 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)
(conversely for '<')

Treatment name	UNTREATED CHECK	CA3301 0,5 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,7 l/ha is >, = or < compared to
Rate						
Rate unit						
Appl. Code						
Levels of efficacy (% Abbott efficacy)						
>80%	High efficacy					
60-80%	Medium efficacy					
<60%	Low efficacy					

Min. Eff. Dose evaluation of CA3301 with 2 applications in spring – South-Eastern East EPPO zone

In the South-East EPPO zone, 14 trials were available against *Plenodomus lingam* on oilseed rape. Among these trials, 12 valid trials had a level of disease severity higher than 5% on leaves, stems, pods or roots and were included to support the evaluation of CA3301. Several dose rates (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). Among the 12 valid trials, CA3301 was applied twice in spring in 3 trials, first at crop stage BBCH 55 and the 2nd application was at BBCH 65-67. The analysis was conducted on leaves and stems. Two assessment timings were available on leaves, whereas a single assessment timing was available on stems.

Summary results are presented in Table 3.2-202.

When evaluating the reduction of disease severity, the data demonstrated positive fungicidal effects against *Plenodomus lingam* after two applications of CA3301 at 0.6-0.7 l/ha.

When applied at 0.6 l/ha, CA3301 showed 99.34% of efficacy to control the disease severity on leaves around 3 weeks after the 2nd application and 61.04% before harvest. On stems, CA3301 at 0.6 l/ha provided 70.93% efficacy before harvest.

When applied at 0.7 l/ha, CA3301 showed 98.80% of efficacy to control the disease severity on leaves around 3 weeks after the 2nd application and 68.92% before harvest. On stems, CA3301 at 0.6 l/ha provided 83.58% efficacy before harvest.

In the South-Eastern East EPPO zone, a limited dataset was available for assessment of control of *Plenodomus lingam* when CA3301 was applied twice in spring mainly due to the fact that fungicides are generally applied earlier to prevent the early infection of *Plenodomus lingam* in the young stages of oilseed rape plants. No clear trend was observed to support the minimum effective dose. However, a larger supportive dataset has been presented in the previous section which demonstrated that CA3301 at 0.6-0.7 l/ha provided better fungicidal effects than the 0.5 l/ha dose rate. Therefore, it can be considered that CA3301 at 0.6 l/ha will provided acceptable efficacy in low to medium disease pressure whereas the 0.7 l/ha dose rate will be useful in more challenging conditions.

Considering all elements presented above, CA3301 at 0.6-0.7 l/ha with two applications in spring, is the minimum effective dose to control *Plenodomus lingam* on oilseed rape in the South-Eastern East EPPO zone.

Table 3.2-202: Summary table – Minimum effective dose evaluation – Oilseed rape – LEPTMA – South-East EPPO zone

Treatment name	UNTREATED CHECK	CA3301 0,5 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,7 l/ha is >, = or < compared to
% Disease severity LEAF - 21 DA-B						
Number of values	1	1	1	1	UTC 1	CA33 01 UT C CA33 01 CA33 01

Minimum value	24,23	0,25	0,16	0,29		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	24,23	0,25	0,16	0,29	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	24,23	0,25	0,16	0,29	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	98,97%	99,34%	98,80%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity LEAF - 32-46 DA-B										
Number of values	2	2	2	2	UTC	CA330 1 0,5 l/ha	CA33 01 0,7 l/ha	UT C	CA33 01 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	28,40	1,84	1,30	1,33	2 >	0 >	0 >	2 >	1 >	1 >
Maximum value	36,95	20,23	21,13	16,63	0 =	2 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	32,68	11,03	11,21	8,98	0 <	0 <	1 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	61,89%	61,04%	68,92%	0 <	0 <	1 <	0 <	0 <	0 <
% Disease severity STEM - 55-56 DA-B										
Number of values	2	2	2	2	UTC	CA330 1 0,5 l/ha	CA33 01 0,7 l/ha	UT C	CA33 01 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	26,30	5,40	8,68	3,70	2 >	0 >	0 >	2 >	0 >	0 >
Maximum value	36,20	6,80	9,10	5,95	0 =	2 =	2 =	0 =	2 =	2 =
Mean disease severity (%)	31,25	6,10	8,89	4,83	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	80,34%	70,93%	83,58%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 with one application in autumn and one application in spring - Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia.

In this situation, 40 trials were available against *Plenodomus lingam* on oilseed rape. 14 trials out of 40 were considered valid. These trials enabled to compare the efficacy of several dose rates of CA3301 (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 (0.83N) l/ha applied twice) on disease severity (%). Among these 14 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis. In Poland and the neighbouring countries, among the 14 valid trials, CA3301 was applied once in autumn and once in spring in 8 trials, first at crop stages BBCH 14-19 and the 2nd application was at BBCH 63-69. 2 assessment timings were available and the analysis was conducted on leaves, on stems and on pods.

Summary results are presented in Table 3.2-203.

When evaluating the reduction of disease severity, the data demonstrated the fungicidal effect against *Plenodomus lingam*, provided after two applications of CA3301 at 0.6-0.7 l/ha. When applied at 0.6 l/ha, CA3301 showed 63.55% of efficacy to control the disease on leaves around four weeks after the 2nd application and 74.59% before harvest. CA3301 at 0.6 l/ha provided 61.60% efficacy on stems and 85.03% efficacy on pods before harvest.

When applied at 0.7 l/ha, CA3301 showed 76.39% of efficacy to control the disease on leaves around four weeks after the 2nd application and 82.70% before harvest. CA3301 at 0.7 l/ha provided 73.89% efficacy on stems and 95.08% efficacy on pods before harvest.

These positive effects to control the disease of CA3301 at 0.6-0.7 l/ha were overTable 3.2-203rall superior

than the 0.5 l/ha dose rate tested.

Over the whole dataset, a clear trend of decreasing disease severity with increasing dose rates was observed, although differences were not always significant. The trend is more apparent in the assessments on stems and pods, and particularly close to harvest where the disease pressure was higher. In many instances the rate of 0.6 l/ha gave acceptable control of *Plenodomus lingam* and most of the time statistically equivalent to that of 0.7 l/ha. Nevertheless, in conditions of high disease pressure, or with strong historical presence of the disease, the additional disease reduction obtained from the higher rate of 0.7 l/ha may be more appropriate.

Considering all elements presented above, CA3301 at 0.6-0.7 l/ha with one application in autumn and one application in spring, is the minimum effective dose to control *Plenodomus lingam* on oilseed rape in Poland.

Table 3.2-203: Summary table - Minimum effective dose evaluation – Oilseed rape – LEPTMA – Data relevant for Poland

Data Relevant for Poland										
Treatment name	UNTREATED CHECK	CA330 1	CA33 01	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or <			No of trials where CA3301 at 0,7 l/ha is >, = or <		
Rate		0,5	0,6	0,7						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
% Disease severity LEAF- 28 DA-B										
Number of values	3	3	3	3	UT C	CA330 1 0,5 l/ha	CA330 1 0,7 l/ha	UT C	CA330 1 0,5 l/ha	CA330 1 0,6 l/ha
Minimum value	7,10	2,12	1,60	1,38	3 > 0 =	1 > 2 =	0 > 3 =	3 > 0 =	1 > 2 =	0 > 3 =
Maximum value	14,73	6,48	7,42	3,75		0 <	0 <	0 <	0 <	0 <
Mean disease severity (%)	11,76	4,81	4,64	2,87						
Abbott efficacy (%)	0,00%	60,77%	63,55 %	76,39 %						
% Disease severity LEAF- 42 DA-B										
Number of values	1	1	1	1	UT C	CA330 1 0,5 l/ha	CA330 1 0,7 l/ha	UT C	CA330 1 0,5 l/ha	CA330 1 0,6 l/ha
Minimum value	7,40	2,08	1,88	1,28	1 > 0 =	0 > 1 =	0 > 1 =	1 > 0 =	0 > 1 =	0 > 1 =
Maximum value	7,40	2,08	1,88	1,28		0 <	0 <	0 <	0 <	0 <
Mean disease severity (%)	7,40	2,08	1,88	1,28						
Abbott efficacy (%)	0,00%	71,89%	74,59 %	82,70 %						
% Disease severity STEM - 50-84 DA-B										
Number of values	6	6	6	6	UT C	CA330 1 0,5 l/ha	CA330 1 0,7 l/ha	UT C	CA330 1 0,5 l/ha	CA330 1 0,6 l/ha
Minimum value	6,80	1,70	1,20	0,43	6 > 0 =	2 > 4 =	0 > 5 =	6 > 0 =	3 > 3 =	1 > 5 =
Maximum value	63,25	38,63	30,75	24,13		0 <	0 <	1 <	0 <	0 <
Mean disease severity (%)	34,32	17,82	14,66	10,75						
Abbott efficacy (%)	0,00%	55,28%	61,60 %	73,89 %						
% Disease severity POD - 50 DA-B										
Number of values	1	1	1	1	UT C	CA330 1 0,5 l/ha	CA330 1 0,7 l/ha	UT C	CA330 1 0,5 l/ha	CA330 1 0,6 l/ha
Minimum value	9,35	2,60	1,40	0,46	1 > 0 =	0 > 1 =	0 > 1 =	1 > 0 =	0 > 1 =	0 > 1 =
Maximum value	9,35	2,60	1,40	0,46		0 <	0 <	0 <	0 <	0 <
Mean disease severity (%)	9,35	2,60	1,40	0,46						
Abbott efficacy (%)	0,00%	72,19%	85,03 %	95,08 %						

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)	
>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 with 2 applications in spring – Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, 40 trials were available against *Plenodomus lingam* on oilseed rape. 14 trials out of 40 were considered valid. These trials enabled to compare the efficacy of several dose rates of CA3301 (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 (0.83N) l/ha applied twice) on disease severity (%). Among these 14 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis.

In Poland and the neighbouring countries, among the 14 valid trials, CA3301 was applied twice spring in 6 trials, first at crop stages BBCH 14-19 and the 2nd application was at BBCH 63-69. 2 assessment timings were available and the analysis was conducted on leaves, on stems and on pods.

Summary results are presented in Table 3.2-204.

When evaluating the reduction of disease severity, the data demonstrated the fungicidal effect against *Plenodomus lingam*, provided after two applications of CA3301 at 0.6-0.7 l/ha. When applied at 0.6 l/ha, CA3301 showed 87.80% of efficacy to control the disease on leaves around three weeks after the 2nd application and 97.63% before harvest. CA3301 at 0.6 l/ha provided 56.44% efficacy on stems and 95.02% efficacy on pods before harvest.

When applied at 0.7 l/ha, CA3301 showed 93.22% of efficacy to control the disease on leaves around three weeks after the 2nd application and 99.19% before harvest. CA3301 at 0.7 l/ha provided 66.27% efficacy on stems and 97.84% efficacy on pods before harvest.

In Poland and neighbouring countries, an overall trend of decreasing disease severity with increasing dose rates was observed in the datasets, although differences were not always significant. This trend appeared markedly in each assessments on leaves, stems and pods. Furthermore, these data are consistent with the data recorded in the case where CA3301 was applied on in autumn and once in spring, in which the dataset was larger and an overall trend was observed whereby efficacy increases with higher dose rates. The rate of 0.6 l/ha gave acceptable control of *Plenodomus lingam* very comparable to that of 0.7 l/ha, however under conditions of high disease pressure further disease reduction obtained from the higher rate of 0.7 l/ha may be greater appropriate.

Considering all elements presented above, 2 applications in spring of CA3301 at 0.6-0.7 l/ha is the minimum effective dose to control *Plenodomus lingam* on oilseed rape in Poland.

Table 3.2-204: Summary table - Minimum effective dose evaluation – Oilseed rape – LEPTMA – Data relevant for Poland

Treatment name	UNTREATED CHECK	CA3301 1 0,5 L/ha AB	CA3301 1 0,6 L/ha AB	CA3301 1 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,7 l/ha is >, = or < compared to
% Disease severity STEM - 24 DA-B						
Number of values	1	1	1	1	UT C	CA3301 1 0,5 l/ha
Minimum value	8,85	1,83	1,08	0,60	1 >	0 >
Maximum value	8,85	1,83	1,08	0,60	0 >	0 >

Mean disease severity (%)	8,85	1,83	1,08	0,60	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	79,32 %	87,80 %	93,22 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity LEAF - 36-39 DA-B										
Number of values	2	2	2	2	UT	CA330 1	CA330 1	UT	CA330 1	CA330 1
Minimum value	5,83	0,00	0,00	0,00	C	0,5 l/ha	0,7 l/ha	C	0,5 l/ha	0,6 l/ha
Maximum value	8,00	1,23	0,38	0,13	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	6,91	0,61	0,19	0,06	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	92,31 %	97,63 %	99,19 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity STEM - 51-73 DA-B										
Number of values	3	3	3	3	UT	CA330 1	CA330 1	UT	CA330 1	CA330 1
Minimum value	9,42	4,50	3,94	1,90	C	0,5 l/ha	0,7 l/ha	C	0,5 l/ha	0,6 l/ha
Maximum value	24,70	10,95	11,28	12,85	3 >	1 >	0 >	3 >	1 >	0 >
Mean disease severity (%)	15,04	7,67	6,66	5,98	0 =	2 =	3 =	0 =	2 =	3 =
Abbott efficacy (%)	0,00%	46,39 %	56,44 %	66,27 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity POD- 36 DA-B										
Number of values	1	1	1	1	UT	CA330 1	CA330 1	UT	CA330 1	CA330 1
Minimum value	10,65	0,98	0,53	0,23	C	0,5 l/ha	0,7 l/ha	C	0,5 l/ha	0,6 l/ha
Maximum value	10,65	0,98	0,53	0,23	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	10,65	0,98	0,53	0,23	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	90,80 %	95,02 %	97,84 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

11 trials have been submitted to determine minimum effective dose in **the Maritime EPPO climatic zone**. 8 out of 11 trials were conducted with 2 application, in autumn and spring. CA3301 applied at dose rate of 0,7 l/ha achieved medium efficacy while lower dose of 0,6 l/ha had low to medium level of control. The dose rate of 0,48 l/ha was insufficient in all assessments, either after second application and before harvest. Also results from 3 trials with 2 spring applications were presented. CA3301 at 0,48-0,7 l/ha achieved very low efficacy in 2 trials and full effectiveness in 1 trial. Due to the limited number of trials and varied results, the cMSs are kindly asked to consider MED for this use on the national level.

7 trials were available to determine MED in **the North-East EPPO zone**. 4 out of 7 trials were provided with using of 2 application, in autumn and spring. CA3301 at 0,7 l/ha achieved high efficacy while lower dose of 0,6 l/ha showed medium to high level of control. The dose rate of 0,48 l/ha was effective on medium level in all assessments. The results from 3 trials with 2 spring applications presented high efficacy of dose rate of 0,7 l/ha. The test product at 0,48-0,6 l/ha achieved low efficacy in 1 trial before harvest while the highest dose had medium level. However, the trials from the neighbouring countries confirmed sufficient efficacy of dose rate of 0,6-0,7 l/ha in control of LEPTMA in both schema of application.

12 trials were presented to determine MED in **the South-East EPPO zone**. 9 out of 12 trials were provided with using of 2 application, in autumn and spring. CA3301 at 0,48-0,7 l/ha achieved high efficacy in part of trials. The lower results were noted in 6 trials before harvest on stem. The dose rate of 0,6-0,7 l/ha showed medium level of control while the dose of 0,48 l/ha was insufficient. Only 3 trials were conducted with 2 spring applications. The test product at 0,48-0,7 l/ha achieved medium to high level of control with varied results on stem

before harvest (55-56 DA-B). No additional trials from the Mediterranean zone have been submitted to support of product registration in other zones. Due to the limited number of trials, the cMSs are kindly asked to consider MED for this use on the national level.

Taking into account all EPPO zones, the dose rate of 0,6 l/ha can be considered minimum effective dose to control of *Plenodomus lingam* in winter oilseed rape. It should be noted that the dose rate of 0,6 l/ha can be considered MED mainly in situation of low disease pressure. In more challenging conditions, the dose rate of 0,7 l/ha will be more justified.

3.2.2.12 Oilseed rape (BRSNW) / *Erysiphe cruciferarum* (ERYSCR)

Between 2019 and 2020, a total of 31 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the minimum effective dose of CA3301 against *Erysiphe cruciferarum* on oilseed rape. The trials were carried out by certified testing institutes. The proposed dose rate is 0.6-0.7 l/ha.

In the Maritime EPPO zone, 2 trials were performed in Czech Republic (1) and France (1).

In the Mediterranean EPPO zone, 11 trials were performed in France (8), Spain (2) and Italy (1).

In the North-Eastern East EPPO zone, 3 trials were performed in Lithuania (3).

In the South-Eastern East EPPO zone, a total of 15 trials were performed in Hungary (7), Slovakia (3) and Romania (5).

Data groupings were also made specifically for Poland evaluation and trials involved (7) were performed Lithuania (2), Latvia (1), Czech Republic (1) and Slovakia (3).

Min. Eff. Dose evaluation of CA3301 with one application in autumn and one application in spring – Maritime EPPO zone

In the Maritime EPPO zone, 2 trials were available against *Erysiphe cruciferarum* on oilseed rape. Among these trials, 2 valid trials had a level of disease severity higher than 5% and were included to support the evaluation of CA3301. Several dose rates (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). Among these 2 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis. Among the 2 valid trials, CA3301 was applied once in autumn and once in spring in 1 trial, first at crop stages BBCH 19 and the 2nd application was at BBCH 67. A single assessment timing was available and the analysis was conducted on leaves.

Summary results are presented in Table 3.2-205.

When evaluating the reduction of disease severity, the data demonstrated a positive fungicidal effect of CA3301 at 0.6-0.7 l/ha against *Erysiphe cruciferarum*. When applied at 0.6 l/ha, CA3301 showed 33.71% of efficacy to control the disease on leaves around 6 weeks after the 2nd application and 28.31% at 0.7 l/ha.

In the Maritime EPPO zone, a limited dataset was available for assessment of control of *Erysiphe cruciferarum*. In this trial application timing was targeted for a different disease, hence the first application as less effective against this pathogen. However, the situation was representative of a challenging disease pressure and the 2nd application in spring was followed by a very rainy day (24.5 mm) which may cause leaching of the products and reduced efficacies. In these special conditions, CA3301 at 0.6 l/ha and 0.7 l/ha gave low disease control, equivalent compared to the 0.5 l/ha dose rate. Nevertheless, the proposed dose rates still did significantly reduce disease severity compared to the untreated. However, considering larger datasets presented in this dossier, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient to control *Erysiphe cruciferarum*. Then, when conditions are conducive to heavy disease infestation the rate of 0.7 l/ha may be beneficial to further reduce disease pressure.

Considering all elements presented above, CA3301 at 0.6-0.7 l/ha with one application in autumn and one application in spring, is the minimum effective dose to control *Erysiphe cruciferarum* on oilseed rape in the Maritime EPPO zone.

Table 3.2-205: Summary table – Minimum effective dose evaluation – Oilseed rape – ERYSCR - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA33 01	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to		
Rate		0,5	0,6	0,7						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Disease severity LEAF - 42 DA-B										
Number of values	1	1	1	1	UT C	CA33 01 0,5 l/ha	CA33 01 0,7 l/ha	UT C	CA33 01 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	26,70	18,82	17,70	19,14	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	26,70	18,82	17,70	19,14	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	26,70	18,82	17,70	19,14	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	29,51 %	33,71 %	28,31 %						

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 with 2 applications in spring – Maritime EPPO zone

In the Maritime EPPO zone, 2 trials were available against *Erysiphe cruciferarum* on oilseed rape. Among these trials, 2 valid trials had a level of disease severity higher than 5% and were included to support the evaluation of CA3301. Several dose rates (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). Among the 2 valid trials, CA3301 was applied twice in spring in 1 trial, first at crop stages BBCH 50 and the 2nd application was at BBCH 65. A single assessment timing was available and the analysis was conducted on leaves.

Summary results are presented in Table 3.2-206.

When evaluating the reduction of disease severity, the data demonstrated a positive effect against *Erysiphe cruciferarum* of CA3301 at 0.6-0.7 l/ha. When applied at 0.6 l/ha, CA3301 showed 49.78% of efficacy to control the disease on leaves before harvest and 65.88% of efficacy at 0.7 l/ha.

In the Maritime EPPO zone, a limited dataset was available for assessment of control of *Erysiphe cruciferarum* at this application timing. In the single trial presented, disease pressure was challenging and data demonstrated low to medium efficacy of CA3301 to reduce disease severity, although the proposed dose rates did significantly reduce disease severity. Moreover, no significant differences were observed between the three tested dose rates although a clear numerical trend appeared where disease severity decreased with increasing dose rates and particularly for 0.7 l/ha compared to lower dose rates. Considering larger datasets presented on other diseases, this trial follows the overall trend observed where in most cases 0.6 l/ha dose rate provide acceptable disease reduction and 0.7 l/ha dose rate is more appropriate in challenging conditions.

Considering all elements presented above, CA3301 at 0.6-0.7 l/ha with two applications in spring, is the minimum effective dose to control *Erysiphe cruciferarum* on oilseed rape in the Maritime EPPO zone.

Table 3.2-206: Summary table – Minimum effective dose evaluation – Oilseed rape – ERYSCR - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA33 01	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to		
Rate		0,5	0,6	0,7						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Disease severity LEAF - 59 DA-B										
Number of values	1	1	1	1	UT C	CA33 01 0,5 l/ha	CA33 01 0,7 l/ha	UT C	CA33 01 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	30,13	15,10	15,13	10,28	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	30,13	15,10	15,13	10,28	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	30,13	15,10	15,13	10,28	0 <	1 <	1 <	0 <	1 <	1 <
Abbott efficacy (%)	0,00%	49,88 %	49,78 %	65,88 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 with 2 applications in spring - Mediterranean EPPO zone

In the Mediterranean EPPO zone, 11 trials were available against *Erysiphe cruciferarum* on oilseed rape. Among these trials, 2 were considered valid and were included to support the evaluation of CA3301. Several dose rates (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). In these 2 trials, CA3301 was applied twice in spring, first at crop stages BBCH 33-55 and the 2nd application was at BBCH 65. One assessment timing was available and the analysis was conducted on leaves, stems and pods.

Summary results are presented in Table 3.2-207.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect on *Erysiphe cruciferarum* was provided after two applications of CA3301 at 0.6-0.7 l/ha. When applied at 0.6 l/ha, CA3301 showed 74.52% of efficacy to control the disease on total leaves around 5-6 weeks after the 2nd application. At this dose rate, CA3301 provided 100.00% mean efficacy on stem and 100.00% mean efficacy on pods.

At 0.7 l/ha, CA3301 showed 72.60% of efficacy to control the disease on total leaves around 5-6 weeks after the 2nd application. At this dose rate, CA3301 provided 100.00% mean efficacy on stem and 100.00% mean efficacy on pods.

In the Mediterranean EPPO zone, the dataset does not highlight significant differences between the three tested dose rates since the higher dose rates provided a full disease control on stems and on pods. However, a general trend was observed for reduced disease severity when increasing dose rate from 0.5 l/ha to 0.6 or 0.7 l/ha, particularly on leaves. Moreover, in consistent dataset presented on other diseases a clear trend appears where disease control increases with the dose rates.

Therefore in most instances 0.6 l/ha will be sufficient to control disease severity whereas in conditions of high pressure the additional disease reduction obtained from the higher rate of 0.7 l/ha may be more appropriate.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.7 l/ha is the minimum effective dose to control *Erysiphe cruciferarum* on oilseed rape in the Mediterranean EPPO zone.

Table 3.2-207: Summary table – Minimum effective dose evaluation – Oilseed rape – ERYSCR - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA33 01	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to		
Rate		0,5	0,6	0,7						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Disease severity LEAF - 35-41 DA-B										
Number of values	2	2	2	2	UT C	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	27,13	5,60	2,68	2,40		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	54,93	16,60	12,50	13,68	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	41,03	11,10	7,59	8,04	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	64,31 %	74,52 %	72,60 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity STEM - 35 DA-B										
Number of values	1	1	1	1	UT C	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	30,35	0,95	0,00	0,00		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	30,35	0,95	0,00	0,00	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	30,35	0,95	0,00	0,00	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	96,87 %	100,00 %	100,00 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity POD - 35 DA-B										
Number of values	1	1	1	1	UT C	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	14,50	0,80	0,00	0,00		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	14,50	0,80	0,00	0,00	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	14,50	0,80	0,00	0,00	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	94,48 %	100,00 %	100,00 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 against *Erysiphe cruciferarum* - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, 3 trials were conducted to assess the control of powdery mildew *Erysiphe cruciferarum* on oilseed rape by CA3301 but were not valid due to lack of disease infestation. However, the dataset for this pathogen in the other climatic zones shows that CA3301 applied at the proposed dose rates of 0.6-0.7 l/ha is sufficient for control, and across the whole dataset generated on oilseed rape the efficacy of these dose rates are comparable between the different EPPO zones.

In addition, the pathogen *Erysiphe cruciferarum* is very comparable to *Blumeria graminis*/*Erysiphe graminis* specie, both of the order Erysiphales and the family Erysiphaceae, which causes powdery mildew on cereals. It is therefore possible to take into account the positive effects of CA3301 applied at 0.6-0.8 l/ha on oilseed rape from the robust dataset proposed on other crops.

The dataset presented on other crops against powdery mildew demonstrated that CA3301 applied at 0.6-0.8 l/ha provided significant disease control in the two main assessment timing. Both dose rates were frequently better than the lower rate of 0.48 l/ha. Moreover, the level of disease control observed was medium to high depending on the disease pressure. Indeed, whereas differences were not always significant, a numerical trend appeared where CA3301 at 0.8 l/ha provided better efficacy than 0.6 l/ha dose in the most challenging conditions. Moreover, phytosanitary products formulated or co-formulated with the active substance prothioconazole are commonly used and provided consistent efficacy to control powdery mildew in a large range of crops.

Finally, since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.7 l/ha generally gave adequate disease control, it is supposed that the dose range of 0.6-0.7 will be acceptable to control powdery mildew on oilseed rape in the North-Eastern East EPPO zone.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.7 l/ha is the minimum effective dose to control *Erysiphe cruciferarum* on oilseed rape in the North-Eastern East EPPO zone.

Min. Eff. Dose evaluation of CA3301 with one application in autumn and one application in spring – South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, 15 trials were available against *Erysiphe cruciferarum* on oilseed rape. All 15 trials had a level of disease severity higher than 5% on leaves, stems or pods and were included to support the minimum effective dose evaluation of CA3301. Several dose rates (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). Among these 15 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis. Among the 15 valid trials, CA3301 was applied once in autumn and then once in spring in 4 trials, first at crop stages BBCH 14-16 and the 2nd application was at BBCH 65-66. One main assessment timing was available: close to harvest (31-62 DA-B), and the analysis was conducted on leaves, stems and pods.

Summary results are presented in Table 3.2-208.

When evaluating the reduction of disease severity, the data demonstrated that the highest fungicidal effect to *Erysiphe cruciferarum* was provided after two applications of CA3301 at 0.6-0.7 l/ha.

At the single assessment timing close to harvest, when applied at 0.6 l/ha, CA3301 provided 69.09% efficacy on leaves, 55.47% efficacy on stems and 58.39% efficacy on pods.

When applied at 0.7 l/ha, CA3301 provided 78.08% efficacy on leaves, 63.69% efficacy on stems and 68.12% efficacy on pods.

In the South-Eastern East EPPO zone, a limited dataset was available for assessment of control of powdery mildew when CA3301 was applied once in autumn and once in spring. A general trend was observed for reduced disease severity with increasing dose rates, but the differences between the three dose rates were not always significant. However, these data are consistent with the data recorded in the case where CA3301 is applied twice in spring. Therefore, we can conclude that the highest fungicidal effect on *Erysiphe cruciferarum* was provided after two applications of CA3301 at 0.6-0.7 l/ha.

Considering all elements presented above, 2 applications of CA3301 (one in spring and one in autumn) at 0.6-0.7 l/ha is the minimum effective dose to control *Erysiphe cruciferarum* on oilseed rape in the South-Eastern East EPPO zone.

Table 3.2-208: Summary table – Minimum effective dose evaluation – Oilseed rape – ERYSCR – South-Eastern East EPPO zone

Treatment name	UNTREATED	CA3301	CA3301	CA3301	No of trials where	No of trials where
Rate	CHECK	0,5	0,6	0,7	CA3301	CA3301

Rate unit		L/ha	L/ha	L/ha	at 0,6 l/ha is >, = or <			at 0,7 l/ha is >, = or <		
Appl. Code		AB	AB	AB	compared to			compared to		
% Disease severity LEAF - 31-48 DA-B										
Number of values	4	4	4	4	UT C	CA330 1 0,5 l/ha	CA330 1 0,7 l/ha	UT C	CA330 1 0,5 l/ha	CA330 01 0,6 l/ha
Minimum value	11,84	2,05	4,06	0,46	4 >	0 >	2 >	4 >	2 >	2 >
Maximum value	55,00	30,00	26,25	17,500		0 >	2 >	4 >	2 >	2 >
Mean disease severity (%)	36,71	11,03	10,38	7,05	0 =	3 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	67,27 %	69,09 %	78,08 %	0 <	1 <	0 <	0 <	0 <	0 <
% Disease severity STEM - 48-62 DA-B										
Number of values	3	3	3	3	UT C	CA330 1 0,5 l/ha	CA330 1 0,7 l/ha	UT C	CA330 1 0,5 l/ha	CA330 01 0,6 l/ha
Minimum value	10,3	4,91	3,46	2,98	3 >	0 >	0 >	3 >	1 >	1 >
Maximum value	50,00	30,00	30,00	20,00		0 >	0 >	3 >	1 >	1 >
Mean disease severity (%)	36,77	18,30	17,82	14,33	0 =	3 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	50,78 %	55,47 %	63,69 %	0 <	0 <	1 <	0 <	0 <	0 <
% Disease severity POD - 48-62 DA-B										
Number of values	3	3	3	3	UT C	CA330 1 0,5 l/ha	CA330 1 0,7 l/ha	UT C	CA330 1 0,5 l/ha	CA330 01 0,6 l/ha
Minimum value	9,68	6,37	4,34	3,45	3 >	0 >	0 >	3 >	2 >	1 >
Maximum value	50,00	30,00	30,00	20,00		0 >	0 >	3 >	2 >	1 >
Mean disease severity (%)	36,56	15,46	14,78	11,15	0 =	3 =	2 =	0 =	1 =	2 =
Abbott efficacy (%)	0,00%	51,40 %	58,39 %	68,12 %	0 <	0 <	1 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 with 2 applications in spring – South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, 15 trials were available against *Erysiphe cruciferarum* on oilseed rape. All 15 trials had a level of disease severity higher than 5% on leaves, stems or pods and were included to support the minimum effective dose evaluation of CA3301. Several dose rates (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). Among these 15 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis. Among the 15 valid trials, CA3301 was applied twice in spring in 11 trials, first at crop stages BBCH 37-55 and the 2nd application was at BBCH 65-69. Two main assessment timings were selected: around 2-3 weeks after application B (14-21 DA-B) and the last timing close to harvest (36-57 DA-B), and the analysis was conducted on leaves, stems and pods.

Summary results are presented in Table 3.2-209.

When evaluating the reduction of disease severity on different part rated of oilseed rape, the data demonstrated that the highest fungicidal effect to control *Erysiphe cruciferarum* was provided after two applications of CA3301 at 0.6-0.7 l/ha.

These positive effects to control the disease of CA3301 at 0.6-0.7 l/ha were overall superior than the 0.5 l/ha dose rate tested with significant differences being observed

Over the whole dataset, the disease pressure varied from low to high on each part assessed and a clear trend of decreased disease severity when increasing dose rates above 0.5 l/ha was observed, although differences were not always significant. In the assessments close to harvest, the rates of 0.6 l/ha and 0.7 l/ha gave medium to high mean efficacy, whereas the rate of 0.5 l/ha only achieved low to medium mean efficacy. In many instances with a low-medium disease pressure, the rate of 0.6 l/ha gave acceptable control of *Erysiphe cruciferarum* very comparable to that of 0.7 l/ha. However, in situations of high disease pressure the numerical and statistical increase in efficacy of the 0.7 l/ha rate may be more appropriate.

Considering all elements presented above, CA3301 applied twice in spring, at 0.6-0.7 l/ha is the minimum effective dose to control *Erysiphe cruciferarum* on oilseed rape in the South-Eastern East EPPO zone.

Table 3.2-209: Summary table – Minimum effective dose evaluation – Oilseed rape – ERYSCR – South-Eastern East EPPo zone

Treatment name	UNTREATED CHECK	CA3301 0,5 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to		
% Disease severity LEAF - 14-21 DA-B										
Number of values	5	5	5	5	UTC	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	9,76	0,00	0,00	0,00		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	50,00	5,31	3,73	2,32	5 >	1 >	0 >	5 >	1 >	0 >
Mean disease severity (%)	22,38	1,83	1,23	0,77	0 =	4 =	5 =	0 =	4 =	5 =
Abbott efficacy (%)	0,00%	89,01%	92,74%	95,46%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity STEM - 21 DA-B										
Number of values	1	1	1	1	UTC	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	11,16	1,87	1,39	0,70		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	11,16	1,87	1,39	0,70	1 >	0 >	0 >	1 >	1 >	0 >
Mean disease severity (%)	11,16	1,87	1,39	0,70	0 =	1 =	1 =	0 =	0 =	1 =
Abbott efficacy (%)	0,00%	83,24%	87,54%	93,73%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity LEAF - 36-54 DA-B										
Number of values	11	11	11	11	UTC	CA33 01	CA33 01	UT C	CA33 01	CA33 01
Minimum value	19,80	2,37	1,68	1,23		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	95,48	30,00	11,70	10,00	11 >	9 >	0 >	11 >	10 >	4 >
Mean disease severity (%)	42,85	10,61	5,20	3,74	0 =	2 =	7 =	0 =	1 =	7 =
Abbott efficacy (%)	0,00%	73,71%	86,25%	90,58%	0 <	0 <	4 <	0 <	0 <	0 <
% Disease severity STEM - 36-57 DA-B										

Number of values	11	11	11	11	UTC	CA33 01 0,5 l/ha	CA33 01 0,7 l/ha	UT C	CA33 01 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	8,43	1,56	0,94	0,49						
Maximum value	88,82	30,00	30,00	30,00	11 >	7 >	0 >	11 >	8 >	4 >
Mean disease severity (%)	29,67	8,48	6,14	5,21	0 =	4 =	7 =	0 =	3 =	7 =
Abbott efficacy (%)	0,00%	68,49%	78,81%	84,91%	0 <	0 <	4 <	0 <	0 <	0 <
% Disease severity POD - 38-57 DA-B										
Number of values	8	8	8	8	UTC	CA33 01 0,5 l/ha	CA33 01 0,7 l/ha	UT C	CA33 01 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	5,60	0,34	0,00	0,00						
Maximum value	60,00	50,00	50,00	50,00	8 >	3 >	0 >	8 >	4 >	2 >
Mean disease severity (%)	23,29	13,14	11,09	10,53	0 =	5 =	6 =	0 =	4 =	6 =
Abbott efficacy (%)	0,00%	58,41%	68,64%	73,69%	0 <	0 <	2 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (con-
versely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Min. Eff. Dose evaluation of CA3301 with 2 applications in spring – Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, a total of 7 trials evaluated the efficacy of CA3301 applied twice in spring on oilseed rape against *Erysiphe cruciferarum*. 4 trials out of 7 were considered valid and enabled to compare the efficacy of several dose rates of CA3301 (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 (0.83N) l/ha applied twice) on disease severity (%). CA3301 was first applied at crop stages BBCH 37-51 and the 2nd application was at BBCH 65-67. Two assessment timings were available and the analysis was conducted on leaves, on stems and on pods.

Summary results are presented in Table 3.2-210.

When evaluating the reduction of disease severity, the data demonstrated the fungicidal effect against *Erysiphe cruciferarum*, provided after two applications of CA3301 at 0.6-0.7 l/ha. On leaves, when applied at 0.6 l/ha, CA3301 showed 91.09% of efficacy to control the disease 4 weeks after the 2nd application and 72.57% before harvest. Moreover, at this dose rate CA3301 showed 72.60% of efficacy on stems and 75.33% on pods before harvest.

When applied at 0.7 l/ha, on leaves, CA3301 showed 95.84% of efficacy to control the disease 4 weeks after the 2nd application and 83.61% before harvest. Moreover, at this dose rate CA3301 showed 87.71% of efficacy on stems and 87.34% on pods before harvest.

These positive effects to control the disease of CA3301 at 0.6-0.7 l/ha were overall superior than the 0.5 l/ha dose rate tested, providing medium to high efficacy compared to low to medium efficacy at the lower rate.

In Poland and neighbouring countries, an overall trend of decreasing disease severity with increasing dose rates was observed in the datasets, although differences were not always significant. The trend is more apparent in the late assessments on leaves, stems and pods where the dose response effect of CA3301 is more discernible. The rate of 0.6 l/ha gave acceptable control of *Erysiphe cruciferarum* very comparable to that of 0.7 l/ha, however under conditions of high disease pressure further disease reduction obtained from the higher rate of 0.7 l/ha may be more appropriate.

Considering all elements presented above, 2 applications in spring of CA3301 at 0.6-0.7 l/ha is the minimum effective dose to control *Erysiphe cruciferarum* on oilseed rape in Poland.

Table 3.2-210: Summary table - Minimum effective dose evaluation – Oilseed rape – ERYSCR – Data relevant for Poland

Treatment name	UNTREATED CHECK	CA33 01	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or <			No of trials where CA3301 at 0,7 l/ha is >, = or <		
Rate		0,5	0,6	0,7						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
% Disease severity LEAF - 28 DA-B										
Number of values	1	1	1	1	UT C	CA33 01 0,5 l/ha	CA33 01 0,7 l/ha	UT C	CA33 01 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	5,05	1,20	0,45	0,21						
Maximum value	5,05	1,20	0,45	0,21	1 >	0 >	0 >	1 >	1 >	0 >
Mean disease severity (%)	5,05	1,20	0,45	0,21	0 =	1 =	1 =	0 =	0 =	1 =
Abbott efficacy (%)	0,00%	76,24 %	91,09 %	95,84 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity LEAF - 50-59 DA-B										
Number of values	4	4	4	4	UT C	CA33 01 0,5 l/ha	CA33 01 0,7 l/ha	UT C	CA33 01 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	24,45	8,90	4,70	2,86						
Maximum value	47,50	20,35	15,13	10,28	4 >	3 >	0 >	4 >	3 >	2 >
Mean disease severity (%)	36,77	14,80	9,64	5,57	0 =	1 =	2 =	0 =	1 =	2 =
Abbott efficacy (%)	0,00%	59,41 %	72,57 %	83,61 %	0 <	0 <	2 <	0 <	0 <	0 <
% Disease severity STEM - 50-53 DA-B										
Number of values	3	3	3	3	UT C	CA33 01 0,5 l/ha	CA33 01 0,7 l/ha	UT C	CA33 01 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	13,40	6,25	3,13	0,93						
Maximum value	26,00	12,00	7,60	5,50	3 >	3 >	0 >	3 >	3 >	2 >
Mean disease severity (%)	18,46	8,88	5,15	2,61	0 =	0 =	1 =	0 =	0 =	1 =
Abbott efficacy (%)	0,00%	51,55 %	72,60 %	87,71 %	0 <	0 <	2 <	0 <	0 <	0 <
% Disease severity POD - 50-53 DA-B										
Number of values	3	3	3	3	UT C	CA33 01 0,5 l/ha	CA33 01 0,7 l/ha	UT C	CA33 01 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	9,85	3,65	2,50	1,03						
Maximum value	12,60	5,83	3,00	2,00	3 >	2 >	0 >	3 >	2 >	2 >
Mean disease severity (%)	11,16	4,66	2,73	1,36	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	58,12 %	75,33 %	87,34 %	0 <	0 <	2 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)	
>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

2 trials have been submitted to determine minimum effective dose in the **Maritime EPPO climatic zone**. 1 trial was provided with using of 2 application, in autumn and spring. CA3301 applied at dose rate of 0,48-0,7 l/ha

achieved very low efficacy. Also 1 trial with 2 spring application showed low results for dose rate of 0,48-0,6 l/ha while higher dose of 0,7 l/ha had medium level of control. Due to the limited number of trials and insufficient results, the cMSs are kindly asked to consider MED for this use on the national level.

No trials were available to determine MED in **the North-East EPPO zone**. The trials from the neighbouring countries showed high level of control after application of dose rate of 0,7 l/ha and medium to high efficacy at 0,6 l/ha. CA3301 at 0,48 l/ha was insufficient to control of ERYSCR.

15 trials were presented to determine MED in **the South-East EPPO zone**. 4 out of 15 trials were provided with using of 2 application, in autumn and spring. CA3301 applied at dose rate of 0,7 l/ha achieved medium efficacy in all assessments. The lower doses of 0,48-0,6 l/ha were effective on medium level of control in all trials after second application (31-48 DA-B). The reduce of effectiveness to insufficient level was observed in 3 trials in the next period of assessment (before harvest). Due to the limited number of trials, the cMSs are kindly asked to consider MED for this use on the national level. 2 spring applications were used in 11 out of 15 trials. CA3301 at 0,6-0,7 l/ha achieved medium to high efficacy with visible reduce of effectiveness in the second period of assessment, before harvest. The dose rate of 0,48 l/ha showed low to high level of control. An insufficient efficacy was noted after 38-57 DA-B in 8 out of 11 trials. Overall, the dose rate of 0,6 l/ha can be considered MED mainly in situation of low disease pressure. In more challenging conditions, the dose rate of 0,7 l/ha will be more justified.

3.2.2.13 Oilseed rape (BRSNW) / *Pyrenopeziza brassicae* (PYRPBR)

Between 2018 and 2020, a total of 5 trials were conducted in several countries of the Maritime EPPO zone to evaluate the efficacy of CA3301 against *Pyrenopeziza brassicae* on oilseed rape. The trials were carried out by certified testing institutes. The proposed dose rate is 0.6-0.7 l/ha.

For this pathogen trials were focused on the Maritime EPPO zone where the disease is most problematic and conditions are more challenging.

In the Maritime EPPO zone, 5 trials were performed in United Kingdom (1), France (3) and Denmark (1).

No data were available for the other EPPO zones.

Min. Eff. Dose evaluation of CA3301 with one application in autumn and one application in spring – Maritime EPPO zone

In the Maritime EPPO zone, 5 trials were available against *Pyrenopeziza brassicae* on oilseed rape. Among these trials, 3 valid trials had a level of disease severity higher than 5% and were included to support the evaluation of CA3301. Several dose rates (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). Among the 3 valid trials, CA3301 was applied once in autumn and once in spring in 2 trials, first at crop stages BBCH 18-19 and the 2nd application was at BBCH 65-67. Two assessment timings were available and the analysis was conducted on leaves and on stems.

Summary results are presented in Table 3.2-211.

When evaluating the reduction of disease severity, the data demonstrated a positive fungicidal effect against *Pyrenopeziza brassicae* after two applications of CA3301 at 0.6-0.7 l/ha. When applied at 0.6 l/ha, CA3301 showed 43.94% of efficacy to control the disease on leaves 2 weeks after the 2nd application and 33.04% before harvest. At this dose rate, CA3301 showed 64.88% mean efficacy 2 weeks after the 2nd application on stems and 47.40% before harvest.

When applied at 0.7 l/ha, CA3301 showed 64.98% of efficacy to control the disease on leaves 2 weeks after the 2nd application and 37.37% before harvest. At this dose rate, CA3301 showed 70.57% mean efficacy 2 weeks after the 2nd application on stems and 67.92% before harvest.

In the Maritime EPPO zone, in a limited dataset, CA3301 at 0.6-0.7 l/ha showed low to medium efficacy in reducing the severity of *Pyrenopeziza brassicae* on oilseed rape on leaves and stems. To put these low levels of efficacy into perspective, it is important to notice that the 2nd application timing of EU20-014-19 was followed by a very rainy week (25.5mm) which can cause leaching of the products. Averaged across the dataset the efficacy of CA3301 at 0.6 l/ha was comparable to that of the dose rate of 0.7 l/ha, however at some assessments a clear numerical benefit was derived from increasing the dose rate to 0.7 l/ha. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for control of *Pyrenopeziza brassicae* and that 0.7 l/ha dose rate may be appropriate in more challenging conditions.

Considering all elements presented above, CA3301 at 0.6-0.7 l/ha with two applications in spring, is the minimum effective dose to control *Pyrenopeziza brassicae* on oilseed rape in the Maritime EPPO zone.

Table 3.2-211: Summary table – Minimum effective dose evaluation – Oilseed rape – PYRPBR - Maritime EPPO zone

Maritime LFO zone										
Treatment name	UNTREATED CHECK	CA330 1	CA330 1	CA330 1	No of trials where CA3301			No of trials where CA3301		
Rate		0,5	0,6	0,7	at 0,6 l/ha is >, = or <			at 0,7 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
% Disease severity LEAF - 14 DA-B										
Number of values	1	1	1	1	UT C	CA33 01	CA330 1	UT C	CA330 1	CA33 01
Minimum value	12,45	3,69	6,98	4,36		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	12,45	3,69	6,98	4,36	0 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	12,45	3,69	6,98	4,36	1 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	70,36 %	43,94 %	64,98 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity STEM - 14 DA-B										
Number of values	1	1	1	1	UT C	CA33 01	CA330 1	UT C	CA330 1	CA33 01
Minimum value	6,15	1,93	2,16	1,81		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	6,15	1,93	2,16	1,81	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	6,15	1,93	2,16	1,81	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	68,62 %	64,88 %	70,57 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity LEAF - 42 DA-B										
Number of values	1	1	1	1	UT C	CA33 01	CA330 1	UT C	CA330 1	CA33 01
Minimum value	16,86	11,23	11,29	10,56		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	16,86	11,23	11,29	10,56	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	16,86	11,23	11,29	10,56	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	33,39 %	33,04 %	37,37 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity STEM 60-83 DA-B										
Number of values	2	2	2	2	UT C	CA33 01	CA330 1	UT C	CA330 1	CA33 01
Minimum value	6,48	1,91	1,93	2,15		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	15,33	7,56	11,56	4,75	1 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	10,91	4,74	6,75	3,45	1 =	2 =	2 =	0 =	2 =	2 =

'>' means CA3301 is significantly more efficient than plants treated with (treatment)
(conversely for '<')

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

In the Maritime EPPO zone, 5 trials were available against *Pyrenopeziza brassicae* on oilseed rape. Among these trials, 3 valid trials had a level of disease severity higher than 5% and were included to support the evaluation of CA3301. Several dose rates (0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N) applied twice) were tested to compare the efficacy of CA3301 on disease severity (%). In the Maritime EPPO zone, among the 3 valid trials, CA3301 was applied twice in spring in 1 trial, first at crop stages BBCH 55 and the 2nd application was at BBCH 69. Two assessment timings were available and the analysis was conducted on leaves, on stem and on pods.

When evaluating the reduction of disease severity, the data demonstrated a positive fungicidal effect against *Pyrenopeziza brassicae* after two applications of CA3301 at 0.6-0.7 l/ha. When applied at 0.6 l/ha, CA3301 showed 35.94% of efficacy to control the disease on leaves 3 weeks after the 2nd application and. At this dose rate, CA3301 showed 32.19% mean efficacy on stems and 42.51% mean efficacy on pods before harvest.

When applied at 0.7 l/ha, CA3301 showed 51.88% of efficacy to control the disease on leaves 3 weeks after the 2nd application and. At this dose rate, CA3301 showed 46.52% mean efficacy on stems and 40.20% mean efficacy on pods before harvest.

In the Maritime EPPO zone, in a limited dataset, CA3301 at 0.6-0.7 l/ha showed low to medium efficacy in reducing the severity of *Pyrenopeziza brassicae* on oilseed rape on leaves, stems and pods. To put these low levels of efficacy into perspective, it is important to notice that the 2nd application timing of EU20-038-14 was followed by a very rainy week (33.2 mm) which can cause leaching of the products. Nevertheless, the proposed dose rates still significantly reduced disease severity on stem and pods. Averaged across the dataset the efficacy of CA3301 at 0.6 l/ha was comparable to that of the dose rate of 0.7 l/ha, however at some assessments a clear numerical benefit was derived from increasing the dose rate to 0.7 l/ha. Moreover, in consistent dataset presented on other diseases a clear trend appears where disease control increases with the dose rates. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for control of *Pyrenopeziza brassicae* and that 0.7 l/ha dose rate may be appropriate in more challenging conditions.

Considering all elements presented above, CA3301 at 0.6-0.7 l/ha with two applications in spring, is the minimum effective dose to control *Pyrenopeziza brassicae* on oilseed rape in the Maritime Eppo zone.

Maritime LEAF Zone						
Treatment name	UNTREATED CHECK	CA33 01	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or <	No of trials where CA3301 at 0,7 l/ha is >, = or <
Rate		0,5	0,6	0,7		
Rate unit		L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	compared to	compared to
% Disease severity LEAF - 21 DA-B						

Number of values	1	1	1	1	UTC	CA3 301	CA33 01	UT C	CA33 01	CA33 01
Minimum value	18,39	7,16	11,78	8,85		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	18,39	7,16	11,78	8,85	0 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	18,39	7,16	11,78	8,85	1 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	61,07 %	35,94 %	51,88 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity STEM - 57 DA-B										
Number of values	1	1	1	1	UTC	CA3 301	CA33 01	UT C	CA33 01	CA33 01
Minimum value	27,90	16,56	18,92	14,92		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	27,90	16,56	18,92	14,92	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	27,90	16,56	18,92	14,92	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	40,65 %	32,19 %	46,52 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity POD - 50 DA-B										
Number of values	1	1	1	1	UTC	CA3 301	CA33 01	UT C	CA33 01	CA33 01
Minimum value	13,88	5,63	7,98	8,30		0,5 l/ha	0,7 l/ha		0,5 l/ha	0,6 l/ha
Maximum value	13,88	5,63	7,98	8,30	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	13,88	5,63	7,98	8,30	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	59,44 %	42,51 %	40,20 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (con-
versely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Other EPPO zones

(Bush, M. N., & Flind, A. (2012). Management of *Pyrenopeziza brassicae* in oilseed rape in Northern Britain. In *The Dundee Conference. Crop Protection in Northern Britain, 2012, Dundee, UK, 28-29 February 2012* (pp. 101-105). The Association for Crop Protection in Northern Britain.)

(Oxley, S. J., & Walters, D. R. (2012). Control of light leaf spot (*Pyrenopeziza brassicae*) on winter oilseed rape (*Brassica napus*) with resistance elicitors. *Crop Protection*, 40, 59-62)

In the North-Eastern East, South-Eastern East and Mediterranean EPPO zones, no trials were available against *Pyrenopeziza brassicae* on oilseed rape.

However, other similar prothioconazole products such as Proline are authorised for use against *Pyrenopeziza brassicae* at the same dose rate of 0.7 l/ha, and since data across the various pathogens of oilseed rape has demonstrated comparability with this approved product it is anticipated that CA3301 applied at the proposed dose rates would also provide acceptable control of this pathogen. Furthermore, the data generated in the Maritime EPPO zone supports the minimum effective dose against *Pyrenopeziza brassicae*, and across the dataset on oilseed rape the efficacy against pathogens appears comparable regardless of the climatic zone.

Considering all elements presented above, CA3301 at 0.6-0.7 l/ha with two applications in spring or one application in autumn and one application in spring, is the minimum effective dose to control *Pyrenopeziza brassicae* on oilseed rape in all EPPO climatic zones.

Comments of zRMS:

The limited number of trials have been submitted to determine minimum effective dose to control of *Pyr-enopeziza brassicae* on winter oilseed rape. 3 valid trials were presented in the **Maritime EPPO climatic zone**. 2 out of 3 trials were provided with using of 2 applications, in autumn and spring. CA3301 applied at 0,7 l/ha achieved medium efficacy in both trials. The lower doses of 0,48-0,6 l/ha showed varied results, from very low to medium level of control. Also 1 trial with 2 spring applications presented insufficient efficacy after application of CA3301 at 0,48-0,7 l/ha. No dataset was available in other EPPO zones. The cMSs are kindly asked to consider MED for this use on the national level.

3.2.2.14 Oilseed rape (BRSNW) / Green leaf area

Min. Eff. Dose evaluation of CA3301 with one application in autumn and one application in spring – Maritime EPPO zone

Green leaf area was recorded in 7 valid trials on oilseed rape after two applications of CA3301 at 0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N). Among these 7 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis. Among the 7 valid trials, CA3301 was applied once in autumn and once in spring in 6 trials. In these trials, the green leaf area was assessed at 64-84 DA-B on the whole plant.

Summary results are presented in Table 3.2-213.

Data demonstrated a better effect of 2 applications of CA3301 at 0.7 l/ha compared to lower dose rate for the increase of green leaf area on oilseed rape infected by foliar diseases. In 1 assessment the difference was statistically significant compared to 0.5 l/ha (0.83N) In the 6 trials assessing green leaf area on the whole plant, an increase of 88.83%, 62.73% and 75.61% was recorded with CA3301 at 0.7 l/ha, 0.6 l/ha and 0.5 l/ha compared to the untreated check on oilseed rape.

Considering the whole dataset, the positive effects of CA3301 at 0.6 l/ha on green leaf area were overall equivalent to those of 0.7 l/ha dose rate. In addition, compared to 0.5 l/ha, these positive effects were statistically equivalent except in 1 trial. A relatively small number of trials were available to assess green leaf area, as this parameter is usually not required in oilseed rape crop. Nevertheless, given the larger dataset on disease control which demonstrates a benefit in increasing the dose rate above 0.5 l/ha, it is expected that this would also be reflected in the green leaf area

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.7 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on oilseed rape infected by a range of diseases in the Maritime EPPO zone.

Table 3.2-213: Summary table – Minimum effective dose evaluation – Oilseed rape – Green leaf area – Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA33 01	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to		
Rate		0,5	0,6	0,7						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Green leaf area - 64-84 DA-B										
Number of values	6	6	6	6	UT C	CA33 01 0,5 l/ha	CA33 01 0,7 l/ha	UT C	CA33 01 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	1,25	2,00	2,25	2,50	3 >	0 >	0 >	3 >	1 >	0 >
Maximum value	71,25	77,50	75,00	72,50	3 =	5 =	6 =	3 =	5 =	6 =
Mean green leaf area (%)	20,83	28,54	27,04	28,38						

Mean %UTC	100,00%	175,61 %	162,73 %	188,83 %	0 <	1 <	0 <	0 <	0 <	0 <
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'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Min. Eff. Dose evaluation of CA3301 with 2 applications in spring – Maritime EPPO zone

Green leaf area was recorded in 7 valid trials on Oilseed rape after two applications of CA3301 at 0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N). Among these 7 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis. Among the 7 valid trials, CA3301 was applied twice in spring in 1 trial. In this trial, the green leaf area was assessed at 50 DA-B on stems and on pods.

Summary results are presented in Table 3.2-214.

Data demonstrated a positive effect of 2 applications of CA3301 at 0.6-0.7 l/ha compared to untreated control for the increase of green leaf area on oilseed rape infected by foliar diseases. However, no difference was considered significant in this dataset. After two applications in spring, an increase of 28.57%, 50.00% and 57.14% was recorded on pods and an increase of 40.00%, 52.00% and 60.00% was recorded on stems with CA3301 at 0.7 l/ha, 0.6 l/ha and 0.5 l/ha compared to the untreated check.

Considering the whole dataset, the positive effects of CA3301 at 0.6 l/ha on green leaf area were overall equivalent to those of 0.7 l/ha and 0.5 l/ha dose rates. Only a single trial was available to assess green leaf area. Nevertheless, given the larger dataset on disease control which demonstrates a benefit in increasing the dose rate above 0.5 l/ha, it is expected that this would also be reflected in the green leaf area.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.7 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on oilseed rape infected by a range of diseases in the Maritime EPPO zone.

Table 3.2-214: Summary table – Minimum effective dose evaluation – Oilseed rape – Green leaf area – Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA33 01 0,5 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to		
Rate										
Rate unit										
Appl. Code										
% Green area- STEM - 50 DA-B										
Number of values	1	1	1	1	UT	CA33 01	CA33 01	UT	CA33 01	CA33 01
Minimum value	31,25	50,00	47,50	43,75	C	0,5 l/ha	0,7 l/ha	C	0,5 l/ha	0,6 l/ha
Maximum value	31,25	50,00	47,50	43,75	0 >	0 >	0 >	0 >	0 >	0 >
Mean green leaf area (%)	31,25	50,00	47,50	43,75	1 =	1 =	1 =	1 =	1 =	1 =
Mean %UTC	100,00%	160,00 %	152,00 %	140,00 %	0 <	0 <	0 <	0 <	0 <	0 <
% Green area - POD - 50 DA-B										
Number of values	1	1	1	1	UT	CA33 01	CA33 01	UT	CA33 01	CA33 01
Minimum value	17,50	27,50	26,25	22,50	C	0,5 l/ha	0,7 l/ha	C	0,5 l/ha	0,6 l/ha
Maximum value	17,50	27,50	26,25	22,50	0 >	0 >	0 >	0 >	0 >	0 >
Mean green leaf area (%)	17,50	27,50	26,25	22,50	1 =	1 =	1 =	1 =	1 =	1 =
Mean %UTC	100,00%	157,14 %	150,00 %	128,57 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Min. Eff. Dose evaluation of CA3301 with one application in autumn and one application in spring – Mediterranean EPPO zone

Green leaf area was recorded in 1 valid trial on oilseed rape after two applications of CA3301 0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N). In this trial, CA3301 was applied once in autumn and once in spring and the green leaf area was assessed at 64 DA-B on the whole plant.

Summary results are presented in Table 3.2-215.

Data demonstrated a higher effect of 2 applications of CA3301 at 0.7 l/ha and 0.6 l/ha (1N) compared to lower dose rate for the increase of green leaf area on oilseed rape infected by foliar diseases. In this trial assessing green leaf area on the whole plant, an increase of 114.29%, 71.43% and 42.86% was recorded with CA3301 at 0.7 l/ha, 0.6 l/ha and 0.5 l/ha compared to the untreated check on oilseed rape.

In this limited dataset, whereas differences were not significant, a clear numerical trend was observed where green leaf area increased with the dose rates and particularly for 0.6-0.7 l/ha compared to 0.5 l/ha.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.7 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on oilseed rape infected by a range of diseases in the Mediterranean EPPO zone.

Table 3.2-215: Summary table – Minimum effective dose evaluation – Oilseed rape – Green leaf area – Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA33 01	CA33 01	CA33 01	No of trials where CA3301			No of trials where CA3301		
Rate		0,5	0,6	0,7	at 0,6 l/ha is >, = or			at 0,7 l/ha is >, = or		
Rate unit		L/ha	L/ha	L/ha	<			<		
Appl. Code		AB	AB	AB	compared to			compared to		
% Green leaf area - 64 DA-B										
Number of values	1	1	1	1	UT	CA33 01	CA33 01	UT	CA33 01	CA33 01
Minimum value	8,75	12,50	15,00	18,75	C	0,5 l/ha	0,7 l/ha	C	0,5 l/ha	0,6 l/ha
Maximum value	8,75	12,50	15,00	18,75	0 >	0 >	0 >	0 >	0 >	0 >
Mean green leaf area (%)	8,75	12,50	15,00	18,75	1 =	1 =	1 =	1 =	1 =	1 =
%UTC	100,00%	142,86 %	171,43 %	214,29 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Min. Eff. Dose evaluation of CA3301 with one application in autumn and one application in spring – North-Eastern East EPPO zone

Green leaf area was recorded in 5 valid trials on oilseed rape after two applications of CA3301 at 0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N). In these trials, CA3301 was applied once in autumn and once in spring and the green leaf area was assessed at 50-62 DA-B on the whole plant.

Summary results are presented in Table 3.2-216.

Data demonstrated a positive effect of 2 applications of CA3301 at 0.7 l/ha and 0.6 l/ha (N rates) compared to untreated control for the increase of green leaf area on oilseed rape infected by foliar diseases. In these trials assessing green leaf area on the whole plant, an augmentation of 22.41%, 15.74% and 21.74% was recorded with CA3301 at 0.7 l/ha, 0.6 l/ha and 0.5 l/ha compared to the untreated check on oilseed rape.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.7 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on oilseed rape infected by a range of diseases in the North-Eastern East EPPO zone.

Summary table – Minimum effective dose evaluation – Oilseed rape – Green leaf area – North-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA33 01	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to		
Rate		0,5	0,6	0,7						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Green leaf area - 50-62 DA-B										
Number of values	5	5	5	5	UT C	CA33 01 0,5 l/ha	CA33 01 0,7 l/ha	UT C	CA33 01 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	15,00	25,00	18,75	21,25						
Maximum value	75,00	88,75	90,00	100,00	2 >	0 >	0 >	2 >	1 >	1 >
Mean green leaf area (%)	59,00	67,00	67,50	70,50	3 =	5 =	4 =	3 =	4 =	4 =
Mean %UTC	100,00%	121,74 %	115,74 %	122,41 %	0 <	0 <	1 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Min. Eff. Dose evaluation of CA3301 with one application in autumn and one application in spring
– South-Eastern East EPPO zone

Green leaf area was recorded in 5 valid trials on oilseed rape after two applications of CA3301 at 0.7 l/ha, 0.6 l/ha (N rates) and 0.5 l/ha (0.83N). In these trials, CA3301 was applied once in autumn and once in spring and the green leaf area was assessed at 41-79 DA-B on the whole plant.

Summary results are presented in Table 3.2-217.

Data demonstrated a better effect of 2 applications of CA3301 at 0.7 l/ha and 0.6 l/ha (1N) compared to lower dose rate for the increase of green leaf area on oilseed rape infected by foliar diseases. In these trials assessing green leaf area on the whole plant, an increase of 173.56%, 110.80% and 93.16% was recorded with CA3301 at 0.7 l/ha, 0.6 l/ha and 0.5 l/ha compared to the untreated check on oilseed rape.

An overall trend of increasing the green leaf area with increasing dose rates was observed in the whole dataset, although differences were not always significant.

Considering all elements presented above, 2 applications of CA3301 at 0.6-0.7 l/ha is the minimum effective dose that induce a positive effect on the green leaf area on oilseed rape infected by a range of diseases in the South-Eastern East EPPo zone.

Summary table – Minimum effective dose evaluation – Oilseed rape – Green leaf area – South-Eastern East EPPO zone

Treatment name	UNTRE	CA3301	CA3301	CA3301	No of trials where CA3301	No of trials where CA3301
Rate	ATED	0,5	0,6	0,7		
Rate unit	CHECK	L/ha	L/ha	L/ha	at 0,6 L/ha is >, = or <	at 0,7 L/ha is >, = or <
Appl. Code		AB	AB	AB	compared to	compared to
% Green leaf area - 41-79 DA-B						

Number of values	8	8	8	8	UTC	CA330 1 0,5 l/ha	CA33 01 0,7 l/ha	UTC	CA33 01 0,5 l/ha	CA33 01 0,6 l/ha
Minimum value	2,50	2,50	6,25	5,00						
Maximum value	72,50	95,00	97,50	100,00	6 >	1 >	0 >	6 >	4 >	4 >
Mean green leaf area (%)	19,59	34,22	34,78	41,09	2 =	7 =	4 =	2 =	4 =	4 =
%UTC	100,00%	193,16%	210,80%	273,56%	0 <	0 <	4 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Comments of zRMS:

Very positive effect was observed after application of 0,6-0,7 l/ha in winter oilseed rape. An augmentation of green leaf area was visible in all EPPO climatic zones. The use of 0,6 l/ha as minimum effective dose is justified.

3.2.2.1 Oilseed rape (BRSNW) / Conclusion - Minimum effective dose tests

On oilseed rape, 5 diseases were assessed in 128 trials across 4 EPPO zones. Among these trials, in order to cover the different agricultural spraying practices of oilseed rape, CA3301 was applied according to two different timings of application and the trials were separated in two groups in the analysis. One group was composed of trials with 2 applications in spring and the other group with trials with one application in autumn and one application in spring. Disease severity was assessed and analysed on leaves, stems, pods and roots. Depending on the EPPO zone, the disease, the assessment timing and the crop part assessed, the dataset available was sometimes limited with results not necessarily representative of the true efficacy of CA3301. Therefore, to get an overview of the efficacy of CA3301 at 0.6-0.7 l/ha, summary tables are presented, on each part assessed (see

Table 3.2-661 to Table 3.2-668).

Globally, across the 4 EPPO zones and all diseases the efficacy of CA3301 at 0.6-0.7 l/ha was acceptable to very high, with some exceptions especially in case of limited dataset. Nevertheless, since in the fields a complex of disease is often observed instead of a single disease, it is of interest to look at the efficacy of CA3301 across the diseases and to not focus on a single one. Overall, across the 4 EPPO zones and considering the two timings of applications analysed, a consistent trend of decreasing disease severity when increasing the dose rates was observed with CA3301 at 0.6-0.7 l/ha providing a better disease control than the lower rate of 0.5 l/ha. The rate of 0.6 l/ha was most of the time very comparable to the 0.7 l/ha rate nevertheless in some trials the differences were significant. Therefore, in circumstances of low to medium disease pressure the rate of 0.6 l/ha will provide sufficient efficacy to maintain crop quality whereas in more challenging condition 0.7 l/ha dose rate will be more appropriate.

Similarly, the same dose rate trends were observed for improving green leaf area in situations of infection from a single pathogen or in cases of disease complexes. Green leaf area not only indicates the area free of infection but also the ability of the plant to continue effective growth and develop to productive stages, enabling a longer duration of grain filling and therefore improved yield quantity and quality.

In this dossier data presented for minimum effective dose is primarily from assessments where 2 applications of the test product were made. However, according to disease development conditions, a single application may provide sufficient disease control, therefore users should not be restricted to always applying twice, hence in the GAP the proposed use is for 1-2 applications. In addition, crop pathogens are commonly controlled using a programme of different fungicides with varied modes of action, therefore the choice should be available to growers to make a single application of CA3301, followed by application of a different appropriate fungicide. Prothioconazole is well established over a number of years in providing good broad spectrum efficacy across a range of common crop pathogens, with either 1 or more applications appropriate according to disease development conditions, risk of resistance development and local conditions. Current authorisations for similar products containing prothioconazole

including Proline/Praktis/Joao (CA2445) are for 1-2 applications at comparative rates of prothioconazole to the requested use for CA3301 in oilseed rape. Considering these elements, and that data in the efficacy section shows comparability of CA3301 to these authorised products, registration of CA3301 at the proposed minimum effective dose rate and with a number of applications of 1- 2, is requested.

Considering all elements presented in the previous sections of each disease, CA3301 applied at 0.6-0.7 l/ha is the minimum effective dose to control a range of foliar diseases on oilseed rape.

3.2.2.1 Spring oilseed rape (BRSNS) / Minimum effective dose

Oilseed rape is one of the major crop in Europe. Most of the time it is sown at the end of the summer or the beginning of the autumnal season but in marginal cases oilseed rape may be sown in the early spring. Sowing oilseed rape in spring is an alternative to produce green fodder in early summer when no other fodder is available. It is also used as replacement crop for winter sown oilseed rape after a failure of the implanting. However, spring-sown oilseed rape is more likely to be cultivated in northern countries where spring is more humid and the crop has chances to succeed.

In addition, spring sown oilseed is susceptible to face the same pathogens than winter oilseed rape and particularly powdery mildew or dark leaf spot. Considering that the profitability of this crop is not always insured, it is all the more important to protect it from disease infestation and to preserve all the yield potential.

Spring-sown oilseed rape is considered a minor crop and extrapolation of data from winter-sown oilseed rape is acceptable as indicated in EPPO extrapolation tables PP 1/257 FEET 70 (1) and PP 1/257 FEET 69 (1).

In the previous sections, the minimum efficacy dose of CA3301 was demonstrated with both 2 applications in spring or 1 in autumn and 1 in spring against a diversity of pathogens. In many instances, a trend of decreasing disease severity when increasing the dose rates was observed with CA3301 at 0.6-0.7 l/ha providing a better disease control than the lower rate of 0.5 l/ha. The rate of 0.6 l/ha was most of the time fairly comparable to the 0.7 l/ha rate nevertheless in some trials the differences were significant. Therefore, in circumstances of common disease pressure the rate of 0.6 l/ha will provide sufficient efficacy to maintain crop quality whereas in more challenging conditions 0.7 l/ha dose rate will be more appropriate.

In addition, other authorised products containing prothioconazole are also approved for use in spring sown as well as winter sown oilseed rape, for example Pecari 300 EC.

Considering all elements presented in the previous sections of each disease, CA3301 applied at 0.6-0.7 l/ha is the minimum effective dose to control a range of foliar diseases on spring oilseed rape.

Comments of zRMS:

No trials have been submitted to determine minimum effective dose to control of disease pathogens in spring oilseed rape. The cMSs are kindly asked to consider MED for this use on the national level.

3.2.2.1 Other Brassicaceae (minor crops) / Minimum effective dose

(G. Séguin-Swartz, G. *et al.*, Diseases of *Camelina sativa* (false flax) *Canadian Journal of Plant Pathology*, 2010)

The Brassicaceae family (formerly Cruciferaceae family) includes various *Brassica* species, representing oilseed, vegetable and fodder crops. For example, *Camelina sativa* and *Brassica juncea* are members

of this genus. *Camelina sativa* (L.) Crantz (false flax) belongs to *Brassicaceae* and is generating substantial interest as an alternative oilseed crop in many regions of the world because of its potential value for food, feed, and industrial applications. This plant is known to its early maturity, high seed yield potential, drought tolerance, and its resistance to some of the common pests and diseases of Brassica oilseeds. Mustards have been consumed for centuries as vegetables, and their products used as condiments and as edible and industrial oils. The oil is commonly used for cooking and to add a hot and spicy flavor to food. As a crop, they are also one of the highest oil yielding and high protein containing oilseed species.

Because of their close genus relationship, these crops are often susceptible to the same pathogens and therefore to the same diseases than winter oilseed rape.

These Brassicae crops are considered minor crops and extrapolation of data from winter-sown oilseed rape is acceptable as indicated in EPPO extrapolation tables PP 1/257 FEET 70 (1) and PP 1/257 FEET 69 (1).

In the previous sections, the minimum efficacy dose of CA3301 was demonstrated with both 2 applications in spring or 1 in autumn and 1 in spring against a diversity of pathogens. In many instances, a trend of decreasing disease severity when increasing the dose rates was observed with CA3301 at 0.6-0.7 l/ha providing a better disease control than the lower rate of 0.5 l/ha. The rate of 0.6 l/ha was most of the time fairly comparable to the 0.7 l/ha rate nevertheless in some trials and where the disease pressure was high, the differences were significant. Therefore, in circumstances of low to relatively medium disease pressure the rate of 0.6 l/ha will provide sufficient efficacy to maintain crop quality whereas in more challenging conditions 0.7 l/ha dose rate will be more appropriate.

Considering all elements presented in the previous sections of each disease, CA3301 applied at 0.6-0.7 l/ha is proposed as the minimum effective dose to control a range of foliar diseases on various seed-producing *Brassicaceae*.

Comments of zRMS:

Based on the GAP table, the various seed-producing *Brassicaceae* are considered according art. 51. The assessment of efficacy and phytotoxicity is not required in this case.

3.2.2.2 Flax (Fibre) / *Oidium lini*/ *Erysiphe orontii* (ERYSPP) – Minimum Effective Dose

Linseed (*Linum usitatissimum* L.) varieties are two types, fiber or seed and differ considerably in character of the plant growth. The fiber plants having tall and slender stem, produces a high amount of good quality fiber and bears seeds of poor quality oil content. Sown between March and April, 100 days are sufficient to mature and will quickly grow to reach 1 m. A mild and regularly rainy spring will ensure regular fiber growth.

Powdery mildew is an important disease of flax. The disease is caused by *Oidium lini*/ *Erysiphe orontii* an obligate biotrophic ascomycete. Typical infection symptoms start with the appearance of a white powdery mass of mycelia visible as small spots that eventually spread to cover the entire leaf surface. Heavily infected leaves wither, dry up, and die. Early infections may cause severe defoliation of the flax plant and reduce the yield and quality of seed. Some flax varieties are resistant to this disease.

Flax is considered a minor crop as indicated in Table 3.2-21, therefore it is considered acceptable to extrapolate data from cereals and oilseed rape to this crop. Data generated on *Erysiphe* spp in cereals and oilseed rape indicates that the proposed dose rate of 0.6-0.8 l/ha (cereals) and 0.6-0.7 l/ha (oilseed rape) of CA3301 provides acceptable efficacy of these pathogens.

No data were available for assessment of control of Powdery mildew on flax in this dossier. However, prothioconazole is one of the active substances the most used as fungicide in commercial practices.

Standard reference products containing prothioconazole, such as JOAO are registered to control powdery mildew on flax, at the same application rates as for the other authorised pathogens, which indicates that prothioconazole controls powdery mildew at dose rates which have demonstrated to control the other major disease pathogens in cereals. Since the proposed dose rate for CA3301 (200-150 g/ha prothioconazole) is comparable to that of the authorised product JOAO (200 g/ha prothioconazole), and data shows equivalence of efficacy between these products in other pathogens, it is considered that CA3301 will also provide acceptable control of powdery mildew at the proposed dose rate.

Considering all elements presented in the previous sections of each disease, CA3301 applied at 0.6-0.7 l/ha is the minimum effective dose to control *Erysiphe orontii* on flax in all EPPO zones.

Comments of zRMS:

Based on the GAP table, the flax is considered according art. 51. The assessment of efficacy and phytotoxicity is not required in this case.

3.2.3 Efficacy tests (KCP 6.2)

General Materials and Methods

General information about the materials and methods implemented for the registration of CA3301 against foliar and ear diseases in winter wheat, spring wheat, durum wheat, winter barley, spring barley, triticale, rye, oat and oilseed rape will be presented at the beginning of this section. This general method will be applicable to all uses presented in this BAD, for minimum effective dose as well as efficacy sections.

Specific information related to the different uses will be then presented in further details in material and methods paragraphs of each use.

Sites

Efficacy trial sites were selected in homogeneous fields sown with commercial varieties, in areas representative where the target crops are produced commercially.

Experimental details

Efficacy trials were carried out to evaluate the fungicidal effect, preventive effect and crop safety of CA3301 when applied at a range of dose rates for the control of several foliar and ear diseases.

All trials presented in this biological assessment dossier were implemented with Randomized complete blocks experimental design including four replicates (i.e. 4 blocks).

Plot size varied depending on the trials and commercial production practices of each crop.

In all trials, CA3301 was compared to at least one registered fungicide used as standard reference for comparison. These commercial fungicide products are known to achieve a high level of control of the target diseases in the target crops. The comparison between CA3301 and at least one of these common and effective fungicides guarantees a strong relevancy to the results and conclusions presented in this biological assessment dossier.

These standard references are detailed in the Materials and Methods paragraphs of each use.

Application method

CA3301 is an emulsifiable concentrate (EC). It was therefore applied by foliar sprays. Water volumes were adapted to the vegetation development and local practices and did not exceed 500 l/ha.

One or two applications, depending of the crop, were performed according to crop stages recommended in the GAP table.

Further details on the method and timings of applications used in each trial are summarized in individual trial reports.

Assessment method

The evaluation of the efficacy of the tested product CA3301 was performed according to various EPPO guidelines.

The general guidelines that were followed for all uses are the following:

- PP 1/135 (4) “Phytotoxicity assessment”
- PP 1/152 (4) “Design and analysis of efficacy evaluation trials”
- PP 1/181 (4) “Conduct and reporting of efficacy evaluation trials”
- PP 1/239 (2) “Dose expression for plant protection products”
- PP 1/214 (3) “Principles of acceptable efficacy”

The specific guidelines that were followed according to the uses or all uses are the following:

- PP 1/26 (4) “Foliar and ear diseases on cereals”
- PP 1/28 (3) “Eyespot of cereals”
- PP 1/78 (3) “Root, stem, foliar and pod diseases on oilseed rape”

The **effectiveness** of CA3301 was evaluated by assessing:

- *Disease severity*: for each individual trial, the effectiveness of CA3301 has been calculated thanks to the Abbott formula and the global effectiveness of CA3301 for each use corresponds to the mean of the calculated effectiveness of each individual trial. CA3301 is expected to **reduce disease severity** in comparison to the untreated control.
In the particular cases of root infection on oilseed rape, according the EPPO guideline PP1/78 (4), an assessment scale was made based upon the target disease and a *severity index* or *disease index* was calculated.

In the particular case of eyespot infection on winter wheat, according the EPPO guideline PP 1/28(3), an assessment conducted on 25-ear-bearing tillers taken randomly per plot at BBCH 71-77 was made based upon the target disease and a *severity index* was calculated.

Assessment was conducted on a 1-4 index where:

1. Healthy: no symptoms
2. slight lesions: less than 50 % of tiller circumference attacked at place where infection is the most severe, but tissue still firm,
3. Moderate lesions: more than 50 % of tiller circumference attacked at place where infection is most severe, but tissue still firm
4. Severe lesions: 100 % of tiller circumference attacked with tissue rotted (softening)

Additionally, total damage value was calculated by using the following formula:

$$X = \frac{(n(II) \times 0.25) + (n(III) \times 0.75) + n(IV)}{n(I + II + III + IV)}$$

On the base of total damage value, the effectiveness of CA3301 has been calculated thanks to the Abbott formula and the global effectiveness of CA3301 for each use corresponds to the mean of the calculated effectiveness of each individual trial.

- *Disease incidence*: in specific cases, such as the *Blumeria graminis*, the analysis has been conducted on four foliar levels L1 to L4 with the parameter ‘Disease incidence %’. CA3301 is

expected to **reduce disease incidence** in comparison to the untreated control.

- *Green leaf area*: for each individual trial, the percentage of recorded Green Leaf Area was calculated relative to the untreated control (UTC = 100%). Then, the mean of the %UTC for each trial was calculated for each treatment. CA3301 is expected to **increase green leaf area** in comparison to the untreated control

The **crop safety** of CA3301 was evaluated by assessing several parameters (not included in all trials):

- Phytotoxicity in %
- Yield in t/ha or %UNCK when the T/ha data were not available
- Vigor in % or index 0-10
- Moisture content in %
- Oil content in %, Oilseed rape uses only
- Thousand Kernel Weight (TKW) in g/1000 grains
- Hectoliter Weight (HLW) in kg/hl
- Toxins analysis: Deoxynivalenol (DON) in PPB, Nivalenol (NIV) in PPB, T-2 mycotoxin (T-2) in PPB, HT-2 mycotoxin (HT-2) in PPB. *Fusarium* uses only.

Data relative to those parameters will be presented in the appropriate chapter of the section KCP 6.4 “Adverse effects on treated crops”.

Validity of trials

Only agronomically valid assessments are presented in this dossier.

One assessment is considered valid when:

- There has been no major deviation from the GAP table;
- Crops at application were within the GAP table growth stage ranges;
- The reference product performed as expected
- The disease infestation reach at least 5% in the untreated check (1% for the *Fusarium* species)

Statistical analysis – Individual trial results

Data were analyzed by the ARM program, using two-way analysis of variance (ANOVA) on untransformed and transformed raw data. The probability of no significant difference occurring between treatment's means was calculated as the F probability value $pF=0.05$ (95% confidence limit).

In all trials, Student-Newman and Keuls' test (noted N&K in the efficacy table included in Appendix 5 of this dossier) was then applied to assess any treatment differences identified on the basis of the ANOVA test.

Results obtained are indicated by a letter. Treatment's means with no letter in common are significantly different in accordance with a Student-Newman and Keuls' or Least Significant Difference test conducted at a 95% confidence level.

The ANOVA assumption of homogeneity of variance has been checked using a Bartlett's chi-square test. In case of non-respect of these assumptions, data were transformed using traditional ways such as $\log(x)$ or $\sqrt[3]{x}$. When data were transformed, treatment's means are presented untransformed in the trial report, with the appropriate letter test derived from the transformed ANOVA.

The tabulated data presented in this biological assessment dossier only represent the means of selected treatments, within an assessment. However, the statistics presented in conjunction with these data are derived from all data points from all treatments within the assessment. Tables of data comprising all treatments means are presented in each individual trial report summaries.

Data selection and groupings

In addition to the presentation of the individual trial results of the valid assessments, data groupings combining the results of one assessment type were also performed. This allowed giving an overall evaluation of the products efficacy throughout several test conditions.

Evaluation of CA3301 efficacy will be conducted with the analysis of the following parameters:

- **Disease severity (%) (or disease incidence (%)).** Assessment timing selected are around 2 weeks after the 2nd application and before harvest (last assessment date). For each individual trial, the effectiveness of CA3301 will be calculated thanks to the Abbott formula and the global effectiveness of CA3301 for each use corresponds to the mean of the calculated effectiveness of each individual trial. These assessment timings will be used for efficacy evaluation and for minimum effective dose evaluation.
- **Green leaf area (%)** and the % compared to the untreated control. In most instances, green leaf area was recorded in a single assessment by trial, usually at the last assessment before harvest. Therefore, a single data grouping for average calculation will be made for the green leaf area. As is also the case for efficacy evaluation, the mean values summarised are the average of the calculated value of each individual trial.

Data groupings will be organized by crop, by disease and then by EPPO zone. Regarding to cereal crops, the data groupings will primarily target foliar levels 1 and 2 as they are the most important foliar levels responsible for providing the photosynthetic products for grain filling. Moreover, regarding to oilseed rape, the groupings will target leaves, stem, pods and roots since all parts can be attacked by several diseases. Data groupings for the green leaf area will be organised by EPPO zone.

Data groupings will be performed thanks to an add-in option of the ARM program: ARM ST (Summary Across Trials). This tool combines and averages similar assessments in ARM trials across locations and years. It can therefore provide tables presenting the individual results from each trial (with the corresponding letters from N&K test) as well as data grouping calculations. For each data grouping, several calculations are presented:

- Number of values
- Minimum disease severity or incidence in % (or % green leaf area)
- Maximum disease severity or incidence in % (or % green leaf area)
- Mean
- Mean Abbott efficacy in % (or %UTC for the green leaf area) : calculated from each individual trial

Three other types of information were also recorded and reported in the data grouping tables:

- For minimum effective dose evaluation: number of trials where CA3301 at N dose is significantly more efficient (>), statistically equivalent (=) or significantly less efficient (<) compared to CA3301 applied at another rate
- For efficacy evaluation: number of trials where CA3301 at N dose is significantly more efficient (>), statistically equivalent (=) or significantly less efficient (<) compared to UTC
- For efficacy evaluation: number of trials where CA3301 at N dose is significantly more efficient (>), statistically equivalent (=) or significantly less efficient (<) compared to reference product

For clarity, where the term “significant” is used, this means statistically significant according to the calculations.

3.2.3.1 Winter barley (HORVW) / *Ramularia collo-cygni* (RAMUCC)

Materials and Methods – Winter barley - RAMUCC

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2017 and 2020, a series of 52 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the efficacy of CA3301 against *Ramularia collo-cygni* on winter barley (see Table 3.2-218). The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, a total of 17 trials were performed in Denmark (1), France (6), Germany (7) and the United Kingdom (3).

In the Mediterranean EPPO zone, a total of 19 trials were performed in France (15) and Spain (4).

In the North-Eastern East EPPO zone, a total of 7 trials were performed in Latvia (2) and Poland (5).

In the South-Eastern East EPPO zone, a total of 9 trials were performed in Hungary (2), Romania (2) and Slovakia (5).

Data groupings were also made specifically for Poland evaluation and trials involved (19) were performed in the North-Eastern East EPPO zone (7), in Germany (7) and in Slovakia (5).

Table 3.2-218: Presentation of trials – Winter barley (HORVW) - RAMUCC

Crop(s)) *	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Winter barley	RAMUCC	Denmark	2018	MED + E	1 (0)	-	-	-	GEP	
		France (N)	2019- 2020	MED + E	6 (4)	-	-	-	GEP	
		Germany	2019- 2012 0	MED + E	7 (6)	-	-	-	GEP	
		United Kingdo m	2019- 2020	MED + E	3 (2)	-	-	-	GEP	
Winter barley	RAMUCC	France (S)	2019- 2020	MED + E	-	15 (11)	-	-	GEP	
		Spain	2019- 2020	MED + E	-	4 (3)	-	-	GEP	
Winter barley	RAMUCC	Latvia	2020	MED + E	-	-	2 (2)	-	GEP	
		Poland	2017- 2020	MED + E	-	-	5 (1)	-	GEP	
Winter barley	RAMUCC	Hungary	2017	MED + E	-	-	-	2 (2)	GEP	
		Romania	2020	MED + E	-	-	-	2 (2)	GEP	
		Slovakia	2020	MED + E				5 (5)	GEP	

Crop(s)) *	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
TOTAL	-	-	2017 - 2020	MED + E	17 (12)	19 (14)	7 (3)	9 (9)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

In all trials, CA3301 was compared to at least one commercial and registered fungicide used as standard reference for comparison.

Table 3.2-219: Efficacy evaluation - Presentation of reference standards used in trials – Winter barley (HORVW) – RAMUCC – Maritime EPPO zone

Crop(s))	Refer- ence standard	Country(ies) where the product is used ⁽¹⁾	Authoriza- tion number	Active sub- stance(s)	Formulation		Regis- tered ap- plication rate ⁽³⁾	Applica- tion rate in tri- als (per treat- ment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concentra- tion of a.s.			
Winter barley	JOAO	FR (N)	2060116	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO- LINE 275	UK	14790	Prothiocona- zole	EC	275 g/l	2 x 0.72 l/ha	2 x 0.72 l/ha	
	CA2445	UK	12084	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO- LINE	DE	025287-00	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO- LINE 250 EC	DK	18-473	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

Table 3.2-220: Efficacy evaluation - Presentation of reference standards used in trials – Winter barley (HORVW) – RAMUCC – Mediterranean EPPO zone

Crop(s))	Refer- ence standard	Country(ies) where the product is used ⁽¹⁾	Authoriza- tion number	Active sub- stance(s)	Formulation		Regis- tered ap- plication rate ⁽³⁾	Applica- tion rate in tri- als (per treat- ment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concentra- tion of a.s.			
Winter barley	JOAO	FR (S)	2060116	Prothiocona- zole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials
	PRAK- TIS	ES	01135	Prothiocona- zole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
	PRO-SARO	ES	25661	Prothioconazole + Tebuconazole	EC	125 g/l + 125 g/l	1 l/ha	1 l/ha	

Table 3.2-221: Efficacy evaluation - Presentation of reference standards used in trials – Winter barley (HORVW) – RAMUCC – North-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter barley	PRAKTIS	PL	R-222/2019	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.6-0.8 l/ha	CA2445 in some trials
	PRO-LINE	LV	0637	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

Table 3.2-222: Efficacy evaluation - Presentation of reference standards used in trials – Winter barley (HORVW) – RAMUCC – South-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter barley	PRO-LINE	HU	6300/1205-1/2020	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.6-0.8 l/ha	CA2445 in some trials
	PRO-LINE	RO	457PC/15.11.2018	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE 250 EC	SK	06-02-0768	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRI-AXOR	SK	16-02-1746	Fluxapyroxad Pyraclostrobin	EC	225 g/l	2 x 0.75-1.5 l/ha	2 x 1.5 l/ha	

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-223.

Table 3.2-223: Details on trial methodology – Winter barley (HORVW) - RAMUCC

Maritime EPPO zone	Mediterranean EPPO zone	North-Eastern EPPO zone	South-Eastern EPPO zone	Data relevant for Poland
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Trials	Total number (valid number)	17 (12)	19 (14)	7 (3)	9 (9)	19 (14)
	Supportive trials	-	-	-	-	
Guidelines	General guidelines	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)
	Specific guidelines	PP 1/26(4)	PP 1/26(4)	PP 1/26(4)	PP 1/26(4)	PP 1/26(4)
Experimental design	Plot design	Randomized complete blocks, Un-treated included	Randomized complete blocks, Un-treated included	Randomized complete blocks, Un-treated included	Randomized complete blocks, Un-treated included	Randomized complete blocks, Un-treated included
	Plot size	20.79-30 m ²	20-24 m ²	21-30 m ²	21-30 m ²	21-30 m ²
	Number of replications	4	4	4	4	4
Crop	Trials per crop	Winter barley (17)	Winter barley (19)	Winter barley (7)	Winter barley (9)	Winter barley (19)
	Varieties per crop	Bazooka (1), Meridian (2), Sandra (1), KWS Orwell (2), Etincel (3), Etincelle (1), SU Ellen (1), SU Vireni (1), Tonic (1), Kosmos (1), Kingsbam (1), Maltesse (1), KWS Jaguar (1)	Ordinale (1), Etincel (3), California (1), Hi-rondella (1), Meseta (1), Maltesse (2), Basic (2), KWS Infinity (1), Rafaella (3), Margaux (1), Amistar (1), Borrelly (1), Solist (1)	Sandra (1), Hobbit (1), Kosmos (1), Zenek (1), Meridian (1), Gloria (1), KWS Tenor (1)	Larverda (1), KWS Gigga (1), Ametist (1), Bravo (1), LG Triumph (3), Jup (2)	Sandra (2), Hobbit (1), Kosmos (1), Zenek (1), Meridian (3), Gloria (1), KWS Tenor (1), LG Triumph (3), Jup (2), SU Ellen (1), SU Vireni (1), Tonic (1), Kosmos (1)
	Sowing period	September (8), October (6), November (2), NA (1)	October (11), November (3), December (4), January (1)	September (6), October (1)	October (9)	September (10), October (9)
Application	Crop stage (BBCH)* at application	A: BBCH 30-37 B: BBCH 39-61	A: BBCH 32-39 B: BBCH 45-61	A: BBCH 31-39 B: BBCH 45-61	A: BBCH 31-39 B: BBCH 49-63	A: BBCH 31-39 B: BBCH 45-61
	Timing Disease stage at application	BBCH 30-61 A: PRINFC (15), MIXED (2) B: PRINFC (11), MIXED (6)	BBCH 30-61 A: PRINFC (16), MIXED (2) B: PRINFC (12), MIXED (6), NA (1)	BBCH 30-61 A: PRINFC (3), MIXED (1), NA (3) B: PRINFC (3), MIXED (1), NA (3)	BBCH 30-61 A: PRINFC (7), MIXED (2) B: PRINFC (3), MIXED (6)	BBCH 30-61 A: PRINFC (15), MIXED (1), NA (3) B: PRINFC (12), MIXED (4), NA (3)
	Number of applications Intervals between applications	2 applications (14-35 days) (17)	1 application (1) 2 applications (14-40 days) (18)	2 applications (9-34 days) (7)	2 applications (10-32 days) (9)	2 applications (9-34 days) (19)
	Spray volumes	200-300 l/ha	182-400 l/ha	200-300 l/ha	200-300 l/ha	200-300 l/ha
Assessment	Assessment types	Disease severity (%), Disease incidence (%),	Disease severity (%), Disease incidence (%),	Disease severity (%), Disease incidence (%),	Disease severity (%), Disease incidence (%),	Disease severity (%), Disease incidence (%),

		Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)
	Assessment dates	-1-0 DA-A; 13-15 DA-A; 21 DA-A 0 DA-B; 14-17 DA-B; 25-57 DA-B; 60-84 DA-B	0 DA-A; 13-16 DA-A 0-1 DA-B; 13-20 DA-B; 23-58 DA-B; 62-91 DA-B	-2-0 DA-A; 14-18 DA-A, 32 DA-A 0 DA-B; 13-16 DA-B; 22-49 DA-B	0 DA-A; 14-15 DA-A 0 DA-B; 14-15 DA-B; 25-51 DA-B	-2-0 DA-A; 14-18 DA-A, 32 DA-A 0 DA-B; 13-16 DA-B; 22-52 DA-B, 60-70 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Natural (17)	Natural (19)	Natural (7)	Natural (9)	Natural (19)
	e.g. Field / Greenhouse...	Field trials	Field trials	Field trials	Field trials	Field trials

Out of the 52 trials performed on winter barley against *Ramularia collo-cygni*, 38 were considered valid.

Use of CA3301 at 2x 0.6 l/ha against RAMUCC - Maritime EPPO zone

In the Maritime EPPO zone, a total of 17 trials evaluated the efficacy of CA3301 on winter barley against *Ramularia collo-cygni*. 12 trials out of 17 were considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 30-37 and the 2nd application was at BBCH 39-61. The analysis was conducted on foliar level 1 and foliar level 2.

Summary results are presented in Table 3.2-224.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the reduction of disease severity on winter barley against *Ramularia collo-cygni*. On foliar level 2, CA3301 at 0.6 l/ha showed 68.67% mean efficacy over 12 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 70.16% efficacy on reduction of disease severity over 11 trials before harvest.

In the Maritime EPPO zone, CA3301 at 0.6 l/ha provided medium to high efficacy in reducing the severity of *Ramularia collo-cygni* on winter barley at the last assessment timing, on both main foliar levels 1 (L1) and 2 (L2). In all assessments, at the proposed dose rate the tested product gave equivalent or higher disease control compared to the authorized reference products PROLINE 275 and CA2445 applied at a higher rate of prothioconazole, except in 1 trial on L2. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient to provide an acceptable control against *Ramularia collo-cygni*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Ramularia collo-cygni* on winter barley in the Maritime EPPO zone.

Table 3.2-224: Summary table - Efficacy evaluation – Winter barley – RAMUCC - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA2445	PROLINE 275	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	0,72	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
% Disease severity L2 - 24-51 DA-B					
Number of values	12			12	UTC
Minimum value	6,80			2,46	
Maximum value	100,00	-	-	24,11	12 >
Mean disease severity (%)	37,91			9,16	0 =
Abbott efficacy (%)	0,00%			68,67%	0 <
Number of values	11	11		11	CA2445
Minimum value	6,80	1,38		2,46	0,8 l/ha
Maximum value	100,00	15,05	-	24,11	0 >
Mean disease severity (%)	39,54	7,11		8,83	10 =
Abbott efficacy (%)	0,00%	75,79%		70,92%	1 <
Number of values	1		1	1	PROLINE 275
Minimum value	19,96		6,89	11,20	0,72 l/ha
Maximum value	19,96	-	6,89	11,20	0 >
Mean disease severity (%)	19,96		6,89	11,20	1 =
Abbott efficacy (%)	0,00%		65,48%	43,89%	0 <
% Disease severity L1 - 24-51 DA-B					
Number of values	11			11	UTC
Minimum value	5,70			0,71	
Maximum value	100,00	-	-	22,63	10 >
Mean disease severity (%)	29,52			7,21	1 =
Abbott efficacy (%)	0,00%			70,16%	0 <
Number of values	10	10		10	CA2445
Minimum value	5,70	0,81		0,71	0,8 l/ha
Maximum value	100,00	23,25	-	22,63	2 >
Mean disease severity (%)	31,21	7,28		7,21	8 =
Abbott efficacy (%)	0,00%	70,95%		71,97%	0 <
Number of values	1		1	1	PROLINE 275
Minimum value	12,63		5,08	6,06	0,72 l/ha
Maximum value	12,63	-	5,08	6,06	0 >
Mean disease severity (%)	12,63		5,08	6,06	1 =
Abbott efficacy (%)	0,00%		59,78%	52,02%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against RAMUCC - Mediterranean EPPO zone

In the Mediterranean EPPO zone, a total of 19 trials evaluated the efficacy of CA3301 on winter barley against *Ramularia collo-cygni*. 15 trials out of 19 were considered valid and 14 enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference products on disease severity (%). One trial (EU20-037-39) was valid but tested CA3301 applied only once.

CA3301 was first applied at crop stages BBCH 32-39 and the 2nd application was at BBCH 45-61. The analysis was conducted on foliar level 1 and foliar level 2.

Summary results are presented in Table 3.2-225.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the reduction of disease severity on winter barley against *Ramularia collo-cygni*. On foliar level 2, CA3301 at 0.6 l/ha showed 90.95% efficacy over 5 trials two weeks after the 2nd application and 69.14% over 12 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 96.23% efficacy over 3 trials on reduction of disease severity around two weeks after the 2nd application and 62.17% over 13 trials before harvest.

In the Mediterranean EPPO zone, CA3301 at 0.6 l/ha provided medium to high efficacy in reducing the severity of *Ramularia collo-cygni* on winter barley two weeks after the 2nd application and at the last assessment timing, on both main foliar levels 1 (L1) and 2 (L2). CA3301 applied at the proposed dose rate consistently gave equivalent disease control to the authorized reference product PROSARO at 1 l/ha. Compared to CA2445 (applied at a higher rate of prothioconazole), CA3301 most frequently gave comparable disease control, whilst in 2 assessments control was lower but in 6 assessments control was higher. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient to provide acceptable levels of control against *Ramularia collo-cygni*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Ramularia collo-cygni* on winter barley in the Mediterranean EPPO zone.

Table 3.2-225: Summary table - Efficacy evaluation – Winter barley – RAMUCC - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA2445	PROSARO	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	1	0,6		
Rate unit		L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB		
% Disease severity L2 - 13-18 DA-B						
Number of values	5	5		5	UTC	CA2445
Minimum value	15,40	0,25		0,44		0,8 l/ha
Maximum value	44,13	7,00	-	5,88	5 >	0 >
Mean disease severity (%)	31,49	2,90		2,79	0 =	5 =
Abbott efficacy (%)	0,00%	90,37%		90,95%	0 <	0 <
Number of values	2	2	2	2	PROSARO	
Minimum value	38,06	0,25	0,25	0,44	1 l/ha	
Maximum value	44,13	7,00	11,19	5,88	0 >	
Mean disease severity (%)	41,10	3,63	5,72	3,16	2 =	
Abbott efficacy (%)	0,00%	90,52%	85,02%	91,78%	0 <	
% Disease severity L1 - 17-18 DA-B						
Number of values	3	3		3	UTC	CA2445
Minimum value	12,78	0,13		0,06		0,8 l/ha
Maximum value	29,19	1,50	-	1,06	3 >	0 >
Mean disease severity (%)	21,07	0,76		0,63	0 =	3 =
Abbott efficacy (%)	0,00%	95,78%		96,23%	0 <	0 <
Number of values	2	2	2	2	PROSARO	
Minimum value	21,25	0,13	0,00	0,06	1 l/ha	
Maximum value	29,19	1,50	3,75	1,06	0 >	
Mean disease severity (%)	25,22	0,82	1,88	0,56	2 =	
Abbott efficacy (%)	0,00%	96,25%	91,18%	97,40%	0 <	
% Disease severity L2 - 23-36 DA-B						
Number of values	12			12	UTC	
Minimum value	8,09			0,35		
Maximum value	100,00	-	-	78,35	11 >	
Mean disease severity (%)	69,10			26,31	1 =	
Abbott efficacy (%)	0,00%			69,14%	0 <	
Number of values	11	11		11	CA2445	
Minimum value	8,09	0,15		0,35	0,8 l/ha	
Maximum value	100,00	71,90	-	78,35	3 >	
Mean disease severity (%)	74,48	30,36		28,62	8 =	
Abbott efficacy (%)	0,00%	64,09%		67,19%	0 <	
Number of values	3		3	3	PROSARO	

Treatment name	UNTREATED CHECK	CA2445	PROSARO	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	1	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
Minimum value	9,95		1,30	0,94	1 l/ha
Maximum value	98,00	-	6,50	75,13	0 >
Mean disease severity (%)	62,28		36,60	40,15	3 =
Abbott efficacy (%)	0,00%		55,36%	52,54%	0 <
% Disease severity L1 - 23-36 DA-B					
Number of values	13			13	UTC
Minimum value	5,28			0,41	
Maximum value	100,00	-	-	72,00	12 >
Mean disease severity (%)	63,07			26,32	1 =
Abbott efficacy (%)	0,00%			62,17%	0 <
Number of values	12	12		12	CA2445
Minimum value	6,10	0,23		0,41	0,8 l/ha
Maximum value	100,00	57,04	-	72,00	3 >
Mean disease severity (%)	67,89	28,42		28,40	7 =
Abbott efficacy (%)	0,00%	56,81%		61,24%	2 <
Number of values	3		3	3	PROSARO
Minimum value	5,28		0,41	1,41	1 l/ha
Maximum value	89,75	-	56,63	66,50	0 >
Mean disease severity (%)	60,64		33,76	40,43	3 =
Abbott efficacy (%)	0,00%		59,25%	45,76%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against RAMUCC - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 7 trials evaluated the efficacy of CA3301 on winter barley against *Ramularia collo-cygni*. 3 trials out of 7 were considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 31-39 and the 2nd application was at BBCH 45-61. The analysis was conducted on foliar level 1 and foliar level 2.

Summary results are presented in Table 3.2-226.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the reduction of disease severity on winter barley against *Ramularia collo-cygni*. On foliar level 2, CA3301 at 0.6 l/ha showed 34.79% efficacy over 2 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 54.74% efficacy in a single trial on reduction of disease severity before harvest.

In the North-Eastern East EPPO zone, due to the limited occurrence of this disease in the zone, a limited dataset was available to support the evaluation of CA3301 against *Ramularia collo-cygni*. However, this situation is representative of a relatively low to medium disease pressure and show the performance of the tested product in these conditions, and compared to authorised products. CA3301 at 0.6 l/ha gave comparable disease control compared to CA2445 applied at the same dose rate of 150 g/ha prothioconazole in all trials, and also compared to the higher rate of 0.8 l/ha, except in 1 trial assessing L1. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient to provide acceptable levels of control against *Ramularia collo-cygni*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Ramularia collo-cygni* on winter barley in the North-Eastern East EPPO zone.

Table 3.2-226: Summary table - Efficacy evaluation – Winter barley – RAMUCC – North-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA2445	CA2445	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
Rate		0,6	0,8	0,6			
Rate unit		L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB			
% Disease severity L2 - 22-29 DA-B							
Number of values	2		2	2	UTC	CA2445	CA2445
Minimum value	14,00		9,38	10,13		0,6 l/ha	0,8 l/ha
Maximum value	23,25	-	14,63	13,50	2 >		0 >
Mean disease severity (%)	18,63		12,00	11,81	0 =	-	2 =
Abbott efficacy (%)	0,00%		35,04%	34,79%	0 <		0 <
% Disease severity L1 - 27 DA-B							
Number of values	1	1	1	1	UTC	CA2445	CA2445
Minimum value	12,46	6,05	4,65	5,64		0,6 l/ha	0,8 l/ha
Maximum value	12,46	6,05	4,65	5,64	1 >	0 >	0 >
Mean disease severity (%)	12,46	6,05	4,65	5,64	0 =	1 =	0 =
Abbott efficacy (%)	0,00%	51,44%	62,68%	54,74%	0 <	0 <	1 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against RAMUCC - South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 9 trials evaluated the efficacy of CA3301 on winter barley against *Ramularia collo-cygni*. All 9 trials were considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 31-39 and the 2nd application was at BBCH 49-63. The analysis was conducted on foliar level 1 and foliar level 2.

Summary results are presented in Table 3.2-227.

On foliar level 2, CA3301 at 0.6 l/ha showed 85.78% efficacy over 3 trials against *Ramularia collo-cygni* two weeks after the 2nd application and 82.48% over 9 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 82.31% efficacy over 6 trials on reduction of disease severity before harvest.

In the South-East EPPO zone, CA3301 at 0.6 l/ha provided medium to high efficacy in reducing the severity of *Ramularia collo-cygni* on winter barley 2 weeks after the 2nd application and at the last assessment timing, on both main foliar levels 1 (L1) and 2 (L2). In all trials the proposed dose rate of CA3301 significantly reduced disease severity. CA3301 at 0.6 l/ha (150 g/ha of Prothioconazole) gave equivalent disease control compared to the authorized reference product CA2445 applied at the same dose rate but in some instances gave lower disease control than CA2445 applied at the higher rate of 0.8 l/ha (200 g/ha of Prothioconazole) and PRIAXOR which is an authorized reference product with different active substances (150g/ha of Fluxapyroxad and 300g/ha of Pyraclostrobin) and modes of action. However, despite some significant differences with CA2445 at the higher rate of 0.8 l/ha, the numerical differences in mean disease severity between CA2445 and CA3301 did not exceed 5% and the mean averaged efficacies remained higher than 80%. Therefore, CA3301 at 0.6 l/ha provided high efficacy and it is envisaged that in most instances applications of 0.6 l/ha will be sufficient to provide acceptable levels of control against *Ramularia collo-cygni*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Ramularia collo-cygni* on winter barley in the South-Eastern East EPPO zone.

Table 3.2-227: Summary table - Efficacy evaluation – Winter barley – RAMUCC – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA2445	CA2445	PRIAXOR	CA3301	No of trials where CA3301 at 0,6 l/ha is >, =, or < compared to	
Rate		0,6	0,8	1,5	0,6		
Rate unit		L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	AB		
% Disease severity L2 - 15 DA-B							
Number of values	3		3	3	3	UTC	CA2445 0,8 l/ha
Minimum value	7,76		0,55	0,14	0,93		PRIAXOR
Maximum value	9,36	-	1,15	0,50	1,34	3 >	0 >
Mean disease severity (%)	8,38		0,84	0,34	1,19	0 =	0 =
Abbott efficacy (%)	0,00%		90,18%	96,04%	85,78%	0 <	3 <
% Disease severity L2 - 25-34 DA-B							
Number of values	9		9		9	UTC	CA2445 0,8 l/ha
Minimum value	6,49		0,16		0,06		
Maximum value	65,81	-	16,06	-	23,55	9 >	0 >
Mean disease severity (%)	27,51		5,81		6,65	0 =	4 =
Abbott efficacy (%)	0,00%		82,53%		82,48%	0 <	5 <
Number of values	5		5	5	5	PRIAXOR 1,5 l/ha	
Minimum value	19,81		3,81	1,68	4,66		
Maximum value	65,81	-	16,06	11,31	23,55	0 >	
Mean disease severity (%)	38,78		8,29	5,48	10,63	0 =	
Abbott efficacy (%)	0,00%		79,70%	80,08%	74,66%	5 <	
Number of values	2	2	2		2	CA2445 0,6 l/ha	
Minimum value	12,64	1,34	1,73		0,78		
Maximum value	26,99	6,64	8,44	-	5,68	0 >	
Mean disease severity (%)	19,82	3,99	5,09		3,23	2 =	
Abbott efficacy (%)	0,00%	89,40%	77,52%		86,39%	0 <	
% Disease severity L1 - 25-34 DA-B							
Number of values	6		6		6	UTC	CA2445 0,8 l/ha
Minimum value	7,64		0,76		0,31		
Maximum value	47,50	-	11,03	-	15,93	6 >	0 >
Mean disease severity (%)	21,66		3,76		4,97	0 =	0 =
Abbott efficacy (%)	0,00%		85,72%		82,31%	0 <	5 <
Number of values	5		5	5	5	PRIAXOR 1,5 l/ha	
Minimum value	8,04		0,78	0,53	1,23		
Maximum value	47,50	-	11,03	6,83	15,93	0 >	
Mean disease severity (%)	24,47		4,36	2,39	5,91	1 =	
Abbott efficacy (%)	0,00%		84,85%	88,97%	79,58%	5 <	
Number of values	1	1	1		1	CA2445 0,6 l/ha	
Minimum value	7,64	0,53	0,76		0,31		
Maximum value	7,64	0,53	0,76	-	0,31	0 >	
Mean disease severity (%)	7,64	0,53	0,76		0,31	1 =	
Abbott efficacy (%)	0,00%	93,06%	90,05%		95,94%	0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against RAMUCC - Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, a total of 19 trials from the North-Eastern East EPPO zone and the neighbouring countries Germany and Slovakia evaluated the efficacy of CA3301 on winter barley against *Ramularia collo-cygni*. 14 trials were considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 31-39 and the 2nd application was at BBCH 45-61. The analysis was conducted on foliar level 1 and foliar level 2.

Summary results are presented in

Table 3.2-228.

On foliar level 2, CA3301 at 0.6 l/ha showed 85.78% efficacy over 3 trials against *Ramularia collo-cygni* two weeks after the 2nd application and 64.21% over 13 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 72.63% efficacy over 12 trials on reduction of disease severity before harvest. In all assessments CA3301 at the proposed dose rate significantly reduced the severity of *Ramularia collo-cygni*.

Over this dataset which is relevant for Poland, CA3301 at 0.6 l/ha provided medium to high efficacy in reducing the severity of *Ramularia collo-cygni* on winter barley 2 weeks after the 2nd application and at the last assessment timing, on both main foliar levels 1 (L1) and 2 (L2). CA3301 at 0.6 l/ha (150 g/ha of prothioconazole) gave equivalent disease control to CA2445 at 0.6 l/ha but compared to CA2245 applied at higher rate (200 g/ha of prothioconazole), this performance was more mitigated since the tested product provided either higher, equivalent or lower efficacy. In addition, CA3301 gave also lower disease control than PRIAXOR, an authorized reference product with different active substances (150g/ha of Fluxapyroxad and 300g/ha of Pyraclostrobin) and modes of action. However, despite significant differences with CA2445 at the higher rate of 0.8 l/ha, the overall numerical differences in mean disease severity between CA2445 and CA3301 did not exceed 5%. Therefore, CA3301 at 0.6 l/ha provided an expected behaviour and it is envisaged that in most instances applications of 0.6 l/ha will be sufficient to provide acceptable control against *Ramularia collo-cygni*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Ramularia collo-cygni* on winter barley in Poland.

Table 3.2-228: Summary table - Efficacy evaluation – Winter barley – RAMUCC – Data relevant for Poland

Treatment name	UNTREATED CHECK	CA244 5	CA244 5	PRIAXO R	CA330 1	No of trials where CA3301	
Rate		0,6	0,8	1,5	0,6	at 0,6 l/ha is >, = or <	
Rate unit		L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	AB	compared to	
% Disease severity L2 - 15 DA-B							
Number of values	3		3	3	3	UT C	CA2445 0,8 l/ha PRIAXOR
Minimum value	7,76		0,55	0,14	0,93		
Maximum value	9,36	-	1,15	0,50	1,34	3 >	0 >
Mean disease severity (%)	8,38		0,84	0,34	1,19	0 =	0 =
Abbott efficacy (%)	0.00%		90.18%	96.04%	85.78%	0 <	3 <

% Disease severity L2 - 22-51 DA-B							
Number of values	13		13		13	UT	CA2445
Minimum value	6,80		1,38		2,46	C	0,8 l/ha
Maximum value	100,00	-	16,06	-	23,55	13 >	0 >
Mean disease severity (%)	31,78		7,95		8,93	0 =	7 =
Abbott efficacy (%)	0,00%		67,65%		64,21%	0 <	6 <
Number of values	5		5	5	5	PRIAXOR	
Minimum value	19,81		3,81	1,68	4,66	1,5 l/ha	
Maximum value	65,81	-	16,06	11,31	23,55	0 >	
Mean disease severity (%)	38,78		8,29	5,48	10,63	0 =	
Abbott efficacy (%)	0,00%		79,70%	86,42%	74,66%	5 <	
% Disease severity L1 - 27-51 DA-B							
Number of values	12		12		12	UT	CA2445
Minimum value	5,70		0,78		1,23	C	0,8 l/ha
Maximum value	100,00	-	23,25	-	19,83	12 >	2 >
Mean disease severity (%)	28,67		6,79		6,37	0 =	4 =
Abbott efficacy (%)	0,00%		72,09%		72,63%	0 <	6 <
Number of values	5		5	5	5	PRIAXOR	
Minimum value	8,04		0,78	0,53	1,23	1,5 l/ha	
Maximum value	47,50	-	11,03	6,83	15,93	0 >	
Mean disease severity (%)	24,47		4,36	2,39	5,91	0 =	
Abbott efficacy (%)	0,00%		84,85%	91,80%	79,58%	5 <	
Number of values	1	1	1		1	CA2445	
Minimum value	12,46	6,05	4,65		5,64	0,6 l/ha	
Maximum value	12,46	6,05	4,65	-	5,64	0 >	
Mean disease severity (%)	12,46	6,05	4,65		5,64	1 =	
Abbott efficacy (%)	0,00%	51,44%	62,68%		54,74%	0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

12 valid trials were conducted in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,6 l/ha achieved medium efficacy after 24-51 days after second application.

3 valid trials were available in **the North-East EPPO zone**. A very low level of control was presented after application of the test product (34,79-54,74%). Also 11 trials from the neighbouring countries (Germany and Slovakia) have been included to the overall calculation to support of Polish registration. Taking into account all results, CA3301 at 0,6 l/ha achieved medium to high efficacy after 15-51 DA-B. Because a high level of control was noted in only 3 out of 14 trials, medium efficacy can be recommended in Poland.

9 valid trials were carried out in **the South-East EPPO zone**. The test product at 0,6 l/ha showed high level of control after 15-34 days after second application. Moreover, 13 additional trials from the Mediterranean zone have been submitted. The results presented medium to high efficacy of CA3301 but significant better results were noted 13-18 DA-B (>90%).

Taking into account all trials, CA3301 used in 2 applications can be recommended to control of *Ramularia collo-cygni* in winter barley. No significant differences between test and reference product have been noted.

3.2.3.2 Winter barley (HORVW) / *Puccinia hordei* (PUCCHD)

Materials and Methods – Winter barley - PUCCHD

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2018 and 2020, a series of 59 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the efficacy of CA3301 against *Puccinia hordei* on winter barley (see Table 3.2-229). The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, a total of 17 trials were performed in the Czech Republic (1), Denmark (2), France (5), Germany (7) and the United Kingdom (2).

In the Mediterranean EPPO zone, a total of 7 trials were performed in France (3) and Spain (4).

In the North-eastern East EPPO zone, a total of 22 trials were performed in Latvia (7), Lithuania (1) and Poland (14).

In the South-eastern East EPPO zone, a total of 13 trials were performed in Bulgaria (2), Hungary (8), Romania (2) and Slovakia (1).

Table 3.2-229: Presentation of trials – Winter barley (HORVW) - PUCCHD

Crop(s) *)	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, offi- cial***	Comments (any other relevant in- formation)
					Mar- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Winter barley	PUCCHD	Czech Republic	2020	MED + E	1 (0)	-	-	-	GEP	
		Denmark	2018	MED + E	2 (0)	-	-	-	GEP	
		France (N)	2019- 2020	MED + E	5 (3)	-	-	-	GEP	
		Germany	2019- 2020	MED + E	7 (4)	-	-	-	GEP	
		United Kingdom	2019- 2020	MED + E	2 (2)	-	-	-	GEP	
Winter barley	PUCCHD	France (S)	2019- 2020	MED + E	-	3 (0)	-	-	GEP	
		Spain	2019- 2020	MED + E	-	4 (3)	-	-	GEP	
Winter barley	PUCCHD	Latvia	2019- 2020	MED + E	-	-	7 (3)	-	GEP	
		Lithuani a	2019	MED + E	-	-	1 (1)	-	GEP	
		Poland	2019- 2020	MED + E	-	-	14 (4)	-	GEP	
Winter barley	PUCCHD	Bulgaria	2018- 2019	MED + E	-	-	-	2 (1)	GEP	
		Hungary	2019- 2020	MED + E	-	-	-	8 (6)	GEP	
		Romania	2020	MED	-	-	-	2 (2)	GEP	

Crop(s)) *	Tar- get(s)*	Country	Year s	Type of trial*	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
				+ E						
		Slovakia	2020	MED + E				1 (1)	GEP	
TOTAL	-	-	2018- 2020	MED + E	17 (9)	7 (3)	22 (8)	13 (10)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-emergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

In all trials, CA3301 was compared to at least one commercial and registered fungicide used as standard reference for comparison.

Table 3.2-230: Efficacy evaluation - Presentation of reference standards used in trials – Winter barley (HORVW) – PUCCHD – Maritime EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authoriza- tion number	Active sub- stance(s)	Formulation		Regis- tered ap- plication rate ⁽³⁾	Applica- tion rate in tri- als (per treat- ment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concentra- tion of a.s.			
Winter barley	PROLINE 250 EC	CZ	4523-1	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	MIRA- DOR XTRA	CZ	4626-1	Azoxystrobin + cyprocona- zole	SC	280 g/l	2 x 1 l/ha	2 x 1 l/ha	
	JOAO	FR (N)	2060116	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PROLINE 275	UK	14790	Prothiocona- zole	EC	275 g/l	2 x 0.72 l/ha	2 x 0.72 l/ha	
	CA2445	UK	12084	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PROLINE	DE	025287-00	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PROLINE 250 EC	DK	18-473	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

Table 3.2-231: Efficacy evaluation - Presentation of reference standards used in trials – Winter barley (HORVW) – PUCCHD – Mediterranean EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter barley	JOAO	FR (S)	2060116	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRAKTIS	ES	01135	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

Table 3.2-232: Efficacy evaluation - Presentation of reference standards used in trials – Winter barley (HORVW) – PUCCHD – North-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter barley	PRAKTIS	PL	R-222/2019	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	OSIRIS 65 EC	PL	R-87/2012	Epoxiconazole + metconazole	EC	65 g/l	1 x 1.5-2.5 l/ha	2 x 2 l/ha	
	PRO-LINE	LV	0637	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE	LT	AS2-6F(2018) 2019-07-31	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

Table 3.2-233: Efficacy evaluation - Presentation of reference standards used in trials – Winter barley (HORVW) – PUCCHD – South-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter barley	PRI-AXOR	BG	04.2/2426-1/2018	Fluxapyroxad Pyra-clostrobin	EC	225 g/l	N/A	2 x 1.5 l/ha	
	PRO-LINE	HU	6300/1205-1/2020	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRI-AXOR	HU	04.2/4127-1/2016	Fluxapyroxad Pyra-clostrobin	EC	225 g/l	N/A	2 x 1.5 l/ha	

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
	PRO-LINE	RO	457PC/15.11.2018	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE 250 EC	SK	06-02-0768	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRI-AXOR	SK	16-02-1746	Fluxapyroxad Pyraclostrobin	EC	225 g/l	2 x 0.75-1.5 l/ha	2 x 1.5 l/ha	

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-234.

Table 3.2-234: Details on trial methodology – Winter barley (HORVW) - PUCCHD

		Maritime EPPO zone	Mediterranean EPPO zone	North-Eastern EPPO zone	South-Eastern EPPO zone
Trials	Total number (valid number)	17 (9)	7 (3)	22 (8)	13 (10)
	Supportive trials	-	-	-	-
Guidelines	General guidelines	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)
	Specific guidelines	PP 1/26(4)	PP 1/26(4)	PP 1/26(4)	PP 1/26(4)
Experimental design	Plot design	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included
	Plot size	19.635-36 m ²	15-22.5 m ²	21-31.5 m ²	21-30 m ²
	Number of replications	4	4	4	4
Crop	Trials per crop	Winter barley (17)	Winter barley (7)	Winter barley (22)	Winter barley (13)
	Varieties per crop	Bazooka (1), Belfry (1), Su Ellen (1), Kosmos (2), Carat (1), Lomerit (2), Etincelle (1), Etincel (2), Meridian (2), Tonic (1), Hawking (1), Maltesse (2),	California (1), Maltesse (1), Solis (2), Solist R2 (1), Sandra (1), Basic (1),	Kosmos (4), Meridian (6), Zenek (1), KWS Tenor (3), Quantiga (1), Lomerit (1), Titus (1), Mercurioo (1), Arenia (1), Antonella (1), Wootan (1), Melania (1)	Ahat (2), KWS Scala (1), SY Tepee (1), Antonella (1), Etincel (1), KH Tas (1), Laverda (1), Alora (1), Hanzi (1), Jup (2), Saturn (1)
	Sowing period	September (10), October (5), November (1), NA (1)	October (2), November (2), December (1), January (1), NA (1)	August (1), September (20), October (1)	October (8), November (4), NA (1)

Application	Crop stage (BBCH)* at application	A: BBCH 30-53 B: BBCH 39-65	A: BBCH 32-47 B: BBCH 39-59	A: BBCH 31-37 B: BBCH 43-61	A: BBCH 31-39 B: BBCH 41-61
	Timing Disease stage at application	BBCH 30-61 A: PRINFC (8), MIXED (6), ACTIVE (2 NA (1) B: PRINFC (6), MIXED (9), ACTIVE (1), NA (1)	BBCH 30-61 A: PRINFC (3), MIXED (2), SPORUL (2) B: PRINFC (2), MIXED (5)	BBCH 30-61 A: PRINFC (9), MIXED (2), NA (11) B: PRINFC (7), MIXED (4), NA (11)	BBCH 30-61 A: PRINFC (10), MIXED (3) B: PRINFC (7), MIXED (5), SPORUL (1)
	Number of applications Intervals between applications	2 applications (9-31 days) (17)	2 applications (14-27 days) (7)	2 applications (15-49 days) (22)	2 applications (14-35 days) (13)
	Spray volumes	200-300 l/ha	182-400 l/ha	200-300 l/ha	200-300 l/ha
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)
	Assessment dates	-1-1 DA-A; 13-18 DA-A; 21 DA-A 0 DA-B; 5 DA-B, 14-18 DA-B; 24-56 DA-B; 62-91 DA-B	0 DA-A; 13-15 DA-A 0 DA-B; 13-17 DA-B; 23-35 DA-B; 70 DA-B	-2-0 DA-A; 14-18 DA-A, 32 DA-A 0 DA-B; 13-17 DA-B; 22-52 DA-B 59-89 DA-B	0 DA-A; 15 DA-A, 28 DA-A 0 DA-B; 14-16 DA-B; 21-66 DA-B, 71-107 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Natural (17)	Natural (7)	Natural (22)	Natural (13)
	e.g. Field / Greenhouse...	Field trials	Field trials	Field trials	Field trials

Out of the 59 trials performed on winter wheat against *Puccinia hordei*, 30 were considered valid.

Use of CA3301 at 2x 0.6 l/ha against PUCCHD - Maritime EPPO zone

In the Maritime EPPO zone, a total of 17 trials evaluated the efficacy of CA3301 on winter barley against *Puccinia hordei*. 9 trials out of 17 were considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 30-53 and the 2nd application was at BBCH 39-65. The analysis was conducted on foliar level 1 and foliar level 2.

Summary results are presented in Table 3.2-235.

Over this dataset, CA3301 at 0.6 l/ha provided on average high efficacy in reducing the severity of *Puccinia hordei* on winter barley. On foliar level 2, CA3301 at 0.6 l/ha showed 94.78% efficacy over 6 trials two weeks after the 2nd application and 87.35% over 8 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 85.53% efficacy over 6 trials on reduction of disease severity before harvest.

In all assessments applications of CA3301 at the proposed dose rate significantly reduced disease severity.

In the Maritime EPPO zone, CA3301 gave equivalent disease control compared to the authorized reference products CA2445 at 0.8 l/ha and PROLINE 275, except in one trial in which CA3301 at 0.6 l/ha provided lower efficacy than CA2445. In overall, the disease pressure was relatively low to medium and in most of assessments the application of CA3301 at 0.6 l/ha (150 g/ha prothioconazole gave comparable disease control than the reference product at the higher dose of 0.8 l/ha (200 g/ha prothioconazole). Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient to provide acceptable levels of control against brown rust in winter barley.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Puccinia hordei* on winter barley in the Maritime EPPO zone.

Table 3.2-235: Summary table - Efficacy evaluation – Winter barley – PUCCHD - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA2445	PROLINE 275	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	0,72	0,6		
Rate unit		L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB		
% Disease severity L2 - 14-17 DA-B						
Number of values	6	6		6	UTC	CA2445
Minimum value	4,99	0,00		0,00		0,8 l/ha
Maximum value	57,28	4,08	-	3,93	6 >	0 >
Mean disease severity (%)	15,85	0,92		1,00	0 =	5 =
Abbott efficacy (%)	0,00%	95,92%		94,78%	0 <	1 <
% Disease severity L2 - 27-40 DA-B						
Number of values	8			8	UTC	
Minimum value	6,38			0,00		
Maximum value	95,50	-	-	61,50	8 >	
Mean disease severity (%)	47,50			9,69	0 =	
Abbott efficacy (%)	0,00%			87,35%	0 <	
Number of values	7	7		7	CA2445	
Minimum value	6,38	0,00		0,00	0.8 l/ha	
Maximum value	95,50	53,63	-	61,50	0 >	
Mean disease severity (%)	53,13	9,44		10,99	6 =	
Abbott efficacy (%)	0,00%	88,23%		86,60%	1 <	
Number of values	1		1	1	PROLINE 275	
Minimum value	8,10		1,48	0,60	0.72 l/ha	
Maximum value	8,10	-	1,48	0,60	0 >	
Mean disease severity (%)	8,10		1,48	0,60	1 =	
Abbott efficacy (%)	0,00%		81,73%	92,59%	0 <	
% Disease severity L1 - 28-40 DA-B						
Number of values	6	6		6	UTC	CA2445
Minimum value	12,10	0,00		0,00		0,8 l/ha
Maximum value	70,00	36,50	-	47,88	6 >	0 >
Mean disease severity (%)	28,33	6,64		8,60	0 =	5 =
Abbott efficacy (%)	0,00%	88,09%		85,53%	0 <	1 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against PUCCHD - Mediterranean EPPO zone

In the Mediterranean EPPO zone, a total of 7 trials evaluated the efficacy of CA3301 on winter barley against *Puccinia hordei*. 3 trials out of 7 were considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 32-47 and the 2nd application was at BBCH 39-59. The analysis was conducted on foliar level 1 and foliar level 2.

Summary results are presented in Table 3.2-236.

Data demonstrated that CA3301 at 0.6 l/ha provided low to high efficacy in reducing the severity of *Puccinia hordei* on winter barley. On foliar level 2, CA3301 at 0.6 l/ha showed 74.12% efficacy over 3 trials two weeks after the 2nd application and 6.31% on a single trial before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 85.80% efficacy on a single trial on reduction of disease severity around two weeks after the 2nd application and 17.07% on a single trial before harvest.

In the Mediterranean EPPO zone, a limited dataset was available to support the evaluation of CA3301 against *Puccinia hordei*. Medium to high efficacy was demonstrated from applications of CA3301 at the earlier assessments. However, in later assessments made on a single trial with very high disease severity, efficacy of both the test product and the reference was low and, in these circumstances, the increased loading of the reference product led to significant differences between the products. Even so under this level of disease pressure even the authorised product did not provide acceptable control of brown rust. However, in the other trial assessments with disease severity ranging from 5.51% to 92.5%, CA3301 gave medium to high control comparable with the authorised reference product. Therefore it is expected that in most instances, applications of 0.6 l/ha will be sufficient to provide acceptable levels of control against brown rust.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Puccinia hordei* on winter barley in the Mediterranean EPPO zone.

Table 3.2-236: Summary table - Efficacy evaluation – Winter barley – PUCCHD - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA2445	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	0,6		
Rate unit		L/ha	L/ha		
Appl. Code		AB	AB		
% Disease severity L2 - 17 DA-B					
Number of values	3	3	3	UTC	CA2445
Minimum value	5,51	1,15	1,24		0,8 l/ha
Maximum value	92,50	12,91	18,61	3 >	0 >
Mean disease severity (%)	34,58	5,24	7,29	0 =	3 =
Abbott efficacy (%)	0,00%	78,81%	74,12%	0 <	0 <
% Disease severity L1 - 17 DA-B					
Number of values	1	1	1	UTC	CA2445
Minimum value	64,31	7,09	9,13		0,8 l/ha
Maximum value	64,31	7,09	9,13	1 >	0 >
Mean disease severity (%)	64,31	7,09	9,13	0 =	1 =
Abbott efficacy (%)	0,00%	88,98%	85,80%	0 <	0 <
% Disease severity L2 - 34 DA-B					
Number of values	1	1	1	UTC	CA2445
Minimum value	100,00	84,06	93,69		0,8 l/ha
Maximum value	100,00	84,06	93,69	0 >	0 >
Mean disease severity (%)	100,00	84,06	93,69	1 =	0 =
Abbott efficacy (%)	0,00%	15,94%	6,31%	0 <	1 <
% Disease severity L1 - 34 DA-B					
Number of values	1	1	1	UTC	CA2445
Minimum value	99,94	62,56	82,88		0,8 l/ha

Maximum value	99,94	62,56	82,88	1 >	0 >
Mean disease severity (%)	99,94	62,56	82,88	0 =	0 =
Abbott efficacy (%)	0,00%	37,40%	17,07%	0 <	1 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against PUCCHD - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 22 trials evaluated the efficacy of CA3301 on winter barley against *Puccinia hordei*. 8 trials out of 22 were considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 31-37 and the 2nd application was at BBCH 43-61. The analysis was conducted on foliar level 1 and foliar level 2.

Summary results are presented in Table 3.2-237.

Data demonstrated that CA3301 at 0.6 l/ha provided high efficacy in reducing the severity of *Puccinia hordei* on winter barley. On foliar level 2, CA3301 at 0.6 l/ha showed 92.38% efficacy over 2 trials two weeks after the 2nd application and 97.49% over 6 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 94.29% efficacy on a single trial on reduction of disease severity around two weeks after the 2nd application and 87.51% over 4 trials before harvest. Applications of CA3301 at the proposed dose rate significantly reduced disease severity at all assessments.

In the North-Eastern EPPO zone, the disease pressure was relatively low to medium. In these conditions, CA3301 at 0.6 l/ha (150 g/ha prothioconazole) gave always equivalent disease control compared to the authorised reference products CA2445 at 0.8 l/ha (200 g/ha prothioconazole) and OSIRIS 65 EC. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for the control of brown rust.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Puccinia hordei* on winter barley in the North-Eastern East EPPO zone.

Table 3.2-237: Summary table - Efficacy evaluation – Winter barley – PUCCHD – North-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA2445	OSIRIS 65 EC	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	2	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
% Disease severity L2 - 15 DA-B					
Number of values	2			2	UTC
Minimum value	10,13			0,81	
Maximum value	10,63	-	-	0,88	2 >
Mean disease severity (%)	10,38			0,84	0 =
Abbott efficacy (%)	0,00%			92,38%	0 <
Number of values	1	1		1	CA2445
Minimum value	10,13	0,75		0,88	0.8 l/ha
Maximum value	10,13	0,75	-	0,88	0 >
Mean disease severity (%)	10,13	0,75		0,88	1 =
Abbott efficacy (%)	0,00%	92,60%		91,31%	0 <
Number of values	1		1	1	OSIRIS 65 EC
Minimum value	10,63		0,19	0,81	2 l/ha
Maximum value	10,63	-	0,19	0,81	0 >

Treatment name	UNTREATED CHECK	CA2445	OSIRIS 65 EC	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	2	0,6		
Rate unit		L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB		
Mean disease severity (%)	10,63		0,19	0,81	1 =	
Abbott efficacy (%)	0,00%		98,21%	92,38%	0 <	
% Disease severity L1 - 15 DA-B						
Number of values	1	1		1	UTC	CA2445
Minimum value	6,30	0,14		0,36		0,8 l/ha
Maximum value	6,30	0,14	-	0,36	1 >	0 >
Mean disease severity (%)	6,30	0,14		0,36	0 =	1 =
Abbott efficacy (%)	0,00%	97,78%		94,29%	0 <	0 <
% Disease severity L2 - 22-36 DA-B						
Number of values	6			6	UTC	
Minimum value	10,13			0,00		
Maximum value	24,00	-	-	1,60	6 >	
Mean disease severity (%)	15,93			0,42	0 =	
Abbott efficacy (%)	0,00%			97,49%	0 <	
Number of values	5	5		5	CA2445	
Minimum value	10,13	0,00		0,00	0,8 l/ha	
Maximum value	16,59	0,99	-	1,60	0 >	
Mean disease severity (%)	14,32	0,29		0,39	5 =	
Abbott efficacy (%)	0,00%	98,09%		97,45%	0 <	
Number of values	3		3	3	OSIRIS 65 EC	
Minimum value	11,91		0,06	0,09	2 l/ha	
Maximum value	24,00	-	0,54	0,56	0 >	
Mean disease severity (%)	17,50		0,23	0,26	3 =	
Abbott efficacy (%)	0,00%		98,22%	98,68%	0 <	
% Disease severity L1 - 24-33 DA-B						
Number of values	4			4	UTC	
Minimum value	5,84			0,06		
Maximum value	28,19	-	-	2,20	4 >	
Mean disease severity (%)	14,18			0,90	0 =	
Abbott efficacy (%)	0,00%			87,51%	0 <	
Number of values	3		3	3	OSIRIS 65 EC	
Minimum value	5,84		0,06	0,06	2 l/ha	
Maximum value	28,19	-	2,78	2,20	0 >	
Mean disease severity (%)	16,62		0,97	0,98	3 =	
Abbott efficacy (%)	0,00%		83,89%	86,50%	0 <	
Number of values	2	2		2	CA2445	
Minimum value	6,88	0,10		0,06	0,8 l/ha	
Maximum value	15,83	0,46	-	0,65	0 >	
Mean disease severity (%)	11,36	0,28		0,36	2 =	
Abbott efficacy (%)	0,00%	96,34%		95,09%	0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against PUCCHD - South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 13 trials evaluated the efficacy of CA3301 on winter barley against *Puccinia hordei*. 10 trials out of 13 were considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 31-39 and the 2nd application was at BBCH 41-61. The analysis was conducted on foliar level 1 and foliar level 2.

Summary results are presented in Table 3.2-238.

Data demonstrated that CA3301 at 0.6 l/ha provided medium to high efficacy in reducing the severity of *Puccinia hordei* on winter barley. On foliar level 2, CA3301 at 0.6 l/ha showed 76.38% efficacy over 2 trials two weeks after the 2nd application and 97.03% over 9 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 89.60% efficacy on a single trial on reduction of disease severity around two weeks after the 2nd application and 95.67% over 7 trials before harvest. At all assessments the proposed dose rate of CA3301 significantly reduced disease severity.

In the South-Eastern East EPPO zone, the disease pressure was low to high. In these conditions, CA3301 at 0.6 l/ha (150g/ha of Prothioconazole) showed medium to high levels of efficacy against *Puccinia hordei*. At early assessments CA3301 consistently gave comparable disease control to CA2445 which was applied at a higher rate of prothioconazole (200g/ha). At later assessments CA3301 was comparable in 6 assessments and gave lower disease control in 3 assessments compared to CA2445. Similarly, in the trials containing PRIAXOR assessed close to harvest, CA3301 gave comparable disease control in the majority of assessments (10) and lower control in 3 assessments. Nevertheless, at this assessment timing CA3301 still provided high efficacy. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for the control of brown rust.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Puccinia hordei* on winter barley in the South-Eastern East EPPO zone.

Table 3.2-238: Summary table - Efficacy evaluation – Winter barley – PUCCHD – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA2445	PRIAXOR	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	1,5	0,6		
Rate unit		L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB		
% Disease severity L2 - 15 DA-B						
Number of values	2	2		2	UTC	CA2445
Minimum value	8,50	0,51		0,59		0,8 l/ha
Maximum value	8,86	3,28	-	3,45	2 >	0 >
Mean disease severity (%)	8,68	1,89		2,02	0 =	2 =
Abbott efficacy (%)	0,00%	77,83%		76,38%	0 <	0 <
% Disease severity L1 - 15 DA-B						
Number of values	1	1		1	UTC	CA2445
Minimum value	7,50	2,20		0,78		0,8 l/ha
Maximum value	7,50	2,20	-	0,78	1 >	0 >
Mean disease severity (%)	7,50	2,20		0,78	0 =	1 =
Abbott efficacy (%)	0,00%	70,67%		89,60%	0 <	0 <
% Disease severity L2 - 24-45 DA-B						
Number of values	9			9	UTC	
Minimum value	11,18			0,00		
Maximum value	41,81	-	-	3,35	9 >	
Mean disease severity (%)	18,47			0,61	0 =	
Abbott efficacy (%)	0,00%			97,03%	0 <	
Number of values	7		7	7	PRIAXOR	
Minimum value	11,18		0,00	0,00	1.5 l/ha	
Maximum value	41,81	-	0,34	1,58	0 >	
Mean disease severity (%)	19,11		0,06	0,28	6 =	
Abbott efficacy (%)	0,00%		99,64%	98,62%	1 <	
Number of values	5	5		5	CA2445	
Minimum value	11,18	0,00		0,00	0.8 l/ha	
Maximum value	21,00	7,88	-	3,35	0 >	
Mean disease severity (%)	15,63	1,89		1,02	4 =	
Abbott efficacy (%)	0,00%	90,69%		94,82%	1 <	
% Disease severity L1 - 28-45 DA-B						
Number of values	7			7	UTC	

Treatment name	UNTREATED CHECK	CA2445	PRIAXOR	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	1,5	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
Minimum value	5,80			0,00	
Maximum value	46,38	-	-	2,45	7 >
Mean disease severity (%)	13,83			0,74	0 =
Abbott efficacy (%)	0,00%			95,67%	0 <
Number of values	6		6	6	PRIAXOR
Minimum value	5,80		0,00	0,00	1.5 l/ha
Maximum value	46,38	-	0,03	2,45	0 >
Mean disease severity (%)	14,30		0,00	0,51	4 =
Abbott efficacy (%)	0,00%		99,95%	98,15%	2 <
Number of values	4	4		4	CA2445
Minimum value	6,21	0,00		0,00	0.8 l/ha
Maximum value	11,00	1,29	-	2,11	0 >
Mean disease severity (%)	8,73	0,41		0,68	2 =
Abbott efficacy (%)	0,00%	96,19%		93,75%	2 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

9 valid trials were carried out in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,6 l/ha achieved high efficacy after 14-40 days after second application. No significant differences between test and reference product were observed.

8 valid trials have been submitted in **the North-East EPPO zone**. The test product showed high level of control after 15-36 DA-B. The results from the test and reference product were comparable.

10 valid trials were conducted in **the South-East EPPO zone**. CA3301 at 0,6 l/ha achieved medium to high efficacy after 15-45 days after second application. Moreover, 3 additional trials from the Mediterranean zone were presented to support of product registration in other zones. The results showed in these trials confirm the conclusion from the SE zone.

Taking into account all trials, CA3301 can be recommended to control of *Puccinia hordei* in winter barley.

3.2.3.3 Winter barley (HORVW) / *Rhynchosporium secalis* (RHYNSE/RHYNSP)

Materials and Methods – Winter barley - RHYNSE

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2017 and 2020, a series of 57 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the efficacy of CA3301 against *Rhynchosporium secalis* on winter barley (see Table 3.2-343). The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, a total of 20 trials were performed in the Czech Republic (3), Denmark (2), France (4), Germany (8) and the United Kingdom (3).

In the Mediterranean EPPO zone, a total of 17 trials were performed in France (6), Portugal (5) and Spain (6).

In the North-eastern East EPPO zone, a total of 13 trials were performed in Latvia (7) and Poland (6).

In the South-eastern East EPPO zone, a total of 7 trials were performed in Bulgaria (1), Hungary (1), Romania (3) and Slovakia (2).

Data groupings were also made specifically for Poland evaluation and trials involved (26) were performed in the North-Eastern East EPPO zone (13), in the Czech Republic (3), in Germany (8) and in Slovakia (2).

Table 3.2-239: Presentation of trials – Winter barley (HORVW) - RHYNSE

Crop(s) *)	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Winter barley	RHYNSE	Czech Republic	2018- 2019	MED + E	3 (1)	-	-	-		
		Denmark	2018	MED + E	2 (0)	-	-	-	GEP	
		France (N)	2019- 2020	MED + E	4 (2)	-	-	-	GEP	
		Germany	2019- 2020	MED + E	8 (3)	-	-	-	GEP	
		United Kingdo m	2019- 2020	MED + E	3 (2)	-	-	-	GEP	
Winter barley	RHYNSE	France (S)	2019- 2020	MED + E	-	6 (0)	-	-	GEP	
		Portugal	2018- 2020	MED + E		5 (5)			GEP	
		Spain	2019- 2020	MED + E	-	6 (2)	-	-	GEP	
Winter barley	RHYNSE	Latvia	2019- 2020	MED + E	-	-	7 (1)	-	GEP	
		Poland	2017- 2020	MED + E	-	-	6 (4)	-	GEP	
Winter barley	RHYNSE	Bulgaria	2019	MED + E	-	-	-	1 (1)	GEP	
		Hungary	2017	MED + E	-	-	-	1 (1)	GEP	
		Slovakia	2020	MED + E				2 (2)	GEP	
		Romania	2020	MED + E	-	-	-	3 (0)	GEP	
TOTA L	-	-	2018- 2020	MED + E	20 (8)	17 (7)	13 (5)	7 (4)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

In all trials, CA3301 was compared to at least one commercial and registered fungicide used as standard reference for comparison.

Table 3.2-240: Efficacy evaluation - Presentation of reference standards used in trials – Winter barley (HORVW) – RHYNSE – Maritime EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter barley	PRO-LINE 250 EC	CZ	4523-1	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	JOAO	FR (N)	2060116	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE 275	UK	14790	Prothioconazole	EC	275 g/l	2 x 0.72 l/ha	2 x 0.72 l/ha	
	PRO-LINE	DE	025287-00	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE 250 EC	DK	18-473	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

Table 3.2-241: Efficacy evaluation - Presentation of reference standards used in trials – Winter barley (HORVW) – RHYNSE – Mediterranean EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter barley	JOAO	FR (S)	2060116	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRAK-TIS	ES	01135	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-SARO	ES	25661	Prothioconazole + Tebuconazole	EC	125 g/l + 125 g/l	2 x 1 l/ha	2 x 1 l/ha	
	PRAK-TIS	PT	AV 1485	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	MYSTIC EW	PT	AV 0838	Tebuconazole	EW	250 g/l	1 x 1 l/ha	2 x 1 l/ha	MYSTIC SUL in the trial

Table 3.2-242: Efficacy evaluation - Presentation of reference standards used in trials – Winter barley (HORVW) – RHYNSE – North-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter barley	PRAKTIS	PL	R-222/2019	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.6-0.8 l/ha	CA2445 in some trials
	OSIRIS 65 EC	PL	R-87/2012	Epoxiconazole + metconazole	EC	65 g/l	1 x 1.5-2.5 l/ha	2 x 2 l/ha	
	PRO-LINE	LV	0637	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

Table 3.2-243: Efficacy evaluation - Presentation of reference standards used in trials – Winter barley (HORVW) – RHYNSE – South-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter barley	RISA 20 EC	BG	01389 – PPP-1 / 03/23/2016	Fluxapyroxad + Pyraclostrobin	EC	200 g/l	N/A	2 x 1.25 l/ha	
	PRO-LINE	HU	6300/1205-1/2020	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE	RO	457PC/15.11.2018	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	1 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE 250 EC	SK	06-02-0768	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRI-AXOR	SK	16-02-1746	Fluxapyroxad + Pyraclostrobin	EC	225 g/l	2 x 0.75-1.5 l/ha	2 x 1.5 l/ha	

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-243.

Table 3.2-244: Details on trial methodology – Winter barley (HORVW) - RHYNSE

Maritime	Mediterranean	North-Eastern	South-Eastern	Data relevant
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		EPPO zone	EPPO zone	EPPO zone	EPPO zone	for Poland
Trials	Total number (valid number)	20 (8)	17 (7)	13 (5)	7 (4)	26 (11)
	Supportive trials	-	-	-	-	
Guidelines	General guidelines	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)
	Specific guidelines	PP 1/26(4)	PP 1/26(4)	PP 1/26(4)	PP 1/26(4)	PP 1/26(4)
Experimental design	Plot design	Randomized complete blocks, Un-treated included	Randomized complete blocks, Un-treated included	Randomized complete blocks, Un-treated included	Randomized complete blocks, Un-treated included	Randomized complete blocks, Un-treated included
	Plot size	19.635-36.9 m ²	12-30 m ²	21-31.5 m ²	21-30 m ²	21-36.9 m ²
	Number of replications	4	4	4	4	4
Crop	Trials per crop	Winter barley (20)	Winter barley (17)	Winter barley (13)	Winter barley (7)	Winter barley (26)
	Varieties per crop	Henriette (1), Bazzoka (1), Belfry (1), Meridian (3), Sandra (1), KWS Cassia (2), Etincel (3), Kosmos (2), Triumpf (1), Lomerit (1), Titus (1), KWS Orwell (1), Tonic (1), Maltesse (1)	Pewter (1), Encama (1), Esterell (1), Ordinale (1), Hirondeella (1), Saratoga (1), Meseta (1), KWS Infinity (1), Solis (1), Sandra (1), Cassia (1), Basic (1), Gustav (1), Signora (1), Mystic (1), Cartel (1), Etincel (1),	Metaxa (1), Meridian (5), KWS Tenor (3), Gloria (1), Lomerit (1), Arenia (1), Kosmos (1),	KWS Scala (1), Obzor (1), Wendy (1), Saphira (1), Cardinal (1), Jup (2)	Metaxa (1), Meridian (8), KWS Tenor (3), Gloria (1), Lomerit (2), Arenia (1), Kosmos (2), Jup (2), Henriette (1), Sandra (1), Triumpf (1), Titus (1), Tonic (1), Kosmos (1)
	Sowing period	September (14), October (3), November (2), NA (1)	October (6), November (3), December (3), January (3), February (2)	August (1), September (11), October (1)	September (1), October (6)	August (1), September (20), October (5)
Application	Crop stage (BBCH)* at application	A: BBCH 30-53 B: BBCH 39-65	A: BBCH 32-37 B: BBCH 39-69	A: BBCH 31-37 B: BBCH 51-61	A: BBCH 32-37 B: BBCH 49-59	A: BBCH 31-37 B: BBCH 45-61
	Timing Disease stage at application	BBCH 30-61 A: PRINFC (4), MIXED (13), ACTIVE (1), SPORUL (1), NA (1) B: PRINFC (3), MIXED (14), ACTIVE (1), SPORUL (1), NA (1)	BBCH 30-61 A: PRINFC (9), MIXED (5), SPORUL (3) B: PRINFC (3), MIXED (11), SPORUL (2), ACTIVE (1)	BBCH 30-61 A: PRINFC (3), MIXED (3), NA (7) B: PRINFC (3), MIXED (3), NA (7)	BBCH 30-61 A: PRINFC (3), MIXED (1) B: PRINFC (1), MIXED (6)	BBCH 30-61 A: PRINFC (5), MIXED (13), NA (8) B: PRINFC (3), MIXED (15), NA (8)
	Number of applications Intervals	2 applications (9-31 days) (20)	2 applications (13-28 days) (17)	1 application (1) 2 applications (15-37 days)	1 application (3) 2 applications (16-21 days) (4)	1 application (1) 2 applications

	between applications			(13)		(14-37 days) (26)
	Spray volumes	200-300 l/ha	182-400 l/ha	200-400 l/ha	200-300 l/ha	200-400 l/ha
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)
	Assessment dates	-1-1 DA-A; 13-17 DA-A; 21 DA-A 0 DA-B; 5 DA-B; 13-17 DA-B; 21-49 DA-B; 51-91 DA-B	-1-0 DA-A; 13-19 DA-A 0-1 DA-B; 14-17 DA-B; 21-43 DA-B; 60-91 DA-B	-2-1 DA-A; 14-18 DA-A; 28 DA-A 0 DA-B; 13-16 DA-B; 22-38 DA-B; 52-96 DA-B	0 DA-A; 14-15 DA-A; 21-22 DA-A 0 DA-B; 14-15 DA-B; 24-31 DA-B; 56-83 DA-B	-2-1 DA-A; 14-18 DA-A; 28 DA-A 0 DA-B; 13-16 DA-B; 21-49 DA-B; 51-96 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Natural (20)	Natural (17)	Natural (13)	Natural (7)	Natural (26)
	e.g. Field / Greenhouse...	Field trials	Field trials	Field trials	Field trials	Field trials

Out of the 57 trials performed on winter wheat against *Rhynchosporium secalis*, 24 were considered valid.

Use of CA3301 at 2x 0.6 l/ha against RHYNSE - Maritime EPPO zone

In the Maritime EPPO zone, a total of 20 trials evaluated the efficacy of CA3301 on winter barley against *Rhynchosporium secalis*. 8 trials out of 20 were considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 30-53 and the 2nd application was at BBCH 39-65. The analysis was conducted on foliar level 1 and foliar level 2.

Summary results are presented in Table 3.2-245.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the reduction of disease severity on winter barley against *Rhynchosporium secalis*. On foliar level 2, CA3301 at 0.6 l/ha showed 84.70% efficacy over 4 trials two weeks after the 2nd application and 82.00% over 6 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 80.82% efficacy over 2 trials on reduction of disease severity two weeks after the 2nd application and 79.65% over 4 trials before harvest.

In the Maritime EPPO zone, the disease pressure was relatively medium to high. In these conditions, CA3301 gave higher or equivalent disease control compared to the authorized reference product CA2445 applied at higher rate and to PROLINE 275, except in one trial where CA3301 at 0.6 l/ha provided lower efficacy than PROLINE 275, applied at a higher rate of prothioconazole. Therefore, it

is envisaged that in most instances applications of 0.6 l/ha will be sufficient to provide acceptable levels of control against *Rhynchosporium secalis*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Rhynchosporium secalis* on winter barley in the Maritime EPPO zone.

Table 3.2-245: Summary table - Efficacy evaluation – Winter barley – RHYNSE - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA2445	PROLINE 275	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	0,72	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
% Disease severity L2 - 15 DA-B					
Number of values	4			4	UTC
Minimum value	7,09			0,00	
Maximum value	14,06	-	-	2,84	4 >
Mean disease severity (%)	10,55			1,68	0 =
Abbott efficacy (%)	0,00%			84,70%	0 <
Number of values	2	2		2	CA2445
Minimum value	7,09	1,13		1,44	0,8 l/ha
Maximum value	14,06	4,11	-	2,84	0 >
Mean disease severity (%)	10,58	2,62		2,14	2 =
Abbott efficacy (%)	0,00%	77,42%		79,75%	0 <
Number of values	2		2	2	PROLINE 275
Minimum value	9,31		1,11	0,00	0,72 l/ha
Maximum value	11,74	-	1,49	2,43	0 >
Mean disease severity (%)	10,53		1,30	1,22	2 =
Abbott efficacy (%)	0,00%		87,69%	89,65%	0 <
% Disease severity L1 - 15 DA-B					
Number of values	2			2	UTC
Minimum value	5,11			0,98	
Maximum value	11,11	-	-	2,63	2 >
Mean disease severity (%)	8,11			1,80	0 =
Abbott efficacy (%)	0,00%			80,82%	0 <
Number of values	1		1	1	PROLINE 275
Minimum value	11,11		4,59	2,63	0,72 l/ha
Maximum value	11,11	-	4,59	2,63	0 >
Mean disease severity (%)	11,11		4,59	2,63	1 =
Abbott efficacy (%)	0,00%		58,69%	76,33%	0 <
Number of values	1	1		1	CA2445
Minimum value	5,11	0,91		0,98	0,8 l/ha
Maximum value	5,11	0,91	-	0,98	0 >
Mean disease severity (%)	5,11	0,91		0,98	1 =
Abbott efficacy (%)	0,00%	82,19%		80,82%	0 <
% Disease severity L2 - 37-49 DA-B					
Number of values	6			6	UTC
Minimum value	7,05			0,38	
Maximum value	51,50	-	-	10,35	6 >
Mean disease severity (%)	19,81			4,36	0 =
Abbott efficacy (%)	0,00%			82,00%	0 <
Number of values	5	5		5	CA2445
Minimum value	7,05	0,30		0,38	0,8 l/ha
Maximum value	26,70	14,36	-	10,35	1 >
Mean disease severity (%)	13,47	4,51		3,18	4 =
Abbott efficacy (%)	0,00%	74,77%		82,39%	0 <
Number of values	1		1	1	PROLINE 275
Minimum value	51,50		5,91	10,28	0,72 l/ha
Maximum value	51,50	-	5,91	10,28	0 >
Mean disease severity (%)	51,50		5,91	10,28	0 =
Abbott efficacy (%)	0,00%		88,52%	80,04%	1 <

Treatment name	UNTREATED CHECK	CA2445	PROLINE 275	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	0,72	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
% Disease severity L2 - 15 DA-B					
% Disease severity L1 - 37-49 DA-B					
Number of values	4			4	UTC
Minimum value	8,41			1,14	
Maximum value	29,35	-	-	5,41	4 >
Mean disease severity (%)	16,17			3,36	0 =
Abbott efficacy (%)	0,00%			79,65%	0 <
Number of values	3	3		3	CA2445
Minimum value	8,41	1,66		1,14	0,8 l/ha
Maximum value	14,83	4,60	-	5,01	0 >
Mean disease severity (%)	11,78	3,44		2,68	3 =
Abbott efficacy (%)	0,00%	71,91%		79,01%	0 <
Number of values	1		1	1	PROLINE 275
Minimum value	29,35		1,76	5,41	0,72 l/ha
Maximum value	29,35	-	1,76	5,41	0 >
Mean disease severity (%)	29,35		1,76	5,41	0 =
Abbott efficacy (%)	0,00%		94,00%	81,57%	1 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against RHYNSE - Mediterranean EPPO zone

In the Mediterranean EPPO zone, a total of 17 trials evaluated the efficacy of CA3301 on winter barley against *Rhynchosporium secalis*. 7 trials out of 17 were considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 32-37 and the 2nd application was at BBCH 39-69. The analysis was conducted on foliar level 1 and foliar level 2. In all except one assessment CA3301 significantly reduced disease severity.

Summary results are presented in Table 3.2-246.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the reduction of disease severity on winter barley against *Rhynchosporium secalis*. On foliar level 2, CA3301 at 0.6 l/ha showed 82.57% efficacy over 4 trials two weeks after the 2nd application and 58.58% over 7 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 85.22% efficacy over 4 trials on reduction of disease severity two weeks after the 2nd application and 58.94% over 6 trials before harvest.

In the Mediterranean EPPO zone, the disease pressure was relatively medium to high. In these conditions, CA3301 gave higher or equivalent disease control compared to the authorized reference products PROSARO, CA2445 applied at 0.8 l/ha and MYSTIC SUL. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient to provide acceptable levels of control against *Rhynchosporium secalis*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Rhynchosporium secalis* on winter barley in the Mediterranean EPPO zone.

Treatment name	UNTREATED CHECK	CA2445	PROSAR O	MYSTIC SUL	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	1	1	0,6		
Rate unit		L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	AB		
% Disease severity L2 - 14-15 DA-B							
Number of values	4	4			4	UT C	CA2445
Minimum value	14,25	0,00			0,00		5
Maximum value	63,73	29,10	-	-	28,20	4 >	0,8 l/ha
Mean disease severity (%)	32,40	8,04			8,10	0 =	0 >
Abbott efficacy (%)	0,00%	83,77%			82,57%	0 <	4 =
Number of values	2	2		2	2	MYSTIC SUL	
Minimum value	14,25	0,00		5,63	0,00	1 l/ha	
Maximum value	35,75	0,00	-	5,88	0,31	2 >	
Mean disease severity (%)	25,00	0,00		5,75	0,16	0 =	
Abbott efficacy (%)	0,00%	100,00 %		72,02%	99,57%	0 <	
% Disease severity L1 - 14-15 DA-B							
Number of values	4	4			4	UT C	CA2445
Minimum value	9,38	0,00			0,00		5
Maximum value	44,95	12,30	-	-	15,00	4 >	0,8 l/ha
Mean disease severity (%)	22,31	4,40			5,01	0 =	0 >
Abbott efficacy (%)	0,00%	86,40%			85,22%	0 <	4 =
Number of values	2	2		2	2	MYSTIC SUL	
Minimum value	9,38	0,00		1,94	0,00	1 l/ha	
Maximum value	15,31	0,00	-	3,13	0,00	2 >	
Mean disease severity (%)	12,35	0,00		2,53	0,00	0 =	
Abbott efficacy (%)	0,00%	100,00 %		79,44%	100,00 %	0 <	
% Disease severity L2 - 26-43 DA-B							
Number of values	7				7	UTC	
Minimum value	7,53				0,00		
Maximum value	75,00	-	-	-	59,75	7 >	
Mean disease severity (%)	40,08				20,98	0 =	
Abbott efficacy (%)	0,00%				58,58%	0 <	
Number of values	6	6			6	CA2445	
Minimum value	15,85	0,00			0,00	0,8 l/ha	
Maximum value	75,00	60,75	-	-	59,75	0 >	
Mean disease severity (%)	45,51	24,81			24,05	6 =	
Abbott efficacy (%)	0,00%	56,74%			57,32%	0 <	
Number of values	2		2		2	PROSARO	
Minimum value	7,53		0,13		0,00	1 l/ha	
Maximum value	39,25	-	2,17	-	2,55	0 >	
Mean disease severity (%)	23,39		1,15		1,28	2 =	
Abbott efficacy (%)	0,00%		85,43%		83,07%	0 <	
Number of values	2	2		2	2	MYSTIC SUL	
Minimum value	55,00	49,50		53,88	46,38	1 l/ha	
Maximum value	75,00	60,75	-	64,00	59,75	1 >	
Mean disease severity (%)	65,00	55,13		58,94	53,07	1 =	
Abbott efficacy (%)	0,00%	14,50%		8,35%	18,00%	0 <	
% Disease severity L1 - 26-43 DA-B							

Treatment name	UNTREATED CHECK	CA2445	PROSAR O	MYSTIC SUL	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	1	1	0,6		
Rate unit		L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	AB		
Number of values	6	6			6	UT	CA244
Minimum value	19,60	0,00			0,00	C	5
Maximum value	75,25	56,25	-	-	51,25	5 >	0,8 l/ha
Mean disease severity (%)	41,30	23,17			20,95	1 =	5 =
Abbott efficacy (%)	0,00%	56,81%			58,94%	0 <	0 <
Number of values	2	2		2	2	MYSTIC SUL	
Minimum value	52,69	55,75		50,88	44,88	1 l/ha	
Maximum value	75,25	56,25	-	58,63	51,25	0 >	
Mean disease severity (%)	63,97	56,00		54,75	48,07	2 =	
Abbott efficacy (%)	0,00%	12,62%		16,19%	21,55%	0 <	
Number of values	1	1	1		1	PROSARO	
Minimum value	29,25	0,00	0,00		0,00	1 l/ha	
Maximum value	29,25	0,00	0,00	-	0,00	0 >	
Mean disease severity (%)	29,25	0,00	0,00		0,00	1 =	
Abbott efficacy (%)	0,00%	100,00 %	100,00%		100,00 %	0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against RHYNSE - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 13 trials evaluated the efficacy of CA3301 on winter barley against *Rhynchosporium secalis*. 5 trials out of 13 were considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 31-37 and the 2nd application was at BBCH 51-61. The analysis was conducted on foliar level 1 and foliar level 2.

Summary results are presented in Table 3.2-247.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the reduction of disease severity on winter barley against *Rhynchosporium secalis*. On foliar level 2, CA3301 at 0.6 l/ha showed 95.52% efficacy over 2 trials two weeks after the 2nd application and 76.22% over 4 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 92.96% efficacy over 3 trials on reduction of disease severity before harvest. At all assessments CA3301 significantly reduced disease severity.

In the North-Eastern East EPPO zone, the disease pressure was moderate (5.76% - 14.06%) and CA3301 at 0.6 l/ha provided medium to very high levels of control.

CA3301 at 0.6 l/ha showed higher or equivalent disease control compared to the authorized reference products CA2245 at 0.6-0.8 l/ha and OSIRIS except in 1 trial. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient to provide acceptable levels of control against *Rhynchosporium secalis*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Rhynchosporium secalis* on winter barley in the North-Eastern East EPPO zone.

Table 3.2-247: Summary table - Efficacy evaluation – Winter barley – RHYNSE – North-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA2445 0,6 L/ha AB	CA2445 0,8 L/ha AB	OSIRIS 2 L/ha AB	CA3301 0,6 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
% Disease severity L2 - 13-15 DA-B						
Number of values	2				2	UTC
Minimum value	7,63				0,20	
Maximum value	8,30	-	-	-	0,50	2 >
Mean disease severity (%)	7,96				0,35	0 =
Abbott efficacy (%)	0,00%				95,52%	0 <
Number of values	1			1	1	OSIRIS
Minimum value	7,63			0,06	0,50	2 l/ha
Maximum value	7,63	-	-	0,06	0,50	0 >
Mean disease severity (%)	7,63			0,06	0,50	1 =
Abbott efficacy (%)	0,00%			99,21%	93,45%	0 <
Number of values	1	1	1		1	CA2445
Minimum value	8,30	0,41	0,28		0,20	0,6 l/ha and 0,8 l/ha
Maximum value	8,30	0,41	0,28	-	0,20	0 >
Mean disease severity (%)	8,30	0,41	0,28		0,20	1 =
Abbott efficacy (%)	0,00%	95,06%	96,63%		97,59%	0 <
% Disease severity L2 - 24-33 DA-B						
Number of values	4				4	UTC
Minimum value	6,94				0,38	
Maximum value	14,06	-	-	-	6,09	4 >
Mean disease severity (%)	9,53				2,46	0 =
Abbott efficacy (%)	0,00%				76,22%	0 <
Number of values	3		3		3	CA2445
Minimum value	6,94		0,31		0,41	0,8 l/ha
Maximum value	14,06	-	3,40	-	6,09	0 >
Mean disease severity (%)	9,33		1,83		3,15	2 =
Abbott efficacy (%)	0,00%		78,10%		69,54%	1 <
Number of values	2			2	2	OSIRIS
Minimum value	6,94			0,31	0,38	2 l/ha
Maximum value	10,13	-	-	0,33	0,41	0 >
Mean disease severity (%)	8,54			0,32	0,40	2 =
Abbott efficacy (%)	0,00%			96,09%	95,17%	0 <
Number of values	1	1	1		1	CA2445
Minimum value	14,06	1,79	1,78		6,09	0,6 l/ha
Maximum value	14,06	1,79	1,78	-	6,09	0 >
Mean disease severity (%)	14,06	1,79	1,78		6,09	0 =
Abbott efficacy (%)	0,00%	87,27%	87,34%		56,69%	1 <
% Disease severity L1 - 24-35 DA-B						
Number of values	3				3	UTC
Minimum value	5,76				0,18	
Maximum value	13,75	-	-	-	1,14	3 >
Mean disease severity (%)	9,15				0,60	0 =
Abbott efficacy (%)	0,00%				92,96%	0 <
Number of values	2		2		2	CA2445
Minimum value	5,76		0,59		0,18	0,8 l/ha
Maximum value	7,94	-	0,93	-	1,14	1 >
Mean disease severity (%)	6,85		0,76		0,66	1 =
Abbott efficacy (%)	0,00%		89,02%		91,26%	0 <
Number of values	1	1	1		1	CA2445
Minimum value	5,76	0,60	0,59		0,18	0,6 l/ha
Maximum value	5,76	0,60	0,59	-	0,18	1 >
Mean disease severity (%)	5,76	0,60	0,59		0,18	0 =
Abbott efficacy (%)	0,00%	89,58%	89,76%		96,88%	0 <
Number of values	1			1	1	OSIRIS
Minimum value	13,75			0,19	0,50	2 l/ha
Maximum value	13,75	-	-	0,19	0,50	0 >
Mean disease severity (%)	13,75			0,19	0,50	1 =

Treatment name	UNTREATED CHECK	CA2445	CA2445	OSIRIS	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,6	0,8	2	0,6	
Rate unit		L/ha	L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	AB	
Abbott efficacy (%)	0,00%			98,62%	96,36%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against RHYNSE - South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 7 trials evaluated the efficacy of CA3301 on winter barley against *Rhynchosporium secalis*. 4 trials out of 7 were considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 32-37 and the 2nd application was at BBCH 49-59. The analysis was conducted on foliar level 1 and foliar level 2

Summary results are presented in Table 3.2-248.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the reduction of disease severity on winter barley against *Rhynchosporium secalis*. On foliar level 2, CA3301 at 0.6 l/ha showed 89.36% efficacy over 2 trials two weeks after the 2nd application and 79.75% over 3 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 100.00% efficacy over 1 trial on reduction of disease severity two weeks after the 2nd application and 85.67% over 3 trials before harvest. At all assessments CA3301 applied at the proposed dose rate significantly reduced disease severity.

In the South-Eastern East EPPO zone, a limited dataset was available to support the evaluation of CA3301 against *Rhynchosporium secalis*. However, this situation highlights the performance of the tested product in conditions of low to medium disease pressure (around 8 to 16%). CA3301 at 0.6 l/ha provided overall high efficacy in reducing the severity of *Rhynchosporium secalis* on winter barley on both main foliar levels 1 (L1) and 2 (L2). In all instances, CA3301 gave higher disease control than the authorised reference product RISA (250 g/ha Fluxapyroxad straight). Compared to the reference products CA2445 at 0.8 l/ha (200 g/ha Prothioconazole) and PRIAXOR, a product containing different active substances (150g/ha Fluxapyroxad and 300g/ha Pyraclostrobin), CA3301 provided equivalent disease control at early assessments and lower disease control at later assessments, whilst nevertheless obtaining the same high level of efficacy in those trials.

In addition, 6 supportive trials carried out on spring barley (see **Spring Barley (HORVS) / Rhynchosporium secalis (RHYNSE/RHYNSP)**) demonstrated that CA3301 at the proposed dose rate of 0.6 l/ha (150 g/ha prothioconazole) gave comparable disease control than the reference product CA2445 applied at a higher rate of prothioconazole (200 g/ha) and higher disease control than the authorized reference products NATIVO PRO (105 g/ha Prothioconazole and 90 g/ha Trifloxystrobin) and BUMPER 25 EC (125 g/ha Propiconazole). Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient to provide acceptable levels of control against *Rhynchosporium secalis*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Rhynchosporium secalis* on winter barley in the South-Eastern East EPPO zone.

Table 3.2-248: Summary table - Efficacy evaluation – Winter barley – RHYNSE – South-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA2445	RISA	PRIAXOR	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	1,25	1,5	0,6		
Rate unit		L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	AB		
% Disease severity L2 - 14-15 DA-B							
Number of values	2				2	UTC	
Minimum value	12,83				1,30		
Maximum value	14,13	-	-	-	1,55	2 >	
Mean disease severity (%)	13,48				1,43	0 =	
Abbott efficacy (%)	0,00%				89,36%	0 <	
Number of values	1	1			1	CA2445	
Minimum value	14,13	1,34			1,30	0,8 l/ha	
Maximum value	14,13	1,34	-	-	1,30	0 >	
Mean disease severity (%)	14,13	1,34			1,30	1 =	
Abbott efficacy (%)	0,00%	90,52%			90,80%	0 <	
Number of values	1		1		1	RISA	
Minimum value	12,83		7,41		1,55	1,25 l/ha	
Maximum value	12,83	-	7,41	-	1,55	1 >	
Mean disease severity (%)	12,83		7,41		1,55	0 =	
Abbott efficacy (%)	0,00%		42,24%		87,92%	0 <	
% Disease severity L1 - 15 DA-B							
Number of values	1	1			1	UTC	CA2445
Minimum value	9,41	0,00			0,00		0,8 l/ha
Maximum value	9,41	0,00	-	-	0,00	1 >	0 >
Mean disease severity (%)	9,41	0,00			0,00	0 =	1 =
Abbott efficacy (%)	0,00%	100,00%			100,00%	0 <	0 <
% Disease severity L2 - 24-31 DA-B							
Number of values	3				3	UTC	
Minimum value	13,23				2,34		
Maximum value	17,61	-	-	-	4,05	3 >	
Mean disease severity (%)	15,78				3,22	0 =	
Abbott efficacy (%)	0,00%				79,75%	0 <	
Number of values	2	2		2	2	CA2445	
Minimum value	13,23	1,73		0,23	2,34	PRIAXOR	
Maximum value	17,61	2,73	-	1,18	3,26	0 >	
Mean disease severity (%)	15,42	2,23		0,70	2,80	0 =	
Abbott efficacy (%)	0,00%	85,71%		95,78%	81,90%	2 <	
Number of values	1		1		1	RISA	
Minimum value	16,50		9,38		4,05	1,25 l/ha	
Maximum value	16,50	-	9,38	-	4,05	1 >	
Mean disease severity (%)	16,50		9,38		4,05	0 =	
Abbott efficacy (%)	0,00%		43,15%		75,45%	0 <	
% Disease severity L1 - 24-31 DA-B							
Number of values	3				3	UTC	
Minimum value	5,99				0,75		
Maximum value	10,30	-	-	-	1,34	3 >	
Mean disease severity (%)	7,94				1,10	0 =	
Abbott efficacy (%)	0,00%				85,67%	0 <	
Number of values	2	2		2	2	CA2445	
Minimum value	7,53	0,58		0,08	0,75	PRIAXOR	
Maximum value	10,30	1,11	-	0,34	1,34	0 >	
Mean disease severity (%)	8,92	0,84		0,21	1,05	0 =	
Abbott efficacy (%)	0,00%	90,76%		97,82%	88,52%	2 <	
Number of values	1		1		1	RISA	
Minimum value	5,99		4,65		1,20	1,25 l/ha	
Maximum value	5,99	-	4,65	-	1,20	1 >	
Mean disease severity (%)	5,99		4,65		1,20	0 =	
Abbott efficacy (%)	0,00%		22,37%		79,97%	0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against RHYNSE - Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, a total of 26 trials from the North-Eastern East EPPO zone and the neighbouring countries Czech Republic, Germany and Slovakia evaluated the efficacy of CA3301 on winter barley against *Rhynchosporium secalis*. 11 trials out of 26 were considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 31-37 and the 2nd application was at BBCH 45-61. The analysis was conducted on foliar level 1 and foliar level 2.

Summary results are presented in Table 3.2-249.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the reduction of disease severity on winter barley against *Rhynchosporium secalis*. On foliar level 2, CA3301 at 0.6 l/ha showed 87.63% efficacy over 4 trials two weeks after the 2nd application and 77.50% over 9 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 80.82% efficacy over 1 trial on reduction of disease severity two weeks after the 2nd application and 86.62% over 8 trials before harvest. At all assessments CA3301 applied at the proposed dose rate significantly reduced disease severity.

In Poland and neighbouring countries, CA3301 at 0.6 l/ha provided medium to high efficacy in reducing the disease severity of *Rhynchosporium secalis* on winter barley, on both main foliar levels 1 (L1) and 2 (L2). According to the reference products, the performance of CA3301 was higher, equivalent or lower but in overall the tested product was in most instances comparable to products containing Prothioconazole at equivalent or higher dose rate than the tested product. In addition, in all except 1 instance where disease control was lower than the reference products the efficacy remained high. Therefore, it is envisaged that applications of 0.6 l/ha will be sufficient to provide acceptable control of *Rhynchosporium secalis*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Rhynchosporium secalis* on winter barley in Poland.

Table 3.2-249: Summary table - Efficacy evaluation – Winter barley – RHYNSE – Data relevant for Poland

Treatment name	UNTREATED CHECK	CA244 5	CA244 5	PRIAXO R	OSIRI S	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,6	0,8	1,5	2	0,6	
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	AB	AB	
% Disease severity L2 - 13-15 DA-B							
Number of values	4					4	UTC
Minimum value	7,09					0,2	
Maximum value	14,06	-	-	-	-	2,84	4 >
Mean disease severity (%)	9,27					1,24	0 =
Abbott efficacy (%)	0,00%					87,63%	0 <
Number of values	3		3			3	CA2445
Minimum value	7,09		0,28			0,2	0,8 l/ha
Maximum value	14,06	-	4,11	-	-	2,84	0 >
Mean disease severity (%)	9,82		1,84			1,49	3 =

Treatment name	UNTREATED CHECK	CA244 5	CA244 5	PRIAXO R	OSIRI S	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,6	0,8	1,5	2	0,6		
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	AB	AB		
Abbott efficacy (%)	0,00%		83,82%			85,69%	0 <	
Number of values	1	1	1			1	CA2445	
Minimum value	8,3	0,41	0,28			0,2	0,6 l/ha	
Maximum value	8,3	0,41	0,28	-	-	0,2	0 >	
Mean disease severity (%)	8,3	0,41	0,28			0,2	1 =	
Abbott efficacy (%)	0,00%	95,06%	96,63%			97,59%	0 <	
Number of values	1				1	1	OSIRIS	
Minimum value	7,63				0,06	0,5	1 l/ha	
Maximum value	7,63	-	-	-	0,06	0,5	0 >	
Mean disease severity (%)	7,63				0,06	0,5	1 =	
Abbott efficacy (%)	0,00%				99,21%	93,45%	0 <	
% Disease severity L1 - 15 DA-B								
Number of values	1		1			1	UT C	CA244 5
Minimum value	5,11		0,91			0,98		0,8 l/ha
Maximum value	5,11	-	0,91	-	-	0,98	1 >	0 >
Mean disease severity (%)	5,11		0,91			0,98	0 =	1 =
Abbott efficacy (%)	0,00%		82,19%			80,82%	0 <	0 <
% Disease severity L2 - 24-49 DA-B								
Number of values	9					9	UTC	
Minimum value	6,94					0,38	9 >	
Maximum value	26,7	-	-	-	-	10,35	0 =	
Mean disease severity (%)	12,83					3,28	0 <	
Abbott efficacy (%)	0,00%					77,50%		
Number of values	8		8			8	CA2445	
Minimum value	6,94		0,31			0,41	0,8 l/ha	
Maximum value	26,7	-	14,36	-	-	10,35	1 >	
Mean disease severity (%)	13,17		3,88			3,64	4 =	
Abbott efficacy (%)	0,00%		74,17%			75,16%	3 <	
Number of values	2		2	2		2	PRIAXOR	
Minimum value	13,23		1,73	0,23		2,34	1,5 l/ha	
Maximum value	17,61	-	2,73	1,18	-	3,26	0 >	
Mean disease severity (%)	15,42		2,23	0,7		2,8	0 =	
Abbott efficacy (%)	0,00%		85,71%	95,78%		81,90%	2 <	
Number of values	2				2	2	OSIRIS	
Minimum value	6,94				0,31	0,38	1 l/ha	
Maximum value	10,13	-	-	-	0,33	0,41	0 >	
Mean disease severity (%)	8,54				0,32	0,4	2 =	
Abbott efficacy (%)	0,00%				96,09%	95,17%	0 <	
Number of values	1	1	1			1	CA2445	
Minimum value	14,06	1,79	1,78			6,09	0,6 l/ha	
Maximum value	14,06	1,79	1,78	-	-	6,09	0 >	
Mean disease severity (%)	14,06	1,79	1,78			6,09	0 =	
Abbott efficacy (%)	0,00%	87,34%	87,34%			56,69%	1 <	
% Disease severity L1 - 24-49 DA-B								
Number of values	8					8	UTC	
Minimum value	5,76					0,18	8 >	
Maximum value	14,83	-	-	-	-	5,01	0 =	
Mean disease severity (%)	10,08					1,49		

Treatment name	UNTREATED CHECK	CA244 5	CA244 5	PRIAXO R	OSIRI S	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,6	0,8	1,5	2	0,6	
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	AB	AB	
Abbott efficacy (%)	0,00%					86,62%	0 <
Number of values	7		7			7	CA2445
Minimum value	5,76		0,58			0,18	0,8 l/ha
Maximum value	14,83	-	4,6	-	-	5,01	1 >
Mean disease severity (%)	9,55		1,93			1,64	4 =
Abbott efficacy (%)	0,00%		82,19%			85,23%	2 <
Number of values	2		2	2		2	PRIAXOR
Minimum value	7,53		0,58	0,08		0,75	1,5 l/ha
Maximum value	10,3	-	1,11	0,34	-	1,34	0 >
Mean disease severity (%)	8,92		0,85	0,21		1,05	0 =
Abbott efficacy (%)	0,00%		90,76%	97,82%		88,52%	2 <
Number of values	2				1	1	OSIRIS
Minimum value	13,75				0,19	0,5	1 l/ha
Maximum value	13,75	-	-	-	0,19	0,5	0 >
Mean disease severity (%)	13,75				0,19	0,5	1 =
Abbott efficacy (%)	0,00%				98,62%	96,36%	0 <
Number of values	1	1	1			1	CA2445
Minimum value	5,76	0,6	0,59			0,18	0,6 l/ha
Maximum value	5,76	0,6	0,59	-	-	0,18	1 >
Mean disease severity (%)	5,76	0,6	0,59			0,18	0 =
Abbott efficacy (%)	0,00%	89,58%	89,76%			96,88%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

8 valid trials were presented in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,6 l/ha was effective on a medium to high level of control after 15-49 days after second application.

5 valid trials were carried out in **the North-East EPPO zone**. The test product at 0,6 l/ha achieved medium to high efficacy after 13-35 DA-B. Also 6 additional trials from the neighbouring countries (the Czech Republic, Germany and Slovakia) have been submitted to support of Polish registration. The results achieved in these efficacy trials confirm the conclusion from the NE zone.

4 valid trials were conducted in **the South-East EPPO zone**. CA3301 at 0,6 l/ha presented similar results compared to other zones. The test product was effective on medium to high level of control after 14-31 DA-B. 7 trials from the Mediterranean zone have been submitted to support of product registration in the other zones. CA3301 achieved high efficacy (14-15 DA-B) and low (26-43 DA-B). However, the lower level is near of 60% (medium efficacy).

Taking into account all trials, CA3301 used in 2 applications can be recommended to control of *Rhynchosporium secalis* in winter barley. No significant differences between the test and reference product were detected.

3.2.3.4 Winter barley (HORVW) / *Pyrenophora teres* (PYRNTE)

Materials and Methods – Winter barley - PYRNTE

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2017 and 2020, a total of 89 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the efficacy of CA3301 against *Pyrenophora teres* on **winter barley** (see Table 3.2-250). The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, a total of 20 trials were performed in the Czech Republic (4), Denmark (2), France (2), Germany (10) and the United Kingdom (2).

In the Mediterranean EPPO zone, a total of 21 trials were performed in France (9), Italy (4), Portugal (1) and Spain (7).

In the North-Eastern East EPPO zone, a total of 30 trials were performed in Latvia (3), Lithuania (1) and Poland (26).

In the South-Eastern East EPPO zone, a total of 18 trials were performed in Bulgaria (10), Hungary (6) and Romania (2).

Table 3.2-250: Presentation of trials – Winter barley (HORVW) - PYRNTE

Crop(s)) *	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mar- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Winter barley	PYRNTE	Czech Republic	2018- 2020	MED + E	4 (3)	-	-	-	GEP	
		Denmark	2018	MED + E	2 (0)	-	-	-	GEP	
		France (N)	2019- 2020	MED + E	2 (2)	-	-	-	GEP	
		Germany	2019- 2020	MED + E	10 (5)	-	-	-	GEP	
		United Kingdom	2019	MED + E	2 (2)	-	-	-	GEP	
Winter barley	PYRNTE	France (S)	2019- 2020	MED + E	-	9 (7)	-	-	GEP	
		Italy	2019	MED + E	-	4 (4)	-	-	GEP	
		Portugal	2019	MED + E	-	1 (1)	-	-	GEP	
		Spain	2019- 2020	MED + E	-	7 (7)	-	-	GEP	
Winter barley	PYRNTE	Latvia	2019	MED + E	-	-	3 (2)	-	GEP	
		Lithuani a	2019	MED + E	-	-	1 (0)	-	GEP	
		Poland	2017- 2020	MED + E	-	-	26 (20)	-	GEP	
Winter barley	PYRNTE	Bulgaria	2018- 2019	MED + E	-	-	-	10 (9)	GEP	
		Hungary	2018- 2020	MED + E	-	-	-	6 (5)	GEP	
		Romania	2019	MED + E	-	-	-	2 (2)	GEP	

Crop(s)) *	Tar- get(s)*	Country	Year s	Type of trial*	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
TOTAL	-	-	2017- 2020	MED + E	20 (12)	21 (19)	30 (22)	18 (16)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

In all trials, CA3301 was compared to at least one commercial and registered fungicide used as standard reference for comparison.

Table 3.2-251: Efficacy evaluation - Presentation of reference standards used in trials – Winter barley (HORVW) – PYRNTE – Maritime EPPO zone

Crop(s)	Refer- ence standard	Country(ies) where the product is used ⁽¹⁾	Authoriza- tion number	Active sub- stance(s)	Formulation		Regis- tered ap- plication rate ⁽³⁾	Applica- tion rate in tri- als (per treat- ment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concentra- tion of a.s.			
Winter barley	JOAO	FR (N)	2060116	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PROLINE 275	UK	14790	Prothiocona- zole	EC	275 g/l	2 x 0.72 l/ha	2 x 0.72 l/ha	
	CA2445	UK	12084	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PROLINE	DE	025287-00	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PROLINE 250 EC	DK	18-473	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PROLINE 250 EC	CZ	4523-1	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	MIRA- DOR XTRA	CZ	4626-1	Azoxystrobin + cyprocona- zole	SC	280 g/l	2 x 1 l/ha	2 x 0.8-1 l/ha	

Table 3.2-252: Efficacy evaluation - Presentation of reference standards used in trials – Winter barley (HORVW) – PYRNTE – Mediterranean EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter barley	JOAO	FR (S)	2060116	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRAKTIS	ES	01135	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-SARO	ES	25661	Prothioconazole + Tebuconazole	EC	125 g/l + 125 g/l	2 x 1 l/ha	2 x 1 l/ha	
	BUMPER 25 EC	PT	0299	Propiconazole	EC	250 g/l	2 x 0.5 l/ha	2 x 0.5 l/ha	
	PRO-LINE	IT	013385	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials

Table 3.2-253: Efficacy evaluation - Presentation of reference standards used in trials – Winter barley (HORVW) – PYRNTE – North-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter barley	PRAKTIS	PL	R-222/2019	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.6-0.8 l/ha	CA2445 in some trials
	OSIRIS 65 EC	PL	R-87/2012	Epoxiconazole + metconazole	EC	65 g/l	1 x 1.5-2.5 l/ha	2 x 2 l/ha	
	PRO-LINE	LV	0637	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE	LT	AS2-6F(2018) 2019-07-31	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

Table 3.2-254: Efficacy evaluation - Presentation of reference standards used in trials – Winter barley (HORVW) – PYRNTE – South-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter barley	PRO-LINE	HU	6300/1205-1/2020	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.6-0.8 l/ha	CA2445 in some

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
									trials
	PRI-AXOR	HU	04.2/4127-1/2016	Fluxapyroxad Pyraclostrobin	EC	225 g/l	N/A	2 x 1.5 l/ha	
	PRO-LINE	RO	457PC/15.11.2018	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	RISA 20 EC	BG	01389 – PPP-1 / 03/23/2016	Tebuconazole	EC	200 g/l	N/A	2 x 1.25 l/ha	

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-255.

Table 3.2-255: Details on trial methodology – Winter barley (HORVW) - PYRNT

		Maritime EPPO zone	Mediterranean EPPO zone	North-Eastern EPPO zone	South-Eastern EPPO zone
Trials	Total number (valid number)	20 (12)	21 (19)	30 (22)	18 (16)
	Supportive trials	-	-	-	-
Guidelines	General guidelines	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)
	Specific guidelines	PP 1/26(4)	PP 1/26(4)	PP 1/26(4)	PP 1/26(4)
Experimental design	Plot design	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included
	Plot size	20.79-36.9 m ²	12-24 m ²	21-35 m ²	21-30 m ²
	Number of replications	4	4	4	4
Crop	Trials per crop	Winter barley (20)	Winter barley (21)	Winter barley (30)	Winter barley (18)
	Varieties per crop	Nero (1), Bazooka (1), Belfry (1), Meridian (4), Sandra (1), KWS Cassia (1), Etincelle (1), Kosmos (2), Triumf (1), Lomerit (2), SU Vireni (1), Titus (1), KWS Orwell (1), Tonic (1), KWS Jaguar (1)	Ketos (3), California (1), Touareg (1), Etincel (3), Maltesse (1), Volume (1), Basic (1), Scrabble (1), Prestige (1), Solis (1), Sandra (1), Cassia (1), Basic (1), Gustav (1), Amistar (1), Graphic (1), Solist (1)	Metaxa (1), Antonella (1), Meridian (4), Kosmos (6), Quadriga (1), Zenek (3), KWS Tenor (2), Kobuz (1), Quantiga (1), Ordinale (1), Lomerit (1), Titus (1), Arenia (1), Antonella (1), Gloria (1), Wootan (1), Melania (2), NA (1)	Multie (1), Odisey (1), Ahat (2), Calypso (1), KWS Scala (1), SY Teepee (1), Obzor (4), Gerhart (1), Carolina (1), Antonella (1), Etincel (1), Kasanova (2), Hanzl (1)

	Sowing period	August (1), September (15), October (4)	October (9), November (5), December (6), NA (1)	August (2), September (27), October (1)	September (2), October (11), November (4), NA (1)
Application	Crop stage (BBCH)* at application	A: BBCH 31-53 B: BBCH 39-65	A: BBCH 31-47 B: BBCH 39-65	A: BBCH 30-39 B: BBCH 45-61	A: BBCH 31-39 B: BBCH 41-61
	Timing Disease stage at application	BBCH 30-61 A: PRINFC (11), MIXED (7), ACTIVE (1), NA (1) B: PRINFC (8), MIXED (10), ACTIVE (1), NA (1)	BBCH 30-61 A: PRINFC (12), MIXED (8), SPORUL (1) B: PRINFC (4), MIXED (16), SPORUL (1)	BBCH 30-61 A: PRINFC (13), MIXED (2), NA (15) B: PRINFC (10), MIXED (5), NA (15)	BBCH 30-61 A: PRINFC (13), MIXED (4), NA (1) B: PRINFC (10), MIXED (6), SPORUL (1), NA (1)
	Number of applications Intervals between applications	2 applications (9-31 days) (20)	2 applications (14-40 days) (21)	1 application (1) 2 applications (15-48 days) (30)	2 applications (14-29 days) (18)
	Spray volumes	200-300 l/ha	200-300 l/ha	200-400 l/ha	200-400 l/ha
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)
	Assessment dates	-1-1 DA-A; 14-18 DA-A 0 DA-B; 5 DA-B; 13-18 DA-B; 21-49 DA-B; 51-83 DA-B	-1-1 DA-A; 13-19 DA-A 0 DA-B; 7-8 DA-B; 13-21 DA-B; 25-45 DA-B; 54-80 DA-B	-1-0 DA-A; 14-18 DA-A 0 DA-B; 13-22 DA-B; 24-49 DA-B; 50-95 DA-B	0 DA-A; 7 DA-A; 14-16 DA-A, 28 DA-A 0 DA-B; 7 DA-B; 14-19 DA-B; 22-50 DA-B, 53-107 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Natural (20)	Natural (21)	Natural (30)	Natural (18)
	e.g. Field / Greenhouse...	Field trials	Field trials	Field trials	Field trials

Out of the 89 trials performed on winter barley against *Pyrenophora teres*, 69 were considered valid.

Use of CA3301 at 2x 0.6 l/ha against PYRNTE - Maritime EPPO zone

In the Maritime EPPO zone, a total of 20 trials evaluated the efficacy of CA3301 on winter barley against *Pyrenophora teres*. 12 trials out of 20 were considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 31-53 and the 2nd application was at BBCH 39-65. The analysis was conducted on foliar level 1 and foliar level 2.

Summary results are presented in Table 3.2-256.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the reduction of disease

severity on winter barley against *Pyrenophora teres*. On foliar level 2, CA3301 at 0.6 l/ha showed 83.40% efficacy over 4 trials two weeks after the 2nd application and 78.60% over 10 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 81.21% efficacy over 2 trials on reduction of disease severity two weeks after the 2nd application and 72.85% over 9 trials before harvest. At all assessments CA3301 applied at the proposed dose rate significantly reduced disease severity.

In the Maritime EPPO zone, disease pressure was moderate to high and CA3301 at 0.6 l/ha provided medium to high efficacy against *Pyrenophora teres*. In most instances, CA3301 gave higher or equivalent disease control compared to the authorised reference products CA2445 at 0.8 l/ha and MIRADOR XTRA. CA3301 also gave equivalent disease control compared to the authorised reference product PROLINE 275 except in 2 trials before harvest where CA3301 provided lower efficacy. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient to provide acceptable control of *Pyrenophora teres*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Pyrenophora teres* on winter barley in the Maritime EPPO zone.

Table 3.2-256: Summary table - Efficacy evaluation – Winter barley – PYRNTE - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA244 5 0,8 L/ha AB	PROLINE 275 0,72 L/ha AB	MIRADOR XTRA 0,8 L/ha AB	CA330 1 0,6 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
% Disease severity L2 - 14-15 DA-B						
Number of values	4				4	UTC
Minimum value	5,29				0,00	
Maximum value	20,00	-	-	-	7,36	4 >
Mean disease severity (%)	10,05				2,43	0 =
Abbott efficacy (%)	0,00%				83,40 %	0 <
Number of values	3	3			3	CA2445 0,8 l/ha
Minimum value	5,29	0,00			0,00	
Maximum value	9,14	1,48	-	-	1,91	0 >
Mean disease severity (%)	6,74	0,57			0,79	3 =
Abbott efficacy (%)	0,00%	93,28 %			90,14 %	0 <
Number of values	1		1		1	PROLINE 275 0,72 l/ha
Minimum value	20,00		3,08		7,36	
Maximum value	20,00	-	3,08	-	7,36	0 >
Mean disease severity (%)	20,00		3,08		7,36	1 =
Abbott efficacy (%)	0,00%		84,60%		63,20 %	0 <
% Disease severity L1 - 15 DA-B						
Number of values	2				2	UTC
Minimum value	5,21				1,09	
Maximum value	22,80	-	-	-	3,80	2 >
Mean disease severity (%)	14,01				2,44	0 =
Abbott efficacy (%)	0,00%				81,21 %	0 <
Number of values	1	1			1	CA2445 0,8 l/ha
Minimum value	5,21	0,96			1,09	
Maximum value	5,21	0,96	-	-	1,09	0 >
Mean disease severity (%)	5,21	0,96			1,09	1 =
Abbott efficacy (%)	0,00%	81,57 %			79,08 %	0 <

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA244 5 0,8 L/ha AB	PROLINE 275 0,72 L/ha AB	MIRADOR XTRA 0,8 L/ha AB	CA330 1 0,6 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Number of values	1		1		1	PROLINE 275
Minimum value	22,80		7,78		3,80	0,72 l/ha
Maximum value	22,80	-	7,78	-	3,80	0 >
Mean disease severity (%)	22,80		7,78		3,80	1 =
Abbott efficacy (%)	0,00%		65,88%		83,33 %	0 <
% Disease severity L2 - 25-46 DA-B						
Number of values	10				10	UTC
Minimum value	10,25				0,31	
Maximum value	83,19	-	-	-	30,38	10 >
Mean disease severity (%)	28,57				6,58	0 =
Abbott efficacy (%)	0,00%				78,60 %	0 <
Number of values	6	6			6	CA2445
Minimum value	12,74	0,19			0,31	0,8 l/ha
Maximum value	40,34	10,54	-	-	4,86	1 >
Mean disease severity (%)	19,25	3,97			2,94	5 =
Abbott efficacy (%)	0,00%	76,76 %			81,16 %	0 <
Number of values	2		2		2	PROLINE 275
Minimum value	40,19		4,39		5,69	0,72 l/ha
Maximum value	83,19	-	17,99	-	30,38	0 >
Mean disease severity (%)	61,69		11,19		18,04	1 =
Abbott efficacy (%)	0,00%		83,73%		74,66 %	1 <
Number of values	2			2	2	MIRADOR XTRA
Minimum value	10,25			6,78	2,44	0,8 l/ha
Maximum value	36,56	-	-	10,13	9,69	1 >
Mean disease severity (%)	23,41			8,45	6,07	1 =
Abbott efficacy (%)	0,00%			53,07%	74,85 %	0 <
% Disease severity L1 - 25-46 DA-B						
Number of values	9				9	UTC
Minimum value	5,51				1,20	
Maximum value	86,88	-	-	-	39,69	9 >
Mean disease severity (%)	19,26				6,29	0 =
Abbott efficacy (%)	0,00%				72,85 %	0 <
Number of values	6	6			6	CA2445
Minimum value	5,51	0,31			1,20	0,8 l/ha
Maximum value	9,65	4,68	-	-	2,89	0 >
Mean disease severity (%)	7,07	1,88			1,86	6 =
Abbott efficacy (%)	0,00%	73,38 %			72,61 %	0 <
Number of values	2		2		2	PROLINE 275
Minimum value	30,81		0,00		2,05	0,72 l/ha
Maximum value	86,88	-	19,94	-	39,69	0 >
Mean disease severity (%)	58,85		9,97		20,87	1 =
Abbott efficacy (%)	0,00%		88,52%		73,83 %	1 <

Treatment name	UNTREATED CHECK	CA244 5 0,8 L/ha AB	PROLINE 275 0,72 L/ha AB	MIRADOR XTRA 0,8 L/ha AB	CA330 1 0,6 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Number of values	1			1	1	MIRADOR XTRA 0,8 l/ha
Minimum value	13,25			4,39	3,66	
Maximum value	13,25	-	-	4,39	3,66	0 >
Mean disease severity (%)	13,25			4,39	3,66	1 =
Abbott efficacy (%)	0,00%			66,87%	72,38 %	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against PYRNTE - Mediterranean EPPO zone

In the Mediterranean EPPO zone, a total of 21 trials evaluated the efficacy of CA3301 on winter barley against *Pyrenophora teres*. 19 trials out of 21 were considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 31-47 and the 2nd application was at BBCH 39-65. The analysis was conducted on foliar level 1 and foliar level 2.

Summary results are presented in Table 3.2-257.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the reduction of disease severity on winter barley against *Pyrenophora teres*. On foliar level 2, CA3301 at 0.6 l/ha showed 81.63% efficacy over 11 trials two weeks after the 2nd application and 81.06% over 10 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 78.20% efficacy over 9 trials on reduction of disease severity two weeks after the 2nd application and 72.69% over 10 trials before harvest. At all assessments CA3301 applied at the proposed dose rate significantly reduced disease severity.

In the Mediterranean EPPO zone, disease pressure was relatively medium and in most instances CA3301 at 0.6 l/ha (150g/ha Prothioconazole) gave equivalent disease control to the reference product containing Prothioconazole at the higher dose of 0.8 l/ha (200g/ha Prothioconazole). In overall, CA3301 gave also equivalent disease control to the other authorised reference product PROSARO, and higher disease control compared to BUMPER 25 EC. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient to provide acceptable control of *Pyrenophora teres*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Pyrenophora teres* on winter barley in the Mediterranean EPPO zone.

Table 3.2-257: Summary table - Efficacy evaluation – Winter barley – PYRNTE - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA244 5 0,8 L/ha AB	PROSAR O 1 L/ha AB	BUMPER 25 EC 0,5 L/ha AB	CA330 1 0,6 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
% Disease severity L2 - 13-20 DA-B						
Number of values	11				11	UTC
Minimum value	5,20				0,44	

Treatment name	UNTREATED CHECK	CA244 5 0,8 L/ha AB	PROSAR O 1 L/ha AB	BUMPER 25 EC 0,5 L/ha AB	CA330 1 0,6 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Maximum value	64,56	-	-	-	10,26	11 >
Mean disease severity (%)	28,68				4,69	0 =
Abbott efficacy (%)	0,00%				81,63%	0 <
Number of values	9	9			9	CA2445
Minimum value	6,95	1,21			1,59	0,8 l/ha
Maximum value	64,56	7,91	-	-	10,26	0 >
Mean disease severity (%)	32,67	4,59			5,28	8 =
Abbott efficacy (%)	0,00%	80,63%			81,00%	1 <
Number of values	6		6		6	PROSARO
Minimum value	5,20		0,00		0,44	1 l/ha
Maximum value	53,25	-	7,94	-	6,51	0 >
Mean disease severity (%)	21,75		3,59		3,49	5 =
Abbott efficacy (%)	0,00%		82,34%		82,22%	1 <
% Disease severity L1 - 13-20 DA-B						
Number of values	9				9	UTC
Minimum value	5,71				0,25	
Maximum value	99,1	-	-	-	76,55	9 >
Mean disease severity (%)	32,83				11,07	0 =
Abbott efficacy (%)	0,00%				78,20%	0 <
Number of values	8	8			8	CA2445
Minimum value	5,71	0,75			0,25	0,8 l/ha
Maximum value	99,10	75,24	-	-	76,55	0 >
Mean disease severity (%)	35,56	12,03			12,26	8 =
Abbott efficacy (%)	0,00%	77,31%			77,24%	0 <
Number of values	4		4		4	PROSARO
Minimum value	7,95		1,50		0,25	1 l/ha
Maximum value	28,70	-	2,85	-	5,53	0 >
Mean disease severity (%)	16,91		2,05		2,32	4 =
Abbott efficacy (%)	0,00%		83,68%		85,27%	0 <
% Disease severity L2 - 25-37 DA-B						
Number of values	10				10	UTC
Minimum value	9,38				0,60	
Maximum value	38,06	-	-	-	7,90	10 >
Mean disease severity (%)	25,73				4,79	0 =
Abbott efficacy (%)	0,00%				81,06%	0 <
Number of values	8	8			8	CA2445
Minimum value	9,38	0,53			0,60	0,8 l/ha
Maximum value	38,06	5,18	-	-	7,90	0 >
Mean disease severity (%)	25,64	3,03			4,84	7 =
Abbott efficacy (%)	0,00%	88,12%			80,48%	1 <
Number of values	4		4		4	PROSARO
Minimum value	14,75		0,24		2,36	1 l/ha
Maximum value	35,56	-	7,39	-	7,90	0 >
Mean disease severity (%)	25,59		3,98		5,84	4 =
Abbott efficacy (%)	0,00%		85,63%		75,41%	0 <
% Disease severity L1 - 25-37 DA-B						
Number of values	10				10	UTC
Minimum value	5,13				0,28	
Maximum value	92,13	-	-	-	47,71	10 >

Treatment name	UNTREATED CHECK	CA244 5 0,8 L/ha AB	PROSAR O 1 L/ha AB	BUMPER 25 EC 0,5 L/ha AB	CA330 1 0,6 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate						
Rate unit						
Appl. Code						
Mean disease severity (%)	26,66				10,05	0 =
Abbott efficacy (%)	0,00%				72,69%	0 <
Number of values	7	7			7	CA2445
Minimum value	5,13	1,01			1,15	0,8 l/ha
Maximum value	92,13	29,99	-	-	47,71	0 >
Mean disease severity (%)	28,84	7,00			11,35	6 =
Abbott efficacy (%)	0,00%	82,31%			69,55%	1 <
Number of values	4		4		4	PROSARO
Minimum value	10,04		0,19		0,28	1 l/ha
Maximum value	35,25	-	17,5	-	12,50	0 >
Mean disease severity (%)	21,24		6,50		6,27	4 =
Abbott efficacy (%)	0,00%		76,99%		77,19%	0 <
Number of values	1			1	1	BUMPER 25
Minimum value	39,56			29,81	19,59	EC
Maximum value	39,56	-	-	29,81	19,59	0,5 l/ha
Mean disease severity (%)	39,56			29,81	19,59	0 =
Abbott efficacy (%)	0,00%			24,65%	50,48%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against PYRNTE - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 30 trials evaluated the efficacy of CA3301 on winter barley against *Pyrenophora teres*. 22 trials out of 30 were considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 30-39 and the 2nd application was at BBCH 45-61. The analysis was conducted on foliar level 1 and foliar level 2.

Summary results are presented in Table 3.2-258.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the reduction of disease severity on winter barley against *Pyrenophora teres*. On foliar level 2, CA3301 at 0.6 l/ha showed 72.29% efficacy over 7 trials two weeks after the 2nd application and 85.67% over 16 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 83.28% efficacy over 3 trials on reduction of disease severity two weeks after the 2nd application and 81.70% over 9 trials before harvest. At all assessments CA3301 applied at the proposed dose rate significantly reduced disease severity.

In the North-Eastern East EPPO zone, the disease pressure was relatively low to medium and in most instances CA3301 at 0.6 l/ha (150 g/ha Prothioconazole) gave similar or higher disease control than the reference product CA2245 at 0.8 l/ha (200 g/ha Prothioconazole). In overall, CA3301 provided also higher or equivalent disease control compared to the other authorised reference product OSIRIS 65 EC. CA3301 provided medium to high efficacy in this dataset. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient to provide a suitable control of *Pyrenophora teres*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Pyrenophora teres* on winter barley in the North-Eastern EPPO zone.

Table 3.2-258: Summary table - Efficacy evaluation – Winter barley – PYRNTE – North-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA2445	CA2445	OSIRIS 65 EC	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,6	0,8	2	0,6	
Rate unit		L/ha	L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	AB	
% Disease severity L2 - 13-15 DA-B						
Number of values	7				7	UTC
Minimum value	5,44				0,44	
Maximum value	37,63	-	-	-	16,53	7 >
Mean disease severity (%)	15,59				5,24	0 =
Abbott efficacy (%)	0,00%				72,29%	0 <
Number of values	4			4	4	OSIRIS
Minimum value	5,44			0,00	0,44	2 l/ha
Maximum value	11,51	-	-	5,33	4,63	0 >
Mean disease severity (%)	8,02			1,93	1,89	4 =
Abbott efficacy (%)	0,00%			78,24%	77,77%	0 <
Number of values	3		3		3	CA2445
Minimum value	13,50		0,50		1,54	0,8 l/ha
Maximum value	37,63	-	8,99	-	16,53	0 >
Mean disease severity (%)	25,69		6,07		9,70	2 =
Abbott efficacy (%)	0,00%		79,46%		64,98%	1 <
Number of values	1	1	1		1	CA2445
Minimum value	13,85	1,64	0,50		1,54	0,6 l/ha
Maximum value	13,85	1,64	0,50	-	1,54	0 >
Mean disease severity (%)	13,85	1,64	0,50		1,54	1 =
Abbott efficacy (%)	0,00%	88,16%	96,39%		88,88%	0 <
% Disease severity L1 - 14-15 DA-B						
Number of values	3				3	UTC
Minimum value	6,50				1,26	
Maximum value	28,56	-	-	-	5,16	3 >
Mean disease severity (%)	15,20				2,58	0 =
Abbott efficacy (%)	0,00%				83,28%	0 <
Number of values	2		2		2	CA2445
Minimum value	10,55		0,98		1,26	0,8 l/ha
Maximum value	28,56	-	3,95	-	5,16	0 >
Mean disease severity (%)	19,56		2,46		3,21	2 =
Abbott efficacy (%)	0,00%		88,44%		84,99%	0 <
Number of values	1			1	1	OSIRIS
Minimum value	6,50			1,68	1,31	2 l/ha
Maximum value	6,50	-	-	1,68	1,31	0 >
Mean disease severity (%)	6,50			1,68	1,31	1 =
Abbott efficacy (%)	0,00%			74,15%	79,85%	0 <
% Disease severity L2 - 24-38 DA-B						
Number of values	16				16	UTC
Minimum value	5,40				0,06	
Maximum value	28,25	-	-	-	7,63	16 >
Mean disease severity (%)	11,39				1,79	0 =
Abbott efficacy (%)	0,00%				85,67%	0 <
Number of values	15		15		15	CA2445
Minimum value	5,40		0,21		0,06	0,8 l/ha
Maximum value	28,25	-	5,53	-	7,63	3 >
Mean disease severity (%)	11,65		2,08		1,89	12 =
Abbott efficacy (%)	0,00%		81,36%		84,98%	0 <
Number of values	13			13	13	OSIRIS
Minimum value	5,40			0,09	0,06	2 l/ha

Treatment name	UNTREATED CHECK	CA2445	CA2445	OSIRIS 65 EC	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,6	0,8	2	0,6	
Rate unit		L/ha	L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	AB	
Maximum value	28,25	-	-	8,63	7,63	3 >
Mean disease severity (%)	10,84			2,55	1,44	10 =
Abbott efficacy (%)	0,00%			76,11%	87,26%	0 <
Number of values	1	1	1		1	CA2445
Minimum value	13,19	1,68	2,99		3,56	0,6 l/ha
Maximum value	13,19	1,68	2,99	-	3,56	0 >
Mean disease severity (%)	13,19	1,68	2,99		3,56	0 =
Abbott efficacy (%)	0,00%	87,26%	77,33%		73,01%	1 <
% Disease severity L1 - 24-37 DA-B						
Number of values	9				9	UTC
Minimum value	5,06				0,16	
Maximum value	29,19	-	-	-	5,44	9 >
Mean disease severity (%)	10,99				1,86	0 =
Abbott efficacy (%)	0,00%				81,70%	0 <
Number of values	8			8	8	OSIRIS
Minimum value	5,06			0,06	0,16	2 l/ha
Maximum value	14,41	-	-	4,93	4,40	0 >
Mean disease severity (%)	8,71			1,53	1,41	8 =
Abbott efficacy (%)	0,00%			81,39%	81,74%	0 <
Number of values	5		5		5	CA2445
Minimum value	5,25		0,16		0,16	0,8 l/ha
Maximum value	29,19	-	4,74	-	5,44	0 >
Mean disease severity (%)	13,23		1,61		1,75	5 =
Abbott efficacy (%)	0,00%		86,29%		85,62%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against PYRNTE - South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 18 trials evaluated the efficacy of CA3301 on winter barley against *Pyrenophora teres*. 16 trials out of 18 were considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 31-39 and the 2nd application was at BBCH 41-61. The analysis was conducted on foliar level 1 and foliar level 2.

Summary results are presented in Table 3.2-259.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the reduction of disease severity on winter barley against *Pyrenophora teres*. On foliar level 2, CA3301 at 0.6 l/ha showed 70.28% efficacy over 4 trials two weeks after the 2nd application and 77.37% over 13 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 57.02% efficacy over 1 trial on reduction of disease severity two weeks after the 2nd application and 83.10% over 11 trials before harvest. At all assessments CA3301 applied at the proposed dose rate significantly reduced disease severity.

In the South-Eastern East EPPO zone, disease pressure was relatively low to medium and in most of instances CA3301 at 0.6 l/ha (150 g/ha Prothioconazole) gave comparable disease control than the reference product CA2245 containing Prothioconazole at 0.8 l/ha (200 g/ha Prothioconazole). In overall, CA3301 gave equivalent disease control to the other authorised reference products RISA 20 EC and

PRIAXOR. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient to provide acceptable control of *Pyrenophora teres*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Pyrenophora teres* on winter barley in the South-Eastern East EPPO zone.

Table 3.2-259: Summary table - Efficacy evaluation – Winter barley – PYRNTE – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA2445	RISA 20 EC	PRIAXOR	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	1,25	1,5	0,6		
Rate unit		L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	AB		
% Disease severity L2 - 15-19 DA-B							
Number of values	4				4	UTC	
Minimum value	7,25				1,48		
Maximum value	26,61	-	-	-	7,16	4 >	
Mean disease severity (%)	15,17				4,33	0 =	
Abbott efficacy (%)	0,00%				70,28%	0 <	
Number of values	3	3			3	CA2445	
Minimum value	7,25	0,23			1,48	0,8 l/ha	
Maximum value	16,38	6,06	-	-	7,16	0 >	
Mean disease severity (%)	11,35	2,65			3,82	1 =	
Abbott efficacy (%)	0,00%	79,35%			67,69%	2 <	
Number of values	1			1	1	PRIAXOR	
Minimum value	25,61			5,11	5,84	1,5 l/ha	
Maximum value	25,61	-	-	5,11	5,84	0 >	
Mean disease severity (%)	25,61			5,11	5,84	1 =	
Abbott efficacy (%)	0,00%			80,80%	78,05%	0 <	
% Disease severity L1 - 19 DA-B							
Number of values	1	1			1	UTC	CA2445
Minimum value	7,19	1,68			3,09		0,8 l/ha
Maximum value	7,19	1,68	-	-	3,09	1 >	0 >
Mean disease severity (%)	7,19	1,68			3,09	0 =	0 =
Abbott efficacy (%)	0,00%	76,63%			57,02%	0 <	1 <
% Disease severity L2 - 21-45 DA-B							
Number of values	13				13	UTC	
Minimum value	6,50				0,00		
Maximum value	100,00	-	-	-	8,56	13 >	
Mean disease severity (%)	23,85				3,45	0 =	
Abbott efficacy (%)	0,00%				77,37%	0 <	
Number of values	7		7		7	RISA 20 EC	
Minimum value	6,50		1,80		1,35	1,25 l/ha	
Maximum value	29,25	-	8,81	-	8,56	0 >	
Mean disease severity (%)	14,70		4,60		4,74	6 =	
Abbott efficacy (%)	0,00%		68,02%		65,61%	1 <	
Number of values	7			4	4	PRIAXOR	
Minimum value	10,35			0,00	0,00	1,5 l/ha	
Maximum value	30,04	-	-	4,89	6,55	0 >	
Mean disease severity (%)	18,63			2,24	2,90	3 =	
Abbott efficacy (%)	0,00%			89,69%	86,63%	1 <	
Number of values	3	3			3	CA2445	
Minimum value	15,48	0,00			0,00	0,8 l/ha	
Maximum value	100,00	3,25	-	-	4,13	0 >	
Mean disease severity (%)	49,37	1,10			1,40	3 =	
Abbott efficacy (%)	0,00%	92,98%			91,08%	0 <	
% Disease severity L1 - 21-45 DA-B							
Number of values	11				11	UTC	
Minimum value	5,56				0,00		
Maximum value	29,31	-	-	-	6,25	11 >	
Mean disease severity (%)	11,38				1,71	0 =	

Treatment name	UNTREATED CHECK	CA2445	RISA 20 EC	PRIAXOR	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	1,25	1,5	0,6	
Rate unit		L/ha	L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	AB	
Abbott efficacy (%)	0,00%				83,10%	0 <
Number of values	5		5		5	RISA 20 EC
Minimum value	7,38		1,73		2,15	1,25 l/ha
Maximum value	17,50	-	6,69	-	6,25	0 >
Mean disease severity (%)	9,85		3,14		3,07	5 =
Abbott efficacy (%)	0,00%		69,49%		69,83%	0 <
Number of values	4			4	4	PRIAXOR
Minimum value	5,56			0,00	0,00	1,5 l/ha
Maximum value	14,25	-	-	5,06	2,08	0 >
Mean disease severity (%)	8,46			1,32	0,87	4 =
Abbott efficacy (%)	0,00%			90,45%	91,27%	0 <
Number of values	3	3			3	CA2445
Minimum value	6,28	0,00			0,00	0,8 l/ha
Maximum value	29,31	1,28	-	-	0,71	0 >
Mean disease severity (%)	16,13	0,44			0,25	3 =
Abbott efficacy (%)	0,00%	93,17%			96,19%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

12 valid trials were carried out in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,6 l/ha achieved medium to high efficacy after 14-46 days after second application.

22 valid trials were presented in **the North-East EPPO zone**. The test product at 0,6 l/ha showed medium to high level of control after 13-38 DA-B.

16 valid trials were conducted in **the South-East EPPO zone**. CA3301 at 0,6 l/ha achieved medium to high efficacy after 15-45 DA-B. Moreover, 19 additional trials from the Mediterranean zone confirm the conclusion in the SE zone.

Taking into account all trials, CA3301 used in 2 applications can be recommended to control of *Pyrenophora teres* in winter barley. No significant differences between the test and reference product were noted.

3.2.3.5 Winter barley (HORVW) / *Blumeria graminis* f. sp. *hordei* (ERYSGH / ERYSGR)

Materials and Methods – Winter barley - ERYSGH

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2017 and 2020, a total of 35 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the efficacy of CA3301 against *Blumeria graminis* f. sp. *hordei* on **winter barley** (see Table 3.2-260). The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, a total of 10 trials were performed in the Czech Republic (3), Denmark (2), France (2) and Germany (3).

In the Mediterranean EPPO zone, a total of 2 trials were performed in France (1) and Spain (1).

In the North-Eastern East EPPO zone, a total of 18 22 trials were performed in Latvia (5 7), Lithuania (2 3) and Poland (11 12).

In the South-Eastern East EPPO zone, a total of 5 trials were performed in Hungary (5).

Table 3.2-260: Presentation of trials – Winter barley (HORVW) - ERYSGH

Crop(s) *)	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Winter barley	ERYSGH	Czech Republic	2018- 2020	MED + E	3 (0)	-	-	-	GEP	
		Denmark	2018	MED + E	2 (0)	-	-	-	GEP	
		France (N)	2019	MED + E	2 (2)	-	-	-	GEP	
		Germany	2019	MED + E	3 (0)	-	-	-	GEP	
Winter barley	ERYSGH	France (S)	2019	MED + E	-	1 (0)	-	-	GEP	
		Spain	2020	MED + E	-	1 (0)	-	-	GEP	
Winter barley	ERYSGH	Latvia	2019	MED + E	-	-	5 (1)	-	GEP	
			2021	E	-	-	2 (2)	-	GEP	
		Lithuani a	2019	MED + E	-	-	2 (1)	-		
			2021	E	-	-	1 (1)	-	GEP	
		Poland	2017- 2020	MED + E	-	-	11 (1)	-	GEP	
			2021	E	-	-	1 (0)	-	GEP	
Winter barley	ERYSGH	Hungary	2019- 2020	MED + E	-	-	-	5 (2)	GEP	
TOTA L	-	-	2017- 2020	MED + E	10 (2)	2 (0)	18 (3)	5 (2)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

In all trials, CA3301 was compared to at least one commercial and registered fungicide used as standard reference for comparison.

Table 3.2-261: Efficacy evaluation - Presentation of reference standards used in trials – Winter barley (HORVW) – ERYSGH – Maritime EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter barley	PROLINE 250 EC	CZ	4523-1	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	MIRADOR XTRA	CZ	4626-1	Azoxystrobin + cyproconazole	SC	280 g/l	2 x 1 l/ha	2 x 1 l/ha	
	JOAO	FR (N)	2060116	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PROLINE	DE	025287-00	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PROLINE 250 EC	DK	18-473	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

Table 3.2-262: Efficacy evaluation - Presentation of reference standards used in trials – Winter barley (HORVW) – ERYSGH – Mediterranean EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter barley	JOAO	FR (S)	2060116	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRAKTIS	ES	01135	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PROSARO	ES	25661	Prothioconazole + Tebuconazole	EC	125 g/l + 125 g/l	2 x 1 l/ha	2 x 1 l/ha	

Table 3.2-263: Efficacy evaluation - Presentation of reference standards used in trials – Winter barley (HORVW) – ERYSGH – North-Eastern East

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter barley	PRAKTIS	PL	R-222/2019	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	OSIRIS 65 EC	PL	R-87/2012	Epoxiconazole +	EC	65 g/l	1 x 1.5-2.5 l/ha	2 x 2 l/ha	

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
				metconazole					
	PRO-LINE	LV	0637	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE	LT	AS2-6F(2018) 2019-07-31	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

Table 3.2-264: Efficacy evaluation - Presentation of reference standards used in trials – Winter barley (HORVW) – ERYSGH – South-Eastern East

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter barley	PRO-LINE	HU	6300/1205-1/2020	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.6-0.8 l/ha	CA2445 in some trials
	PRI-AXOR	HU	04.2/4127-1/2016	Fluxapyroxad Pyraclostrobin	EC	225 g/l	N/A	2 x 1.5 l/ha	

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-265.

Table 3.2-265: Details on trial methodology – Winter barley (HORVW) - ERYSGH

		Maritime EPPO zone	Mediterranean EPPO zone	North-Eastern EPPO zone	South-Eastern EPPO zone
Trials	Total number (valid number)	10 (2)	2 (0)	18 22 (3 6)	5 (2)
	Supportive trials	-	-	-	-
Guidelines	General guidelines	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)
	Specific guidelines	PP 1/26(4)	PP 1/26(4)	PP 1/26(4)	PP 1/26(4)
Experimental design	Plot design	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included
	Plot size	18.48-27 m ²	12-21 m ²	21-35 m ²	21 m ²
	Number of replications	4	4	4	4

Crop	Trials per crop	Winter barley (10)	Winter barley (2)	Winter barley (4 22)	Winter barley (5)
	Varieties per crop	Nero (1), Henriette (1), Bazooka (1), Belfry (1), SU Ellen (1), Kosmos (1), Lomerit (1), Rafaela (1), Etincel (1), KWS Meridian (1)	Etincel (1), Gustav (1)	Sandra (1), Metaxa (1), Antonielli (1), Kosmos (1), Meridian (5 7), KWS Tenor (2), Quantiga (1), Titus (1), Mercurio (1), Zenek (1), Arenia (1), Wootan (1), Melania (1), Torerro (1), Concordia (1)	SY Tepee (1), Antonella (1), Etincel (1), Laverda (1), Alora (1)
	Sowing period	August (1), September (6), October (3)	October (2)	August (1), September (4 20), October (1)	October (3), November (1), NA (1)
Application	Crop stage (BBCH)* at application	A: BBCH 31-53 B: BBCH 39-65	A: BBCH 32-37 B: BBCH 39-61	A: BBCH 30-39 B: BBCH 43-61	A: BBCH 31-39 B: BBCH 43-61
	Timing Disease stage at application	BBCH 30-61 A: PRINFC (1), MIXED (9) B: PRINFC (1), MIXED (9)	BBCH 30-61 A: PRINFC (2) B: PRINFC (1), MIXED (1)	BBCH 30-61 A: PRINFC (4), MIXED (3), NA (11) B: PRINFC (4), MIXED (3), NA (11)	BBCH 30-61 A: PRINFC (4), SPORUL (1) B: PRINFC (1), MIXED (3), SPORUL (1)
	Number of applications Intervals between applications	2 applications (9-24 days) (10)	2 applications (20 days) (2)	1 application (2) 2 applications (9-49 days) (4 22)	2 applications (14-29 days) (5)
	Spray volumes	200-300 l/ha	200-300 l/ha	200-400 l/ha	250-300 l/ha
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)
	Assessment dates	0-1 DA-A; 14-18 DA-A 0 DA-B; 5 DA-B; 15-18 DA-B; 25-43 DA-B; 51-91 DA-B	0 DA-A; 15-19 DA-A 0 DA-B; 15-21 DA-B; 28-36 DA-B; 60-71 DA-B	-1-1 DA-A; 14-18 DA-A 0 DA-B; 13-22 DA-B; 24-49 DA-B; 50-89 DA-B	0 DA-A; 15-16 DA-A, 28 DA-A 0 DA-B; 14-21 DA-B; 27-39 DA-B, 61-81 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Natural (10)	Natural (2)	Natural (4 22)	Natural (5)
	e.g. Field / Greenhouse...	Field trials	Field trials	Field trials	Field trials

Out of the ~~35~~ 39 trials performed on winter barley against *Blumeria graminis* f. sp. *hordei*, ~~7~~ 10 were considered valid.

Use of CA3301 at 2x 0.6 l/ha against ERYSGH - Maritime EPPO zone

In the Maritime EPPO zone, a total of 10 trials evaluated the efficacy of CA3301 on winter barley against *Blumeria graminis f. sp. hordei*. 2 trials out of 10 were considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 31-53 and the 2nd application was at BBCH 39-65. The analysis was conducted on foliar level 2 only.

Summary results are presented in Table 3.2-266.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the reduction of disease severity on winter barley against *Blumeria graminis f. sp. hordei*. On foliar level 2, CA3301 at 0.6 l/ha provided 87.18% efficacy over 2 trials before harvest. At all assessments CA3301 applied at the proposed dose rate significantly reduced disease severity.

In the Maritime EPPO zone, a limited dataset was available to support the evaluation of CA3301 against *Blumeria graminis f. sp. hordei*. However, this situation highlights the performance of the tested product in conditions of relatively low disease pressure (around 6 to 12%) and CA3301 provided high efficacy. In these conditions, CA3301 gave also equivalent disease control to the authorised reference product CA2445 at 0.8 l/ha. In addition, 14 supportive trials carried out on winter wheat demonstrated that in most instances CA3301 at 0.6 l/ha provided results statistically equivalents to the authorized reference products and that differences between the 0.6 l/a dose rate and the 0.8 l/ha dose rate were not always significant. Due to the low disease pressure recorded on wheat, disease incidence was assessed on this crop and the data demonstrated good results to control the disease, so it is possible to assume that Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient to provide acceptable control of *Blumeria graminis f. sp. hordei*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Blumeria graminis f. sp. hordei* on winter barley in the Maritime EPPO zone.

Table 3.2-266: Summary table - Efficacy evaluation – Winter barley – ERYSGH/ERYSGR - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA2445	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	0,6		
Rate unit		L/ha	L/ha		
Appl. Code		AB	AB		
% Disease severity L2 - 32-39 DA-B					
Number of values	2	2	2	UTC	CA2445
Minimum value	6,76	0,00	0,00		0,8 l/ha
Maximum value	12,25	4,05	3,14	2 >	0 >
Mean disease severity (%)	9,51	2,03	1,57	0 =	2 =
Abbott efficacy (%)	0,00%	83,47%	87,18%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against ERYSGH - Mediterranean EPPO zone

In the Mediterranean EPPO zone no data were available to support the efficacy evaluation of CA3301 applied at 0.6 l/ha on disease severity (%). However, spring and winter sown barley are the same crops,

Hordeum vulgare and the proposed applications are the same (dose rate, application timing etc), therefore reference is made to the data presented on spring barley in support of the proposed minimum effective dose. The validity of this argumentation is supported by the fact that existing authorisations of similar prothioconazole products also have the same dose rates registered for both spring and winter barley, hence the pathogens are controlled similarly in each crop at the same dose rate.

In the Mediterranean EPPO zone, 2 supportive trials carried out on spring barley demonstrated that in trials with relatively low disease pressure (around 12%), a consistent trend was however observed whereby CA3301 at 0.6 l/ha gave equivalent disease control compared to the authorised reference product CA2445 and that the tested product showed also high efficacy in reducing the severity of *Blumeria graminis* on foliar level 2. Furthermore, prothioconazole is well established as an effective control for this pathogen. Therefore, it is proposed that a dose rate of 0.6 L/ha is appropriate for control of *Blumeria graminis* in spring barley.

Considering all elements presented above, 2 applications of CA3301 at 0.6 l/ha is the minimum effective dose to control *Blumeria graminis* f. sp. *hordei* on winter barley in the Mediterranean EPPO zone.

Use of CA3301 at 2x 0.6 l/ha against ERYSGH - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 18 22 trials evaluated the efficacy of CA3301 on winter barley against *Blumeria graminis* f. sp. *hordei*. 3 6 trials out of 18 22 were considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 30-39 and the 2nd application was at BBCH 43-61. The analysis was conducted on foliar level 1 and foliar level 2.

Summary results are presented in Table 3.2-267.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the reduction of disease severity on winter barley against *Blumeria graminis* f. sp. *hordei*. On foliar level 2, CA3301 at 0.6 l/ha showed 58.97% efficacy over 2 trials two weeks after the 2nd application and 78.24% over 1 trial before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 82.26% efficacy over 1 trial on reduction of disease severity two weeks after the 2nd application. At all assessments CA3301 applied at the proposed dose rate significantly reduced disease severity.

3 additional trials have been submitted to support of Polish registration. On foliar level 2, CA3301 at 0,6 l/ha showed 96.99% efficacy in 3 trials two weeks after the second application. The comparable effect was achieved after application of reference product.

In the North-Eastern East zone, a limited dataset was available to support the evaluation of CA3301 against *Blumeria graminis* f. sp. *hordei*. However, this situation highlights the high efficacy of the tested product in conditions of relatively low to medium disease pressure. In these conditions, CA3301 at 0.6 l/ha gave comparable disease control to the authorized reference product CA2445 containing Prothioconazole applied at 0.8 l/ha. In addition, the same trend was observed in a supportive trial carried out on spring barley (see **Spring barley (HORVS) / *Blumeria graminis* f. sp. *hordei* (ERYSGH/ERYSGR)**)).

Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient to provide acceptable control of *Blumeria graminis* f. sp. *hordei*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Blumeria graminis* f. sp. *hordei* on winter barley in the North-Eastern East EPPO zone.

Table 3.2-267: Summary table - Efficacy evaluation – Winter barley – ERYSGH/ERYSGR – North-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA2445	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	0,6		
Rate unit		L/ha	L/ha		
Appl. Code		AB	AB		
% Disease severity L2 - 14-15 DA-B					
Number of values	2	2	2	UTC	CA2445
Minimum value	21,95	8,73	11,69		0,8 l/ha
Maximum value	54,31	14,13	15,64	2 >	0 >
Mean disease severity (%)	38,13	11,43	13,66	0 =	2 =
Abbott efficacy (%)	0,00%	67,11%	58,97%	0 <	0 <
% Disease severity L1 - 15 DA-B					
Number of values	1	1	1	UTC	CA2445
Minimum value	9,30	1,78	1,65		0,8 l/ha
Maximum value	9,30	1,78	1,65	1 >	0 >
Mean disease severity (%)	9,30	1,78	1,65	0 =	1 =
Abbott efficacy (%)	0,00%	80,86%	82,26%	0 <	0 <
% Disease severity L2 - 33 DA-B					
Number of values	1	1	1	UTC	CA2445
Minimum value	5,33	0,88	1,16		0,8 l/ha
Maximum value	5,33	0,88	1,16	1 >	0 >
Mean disease severity (%)	5,33	0,88	1,16	0 =	1 =
Abbott efficacy (%)	0,00%	83,49%	78,24%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Table 3.2-266b: Summary table – Efficacy evaluation from 3 additional trials (submitted in September 2022)

Treatment name	UNTREATED CHECK	CA2445	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	0,6		
Rate unit		L/ha	L/ha		
Appl. Code		AB	AB		
% Disease severity L2 - 14-17 DA-B					
Number of values	3	3	3	UTC	CA2445
Minimum value	5,6	0,13	0,1		0,8 l/ha
Maximum value	8,4	0,8	0,4	3 >	0 >
Mean disease severity (%)	6,91	0,37	0,22	0 =	3 =
Abbott efficacy (%)	0,00%	95,08%	96,99%	0 <	0 <

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against ERYSGH - South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 5 trials evaluated the efficacy of CA3301 on winter barley against *Blumeria graminis f. sp. hordei*. 2 trials out of 5 were considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 31-39 and the 2nd application was at BBCH 43-61. The analysis was conducted on foliar level 1 and foliar level 2.

Summary results are presented in Table 3.2-268.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the reduction of disease severity on winter barley against *Blumeria graminis f. sp. hordei*. On foliar level 2, CA3301 at 0.6 l/ha showed 99.11% efficacy over 1 trial two weeks after the 2nd application and 94.23% over 2 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 94.78% efficacy over 1 trial on reduction of disease

severity two weeks after the 2nd application. At all assessments CA3301 applied at the proposed dose rate significantly reduced disease severity.

In the South-Eastern East zone, a limited dataset was available to support the evaluation of CA3301 against *Blumeria graminis f. sp. hordei*. However, this situation highlights the high efficacy of the tested product in conditions of relatively low to medium disease pressure. In these conditions, CA3301 gave comparable disease control to the authorised reference product PRIAXOR. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient to provide acceptable control of *Blumeria graminis f. sp. hordei*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Blumeria graminis f. sp. hordei* on winter barley in the South-Eastern East EPPO zone.

Table 3.2-268: Summary table - Efficacy evaluation – Winter barley – ERYSGH – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	PRIAXOR	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		1,5	0,6		
Rate unit		L/ha	L/ha		
Appl. Code		AB	AB		
% Disease severity L2 - 15 DA-B					
Number of values	1	1	1	UTC	CA2445
Minimum value	5,61	0,33	0,05		0,8 l/ha
Maximum value	5,61	0,33	0,05	1 >	0 >
Mean disease severity (%)	5,61	0,33	0,05	0 =	1 =
Abbott efficacy (%)	0,00%	94,12%	99,11%	0 <	0 <
% Disease severity L2 - 21-37 DA-B					
Number of values	2	2	2	UTC	CA2445
Minimum value	6,96	0,03	0,00		0,8 l/ha
Maximum value	54,63	4,03	6,30	2 >	0 >
Mean disease severity (%)	30,79	2,03	3,15	0 =	2 =
Abbott efficacy (%)	0,00%	96,10%	94,23%	0 <	0 <
% Disease severity L1 - 37 DA-B					
Number of values	1	1	1	UTC	CA2445
Minimum value	37,13	0,79	1,94		0,8 l/ha
Maximum value	37,13	0,79	1,94	1 >	0 >
Mean disease severity (%)	37,13	0,79	1,94	0 =	1 =
Abbott efficacy (%)	0,00%	97,87%	94,78%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

2 valid trials were carried out in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,6 l/ha achieved high efficacy after 32-39 days after second application. Due to the limited number of trials, the cMSs are kindly asked to consider this use on the national level.

6 valid trials were presented in **the North-East EPPO zone**. The test product at 0,6 l/ha was effective on the low to high level after 14-33 DA-B. Higher effectiveness was noted in situation of low disease pressure with results of 96,99% in 3 out of 6 trials. With the increase of PESSEV, the efficacy of CA3301 decreased significantly. Taking into account varied results, it can be considered medium level of control of ERYSGH after application of test product at dose rate of 0,6 l/ha.

2 valid trials were conducted in **the South-East EPPO zone**. A very high level of control was observed on major leaves after application of CA3301 at 0,6 l/ha. No trials from the Mediterranean zone have been submitted. Due to the limited number of trials, the cMSs are kindly asked to consider this use on the national level.

No data were available for the evaluation of CA3301 against *Fusarium* spp. on barley. Since *Fusarium* spp. including *F. culmorum* and *F. graminearum* are highly destructive pathogens affecting many cereal species with small grains such as wheat, barley, triticale and oats, the extrapolation of the data presented on winter wheat for the same disease is possible.

Over the supportive dataset available on winter wheat, data demonstrated that CA3301 at 0.6 l/ha consistently showed efficacy to control *Fusarium graminearum* and gave always equivalent disease control to the authorized reference product. In all the assessments, there were no significant differences in disease control between the rates of 0.6 l/ha or 0.8 l/ha of CA3301. Moreover, the same trend was also observed to control *Fusarium culmorum*. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient to control *Fusarium* species on winter barley.

Considering all elements presented above, 0.6 l/ha is the minimum effective dose to control *Fusarium sp.* on winter barley in all EPPO zones.

No efficacy trials have been submitted in any EPP0 climatic zone. The cMSs from the Maritime and South-East zones are kindly asked to consider this use on the national level. The use of CA3301 to control of FUSASP in winter barley can not be accepted in Poland because an extrapolation is not possible.

Use of CA3301 at 2x 0.6 l/ha - Maritime EPP0 zone

Green leaf area was recorded at 15-56 DA-B in 33 valid trials on winter barley affected by a range of pathogens after the application of CA3301 at 0.6 l/ha applied twice. In 31 trials, green leaf area was assessed on the whole plant while in 2 trials it was assessed by foliar levels. For those 2 trials, green leaf area will be presented separately and on foliar levels 2 to 1.

Summary results are presented in Table 3.2-269.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the increase of green leaf area on winter barley infected by foliar and ears diseases. In the 31 trials assessing green leaf area on the whole plant, an increase of 214.77% was recorded compared to the untreated check on winter barley. In the 2 trials assessing green leaf area by foliar level, 3038.67% of increase were recorded on foliar level 2 and 1191.58% on foliar level 1.

In overall, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha, PROLINE 275 at 0.72 l/ha and MIRADOR XTRA at 0.8-1 l/ha.

Therefore, it is concluded that 2 applications of CA3301 at 0.6 l/ha will have a positive effect on the green leaf area in winter barley affected by a range of pathogens in the Maritime EPPO zone.

Treatment name	UNTREATED CHECK	CA24 45	PROLINE 275	MIRADOR XTRA	MIRADOR XTRA	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	0,72	0,8	1	0,6	
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	AB	AB	

Treatment name	UNTREATED CHECK	CA24 45 0,8 L/ha AB	PROLINE 275 0,72 L/ha AB	MIRADOR XTRA 0,8 L/ha AB	MIRADOR XTRA 1 L/ha AB	CA330 1 0,6 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate								
Rate unit								
Appl. Code								
Number of values	31					31	UTC	
Minimum value	0,00					4,00		
Maximum value	71,25	-	-	-	-	82,50	25 >	
Mean green leaf area (%)	25,10					44,58	6 =	
Mean %UTC*	100,00%					314,77 %	0 <	
Number of values	27	27				27	CA2445	
Minimum value	0,00	4,00				4,00	0,8 l/ha	
Maximum value	60,00	85,00	-	-	-	82,50	1 >	
Mean green leaf area (%)	21,41	43.58				41,32	21 =	
Mean %UTC	100,00%	387,9 8%				342,18 %	5 <	
Number of values	2		2			2	PROLINE 275	
Minimum value	11,25		30,00			27,50	0,72 l/ha	
Maximum value	71,25	-	90,00	-	-	82,50	0 >	
Mean green leaf area (%)	41,25		60,00			55,00	2 =	
Mean %UTC	100,00%		196,49%			180,12 %	0 <	
Number of values	2			2		2	MIRADOR	
Minimum value	52,50			77,50		76,25	XTRA	
Maximum value	65,00	-	-	82,50	-	80,00	0,8 l/ha	
Mean green leaf area (%)	58,75			80,00		78,13	0 >	
Mean %UTC	100,00%			138,19%		134,16 %	2 =	
Number of values	1	1			1	1	MIRADOR	
Minimum value	60,00	77,50			67,50	82,50	XTRA	
Maximum value	60,00	77,50	-	-	67,50	82,50	1 l/ha	
Mean green leaf area (%)	60,00	77,50			67,50	82,50	1 >	
%UTC	100,00%	129,1 7%			112,50%	137,50 %	0 =	
							0 <	
Green leaf area L2 - 41-46 DA-B								
Number of values	2		2			2	UT C	PROLINE 275
Minimum value	0,94		54,95			49,58		0,72 l/ha
Maximum value	8,38	-	89,70	-	-	84,04	2 >	0 >
Mean green leaf area (%)	4,66		72,33			66,81	0 =	1 =
Mean %UTC	100,00%		3458,08%			3138,6 7%	0 <	1 <
Green leaf area L1 - 41-46 DA-B								
Number of values	2		2			2	UT C	PROLINE 275
Minimum value	1,69		63,55			39,73		0,72 l/ha
Maximum value	39,84	-	98,24	-	-	92,54	2 >	0 >
Mean green leaf area (%)	20,76		80,89			66,13	0 =	0 =
Mean %UTC	100,00%		2003,47%			1291,5 8%	0 <	2 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 at 2x 0.6 l/ha - Mediterranean EPPO zone

Green leaf area was recorded at 15-43 DA-B in 42 valid trials on winter barley affected by a range of pathogens after the application of CA3301 at 0.6 l/ha applied twice. In all 42 trials, green leaf area was assessed on the whole plant.

Summary results are presented in Table 3.2-270.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the increase of green leaf area on winter barley affected by foliar and ears diseases. In the 42 trials assessing green leaf area on the whole plant, an increase of 182.00% was recorded compared to the untreated check on winter barley.

In overall, CA3301 at 0.6 l/ha was statistically equivalent to the several reference products CA2445 at 0.8 l/ha, PROSARO at 1 l/ha, MYSTIC SUL at 1 l/ha and BUMPER 25 EC at 0.5 l/ha.

Therefore, it is concluded that 2 applications of CA3301 at 0.6 l/ha will have a positive effect on the green leaf area in winter barley affected by a range of pathogens in the Mediterranean EPPO zone.

Table 3.2-270: Summary table – Efficacy evaluation – Winter barley – Green leaf area - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA24 45	PROSA RO	MYSTIC SUL	BUMPER 25 EC	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	1	1	0,5	0,6	
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	AB	AB	
Green leaf area - 15-43 DA-B							
Number of values	42					42	UTC
Minimum value	0,50					3,50	
Maximum value	90,00	-	-	-	-	100,00	23 >
Mean green leaf area (%)	33,62					52,62	19 =
Mean %UTC	100,00%					282,00 %	0 <
Number of values	37	37				37	CA2445
Minimum value	0,50	3,25				3,50	0,8 l/ha
Maximum value	90,00	100,00	-	-	-	100,00	3 >
Mean green leaf area (%)	33,04	54,14				53,36	32 =
Mean %UTC	100,00%	314,58 %				302,94 %	2 <
Number of values	12		12			12	PROSARO
Minimum value	8,75		17,50			20,00	1 l/ha
Maximum value	60,00	-	73,13	-	-	70,00	0 >
Mean green leaf area (%)	37,03		57,13			53,66	11 =
Mean %UTC	100,00%		204,22%			190,82 %	1 <
Number of values	2	2		2		2	MYSTIC
Minimum value	55,00	60,00		57,50		60,00	SUL
Maximum value	70,00	70,00	-	70,00	-	70,00	1 l/ha
Mean green leaf area (%)	62,50	65,00		63,75		65,00	0 >
Mean %UTC	100,00%	104,55 %		102,27%		104,55 %	2 =
Number of values	1				1	1	BUMPER 25
Minimum value	13,75				16,25	15,00	EC
Maximum value	13,75	-	-	-	16,25	15,00	0,5 l/ha
							0 >

Mean green leaf area (%)	13,75			16,25	15,00	1 =
%UTC	100,00%			118,18%	109,09%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 at 2x 0.6 l/ha - North-Eastern East EPPO zone

Green leaf area was recorded at 14-62 DA-B in 38 valid trials on winter barley affected by a range of pathogens after the application of CA3301 at 0.6 l/ha (x2). In all 38 trials, green leaf area was assessed on the whole plant.

Summary results are presented in Table 3.2-271.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the increase of green leaf area on winter barley affected by foliar and ears diseases. In the 38 trials assessing green leaf area on the whole plant, an increase of 102.26% was recorded compared to the untreated check on winter barley.

In overall, CA3301 at 0.6 l/ha was statistically equivalent to the reference products CA2445 at 0.6 and 0.8 l/ha and OSIRIS 65 EC.

Therefore, it is concluded that 2 applications of CA3301 at 0.6 l/ha will have a positive effect on the green leaf area in winter barley affected by a range of pathogens in the North-Eastern East EPPO zone.

Table 3.2-271: Summary table – Efficacy evaluation – Winter barley – Green leaf area – North-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA2445 0,6 L/ha AB	CA2445 0,8 L/ha AB	OSIRIS 65 EC 2 L/ha AB	CA3301 0,6 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Green leaf area - 14-62 DA-B						
Number of values	38				38	UTC
Minimum value	1,50				7,25	
Maximum value	75,00	-	-	-	95,00	20 >
Mean green leaf area (%)	31,19				42,46	17 =
Mean %UTC	100,00%				202,26%	1 <
Number of values	27		27		27	CA2445 0,8 l/ha
Minimum value	1,50		5,75		7,25	
Maximum value	75,00	-	92,50	-	95,00	0 >
Mean green leaf area (%)	35,81		49,62		49,39	27 =
Mean %UTC	100,00%		230,69%		220,18%	0 <
Number of values	23			23	23	OSIRIS 65 EC 2 l/ha
Minimum value	0,00			15,00	0,00	
Maximum value	75,00	-	-	86,25	95,00	0 >
Mean green leaf area (%)	38,39			47,66	50,76	22 =
Mean %UTC	100,00%			146,14%	146,23%	1 <
Number of values	3	3	3		3	CA2445 0,6 l/ha
Minimum value	1,50	5,75	7,75		7,25	
Maximum value	50,00	55,00	62,50	-	62,50	0 >
Mean green leaf area (%)	22,58	33,58	37,17		36,58	3 =
Mean %UTC	100,00%	267,26%	327,93%		315,98%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 at 2x 0.6 l/ha - South-Eastern East EPPO zone

Green leaf area was recorded at 15-45 DA-B in 34 valid trials on winter barley affected by a range of pathogens after the application of CA3301 at 0.6 l/ha (x2). In 31 trials, green leaf area was assessed on the whole plant while in 3 trials it was assessed by foliar levels. For those 2 trials, green leaf area will be presented separately and on foliar levels 2 to 1.

Summary results are presented in Table 3.2-272.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the increase of green leaf area on winter barley infected by foliar and ears diseases. In the 31 trials assessing green leaf area on the whole plant, an increase of 242.53% was recorded compared to the untreated check on winter barley. In the 2 trials assessing green leaf area by foliar level, an increase of 5250.88% was recorded on foliar level 2 and 505.66% on foliar level 1.

In overall, CA3301 was statistically equivalent to the reference products CA2445 at 0.6-0.8 l/ha, RISA 20 EC at 1.25 l/ha and PRIAXOR at 1.5 l/ha.

Therefore, it is concluded that 2 applications of CA3301 at 0.6 l/ha will have a positive effect on the green leaf area in winter barley affected by a range of pathogens in the South-Eastern East EPPO zone.

Table 3.2-272: Summary table – Efficacy evaluation – Winter barley – Green leaf area – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA2445 0,6 L/ha AB	CA2445 0,8 L/ha AB	RISA 20 EC 1,25 L/ha AB	PRIAXO R 1,5 L/ha AB	CA3301 0,6 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Green leaf area Plant - 15-45 DA-B							
Number of values	31					31	UTC
Minimum value	1,68					3,75	
Maximum value	90,00	-	-	-	-	92,00	23 >
Mean green leaf area (%)	31,06					55,19	8 =
Mean %UTC	100,00%					342,53%	0 <
Number of values	18		18			18	CA2445 0,8 l/ha
Minimum value	1,68		3,50			3,75	
Maximum value	66,00	-	93,75	-	-	92,00	0 >
Mean green leaf area (%)	35,86		64,51			62,35	12 =
Mean %UTC	100,00%		394,37%			400,81%	6 <
Number of values	14				14	14	RISA 20 EC 1,25 l/ha
Minimum value	10,00				15,00	15,00	
Maximum value	90,00	-	-	-	95,00	92,00	1 >
Mean green leaf area (%)	42,55				71,00	69,39	6 =
Mean %UTC	100,00%				229,23%	225,62%	0 <
Number of values	7			7		7	PRIAXOR 1,5 l/ha
Minimum value	7,50			15,00		15,00	
Maximum value	12,50	-	-	20,00	-	22,50	0 >
Mean green leaf area (%)	9,82			17,14		19,46	8 =
Mean %UTC	100,00%			179,40%		203,80%	6 <
Number of values	2	2	2			2	CA2445 0,6 l/ha
Minimum value	2,75	3,50	3,50			3,75	
Maximum value	53,75	70,00	78,75	-	-	73,75	0 >
Mean green leaf area (%)	28,25	36,75	41,13			38,75	2 =

Mean %UTC	100,00%	128,75 %	136,89%			136,79%	0 <	
Green leaf area L2 - 24-29 DA-B								
Number of values	3		3			3	UT C	CA244 5 0,8 l/ha
Minimum value	0,25		27,00			30,00		
Maximum value	4,75	-	53,50	-	-	50,00	3 >	2 >
Mean green leaf area (%)	2,50		36,92			38,17	0 =	0 =
Mean %UTC	100,00%		4768,77 %			5350,88 %	0 <	1 <
Green leaf area L1 - 24-29 DA-B								
Number of values	3		3			3	UT C	CA244 5 0,8 l/ha
Minimum value	2,50		28,25			29,00		
Maximum value	17,75	-	58,50	-	-	58,50	3 >	0 >
Mean green leaf area (%)	11,58		43,50			44,17	0 =	3 =
Mean %UTC	100,00%		593,31%			605,66%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Comments of zRMS:

33 valid trials were presented in **the Maritime EPPO climatic zone**. The trial results showed very positive effect after second application of CA3301. The whole plants were observed in 31 out of 33 trials. An augmentation of green leaf area amounted 214,77%. Furthermore, the observations on leaves were provided in 2 trials. An augmentation was 3038% in case of L2 and 1191% for L1 after 41-46 DA-B.

38 valid trials were carried out in **the North-East EPPO zone**. The results from whole plants showed an augmentation of green leaf area of 102,26% after 14-62 days after second application.

34 valid trials have been submitted in **the South-East EPPO zone**. CA3301 applied at dose rate 0,6 l/ha achieved very positive effect after 2 applications. The whole plants were observed in 31 out of 34 trials. An augmentation of green leaf area amounted 242,53%. Also results from the major leaves confirm positive influence of the test product. CA3301 showed an augmentation of 5250,88% for L2 and 505,66% for L1. Moreover, 42 additional trials from the Mediterranean zone presented the good results of 182%.

3.2.3.8 Winter barley (HORVW) / Conclusion

On winter barley, 5 foliar diseases were assessed in 156 trials across 4 EPPO zones. Disease severity was assessed and analysed on the main foliar levels 1 and 2. Depending on the EPPO zone, the disease, the assessment timing and the crop part assessed, the dataset available was sometimes limited with results not necessarily representative of the true efficacy of CA3301. Therefore, to get an overview of the efficacy of CA3301 at 0.6 l/ha, summary tables are presented hereunder, on foliar levels 1&2 (see Table 3.2-273 & Table 3.2-274).

Globally, across the 4 EPPO zones and all diseases the efficacy of CA3301 at 0.6 l/ha was acceptable to very high, with some exceptions especially in case of limited dataset. Nevertheless, since in the fields a complex of disease is often observed instead of a single disease, it is of interest to look at the efficacy of CA3301 across the diseases and to not focus on a single one.

It has been shown in the previous sections that the efficacy of CA3301 at 0.6 l/ha was overall equivalent to the approved reference standards used in the trials, a trend of decreasing disease severity when increasing the dose rates was observed with CA3301 at 0.6 l/ha providing a better disease control than the lower rate of 0.48 l/ha. The rate of 0.6 l/ha (100% dose rate) was in the majority of cases statistically comparable to the 0.8 l/ha rate (133% dose rate), although in limited cases the differences were statisti-

cally significant. Moreover, in circumstances of high disease pressure the rate of 0.6 l/ha showed sufficient efficacy to maintain crop quality. The same observations were made in the sections assessing the efficacy of CA3301 against the same pathogens on spring barley and are supportive of the proposed dose rate of 0.6 l/ha. Finally, due to the importance of the diseases and given the possibility of resistance in several of the pathogens assessed, the 100% dose rate of 0.6 l/ha, demonstrated to provide equivalent control to authorised reference standards, is considered the most appropriate dose rate.

In this dossier efficacy data presented is primarily from assessments where 2 applications of the test product were made. However, according to disease development conditions, a single application may provide sufficient disease control, therefore users should not be restricted to always applying twice, hence in the GAP the proposed use is for 1-2 applications. In addition, crop pathogens are commonly controlled using a programme of different fungicides with varied modes of action, therefore the choice should be available to growers to make a single application of CA3301, followed by application of a different appropriate fungicide. Prothioconazole is well established over a number of years in providing good broad spectrum efficacy across a range of common crop pathogens, with either 1 or more applications appropriate according to disease development conditions, risk of resistance development and local conditions. Current authorisations for similar products containing prothioconazole including Proline 275, and Proline/Praktis/Joao (CA2445) are for 1-2 applications at comparative rates of prothioconazole to the requested use for CA3301. Considering these elements, and that data shows comparability of CA3301 to these authorised products, registration of CA3301 at the proposed dose rate and with a number of applications of 1- 2, is requested.

Considering all elements presented in the previous sections of each disease and in the spring barley section, it is justified to claim the registration of 1 or 2 applications of CA3301 at 0.6 l/ha to control a range of foliar diseases on winter barley.

Table 3.2-273: Summary table – Winter barley – All foliar diseases (L2)

Foliar level 2			MAR	MED	NE	SE	NE + DE CZ SK
Disease	Application timing		CA3301 0,6 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,6 L/ha AB
RAMUCC	2 weeks after B	Number of values Abbott efficacy (%)	0 -	5 90,95	0 -	3 85,78	3 85,78
	Before harvest	Number of values Abbott efficacy (%)	12 68,67	12 69,14	2 34,79	9 82,48	13 64,21
PUCCHD	2 weeks after B	Number of values Abbott efficacy (%)	6 94,78	3 74,12	2 92,38	2 76,38	- -
	Before harvest	Number of values Abbott efficacy (%)	8 87,35	1 6,31	6 97,49	9 97,03	- -
RHYNSE	2 weeks after B	Number of values Abbott efficacy (%)	4 84,70	4 82,57	2 95,52	2 89,36	4 87,63
	Before harvest	Number of values Abbott efficacy (%)	6 82,00	7 58,58	4 76,22	3 79,75	9 77,50
PYRNTE	2 weeks after B	Number of values Abbott efficacy (%)	4 83,40	11 81,63	7 72,29	4 70,28	- -
	Before harvest	Number of values Abbott efficacy (%)	10 78,60	10 81,06	16 85,67	13 77,37	- -
ERYSGH ERYSGR	2 weeks after B	Number of values Abbott efficacy (%)	0 -	0 -	2 58,97	1 99,11	- -
		Number of values	0	0	3	0	-
		Abbott efficacy (%)	-	-	96,99	-	-
	Before harvest	Number of values Abbott efficacy (%)	2 87,18	0 -	1 78,24	2 94,23	- -

Table 3.2-274: Summary table – Winter barley – All foliar diseases (L1)

Foliar level 1			MAR	MED	NE	SE	NE + DE CZ SK
Disease	Application timing		CA3301 0,6 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,6 L/ha AB
RAMUCC	2 weeks after B	Number of values	0	3	0	0	0
		Abbott efficacy (%)	-	96,23	-	-	-
	Before harvest	Number of values	11	13	1	6	12
		Abbott efficacy (%)	75,58	62,17	54,74	82,31	72,63
PUCCHD	2 weeks after B	Number of values	0	1	1	1	-
		Abbott efficacy (%)	-	85,80	94,29	89,60	-
	Before harvest	Number of values	6	1	4	7	-
		Abbott efficacy (%)	85,53	17,07	87,51	95,67	-
RHYNSE	2 weeks after B	Number of values	2	4	0	1	1
		Abbott efficacy (%)	80,82	85,22	-	100,00	80,82
	Before harvest	Number of values	4	6	3	3	8
		Abbott efficacy (%)	79,65	58,94	92,96	85,67	86,62
PYRNTE	2 weeks after B	Number of values	2	9	3	1	-
		Abbott efficacy (%)	81,21	78,20	83,28	57,02	-
	Before harvest	Number of values	9	10	9	11	-
		Abbott efficacy (%)	72,85	72,69	81,70	83,10	-
ERYSGH ERYSGR	2 weeks after B	Number of values	0	0	1	0	-
		Abbott efficacy (%)	-	-	82,26	-	-
	Before harvest	Number of values	0	0	0	1	-
		Abbott efficacy (%)	-	-	-	94,78	-

Comments of zRMS:

All submitted trials were provided with 2 applications of CA3301 at 0,6 l/ha. An effectiveness after the first application was not assessed in case of any disease pathogens. The cMSs from the Maritime and South-East zone are kindly asked to consider single application on the national level. This use can not be accepted in Poland. Moreover, no efficacy trials have been submitted for control of PSDCHA in winter barley in any EPPO zones. The cMSs from the Maritime and South-East zone are kindly asked to consider this use on the national level. This use can not be accepted in Poland.

3.2.3.9 Spring barley (HORVS) / *Ramularia collo-cygni* (RAMUCC)

Materials and Methods – Spring barley - RAMUCC

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2018 and 2020, a series of 28 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the efficacy of CA3301 against *Ramularia collo-cygni* on **spring barley** (see Table 3.2-275). The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, a total of 8 trials were performed in the Czech Republic (1), Denmark (1), Germany (2) and the United Kingdom (4).

In the Mediterranean EPPO zone, a total of 12 trials were performed in France (1), Italy (6) and Spain (5).

In the North-Eastern East EPPO zone, a total of 2 trials were performed in Poland (2).

In the South-Eastern East EPPO zone, a total of 6 trials were performed in Slovakia (3), Hungary (1), Romania (2).

Data groupings were also made specifically for Poland evaluation and trials involved (8) were performed in the North-Eastern East EPPO zone (2), in Czech Republic (1), in Germany (2) and in Slovakia (3).

Table 3.2-275: Presentation of trials – Spring barley (HORVS) - RAMUCC

Crop(s) *	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Spring barley	RAMUCC	Czech Republic	2018	MED + E	1 (1)	-	-	-	GEP	
		Denmark	2019	MED + E	1 (0)	-	-	-	GEP	
		Germany	2019	MED + E	2 (2)	-	-	-	GEP	
		United Kingdo m	2019	MED + E	4 (3)	-	-	-	GEP	
Spring barley	RAMUCC	France (S)	2019	MED + E	-	1 (0)	-	-	GEP	
		Italy	2019- 2020	MED + E	-	6 (5)	-	-	GEP	
		Spain	2019- 2020	MED + E	-	5 (3)	-	-	GEP	
Spring barley	RAMUCC	Poland	2019	MED + E	-	-	2 (0)	-	GEP	
Spring barley	RAMUCC	Hungary	2020	MED + E	-	-	-	1 (0)	GEP	
		Romania	2020	MED + E	-	-	-	2 (2)	GEP	
		Slovakia	2019- 2020	MED + E	-	-	-	3 (3)	GEP	
TOTA L	-	-		MED + E	8 (6)	12 (8)	2 (0)	6 (5)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

In all trials, CA3301 was compared to at least one commercial and registered fungicide used as standard reference for comparison:

Table 3.2-276: Efficacy evaluation - Presentation of reference standards used in trials – Spring barley (HORVS) – RAMUCC – Maritime EPPO Zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Spring barley	PRO-LINE 250 EC	CZ	4523-1	Prothioconazole	EC	250 g/l	0.8 l/ha max	0.8 l/ha	CA2445 in some trials
	PRO-LINE	DE	025287-00	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials
	PRO-LINE EC 250	DK	18-473	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials
	PRO-LINE 275	UK	14790	Prothioconazole	EC	275 g/l	0.72 l/ha	0.72 l/ha	

Table 3.2-277: Efficacy evaluation - Presentation of reference standards used in trials – Spring barley (HORVS) – RAMUCC – Mediterranean EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Spring barley	PRO-LINE	IT	13385	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials
	PRO-SARO	IT	13386	Prothioconazole + Tebuconazole	EC	125 g/l + 125 g/l	1 l/ha	1 l/ha	
	JOAO	FR	2060116	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials
	PRO-SARO	SP	25661	Prothioconazole + Tebuconazole	EC	125 g/l + 125 g/l	1 l/ha	1 l/ha	

Table 3.2-278: Efficacy evaluation - Presentation of reference standards used in trials – Spring barley (HORVS) – RAMUCC – North-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
HORVS	OSIRIS 65 EC	POLAND	R-414/2018d	Epoxiconazole + Metconazole	EC	37.5 g/l + 27.5 g/l	2 x 2.5 l/ha max	2 x 2.0 l/ha	

Table 3.2-279: Efficacy evaluation - Presentation of reference standards used in trials – Spring barley (HORVS) – RAMUCC – South-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Spring barley	BUMPER 25 EC	SK	15-02-1617	Propiconazole	EC	250 g/l	0.5 l/ha	0.5 l/ha	
	PRI-AXOR	HU	04.2/4127-1/2016	Fluxapyroxad + Pyraclostrobin	EC	75 g/l + 150 g/l	1.5 l/ha	1.5 l/ha	
	NATIVO PRO	RO	056PC/29.09.2014	Prothioconazole + Trifloxistrobin	SC	175 g/l + 150 g/l	0.6 l/ha	0.6 l/ha	

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-280.

Table 3.2-280: Details on trial methodology – Spring barley (HORVS) - RAMUCC

		Maritime EPPO zone	Mediterranean EPPO zone	South-East EPPO zone	Data relevant for Poland
Trials	Total number (valid number)	8 (6)	12 (8)	6 (5)	8 (6)
	Supportive trials	-	-	-	-
Guidelines	General guidelines	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3) PP 1/225 (2) PP 1/262 (1)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)
	Specific guidelines	PP 1/26 (4) PP 1/28 (3)	PP 1/26 (4)	PP 1/26 (4)	PP 1/26 (4)
Experimental design	Plot design	Randomized Complete Blocks, Untreated included	Randomized Complete Blocks, Untreated included	Randomized Complete Blocks, Untreated included	Randomized Complete Blocks, Untreated included
	Plot size	21 - 30 m ²	21 - 30 m ²	21 – 30 m ²	21 – 30 m ²
	Number of replications	4	4	4	4
Crop	Trials per crop	Spring barley (8)	Spring barley (12)	Spring barley (6)	Spring barley (8)
	Varieties per crop	Sebastien (1), RGT Planet (3), Avalon (1), Proprino (2), Concerto (1)	Alastro (4), Jallon (1), RGT Planet (3), Solist R2 (1), Scrabble (1), Gomera (1), Signora (1)	Kangoo (1), Malz (1), Pribina (1), Bojos (1) Alastro (1) Donau (1)	Sebastien (1), Planet (1), Avalon (1), Nokia (1), Stratus (1), Malz (1), Pribina (1), Kangoo (1)

	Sowing period	February (1), March (4), April (3)	December (1), January (3), February (4), March (3), May (1)	March (6)	March (6), April (2)
Application	Crop stage (BBCH)* at application	A: BBCH 31-37 B: BBCH 42-65	A: BBCH 30-37 B: BBCH 55-61	A: BBCH 32-37 B: BBCH 55-61	A: BBCH 35-37 B: BBCH 55-61
	Timing Disease stage at application	BBCH 30-61 A: Mixed (1), PRINFC (2), ACTIVE (2) B: Mixed (1), PRINFC (2), ACTIVE (1)	BBCH 30-61 A: Mixed (2), PRINFC (10) B: Mixed (3), PRINFC (8), SPORUL (1)	BBCH 30-61 A: PRINFC (5), MIXED (1) B: PRINFC (3), MIXED (3)	BBCH 30-61 A: PRINFC (4), MIXED (2), N/A (2) B: PRINFC (4), MIXED (2), N/a (2)
	Number of applications Intervals between applications	2 applications (8-26 days) (8)	2 applications (14-27 days) (12)	2 applications (13-21 days) (6)	2 applications (8-30 days) (8)
	Spray volumes	160-200 l/ha	250-400 l/ha	200-250 l/ha	160-300 l/ha
Assessment	Assessment types	Desease severity (%), Desease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg), Yield (T-MET), Moisture content (%), TKW (g), HLW (kg/ha)	Desease severity (%), Desease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg), Yield (T-MET), Moisture content (%), TKW (g), HLW (kg/ha)	Desease severity (%), Desease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg), Yield (T-MET), Moisture content (%), TKW (g), HLW (kg/ha)	Desease severity (%), Desease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg), Yield (T-MET), Moisture content (%), TKW (g), HLW (kg/ha)
	Assessment dates	0 DA-A, 8-20 DA-A, -10-0 DA-B, 14-21 DA-B, 25-32 DA-B, 34-72 DA-B	0 DA-A, 12-24 DA-A, -7-0 DA-B, 9-21 DA-B, 27-36 DA-B, 48-63 DA-B	0- -1 DA-A, 13-18 DA-A, -6-0 DA-B, 15-16 DA-B, 20-26 DA-B, 42-51 DA-B	0 DA-A, 8-13 DA-A, 0 DA-B, 14-21 DA-B, 28-52 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Natural (8)	Natural (12)	Natural (6)	Natural (8)
	e.g. Field / Greenhouse...	Field trials (8)	Field trials (12)	Field trials (6)	Field trials (8)

Out of the 28 trials performed on spring barley against *Ramularia collo-cygni*, 24 were considered valid:

Use of CA3301 at 2x 0.6 l/ha against RAMUCC - Maritime EPPO Zone

In the Maritime EPPO zone, a total of 8 trials evaluated the efficacy of CA3301 on spring barley against *Ramularia collo-cygni*. 6 trials out of 8 were considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 31-37 and the 2nd application was at BBCH 42-65.

Summary results are presented in Table 3.2-281.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the reduction of disease severity on spring barley against *Ramularia collo-cygni*.

On foliar level 2, the efficacy reached 76.71% around two weeks after the 2nd application and 60.12% before harvest respectively calculated in 2 and 4 trials. At the assessment before harvest, in 1 trial disease severity was very high (100%) and efficacy was lower than the other 3 trials. In this trial only CA3301 and Proline 275 were tested, hence the overall mean efficacy for CA3301 and for Proline 275 from this dataset is lower than that of CA2445. On foliar level 1, in a single trial, CA3301 at 0.6 l/ha showed 62.99% efficacy on reduction of disease severity around two weeks after the 2nd application and 58.25% in 6 trials before harvest.

In the Maritime EPPO zone, CA3301 at 0.6 l/ha showed medium efficacy in reducing the severity of *Ramularia collo-cygni* on spring barley around two weeks after the 2nd application, on both main foliar levels 1 (L1) and 2 (L2). The efficacy of CA3301 0.6 l/ha was medium at the last assessment timing before harvest on L2, and low on L1. Moreover, when applied at 0.6 l/ha, CA3301 gave equivalent disease control compared to the authorised reference products CA2445, applied at a higher rate of prothioconazole whatever the foliar level. Compared to Proline 275, which was also applied at a higher rate of prothioconazole, CA3301 was comparable in 4 assessments and gave lower control in 3 assessments. Therefore, it is envisaged that applications of 0.6 l/ha will be sufficient for control of *Ramularia collo-cygni* on spring barley.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Ramularia collo-cygni* on spring barley in the Maritime EPPO zone.

Table 3.2-281: Summary table - Efficacy evaluation – Spring barley – RAMUCC – Maritime EPPO zone

Treatment name	UNTREATED CHECK	PROLINE 275	CA2445	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,72	0,8	0,6		
Rate unit		L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB		
% Disease severity L2 - 15 DA-B						
Number of values	2	2		2	UTC	PROLINE 275
Minimum value	38,59	5,59		8,49		0,72 l/ha
Maximum value	60,31	11,05	-	12,48	2 >	0 >
Mean disease severity (%)	49,45	8,32		10,53	0 =	1 =
Abbott efficacy (%)	0,00%	81,07%		76,71%	0 <	1 <
% Disease severity L1 - 15 DA-B						
Number of values	1	1		1	UTC	PROLINE 275
Minimum value	21,05	9,54		7,79		0,72 l/ha
Maximum value	21,05	9,54	-	7,79	1 >	0 >
Mean disease severity (%)	21,05	9,54		7,79	0 =	1 =
Abbott efficacy (%)	0,00%	54,68%		62,99%	0 <	0 <
% Disease severity L2 - 25-34 DA-B						
Number of values	4			4	UTC	
Minimum value	20,19			4,39		
Maximum value	100,00	-	-	82,01	4 >	
Mean disease severity (%)	41,63			24,83	0 =	
Abbott efficacy (%)	0,00%			60,12%	0 <	
Number of values	1	1		1	PROLINE 275	
Minimum value	100,00	79,60		82,01	0,72 l/ha	
Maximum value	100,00	79,60	-	82,01	0 >	
Mean disease severity (%)	100,00	79,60		82,01	1 =	
Abbott efficacy (%)	0,00%	20,40%		17,99%	0 <	
Number of values	3		3	3	CA2445	
Minimum value	20,19		4,88	4,39	0,8 l/ha	
Maximum value	25,13	-	6,90	6,99	0 >	
Mean disease severity (%)	22,18		6,12	5,77	3 =	

Abbott efficacy (%)	0,00%		72,46%	74,17%	0 <
% Disease severity L1 - 28-34 DA-B					
Number of values	6			6	UTC
Minimum value	11,30			0,69	
Maximum value	100,00	-	-	86,25	6 >
Mean disease severity (%)	44,50			25,66	0 =
Abbott efficacy (%)	0,00%			58,25%	0 <
Number of values	3	3		3	PROLINE 275
Minimum value	21,14	0,01		0,69	0,72 l/ha
Maximum value	100,00	74,60	-	86,25	0 >
Mean disease severity (%)	73,71	40,16		45,31	1 =
Abbott efficacy (%)	0,00%	59,83%		53,83%	2 <
Number of values	3		3	3	CA2445
Minimum value	11,30		2,56	2,63	0,8 l/ha
Maximum value	20,63	-	9,60	9,31	0 >
Mean disease severity (%)	15,29		6,17	6,01	3 =
Abbott efficacy (%)	0,00%		61,76%	62,67%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against RAMUCC - Mediterranean EPPO zone

In the Mediterranean EPPO zone, a total of 12 trials evaluated the efficacy of CA3301 on spring barley against *Ramularia collo-cygni*. 8 trials out of 12 were considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha (applied twice), and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 30-37 and the 2nd application was at BBCH 55-61.

Summary results are presented in Table 3.2-282.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the reduction of disease severity on spring barley against *Ramularia collo-cygni*. In all assessments CA3301 gave a significant reduction of disease compared to the untreated.

On foliar level 2, CA3301 at 0.6 l/ha showed 60.75% of efficacy against *Ramularia collo-cygni* two weeks after the 2nd application and 68.88% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 69.16% efficacy on reduction of disease severity around two weeks after the 2nd application and 63.57% before harvest.

In the Mediterranean EPPO zone, CA3301 at 0.6 l/ha showed overall medium efficacy in reducing the severity of *Ramularia collo-cygni* on spring barley. CA3301 at 0.6 l/ha (150 g prothioconazole/ha) gave in overall equivalent disease control compared to the authorised reference products CA2445 (200 g prothioconazole/ha) and PROSARO (prothioconazole & tebuconazole) in most instances. Therefore, it is envisaged that applications of 0.6 l/ha will be sufficient for control of *Ramularia collo-cygni* on spring barley.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Ramularia collo-cygni* on spring barley in the Mediterranean EPPO zone.

Table 3.2-282: Summary table - Efficacy evaluation – Spring barley – RAMUCC - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA2445	PROSARO	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	1	0,6		
Rate unit		L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB		
% Disease severity L2 - 13-14 DA-B						
Number of values	3			3	UTC	
Minimum value	5,63			0,45		
Maximum value	100,00	-	-	80,56	3 >	
Mean disease severity (%)	47,15			30,49	0 =	
Abbott efficacy (%)	0,00%			60,75%	0 <	
Number of values	2	2		2	CA2445	
Minimum value	35,82	10,58		10,46	0,8 l/ha	
Maximum value	100,00	42,58	-	80,56	0 >	
Mean disease severity (%)	67,91	26,58		45,51	1 =	
Abbott efficacy (%)	0,00%	63,94%		45,12%	1 <	
Number of values	2		2	2	PROSARO	
Minimum value	5,63		1,05	0,45	1,0 l/ha	
Maximum value	100,00	-	40,44	80,56	0 >	
Mean disease severity (%)	52,82		20,74	40,51	1 =	
Abbott efficacy (%)	0,00%		70,45%	55,72%	1 <	
% Disease severity L1 - 13-14 DA-B						
Number of values	2	2		2	UTC	CA2445
Minimum value	30,50	6,30		5,00		1,0 l/ha
Maximum value	84,75	12,38	-	38,38	2 >	0 >
Mean disease severity (%)	57,62	9,34		21,69	0 =	1 =
Abbott efficacy (%)	0,00%	82,37%		69,16%	0 <	1 <
Number of values	1		1	1	PROSARO	
Minimum value	84,75		12,55	38,88	1,0 l/ha	
Maximum value	84,75	-	12,55	38,88	0 >	
Mean disease severity (%)	84,75		12,55	38,88	0 =	
Abbott efficacy (%)	0,00%		85,19%	54,71%	1 <	
% Disease severity L2 - 26-32 DA-B						
Number of values	6			6	UTC	
Minimum value	6,44			0		
Maximum value	16,15	-	-	11,78	6 >	
Mean disease severity (%)	11,98			4,06	0 =	
Abbott efficacy (%)	0,00%			68,88%	0 <	
Number of values	4	4		4	CA2445	
Minimum value	6,44	0,06		0	0,8 l/ha	
Maximum value	15,38	3,69	-	4,81	0 >	
Mean disease severity (%)	11,49	1,45		1,97	4 =	
Abbott efficacy (%)	0,00%	88,48%		83,68%	0 <	
Number of values	5		5	5	PROSARO	
Minimum value	6,44		1	1,14	1,0 l/ha	
Maximum value	16,15	-	7,04	11,78	0 >	
Mean disease severity (%)	11,91		3,31	4,88	5 =	
Abbott efficacy (%)	0,00%		73,70%	62,65%	0 <	
% Disease severity L1 - 28 DA-B						
Number of values	1		1	1	UTC	PROSARO
Minimum value	6,45		2,74	2,35		1,0 l/ha
Maximum value	6,45	-	2,74	2,35	1 >	0 >
Mean disease severity (%)	6,45		2,74	2,35	0 =	1 =
Abbott efficacy (%)	0,00%		57,52%	63,57%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against RAMUCC - North-Eastern East EPPO zone

No data were available from the North-eastern East EPPO zone for *Ramularia collo-cygni* in spring-sown barley, however data collected in winter-sown barley for the same pathogen is considered supportive for this use. In this submission Poland is the sole cMS for the North-East EPPO zone in the CEU zone. According to Poland national guidance extrapolation table, data submitted in support of this pathogen is equivalent in either winter-sown or spring-sown barley.

Over the dataset presented for the same crop sown in winter disease severity was low to medium, and CA3301 at 0.6 l/ha gave comparable disease control compared to CA2445 applied at the same dose rate of 150 g/ha prothioconazole in all trials, and also compared to the higher rate of 0.8 l/ha, except in 1 trial assessing L1. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient to provide acceptable levels of control against *Ramularia collo-cygni*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Ramularia collo-cygni* on spring barley in the North-Eastern East EPPO zone.

Use of CA3301 at 2x 0.6 l/ha against RAMUCC - South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 6 trials evaluated the efficacy of CA3301 on spring barley against *Ramularia collo-cygni*. 5 trials out of 6 were considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha (applied twice), and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 32-37 and the 2nd application was at BBCH 55-61.

Summary results are presented in Table 3.2-283.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the reduction of disease severity on spring barley against *Ramularia collo-cygni*. In all assessments CA3301 gave a significant reduction of disease compared to the untreated. On foliar level 2, CA3301 at 0.6 l/ha showed 92.92% efficacy two weeks after the 2nd application and 80.64% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 86.64% efficacy on reduction of disease severity two weeks after the 2nd application and 83.00% before harvest.

In the South-eastern East EPPO zone, CA3301 at 0.6 l/ha showed high efficacy in reducing the severity of *Ramularia collo-cygni* on spring barley. CA3301 at 0.6 l/ha was overall equivalent to the reference products CA2445, applied at a higher rate of prothioconazole, with no significant differences in 6 of 8 assessments. CA3301 was statistically less efficient than reference product PRIAXOR (fluxapyroxad & pyraclostrobin) in 2 trials with high disease severity, but still provided high to medium efficacy in these trials. However, compared to BUMPER 25 EC and NATIVO PRO, CA3301 at 0.6 l/ha dose rate was overall equivalent or more efficient. Therefore, it is envisaged that a dose rate of 0.6 L/ha is appropriate to control *Ramularia collo-cygni* on spring barley.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Ramularia collo-cygni* on spring barley in the South-Eastern East EPPO zone.

Table 3.2-283: Summary table - Efficacy evaluation – Spring barley – RAMUCC – South-Eastern East EPPO zone

East LPTO zone								
Treatment name	UNTREATED CHECK	BUMPER 25 EC 0,5 L/ha AB	NATIVO PRO 0,6 L/ha AB	CA24 45 0,8 L/ha AB	PRIAX OR 1,5 L/ha AB	CA33 01 0,6 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
% Disease severity L2 - 15-16 DA-B								
Number of values	3			3		3	UT	NATIVO PRO
Minimum value	5,09			0,00		0,00	C	0,6 l/ha
Maximum value	76,88	-	-	14,98	-	16,34	3 >	1 >
Mean disease severity (%)	29,11			4,99		5,45	0 =	1 =
Abbott efficacy (%)	0,00%			93,51 %		92,92 %	0 <	0 <
Number of values	2		2	2		2	CA2445	
Minimum value	5,09		0,14	0,00		0,00	0,8 l/ha	
Maximum value	5,38	-	0,29	0,00	-	0,00	0 >	
Mean disease severity (%)	5,24		0,21	0,00		0,00	3 =	
Abbott efficacy (%)	0,00%		95,93%	100,00 %		100,00 %	0 <	
Number of values	1			1	1	1	PRIAXOR	
Minimum value	76,88			14,98	4,66	16,34	1,5 l/ha	
Maximum value	76,88	-	-	14,98	4,66	16,34	0 >	
Mean disease severity (%)	76,88			14,98	4,66	16,34	0 =	
Abbott efficacy (%)	0,00%			80,52 %	93,94%	78,75 %	1 <	
% Disease severity L1 - 16 DA-B								
Number of values	1			1	1	1	UT	CA2445 0,8 l/ha
Minimum value	54,88			6,16	2,05	7,33	C	PRIAXOR 1,5 l/ha
Maximum value	54,88	-	-	6,16	2,05	7,33	1 >	0 >
Mean disease severity (%)	54,88			6,16	2,05	7,33	0 =	0 =
Abbott efficacy (%)	0,00%			88,78 %	96,26%	86,64 %	0 <	1 <
% Disease severity L2 - 20-23 DA-B								
Number of values	4					4	UT	NATIVO PRO
Minimum value	15,38					2,98	C	0,6 l/ha
Maximum value	45,13	-	-	-	-	8,35	4 >	2 >
Mean disease severity (%)	28,64					5,52	0 =	0 =
Abbott efficacy (%)	0,00%					80,64 %	0 <	0 <
Number of values	2	2				2	CA2445	
Minimum value	38,44	16,06				7,76	0,8 l/ha	
Maximum value	45,13	30,53	-	-	-	8,35	2 >	
Mean disease severity (%)	41,79	23,29				8,06	0 =	
Abbott efficacy (%)	0,00%	45,29%				80,54 %	0 <	
Number of values	2		2	2		2	PRIAXOR	
Minimum value	15,38		4,51	1,95		2,98	1,5 l/ha	
Maximum value	15,63	-	4,93	2,05	-	2,99	0 >	
Mean disease severity (%)	15,51		4,72	2,00		2,99	1 =	
Abbott efficacy (%)	0,00%		69,55%	87,10 %		80,75 %	1 <	
% Disease severity L1 - 20-23 DA-B								
Number of values	4					4	UT	NATIVO PRO
Minimum value	8,28					1,30	C	0,6 l/ha

Treatment name	UNTREATED CHECK	BUMPER 25 EC 0,5 L/ha AB	NATIVO PRO 0,6 L/ha AB	CA24 45 0,8 L/ha AB	PRIAX OR 1,5 L/ha AB	CA33 01 0,6 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate							
Rate unit							
Appl. Code							
Maximum value	27,05	-	-	-	-	4,10	4 > 2 >
Mean disease severity (%)	17,19					2,82	0 = 0 =
Abbott efficacy (%)	0,00%					83,00 %	0 < 0 <
Number of values	2	2				2	CA2445
Minimum value	23,86	9,01				4,03	0,8 l/ha
Maximum value	27,05	14,96	-	-	-	4,10	2 >
Mean disease severity (%)	25,56	11,99				4,07	0 =
Abbott efficacy (%)	0,00%	53,47%				83,98 %	0 <
Number of values	2		2	2		2	PRIAXOR
Minimum value	8,28		3,08	1,16		1,30	1,5 l/ha
Maximum value	9,56	-	3,53	1,30	-	1,85	0 >
Mean disease severity (%)	8,92		3,30	1,23		1,58	2 =
Abbott efficacy (%)	0,00%		62,57%	86,20 %		82,03 %	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against RAMUCC - Data relevant for Poland

Although trials were instigated in the North-East EPPO zone to assess the efficacy of CA3301 against *Ramularia collo-cygni* in spring barley no valid trials were available due to lack of infection.

According to guidance provided by the Polish National authority, where data from the North-East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, a total of 6 valid trials from the neighbouring countries Slovakia, Germany and Czech Republic evaluated the efficacy of CA3301 on spring barley against *Ramularia collo-cygni*. These trials enabled to evaluate the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 32-37 and the 2nd application was at BBCH 55-61

Summary results are presented in Table 3.2-284.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the reduction of disease severity on spring barley against *Ramularia collo-cygni*. In all assessments CA3301 gave a significant reduction of disease compared to the untreated. On foliar level 2, CA3301 at 0.6 l/ha showed 78.75% efficacy two weeks after the 2nd application and 76.72% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 86.64% efficacy two weeks after the 2nd application and 71.19% before harvest.

In the Poland grouping, CA3301 at 0.6 l/ha showed medium to high efficacy in reducing the severity of *Ramularia collo-cygni* on spring barley at the last assessment timing before harvest on both main foliar levels 1 (L1) and 2 (L2). The performance of the tested product CA3301 at 0.6 l/ha was consistently equivalent to the reference product CA2445, applied at a higher rate of prothioconazole. Compared to PRIAXOR (75 g/l fluxapyroxade and 150 g/l pyraclostrobine) at 1.5 l/ha, CA3301 at 0.6 l/ha was less

efficient in all comparisons. Then compared to BUMPER 25 EC (250 g/l propiconazole) at 0.5 l/ha, CA3301 at the tested dose rate was always statistically more efficient.

Furthermore, 14 valid trials are available for the use of CA3301 against *Ramularia collo-cygni* in winter barley – (**Winter barley (HORVW) / *Ramularia collo-cygni* (RAMUCC)**) – which demonstrate that CA3301 applied at 0.6 l/ha provides high to medium efficacy and is overall more effective compared to the authorised reference standard CA2445 for control of this pathogen. Poland is the sole MS concerned in this application for the North-East EPPO zone, and the Poland authority allow extrapolations between winter and spring barley. Therefore, since application conditions are the same for winter barley and for spring barley – identical dose rate, water rate, crop timing, and timing against the pathogen – it is proposed that the data for winter barley supports the same use in spring barley.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Ramularia collo-cygni* on spring barley in Poland.

Table 3.2-284 Summary table - Efficacy evaluation – Spring barley – RAMUCC – Data relevant for Poland

Treatment name	UNTREATED CHECK	BUMPER 25 EC	CA244 5	PRIAXO R	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		
Rate		0,5	0,8	1,5	0,6			
Rate unit		L/ha	L/ha	L/ha	L/ha			
Appl. Code		AB	AB	AB	AB			
% Disease severity L2 - 16 DA-B								
Number of values	1		1	1	1	UT C	CA244 5	PRI- AXOR
Minimum value	76,88		14,98	4,66	16,34		0,8 l/ha	1,5 l/ha
Maximum value	76,88	-	14,98	4,66	16,34	1 >	0 >	0 >
Mean disease severity (%)	76,88		14,98	4,66	16,34	0 =	1 =	0 =
Abbott efficacy (%)	0,00%		80,52%	93,94%	78,75%	0 <	0 <	1 <
% Disease severity L1 - 16 DA-B								
Number of values	1		1	1	1	UT C	CA244 5	PRI- AXOR
Minimum value	54,88		6,16	2,05	7,33		0,8 l/ha	1,5 l/ha
Maximum value	54,88	-	6,16	2,05	7,33	1 >	0 >	0 >
Mean disease severity (%)	54,88		6,16	2,05	7,33	0 =	0 =	0 =
Abbott efficacy (%)	0,00%		88,78%	96,26%	86,64%	0 <	1 <	1 <
% Disease severity L2 - 23-34 DA-B								
Number of values	5				5	UTC		
Minimum value	20,19				4,39			
Maximum value	45,13	-	-	-	8,35	5 >		
Mean disease severity (%)	30,02				6,68	0 =		
Abbott efficacy (%)	0,00%				76,72%	0 <		
Number of values	2	2			2	BUMPER 25 EC		
Minimum value	38,44	16,06			7,76	0,5 l/ha		
Maximum value	45,13	30,53	-	-	8,35	2 >		
Mean disease severity (%)	41,79	23,29			8,06	0 =		
Abbott efficacy (%)	0,00%	45,29%			80,54%	0 <		
Number of values	3		3		3	CA2445		
Minimum value	20,19		4,88		4,39	0,8 l/ha		
Maximum value	25,13	-	6,90	-	6,99	0 >		
Mean disease severity (%)	22,18		6,12		5,77	3 =		
Abbott efficacy (%)	0,00%		72,46%		74,17%	0 <		
% Disease severity L1 - 23-34 DA-B								
Number of values	5				5	UTC		
Minimum value	11,30				2,63			

Treatment name	UNTREATED CHECK	BUMPER 25 EC 0,5 L/ha AB	CA244 5 0,8 L/ha AB	PRIAXO R 1,5 L/ha AB	CA330 1 0,6 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate						
Rate unit						
Appl. Code						
Maximum value	27,05	-	-	-	9,31	5 >
Mean disease severity (%)	19,39				5,23	0 =
Abbott efficacy (%)	0,00%				71,19%	0 <
Number of values	2	2			2	BUMPER 25 EC
Minimum value	23,86	9,01			4,03	0,5 l/ha
Maximum value	27,05	14,96	-	-	4,10	2 >
Mean disease severity (%)	25,46	11,99			4,07	0 =
Abbott efficacy (%)	0,00%	53,47%			83,98%	0 <
Number of values	3		3		3	CA2445
Minimum value	11,30		2,56		2,63	0,8 l/ha
Maximum value	20,63	-	9,60	-	9,31	0 >
Mean disease severity (%)	15,29		6,17		6,01	3 =
Abbott efficacy (%)	0,00%		61,76%		62,67%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (%) Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

6 valid trials were carried out in **the Maritime EPPO zone**. CA3301 applied at dose rate of 0,6 l/ha achieved low to medium efficacy after 15-34 days after second application. However, the low level on L1 was near to 60% (medium efficacy). No significant differences between the test and reference product were noted in these trials.

No valid field trials have been submitted in **the North-East EPPO zone**. The results from 6 trials conducted in the neighbouring countries (the Czech Republic, Germany and Slovakia) have been included to the overall calculation to support of Polish registration. Data relevant for Poland showed medium to high level of control after application of CA3301 at 0,6 l/ha after 16-34 DA-B. **However, medium level of control was noted in 5 out of 6 trials. It should be emphasized in the product label that CA3301 at 0,6 l/ha is effective on medium level.**

5 valid trials were conducted in **the South-East EPPO zone**. CA3301 applied at dose rate of 0,6 l/ha was effective on high level of control. 8 additional trials from the Mediterranean zone have been presented to support of product registration in other zones. The test product achieved medium efficacy (<70%) after 13-28 days after second application. The cMSs are kindly asked to consider this use on the national level.

Taking into account all trials, CA3301 used in 2 applications can be recommended to control of *Ramularia collo-cygni* in spring barley in the Maritime and North-East zone.

3.2.3.10 Spring barley (HORVS) / *Puccinia hordei* (PUCCHD)

Materials and Methods – Spring barley – PUCCHD

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2018 and 2020, a series of 27 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the efficacy of CA3301 against *Puccinia hordei* on **spring barley** (Table 3.2-285). The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, 8 trials were performed in Czech Republic (1), Germany (4), Denmark (2) and United Kingdom (1).

In the Mediterranean EPPO zone, 4 trials were performed in Spain (3) and Italy (1).

In the North-Eastern East EPPO zone, 9 trials were performed in Poland (5), Lithuania (1) and Latvia (3).

In the South-Eastern East EPPO zone, 6 trials were performed in Hungary (3) and Slovakia (3).

Table 3.2-285: Presentation of trials – Spring barley (HORVS) - PUCCHD

Crop(s) *)	Tar- get(s)*	Country	Year s	Type of trial*	Number of trials (number of valid trials)				GEP, non-GEP, offi- cial***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Spring barley	PUCCHD	Czech Republic	2018	MED + E	1 (1)	-	-	-	GEP	
		Germany	2019- 2020	MED + E	4 (2)	-	-	-	GEP	
		Denmark	2018	MED + E	2 (1)	-	-	-	GEP	
		United Kingdom	2019	MED + E	1 (1)	-	-	-	GEP	
Spring barley	PUCCHD	Italy	2019	MED + E	-	1 (1)	-	-	GEP	
		Spain	2019- 2020	MED + E	-	3 (0)	-	-	GEP	
Spring barley	PUCCHD	Poland	2018- 2020	MED + E	-	-	5 (2)	-	GEP	
		Lithuani a	2019	MED + E	-	-	1 (0)	-	GEP	
		Latvia	2020	MED + E	-	-	3 (2)	-	GEP	
Spring barley	PUCCHD	Hungary	2019- 2020	MED + E	-	-	-	3 (2)	GEP	
		Slovakia	2019	MED + E	-	-	-	3 (3)	GEP	
TOTA L	-	-	2018- 2020	MED + E	8 (5)	4 (1)	9 (4)	6 (5)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation

In all trials, CA3301 was compared to at least one commercial fungicide used as standard reference for comparison.

Table 3.2-286: Efficacy evaluation - Presentation of reference standards used in trials – Spring barley (HORVS) – PUCCHD – Maritime EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
HORVS	PRO-LINE 250 EC	CZ	4523-1	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha max	2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE	DE	025287-00	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE EC 250	DK	18-473	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE 275	UK	14790	Prothioconazole	EC	275 g/l	2 x 0.72 l/ha	2 x 0.72 l/ha	

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-287: Efficacy evaluation - Presentation of reference standards used in trials – Spring barley (HORVS) – PUCCHD – Mediterranean EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
HORVS	PRO-LINE	ITALY	13385	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha max	2 x 0.8 l/ha	CA2445 in some trials
	PRO-SARO	SPAIN	25661	Prothioconazole + Tebuconazole	EC	125 g/l + 125 g/l	2 x 1 l/ha max	2 x 1 l/ha	

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-288: Efficacy evaluation - Presentation of reference standards used in trials – Spring barley (HORVS) – PUCCHD – North-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
HORVS	OSIRIS 65 EC	POLAND	R-414/2018d	Epoxiconazole + Metconazole	EC	37.5 g/l + 27.5 g/l	2.5 l/ha	2.0 l/ha	

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
	PRAKTIS	POLAND	R-222/2019	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials
	PRO-LINE	LITHUANIA	AS2-6F(2018)	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials
	PRO-LINE	LATVIA	0637(LV)	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-289: Efficacy evaluation - Presentation of reference standards used in trials – Spring barley (HORVS) – PUCCHD – South-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
HORVS	BUMPER 25 EC	SK	15-02-1617	Propiconazole	EC	250 g/l	0.5 l/ha	0.5 l/ha	
	PRIAXOR	HU	04.2/2426-1/2018 04.2/4127-1/2016	Fluxapyroxad + Pyraclostrobin	EC	75 g/l + 150 g/l	1.5 l/ha	1.5 l/ha	

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-290.

Table 3.2-290: Details on trial methodology – Spring barley (HORVS) – PUCCHD

		Maritime EPPO zone	Mediterranean EPPO zone	North –East EPPO zone	South-East EPPO zone
Trials	Total number (valid number)	8 (5)	4 (1)	9 (4)	6 (5)
	Supportive trials	-	-	-	-
Guidelines	General guidelines	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3) PP 1/225 (2)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)
	Specific guidelines	PP 1/26 (4)	PP 1/26 (4)	PP 1/26 (4)	PP 1/26 (4)

Experimental design	Plot design	Randomized Complete Blocks, Untreated included	Randomized Complete Blocks, Untreated included	Randomized Complete Blocks, Untreated included	Randomized Complete Blocks, Untreated included
	Plot size	21 - 36 m ²	21 m ²	21 – 30 m ²	21 – 30 m ²
	Number of replications	4	4	4	4
Crop	Trials per crop	HORVS (8)	HORVS (4)	HORVS (9)	HORVS (6)
	Varieties per crop	Beckie (1), Fantex (1), Malz (1), Marthe (1), Quench (1), Planet (1), Proprino (1), Ovation (1)	Atlante (1), KWS Fantex (1), Gomera (1), Solist R2 (1)	Abava (2), Atrika (1), Ella (1), Nokia (1), RGT Planet (1), Soldo (1), Stratus (1), Tesla (1)	Bojos (2), Kangoo (1), Malz (2), Planet (1)
	Sowing period	February (1), March (4), April (3)	February (2), March (1), May (1)	March (2), April (6), May (1)	February (2), March (4)
Application	Crop stage (BBCH)* at application	A: BBCH 31-47 B: BBCH 49-69	A: BBCH 30-37 B: BBCH 55-59	A: BBCH 31-38 B: BBCH 53-61	A: BBCH 32-37 B: BBCH 51-61
	Timing Pest stage at application	BBCH 31-69 A: MIXED (2), PRINFC (5), ACTIVE (1) B: MIXED (3), PRINFC (3)	BBCH 30-59 A: MIXED (1), PRINFC (1), SPORUL (2) B: MIXED (3), PRINFC (1)	BBCH 31-61 A: PRINFC (6), MIXED (1), N/A (2) B: PRINFC (4), MIXED (3), N/A (2)	BBCH 32-61 A: PRINFC (6) B: PRINFC (3), MIXED (3)
	Number of applications Intervals between applications	2 applications (13-22 days) (8)	2 applications (22-27 days) (4)	2 applications (14-24 days) (2)	2 applications (13-27 days) (6)
	Spray volumes	A: 200 l/ha B: 200 l/ha	A: 300-400 l/ha B: 300-400 l/ha	A: 200-400 l/ha B: 200-400 l/ha	A: 200-300 l/ha B: 200-300 l/ha
Assessment	Assessment types	Pest severity (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg), Moisture content (%), TKW (g), HLW (kg), GRNARE (%)	Pest severity (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg), Moisture content (%), TKW (g), HLW (kg), GRNARE (%)	Pest severity (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg/ha), TKW (g), HLW (kg/hl), Moisture content (%), GRNARE (%)	Pest severity (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg), HLW(kg), TKW (g), Moisture content (%), GRNARE (%)
	Assessment dates	0 DA-A, 7-21 DA-A, 0 DA-B, 6-14 DA-B, 19-39 DA-B	0 DA-A, 15-27 DA-A, 0-5 DA-B, 13-20 DA-B, 28-57 DA-B	-2-0 DA-A, 11-15 DA-A, 0 DA-B, 8-15 DA-B, 17-23 DA-B, 35-84 DA-B	0 DA-A, 13-15 DA-A, 0 DA-B, 12-17 DA-B, 20-27 DA-B, 48-54 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Natural (8)	Natural (4)	Natural (9)	Natural (6)
	e.g. Field / Greenhouse...	Field trials (8)	Field trials (4)	Field trials (9)	Field trials (6)

27 trials were carried out against *Puccinia hordei* (PUCCHD) on spring barley.

Use of CA3301 at 2x 0.6 l/ha against PUCCHD - Maritime EPPO zone

In the Maritime EPPO zone, 8 trials were available against *Puccinia hordei* (PUCCHD), on spring barley. 5 trials out of 8 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6 l/ha applied twice, compared to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 32-39 and the 2nd application was at BBCH 52-69.

Summary results are presented in Table 3.2-291.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Puccinia hordei* on spring barley. In all assessments CA3301 gave a significant reduction of disease compared to the untreated.

On foliar level 2, at this dose rate, CA3301 showed 97.72% of efficacy on disease severity two weeks after the 2nd application and 81.49% before harvest. On foliar level 1, at this dose rate, CA3301 showed 92.99% of efficacy on disease severity two weeks after the 2nd application and 86.50% before harvest.

In the Maritime EPPO zone, applications of CA3301 at 0.6 l/ha demonstrated high efficacy in reducing the severity of *Puccinia hordei* on spring barley, in conditions of relatively low disease pressure. CA3301 gave equivalent disease control compared to the reference standard products CA2445 and PROLINE 275 (both applied at a higher rate of prothioconazole) in all trials. Therefore, it is envisaged that a dose rate of 0.6 L/ha is appropriate to control *Puccinia hordei* on spring barley.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Puccinia hordei* on spring barley in the Maritime EPPO zone.

Table 3.2-291: Summary table - Efficacy evaluation – Spring barley – PUCCHD - Maritime EPPO zone

Table 3.2-271: Summary table - Efficacy evaluation - Spring barley - FUECHD - Maritime EPO zone						
Treatment name	UNTREATED CHECK	PROLINE 275 0,72 L/ha AB	CA2445 0,8 L/ha AB	CA3301 0,6 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate						
Rate unit						
Appl. Code						
% Disease severity L2 - 14-17 DA-B						
Number of values	2		2	2	UT C	CA244 5 0,8 l/ha
Minimum value	7,28		0,00	0,03		
Maximum value	27,7	-	0,69	1,15	2 >	0 >
Mean disease severity (%)	17,49		0,34	0,59	0 =	2 =
Abbott efficacy (%)	0,00%		98,75%	97,72%	0 <	0 <
% Disease severity L2 - 17 DA-B						
Number of values	1		1	1	UT C	CA244 5 0,8 l/ha
Minimum value	9,84		0,38	0,69		
Maximum value	9,84	-	0,38	0,69	1 >	0 >
Mean disease severity (%)	9,84		0,38	0,69	0 =	1 =
Abbott efficacy (%)	0,00%		96,14%	92,99%	0 <	0 <
% Disease severity L2 - 19-39 DA-B						
Number of values	3			3	UTC	
Minimum value	8,51			1,43		
Maximum value	12,94	-	-	2,20	2 >	
Mean disease severity (%)	10,96			1,92	0 =	
Abbott efficacy (%)	0,00%			81,49%	0 <	
Number of values	1	1		3	PROLINE 275 0,72 l/ha	
Minimum value	8,51	1,58		2,20		
Maximum value	8,51	1,58	-	2,20	0 >	
Mean disease severity (%)	8,51	1,58		2,20	1 =	

Abbott efficacy (%)	0,00%	81,43%		74,15%	0 <
Number of values	2		2	2	CA2445
Minimum value	11,44		1,46	1,43	0,8 l/ha
Maximum value	12,94	-	1,71	2,13	0 >
Mean disease severity (%)	12,19		1,59	1,78	2 =
Abbott efficacy (%)	0,00%		86,88%	85,17%	0 <
% Disease severity L1 - 19-39 DA-B					
Number of values	3			3	UTC
Minimum value	6,37			1,03	
Maximum value	10,06	-	-	1,40	2 >
Mean disease severity (%)	8,79			1,15	0 =
Abbott efficacy (%)	0,00%			86,50%	0 <
Number of values	1	1		1	PROLINE 275
Minimum value	6,37	0,71		1,03	0,72 l/ha
Maximum value	6,37	0,71	-	1,03	0 >
Mean disease severity (%)	6,37	0,71		1,03	1 =
Abbott efficacy (%)	0,00%	88,85%		83,83%	0 <
Number of values	2		2	2	CA2445
Minimum value	9,94		0,56	1,03	0,8 l/ha
Maximum value	10,06	-	1,08	1,40	0 >
Mean disease severity (%)	10,00		0,82	1,22	2 =
Abbott efficacy (%)	0,00%		91,78%	87,84%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

* at 19-39 DA-B, UTC was excluded from statistical analysis in 1 trial out of 3

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against PUCCHD - Mediterranean EPPO zone

In the Mediterranean EPPO zone, a total of 4 trials evaluated the efficacy of CA3301 on spring barley against *Puccinia hordei*. 1 trial out of 4 was considered valid and enabled to support the efficacy evaluation of CA3301 at 0.6 l/ha compared to standard references. CA3301 was first applied at crop stages BBCH 30 and the 2nd application was at BBCH 55. One assessment timing was available: close to harvest (33 DA-B), and the analysis was conducted on foliar level 2 (L2).

Summary results are presented in Table 3.2-292.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control the severity of rust of barley. On foliar level 2, at this dose rate, CA3301 showed 88.07% before harvest (33 DA-B). In addition, CA3301 at 0.6 l/ha was equivalent to standard reference CA2445.

In the Mediterranean EPPO zone, CA3301 at 0.6 l/ha showed high efficacy in reducing the severity of *Puccinia hordei* on spring barley but the dataset was very limited. However, a larger dataset was presented for the closely related crop winter barley (see **Winter barley (HORVW) / *Puccinia hordei* (PUCCHD)**) which rust *Puccinia hordei* is of a different strain but with a very similar biology. This dataset demonstrated a comparable behaviour of the product and can be supportive for the spring barley species. Whereas differences were not always significant, the dataset for rust of winter barley demonstrated the same positive effects of CA3301 at 0.6 l/ha comparable to that of reference standard.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Puccinia hordei* on spring in the Mediterranean EPPO zone.

Table 3.2-292: Summary table - Efficacy evaluation – Spring barley – PUCCHD - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA2445 0,8 L/ha AB	CA3301 0,6 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
% Disease severity L2 - 33 DA-B					
Number of values	1	1	1	UT C	CA244 5 0,8 l/ha
Minimum value	5,28	0,49	0,63		
Maximum value	5,28	0,49	0,63	1 >	0 >
Mean disease severity (%)	5,28	0,49	0,63	0 =	1 =
Abbott efficacy (%)	0,00%	90,72%	88,07%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against PUCCHD - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, 9 trials were available against *Puccinia hordei* (PUCCHD) on spring barley. 4 trials out of 9 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6 l/ha applied twice, compared to the reference products on disease severity (%).

Summary results are presented in Table 3.2-293.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control brown rust of barley. In all assessments CA3301 gave a significant reduction of disease compared to the untreated.

On foliar level 2, at this dose rate, CA3301 showed 91.17% of efficacy on reduction of disease severity around two weeks after the 2nd application and 96.61% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 88.61% of efficacy on reduction of disease severity before harvest.

In the North-Eastern East EPPO zone, CA3301 showed high efficacy in reducing disease severity of *Puccinia hordei*. In addition, CA3301 at the proposed dose rate of 0.6 l/ha was consistently comparable to the reference products CA2445 (applied at a higher rate of prothioconazole) and OSIRIS 65 EC (epoxiconazole & metconazole) in terms of disease control. Therefore, it is envisaged that a dose rate of 0.6 L/ha is appropriate for control of *Puccinia hordei* in spring barley.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Puccinia hordei* on spring barley in the North-Eastern East EPPO zone.

Table 3.2-293: Summary table - Efficacy evaluation – Spring barley – PUCCHD – North-Eastern East EPPO zone

Treatment name		CA2445	OSIRIS 65 EC	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate	UNTREATED CHECK	0,8	2	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
% Disease severity L2 - 14-15 DA-B					
Number of values	3			3	UTC
Minimum value	8,48			0,75	
Maximum value	46,88	-	-	1,53	3 >
Mean disease severity (%)	22,89			1,21	0 =
Abbott efficacy (%)	0,00%			91,14%	0 <
Number of values	2	2		2	CA2445 0,8 l/ha
Minimum value	8,48	1,15		1,36	
Maximum value	46,88	1,41	-	1,53	0 >
Mean disease severity (%)	27,68	1,28		1,45	2 =
Abbott efficacy (%)	0,00%	90,46%		89,53%	0 <
Number of values	1		1	1	OSIRIS 65 EC 2,0 l/ha
Minimum value	13,31		0,25	0,75	
Maximum value	13,31	-	0,25	0,75	0 >
Mean disease severity (%)	13,31		0,25	0,75	1 =
Abbott efficacy (%)	0,00%		98,12%	94,37%	0 <
% Disease severity L2 - 17-21 DA-B					
Number of values	2			2	UTC
Minimum value	7,74			0,19	
Maximum value	14,56	-	-	0,63	2 >
Mean disease severity (%)	11,15			0,41	0 =
Abbott efficacy (%)	0,00%			96,61%	0 <
Number of values	1	1		1	CA2445 0,8 l/ha
Minimum value	7,74	0,11		0,19	
Maximum value	7,74	0,11	-	0,19	0 >
Mean disease severity (%)	7,74	0,11		0,19	1 =
Abbott efficacy (%)	0,00%	98,58%		97,55%	0 <
Number of values	1		1	2	OSIRIS 65 EC 2,0 l/ha
Minimum value	14,56		0,25	0,63	
Maximum value	14,56	-	0,25	0,63	0 >
Mean disease severity (%)	14,56		0,25	0,63	1 =
Abbott efficacy (%)	0,00%		98,28%	95,67%	0 <
% Disease severity L1 - 17-21 DA-B					
Number of values	2			2	UTC
Minimum value	6,14			0,69	

Treatment name		CA2445	OSIRIS 65 EC	CA3301	No of trials where CA3301 is >, = or < compared to
Rate	UNTREATED CHECK	0,8	2	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
Maximum value	20,25	-	-	1,19	2 >
Mean disease severity (%)	13,19			0,94	0 =
Abbott efficacy (%)	0,00%			88,61%	0 <
Number of values	1	1		1	CA2445
Minimum value	6,14	1,01		1,19	0,8 l/ha
Maximum value	6,14	1,01	-	1,19	0 >
Mean disease severity (%)	6,14	1,01		1,19	1 =
Abbott efficacy (%)	0,00%	83,55%		80,62%	0 <
Number of values	1		1	2	OSIRIS 65 EC
Minimum value	20,25		0,31	0,69	2,0 l/ha
Maximum value	20,25	-	0,31	0,69	0 >
Mean disease severity (%)	20,25		0,31	0,69	1 =
Abbott efficacy (%)	0,00%		98,47%	96,59%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)	
>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against PUCCHD - South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, 6 trials were conducted against *Puccinia hordei* (PUCCHD) on spring barley. 5 trials out of 6 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6 l/ha applied twice, compared to the reference products on disease severity (%).

Summary results are presented in Table 3.2-294.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Puccinia hordei*. In all assessments CA3301 gave a significant reduction of disease compared to the untreated.

On foliar level 2, CA3301 at 0.6 l/ha showed 81.12% of efficacy on reduction of disease severity around two weeks after the 2nd application and 86.34% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 88.44% before harvest.

In the South-eastern East EPPO zone, CA3301 at 0.6 l/ha showed high efficacy in reducing the severity of *Puccinia hordei* on spring barley. CA3301 at 0.6 l/ha was equivalent to the reference product CA2445 (applied at a higher rate of prothioconazole). CA3301 was statistically less efficient than reference product PRIAXOR in 2 trials and equivalent in 1 trial, but nevertheless provided high efficacy in these trials.

However, compared to BUMPER 25 EC, CA3301 at 0.6 l/ha dose rate was more efficient in all trials. Therefore, it is envisaged that a dose rate of 0.6 L/ha is appropriate for control of *Puccinia hordei* in spring barley.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Puccinia hordei* on spring barley in the South-Eastern East EPPO zone.

Table 3.2-294: Summary table - Efficacy evaluation – Spring barley – PUCCHD – South-Eastern East EPPO zone

East LTPG zone							
Treatment name	UNTREATED CHECK	BUMPER 25 EC	CA244 5	PRIAX OR	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,5	0,8	1,5	0,6		
Rate unit		L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	AB		
% Disease severity L2 - 15 DA-B							
Number of values	1	1			1	UT C	BUMPER 25 EC 0,5 l/ha
Minimum value	5,56	1,39			1,05		
Maximum value	5,56	1,39	-	-	1,05	1 >	1 >
Mean disease severity (%)	5,56	1,39			1,05	0 =	0 =
Abbott efficacy (%)	0,00%	75,00%			81,12 %	0 <	0 <
% Disease severity L2 - 20-27 DA-B							
Number of values	5				5	UTC	
Minimum value	5,80				0,28		
Maximum value	28,25	-	-	-	2,93	5 >	
Mean disease severity (%)	11,75				1,46	0 =	
Abbott efficacy (%)	0,00%				86,34 %	0 <	
Number of values	3	3			3	BUMPER 65 EC 0,5 l/ha	
Minimum value	5,80	1,91			0,98		
Maximum value	8,53	2,76	-	-	1,69	3 >	
Mean disease severity (%)	7,41	2,41			1,36	0 =	
Abbott efficacy (%)	0,00%	67,39%			81,82 %	0 <	
Number of values	1		1		1	CA2445 0,8 l/ha	
Minimum value	8,29		0,00		0,28		
Maximum value	8,29	-	0,00	-	0,28	0 >	
Mean disease severity (%)	8,29		0,00		0,28	1 =	
Abbott efficacy (%)	0,00%		100,00 %		96,62 %	0 <	
Number of values	2			2	2	PRIAXOR 1,5 l/ha	
Minimum value	8,29			0,00	0,28		
Maximum value	28,25	-	-	0,46	2,93	0 >	
Mean disease severity (%)	18,27			0,23	1,61	1 =	
Abbott efficacy (%)	0,00%			97,23%	93,13 %	1 <	
% Disease severity L1 - 24 DA-B							
Number of values	1			1	1	UT C	PRIAXOR 1,5 l/ha
Minimum value	21,88			0,00	2,53		
Maximum value	21,88	-	-	0,00	2,53	1 >	1 >
Mean disease severity (%)	21,88			0,00	2,53	0 =	0 =
Abbott efficacy (%)	0,00%			100,00%	88,44 %	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

5 valid trials were carried out in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,6 l/ha achieved high efficacy after 14-39 days after second application. Due to the limited number of trials, the cMSs are kindly asked to consider this use on the national level.

4 valid trials were available in **the North-East EPPO zone**. The test product at 0,6 l/ha was effective on high level after 14-21 DA-B. Also the results from 6 trials conducted in the neighbouring countries (the Czech Republic, Germany and Slovakia) have been included to the overall calculation to support of Polish registration. Taking into account all trials it can be concluded that CA3301 is effective to control of PUCCHD in spring barley in the NE zone.

5 valid trials were conducted in **the South-East EPPO zone**. Similar other zones, CA3301 applied at dose rate of 0,6 l/ha achieved high efficacy after 15-27 DA-B. 1 additional trial from the Mediterranean zone has been submitted to support of product registration in other zone. The high efficacy was noted in this trial. Due to the limited number of trials, the cMSs are kindly asked to consider this use on the national level.

3.2.3.11 Spring barley (HORVS) / *Pyrenophora teres* (PYRNTE)

Materials and Methods – Spring barley – PYRNTE

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2018 and 2020, a series of 66 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern and South-Eastern EPPO zones to evaluate the efficacy of CA3301 against *Pyrenophora teres* on **spring barley** (see Table 3.2-295). The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, 13 trials were performed in Czech Republic (2), Germany (3), Denmark (3) and United Kingdom (5).

In the Mediterranean EPPO zone, 12 trials were performed in Spain (7), France (1) and Italy (4).

In the North-eastern **East** EPPO zone, 30 trials were performed in Poland (22), Lithuania (1) and Latvia (7).

In the South-eastern **East** EPPO zone, 11 trials were performed in Hungary (5), Bulgaria (1), Romania (3) and Slovakia (2).

Table 3.2-295: Presentation of trials – Spring barley (HORVS) - PYRNTE

Crop(s)) *	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, offi- cial***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Spring barley	PYRNTE	Czech Republic	2018- 2019	MED + E	2 (1)	-	-	-	GEP	
		Germany	2019- 2020	MED + E	3 (2)	-	-	-	GEP	
		Denmark	2018- 2019	MED + E	3 (1)	-	-	-	GEP	

Crop(s)) *	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
		United Kingdom	2019-2020	MED + E	5 (4)	-	-	-	GEP	
Spring barley	PYRNTE	Italy	2020	MED + E	-	4 (4)	-	-	GEP	
		Spain	2019-2020	MED + E	-	7 (4)	-	-	GEP	
		France	2019	MED + E	-	1 (1)	-	-	GEP	
Spring barley	PYRNTE	Poland	2018-2020	MED + E	-	-	22 (16)	-	GEP	
		Lithuania	2019	MED + E	-	-	1 (0)	-	GEP	
		Latvia	2019-2020	MED + E	-	-	7 (4)	-	GEP	
Spring barley	PYRNTE	Hungary	2018-2020	MED + E	-	-	-	5 (5)	GEP	
		Bulgaria	2018	MED + E	-	-	-	1 (1)	GEP	
		Romania	2018-2019	MED + E	-	-	-	3 (3)	GEP	
		Slovakia	2019-2020	MED + E	-	-	-	2 (2)	GEP	
TOTAL	-	-	2018-2020	MED + E	13 (8)	12 (9)	30 (20)	11 (11)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation

In all trials, CA3301 was compared to at least one commercial fungicide used as standard reference.

Table 3.2-296: Efficacy evaluation - Presentation of reference standards used in trials – Spring barley (HORVS) – PYRNTE – Maritime EPPO zone

Crop(s))	Refer- ence standard	Coun- try(ies) where the product is used ⁽¹⁾	Authoriza- tion number	Active sub- stance(s)	Formulation		Regis- tered ap- plication rate ⁽³⁾	Applica- tion rate in tri- als (per treat- ment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concentra- tion of a.s.			
HORVS	PRO-LINE 250 EC	CZ	4523-1	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha max	2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE	DE	025287-00	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE EC	DK	18-473	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
	250								trials
	PRO-LINE 275	UK	14790	Prothioconazole	EC	275 g/l	2 x 0.72 l/ha	2 x 0.72 l/ha	CA2445 in some trials
	PRO-LINE	UK	12084	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-297: Efficacy evaluation - Presentation of reference standards used in trials – Spring barley (HORVS) – PYRNTE – Mediterranean EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
HORVS	PRO-LINE	ITALY	013385	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha max	2 x 0.8 l/ha	CA2445 in some trials
	PRO-SARO	ITALY	013386	Prothioconazole + Tebuconazole	EC	125 g/l + 125 g/l	2 x 1 l/ha max	2 x 1 l/ha	
	JOAO	FRANCE	2060116	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha max	2 x 0.8 l/ha	CA2445 in some trials
	PRO-SARO	SPAIN	25661	Prothioconazole + Tebuconazole	EC	125 g/l + 125 g/l	2 x 1 l/ha max	2 x 1 l/ha	
	PRAKTIS	SPAIN	ES-01135	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha max	2 x 0.8 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-298: Efficacy evaluation - Presentation of reference standards used in trials – Spring barley (HORVS) – PYRNTE – North-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
HORVS	OSIRIS 65 EC	POLAND	R-87/2012	Epoxiconazole + Metconazole	EC	37.5 g/l + 27.5 g/l	2.5 l/ha	2.0 l/ha	
	CA2445	POLAND		Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	
	PRO-LINE	LITHUANIA	AS2-6F(2018)	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials
	PRO-LINE	LATVIA	0637(LV)	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-299: Efficacy evaluation - Presentation of reference standards used in trials – Spring barley (HORVS) – PYRNTE – South-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
HORVS	PRAKTIS	BULGARIA	01860	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials
	PRI-AXOR	HUNGARY	04.2/2426-1/2018 04.2/4127-1/2016	Fluxapyroxad + Pyraclostrobin	EC	75 g/l + 150 g/l	1.5 l/ha	1.5 l/ha	
	PRO-LINE	HUNGARY	6300/1205-1/2020	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials
	PRO-LINE 250 EC	ROMANIA	457PC/15.11.2018	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials
	BUMPER 25 EC	SLOVAKIA	15-02-1617	Propiconazole	EC	250 g/l	0.5 l/ha	0.5 l/ha	

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-300.

Table 3.2-300: Details on trial methodology – Spring barley (HORVS) – PYRNTE

		Maritime EPPO zone	Mediterranean EPPO zone	North-East EPPO zone	South-East EPPO zone
Trials	Total number (valid number)	13 (8)	12 (9)	30 (20)	11 (11)
	Supportive trials	-	-	-	-
Guidelines	General guidelines	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3) PP 1/225 (2)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)
	Specific guidelines	PP 1/26 (4) PP 1/28 (3) PP 1/262 (1)	PP 1/26 (4)	PP 1/26 (4)	PP 1/26 (4)
Experimental design	Plot design	Randomized Complete Blocks, Untreated included	Randomized Complete Blocks, Untreated included	Randomized Complete Blocks, Untreated included	Randomized Complete Blocks, Untreated included
	Plot size	21 - 30 m ²	20 - 21 m ²	21 – 30 m ²	21 – 30 m ²
	Number of replications	4	4	4	4
Crop	Trials per crop	HORVS (13)	HORVS (12)	HORVS (30)	HORVS (12)
	Varieties per crop	Beckie, Fantex, Kampa, Malz, Quench, RGT Planet (5), Propino (2), Ovation	Alastro (1), Gustav (1), RGT Planet (3), Shakyra R12 (2), Scrabble (1), Gomera (1), Lukhas (1), Campagne SIS, Sydney	Abava (3), Ansis (1), Atrika (3), Avalon(1), Conchita (1), Ella (5), Extase (1), Harris (1), Kucyk (1), Nokia (2), Nagradowicki (1) RGT Planet (1), Propino (1), Rufus (1), Soldo (3), Stratus (2), Teksas (1), Tesla (1)	Bojos (4), Maltea (1), Malz (1), Pribina (1), Romanita (1), Signora (1), Wilma (1), Xanadu (1)
	Sowing period	February (1), March (7), April (5)	January (3), February (4), March (1), April (2), May (1)	March (9), April (19), May (2)	February (2), March (5), April (4)
Application	Crop stage (BBCH)* at application	A: BBCH 31-47 B: BBCH 42-69	A: BBCH 30-37 B: BBCH 55-61	A: BBCH 31-38 B: BBCH 49-61	A: BBCH 31-39 B: BBCH 51-61
	Timing Pest stage at application	BBCH 31-69 A: ACTIVE (5), MIXED (6), PRINFC (1), SPORUL (1) B: ACTIVE (2), MIXED (7), LATENT (1)	BBCH 30-61 A: Mixed (3), PRINFC (9) B: Mixed (6), PRINFC (4), ACTIVE (2)	BBCH 31-61 A: PRINFC (13), MIXED (7), N/A (10) B: PRINFC (4), MIXED (14), N/A (10), SPORUL (2)	BBCH 31-61 A: PRINFC (5), MIXED (5) B: PRINFC (1), MIXED (10)
	Number of applications Intervals between applications	2 applications (13-22 days) (8)	2 applications (14-24 days) (12)	2 applications (14-30 days)	2 applications (14-27 days) (12)
	Spray volumes	A: 200-250 l/ha B: 200-250 l/ha	A: 250-400 l/ha B: 250-400 l/ha	A: 200-400 l/ha B: 200-400 l/ha	A: 200-300 l/ha B: 200-300 l/ha
Assessment	Assessment	Pest severity (%),	Pest severity (%),	Pest severity (%),	Pest severity (%),

	types	Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg), Moisture content (%), TKW (g), HLW (kg/hl), GNRARE (%)	Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg), Moisture content (%), TKW (g), HLW (kg/hl), GNRARE (%)	Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg/ha), TKW (g), HLW (kg/hl), Moisture content (%), GRNARE (%)	Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg), HLW(kg/hl), TKW (g), Moisture content (%), GNRARE (%)
	Assessment dates	0 DA-A, 7-21 DA-A, 0 DA-B, 6-14 DA-B, 19-39 DA-B	0 DA-A, 15-21 DA- A, 0 DA-B, 12-19 DA-B, 23-40 DA-B, 55-63 DA-B	-2-0 DA-B, 13-19 DA-A, 0 DA-B, 14- 20 DA-B, 21-40 DA- B, 44-84 DA-B	-1-0 DA-A, 13-18 DA-A, -1-0 DA-B, 12-16 DA-B, 21-34 DA-B, 35-83 DA-B
Other rele- vant infor- mation	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial innoculation...	Natural (8)	Natural (12)	Natural (30)	Natural (11)
	e.g. Field / Greenhouse...	Field trials (8)	Field trials (12)	Field trials (30)	Field trials (11)

66 trials were carried out against *Pyrenophora teres* (PYRNTE) on spring barley.

Use of CA3301 at 2x 0.6 l/ha against PYRNTE - Maritime EPPO zone

In the Maritime EPPO zone, 13 trials were available against *Pyrenophora teres* (PYRNTE), on spring barley. 8 trials out of 13 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6 l/ha applied twice, compared to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 31-39 and the 2nd application was at BBCH 42-69.

Summary results are presented in Table 3.2-301.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Pyrenophora teres* on spring barley. In all assessments CA3301 gave a significant reduction of disease compared to the untreated.

On foliar level 2, at this dose rate, CA3301 showed 77.81% two weeks after the 2nd application and 51.69% before harvest.

On foliar level 1, CA3301 at 0.6 l/ha showed 69.41% two weeks after the 2nd application and 77.00% before harvest.

In the Maritime EPPO zone, applications of CA3301 at 0.6 l/ha demonstrated medium to high efficacy ~~medium to high efficacy~~ in reducing the severity of *Pyrenophora teres* on spring barley in conditions of medium disease pressure. At this rate CA3301 gave in most instances equivalent or higher disease control compared to the authorised reference products CA2445 and PROLINE 275, which were both applied with a higher rate of prothioconazole. Therefore, it is proposed that a dose rate of 0.6 L/ha is appropriate for control of *Pyrenophora teres* in spring barley.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Pyrenophora teres* on spring barley in the Maritime EPPO zone.

Table 3.2-301: Summary table - Efficacy evaluation – Spring barley – PYRNTE - Maritime EPPO zone

Treatment name	UNTREATED	PROLINE 275	CA2445	CA3301	No of trials where CA3301
Rate	CHECK	0,72	0,8	0,6	

Rate unit		L/ha	L/ha	L/ha	at 0,6 l/ha is >, = or < compared to	
Appl. Code		AB	AB	AB		
% Disease severity L2 - 14-21 DA-B						
Number of values	5*			5	UTC	
Minimum value	12,5			1,41		
Maximum value	54,19	-	-	19,59	4 >	
Mean disease severity (%)	34,56			9,13	0 =	
Abbott efficacy (%)	0,00%			77,81%	0 <	
Number of values	1	1		1	PROLINE 275	
Minimum value	54,19	9,64		19,59	0,72 l/ha	
Maximum value	54,19	9,64	-	19,59	0 >	
Mean disease severity (%)	54,19	9,64		19,59	0 =	
Abbott efficacy (%)	0,00%	82,21%		63,85%	1 <	
Number of values	4		4	4	CA2445	
Minimum value	12,50		0,23	1,41	0,8 l/ha	
Maximum value	47,50	-	6,56	18,06	0 >	
Mean disease severity (%)	29,65		3,63	6,51	3 =	
Abbott efficacy (%)	0,00%		88,42%	81,30%	1 <	
% Disease severity L1 - 15-21 DA-B						
Number of values	5*			5	UTC	
Minimum value	5,49			0,00		
Maximum value	27,31	-	-	10,53	4 >	
Mean disease severity (%)	14,09			4,4	0 =	
Abbott efficacy (%)	0,00%			69,41%	0 <	
Number of values	1	1		1	PROLINE 275	
Minimum value	22,28	4,78		10,53	0,72 l/ha	
Maximum value	22,28	4,78	-	10,53	0 >	
Mean disease severity (%)	22,28	4,78		10,53	1 =	
Abbott efficacy (%)	0,00%	78,55%		52,47%	0 <	
Number of values	4		4	4	CA2445	
Minimum value	5,49		0,00	0,00	0,8 l/ha	
Maximum value	27,31	-	5,25	6,75	0 >	
Mean disease severity (%)	12,05		2,25	2,87	3 =	
Abbott efficacy (%)	0,00%		79,07%	73,57%	1 <	
% Disease severity L2 - 29-39 DA-B						
Number of values	4		4	4	UTC	CA2445
Minimum value	5,03		0,91	1,96		5
Maximum value	91,81	-	21,66	29,48	4 >	0,8 l/ha
Mean disease severity (%)	34,83		9,17	13,41	0 =	0 >
Abbott efficacy (%)	0,00%		69,03%	51,69%	0 <	3 =
% Disease severity L1 - 29-37 DA-B						
Number of values	3			3	UTC	
Minimum value	15,33			4,19		
Maximum value	100,00	-	-	27,15	3 >	
Mean disease severity (%)	60,28			13,62	0 =	
Abbott efficacy (%)	0,00%			77,00%	0 <	
Number of values	1	1		1	PROLINE 275	
Minimum value	100,00	75,00		27,15	0,72 l/ha	
Maximum value	100,00	75,00	-	27,15	1 >	
Mean disease severity (%)	100,00	75,00		27,15	0 =	
Abbott efficacy (%)	0,00%	25,00%		72,85%	0 <	
Number of values	2		2	2	CA2445	
Minimum value	15,33		3,99	4,19	0,8 l/ha	

Maximum value	65,50	-	17,00	9,51	1 >
Mean disease severity (%)	40,42		10,49	6,85	0 =
Abbott efficacy (%)	0,00%		74,01%	79,07%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

*UTC removed from statistical analysis

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against PYRNTE - Mediterranean EPPO zone

In the Mediterranean EPPO zone, 12 trials were available against *Pyrenophora teres* (PYRNTE), on spring barley. 9 trials out of 12 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6 l/ha applied twice, compared to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 30-37 and the 2nd application was at BBCH 55-61.

Summary results are presented in Table 3.2-302.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Pyrenophora teres* on spring barley. In all assessments except 1, CA3301 gave a significant reduction of disease compared to the untreated. In the other assessment both CA3301 and the authorised reference standard provided low efficacy.

On foliar level 2, at this dose rate, CA3301 showed 74.11% of efficacy on disease severity two weeks after the 2nd application and 63.63% before harvest.

On foliar level 1, CA3301 at 0.6 l/ha showed 96.18% of efficacy on reduction of disease severity two weeks after the 2nd application and 94.69% before harvest.

In the Mediterranean EPPO zone, CA3301 at 0.6 l/ha showed medium to high efficacy in reducing the severity of *Pyrenophora teres* on spring barley. In 1 trial CA3301 at 0.6 l/ha did not significantly reduce disease severity and was less efficient than the reference CA2445, which was applied at a higher rate of prothioconazole. However, considering the whole dataset, CA3301 at 0.6 l/ha was equivalent to the reference products CA2445 and PROSARO. Therefore, it is proposed that a dose rate of 0.6 L/ha is appropriate for control of *Pyrenophora teres* in spring barley.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Pyrenophora teres* on spring barley in the Mediterranean EPPO zone

Table 3.2-302: Summary table - Efficacy evaluation – Spring barley – PYRNTE - Mediterranean EPPO zone

Zone						
Treatment name	UNTREATED CHECK	CA2445	PROSAR O	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	1	0,6		
Rate unit		L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB		
% Disease severity L2 - 12-19 DA-B						
Number of values	5		5	5	UTC	CA2445
Minimum value	5,18		0,98	1,19		0,8 l/ha
Maximum value	14,20	-	5,83	4,71	5 >	0 >
Mean disease severity (%)	10,04		2,99	2,63	0 =	3 =
Abbott efficacy (%)	0,00%		70,96%	74,11%	0 <	0 <
Number of values	3	3		3	PROSARO	

Minimum value	5,18	2,50		1,76	1,0 l/ha
Maximum value	14,20	4,58	-	4,71	0 >
Mean disease severity (%)	10,09	3,35		2,75	5 =
Abbott efficacy (%)	0,00%	64,01%		72,04%	0 <
% Disease severity L1 - 14-19 DA-B					
Number of values	2		2	2	UTC
Minimum value	5,05		0,18	0,05	PRO-SARO
Maximum value	8,11	-	0,71	0,54	1,0 l/ha
Mean disease severity (%)	6,58		0,44	0,29	2 >
Abbott efficacy (%)	0,00%		93,84%	96,18%	0 =
					0 <
% Disease severity L2 - 23-40 DA-B					
Number of values	7			7	UTC
Minimum value	6,25			0,85	
Maximum value	40,19	-	-	9,88	6 >
Mean disease severity (%)	14,06			4,71	1 =
Abbott efficacy (%)	0,00%			63,63%	0 <
Number of values	4	4		4	CA2445
Minimum value	6,25	0,58		0,85	0,8 l/ha
Maximum value	10,55	5,59	-	8,50	0 >
Mean disease severity (%)	8,41	2,90		3,63	3 =
Abbott efficacy (%)	0,00%	67,24%		47,96%	1 <
Number of values	6		6	6	PROSARO
Minimum value	6,25		0,74	0,85	1,0 l/ha
Maximum value	40,19	-	8,85	9,88	0 >
Mean disease severity (%)	14,64		3,82	4,08	6 =
Abbott efficacy (%)	0,00%		73,10%	70,99%	0 <
% Disease severity L1 - 40 DA-B					
Number of values	1		1	1	UTC
Minimum value	17,69		1,94	0,94	PRO-SARO
Maximum value	17,69	-	1,94	0,94	1,0 l/ha
Mean disease severity (%)	17,69		1,94	0,94	1 >
Abbott efficacy (%)	0,00%		89,03%	94,69%	0 =
					0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against PYRNTE - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 30 trials evaluated the efficacy of CA3301 on spring barley against *Pyrenophora teres*. 20 trials out of 30 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6 l/ha applied twice CA3301, compared to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 31-38 and the 2nd application was at BBCH 49-61.

Summary results are presented in Table 3.2-303.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Pyrenophora teres* on spring barley. In all assessments CA3301 gave a significant reduction of disease compared to the untreated. On foliar level 2, at this dose rate, CA3301 showed 84.07% two weeks after the 2nd application and 75.76% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 81.65% two weeks after the 2nd application and 75.81% before harvest.

In the North-Eastern East EPPO zone, CA3301 showed high to medium efficacy in reducing disease

severity of *Pyrenophora teres*. In addition, CA3301 at the proposed dose rate of 0.6 l/ha was overall comparable to the reference products CA2445 and OSIRIS 65 EC in terms of disease control. Therefore, it is envisaged that a dose rate of 0.6 L/ha is appropriate to control *Pyrenophora teres* on spring barley.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Pyrenophora teres* on spring barley in the North-Eastern East EPPO zone.

Table 3.2-303: Summary table - Efficacy evaluation – Spring barley – PYRNTE – North-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA2445	OSIRIS 65 EC	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	2	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
% Disease severity L2 - 14-18 DA-B					
Number of values	10			10	UTC
Minimum value	6,96			0,13	
Maximum value	68,75	-	-	28,75	10 >
Mean disease severity (%)	26,68			6,01	0 =
Abbott efficacy (%)	0,00%			84,07%	0 <
Number of values	7	7		7	CA2445
Minimum value	6,96	0,06		0,13	0,8 l/ha
Maximum value	68,75	25,00	-	28,75	0 >
Mean disease severity (%)	31,42	5,53		7,36	6 =
Abbott efficacy (%)	0,00%	88,44%		84,64%	1 <
Number of values	4		4	4	OSIRIS 65 EC
Minimum value	6,96		0,75	0,13	2,0 l/ha
Maximum value	23,00	-	6,00	4,90	2 >
Mean disease severity (%)	13,44		3,71	2,19	2 =
Abbott efficacy (%)	0,00%		73,79%	86,60%	0 <
% Disease severity L1 - 14-18 DA-B					
Number of values	5			5	UTC
Minimum value	8,94			1,50	
Maximum value	48,13	-	-	13,75	5 >
Mean disease severity (%)	29,51			5,77	0 =
Abbott efficacy (%)	0,00%			81,65%	0 <
Number of values	4	4		4	CA2445
Minimum value	9,59	1,34		1,63	0,8 l/ha
Maximum value	48,13	10,00	-	13,75	0 >
Mean disease severity (%)	34,66	4,28		6,84	3 =
Abbott efficacy (%)	0,00%	87,72%		81,25%	1 <
Number of values	1		1	1	OSIRIS 65 EC
Minimum value	8,94		3,15	1,50	2,0 l/ha
Maximum value	8,94	-	3,15	1,50	1 >
Mean disease severity (%)	8,94		3,15	1,50	0 =
Abbott efficacy (%)	0,00%		64,77%	83,22%	0 <
% Disease severity L2 - 21-36 DA-B					
Number of values	14			14	UTC

Treatment name	UNTREATED CHECK	CA2445	OSIRIS EC 65	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	2	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
Minimum value	5,81			0,31	
Maximum value	80,31	-	-	32,94	14 >
Mean disease severity (%)	19,56			6,65	0 =
Abbott efficacy (%)	0,00%			75,76%	0 <
Number of values	13	13		13	CA2445
Minimum value	5,81	0,23		0,31	0,8 l/ha
Maximum value	80,31	31,25	-	32,94	0 >
Mean disease severity (%)	20,22	5,83		6,94	11 =
Abbott efficacy (%)	0,00%	77,42%		75,94%	2 <
Number of values	12		12	12	OSIRIS 65 EC
Minimum value	5,81		0,56	0,31	2,0 l/ha
Maximum value	18,25	-	6,44	6,88	0 >
Mean disease severity (%)	11,13		2,73	2,69	11 =
Abbott efficacy (%)	0,00%		77,86%	79,18%	1 <
% Disease severity L1 - 21-36 DA-B					
Number of values	12			12	UTC
Minimum value	6,75			0,84	
Maximum value	59,00	-	-	12,7	12 >
Mean disease severity (%)	14,00			3,36	0 =
Abbott efficacy (%)	0,00%			75,81%	0 <
Number of values	10	10		10	CA2445
Minimum value	6,76	0,28		0,84	0,8 l/ha
Maximum value	59,00	6,96	-	12,7	0 >
Mean disease severity (%)	14,83	3,31		3,73	3 =
Abbott efficacy (%)	0,00%	73,41%		73,91%	1 <
Number of values	9		9	9	OSIRIS 65 EC
Minimum value	6,75		0,38	0,84	2,0 l/ha
Maximum value	13,00	-	4,00	4,10	2 >
Mean disease severity (%)	8,58		2,27	2,14	7 =
Abbott efficacy (%)	0,00%		74,77%	75,88%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)	
>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against PYRNTE - South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 11 trials evaluated the efficacy of CA3301 on spring barley against *Pyrenophora teres*. All 11 trials were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6 l/ha applied twice CA3301, compared to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 31-39 and the 2nd application was at BBCH 51-61.

Summary results are presented in Table 3.2-304.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Pyrenophora teres* on spring barley. In all assessments CA3301 gave a significant reduction of disease compared to the untreated.

On foliar level 2, at this dose rate, CA3301 showed 80.15% two weeks after the 2nd application and 69.22% before harvest.

On foliar level 1, CA3301 at 0.6 l/ha showed 90.84% two weeks after the 2nd application and 75.77% before harvest.

In the South-Eastern East EPPO zone, CA3301 showed high to medium efficacy in reducing disease severity of *Pyrenophora teres*. In addition, CA3301 at the proposed dose rate of 0.6 l/ha was overall comparable to the reference products CA2445 applied at a higher rate of prothioconazole, and PRIAXOR containing fluxapyroxad and pyraclostrobin, in terms of disease control. In some assessments, CA3301 was less efficient than these references but in the majority of instances there were no significant differences. CA3301 gave significantly higher disease control compared to BUMPER 25 EC in all assessments where the 2 were compared. Therefore, it is envisaged that a dose rate of 0.6 L/ha is appropriate to control *Pyrenophora teres* on spring barley.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Pyrenophora teres* on spring barley in the South-Eastern East EPPO zone

Table 3.2-304: Summary table - Efficacy evaluation – Spring barley – PYRNTE – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	BUMPER 25 EC 0,5 L/ha AB	CA2445 0,8 L/ha AB	PRIAXOR 1,5 L/ha AB	CA3301 0,6 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
% Disease severity L2 - 15-16 DA-B						
Number of values	7				7	UTC
Minimum value	6,10				0,58	
Maximum value	24,19	-	-	-	4,01	7 >
Mean disease severity (%)	12,67				1,86	0 =
Abbott efficacy (%)	0,00%				80,15%	0 <
Number of values	1	1			1	BUMPER 25 EC 0,5 l/ha
Minimum value	12,34	5,98			0,58	
Maximum value	12,34	5,98	-	-	0,58	1 >
Mean disease severity (%)	12,34	5,98			0,58	0 =
Abbott efficacy (%)	0,00%	51,54%			95,30%	0 <
Number of values	6		6		6	CA2445 0,8 l/ha
Minimum value	6,10		0,55		1,26	
Maximum value	24,19	-	3,48	-	4,01	0 >
Mean disease severity (%)	12,73		1,59		2,08	4 =
Abbott efficacy (%)	0,00%		82,78%		77,63%	2 <
Number of values	1			1	1	PRIAXOR 1,5 l/ha
Minimum value	8,78			1,06	2,14	
Maximum value	8,78	-	-	1,06	2,14	0 >
Mean disease severity (%)	8,78			1,06	2,14	0 =
Abbott efficacy (%)	0,00%			87,93%	75,63%	1 <
% Disease severity L1 - 15 DA-B						
Number of values	2		2		2	UTC
Minimum value	9,00		0,55		0,63	CA2445 0,8 l/ha

Treatment name	UNTREATED CHECK	BUMPER 25 EC 0,5 L/ha AB	CA2445 0,8 L/ha AB	PRIAXOR 1,5 L/ha AB	CA3301 0,6 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate						2 >	0 >
Rate unit						0 =	1 =
Appl. Code						0 <	1 <
Maximum value	9,81	-	0,75	-	1,11		
Mean disease severity (%)	9,41		0,65		0,87		
Abbott efficacy (%)	0,00%		93,12%		90,84%		
% Disease severity L2 - 21-29 DA-B							
Number of values	6				6	UTC	
Minimum value	5,94				1,63		
Maximum value	68,88	-	-	-	22,00	6 >	
Mean disease severity (%)	25,37				7,50	0 =	
Abbott efficacy (%)	0,00%				69,22%	0 <	
Number of values	1	1			1	BUMPER 25 EC 0,5 l/ha	
Minimum value	26,50	14,88			7,93		
Maximum value	26,50	14,88	-	-	7,93	1 >	
Mean disease severity (%)	26,50	14,88			7,93	0 =	
Abbott efficacy (%)	0,00%	43,85%			70,08%	0 <	
Number of values	4		4		4	CA2445 0,8 l/ha	
Minimum value	5,94		1,64		1,63		
Maximum value	68,88	-	15,88	-	22,00	0 >	
Mean disease severity (%)	24,35		6,51		8,41	3 =	
Abbott efficacy (%)	0,00%		69,86%		64,35%	1 <	
Number of values	5			5	5	PRIAXOR 1,5 l/ha	
Minimum value	5,94			0,95	1,63		
Maximum value	68,88	-	-	12,00	22,00	0 >	
Mean disease severity (%)	25,14			4,47	7,42	4 =	
Abbott efficacy (%)	0,00%			80,28%	69,05%	1 <	
% Disease severity L1 - 24-34 DA-B							
Number of values	5				5	UTC	
Minimum value	5,01				0,43		
Maximum value	41,94	-	-	-	12,50	5 >	
Mean disease severity (%)	16,63				3,77	0 =	
Abbott efficacy (%)	0,00%				75,77%	0 <	
Number of values	4		4		4	CA2445 0,8 l/ha	
Minimum value	5,01		0,13		0,43		
Maximum value	41,94	-	7,26	-	12,50	0 >	
Mean disease severity (%)	16,04		2,80		4,34	2 =	
Abbott efficacy (%)	0,00%		77,79%		71,67%	2 <	
Number of values	3			3	3	PRIAXOR 1,5 l/ha	
Minimum value	5,01			0,81	1,31		
Maximum value	41,94	-	-	4,50	12,50	0 >	
Mean disease severity (%)	21,98			2,15	5,10	1 =	
Abbott efficacy (%)	0,00%			87,48%	78,74%	2 <	

>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)	
>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

8 valid trials were carried out in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,6 l/ha achieved low to medium efficacy after 14-39 days after second application. However the lowest results were noted near to harvest.

20 valid trials were available in **the North-East EPPO zone**. The test product at 0,6 l/ha showed medium to high level of control after 14-36 DA-B.

11 valid trials were conducted in **the South-East EPPO zone**. CA3301 at 0,6 l/ha achieved medium to high efficacy after 15-34 DA-B. Also 9 additional trials from the Mediterranean zone presented medium to high level of control after double application of test product after 12-40 DA-B.

Taking into account all trials, CA3301 used in 2 applications can be recommended to control of *Pyrenophora teres* in spring barley. No significant differences between the test and reference product were observed.

3.2.3.12 Spring barley (HORVS) / *Blumeria graminis* (ERYSGR-ERYSGH)

Materials and Methods – Spring barley – ~~PYRNTE~~ ERYSGR/ERYSGH

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2019 and 2020, a series of 13 trials were conducted in several countries of the Maritime, Mediterranean, North-~~Eastern~~ East and South-~~Eastern~~ East EPPO zones to evaluate the efficacy of CA3301 against *Blumeria graminis* or *Blumeria graminis f. sp. hordei* on **spring barley** (see Table 3.2-305). The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, 4 trials were performed in Czech Republic (2) and Germany (2).

In the Mediterranean EPPO zone, 2 trials were performed in Italy (2).

In the North-~~Eastern~~ East EPPO zone, 3 trials were performed in Latvia (3).

In the South-~~Eastern~~ East EPPO zone, a total of 4 trials were performed in Hungary (1) and Slovakia (3).

Data groupings were also made specifically for Poland evaluation and trials involved (10) were performed in North-~~Eastern~~ East EPPO zone (3), in Germany (2), Czech Republic (2) and Slovakia (3).

Out of the 13 trials performed on spring barley against *Blumeria graminis* or *Blumeria graminis f. sp. hordei*, 5 were considered valid (see Table 3.2-305).

Blumeria graminis (ERYSGR) and *Blumeria graminis f. sp. hordei* (ERYSGH) are the causal agents of the powdery mildew on barley and are considered as the same pathogen in this analysis.

Table 3.2-305: Presentation of trials – Spring barley (HORVS) – ERYSGR-ERYSGH

Crop(s)) *	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, offi- cial***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Spring barley	ERYSGR / ERYSGH	Czech Republic	2019	MED + E	2 (2)	-	-	-	GEP	
		German y	2019	MED + E	2 (1)	-	-	-	GEP	
Spring	ERYSGR	Italy	2019	MED	-	2 (1)	-	-	GEP	

Crop(s)) *	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
barley	/ ERYSGH			+ E						
Spring barley	ERYSGR / ERYSGH	Latvia	2019- 2020	MED + E	-	-	3 (1)	-	GEP	
Spring barley	ERYSGR / ERYSGH	Hungary	2020	MED + E	-	-	-	1 (0)	GEP	
		Slovakia	2019	MED + E	-	-	-	3 (0)	GEP	
TOTAL	-	-	2018- 2020	MED + E	4 (3)	2 (1)	3 (1)	4 (0)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation

In all trials, CA3301 was compared to at least one commercial fungicide used as standard reference for comparison.

Table 3.2-306: Efficacy evaluation - Presentation of reference standards used in trials – Spring barley (HORVS) – ERYSGR-ERYSGH – Maritime EPPO zone

Crop(s))	Refer- ence standard	Coun- try(ies) where the product is used ⁽¹⁾	Authoriza- tion number	Active sub- stance(s)	Formulation		Regis- tered ap- plication rate ⁽³⁾	Applica- tion rate in tri- als (per treat- ment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concentra- tion of a.s.			
HORV S	Proline 250 EC	CZECH REPUBLIC	4523-1	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha max	2 x 0.8 l/ha	CA2445 in some trials
	Proline	GER- MANY	025287-00	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-307: Efficacy evaluation - Presentation of reference standards used in trials – Spring barley (HORVS) – ERYSGR-ERYSGH – Mediterranean EPPO zone

Crop(s))	Refer- ence standard	Coun- try(ies) where the product is used ⁽¹⁾	Authoriza- tion number	Active sub- stance(s)	Formulation		Regis- tered ap- plication rate ⁽³⁾	Applica- tion rate in tri- als (per treat- ment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concentra- tion of a.s.			
HORV S	PRO- LINE	ITALY	13385	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha max	2 x 0.8 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-308: Efficacy evaluation - Presentation of reference standards used in trials – Spring barley (HORVS) – ERYSGR-ERYSGH – North-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
HORVS	PRO-LINE	LATVIA	0637(LV)	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-309.

Table 3.2-309: Details on trial methodology – Spring barley (HORVS) – ERYSGR-ERYSGH

		Maritime EPPO zone	Mediterranean EPPO zone	North-East EPPO zone	Data relevant for Poland
Trials	Total number (valid number)	4 (3)	2 (1)	3 (1)	10 (4)
	Supportive trials	-	-	-	-
Guidelines	General guidelines	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)
	Specific guidelines	PP 1/26 (4)	PP 1/26 (4)	PP 1/26 (4)	PP 1/26 (4)
Experimental design	Plot design	Randomized Complete Blocks, Untreated included	Randomized Complete Blocks, Untreated included	Randomized Complete Blocks, Untreated included	Randomized Complete Blocks, Untreated included
	Plot size	21 - 30 m ²	21 - 24 m ²	21 – 30 m ²	21 – 30 m ²
	Number of replications	4	4	4	4
Crop	Trials per crop	HORVS (4)	HORVS (2)	HORVS (3)	HORVS (10)
	Varieties per crop	Avalon (1), Kampa (1), Grace (1), Planet (1)	Alastro (1), Touareg (1)	Abava (2), Ansis (1)	Abava (3), Avalon (1), Grace (1), Planet (1), Kampa (1), Pribina (1), Malz (1), kangoo (1)
	Sowing period	March (4)	March (2)	April (2), May (1)	March (7), April (2), May (1)
Application	Crop stage (BBCH)* at application	A: BBCH 33-37 B: BBCH 55-59	A: BBCH 30-32 B: BBCH 55-59	A: BBCH 31-37 B: BBCH 55	A: BBCH 31-37 B: BBCH 49-59
	Timing	BBCH 31-65	BBCH 30-59	BBCH 31-55	BBCH 32-59

	Desease stage at application	A: MIXED (4) B: MIXED (4)	A: PRINFC (2) B: PRINFC (1), SPORUL (1)	A: PRINFC (2), N/A (1) B: MIXED (2), N/A (1)	A: PRINFC (2), N/A (1), MIXED (7) B: MIXED (9), N/A (1)
	Number of applications Intervals between applications	2 applications (8-19 days) (4)	2 applications (17-21 days) (2)	2 applications (14-24 days)	2 applications (8-24 days)
	Spray volumes	A: 200-250 l/ha B: 200-250 l/ha	A: 400 l/ha B: 400 l/ha	A: 200 l/ha B: 200 l/ha	A: 200-250 l/ha B: 200-250 l/ha
Assessment	Assessment types	Pest severity (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg), Moisture content (%), TKW (g), HLW (kg), GRNARE (%)	Pest severity (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg), Moisture content (%), TKW (g), HLW (kg), GRNARE (%)	Pest severity (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg/ha), TKW (g), HLW (kg/hl), Moisture content (%), GRNARE (%)	Pest severity (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg/ha), TKW (g), HLW (kg/hl), Moisture content (%), GRNARE (%)
	Assessment dates	-7-0 DA-A, 8-17 DA-A, 0 DA-B, 13-15 DA-B, 19-25 DA-B, 29- 54 DA-B	0 DA-A, 14-16 DA-A, 21-31 DA-A, 0 DA-B, 14 DA-B, 24-26 DA-B, 47-51 DA-B	-1-0 DA-A, 14-15 DA-A, 0 DA-B, 14-18 DA-B, 21-26 DA-B, 37-56 DA-B	-7-0 DA-A, 8-17 DA-A, 0 DA-B, 13-19 DA-B, 21-40 DA-B, 51-75 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Natural (4)	Natural (2)	Natural (3)	Natural (10)
	e.g. Field / Greenhouse...	Field trials (4)	Field trials (2)	Field trials (3)	Field trials (10)

6 trials were carried out against *Blumeria graminis* (ERYSGR) and 7 trials against *Blumeria graminis* f. sp. *hordei* (ERYSGH) on spring barley.

Use of CA3301 at 2x 0.6 l/ha against ERYSGR-ERYSGH - Maritime EPPO zone

In the Maritime EPPO zone, 4 trials were available against *Blumeria graminis* (ERYSGR), on spring barley. 3 trials out of 4 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6 l/ha applied twice, compared to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 33-37 and the 2nd application was at BBCH 55-59.

Summary results are presented in Table 3.2-310.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Blumeria graminis* on spring barley. CA3301 significantly reduced disease severity in all trials.

On foliar level 2, at this dose rate, CA3301 showed 80.50% of efficacy on disease severity two weeks after the 2nd application and 94.74% before harvest.

In the Maritime EPPO zone with a limited dataset for this pathogen, a consistent trend was however observed whereby CA3301 at 0.6 l/ha gave equivalent disease control compared to the authorised ref-

erence product CA2445 and the data demonstrated that the tested product showed high efficacy in reducing the severity of *Blumeria graminis* on spring barley whatever the foliar level. Therefore, it is proposed that a dose rate of 0.6 L/ha is appropriate for control of *Blumeria graminis* in spring barley.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Blumeria graminis* on spring barley in the Maritime EPPO zone.

Table 3.2-310: Summary table - Efficacy evaluation – Spring barley – ERYSGR-ERYSGH - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA2445	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	0,6		
Rate unit		L/ha	L/ha		
Appl. Code		AB	AB		
% Disease severity L2 - 13-15 DA-B					
Number of values	3	3	3	UT C	CA244 5 0,8 l/ha
Minimum value	7,00	0,06	0,06		
Maximum value	23,94	5,88	6,63	3 >	0 >
Mean disease severity (%)	15,47	3,88	3,77	0 =	3 =
Abbott efficacy (%)	0,00%	79,11%	80,50%	0 <	0 <
% Disease severity L2 - 19 DA-B					
Number of values	1	1	1	UT C	CA244 5 0,8 l/ha
Minimum value	8,74	0,39	0,46		
Maximum value	8,74	0,39	0,46	1 >	0 >
Mean disease severity (%)	8,74	0,39	0,46	0 =	1 =
Abbott efficacy (%)	0,00%	95,54%	94,74%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against ERYSGR-ERYSGH - Mediterranean EPPO zone

In the Mediterranean EPPO zone, 2 trials were available against *Blumeria graminis* (ERYSGR), on spring barley. 1 trial out of 2 was considered valid and was included to support the efficacy evaluation of CA3301 at 0.6 l/ha applied twice, compared to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 30-32 and the 2nd application was at BBCH 55-59.

Summary results are presented in Table 3.2-311.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Blumeria graminis* on spring barley, giving a significant reduction in disease severity

On foliar level 2, at this dose rate, CA3301 showed 83.49% of efficacy on disease severity before harvest.

In the Mediterranean EPPO zone with a limited dataset for this pathogen, a consistent trend was however observed whereby CA3301 at 0.6 l/ha gave equivalent disease control compared to the authorised reference product CA2445 and the data demonstrated that the tested product showed high efficacy in re-

ducing the severity of *Blumeria graminis* on spring barley on foliar level 2. Furthermore, prothioconazole is well established as an effective control for this pathogen. Therefore, it is proposed that a dose rate of 0.6 L/ha is appropriate for control of *Blumeria graminis* in spring barley.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Blumeria graminis* on spring barley in the Mediterranean EPPO zone.

Table 3.2-311: Summary table - Efficacy evaluation – Spring barley – ERYSGR-ERYSGH - Mediterranean EPPO zone

Inter Rankan LPTG Zone					
Treatment name	UNTREATED CHECK	CA2445	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	0,6		
Rate unit		L/ha	L/ha		
Appl. Code		AB	AB		
% Disease severity L2 - 24 DA-B					
Number of values	1	1	1	UT C	CA244 5 0,8 l/ha
Minimum value	11,75	0,94	1,94		
Maximum value	11,75	0,94	1,94	1 >	0 >
Mean disease severity (%)	11,75	0,94	1,94	0 =	1 =
Abbott efficacy (%)	0.00%	92.00%	83.49%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against ERYSGR-ERYSGH - South-Eastern EPPO zone

No data were available from the South-eastern EPPO zone for *Blumeria graminis* in spring-sown barley, however data collected in winter-sown barley for the same pathogen is considered supportive for this use. According to NEU efficacy guidance document (version 8, April 2020), data submitted in support of this pathogen is equivalent in either winter-sown or spring-sown barley.

Over the dataset presented for the same crop sown in winter (see **Winter barley (HORVW) / *Blumeria graminis* f. sp. hordei (ERYSGH / ERYSGR)**), disease severity was low to medium, and CA3301 at 0.6 l/ha gave high disease control comparable to the authorised reference product PRIAXOR. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient to provide acceptable control of *Blumeria graminis* f. sp. hordei.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Blumeria graminis* on spring barley in the South-Eastern EPPO zone.

Use of CA3301 at 2x 0.6 l/ha against ERYSGR-ERYSGH - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, 3 trials were available against *Blumeria graminis* (ERYSGR), on spring barley. 1 trial out of 3 was considered valid and was included to support the efficacy evaluation of CA3301 at 0.6 l/ha applied twice, compared to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 31-37 and the 2nd application was at BBCH 55.

Summary results are presented in Table 3.2-312.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Blumeria graminis* on spring barley, significantly reducing disease severity. On foliar level 2, at this dose rate, CA3301 showed 65.00% of efficacy on disease severity before harvest.

In the North-Eastern East EPPO zone with a limited dataset for this pathogen, a consistent trend was however observed whereby CA3301 at 0.6 l/ha gave equivalent disease control compared to the authorised reference product CA2445 and the data demonstrated that the tested product showed medium efficacy in reducing the severity of *Blumeria graminis* on spring barley whatever the foliar level. This trend is confirmed by the data recorded on Winter barley (see **Winter barley (HORVW) / *Blumeria graminis* f. sp. hordei (ERYSGH / ERYSGR)**) although the dataset is also limited in this same EPPO zone. Furthermore, prothioconazole is well established as an effective control for this pathogen. Therefore, it is proposed that a dose rate of 0.6 L/ha is appropriate for control of *Blumeria graminis* in spring barley.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Blumeria graminis* on spring barley in the North-Eastern East EPPO zone.

Table 3.2-312: Summary table - Efficacy evaluation – Spring barley – ERYSGR-ERYSGH – North-Eastern East EPPO zone

North-Eastern East EPTG zone					
Treatment name	UNTREATED	CA2445	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate	CHECK	0,8	0,6		
Rate unit		L/ha	L/ha		
Appl. Code		AB	AB		
% Disease severity L2 - 26 DA-B					
Number of values	1	1	1	UT	CA2445
Minimum value	10,00	2,90	3,50	C	5
Maximum value	10,00	2,90	3,50	1 >	0,8 l/ha
Mean disease severity (%)	10,00	2,90	3,50	0 =	1 =
Abbott efficacy (%)	0.00%	71.00%	65.00%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against ERYSGR-ERYSGH - Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, a total of 10 trials from the North-Eastern East EPPO zone and the neighbouring countries Czech Republic, Germany and Slovakia evaluated the efficacy of CA3301 on spring barley against *Blumeria graminis*. 4 trials were considered valid and enabled to compare the efficacy of CA3301 to authorised reference standards on disease severity (%). CA3301 was first applied at crop stages BBCH 33-37 and the 2nd application was at BBCH 55-59.

Summary results are presented in Table 3.2-313.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Blumeria graminis* on spring barley, significantly reducing disease severity in all trials.

On foliar level 2, at this dose rate, CA3301 showed 80.50% of efficacy on disease severity two weeks after the 2nd application and 79.87% before harvest.

In this dataset, a consistent trend was observed whereby CA3301 at 0.6 l/ha gave equivalent disease control compared to the authorised reference product CA2445 and the data demonstrated that the tested product showed high efficacy in reducing the severity of *Blumeria graminis* on spring barley on foliar level 2 until the harvest timing. Therefore, it is proposed that a dose rate of 0.6 L/ha is appropriate for control of *Blumeria graminis* in spring barley.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Blumeria graminis* on spring barley in Poland.

Table 3.2-313: Summary table - Efficacy evaluation – Spring barley – ERYSGR-ERYSGH – Data relevant for Poland

Treatment name	UNTREATED CHECK	CA2445	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	0,6		
Rate unit		L/ha	L/ha		
Appl. Code		AB	AB		
% Disease severity L2 - 13-15 DA-B					
Number of values	3	3	3	UT C	CA244 5 0,8 l/ha
Minimum value	7,00	0,06	0,06		
Maximum value	23,94	5,88	6,63	3 >	0 >
Mean disease severity (%)	15,47	3,88	3,77	0 =	3 =
Abbott efficacy (%)	0,00%	79.11%	80.50%	0 <	0 <
% Disease severity L2 - 19-26 DA-B					
Number of values	2	2	2	UT C	CA244 5 0,8 l/ha
Minimum value	8,74	0,39	0,46		
Maximum value	10,00	2,90	3,50	2 >	0 >
Mean disease severity (%)	9,37	1,64	1,98	0 =	2 =
Abbott efficacy (%)	0,00%	83.27%	79.87%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

3 valid trials were conducted in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,6 l/ha achieved high efficacy after 13-19 days after second application. Due to the limited number of trials, the cMSs are kindly asked to consider this use on the national level.

Only 1 valid trial was available in **the North-East EPPO zone**. The medium level of control was observed after used of test product at 0,6 l/ha. Furthermore, 3 trials from the neighbouring countries (the Czech Republic and Germany) have been submitted to support of Polish registration. Moreover, the extrapolation of trial results from winter barley to spring barley is possible. The medium level of control of ERYSGH in spring barley is considered in Poland.

No trials have been presented in **the South-East EPPO zone**. Only 1 trial from the Mediterranean was available to support of product registration in other zones. CA3301 at 0,6 l/ha achieved high efficacy after 24 DA-B. Due to the limited number of trials, the cMSs are kindly asked to consider this use on the national level.

3.2.3.13 Spring barley (HORVS) / *Rhynchosporium secalis* (RHYNSE)

Materials and Methods – Spring barley – RHYNSE

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2018 and 2020, a series of 26 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the efficacy of CA3301 against *Rhynchosporium secalis* on **spring barley**. The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, 12 trials were performed in United Kingdom (7), Denmark (2) and Germany (3).

In the Mediterranean EPPO zone, 5 trials were performed in Italy (1), Portugal (1) and Spain (3).

In the North-Eastern East EPPO zone, 2 trial was performed in Poland (2).

In the South-Eastern East EPPO zone, a total of 7 trials were performed in Hungary (1), Romania (5) and Slovakia (1).

Data groupings were also made specifically for Poland evaluation and trials involved (6) were performed in Germany (3), Poland (2) and Slovakia (1).

Table 3.2-314: Presentation of trials – Spring barley (HORVS) - RHYNSE

Crop(s) *)	Target(s)*	Country	Years	Type of trial*	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					Maritime zone	Mediterranean zone	North-Eastern zone	South-Eastern zone		
Spring barley	RHYNSE	United Kingdom	2019-2020	MED + E	7 (3)	-	-	-	GEP	
		Germany	2019-2020	MED + E	3 (2)	-	-	-	GEP	
		Denmark	2018	MED + E	2 (0)	-	-	-	GEP	
Spring barley	RHYNSE	Italy	2020	MED + E	-	1 (0)	-	-	GEP	
		Spain	2019-2020	MED + E	-	3 (1)	-	-	GEP	
		Portugal	2018	MED + E	-	1 (1)	-	-	GEP	
Spring barley	RHYNSE	Poland	2019-2020	MED + E	-	-	2 (1)	-	GEP	
Spring barley	RHYNSE	Hungary	2020	MED + E	-	-	-	1 (0)	GEP	
		Slovakia	2019	MED + E	-	-	-	1 (1)	GEP	
		Romania	2019-2020	MED + E	-	-	-	5 (5)		
TOTAL	-	-	2018-2020	MED + E	12 (5)	5 (2)	2 (1)	7 (6)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation

In all trials, CA3301 was compared to at least one commercial fungicide used as standard reference for comparison.

Table 3.2-315: Efficacy evaluation - Presentation of reference standards used in trials – Spring barley (HORVS) – RHYNSE – Maritime EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
HORVS	PRO-LINE 275	UK	14790	Prothioconazole	EC	275 g/l	2 x 0.72 l/ha	2 x 0.72 l/ha	
	PRO-LINE	DE	025287-00	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE EC 250	DK	18-473	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-316: Efficacy evaluation - Presentation of reference standards used in trials – Spring barley (HORVS) – RHYNSE – Mediterranean EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
HORVS	PRO-LINE	ITALY	13385	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha max	2 x 0.8 l/ha	CA2445 in some trials
	PRO-SARO	ITALY	013386	Prothioconazole + Tebuconazole	EC	125 g/l + 125 g/l	2 x 1 l/ha max	2 x 1 l/ha	
	PRAK-TIS	PORTUGAL	AV 1485	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha max	2 x 0.8 l/ha	CA2445 in some trials
	PRO-SARO	SPAIN	25661	Prothioconazole + Tebuconazole	EC	125 g/l + 125 g/l	2 x 1 l/ha max	2 x 1 l/ha	
	PRAK-TIS	SPAIN	01135	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha max	2 x 0.8 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-317: Efficacy evaluation - Presentation of reference standards used in trials – Spring barley (HORVS) – RHYNSE – North-East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
HORVS	OSIRIS 65 EC	POLAND	R-87/2012	Epoxiconazole + Metconazole	EC	37.5 g/l + 27.5 g/l	2.5 l/ha	2.0 l/ha	
	PRAKTIS	POLAND	R-222/2019	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials

Table 3.2-318: Efficacy evaluation - Presentation of reference standards used in trials – Spring barley (HORVS) – RHYNSE – South-East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
HORVS	BUMPER 25 EC	SLOVAKIA	15-02-1617	Propiconazole	EC	250 g/l	1 x 0.5 l/ha	2 x 0.5 l/ha	
	PRIAXOR	HUNGARY	04.2/4127-1/2016	Fluxapyroxad + Pyraclostrobin	EC	75 g/l + 150 g/l	1 x 1.5 l/ha	2 x 1.5 l/ha	
	PROLINE	HUNGARY	6300/1205-1/2020	Prothioconazole	EC	250 g/l	1 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	NATIVO PRO	ROMANIA	056PC/29.09.2014	Prothioconazole + Trifloxistrobin	SC	175 g/l + 150 g/l	2 x 0.6 l/ha	2 x 0.6 l/ha	
	PROLINE 250 EC	ROMANIA	457PC/15.11.2018	Prothioconazole	EC	250 g/l	1 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-319.

Table 3.2-319: Details on trial methodology – Spring barley (HORVS) – RHYNSE

		Maritime EPPO zone	Mediterranean EPPO zone	North-East EPPO zone	South-East EPPO zone	Data relevant for Poland
Trials	Total number (valid number)	12 (5)	5 (2)	2 (1)	7 (6)	6 (3)
	Supportive trials	-	-	-	-	-
Guidelines	General guidelines	PP 1/152 (4) PP 1/181 (4)	PP 1/152 (4) PP 1/181 (4)	PP 1/152 (4) PP 1/181 (4)	PP 1/152 (4) PP 1/181 (4)	PP 1/152 (4) PP 1/181 (4)

		PP 1/239 (2) PP 1/135 (4) PP 1/214 (3) PP 1/225 (2)	PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)	PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)	PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)	PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)
	Specific guidelines	PP 1/26 (4) PP 1/28 (3) PP 1/262 (1)	PP 1/26 (4)	PP 1/26 (4)	PP 1/26 (4)	PP 1/26 (4)
Experimental design	Plot design	Randomized Complete Blocks, Un-treated included	Randomized Complete Blocks, Un-treated included	Randomized Complete Blocks, Un-treated included	Randomized Complete Blocks, Un-treated included	Randomized Complete Blocks, Un-treated included
	Plot size	21 - 30 m ²	21 - 30 m ²	21-30 m ²	20 – 30 m ²	21 – 30 m ²
	Number of replications	4	4	4	4	4
Crop	Trials per crop	HORVS (12)	HORVS (5)	HORVS (2)	HORVS (7)	HORVS (6)
	Varieties per crop	Avalon (1), Beckie (1), Con-certo (2), Fantex (1), Marthe (1), RGT Planet (5), Ovation (1)	Esterel (1), KWS Fantex (1), RGT Planet (1), Cam-pagne SIS (1), Sydney (1)	Tek-sas (1), Stra-tus (1)	Aligator (2), El-ektra (1), Prib-ina (1), Romanita (1), Thuringia (1), Xandu (1)	Avalon (1), Marthe (1), Pribina (1), Teksas (1), Stra-tus (1), Beckie (1)
	Sowing period	February (1), March (7), April (4)	January (2), Feb-ruary (1), March (1), May (1)	March (2)	March (7)	March (6)
Application	Crop stage (BBCH)* at application	A: BBCH 31-47 B: BBCH 43-65	A: BBCH 32-37 B: BBCH 59-61	A: BBCH 37 B: BBCH 58-59	A: BBCH 32-37 B: BBCH 55-61	A: BBCH 32-37 B: BBCH 53-61
	Timing Pest stage at application	BBCH 31-65 A: ACTIVE (7), MIXED (2), PRINFC (3) B: ACTIVE (2), MIXED (3), PRINFC (2), N/A (5)	BBCH 32-61 A: MIXED (2), PRINFC (2), SPORUL (1) B: MIXED (4), PRINFC (1)	BBCH 37-59 A: PRINFC (2) B: MIXED (2)	BBCH 32-61 A: PRINFC (4), MIXED (3) B: PRINFC (1), MIXED (6)	BBCH 32-61 A: PRINFC (3), MIXED (3) B: PRINFC (2), MIXED (4)
	Number of applications Intervals between applications	2 applications (12-27 days)	2 applications (14-23 days)	2 applications (14-19 days)	2 applications (15-20 days)	2 applications (12-19 days)
	Spray volumes	A: 150-200 l/ha B: 150-200 l/ha	A: 300-400 l/ha B: 300-400 l/ha	A: 300 l/ha B: 300 l/ha	A: 200-300 l/ha B: 200-300 l/ha	A: 200-300 l/ha B: 200-300 l/ha
Assessment	Assessment types	Pest severity (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg), Moisture content (%), TKW (g), HLW (kg)	Pest severity (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg), Moisture content (%), TKW (g), HLW (kg)	Pest severity (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg/ha), TKW (g), HLW (kg/hl), MOICON (%), GRNARE (%)	Pest severity (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg), HLW(kg), TKW (g), Moisture content (%)	Pest severity (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg), HLW(kg), TKW (g), Moisture content (%)
	Assessment dates	0 DA-A, 12-27 DA-A, 0 DA-B, 8-17 DA-B, 23-82 DA-B	0 DA-A, 15-23 DA-A, 0 DA-B, 14-15 DA-B, 30-51 DA-B	0 DA-A, 14-15 DA-A, 0 DA-B, 15-17 DA-B, 27-38 DA-B	0- DA-A, 14-18 DA-A, 0 DA-B, 15 DA-B, 22-27 DA-B, 30-52 DA-B	0 DA-A, 12-18 DA-A, 0 DA-B, 8-17 DA-B, 23-29 DA-B, 38-57 DA-B

Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Natural (12)	Natural (5)	Natural (2)	Natural (7)	Natural (6)
	e.g. Field / Greenhouse...	Field trials (12)	Field trials (5)	Field trials (2)	Field trials (7)	Field trials (6)

26 trials were carried out against *Rhynchosporium secalis* (RHYNSE) on spring barley.

Use of CA3301 at 2x 0.6 l/ha against RHYNSE - Maritime EPPO zone

In the Maritime EPPO zone, 12 trials were available against *Rhynchosporium secalis* (RHYNSE), on spring barley. 5 trials out of 12 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6 l/ha applied twice, compared to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 31-37 and the 2nd application was at BBCH 43-61.

Summary results are presented in Table 3.2-320.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Rhynchosporium secalis* on spring barley, significantly reducing disease severity in all trials.

On foliar level 2, at this dose rate, CA3301 showed 88.96% of efficacy on disease severity two weeks after the 2nd application and 68.61% before harvest.

On foliar level 1, at this dose rate, CA3301 showed 85.25% of efficacy on disease severity before harvest.

In the Maritime EPPO zone, CA3301 at 0.6 l/ha showed high efficacy in reducing the severity of *Rhynchosporium secalis* on spring barley. In addition, CA3301 at 0.6 l/ha gave equivalent control of the disease compared to the reference products CA2445 and PROLINE 275 (both applied at a higher rate of prothioconazole) in most instances. Therefore, it is envisaged that a dose rate of 0.6 L/ha is appropriate to control *Rhynchosporium secalis* on spring barley.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Rhynchosporium secalis* on spring barley in the Maritime EPPO zone.

Table 3.2-320: Summary table - Efficacy evaluation – Spring barley – RHYNSE - Maritime EPPO zone

Treatment name	UNTREATED CHECK	PROLINE 275	CA2445	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,72	0,8	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
% Disease severity L2 - 14-17 DA-B					
Number of values	5			5	UTC
Minimum value	5,56			0,00	
Maximum value	21,14	-	-	5,00	5 >
Mean disease severity (%)	9,52			1,39	0 =
Abbott efficacy (%)	0,00%			88,96%	0 <
Number of values	2	2		2	PROLINE 275
Minimum value	7,95	0,00		0,53	0,72

Maximum value	21,14	3,91	-	5,00	0 >
Mean disease severity (%)	14,55	1,96		2,77	1 =
Abbott efficacy (%)	0,00%	90,75%		84,84%	1 <
Number of values	3		3	3	CA2445
Minimum value	5,56		0,21	0,00	0,8 l/ha
Maximum value	7,29	-	1,43	0,85	0 >
Mean disease severity (%)	6,18		0,84	0,47	3 =
Abbott efficacy (%)	0,00%		85,37%	91,71%	0 <
% Disease severity L2 - 25-34 DA-B					
Number of values	3			3	UTC
Minimum value	7,56			3,61	
Maximum value	51,96	-	-	5,63	3 >
Mean disease severity (%)	24,46			4,52	0 =
Abbott efficacy (%)	0,00%			68,61%	0 <
Number of values	1	1		1	PROLINE
Minimum value	51,96	2,99		5,63	275
Maximum value	51,96	2,99	-	5,63	0,72
Mean disease severity (%)	51,96	2,99		5,63	0 >
Abbott efficacy (%)	0,00%	94,25%		89,16%	1 =
Number of values	2		2	2	0 <
Minimum value	7,56		3,11	3,61	CA2445
Maximum value	13,86	-	4,05	4,33	0,8 l/ha
Mean disease severity (%)	10,71		3,58	3,97	0 >
Abbott efficacy (%)	0,00%		64,82%	58,34%	2 =
					0 <
% Disease severity L1 - 29-34 DA-B					
Number of values	2			2	UTC
Minimum value	8,63			0,76	
Maximum value	12,73	-	-	2,03	2 >
Mean disease severity (%)	10,68			1,39	0 =
Abbott efficacy (%)	0,00%			85,25%	0 <
Number of values	1	1		1	PROLINE
Minimum value	12,73	0,06		0,76	275
Maximum value	12,73	0,06	-	0,76	0,72
Mean disease severity (%)	12,73	0,06		0,76	0 >
Abbott efficacy (%)	0,00%	99,53%		94,03%	1 =
Number of values	1		1	1	0 <
Minimum value	8,63		2,14	2,03	CA2445
Maximum value	8,63	-	2,14	2,03	0,8 l/ha
Mean disease severity (%)	8,63		2,14	2,03	0 >
Abbott efficacy (%)	0,00%		75,20%	76,48%	1 =
					0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)	
>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against RHYNSE - Mediterranean EPPO zone

In the Mediterranean EPPO zone, 5 trials were available against *Rhynchosporium secalis* (RHYNSE), on spring barley. 2 trials out of 5 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6 l/ha applied twice, compared to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 32-37 and the 2nd application was at BBCH 59-61.

Summary results are presented in Table 3.2-321.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Rhynchosporium secalis* on spring barley. In all assessments, CA3301 gave a significant reduction of disease compared to the untreated.

On foliar level 2, at this dose rate, CA3301 showed 65.98% two weeks after the 2nd application and 51.50% before harvest.

On foliar level 1, CA3301 at 0.6 l/ha showed 69.32% of efficacy on reduction of disease severity two weeks after the 2nd application and 64.37% before harvest.

In the Mediterranean EPPO zone, despite the reduced size of the dataset, CA3301 at 0.6 l/ha showed medium efficacy in reducing the severity of *Rhynchosporium secalis* on spring barley and was statistically equivalent to the reference products CA2445 and PROSARO. However, a larger dataset was presented for the closely related crop winter barley (see **Winter barley (HORVW) / *Rhynchosporium secalis* (RHYNSE / RHYNSP)**) which is infected by the same strain *Rhynchosporium secalis*. This dataset demonstrated a comparable behaviour of the product in conditions of high disease pressure and can be supportive for the spring barley species. Therefore, it is envisaged that a dose rate of 0.6 L/ha is appropriate to control *Rhynchosporium secalis* on spring barley.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Rhynchosporium secalis* on spring barley in the Mediterranean EPPO zone.

Table 3.2-321: Summary table - Efficacy evaluation – Spring barley – RHYNSE - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA2445	PROSARO	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	1	0,6		
Rate unit		L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB		
% Disease severity L2 - 14-15 DA-B						
Number of values	2	2		2	UTC	CA24 45
Minimum value	6,64	2,24		1,64		0,8 l/ha
Maximum value	21,00	7,95	-	9,10	2 >	0 >
Mean disease severity (%)	13,82	5,09		5,37	0 =	2 =
Abbott efficacy (%)	0,00%	64,20%		65,98%	0 <	0 <
Number of values	1		1	2	PROSARO	
Minimum value	6,64		1,76	1,64	1,0 l/ha	
Maximum value	6,64	-	1,76	1,64	0 >	
Mean disease severity (%)	6,64		1,76	1,64	1 =	
Abbott efficacy (%)	0,00%		73,49%	75,30%	0 <	
% Disease severity L1 - 15 DA-B						
Number of values	1	1		1	UTC	CA24 45
Minimum value	18,25	5,45		5,60		0,8 l/ha
Maximum value	18,25	5,45	-	5,60	1 >	0 >

Mean disease severity (%)	18,25	5,45		5,60	0 =	1 =
Abbott efficacy (%)	0,00%	70,14%		69,32%	0 <	0 <
% Disease severity L2 - 30 DA-B						
Number of values	1	1		1	UTC	CA24 45
Minimum value	23,30	10,75		11,30		0,8 l/ha
Maximum value	23,30	10,75	-	11,30	1 >	0 >
Mean disease severity (%)	23,30	10,75		11,30	0 =	1 =
Abbott efficacy (%)	0,00%	53,86%		51,50%	0 <	0 <
% Disease severity L1 - 30 DA-B						
Number of values	1	1		1	UTC	CA24 45
Minimum value	21,05	7,75		7,50		0,8 l/ha
Maximum value	21,05	7,75	-	7,50	1 >	0 >
Mean disease severity (%)	21,05	7,75		7,50	0 =	1 =
Abbott efficacy (%)	0,00%	63,18%		64,37%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against RHYNSE - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, 3 2 trials were available against *Rhynchosporium secalis* (RHYNSE), on spring barley. 1 trial out of 2 was considered valid and was included to support the efficacy evaluation of CA3301 at 0.6 l/ha applied twice, compared to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 37 and the 2nd application was at BBCH 59.

Summary results are presented in Table 3.2-322.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Blumeria graminis* on spring barley, significantly reducing disease severity

On foliar level 1, at this dose rate, CA3301 showed 89.72%% of efficacy on disease severity two weeks after the 2nd application.

In the North-Eastern East EPPO zone with a limited dataset for this pathogen, a consistent trend was however observed whereby CA3301 at 0.6 l/ha gave equivalent disease control compared to the authorised reference product OSIRIS 65 EC and the data demonstrated that the tested product showed high efficacy in reducing the severity of *Rhynchosporium secalis* on spring barley. This trend is confirmed by the data recorded on winter barley although the dataset is also limited in this same EPPO zone (see **Winter barley (HORVW) / *Rhynchosporium secalis* (RHYNSE / RHYNSP)**). Furthermore, prothioconazole is well established as an effective control for this pathogen. Therefore, it is proposed that a dose rate of 0.6 L/ha is appropriate for control of *Rhynchosporium secalis* in spring barley.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Rhynchosporium secalis* on spring barley in the North-Eastern East EPPO zone.

Table 3.2-322: Summary table - Efficacy evaluation – Spring barley – RHYNSE – North-Eastern East EPPO zone

LTPO zone					
Treatment name	UNTREATED CHECK	OSIRIS 65 EC 2 L/ha AB	CA3301 0,6 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate					
Rate unit					
Appl. Code					
% Disease severity L1 - 17 DA-B					
Number of values	1	1	1	UT C	OSIRIS 65 EC 2,0 l/ha
Minimum value	6,13	0,25	0,63	1 >	0 >
Maximum value	6,13	0,25	0,63	0 =	1 =
Mean disease severity (%)	6,13	0,25	0,63	0 <	0 <
Abbott efficacy (%)	0.00%	95.92%	89.72%		

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against RHYNSE - South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 7 trials evaluated the efficacy of CA3301 on spring barley against *Rhynchosporium secalis*. All 6 trials were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6 l/ha applied twice CA3301, compared to several reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 32-37 and the 2nd application was at BBCH 55-61.

Summary results are presented in Table 3.2-323.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Rhynchosporium secalis* on spring barley. In all assessments CA3301 gave a significant reduction of disease compared to the untreated. On foliar level 2, at this dose rate, CA3301 showed 95.01% of efficacy on disease severity two weeks after the 2nd application and 81.49% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 89.92% two weeks after the 2nd application and 86.85% before harvest.

In the South-Eastern East EPPO zone, CA3301 showed high efficacy in reducing disease severity of *Rhynchosporium secalis*. In addition, despite being statistically less efficient in some assessments, CA3301 at the proposed dose rate of 0.6 l/ha (150 g/ha/prothioconazole) gave comparable disease control than the reference product CA2445 applied at a higher rate of prothioconazole (200 g/ha), in terms of disease control. Compared to other reference products NATIVO PRO and BUMPER 25 EC, CA3301 at 0.6 l/ha was significantly more efficient in all trials. Therefore, it is envisaged that a dose rate of 0.6 L/ha is appropriate to control *Rhynchosporium secalis* on spring barley.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Rhynchosporium secalis* on spring barley in the South-Eastern East EPPO zone.

Table 3.2-323: Summary table - Efficacy evaluation – Spring barley – RHYNSE – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	BUMPER 25 EC 0,5 L/ha	NATIVO PRO 0,6 L/ha	CA2445 0,8 L/ha	CA3301 0,6 L/ha	No of trials where CA3301 at 0,6 l/ha is >, = or <
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Appl. Code		AB	AB	AB	AB	compared to	
% Disease severity L2 - 15 DA-B							
Number of values	5			5	5	UTC	CA24 45
Minimum value	5,29			0,00	0,00		0,8 l/ha
Maximum value	18,00	-	-	1,59	2,55	5 >	0 >
Mean disease severity (%)	10,32			0,50	0,89	0 =	3 =
Abbott efficacy (%)	0,00%			97,22%	95,01%	0 <	2 <
Number of values	3		3		3	NATIVO PRO	
Minimum value	5,29		0,66		0,00	0,6 l/ha	
Maximum value	5,51	-	0,79	-	0,00	3 >	
Mean disease severity (%)	5,36		0,72		0,00	0 =	
Abbott efficacy (%)	0,00%		86,62%		100,00%	0 <	
% Disease severity L1 - 15 DA-B							
Number of values	2			2	2	UTC	CA24 45
Minimum value	6,48			0,30	0,51		0,8 l/ha
Maximum value	7,76	-	-	0,66	0,88	2 >	0 >
Mean disease severity (%)	7,12			0,48	0,69	0 =	2 =
Abbott efficacy (%)	0,00%			92,97%	89,92%	0 <	0 <
% Disease severity L2 - 22-23 DA-B							
Number of values	4				4	UTC	CA24 45
Minimum value	6,11				1,60		0,8 l/ha
Maximum value	20,69	-	-	-	3,53	4 >	0 >
Mean disease severity (%)	16,93				2,86	0 =	1 =
Abbott efficacy (%)	0,00%				81,49%	0 <	2 <
Number of values	1	1			1	BUMPER 25 EC	
Minimum value	6,11	3,50			1,60	0,5 l/ha	
Maximum value	6,11	3,50	-	-	1,60	1 >	
Mean disease severity (%)	6,11	3,50			1,60	0 =	
Abbott efficacy (%)	0,00%	42,72%			73,81%	0 <	
Number of values	3		3	3	3	NATIVO PRO	
Minimum value	20,38		4,70	2,21	3,05	0,6 l/ha	
Maximum value	20,69	-	5,36	2,51	3,53	3 >	
Mean disease severity (%)	20,54		5,05	2,35	3,28	0 =	
Abbott efficacy (%)	0,00%		75,44%	88,54%	84,05%	0 <	
% Disease severity L1 - 22-23 DA-B							
Number of values	3		3	3	3	UTC	CA24 45
Minimum value	9,30		2,66	0,59	1,30	Nativo Pro	0,8 l/ha
Maximum value	11,94	-	3,64	0,86	1,49	3 >	0 >
Mean disease severity (%)	10,90		3,08	0,70	1,41	0 =	0 =
Abbott efficacy (%)	0,00%		70,97%	93,36%	86,85%	0 <	3 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)
(conversely for '<')

Levels of efficacy (% Abbott efficacy)	
>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against RHYNSE - Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, a total of 6 trials from North-eastern East EPPO zone the neighbouring countries Germany and Slovakia evaluated the efficacy of CA3301 on spring barley against *Rhynchosporium secalis*. 4 trials were considered valid and enabled to compare the efficacy of CA3301 at 0.6 l/ha compared to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 32-37 and the 2nd application was at BBCH 55-61.

Summary results are presented in Table 3.2-324.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Rhynchosporium secalis* on spring barley in the neighbouring countries of Poland. CA3301 significantly reduced disease severity in all assessments.

On foliar level 2, at this dose rate, CA3301 showed 87.57% of efficacy on disease control two weeks after the 2nd application and 58.27% before harvest.

On foliar level 1, at this dose rate, CA3301 showed 89.72% of efficacy on disease control two weeks after the 2nd application and 76.48% before harvest.

In the Poland groupings, CA3301 at 0.6 l/ha showed medium to high efficacy in reducing the severity of *Rhynchosporium secalis* on spring barley. CA3301 at 0.6 l/ha was statistically equivalent to the reference product CA2445 and OSIRIS 65 EC, and better than the reference Bumper 25 EC in all trials available.

Furthermore, 7 valid trials are available for the use of CA3301 against *Rhynchosporium secalis* in winter barley (see **Winter barley (HORVW) / *Rhynchosporium secalis* (RHYNSE / RHYNSP)**) which demonstrate that CA3301 applied at 0.6 l/ha provides high to medium efficacy and is overall more effective compared to the authorised reference standard CA2445 for control of this pathogen. Poland is the only one MS concerned in this application for the North-East EPPO zone, and the Poland authority allows extrapolations between spring and winter barley for this pathogen. Therefore, since application conditions are the same for winter barley and for spring barley – identical dose rate, water rate, crop timing, and timing against the pathogen – it is proposed that the data for winter barley supports the same use in spring barley.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Rhynchosporium secalis* on spring barley in Poland.

Table 3.2-324: Summary table - Efficacy evaluation – Spring barley – RHYNSE – Data relevant for Poland

Treatment name	UNTREATED CHECK	BUMPER 25 EC	CA224 5	OSIRIS 65 EC	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,5	0,8	2	0,6		
Rate unit		L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	AB		
% Disease severity L2 - 14-17 DA-B							
Number of values	2		2		2	UTC	CA2445
Minimum value	5,56		0,88		0,55		0,8 l/ha

Maximum value	5,68	-	1,43	-	0,85	2 >	0 >
Mean disease severity (%)	5,62		1,15		0,70	0 =	2 =
Abbott efficacy (%)	0,00%		79,50 %		87,57%	0 <	0 <
% Disease severity L1 - 17 DA-B							
Number of values	1			1	1	UTC	OSIRIS 65 EC 2,0 l/ha
Minimum value	6,13			0,25	0,63		
Maximum value	6,13	-	-	0,25	0,63	1 >	0 >
Mean disease severity (%)	6,13			0,25	0,63	0 =	1 =
Abbott efficacy (%)	0,00%			95,92%	89,72%	0 <	0 <
% Disease severity L2 - 23-25 DA-B							
Number of values	2				2	UTC	
Minimum value	6,11				1,60		
Maximum value	7,56	-	-	-	4,33	2 >	
Mean disease severity (%)	6,84				2,96	0 =	
Abbott efficacy (%)	0,00%				58,27%	0 <	
Number of values	1	1			1	OSIRIS 65 EC 2,0 l/ha	
Minimum value	6,11	3,50			1,60	1 >	
Maximum value	6,11	3,50	-	-	1,60	0 =	
Mean disease severity (%)	6,11	3,50			1,60	0 <	
Abbott efficacy (%)	0,00%	42,72%			73,81%		
Number of values	1		1		1	CA2445 0,8 l/ha	
Minimum value	7,56		3,11		4,33	0 >	
Maximum value	7,56	-	3,11	-	4,33	1 =	
Mean disease severity (%)	7,56		3,11		4,33	0 <	
Abbott efficacy (%)	0,00%		58,86 %		42,72%		
% Disease severity L1 - 29 DA-B							
Number of values	1		1		1	UTC	CA2445 0,8 l/ha
Minimum value	8,63		2,14		2,03		
Maximum value	8,63	-	2,14	-	2,03	1 >	0 >
Mean disease severity (%)	8,63		2,14		2,03	0 =	1 =
Abbott efficacy (%)	0,00%		75,20 %		76,48%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

5 valid trials were conducted in the **Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,6 l/ha achieved medium to high efficacy after 14-34 days after second application. Due to the limited number of trials, the cMSs are kindly asked to consider this use on the national level.

Only 1 trial was available in the **North-East EPPO zone**. A high level of control was noted in this trial for

objectives treated of the test product at 0,6 l/ha. Also results from 3 efficacy trials conducted in the neighbouring countries (Germany and Slovakia) have been included to the overall calculation to support of Polish registration. Moreover, an extrapolation of trial results from winter barley to spring barley was used. 6 valid trials were carried out **in the South-East EPPO zone**. CA3301 at 0,6 l/ha achieved high level of control after 15-23 DA-B. In the additional 2 trials from the Mediterranean zone, the test product showed medium efficacy.

Taking into account all trials, CA3301 used in 2 applications can be recommended to control of *Rhynchosporium secalis* in spring barley in the North-East and South-East zone.

3.2.3.14 Spring barley (HORVS) / *Oculimacula acufformis* (PSDCHA)

(Ramanauskiene *et al.*, Effects of fungicides on the occurrence of winter wheat eyespot caused by fungi *Oculimacula acufformis* and *O. yal-lundae*, *Crop protection*, 2016)

No data were available for assessment of control of eyespot of cereals *Oculimacula acufformis* on any crop. Although early symptoms can be confused with *Fusarium spp.*, the diseases are not related and therefore it is impossible to extrapolate from these data.

However, Ramanauskiene *et al.*, showed that 2, 3 and 4 years of prothioconazole treatments allowed to reduce the population of *O. acufformis* assessed from 2009 to 2011 on winter wheat. This positive effect was observed as early as 10 days after treatment. This pathogen infecting both winter wheat and barley, it is therefore possible to transpose these results to spring barley.

Moreover, prothioconazole is one of the active substances the most used as fungicide in commercial practices (*Forecasting eyespot development and yield losses in winter wheat, HGCA, 2012*). Standard reference products containing prothioconazole, such as Proline 275 are registered to control eyespot on cereals, at the same application rates as for the other authorised pathogens, which indicates that prothioconazole controls eyespot at dose rates which are demonstrated to control the other major disease pathogens in cereals. Since the proposed dose rate for CA3301 against this pathogen is comparable to the rates demonstrated against other pathogens, and data shows overall equivalence of efficacy between Proline 275 and CA3301 in other pathogens, it is considered that CA3301 will also provide acceptable control of eyespot at the proposed dose rate.

Since on cereals a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the range of 0.6 l/ha gave in overall equivalent disease control compared to the authorized reference products containing prothioconazole, we assume that in most instances CA3301 at 0.6 l/ha will give sufficient control of eyespot.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Oculimacula acufformis* on spring barley in all EPPO zones.

Comments of zRMS:

No dataset has been submitted from any EPPO zones. The cMSs from the Maritime and South-East zone are kindly asked to consider this use on the national level. This use can not be accepted in Poland because an extrapolation is not possible.

3.2.3.15 Spring barley (HORVS) / Green leaf area

Use of CA3301 at 2x 0.6 l/ha - Maritime EPPO zone

Green leaf area was recorded at 14-40 DA-B in 22 valid trials on spring barley after two applications of CA3301 at 0.6 l/ha and authorised reference standards. In 16 trials, green leaf area was assessed on the whole plant while it was assessed on foliar level 2 and 1, respectively in 2 and 6 trials.

Summary results are presented in Table 3.2-325.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the increase of green leaf area on spring barley infected by foliar diseases. In the 16 trials assessing green leaf area on the whole plant, an augmentation of 151.50% was recorded compared to the untreated check on spring barley. In the additional trials assessing green leaf area by foliar level, an increase of 675.00% was recorded on foliar level 2 and 114.33% on foliar level 1.

In a majority of trials CA3301 at 0.6 l/ha was overall equivalent to the reference products CA2445 at 0.8 l/ha and PROLINE 275 at 0.72 l/ha except in 1 trial.

Therefore, it is concluded that 2 applications of CA3301 at 0.6 l/ha will have a positive effect on the green leaf area in spring barley affected by a range of pathogens in the Maritime EPPO zone.

Table 3.2-325: Summary table – Efficacy evaluation – Spring barley – Green leaf area - Maritime EPPO zone

Treatment name	UNTREATED CHECK	PROLINE 275	CA2445	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,72	0,8	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
% Green leaf area - 14-39 DA-B					
Number of values	16			16	UTC
Minimum value	0,00			4,50	
Maximum value	85,00	-	-	93,00	14 >
Mean green leaf area (%)	32,88			51,17	2 =
Mean %UTC	100,00%			251,50%	0 <
Number of values	4	4		4	PROLINE 275
Minimum value	0,00	18,75		18,75	0,72 l/ha
Maximum value	48,25	91,75	-	88,00	0 >
Mean green leaf area (%)	20,81	49,81		47,31	4 =
Mean %UTC	100,00%	186,15%		173,33%	0 <
Number of values	12		12	12	CA2445
Minimum value	0,75		5,50	4,50	0,8 l/ha
Maximum value	85,00	-	95,00	93,00	0 >
Mean green leaf area (%)	36,90		52,96	52,46	11 =
Mean %UTC	100,00%		278,30%	264,53%	1 <
% Green leaf area - L2 - 29-32 DA-B					
Number of values	2			2	UTC
Minimum value	0,00			17,99	
Maximum value	10,00	-	-	77,50	2 >
Mean green leaf area (%)	5,00			47,74	0 =
Mean %UTC	100,00%			775,00%	0 <
Number of values	1	1		1	PROLINE 275
Minimum value	0,00	20,40		17,99	0,72 l/ha
Maximum value	0,00	20,40	-	17,99	0 >
Mean green leaf area (%)	0,00	20,40		17,99	1 =
Mean %UTC	*	*		*	0 <
Number of values	1		1	1	CA2445
Minimum value	10,00		73,75	77,50	0,8 l/ha
Maximum value	10,00	-	73,75	77,50	0 >
Mean green leaf area (%)	10,00		73,75	77,50	1 =

Treatment name		PROLINE 275	CA2445	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to 0 <
Rate	UNTREATED CHECK	0,72	0,8	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
Mean % UTC	100,00%		737,50%	775,00%	
% Green leaf area - L1 - 19-40 DA-B					
Number of values	6			6	UTC
Minimum value	0,00			51,01	
Maximum value	71,25	-	-	87,50	6 >
Mean green leaf area (%)	30,83			72,85	0 =
Mean % UTC	100,00%			214,33%	0 <
Number of values	2	2		2	PROLINE 275
Minimum value	0,00	25,00		51,01	0,72 l/ha
Maximum value	0,00	54,14	-	72,85	1 >
Mean green leaf area (%)	0,00	39,57		61,93	1 =
Mean % UTC	*	*		*	0 <
Number of values	4		4	4	CA2445
Minimum value	17,50		57,50	55,00	0,8 l/ha
Maximum value	71,25	-	86,25	87,50	1 >
Mean green leaf area (%)	46,25		76,13	78,31	3 =
Mean % UTC	100,00%		209,38%	214,33%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 at 2x 0.6 l/ha - Mediterranean EPPO zone

Green leaf area was recorded at 12-40 DA-B in 27 valid trials on spring barley after two applications of CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha. In 26 trials, green leaf area was assessed on the whole plant while in 1 additional trial it was assessed by foliar level.

Summary results are presented in Table 3.2-326.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the increase of green leaf area on spring barley infected by foliar diseases. In the 26 trials assessing green leaf area on the whole plant, an augmentation of 13.86% was recorded compared to the untreated check on spring barley. In the additional trial assessing green leaf area by foliar level, an increase of 89.40% was recorded on foliar level 2 and 45.40% on foliar level 1.

In most instances CA3301 at 0.6 l/ha was equivalent to the reference products CA2445 at 0.8 l/ha and PROSARO at 1.00 l/ha.

Therefore, it is concluded that 2 applications of CA3301 at 0.6 l/ha will have a positive effect on the green leaf area in spring barley affected by a range of pathogens in the Mediterranean EPPO zone.

Table 3.2-326: Summary table - Efficacy evaluation – Spring barley – Green leaf area - Mediterranean EPPO zone

Treatment name		CA2445	PROSARO	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate	UNTREATED CHECK	0,8	1	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
% Green leaf area - 12-40 DA-B					
Number of values	26			26	UTC
Minimum value	0,00			6,38	
Maximum value	85,00	-	-	92,25	12 >
Mean Green Leaf Area (%)	48,51			56,06	14 =
Mean % UTC (%)	100,00%			113,86%	0 <
Number of values	18	18		18	CA2445

Minimum value	0,00	5,50	-	6,38	0,8 l/ha
Maximum value	85,00	95,00	-	92,25	0 >
Mean Green Leaf Area (%)	51,98	60,89	-	59,79	14 =
Mean % UTC (%)	100,00%	120,04%	-	118,99%	4 <
Number of values	20		20	20	PROSARO
Minimum value	0,00		12,00	6,38	1,0 l/ha
Maximum value	85,00	-	95,00	92,25	0 >
Mean Green Leaf Area (%)	47,60		56,89	56,78	16 =
Mean % UTC (%)	100,00%		123,28%	119,79%	4 <
% Green leaf area - L2 - 13 DA-B					
Number of values	1	1		1	UTC
Minimum value	20,00	39,47		37,88	CA2445
Maximum value	20,00	39,47	-	37,88	0,8 l/ha
Mean Green Leaf Area (%)	20,00	39,47	-	37,88	0 >
Mean % UTC (%)	100,00%	197,35%	-	189,40%	1 =
					0 <
% Green leaf area - L1 - 13 DA-B					
Number of values	1	1		1	UTC
Minimum value	28,50	48,75		41,44	CA2445
Maximum value	28,50	48,75	-	41,44	0,8 l/ha
Mean Green Leaf Area (%)	28,50	48,75	-	41,44	0 >
Mean % UTC (%)	100,00%	171,05%	-	145,40%	1 =
					0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 at 2x 0.6 l/ha - North-Eastern East EPPO zone

Green leaf area was recorded at 8-40 DA-B in 31 valid trials on spring barley affected by a range of pathogens after two applications of CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha. In all 31 trials, green leaf area was assessed on the whole plant.

Summary results are presented in Table 3.2-327.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the augmentation of green leaf area on spring barley affected by foliar diseases. In the 31 trials assessing green leaf area on the whole plant, an augmentation of 53.56% was recorded compared to the untreated check on spring barley.

Over the whole dataset, CA3301 at 0.6 l/ha was equivalent or very comparable to the reference products CA2445 at 0.8 l/ha and OSIRIS 25 EC at 2.00 l/ha although in some assessments it was statistically less efficient.

Therefore, it is concluded that 2 applications of CA3301 at 0.6 l/ha will have a positive effect on the green leaf area in spring barley affected by a range of pathogens in the North-Eastern East EPPO zone.

Table 3.2-327: Summary table - Efficacy evaluation – Spring barley – Green leaf area – North-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA2445	OSIRIS 65 EC	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	2	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
% Green leaf area - 8-40 DA-B					
Number of values	31			31	UTC
Minimum value	1,75			4,50	
Maximum value	73,75	-	-	83,75	21 >
Mean green leaf area (%)	29,94			37,70	10 =
Mean % UTC (%)	100,00%			153,56%	0 <
Number of values	21	21		21	CA2445
Minimum value	5,50	8,50		6,75	0,8 l/ha
Maximum value	73,75	87,50	-	83,75	0 >

Mean green leaf area (%)	30,49	45,47		43,83	18 =
Mean %UTC (%)	100,00%	157,72%		153,50%	3 <
Number of values	21		21	21	OSIRIS 65 EC
Minimum value	1,75		7,50	4,50	2,0 l/ha
Maximum value	73,75	-	88,75	83,73	0 >
Mean green leaf area (%)	29,69		41,13	38,90	20 =
Mean %UTC (%)	100,00%		161,43%	147,61%	1 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 at 2x 0.6 l/ha - South-Eastern East EPPO zone

Green leaf area was recorded at 15-34 DA-B in 25 valid trials on spring barley after two applications of CA3301 at 0.8 l/ha, 0.6 l/ha and 0.48 l/ha. In all 25 trials, green leaf area was assessed on the entire plant.

Summary results are presented in Table 3.2-328.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the augmentation of green leaf area on spring barley affected by foliar diseases. In the 25 trials assessing green leaf area on the whole plant, an augmentation of 79.98% was recorded compared to the untreated check on spring barley.

Over the whole dataset, CA3301 at 0.6 l/ha was equivalent or very comparable to the reference products CA2445, PRIAXOR, NATIVO PRO and BUMPER 25 EC although in 2 assessments it was statistically less efficient than CA2445 applied at a higher rate of prothioconazole, and than PRIAXOR (fluxapyroxad & pyraclostrobin) .

Therefore, it is concluded that 2 applications of CA3301 at 0.6 l/ha will have a positive effect on the green leaf area in spring barley affected by a range of pathogens in the South-Eastern East EPPO zone.

Table 3.2-328: Summary table - Efficacy evaluation – Spring barley – Green leaf area – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	BUMPER 25 EC	NATIVO PRO	CA24 45	PRIAX OR	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,5	0,6	0,8	1,5	0,6	
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	AB	AB	
% Green leaf area - 15-34 DA-B							
Number of values	25					25	UTC
Minimum value	10,00					30,00	
Maximum value	100,00	-	-	-	-	100,00	13 >
Mean green leaf area (%)	47,25					70,82	12 =
Mean %UTC	100,00%					179,98%	0 <
Number of values	5	5				5	BUMPER 25 EC 0,5 l/ha
Minimum value	55,00	65,00				80,00	
Maximum value	67,00	80,00	-	-	-	85,00	0 >
Mean green leaf area (%)	59,40	72,00				84,00	5 =
Mean %UTC	100,00%	121,22%				142,44%	0 <
Number of values	5		5			5	NATIVO PRO 0,6 l/ha
Minimum value	55,00		80,00			82,50	
Maximum value	60,00	-	80,00	-	-	85,00	0 >

Mean green leaf area (%)	57,50		80,00			84,50	5 =
Mean %UTC	100,00%		139,24%			147,07%	0 <
Number of values	18			18		18	CA2445
Minimum value	10,00			30,00		30,00	0,8 l/ha
Maximum value	100,00	-	-	100,00	-	100,00	0 >
Mean green leaf area (%)	44,13			68,99		67,53	16 =
Mean %UTC	100,00%			198,90%		193,46%	2 <
Number of values	8			8		8	PRIAXOR
Minimum value	25,00			30,00		30,00	1,5 l/ha
Maximum value	70,00	-	-	93,75	-	83,50	0 >
Mean green leaf area (%)	46,94			69,38		66,00	6 =
Mean %UTC	100,00%			170,83%		164,37%	2 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Comments of zRMS:

22 valid trials were presented in **the Maritime EPPO climatic zone**. The whole plants were observed in 16 out of 22 trials. An augmentation of green leaf area amounted 151,5%. Also results from major leaves of L2 and L1 were noted in 2 and 6 trials respectively. A very positive effect was visible with an augmentation of 675% for L2 and 114,33% for L1.

31 valid trials were available in **the North-East EPPO zone**. All observations were provided on whole plants. CA3301 at 0,6 l/ha achieved an augmentation of green leaf area of 53,56%.

25 valid trials showed positive effect on green leaf area in **the South-East EPPO zone**. The test product at 0,6 l/ha showed an augmentation of 79,98% in case of whole plants.

3.2.3.16 Spring barley (HORVS) / Conclusion

On spring barley, 5 foliar diseases were assessed in 106 trials across 4 EPPO zones. Disease severity was assessed and analysed on the main foliar levels 1 and 2. Depending on the EPPO zone, the disease, the assessment timing and the crop part assessed, the dataset available was sometimes limited with results not necessarily representative of the true efficacy of CA3301. However, globally, across the 4 EPPO zones and all diseases the efficacy of CA3301 at 0.6 l/ha was acceptable to very high, with some exceptions especially in case of limited dataset. Since in the fields a complex of disease is often observed instead of a single disease, it is of interest to look at the efficacy of CA3301 across the diseases and to not focus on a single one. Therefore, to get an overview of the efficacy of CA3301 at 0.6 l/ha, summary tables are presented here under, on foliar levels 1&2 (see Table 3.2-329 and Table 3.2-330).

It has been shown in the previous sections that the efficacy of CA3301 at 0.6 l/ha was overall equivalent to the one provided by the approved reference standards used in the trials. A trend of decreasing disease severity when increasing the dose rates was observed with CA3301 at 0.6 l/ha providing a better disease control than the lower rate of 0.48 l/ha. The rate of 0.6 l/ha (100% dose rate) was in the majority of cases statistically comparable to the 0.8 l/ha rate (133% dose rate), although in limited cases the differences were statistically significant. Moreover, in circumstances of high disease pressure the rate of 0.6 l/ha showed sufficient efficacy to maintain crop quality. Finally, due to the importance of the diseases and given the possibility of resistance in several of the pathogens assessed, the 100% dose rate of 0.6 l/ha, demonstrated to provide equivalent control to authorised reference standards, is considered the most appropriate dose rate.

In this dossier efficacy data presented is primarily from assessments where 2 applications of the test product were made. However, according to disease development conditions, a single application may provide sufficient disease control, therefore users should not be restricted to always applying twice, hence in the GAP the proposed use is for 1-2 applications. In addition, crop pathogens are commonly controlled using a programme of different fungicides with varied modes of action, therefore the choice should be available to growers to make a single application of CA3301, followed by application of a different appropriate fungicide. Prothioconazole is well established over a number of years in providing good broad spectrum efficacy across a range of common crop pathogens, with either 1 or more applications appropriate according to disease development conditions, risk of resistance development and local conditions. Current authorisations for similar products containing prothioconazole including Proline 275 and Proline/Praktis/Joao (CA2445) are for 1-2 applications at comparative rates of prothioconazole to the requested use for CA3301. Considering these elements, and that data shows comparability of CA3301 to these authorised products, registration of CA3301 at the proposed dose rate and with a number of applications of 1- 2, is requested.

Considering all elements presented in the previous sections of each disease, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control a range of foliar diseases on spring barley.

Table 3.2-329: Summary table – Spring barley – All foliar diseases (L2)

Foliar level 2			MAR	MED	NE	SE	Poland + DE CZ SK
Disease	Application timing		CA3301 0,6 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,6 L/ha AB
RAMUCC	2 weeks after B	Number of values Abbott efficacy (%)	2 76.71	3 60.75	0 -	3 92.92	1 78.75
	Before harvest	Number of values Abbott efficacy (%)	4 60.12	6 68.88	0 -	4 80.64	5 76.72
PUCCHD	2 weeks after B	Number of values Abbott efficacy (%)	2 97.72	0 -	3 91.14	1 81.12	0 -
	Before harvest	Number of values Abbott efficacy (%)	3 81.49	1 88.07	2 96.61	5 86.34	0 -
PYRNTE	2 weeks after B	Number of values Abbott efficacy (%)	5 77.81	5 74.11	10 84.07	7 80.15	0 -
	Before harvest	Number of values Abbott efficacy (%)	4 51.69	7 63.63	14 75.76	6 69.22	0 -
ERYSGR ERYSGH	2 weeks after B	Number of values Abbott efficacy (%)	3 80.50	0 -	0 -	0 -	3 80.50
	Before harvest	Number of values Abbott efficacy (%)	1 94.74	1 83.94	1 65.00	0 -	2 79.87
RHYNSE	2 weeks after B	Number of values Abbott efficacy (%)	5 88.96	2 65.98	0 -	5 95.01	2 87.57
	Before harvest	Number of values Abbott efficacy (%)	3 68.61	1 51.50	0 -	4 81.49	2 58.27

Table 3.2-330: Summary table – Spring barley – All foliar diseases (L1)

Foliar level 1			MAR	MED	NE	SE	Poland + DE CZ SK
Disease	Application timing		CA3301 0,6 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,6 L/ha AB
RAMUCC	2 weeks after B	Number of values Abbott efficacy (%)	1 62.99	2 69.16	0 -	1 86.64	1 86.64
	Before harvest	Number of values	6	1	0	4	5

		Abbott efficacy (%)	58.25	63.57	-	83.00	71.19
PUCCHD	2 weeks after B	Number of values	1	0	0	0	0
		Abbott efficacy (%)	92.99	-	-	-	-
	Before harvest	Number of values	3	0	2	1	0
		Abbott efficacy (%)	86.50	-	88.61	88.44	-
PYRNTE	2 weeks after B	Number of values	5	2	5	2	0
		Abbott efficacy (%)	69.41	96.18	81.65	90.84	-
	Before harvest	Number of values	3	1	12	5	0
		Abbott efficacy (%)	77.00	94.69	75.81	73.77	-
ERYSGR ERYSGH	2 weeks after B	Number of values	0	0	0	0	0
		Abbott efficacy (%)	-	-	-	-	-
	Before harvest	Number of values	0	0	0	0	0
		Abbott efficacy (%)	-	-	-	-	-
RHYNSE	2 weeks after B	Number of values	0	1	1	2	1
		Abbott efficacy (%)	-	69.32	89.72	89.92	89.72
	Before harvest	Number of values	2	1	0	3	1
		Abbott efficacy (%)	82.25	64.37	-	86.85	76.48

Comments of zRMS:

All submitted trials were provided with 2 applications of CA3301 at 0,6 l/ha. An effectiveness after the first application was not assessed in case of any disease pathogens. The cMSs from the Maritime and South-East zone are kindly asked to consider single application on the national level. This use can not be accepted in Poland.

3.2.3.17 Oat (AVESS/AVESA) / *Puccinia coronata* (PUCCCA/PUCCCO)

Materials and Methods – Oat – PUCCCA/PUCCCO

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2018 and 2020, a total of 19 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the efficacy of CA3301 against *Puccinia coronata* on oat (see Table 3.2-331). The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, a total of 5 trials were performed in the Czech Republic (2) and Germany (3).

In the Mediterranean EPPO zone, a total of 6 trials were performed in Italy (2), Portugal (1) and Spain (3).

In the North-Eastern East EPPO zone, a total of 4 5 trials were performed in Latvia (1) and Poland (3 4).

In the South-Eastern East EPPO zone, a total of 4 trials were performed in Hungary (2) and Romania (2).

Data groupings were also made specifically for Poland evaluation and trials involved (9) were performed in the North-Eastern East EPPO zone (4), in the Czech Republic (2) and in Germany (3).

Table 3.2-331: Presentation of trials – Oat (AVESS/AVESA) – PUCCCA/PUCCCO

Crop(s)) *	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, offi- cial***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Oat	PUCCCA PUCCCO	Czech Republic	2018	MED + E	2 (1)	-	-	-	GEP	
		German y	2019- 2020	MED + E	3 (2)	-	-	-	GEP	
Oat	PUCCCA PUCCCO	Italy	2019- 2020	MED + E	-	2 (0)	-	-	GEP	
		Portugal	2020	MED + E		1 (1)	-	-	GEP	
		Spain	2019- 2020	MED + E	-	3 (1)	-	-	GEP	
Oat	PUCCCA PUCCCO	Latvia	2019	MED + E	-	-	1 (0)	-	GEP	
		Poland	2018- 2019	MED + E	-	-	3 (1)	-	GEP	
			2021	E	-	-	1 (1)	-	GEP	
Oat	PUCCCA PUCCCO	Hungary	2018	MED + E	-	-	-	2 (2)	GEP	
		Romania	2019	MED + E	-	-	-	2 (1)	GEP	
TOTA L	-	-	2018 - 2020	MED + E	5 (3)	6 (2)	4 (1)	4 (3)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

In all trials, CA3301 was compared to at least one commercial and registered fungicide used as standard reference for comparison.

Table 3.2-332: Efficacy evaluation - Presentation of reference standards used in trials – Oat (AVESS/AVESA) – PUCCCA/PUCCCO – Maritime EPPO zone

Crop(s))	Refer- ence standard	Coun- try(ies) where the product is used ⁽¹⁾	Authoriza- tion number	Active sub- stance(s)	Formulation		Regis- tered ap- plication rate ⁽³⁾	Applica- tion rate in tri- als (per treat- ment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concentra- tion of a.s.			
Oat	PRO- LINE 250 EC	CZ	4523-1	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO- LINE	DE	025287-00	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
	TO-RERO	DE	008235-00	Azoxystrobin	SC	250 g/l	2 x 1 l/ha	2 x 1 l/ha	

Table 3.2-333: Efficacy evaluation - Presentation of reference standards used in trials – Oat (AVESS/AVESA) – PUCCCA/PUCCCO – Mediterranean EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Oat	PRAK-TIS	ES	01135	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials
	PRO-SARO	ES	25661	Prothioconazole + Tebuconazole	EC	125 g/l + 125 g/l	1 l/ha	1 l/ha	
	PRO-LINE	IT	013386	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials
	RIKALI	IT	016561	Isopyrazam + Cyproconazole	SC	205 g/l	1 l/ha	1 l/ha	
	ORIUS P	IT	013913	Tebuconazole + Prochloraz	EW	400 g/l	1.2 l/ha	1.2 l/ha	
	PRAK-TIS	PT	AV 1485	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	MYSTIC EW	PT	AV 0838	Tebuconazole	EW	250 g/l	1 x 1 l/ha	2 x 1 l/ha	MYSTIC SUL in the trial

Table 3.2-334: Efficacy evaluation - Presentation of reference standards used in trials – Oat (AVESS/AVESA) – PUCCCA/PUCCCO – North – Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Oat	PRAK-TIS	PL	R-222/2019	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.6-0.8 l/ha	CA2445 in some trials
	PRO-LINE	LV	0637	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

Table 3.2-335: Efficacy evaluation - Presentation of reference standards used in trials – Oat (AVESS/AVESA) – PUECCA/PUECCO – South-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Oat	PRO-LINE	HU	6300/1205-1/2020	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.6-0.8 l/ha	CA2445 in some trials
	PRO-LINE	RO	457PC/15.11.2018	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-336.

Table 3.2-336: Details on trial methodology – Oat (AVESS/AVESA) – PUECCA/PUECCO

		Maritime EPPO zone	Mediterranean EPPO zone	North-Eastern EPPO zone	South-Eastern EPPO zone	Data relevant for Poland
Trials	Total number (valid number)	5 (3)	6 (2)	4 (5) (+2)	4 (3)	9 (4)
	Supportive trials	-	-	-	-	
Guidelines	General guidelines	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)
	Specific guidelines	PP 1/26(4)	PP 1/26(4)	PP 1/26(4) (+5)	PP 1/26(4)	PP 1/26(4)
Experimental design	Plot design	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included
	Plot size	21-30 m ²	21 m ²	21-30 m ²	21-30 m ²	21-30 m ²
	Number of replications	4	4	4	4	4
Crop	Trials per crop	Oat (5)	Oat (6)	Oat (+5)	Oat (4)	Oat (9)
	Varieties per crop	Korok (1), Spartan (1), Max (1), Prokop (2)	Prevision (3), Prokop (1), Genziana (1), Sto Aleixo (1)	Harnas (2), Breton (1), Edvins (1), Bingo (1)	Poseidon (1), GK Pillango (1), Expreso (1), Mureseanca (1)	Korok (1), Spartan (1), Max (1), Prokop (2), Harnas (2), Breton (1), Edvins (1)
	Sowing period	March (2), April (3)	November (1), January (3), February (2)	October (1), March (1), April (+3)	March (4)	October (1), March (3), April (5)
Application	Crop stage (BBCH)* at	A: BBCH 30-39 B: BBCH 55-61	A: BBCH 30-37 B: BBCH 39-58	A: BBCH 33-38 B: BBCH 52-59	A: BBCH 35-39 B: BBCH 59-65	A: BBCH 30-39

	application					B: BBCH 52-61
	Timing Disease stage at application	BBCH 30-61 A: PRINFC (4), MIXED (1) B: PRINFC (2), MIXED (3)	BBCH 30-61 A: PRINFC (5), SPORUL (1) B: PRINFC (2), MIXED (3), SPORUL (1)	BBCH 30-61 A: PRINFC (3), NA (1) B: PRINFC (1), MIXED (2), NA (1)	BBCH 30-61 A: PRINFC (2), MIXED (2) B: MIXED (2), SPORUL (2)	BBCH 30-61 A: PRINFC (7), MIXED (1), NA (1) B: PRINFC (3), MIXED (5), NA (1)
	Number of applications Intervals between applications	2 applications (14-24 days) (5)	2 applications (14-21 days) (6)	2 applications (14-25 days) (4+5)	2 applications (15-21 days) (4)	2 applications (14-25 days) (9)
	Spray volumes	160-200 l/ha	300-400 l/ha	200-400 l/ha	200-300 l/ha	160-400 l/ha
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)
	Assessment dates	0 DA-A; 7 DA-A; 14-15 DA-A 0 DA-B; 14-15 DA-B; 25-31 DA-B	0 DA-A; 14-15 DA-A 0 DA-B; 13-15 DA-B; 25-36 DA-B	0 DA-A; 15 DA-A 0 DA-B; 13-15 DA-B; 21-40 DA-B	0 DA-A; 14 DA-A 0 DA-B; 14-15 DA-B; 21-26 DA-B	0 DA-A; 7 DA-A; 14-15 DA-A 0 DA-B; 13-15 DA-B; 21-40 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Natural (5)	Natural (6)	Natural (4+5)	Natural (4)	Natural (9)
	e.g. Field / Greenhouse...	Field trials	Field trials	Field trials	Field trials	Field trials

Out of the 19 trials performed on oat against *Puccinia coronata*, 9 were considered valid.

Use of CA3301 at 2x 0.6 l/ha against PuccCA/PuccCO - Maritime EPPO zone

In the Maritime EPPO zone, a total of 5 trials evaluated the efficacy of CA3301 on oat against *Puccinia coronata*. 3 trials out of 5 were considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 30-39 and the 2nd application was at BBCH 55-61.

Summary results are presented in Table 3.2-337.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the reduction of disease severity on oat against *Puccinia coronata*. On foliar level 2, CA3301 at 0.6 l/ha showed 87.75% efficacy before harvest. On foliar level 1 at this dose rate, the tested product provided 100.00% efficacy on reduction of disease severity two weeks after the 2nd application and 94.65% before harvest.

In the Maritime EPPO zone, a limited dataset was available for assessment of control of *Puccinia coronata*. However, the situation reflected the high efficacy of the tested product in conditions of low to relatively high disease pressure on main foliar levels 1 (L1) and 2 (L2). In these conditions, CA3301 at 0.6 l/ha gave always statistically comparable disease control to the authorised reference products CA2445 and TORERO. Therefore, it is envisaged that applications of 0.6 l/ha will be sufficient to provide acceptable control of *Puccinia coronata*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Puccinia coronata* on oat in the Maritime EPPO zone.

Table 3.2-337: Summary table - Efficacy evaluation – Oat – PuccCA/PUCCO - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA2445	TORERO	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	1	0,6		
Rate unit		L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB		
% Disease severity L1 - 15 DA-B						
Number of values	1		1	1	UTC	TORERO
Minimum value	5,56		0,00	0,00		1 l/ha
Maximum value	5,56	-	0,00	0,00	1 >	0 >
Mean disease severity (%)	5,56		0,00	0,00	0 =	1 =
Abbott efficacy (%)	0,00%		100,00%	100,00%	0 <	0 <
% Disease severity L2 - 47 DA-B						
Number of values	1	1		1	UTC	CA2245
Minimum value	40,81	2,13		5,00		0,8 l/ha
Maximum value	40,81	2,13	-	5,00	1 >	0 >
Mean disease severity (%)	40,81	2,13		5,00	0 =	1 =
Abbott efficacy (%)	0,00%	94,78%		87,75%	0 <	0 <
% Disease severity L1 - 25-47 DA-B						
Number of values	2			2	UTC	
Minimum value	11,44			0,18		
Maximum value	25,31	-	-	2,31	2 >	
Mean disease severity (%)	18,38			1,24	0 =	
Abbott efficacy (%)	0,00%			94,65%	0 <	
Number of values	1	1		1	CA2245	
Minimum value	25,31	1,25		2,31	0,8 l/ha	
Maximum value	25,31	1,25	-	2,31	0 >	
Mean disease severity (%)	25,31	1,25		2,31	1 =	
Abbott efficacy (%)	0,00%	95,06%		90,87%	0 <	
Number of values	1		1	1	TORERO	
Minimum value	11,44		0,29	0,18	1 l/ha	
Maximum value	11,44	-	0,29	0,18	0 >	
Mean disease severity (%)	11,44		0,29	0,18	1 =	
Abbott efficacy (%)	0,00%		97,47%	98,43%	0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against PuccCA/PUCCO - Mediterranean EPPO zone

In the Mediterranean EPPO zone, a total of 6 trials evaluated the efficacy of CA3301 on oat against *Puccinia coronata*. 2 trials out of 6 were considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 30-37 and the 2nd application was at BBCH 39-58.

Summary results are presented in Table 3.2-338.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the reduction of disease severity on oat against *Puccinia coronata*. On foliar level 2, CA3301 at 0.6 l/ha showed 100.00% efficacy two weeks after the 2nd application and 96.52% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 100.00% efficacy on reduction of disease severity around two weeks after the 2nd application and 100.00% before harvest.

In the Mediterranean EPPO zone, a limited dataset was available for assessment of control of *Puccinia coronata*. However, the situation reflected the high efficacy of the tested product in conditions of low to really high disease pressure on main foliar levels 1 (L1) and 2 (L2). In these conditions, CA3301 at 0.6 l/ha gave statistically higher or equivalent disease control compared to the authorised reference products CA2445, PROSARO and MYSTIC SUL. Therefore, it is envisaged that applications of 0.6 l/ha will be sufficient to provide acceptable control of *Puccinia coronata*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Puccinia coronata* on oat in the Mediterranean EPPO zone.

Table 3.2-338: Summary table - Efficacy evaluation – Oat – PUCCCA/PUCCCO - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA2445	PROSAR O	MYSTIC SUL	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	1	1	0,6		
Rate unit		L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	AB		
% Disease severity L2 - 13-14 DA-B							
Number of values	2	2			2	UT C	CA224 5
Minimum value	26,56	0,00			0,00		0,8 l/ha
Maximum value	34,25	0,00	-	-	0,00	2 >	0 >
Mean disease severity (%)	30,41	0,00			0,00	0 =	2 =
Abbott efficacy (%)	0,00%	100,00 %			100,00 %	0 <	0 <
Number of values	1	1	1		1	PROSARO	
Minimum value	26,56	0,00	0,00		0,00	1 l/ha	
Maximum value	26,56	0,00	0,00	-	0,00	0 >	
Mean disease severity (%)	26,56	0,00	0,00		0,00	1 =	
Abbott efficacy (%)	0,00%	100,00 %	100,00%		100,00 %	0 <	
Number of values	1	1		1	1	MYSTIC SUL	
Minimum value	34,25	0,00		0,00	0,00	1 l/ha	
Maximum value	34,25	0,00	-	0,00	0,00	0 >	
Mean disease severity (%)	34,25	0,00		0,00	0,00	1 =	
Abbott efficacy (%)	0,00%	100,00 %		100,00%	100,00 %	0 <	
% Disease severity L1 - 13-14 DA-B							
Number of values	2	2			2	UT C	CA224 5
Minimum value	9,25	0,00			0,00		0,8 l/ha
Maximum value	17,66	0,00	-	-	0,00	2 >	0 >
Mean disease severity (%)	13,46	0,00			0,00	0 =	2 =
Abbott efficacy (%)	0,00%	100,00 %			100,00 %	0 <	0 <
Number of values	1	1	1		1	PROSARO	
Minimum value	17,66	0,00	0,00		0,00	1 l/ha	

Maximum value	17,66	0,00	0,00	-	0,00	0 >	
Mean disease severity (%)	17,66	0,00	0,00		0,00	1 =	
Abbott efficacy (%)	0,00%	100,00 %	100,00%		100,00 %	0 <	
Number of values	1	1		1	1	MYSTIC SUL	
Minimum value	9,25	0,00		0,00	0,00	1 l/ha	
Maximum value	9,25	0,00	-	0,00	0,00	0 >	
Mean disease severity (%)	9,25	0,00		0,00	0,00	1 =	
Abbott efficacy (%)	0,00%	100,00 %		100,00%	100,00 %	0 <	
% Disease severity L2 - 27-35 DA-B							
Number of values	2	2			2	UT C	CA224 5
Minimum value	22,56	0,00			0,00		0,8 l/ha
Maximum value	93,38	8,75	-	-	6,50	2 >	0 >
Mean disease severity (%)	57,97	4,38			3,25	0 =	2 =
Abbott efficacy (%)	0,00%	90,36			96,52%	0 <	0 <
Number of values	1	1	1		1	PROSARO	
Minimum value	22,56	0,00	0,00		0,00	1 l/ha	
Maximum value	22,56	0,00	0,00	-	0,00	0 >	
Mean disease severity (%)	22,56	0,00	0,00		0,00	1 =	
Abbott efficacy (%)	0,00%	100,00 %	100,00%		100,00 %	0 <	
Number of values	1	1	-	1	1	MYSTIC SUL	
Minimum value	93,38	8,75		20,38	6,50	1 l/ha	
Maximum value	93,38	8,75		20,38	6,50	0 >	
Mean disease severity (%)	93,38	8,75	-	20,38	6,50	1 =	
Abbott efficacy (%)	0,00%	90,63%		78,18%	93,04%	0 <	
% Disease severity L1 - 27-35 DA-B							
Number of values	2	2			2	UT C	CA224 5
Minimum value	26,50	0,00			0,00		0,8 l/ha
Maximum value	76,00	0,00	-	-	0,00	2 >	0 >
Mean disease severity (%)	51,25	0,00			0,00	0 =	2 =
Abbott efficacy (%)	0,00%	100,00 %			100,00 %	0 <	0 <
Number of values	1	1	1		1	PROSARO	
Minimum value	26,50	0,00	0,00		0,00	1 l/ha	
Maximum value	26,50	0,00	0,00	-	0,00	0 >	
Mean disease severity (%)	26,50	0,00	0,00		0,00	1 =	
Abbott efficacy (%)	0,00%	100,00 %	100,00%		100,00 %	0 <	
Number of values	1	1		1	1	MYSTIC SUL	
Minimum value	76,00	0,00		0,00	0,00	1 l/ha	
Maximum value	76,00	0,00	-	0,00	0,00	0 >	
Mean disease severity (%)	76,00	0,00		0,00	0,00	1 =	
Abbott efficacy (%)	0,00%	100,00 %		100,00%	100,00 %	0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against PuccCA/PuccCO - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 45 trials evaluated the efficacy of CA3301 on oat against *Puccinia coronata*. 12 trial out of 45 was considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference product on disease severity (%). CA3301 was first applied at crop stages BBCH 33-38 and the 2nd application was at BBCH 52-59.

Summary results are presented in Table 3.2-339.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the reduction of disease severity on oat against *Puccinia coronata*. On foliar level 1, CA3301 at 0.6 l/ha provided 89.33% efficacy before harvest. In 1 additional trial, CA3301 at 0,6 l/ha achieved significantly lower effectiveness compare to the reference product with results of 75,63% on foliar level 2 and 67,77% on foliar level 1.

In the North-Eastern East EPPO zone, a limited dataset was available for assessment of control of *Puccinia coronata*. However, the situation reflected the high efficacy of CA3301 in conditions of relatively low disease pressure. Applied at 0.6 l/ha (150 g/ha prothioconazole), the tested product gave equivalent disease control to the authorised reference product CA2445 (applied at 200 g/ha prothioconazole). Therefore, it is envisaged that applications of 0.6 l/ha will be sufficient to provide acceptable control of *Puccinia coronata*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Puccinia coronata* on oat in the North-Eastern EPPO zone.

Table 3.2-339: Summary table - Efficacy evaluation – Oat – PuccCA/PuccCO– North-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA2445	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	0,6		
Rate unit		L/ha	L/ha		
Appl. Code		AB	AB		
% Disease severity L1 - 26 DA-B					
Number of values	1	1	1	UTC	CA2245
Minimum value	6,56	0,71	0,70		0,8 l/ha
Maximum value	6,56	0,71	0,70	1 >	0 >
Mean disease severity (%)	6,56	0,71	0,70	0 =	1 =
Abbott efficacy (%)	0,00%	89,18%	89,33%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Table 3.2-340b: Summary table - Efficacy evaluation in 1 additional trial (submitted in September 2022)

Treatment name	UNTREATED CHECK	CA2445	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	0,6		
Rate unit		L/ha	L/ha		
Appl. Code		AB	AB		
% Disease severity L2 - 29 DA-B					
Number of values	1	1	1	UTC	CA2245
Minimum value	5,44	0,10	1,33		0,8 l/ha
Maximum value	5,44	0,10	1,33	1 >	0 >
Mean disease severity (%)	5,44	0,10	1,33	0 =	0 =
Abbott efficacy (%)	0,00%	98,16%	75,63%	0 <	1 <
% Disease severity L1 - 29 DA-B					
Number of values	1	1	1	UTC	CA2245
Minimum value	20,75	0,49	6,69		0,8 l/ha
Maximum value	20,75	0,49	6,69	1 >	0 >
Mean disease severity (%)	20,75	0,49	6,69	0 =	0 =
Abbott efficacy (%)	0,00%	97,65%	67,77%	0 <	1 <

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against PUCCCA/PUCCCO in South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 4 trials evaluated the efficacy of CA3301 on oat against *Puccinia coronata*. 3 trials out of 4 were considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 35-39 and the 2nd application was at BBCH 59-65.

Summary results are presented in Table 3.2-341.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the reduction of disease severity on oat against *Puccinia coronata*. On foliar level 2, CA3301 at 0.6 l/ha provided 86.96% efficacy two weeks after the 2nd application and 92.29% over 2 trials before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 85.90% efficacy before harvest.

In the South-Eastern East EPPO zone, a limited dataset was available for assessment of control of *Puccinia coronata*. However, the situation reflected the high efficacy of CA3301 in conditions of relatively low disease pressure. Applied at 0.6 l/ha (150g/ha prothioconazole), the tested product gave always equivalent disease control to the authorised reference product CA2445 (200 g/ha prothioconazole). Therefore, it is envisaged that applications of 0.6 l/ha will be sufficient to provide acceptable control of *Puccinia coronata*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Puccinia coronata* on oat in the South-Eastern East EPPO zone

Table 3.2-341: Summary table - Efficacy evaluation – Oat – PUCCCA/PUCCCO– South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA2445	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	0,6		
Rate unit		L/ha	L/ha		
Appl. Code		AB	AB		
% Disease severity L2 - 14-15 DA-B					
Number of values	2	2	2	UTC	CA2245
Minimum value	6,00	0,00	0,05		0,8 l/ha
Maximum value	11,25	1,85	2,84	2 >	0 >
Mean disease severity (%)	8,63	0,93	1,44	0 =	2 =
Abbott efficacy (%)	0,00%	91,78%	86,96%	0 <	0 <
% Disease severity L2 - 25-26 DA-B					
Number of values	2	2	2	UTC	CA2245
Minimum value	9,17	0,04	0,02		0,8 l/ha
Maximum value	11,90	1,19	1,81	2 >	0 >
Mean disease severity (%)	10,53	0,61	0,92	0 =	2 =
Abbott efficacy (%)	0,00%	94,78%	92,29%	0 <	0 <
% Disease severity L1 - 25 DA-B					
Number of values	1	1	1	UTC	CA2245
Minimum value	6,10	0,46	0,86		0,8 l/ha
Maximum value	6,10	0,46	0,86	1 >	0 >
Mean disease severity (%)	6,10	0,46	0,86	0 =	1 =
Abbott efficacy (%)	0,00%	92,46%	85,90%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against PUCCCA/PUCCCO - Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-Eastern East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, a total of 9 trials from the North-Eastern East EPPO zone and the neighbouring countries Germany and Czech Republic evaluated the efficacy of CA3301 on oat against *Puccinia coronata*. 4 5 trials were considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 30-39 and the 2nd application was at BBCH 52-61.

Summary results are presented in Table 3.2-342.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the reduction of disease severity on oat against *Puccinia coronata*. On foliar level 2, CA3301 at 0.6 l/ha provided 87.75% efficacy before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 100.00% efficacy on reduction of disease severity two weeks after the 2nd application and 92.88% before harvest.

Over this dataset intended to Poland, CA3301 at 0.6 l/ha provided high efficacy in reducing the severity of *Puccinia coronata* on oat on both main foliar levels 1 (L1) and 2 (L2), in conditions of low to medium disease pressure. In these conditions, the tested product gave always comparable disease control to the authorised reference products CA2445 and TORERO. Therefore, it is envisaged that applications of 0.6 l/ha will be sufficient to provide acceptable control of *Puccinia coronata*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Puccinia coronata* on oat in Poland.

Table 3.2-342: Summary table - Efficacy evaluation – Oat – PUCCCA/PUCCCO – Data relevant for Poland

Treatment name	UNTREATED CHECK	CA2445	TORERO	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	1	0,6		
Rate unit		L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB		
% Disease severity L1 - 15 DA-B						
Number of values	1		1	1	UTC	TORERO 1 l/ha
Minimum value	5,56		0,00	0,00	1 >	0 >
Maximum value	5,56	-	0,00	0,00	0 =	1 =
Mean disease severity (%)	5,56		0,00	0,00	0 <	0 <
Abbott efficacy (%)	0,00%		100,00%	100,00%		
% Disease severity L2 - 47 DA-B						
Number of values	1	1		1	UTC	CA2245 0,8 l/ha
Minimum value	40,81	2,13		5,00	1 >	0 >
Maximum value	40,81	2,13	-	5,00	0 =	1 =
Mean disease severity (%)	40,81	2,13		5,00	0 <	0 <
Abbott efficacy (%)	0,00%	94,78%		87,75%		
% Disease severity L1 - 25-47 DA-B						
Number of values	3			3	UTC	
Minimum value	6,56			0,18	2 >	
Maximum value	25,31	-	-	2,31	0 =	
Mean disease severity (%)	14,44			1,06	0 <	
Abbott efficacy (%)	0,00%			92,88%		
Number of values	2	2		2	CA2245 0,8 l/ha	
Minimum value	6,56	0,71		0,70	0 >	
Maximum value	25,31	1,25	-	2,31	1 =	
Mean disease severity (%)	15,94	0,98		1,51	0 <	
Abbott efficacy (%)	0,00%	92,12%		90,10%		

Number of values	1		1	1	TORERO
Minimum value	11,44		0,29	0,18	1 l/ha
Maximum value	11,44	-	0,29	0,18	0 >
Mean disease severity (%)	11,44		0,29	0,18	1 =
Abbott efficacy (%)	0,00%		97,47%	98,43%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Table 3.2-340b: Summary table - Efficacy evaluation in 1 additional trial (submitted in September 2022)

Treatment name	UNTREATED CHECK	CA2445	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	0,6		
Rate unit		L/ha	L/ha		
Appl. Code		AB	AB		
% Disease severity L2 - 29 DA-B					
Number of values	1	1	1	UTC	CA2245
Minimum value	5,44	0,10	1,33		0,8 l/ha
Maximum value	5,44	0,10	1,33	1 >	0 >
Mean disease severity (%)	5,44	0,10	1,33	0 =	0 =
Abbott efficacy (%)	0,00%	98,16%	75,63%	0 <	1 <
% Disease severity L1 - 29 DA-B					
Number of values	1	1	1	UTC	CA2245
Minimum value	20,75	0,49	6,69		0,8 l/ha
Maximum value	20,75	0,49	6,69	1 >	0 >
Mean disease severity (%)	20,75	0,49	6,69	0 =	0 =
Abbott efficacy (%)	0,00%	97,65%	67,77%	0 <	1 <

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

3 valid field trials were carried out in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,6 l/ha achieved high efficacy after 15-47 days after second application. No significant difference between the test and reference product were noted. Due to the limited number of trials, the cMSs are kindly asked to consider this use on the national level.

Only 2 valid trial were conducted in **the North-East EPPO zone**. CA3301 applied at dose rate of 0,6 l/ha presented medium to high level of control. Despite of including results from the neighboring countries (Czech Republic and Germany), the number of submitted trials is still insufficient (5 trials). This use can not be accepted in the NE zone.

3 valid field trials were conducted in **the South-East EPPO zone**. The test product achieved high efficacy after 14-26 DA-B (>85%). Also results from the Mediterranean zone (2 trials) show on very high effectiveness of CA3301 in control of PUCCCA. The results from objectives with test and reference product were comparable. The cMSs are kindly asked to consider this use on the national level.

3.2.3.18 Oat (AVESS/AVESA) / *Blumeria graminis f. sp. avenae* (ERYSGA)

Materials and Methods – Oat - ERYSGA

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2017 and 2020, a total of 6 trials were conducted in several countries of the Maritime and North-East EPPO zones to evaluate the efficacy of CA3301 against *Blumeria graminis f. sp. avenae* on oat (see Table 3.2-343). The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, a total of 4 trials were performed in the Czech Republic (2), and Germany (2).

In the Mediterranean EPPO zone, no trials were performed.

In the North-Eastern EPPO zone, a total of 2 trials were performed in Poland (2).

In the South-Eastern EPPO zone, no trials were performed.

Data groupings were also made specifically for Poland evaluation and trials involved (6) were performed in the North-Eastern EPPO zone (2), in the Czech Republic (2) and in Germany (2).

Table 3.2-343: Presentation of trials – Oat (AVESS/AVESA) - ERYSGA

Crop(s)) *	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mar- itime zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Oat	ERYSGA	Czech Republic	2017- 2018	MED + E	2 (0)	-	-	-	GEP	
		German y	2020	MED + E	2 (1)	-	-	-	GEP	
Oat	ERYSGA	Poland	2020	MED + E	-	-	2 (2)	-	GEP	
TOTAL	-	-	2017- 2020	MED + E	4 (1)	-	2 (2)	-	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-emergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

In all trials, CA3301 was compared to at least one commercial and registered fungicide used as standard reference for comparison.

Table 3.2-344: Efficacy evaluation - Presentation of reference standards used in trials – Oat (AVESS) - ERYSGA

Crop(s))	Refer- ence standard	Coun- try(ies) where the product is used ⁽¹⁾	Authoriza- tion number	Active sub- stance(s)	Formulation		Regis- tered ap- plication rate ⁽³⁾	Applica- tion rate in tri- als (per treat- ment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concentra- tion of a.s.			
Oat	PRO- LINE	DE	025287-00	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

Crop(s))	Refer- ence standard	Coun- try(ies) where the product is used ⁽¹⁾	Authoriza- tion number	Active sub- stance(s)	Formulation		Regis- tered ap- plication rate ⁽³⁾	Applica- tion rate in tri- als (per treat- ment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concentra- tion of a.s.			
Oat	PRAK- TIS	PL	R-222/2019	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.6-0.8 l/ha	CA2445 in some

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
									trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-345.

Table 3.2-345: Details on trial methodology – Oat (AVESS/AVESA) - ERYSGA

		Maritime EPPO zone	North-Eastern EPPO zone	Data relevant for Poland
Trials	Total number (valid number)	4 (1)	2 (2)	6 (3)
	Supportive trials	-	-	
Guidelines	General guidelines	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)
	Specific guidelines	PP 1/26(4)	PP 1/26(4)	PP 1/26(4)
Experimental design	Plot design	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included
	Plot size	21-30 m ²	21 m ²	21-30 m ²
	Number of replications	4	4	4
Crop	Trials per crop	Oat (4)	Oat (2)	Oat (6)
	Varieties per crop	Spartan (1), Prokop (2), Kamil (1)	Kozak (2)	Kozak (2), Spartan (1), Prokop (2), Kamil (1)
	Sowing period	March (2), April (2)	March (1), April (1)	March (3), April (3)
Application	Crop stage (BBCH)* at application	A: BBCH 32-37 B: BBCH 55-61	A: BBCH 32 B: BBCH 57-58	A: BBCH 32-37 B: BBCH 55-61
	Timing Disease stage at application	BBCH 30-61 A: PRINFC (2), MIXED (1), NA (1) B: PRINFC (2), MIXED (1), NA (1)	BBCH 30-61 A: PRINFC (2) B: MIXED (2)	BBCH 30-61 A: PRINFC (4), MIXED (1), NA (1) B: PRINFC (2), MIXED (3), NA (1)
	Number of applications Intervals between applications	1 application (1) 2 applications (14-27 days) (4)	2 applications (14-16 days) (2)	1 application (1) 2 applications (14-27 days) (6)
	Spray volumes	100-200 l/ha	200-300 l/ha	100-300 l/ha
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%),	Disease severity (%), Disease incidence (%), Green leaf area (%),	Disease severity (%), Disease incidence (%), Green leaf area (%),

		Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)
	Assessment dates	0 DA-A; 14-15 DA-A 0 DA-B; 14-15 DA-B; 23-31 DA-B	0 DA-A -1-0 DA-B; 14-15 DA-B; 33-35 DA-B;	0 DA-A; 14-15 DA-A -1-0 DA-B; 14-15 DA-B; 23- 35 DA-B
Other rele- vant infor- mation	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial innoculation...	Natural (4)	Natural (3)	Natural (6)
	e.g. Field / Greenhouse...	Field trials	Field trials	Field trials

Out of the 6 trials performed on oat against *Blumeria graminis f. sp. avenae*, 3 were considered valid.

Considering that a single valid trial was available on this disease in the Maritime EPPO zone and two valid trials were available in the North-Eastern East EPPO zone, the argumentation on efficacy of CA3301 for the control of *Blumeria graminis* on oat was based also on data presented on winter wheat in the same EPPO zones and for the same disease.

This argumentation is possible since *Avena sp.* or *Avena sativa* and *Triticum aestivum* have the same life cycle with the same exposure to *Blumeria graminis* infection.

Triticum aestivum and *Avena sp.* or *Avena sativa* belong to the same Order (Poales) and the same Family (Poaceae), are two crops with the same life cycle and are cultivated following the same agricultural practice. At the end the two crops are showing a very similar sensitivity to *Blumeria graminis f. sp. avenae* (ERYSGA) or *Blumeria graminis f. sp. tritici* (ERYSGT) infection.

For these reasons, due the lack of valid trials, it is possible to refer to the data presented on winter wheat for the evaluation of the minimum effective dose in each EPPO zone.

Use of CA3301 at 2x 0.6 l/ha against ERYSGA - Maritime EPPO zone

In the Maritime EPPO zone, a total of 4 trials evaluated the efficacy of CA3301 on oat against *Blumeria graminis f. sp. avenae*. 1 trial out of 4 was considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference product on disease severity (%). CA3301 was first applied at crop stages BBCH 32-37 and the 2nd application was at BBCH 55-61.

Summary results are presented in Table 3.2-346.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the reduction of disease severity on oat against *Blumeria graminis f. sp. avenae*. On foliar level 2, CA3301 at 0.6 l/ha provided 76.82% efficacy before harvest.

In the Maritime EPPO zone, a limited dataset was available for assessment of control of *Blumeria graminis f. sp. avenae*. However, the situation reflected the medium efficacy of the tested product in conditions of low disease pressure. In this condition, CA3301 at 0.6 l/ha (150 g/ha prothioconazole) gave comparable disease control than the authorised reference product CA2445 containing also prothioconazole (and applied at 200 g/ha). Therefore, it is envisaged that applications of 0.6 l/ha will be sufficient to provide acceptable control of *Blumeria graminis f. sp. avenae*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Blumeria graminis f. sp. avenae* on oat in the Maritime EPPO zone.

Table 3.2-346: Summary table - Efficacy evaluation – Oat – ERYSGA - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA2445	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	0,6		
Rate unit		L/ha	L/ha		
Appl. Code		AB	AB		
% Disease severity L2- 47 DA-B					
Number of values	1	1	1	UTC	CA2245
Minimum value	9,19	0,13	2,13		0,8 l/ha
Maximum value	9,19	0,13	2,13	1 >	0 >
Mean disease severity (%)	9,19	0,13	2,13	0 =	1 =
Abbott efficacy (%)	0,00%	98,59%	76,82%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against ERYSGA - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 2 trials evaluated the efficacy of CA3301 on oat against *Blumeria graminis f. sp. avenae*. All 2 trials were considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 32 and the 2nd application was at BBCH 57-58.

Summary results are presented in Table 3.2-347.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the reduction of disease severity on oat against *Blumeria graminis f. sp. avenae*. On foliar level 2, CA3301 at 0.6 l/ha provided 100.00% efficacy two weeks after the 2nd application and 93.64% before harvest.

In the North-Eastern East EPPO zone, a limited dataset was available for assessment of control of *Blumeria graminis f. sp. avenae*. However, the situation reflected the high efficacy of the tested product in conditions of low disease pressure. In these conditions, CA3301 at 0.6 l/ha (150 g/ha prothioconazole) gave always comparable disease control to the authorised reference product CA2445 containing also prothioconazole (and applied at 200 g/ha). Therefore, it is envisaged that applications of 0.6 l/ha will be sufficient to provide acceptable control of *Blumeria graminis f. sp. avenae*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Blumeria graminis f. sp. avenae* on oat in the North-Eastern East EPPO zone.

Table 3.2-347: Summary table - Efficacy evaluation – Oat – ERYSGA – North-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA2445	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	0,6		
Rate unit		L/ha	L/ha		
Appl. Code		AB	AB		
% Disease severity L2- 14 DA-B					
Number of values	1	1	1	UTC	CA2245
Minimum value	7,44	0,00	0,00		0,8 l/ha
Maximum value	7,44	0,00	0,00	1 >	0 >
Mean disease severity (%)	7,44	0,00	0,00	0 =	1 =
Abbott efficacy (%)	0,00%	100,00%	100,00%	0 <	0 <
% Disease severity L2- 33-35 DA-B					
Number of values	2	2	2	UTC	CA2245
Minimum value	6,60	0,00	0,00		0,8 l/ha

Maximum value	11,94	0,63	0,84	2 >	0 >
Mean disease severity (%)	9,27	0,31	0,42	0 =	2 =
Abbott efficacy (%)	0,00%	95,23%	93,64%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 l/ha against ERYSGA – Other EPPO zones

Conclusion – all EPPO zones

Considering that no data were available to support the evaluation of CA3301 in the Mediterranean and South-Eastern East EPPO zones, the argue regarding the minimum effective dose of CA3301 for the control of *Blumeria graminis* on oat was based on the extrapolation of the data presented on winter wheat for the same disease.

This argumentation is possible since *Avena sp.* or *Avena sativa* and *Triticum aestivum* have the same life cycle with the same exposure to *Blumeria graminis* infection.

Triticum aestivum and *Avena sp.* or *Avena sativa* belong to the same Order (Poales) and the same Family (Poaceae), are two crops with the same life cycle and are cultivated following the same agricultural practice. At the end the two crops are showing a very similar sensitivity to *Blumeria graminis f. sp. avenae* (ERYSGA) or *Blumeria graminis f. sp. tritici* (ERYSGT) infection.

Over the dataset available on winter wheat, the tested product demonstrated comparable efficacy from CA3301 dose rates on the related pathogen *Blumeria graminis* for which the higher rate of 0.8 l/ha is more appropriate in situations of high disease pressure, but in case of low disease pressure the 0.6 l/ha rate might be sufficient to obtain a suitable level of disease control.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Blumeria graminis f. sp. avenae* on oat in all EPPO zones.

Use of CA3301 at 2x 0.6 l/ha against ERYSGA - Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-Eastern East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, a total of 6 trials from the North-Eastern East EPPO zone and the neighbouring countries Czech Republic and Germany evaluated the efficacy of CA3301 on oat against *Blumeria graminis f. sp. avenae*. 3 trials out of 6 were considered valid and enabled to determine the efficacy of CA3301 at 0.6 l/ha applied twice, and to compare it to the reference product on disease severity (%). CA3301 was first applied at crop stages BBCH 32-37 and the 2nd application was at BBCH 55-61.

Summary results are presented in Table 3.2-348.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the reduction of disease severity on oat against *Blumeria graminis f. sp. avenae*. On foliar level 2, CA3301 at 0.6 l/ha provided 100.00% efficacy two weeks after the 2nd application and 88.03% before harvest.

In this data grouping intended to Poland evaluation, the dataset was limited but reflected the high efficacy of CA3301 in conditions of low disease pressure. In these conditions, CA3301 at 0.6 l/ha (150 g/ha prothioconazole) gave always equivalent disease control to the authorised reference product CA2445 containing also prothioconazole (and applied at 200 g/ha). Therefore, it is envisaged that applications of 0.6 l/ha will be sufficient to provide acceptable control of *Blumeria graminis f. sp. avenae*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Blumeria graminis f. sp. avenae* on oat in Poland.

Table 3.2-348: Summary table - Efficacy evaluation – Oat – ERYSGA – Data relevant for Poland

Treatment name	UNTREATED CHECK	CA2445	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	0,6		
Rate unit		L/ha	L/ha		
Appl. Code		AB	AB		
% Disease severity L2- 14 DA-B					
Number of values	1	1	1	UTC	CA2245
Minimum value	7,44	0,00	0,00		0,8 l/ha
Maximum value	7,44	0,00	0,00	1 >	0 >
Mean disease severity (%)	7,44	0,00	0,00	0 =	1 =
Abbott efficacy (%)	0,00%	100,00%	100,00%	0 <	0 <
% Disease severity L2- 33-47 DA-B					
Number of values	3	3	3	UTC	CA2245
Minimum value	6,60	0,00	0,00		0,8 l/ha
Maximum value	11,94	0,63	2,13	3 >	0 >
Mean disease severity (%)	9,24	0,25	0,99	0 =	3 =
Abbott efficacy (%)	0,00%	96,35%	88,03%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

Only 1 valid field trials was carried out in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate rate of 0,6 l/ha achieved medium level of control after 47 DA-B. Due to the limited number of trials, the cMSs are kindly asked to consider this use on the national level.

2 valid field trials were conducted in **the North-East EPPO zone**. Very high effectiveness were observed after second application, either 14 and 33-35 DA-B. Despite of including trials from the neighboring countries, the number of trials is still insufficient (3 trials). This use can not be accepted.

No efficacy trials have been submitted in the South-East and Mediterranean EPPO zones. The cMSs are kindly asked to consider this use on the national level.

3.2.3.19 Oat (AVESS/AVESA) / *Oculimacula acuformis* (PSDCHA)

(Ramanauskiene *et al.*, Effects of fungicides on the occurrence of winter wheat eyespot caused by fungi *Oculimacula acuformis* and *O. yal-lundae*, *Crop protection*, 2016)

No data were available for assessment of control of eyespot of cereals *Oculimacula acuformis* on any crop. Although early symptoms can be confused with *Fusarium spp.*, the diseases are not related and therefore it is impossible to extrapolate from these data.

However, Ramanauskiene *et al.*, showed that 2, 3 and 4 years of prothioconazole treatments allowed to reduce the population of *O. acuformis* assessed from 2009 to 2011 on winter wheat. This positive effect was observed as early as 10 days after treatment. This pathogen infecting both winter wheat and oat, it is therefore possible to transpose these results to oat.

Moreover, prothioconazole is one of the active substances the most used as fungicide in commercial practices (*Forecasting eyespot development and yield losses in winter wheat, HGCA, 2012*). Standard reference products containing prothioconazole, such as Proline 275 and Proline are registered to control eyespot on cereals, at the same application rates as for the other authorised pathogens, which indicates that prothioconazole controls eyespot at dose rates which are demonstrated to control the other major disease pathogens in cereals. Since data shows equivalence of efficacy between CA3301 at the proposed

dose rate and the authorised products Proline 275 and Proline in other pathogens, it is considered that CA3301 will also provide acceptable control of eyespot at the proposed dose rate.

Since on cereals a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the 0.6 l/ha dose rate gave in overall equivalent disease control compared to the authorized reference products containing prothioconazole, we assume that CA3301 at 0.6 l/ha will give acceptable control of eyespot on oat.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6 l/ha to control *Oculimacula acufomis* on oat in all EPPO zones.

Comments of zRMS:

No efficacy trials have been submitted from any EPPO climatic zones. The cMSs from the Maritime and South-Eats EPPO zones are kindly asked to consider this use on the national level. This use can not be accepted in the North-East zone because extrapolation is not possible.

3.2.3.20 Oat (AVESS/AVESA) / Green leaf area

Use of CA3301 at 2x 0.6 l/ha in Maritime EPPO zone

Green leaf area was recorded at 15-47 DA-B in 5 valid trials on oat affected by a range of pathogens after treatment with CA3301 at 0.6 l/ha applied twice. In all 5 trials, green leaf area was assessed on the whole plant.

Summary results are presented in Table 3.2-349.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the increase of green leaf area on oat infected by foliar diseases. In the 5 trials assessing green leaf area on the whole plant, an increase of 154.36% was recorded compared to the untreated check on oat.

In a majority of trials CA3301 was overall equivalent to the reference products TORERO at 1 l/ha and CA2445 at 0.8 l/ha except in 1 trial.

Therefore, it is concluded that 2 applications of CA3301 at 0.6 l/ha will have a positive effect on the green leaf area in oat affected by a range of pathogens in the Maritime EPPO zone.

Table 3.2-349: Summary table – Efficacy evaluation – Oat – Green leaf area - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA2445 0,8 L/ha AB	TORERO 1 L/ha AB	CA3301 0,6 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Green leaf area Plant - 15-47 DA-B					
Number of values	5			5	UTC
Minimum value	1,50			4,00	
Maximum value	50,00	-	-	57,50	5 >
Mean green leaf area (%)	19,75			30,65	0 =
%UTC	100,00%			254,36%	0 <
Number of values	3	3		3	CA2245
Minimum value	5,00	25,00		21,25	0,8 l/ha
Maximum value	50,00	64,00	-	57,50	0 >
Mean green leaf area (%)	30,83	49,67		44,75	2 =
%UTC	100,00%	262,67%		229,78%	1 <
Number of values	2		2	2	TORERO
Minimum value	1,50		4,50	4,00	1 l/ha

Maximum value	4,75	-	12,50	15,00	0 >
Mean green leaf area (%)	3,13		8,50	9,50	2 =
%UTC	100,00%		281,58%	291,23%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 at 2x 0.6 l/ha in Mediterranean EPPO zone

Green leaf area was recorded at 25-36 DA-B in 8 valid trials on oat affected by a range of pathogens after treatment with CA3301 at 0.6 l/ha applied twice. In all 8 trials, green leaf area was assessed on the entire plant.

Summary results are presented in Table 3.2-350.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the increase of green leaf area on oat affected by foliar diseases. In the 8 trials assessing green leaf area on the whole plant, an increase of 62.04% was recorded compared to the untreated check on oat. In a majority of the trials CA3301 at 0.6 l/ha was overall equivalent to the reference products CA2445 at 0.8 l/ha, PROSARO at 1 l/ha, MYSTIC SUL at 1 l/ha, ORIUS P at 1.2 l/ha and RIKALI at 1 l/ha except in a couple of trials where CA3301 at 0.6 l/ha was either more efficient or less efficient.

Therefore, it is concluded that 2 applications of CA3301 at 0.6 l/ha will have a positive effect on the green leaf area in oat affected by a range of pathogens in the Mediterranean EPPO zone.

Table 3.2-350: Summary table – Efficacy evaluation – Oat – Green leaf area - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA2445	PROSARO	MYSTIC SUL	ORIOUS P	RIKALI	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	1	1	1,2	1	0,6	
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	AB	AB	AB	
Green leaf area Plant - 25-36 DA-B								
Number of values	8						8	UTC
Minimum value	8,00						9,13	
Maximum value	80,00	-	-	-	-	-	80,00	3 >
Mean green leaf area (%)	38,47						49,89	5 =
%UTC*	100,00%						162,04%	0 <
Number of values	5	5					5	CA2245
Minimum value	8,00	9,38					9,13	0,8 l/ha
Maximum value	80,00	80,00	-	-	-	-	80,00	0 >
Mean green leaf area (%)	27,05	42,38					42,83	5 =
%UTC	100,00%	190,49%					195,10%	0 <
Number of values	3		3				3	PROSARO
Minimum value	25,00		30,00				35,00	1 l/ha
Maximum value	77,50	-	80,00	-	-	-	77,50	0 >
Mean green leaf area (%)	45,83		60,00				60,83	3 =
%UTC	100,00%		156,31%				160,00%	0 <
Number of values	1	1		1			1	MYSTIC SUL
Minimum value	12,50	40,00		28,75			41,25	1 l/ha
Maximum value	12,50	40,00	-	28,75	-	-	41,25	1 >
Mean green leaf area (%)	12,50	40,00		28,75			41,25	0 =
%UTC	100,00%	320,00%		230,00%			330,00%	0 <
Number of values	1	1			1		1	ORIOUS P
Minimum value	80,00	80,00			80,00		80,00	1 l/ha
Maximum value	80,00	80,00	-	-	80,00	-	80,00	0 >
Mean green leaf area (%)	80,00	80,00			80,00		80,00	1 =
%UTC	100,00%	100,00%			100,00%		100,00%	0 <
Number of values	1					1	1	RIKALI
Minimum value	60,00					80,00	72,50	1 l/ha
Maximum value	60,00	-	-	-	-	80,00	72,50	0 >
Mean green leaf area (%)	60,00					80,00	72,50	0 =
%UTC	100,00%					133,33%	120,83%	1 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 at 2x 0.6 l/ha in North-Eastern East EPPO zone

Green leaf area was recorded at 21-54 DA-B in 7 valid trials on oat affected by a range of pathogens after treatment with CA3301 at 0.6 l/ha applied twice. In all 7 trials, green leaf area was assessed on the whole plant.

Summary results are presented in Table 3.2-351.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the increase of green leaf area on oat affected by foliar diseases. In the 7 trials assessing green leaf area on the whole plant, an increase of 39.62% was recorded compared to the untreated check on oat.

In a majority of the trials CA3301 at 0.6 l/ha was overall equivalent to the reference products CA2445 at 0.8 l/ha and PROSARO at 1 l/ha except in 1 trial where CA3301 at 0.6 l/ha was less efficient than CA2445.

Therefore, it is concluded that 2 applications of CA3301 at 0.6 l/ha will have a positive effect on the green leaf area in oat affected by a range of pathogens in the North-Eastern East EPPO zone.

Table 3.2-351: Summary table – Efficacy evaluation – Oat – Green leaf area – North-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA2445	PROSARO	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	1	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
Green leaf area Plant - 21-54 DA-B					
Number of values	7			7	UTC
Minimum value	7,50			11,25	
Maximum value	86,25	-	-	87,50	2 >
Mean green leaf area (%)	32,68			42,86	5 =
%UTC	100,00%			139,62%	0 <
Number of values	6	6		6	CA2245
Minimum value	7,50	15,00		11,25	0,8 l/ha
Maximum value	86,25	95,00	-	87,50	0 >
Mean green leaf area (%)	34,17	48,96		45,83	5 =
%UTC	100,00%	159,54%		145,34%	1 <
Number of values	2		2	2	PROSARO
Minimum value	23,75		23,00	25,00	1 l/ha
Maximum value	31,25	-	31,25	40,00	0 >
Mean green leaf area (%)	27,50		27,13	32,50	2 =
%UTC	100,00%		98,42%	116,63%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 at 2x 0.6 l/ha in South-Eastern East EPPO zone

Green leaf area was recorded at 14-30 DA-B in 5 valid trials on oat affected by a range of pathogens after treatment with CA3301 at 0.6 l/ha applied twice. In 4 trials, green leaf area was assessed on the whole plant while in 1 trial it was assessed by foliar levels. For this trial, green leaf area will be presented separately and on foliar levels 2 to 1.

Summary results are presented in Table 3.2-352.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6 l/ha for the increase of green leaf area on oat infected by foliar and ears diseases. In the 4 trials assessing green leaf area on the whole plant, an increase of 199.77% was recorded compared to the untreated check on oat. In the trial assessing green leaf area by foliar level, and an increase of 12.07% on foliar level 2 and 3.81% on foliar level 1 were observed.

In overall, CA3301 at 0.6 l/ha (150 g/ha of prothioconazole) was equivalent to the reference product CA2445 containing prothioconazole and applied at the higher dose rate of 0.8 l/ha (200 g/ha of prothioconazole).

Therefore, it is concluded that 2 applications of CA3301 at 0.6 l/ha may have a positive effect on the green leaf area in oat affected by a range of pathogens in the South-Eastern East EPPO zone.

Table 3.2-352: Summary table – Efficacy evaluation – Oat – Green leaf area – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA2445	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	0,6		
Rate unit		L/ha	L/ha		
Appl. Code		AB	AB		
Green leaf area Plant - 14-30 DA-B					
Number of values	4	4	4	UTC	CA2245
Minimum value	8,75	48,75	38,75		0,8 l/ha
Maximum value	77,50	88,75	87,50	4 >	0 >
Mean green leaf area (%)	37,19	70,00	62,50	0 =	2 =
% UTC	100,00%	349,23%	299,77%	0 <	2 <
Green leaf area L2 - 26 DA-B					
Number of values	1	1	1	UTC	CA2245
Minimum value	58,00	59,25	65,00		0,8 l/ha
Maximum value	58,00	59,25	65,00	1 >	0 >
Mean green leaf area (%)	58,00	59,25	65,00	0 =	1 =
% UTC	100,00%	102,16%	112,07%	0 <	0 <
Green leaf area L1 - 26 DA-B					
Number of values	1	1	1	UTC	CA2245
Minimum value	52,50	43,00	54,50		0,8 l/ha
Maximum value	52,50	43,00	54,50	1 >	0 >
Mean green leaf area (%)	52,50	43,00	54,50	0 =	1 =
% UTC	100,00%	81,90%	103,81%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Comments of zRMS:

5 valid trials were carried out in the **Maritime EPPO climatic zone**. CA3301 presented positive effect in assessment of green leaf area. The test product applied at dose rate 0,6 l/ha achieved a mean augmentation of green leaf area of 154,36% in trials where whole plants were observed. No significant differences between test and reference product were detected.

7 valid trials were carried out in the **North-East EPPO zone**. The whole plants were observed to evaluation of green leaf area in all submitted trials. An augmentation of green leaf area amounted 39,62% at dose rate of 0,6 l/ha after 21-54 DA-B. The results from the test and reference product were comparable.

5 valid trials were conducted in the **South-East EPPO zone**. The majorities trials show results from whole plants. CA3301 achieved a very positive effect in compared to untreated objectives and standards. An augmentation of green leaf area amounted nearly 200% in case of whole plants. In 1 trial an augmentation was above 12% on foliar L2 and 3% on foliar L1 after 27 days after second application. Furthermore, an augmentation of nearly 100% was noted in 8 trials conducted in the Mediterranean zone. No significant differences between test and reference product were observed.

3.2.3.21 Oat (AVESS/AVESA) / Conclusion

On oat, 2 foliar diseases were assessed in 28 valid trials across 4 EPPO zones. Winter and spring oat were analysed together despite different climatic conditions due to the availability of a low dataset. Moreover, when observed separately the data demonstrated the same trend allowing to draw the same conclusions. Disease severity was assessed and analysed on the main foliar levels 1 and 2. Depending on the EPPO zone, the disease, the assessment timing and the crop part assessed, the dataset available

was sometimes limited with results not necessarily representative of the true efficacy of CA3301. Therefore, to get an overview of the efficacy of CA3301 at 0.6 l/ha, summary tables are presented hereunder, on foliar levels 1&2 (see Table 3.2-353 and Table 3.2-354).

In overall, across the 4 EPPO zones and all diseases the efficacy of CA3301 at 0.6 l/ha was high. Nevertheless, since in the fields a complex of disease is often observed instead of a single disease, it is of interest to look at the efficacy of CA3301 across the diseases and to not focus on a single one. It has been shown in the previous sections that the efficacy of CA3301 at 0.6 l/ha was overall equivalent to the one provided by the authorised reference products used in the trials, a trend of decreasing disease severity with increasing dose rate was observed with CA3301 at 0.6 l/ha providing a higher disease control than the lower rate of 0.48 l/ha although it was not always significant. The rate of 0.6 l/ha (100% dose rate) was in most instances statistically equivalent to the 0.8 l/ha rate (133% dose rate). Moreover, in circumstances of high disease pressure the rate of 0.6 l/ha showed sufficient efficacy to maintain crop quality. Finally, due to the importance of the diseases and given the possibility of resistance in some of the pathogens assessed, the 100% dose rate of 0.6 l/ha, demonstrated to provide equivalent control to authorised reference standards, is considered the most appropriate dose rate.

In the efficacy dataset presented for oats CA3301 was always compared with similar prothioconazole products which are already authorised for use against the target pathogens in oats in each EPPO climatic zone. The dataset demonstrates that CA3301 gives comparable disease control to these authorised products in each EPPO climatic zone. Therefore, and since prothioconazole is well-established as an effective fungicide against the target pathogens, it is considered justified to request authorisation as proposed in the GAP even where data is low.

In this dossier efficacy data presented is primarily from assessments where 2 applications of the test product were made. However, according to disease development conditions, a single application may provide sufficient disease control, therefore users should not be restricted to always applying twice, hence in the GAP the proposed use is for 1-2 applications. In addition, crop pathogens are commonly controlled using a programme of different fungicides with varied modes of action, therefore the choice should be available to growers to make a single application of CA3301, followed by application of a different appropriate fungicide. Prothioconazole is well established over a number of years in providing good broad spectrum efficacy across a range of common crop pathogens, with either 1 or more applications appropriate according to disease development conditions, risk of resistance development and local conditions. Current authorisations for similar products containing prothioconazole including Proline 275, and Proline/Praktis/Joao (CA2445) are for 1-2 applications at comparative rates of prothioconazole to the requested use for CA3301. Considering these elements, and that data shows comparability of CA3301 to these authorised products, registration of CA3301 at the proposed dose rate and with a number of applications of 1- 2, is requested.

Considering all elements presented in the previous sections of each disease, it is justified to claim the registration of 1-2 applications of CA3301 at 0.6 l/ha to control a range of foliar diseases on oat.

Table 3.2-353: Summary table – Oat – All foliar diseases (L2)

Foliar level 2			MAR	MED	NE	SE	NE + DE CZ SK
Disease	Application timing		CA3301 0,6 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,6 L/ha AB
PUCCCA PUCCCO	2 weeks after B	Number of values	0	2	0	2	0
		Abbott efficacy (%)	-	100,00	-	86,96	-
	Before harvest	Number of values	1	2	0	2	1
		Abbott efficacy (%)	87,75	96,52	-	92,29	87,75
ERYSGA	2 weeks after B	Number of values	0	0	1	0	1
		Abbott efficacy (%)	-	-	100,00	-	100,00

	Before harvest	Number of values Abbott efficacy (%)	1 76,82	0 -	2 93,64	0 -	3 88,03
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Table 3.2-354: Summary table – Oat – All foliar diseases (L1)

Foliar level 1			MAR	MED	NE	SE	NE + DE CZ SK
Disease	Application timing		CA3301 0,6 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,6 L/ha AB
PUCCCA PUCCCO	2 weeks after B	Number of values	1	2	0	0	1
		Abbott efficacy (%)	100,00	100,00	-	-	100,00
	Before harvest	Number of values	1	2	1	1	3
		Abbott efficacy (%)	94,65	100,00	89,33	85,90	92,88
ERYSGA	2 weeks after B	Number of values	0	0	0	0	0
		Abbott efficacy (%)	-	-	-	-	-
	Before harvest	Number of values	0	0	0	0	0
		Abbott efficacy (%)	-	-	-	-	-

Comments of zRMS:

All efficacy trials were conducted on spring oat and no evaluation of efficacy after single application have been provided by the applicant. The cMSs are kindly asked to consider use CA3301 to protection of winter oat and single application on the national level.

3.2.3.22 Winter wheat (TRZAW) / *Zymoseptoria tritici* (SEPTTR)

Materials and Methods – Winter wheat - SEPTTR

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2017 and 2020, a series of 112 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the efficacy of CA3301 against *Zymoseptoria tritici* on winter wheat (see Table 3.2-355). The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, a total of 37 trials were performed in the Czech Republic (3), Denmark (3), France (8), Germany (10) and the United Kingdom (13)

In the Mediterranean EPPO zone, a total of 23 trials were performed in France (11), Greece (2), Italy (3), Portugal (4) and Spain (3)

In the North-Eastern East EPPO zone, a total of 29 trials were performed in Latvia (5), Lithuania (3) and Poland (21)

In the South-Eastern East EPPO zone, a total of 23 trials were performed in Bulgaria (1), Hungary (15), Romania (7)

Table 3.2-355: Presentation of trials – Winter wheat (TRZAW)

Crop(s) *)	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Winter	SEPTTR	Czech	2017-	MED	3 (0)	-	-	-	GEP	

Crop(s)) *	Tar- get(s)*	Country	Year s	Type of trial*	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
wheat		Republic	2018	+ E						
		Denmark	2018	MED + E	3 (0)	-	-	-	GEP	
		France (N)	2019- 2020	MED + E	8 (6)	-	-	-	GEP	
		Germany	2019- 2012 0	MED + E	10 (6)	-	-	-	GEP	
		United Kingdom	2019- 2020	MED + E	13 (10)	-	-	-	GEP	
Winter wheat	SEPTTR	France (S)	2018- 2020	MED + E	-	11 (9)	-	-	GEP	
		Greece	2019	MED + E	-	2 (2)	-	-	GEP	
		Italy	2020	MED + E	-	3 (3)	-	-	GEP	
		Portugal	2018- 2020	MED + E	-	4 (4)	-	-	GEP	
		Spain	2019- 2020	MED + E	-	3 (2)	-	-	GEP	
Winter wheat	SEPTTR	Latvia	2019- 2020	MED + E	-	-	5 (3)	-	GEP	
		Lithuani a	2019- 2020	MED + E	-	-	3 (1)	-	GEP	
		Poland	2017- 2020	MED + E	-	-	21 (18)	-	GEP	
Winter wheat	SEPTTR	Bulgaria	2018	MED + E	-	-	-	1 (1)	GEP	
		Hungary	2018- 2020	MED + E	-	-	-	15 (13)	GEP	
		Romania	2019- 2020	MED + E	-	-	-	7 (4)	GEP	
TOTA L	-	-	2017 - 2020	MED + E	37 (22)	23 (20)	29 (22)	23 (18)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

In all trials, CA3301 was compared to at least one commercial and registered fungicide used as standard reference for comparison.

Table 3.2-356: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – SEPTTR – Maritime EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter wheat	JOAO	FR (N)	2060116	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE 275	UK	14790	Prothioconazole	EC	275 g/l	2 x 0.72 l/ha	2 x 0.72 l/ha	
	CA2445	UK	12084	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE	DE	025287-00	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE 250 EC	CZ	4523-1	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha 3 x 0.6-0.8 l/ha	CA2445 in some trials
	PRO-LINE 250 EC	DK	18-473	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

Table 3.2-357: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – SEPTTR – Mediterranean EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter wheat	JOAO	FR (S)	2060116	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials
	PRO-LINE	GR	60838	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials
	PRO-LINE	IT	013385	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials
	PRAK-TIS	PT	AV 1485	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials
	PRO-SARO	PT	AV 427	Prothioconazole + Tebuconazole	EC	125 g/l + 125 g/l	1 l/ha	1 l/ha	
	PRAK-TIS	ES	01135	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials
	PRO-SARO	ES	25661	Prothioconazole +	EC	125 g/l + 125 g/l		1 l/ha	

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
				Tebuconazole					

Table 3.2-358: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – SEPTTR – North-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter wheat	PRAKTIS	PL	R-222/2019	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha 3 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE	LV	0637	Prothioconazole	EC	250 g/l		2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE	LT	0637(LV)	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	OSIRIS 65 EC	PL	R-87/2012	Epoxiconazole + metconazole	EC	65 g/l	1 x 1.5-2.5 l/ha	2 x 2 l/ha	

Table 3.2-359: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – SEPTTR – South-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter wheat	PRO-LINE	HU	6300/1205-1/2020	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRI-AXOR	HU	04.2/4127-1/2016	Fluxapyroxad Pyraclostrobin	EC	225 g/l	2 x 1.5 l/ha	2 x 1.5 l/ha	
	PRO-LINE	RO	457PC/15.11.2018	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRAKTIS	BG	01860	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-360.

Table 3.2-360: Details on trial methodology – Winter wheat (TRZAW) - SEPTTR

		Maritime EPPO zone	Mediterranean EPPO zone	North-Eastern EPPO zone	South-Eastern EPPO zone
Trials	Total number (valid number)	37 (23)	23 (19)	29 (22)	23 (18)
	Supportive trials	-	-	-	-
Guidelines	General guidelines	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3) PP 1/225 (2) PP 1/262 (1)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)
	Specific guidelines	PP 1/26(4) PP 1/28 (3)	PP 1/26(4)	PP 1/26(4)	PP 1/26(4)
Experimental design	Plot design	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included
	Plot size	15-32 m ²	12-30 m ²	11.25-30 m ²	19.5-30 m ²
	Number of replications	4	4	4	4
Crop	Trials per crop	Winter wheat (37)	Winter wheat (23)	Winter wheat (29)	Winter wheat (23)
	Varieties per crop	Seladon (1), Dagmar (1) Pannomia (1), KWS Lilli (1), Benchmark (1), KWS Decanto (1), ES Cesario (1), Ritmo (1), KWS Santiago (1), Apache (2), Chevron (1), Siskin (1), Faustus (1), Boregar (1), Expert (1), Belepi (2), Skycraper (1), Skyfall (4), Rubisko (1), Oregrain (2), Monopol (2), SU Tobak (1), Tobak (1), Revelation (1), Sy Moisson (1), RGT Gravity (1), Gravity (1) Elation (1), RGT Reform (1), Barranco (1)	Rebelde (1), Local Landrace (1), Nogal (2), Chambo (1), Pistolerito (1), Dodoni (1), Vergina (1), Bologna (3), Soissons (1), Calumet (1), Apache (2), Calabro (1), Complice (1), Tocayo (1), Cellule (1), Oregrain (1), Taylor (1), Anvergur (1), Marco Polo (1)	Arkadia (3), Tobak (1), Delawar (1), Banderola (2), Ozon (5), Edvins (1), Emil (2), Skagen (2), Skagen (2), Talsis (1), Wilejka (1), Etna (1), Etana (1), Kilimandzaro (1), Hondia (1), Medalistka (1), Patras (1), Julius (1), Jantarka (1)	Anapuma (1), GK Békés (1), Akteur (1), Emilio (1), Rebell (1), Glosa (2), Miranda (2), MV Kolo (1), GK Csillag (1), MV Nador (1), GK Körös (1), Altigo (1), Alex (1), Joker (1), Astaro (1), Farneur (1), MV Ikva (1), Complice (1), Bernstein (1), PG102 (1), Rubisko (1)
	Sowing period	September (6), October (23), November (2), December (2), January (1), N/A (3)	October (6), November (10), December (6), January (1)	September (16), October (13)	September (4), October (18), N/A (1)
Application	Crop stage (BBCH)* at application	A: BBCH 31-41 B: BBCH 37-69	A: BBCH 30-51 B: BBCH 39-69	A: BBCH 30-39 B: BBCH 37-65	A: BBCH 31-47 B: BBCH 39-65
	Timing Disease stage at application	BBCH 30-69 A: MIXED (13), PRINFC (9), SPORUL (2), ACTIVE (4), N/A (9)	BBCH 30-69 A: MIXED (8), PRINFC (9), SPORUL (5), ACTIVE (1) B: MIXED (14),	BBCH 30-69 A: MIXED (3), PRINFC (12), SPORUL (1), ACTIVE (1), N/A (12)	BBCH 30-69 A: MIXED (4), PRINFC (19), SPORUL (0) B: MIXED (9), PRINFC (12),

		B: MIXED (18), PRINFC (3), SPORUL (1), ACTIVE (6), N/A (9)	PRINFC (5), SPORUL (2), ACTIVE (2)	B: MIXED (10), PRINFC (7), SPORUL (1), ACTIVE (1), N/A (10)	SPORUL (2)
	Number of applications Intervals between applications	1 application (1) 2 applications (15-39 days) (33) 3 applications (14-24 and 6-14 days) (3)	1 application (1) 2 applications (13-30 days) (23)	2 applications (12-53 days) (33) 3 applications (15-28 and 10-11 days) (2)	1 application (2) 2 applications (13-36 days) (23)
	Spray volumes	150-500 l/ha*	182-400 l/ha	200-500 l/ha*	200-500 l/ha*
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)
	Assessment dates	-1-0 DA-A, 13-17 DA-A -2-2 DA-B, 11-20 DA-B, 21-53 DA-B, 58-101 DA-B	-1-0 DA-A, 13-17 DA-A, 28 DA-A -1-1 DA-B, 11-19 DA-B, 23-42 DA-B, 49-141 DA-B	-1-0 DA-A, 14-16 DA-A -1-0 DA-B, 9-20 DA-B, 21-45 DA-B, 48-115 DA-B	-1-0 DA-A, 14-16 DA-A 0 DA-B, 9-17 DA-B, 21-48 DA-B, 50-188 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Natural (37)	Natural (23)	Natural (29)	Natural (23)
	e.g. Field / Greenhouse...	Field trials	Field trials	Field trials	Field trials

*In a few trials the water volume applied was 500 l/ha. This small deviation did not impact the validity of the trials.

Out of the 112 trials performed on winter wheat against *Zymoseptoria tritici*, 82 were considered valid.

Use of CA3301 at 2x 0.6-0.8 l/ha against SEPTTR – Maritime EPPO zone

In the Maritime EPPO zone, a total of 37 trials evaluated the efficacy of CA3301 on winter wheat against *Zymoseptoria tritici*. 23 trials out of 37 were considered valid and 22 trials enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha applied twice, and to compare it to the reference products on disease severity (%). One trial (EU20-036-26) was valid but tested CA3301 applied only once. CA3301 was first applied at crop stages BBCH 31-41 and the 2nd application was at BBCH 37-69. The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.8 l/ha.

Summary results are presented in Table 3.2-361.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on winter wheat against *Zymoseptoria tritici*. On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 68.28-67.67% efficacy two weeks after the 2nd application and 63.89-68.65% before harvest. On foliar level 1, in a single trial, CA3301 at 0.6-0.8 l/ha showed 35.85-37.45% efficacy on reduction of disease severity around two weeks after the 2nd application and 67.86-71.94% in 17 trials before harvest.

In the Maritime EPPO zone, CA3301 at 0.6-0.8 l/ha showed medium efficacy in reducing the severity of *Zymoseptoria tritici* on winter wheat two weeks after the 2nd application and at the last assessment

timing, on both main foliar levels 1 (L1) and 2 (L2). The performance of the tested product was overall equivalent to the authorised reference products CA2445 and PROLINE 275. Averaged across the dataset the efficacy of CA3301 at 0.6 l/ha was comparable to 0.8 l/ha, however at some assessments a statistical benefit was derived from increasing the dose rate to 0.8 l/ha. Therefore, in situations with high disease pressure, historical difficulties in control of this disease or where some level of resistance is suspected it may be appropriate to use 0.8 l/ha for control of *Zymoseptoria tritici*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Zymoseptoria tritici* on winter wheat in the Maritime EPPO zone.

Table 3.2-361: Summary table - Efficacy evaluation – Winter wheat – SEPTTR - Maritime EPPO zone

Treatment name	UNTR EATE D CHEC K	CA2445 0,8 L/ha AB	PROLI NE 275 0,72 L/ha AB	CA330 1 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to			
% Disease severity L2 - 13-20 DA-B											
Number of values	9			9	9	UTC	CA3301 0,8 l/ha	UTC	CA3301 0,6 l/ha		
Minimum value	5,19			0,00	0,00						
Maximum value	18,76	-	-	7,03	9,59	9 >	0 >	9 >	2 >		
Mean disease severity (%)	11,32			3,67	3,94	0 =	7 =	0 =	7 =		
Abbott efficacy (%)	0,00%			68,28%	67,67%	0 <	2 <	0 <	0 <		
Number of values	5	5		5	5	CA2445 0,8 l/ha		CA2445 0,8 l/ha			
Minimum value	5,19	0,00		0,00	0,00						
Maximum value	17,76	4,69	-	4,00	6,44	1 >		1 >			
Mean disease severity (%)	9,60	2,18		1,63	2,20	4 =		4 =			
Abbott efficacy (%)	0,00%	75,23		81,67%	77,63%	0 <		0 <			
Number of values	4		4	4	4	PROLINE 275 0,72 l/ha		PROLINE 275 0,72 l/ha			
Minimum value	9,75		3,56	5,25	4,30						
Maximum value	18,76	-	11,55	7,03	9,59	0 >		1 >			
Mean disease severity (%)	13,46		6,77	6,22	6,11	3 =		2 =			
Abbott efficacy (%)	0,00%		51,02	51,54%	55,21%	1 <		1 <			
% Disease severity L1 - 13-20 DA-B											
Number of values	1		1	1	1	UT C	PRO- LINE 275 0,72 l/ha	CA33 01 0,8 l/ha	UTC	PRO- LINE 275 0,72 l/ha	CA33 01 0,6 l/ha
Minimum value	8,09		5,93	5,19	5,06						
Maximum value	8,09	-	5,93	5,19	5,06	0 >	0 >	0 >	0 >	0 >	0 >
Mean disease severity (%)	8,09		5,93	5,19	5,06	1 =	1 =	1 =	1 =	1 =	1 =
Abbott efficacy (%)	0,00%		26,70%	35,85%	37,45%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 25-53 DA-B											
Number of values	19			19	19	UTC	CA3301 0,8 l/ha	UTC	CA3301 0,6 l/ha		
Minimum value	6,90			0,69	0,40						
Maximum value	100,00	-	-	74,50	67,86	19 >	1 >	19 >	4 >		
Mean disease severity (%)	34,98			15,22	13,62	0 =	14 =	0 =	14 =		
Abbott efficacy (%)	0,00%			63,89%	68,65%	0 <	4 <	0 <	1 <		
Number of values	15	15		15	15	CA2445 0,8 l/ha		CA2445 0,8 l/ha			
Minimum value	6,90	0,86		0,69	0,40						
Maximum value	100,00	64,94	-	74,50	67,86	1 >		3 >			
Mean disease severity (%)	36,78	13,34		15,69	13,32	13 =		11 =			
Abbott efficacy (%)	0,00%	67,65		65,58%	73,13%	1 <		1 <			
Number of values	4		4	4	4	PROLINE 275 0,72 l/ha		PROLINE 275 0,72 l/ha			
Minimum value	14,69		2,28	0,98	2,97						

Treatment name	UNTR EATE D CHEC K	CA2445 0,8 L/ha AB	PROLI NE 275 0,72 L/ha AB	CA330 1 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Rate	52,88	-	24,58	27,38	29,88	1 >	2 >
Rate unit						2 =	2 =
Appl. Code						1 <	0 <
Maximum value	28,22		13,83	13,45	14,74		
Mean disease severity (%)	0,00%		52,98	57,55%	51,84%		
Abbott efficacy (%)							
% Disease severity L1 - 30-53 DA-B							
Number of values	17			17	17	UTC	CA3301 0,8 l/ha
Minimum value	6,26			0,56	0,00		UTC
Maximum value	67,19	-	-	30,50	29,81	17 >	1 >
Mean disease severity (%)	21,51			7,36	6,35	0 =	14 =
Abbott efficacy (%)	0,00%			67,86%	71,94%	0 <	2 <
Number of values	12	12		12	12	CA2445 0,8 l/ha	CA2445 0,8 l/ha
Minimum value	8,12	0,41		0,56	0,00		
Maximum value	67,19	33,25	-	30,50	29,81	2 >	2 >
Mean disease severity (%)	23,32	7,34		7,82	6,68	8 =	9 =
Abbott efficacy (%)	0,00%	68,01		68,74%	74,12%	2 <	1 <
Number of values	5		5	5	5	PROLINE 275 0,72 l/ha	PROLINE 275 0,72 l/ha
Minimum value	6,26		1,50	0,63	1,72		
Maximum value	37,36	-	6,79	12,53	12,39	1 >	0 >
Mean disease severity (%)	17,18		4,86	6,26	5,57	3 =	4 =
Abbott efficacy (%)	0,00%		66,67	65,72%	66,70%	1 <	1 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against SEPTTR– Mediterranean EPPO zone

In the Mediterranean EPPO zone, a total of 23 trials evaluated the efficacy of CA3301 on winter wheat against *Zymoseptoria tritici*. 20 trials out of 23 were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha (applied twice), and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 30-51 and the 2nd application was at BBCH 39-69.

Summary results are presented in Table 3.2-362.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on winter wheat against *Zymoseptoria tritici*. On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 73.70-76.50% of efficacy two weeks after the 2nd application and 57.01-64.73% before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 82.51-84.33% efficacy on reduction of disease severity around two weeks after the 2nd application and 70.64-77.08% before harvest. These positive effects to control *Zymoseptoria tritici* of CA3301 at 0.6-0.8 l/ha were in most instances equivalent to the reference products CA2445 and PROSARO.

In the Mediterranean EPPO zone, CA3301 at 0.6-0.8 l/ha showed medium to high efficacy in reducing the severity of *Zymoseptoria tritici* on winter wheat. The tested product at 0.6-0.8 l/ha gave in overall equivalent disease control compared to the reference products CA2445 and PROSARO, and at the rate of 0.8 l/ha CA3301 was in some instances more effective for disease control compared to the reference products. Averaged across the dataset the efficacy of CA3301 at 0.6 l/ha was fairly comparable to that of the dose rate of 0.8 l/ha, however at some assessments a statistical benefit was derived from increasing

the dose rate to 0.8 l/ha. Therefore, in situations with high disease pressure, historical difficulties in control of this disease or where some level of resistance is suspected it may be appropriate to use 0.8 l/ha for control of *Zymoseptoria tritici*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Zymoseptoria tritici* on winter wheat in the Mediterranean EPPO zone.

Table 3.2-362: Summary table - Efficacy evaluation – Winter wheat – SEPTTR - Mediterranean EPPO zone

Treatment name	UNTREATE D CHECK	CA244 5 0,8 L/ha AB	PROSAR O 1 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
% Disease severity L2 - 13-19 DA-B									
Number of values	9			9	9	UTC	CA3301 0,8 l/ha	UTC	CA3301 0,6 l/ha
Minimum value	6,75			0,23	0,13				
Maximum value	63,73	-	-	28,20	24,90	9 >	0 >	9 >	1 >
Mean disease severity (%)	27,72			9,39	8,23	0 =	8 =	0 =	8 =
Abbott efficacy (%)	0,00%			73,70%	76,50%	0 <	1 <	0 <	0 <
Number of values	8	8		8	8	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	6,75	0,40		0,23	0,13				
Maximum value	63,73	29,10	-	28,20	24,90	0 >		0 >	
Mean disease severity (%)	29,40	9,52		9,81	8,45	7 =		8 =	
Abbott efficacy (%)	0,00%	75,94%		75,67%	79,17%	1 <		0 <	
Number of values	1		1	1	1	PROSARO 1,0 l/ha		PROSARO 1,0 l/ha	
Minimum value	14,34		4,13	6,03	6,43				
Maximum value	14,34	-	4,13	6,03	6,43	0 >		0 >	
Mean disease severity (%)	14,34		4,13	6,03	6,43	1 =		1 =	
Abbott efficacy (%)	0,00%		-	57,95%	55,16%	0 <		0 <	
% Disease severity L1 - 14-19 DA-B									
Number of values	5			5	5	UTC	CA3301 0,8 l/ha	UTC	CA3301 0,6 l/ha
Minimum value	5,75			0,00	0,00				
Maximum value	44,96	-	-	15,00	14,20	5 >	0 >	5 >	0 >
Mean disease severity (%)	19,71			4,87	4,45	0 =	5 =	0 =	5 =
Abbott efficacy (%)	0,00%			82,51%	84,33%	0 <	0 <	0 <	0 <
Number of values	4	4		4	4	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	5,75	0,00		0,00	0,00				
Maximum value	44,96	12,30	-	15,00	14,20	0 >		0 >	
Mean disease severity (%)	21,34	4,31		4,85	4,49	4 =		4 =	
Abbott efficacy (%)	0,00%	88,48%		87,52%	88,56%	0 <		0 <	
Number of values	1		1	1	1	PROSARO 1,0 l/ha		PROSARO 1,0 l/ha	
Minimum value	13,18		2,83	4,95	4,30				
Maximum value	13,18	-	2,83	4,95	4,30	0 >		0 >	
Mean disease severity (%)	13,18		2,83	4,95	4,30	1 =		1 =	
Abbott efficacy (%)	0,00%		71,20%	62,44%	67,37%	0 <		0 <	
% Disease severity L2 - 23-42 DA-B									
Number of values	13	13		13	13	UTC	CA3301 0,8 l/ha	UTC	CA3301 0,6 l/ha
Minimum value	11,93	5,31		0,34	0,15				
Maximum value	99,63	70,15	-	55,94	52,24	11 >	0 >	12 >	3 >
Mean disease severity (%)	49,66	21,13		22,46	18,57	2 =	10 =	1 =	10 =
Abbott efficacy (%)	0,00%	60,71%		57,01%	64,73%	0 <	3 <	0 <	0 <
Number of values	4	4	4	4	4	CA244 5	PRO- SARO	CA244 5	PRO- SARO

Minimum value	11,93	5,31	3,94	6,00	5,44	0,8 l/ha	1,0 l/ha	0,8 l/ha	1,0 l/ha
Maximum value	99,63	70,15	23,94	55,94	52,24	1 >	0 >	1 >	0 >
Mean disease severity (%)	41,86	22,52	11,57	21,54	19,52	9 =	2 =	11 =	3 =
Abbott efficacy (%)	0,00%	53,08%	65,98	51,17%	57,35%	3 <	2 <	1 <	1 <
% Disease severity L1 - 23-42 DA-B									
Number of values	11	11		11	11	UTC	CA3301 0,8 l/ha	UTC	CA3301 0,6 l/ha
Minimum value	5,53	1,69		2,11	1,42				
Maximum value	59,31	28,38	-	39,88	18,88	11 >	0 >	11 >	3 >
Mean disease severity (%)	31,26	8,23		9,29	6,49	0 =	8 =	0 =	8 =
Abbott efficacy (%)	0,00%	73,02%		70,64%	77,08%	0 <	3 <	0 <	0 <
Number of values	3	3	3	3	3	CA244 5	PRO- SARO 1,0 l/ha	CA244 5	PRO- SARO 1,0 l/ha
Minimum value	5,53	2,88	2,55	2,15	1,80	0,8 l/ha	1,0 l/ha	0,8 l/ha	1,0 l/ha
Maximum value	59,31	15,18	7,50	11,12	9,39	0 >	0 >	2 >	0 >
Mean disease severity (%)	29,99	7,98	5,47	6,74	6,00	9 =	3 =	9 =	3 =
Abbott efficacy (%)	0,00%	66,31%	71,11	71,59%	74,84%	2 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against SEPTTR– North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 29 trials evaluated the efficacy of CA3301 on winter wheat against *Zymoseptoria tritici*. 22 trials out of 29 were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha (applied twice), and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 30-39 and the 2nd application was at BBCH 37-65.

Summary results are presented in Table 3.2-363.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on winter wheat against *Zymoseptoria tritici*. On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 79,13-79,98% efficacy two weeks after the 2nd application and 68.35-76.96% before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 68.04-74.45% efficacy on reduction of disease severity before harvest.

In the North-eastern East EPPO zone, CA3301 at 0.6-0.8 l/ha showed medium to high efficacy in reducing the severity of *Zymoseptoria tritici* on winter wheat, with the highest efficacy reached two weeks after the 2nd application on foliar level 2. The performance of the tested product was overall equivalent to the reference products CA2445 and OSIRIS 65 EC. Averaged across the dataset the efficacy of CA3301 at 0.6 l/ha was fairly comparable to that of the dose rate of 0.8 l/ha, however at some later assessments a statistical benefit was derived from increasing the dose rate to 0.8 l/ha. Therefore, in situations with high disease pressure, historical difficulties in control of this disease or where some level of resistance is suspected it may be appropriate to use 0.8 l/ha for control of *Zymoseptoria tritici*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Zymoseptoria tritici* on winter wheat in the North-Eastern East EPPO zone.

Table 3.2-363: Summary table - Efficacy evaluation – Winter wheat – SEPTTR – North-Eastern East EPPO zone

East LFPO zone									
Treatment name	UNTREATE D CHECK	CA244 5	OSIRIS 65 EC	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		0,8	2	0,6	0,8				
Rate unit		L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB				
% Disease severity L2 - 15-20 DA-B									
Number of values	6			6	6	UT C	CA330 1 0,8 l/ha	UT C	CA330 1 0,6 l/ha
Minimum value	5,05			0,25	0,00	6 >	0 >	6 >	0 >
Maximum value	23,75	-	-	5,88	5,25	0 =	6 =	0 =	6 =
Mean disease severity (%)	10,91			1,97	1,88	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%			79,13%	79,98%				
Number of values	3	3		3	3	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	8,38	0,63		0,25	0,56	0 >		0 >	
Maximum value	12,88	6,00	-	5,88	5,25	3 =		3 =	
Mean disease severity (%)	10,42	3,19		3,00	3,10	0 <		0 <	
Abbott efficacy (%)	0,00%	72,17		74,19%	72,52%				
Number of values	4		4	4	4	OSIRIS 65 EC 2,0 l/ha		OSIRIS 65 EC 2,0 l/ha	
Minimum value	5,05		0,00	0,25	0,56	0 >		0 >	
Maximum value	23,75	-	1,75	1,45	1,18	4 =		4 =	
Mean disease severity (%)	10,65		0,78	0,77	0,64	0 <		0 <	
Abbott efficacy (%)	0,00%		85,95	87,30%	88,91%				
% Disease severity L2 - 21-42 DA-B									
Number of values	16			16	16	UT C	CA330 1 0,8 l/ha	UT C	CA330 1 0,6 l/ha
Minimum value	5,25			0,44	0,04	16 >	0 >	16 >	3 >
Maximum value	45,00	-	-	17,08	16,75	0 =	13 =	0 =	13 =
Mean disease severity (%)	16,77			5,60	4,48	0 <	3 <	0 <	0 <
Abbott efficacy (%)	0,00%			68,35%	76,96%				
Number of values	13	13		13	13	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	5,25	0,08		0,49	0,04	0 >		2 >	
Maximum value	42,88	11,91	-	17,08	10,58	12 =		10 =	
Mean disease severity (%)	14,89	4,15		4,88	3,29	1 <		1 <	
Abbott efficacy (%)	0,00%	72,59		68,57%	78,60%				
Number of values	12		12	12	12	OSIRIS 65 EC 2,0 l/ha		OSIRIS 65 EC 2,0 l/ha	
Minimum value	9,63		0,00	0,44	0,13	0 >		0 >	
Maximum value	45,00	-	11,78	17,08	16,75	8 =		11 =	
Mean disease severity (%)	17,98		3,98	6,18	4,81	4 <		1 <	
Abbott efficacy (%)	0,00%		75,85	66,88%	75,85%				
% Disease severity L1 - 21-42 DA-B									
Number of values	14			14	14	UT C	CA330 1 0,8 l/ha	UT C	CA330 1 0,6 l/ha
Minimum value	5,01			0,00	0,00	14 >	0 >	14 >	2 >
Maximum value	36,56	-	-	8,19	9,38	0 =	12 =	0 =	12 =
Mean disease severity (%)	12,62			3,57	3,17	0 <	2 <	0 <	0 <
Abbott efficacy (%)	0,00%			68,04%	74,45%				
Number of values	8	8		8	8	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	5,01	1,19		1,19	0,74	0 >		0 >	
Maximum value	36,56	6,74	-	7,01	6,90	8 =		8 =	
Mean disease severity (%)	11,41	2,55		2,83	2,11	0 <		0 <	
Abbott efficacy (%)	0,00%	68,1		66,24%	75,31%				

Treatment name	UNTREATE D CHECK	CA244 5 0,8 L/ha AB	OSIRIS 65 EC 2 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Number of values	13		13	13	13	OSIRIS 65 EC 2,0 l/ha	OSIRIS 65 EC 2,0 l/ha
Minimum value	5,01		0,00	0,00	0,00	0 >	1 >
Maximum value	36,56	-	3,70	8,19	9,38	10 =	10 =
Mean disease severity (%)	12,75		2,05	3,40	2,89	3 <	2 <
Abbott efficacy (%)	0,00%		79,71	69,69%	76,47%		

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against SEPTTR– South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 23 trials evaluated the efficacy of CA3301 on winter wheat against *Zymoseptoria tritici*. 18 trials out of 23 were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha (applied twice), and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 31-47 and the 2nd application was at BBCH 39-65.

Summary results are presented in Table 3.2-364.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on winter wheat against *Zymoseptoria tritici*. On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 66.05-79.15% efficacy against *Zymoseptoria tritici* two weeks after the 2nd application and 70.31-75.25% before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 81.49-86.25% efficacy on reduction of disease severity two weeks after the 2nd application and 75.39-77.82% before harvest.

In the South-eastern East EPPO zone, CA3301 at 0.6-0.8 l/ha showed medium to high efficacy in reducing the severity of *Zymoseptoria tritici* on winter wheat, with the highest efficacy reached two weeks after the 2nd application on foliar level 1. CA3301 at 0.6 l/ha was overall equivalent to the reference products CA2445 and PRIAXOR. At the rate of 0.8 l/ha CA3301 was more frequently comparable to or better than the reference products for disease control. Averaged across the dataset the efficacy of CA3301 at 0.6 l/ha was fairly comparable to that of the dose rate of 0.8 l/ha, however in some assessments a statistical benefit was derived from increasing the dose rate to 0.8 l/ha for disease control. Therefore, in situations with high disease pressure, historical difficulties in control of this disease or where some level of resistance is suspected it may be appropriate to use 0.8 l/ha for control of *Zymoseptoria tritici*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Zymoseptoria tritici* on winter wheat in the South-Eastern East EPPO zone.

Table 3.2-364: Summary table - Efficacy evaluation – Winter wheat – SEPTTR – South-Eastern East EPPO zone

Treatment name	UNTREAT ED CHECK	CA24 45 0,8 L/ha AB	PRIAX OR 1,5 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
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% Disease severity L2 - 14-17 DA-B											
Number of values	4	4		4	4	UT C	CA244 5 0,8 l/ha	CA33 01 0,8 l/ha	UTC	CA244 5 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	8,83	1,40		2,75	1,25						
Maximum value	24,56	8,38	-	9,50	8,00	4 >	0 >	0 >	4 >	0 >	2 >
Mean disease severity (%)	18,13	5,42		6,14	4,14	0 =	2 =	2 =	0 =	4 =	2 =
Abbott efficacy (%)	0,00%	71,72 %		66,05 %	79,15 %	0 <	2 <	2 <	0 <	0 <	0 <
% Disease severity L1 - 14-17 DA-B											
Number of values	3	3		3	3	UT C	CA244 5 0,8 l/ha	CA33 01 0,8 l/ha	UTC	CA244 5 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	12,11	0,00		0,18	0,00						
Maximum value	30,00	3,13	-	4,65	3,69	3 >	0 >	0 >	3 >	0 >	2 >
Mean disease severity (%)	18,85	1,81		2,53	1,86	0 =	2 =	1 =	0 =	2 =	1 =
Abbott efficacy (%)	0,00%	86,41 %		81,49 %	86,25 %	0 <	1 <	2 <	0 <	1 <	0 <
% Disease severity L2 - 21-45 DA-B											
Number of values	13			13	13	UTC	CA3301 0,8 l/ha		UTC		CA3301 0,6 l/ha
Minimum value	5,96			0,00	0,00						
Maximum value	100,00	-	-	13,98	17,36	11 >	0 >		11 >		2 >
Mean disease severity (%)	26,46			5,37	4,86	2 =	11 =		2 =		11 =
Abbott efficacy (%)	0,00%			70,31 %	75,25 %	0 <	2 <		0 <		0 <
Number of values	10	10		10	10	CA2445 0,8 l/ha		CA2445 0,8 l/ha			
Minimum value	5,96	0,00		0,00	0,00						
Maximum value	100,00	9,06	-	13,00	13,75	0 >		1 >			
Mean disease severity (%)	28,05	3,28		4,45	3,65	9 =		9 =			
Abbott efficacy (%)	0,00%	83,93		78,34 %	83,71 %	1 <		0 <			
Number of values	8		8	8	8	PRIAXOR 1,5 l/ha		PRIAXOR 1,5 l/ha			
Minimum value	13,19		0,00	4,25	0,68						
Maximum value	56,50	-	9,98	13,98	17,36	0 >		0 >			
Mean disease severity (%)	26,59		3,03	7,91	7,23	4 =		5 =			
Abbott efficacy (%)	0,00%		79,62	61,84 %	67,19 %	4 <		3 <			
% Disease severity L1 - 24-48 DA-B											
Number of values	7			7	7	UTC	CA3301 0,8 l/ha		UTC		CA3301 0,6 l/ha
Minimum value	10,26			0,14	0,06						
Maximum value	33,75	-	-	12,16	14,38	5 >	0 >		5 >		0 >
Mean disease severity (%)	19,89			5,19	4,97	2 =	7 =		2 =		7 =
Abbott efficacy (%)	0,00%			75,39 %	77,82 %	0 <	0 <		0 <		0 <
Number of values	4	4		4	4	CA2445 0,8 l/ha		CA2445 0,8 l/ha			
Minimum value	10,26	0,08		0,14	0,06						
Maximum value	33,75	10,30	-	12,16	10,31	0 >		0 >			
Mean disease severity (%)	20,37	3,74		4,62	4,09	4 =		4 =			
Abbott efficacy (%)	0,00%	83,11		80,68 %	80,77 %	0 <		0 <			
Number of values	5		5	5	5	PRIAXOR 1,5 l/ha		PRIAXOR 1,5 l/ha			
Minimum value	10,88		0,00	0,68	0,41						
Maximum value	33,75	-	8,69	7,65	14,38	0 >		0 >			
Mean disease severity (%)	20,48		2,21	4,81	4,89	4 =		4 =			
Abbott efficacy (%)	0,00%		91,26	74,97 %	76,82 %	1 <		1 <			

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

22 valid field trials were conducted in **the Maritime EPPO climatic zone**. CA3301 applied at dose rates of 0,6-0,8 l/ha achieved a medium level of effectiveness. On L2 after 13-20 days after second application, the test product at 0,6 l/ha showed the mean efficacy of 68,28% and 67,67% in case of higher dose. 25-53 days after second application, the results were still on similar level (63,89% and 68,65%, respectively). Also on leaf L1 CA3301 controlled SEPTTR at the medium level of efficacy (67,86% for 0,6 l/ha and 71,94% for 0,8 l/ha). The efficacy of the test and reference product was comparable.

22 valid field trials were conducted in **the North-East EPPO climatic zone**. CA3301 applied at dose rates of 0,6-0,8 l/ha achieved a medium level of effectiveness. The efficacy amounted above 79% on L1 after 15-20 days after second application. The medium efficacy was also noted in the next observations. The test product achieved 68,35% at 0,6 l/ha and 76,96% at 0,8 l/ha. The similar results were observed in case of L1. No differences between test and reference products were detected.

18 valid field trials were conducted in **the South-East EPPO climatic zone**. CA3301 applied at dose rates of 0,6-0,8 l/ha achieved a medium level of effectiveness. The trial results show that only 14-17 days after second application the test product achieved control above 80% on L1. However in most cases efficacy amounted 60-80% from 14 to 48 days after last application. The efficacy of the test and reference product was comparable.

In the opinion of zRMS, CA3301 can be recommended to protection of winter wheat against *Zymoseptoria tritici*. However it should be noted that the level of effectiveness is medium. Moreover, the higher dose rate of 0,8 l/ha is recommended in case of high disease pressure.

3.2.3.23 Winter wheat (TRZAW) / *Puccinia recondita*- *Puccinia triticina* (PUCCRE-PUCCRT)

Materials and Methods – Winter wheat – PUCCRE/PUCCRT

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Puccinia recondita and *Puccinia triticina* are the causal agents of the brown rust on wheat and are considered as the same pathogen in this analysis.

Between 2017 and 2020, a series of 61 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the efficacy of CA3301 against *Puccinia recondite* or *P. triticina* on winter wheat. The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, 18 trials were performed in Czech Republic (5), Germany (5), France (7) and United Kingdom (1) (see Table 3.2-285).

In the Mediterranean EPPO zone, 19 trials were performed in France (13), Spain (5) and Italy (1) (see Table 3.2-285).

In the North-eastern East EPPO zone, 16 trials were performed in Poland (13) and Latvia (3) (see Table 3.2-285).

In the South-eastern East EPPO zone, a total of 8 trials were performed in Hungary (5), Romania (2) and Bulgaria (1) (see Table 3.2-285).

Table 3.2-365: Presentation of trials – Winter wheat (TRZAW)

Crop(s))*	Target(s)*	Country	Years	Type of trial*	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					Mari-time zone	Mediterranean zone	North-Eastern zone	South-Eastern zone		
Winter wheat	PUCCRE/PUCCRT	Czech Republic	2018 - 2020	MED + E	5 (2)	-	-	-	GEP	
		Germany	2019 - 2020	MED + E	5 (2)	-	-	-	GEP	
		France	2019 - 2020	MED + E	7 (4)	-	-	-	GEP	
		United Kingdom	2020	MED + E	1 (1)	-	-	-	GEP	
TOTAL	-	-	2018 - 2020	MED + E	18 (9)	-	-	-	GEP	
Winter wheat	PUCCRE/PUCCRT	France	2019 - 2020	MED + E	-	13 (11)	-	-	GEP	
		Spain	2019 - 2020	MED + E	-	5 (5)	-	-	GEP	
		Italy	2020	MED + E	-	1 (1)	-	-	GEP	
TOTAL	-	-	2018 - 2020	MED + E	-	19 (17)	-	-	GEP	
Winter wheat	PUCCRE/PUCCRT	Poland	2018 - 2020	MED + E	-	-	13 (13)	-	GEP	
		Latvia	2019	MED + E	-	-	3 (3)	-	GEP	
TOTAL	-	-	2018 - 2020	MED + E	-	-	16 (16)	-	GEP	
Winter wheat	PUCCRE/PUCCRT	Hungary	2018 - 2019	MED + E	-	-	-	5 (4)	GEP	
		Romania	2019 - 2020	MED + E	-	-	-	2 (2)	GEP	
		Bulgaria	2019	MED + E	-	-	-	1 (1)	GEP	
TOTAL	-	-	2018 - 2020	MED + E	-	-	-	8 (7)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation

In all trials, CA3301 was compared to at least one commercial fungicide used as standard reference for comparison.

Table 3.2-366: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – PUCCRE/PUCCRT – Maritime EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter wheat	PRO-LINE 250 EC	CZ	4523-1	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha max	1 x 0.6-0.8 l/ha 2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE	DE	025287-00	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	JOAO	FR (N)	2060116	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE	UK	12084	Prothioconazole	EC	250 g/l	3 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-367: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – PUCCRE/PUCCRT – Mediterranean EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
TRZAW	JOAO	FR (S)	2060116	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-SARO	ES	25661	Prothioconazole + Tebuconazole	EC	250 g/L	1 l/ha	2 x 1 l/ha	CA2445 in some trials
	PRO-SARO	IT	013386	Prothioconazole + Tebuconazole	EC	250 g/L	1 or 2 x 1 l/ha	2 x 1 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-368: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – PUCCRE/PUCCRT – North-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
TRZAW	PRAKTIS	PL	R-222/2019	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	OSIRIS 65 EC	PL	R-87/2012	Epoxiconazole + metconazole	EC	65 g/l	1 x 1.5-2.5 l/ha	2 x 2 l/ha	
	PRO-LINE	LV	0637	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-369: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – PUCCRE/PUCCRT – South-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
TRZAW	PRO-LINE	RO	457PC/15/11/2018	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE	HU	6300 / 1205-1 / 2020	Prothioconazole	EC	250 g/l	2 x 0.6-0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRI-AXOR	HU	04.2/1063-4/2018	Fluxapiraxad + Pyraclostrobin	EC	225 g/l	N/A	2 x 1.5 l/ha	
	RISA 20 EC	BG	01389-PPP-1/03/23/2016	Tebuconazole	EC	200 g/L	N/A	2 x 1.25 l/ha	

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-370.

Table 3.2-370: Details on trial methodology – Winter wheat (TRZAW) – PUCCRE/PUCCRT

		Maritime EPPO zone	Mediterranean EPPO zone	North –East EPPO zone	South-Eastern EPPO zone
Trials	Total number (valid number)	18 (9)	19 (18)	16 (16)	8 (7)
	Supportive trials	-			

Guidelines	General guidelines	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3) PP 1/225 (2)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3) PP 1/225 (2)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3) PP 1/225 (2)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3) PP 1/225 (2)
	Specific guidelines	PP 1/26 (4) PP 1/28 (3) PP 1/262 (1)	PP 1/26 (4)	PP 1/26 (4)	PP 1/26 (4)
Experimental design	Plot design	Randomized Complete Blocks, Untreated included	Randomized Complete Blocks, Untreated included	Randomized Complete Blocks, Untreated included	Randomized Complete Blocks, Untreated included
	Plot size	15 - 30 m ²	20 – 24 m ²	11.25-30 m ²	20-30 m ²
	Number of replications	4	4	4	4
Crop	Trials per crop	TRZAW (18)	TRZAW (19)	TRZAW (16)	TRZAW (8)
	Varieties per crop	Tobak (1), Pannonia (1), Ilona (1), JB Asano (1), Ritmo (1), Apache (2), Chevron (1), Faustus (1), Expert (1), Rubisko (1), Oregrain (2), Matchball (1), Gravity (1), Monopol (2), Baranco (1).	Bologna (3), Soissons (1), Sepia (1), Rebelde (1), Bonifacio (1), Marius (1), Calumet (1), Orloge (1), Soleiho (1), Calabro (1), Complice (1), Tocayo (2), Marco Polo (1), Illico (1), Cellule (1), Oregrain (1)	Jantarka (1), Bogatka (1), Delawar (1), Banderola (2), Ozon (3), Markiza (1), Edvins (1), Emil (1), Urbanus (1), Skagen (1), Talsis (1), Kili-mandzaro (1), Hondia (1)	KWS Basmati (1), Akteur (1), GK Csilog (1), Avenue (1), Altigo (1), Alex (1), Astaro (1), Midas (1)
	Sowing period	September (1), October (11), November (3), December (1)	January (1), February (1), April (1), September (1), October (3), November (10), December (2)	September (8), October (8)	September (1), October (6), November (1)
Application	Crop stage (BBCH)* at application	A : BBCH 30-41 B: BBCH 37-69	A: BBCH 30-41 B: BBCH 39-69	A: BBCH 24-45 B: BBCH 41-69	A: BBCH 31-41 B: BBCH 47-69
	Timing Pest stage at application	BBCH 30-69 A: Mixed (4), PRINFC (10), SPORUL (1) B: Mixed (7), PRINFC (8)	BBCH 30-69 A: SPORUL (1), PRINFC (17), MIXED (1) B: SPORUL (2), PRINFC (11), MIXED (6)	BBCH 24-69 A: PRINFC (8), N/A (8) B: PRINFC (7), MIXED (1), N/A (8)	BBCH A: MYCELI (1), MIXED (1), PRINFC (6) B: SPORUL (1), MIXED (4), PRINFC (3)
	Number of applications Intervals between applications	1 application (2) 2 applications (15-35 days) (17)	2 applications (14-42 days) (19)	1 application (2) 2 applications (12-53 days) (16)	1 application (1) 2 applications (13-29 days) (8)
	Spray volumes	A: 150-400 l/ha B: 150-500 l/ha*	A: 182-400 l/ha B: 182-400 l/ha	A: 200-300 l/ha B: 200-500 l/ha*	A: 200-500 l/ha* B: 200-500 l/ha*
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 or %)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 or %)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 or %)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 or %)
	Assessment dates	0 DA-A, 10-16 DA-A, -1-2 DA-B, 9-16 DA-B, 21-32 DA-B,	-1-0 DA-A, 13-19 DA-A, -1-1 DA-B, 6-16 DA-B, 18-29	-1-0 DA-A, 12-18 DA-A, 0 DA-B, 14-18 DA-B, 20-37 DA-	0 DA-A, 15 DA-A, 0 DA-B, 14-17 DA-B, 21-43 DA-B, 47-126

		34-69 DA-B	DA-B, 32-71 DA-B	B	DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Natural (18)	Natural (19)	Natural (16)	Natural (8)
	e.g. Field / Greenhouse...	Field trials	Field trials	Field trials	Field trials

*In a few trials the water volume applied was 500 l/ha. This small deviation did not impact the validity of the trials.

Use of CA3301 at 2x 0.6-0.8 l/ha against Puccinia recondita/PuccRT – Maritime EPPO zone

In the Maritime EPPO zone, 18 trials were available against *Puccinia recondita* (PuccRE) or *Puccinia triticina* (PuccRT), on winter wheat. 9 trials out of 18 were considered as valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.8 l/ha applied twice, compared to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 31-37 and the 2nd application was at BBCH 39-67.

Summary results are presented in Table 3.2-371.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control brown rust. On foliar level 2, at this dose rate, CA3301 showed 87.93% of efficacy on disease severity two weeks after the 2nd application and 63.06% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 83.61% of efficacy on reduction of disease severity around two weeks after the 2nd application and 63.99% before harvest.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.8 l/ha to control brown rust. On foliar level 2, at this dose rate, CA3301 showed 93.83% of efficacy to control the disease two weeks after the 2nd application and 66.43% before harvest. On foliar level 1, CA3301 at 0.8 l/ha showed 88.03% of efficacy on reduction of disease severity 2 around two weeks after the 2nd application and 70.58% before harvest.

In all trials in the Maritime EPPO zone both dose rates of CA3301 gave equivalent or higher disease control compared to the authorised reference product CA2445. In the majority of assessments there were no significant differences in disease control between the rate of 0.6 l/ha or 0.8 l/ha of CA3301. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for control of brown rust, however when conditions are conducive to heavy disease infestation the rate of 0.8 l/ha may be beneficial to further reduce disease incidence.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Puccinia recondita* or *Puccinia triticina* on winter wheat in the Maritime EPPO zone.

Table 3.2-371: Summary table - Efficacy evaluation – Winter wheat – PuccRE/PuccRT - Maritime EPPO zone

time EFFO zone										
Treatment name	UNTREATED CHECK	CA244 5	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or <			No of trials where CA3301 at 0,8 l/ha is >, = or <		
Rate		0,8	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
% Disease severity L2 - 16-18 DA-B										
Number of values	2	2	2	2	UT C	CA244 5	CA330 1	UTC	CA244 5	CA330 1
Minimum value	7,84	0,23	0,74	0,19		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha

Maximum value	8,90	1,11	1,24	0,80	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	8,37	0,67	0,99	0,49	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	91,63 %	87,93 %	93,83 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 18 DA-B										
Number of values	1	1	1	1	UTC	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UTC	CA244 5 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	6,10	0,94	1,00	0,73	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	6,10	0,94	1,00	0,73	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	6,10	0,94	1,00	0,73	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	84,59 %	83,61 %	88,03 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 – 27-42 DA-B										
Number of values	5	5	5	5	UTC	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UTC	CA244 5 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	5,75	0,85	0,00	0,00	5 >	1 >	0 >	5 >	1 >	0 >
Maximum value	25,80	18,19	16,66	15,99	0 =	4 =	5 =	0 =	4 =	5 =
Mean disease severity (%)	11,41	5,81	5,36	5,11	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	58,70 %	63,06 %	66,43 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 – 27-53 DA-B										
Number of values	8	8	8	8	UTC	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UTC	CA244 5 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	7,68	0,89	0,46	0,56	8 >	0 >	0 >	8 >	2 >	1 >
Maximum value	26,16	16,28	13,58	13,54	0 =	8 =	7 =	0 =	6 =	7 =
Mean disease severity (%)	17,01	6,68	6,34	5,25	0 <	0 <	1 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	62,09 %	63,99 %	70,58 %	0 <	0 <	1 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against PUCCRE/PUCCRT – Mediterranean EPPO zone

In the Mediterranean EPPO zone, 19 trials were available against *Puccinia recondita* (PUCCRE) or *Puccinia tritricina* (PUCCRT), on winter wheat. 17 trials out of 19 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.8 l/ha applied twice, compared to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 30-39 and the 2nd application was at BBCH 49-69.

Summary results are presented in Table 3.2-372.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control the severity of brown rust. On foliar level 2, at this dose rate, CA3301 showed 49.63 % of efficacy to control the disease two weeks after the 2nd application and 58.73% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 57.12% of efficacy on reduction of disease severity around two weeks after the 2nd application and 70.01% before harvest.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.8 l/ha to control brown rust. On foliar level 2, at this dose rate, CA3301 showed 63.94% of efficacy to control the disease two weeks after the 2nd application and 66.94% before harvest. On foliar level 1, CA3301 at 0.8 l/ha showed 69.15% of efficacy on reduction of disease severity around two weeks after the 2nd application and 76.46% before harvest.

In the Mediterranean EPPO zone where warmer conditions are overall more conducive for this pathogen the disease severity in the trials was medium-high (12-91%). With these conditions the increased 0.8 l/ha dose rate of CA3301 was more effective at reducing disease compared to the 0.6 l/ha rate, often significantly so. In addition, the performance of CA3301 at 0.8 l/ha was more comparable to the reference product CA2445 applied at the same rate of active substance. However, in some evaluations made with lower disease incidence, the 0.6 l/ha rate of CA3301 was sufficient to give comparable control. Therefore, it is proposed that the higher rate is applied when disease pressure is medium-high, and 0.6 l/ha applied in situations of lower disease pressure, with less conducive conditions for disease development.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Puccinia recondita* or *Puccinia triticina* on winter wheat in the Mediterranean EPPO zone.

Table 3.2-372: Summary table - Efficacy evaluation – Winter wheat – PUCCRE/PUCCRT - ~~Mari-~~time Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA24 45	PROSA RO	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		0,8	1	0,6	0,8				
Rate unit		L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB				
% Disease severity L2 - 12-16 DA-B									
Number of values	7			7	7	UT C	CA33 01 0,8 l/ha	UT C	CA33 01 0,6 l/ha
Minimum value	9,34			0,81	0,31				
Maximum value	80,75	-	-	59,00	37,63	5 >	0 >	6 >	3 >
Mean disease severity (%)	30,66			20,76	13,35	2 =	4 =	1 =	4 =
Abbott efficacy (%)	0,00%			49,63 %	63,94 %	0 <	3 <	0 <	0 <
Number of values	6	6		6	6	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	9,34	0,43		0,81	0,31				
Maximum value	80,75	36,75	-	59,00	37,63	0 >		0 >	
Mean disease severity (%)	33,87	13,01		23,07	14,16	3 =		5 =	
Abbott efficacy (%)	0,00%	74.68		51,41 %	70,41 %	3 <		1 <	
Number of values	3		3	3	3	PROSARO 1,0 l/ha		PROSARO 1,0 l/ha	
Minimum value	11,36		2,19	0,86	0,40				
Maximum value	20,01	-	5,48	20,74	11,28	0 >		0 >	
Mean disease severity (%)	15,50		3,81	9,51	6,73	2 =		2 =	
Abbott efficacy (%)	0,00%		72.80	44,40 %	55,44 %	1 <		1 <	
% Disease severity L1 - 12-16 DA-B									
Number of values	7			7	7	UT C	CA33 01 0,8 l/ha	UT C	CA33 01 0,6 l/ha
Minimum value	5,76			0,05	0,01				
Maximum value	58,63	-	-	49,75	29,63	6 >	0 >	7 >	2 >
Mean disease severity (%)	19,10			13,58	9,11	1 =	5 =	0 =	5 =

Abbott efficacy (%)	0,00%			57,12 %	69,15 %	0 <	2 <	0 <	0 <
Number of values	6	6		6	6	CA2445		CA2445	
Minimum value	5,76	0,04		0,05	0,01	0,8 l/ha		0,8 l/ha	
Maximum value	58,63	29,13	-	49,75	29,63	0 >		0 >	
Mean disease severity (%)	21,29	9,47		15,32	10,34	3 =		5 =	
Abbott efficacy (%)	0,00%	76,23		58,77 %	68,96 %	3 <		1 <	
Number of values	3		3	3	3	PROSARO		PROSARO	
Minimum value	5,76		0,69	0,20	0,05	1,0 l/ha		1,0 l/ha	
Maximum value	10,66	-	1,81	5,56	6,24	0 >		0 >	
Mean disease severity (%)	7,45		1,13	2,96	2,68	2 =		2 =	
Abbott efficacy (%)	0,00%		83,08	63,86 %	70,31 %	1 <		1 <	
% Disease severity L2 - 20-43 DA-B									
Number of values	9			9	9	UT C	CA33 01 0,8 l/ha	UT C	CA33 01 0,6 l/ha
Minimum value	91,94			0,00	0,00				
Maximum value	8,81	-	-	84,44	46,19	7 >	0 >	9 >	2 >
Mean disease severity (%)	39,13			22,45	15,73	2 =	7 =	0 =	7 =
Abbott efficacy (%)	0,00%			58,73 %	66,94 %	0 <	2 <	0 <	0 >
Number of values	8	8		8	8	CA2445		CA2445	
Minimum value	8,81	0,00		0,00	0,00	0,8 l/ha		0,8 l/ha	
Maximum value	39,13	45,88	-	84,44	46,19	0 >		0 >	
Mean disease severity (%)	41,18	14,97		24,51	16,61	6 =		8 =	
Abbott efficacy (%)	0,00%	69,63		56,82 %	67,60 %	2 <		0 <	
Number of values	3		3	3	3	PROSARO		PROSARO	
Minimum value	22,77		3,75	5,92	8,72	1,0 l/ha		1,0 l/ha	
Maximum value	91,94	-	31,08	84,44	46,19	0 >		0 >	
Mean disease severity (%)	58,37		14,43	39,20	26,22	1 =		2 =	
Abbott efficacy (%)	0,00%		78,57	45,68 %	57,38 %	2 <		1 <	
% Disease severity L1 - 20-42 DA-B									
Number of values	14			14	14	UT C	CA33 01 0,8 l/ha	UT C	CA33 01 0,6 l/ha
Minimum value	8,60			0,00	0,00				
Maximum value	66,13	-	-	36,88	24,48	13 >	0 >	14 >	2 >
Mean disease severity (%)	30,16			10,41	7,17	1 =	12 =	0 =	12 =
Abbott efficacy (%)	0,00%			70,01 %	76,46 %	0 <	2 <	0 <	0 <
Number of values	12	12		12	12	CA2445		CA2445	
Minimum value	8,60	0,00		0,00	0,00	0,8 l/ha		0,8 l/ha	
Maximum value	66,13	23,13	-	36,88	24,48	1 >		1 >	
Mean disease severity (%)	31,24	7,16		10,96	6,75	9 =		11 =	
Abbott efficacy (%)	0,00%	78,4		70,20 %	79,56 %	2 <		0 <	
Number of values	5		5	5	5	PROSARO		PROSARO	
Minimum value	10,13		0,27	1,81	1,66	1,0 l/ha		1,0 l/ha	
Maximum value	66,13	-	9,13	29,44	13,90	0 >		0 >	
Mean disease severity (%)	34,90		3,99	13,01	8,00	3 =		3 =	
Abbott efficacy (%)	0,00%		88,87	66,43 %	73,64 %	2 <		2 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against PUCCRE/PUCCRT – North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, 16 trials were available against *Puccinia recondita* (PUCCRE) or *Puccinia triticina* (PUCCRT), on winter wheat. 10 trials out of 16 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.8 l/ha applied twice, compared to the reference products on disease severity (%). CA3301 was first applied at crop BBCH stage 30-39 and the 2nd application was at BBCH 52-65.

Summary results are presented in Table 3.2-373.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control brown rust. On foliar level 2, at this dose rate, CA3301 showed 99.22% of efficacy on reduction of disease severity around two weeks after the 2nd application and 85.46% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 83.31% of efficacy on reduction of disease severity around two weeks after the 2nd application and 68.19% before harvest.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.8 l/ha to control brown rust. On foliar level 2, at this dose rate, CA3301 showed 100% of efficacy on reduction of disease severity around two weeks after the 2nd application and 90.15% before harvest. On foliar level 1, CA3301 at 0.8 l/ha showed 88.27% of efficacy on reduction of disease severity around two weeks after the 2nd application and 75.86% before harvest.

In the North-Eastern East EPPO zone the trials had low-medium disease severity (5.0-18.8%). In this dataset both dose rates of CA3301 demonstrated high-medium efficacy against brown rust. In addition, both dose rates were overall comparable to the reference products in terms of disease control. Therefore, it is envisaged that a dose rate of 0.6 L/ha is appropriate for control of brown rust at this level of disease pressure. However, when disease pressure is high the increased dose rate of 0.8 L/ha with the observed marginal increase in disease reduction seen in these trials may be beneficial to maximise protection close to harvest.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Puccinia recondita* or *Puccinia triticina* on winter wheat in the North-Eastern East EPPO zone.

Table 3.2-373: Summary table - Efficacy evaluation – Winter wheat – PUCCRE/PUCCRT – North-Eastern East EPPO zone

Treatment name	UNTREA TED CHECK	CA24 45 0,8 L/ha AB	OSIRIS 65 EC 2 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity L2 - 15 DA-B											
Number of values	1		1	1	1	UT C	OSIRIS 65 EC 2,0 l/ha	CA33 01 0,8 l/ha	UT C	OSIRIS 65 EC 2,0 l/ha	CA33 01 0,6 l/ha
Minimum value	7,69		0,19	0,06	0,00	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	7,69	-	0,19	0,06	0,00	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	7,69		0,19	0,06	0,00						

Treatment name	UNTREA TED CHECK	CA24 45 0,8 L/ha AB	OSIRIS 65 EC 2 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Abbott efficacy (%)	0,00%		97,53%	99,22 %	100,00 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 15 DA-B											
Number of values	1	1		1	1	UT C	CA2445 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA2445 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	18,75	2,56		3,13	2,20						
Maximum value	18,75	2,56	-	3,13	2,20	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	18,75	2,56		3,13	2,20	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	86,35 %		83,31 %	88,27 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 20-35 DA-B											
Number of values	6			6	6	UTC	CA3301 0,8 l/ha		UTC	CA3301 0,6 l/ha	
Minimum value	5,00			0,13	0,06						
Maximum value	17,25	-	-	1,39	1,16	6 >	0 >		6 >	0 >	
Mean disease severity (%)	8,48			1,03	0,68	0 =	6 =		0 =	6 =	
Abbott efficacy (%)	0,00%			85,46 %	90,15 %	0 <	0 <		0 <	0 <	
Number of values	5	5		5	5	CA2445 0,8 l/ha		CA2445 0,8 l/ha			
Minimum value	5,00	0,56		0,88	0,56						
Maximum value	17,25	1,24	-	1,39	1,16	0 >		0 >			
Mean disease severity (%)	8,43	0,80		1,22	0,81	5 =		5 =			
Abbott efficacy (%)	0,00%	88,15		82,85 %	88,32 %	0 <		0 <			
Number of values	2		2	2	2	OSIRIS 65 EC 2,0 l/ha		OSIRIS 65 EC 2,0 l/ha			
Minimum value	5,88		0,06	0,13	0,06						
Maximum value	8,75	-	0,81	0,88	0,56	0 >		0 >			
Mean disease severity (%)	7,31		0,44	0,50	0,31	2 =		2 =			
Abbott efficacy (%)	0,00%		92,77	91,77 %	94,90 %	0 <		0 <			
% Disease severity L1 - 20-35 DA-B											
Number of values	6			6	6	UTC	CA3301 0,8 l/ha		UTC	CA3301 0,6 l/ha	
Minimum value	8,23			0,56	0,75						
Maximum value	16,44	-	-	9,65	10,69	5 >	0 >		6 >	0 >	
Mean disease severity (%)	11,77			4,13	3,28	1 =	6 =		0 =	6 =	
Abbott efficacy (%)	0,00%			68,19 %	75,86 %	0 <	0 <		0 <	0 <	
Number of values	3	3		3	3	CA2445 0,8 l/ha		CA2445 0,8 l/ha			
Minimum value	0,60	0,88		0,60	0,75						
Maximum value	13,63	1,69	-	2,33	1,61	0 >		0 >			
Mean disease severity (%)	11,03	1,35		1,32	1,06	3 =		3 =			
Abbott efficacy (%)	0,00%	87,85		87,37 %	90,17 %	0 <		0 <			
Number of values	4		4	4	4	OSIRIS 65 EC 2,0 l/ha		OSIRIS 65 EC 2,0 l/ha			
Minimum value	8,23		0,00	3,92	0,75						
Maximum value	16,44	-	1,48	9,65	10,69	0 >		0 >			
Mean disease severity (%)	11,94		1,06	5,35	4,31	2 =		3 =			
Abbott efficacy (%)	0,00%		93,61	58,68 %	68,98 %	2 <		1 <			

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (con-
versely for '<')

Levels of efficacy (% Abbott efficacy)

Use of CA3301 at 2x 0.6-0.8 l/ha against PUCCRE/PUCCRT – South-Eastern East EPPO zone

Summary results are presented in Table 3.2-374.

When sprayed at 0.8 l/ha, on foliar level 2, CA3301 showed 93.85% of efficacy on reduction of disease severity around two weeks after the 2nd application and 89.27% before harvest. On foliar level 1, CA3301 at 0.8 l/ha showed 100% of efficacy on reduction of disease severity around two weeks after the 2nd application and 91.36% before harvest.

In the Southern Eastern South-East EPPO zone disease severity was initially low (5.3-15%), increasing to medium severity close to harvest (6.2-56.8%). At early assessments when disease pressure was low, both rates of CA3301 demonstrated high efficacy against brown rust and were comparable to the reference products. As disease pressure increased, at later assessments, the averaged efficacy of CA3301 applied at 0.6 l/ha was medium compared to high for the rate of 0.8 l/ha and the reference products. CA3301 applied at 0.8 l/ha was comparable to or better than the reference products at all assessments. For applications of CA3301 at 0.6 l/ha, the lower content of active substance compared to CA2445 resulted in lower efficacy in some later assessments. Therefore, it is envisaged that in situations of low disease pressure CA3301 applied at 0.6 l/ha would be sufficient to control disease, but where disease pressure is medium to high a rate of 0.8 l/ha is more appropriate.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Puccinia recondita* or *Puccinia triticina* on winter wheat in the South-Eastern East EPPO zone.

Table 3.2-374: Summary table - Efficacy evaluation – Winter wheat – PUCCRE/PUCCRT – South-Eastern East EPPO zone

Treatment name	UNTREA	CA24	RISA 20	PRIAX	CA33	CA33	No of trials where			No of trials where		
Rate	TED	45	EC	OR	01	01	CA3301			CA3301		
Rate unit	CHECK	0,8	1,25	1,5	0,6	0,80	at 0,6 l/ha is >, =			at 0,8 l/ha is >, =		
Appl. Code		L/ha	L/ha	L/ha	L/ha	L/ha	or <			or <		
		AB	AB	AB	AB	AB	compared to			compared to		
% Disease severity L2 - 15-17 DA-B												
Number of values	3	3			3	3	UT	CA24	CA33	UT	CA24	CA33
							C	45	01	C	45	01

Treatment name	UNTREA TED CHECK	CA24 45 0,8 L/ha AB	RISA 20 EC 1,25 L/ha AB	PRIAX OR 1,5 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,80 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Minimum value	5,85	0,00			0,00	0,00		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	15,00	1,15	-	-	1,35	1,08	3 >	0 >	0 >	3 >	0 >	0 >
Mean disease severity (%)	8,95	0,38			0,45	0,36	0 =	3 =	3 =	0 =	3 =	3 =
Abbott efficacy (%)	0,00%	93,45 %			92,31 %	93,85 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 14-15 DA-B												
Number of values	2	2			2	2	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	5,30	0,00			0,00	0,00	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	5,50	0,00	-	-	1,25	0,00	1 =	2 =	2 =	1 =	2 =	2 =
Mean disease severity (%)	5,40	0,00			0,63	0,00						
Abbott efficacy (%)	0,00%	100,0 0%			88,64 %	100,00 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 21-43 DA-B												
Number of values	5				5	5	UTC	CA3301 0,8 l/ha		UTC	CA3301 0,6 l/ha	
Minimum value	6,23				1,34	0,30	5 >	0 >		5 >	2 >	
Maximum value	56,75	-	-	-	13,51	4,95	0 =	3 =		0 =	3 =	
Mean disease severity (%)	21,50				4,85	2,33						
Abbott efficacy (%)	0,00%				77,91 %	89,27 %	0 <	2 <		0 <	0 <	
Number of values	3	3			3	3	CA2445 0,8 l/ha			CA2445 0,8 l/ha		
Minimum value	6,23	0,66			1,34	0,30	0 >			0 >		
Maximum value	22,38	3,75	-	-	4,41	3,56	1 =			3 =		
Mean disease severity (%)	12,57	1,71			2,47	1,52	2 <			0 <		
Abbott efficacy (%)	0,00%	88,29			79,70 %	90,53 %						
Number of values	1		1		1	1	RISA 20 EC 1,25 l/ha			RISA 20 EC 1,25 l/ha		
Minimum value	13,01		3,74		3,35	2,15	0 >			1 >		
Maximum value	13,01	-	3,74	-	3,35	2,15	1 =			0 =		
Mean disease severity (%)	13,01		3,74		3,35	2,15	0 <			0 <		
Abbott efficacy (%)	0,00%		71,25%		74,25 %	83,47 %						
Number of values	1			1	1	1	PRIAXOR 1,5 l/ha			PRIAXOR 1,5 l/ha		
Minimum value	56,75			0,41	13,51	4,95	0 >			0 >		
Maximum value	56,75	-	-	0,41	13,51	4,95	1 =			1 =		
Mean disease severity (%)	56,75			0,41	13,51	4,95	0 <			0 <		
Abbott efficacy (%)	0,00%			99,28	76,19 %	91,28 %						
% Disease severity L1 - 21-43 DA-B												
Number of values	4				4	4	UTC	CA3301 0,8 l/ha		UTC	CA3301 0,6 l/ha	
Minimum value	7,43				0,55	0,00	4 >	0 >		4 >	3 >	
Maximum value	52,63	-	-	-	13,85	7,51	0 =	1 =		0 =	1 =	
Mean disease severity (%)	19,83				4,70	2,37						
Abbott efficacy (%)	0,00%				80,13 %	91,36 %	0 <	3 <		0 <	0 <	
Number of values	2	2			2	2	CA2445 0,8 l/ha			CA2445 0,8 l/ha		
Minimum value	7,43	0,00	-	-	0,55	0,00	0 >			0 >		
Maximum value	9,69	1,65	-	-	2,76	1,51	0 =			2 =		
Mean disease severity (%)	8,56	0,83			1,66	0,76						

Treatment name	UNTREA TED CHECK	CA24 45 0,8 L/ha AB	RISA 20 EC 1,25 L/ha AB	PRIAX OR 1,5 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,80 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Abbott efficacy (%)	0,00%	91,49			82,06 %	92,21 %	2 <	0 <
Number of values	1		1		1	1	RISA 20 EC 1,25 l/ha	RISA 20 EC 1,25 l/ha
Minimum value	9,56		1,39		1,65	0,45	0 >	1 >
Maximum value	9,56	-	1,39	-	1,65	0,45	1 =	0 =
Mean disease severity (%)	9,56		1,39		1,65	0,45	0 <	0 <
Abbott efficacy (%)	0,00%		85,46%		82,74 %	95,29 %		
Number of values	1			1	1	1	PRIAXOR 1,5 l/ha	PRIAXOR 1,5 l/ha
Minimum value	52,63			1,13	13,85	7,51	0 >	0 >
Maximum value	52,63	-	-	1,13	13,85	7,51	1 =	1 =
Mean disease severity (%)	52,63			1,13	13,85	7,51	0 <	0 <
Abbott efficacy (%)	0,00%			97,85%	73,68 %	85,73 %		

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

9 valid field trials were conducted in **the Maritime EPPO climatic zone**. CA3301 applied at dose rates of 0,6-0,8 l/ha achieved a medium level of effectiveness. However, on L1 and L2 after 16-18 days after second application, the test product showed the mean efficacy above 80% but it was noted in only 2 trials. 27-53 days after second application, the results were lower (60-70%) for both doses in most trials. The efficacy of the test and reference product was comparable.

10 valid field trials were conducted in **the North-East EPPO climatic zone**. CA3301 applied at dose rates of 0,6-0,8 l/ha achieved a high level of effectiveness. The efficacy amounted above 80% on L1 and L2 after 15 days after second application. The high level was noted also on L2 in the later observation (20-35 days after last application). The medium level of efficacy was noted in the same term on L1. The test product achieved 68,19% at 0,6 l/ha and 75,86% at 0,8 l/ha. No differences between test and reference products were detected.

7 valid field trials were conducted in **the South-East EPPO climatic zone**. CA3301 applied at dose rates of 0,6-0,8 l/ha achieved a high level of effectiveness. The trial results show that 14-43 days after second application the test product achieved control above 80% on L1 and L2. The efficacy of the test and reference product was comparable.

In the opinion of zRMS, CA3301 can be recommended to protection of winter wheat against *Puccinia recondite*. The higher dose rate of 0,8 l/ha should be use in case of high disease pressure.

3.2.3.24 Winter wheat (TRZAW) / *Puccinia striiformis* - *Puccinia striiformis* f. *sp. tritici* (PUCCST-PUCCSI)

Materials and Methods – Winter wheat – PUCCST-PUCCSI

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Puccinia striiformis and *Puccinia striiformis* f. *sp. tritici* are the causal agents of the yellow or stripe rust on wheat and are considered as the same pathogen in this analysis.

Between 2018 and 2020, a series of 24 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the efficacy of CA3301 against *Puccinia striiformis* or *Puccinia striiformis f. sp. tritici* on winter wheat. The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, 18 trials were performed in Czech Republic (1), Germany (2) and United Kingdom (15).

In the Mediterranean EPPO zone, 2 trials were performed in Greece (1) and Spain (1).

In the North-Eastern East EPPO zone, 1 trial was performed in Poland (1).

In the South-Eastern East EPPO zone, a total of 3 trials were performed in Hungary (1) and Romania (2) (see Table 3.2-375).

Groupings were also made specifically for Poland and trials involved (4) were performed in Poland (1), in the Czech Republic (1) and in Germany (2).

Table 3.2-375: Presentation of trials – Winter wheat (TRZAW)

Crop(s) *)	Target(s)*	Country	Year s	Type of trial*	Number of trials (number of valid trials)				GEP, non- GEP, of- ficial***	Comments (any other relevant in- formation)
					Mar- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Winter wheat	PUCCST/PUCC SI	Czech Republi- c	2018 - 2020	MED + E	1 (1)	-	-	-	GEP	
		German y	2019 - 2020	MED + E	2 (1)	-	-	-	GEP	
		United Kingdo m	2020	MED + E	15 (11)	-	-	-	GEP	
TOTA L	-	-	2018 - 2020	MED + E	18 (13)	-	-	-	GEP	
Winter wheat	PUCCST/PUCC SI	Greece	2020	MED + E	-	1 (1)	-	-	GEP	
		Spain	2020	MED + E	-	1 (1)	-	-	GEP	
TOTA L	-	-	2020	MED + E	-	2 (2)	-	-	GEP	
Winter wheat	PUCCST/PUCC SI	Poland	2020	MED + E	-	-	1 (1)	-	GEP	
TOTA L	-	-	2020	MED + E	-	-	1 (1)	-	GEP	
Winter wheat	PUCCST/PUCC SI	Hungar y	2018	MED + E	-	-	-	1 (1)	GEP	
		Romani a	2019	MED + E	-	-	-	2 (2)	GEP	
TOTA L	-	-	2018 - 2020	MED + E	-	-	-	3 (3)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-

emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation

In all trials, CA3301 was compared to at least one commercial fungicide used as standard reference for comparison.

Table 3.2-376: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – PUCST-PUCCSI – Maritime EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter wheat	PRO-LINE 250 EC	CZ	4523-1	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha max	1 x 0.6-0.8 l/ha 2 x 0.8 l/ha	CA2445 in the trial
	PRO-LINE	DE	025287-00	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE 275	UK	14790	Prothioconazole	EC	275 g/l	3 x 0.72 l/ha	2 x 0.72 l/ha	
	PRO-LINE	UK	12084	Prothioconazole	EC	250 g/l	3 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

Table 3.2-377: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – PUCST-PUCCSI – Mediterranean EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
TRZAW	PRO-LINE	GR	60838	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-SARO	ES	25661	Prothioconazole + Tebuconazole	EC	250 g/L	1 l/ha	2 x 1 L/ha	CA2445 in some trials

Table 3.2-378: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – PUCST-PUCCSI – North-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
	OSIRIS 65 EC	PL	R-87/2012	Epoxiconazole + metconazole	EC	65 g/l	1 x 1.5-2.5 l/ha	2 x 2 l/ha	

Table 3.2-379: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – PUCST-PUCCSI – ~~Southern~~ South-East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
TRZAW	PRO-LINE	RO	457PC/15/11/2018	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE	HU	6300 / 1205-1 / 2020	Prothioconazole	EC	250 g/l	2 x 0.6-0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-380.

Table 3.2-380: Details on trial methodology – Winter wheat (TRZAW) – PUCST-PUCCSI

		Maritime EPPO zone	Mediterranean EPPO zone	North –East EPPO zone	South-Eastern EPPO zone	Data relevant for Poland
Trials	Total number (valid number)	18 (18)	2 (2)	1 (1)	3 (3)	4 (3)
	Supportive trials	-	-	-	-	-
Guidelines	General guidelines	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3) PP 1/225 (2)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)
	Specific guidelines	PP 1/26 (4) PP 1/28 (3) PP 1/262 (1)	PP 1/26 (4)	PP 1/26 (4)	PP 1/26 (4)	PP 1/26 (4)
Experimental design	Plot design	Randomized Complete Blocks, Un-treated included	Randomized Complete Blocks, Un-treated included	Randomized Complete Blocks, Un-treated included	Randomized Complete Blocks, Un-treated included	Randomized Complete Blocks, Un-treated included
	Plot size	15-36 m ²	21 m ²	21 m ²	21-30 m ²	21-30 m ²
	Number of replications	4	4	4	4	4
Crop	Trials per crop	TRZAW (18)	TRZAW (2)	TRZAW (1)	TRZAW (3)	TRZAW (4)
	Varieties per crop	Arkeos (1), Bel-epi (2), Claire (1), Skyscraper (1), Skyfall (6), Bennington (2), Gleam (1), Monopol (1), Tobak (1), Reflection (1), RGT Gravity (1)	Yecora (1), Ibiza (1)	Banderola	GK Békés (1), Izvor (1), Miranda (1)	Banderola (1), Arkeos (1), Monopol (1), Tobak (1)
	Sowing period	January (1), September (1)	November (1), December (1)	October	October (3)	October (4)

		October (12), November (3), December (1)				
Application	Crop stage (BBCH)* at application	A : BBCH 31-39 B: BBCH 39-65	A: BBCH 37 B: BBCH 58-65	A: BBCH 30 B: BBCH 57	A: BBCH 33-47 B: BBCH 59-65	A: BBCH 30-37 B: BBCH 39-65
	Timing Pest stage at application	BBCH 30-69 A: MIXED (8), PRINFC (6), ACTIVE (3), N/A (1) B: MIXED (10), PRINFC (4), ACTIVE (3), N/A (1)	BBCH 30-69 A: PRINFC (2) B: MIXED (1), PRINFC (1)	BBCH 30-69 A: PRINFC B: PRINFC	BBCH 30-69 A: MIXED (1), PRINFC (2) B: MIXED (1), SPORUL (2)	BBCH 30-69 A: PRINFC (3), MIXED (1) B: PRINFC (3), MIXED (1)
	Number of applications Intervals between applications	1 application (1) 2 applications (17-35 days) (18)	2 applications (17-21 days) (2)	2 applications (49 days)	1 application (1) 2 applications (14-28 days) (3)	1 application (1) 2 applications (17-49 days) (4)
	Spray volumes	A: 150-300 l/ha B: 150-500 l/ha*	A: 250-400 l/ha B: 250-400 l/ha	A: 300 l/ha B: 300 l/ha	A: 200-400 l/ha B: 250- 400 l/ha	A: 200-300 l/ha B: 200-500 l/ha*
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 or 0-100)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 or 0-100)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10)
	Assessment dates	0 DA-A, 8-18 DA-A, -1-0 DA-B, 14-19 DA-B, 27-46 DA-B, 56-80 DA-B	0 DA-A, 0 DA-B, 15-16 DA-B, 22 DA-B	0 DA-A, 15 DA-A, 0 DA-B, 15 DA-B, 35 DA-B	0 DA-A, 14-15 DA-A, 0 DA-B, 14-17 DA-B, 27-36 DA-B	0 DA-A, 8-15 DA-A, 0 DA-B, 14-19 DA-B, 28-56 DA-B, 70 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Natural (18)	Natural (2)	Natural (1)	Natural (3)	Natural (4)
	e.g. Field / Greenhouse...	Field trials	Field trials	Field trials	Field trials	Field trials

*In a few trials the water volume applied was 500 l/ha. This small deviation did not impact the validity of the trials.

24 trials were carried out against *Puccinia striiformis* (PUCCST) and *Puccinia striiformis f. sp. tritici* (PUCCSI) on winter wheat.

Use of CA3301 at 2x 0.6-0.8 l/ha against PUCCST-PUCCSI– Maritime EPPO zone

In the Maritime EPPO zone, 18 trials were available against *Puccinia striiformis* (PUCCST) or *Puccinia striiformis f. sp. tritici* (PUCCSI), on winter wheat. 13 trials out of 18 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.8 l/ha applied twice, compared to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 31-39 and the 2nd application was at BBCH 39-65.

Summary results are presented in Table 3.2-381.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.8 l/ha to control yellow rust. On foliar level 2, at this dose rate, CA3301 showed 90.85% of efficacy to control the disease two weeks after the 2nd application and 83.49% before harvest. On foliar level 1, CA3301 at 0.8 l/ha showed 92.30% of efficacy on reduction of disease severity around two weeks after the 2nd application and 83.41% before harvest.

In the Maritime EPPO zone, the disease severity of yellow rust on winter wheat was initially low to medium, increasing to high disease severity (88-100% in some trials) as the trials progressed. Following the second application (14-19 DA-B), high efficacy was again observed from both dose rates on both leaf levels, comparable to the reference standards. At the assessment close to harvest, high efficacy was maintained for CA3301 at 0.8 l/ha at both leaf levels, and for 0.6 l/ha on L1. For this lower dose rate however, the efficacy was slightly lower (medium efficacy) on L2. Therefore, the dataset demonstrates that CA3301 applied at 0.6 l/ha can be sufficient to provide medium to high efficacy against yellow rust, but in some instances there is a benefit in increasing the dose rate to 0.8 l/ha to provide fuller control close to harvest, for example where disease pressure is high.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Puccinia striiformis* or *Puccinia striiformis* f. sp. *tritici* on winter wheat in the Maritime EPPQ zone.

Table 3.2-381: Summary table - Efficacy evaluation – Winter wheat – PUC CST-PUC CSI - Mari-time EPPO zone

time L1 L2 L3 L4 L5 L6 L7 L8 L9 L10 L11 L12 L13 L14 L15 L16 L17 L18 L19 L20 L21 L22 L23 L24 L25 L26 L27 L28 L29 L30 L31 L32 L33 L34 L35 L36 L37 L38 L39 L40 L41 L42 L43 L44 L45 L46 L47 L48 L49 L50 L51 L52 L53 L54 L55 L56 L57 L58 L59 L60 L61 L62 L63 L64 L65 L66 L67 L68 L69 L70 L71 L72 L73 L74 L75 L76 L77 L78 L79 L80 L81 L82 L83 L84 L85 L86 L87 L88 L89 L90 L91 L92 L93 L94 L95 L96 L97 L98 L99 L100 L101 L102 L103 L104 L105 L106 L107 L108 L109 L110 L111 L112 L113 L114 L115 L116 L117 L118 L119 L120 L121 L122 L123 L124 L125 L126 L127 L128 L129 L130 L131 L132 L133 L134 L135 L136 L137 L138 L139 L140 L141 L142 L143 L144 L145 L146 L147 L148 L149 L150 L151 L152 L153 L154 L155 L156 L157 L158 L159 L160 L161 L162 L163 L164 L165 L166 L167 L168 L169 L170 L171 L172 L173 L174 L175 L176 L177 L178 L179 L180 L181 L182 L183 L184 L185 L186 L187 L188 L189 L190 L191 L192 L193 L194 L195 L196 L197 L198 L199 L200 L201 L202 L203 L204 L205 L206 L207 L208 L209 L210 L211 L212 L213 L214 L215 L216 L217 L218 L219 L220 L221 L222 L223 L224 L225 L226 L227 L228 L229 L230 L231 L232 L233 L234 L235 L236 L237 L238 L239 L240 L241 L242 L243 L244 L245 L246 L247 L248 L249 L250 L251 L252 L253 L254 L255 L256 L257 L258 L259 L260 L261 L262 L263 L264 L265 L266 L267 L268 L269 L270 L271 L272 L273 L274 L275 L276 L277 L278 L279 L280 L281 L282 L283 L284 L285 L286 L287 L288 L289 L290 L291 L292 L293 L294 L295 L296 L297 L298 L299 L300 L301 L302 L303 L304 L305 L306 L307 L308 L309 L310 L311 L312 L313 L314 L315 L316 L317 L318 L319 L320 L321 L322 L323 L324 L325 L326 L327 L328 L329 L330 L331 L332 L333 L334 L335 L336 L337 L338 L339 L340 L341 L342 L343 L344 L345 L346 L347 L348 L349 L350 L351 L352 L353 L354 L355 L356 L357 L358 L359 L360 L361 L362 L363 L364 L365 L366 L367 L368 L369 L370 L371 L372 L373 L374 L375 L376 L377 L378 L379 L380 L381 L382 L383 L384 L385 L386 L387 L388 L389 L390 L391 L392 L393 L394 L395 L396 L397 L398 L399 L400 L401 L402 L403 L404 L405 L406 L407 L408 L409 L410 L411 L412 L413 L414 L415 L416 L417 L418 L419 L420 L421 L422 L423 L424 L425 L426 L427 L428 L429 L430 L431 L432 L433 L434 L435 L436 L437 L438 L439 L440 L441 L442 L443 L444 L445 L446 L447 L448 L449 L450 L451 L452 L453 L454 L455 L456 L457 L458 L459 L460 L461 L462 L463 L464 L465 L466 L467 L468 L469 L470 L471 L472 L473 L474 L475 L476 L477 L478 L479 L480 L481 L482 L483 L484 L485 L486 L487 L488 L489 L490 L491 L492 L493 L494 L495 L496 L497 L498 L499 L500 L501 L502 L503 L504 L505 L506 L507 L508 L509 L510 L511 L512 L513 L514 L515 L516 L517 L518 L519 L520 L521 L522 L523 L524 L525 L526 L527 L528 L529 L530 L531 L532 L533 L534 L535 L536 L537 L538 L539 L540 L541 L542 L543 L544 L545 L546 L547 L548 L549 L550 L551 L552 L553 L554 L555 L556 L557 L558 L559 L560 L561 L562 L563 L564 L565 L566 L567 L568 L569 L570 L571 L572 L573 L574 L575 L576 L577 L578 L579 L580 L581 L582 L583 L584 L585 L586 L587 L588 L589 L590 L591 L592 L593 L594 L595 L596 L597 L598 L599 L600 L601 L602 L603 L604 L605 L606 L607 L608 L609 L610 L611 L612 L613 L614 L615 L616 L617 L618 L619 L620 L621 L622 L623 L624 L625 L626 L627 L628 L629 L630 L631 L632 L633 L634 L635 L636 L637 L638 L639 L640 L641 L642 L643 L644 L645 L646 L647 L648 L649 L650 L651 L652 L653 L654 L655 L656 L657 L658 L659 L660 L661 L662 L663 L664 L665 L666 L667 L668 L669 L670 L671 L672 L673 L674 L675 L676 L677 L678 L679 L680 L681 L682 L683 L684 L685 L686 L687 L688 L689 L690 L691 L692 L693 L694 L695 L696 L697 L698 L699 L700 L701 L702 L703 L704 L705 L706 L707 L708 L709 L710 L711 L712 L713 L714 L715 L716 L717 L718 L719 L720 L721 L722 L723 L724 L725 L726 L727 L728 L729 L730 L731 L732 L733 L734 L735 L736 L737 L738 L739 L740 L741 L742 L743 L744 L745 L746 L747 L748 L749 L750 L751 L752 L753 L754 L755 L756 L757 L758 L759 L760 L761 L762 L763 L764 L765 L766 L767 L768 L769 L770 L771 L772 L773 L774 L775 L776 L777 L778 L779 L780 L781 L782 L783 L784 L785 L786 L787 L788 L789 L790 L791 L792 L793 L794 L795 L796 L797 L798 L799 L800 L801 L802 L803 L804 L805 L806 L807 L808 L809 L810 L811 L812 L813 L814 L815 L816 L817 L818 L819 L820 L821 L822 L823 L824 L825 L826 L827 L828 L829 L830 L831 L832 L833 L834 L835 L836 L837 L838 L839 L840 L841 L842 L843 L844 L845 L846 L847 L848 L849 L850 L851 L852 L853 L854 L855 L856 L857 L858 L859 L860 L861 L862 L863 L864 L865 L866 L867 L868 L869 L870 L871 L872 L873 L874 L875 L876 L877 L878 L879 L880 L881 L882 L883 L884 L885 L886 L887 L888 L889 L890 L891 L892 L893 L894 L895 L896 L897 L898 L899 L900 L901 L902 L903 L904 L905 L906 L907 L908 L909 L910 L911 L912 L913 L914 L915 L916 L917 L918 L919 L920 L921 L922 L923 L924 L925 L926 L927 L928 L929 L930 L931 L932 L933 L934 L935 L936 L937 L938 L939 L940 L941 L942 L943 L944 L945 L946 L947 L948 L949 L950 L951 L952 L953 L954 L955 L956 L957 L958 L959 L960 L961 L962 L963 L964 L965 L966 L967 L968 L969 L970 L971 L972 L973 L974 L975 L976 L977 L978 L979 L980 L981 L982 L983 L984 L985 L986 L987 L988 L989 L990 L991 L992 L993 L994 L995 L996 L997 L998 L999 L1000 L1001 L1002 L1003 L1004 L1005 L1006 L1007 L1008 L1009 L1010 L1011 L1012 L1013 L1014 L1015 L1016 L1017 L1018 L1019 L1020 L1021 L1022 L1023 L1024 L1025 L1026 L1027 L1028 L1029 L1030 L1031 L1032 L1033 L1034 L1035 L1036 L103									
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Treatment name	UNTREAT ED CHECK	PROLINE 275	CA24 45	CA330 1	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		0,72	0,8	0,6	0,8	UT C	CA330 1 0,8 l/ha	UT C	CA330 1 0,6 l/ha
Rate unit		L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB				
Number of values		5		5	5				
Minimum value		6,48		0,00	0,00				
Maximum value	50,63	-	-	3,90	2,15	5 >	0 >	5 >	0 >
Mean disease severity (%)	24,98			1,35	0,99	0 =	5 =	0 =	5 =
Abbott efficacy (%)	0,00%			93,63%	92,30 %	0 <	0 <	0 <	0 <
Number of values	1	1		1	1	PROLINE 275		PROLINE 275	
Minimum value	8,50	0,24		0,09	1,78	0,72 l/ha		0,72 l/ha	
Maximum value	8,50	0,24	-	0,09	1,78	0 >		0 >	
Mean disease severity (%)	8,50	0,24		0,09	1,78	1 =		1 =	
Abbott efficacy (%)	0,00%	97,18%		98,94%	79,06 %	0 <		0 <	
Number of values	4		4	4	4	CA2445		CA2445	
Minimum value	6,48		0,00	0,00	0,00	0,8 l/ha		0,8 l/ha	
Maximum value	50,63	-	5,35	3,90	2,15	0 >		1 >	
Mean disease severity (%)	29,11		1,85	1,67	0,80	4 =		3 =	
Abbott efficacy (%)	0,00%		92,25 %	92,30%	95,61 %	0 <		0 <	
% Disease severity L2 - 27-46 DA-B									
Number of values	11			11	11	UT C	CA330 1 0,8 l/ha	UT C	CA330 1 0,6 l/ha
Minimum value	5,24			0,00	0,00				
Maximum value	100,00	-	-	48,88	30,38				
Mean disease severity (%)	46,58			11,18	7,70				
Abbott efficacy (%)	0,00%			79,27%	83,49 %				
Number of values	4	4		4	4	PROLINE 275		PROLINE 275	
Minimum value	5,24	0,00		0,00	0,00	0,72 l/ha		0,72 l/ha	
Maximum value	82,06	13,66	-	18,20	11,49	0 >		1 >	
Mean disease severity (%)	28,90	6,58		8,12	5,37	3 =		3 =	
Abbott efficacy (%)	0,00%	81,94%		75,64%	85,52 %	1 <		0 <	
Number of values	7		7	7	7	CA2445		CA2445	
Minimum value	8,44		0,00	0,00	0,00	0,8 l/ha		0,8 l/ha	
Maximum value	100,00	-	80,94	48,88	30,38	1 >		2 >	
Mean disease severity (%)	56,69		17,45	12,93	9,04	6 =		4 =	
Abbott efficacy (%)	0,00%		78,97 %	81,35%	82,32 %	0 <		1 <	
% Disease severity L1 - 27-46 DA-B									
Number of values	10			10	10	UT C	CA330 1 0,8 l/ha	UT C	CA330 1 0,6 l/ha
Minimum value	5,58			0,00	0,00				
Maximum value	88,94	-	-	17,18	19,68				
Mean disease severity (%)	35,48			5,15	4,91				

Treatment name	UNTREAT ED CHECK	PROLINE 275 0,72 L/ha AB	CA24 45 0,8 L/ha AB	CA330 1 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Abbott efficacy (%)	0,00%			83,22%	83,41 %	0 < 3 <	0 < 1 <
Number of values	3	3		3	3	PROLINE 275 0,72 l/ha	PROLINE 275 0,72 l/ha
Minimum value	5,58	0,45		2,38	0,75	0 >	0 >
Maximum value	42,00	10,33	-	11,05	9,89	2 =	3 =
Mean disease severity (%)	19,27	4,49		5,65	4,54	1 <	0 <
Abbott efficacy (%)	0,00%	82,34%		65,54%	77,99 %		
Number of values	7		7	7	7	CA2445 0,8 l/ha	CA2445 0,8 l/ha
Minimum value	9,13		0,15	0,00	0,00	2 >	2 >
Maximum value	88,94	-	42,88	17,18	19,68	5 =	4 =
Mean disease severity (%)	41,52		8,98	4,88	5,00	0 <	1 <
Abbott efficacy (%)	0,00%		85,50 %	90,79%	85,73 %		

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against PuccST-PuccSI– Mediterranean EPPO zone

In the Mediterranean EPPO zone, 2 trials were available against *Puccinia striiformis* (PuccST) or *Puccinia striiformis f. sp. tritici* (PuccSI), on winter wheat. All 2 trials were considered valid (and were included to support the efficacy evaluation of CA3301 at 0.6-0.8 l/ha applied twice, compared to the reference products on disease severity (%). CA3301 was first applied at crop stage BBCH 37 and the 2nd application was at BBCH 58-65.

Summary results are presented in Table 3.2-383.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control the severity of yellow rust. On foliar level 2, at this dose rate, CA3301 showed 70.64% of efficacy two weeks after the 2nd application. On foliar level 1, CA3301 at 0.6 l/ha showed 89.08% around two weeks after the 2nd application and 89.83% before harvest.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.8 l/ha to control yellow rust. On foliar level 2, at this dose rate, CA3301 showed 81.85% two weeks after the 2nd application. On foliar level 1, CA3301 at 0.8 l/ha showed 89.35% around two weeks after the 2nd application and 89.60% before harvest.

In the Mediterranean EPPO zone, with a limited dataset for this pathogen, a consistent trend was however observed whereby applications of CA3301 resulted in medium to high efficacy comparable to that of the authorised reference products throughout the assessments. In this dataset, where the majority of assessments were made in conditions of relatively low disease pressure there were no statistical differences in control of yellow rust between the dose rates of 0.6 l/ha and 0.8 l/ha, although a trend was observed for lower disease with higher dose rate. However, a larger dataset has been presented for the closely associated pathogen brown rust in the Mediterranean zone, which demonstrates the same trends, and can be supportive for the species yellow rust. The dataset for brown rust in the Mediterranean zone

demonstrated a benefit in increasing the dose rate to 0.8 l/ha in situations of high disease pressure, therefore it is highly probable that the slight increase in control of yellow rust provided by 0.8 l/ha seen in this dataset would be of significant benefit in situations of greater disease incidence.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Puccinia striiformis* or *Puccinia striiformis* f. sp. *tritici* on winter wheat in the Mediterranean EPPO zone.

Table 3.2-382: Summary table - Efficacy evaluation – Winter wheat – PUCST-PUCCSI - Mediterranean EPPO zone

Treatment name	UNTREAT ED CHECK	CA24 45 0,8 L/ha AB	PROSA RO 1 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to					
% Disease severity L2 - 15-16 DA-B													
Number of values	2	2	-	2	2	UTC	CA3301 0,8 l/ha	UTC	CA3301 0,6 l/ha				
Minimum value	16,94	1,64		2,35	1,86	2 >	0 >	2 >	0 >				
Maximum value	33,18	18,03		14,88	8,40	0 =	2 =	0 =	2 =				
Mean disease severity (%)	25,06	9,83		8,61	5,13	0 <	0 <	0 <	0 <				
Abbott efficacy (%)	0,00%	67,99 %		70,64 %	81,85 %								
Number of values	1	1	1	1	1	CA2445 0,8 l/ha	PROSARO 1,0 l/ha	CA2445 0,8 l/ha	PROSARO 1,0 l/ha				
Minimum value	16,94	1,64	1,75	2,35	1,86	0 >	0 >	1 >	0 >				
Maximum value	16,94	1,64	1,75	2,35	1,86	2 =	1 =	1 =	1 =				
Mean disease severity (%)	16,94	1,64	1,75	2,35	1,86								
Abbott efficacy (%)	0,00%	90,32 %	89,67%	86,13 %	89,02 %	0 <	0 <	0 <	0 <				
% Disease severity L1 - 15-16 DA-B													
Number of values	2	2	-	2	2	UTC	CA3301 0,8 l/ha	UTC	CA3301 0,6 l/ha				
Minimum value	15,20	2,13		1,75	1,53	2 >	0 >	2 >	0 >				
Maximum value	26,53	2,58		2,74	2,98	0 =	2 =	0 =	2 =				
Mean disease severity (%)	20,86	2,35		2,24	2,25	0 <	0 <	0 <	0 <				
Abbott efficacy (%)	0,00%	88,13 %		89,08 %	89,35 %								
Number of values	1	1	1	1	1	CA2445 0,8 l/ha	PROSARO 1,0 l/ha	CA2445 0,8 l/ha	PROSARO 1,0 l/ha				
Minimum value	26,53	2,58	2,00	2,74	2,98	0 >	0 >	0 >	0 >				
Maximum value	26,53	2,58	2,00	2,74	2,98	2 =	1 =	2 =	1 =				
Mean disease severity (%)	26,53	2,58	2,00	2,74	2,98								
Abbott efficacy (%)	0,00%	90,28 %	92,46%	89,67 %	88,77 %	0 <	0 <	0 <	0 <				
% Disease severity L1 - 22 DA-B													
Number of values	1	1	1	1	1	UT C	CA24 45 0,8 l/ha	PRO- SARO 1,0 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	PRO- SARO 1,0 l/ha	CA33 01 0,6 l/ha
Minimum value	51,94	5,96	3,75	5,28	5,40								
Maximum value	51,94	5,96	3,75	5,28	5,40	1 >	0 >	0 >	0 >	1 >	0 >	0 >	0 >
Mean disease severity (%)	51,94	5,96	3,75	5,28	5,40	0 =	1 =	1 =	1 =	0 =	1 =	1 =	1 =
Abbott efficacy (%)	0,00%	88,53 %	92,78%	89,83 %	89,60 %	0 <	0 <	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)
>80% High efficacy
60-80% Medium efficacy

<60% Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against PuccST-PuccSI – North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a single was available against *Puccinia striiformis* (PuccST) or *Puccinia striiformis f. sp. tritici* (PuccSI), on winter wheat. This trial was considered valid and was included to support the efficacy evaluation of CA3301 at 0.6-0.8 l/ha applied twice, compared to the reference products on disease severity (%). CA3301 was first applied at crop stage BBCH 30 and the 2nd application was at BBCH 57.

Summary results are presented in Table 3.2-384.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control the severity of yellow rust. On foliar level 1, CA3301 at 0.6 l/ha showed 79.04% before harvest on winter wheat and 91.08% when applied at 0.8 l/ha.

In the North-Eastern East EPPO zone, a very limited dataset was available for this pathogen, mainly due to the low to medium presence of this disease in the area. Nevertheless, applications of CA3301 at 0.6-0.8 l/ha demonstrated medium to high efficacy comparable to the reference standards in conditions of low disease pressure. Furthermore, the rate of 0.6 l/ha of CA3301 demonstrated slightly lower (medium) efficacy compared to 0.8 l/ha (high efficacy). However, a larger dataset has been presented for the closely associated pathogen brown rust in the North-Eastern East zone, which demonstrates the same trends, and can be supportive for the species yellow rust. Therefore, it is proposed that the dose rate of 0.6 l/ha to is used for instances of low disease pressure and an increased rate of 0.8 l/ha for high disease pressure.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Puccinia striiformis* or *Puccinia striiformis f. sp. tritici* on winter wheat in the North-Eastern East EPPO zone.

Table 3.2-383: Summary table - Efficacy evaluation – Winter wheat – PuccST-PuccSI – North-Eastern East EPPO zone

Treatment name	UNTR EATE	CA2 445	OSIRI S 65 EC	CA3 301	CA 330 1	No of trials where CA3301				No of trials where CA3301			
Rate	D	0,8	2	0,6	0,8	at 0,6 l/ha is >, = or <				at 0,8 l/ha is >, = or <			
Rate unit	CHEC K	L/ha	L/ha	L/ha	L/h a	compared to				compared to			
Appl. Code		AB	AB	AB	AB								
% Disease severity L1 - 35 DA-B													
Number of values	1	1	1	1	1	U T C	CA 244 5 0,8 l/ha	OSI- RIS 65 EC 2,0 l/ha	CA3 301 0,8 l/ha	U T C	CA2 445 0,8 l/ha	OSI- RIS 65 EC 2,0 l/ha	CA 330 1 0,6 l/ha
Minimum value	7,06	0,69	1,06	1,48	0,6 3	1 >	0 >	0 >	0 >	1 >	0 >	0 >	0 >
Maximum value	7,06	0,69	1,06	1,48	0,6 3	0 =	1 =	1 =	1 =	0 =	1 =	1 =	1 =
Mean disease severity (%)	7,06	0,69	1,06	1,48	0,6 3	0 =	1 =	1 =	1 =	0 =	1 =	1 =	1 =
Abbott efficacy (%)	0,00%	90,2 3%	84,99%	79,0 4%	91, 08 %	0 <	0 <	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80% High efficacy
60-80% Medium efficacy

<60% Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against PUCCST-PUCCSI – South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, 3 trials were available against *Puccinia striiformis* (PUCCST) or *Puccinia striiformis f. sp. tritici* (PUCCSI), on winter wheat. All 3 trials were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.8 l/ha applied twice, compared to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 33-47 and the 2nd application was at BBCH 59-65.

Summary results are presented in Table 3.2-384.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control the severity of yellow rust. On foliar level 2, CA3301 showed 63.83% two weeks after the 2nd application and 99.36% before harvest. On foliar level 1, CA3301 at 0.8 l/ha showed 65.81% around two weeks after the 2nd application and 99.66% before harvest.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.8 l/ha to control yellow rust. On foliar level 2, at this dose rate, CA3301 showed 72.89% of efficacy to control the disease two weeks after the 2nd application and 99.50% before harvest. On foliar level 1, CA3301 at 0.8 l/ha showed 73.03% of efficacy on reduction of disease severity around two weeks after the 2nd application and 99.62% before harvest.

In the South-Eastern East EPPO zone, a limited dataset was available for this pathogen. Nevertheless, applications of CA3301 at 0.6-0.8 l/ha demonstrated medium to high efficacy in conditions of relatively low disease pressure. At the rate of 0.8 l/ha CA3301 was always comparable to the reference standard. Applied at 0.6 l/ha CA3301 gave significant lower disease control compared to the reference standard, containing more prothioconazole and compared to 0.8 l/ha rate at early assessments. Furthermore, the rate of 0.6 l/ha of CA3301 demonstrated slightly lower (medium) efficacy compared to 0.8 l/ha (high efficacy) on L2 at this time. However, final assessments showed very high efficacy against yellow rust for both dose rates (99%). A larger dataset has been presented for the closely associated pathogen brown rust in the South-Eastern zone, which demonstrates the same trends, and can be supportive for the species yellow rust. In that dataset where disease pressure increased there was an observed benefit in increasing the dose rate of CA3301 to 0.8 l/ha. Therefore, it is proposed that the dose rate of 0.6 l/ha to be used for instances of low disease pressure and an increased rate of 0.8 l/ha for high disease pressure.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Puccinia striiformis* or *Puccinia striiformis f. sp. tritici* on winter wheat in the South-Eastern East EPPO zone.

Table 3.2-384: Summary table - Efficacy evaluation – Winter wheat – PUCCST-PUCCSI – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA24 45	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		0,8	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Disease severity L2 -17 DA-B										
Number of values	1	1	1	1	UT C	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UTC	CA244 5 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	12,69	3,28	4,59	3,44	1 >	0 >	0 >	1 >	0 >	1 >
Maximum value	12,69	3,28	4,59	3,44	0 =	0 =	0 =	0 =	1 =	0 =
Mean disease severity (%)	12,69	3,28	4,59	3,44	0 <	1 <	1 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	74,15 %	63,83 %	72,89 %						

% Disease severity L1 -17 DA-B										
Number of values	1	1	1	1	UT C	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UTC	CA244 5 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	18,28	4,73	6,25	4,93						
Maximum value	18,28	4,73	6,25	4,93	1 >	0 >	0 >	1 >	0 >	1 >
Mean disease severity (%)	18,28	4,73	6,25	4,93	0 =	0 =	0 =	0 =	1 =	0 =
Abbott efficacy (%)	0,00%	74,12 %	65,81 %	73,03 %	0 <	1 <	1 <	0 <	0 <	0 <
% Disease severity L2 - 27-36 DA-B										
Number of values	2	2	2	2	UT C	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UTC	CA244 5 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	5,16	0,02	0,04	0,02						
Maximum value	29,56	0,15	0,15	0,18	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	17,36	0,08	0,09	0,10	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	99,55 %	99,36 %	99,50 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 27-36 DA-B										
Number of values	1	1	1	1	UT C	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UTC	CA244 5 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	20,88	0,06	0,07	0,08						
Maximum value	20,88	0,06	0,07	0,08	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	20,88	0,06	0,07	0,08	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	99,71 %	99,66 %	99,62 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)	
>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against PuccST-PuccSI– Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, a total of 4 trials evaluated the efficacy of CA3301 on winter wheat against *Puccinia striiformis* (PuccST) or *Puccinia striiformis f. sp. tritici* (PuccSI). 3 trials out of 4 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.8 l/ha applied twice, compared to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 30-37 and the 2nd application was at BBCH 39-65.

Summary results are presented in Table 3.2-385.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control the severity of yellow rust. On foliar level 2, at this dose rate, CA3301 showed 81.04% of efficacy to control the disease two weeks after the 2nd application and 79.15% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 83.95% of efficacy on reduction of disease severity around two weeks after the 2nd application and 85.25% before harvest.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.8 l/ha to control yellow rust. On foliar level 2, at this dose rate, CA3301 showed 85.71% of efficacy to control the disease two weeks after the 2nd application and 49.05% before harvest. On foliar level 1,

CA3301 at 0.8 l/ha showed 89.35% of efficacy on reduction of disease severity around two weeks after the 2nd application and 68.81% before harvest.

A limited dataset was available in Poland and neighbouring countries and the disease severity of yellow rust on winter wheat relatively low (6.48-8.44%). Overall CA3301 at 0.6-0.8 l/ha provided a high efficacy and gave equivalent disease control to the reference product, except in 1 trial in which the efficacy of the 0.8 l/ha dose rate was lower than the 0.6 l/ha dose rate. At the exception of this trial, the dataset demonstrated that CA3301 applied at 0.6 l/ha can be sufficient to provide a high efficacy against yellow rust, but that increasing the dose rate to 0.8 l/ha to provide fuller control close to harvest could be beneficial when disease pressure is high. In addition, this trend is also observed on the similar pathogen brown rust in similar climatic conditions.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Puccinia striiformis* or *Puccinia striiformis* f. sp. *tritici* on winter wheat in Poland.

Table 3.2-385: Summary table - Efficacy evaluation – Winter wheat – PUCGST-PUCCSI – Data relevant for Poland

Relevant for Poland											
Treatment name	UNTRE ATED CHECK	CA24 45	OSIRIS 65 EC	CA3 301	CA33 01	No of trials where CA3301			No of trials where CA3301		
Rate		0,8	2	0,6	0,8	at 0,6 l/ha is >, = or <			at 0,8 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	AB	compared to			compared to		
% Disease severity L2 - 19 DA-B											
Number of values	1	1		1	1	U TC	CA24 45	CA3 301	U TC	CA244 5	CA3 301
Minimum value	7,70	1,34		1,46	1,10		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	7,70	1,34	-	1,46	1,10	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	7,70	1,34		1,46	1,10	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	82,60 %		81,0 4%	85,71 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 19 DA-B											
Number of values	1	1		1	1	U TC	CA24 45	CA3 301	U TC	CA244 5	CA3 301
Minimum value	6,48	0,85		1,04	0,69		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	6,48	0,85	-	1,04	0,69	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	6,48	0,85		1,04	0,69	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	86,88 %		83,9 5%	89,35 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 46 DA-B											
Number of values	1	1		1	1	U TC	CA24 45	CA3 301	U TC	CA244 5	CA3 301
Minimum value	8,44	0,30		1,76	4,30		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	8,44	0,30	-	1,76	4,30	1 >	0 >	1 >	1 >	0 >	0 >
Mean disease severity (%)	8,44	0,30		1,76	4,30	0 =	1 =	0 =	0 =	0 =	0 =
Abbott efficacy (%)	0,00%	96,45 %		79,1 5%	49,05 %	0 <	0 <	0 <	0 <	1 <	1 <
% Disease severity L1 - 35-46 DA-B											
Number of values	2	2		2	2	UTC	CA3301		UTC	CA3301	
Minimum value	7,06	0,69		0,78	0,63		0,8 l/ha			0,6 l/ha	
Maximum value	9.13	0.93	-	1.48	4.88	2 >	1 >		2 >	0 >	

Mean disease severity (%)	8,09	0,81		1,13	2,75	0 =	1 =	0 =	1 =
Abbott efficacy (%)	0,00%	90,02 %		85,2 5%	68,81 %	0 <	0 <	0 <	1 <
Number of values	1	1	1	1	1	CA244 5	OSIRIS 65 EC	CA2445	OSIRIS 65 EC
Minimum value	7,06	0,69	1,06	1,48	0,63	0,8 l/ha	2,0 l/ha	0,8 l/ha	2,0 l/ha
Maximum value	7,06	0,69	1,06	1,48	0,63	0 >	0 >	0 >	0 >
Mean disease severity (%)	7,06	0,69	1,06	1,48	0,63	2 =	1 =	1 =	1 =
Abbott efficacy (%)	0,00%	90,23 %	84,99%	79,0 4%	91,08 %	0 <	0 <	1 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

13 valid field trials were conducted in **the Maritime EPPO climatic zone**. CA3301 applied at dose rates of 0,6-0,8 l/ha achieved a high level of effectiveness. On L1 and L2 after 14-46 days after second application, the test product showed the mean efficacy above 80%. The efficacy of the test and reference product was comparable. Only 1 valid field trial was conducted in **the North-East EPPO climatic zone**. CA3301 applied at dose rates of 0,8 l/ha achieved a high level of effectiveness. The dose rate of 0,6 l/ha caused efficacy reduction to 79%. The limited number of trials has been submitted for NE zone. The extrapolation results from trials conducted in Germany and Czech Republic can be used to support the efficacy evaluation. However, total of 4 trials is still insufficient number of trials in the opinion of zRMS. No differences between test and reference products were detected.

3 valid field trials were conducted in **the South-East EPPO climatic zone**. CA3301 applied at dose rates of 0,6-0,8 l/ha achieved a medium level of effectiveness after 17 days after second application. The trial results show that 27-36 days after second application the effectiveness increased to above 90%. In the opinion of zRMS the number of trials is not sufficient to efficacy evaluation. 2 field trials conducted in Spain and Greece were presented to support of product registration in SE zone. CA3301 controlled PuccST on high level. The efficacy of the test and reference product was comparable. Because total number of trials is still too low, the cMSs are kindly asked to consider this use on the national level.

In the opinion of zRMS, CA3301 can be recommended to protection of winter wheat against *Puccinia striiformis* in the Maritime EPPO climatic zone. The higher dose rate of 0,8 l/ha should be used in case of high disease pressure.

3.2.3.25 Winter wheat (TRZAW) / *Blumeria graminis* (ERYSGR-ERYSGT)

Materials and Methods – Winter wheat – ERYSGR-ERYSGT

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Blumeria graminis and *Blumeria graminis* f. sp. *tritici* are the causal agents of the powdery mildew on wheat and are considered as the same pathogen in this analysis.

Between 2017 and 2020, a series of 51 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the efficacy of CA3301 against *Blumeria graminis* or *Blumeria graminis* f. sp. *tritici* on **winter wheat**. The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, 15 trials were performed in Czech Republic (7), Germany (3), United Kingdom (3) and France (2).

In the Mediterranean EPPO zone, 7 trials were performed in Southern France (4), Spain (2) and Portugal (1).

In the North-Eastern EPPO zone, 19 trials were performed in Poland (12), Lithuania (5) and Latvia (2).

In the South-Eastern EPPO zone, a total of 10 trials were performed in Hungary (4), Romania (4) and Slovakia (2) (see Table 3.2-386).

Table 3.2-386: Presentation of trials – Winter wheat (TRZAW)

Crop(s) *	Tar- get(s)*	Country	Year s	Type of trial*	Number of trials (number of valid trials)				GEP, non-GEP, offi- cial***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Winter wheat	ERYSGR / ERYSGT	Czech Republic	2017- 2019	MED + E	7 (7)	-	-	-	GEP	
		Germany	2019- 2020	MED + E	3 (3)	-	-	-	GEP	
		United Kingdo m	2019- 2020	MED + E	3 (2)	-	-	-	GEP	
		France	2019	MED + E	2 (2)					
TOTA L	-	-	2017- 2020	MED + E	15 (14)	-	-	-	GEP	
Winter wheat	ERYSGR / ERYSGT	France	2019- 2020	MED + E	-	4 (2)	-	-	GEP	
		Spain	2019	MED + E	-	2 (2)	-	-	GEP	
		Portugal	2019	MED + E	-	1 (1)	-	-	GEP	
TOTA L	-	-	2019- 2020	MED + E	-	7 (5)	-	-	GEP	
Winter wheat	ERYSGR / ERYSGT	Poland	2017- 2020	MED + E	-	-	12(11)	-	GEP	
		Lithuani a	2019- 2020	MED + E	-	-	5 (5)	-	GEP	
		Latvia	2019	MED + E	-	-	2 (0)	-	GEP	
TOTA L	-	-	2017- 2020	MED + E	-	-	19 (17)	-	GEP	
Winter wheat	ERYSGR / ERYSGT	Hungary	2019- 2020	MED + E	-	-	-	4 (4)	GEP	
		Romania	2019- 2020	MED + E	-	-	-	4 (4)	GEP	
		Slovakia	2020	MED + E	-	-	-	2 (2)	GEP	
TOTA L	-	-	2019- 2020	MED + E	-	-	-	10 (10)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation

In all trials, CA3301 was compared to at least one commercial fungicide used as standard reference for comparison.

Table 3.2-387: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – ERYSGR-ERYSGT – Maritime EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
TRZAW	JOAO	FR	2060116	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE 275	UK	14790	Prothioconazole	EC	275 g/l	2 x 0.72 l/ha	2 x 0.72 l/ha	
	PRO-LINE	DE	025287-00	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE 250 EC	CZ	4523-1	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha 3 x 0.6-0.8 l/ha	CA2445 in some trials

Table 3.2-388: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – ERYSGR-ERYSGT – Mediterranean EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
TRZAW	CA2445 (JOAO)	FRANCE	2060116	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	
	PRO-SARO	SPAIN	25661	Prothioconazole + Tebuconazole	EC	250 g/L	1 l/ha	2 x 1 l/ha	
	BUMPER	PORTUGAL	0299	Propiconazole	EC	250 g/L		2 x 0.5 l/ha	

Table 3.2-389: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – ERYSGR-ERYSGT – North-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
TRZAW	PRAKTIS	PL	R-222/2019	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	OSIRIS 65 EC	POLAND	R-87/2012	Epoxiconazole + metconazole	EC	65 g/l	1 x 1.5-2.5 l/ha	2 x 2 l/ha	

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
	PRO-LINE	LI	AS2-6F(2018) 2019-07-31	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE	LV	0637	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

Table 3.2-390: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – ERYSGR-ERYSGT – South-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
TRZAW	PRI-AXOR	HU	04.2/2426-1/2018 04.2/4127-1/2016	Fluxapyrixad Pyraclostrobin	EC	225 g/l	N/A	2 x 1.5 l/ha	
	PRO-LINE	HU	6300 / 1205-1 / 2020	Prothioconazole	EC	250 g/l	2 x 0.6-0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE	RO	457PC, 15/11/2018	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	CA2445	SK	N/A	Prothioconazole	EC	250 g/l	N/A	2 x 0.8 l/ha	
	PRI-AXOR	SK	16-02-1746	Fluxapyrixad Pyraclostrobin	EC	75 g/l + 150 g/l	2 x 0,75 - 1,5 l/ha	2 x 1.5 l/ha	

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in

Table 3.2-392.

Table 3.2-391: Details on trial methodology – Winter wheat (TRZAW) – ERYSGR-ERYSGT

		Maritime EPPO zone	Mediterranean EPPO zone	North-Eastern EPPO zone	South-Eastern EPPO zone
Trials	Total number (valid number)	15 (14)	7 (5)	19 (17)	10 (10)
	Supportive trials	-	-	-	-
Guidelines	General guidelines	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)	PP 1/152 (4); PP 1/181 (4); PP 1/239 (2); PP 1/135 (4); PP 1/214 (3)	PP 1/152 (4); PP 1/181 (4); PP 1/239 (2); PP 1/135 (4); PP 1/214 (3)

		PP 1/225 (2)	PP 1/225 (2)		
	Specific guidelines	PP 1/26 (4)	PP 1/26 (4)	PP 1/26 (4)	PP 1/26 (4)
Experimental design	Plot design	Randomized Complete Blocks, Untreated included	Randomized Complete Blocks, Untreated included	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included
	Plot size	21 – 30 m ²	20 – 24 m ²	11.25 – 27 m ²	21 – 30 m ²
	Number of replications	4	4	4	4
Crop	Trials per crop	TRZAW (15)	TRZAW (7)	Winter wheat (19)	Winter wheat (10)
	Varieties per crop	Seladon (2), Dagmar (1), Tobak (2), Pannonia (1), Ilona (1), Chevron (1), Boregar (1), Claire (1), Rubisko (1), Monopol (1), Matchball (1), Skyfall (1), Gravity (1)	Calumet (1), Nemo (1), Akim (2), Estero (1), Illico (1), Oregrain (1)	Arkadia (3), Skagen (1), Banderola (2), Ozon (1), Wilejka (2), Etana (2), Emil (2), Famulus (1), Skagen (1), Talsis (1), Etna (1), Patras (1), Findus (1)	Levante (1), Miranda (1), Glosa (1), Farmeur (1), MV Ikva (1), Bernstein (1), Lennox (1), Exotic (1), Capo (1), Antonius (1)
	Sowing period	September (2), October (9), November (3), December (1)	October (1), November (4), December (2)	September (10), October (9)	August (1), October (9)
Application	Crop stage (BBCH)* at application	A: BBCH 31-39 B: BBCH 39-65	A: BBCH 30-39 B: BBCH 39-61	A : BBCH 30-39 B: BBCH 37-65	A: BBCH 31-35 B: BBCH 41-57
	Timing Pest stage at application	A: MYCELI (1), PRINFC (1), MIXED (7) B: MYCELI (1), PRINFC (2), MIXED (6) N/A (6)	A: SPORUL (1), PRINFC (4), MIXED (2) B: SPORUL (1), PRINFC (3), MIXED (3)	A: PRINFC (4), MYCELI (1), SPORUL (2), or ACTIVE (1), MIXED (6), NA (5) B: PRINFC (3), MYCELI (1), SPORUL (3), ACTIVE (1) MIXED (7), NA (4)	A: PRINFC (4), MYCELI (2), SPORUL (1), MIXED (3) B: PRINFC (1), MYCELI (2), SPORUL (2), MIXED (5)
	Number of applications Intervals between applications	2 applications (14-35 days) (15)	2 applications (15-23 days) (7)	1 application (2) 2 applications (12-53 days) (19)	2 applications (15-36 days) (10)
	Spray volumes	A: 200-400 l/ha B: 200-400 l/ha	A: 182-400 l/ha B: 200-400 l/ha	200 - 500 l/ha*	200 - 300 l/ha
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)
	Assessment dates	Before application A, 15 DA-A, 0 DA-B, 15 DA-B, BBCH 75-83	Before application A, 15 DA-A, 0 DA-B, 15 DA-B, BBCH 75-83	Before application A, 15 DA-A, 0 DA-B, 15 DA-B, BBCH 75-83	Before application A, 15 DA-A, 0 DA-B, 15 DA-B, BBCH 75-83
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant	Not relevant

	e.g. Natural / artificial inoculation...	Natural (15)	Natural (7)	Natural (19)	Natural (10)
	e.g. Field / Greenhouse...	Field trials	Field trials	Field trials	Field trials

*In a few trials the water volume applied was 500 l/ha. This small deviation did not impact the validity of the trials.

40 trials were carried out against *Blumeria graminis* (ERYSGR) and 10 trials against *Blumeria graminis f. sp. tritici* (ERYSGT) on winter wheat. *Blumeria graminis f. sp. hordei* (ERYSGH) was observed in 1 trial but considered as equivalent to *Blumeria graminis* or *Blumeria graminis f. sp. Tritici* because the disease was observed on wheat.

Over this dataset, due to the low disease severity occurring on the infected plants with *Blumeria graminis*, the parameter ‘Disease severity %’ could not be used. Considering the fact that treatment against *Blumeria graminis* is triggered when 20% of leaves (L1 to L4 considered together) are attacked by the fungus on sensitive varieties (source ARVALIS Institut du végétal), the analysis will be conducted on four foliar levels L1 to L4 with the parameter ‘Disease incidence %’.

A trial was considered valid when the level of disease incidence was higher than 5% in the untreated control and if the reference product shows a significant difference compared to the untreated control. Therefore, out of the 51 trials performed on winter wheat against *Blumeria graminis* or *Blumeria graminis f. sp. tritici*, 46 were considered valid.

Use of CA3301 at 2x 0.6-0.8 l/ha against ERYSGR-ERYSGT – Maritime EPPO zone

In the Maritime EPPO zone, a total of 15 trials evaluated the efficacy of CA3301 on winter wheat against *Blumeria graminis*. 14 trials out of 15 were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha applied twice, and to compare it to the reference products on disease incidence (%). CA3301 was first applied at crop stages BBCH 31-39 and the 2nd application was at BBCH 39-65. The analysis was conducted on the fourth main foliar levels L1, L2, L3 and L4.

Summary results are presented in Table 3.2-392.

Following 2 applications, the fungicidal performance of CA3301 enabled to significantly decrease the disease incidence on leaves in most of trials, compared to the untreated control and whatever the dose rate considered.

On L4 CA3301 applied at 0.8-0.6 l/ha gave 43.03-63.50% efficacy compared to 34.91% for the reference. On L3 CA3301 applied at 0.8-0.6 l/ha gave 61.87-93.23% efficacy compared to 73.87% for the reference at the earlier assessment and all treatments gave 100% efficacy at the later timing. On L2 overall efficacy was medium at the earlier assessment – 64.25-71.82% from applications of CA3301 at 0.6-0.8 l/ha respectively and was comparable with the reference products in the same trials. At the later assessment on L2 efficacy was low for all treatments at 38.45-48.16% for the test product and 47.92% for the reference. However, on L1 medium efficacy was obtained from CA3301 (66.67-63.89%) and also from the reference product (77.78%) with no significant differences between the treatments.

In the majority of assessments CA3301 at 0.6-0.8 l/ha provided results statistically equivalent to the approved reference standard, and on L4 statistically better results were even obtained. Although the rate of 0.8 l/ha overall reduced disease incidence to a greater extent than the 0.6 l/ha rate, the differences were not always statistically significant. Nevertheless, it is likely that in circumstances of high disease pressure the increased disease control obtained from the higher rate may be of significant benefit.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Blumeria graminis* on winter wheat in the Maritime EPPO

zone.

Table 3.2-392: Summary table - Efficacy evaluation – Winter wheat – ERYSGR-ERYSGT – Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA2 445 0,8 L/ha AB	PROLINE 275 0,72 L/ha AB	CA3 301 0,6 L/ha AB	CA3 301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease incidence L4 - 14-15 DA-B											
Number of values	2	2		2	2	U T C	CA24 45 0,8 l/ha	CA3 301 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA3 301 0,6 l/ha
Minimum value	83,75	52,5 0		51,2 5	23,7 5						
Maximum value	100,00	67,5 0	-	52,5 0	41,2 5	2 >	0 >	0 >	2 >	1 >	1 >
Mean disease incidence (%)	91,88	60,0 0		51,8 8	32,5 0	0 =	2 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	34,9 1%		43,0 3%	63,5 0%	0 <	0 <	1 <	0 <	0 <	0 <
% Disease incidence L3 - 14-15 DA-B											
Number of values	3	3		3	3	U T C	CA24 45 0,8 l/ha	CA3 301 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA3 301 0,6 l/ha
Minimum value	66,25	0,00		26,2 5	0,00						
Maximum value	97,50	61,2 5	-	41,2 5	8,75	2 >	1 >	0 >	3 >	1 >	2 >
Mean disease incidence (%)	86,67	25,4 2		32,9 2	5,42	1 =	1 =	1 =	0 =	2 =	1 =
Abbott efficacy (%)	0,00%	73,8 7%		61,8 7%	93,2 3%	0 <	1 <	2 <	0 <	0 <	0 <
% Disease incidence L3 - 38 DA-B											
Number of values	1	1		1	1	U T C	CA24 45 0,8 l/ha	CA3 301 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA3 301 0,6 l/ha
Minimum value	26,25	0,00		0,00	0,00						
Maximum value	26,25	0,00	-	0,00	0,00	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease incidence (%)	26,25	0,00		0,00	0,00	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	100, 00%		100, 00%	100, 00%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease incidence L2 - 13-16 DA-B											
Number of values	4			4	4	UTC	CA3301 0,8 l/ha		UTC	CA3301 0,6 l/ha	
Minimum value	76,25			0,00	0,00						
Maximum value	100,00	-	-	70,0 0	55,0 0	2 >	0 >		3 >	0 >	
Mean disease incidence (%)	91,25			33,7 5	26,5 6	2 =	4 =		1 =	4 =	
Abbott efficacy (%)	0,00%			64,2 5%	71,8 2%	0 <	0 <		0 <	0 <	
Number of values	3	3		3	3	CA2445 0,8 l/ha		CA2445 0,8 l/ha			
Minimum value	76,25	0,00		0,00	0,00						
Maximum value	96,25	62,5 0	-	70,0 0	55,0 0	0 >		0 >			
Mean disease incidence (%)	88,33	38,3 3		45,0 0	35,4 2	3 =		3 =			
Abbott efficacy (%)	0,00%	59,3 0%		52,3 3%	62,4 3%	0 <		0 <			
Number of values	1		1	1	1	PROLINE 275 0,72 l/ha		PROLINE 275 0,72 l/ha			
Minimum value	100,00		0,00	0,00	0,00						
Maximum value	100,00	-	0,00	0,00	0,00	0 >		0 >			
Mean disease incidence (%)	100,00		0,00	0,00	0,00	1 =		1 =			

Abbott efficacy (%)	0,00%		100%	100,00%	100,00%	0 <			0 <		
% Disease incidence L2 - 30-46 DA-B											
Number of values	3	3		3	3	U T C	CA24 45 0,8 l/ha	CA3 301 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA3 301 0,6 l/ha
Minimum value	42,50	20,00		28,75	16,25						
Maximum value	80,00	65,00	-	62,50	58,75	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease incidence (%)	67,50	35,42		40,42	33,75	2 =	3 =	3 =	2 =	3 =	3 =
Abbott efficacy (%)	0,00%	47,92%		38,45%	48,16%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease incidence L1 - 46 DA-B											
Number of values	2	2		2	2	U T C	CA24 45 0,8 l/ha	CA3 301 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA3 301 0,6 l/ha
Minimum value	45,00	0,00		0,00	0,00						
Maximum value	62,50	20,00	-	30,00	32,50	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease incidence (%)	53,75	10,00		15,00	16,25	1 =	2 =	2 =	1 =	2 =	2 =
Abbott efficacy (%)	0,00%	77,78%		66,67%	63,89%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against ERYSGR-ERYSGT – Mediterranean EPPO zone

In the Mediterranean EPPO zone, a total of 7 trials evaluated the efficacy of CA3301 on winter wheat against *Blumeria graminis*. 5 trials out of 7 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.8 l/ha applied twice, compared to the reference products on disease incidence (%). CA3301 was first applied at crop stages BBCH 30-39 and the 2nd application was at BBCH 39-61. The analysis was conducted on the fourth main foliar levels L1, L2, L3 and L4.

Summary results are presented in Table 3.2-393.

Following 2 applications, the fungicidal performance of CA3301 enabled to significantly decrease the disease incidence on leaves in most of trials, compared to the untreated control and whatever the dose rate considered.

In all trials, CA3301 at 0.6-0.8 l/ha gave always equivalent disease control to the approved reference standards no matter the foliar level or assessment timing considered. Although the rate of 0.8 l/ha overall reduced disease incidence to a greater extent than the 0.6 l/ha rate, the differences were usually not statistically significant. Nevertheless, it is likely that in circumstances of high disease pressure the increased disease control obtained from the higher rate may be of significant benefit.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Blumeria graminis* on winter wheat in the Mediterranean EPPO zone.

Treatment name	UNTREATED CHECK	CA2 445 0,8 L/ha AB	PROSARO 1 L/ha AB	CAS301 0,6 L/ha AB	CAS301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to				
% Disease incidence L4 - 14 DA-B											
Number of values	2			2	2	UTC	CA3301 0,8 l/ha	UTC	CA3301 0,6 l/ha		
Minimum value	28,75	-	-	2,50	0,00	2 >	0 >	2 >	0 >		
Maximum value	88,75			40,00	31,25	0 =	2 =	0 =	2 =		
Mean disease incidence (%)	58,75			21,25	22,10	0 <	0 <	0 <	0 <		
Abbott efficacy (%)	0,00%			73,12 %	82,39 %						
Number of values	1	1		1	1	CA2445 0,8 l/ha		CA2445 0,8 l/ha			
Minimum value	88,75	35,00	-	40,00	31,25	0 >		0 >			
Maximum value	88,75	35,00		40,00	31,25	1 =		1 =			
Mean disease incidence (%)	88,75	35,00		40,00	31,25	0 <		0 <			
Abbott efficacy (%)	0,00%	60,56 %		54,93 %	64,79 %						
Number of values	1		1	1	1	PROSARO 1,0 l/ha		PROSARO 1,0 l/ha			
Minimum value	28,75	-	7,50	2,50	0,00	0 >		1 >			
Maximum value	28,75		7,50	2,50	0,00	1 =		0 =			
Mean disease incidence (%)	28,75		7,50	2,50	0,00	0 <		0 <			
Abbott efficacy (%)	0,00%		73,91%	91,30 %	100,0 0%						
% Disease incidence L4 - 26 DA-B											
Number of values	1		1	1	1	U TC	PRO-SARO 1,0 l/ha	CA3 301 0,8 l/ha	U TC	PRO-SARO 1,0 l/ha	CA3 301 0,6 l/ha
Minimum value	27,50	-	8,75	6,25	0,00	1 > 0 = 0 <	0 > 1 = 0 <	0 > 1 = 0 <	1 > 0 = 0 <	0 > 1 = 0 <	0 > 1 = 0 <
Maximum value	27,50		8,75	6,25	0,00						
Mean disease incidence (%)	27,50		8,75	6,25	0,00						
Abbott efficacy (%)	0,00%		68,18%	77,27 %	100,0 0%						
% Disease incidence L3 - 14 DA-B											
Number of values	4			4	4	UTC	CA3301 0,8 l/ha	UTC	CA3301 0,6 l/ha		
Minimum value	21,25	-	-	1,25	0,00	4 >	0 >	2 >	0 >		
Maximum value	100,00			61,25	50,00	0 =	4 =	0 =	4 =		
Mean disease incidence (%)	54,38			19,69	13,75	0 <	0 <	0 <	0 <		
Abbott efficacy (%)	0,00%			74,96 %	85,54 %						
Number of values	2	2		2	2	CA2445 0,8 l/ha		CA2445 0,8 l/ha			
Minimum value	63,75	0,00	-	11,25	5,00	0 >		0 >			
Maximum value	100,00	56,25		61,25	50,00	2 =		2 =			
Mean disease incidence (%)	81,88	28,13		36,25	27,50	0 <		0 <			
Abbott efficacy (%)	0,00%	71,88 %		60,55 %	71,08 %						
Number of values	2		2	2	2	PROSARO 1,0 l/ha		PROSARO 1,0 l/ha			
Minimum value	21,25	-	0,00	1,25	0,00	0 >		0 >			
Maximum value	32,50		5,00	5,00	0,00	2 =		2 =			
Mean disease incidence (%)	26,86		2,50	3,13	0,00	0 <		0 <			
Abbott efficacy (%)	0,00%		92.31%	89,37 %	100,0 0%						
% Disease incidence L3 - 27-28 DA-B											

Number of values	2		2	2	2	U TC	PRO- SARO 1,0 l/ha	CA3 301 0,8 l/ha	U TC	PRO- SARO 1,0 l/ha	CA3 301 0,6 l/ha
Minimum value	30,00		8,75	0,00	0,00						
Maximum value	31,25	-	10,00	7,50	0,00	2 > 0 =	0 >	0 >	2 > 0 =	0 >	0 >
Mean disease incidence (%)	30,63		9,38	3,75	0,00		2 =	2 =		2 =	2 =
Abbott efficacy (%)	0,00%		69,33%	87,50 %	100,0 0%	0 <	0 <	0 <	0 <	0 <	0 <

Treatment name	UNTREAT ED	CA24 45	PROSA RO	CA33 01	CA33 01	No of trials where CA3301		No of trials where CA3301	
Rate	CHECK	0,8	1	0,6	0,8	at 0,6 l/ha is		at 0,8 l/ha is >, =	
Rate unit		L/ha	L/ha	L/ha	L/ha	>, = or <		or <	
Appl. Code		AB	AB	AB	AB	compared to		compared to	
% Disease incidence L2 - 14 DA-B									
Number of values	2			2	2	UT C	CA33 01 0,8 l/ha	UTC	CA330 1
Minimum value	15,00			2,50	0,00				0,6 l/ha
Maximum value	95,00	-	-	18,75	7,50	2 >	0 >	2 >	0 >
Mean disease incidence (%)	55,00			10,63	3,75	0 =	2 =	0 =	2 =
Abbott efficacy (%)	0,00%			81,80 %	96,05 %	0 <	0 <	0 <	0 <
Number of values	1	1		1	1	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	95,00	20,00		18,75	7,50	0 >		0 >	
Maximum value	95,00	20,00	-	18,75	7,50	1 =		1 =	
Mean disease incidence (%)	95,00	20,00		18,75	7,50	0 <		0 <	
Abbott efficacy (%)	0,00%	78,95 %		80,26 %	92,11 %	0 <		0 <	
Number of values	1		1	1	1	PROSARO 1,0 l/ha		PROSARO 1,0 l/ha	
Minimum value	15,00		2,50	2,50	0,00	0 >		0 >	
Maximum value	15,00	-	2,50	2,50	0,00	1 =		1 =	
Mean disease incidence (%)	15,00		2,50	2,50	0,00	0 <		0 <	
Abbott efficacy (%)	0,00%		83,33%	83,33 %	100,00 %	0 <		0 <	
% Disease incidence L2 - 27-43 DA-B									
Number of values	4			4	4	UT C	CA33 01 0,8 l/ha	UTC	CA330 1
Minimum value	17,50			0,00	0,00				0,6 l/ha
Maximum value	100,00	-	-	55,00	30,00	4 >	0 >	4 >	1 >
Mean disease incidence (%)	57,43			18,44	9,38	0 =	3 =	0 =	3 =
Abbott efficacy (%)	0,00%			76,88 %	90,29 %	0 <	1 <	0 <	0 <
Number of values	2	2		2	2	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	84,74	11,25		12,50	7,50	0 >		0 >	
Maximum value	100,00	41,25	-	100,00	30,00	2 =		2 =	
Mean disease incidence (%)	92,37	26,25		33,75	18,75	0 <		0 <	
Abbott efficacy (%)	0,00%	72.74 %		65,12 %	80,57 %	0 <		0 <	
Number of values	2		2	2	2	PROSARO 1,0 l/ha		PROSARO 1,0 l/ha	
Minimum value	17,50		1,25	0,00	0,00	0 >		0 >	
Maximum value	27,50	-	10,00	6,25	0,00	2 =		2 =	
Mean disease incidence (%)	22,50		5,63	3,13	0,00				

Abbott efficacy (%)	0,00%		78.25%	88,64 %	100,00 %	0 <		0 <	
% Disease incidence L1 - 27-39 DA-B									
Number of values	2			2	2	UT C	CA33 01 0,8 l/ha	UTC	CA330 1 0,6 l/ha
Minimum value	20,00			1,25	0,00				
Maximum value	67,50	-	-	20,00	17,50	2 >	0 >	2 >	0 >
Mean disease incidence (%)	43,75			10,63	8,75	0 =	2 =	0 =	2 =
Abbott efficacy (%)	0,00%			82,06 %	87,04 %	0 <	0 <	0 <	0 <
Number of values	1	1		1	1	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	67,50	17,50		20,00	17,50				
Maximum value	67,50	17,50	-	20,00	17,50	0 >		0 >	
Mean disease incidence (%)	67,50	17,50		20,00	17,50	1 =		1 =	
Abbott efficacy (%)	0,00%	74,07 %		70,37 %	74,07 %	0 <		0 <	
Number of values	1		1	1	1	PROSARO 1,0 l/ha		PROSARO 1,0 l/ha	
Minimum value	20,00		0,00	1,25	0,00				
Maximum value	20,00	-	0,00	1,25	0,00	0 >		0 >	
Mean disease incidence (%)	20,00		0,00	1,25	0,00	1 =		1 =	
Abbott efficacy (%)	0,00%		100%	93,75 %	100,00 %	0 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against ERYSGR-ERYSGT – North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 19 trials evaluated the efficacy of CA3301 on winter wheat against *Blumeria graminis*. 17 trials out of 19 were considered valid and 16 were included to support the efficacy evaluation of CA3301 at 0.6-0.8 l/ha applied twice, compared to the reference products on disease incidence (%). One trial (EU17-056-01) was valid but tested CA3301 applied only once and was therefore excluded in this analysis, which will therefore be conducted on 16 trials. CA3301 was first applied at crop stages BBCH 30-39 and the 2nd application was at BBCH 37-65. The analysis was conducted on the fourth main foliar levels L1, L2, L3 and L4.

Summary results are presented in Table 3.2-394.

Following 2 applications, the fungicidal performance of CA3301 enabled to significantly decrease the disease incidence on leaves in most of trials, compared to the untreated control and whatever the dose rate considered. In all trials, CA3301 at 0.6-0.8 l/ha always provided results statistically equivalents to the approved reference standards no matter the foliar level or assessment timing considered. Although the rate of 0.8 l/ha overall reduced disease incidence to a greater extent than the 0.6 l/ha rate, the differences were usually not statistically significant. Nevertheless, it is likely that in circumstances of high disease pressure the increased disease control obtained from the higher rate may be of significant benefit.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Blumeria graminis* on winter wheat in the North-Eastern East EPPO zone.

Table 3.2-394: Summary table - Efficacy evaluation – Winter wheat – ERYSGR-ERYSGT – North-eastern East EPPO zone

Treatment name	UNTR EATE D C HECK	OSIRI S 65 EC	CA 244 5	CA 330 1	CA 330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Rate	K	2	0,8	0,6	0,8		
Rate unit		L/ha	L/h	L/h	L/h		
Appl. Code		AB	AB	AB	AB		
% Disease incidence L4 - 13-16 DA-B							
Number of values	1	1	1	1	1	U T C	OSI- RIS 65 EC 2,0 l/ha
Minimum value	26,25	12,50	6,25	16,25	11,25	0	0 >
Maximum value	26,25	12,50	6,25	16,25	11,25	1	0 >
Mean disease incidence (%)	26,25	12,50	6,25	16,25	11,25	0	0 >
Abbott efficacy (%)	0,00%	52,38%	76,19%	38,10%	57,14%	0	0 <
% Disease incidence L3 - 13-15 DA-B							
Number of values	7	7		7	7	UTC	CA3301 0,8 l/ha
Minimum value	12,50	0,00		0,00	0,00	6 >	0 >
Maximum value	100,00	43,75	-	58,75	31,25	1 =	7 =
Mean disease incidence (%)	61,25	17,86		20,71	13,57	0 <	0 <
Abbott efficacy (%)	0,00%	70,84%		77,08%	82,57%		
Number of values	5	5	5	5	5	OSIRIS 65 EC 2,0 l/ha	CA2445 0,8 l/ha
Minimum value	12,50	0,00	0,00	0,00	0,00	1 >	0 >
Maximum value	100,00	43,75	47,50	58,75	31,25	6 =	5 =
Mean disease incidence (%)	69,25	24,75	22,00	28,75	19,00	0 <	0 <
Abbott efficacy (%)	0,00%	69,85%	74,07%	68,31%	75,60%		
% Disease incidence L2 - 13-15 DA-B							
Number of values	7			7	7	UTC	CA3301 0,8 l/ha
Minimum value	5,00			0,00	0,00	5 >	0 >
Maximum value	98,75	-	-	35,00	27,50	2 =	7 =
Mean disease incidence (%)	56,25			8,04	6,25	0 <	0 <
Abbott efficacy (%)	0,00%			90,77%	93,15%		
Number of values	6	6		6	6	OSIRIS 65 EC 2,0 l/ha	OSIRIS 65 EC 2,0 l/ha
Minimum value	5,00	0,00		0,00	0,00	0 >	0 >
Maximum value	98,75	21,25	-	17,50	15,00	6 =	6 =
Mean disease incidence (%)	49,79	3,75		3,54	2,71	0 <	0 <
Abbott efficacy (%)	0,00%	95,72%		95,37%	96,83%		
Number of values	5		5	5	5	CA2445	CA2445

Treatment name	UNTR EATE D CHEC K	OSIRI S 65 EC 2 L/ha AB	CA 244 5 L/h a AB	CA 330 1 L/h a AB	CA 330 1 L/h a AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to 0,8 l/ha		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to 0,8 l/ha	
Rate			0,8	0,6	0,8				
Rate unit			L/h a	L/h a	L/h a				
Appl. Code			AB	AB	AB				
Minimum value	5,00		0,00	0,00	0,00				
Maximum value	98,75	-	37,50	35,00	27,50	0 >		0 >	
Mean disease incidence (%)	63,00		10,75	10,50	8,80	5 =		5 =	
Abbott efficacy (%)	0,00%		88,64	88,90	91,01	0 <		0 <	
% Disease incidence L2 - 18-42 DA-B									
Number of values	4			4	4	UTC	CA3301	UTC	CA3301
Minimum value	13,75			0,00	0,00		0,8 l/ha		0,6 l/ha
Maximum value	100,00	-	-	8,75	5,00	3 >	0 >	3 >	0 >
Mean disease incidence (%)	55,00			3,44	1,56	1 =	4 =	1 =	4 =
Abbott efficacy (%)	0,00%			80,70	89,59	0 <	0 <	0 <	0 <
Number of values	3	3		3	3	OSIRIS 65 EC		OSIRIS 65 EC	
Minimum value	13,75	0,00		0,00	0,00	2,0 l/ha		2,0 l/ha	
Maximum value	100,00	3,75	-	8,75	5,00	0 >		0 >	
Mean disease incidence (%)	45,83	1,67		3,75	2,08	3 =		3 =	
Abbott efficacy (%)	0,00%	89,15%		75,28	86,12	0 <		0 <	
Number of values	3		3	3	3	CA2445		CA2445	
Minimum value	13,75		0,00	0,00	0,00	0,8 l/ha		0,8 l/ha	
Maximum value	100,00	-	6,25	8,75	5,00	0 >		0 >	
Mean disease incidence (%)	65,42		2,92	3,75	1,67	3 =		3 =	
Abbott efficacy (%)	0,00%		83,84	77,78	87,88	0 <		0 <	
% Disease incidence L1 - 14-15 DA-B									
Number of values	4			4	4	UTC	CA3301	UTC	CA3301
Minimum value	11,25			0,00	0,00		0,8 l/ha		0,6 l/ha
Maximum value	96,25	-	-	47,50	35,00	4 >	0 >	4 >	0 >
Mean disease incidence (%)	57,50			17,50	11,88	0 =	4 =	0 =	4 =
Abbott efficacy (%)	0,00%			78,73	86,15	0 <	0 <	0 <	0 <
Number of values	1	1		1	1	OSIRIS 65 EC		OSIRIS 65 EC	
Minimum value	11,25	0,00		0,00	0,00	2,0 l/ha		2,0 l/ha	
Maximum value	11,25	0,00	-	0,00	0,00	0 >		0 >	
Mean disease incidence (%)	11,25	0,00		0,00	0,00	1 =		1 =	

Treatment name	UNTR EATE D CHEC K	OSIRI S 65 EC 2 L/ha AB	CA 244 5 0,8 L/h a AB	CA 330 1 0,6 L/h a AB	CA 330 1 0,8 L/h a AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to 0 <		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to 0 <	
Abbott efficacy (%)	0,00%	100,00 %		100,00%	100,00%				
Number of values	3		3	3	3	CA2445		CA2445	
Minimum value	52,50		7,50	7,50	2,50	0,8 l/ha		0,8 l/ha	
Maximum value	96,25	-	35,00	47,50	35,00	0 >		0 >	
Mean disease incidence (%)	72,92		18,75	23,33	15,83	3 =		3 =	
Abbott efficacy (%)	0,00%		76,57%	71,67%	81,5%	0 <		0 <	
% Disease incidence L1 – 23-33 DA-B									
Number of values	5			5	5	UTC	CA3301	UTC	CA3301
Minimum value	10			0	0		0,8 l/ha		0,6 l/ha
Maximum value	70	-	-	17,5	12,5	3 >	0 >	4 >	0 >
Mean disease incidence (%)	38,25			5,25	4,75	2 =	5 =	1 =	5 =
Abbott efficacy (%)	0,00%			85,89%	84,38%	0 <	0 <	0 <	0 <
Number of values	2	2		2	2	OSIRIS 65 EC		OSIRIS 65 EC	
Minimum value	10	0		0	0	2,0 l/ha		2,0 l/ha	
Maximum value	22,5	1,25	-	3,75	1,25	0 >		0 >	
Mean disease incidence (%)	16,25	0,63		1,88	0,63	2 =		2 =	
Abbott efficacy (%)	0,00%	93,75%		81,25%	93,75%	0 <		0 <	
Number of values	4		4	4	4	CA2445		CA2445	
Minimum value	10		0	0	0	0,8 l/ha		0,8 l/ha	
Maximum value	70	-	20	17,5	12,5	0 >		0 >	
Mean disease incidence (%)	42,19		6,25	6,56	5,94	4 =		4 =	
Abbott efficacy (%)	0,00%		85,45%	82,36%	80,48%	0 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against ERYSGR-ERYSGT – South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 10 trials evaluated the efficacy of CA3301 on winter wheat against *Blumeria graminis*. All 10 trials were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.8 l/ha applied twice, compared to the reference products on disease incidence (%).

CA3301 was first applied at crop stages BBCH 31-35 and the 2nd application was at BBCH 41-57. The analysis was conducted on the fourth main foliar levels L1, L2, L3 and L4.

Summary results are presented in Table 3.2-395.

Following 2 applications, the fungicidal performance of CA3301 enabled to significantly decrease the disease incidence on leaves in most of trials, compared to the untreated control and whatever the dose rate considered. In the South-Eastern EPPO zone, CA3301 at 0.6-0.8 l/ha provided a control of the disease that was either statistically equivalent or less efficient than the reference product PRIAXOR (mainly due to the difference of mode of action with a mixture of fluxapyroxad and pyraclostrobin) in a few trials. However in the majority of trials, CA3301, especially at the 0.8 l/ha dose rate, provided a control that was statistically equivalent or even better in some trials, to the one provided by CA2445, the reference product with the same active substance at a comparable rate. Although the rate of 0.8 l/ha overall reduced disease incidence to a greater extent than the 0.6 l/ha rate, the differences were not always statistically significant. Nevertheless, it is likely that in circumstances of high disease pressure the increased disease control obtained from the higher rate may be of significant benefit.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Blumeria graminis* on winter wheat in the South-Eastern East EPPO zone.

Table 3.2-395: Summary table - Efficacy evaluation – Winter wheat – ERYSGR-ERYSGT – South-Eastern East EPPO zone

Treatment name	UNTREA TED CHECK	CA24 45 0,8 L/ha AB	PRIAX OR 1,5 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
% Disease incidence L4 - 14-15 DA-B							
Number of values	2	2		2	2	UTC	CA3301 0,8 l/ha
Minimum value	13,75	0,00		1,25	0,00		
Maximum value	100,00	1,25	-	1,25	0,00	2 >	0 >
Mean disease incidence (%)	56,88	0,63		1,25	0,00	0 =	2 =
Abbott efficacy (%)	0,00%	95,45 %		94,83 %	100,0 0%	0 <	0 <
Number of values	1	1	1	1	1	CA244 5 0,8 l/ha	PRI- AXOR 1,5 l/ha
Minimum value	13,75	1,25	0,00	1,25	0,00		
Maximum value	13,75	1,25	0,00	1,25	0,00	0 >	0 >
Mean disease incidence (%)	13,75	1,25	0,00	1,25	0,00	2 =	1 =
Abbott efficacy (%)	0,00%	90,91 %	100,00 %	90,91 %	100,0 0%	0 <	0 <
% Disease incidence L3 - 14-15 DA-B							
Number of values	9			9	9	UTC	CA3301 0,8 l/ha
Minimum value	16,25			0,00	0,00		
Maximum value	100,00	-	-	98,75	82,50	8 >	0 >
Mean disease incidence (%)	82,08			37,22	32,78	1 =	7 =
Abbott efficacy (%)	0,00%			60.87 %	66.43 %	0 <	2 <
Number of values	8	8		8	8	CA2445 0,8 l/ha	CA2445 0,8 l/ha
Minimum value	16,25	0,00		0,00	0,00		
Maximum value	100,00	85,00	-	98,75	82,50	0 >	0 >
Mean disease incidence (%)	80,16	35,31		39,06	33,59	6 =	8 =
Abbott efficacy (%)	0,00%	63,88 %		58,86 %	65,60 %	2 <	0 <
Number of values	5		5	5	5	PRIAXOR	PRIAXOR

Treatment name	UNTREA TED CHECK	CA24 45 0,8 L/ha AB	PRIAX OR 1,5 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to 1,5 l/ha			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to 1,5 l/ha		
Rate	97,50		0,00	0,00	0,00	1 >			1 >		
Rate unit	100,00	-	76,25	98,75	82,50	2 =			2 =		
Appl. Code	99,50		47,75	41,50	37,00	2 <			2 <		
Minimum value											
Maximum value											
Mean disease incidence (%)											
Abbott efficacy (%)	0,00%		51,95%	58,38 %	62,87 %						
% Disease incidence L3 - 27 DA-B											
Number of values	1	1		1	1	UT C	CA24 45 0,8 l/ha	CA3 301 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA3 301 0,6 l/ha
Minimum value	22,50	0,00		0,00	0,00	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	22,50	0,00	-	0,00	0,00	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease incidence (%)	22,50	0,00		0,00	0,00	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	100,0 0%		100,0 0%	100,0 0%						
% Disease incidence L2 - 14-15 DA-B											
Number of values	9			9	9	UTC	CA3301 0,8 l/ha		UTC	CA3301 0,6 l/ha	
Minimum value	20,00	-	-	0,00	0,00	9 >	0 >		9 >	1 >	
Maximum value	100,00			63,75	56,25	0 =	8 =		0 =	8 =	
Mean disease incidence (%)	73,06			14,86	12,50	0 <	1 <		0 <	0 <	
Abbott efficacy (%)	0,00%			84,69 %	87,13 %						
Number of values	8	8		8	8	CA2445 0,8 l/ha			CA2445 0,8 l/ha		
Minimum value	20,00	0,00		0,00	0,00	0 >			0 >		
Maximum value	100,00	58,75	-	63,75	56,25	7 =			8 =		
Mean disease incidence (%)	74,06	13,91		15,78	13,28	1 <			0 <		
Abbott efficacy (%)	0,00%	86,09 %		84,22 %	86,72 %						

Treatment name	UNTREA TED CHECK	CA24 45 0,8 L/ha AB	PRIAX OR 1,5 L/ha AB	CA3301 0,6 L/ha AB	CA3 301 0,8 L/h a AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate	5		5	5	5	PRIAXOR 1,5 l/ha		PRIAXOR 1,5 l/ha	
Rate unit	65,00	-	0,00	0,00	0,00	0 >		0 >	
Appl. Code	100,00		37,50	63,75	56,2 5	3 =		3 =	
Number of values						2 <		2 <	
Minimum value	91,75		16,50	26,75	22,5 0				
Maximum value	0,00%		82,15%	72,44%	76,8 3%				
Mean disease incidence (%)	% Disease incidence L2 - 27-47 DA-B								
Abbott efficacy (%)	8			8	8	UTC	CA330 1 0,8 l/ha	UTC	CA330 1 0,6 l/ha
Number of values	21,25			0,00	0,00	7 >	0 >	8 >	1 >
Minimum value	100,00	-	-	92,50	86,2 5	1 =	7 =	0 =	7 =
Maximum value						0 <	1 <	0 <	0 <
Mean disease incidence (%)	89,94			50,47	44,8 4				
Abbott efficacy (%)	0,00%			49,31%	54,9 8%				
Number of values	7	7		7	7	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	21,25	0,00		0,00	0,00				

Maximum value	100,00	82,50	-	92,50	86,25	0 > 6 = 1 <	0 > 7 = 0 <		
Mean disease incidence (%)	88,75	44,46		47,86	43,57				
Abbott efficacy (%)	0,00%	55,54 %		52,14%	56,43%				
Number of values	5		5	5	5	PRIAXOR	PRIAXOR		
Minimum value	97,50		0,00	0,00	0,00	1,5 l/ha	1,5 l/ha		
Maximum value	100,00	-	76,25	92,50	86,25	0 > 3 = 2 <	0 > 3 = 2 <		
Mean disease incidence (%)	99,50		37,75	48,00	43,00				
Abbott efficacy (%)	0,00%		62,01%	51,65%	56,72%				
% Disease incidence L1 - 15 DA-B									
Number of values	2		2	2	2	UTC	CA330	UTC	CA330
Minimum value	6,25		0,00	0,00	0,00		1		0,6 l/ha
Maximum value	53,75	-	0,00	0,00	0,00	1 >	0 >	1 >	0 >
Mean disease incidence (%)	30,00		0,00	0,00	0,00	1 =	2 =	1 =	2 =
Abbott efficacy (%)	0,00%		100,00%	100,00%	100,00%	0 <	0 <	0 <	0 <
Number of values	1	1		1	1	CA24	PRI-	CA24	PRI-
Minimum value	53,75	0,00		0,00	0,00	45	AXOR	45	AXOR
Maximum value	53,75	0,00	-	0,00	0,00	0,8 l/ha	1,5 l/ha	0,8 l/ha	1,5 l/ha
Mean disease incidence (%)	53,75	0,00		0,00	0,00	0 >	0 >	0 >	0 >
Abbott efficacy (%)	0,00%	100,00%		100,00%	100,00%	1 =	2 =	1 =	2 =
						0 <	0 <	0 <	0 <
% Disease incidence L1 - 27-47 DA-B									
Number of values	8			8	8	UTC	CA330	UTC	CA330
Minimum value	5,00			0,00	0,00		1		0,6 l/ha
Maximum value	100,00	-	-	77,50	62,50	7 >	0 >	7 >	3 >
Mean disease incidence (%)	70,63			29,22	21,56	1 =	5 =	1 =	5 =
Abbott efficacy (%)	0,00%			70,53%	78,21%	0 <	3 <	0 <	0 <
Number of values	7	7		7	7	CA2445		CA2445	
Minimum value	5,00	0,00		0,00	0,00	0,8 l/ha		0,8 l/ha	
Maximum value	100,00	68,75	-	77,50	62,50	0 > 5 = 2 <		1 > 6 = 0 <	
Mean disease incidence (%)	76,25	26,25		33,39	24,64				
Abbott efficacy (%)	0,00%	73,46 %		66,31%	75,09%				
Number of values	5		5	5	5	PRIAXOR		PRIAXOR	
Minimum value	31,25		0,00	0,00	0,00	1,5 l/ha		1,5 l/ha	
Maximum value	100,00	-	38,75	77,50	62,50	0 > 3 = 2 <		0 > 3 = 2 <	
Mean disease incidence (%)	72,00		13,50	26,00	22,00				
Abbott efficacy (%)	0,00%		86,28 %	73,59%	77,63%				

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

Taking into account of applicant's explanation, the efficacy evaluation was based on the parameter of disease incidence (%PESINC).

14 valid field trials were conducted in **the Maritime EPPO climatic zone**. CA3301 was effective to control of ERYSGR in winter wheat but on the medium level. The effectiveness of dose rate of 0,8 l/ha was significant better compared to 0,6 l/ha, especially in situation with high disease pressure. The majority of trials results presented an efficacy of 60-80% after 14-46 days after second application. No significant differences between test and reference product were observed.

17 valid field trials were conducted in **the North-East EPPO climatic zone**. The high efficacy was noted after application of CA3301 at dose rate of 0,6-0,8 l/ha. The effectiveness above 80% is visible on L1 and L2 13-42 days after second application. The test and reference products achieved comparable results.

10 valid field trials were in **the South-East EPPO zone**. CA3301 achieved the medium to high level of effectiveness. The dose rate of 0,8 l/ha was comparable to the reference product or even better in some trials. Taking into account similarity of trial results between 0,6 and 0,8 l/ha, it can be recommended higher dose for situation with high disease pressure.

In the opinion of zRMS, CA3301 can be used to protection of winter wheat against *Blumeria graminis*. The dose rate of 0,8 l/ha is recommended in case of high disease pressure.

3.2.3.26 Winter wheat (TRZAW) / *Fusarium culmorum* (FUSACU)

Materials and Methods – Winter wheat - FUSACU

General Materials and Methods information are given in paragraph "General Materials and Methods" located in introduction of the section "3.2.3 Efficacy tests (KCP 6.2)".

Between 2017 and 2020, a series of 20 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the efficacy of CA3301 against *Fusarium culmorum* on **winter wheat** (see Table 3.2-396). The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, a total of 6 trials were performed in Denmark (1), Germany (3) and the Czech Republic (2)

In the Mediterranean EPPO zone, 2 trials were performed in Portugal (2)

In the North-eastern East EPPO zone, a total of 9 trials were performed in Poland (9)

In the South-eastern East EPPO zone, a total of 3 trials were performed in Hungary (2) and Romania (1).

Groupings were also made specifically for Poland and trials involved (14) were performed in the North-eastern East EPPO zone (9), in the Czech Republic (2) and in Germany (3).

Table 3.2-396: Presentation of trials – Winter wheat (TRZAW)

Crop(s)) *	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Winter wheat	FUSACU	Denmar k	2018	MED + E	1 (0)	-	-	-	GEP	
		German y	2019- 2020	MED + E	3 (1)	-	-	-	GEP	

Crop(s)) *	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mar- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
		Czech Republic	2018	MED + E	2 (2)	-	-	-	GEP	
Winter wheat	FUSACU	Portugal	2018	MED + E	-	2 (2)	-	-	GEP	
Winter wheat	FUSACU	Poland	2017- 2020	MED + E	-	-	9 (7)		GEP	
Winter wheat	FUSACU	Hungary	2018	MED + E	-	-	-	2 (2)	GEP	
		Romania	2019	MED + E	-	-	-	1 (1)	GEP	
TOTA L	-	-	2017 - 2020	MED + E	6 (3)	2 (2)	9 (7)	3 (3)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

In all trials, CA3301 was compared to at least one commercial and registered fungicide used as standard reference for comparison.

Table 3.2-397: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – FUSACU – Maritime EPPO zone

Crop(s))	Refer- ence standard	Coun- try(ies) where the product is used ⁽¹⁾	Authoriza- tion number	Active sub- stance(s)	Formulation		Regis- tered ap- plication rate ⁽³⁾	Applica- tion rate in tri- als (per treat- ment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concentra- tion of a.s.			
Winter wheat	PRO- LINE 250 EC	CZ	4523-1	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO- LINE	DE	025287-00	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO- LINE 250 EC	DK	18-473	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

Table 3.2-398: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – FUSACU – Mediterranean EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter wheat	PRAKTIS	PT	AV 1485	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter wheat	PRAKTIS	PL	R-222/2019	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

Table 3.2-399: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – FUSACU – South-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter wheat	PRO-LINE	HU	6300/1205-1/2020	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE	RO	457PC/15.11.2018	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-400.

Table 3.2-400: Details on trial methodology – Winter wheat (TRZAW) - SEPTTR

		Maritime EPPO zone	Mediterranean EPPO zone	North-Eastern EPPO zone	South-Eastern EPPO zone	Data relevant for Poland
Trials	Total number (valid number)	6 (3)	2 (2)	9 (7)	3 (3)	14 (10)
	Supportive trials	-	-	-	-	-
Guidelines	General guidelines	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)

	Specific guidelines	PP 1/26(4)	PP 1/26(4)	PP 1/26(4)	PP 1/26(4)	PP 1/26(4)
Experimental design	Plot design	Randomized complete blocks, Un-treated included	Randomized complete blocks, Un-treated included	Randomized complete blocks, Un-treated included	Randomized complete blocks, Un-treated included	Randomized complete blocks, Un-treated included
	Plot size	15-32 m ²	30 m ²	12-30 m ²	20-30 m ²	12-30 m ²
	Number of replications	4	4	4	4	4
Crop	Trials per crop	Winter wheat (6)	Winter wheat (2)	Winter wheat (9)	Winter wheat (3)	Winter wheat (12)
	Varieties per crop	Asano (1), Arkeos (1), KWS Dacanto (1), Tobak (1), RGT Reform (1), Barranco (1)	Nogal (1), Gracias (1)	Tobak (1), Skagen (1), Julius (1), Jantarka (2), Bogatka (1), Urbanus (1), Patras (1), Findus (1)	Romulus (1), Altigo (1), As-tardo (1)	Tobak (2), Skagen (1), Julius (1), Jantarka (2), Bogatka (1), Urbanus (1), Patras (1), Findus (1), Asano (1), Arkeos (1), RGT Reform (1), Barranco (1)
	Sowing period	September (1), October (4), N/A (3)	December (2)	September (4), October (5)	October (3)	September (4), October (9), N/A (1)
Application	Crop stage (BBCH)* at application	A: BBCH 37-39 B: BBCH 65-69	A: BBCH 37-51 B: BBCH 65-67	A: BBCH 37-39 B: BBCH 61-65	A: BBCH 39 B: BBCH 65	A: BBCH 37-39 B: BBCH 61-69
	Timing Pest stage at application	BBCH 30-69 A: PRINFC (5) B: PRINFC (6)	BBCH 30-69 A: MIXED (1), PRINFC (1) B: MIXED (2)	BBCH 30-69 A: MIXED (1), PRINFC (6), MICELI (1), N/A (1) B: PRINFC (8), MICELI (1)	BBCH 30-69 A: PRINFC (3) B: PRINFC (3)	BBCH 30-69 A: MIXED (1), PRINFC (10), MICELI (1), N/A (1) B: PRINFC (13), MICELI (1)
	Number of applications Intervals between applications	1 application (4) 2 applications (17-37 days) (5)	1 application (2) 2 applications (18-22 days) (2)	1 application (4) 2 applications (15-31 days) (9)	1 application (1) 2 applications (17-29 days) (3)	1 application (7) 2 applications (15-37 days) (13)
	Spray volumes	200-500 l/ha*	300-400 l/ha	200-500 l/ha*	250-500 l/ha*	200-500 l/ha*
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (g), Yield (kg), Yield (T-MET), Yield (%), DON (PPB), NIV	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (g), Yield (T-MET), Yield (%), DON (PPB), T-2 (PPB)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (g), Yield (kg), Yield (T-MET), Yield (%), DON (PPB), NIV	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (g), Yield (kg), Yield (T-MET), Yield (%), DON (PPB), NIV	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (g), Yield (kg), Yield (T-MET), Yield (%), DON (PPB), NIV

		(PPB), T-2 (PPB), HT-2 (PPB)		(PPB), T-2 (PPB), HT-2 (PPB)	(PPB), T-2 (PPB), HT-2 (PPB)	(PPB), T-2 (PPB), HT-2 (PPB)
	Assessment dates	0 DA-A, 8-10 DA-A, 14-15 DA-A 0 DA-B, 2-6 DA-B, 9-10 DA-B, 15-19 DA-B, 23-30 DA-B, 49-62 DA-B, 68-182 DA-B	0 DA-A, 14 DA-A 0 DA-B, 15 DA-B, 25-29 DA-B, 37-56 DA-B	0 DA-A, 7 DA-A, 14-16 DA-A -1-0 DA-B, 7 DA-B, 14-20 DA-B, 21-31 DA-B, 41-52 DA-B, 63-115 DA-B	0 DA-A, 15 DA-A 0 DA-B, 6-10 DA-B, 14-15 DA-B, 21-25 DA-B, 47-67 DA-B, 138 DA-B	0 DA-A, 7-10 DA-A, 14-16 DA-A -1-0 DA-B, 2-10 DA-B, 14-20 DA-B, 21-31 DA-B, 41-52 DA-B, 62-182 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Artificial (6)	Artificial (2)	Artificial (9)	Artificial (3)	Artificial (14)
	e.g. Field / Greenhouse...	Field trials	Field trials	Field trials	Field trials	Field trials

*In a few trials the water volume applied was 500 l/ha. This small deviation did not impact the validity of the trials.

Out of the 20 trials performed on winter wheat against *Fusarium culmorum*, 15 were considered valid.

Use of CA3301 at 2x 0.6-0.8 l/ha against FUSACU – Maritime EPPO zone

In the Maritime EPPO zone, a total of 6 trials evaluated the efficacy of CA3301 on winter wheat against *Fusarium culmorum*. 3 trials were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 37-39 and the 2nd application was at BBCH 65-69. The analysis was conducted on ears.

Summary results are presented in Table 3.2-401.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on winter wheat against *Fusarium culmorum*. On ears inoculated, CA3301 at 0.6-0.8 l/ha showed 81.81-83.81% mean efficacy against *Fusarium culmorum* around two weeks after the 2nd application. On ears non-inoculated, CA3301 at 0.6-0.8 l/ha showed 75.31-84.63% efficacy against *Fusarium culmorum* around two weeks after the 2nd application.

In the Maritime EPPO zone there was a limited dataset for this pathogen from the valid number of trials. Nevertheless, applications of CA3301 consistently showed efficacy against *Fusarium culmorum* and provided results comparable to the approved reference standard. In particular in the trials where ears were inoculated, disease severity was relatively high in 1 trial at 62.71%, and CA3301 at both rates significantly reduced disease severity in this challenging condition, even below the level of disease observed from the reference product. In the trials where natural infection occurred the 0.8 l/ha dose rate of CA3301 demonstrated high efficacy compared to medium efficacy obtained from applications at 0.6 l/ha.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Fusarium culmorum* on winter wheat in the Maritime EPPO zone.

Table 3.2-401: Summary table - Efficacy evaluation – Winter wheat – FUSACU - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA24	CA33	CA33	No of trials where			No of trials where		
Rate		45	01	01	CA3301			CA3301		
Rate unit		0,8	0,6	0,8	at 0,6 l/ha is >, = or			at 0,8 l/ha is >, = or		
Appl. Code		L/ha	L/ha	L/ha	<			<		
		AB	AB	AB	compared to			compared to		
% Disease severity Ears I – 15-19 DA-B										
Number of values	3	3	3	3	UT C	CA24 45	CA33 01	UT C	CA24 45	CA33 01
Minimum value	5,60	0,55	0,49	0,37		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	62,71	16,48	14,64	13,92	3 >	0 >	0 >	3 >	0 >	0 >
Mean disease severity (%)	24,73	6,07	5,48	5,15	0 =	3 =	3 =	0 =	3 =	3 =
Abbott efficacy (%)	0,00%	81,21 %	81,81 %	83,81 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity Ears NI – 15-18 DA-B										
Number of values	2	2	2	2	UT C	CA24 45	CA33 01	UT C	CA24 45	CA33 01
Minimum value	1,20	0,23	0,33	0,21		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	800,00	1,50	1,75	1,06	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	4,60	0,86	1,04	0,64	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	81,04 %	75,31 %	84,63 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against FUSACU – Mediterranean EPPO zone

In the Mediterranean EPPO zone, a total of 2 trials evaluated the efficacy of CA3301 on winter wheat against *Fusarium culmorum*. Both trials were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 37-51 and the 2nd application was at BBCH 65-67. The analysis was conducted on ears.

Summary results are presented in Table 3.2-402.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on winter wheat against *Fusarium culmorum*. On ears I, CA3301 at 0.6-0.8 l/ha showed 76.65-78.30% mean efficacy against *Fusarium culmorum* at the 2nd application, mean efficacy around two weeks after the 2nd application and 72.67-73.26% mean efficacy before harvest.

In the Mediterranean EPPO zone there was a limited dataset for this pathogen. However, applications of CA3301 consistently showed efficacy (medium-high) against *Fusarium culmorum* and provided results comparable to the approved reference standard. Disease severity was low to medium in these trials, and although the rate of 0.8 l/ha overall reduced disease to a greater extent than the 0.6 l/ha rate the differences were not significant in this limited dataset. Nevertheless, it is likely that in circumstances of high disease pressure the increased disease control obtained from the higher rate may be of significant benefit.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Fusarium culmorum* on winter wheat in the Mediterranean EPPO zone.

Table 3.2-402: Summary table - Efficacy evaluation – Winter wheat – FUSACU - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA24 45 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
% Disease severity Ears I - 15 DA-B						
Number of values	2	2	2	2	UT C	CA24 45 0,8 l/ha CA33 01 0,8 l/ha UT C
Minimum value	14,13	1,53	1,00	0,48	1 >	0 >
Maximum value	26,50	6,70	10,50	10,60	1 =	2 =
Mean disease severity (%)	20,31	4,11	5,75	5,54	1 <	0 <
Abbott efficacy (%)	0,00%	81,94 %	76,65 %	78,30 %	0 <	0 <
% Disease severity Ears I - 25-29 DA-B						
Number of values	2	2	2	2	UT C	CA24 45 0,8 l/ha CA33 01 0,8 l/ha UT C
Minimum value	22,98	3,00	2,00	0,80	2 >	0 >
Maximum value	32,20	10,60	14,80	16,10	0 =	2 =
Mean disease severity (%)	27,59	6,80	8,40	8,45	0 <	0 <
Abbott efficacy (%)	0,00%	77,01 %	72,67 %	73,26 %	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against FUSACU – North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 9 trials evaluated the efficacy of CA3301 on winter wheat against *Fusarium culmorum*. 7 trials were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 37-39 and the 2nd application was at BBCH 61-65. The analysis was conducted on ears.

Summary results are presented in Table 3.2-403.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on winter wheat against *Fusarium culmorum*. On ears inoculated, CA3301 at 0.6-0.8 l/ha showed 73.07-78.48% mean efficacy around two weeks after the 2nd application and 52.84-67.99% mean efficacy before harvest. On ears non-inoculated, CA3301 at 0.6-0.8 l/ha showed 73.96-78.26% mean efficacy against *Fusarium culmorum* around 2 weeks after the 2nd application and 61.55-75.59% before harvest.

In the North-Eastern East EPPO zone a representative dataset was available for assessment of *Fusarium culmorum*, with disease severity ranging from relatively low to high during the trial. Data demonstrated that at low disease severity CA3301 applied at 0.6 l/ha or at 0.8 l/ha provided comparable efficacy, however as disease progressed there was a significant benefit derived from increasing the dose rate to

0.8 l/ha. This was particularly apparent at the second assessment of ears inoculated where in 3 trials at disease severity of 58.23-71.35% a statistical difference was recorded between the 2 dose rates, but in the trial with 10.81% disease no differences were observed. In addition, the efficacy obtained from applications of 0.8 l/ha was more often comparable with that from the reference standard, but with 0.6 l/ha efficacy was at times lower, since the content of prothioconazole at this dose rate is lower compared to the reference product.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Fusarium culmorum* on winter wheat in the North-Eastern East EPPO zone.

Table 3.2-403: Summary table - Efficacy evaluation – Winter wheat – FUSACU – North-Eastern East EPPO zone

East LFPO zone										
Treatment name	UNTREATED CHECK	CA244	CA330	CA330	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		5	1	1						
Rate unit		0,8	0,6	0,8						
Appl. Code		L/ha	L/ha	L/ha						
		AB	AB	AB						
% Disease severity Ears I - 14-20 DA-B										
Number of values	7	7	7	7	UT	CA244	CA330	UT	CA244	CA330
					C	5	1	C	5	1
Minimum value	7,49	1,87	2,29	1,76		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	38,58	8,04	11,02	7,60	7 >	0 >	0 >	7 >	1 >	2 >
Mean disease severity (%)	23,10	4,95	6,01	4,86	0 =	4 =	5 =	0 =	5 =	5 =
Abbott efficacy (%)	0,00%	75,93 %	73,07 %	78,48 %	0 <	3 <	2 <	0 <	1 <	0 <
% Disease severity Ears I - 21-31 DA-B										
Number of values	4	4	4	4	UT	CA244	CA330	UT	CA244	CA330
					C	5	1	C	5	1
Minimum value	10,81	5,00	4,11	2,60		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	71,35	26,95	38,92	22,53	4 >	0 >	0 >	4 >	1 >	3 >
Mean disease severity (%)	51,57	19,00	25,52	17,47	0 =	1 =	1 =	0 =	3 =	1 =
Abbott efficacy (%)	0,00%	61,11 %	52,84 %	67,99 %	0 <	3 <	3 <	0 <	0 <	0 <
% Disease severity Ears NI - 15-20 DA-B										
Number of values	4	4	4	4	UT	CA244	CA330	UT	CA244	CA330
					C	5	1	C	5	1
Minimum value	2,84	0,45	0,56	0,40		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	16,25	2,00	2,25	1,75	3 >	0 >	0 >	3 >	0 >	0 >
Mean disease severity (%)	7,43	1,33	1,53	1,25	1 =	4 =	4 =	1 =	4 =	4 =
Abbott efficacy (%)	0,00%	76,17 %	73,96 %	78,26 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity Ears NI - 21-31 DA-B										
Number of values	4	4	4	4	UT	CA244	CA330	UT	CA244	CA330
					C	5	1	C	5	1
Minimum value	2,50	0,31	1,25	0,63		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	28,75	8,75	13,75	11,25	3 >	0 >	0 >	3 >	0 >	0 >
Mean disease severity (%)	13,98	3,63	5,52	4,06	1 =	3 =	4 =	1 =	4 =	4 =
Abbott efficacy (%)	0,00%	76,78 %	61,55 %	75,59 %	0 <	1 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80% High efficacy

60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against FUSACU – South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 3 trials evaluated the efficacy of CA3301 on winter wheat against *Fusarium culmorum*. All 3 trials were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 39 and the 2nd application was at BBCH 65. The analysis was conducted on ears.

Summary results are presented in Table 3.2-404.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on winter wheat against *Fusarium culmorum*. On inoculated ears, CA3301 at 0.6-0.8 l/ha showed 84.94-89.80% mean efficacy around two weeks after the 2nd application. On ears non-inoculated, CA3301 at 0.6-0.8 l/ha showed 74.80-79.11% efficacy against *Fusarium culmorum* before harvest.

In the South-Eastern East EPPO zone there was a limited dataset for this pathogen, however disease pressure was relatively high with disease severity of 21.68-66.22% in the assessments, providing challenging conditions for the tested products. In these conditions, applications of CA3301 consistently showed efficacy (medium-high) against *Fusarium culmorum*. CA3301 applied at 0.8 l/ha demonstrated comparable efficacy to the authorised reference standard in all assessments. Applied at 0.6 l/ha disease control was slightly lower and at times this dose rate provided lower efficacy than the reference standard or the higher rate of CA3301, containing more prothioconazole. Nevertheless, in the assessments with the lowest disease severity the efficacy of CA3301 was comparable between the two dose rates.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Fusarium culmorum* on winter wheat in the South-Eastern East EPPO zone.

Table 3.2-404: Summary table - Efficacy evaluation – Winter wheat – FUSACU – South-Eastern East EPPO zone

East EPPO zone										
Treatment name	UNTREATED CHECK	CA244 5	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		0,8	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Disease severity Ears I - 14-15 DA-B										
Number of values	2	2	2	2	UT C	CA244 5	CA330 1	UT C	CA244 5	CA330 1
Minimum value	21,68	1,53	1,34	1,16		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	64,31	9,56	15,39	9,68	2 >	0 >	0 >	2 >	0 >	1 >
Mean disease severity (%)	42,99	5,55	8,36	5,42	0 =	1 =	1 =	0 =	2 =	1 =
Abbott efficacy (%)	0,00%	89,04 %	84,94 %	89,80 %	0 <	1 <	1 <	0 <	0 <	0 <
% Disease severity Ears NI - 21-25 DA-B										
Number of values	3	3	3	3	UT C	CA244 5	CA330 1	UT C	CA244 5	CA330 1
Minimum value	25,26	1,65	1,38	1,17		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	66,22	13,08	16,53	12,70	3 >	0 >	0 >	3 >	0 >	1 >
Mean disease severity (%)	40,61	8,44	10,54	8,19	0 =	2 =	2 =	0 =	3 =	2 =

Abbott efficacy (%)	0,00%	78,12 %	74,80 %	79,11 %	0 <	1 <	1 <	0 <	0 <	0 <
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'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against FUSACU – Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, a total of 14 trials evaluated the efficacy of CA3301 on winter wheat against *Fusarium culmorum*. 10 trials out of 14 were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 37-39 and the 2nd application was at BBCH 61-69. The analysis was conducted on ears.

Summary results are presented in Table 3.2-405.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on winter wheat against *Fusarium culmorum*. On ears inoculated, CA3301 at 0.6-0.8 l/ha showed 75.69-80.08% mean efficacy around two weeks after the 2nd application and 52.84-67.99% mean efficacy before harvest. On ears non-inoculated, CA3301 at 0.6-0.8 l/ha showed 74.41-80.38% mean efficacy against *Fusarium culmorum* around 2 weeks after the 2nd application and 61.55-75.59% before harvest.

A representative dataset was available for assessment of *Fusarium culmorum*, with disease severity ranging from relatively low to high levels during the trials. Data demonstrated that at low disease severity CA3301 applied at 0.6 l/ha or at 0.8 l/ha provided comparable efficacy, however as disease progressed there was a significant benefit derived from increasing the dose rate to 0.8 l/ha. This was particularly apparent at the second assessment of ears inoculated where in 3 trials at disease severity of 58.23-71.35% a statistical difference was recorded between the 2 dose rates, but in the trial with 10.81% disease no differences were observed. In addition, the efficacy obtained from applications of 0.8 l/ha was more often comparable with that from the reference standard, but with 0.6 l/ha efficacy was at times lower.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Fusarium culmorum* on winter wheat in Poland.

Table 3.2-405: Summary table - Efficacy evaluation – Winter wheat – FUSACU – Data relevant for poland

Treatment name	UNTREATED CHECK	CA244 5 0,8 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate										
Rate unit										
Appl. Code										
% Disease severity Ears I - 14-20 DA-B										
Number of values	10	10	10	10	UT	CA244 5	CA330 1	UT	CA244 5	CA330 1
Minimum value	5,60	0,55	0,49	0,37	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	62,71	16,48	14,64	13,92	10 >	0 >	0 >	10 >	1 >	2 >
Mean disease severity (%)	23,59	5,28	5,85	4,94	0 =	7 =	8 =	0 =	8 =	8 =
Abbott efficacy (%)	0,00%	77,52 %	75,69 %	80,08 %	0 <	3 <	2 <	0 <	1 <	0 <

% Disease severity Ears I - 21-31 DA-B										
Number of values	4	4	4	4	UT C	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UT C	CA244 5 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	10,81	5,00	4,11	2,60						
Maximum value	71,35	26,95	38,92	22,53	4 >	0 >	0 >	4 >	1 >	3 >
Mean disease severity (%)	51,57	19,00	25,52	17,47	0 =	1 =	1 =	0 =	3 =	1 =
Abbott efficacy (%)	0,00%	61,11 %	52,84 %	67,99 %	0 <	3 <	3 <	0 <	0 <	0 <
% Disease severity Ears NI - 15-20 DA-B										
Number of values	6	6	6	6	UT C	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UT C	CA244 5 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	1,20	0,23	0,33	0,21						
Maximum value	16,25	2,00	2,25	1,75	5 >	0 >	0 >	5 >	0 >	0 >
Mean disease severity (%)	6,48	1,17	1,36	1,04	1 =	6 =	6 =	1 =	6 =	6 =
Abbott efficacy (%)	0,00%	77,79 %	74,41 %	80,38 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity Ears NI - 21-31 DA-B										
Number of values	4	4	4	4	UT C	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UT C	CA244 5 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	2,50	0,31	1,25	0,63						
Maximum value	28,75	8,75	13,75	11,25	3 >	0 >	0 >	3 >	0 >	0 >
Mean disease severity (%)	13,98	3,63	5,52	4,06	1 =	3 =	4 =	1 =	4 =	4 =
Abbott efficacy (%)	0,00%	76,78 %	61,55 %	75,59 %	0 <	1 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

3 valid field trials were carried out in **the Maritime EPPO climatic zone**. The trial results from ears inoculated show high efficacy of CA3301 at 0,6-0,8 l/ha (above 80%). Also 2 trials with ears non-inoculated were conducted, however the disease pressure was very low in 1 trial (PESSEV 1,2%). The dose rate of 0,8 l/ha achieved better result compared to the lower dose. The limited number of trials has been submitted for Maritime zone. The cMSs are kindly asked to use extrapolation from other zones and consider this use on the national level.

7 valid field trials were conducted in **the North-East EPPO zone**. CA3301 at 0,6-0,8 l/ha achieved medium level of effectiveness. The very low disease pressure was observed in some trials with ears non-inoculated (PESSEV <5%). The dose rate of 0,8 l/ha achieved better result compared to the lower dose, especially in case of high disease pressure. No significant differences between higher dose of test product and reference product were detected.

3 valid field trials were conducted in **the South-East EPPO zone**. CA3301 was effective to control of FUSACU with results of above 80% on ears inoculated after 14-15 days after second application. The medium efficacy for ears non-inoculated was observed in 3 trials after 21-25 days. Due to the limited number of trials for SE zone, the results from Mediterranean EPPO zone were included to the evaluation. The test product applied at dose rate of 0,6-0,8 l/ha achieved efficacy of above 70% in 2 additional trials. Because the dataset is still insufficient, the cMSs are kindly asked to consider this use on the national level.

In the opinion of zRMS, CA3301 can be use to protection of winter wheat against *Fusarium culmorum* in the North-East zone. The higher dose rate of 0,8 l/ha is recommended especially in case of high disease pressure. It should be noted that the test product is effective on the medium level.

3.2.3.27 Winter wheat (TRZAW) / *Fusarium graminearum* (GIBBZE)

Materials and Methods – Winter wheat - GIBBZE

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2017 and 2020, a series of 25 trials were conducted in several countries of the Maritime, Mediterranean North-Eastern East and South-Eastern East EPPO zones to evaluate the efficacy of CA3301 against *Fusarium graminearum*. on winter wheat. The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, a total of 6 trials were performed in the Czech Republic (1), in Germany (2) and in the United Kingdom (3)

In the Mediterranean EPPO zone, 10 trials were performed in the south of France (1), in Italy (3) in Spain (2) and in Portugal (4)

In the North-eastern East EPPO zone, a total of 3 trials were performed in Latvia (2) and in Poland (1)

In the South-eastern East EPPO zone, a total of 6 trials were performed in Hungary (3) and in Romania (3).

Table 3.2-406: Presentation of trials – Winter wheat (TRZAW)

Crop(s) *)	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mar- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Winter wheat	GIBBZE	Czech Republic	2019	MED + E	1 (1)	-	-	-	GEP	
		Germany	2019- 2020	MED + E	2 (1)	-	-	-	GEP	
		United Kingdo m	2019- 2020	MED + E	3 (3)	-	-	-	GEP	
Winter wheat	GIBBZE	France	2020	MED + E	-	1 (1)	-	-	GEP	
		Italy	2019- 2020	MED + E	-	3 (3)	-	-	GEP	
		Spain	2019- 2020	MED + E	-	2 (2)	-	-	GEP	
		Portugal	2018- 2020	MED + E	-	4 (4)	-	-	GEP	
Winter wheat	GIBBZE	Latvia	2019	MED + E	-	-	2 (2)	-	GEP	
		Poland	2019	MED + E	-	-	1 (1)	-	GEP	
Winter wheat	GIBBZE	Hungary	2019- 2020	MED + E	-	-	-	3 (3)	GEP	
		Romania	2019- 2020	MED + E	-	-	-	3 (3)	GEP	
TOTA L	-	-	2018 -	MED + E	6 (5)	10 (10)	3 (3)	6 (6)	GEP	

Crop(s)) *	Tar- get(s)*	Country	Year s	Type of trial*	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
			2020							

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-emergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

In all trials, CA3301 was compared to at least one commercial and registered fungicide used as standard reference for comparison.

Table 3.2-407: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – GIBBZE – Maritime EPPO zone

Crop(s))	Refer- ence standard	Coun- try(ies) where the product is used ⁽¹⁾	Authoriza- tion number	Active sub- stance(s)	Formulation		Regis- tered ap- plication rate ⁽³⁾	Applica- tion rate in tri- als (per treat- ment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concentra- tion of a.s.			
Winter wheat	PRO- LINE 250 EC	CZ	4523-1	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO- LINE	DE	025287-00	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	CA2445	UK	12084	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

Table 3.2-408: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – GIBBZE – Mediterranean EPPO zone

Crop(s))	Refer- ence standard	Coun- try(ies) where the product is used ⁽¹⁾	Authoriza- tion number	Active sub- stance(s)	Formulation		Regis- tered ap- plication rate ⁽³⁾	Applica- tion rate in tri- als (per treat- ment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concentra- tion of a.s.			
Winter wheat	JOAO	FR (S)	2060116	Prothiocona- zole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials
	PRO- LINE	IT	013385	Prothiocona- zole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials
	PRAK- TIS	PT	AV 1485	Prothiocona- zole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials
	PRO- SARO	PT	AV 427	Prothiocona- zole + Tebuconazole	EC	125 g/l + 125 g/l	1 l/ha	1 l/ha	

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
	PRAKTIS	ES	01135	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials
	PRO-SARO	ES	25661	Prothioconazole + Tebuconazole	EC	125 g/l + 125 g/l		1 l/ha	

Table 3.2-409: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – GIBBZE – North-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter wheat	PRAKTIS	PL	R-222/2019	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE	LV	0637	Prothioconazole	EC	250 g/l	N/A	2 x 0.8 l/ha	CA2445 in some trials

Table 3.2-410: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – GIBBZE – South-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter wheat	PRO-LINE	HU	6300/1205-1/2020	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-LINE	RO	457PC/15.11.2018	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-411.

Table 3.2-411: Details on trial methodology – Winter wheat (TRZAW) - GIBBZE

		Maritime EPPO zone	Mediterranean EPPO zone	North-Eastern EPPO zone	South-Eastern EPPO zone
Trials	Total number (valid number)	6 (5)	10 (10)	3 (3)	6 (6)
	Supportive	-	-	-	-

	trials				
Guidelines	General guidelines	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)
	Specific guidelines	PP 1/26(4)	PP 1/26(4)	PP 1/26(4)	PP 1/26(4)
Experimental design	Plot design	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included
	Plot size	15-25 m ²	12-30 m ²	11.25-20 m ²	12-20 m ²
	Number of replications	4	4	4	4
Crop	Trials per crop	Winter wheat (6)	Winter wheat (10)	Winter wheat (3)	Winter wheat (6)
	Varieties per crop	SU Tobak (1), Matchball (1), Re-valuation (1), Barranco (1), Reflection (1), RGT Gravity (1)	Andino (1), Sarina (1), Bologna (1), Nogal (2), Anvergur (1), Marco Polo (1), PR22R58 (1), Hybiza (1), Ibiza (1)	Jantarka (1), Skagen (1), Talsis (1)	GK Koros (1), Alex (1), Joker (1), MV Nador (1), MV Kolompos (1), Rubisko (1)
	Sowing period	September (1), October (3), November (2)	October (2), November (1), December (5), January (2)	September (3)	September (3), October (3)
Application	Crop stage (BBCH)* at application	A: BBCH 37-41 B: BBCH 61-65	A: BBCH 37-39 B: BBCH 59-69	A: BBCH 39 B: BBCH 61-65	A: BBCH 37-39 B: BBCH 59-65
	Timing Pest stage at application	BBCH 30-69 A: PRINFC (6) B: PRINFC (6)	BBCH 30-69 A: PRINFC (10) B: MIXED (2), MYCELI (1), PRINFC (7)	BBCH 30-69 A: PRINFC (3) B: PRINFC (3)	BBCH 30-69 A: PRINFC (6) B: PRINFC (6)
	Number of applications Intervals between applications	2 applications (15-33 days) (6)	1 application (1) 2 applications (13-27 days) (10)	2 applications (12-14 days) (3)	2 applications (14-25 days) (6)
	Spray volumes	200-500 l/ha*	200-400 l/ha	300-500 l/ha*	200-500 l/ha*
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (g), Yield (kg), Yield (T-MET), Yield (%), DON (PPB), NIV (PPB), T-2 (PPB), HT-2 (PPB)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (g), Yield (kg), Yield (T-MET), Yield (%), DON (PPB), NIV (PPB), T-2 (PPB), HT-2 (PPB)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (g), Yield (kg), Yield (T-MET), Yield (%), DON (PPB), NIV (PPB), T-2 (PPB), HT-2 (PPB)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (g), Yield (kg), Yield (T-MET), Yield (%), DON (PPB), NIV (PPB), T-2 (PPB), HT-2 (PPB)
	Assessment dates	0 DA-A, 14-16 DA-A 0 DA-B, 2-6 DA-B, 9-19 DA-B, 22-27 DA-B, 33-49 DA-B, 64-72 DA-B	0 DA-A, 14-16 DA-A 0 DA-B, 6-11 DA-B, 14-19 DA-B, 22-36 DA-B, 52-96 DA-B, 127-141 DA-B	0 DA-A, 7 DA-A 0 DA-B, 6-7 DA-B, 10-15 DA-B, 20-24 DA-B, 29-44 DA-B, 176 DA-B	0 DA-A, 14-15 DA-A 0 DA-B, 6-10 DA-B, 11-16 DA-B, 21-25 DA-B, 47-67 DA-B, 138 DA-B

Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Artificial (6)	Artificial (10)	Artificial (3)	Artificial (6)
	e.g. Field / Greenhouse...	Field trials	Field trials	Field trials	Field trials

*In a few trials the water volume applied was 500 l/ha. This small deviation did not impact the validity of the trials.

Out of the 25 trials performed on winter wheat against *Fusarium graminearum*, 24 were considered valid.

Use of CA3301 at 2x 0.6-0.8 l/ha against GIBBZE – Maritime EPPO zone

In the Maritime EPPO zone, a total of 6 trials evaluated the efficacy of CA3301 on winter wheat against *Fusarium graminearum*. 5 trials were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 37-41 and the 2nd application was at BBCH 61-65. The analysis was conducted on ears.

Summary results are presented in Table 3.2-412.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on winter wheat against *Fusarium graminearum*. On inoculated ears, CA3301 at 0.6-0.8 l/ha showed 67.88-69.00% mean efficacy around two weeks after the 2nd application and 55.00-60.48% mean efficacy at the last assessment timing. On uninoculated ears, CA3301 at 0.6-0.8 l/ha showed 71.69-67.15% mean efficacy around two weeks after the 2nd application and 71.66-71.15% mean efficacy at the last assessment timing.

In the Maritime EPPO zone, CA3301 at 0.6-0.8 l/ha showed medium efficacy in reducing the severity of *Fusarium graminearum* on winter wheat. CA3301 at 0.6-0.8 l/ha consistently showed efficacy to control *Fusarium graminearum* and gave always equivalent disease control to the authorized reference product. In all the assessments, there were no significant differences in disease control between the rates of 0.6 l/ha or 0.8 l/ha of CA3301. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient to control *Fusarium graminearum*, however when disease infestation is high, the rate of 0.8 l/ha may be beneficial to further reduce disease severity.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Fusarium graminearum* on winter wheat in the Maritime EPPO zone.

Table 3.2-412: Summary table - Efficacy evaluation – Winter wheat – GIBBZE - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA244	CA330	CA330	No of trials where CA3301			No of trials where CA3301		
Rate		5	1	1	at 0,6 l/ha is >, = or			at 0,8 l/ha is >, = or		
Rate unit		0,8	0,6	0,8	<			<		
Appl. Code		L/ha	L/ha	L/ha	compared to			compared to		
		AB	AB	AB						
% Disease severity Ears I - 15-19 DA-B										
Number of values	4	4	4	4	UT	CA244	CA330	UT	CA244	CA330
Minimum value	1,51	0,12	0,17	0,20	C	5 0,8 l/ha	1 0,8 l/ha	C	5 0,8 l/ha	1 0,6 l/ha
Maximum value	6,07	3,41	4,37	3,41	4 >	0 >	0 >	4 >	0 >	0 >

Mean disease severity (%)	3,28	1,11	1,42	1,21	0 =	4 =	4 =	0 =	4 =	4 =
Abbott efficacy (%)	0,00%	73,63 %	67,88 %	69,00 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity Ears I - 22-34 DA-B										
Number of values	5	5	5	5	UT	CA244	CA330	UT	CA244	CA330
Minimum value	4,19	1,37	2,20	1,22	C	5 0,8 l/ha	1 0,8 l/ha	C	5 0,8 l/ha	1 0,6 l/ha
Maximum value	82,74	73,12	62,93	73,07	4 >	0 >	0 >	4 >	0 >	0 >
Mean disease severity (%)	38,32	23,24	20,73	22,47	1 =	5 =	5 =	1 =	5 =	5 =
Abbott efficacy (%)	0,00%	57,40 %	55,00 %	60,48 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity Ears NI - 15 DA-B										
Number of values	2	2	2	2	UT	CA244	CA330	UT	CA244	CA330
Minimum value	2,22	0,40	0,56	0,53	C	5 0,8 l/ha	1 0,8 l/ha	C	5 0,8 l/ha	1 0,6 l/ha
Maximum value	2,36	0,72	0,73	0,96	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	2,29	0,56	0,65	0,74	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	75,31 %	71,69 %	67,15 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity Ears NI - 22-34 DA-B										
Number of values	3	3	3	3	UT	CA244	CA330	UT	CA244	CA330
Minimum value	2,56	0,00	0,00	0,00	C	5 0,8 l/ha	1 0,8 l/ha	C	5 0,8 l/ha	1 0,6 l/ha
Maximum value	63,13	48,44	39,06	46,56	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	24,05	16,64	13,52	15,80	1 =	3 =	3 =	1 =	3 =	3 =
Abbott efficacy (%)	0,00%	66,81 %	71,66 %	71,15 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)	
>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against GIBBZE – Mediterranean EPPO zone

In the Mediterranean EPPO zone, a total of 10 trials evaluated the efficacy of CA3301 on winter wheat against *Fusarium graminearum*. All 10 trials were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 37-39 and the 2nd application was at BBCH 59-69. The analysis was conducted on ears.

Summary results are presented in Table 3.2-413.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on winter wheat against *Fusarium graminearum*. On inoculated ears, CA3301 at 0.6-0.8 l/ha showed 56.17-64.15% mean efficacy around two weeks after the 2nd application and 49.83-61.70% mean efficacy at the last assessment timing. On uninoculated ears, CA3301 at 0.6-0.8 l/ha showed 60.44-61.26% mean efficacy around two weeks after the 2nd application and 48.73-57.68% mean efficacy at the last assessment timing.

In the Mediterranean EPPO zone, the disease severity in the trials was low to relatively high (1.12-44.36%). CA3301 at 0.6-0.8 l/ha showed medium efficacy in reducing the severity of *Fusarium graminearum* on winter wheat. In those conditions, the increased 0.8 l/ha dose rate of CA3301 was globally more effective at reducing disease compared to the 0.6 l/ha rate, especially at the last assessment timing where a few statistical effects were observed in favour of 0.8 l/ha. In addition, the performance of CA3301 at 0.8 l/ha was more comparable to the reference products. However, in some evaluations, especially 2 weeks after the 2nd application, the 0.6 rate of CA3301 was sufficient to give comparable control.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Fusarium graminearum* on winter wheat in the Mediterranean EPPO zone.

Table 3.2-413: Summary table - Efficacy evaluation – Winter wheat – GIBBZE - Mediterranean EPPO zone

Treatment name	UNTREA TED CHECK	CA24 45 0,8 L/ha AB	PROSA RO 1 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to			
% Disease severity Ears I - 14-19 DA-B											
Number of values	9	9		9	9	UTC	CA3301 0,8 l/ha	UTC	CA3301 0,6 l/ha		
Minimum value	1,12	0,27		0,21	0,26						
Maximum value	27,95	13,05	-	14,75	17,50	6 >	0 >	6 >	0 >		
Mean disease severity (%)	11,87	3,82		5,13	4,49	3 =	9 =	3 =	9 =		
Abbott efficacy (%)	0,00%	66,75 %		56,17 %	64,15 %	0 <	0 <	0 <	0 <		
Number of values	2	2	2	2	2	CA2445 0,8 l/ha	PRO- SARO 1,0 l/ha	CA2445 0,8 l/ha	PRO- SARO 1,0 l/ha		
Minimum value	9,51	1,51	0,85	1,40	1,18						
Maximum value	21,56	1,86	2,28	5,08	3,85	0 >	0 >	0 >	0 >		
Mean disease severity (%)	15,55	1,69	1,56	3,24	2,52	9 =	2 =	9 =	2 =		
Abbott efficacy (%)	0,00%	87,75 %	90,25%	80,87 %	84,88 %	0 <	0 <	0 <	0 <		
% Disease severity Ears I - 25-36 DA-B											
Number of values	9	9		9	9	UTC	CA3301 0,8 l/ha	UTC	CA3301 0,6 l/ha		
Minimum value	4,44	0,83		1,05	0,99						
Maximum value	44,36	27,41	-	40,18	32,97	5 >	0 >	7 >	2 >		
Mean disease severity (%)	18,79	8,67		11,07	9,37	4 =	7 =	2 =	7 =		
Abbott efficacy (%)	0,00%	59,32 %		49,83 %	61,70 %	0 <	2 <	0 <	0 <		
Number of values	3	3	3	3	3	CA2445 0,8 l/ha	PRO- SARO 1,0 l/ha	CA2445 0,8 l/ha	PRO- SARO 1,0 l/ha		
Minimum value	9,36	0,83	0,75	1,05	1,33						
Maximum value	17,93	2,74	2,53	6,25	4,34	0 >	0 >	1 >	0 >		
Mean disease severity (%)	12,71	1,77	1,83	2,81	2,46	8 =	3 =	8 =	3 =		
Abbott efficacy (%)	0,00%	86,45 %	85,21%	81,15 %	81,92 %	1 <	0 <	0 <	0 <		
% Disease severity Ears NI - 16 DA-B											
Number of values	3	3		3	3	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	4,06	0,94		1,56	1,56						
Maximum value	41,88	15,00	-	17,50	18,63	3 >	0 >	0 >	3 >	0 >	0 >
Mean disease severity (%)	19,38	6,35		7,92	8,08	0 =	3 =	3 =	0 =	3 =	3 =
Abbott efficacy (%)	0,00%	71,78 %		60,44 %	61,26 %	0 <	0 <	0 <	0 <	0 <	0 <

Treatment name	UNTREA TED CHECK	CA24 45 0,8 L/ha AB	PROSA RO 1 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity Ears NI - 25-36 DA-B											
Number of values	5	5	-	5	5	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	4,06	1,25		0,00	0,00	2 >	0 >	0 >	3 >	0 >	1 >
Maximum value	38,13	16,46		18,44	17,56	3 =	3 =	4 =	2 =	4 =	4 =
Mean disease severity (%)	19,50	8,11		10,70	9,20	0 <	2 <	1 <	0 <	1 <	0 <
Abbott efficacy (%)	0,00%	60,74 %		48,73 %	57,68 %						

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against GIBBZE– North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 4 trials evaluated the efficacy of CA3301 on winter wheat against *Fusarium graminearum*. All 4 trials were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 39 and the 2nd application was at BBCH 61-65. The analysis was conducted on ears.

Summary results are presented in Table 3.2-414.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on winter wheat against *Fusarium graminearum*. On inoculated ears, CA3301 at 0.6-0.8 l/ha showed 51.50-63.45% mean efficacy around two weeks after the 2nd application and 41.60-47.93% mean efficacy at the last assessment timing. On uninoculated ears, CA3301 at 0.6-0.8 l/ha showed 69.12-79.05% mean efficacy around two weeks after the 2nd application and 67.12-71.73% mean efficacy at the last assessment timing.

In the North-Eastern East EPPO zone, the disease severity in the trials was low to relatively high (2.29-49.54%) with a limited dataset for *Fusarium graminearum*. In the majority of assessments CA3301 at 0.6-0.8 l/ha gave equivalent disease control to the approved reference standard. Although the rate of 0.8 l/ha overall reduced disease to a greater extent than the 0.6 l/ha rate, the differences were not significant in this limited dataset. Nevertheless, it is likely that in circumstances of high disease pressure the increased disease control obtained from the higher rate may be of significant benefit.

In addition, in the supportive dataset available against *Fusarium culmorum*, the same trend was observed and showed the efficacy obtained from applications of 0.8 l/ha was more often comparable with that from the reference standard. The same effect would then be expected for *Fusarium graminearum*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Fusarium graminearum* on winter wheat in the North-Eastern East EPPO zone.

Table 3.2-414: Summary table - Efficacy evaluation – Winter wheat – GIBBZE – North-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA24 45 0,8	CA33 01 0,6	CA33 01 0,8	No of trials where CA3301	No of trials where CA3301
Rate						

Rate unit		L/ha	L/ha	L/ha	at 0,6 l/ha is >, = or <			at 0,8 l/ha is >, = or <		
Appl. Code		AB	AB	AB	compared to			compared to		
% Disease severity Ears I - 15 DA-B										
Number of values	4	4	4	4	UT C	CA24 45	CA33 01	UT C	CA24 45	CA33 01
Minimum value	5,70	1,74	2,06	1,52		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	19,78	9,62	13,25	9,56	4 >	0 >	0 >	4 >	0 >	1 >
Mean disease severity (%)	13,83	4,96	7,05	5,24	0 =	3 =	3 =	0 =	4 =	3 =
Abbott efficacy (%)	0,00%	65,20 %	51,50 %	63,45 %	0 <	1 <	1 <	0 <	0 <	0 <
% Disease severity Ears I - 29 DA-B										
Number of values	2	2	2	2	UT C	CA24 45	CA33 01	UT C	CA24 45	CA33 01
Minimum value	28,52	15,25	17,33	16,96		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	49,54	21,66	27,76	22,13	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	39,03	18,45	22,54	19,55	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	51,40 %	41,60 %	47,93 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity Ears NI - 15 DA-B										
Number of values	3	3	3	3	UT C	CA24 45	CA33 01	UT C	CA24 45	CA33 01
Minimum value	2,29	0,40	0,83	0,46		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	5,56	2,31	1,69	1,51	3 >	0 >	0 >	3 >	0 >	0 >
Mean disease severity (%)	4,22	1,20	1,25	0,91	0 =	3 =	3 =	0 =	3 =	3 =
Abbott efficacy (%)	0,00%	74,23 %	69,12 %	79,05 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity Ears NI - 29 DA-B										
Number of values	2	2	2	2	UT C	CA24 45	CA33 01	UT C	CA24 45	CA33 01
Minimum value	6,20	2,03	2,13	1,95		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	9,19	2,75	2,64	2,19	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	7,69	2,39	2,38	2,07	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	68,67 %	67,12 %	71,73 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against GIBBZE – South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 6 trials evaluated the efficacy of CA3301 on winter wheat against *Fusarium graminearum*. All 6 trials were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 37-39 and the 2nd application was at BBCH 59-65. The analysis was conducted on ears.

Summary results are presented in Table 3.2-415.

In the South-Eastern East EPPO zone, the disease severity in the trials was low to medium (6.11-35.00%) with a limited dataset for the natural infestation of *Fusarium graminearum*. In the majority of assessments CA3301 at 0.8 l/ha gave equivalent or higher disease control than the authorized reference products while the 0.6 l/ha dose rate globally provided equivalent or lower efficacy than the reference products. The rate of 0.8 l/ha provided also significant higher efficacy than the 0.6 l/ha dose rate in most of trials. Therefore, it is likely that in similar circumstances or in case of high disease pressure, CA3301 at the 0.8 l/ha dose rate would be more appropriate.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Fusarium graminearum* on winter wheat in the South-Eastern East EPPo zone.

EIPG zone											
Treatment name	UNTREAT ED CHECK	CA24 45 0,8 L/ha AB	PROSAR O 1 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or <			No of trials where CA3301 at 0,8 l/ha is >, = or <		
Rate											
Rate unit											
Appl. Code						compared to			compared to		
% Disease severity Ears I - 15-17 DA-B											
Number of values	4	4		4	4	UTC	CA3301 0,8 l/ha	UTC	CA3301 0,6 l/ha		
Minimum value	6,11	0,97		1,34	0,91						
Maximum value	35,00	4,00	-	7,00	5,50	4 >	0 >	4 >	2 >		
Mean disease severity (%)	13,83	2,17		3,21	2,43	0 =	2 =	0 =	2 =		
Abbott efficacy (%)	0,00%	80,19 %		73,77 %	80,97 %	0 <	2 <	0 <	0 <		
Number of values	1	1	1	1	1	CA2445 0,8 l/ha	PRO- SARO 1,0 l/ha	CA2445 0,8 l/ha	PROSARO 1,0 l/ha		
Minimum value	6,11	0,97	1,47	1,34	0,91						
Maximum value	6,11	0,97	1,47	1,34	0,91	0 >	0 >	0 >	1 >		
Mean disease severity (%)	6,11	0,97	1,47	1,34	0,91	3 =	1 =	4 =	0 =		
Abbott efficacy (%)	0,00%	84,12 %	75,94%	78,07 %	85,11 %	1 <	0 <	0 <	0 <		
% Disease severity Ears I - 23-28 DA-B											
Number of values	5	5		5	5	UTC	CA3301 0,8 l/ha	UTC	CA3301 0,6 l/ha		
Minimum value	6,72	1,99		2,71	1,75						
Maximum value	17,61	5,83	-	9,54	5,72	5 >	0 >	5 >	4 >		
Mean disease severity (%)	12,36	3,24		4,62	3,12	0 =	1 =	0 =	1 =		
Abbott efficacy (%)	0,00%	73,95 %		63,66 %	75,21 %	0 <	4 <	0 <	0 <		
Number of values	2	2	2	2	2	CA2445 0,8 l/ha	PRO- SARO 1,0 l/ha	CA2445 0,8 l/ha	PROSARO 1,0 l/ha		
Minimum value	12,04	2,51	4,20	3,34	2,35						
Maximum value	13,27	2,65	4,34	3,47	2,54	0 >	1 >	0 >	2 >		
Mean disease severity (%)	12,66	2,58	4,27	3,41	2,45	1 =	1 =	5 =	0 =		
Abbott efficacy (%)	0,00%	79,59 %	66,15%	73,00 %	80,67 %	4 <	0 <	0 <	0 <		
% Disease severity Ears NI - 15 DA-B											
Number of values	1	1		1	1	UT C	CA24 45	CA33 01	UTC	CA244 5	CA330 1

Minimum value	28,75	6,25		5,75	2,50		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	28,75	6,25	-	5,75	2,50	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	28,75	6,25		5,75	2,50	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	78,26 %		80,00 %	91,30 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity Ears NI - 24 DA-B											
Number of values	1	1		1	1	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UTC	CA244 5 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	19,06	7,69		10,00	5,50	1 >	0 >	0 >	1 >	1 >	1 >
Maximum value	19,06	7,69	-	10,00	5,50	0 =	0 =	0 =	0 =	0 =	0 =
Mean disease severity (%)	19,06	7,69		10,00	5,50	0 =	0 =	0 =	0 =	0 =	0 =
Abbott efficacy (%)	0,00%	59,65 %		47,53 %	71,14 %	0 <	1 <	1 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

5 valid field trials were carried out in **the Maritime EPPO climatic zone**. Most of submitted trials show very low disease pressure on ears, either inoculated and non-inoculated. CA3301 achieved medium efficacy after 15-34 days after second application (60-72%). Taking into account low PESSEV in the submitted trials, the higher dose rate of 0,8 l/ha should be recommended in situation of high disease pressure. Due to the limited number of trials, the cMSs are kindly asked to consider this use on the national level.

4 valid field trials were conducted in **the North-East EPPO climatic zone**. CA3301 applied at dose rate of 0,6-0,8 l/ha achieved low efficacy on ears inoculated. The pest severity less than 5% were noted in some trials on ears non-inoculated. The medium efficacy were observed in these trials. Due to the limited number of trials, results from neighbouring countries (Germany and Czech Republic) were included as support to evaluation. Taking into account all trials, CA3301 can be recommended in NE zone but it should be noted that on the medium level. No significant differences between test and reference product were observed.

6 valid field trials were carried out in **the South-East EPPO zone**. The significant differences between 0,6 l/ha and 0,8 l/ha have been observed. CA3301 achieved the medium efficacy in control of GIBZZE (60-80%). The dose rate of 0,6 l/ha amounted lower effectiveness compared to the higher in situation of lower disease pressure. Due to that, the dose rate of 0,8 l/ha should be recommended in case of high PESSEV.

In the opinion of zRMS, CA3301 can be recommended to protection of winter wheat against *Fusarium graminearum* in NE and SE zone. It should be noted that the test product achieved medium efficacy. The higher dose rate of 0,8 l/ha should be use in case of high disease pressure.

3.2.3.28 Winter wheat (TRZAW) / *Fusarium sp* (FUSASP)

Materials and Methods – Winter wheat - FUSASP

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2017 and 2020, a series of 6 trials were conducted in several countries of the Maritime, Mediterranean and South-Eastern East EPPO zones to evaluate the efficacy of CA3301 against *Fusarium sp.* on **winter wheat** (see Table 3.2-416). The trials were carried out by certified testing institutes.

***Fusarium* sp.** trials were trials with an artificial inoculation of a mix of *Fusarium* species (*Fusarium culmorum* and *Fusarium graminearum*) or trials with a natural infestation where the species has not been identified.

In the Maritime EPPO zone, a total of 2 trials were performed in the Czech Republic (1) and France (1)

In the Mediterranean EPPO zone, 1 trial was performed in Italy (1)

In the South-eastern East EPPO zone, a total of 3 trials were performed in Hungary (3)

Table 3.2-416: Presentation of trials – Winter wheat (TRZAW)

Crop(s)) *	Tar- get(s)*	Coun- try	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, offi- cial***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Winter wheat	FUSASP	Czech Republi c	2017	MED + E	1 (0)	-	-	-	GEP	
		France (N)	2019	MED + E	1 (0)	-	-	-	GEP	
Winter wheat	FUSASP	Italy	2020	MED + E	-	1 (1)	-		GEP	
Winter wheat	FUSASP	Hungary	2018- 2019	MED + E	-	-	-	3 (3)	GEP	
TOTA L	-	-	2017 - 2020	MED + E	2 (0)	1 (1)	0 (0)	3 (3)	GEP	

In all trials, CA3301 was compared to at least one commercial and registered fungicide used as standard reference for comparison.

Table 3.2-417: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – FUSASP – Maritime EPPO zone

Crop(s))	Refer- ence standard	Coun- try(ies) where the product is used ⁽¹⁾	Authoriza- tion number	Active sub- stance(s)	Formulation		Regis- tered ap- plication rate ⁽³⁾	Applica- tion rate in tri- als (per treat- ment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concentra- tion of a.s.			
Winter wheat	JOAO	FR (N)	2060116	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO- LINE 250 EC	CZ	4523-1	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	1 x 0.8 l/ha 2 x 0.6 l/ha	CA2445 in some trials

Table 3.2-418: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – FUSASP – Mediterranean EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter wheat	PRO-LINE	IT	013385	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO-SARO	IT	013386	Prothioconazole + Tebuconazole	EC	250 g/L	1 or 2 x 1 l/ha	2 x 1 l/ha	

Table 3.2-419: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – FUSASP – South-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Winter wheat	PRO-LINE	HU	6300/1205-1/2020	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	1 x 0.8 l/ha 2 x 0.8 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-420.

Table 3.2-420: Details on trial methodology – Winter wheat (TRZAW) - FUSASP

		Maritime EPPO zone	Mediterranean EPPO zone	South-Eastern EPPO zone
Trials	Total number (valid number)	2 (0)	1 (1)	3 (3)
	Supportive trials	-	-	-
Guidelines	General guidelines	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)
	Specific guidelines	PP 1/26(4)	PP 1/26(4)	PP 1/26(4)
Experimental design	Plot design	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included
	Plot size	20-30 m ²	21 m ²	19.5-30 m ²
	Number of replications	4	4	4
Crop	Trials per crop	Winter wheat (2)	Winter wheat (1)	Winter wheat (3)
	Varieties per crop	Tobak (1), Sy Moisson (1)	Bologna (1)	GK Békés (1), Akteur (1), GK Körös (1)

		Maritime EPPO zone	Mediterranean EPPO zone	South-Eastern EPPO zone
	Sowing period	October (2)	October (1)	October (3)
Application	Crop stage (BBCH)* at application	A: BBCH 37 B: BBCH 65	A: BBCH 30 B: BBCH 49	A: BBCH 39-47 B: BBCH 65
	Timing Pest stage at application	BBCH 30-69 A: PRINFC (2) B: PRINFC (2)	BBCH 30-69 A: PRINFC (1) B: PRINFC (1)	BBCH 30-69 A: PRINFC (1), N/A (2) B: PRINFC (1), N/A (2)
	Number of applications Intervals between applications	1 application (1) 2 applications (17-39 days) (33)	2 applications (30 days) (1)	1 application (2) 2 applications (13-14 days) (3)
	Spray volumes	200-400 l/ha	400 l/ha	200-500 l/ha*
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (g), Yield (kg), Yield (T-MET), Yield (%), DON (PPB), NIV (PPB)
	Assessment dates	0 DA-A, 17 DA-A-2--1 DA-B, 6 DA-B, 11-14 DA-B, 17-21 DA-B, 32-34 DA-B	0 DA-A, 17 DA-A, 28 DA-A-23 DA-B, 35 DA-B, 71 DA-B	0 DA-A, 0 DA-B, 17 DA-B, 27 DA-B, 52-54 DA-B, 126-211 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Artificial (2)	Natural (1)	Natural (1), Artificial (2)
	e.g. Field / Greenhouse...	Field trials	Field trials	Field trials

*In one trial the water volume applied was 500 l/ha. This small deviation did not impact the validity of the trial.

Out of the 6 trials performed on winter wheat against *Fusarium sp.*, 4 were considered valid

Use of CA3301 at 2x 0.6-0.8 l/ha against FUSASP – Maritime EPPO zone

In the Maritime EPPO zone, 2 trials were performed zone for assessment of control of *Fusarium sp.* but these trials were not valid. However, since the trials were carried out with artificial inoculation of a mix of *Fusarium* species (*Fusarium culmorum* and *Fusarium graminearum*) or with natural infestation where the species has not been identified, it is possible to refer to the data available on *Fusarium culmorum* and *Fusarium graminearum* in the same EPPO zone.

In the Maritime EPPO zone, 5 supportive trials demonstrated that CA3301 at 0.6-0.8 l/ha consistently showed efficacy to control *Fusarium graminearum* and gave always equivalent disease control to the authorized reference product. In all the assessments, there were no significant differences in disease control between the rates of 0.6 l/ha or 0.8 l/ha of CA3301. Moreover, 3 additional trials demonstrated the same trend to control *Fusarium culmorum*. In particular in the trials where ears were inoculated, disease severity was relatively high in 1 trial at 62.71%, and CA3301 at both rates significantly reduced disease severity in this challenging condition, even below the level of disease observed from the refer-

ence product. In the trials where natural infection occurred the 0.8 l/ha dose rate of CA3301 demonstrated high efficacy compared to medium efficacy obtained from applications at 0.6 l/ha. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient to control *Fusarium species*, however when disease infestation is high, the rate of 0.8 l/ha may be beneficial to further reduce disease severity.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Fusarium sp.* on winter wheat in the Maritime EPPO zone.

Use of CA3301 at 2x 0.6-0.8 l/ha against FUSASP – Mediterranean EPPO zone

In the Mediterranean EPPO zone, a single trial evaluated the efficacy of CA3301 on winter wheat against *Fusarium sp.* The trial was considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stage BBCH 30 and the 2nd application was at BBCH 49. The analysis was conducted on ears.

Summary results are presented in Table 3.2-421.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on winter wheat against *Fusarium sp.* However the targeted disease of this trial was not *Fusarium sp.* initially, which explain the late infestation and the fact that the applications were not performed at an optimal timing to control this disease. On uninoculated ears, CA3301 at 0.6-0.8 l/ha showed 66.37-40.36% of efficacy before harvest. These positive effects to control *Fusarium sp.* of CA3301 at 0.6-0.8 l/ha were equivalent to the reference products CA2445 and PROSARO.

In the Mediterranean EPPO zone a single trial is available for assessment of undetermined *Fusarium sp.*. However, the reference product demonstrated efficacy in this trial, therefore the data has been included. According to statistical analysis both rates of CA3301 were comparable to each other and to the authorised reference products included in the trial. In this single trial, where infection occurred late, and disease severity was low CA3301 demonstrated medium to low efficacy. Whilst a single trial is insufficient to evaluate efficacy, the tested product nevertheless also demonstrated comparable efficacy to the reference products in the trials on the related pathogen *Fusarium culmorum*, with effective disease control from both dose rates but a higher disease suppression from the rate of 0.8 l/ha compared to 0.6 l/ha.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Fusarium sp.* on winter wheat in the Mediterranean EPPO zone.

Table 3.2-421: Summary table - Efficacy evaluation – Winter wheat – FUSASP - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA 2445	PROSARO	CA3301	CA3301	No of trials where CA3301				No of trials where CA3301			
Rate		0,8	1	0,6	0,8	at 0,6 l/ha is >, = or <				at 0,8 l/ha is >, = or <			
Rate unit		L/ha	L/ha	L/ha	L/ha								
Appl. Code		AB	AB	AB	AB	compared to				compared to			
% Disease severity Ears NI - 35 DA-B													
Number of values	1	1	1	1	1	UT C	CA2445	PRO-SARO	CA3301	UT C	CA2445	PRO-SARO	CA3301
Minimum value	7,88	3,95	1,98	2,65	4,70		0,8 l/ha	1,0 l/ha	0,8 l/ha		0,8 l/ha	1,0 l/ha	0,6 l/ha
Maximum value	7,88	3,95	1,98	2,65	4,70	1 >	0 >	0 >	0 >	1 >	0 >	0 >	0 >

Mean disease severity (%)	7,88	3,95	1,98	2,65	4,70	0 =	1 =	1 =	1 =	0 =	1 =	1 =	1 =
Abbott efficacy (%)	0,00%	49,87%	74,87%	66,37%	40,36%	0 <	0 <	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against FUSASP– North-~~Eastern~~ **East** EPPO zone

In the North-~~Eastern~~ **East** EPPO zone, no trials were available for assessment of control of *Fusarium sp.* However, since generally the trials were carried out with artificial inoculation of a mix of *Fusarium* species (*Fusarium culmorum* and *Fusarium graminearum*) or with natural infestation where the species has not been identified, it is possible to refer to the data available on *Fusarium culmorum* and *Fusarium graminearum* in the same EPPO zone.

In the North-~~Eastern~~ **East** zone, 7 supportive trials demonstrated that in a representative dataset was available for assessment of *Fusarium culmorum* with low disease severity, CA3301 applied at 0.6 l/ha or at 0.8 l/ha provided comparable efficacy, although as disease progressed there was a significant benefit derived from increasing the dose rate to 0.8 l/ha. This was particularly apparent at the second assessment of ears inoculated where in 3 trials at disease severity of 58.23-71.35% a statistical difference was recorded between the 2 dose rates, but in the trial with 10.81% disease no differences were observed. In addition, the efficacy obtained from applications of 0.8 l/ha was more often comparable with that from the reference standard, but with 0.6 l/ha efficacy was at times lower. The same trend is also expected for *Fusarium sp.*

Considering all elements presented above and the dataset previously presented against *Fusarium culmorum*, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Fusarium culmorum* on winter wheat in the North-~~Eastern~~ **East EPPO zone.**

Use of CA3301 at 2x 0.6-0.8 l/ha against FUSASP– South-~~Eastern~~ **East** EPPO zone

In the South-~~Eastern~~ **East** EPPO zone, a total of 3 trials evaluated the efficacy of CA3301 on winter wheat against *Fusarium sp.* All 3 trials were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 39-47 and the 2nd application was at BBCH 65. The analysis was conducted on ears.

Summary results are presented in Table 3.2-422.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on winter wheat against *Fusarium sp.* On inoculated ears, CA3301 at 0.6-0.8 l/ha showed 52.14-67.75% mean efficacy around two weeks after the 2nd application. On uninoculated ears, in a single trial with very low infestation, CA3301 at 0.6-0.8 l/ha provided full control against *Fusarium sp.* before harvest.

In the South-~~Eastern~~ **East** EPPO zone a limited dataset is available for assessment of undetermined *Fusarium sp.*. Nevertheless, the data demonstrates the same trends for the related species *Fusarium culmorum* and *Fusarium graminearum* whereby in conditions of higher disease severity CA3301 applied at 0.8 l/ha is more effective compared to the rate of 0.6 l/ha, but at lower disease pressure both rates can give effective control comparable to the authorized reference product.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Fusarium sp.* on winter wheat in the South-~~Eastern~~ **East EPPO zone.**

Table 3.2-422: Summary table - Efficacy evaluation – Winter wheat – FUSASP – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA24 45	CA330 1	CA330 1	No of trials where CA3301			No of trials where CA3301		
Rate		0,8	0,6	0,8	at 0,6 l/ha is >, = or			at 0,8 l/ha is >, = or		
Rate unit		L/ha	L/ha	L/ha	<			<		
Appl. Code		AB	AB	AB	compared to			compared to		
% Disease severity Ears I - 17 DA-B										
Number of values	2	2	2	2	UT C	CA24 45	CA33 01	UT C	CA24 45	CA33 01
Minimum value	34,75	11,46	16,53	12,21		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	72,30	13,43	34,82	21,23	2 >	0 >	0 >	2 >	0 >	2 >
Mean disease severity (%)	53,53	12,44	25,67	16,72	0 =	0 =	0 =	0 =	2 =	0 =
Abbott efficacy (%)	0,00%	74,22 %	52,14%	67,75 %	0 <	2 <	2 <	0 <	0 <	0 <
% Disease severity Ears NI - 27 DA-B										
Number of values	1	1	1	1	UT C	CA24 45	CA33 01	UT C	CA24 45	CA33 01
Minimum value	1,11	0,00	0,00	0,00		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	1,11	0,00	0,00	0,00	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	1,11	0,00	0,00	0,00	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	100,00 %	100,00 %	100,00 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)
(conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

Based on the applicant's explanation that *Fusarium* sp. trials were trials with an artificial inoculation of a mix of *Fusarium* species (*Fusarium culmorum* and *Fusarium graminearum*) or trials with a natural infestation where the species has not been identified, the final conclusions are related with the previous summaries.

3 valid field trials with FUSACU and 5 trials with GIBZZE were carried out in **the Maritime EPPO climatic zone**. In case of FUSACU, the trial results from ears inoculated show high efficacy of CA3301 at 0,6-0,8 l/ha (above 80%). Also 2 trials with ears non-inoculated were conducted, however the disease pressure was very low in 1 trial (PESSEV 1,2%). In case of GIBZZE, most of submitted trials show very low disease pressure on ears, either inoculated and non-inoculated. CA3301 achieved medium efficacy after 15-34 days after second application (60-72%). Taking into account low PESSEV in the submitted trials, the higher dose rate of 0,8 l/ha should be recommended in situation of high disease pressure. The CMSs are kindly asked to consider this use on the national level.

7 valid field trials with FUSACU and 4 trials with GIBZZE were conducted in **the North-East EPPO zone**. In case of FUSACU, CA3301 at 0,6-0,8 l/ha achieved medium level of effectiveness. The very low disease pressure was observed in some trials with ears non-inoculated (PESSEV <5%). The dose rate of 0,8 l/ha achieved better result compared to the lower dose, especially in case of high disease pressure. In case of GIBZZE, CA3301 applied at dose rate of 0,6-0,8 l/ha achieved low efficacy on ears inoculated. The pest severity less than 5% were noted in some trials on ears non-inoculated. The medium efficacy were observed in these trials. Due to the limited number of trials, results from neighbouring countries (Germany and Czech Republic) were included as support to evaluation. Taking into account all trials, CA3301 can be recommended in NE zone but it should be noted that on the medium level. No significant differences between test and reference product were observed.

3 valid field trials with FUSACU and 6 trials with GIBZZE were conducted in **the South-East EPPO zone**. In case of FUSACU, CA3301 was effective to control with results of above 80% on ears inoculated after 14-15 days after second application. The medium efficacy for ears non-inoculated was observed in 3 trials after 21-25

days. Due to the limited number of trials for SE zone, the results from Mediterranean EPPO zone were included to the evaluation. The test product applied at dose rate of 0,6-0,8 l/ha achieved efficacy of above 70% in 2 additional trials. In case of GIBZZE, the significant differences between 0,6 l/ha and 0,8 l/ha have been observed. CA3301 achieved the medium efficacy in control of GIBZZE (60-80%). The dose rate of 0,6 l/ha amounted lower effectiveness compared to the higher in situation of lower disease pressure. Due to that, the dose rate of 0,8 l/ha should be recommended in case of high PESSEV. Moreover, the results of 3 efficacy trials with FUSASP have been submitted. CA3301 applied at dose rate 0,8 l/ha achieved medium efficacy after 17 days after second application and 100% after 27 DA-B.

In the opinion of zRMS, CA3301 can be recommended to protection of winter wheat against *Fusarium* sp. in the NE and SE zones but it should be noted that the product is effective on the medium level. Furthermore, the dose rate of 0,8 l/ha is recommended in case of high disease pressure.

3.2.3.29 Winter wheat (TRZAW) / *Pyrenophora tritici-repentis* (PYRNTR)

Materials and Methods – Winter wheat – PYRNTR

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2017 and 2020, a series of 16 trials were conducted in several countries of the Maritime, North-Eastern East and South-Eastern East EPPO zones to evaluate the efficacy of CA3301 against *Pyrenophora tritici-repentis* on winter wheat. The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, 2 trials were performed in Czech Republic.

In the North-Eastern East EPPO zone, a total of 12 trials were performed in Lithuania (5), Latvia (6) and Poland (1).

In the South-Eastern East EPPO zone, 2 trials were performed in Romania (1) and Slovakia (1) (see Table 3.2-576).

Groupings were also made specifically for Poland and trials involved (15) were performed in the North-Eastern East EPPO zone (12), in the Czech Republic (2) and in Slovakia (1).

Table 3.2-423: Presentation of trials – Winter wheat (TRZAW)

Crop(s) *)	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mar- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Winter wheat	PYRNTR	Czech Republic	2018- 2019	MED + E	2 (1)	-	-	-	GEP	
TOTA L	-	-	2018- 2019	MED + E	2 (1)	-	-		GEP	
Winter wheat	PYRNTR	Lithuani a	2019- 2020	MED + E	-	-	5 (1)	-	GEP	
		Latvia	2019- 2020	MED + E	-	-	6 (6)	-	GEP	
		Poland	2017	MED + E	-	-	1 (0)	-	GEP	
TOTA L	-	-	2017- 2020	MED + E	-	-	12 (7)	-	GEP	
Winter	PYRNTR	Romania	2018	MED	-	-	-	1 (1)	GEP	

Crop(s)) *	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
wheat				+ E						
		Slovakia	2020	MED + E	-	-	-	1 (1)	GEP	
TOTAL	-	-	2018- 2020	MED + E	-	-	-	2 (2)	GEP	
Winter wheat	PYRNTR	Czech Republic	2018- 2019	MED +E	-	-	-	-	GEP	
		Lithuania	2019- 2020	MED +E	-	-	-	-	GEP	
		Latvia	2019- 2020	MED +E	-	-	-	-	GEP	
		Poland	2017	MED +E	-	-	-	-	GEP	
		Slovakia	2020	MED +E	-	-	-	-	GEP	
TOTAL	-	-	2017- 2020	MED +E	-	-	-	-	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation

In all trials, CA3301 was compared to at least one commercial fungicide used as standard reference for comparison.

Table 3.2-424: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – PYRNTR – Maritime EPPO zone

Crop(s))	Refer- ence standard	Country(ies) where the product is used ⁽¹⁾	Authoriza- tion number	Active sub- stance(s)	Formulation		Regis- tered ap- plication rate ⁽³⁾	Applica- tion rate in tri- als (per treat- ment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concentra- tion of a.s.			
Winter wheat	PRO- LINE 250 EC	CZ	4523-1	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha max	1 x 0.6-0.8 l/ha 2 x 0.8 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-425: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – PYRNTR – North-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
TRZAW	PRAKTIS	PL	R-222/2019	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PROLINE	LT	AS2-6F(2018) 2019-07-31	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PROLINE	LV	0637	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-426: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – PYRNTR – South-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
TRZAW	PROLINE	RO	457PC/15/11/2018	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PROLINE 250 EC	SK	06-02-0768	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRIAXOR	SK	16-02-1746	Fluxapyroxad + Pyraclostrobin	EC	75 g/L + 150 g/L	2 x 0,75 - 1,5 l/ha	2 x 1.5 l/ha	

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-427.

Table 3.2-427: Details on trial methodology – Winter wheat (TRZAW) – PYRNTR

		Maritime EPPO zone	North –East EPPO zone	South-Eastern EPPO zone	Data relevant for Poland
Trials	Total number (valid number)	2 (2)	12 (7)	2 (2)	15 (9)
	Supportive trials	-	-	-	-
Guidelines	General guidelines	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4)

		PP 1/214 (3) PP 1/225 (2)	PP 1/214 (3)	PP 1/214 (3)	PP 1/214 (3) PP 1/225 (2)
	Specific guidelines	PP 1/26 (4) PP 1/28 (3) PP 1/262 (1)	PP 1/26 (4)	PP 1/26 (4)	PP 1/26 (4) PP 1/28 (3) PP 1/262 (1)
Experimental design	Plot design	Randomized Complete Blocks, Untreated included	Randomized Complete Blocks, Untreated included	Randomized Complete Blocks, Untreated included	Randomized Complete Blocks, Untreated included
	Plot size	24.9 - 30 m ²	11.25-30 m ²	30 m ²	11.25-30 m ²
	Number of replications	4	4	4	4
Crop	Trials per crop	TRZAW (2)	TRZAW (12)	TRZAW (2)	TRZAW (15)
	Varieties per crop	Ilona (1), Butterfly (1)	Skagen (4), Wilejka (1), Arkadia (1), Etana (2), Edvins (1), Famulus (1), Talsis (1), Artist (1)	Romulus (1), Capo (1)	Skagen (4), Wilejka (1), Arkadia (1), Etana (2), Edvins (1), Famulus (1), Talsis (1), Artist (1), Ilona (1), Butterfly (1), Capo (1)
	Sowing period	October (2)	September (11), October (1)	October (2)	September (11), October (4)
Application	Crop stage (BBCH)* at application	A : BBCH 31-32 B: BBCH 39-69	A: BBCH 31-45 B: BBCH 39-69	A: BBCH 31-39 B: BBCH 47-69	A: BBCH 31-45 B: BBCH 39-69
	Timing Pest stage at application	BBCH 31-69 A: PRINFC (1), MIXED (1) B: PRINFC (1), MIXED (1)	BBCH 31-69 A: MYCELI (1), PRINFC (2), N/A (5), MIXED (2), ACTIVE (1) B: MYCELI (1), PRINFC (4), N/A (2), MIXED (3), ACTIVE (1), SPORUL (1)	BBCH 31-69 A: PRINFC (2) B: MIXED (1), PRINFC (1)	BBCH 31-69 A: MYCELI (1), PRINFC (4), N/A (5), MIXED (3), ACTIVE (1) B: MYCELI (1), PRINFC (6), N/A (2), MIXED (4), ACTIVE (1), SPORUL (1)
	Number of applications Intervals between applications	2 applications (24-28 days) (2)	1 application (1) 2 applications (12-33 days) (11)	1 application (1) 2 applications (17-21 days) (2)	1 application (1) 2 applications (12-33 days) (14)
	Spray volumes	A: 250-300 l/ha B: 250-300 l/ha	A: 200-300 l/ha B: 200-500 l/ha	A: 200-250 l/ha B: 200-250 l/ha	A: 200-300 l/ha B: 200-500 l/ha
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10)
	Assessment dates	-2-0 DA-A, 15-19 DA-A 0 DA-B, 15-17 DA-B, 27-35 DA-B, 64 DA-B	-1-0 DA-A, 7 DA-A, 11-14 DA-A, 0 DA-B, 15-20 DA-B, 25-50 DA-B, 76 DA-B	0 DA-A, 15 DA-A 0 DA-B, 14-15 DA-B, 25-36 DA-B, 56-67 DA-B	-2-0 DA-A, 7 DA-A, 11-19 DA-A 0 DA-B, 15-20 DA-B, 25-50 DA-B, 64-76 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial	Natural (2)	Natural (12)	Natural (2)	Natural (15)

	innoculation...				
	e.g. Field / Greenhouse...	Field trials	Field trials	Field trials	Field trials

*In some trials water volume was 500 l/ha instead of 400 l/ha but this do not change the validity of the results.

16 trials were carried out against *Pyrenophora tritici-repentis* (PYRNTR) on winter wheat.

A trial was considered valid when the level of disease severity was higher than 5% in the untreated control and if the reference product shows a significant difference compared to the untreated control.

Use of CA3301 at 2x 0.6-0.8 l/ha against PYRNTR - Maritime EPPO zone

In the Maritime EPPO zone, a single trial was available against *Pyrenophora tritici-repentis*, on winter wheat and was included to support the efficacy evaluation of CA3301 at 0.6-0.8 l/ha applied twice, compared to the reference products on disease severity (%). CA3301 was first applied at crop BBCH stage 32 and the 2nd application was at BBCH 41. A single assessment timing was available, at the last timing close to harvest (35 DA-B) and the analysis could be conducted only on foliar level 1 (L1). The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.8 l/ha.

Summary results are presented in Table 3.2-428.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6-0.8 l/ha to control the severity of *Pyrenophora tritici-repentis*. On foliar level 1, at 0.6 l/ha, CA3301 showed 55.08% of efficacy to control the disease before harvest and 54.33% at 0.8 l/ha.

In the Maritime EPPO zone, a limited data set was available to assess efficacy against *Pyrenophora tritici-repentis*. In the single trial the foliar level 1 of winter wheat showed a high pressure of disease (58% disease severity). In this challenging condition CA3301 demonstrated comparable efficacy to the authorised reference standard at both dose rates. Efficacy from all tested products was relatively low, however disease severity was halved from all applications. In the single trial assessing disease control there was no apparent difference between the two dose rates of CA3301. Whilst the data presented for this EPPO zone is insufficient for efficacy evaluation, the consistent comparability of CA3301 to the authorised reference products, containing the same rate of active substance, indicates that the test product provides the same spectrum of control.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Pyrenophora tritici-repentis* on winter wheat in the Maritime EPPO zone.

Table 3.2-428: Summary table - Efficacy evaluation – Winter wheat – PYRNTR – Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA22 45	CA33 01	CA33 01	No of trials where CA3301			No of trials where CA3301		
Rate		0,8	0,6	0,8	at 0,6 l/ha is >, = or			at 0,8 l/ha is >, = or		
Rate unit		L/ha	L/ha	L/ha	<			<		
Appl. Code		AB	AB	AB	compared to			compared to		
% Disease severity L1 - 35 DA-B										
Number of values	1	1	1	1	UT	CA24	CA33	UT	CA24	CA33
Minimum value	58,44	29,44	26,25	26,69	C	45	01	C	45	01
Maximum value	58,44	29,44	26,25	26,69	1 >	0,8	0,8	1 >	0,8	0,6
Mean disease severity (%)	58,44	29,44	26,25	26,69	0 =	l/ha	l/ha	0 =	l/ha	l/ha
Abbott efficacy (%)	0,00%	49,62	55,08	54,33	0 <	1 =	1 =	0 <	1 =	1 =
		%	%	%		0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against PYRNTR – Mediterranean EPPO zone

No data were available to support the minimum effective dose of CA3301 against *Pyrenophora tritici-repentis* on winter wheat. However, existing authorisations for prothioconazole products (Proline, Praktis, JOAO) to control *Pyrenophora tritici-repentis* have the same dose rate for this pathogen which indicates the performance of this active substance in this condition.

Nevertheless, since in the fields a complex of disease is often observed instead of a single disease, it is of interest to look at the efficacy of CA3301 across the diseases and to not focus on a single one.

In many instances, a trend of decreasing disease severity when increasing the dose rate was observed with CA3301 applied at 0.6 l/ha or 0.8 l/ha. Although the rate of 0.8 l/ha overall reduced disease to a greater extent than the 0.6 l/ha rate, the differences were not always significant. However, in circumstances of high disease pressure the higher rate of 0.8 l/ha was often observed to be of significant benefit, while in circumstances of low disease pressure, the 0.6 l/ha dose rate may be sufficient to give comparable disease control.

In the majority of efficacy assessments, the disease control obtained from applications of CA3301 was statistically comparable to that from authorised reference products. In some instances, CA3301 applied at 0.8 l/ha provided higher efficacy compared to the range of reference products and in some instances CA3301 applied at 0.6 l/ha provided lower efficacy compared to CA2445 applied at a higher rate of prothioconazole, but more frequently efficacy was comparable.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Pyrenophora tritici-repentis* on winter wheat in the Mediterranean EPPO zone.

Use of CA3301 at 2x 0.6-0.8 l/ha against PYRNTR – North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, 7 valid trials were available against *Pyrenophora tritici-repentis*, on winter wheat and were included to support the efficacy evaluation of CA3301 at 0.6-0.8 l/ha applied twice, compared to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 32-39 and the 2nd application was at BBCH 39-61. The efficacy evaluation will be conducted focussing on CA3301 applied at 0.6 and 0.8 l/ha.

Summary results are presented in Table 3.2-429.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control the severity of *Pyrenophora tritici-repentis*. On foliar level 2, at this dose rate, CA3301 showed 50.10% of efficacy to control the disease two weeks after the 2nd application and 49.60% before harvest. On foliar level 1, at this dose rate, CA3301 showed 68.07% of efficacy to control the disease before harvest.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.8 l/ha to control the severity of *Pyrenophora tritici-repentis*. On foliar level 2, at this dose rate, CA3301 showed 77.25% of efficacy to control the disease two weeks after the 2nd application and 57.96% before harvest. On foliar level 1, at this dose rate, CA3301 showed 77.68% of efficacy to control the disease before harvest.

In the North-~~Eastern~~ **East** EPPO zone, winter wheat leaves showed a disease pressure between 5 and 22% until time to harvest. At all assessments CA3301 was at both rates comparable to the authorised reference standard. All tested products demonstrated medium to high efficacy against *Pyrenophora tritici-repentis*. CA3301 applied at 0.8 l/ha overall gave a greater disease reduction compared to 0.6 l/ha however this was not significant in most of the assessments, except one trial with 31% disease severity in Lithuania.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Pyrenophora tritici-repentis* on winter wheat in the North-~~Eastern~~ **East EPPO zone.**

Table 3.2-429: Summary table - Efficacy evaluation – Winter wheat – PYRNTR – North-~~Eastern~~ **East EPPO zone**

East LTPG zone											
Treatment name	UNTREATED CHECK	CA22 45	CA33 01	CA33 01	No of trials where CA3301			No of trials where CA3301			
Rate		0,8	0,6	0,8	at 0,6 l/ha is >, = or			at 0,8 l/ha is >, = or <			
Rate unit		L/ha	L/ha	L/ha	<						
Appl. Code		AB	AB	AB	compared to			compared to			
% Disease severity L2 - 15 DA-B											
Number of values	1	1	1	1	UT C	CA24 45	CA33 01	UTC	CA24 45	CA33 01	
Minimum value	5,01	2,73	2,50	1,14		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha	
Maximum value	5,01	2,73	2,50	1,14		1 >	0 >		0 >	1 >	0 >
Mean disease severity (%)	5,01	2,73	2,50	1,14		0 =	1 =		1 =	0 =	1 =
Abbott efficacy (%)	0,00%	45,51 %	50,10 %	77,25 %	0 <	0 <	0 <	0 <	0 <	0 <	
% Disease severity L2 - 20-37 DA-B											
Number of values	5	5	5	5	UT C	CA24 45	CA33 01	UTC	CA24 45	CA33 01	
Minimum value	10,63	3,25	4,25	3,75		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha	
Maximum value	34,38	22,38	17,50	18,25		5 >	0 >		0 >	5 >	0 >
Mean disease severity (%)	22,24	11,34	11,68	10,02		0 =	5 =		5 =	0 =	5 =
Abbott efficacy (%)	0,00%	53,45 %	49,60 %	57,96 %	0 <	0 <	0 <	0 <	0 <	0 <	
% Disease severity L1 - 20-37 DA-B											
Number of values	5	5	5	5	UT C	CA24 45	CA33 01	UTC	CA24 45	CA33 01	
Minimum value	6,78	1,53	2,20	1,25		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha	
Maximum value	31,75	15,44	13,88	10,06		5 >	0 >		0 >	5 >	1 >
Mean disease severity (%)	14,94	5,04	4,93	3,64		0 =	5 =		4 =	0 =	4 =
Abbott efficacy (%)	0,00%	71,99 %	68,07 %	77,68 %	0 <	0 <	1 <	0 <	0 <	0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against PYRNTR – South-~~Eastern~~ **East** EPPO zone

In the South-~~Eastern~~ **East** EPPO zone, 2 valid trials were available against *Pyrenophora tritici-repentis*, on winter wheat and were included to support the efficacy evaluation of CA3301 at 0.6-0.8 l/ha applied twice, compared to the reference products on disease severity (%). CA3301 was first applied at crop

stages BBCH 31-39 and the 2nd application was at BBCH 49-65. The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.8 l/ha.

Summary results are presented in Table 3.2-430.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control the severity of *Pyrenophora tritici-repentis*. On foliar level 2, at this dose rate, CA3301 showed 79.92% of efficacy to control the disease two weeks after the 2nd application and 60.91% before harvest. On foliar level 1, at this dose rate, CA3301 showed 63.68% of efficacy to control the disease before harvest.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.8 l/ha to control the severity of *Pyrenophora tritici-repentis*. On foliar level 2, at this dose rate, CA3301 showed 87.23% of efficacy to control the disease two weeks after the 2nd application and 71.33% before harvest. On foliar level 1, at this dose rate, CA3301 showed 75.24% of efficacy to control the disease before harvest.

In the South-Eastern East EPPO zone, a limited dataset was available for assessment of control of *Pyrenophora tritici-repentis*. However, the disease severity increased in the growing period of winter wheat to reach 46% on foliar level 2, providing challenging conditions for the tested products. CA3301 demonstrated medium to high efficacy against *Pyrenophora tritici-repentis* in these conditions. Efficacy was comparable to, or better than the authorised reference product where CA3301 was applied at 0.8 l/ha. Applied at the lower dose rate CA3301 demonstrated efficacy somewhat lower than the authorised reference product or the higher rate of CA3301 in these conditions. Although in assessment at lower disease severity the difference were not always statistically significant.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Pyrenophora tritici-repentis* on winter wheat in the South-Eastern East EPPO zone.

Table 3.2-430: Summary table - Efficacy evaluation – Winter wheat – PYRNTR – South-Eastern East EPPO zone

East Africa Zone									
Treatment name	UNTR EATE D CHE CK	CA 244 5 L/h a AB	PRI AXO R L/ha AB	CA 330 1 L/h a AB	CA33 01 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		0,8	1,5	0,6	0,8				
Rate unit									
Appl. Code									
% Disease severity L2 - 14-15 DA-B									
Number of values	2	2		2	2	UTC	CA3301	UTC	CA3301
Minimum value	7,01	0,60		1,11	0,74		0,8 l/ha		0,6 l/ha
Maximum value	12,66	1,50	-	2,20	1,38	1 >	0 >	1 >	1 >
Mean disease severity (%)	9,84	1,05		1,66	1,06	0 =	1 =	0 =	1 =
Abbott efficacy (%)	0,00%	86,93%		79,92%	87,23%	0 <	1 <	0 <	0 <
Number of values	1	1	1	1	1	CA2445	PRIAXOR	OSIRIS 65 EC	PRIAXOR
Minimum value	7,01	1,50	0,88	2,20	1,38	0,8 l/ha	1,5 l/ha	2,0 l/ha	1,5 l/ha
Maximum value	7,01	1,50	0,88	2,20	1,38	0 >	0 >	0 >	0 >
Mean disease severity (%)	7,01	1,50	0,88	2,20	1,38	1 =	0 =	2 =	0 =

Treatment name	UNTR EATE D CHE CK	CA 244 5	PRI AXO R	CA 330 1	CA33 01	No of trials where CA3301			No of trials where CA3301				
Rate		0,8	1,5	0,6	0,8	at 0,6 l/ha is >, = or <			at 0,8 l/ha is >, = or <				
Rate unit		L/h a	L/ha	L/h a	L/ha								
Appl. Code		AB	AB	AB	AB	compared to			compared to				
Abbott efficacy (%)	0,00%	78,60 %	87,45 %	68,62 %	80,31 %	1 <		1 <	0 <		1 <		
% Disease severity L2 - 36 DA-B													
Number of values	1	1	1	1	1	U T C	CA 244 5	PRI- AXOR	CA 330 1	U T C	CA24 45	PRI- AXOR	CA3 301
Minimum value	46,25	14,19	14,00	18,08	13,26		0,8 l/ha	1,5 l/ha	0,8 l/ha		0,8 l/ha	1,5 l/ha	0,6 l/ha
Maximum value	46,25	14,19	14,00	18,08	13,26	1 >	0 >	0 >	0 >	1 >	0 >	0 >	1 >
Mean disease severity (%)	46,25	14,19	14,00	18,08	13,26	0 =	0 =	0 =	0 =	0 =	1 =	1 =	0 =
Abbott efficacy (%)	0,00%	69,32 %	69,73 %	60,91 %	71,33 %	0 <	1 <	1 <	1 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 36 DA-B													
Number of values	1	1	1	1	1	U T C	CA 244 5	PRI- AXOR	CA 330 1	U T C	CA24 45	PRI- AXOR	CA3 301
Minimum value	25,00	6,74	7,25	9,08	6,19		0,8 l/ha	1,5 l/ha	0,8 l/ha		0,8 l/ha	1,5 l/ha	0,6 l/ha
Maximum value	25,00	6,74	7,25	9,08	6,19	1 >	0 >	0 >	0 >	1 >	1 >	1 >	1 >
Mean disease severity (%)	25,00	6,74	7,25	9,08	6,19	0 =	0 =	0 =	0 =	0 =	0 =	0 =	0 =
Abbott efficacy (%)	0,00%	73,04 %	71,00 %	63,68 %	75,24 %	0 <	1 <	1 <	1 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)
(conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against PYRNTR – Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-Eastern EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, a total of 15 trials evaluated the efficacy of CA3301 on winter wheat against *Pyrenophora tritici-repentis*. 9 trials out of 15 were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 31-45 and the 2nd application was at BBCH 39-69.

Summary results are presented in Table 3.2-431.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control the severity of *Pyrenophora tritici-repentis*. On foliar level 2, at this dose rate, CA3301 showed 59.36% of efficacy to control the disease two weeks after the 2nd application and 51.49% before harvest. On foliar level 1, at this dose rate, CA3301 showed 65.59% of efficacy to control

the disease before harvest.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.8 l/ha to control the severity of *Pyrenophora tritici-repentis*. On foliar level 2, at this dose rate, CA3301 showed 78.78% of efficacy to control the disease two weeks after the 2nd application and 60.19% before harvest. On foliar level 1, at this dose rate, CA3301 showed 74.00% of efficacy to control the disease before harvest.

In this data set, winter wheat leaves showed a disease pressure that ranged from 6.01% around 2 weeks the 2nd application up to 26.24% before harvest. At all assessments, CA3301 at 0.8 l/ha gave comparable or higher disease control compared to the authorized reference product CA2245. Applied at 0.6 l/ha, CA3301 was more frequently comparable to CA2445 but in some instances provided lower efficacy due to the lower content of prothioconazole. CA3301 at 0.6 l/ha provided in overall lower efficacy than the reference product with another active substance PRIAXOR while the 0.8 l/ha dose rate was globally equivalent or more efficient.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Pyrenophora tritici-repentis* on winter wheat in Poland.

Table 3.2-431: Summary table - Efficacy evaluation – Winter wheat – PYRNTR – Data relevant for Poland

Treatment name	UNTREATED CHECK	CA24 45 0,8 L/ha AB	PRIAX OR 1,5 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
% Disease severity L2 - 15 DA-B									
Number of values	2	2		2	2	UTC	CA24 45 0,8 l/ha	UTC	CA24 45 0,8 l/ha
Minimum value	5,01	1,50		2,20	1,14				
Maximum value	7,01	2,73	-	2,50	1,38	2 >	0 >	2 >	0 >
Mean disease severity (%)	6,01	2,11		2,35	1,26	0 =	1 =	0 =	2 =
Abbott efficacy (%)	0,00%	62,06 %		59,36 %	78,78 %	0 <	1 <	0 <	0 <
Number of values	1	1	1	1	1	PRI- AXOR	CA33 01 0,8 l/ha	PRI- AXOR	CA33 01 0,6 l/ha
Minimum value	7,01	1,50	0,80	2,20	1,38	1,5 l/ha		1,5 l/ha	
Maximum value	7,01	1,50	0,88	2,20	1,38	0 >	0 >	0 >	1 >
Mean disease severity (%)	7,01	1,50	0,88	2,20	1,38	0 =	1 =	0 =	1 =
Abbott efficacy (%)	0,00%	78,60 %	87,45%	68,62 %	80,31 %	1 <	1 <	1 <	0 <
% Disease severity L2 - 20-37 DA-B									
Number of values	6	6		6	6	UTC	CA24 45 0,8 l/ha	UTC	CA24 45 0,8 l/ha
Minimum value	10,63	3,25		4,25	3,75				
Maximum value	46,25	22,38	-	18,08	18,25	6 >	0 >	6 >	0 >
Mean disease severity (%)	26,24	11,81		12,74	10,56	0 =	5 =	0 =	6 =
Abbott efficacy (%)	0,00%	56,09 %		51,49 %	60,19 %	0 <	1 <	0 <	0 <
Number of values	1	1	1	1	1	PRI- AXOR	CA33 01 0,8 l/ha	PRI- AXOR	CA33 01 0,6 l/ha
Minimum value	46,25	14,19	14,00	18,08	13,26	1,5 l/ha		1,5 l/ha	
Maximum value	46,25	14,19	14,00	18,08	13,26	0 >	0 >	0 >	1 >
Mean disease severity (%)	46,25	14,19	14,00	18,08	13,26	0 =	5 =	1 =	5 =

Abbott efficacy (%)	0,00%	69,32 %	69,73	60,91 %	71,33 %	1 <	1 <	0 <	0 <
% Disease severity L1 - 20-37 DA-B									
Number of values	7	7		7	7	UTC	CA24 45 0,8 l/ha	UTC	CA24 45 0,8 l/ha
Minimum value	6,78	1,53		2,20	1,25				
Maximum value	58,44	29,44	-	26,25	26,69	7 >	0 >	7 >	2 >
Mean disease severity (%)	22,59	8,91		8,57	7,29	0 =	6 =	0 =	5 =
Abbott efficacy (%)	0,00%	68,95 %		65,59 %	74,00 %	0 <	1 <	0 <	0 <
Number of values	1	1	1	1	1	PRI- AXOR	CA33 01 0,8 l/ha	PRI- AXOR	CA33 01 0,6 l/ha
Minimum value	25,00	6,74	7,25	9,08	6,19	1,5 l/ha		1,5 l/ha	
Maximum value	25,00	6,74	7,25	9,08	6,19	0 >	0 >	1 >	2 >
Mean disease severity (%)	25,00	6,74	7,25	9,08	6,19	0 =	5 =	0 =	5 =
Abbott efficacy (%)	0,00%	73,04 %	71,00%	63,68 %	75,24 %	1 <	2 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

Only 1 valid field trial was carried out in **the Maritime EPPO climatic zone**. CA3301 achieved low efficacy after applied at dose rate of 0,6-0,8 l/ha (55,08% and 54,33% respectively). Due to the limited number of trials and poor effectiveness, the cMSs are kindly asked to consider this use on the national level.

7 valid field trials were conducted in **the North-East EPPO zone**. The dose rate of 0,6 l/ha amounted significant lower efficacy compared to the higher dose. CA3301 controled of PYRNTR on medium level after 15-37 days after second application. However, the dose rate of 0,8 l/ha was more effective and it should be recommended in case of high disease pressure. The results from objectives treated of test product at 0,8 l/ha and reference product were comparable.

2 valid field trials were conducted in **the South-East EPPO zone**. CA3301 achieved medium efficacy after 14-36 days after second application. The dose rate of 0,8 l/ha was more effective (87,23%) after 15 DA-B but this mean result came from only 2 trials. No dataset have been submitted from the Mediterranean zone. Due to the limited number of trials, the cMSs are kindly asked to consider this use on the national level.

In the opinion of zRMS, CA3301 can be recommended to protection of winter wheat against *Pyrenophora tritici-repentis* in the NE zone. It should be noted that the level of effectiveness is medium and the dose rate of 0,8 l/ha is recommended in case of high disease pressure.

3.2.3.30 Winter wheat (TRZAW) / *Parastagonospora nodorum* (LEPTNO)

Materials and Methods – Winter wheat – LEPTNO

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2017 and 2020, a series of 4 trials were conducted in several countries of the Maritime, and Mediterranean EPPO zones to evaluate the efficacy of CA3301 against *Parastagonospora nodorum* on **winter wheat**. The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, 2 trials were performed in Czech Republic.

In the Mediterranean EPPO zone, 2 trials were performed in Spain (1) and Italy (1).

Table 3.2-432: Presentation of trials – Winter wheat (TRZAW)

Crop(s)) *	Tar- get(s)*	Coun- try	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Winter wheat	LEPTNO	Czech Republi c	2017- 2028	MED + E	2 (1)	-	-	-	GEP	
TOTA L	-	-	2018- 2020	MED + E	2 (1)	-	-	-	GEP	
Winter wheat	LEPTNO	Spain	2019	MED + E	-	1 (0)	-	-	GEP	
		Italy	2020	MED + E	-	1 (1)	-	-	GEP	
TOTA L	-	-	2019- 2020	MED + E	-	2 (1)	-	-	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation

In all trials, CA3301 was compared to at least one commercial fungicide used as standard reference for comparison.

Table 3.2-433: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – LEPTNO – Maritime EPPO zone

Crop(s))	Refer- ence standard	Coun- try(ies) where the product is used ⁽¹⁾	Authoriza- tion number	Active sub- stance(s)	Formulation		Regis- tered ap- plication rate ⁽³⁾	Applica- tion rate in tri- als (per treat- ment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concentra- tion of a.s.			
Winter wheat	PRO- LINE 250 EC	CZ	4523-1	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha max	1 x 0.6-0.8 l/ha 2 x 0.8 l/ha	CA2445 in the trial

Table 3.2-434: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) – LEPTNO – Mediterranean EPPO zone

Crop(s))	Refer- ence standard	Coun- try(ies) where the product is used ⁽¹⁾	Authoriza- tion number	Active sub- stance(s)	Formulation		Regis- tered ap- plication rate ⁽³⁾	Applica- tion rate in tri- als (per treat- ment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concentra- tion of a.s.			
TRZA W	PRAK- TIS	ES	ES-01135	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO- LINE	IT	013385	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha max	2 x 0.8 l/ha	CA2445 in the trial

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-435.

Table 3.2-435: Details on trial methodology – Winter wheat (TRZAW) – LEPTNO

		Maritime EPPO zone	Mediterranean EPPO zone
Trials	Total number (valid number)	2 (1)	2 (1)
	Supportive trials	-	-
Guidelines	General guidelines	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)
	Specific guidelines	PP 1/26 (4)	PP 1/26 (4)
Experimental design	Plot design	Randomized Complete Blocks, Untreated included	Randomized Complete Blocks, Untreated included
	Plot size	30 m ²	15-40 m ²
	Number of replications	4	4
Crop	Trials per crop	TRZAW (2)	TRZAW (2)
	Varieties per crop	Tobak (1), Ilona (1)	Galera (1), Marco Polo (1)
	Sowing period	October (2)	November (1), December (1)
Application	Crop stage (BBCH)* at application	A : BBCH 32-37 B : BBCH 65-69	A : BBCH 36-39 B : BBCH 61-69
	Timing Pest stage at application	BBCH 32-39 A : PRINFC (2) B : PRINFC (1), MIXED (1)	BBCH 36-39 A : MIXED (1), PRINFC (1) B : MIXED (2)
	Number of applications Intervals between applications	1 application (1) 2 applications (28 days) (1)	2 applications (17-20 days) (1)
	Spray volumes	A : 300-400 l/ha B : 300-400 l/ha	A : 400-500 l/ha* B : 400-500 l/ha*
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10)
	Assessment dates	0 DA-A, 15 DA-A, 0 DA-B, 15 DA-B, 27 DA-B, 64 DA-B	0 DA-A, 19 DA-A, 0 DA-B, 11 DA-B, 14-16 DA-B, 23-25 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Natural (2)	Natural (2)
	e.g. Field / Greenhouse...	Field trials	Field trials

*In one trial the water volume applied was 500 l/ha. This small deviation did not impact the validity of the trial.

4 trials were carried out against *Parastagonospora nodorum* (LEPTNO) on winter wheat.

In the Maritime EPPO zone, 2 trials were available against *Parastagonospora nodorum* (LEPTNO) on winter wheat. 1 trial out of 2 was considered valid and was included to support the efficacy evaluation of CA3301 at 0.6-0.8 l/ha applied twice, compared to the reference products on disease severity (%). CA3301 was first applied at crop stage BBCH 32 and the 2nd application was at BBCH 67. The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.8 l/ha.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control the severity of *Parastagonospora nodorum*. On foliar level 2, at this dose rate, CA3301 showed 35.38% of efficacy to control the disease two weeks after the 2nd application and 16.35% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 37.66% of efficacy on reduction of disease severity before harvest.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.8 l/ha to control *Parastagonospora nodorum*. On foliar level 2, CA3301 showed 42.37% of efficacy to control the disease after the 2nd application and 17.89% before harvest. On foliar level 1, CA3301 at 0.8 l/ha showed 48.10% of efficacy on reduction of disease before harvest.

In the Maritime zone EPPO zone, a limited dataset was available for assessment of control of *Parastagonospora nodorum*. However, the disease severity increased in the growing period of winter wheat to reach 73% on foliar level 2, providing challenging conditions for the tested products. CA3301 demonstrated a low level of efficacy against *Parastagonospora nodorum* in these conditions but this performance was comparable to the authorized reference product.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Parastagonospora nodorum* on winter wheat in the Maritime EPP0 zone.

Treatment name	UNTREATED	CA22 45 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity L2 - 15 DA-B										
Number of values	1	1	1	1	UTC	CA2 445	CA33 01	UTC	CA24 45	CA33 01
Minimum value	25,44	16,44	16,44	14,66		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	25,44	16,44	16,44	14,66	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	25,44	16,44	16,44	14,66	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	35,38 %	35,38 %	42,37 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 27 DA-B										
Number of values	1	1	1	1	UTC	CA2 445	CA33 01	UTC	CA24 45	CA33 01
Minimum value	73,38	64,75	61,38	60,25		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	73,38	64,75	61,38	60,25	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	73,38	64,75	61,38	60,25	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	11,76 %	16,35 %	17,89 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 27 DA-B										

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

In the Mediterranean EPPO zone, 2 trials were available against *Parastagonospora nodorum* (LEPTNO), on winter wheat. 1 trial out of 2 was considered valid and was included to support the efficacy evaluation of CA3301 at 0.6-0.8 l/ha applied twice, compared to the reference products on disease severity (%). CA3301 was first applied at crop stage BBCH 37 and the 2nd application was at BBCH 61. The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.8 l/ha.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control the severity of *Parastagonospora nodorum*. On foliar level 2, at this dose rate, CA3301 showed 63.65% two weeks after the 2nd application and 59.05% before harvest. On foliar level 1, CA3301 at 0.6 l/ha showed 100% of efficacy to reduce the disease severity around two weeks after the 2nd application and 91.41% before harvest.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.8 l/ha to control the severity of *Parastagonospora nodorum*. On foliar level 2, at this dose rate, CA3301 provided 68.30% two weeks after the 2nd application and 60.51% before harvest. On foliar level 1, CA3301 at 0.8 l/ha showed 100% of efficacy to reduce the disease severity around two weeks after the 2nd application and 92.28% before harvest.

In the Mediterranean EPPO zone, a limited dataset was available for this pathogen. However, the disease severity increased in the growing period of winter wheat to reach 72% on foliar level 2, providing challenging conditions for the tested products. Applications of CA3301 at 0.6-0.8 l/ha demonstrated medium to high efficacy in these conditions. At the rate of 0.8 l/ha CA3301 was always comparable to the reference standard. Applied at 0.6 l/ha CA3301 was overall statistically equivalent compared to the reference standard and compared to 0.8 l/ha rate.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Parastagonospora nodorum* on winter wheat in the Mediterranean EPPO zone.

Treatment name	UNTREATED CHECK	CA224 5 0,8 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
% Disease severity L2 - 16 DA-B						

Treatment name	UNTREATED CHECK	CA224 5 0,8 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to CA244 CA330			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to CA244 CA330		
Rate					UT	CA244	CA330	UTC	CA244	CA330
Rate unit					C	5	1		5	01
Appl. Code						0,8	0,8		0,8	0,6
Number of values	1	1	1	1		l/ha	l/ha		l/ha	l/ha
Minimum value	47,13	14,88	17,13	14,94	1 >	0 >	0 >	1 >	0 >	1 >
Maximum value	47,13	14,88	17,13	14,94	0 =	0 =	0 =	0 =	1 =	0 =
Mean disease severity (%)	47,13	14,88	17,13	14,94	0 <	1 <	1 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	68,43%	63,65%	68,30%						
% Disease severity L1 - 16 DA-B										
Number of values	1	1	1	1	UT	CA244	CA330	UTC	CA244	CA330
Minimum value	15,06	0,00	0,00	0,00	C	5	1		5	01
Maximum value	15,06	0,00	0,00	0,00		0,8	0,8		0,8	0,6
Mean disease severity (%)	15,06	0,00	0,00	0,00	1 >	0 >	0 >	1 >	0 >	0 >
Abbott efficacy (%)	0,00%	100,00%	100,00%	100,00%	0 =	1 =	1 =	0 =	1 =	1 =
					0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 25 DA-B										
Number of values	1	1	1	1	UT	CA244	CA330	UTC	CA244	CA330
Minimum value	72,50	29,19	29,69	28,63	C	5	1		5	01
Maximum value	72,50	29,19	29,69	28,63		0,8	0,8		0,8	0,6
Mean disease severity (%)	72,50	29,19	29,69	28,63	1 >	0 >	0 >	1 >	0 >	0 >
Abbott efficacy (%)	0,00%	59,74%	59,05%	60,51%	0 =	1 =	1 =	0 =	1 =	1 =
					0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 25 DA-B										
Number of values	1	1	1	1	UT	CA244	CA330	UTC	CA244	CA330
Minimum value	21,88	0,94	1,88	1,69	C	5	1		5	01
Maximum value	21,88	0,94	1,88	1,69		0,8	0,8		0,8	0,6
Mean disease severity (%)	21,88	0,94	1,88	1,69	1 >	0 >	0 >	1 >	0 >	0 >
Abbott efficacy (%)	0,00%	95,70%	91,41%	92,28%	0 =	1 =	1 =	0 =	1 =	1 =
					0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (con-
versely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against LEPTNO – North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, no trials were available for assessment of control of glume blotch. *Zymoseptoria tritici* blotch is found commonly in the same fields and on the same plants as *Parastagonospora nodorum*, the fungi responsible of leaf (and glume) blotch of cereals, also known as Septoria nodorum blotch. When both pathogens occur together, they are referred to collectively as the Septoria blotch complex or Septoria complex. Glume blotch occurred in lesser proportion and more heterogeneous way than the Septoria species *Zymoseptoria tritici*, presented earlier in the dossier, which can also be supportive for this dataset.

Therefore with CA3301 at 0.6-0.8 l/ha it is also expected to obtain a control of glume blotch comparable to the authorised reference product. In many instances the rate of 0.6 l/ha should give acceptable control of *Parastagonospora nodorum* very comparable to that of 0.8 l/ha, nevertheless in conditions of high

disease pressure the additional disease reduction obtained from the higher rate of 0.8 l/ha may be more appropriate, in particular if some level of resistance is suspected.

Considering all elements presented above and the dataset previously presented against *Zymoseptoria tritici*, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Parastagonospora nodorum* on winter wheat in the North-Eastern EPPO zone.

Use of CA3301 at 2x 0.6-0.8 l/ha against LEPTNO – South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, no trials were available for assessment of control of glume blotch. *Zymoseptoria tritici* blotch is found commonly in the same fields and on the same plants as *Parastagonospora nodorum*, the fungi responsible of leaf (and glume) blotch of cereals, also known as Septoria nodorum blotch. When both pathogens occur together, they are referred to collectively as the Septoria blotch complex or Septoria complex. Glume blotch occurred in lesser proportion and more heterogeneous way than the Septoria species *Zymoseptoria tritici*, presented earlier in the dossier, which can also be supportive for this dataset.

Therefore with CA3301 at 0.6-0.8 l/ha it is also expected to obtain a control of glume blotch comparable to the authorised reference product. In many instances the rate of 0.6 l/ha should give acceptable control of *Parastagonospora nodorum* very comparable to that of 0.8 l/ha, nevertheless in conditions of high disease pressure the additional disease reduction obtained from the higher rate of 0.8 l/ha may be more appropriate, in particular if some level of resistance is suspected.

Considering all elements presented above and the dataset previously presented against *Zymoseptoria tritici*, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Parastagonospora nodorum* on winter wheat in the South-Eastern East EPPO zone.

Comments of zRMS:

Only 1 valid field trial have been submitted in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,6-0,8 l/ha achieved very low efficacy, either in situation of low and high pest severity. Due to the very limited number of trials and poor results, the cMSs are kindly asked to consider this use on the national level.

No trials have been submitted to the efficacy evaluation in **the North-East EPPO zone**. This use can not be accepted in this zone because extrapolation is not possible.

No trials have been submitted in **the South-East EPPO zone**. However, 1 valid field trial was conducted in the Mediterranean zone which can be support. The cMSs are kindly asked to consider this extrapolation on the national level. CA3301 applied at dose rate of 0,6-0,8 l/ha achieved medium to high efficacy. It should be noted that the higher dose rate of 0,8 l/ha can be recommended in case of high disease pressure.

3.2.3.31 Winter wheat (TRZAW) / *Oculimacula acuformis* (PSDCHA)

Ramanauskiene *et al.*, Effects of fungicides on the occurrence of winter wheat eyespot caused by fungi *Oculimacula acuformis* and *O. yallundae*. *Crop protection*, 2016)

No data were available for assessment of control of eyespot of cereals *Oculimacula acuformis* on any crop. Although early symptoms can be confused with *Fusarium spp.*, the diseases are not related and therefore it is impossible to extrapolate from these data.

However, Ramanauskiene *et al.*, showed that 2, 3 and 4 years of prothioconazole treatments allowed to reduce the population of *O. acuformis* assessed from 2009 to 2011 on winter wheat. This positive effect was observed as early as 10 days after treatment.

Moreover, prothioconazole is one of the active substances the most used as fungicide in commercial practices (*Forecasting eyespot development and yield losses in winter wheat, HGCA, 2012*). Standard reference products containing prothioconazole, such as Proline 275 are registered to control eyespot on cereals, at the same application rates as for the other authorised pathogens, which indicates that prothi-

prothioconazole controls eyespot at dose rates which are demonstrated to control the other major disease pathogens in cereals. Since the proposed dose rate for CA3301 (200–150 g/ha prothioconazole) is comparable to that of the authorised product Proline 275 (200 g/ha prothioconazole), and data shows equivalence of efficacy between these products in other pathogens, it is considered that CA3301 will also provide acceptable control of eyespot at the proposed dose rate.

Since on cereals a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the range of 0.6–0.8 l/ha gave in overall equivalent disease control compared to the authorized reference products containing prothioconazole, we assume that in most instances CA3301 at 0.6 l/ha will give sufficient control of eyespot, but in situations with high disease pressure, it may be appropriate to use 0.8 l/ha.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6–0.8 l/ha to control *Oculimacula acufiformis* on winter wheat in all EPPO zones.

Materials and Methods – Winter wheat – PSDCHA

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

In 2023, 7 trials were conducted in North-East zone in Poland to evaluate the efficacy of CA3301 against *Oculimacula acufiformis* on **winter wheat** (see Table 3.2-438). The trials were carried out by certified testing institute.

Table 3.2-438: Presentation of trials – Winter wheat (TRZAW)

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
					Maritime zone	Mediterranean zone	North-Eastern zone	South-Eastern zone		
Winter wheat	PSDCHA	Poland	2023	MED + E	1	1	7 (7)	1	GEP	1
TOTAL	1	1	2023	MED + E	1	1	7 (7)	1	GEP	1

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

In all trials, CA3301 was compared to one commercial and registered fungicide used as standard reference for comparison (see Table 3.2-439).

Table 3.2-439: Efficacy evaluation - Presentation of reference standards used in trials – Winter wheat (TRZAW) - PSDCHA

Crop	Reference standard	Country(ies) where the product is used	Authorization number	Active substance(s)	Formulation		Registered application rate	Application rate in trials (per treatment)	Remark
					Type	Concentration of a.s.			
Winter	PROTIKON	PL	R-127/2021 (05.10.2021)	Prothioconazole	EC	250 g/l	1 x 0.8 l/ha	1 x 0.8 l/ha	1

Crop	Reference standard	Country(ies) where the product is used	Authorization number	Active substance(s)	Formulation		Registered application rate	Application rate in trials (per treatment)	Remark
					Type	Concentration of a.s.			
wheat	250 EC								

Material and Methods elements are summarized in Table 3.2-440.

Table 3.2-440: Details on trial methodology – Winter wheat (TRZAW) - PSDCHA

Trials	Total number (valid number)	7 (7)
Guidelines	General guidelines	PP 1/152 (4) PP 1/181 (4) PP 1/135 (4)
	Specific guidelines	PP 1/26 (4) PP 1/28 (3)
Experimental design	Plot design	Randomized complete blocks, Untreated included
	Plot size	24-24,5 m ²
	Number of replications	4
Crop	Trials per crop	Winter wheat (7)
	Varieties per crop	Bellisa, Julius, Arkadia, Hondia, Kilimanjaro, Patra, Artist
	Sowing period	26.09.2022, 01.10.2022, 01.10.2022, 20.09.2022, 29.08.2022 20.10.2022, 20.10.2022, 22.10.2022
Application	Crop stage (BBCH) at application	A: BBCH 30-32
	Disease stage at application	A: PRINFC (7) 100%
	Number of applications Intervals between applications	1 application (7)
	Spray volumes	200 l/ha
Assessment	Assessment types	Efficacy (% UNCK), Disease severity (index 1-4), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10), TKW (g), HLW (kg/hl), Moisture content (%), Yield (T-MET), lodging area (%), lodging angle (0-90 degree)
	Assessment dates	Disease severity: 0 DA-A, 52-75 DA-A Phytotoxicity and vigor: 7-8 DA-A, 14-15 DA-A, 57-74 DA-A TKW, HLW, Moisture content, yield: after harvest Lodging area and lodging angle: 61-80 DA-A
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant
	e.g. Natural / artificial inoculation...	Natural (7)
	e.g. Field / Greenhouse...	Field trials

7 trials evaluated the efficacy of CA3301 on winter wheat against *Oculimacula acuformis* and enabled to compare the efficacy of proposed dose rates of CA3301- 0.6 l/ha and 0.8 l/ha applied once to the reference product- Protikon 250 EC. CA3301 at both dose rates and reference product were applied at crop stage BBCH 30-32. Efficacy assessment was conducted between BBCH 71-77, on 25-ear-bearing tillers taken randomly.

Summary results are presented in Table 3.2-442.

Table 3.2-441: Pest severity- PSDCHA (tiller) – Winter wheat (TRZAW)

Trial ID	EPPO Zone	Reg. Zone	Country	Year	CROP	PEST	Infestation (BBCH 71-77) 52-75 DA-A		
							Pest severity (index 1-4)	Total damage value	Pest Incidence (%)
EU23-150-01	N-E	CEU	PL	2023	TRZAW	PSDCHA	1,7	0,24	47,0
EU23-150-02	N-E	CEU	PL	2023	TRZAW	PSDCHA	1,7	0,22	51,0
EU23-150-03	N-E	CEU	PL	2023	TRZAW	PSDCHA	2,2	0,40	71,0
EU23-150-04	N-E	CEU	PL	2023	TRZAW	PSDCHA	2,1	0,34	69,0
EU23-150-05	N-E	CEU	PL	2023	TRZAW	PSDCHA	1,4	0,14	31,0
EU23-150-06	N-E	CEU	PL	2023	TRZAW	PSDCHA	1,8	0,25	45,0
EU23-150-07	N-E	CEU	PL	2023	TRZAW	PSDCHA	1,9	0,29	48,0

Table 3.2-442: Summary table - Winter wheat – PSDCHA – North-East EPPO zone - Disease severity (PESSEV)* / 52-75 DA-A

Treatment name	UNTR EATE D CHEC K	PRO- TIKON 250 EC 0,8 L/ha A	CA3301 0,6 L/ha A	CA3301 0,8 L/ha A	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Disease severity - 52-75 DA-A						
Number of values	7	7	7	7	UTC	CA3301 0,8 l/ha
Minimum value	0,14	0,02	0,02	0,01	7 >	0 >
Maximum value	0,40	0,11	0,17	0,11	0 =	5 =
Mean disease severity*	0,27	0,09	0,09	0,05	0 <	2 <
Abbott efficacy (%)	0,0%	69,1%	81,3%			
Number of values	7	7	7	7	PROTIKON 250 EC 0,8 L/ha	PROTIKON 250 EC 0,8 L/ha
Minimum value	0,14	0,02	0,02	0,01	0 >	0 >
Maximum value	0,4	0,11	0,17	0,11	6 =	7 =
Mean disease severity*	0,27	0,06	0,09	0,05	1 <	0 <
Abbott efficacy (%)	0,0%	78,6 %	69,1%	81,3%		

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

*as total damage value

Levels of efficacy (% Abbott efficacy)	
>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Conclusions:

Data demonstrated that application of CA3301 at 0.6-0.8 l/ha on winter wheat showed medium to high efficacy in reducing of *Oculimacula acuformis* severity. The performance of the tested product at dose

rates 0.6 and 0.8 l/ha was overall equivalent to the authorised reference product Protikon 250 EC at dose rate 0.8 l/ha.

Considering all elements presented it is justified to claim the registration of one application of CA3301 at 0.6-0.8 l/ha to control a eyespot disease on winter wheat.

Comments of zRMS:

No efficacy trials have been submitted in any EPPO zones. The cMSs from the Maritime and South-East zone are kindly asked to consider this use on the national level. This use can not be accepted in the North-East zone because extrapolation is not possible.

7 efficacy trials have been submitted to control *Oculimacula acuformis* (PSDCHA) in winter wheat. All trials were carried out in Poland (belonging to the North-East EPPO climatic zone) in 2023. The test product CA3301 (Joust 250 EC) was applied at dose rates of 0,6 and 0,8 L/ha. Based on the EPPO guideline of PP 1/28(3), the assessment may be provided with using of scale of attack of eyespot on cereals (I-IV). The applicant has included only the summary table with mean disease severity as total damage value. ZRMS decided to present the effectiveness calculated with three parameters using in the trials.

Treatment name Rate Rate unit	Untreated check	CA3301		Protikon 250 EC
		0,6 L/ha	0,8 L/ha	0,8 L/ha
PESINC %				
Number of trials	7	7	7	7
Minimum PESINC	31	7	5	6
Maximum PESINC	71	43	34	35
Mean PESINC	51,7	23,3	16,4	18,9
Abbott efficacy (%)	0,0%	57,1%	70,1%	65,6%
PESSEV (assessment based on index 1-4*)				
Number of trials	7	7	7	7
Minimum PESSEV	1,4	1,1	1,1	1,1
Maximum PESSEV	2,2	1,6	1,4	1,4
Mean PESSEV	1,8	1,3	1,2	1,2
Abbott efficacy (%)	0,0%	28,9%	34,3%	32,9%
PESSEV (assessment based on total damage value)				
Number of trials	7	7	7	7
Minimum PESSEV	0,14	0,02	0,01	0,02
Maximum PESSEV	0,4	0,17	0,11	0,11
Mean PESSEV	0,27	0,09	0,05	0,06
Abbott efficacy (%)	0,0%	69,1%	81,3%	78,6%

* I – healthy: no symptoms

II – slight lesions: less than 50% of tiller circumference attacked at place where infection is most severe

III – moderate lesions: more than 50% of tiller circumference attacked at place where infection is most severe, but tissue still firm

IV – severe lesions: 100% of tiller circumference attacked with tissue rotted (softening)

Based on total damage value, CA3301 (Joust 250 EC) at 0,8 l/ha achieved sufficient level of control PSDCHA in winter wheat. No significant differences between test and reference products have been noted. In opinion of zRMS, dose rate of 0,6 l/ha may be insufficient for control *Oculimacula acuformis* at higher disease pressure. PESSEV in the submitted trials was low. In conclusion, CA3301 (Joust 250 EC) at 0,8 l/ha is recommended for control of PSDCHA in winter wheat in Poland. Also it should be highlighted that the test product should be used against PSDCHA only in BBCH 30-32.

Treatment name	UNTREA TED CHECK	CA2 445 0,8 L/ha AB	PROLIN E 275 0,72 L/ha AB	CA3 301 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or <			No of trials where CA3301 at 0,8 l/ha is >, = or <		
Rate						compared to			compared to		
Rate unit											
Appl. Code											
% Green leaf area - 13-58 DA-B											
Number of values	44			44	44	UTC	CA3301 0,8 l/ha		UTC	CA3301 0,6 l/ha	
Minimum value	0,00			6,25	6,25						
Maximum value	88,75	-	-	97,25	97,75	30 >	2 >		30 >	7 >	
Mean green leaf area (%)	37,48			55,45	59,26	14 =	35 =		14 =	35 =	
% UTC	100,00%			211,7 7%	239,3 6%	0 <	7 <		0 <	2 <	
Number of values	38	38		38	38	CA2445 0,8 l/ha			CA2445 0,8 l/ha		
Minimum value	0,00	3,75		6,25	6,25						
Maximum value	88,75	96,25	-	97,25	97,75	1 >			3 >		
Mean green leaf area (%)	36,49	55,64		54,10	57,65	32 =			33 =		
% UTC	100,00%	236,0 3%		220,5 5%	250,4 4	5 <			2 <		
Number of values	6		6	6	6	PROLINE 275 0,72 l/ha			PROLINE 275 0,72 l/ha		
Minimum value	23,75		52,50	52,50	55,00						
Maximum value	66,25	-	86,25	83,75	83,75	0 >			0 >		
Mean green leaf area (%)	43,75		66,63	63,96	69,42	5 =			6 =		
% UTC	100,00%		165,74%	159,1 2%	172,8 8%	1 <			0 <		
% Green leaf area L2 - 32-47 DA-B											
Number of values	5	5		5	5	UT C	CA24 45	CA3 301	UT C	CA24 45	CA3 301

Minimum value	16,25	53,75		61,25	62,50		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	42,50	85,00	-	87,50	87,50	5 >	0 >	0 >	5 >	0 >	1 >
Mean green leaf area (%)	26,30	71,25		69,25	71,50	0 =	4 =	4 =	0 =	4 =	4 =
%UTC	100,00%	303,7 4%		291,7 6%	304,2 9%	0 <	1 <	1 <	0 <	1 <	0 <
% Green leaf area L1 - 32-47 DA-B											
Number of values	5	5		5	5	UT C	CA24 45 0,8 l/ha	CA3 301 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA3 301 0,6 l/ha
Minimum value	27,50	61,25		63,75	65,00	5 >	0 >	0 >	5 >	0 >	0 >
Maximum value	66,25	90,75	-	92,50	94,25	0 =	4 =	5 =	0 =	5 =	5 =
Mean green leaf area (%)	50,50	80,25		80,25	83,10	0 <	1 <	0 <	0 <	0 <	0 <
%UTC	100,00%	168,4 5%		169,1 5%	175,1 1%						

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 at 2x 0.6-0.8 l/ha – Mediterranean EPPO zone

Green leaf area was recorded at 14-43 DA-B in 46 valid trials on winter wheat affected by a range of pathogens after the application of CA3301 at 0.6-0.8 l/ha applied twice. In all 46 trials, green leaf area was assessed on the whole plant.

Summary results are presented in Table 3.2-444.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the augmentation of green leaf area on winter wheat affected by foliar and ears diseases. In the 46 trials assessing green leaf area on the whole plant, an increase of 82.16-104.62% was recorded compared to the untreated check on winter wheat.

The performance of the tested product was statistically higher at the 0.8 l/ha dose rate than at the 0.6 l/ha dose rate in a few trials. In a majority of the trials it was equivalent to the reference products CA2445 at 0.8 l/ha, PROSARO at 1 l/ha and BUMPER at 0.5 l/ha even if sometimes, CA3301 at 0.6-0.8 l/ha provided a lower or higher increase of the green leaf area.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will have a positive effect on the green leaf area in winter wheat affected by a range of pathogens in the Mediterranean EPPO zone.

Table 3.2-444: Summary table - Efficacy evaluation – Winter wheat – Green leaf area - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA2445 0,8 L/ha AB	PROSARO 1.0 L/ha AB	BUMPER 0,5 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Rate								
Rate unit								
Appl. Code								
% Green leaf area - 14-43 DA-B								
Number of values	46				46	46	UT C	CA3301 0,8 l/ha
Minimum value	2,00				5,75	8,75		
Maximum value	92,50	-	-	-	100,00	100,00	22 > 24 = 0 <	0 > 39 = 7 <
Mean green leaf area (%)	38,05				52,92	55,86		
%UTC	100,00%				182,16 %	204,62 %		

Number of values	39	39			39	39	CA2445 0,8 l/ha	CA2445 0,8 l/ha
Minimum value	2,00	4,25			5,75	8,75		
Maximum value	92,50	100,00	-	-	100,00	100,00	2 >	5 >
Mean green leaf area (%)	37,04	53,34			54,29	57,27	33 =	31 =
%UTC	100,00%	192,06 %			194,99 %	220,22 %	4 <	3 <
Number of values	14		14		14	14	PROSARO 1,0 l/ha	PROSARO 1,0 l/ha
Minimum value	18,63		37,50		30,00	87,50		
Maximum value	74,40	-	92,50	-	84,50	35,00	0 >	1 >
Mean green leaf area (%)	44,28		65,24		58,54	62,78	10 =	9 =
%UTC	100,00%		192,14%		164,33 %	176,06 %	4 <	4 <
Number of values	1			1	1	1	BUMPER 0,5 l/ha	BUMPER 0,5 l/ha
Minimum value	15,00			15,00	16,25	15,00		
Maximum value	15,00	-	-	15,00	16,25	15,00	0 >	0 >
Mean green leaf area (%)	15,00			15,00	16,25	15,00	1 =	1 =
%UTC	100,00%			100,00%	108,33 %	100,00 %	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 at 2x 0.6-0.8 l/ha – North-Eastern East EPPO zone

Green leaf area was recorded at 15-45 DA-B in 33 valid trials on winter wheat affected by a range of pathogens after the application of CA3301 at 0.6-0.8 l/ha applied twice. In all 33 trials, green leaf area was assessed on the whole plant.

Summary results are presented in Table 3.2-445.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the augmentation of green leaf area on winter wheat affected by foliar and ears diseases. In the 33 trials assessing green leaf area on the whole plant, an increase of 56.55-67.42% was recorded compared to the untreated check on winter wheat.

The performance of CA3301 at 0.8 l/ha was statistically equivalent to the 0.6 l/ha dose rate or statistically better in a few trials. In a majority of the trials, CA3301 was overall equivalent to the reference products CA2445 at 0.8 l/ha and OSIRIS at 2 l/ha.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will have a positive effect on the green leaf area in winter wheat affected by a range of pathogens in the North-Eastern East EPPO zone.

Table 3.2-445: Summary table - Efficacy evaluation – Winter wheat – Green leaf area – North-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA244 5 0,8 L/ha AB	OSI- RIS 2 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
% Green leaf area - 15-45 DA-B							
Number of values	33			33	33	UT C	CA330 1 0,8 l/ha
Minimum value	9,00			13,75	13,75		UT C
Maximum value	86,25	-	-	92,50	95,00	18 > 15 =	20 > 13 =
Mean green leaf area (%)	35,64			47,98	50,76	30 =	30 =

%UTC	100,00%			156,55 %	167,42 %	0 <	3 <	0 <	0 <
Number of values	26	26		26	26	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	11,25	16,25		13,75	13,75	0 >		1 >	
Maximum value	86,25	95,00	-	92,50	95,00	22 =		24 =	
Mean green leaf area (%)	40,33	54,59		53,35	55,82	4 <		1 <	
%UTC	100,00%	152,04 %		146,21 %	154,84 %				
Number of values	16		16	16	16	OSIRIS 2,0 l/ha		OSIRIS 2,0 l/ha	
Minimum value	9,00		15,00	15,00	16,25	0 >		0 >	
Maximum value	81,25	-	95,00	92,50	95,00	16 =		16 =	
Mean green leaf area (%)	36,97		51,95	48,67	51,25	0 <		0 <	
%UTC	100,00%		181,27 %	163,18 %	175,17 %				

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 at 1x 0.6-0.8 l/ha – North-Eastern EPPO zone

Green leaf area (%) were recorded in 7 trials implemented to evaluate the effectiveness of CA3301 at 0.6-0.8 l/ha against *Oculimacula acuformis*. Green leaf area was recorded at 45-75 DA-A in 7 valid trials on winter wheat affected by PSDCHA after the application of CA3301 at 0.6-0.8 l/ha applied once. The performance of the tested product was equivalent at the 0.8 l/ha dose rate compared to the 0.6 l/ha dose rate in 6 from 7 trials. In one trial green leaf area was statistically higher at 0.8 l/ha in comparison to dose rate 0,6 l/ha. In all conducted trials CA3301 at dose rates 0,6 and 0,8 l/ha were overall equivalent to the reference product Protikon 250 EC at 0.8 l/ha.

Summary results are presented in Table 3.2-446.

Therefore, it is concluded that one application of CA3301 at 0.6-0.8 l/ha against PSDCHA will have no impact on the green leaf area in winter wheat.

Table 3.2-446: Summary table - Efficacy evaluation – Winter wheat – Green leaf area – North-Eastern EPPO zone

Treatment name	UNTREAT ED CHECK	PROTIKON 250 EC 0,8 L/ha A	CA33 01 0,6 L/ha A	CA33 01 0,8 L/ha A	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
% Green leaf area – 45-75 DA-A						
Number of values	7	7	7	7	UTC	UTC
Minimum value	17,5	17,5	17,5	18,8	0,8 l/ha	0,6 l/ha
Maximum value	43,8	47,5	47,5	52,5	0 >	1 >
Mean green leaf area (%)	30,5	32,3	32,3	32,9	7 =	6 =
%UTC	100,00%	106,5 %	106,5 %	107,9 %	0 <	0 <
Number of values	7	7	7	7	PROTIKON 250 EC 0,8 L/ha	PROTIKON 250 EC 0,8 L/ha
Minimum value	17,5	21,3	17,5	18,8	0 >	0 >
Maximum value	43,8	51,3	47,5	52,5	7 =	7 =
Mean green leaf area (%)	30,5	32,9	32,3	32,9	0 <	0 <
%UTC	100,00%	111,9%	106,5 %	107,9 %		

Use of CA3301 at 2x 0.6-0.8 l/ha – South-Eastern East EPPO zone

Green leaf area was recorded at 16-48 DA-B in 37 valid trials on winter wheat affected by a range of pathogens after the application of CA3301 at 0.6-0.8 l/ha applied twice. In 36 trials, green leaf area was assessed on the whole plant while in 1 trial it was assessed by foliar levels. For this trial, green leaf area will be presented separately and on foliar levels L2 and L1.

Summary results are presented in

Table 3.2-447.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the increase of green leaf area on winter wheat against foliar and ears diseases. In the 36 trials assessing green leaf area on the whole plant, an increase of 207.77-246.57%. % was recorded compared to the untreated check on winter wheat. In the single trial assessing green leaf area by foliar level, an increase of 1015.4-1169.2% was recorded on foliar level 2 and an augmentation of 245.1-243.9% was recorded on foliar level 1.

The performance of CA3301 at 0.8 l/ha was statistically higher or equivalent to the 0.6 l/ha dose rate and was overall equivalent to the reference products. Compared to the reference products, CA3301 at 0.6 l/ha was not always providing a comparable increase of the green leaf area but was more frequently equivalent than less efficient.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will have a positive effect on the green leaf area in winter wheat affected by a range of pathogens in the South-Eastern East EPPO zone.

Table 3.2-447: Summary table - Efficacy evaluation – Winter wheat – Green leaf area – South-Eastern East EPPO zone

Treatment name	UN-TREATED CHECK	CA2 445	PRO-SAR O	RIS A	PRI-AXO R	CA3 301	CA3 301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Rate		0,8	1	1,25	1,5	0,6	0,8		
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	AB	AB	AB		
% Green leaf area - 16-48 DA-B									
Number of values	36					36	36	UTC	CA3301 0,8 l/ha
Minimum value	0,00					15,00	18,75		UTC
Maximum value	100,00	-	-	-	-	100,00	100,00	23 >	25 >
Mean green leaf area (%)	38,31					59,44	64,07	13 =	11 =
%UTC	100,00%					307,77%	346,57%	0 <	0 <
Number of values	29	29				29	29	CA2445 0,8 l/ha	CA2445 0,8 l/ha
Minimum value	0,00	25,00				17,50	22,50		
Maximum value	100,00	100,00	-	-	-	100,00	100,00	0 >	2 >
Mean green leaf area (%)	35,91	62,07				59,18	64,24	22 =	27 =
%UTC	100,00%	381,69%				346,78%	391,66%	7 <	0 <

Number of values	2		2			2	2	PROSARO			PROSARO		
Minimum value	55,00		65,00			60,00	67,50	1,0 l/ha			1,0 l/ha		
Maximum value	62,50	-	66,25	-	-	65,00	68,75	0 >			0 >		
Mean green leaf area (%)	58,75		65,63			62,50	68,13	1 =			2 =		
%UTC	100,00%		112,23%			106,55%	116,50%	1 <			0 <		
Number of values	1			1		1	1	RISA			RISA		
Minimum value	6,25			15,00		15,00	18,75	1,25 l/ha			1,25 l/ha		
Maximum value	6,25	-	-	15,00	-	15,00	18,75	0 >			0 >		
Mean green leaf area (%)	6,25			15,00		15,00	18,75	1 =			1 =		
%UTC	100,00%			240,00%		240,00%	300,00%	0 <			0 <		
Number of values	13				13	13	13	PRIAXOR			PRIAXOR		
Minimum value	10,00				30,00	20,00	27,50	1,5 l/ha			1,5 l/ha		
Maximum value	100,00	-	-	-	100,00	98,25	100,00	0 >			0 >		
Mean green leaf area (%)	51,17				70,77	65,42	67,67	9 =			12 =		
%UTC	100,00%				181,53%	154,05%	163,95%	4 <			1 <		
% Green leaf area L2 - 27 DA-B													
Number of values	1	1				1	1	U T C	CA2 445	CA 330 1	U T C	CA2 445	CA 330 1
Minimum value	3,25	36,00				36,25	41,25		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	3,25	36,00	-	-	-	36,25	41,25	1 >	0 >	0 >	1 >	0 >	0 >
Mean green leaf area (%)	3,25	36,00				36,25	41,25	0 =	1 =	1 =	0 =	1 =	1 =
%UTC	100,00%	1107,70%				1115,40%	1269,20%	0 <	0 <	0 <	0 <	0 <	0 <
% Green leaf area L1 - 27 DA-B													
Number of values	1	1				1	1	U T C	CA2 445	CA 330 1	U T C	CA2 445	CA 330 1
Minimum value	20,50	70,50				70,75	70,50		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	20,50	70,50	-	-	-	70,75	70,50	1 >	0 >	0 >	1 >	0 >	0 >
Mean green leaf area (%)	20,50	70,50				70,75	70,50	0 =	1 =	1 =	0 =	1 =	1 =
%UTC	100,00%	343,90%				345,10%	343,90%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Comments of zRMS:

49 field trials were carried out in **the Maritime EPPO climatic zone**. CA3301 presented positive effect in assessment of green leaf area. The test product applied at dose rate 0,6 and 0,8 l/ha achieved a mean augmentation of green leaf area of 117,7% and 139,3% in trials where whole plants were observed. Moreover, an augmentation of almost 200% was noted on foliar L2 and above 70% on foliar L1. No significant differences between test and reference product were detected.

33 field trials were carried out in **the North-East EPPO zone**. The whole plants were observed to evaluation of green leaf area in all submitted trials. An augmentation of green leaf area amounted 56,55% at dose rate of 0,6 l/ha and 67,42% at dose rate of 0,8 l/ha. The results from the test and reference product were comparable. In additional 7 efficacy trials conducted in 2023, CA3301 at 0,8 l/ha had no adverse effect on green leaf area after application for control PSDCHA in winter wheat.

37 field trials were conducted in **the South-East EPPO zone**. The majorities trials show results from whole plants. CA3301 achieved a very positive effect in compared to untreated objectives and standards. An augmentation of green leaf area amounted above 240% (0,8 l/ha) in case of whole plants. In 5 trials an augmentation was above 1169% (0,8 l/ha) on foliar L2 and 240% on foliar L1 after 27 days after second application. No significant differences between test and reference product were observed.

3.2.3.33 Efficacy tests – Justification of the single application

In this dossier efficacy data presented were primarily from assessments where 2 applications of the test product were made. However, according to disease development conditions, a single application may provide sufficient disease control, therefore users should not be restricted to always applying twice, hence in the GAP the proposed use is for 1-2 applications.

In order to evaluate the efficacy of a single application of CA3301 at 0.6-0.8 l/ha, the trials including a single application and the data from early assessments (before the 2nd application) of trials including two applications are presented here. Main foliar and ear diseases (*Zymoseptoria tritici*, *Puccinia recondita* / *Puccinia triticina*, *Fusarium culmorum*) with a representative number of trials were selected to justify the interest of applying CA3301 at 1 x 0.6-0.8 l/ha.

Zymoseptoria tritici – Mediterranean EPPO Zone

In the Mediterranean EPPO zone, a total of 5 trials evaluated the efficacy of CA3301 applied once on winter wheat against *Zymoseptoria tritici*. 4 trials out of 5 were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha (applied once), and to compare it to the reference products on disease severity (%).

Summary results are presented in Table 3.2-448.

Data demonstrated the positive effect of 1 application of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on winter wheat against *Zymoseptoria tritici*. On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 76.34-81.38% efficacy against *Zymoseptoria tritici* two weeks after one application (A) and 64.62-69.09% two weeks after one application (B). On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 79.97-81.76% efficacy on reduction of disease severity two weeks after one application (A) and 68.19-73.19% two weeks after 1 application (B).

In the Mediterranean EPPO zone, CA3301 at 0.6-0.8 l/ha applied once showed medium to high efficacy in reducing the severity of *Zymoseptoria tritici* on winter wheat two weeks after the application at timing A or B, on both main foliar levels 1 (L1) and 2 (L2). The performance of the tested product was always statistically equivalent to the reference product CA2445 applied once at timing A or twice at AB. Therefore, a single application of CA3301 provides acceptable control of the disease and may be sufficient alone, depending on disease progression, or as part of a fungicide programme.

Considering all elements presented above, it is justified to claim the registration of 1 application of CA3301 at 0.6-0.8 l/ha to control *Zymoseptoria tritici* on winter wheat in the Mediterranean EPPO zone.

Table 3.2-448: Summary table - Efficacy evaluation – 1 application – Winter wheat – SEPTTR - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA24 45 0,8 L/ha A or AB	CA31 01 0,6 L/ha A or B	CA33 01 0,8 L/ha A or B	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity L2 - 13-18 DA-A										
Number of values	4	4	4	4	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	6,40	0,00	0,00	0,00	4 > 0 =	0 > 4 =	0 > 4 =	4 > 0 =	0 > 4 =	0 > 4 =
Maximum value	31,46	10,21	8,83	7,50		0 <	0 <	0 <	0 <	0 <
Mean disease severity (%)	14,10	3,69	3,35	2,75						
Abbott efficacy (%)	0,00%	73,85 %	76,34 %	81,38 %						
% Disease severity L1 - 15 DA-A										
Number of values	1	1	1	1	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	7,29	2,54	1,46	1,33	1 > 0 =	0 > 1 =	0 > 1 =	1 > 0 =	0 > 1 =	0 > 1 =
Maximum value	7,29	2,54	1,46	1,33		0 <	0 <	0 <	0 <	0 <
Mean disease severity (%)	7,29	2,54	1,46	1,33						
Abbott efficacy (%)	0,00%	65,16 %	79,97 %	81,76 %						
% Disease severity L2 - 15 DA-B										
Number of values	1	1	1	1	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	63,73	29,10	22,55	19,70	1 > 0 =	0 > 1 =	0 > 1 =	1 > 0 =	0 > 1 =	0 > 1 =
Maximum value	63,73	29,10	22,55	19,70		0 <	0 <	0 <	0 <	0 <
Mean disease severity (%)	63,73	29,10	22,55	19,70						
Abbott efficacy (%)	0,00%	54,34 %	64,62 %	69,09 %						
% Disease severity L1 - 15 DA-B										
Number of values	1	1	1	1	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	44,95	12,30	14,30	12,05	1 > 0 =	0 > 1 =	0 > 1 =	1 > 0 =	0 > 1 =	0 > 1 =
Maximum value	44,95	12,30	14,30	12,05		0 <	0 <	0 <	0 <	0 <
Mean disease severity (%)	44,95	12,30	14,30	12,05						
Abbott efficacy (%)	0,00%	72,64 %	68,19 %	73,19 %						

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Zymoseptoria tritici – North-Eastern East EPPO Zone

In the North-Eastern East EPPO zone, 2 trials evaluated the efficacy of CA3301 applied once on winter

wheat against *Zymoseptoria tritici*. The trials were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha (applied once), and to compare it to the reference products on disease severity (%).

Summary results are presented in Table 3.2-449.

Data demonstrated the positive effect of 1 application of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on winter wheat against *Zymoseptoria tritici*. On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 86.52-91.20% efficacy against *Zymoseptoria tritici* before harvest after one application (A).

In the North-eastern East EPPO zone, the dataset was very limited with only 1 valid trial. CA3301 at 0.6-0.8 l/ha applied once showed very high efficacy in reducing the severity of *Zymoseptoria tritici* on winter wheat before harvest after the application at timing A. The performance of the tested product was overall statistically equivalent to the reference products CA2445 and OSIRIS applied once at timing A. Therefore, a single application of CA3301 provides acceptable control of the disease and may be sufficient alone, depending on disease progression, or as part of a fungicide programme.

Considering all elements presented above, it is justified to claim the registration of 1 application of CA3301 at 0.6-0.8 l/ha to control *Zymoseptoria tritici* on winter wheat in the North-Eastern East EPPO zone.

Table 3.2-449: Summary table - Efficacy evaluation – 1 application – Winter wheat – SEPTTR – North-Eastern East EPPO zone

North-Eastern East LTPG zone									
Treatment name	UNTREATED CHECK	CA24 45	OSIR IS	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		0,8	2	0,6	0,8				
Rate unit		L/ha	L/ha	L/ha	L/ha				
Appl. Code		A	A	A	A				
% Disease severity L2 - 49 DA-A									
Number of values	2			2	2	UTC	CA33 01 0,8 l/ha	UTC	CA33 01 0,6 l/ha
Minimum value	6.69			0.44	0.31				
Maximum value	16.20	-	-	3.30	2.10	2 >	0 >	2 >	1 >
Mean disease severity (%)	11.45			1.87	1.21	0 =	1 =	0 =	1 =
Abbott efficacy (%)	0.00%			86.52 %	91.20 %	0 <	1 <	0 <	0 <
Number of values	1	1	1	1	1	CA24 45 0,8 l/ha	OSI- RIS 2,0 l/ha	CA24 45 0,8 l/ha	OSI- RIS 2,0 l/ha
Minimum value	6,69	0,88	0,88	0,44	0,31				
Maximum value	6,69	0,88	0,88	0,44	0,31	0 >	0 >	0 >	0 >
Mean disease severity (%)	6,69	0,88	0,88	0,44	0,31	1 =	1 =	1 =	1 =
Abbott efficacy (%)	0,00%	86,85 %	0,88%	93,42 %	95,37 %	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

***Zymoseptoria tritici* – South-Eastern East EPPO Zone**

In the South-Eastern East EPPO zone, a total of 3 trials evaluated the efficacy of CA3301 applied once on winter wheat against *Zymoseptoria tritici*. All 3 trials were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha (applied once), and to compare it to the reference products on

disease severity (%).

Summary results are presented in Table 3.2-450.

Data demonstrated the positive effect of 1 application of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on winter wheat against *Zymoseptoria tritici*. On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 68.27-77.65% efficacy against *Zymoseptoria tritici* two weeks after one application (A), 84.12-90.00% before harvest after one application (A) and 46.35-57.88% two weeks after one application (B). On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 46.08-64.24% efficacy on reduction of disease severity two weeks after one application (B).

In the South-Eastern East EPPO zone, CA3301 at 0.6-0.8 l/ha applied once showed medium to high efficacy in reducing the severity of *Zymoseptoria tritici* on winter wheat two weeks after the application at timing A or B, and at the last assessment timing on both main foliar levels 1 (L1) and 2 (L2). The performance of the tested product was overall statistically equivalent to the reference product CA2445 applied once at timing A but was globally less efficient compared to the reference applied *twice* at timing AB (CA3301 applied at A was compared to CA2445 applied at A while CA3301 applied at B was compared to CA2445 applied at AB).

Therefore, a single application of CA3301 provides acceptable control of the disease and may be sufficient alone, depending on disease progression, or as part of a fungicide programme.

Considering all elements presented above, it is justified to claim the registration of 1 application of CA3301 at 0.6-0.8 l/ha to control *Zymoseptoria tritici* on winter wheat in the South-Eastern East EPPO zone.

Table 3.2-450: Summary table - Efficacy evaluation – 1 application – Winter wheat – SEPTTR – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA2445 0,8 L/ha A or AB	CA3301 0,6 L/ha A or B	CA3301 0,8 L/ha A or B	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity L2 - 14 DA-A										
Number of values	≥ 1	≥ 1	≥ 1	≥ 1	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	6,50	1,55	0,83	0,53	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	10,26	3,79	5,20	3,75	1 >	0 >	0 >	1 >	0 >	1 >
Mean disease severity (%)	8,38	2,67	3,02	2,14	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	68,14 63,06%	68,27 49,32%	77,65 63,45%	0 <	1 <	1 <	0 <	0 <	0 <
% Disease severity L2 - 29 DA-A										
Number of values	1	1	1	1	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	5,10	0,43	0,81	0,51	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	5,10	0,43	0,81	0,51	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	5,10	0,43	0,81	0,51	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	91,57%	84,12%	90,00%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 17 DA-B										
Number of values	2	2	2	2	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	8,83	1,40	4,23	2,85	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	22,90	5,65	13,60	11,90	2 >	0 >	0 >	2 >	0 >	1 >
Mean disease severity (%)	15,87	3,53	8,92	7,38	0 =	0 =	1 =	0 =	1 =	1 =

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Absorb efficacy)	
>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

In the Maritime EPPO zone, a total of 2 trials evaluated the efficacy of CA3301 applied once on winter wheat against *Puccinia recondita* (PUCCRE) or *Puccinia triticina* (PUCCRT). Both trials were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha (applied once), and to compare it to the reference products on disease severity (%).

Data demonstrated the positive effect of 1 application of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on winter wheat against *Puccinia recondita* or *Puccinia triticina*. On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 70.51-73.08% efficacy against brown rust two weeks after one application (B). On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 70.49-73.77% efficacy on reduction of disease severity two weeks after one application (B), and 44.81-50.00% before harvest after one application (B).

In the Maritime EPPO zone, CA3301 at 0.6-0.8 l/ha applied once showed medium to high efficacy in reducing the severity of brown rust on winter wheat two weeks after the application at timing B, and at the last assessment timing on both main foliar levels 1 (L1) and 2 (L2). Before harvest, the performance of the tested product was statistically equivalent to the reference product CA2445 applied once at 0.6-0.8 l/ha at timing B. Two weeks after application B, the tested product gave lower disease control than the one provided by the reference product CA2445 applied *twice* (AB) at 0.8 l/ha. Therefore, a single application of CA3301 provides acceptable control of the disease and may be sufficient alone, depending on disease progression, or as part of a fungicide programme.

Considering all elements presented above, it is justified to claim the registration of 1 application of CA3301 at 0.6-0.8 l/ha to control *Puccinia recondita* or *Puccinia triticina* on winter wheat in the Maritime EPPO zone.

TREATMENT NAME							
Treatment name	UNTREAT ED CHECK	CA 244	CA 244	CA 330	CA 330	No of trials where CA3301	No of trials where CA3301
Rate		5	5	1	1		
Rate unit		0,6 L/h	0,8 L/h	0,6 L/h	0,8 L/h	at 0,6 l/ha is >, = or <	at 0,8 l/ha is >, = or <
Appl. Code		a	a	a	a	compared to	compared to
% Disease severity L2 - 18 DA-B							

Number of values	1	-	1	1	1	UTC	CA244 5	CA330 1	UTC	CA244 5	CA330 1		
Minimum value	7,80	-	1,10	2,30	2,10		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha		
Maximum value	7,80	-	1,10	2,30	2,10	1 >	0 >	0 >	1 >	0 >	0 >		
Mean disease severity (%)	7,80	-	1,10	2,30	2,10	0 =	0 =	1 =	0 =	0 =	1 =		
Abbott efficacy (%)	0,00%	-	85,9 0%	70,5 1%	73,0 8%	0 <	1 <	0 <	0 <	1 <	0 <		
% Disease severity L1- 18 DA-B													
Number of values	1	-	1	1	1	UTC	CA244 5	CA330 1	UTC	CA244 5	CA330 1		
Minimum value	6,10	-	0,90	1,80	1,60		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha		
Maximum value	6,10	-	0,90	1,80	1,60	1 >	0 >	0 >	1 >	0 >	0 >		
Mean disease severity (%)	6,10	-	0,90	1,80	1,60	0 =	0 =	1 =	0 =	0 =	1 =		
Abbott efficacy (%)	0,00%	-	85,2 5%	70,4 9%	73,7 7%	0 <	1 <	0 <	0 <	1 <	0 <		
% Disease severity L1 - 34 DA-B													
Number of values	1	1	1	1	1	U T C	CA2 445	CA2 445	CA 330 1	U T C	CA2 445	CA2 445	CA 330 1
Minimum value	15,40	7,60	5,40	8,50	7,70		0,6 l/ha	0,8 l/ha	0,8 l/ha		0,6 l/ha	0,8 l/ha	0,6 l/ha
Maximum value	15,40	7,60	5,40	8,50	7,70	1 >	0 >	0 >	0 >	1 >	0 >	0 >	0 >
Mean disease severity (%)	15,40	7,60	5,40	8,50	7,70	0 =	1 =	1 =	1 =	0 =	1 =	1 =	1 =
Abbott efficacy (%)	0,00%	50,6 5%	64,9 4%	44,8 1%	50,0 0%	0 <	0 <	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

***Puccinia recondita* (PUCCRE) or *Puccinia triticina* (PUCCRT) – Mediterranean EPPO Zone**

In the Mediterranean EPPO zone, a total of 1 trial evaluated the efficacy of CA3301 applied once on winter wheat against *Puccinia recondita* (PUCCRE) or *Puccinia triticina* (PUCCRT). The trial was considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha (applied once), and to compare it to the reference products on disease severity (%).

Summary results are presented in Table 3.2-452.

Data demonstrated the positive effect of 1 application of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on winter wheat against *Puccinia recondita* or *Puccinia triticina*. On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 36.99-40.75% efficacy against brown rust two weeks after one application (A) and 47.14-58.36% at the last assessment timing. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 61.25-61.73% efficacy on reduction of disease severity at the last assessment timing after one application (A).

In the Mediterranean EPPO zone, with a very limited dataset, CA3301 at 0.6-0.8 l/ha applied once showed medium efficacy in reducing the severity of brown rust on winter wheat two weeks after the application at timing A, and at the last assessment timing on both main foliar levels 1 (L1) and 2 (L2). The performance of the tested product was always statistically equivalent to the reference product

CA2445 applied once at 0.8 l/ha at timing A.. Therefore, a single application of CA3301 provides acceptable control of the disease and may be sufficient alone, depending on disease progression, or as part of a fungicide programme.

Considering all elements presented above, it is justified to claim the registration of 1 application of CA3301 at 0.6-0.8 l/ha to control *Puccinia recondita* or *Puccinia triticina* on winter wheat in the Mediterranean EPPO zone.

Table 3.2-452: Summary table - Efficacy evaluation – 1 application – Winter wheat – PUCCRE/PUCCRT – Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA24 45	CA33 01	CA33 01	No of trials where CA3301			No of trials where CA3301		
Rate		0,8	0,6	0,8	at 0,6 l/ha is >, = or			at 0,8 l/ha is >, = or		
Rate unit		L/ha	L/ha	L/ha	<			<		
Appl. Code		A	A	A	compared to			compared to		
% Disease severity L2 - 15 DA-A										
Number of values	1	1	1	1	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	39,88	25,38	25,13	23,63	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	39,88	25,38	25,13	23,63	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	39,88	25,38	25,13	23,63	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	36,36 %	36,99 %	40,75 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2- 19 DA-A										
Number of values	1	1	1	1	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	56,75	25,63	30,00	23,63	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	56,75	25,63	30,00	23,63	1 >	0 >	0 >	1 >	0 >	1 >
Mean disease severity (%)	56,75	25,63	30,00	23,63	0 =	0 =	0 =	0 =	1 =	0 =
Abbott efficacy (%)	0,00%	54,84 %	47,14 %	58,36 %	0 <	1 <	1 <	0 <	0 <	0 <
% Disease severity L1 - 19 DA-A										
Number of values	1	1	1	1	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	12,75	4,31	4,94	4,88	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	12,75	4,31	4,94	4,88	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	12,75	4,31	4,94	4,88	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	66,20 %	61,25 %	61,73 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Puccinia recondita (PUCCRE) or *Puccinia triticina* (PUCCRT) – North-Eastern East EPPO Zone

In the North-Eastern East EPPO zone, a total of 2 trials evaluated the efficacy of CA3301 applied once on winter wheat against *Puccinia recondita* (PUCCRE) or *Puccinia triticina* (PUCCRT). Both trials were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha (applied once), and to compare it to the reference products on disease severity (%).

Summary results are presented in Table 3.2-453.

Data demonstrated the positive effect of 1 application of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on winter wheat against *Puccinia recondita* or *Puccinia triticina*. On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 79.98-84.08% efficacy against brown rust at the last assessment after one application (B). On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 77.06-85.32% efficacy on reduction of disease severity at the last assessment timing after one application (B).

In the North-~~Eastern~~ East EPPO zone, CA3301 at 0.6-0.8 l/ha applied once showed high efficacy in reducing the severity of brown rust on winter wheat at the last assessment timing after the application at timing B, on both main foliar levels 1 (L1) and 2 (L2). The performance of the tested product was always statistically equivalent to the reference product CA2445 applied *twice* (AB) at 0.8 l/ha. Therefore, a single application of CA3301 provides acceptable control of the disease and may be sufficient alone, depending on disease progression, or as part of a fungicide programme.

Considering all elements presented above, it is justified to claim the registration of 1 application of CA3301 at 0.6-0.8 l/ha to control *Puccinia recondita* or *Puccinia triticina* on winter wheat in the North-~~Eastern~~ East EPPO zone.

Table 3.2-453: Summary table - Efficacy evaluation – 1 application – Winter wheat – PUCCRE/PUCCRT – North-~~Eastern~~ East EPPO zone

Treatment name	UNTREATED CHECK	CA24	CA33	CA33	No of trials where			No of trials where		
Rate		45	01	01	CA3301			CA3301		
Rate unit		0,8	0,6	0,8	at 0,6 l/ha is >, = or			at 0,8 l/ha is >, = or		
Appl. Code		L/ha	L/ha	L/ha	<			<		
		AB	B	B	compared to			compared to		
% Disease severity L2 - 20 DA-B										
Number of values	2	2	2	2	UT C	CA24 45	CA33 01	UT C	CA24 45	CA33 01
Minimum value	6,35	0,80	1,30	0,90		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	7,70	1,24	1,47	1,28	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	7,03	1,02	1,39	1,09	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	85,48 %	79,98 %	84,48 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1- 20 DA-B										
Number of values	1	1	1	1	UT C	CA24 45	CA33 01	UT C	CA24 45	CA33 01
Minimum value	10,90	1,50	2,50	1,60		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	10,90	1,50	2,50	1,60	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	10,90	1,50	2,50	1,60	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	86,24 %	77,06 %	85,32 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

***Puccinia recondita* (PUCCRE) or *Puccinia triticina* (PUCCRT) – South-~~Eastern~~ East EPPO Zone**

In the South-~~Eastern~~ East EPPO zone, a total of 1 trial evaluated the efficacy of CA3301 applied once on winter wheat against *Puccinia recondita* (PUCCRE) or *Puccinia triticina* (PUCCRT). The trial was considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha (applied once), and to compare it to the reference products on disease severity (%).

Summary results are presented in Table 3.2-454.

Data demonstrated the positive effect of 1 application of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on winter wheat against *Puccinia recondita* or *Puccinia triticina*. On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 53.85-70.09% efficacy against brown rust two weeks after one application (B).

In the South-Eastern East EPPO zone, with a very limited dataset, CA3301 at 0.6-0.8 l/ha applied once showed medium to relatively high efficacy in reducing the severity of brown rust on winter wheat two weeks after the application at timing B, on foliar level 2 (L2). The performance of the tested product was always statistically equivalent to the reference product CA2445 applied *twice* (AB) at 0.8 l/ha. Therefore, a single application of CA3301 provides acceptable control of the disease and may be sufficient alone, depending on disease progression, or as part of a fungicide programme.

Considering all elements presented above, it is justified to claim the registration of 1 application of CA3301 at 0.6-0.8 l/ha to control *Puccinia recondita* or *Puccinia triticina* on winter wheat in the South-Eastern East EPPO zone.

Table 3.2-454: Summary table - Efficacy evaluation – 1 application – Winter wheat – PUCCRE/PUCRT – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA24	CA33	CA33	No of trials where			No of trials where		
Rate		45	01	01	CA3301			CA3301		
Rate unit		0,8	0,6	0,8	at 0,6 l/ha is >, = or			at 0,8 l/ha is >, = or		
Appl. Code		L/ha	L/ha	L/ha	<			<		
		AB	B	B	compared to			compared to		
% Disease severity L2 - 17 DA-B										
Number of values	1	1	1	1	UT	CA24	CA33	UT	CA24	CA33
					C	45	01	C	45	01
Minimum value	5,85	1,15	2,70	1,75		0,8	0,8		0,8	0,6
						l/ha	l/ha		l/ha	l/ha
Maximum value	5,85	1,15	2,70	1,75	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	5,85	1,15	2,70	1,75	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	80,34 %	53,85 %	70,09 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

***Fusarium culmorum* – Maritime EPPO Zone**

In the Maritime EPPO zone, a total of 4 trials evaluated the efficacy of CA3301 applied once on winter wheat against *Fusarium culmorum*. 2 trials out of 4 were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha (applied once), and to compare it to the reference products on disease severity (%).

Summary results are presented in Table 3.2-455.

Data demonstrated the positive effect of 1 application of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on winter wheat against *Fusarium culmorum*. On ears I, CA3301 at 0.6-0.8 l/ha showed 78.07-83.88 % efficacy against *Fusarium culmorum* two weeks after one application (B). On ears NI, CA3301 at 0.6-0.8 l/ha showed 71.67-78.33% efficacy on reduction of disease severity two weeks after one application (B).

In the Maritime EPPO zone, CA3301 at 0.6-0.8 l/ha applied once showed high efficacy in reducing the severity of *Fusarium culmorum* on winter wheat two weeks after the application at timing B, on ears inoculated (ears I) and non-inoculated (ears NI). The performance of the tested product was always statistically equivalent to the reference product CA2445 applied *twice* at timing AB. Therefore, a single application of CA3301 provides acceptable control of the disease and may be sufficient alone, depending on disease progression, or as part of a fungicide programme.

Considering all elements presented above, it is justified to claim the registration of 1 application of CA3301 at 0.6-0.8 l/ha to control *Fusarium culmorum* on winter wheat in the Maritime EPPO zone.

Table 3.2-455: Summary table - Efficacy evaluation – 1 application – Winter wheat – FUSACU – Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA24 45 0,8 L/ha AB	CA33 01 0,6 L/ha B	CA33 01 0,8 L/ha B	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
% Disease severity Ears I - 18-19 DA-B						
Number of values	2	2	2	2	UT C	CA24 45 0,8 l/ha CA33 01 0,8 l/ha
Minimum value	5,60	0,55	1,12	0,67		
Maximum value	5,87	1,19	1,40	1,19	2 >	0 >
Mean disease severity (%)	5,74	0,87	1,26	0,93	0 =	2 =
Abbott efficacy (%)	0,00%	84,83 %	78,07 %	83,88 %	0 <	0 <
% Disease severity Ears NI - 18 DA-B						
Number of values	1	1	1	1	UT C	CA24 45 0,8 l/ha CA33 01 0,6 l/ha
Minimum value	1,20	0,23	0,34	0,26		
Maximum value	1,20	0,23	0,34	0,26	1 >	0 >
Mean disease severity (%)	1,20	0,23	0,34	0,26	0 =	1 =
Abbott efficacy (%)	0,00%	80,83 %	71,67 %	78,33 %	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

***Fusarium culmorum* – Mediterranean EPPO Zone**

In the Mediterranean EPPO zone, a total of 2 trials evaluated the efficacy of CA3301 applied once on winter wheat against *Fusarium culmorum*. Both trials were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha (applied once), and to compare it to the reference products on disease severity (%).

Summary results are presented in Table 3.2-456.

Data demonstrated the positive effect of 1 application of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on winter wheat against *Fusarium culmorum*. On ears I, CA3301 at 0.6-0.8 l/ha showed 81.48-77.78% efficacy against *Fusarium culmorum* at the last assessment after one application (A), 58.81-63.41% two weeks after one application (B) and 59.07-66.71% at the last assessment after one application (B).

In the Mediterranean EPPO zone, CA3301 at 0.6-0.8 l/ha applied once showed medium to high efficacy in reducing the severity of *Fusarium culmorum* on winter wheat two weeks after the application at timing A or B, on ears inoculated (ears I). The performance of the tested product was usually statistically equivalent to the reference product CA2445 applied once at the timing A or twice at timing AB.. Therefore, a single application of CA3301 provides acceptable control of the disease and may be sufficient alone, depending on disease progression, or as part of a fungicide programme.

Considering all elements presented above, it is justified to claim the registration of 1 application of CA3301 at 0.6-0.8 l/ha to control *Fusarium culmorum* on winter wheat in the Mediterranean EPPO zone.

Table 3.2-456: Summary table - Efficacy evaluation – 1 application – Winter wheat – FUSACU – Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA244 5	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or <			No of trials where CA3301 at 0,8 l/ha is >, = or <		
Rate		0,8	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		A or AB	A or B	A or B	compared to			compared to		
% Disease severity Ears I - 22 DA-A										
Number of values	1	1	1	1	UT C	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UT C	CA244 5 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	1,35	0,25	0,25	0,30						
Maximum value	1,35	0,25	0,25	0,30	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	1,35	0,25	0,25	0,30	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	81,48%	81,48 %	77,78 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity Ears I - 15 DA-B										
Number of values	2	2	2	2	UT C	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UT C	CA244 5 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	14,13	1,53	2,95	3,33						
Maximum value	26,50	6,70	16,30	13,15	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	20,31	4,11	9,63	8,24	1 =	2 =	2 =	1 =	2 =	2 =
Abbott efficacy (%)	0,00%	79,76%	58,81 %	63,41 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity Ears I - 25-29 DA-B										
Number of values	2	2	2	2	UT C	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UT C	CA244 5 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	22,98	3,00	5,25	5,20						
Maximum value	32,20	10,60	19,00	14,15	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	27,59	6,80	12,13	9,68	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	75,35%	59,07 %	66,71 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Fusarium culmorum – North-Eastern East EPPO Zone

In the North-Eastern East EPPO zone, a total of 4 trials evaluated the efficacy of CA3301 applied once

Summary results are presented in Table 3.2-457.

In the North-Eastern East EPPO zone, CA3301 at 0.6-0.8 l/ha applied once showed relatively low to high efficacy in reducing the severity of *Fusarium culmorum* on winter wheat two weeks or at the last assessment after the application at timing B, on ears, ears inoculated (ears I) and ears non-inoculated (ears NI). CA3301 at 0.6 l/ha gave lower or equivalent disease control compared the reference product CA2445 applied once at the timing B at 0.6-0.8 l/ha while CA3301 at 0.8 l/ha provided higher or equivalent disease. CA3301 applied once at 0.6-0.8 l/ha was also statistically equivalent to the reference product CA2445 applied *twice* (AB) at 0.8 l/ha except in 1 trial in which CA3301 at 0.6 l/ha applied once provided lower efficacy. Therefore, a single application of CA3301 provides acceptable control of the disease and may be sufficient alone, depending on disease progression, or as part of a fungicide programme.

Considering all elements presented above, it is justified to claim the registration of 1 application of CA3301 at 0.6-0.8 l/ha to control *Fusarium culmorum* on winter wheat in the North-Eastern East EPPo zone.

Treatment name		CA2 445		CA2 445		CA3 301		CA3 301		No of trials where CA3301		No of trials where CA3301	
Rate		0,6		0,8		0,6		0,8		at 0,6 l/ha is >, = or <		at 0,8 l/ha is >, = or <	
Rate unit		L/ha		L/ha		L/ha		L/ha					
Appl. Code		B		AB or B		B		B		compared to		compared to	
% Disease severity Total Ears - 12-15 DA-B													
Number of values	2	2	2	2	2	U T C	CA24 45	CA24 45	CA3 301	U T C	CA24 45	CA24 45	CA3 301
Minimum value	33,60	9,60	9,20	9,50	9,20	0,6 l/ha	0,6 l/ha	0,8 l/ha	0,8 l/ha	0,6 l/ha	0,6 l/ha	0,8 l/ha	0,6 l/ha
Maximum value	49,80	14,10	9,80	20,10	10,50	2 >	0 >	0 >	0 >	2 >	1 >	0 >	1 >
Mean disease severity (%)	41,70	11,85	9,50	14,80	9,85	0 =	1 =	1 =	1 =	0 =	1 =	2 =	1 =
Abbott efficacy (%)	0,00%	71,58%	77,22%	60,55%	75,14%	0 <	1 <	1 <	1 <	0 <	0 <	0 <	0 <
% Disease severity Total Ears - 20 DA-B													
Number of values	1	1	1	1	1	U T C	CA24 45	CA24 45	CA3 301	U T C	CA24 45	CA24 45	CA3 301
Minimum value	41,10	21,00	14,10	25,10	14,90	0,6 l/ha	0,6 l/ha	0,8 l/ha	0,8 l/ha	0,6 l/ha	0,6 l/ha	0,8 l/ha	0,6 l/ha
Maximum value	41,10	21,00	14,10	25,10	14,90	1 >	0 >	0 >	0 >	1 >	1 >	0 >	1 >
Mean disease severity (%)	41,10	21,00	14,10	25,10	14,90	0 =	0 =	0 =	0 =	0 =	0 =	1 =	0 =
Abbott efficacy (%)	0,00%	48,91%	65,69%	38,93%	63,75%	0 <	1 <	1 <	1 <	0 <	0 <	0 <	0 <
% Disease severity Ears I - 20 DA-B													

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

In the South-Eastern East EPPO zone, 1 trial evaluated the efficacy of CA3301 applied once on winter wheat against *Fusarium culmorum*. The trial was considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha (applied once), and to compare it to the reference products on disease severity (%).

Data demonstrated the positive effect of 1 application of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on winter wheat against *Fusarium culmorum*. On ears I, with a very limited dataset, CA3301 at 0.6-0.8 l/ha showed 46.61-45.29% efficacy at the last assessment after one application (B).

In the South-Eastern East EPPO zone, CA3301 at 0.6-0.8 l/ha applied once showed medium efficacy in reducing the severity of *Fusarium culmorum* on winter wheat at the last assessment after the application at timing B on ears inoculated (ears I). Despite a relatively high infestation, the performance of CA3301 at 0.6-0.8 l/ha applied once was statistically equivalent to the reference product CA2445 applied *twice* at the timing AB at 0.8 l/ha. Therefore, a single application of CA3301 provides acceptable control of the disease and may be sufficient alone, depending on disease progression, or as part of a fungicide programme.

Considering all elements presented above, it is justified to claim the registration of 1 application of CA3301 at 0.6-0.8 l/ha to control *Fusarium culmorum* on winter wheat in the South-Eastern East EPPO zone.

South East Asia I - 25 DA-B						
Treatment name	UNTREATED CHECK	CA24	CA33	CA33	No of trials where CA3301	No of trials where CA3301
Rate		45	01	01	at 0,6 l/ha is >, = or	at 0,8 l/ha is >, = or
Rate unit		0,8	0,6	0,8	<	<
Appl. Code		L/ha	L/ha	L/ha	compared to	compared to
		AB	B	B		
% Disease severity Ears I - 25 DA-B						

Number of values	1	1	1	1	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	30,34	13,08	16,20	16,60						
Maximum value	30,34	13,08	16,20	16,60	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	30,34	13,08	16,20	16,60	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	56,89 %	46,61 %	45,29 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

In the **Maritime EPPO zone**, the evaluation of efficacy after single application was provided only in case of *Puccinia recondita* and *Fusarium culmorum*. The results from 2 field trials have been submitted to justify of 1 application for control of PUCCRE. CA3301 applied at dose rate of 0,6-0,8 l/ha achieved the medium efficacy after 18 days after last application on foliar L1 and L2. The test product was applied only once in these trials. The effectiveness in the next term was significant lower (44,81-50%). Also the medium efficacy was observed in control of FUSACU. The test product presented results on the level of about 80%, either on inoculated and non-inoculated ears. However, only 2 efficacy trials have been submitted for assessment of these use. Taking into account the limited number of trials and justification for only 2 out of 8 target pests in winter wheat, the cMSs are kindly asked to consider single application on the national level.

In the **North-East EPPO zone**, the evaluation of efficacy after single application was provided only in case of *Zymoseptoria tritici*, *Puccinia recondite* and *Fusarium culmorum*. The results from 2 field trials have been submitted to justify of 1 application for control of SEPTTR. CA3301 at 0,6-0,8 l/ha achieved high efficacy after 49-60 days after last application. Also 2 trials were conducted to justify of single application for PUCCRE. The test product applied at dose rate of 0,6 l/ha presented medium efficacy but higher dose of 0,8 l/ha caused increase of effectiveness to above 84%. The medium efficacy have been observed in control of FUSACU. The results from 4 trials amounted 60-80% after 12-20 days after last application, either on inoculated and non-inoculated ears.

In the **South-East EPPO zone**, the justification of efficacy after single application was provided only in case of *Zymoseptoria tritici*, *Puccinia recondite* and *Fusarium culmorum*. 3 trials have been submitted to justify of single application to control of SEPTTR. CA3301 applied at 0,6-,8 l/ha achieved from medium to high efficacy but the higher dose was significant more effective. Also 4 trials conducted in the Mediterranean zone show that the test product achieved medium to high level of control after 13-15 days after first application. Only 1 trial was carried in SE zone for justify of single application to control of PUCCRE. The medium efficacy was noted in case of dose rate of 0,8 l/ha. The lower dose caused significant decrease of control (53,85%). 1 trial from the Mediterranean zone shows the low effectiveness of the test product after a single treatment. Also results from 1 trial in the SE zone confirm very low level of control after single application of CA3301. In 1 out of 2 trials in the Mediterranean the test product achieved medium efficacy after 22 DA-A. Taking into account the limited number of trials and justification for only 3 out of 8 target pests in winter wheat, the cMSs are kindly asked to consider single application on the national level.

3.2.3.34 Winter wheat (TRZAW) / Conclusion – Efficacy tests

On winter wheat, 6 foliar diseases and 3 ears diseases were assessed in 176 trials across 4 EPPO zones. Disease severity or incidence (for *Blumeria graminis*) was assessed and analysed on the main foliar levels 1 and 2 and on inoculated or non-inoculated ears. Although a comprehensive trials programme was undertaken for this dossier, in some instances, due to the absence of appropriate level of diseases or other agronomic or climatic limitations, the proposed number of valid trials was not fully achieved. Hence, depending on the EPPO zone, the disease, the assessment timing and the crop part assessed, the dataset available was sometimes limited and so not fully representative of the efficacy of CA3301.

Therefore, to get an overview of the efficacy of CA3301 at 0.6-0.8 l/ha, summary tables are presented hereunder, on foliar levels 1&2 and on ears inoculated or non-inoculated (see Table 3.2-459, Table 3.2-460, Table 3.2-461 & Table 3.2-462).

Globally, across the 4 EPPO zones and all diseases the efficacy of CA3301 was acceptable to very high, with some exceptions especially in case of limited dataset. Nevertheless, since in the fields a complex of disease is often observed instead of a single disease, it is of interest to present a summary of the efficacy of CA3301 across the diseases and EPPO zones, as well as considering the green leaf area presented above. Green leaf area not only indicates the area free of infection but also the ability of the plant to continue effective growth and develop to productive stages, enabling a longer duration of grain filling and therefore improved yield quantity and quality.

In many instances, a trend of decreasing disease severity when increasing the dose rate was observed with CA3301 applied at 0.6 l/ha or 0.8 l/ha. Although the rate of 0.8 l/ha overall reduced disease to a greater extent than the 0.6 l/ha rate, the differences were not always significant. However, in circumstances of high disease pressure the higher rate of 0.8 l/ha was often observed to be of significant benefit, while in circumstances of low disease pressure, the 0.6 l/ha dose rate may be sufficient to give comparable disease control. In addition, due to the importance of the diseases and given the possibility of resistance in some of the pathogens assessed, the higher rate may be deemed more appropriate and should be available for users according to disease development conditions, historical control and cultivar tolerance to the pathogens.

In the majority of efficacy assessments, the disease control obtained from applications of CA3301 was statistically comparable to that from authorised reference products. In some instances, CA3301 applied at 0.8 l/ha provided higher efficacy compared to the range of reference products and in some instances CA3301 applied at 0.6 l/ha provided lower efficacy compared to CA2445 applied at a higher rate of prothioconazole, but more frequently efficacy was comparable.

In this dossier efficacy data presented is primarily from assessments where 2 applications of the test product were made. However, according to disease development conditions, a single application may provide sufficient disease control, therefore users should not be restricted to always applying twice, hence in the GAP the proposed use is for 1-2 applications. In addition, crop pathogens are commonly controlled using a programme of different fungicides with varied modes of action, therefore the choice should be available to growers to make a single application of CA3301, followed by application of a different appropriate fungicide. Prothioconazole is well established over a number of years in providing good broad spectrum efficacy across a range of common crop pathogens, with either 1 or more applications appropriate according to disease development conditions, risk of resistance development and local conditions. Current authorisations for similar products containing prothioconazole including Proline 275, Bumper 25 EC and Proline/Praktis/Joao (CA2445) are for 1-2 applications at comparative rates of prothioconazole to the requested use for CA3301. Considering these elements, and that data shows comparability of CA3301 to these authorised products, registration of CA3301 at the proposed dose rate and with a number of applications of 1- 2, is requested.

It has been demonstrated in the preceding sections that the efficacy of CA3301 at 0.6-0.8 l/ha was overall equivalent to that provided by the approved reference standards used in the trials. Hence it is justified to propose that efficacy comparable to that of the authorised products will be obtained on the pathogens where the presented datasets are limited.

Considering all elements presented in the previous sections of each disease, it is justified to claim the registration of 1-2 applications of CA3301 at 0.6-0.8 l/ha to control a range of foliar and ears diseases on winter wheat.

Table 3.2-459: Summary table - Winter wheat – All foliar diseases (Foliar level 2)

Foliar level 2			MAR		MED		NE		SE	
Disease	Application timing		CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB
SEPTTR	2 weeks after B	Number of values	9	9	9	9	6	6	4	4
		Abbott efficacy (%)	67,58%	65,19%	66,13%	70,31%	81,94%	82,77%	66,13%	77,16%
	Before harvest	Number of values	19	19	13	13	16	16	13	13
		Abbott efficacy (%)	56,49%	61,06%	54,77%	62,61%	66,61%	73,29%	79,71%	81,86%
PUCCRE PUCCRT	2 weeks after B	Number of values	2	2	7	7	1	1	3	3
		Abbott efficacy (%)	88,17%	94,15%	32,29%	56,46%	99,22%	100,00%	94,97%	95,98%
	Before harvest	Number of values	5	5	9	9	6	6	5	5
		Abbott efficacy (%)	53,02%	55,21%	42,63%	59,80%	87,85%	91,98%	77,44%	89,16%
PUCCST PUCCSI	2 weeks after B	Number of values	7	7	2	2	0	0	1	1
		Abbott efficacy (%)	88,34%	94,03%	65,64%	79,53%	-	-	63,83%	72,89%
	Before harvest	Number of values	11	11	0	0	0	0	2	2
		Abbott efficacy (%)	76,00%	83,47%	-	-	-	-	99,48%	99,42%
ERYSGR ERYSGT	2 weeks after B	Number of values	4	4	2	2	7	7	9	9
		Abbott efficacy (%)	63,01%	70,89%	80,67%	93,18%	85,71%	88,89%	79,66%	82,89%
	Before harvest	Number of values	3	3	4	4	4	4	8	8
		Abbott efficacy (%)	40,12%	50,00%	67,89%	83,67%	93,75%	97,16%	43,82%	50,09%
PYRNTR	2 weeks after B	Number of values	0	0	0	0	1	1	2	2
		Abbott efficacy (%)	-	-	-	-	50,10%	77,25%	83,13%	89,23%
	Before harvest	Number of values	0	0	0	0	5	5	1	1
		Abbott efficacy (%)	-	-	-	-	47,48%	54,95%	60,91%	71,33%
LEPTNO	2 weeks after B	Number of values	1	1	1	1	0	0	0	0
		Abbott efficacy (%)	35,30%	42,37%	63,65%	68,30%	-	-	-	-
	Before harvest	Number of values	1	1	1	1	0	0	0	0
		Abbott efficacy (%)	16,35%	17,89%	59,05%	60,51%	-	-	-	-

Table 3.2-460: Summary table - Winter wheat – All foliar diseases (Foliar level 1)

Foliar level 1			MAR		MED		NE		SE	
Disease	Application timing		CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB
SEPTTR	2 weeks after B	Number of values	1	1	5	5	0	0	3	3
		Abbott efficacy (%)	35,85%	37,45%	75,29%	77,42%	-	-	86,58%	90,13%
	Before harvest	Number of values	17	17	11	11	13	13	7	7
		Abbott efficacy (%)	65,78%	70,48%	70,28%	79,24%	71,71%	74,88%	73,91%	75,01%
PUCCRE PUCCRT	2 weeks after B	Number of values	1	1	7	7	1	1	2	2
		Abbott efficacy (%)	83,61%	88,03%	28,90%	52,30%	83,31%	88,27%	88,33%	100,00%
	Before harvest	Number of values	8	8	14	14	6	6	4	4
		Abbott efficacy (%)	62,73%	69,14%	65,48%	76,23%	64,91%	72,13%	76,30%	88,05%
PUCCST PUCCSI	2 weeks after B	Number of values	5	5	2	2	0	0	1	1
		Abbott efficacy (%)	94,60%	96,04%	89,26%	89,21%	-	-	65,81%	73,03%
	Before harvest	Number of values	10	10	1	1	1	1	1	1
		Abbott efficacy (%)	85,48%	86,16%	89,83%	89,60%	79,04%	91,08%	99,66%	99,62%
ERYSGR ERYSGT	2 weeks after B	Number of values	0	0	0	0	4	4	2	2
		Abbott efficacy (%)	-	-	-	-	69,57%	79,34%	100,00%	100,00%
	Before harvest	Number of values	2	2	2	2	5	5	8	8
		Abbott efficacy (%)	72,09%	69,77%	75,70%	80,00%	86,27%	87,58%	58,63%	69,47%
PYRNTR	2 weeks after B	Number of values	0	0	0	0	0	0	0	0
		Abbott efficacy (%)	-	-	-	-	-	-	-	-
	Before harvest	Number of values	1	1	0	0	5	5	1	1
		Abbott efficacy (%)	55,08%	54,33%	-	-	67,00%	75,64%	63,68%	75,24%
LEPTNO	2 weeks after B	Number of values	0	0	1	1	0	0	0	0
		Abbott efficacy (%)	-	-	100,00%	100,00%	-	-	-	-
	Before harvest	Number of values	1	1	1	1	0	0	0	0
		Abbott efficacy (%)	37,66%	48,10%	91,41%	92,28%	-	-	-	-

Table 3.2-461: Summary table - Winter wheat – All ears diseases (Ears inoculated)

Ears Inoculated			MAR		MED		NE		SE	
Disease	Application timing		CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB
FUSACU	2 weeks after B	Number of values Abbott efficacy (%)	3 77,84%	3 79,18%	2 71,69%	2 72,72%	7 73,98%	7 78,96%	2 80,55%	2 87,39%
	Before harvest	Number of values Abbott efficacy (%)	0 -	0 -	2 69,55%	2 69,37%	4 50,51%	4 66,12%	0 -	0 -
GIBBZE	2 weeks after B	Number of values Abbott efficacy (%)	4 56,71%	4 63,11%	9 56,78%	9 62,17%	4 49,02%	4 62,11%	4 76,79%	4 82,43%
	Before harvest	Number of values Abbott efficacy (%)	5 45,90%	5 41,36%	9 41,09%	9 50,13%	2 42,25%	2 49,91%	5 62,62%	5 74,76%
FUSASP	2 weeks after B	Number of values Abbott efficacy (%)	0 -	0 -	0 -	0 -	0 -	0 -	2 52,05%	2 68,77%
	Before harvest	Number of values Abbott efficacy (%)	0 -	0 -	0 -	0 -	0 -	0 -	0 -	0 -

Table 3.2-462: Summary table - Winter wheat – All ears diseases (Ears non-inoculated)

Ears Non-Inoculated			MAR		MED		NE		SE	
Disease	Application timing		CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB
FUSACU	2 weeks after B	Number of values Abbott efficacy (%)	2 77,39%	2 86,09%	0 -	0 -	4 79,41%	4 83,18%	0 -	0 -
	Before harvest	Number of values Abbott efficacy (%)	0 -	0 -	0 -	0 -	4 60,52%	4 70,96%	3 74,05%	3 79,83%
GIBBZE	2 weeks after B	Number of values Abbott efficacy (%)	2 71,62%	2 67,69%	3 59,13%	3 58,31%	3 70,38%	3 78,44%	1 80,00%	1 91,30%
	Before harvest	Number of values Abbott efficacy (%)	3 43,78%	3 34,30%	5 45,13%	5 52,82%	2 69,05%	2 73,08%	1 47,53%	1 71,14%
FUSASP	2 weeks after B	Number of values Abbott efficacy (%)	0 -	0 -	0 -	0 -	0 -	0 -	0 -	0 -
	Before harvest	Number of values	0	0	1	1	0	0	1	1

	Abbott efficacy (%)	-	-	66,40%	40,40%	-	-	100,00%	100,00%
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3.2.3.35 Spring wheat (TRZAS) / Efficacy

Spring wheat is planted in the early spring, grows quickly and is normally harvested in late summer or early autumn whereas winter wheat is planted in the autumn and harvested in late spring or early summer. In addition, spring sown wheat is susceptible to face the same pathogens than winter wheat, it therefore seems reasonable from an agronomic perspective to assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on spring wheat from the robust dataset proposed for winter wheat.

Over the dataset for winter wheat, CA3301 provided acceptable to very high efficacy, with some exceptions especially in case of limited dataset. In many instances, a trend of decreasing disease severity when increasing the dose rate was observed with CA3301 applied at 0.6 l/ha or 0.8 l/ha. Although the rate of 0.8 l/ha overall reduced disease to a greater extent than the 0.6 l/ha rate, the differences were not always significant. However, in circumstances of high disease pressure the higher rate of 0.8 l/ha was often observed to be of significant benefit, while in circumstances of low disease pressure, the 0.6 l/ha dose rate may be sufficient to give comparable disease control. In addition, due to the importance of the diseases and given the possibility of resistance in some of the pathogens assessed, the higher rate may be deemed more appropriate and should be available for users according to disease development conditions, historical control and cultivar tolerance to the pathogens. In the majority of efficacy assessments, the disease control obtained from applications of CA3301 was statistically comparable to that from authorised reference products. In some instances, CA3301 applied at 0.8 l/ha provided higher efficacy compared to the range of reference products and in some instances CA3301 applied at 0.6 l/ha provided lower efficacy compared to CA2445 applied at a higher rate of prothioconazole, but more frequently efficacy was comparable.

Furthermore, the same pathogens are assessed for efficacy in triticale and rye with the same dose rates and timing and these results are also supportive for the proposed dose rate range. In addition, the same dose rates are authorised in winter and spring wheat for numerous registered prothioconazole products, indicating that the same pathogens are controlled at the same rates in either crop.

Considering all elements presented in this dossier, it is justified to claim the registration of 1-2 applications of CA3301 at 0.6-0.8 l/ha to control a range of foliar and ears diseases on spring wheat.

Comments of zRMS:

No efficacy trials have been submitted in spring wheat, spelt, Einkorn wheat, Emmer wheat and Tritordeum in any EPPO zones. The cMSs from the Maritime and South-East zone are kindly asked to consider these uses on the national level. These uses can not be accepted in the North-East zone because extrapolation is not possible.

3.2.3.36 Durum wheat (TRZDU) / *Zymoseptoria tritici* (SEPTTR)

Materials and Methods – Durum wheat – SEPTTR

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2017 and 2020, 16 trials were conducted in some countries of the Maritime, Mediterranean, and South-Eastern East EPPO zones to evaluate the efficacy of CA3301 against *Zymoseptoria tritici* on durum wheat (see Table 3.2-463).

In the Maritime EPPO zone, a total of 4 trials were performed in the France (2) and Germany (2).
In the Mediterranean EPPO zone, a total of 7 trials were performed in France (1), Italy (4) and Portugal (2).
In the South-Eastern EPPO zone, a total of 5 trials were performed in Hungary (4) and Romania (1).
No valid trials were presented in this Biological dossier for the North-Eastern EPPO zone.

Table 3.2-463: Presentation of trials – Durum wheat (TRZDU) / *Zymoseptoria tritici* (SEPTTR)

Crop(s)) *	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mar- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Durum wheat	SEPTTR	France (N)	2019	MED + E	2 (2)	-	-	-	GEP	
		German y	2019- 2020	MED + E	2 (0)	-	-	-	GEP	
		France (S)	2019	MED + E	-	1 (0)			GEP	
		Italy	2019- 2020	MED + E	-	4 (3)	-	-	GEP	
		Portugal	2017- 2018	MED + E	-	2 (2)	-	-	GEP	
		Hungary	2017- 2019	MED + E	-	-	-	4 (3)	GEP	
		Romania	2020	MED + E			-	1 (1)	GEP	
TOTA L	-	-	2017 – 2020	MED + E	4 (2)	7 (5)	-	5 (4)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

In all trials, CA3301 was compared to at least one commercial and registered fungicide used as standard reference for comparison.

Table 3.2-464: Efficacy evaluation – Presentation of reference standards used in trials –Durum wheat (TRZDU) – SEPTTR – Maritime EPPO zone

Crop(s))	Refer- ence standard	Coun- try(ies) where the product is used ⁽¹⁾	Authoriza- tion number	Active sub- stance(s)	Formulation		Regis- tered ap- plication rate ⁽³⁾	Applica- tion rate in tri- als (per treat- ment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concentra- tion of a.s.			
Durum Wheat	JOAO	FR (N)	2060116	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO- LINE	DE	025287-00	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

Table 3.2-465: Efficacy evaluation – Presentation of reference standards used in trials –Durum wheat (TRZDU) – SEPTTR – Mediterranean EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Durum Wheat	JOAO	FR (S)	2060116	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials
	PRO-LINE	IT	013385	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials
	PRO-SARO	IT	13386	Prothioconazole + Tebuconazole	EC	125 g/l + 125 g/l	2 x 1 l/ha	2 x 1 l/ha	
	PRAKTIS	PT	AV 1485	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials

Table 3.2-466: Efficacy evaluation – Presentation of reference standards used in trials –Durum wheat (TRZDU) – SEPTTR – South-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Durum wheat	PRO-LINE	HU	6300/1205-1/2020	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRI-AXOR	HU	04.2/4127-1/2016	Fluxapyriaxad Pyraclostrobin	EC	225 g/l	N/A	2 x 1.5 l/ha	
	PRO-LINE	RO	457PC/15.11.2018	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and is the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-467.

Table 3.2-467: Details on trial methodology – Durum wheat (TRZDU) – SEPTTR

		Maritime EPPO zone	Mediterranean EPPO zone	South-Eastern EPPO zone
Trials	Total number (valid number)	4 (2)	7 (5)	5 (4)
	Supportive trials	-	-	-
Guidelines	General guidelines	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)

		PP 1/225 (2) PP 1/262 (1)		
	Specific guidelines	PP 1/26(4) PP 1/28 (3)	PP 1/26(4)	PP 1/26(4)
Experimental design	Plot design	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included
	Plot size	21-25 m ²	20-30 m ²	21-30 m ²
	Number of replications	4	4	4
Crop	Trials per crop	Durum wheat (4)	Durum wheat (7)	Durum wheat (5)
	Varieties per crop	Voilur (1), Anvergur (1), Wintergold (1), Duramonte (1)	Celta (1), D. Ricardo (1), Achille (1), Saragolla (1), Anvergur (1), Colombo (1), Pharaon (1)	Lunadur (2), Wintergold (2), Autoudur (1)
	Sowing period	October (1), November (1), March (1), N/A (1)	October (4), November (1), December (1), January (1)	October (5)
Application	Crop stage (BBCH)* at application	A: BBCH 31-37 B: BBCH 37-69	A: BBCH 31-39 B: BBCH 39-61	A: BBCH 31-37 B: BBCH 49-61
	Timing Disease stage at application	BBCH 31-69 A: MIXED (4) B: MIXED (4)	BBCH 31-61 A: MIXED (1), PRINFC (4), SPORUL (0), ACTIVE (1), N/A (1) B: MIXED (2), PRINFC (3), SPORUL (0), ACTIVE (1), N/A (1)	BBCH 31-61 A: MIXED (2), PRINFC (3), SPORUL (0) B: MIXED (4), PRINFC (1), SPORUL (0)
	Number of applications Intervals between applications	2 applications (14-43 days) (4)	2 applications (13-30 days) (7)	2 applications (14-28 days) (5)
	Spray volumes	200 l/ha	250-400 l/ha	200-300 l/ha
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)
	Assessment dates	0 DA-A, 14-20 DA-A 0 DA-B, 14-19 DA-B, 28-42 DA-B, 51-65 DA-B	0 DA-A, 12-15 DA-A, 19-29 DA-A 0 DA-B, 6-19 DA-B, 21-37 DA-B, 62-76 DA-B	0 DA-A, 13-15 DA-A 0 DA-B, 14-19 DA-B, 32-37 DA-B, 56 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Natural (4)	Natural (7)	Natural (5)
	e.g. Field / Greenhouse...	Field trials	Field trials	Field trials

* BBCH for weeds, pre-emergence, preventive / curative application, insect stage...

Out of the 16 trials performed on durum wheat against *Zymoseptoria tritici*, 11 were considered valid.

Use of CA3301 at 0.6-0.8 l/ha against SEPTTR – Maritime EPPO zone

In the Maritime EPPO zone, 4 trials evaluated the efficacy of CA3301 on durum wheat against *Zymoseptoria tritici*. Only 2 trials were considered valid to determine the efficacy of CA3301 at 0.6-0.8 l/ha applied twice, and to compare it to the reference product on disease severity (%). CA3301 was first applied at crop stages BBCH 31-37 and the 2nd application was at BBCH 49-55.

Summary results are presented in Table 3.2-468.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on durum wheat against *Zymoseptoria tritici*, CA3301 at 0.6 l/ha showed 65.38 % of mean efficacy against *Zymoseptoria tritici* at 31-42 DA-B on foliar level 2 and 76% on foliar level 1 at 42 DA-B. When applied at 0.8 l/ha, the tested product provided 52,49% of efficacy to control the disease at 31 DA-B on foliar level 2 and 74,00% on foliar level 1 at 42 DA-B.

In the Maritime EPPO zone, CA3301 at 0.6-0.8 l/ha showed medium efficacy in reducing the severity of *Zymoseptoria tritici* on durum wheat 31-42 days after last application timing, on both main foliar levels 1 (L1) and 2 (L2). In addition, the proposed dose rates were statistically equivalent to the authorized reference product in all trials. This was confirmed also in the trials on winter wheat presented in the previous chapters. The performance of the tested product was overall equivalent to the reference product CA2445. The efficacy of CA3301 at 0.6 l/ha was comparable to that of the dose rate of 0.8 l/ha, but it was demonstrated that in winter wheat at some assessments a statistical benefit was derived from increasing the dose rate to 0.8 l/ha. Therefore, in situations with high disease pressure, historical difficulties in control of this disease or where some level of resistance is suspected it may be appropriate to use 0.8 l/ha for control of *Zymoseptoria tritici*.

Considering all elements presented above, it is justified to claim the registration of 1-2 applications of CA3301 at 0.6-0.8 l/ha to control *Zymoseptoria tritici* on durum wheat in the Maritime EPPO zone.

Table 3.2-468: Summary table – Efficacy evaluation – Durum wheat – SEPTTR – Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA24 45 0,8 L/ha AB	CA330 1 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity L2 - 31-42 DA-B										
Number of values	2	2	2	2	UT C	CA24 45 0,8 l/ha	CA330 1 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	14,08	7,23	4,70	6,69	2 >	0 >	0 >	1 >	0 >	0 >
Maximum value	34,00	12,25	12,19	19,31	0 =	2 =	2 =	1 =	2 =	2 =
Mean disease severity (%)	24,04	9,74	65,37	47,85	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	56,31 %	65,38%	47,85 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 42 DA-B										
Number of values	1	1	1	1	UT C	CA24 45 0,8 l/ha	CA330 1 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	12,50	2,25	3,00	3,25	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	12,50	2,25	3,00	3,25	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	12,50	2,25	3,00	3,25	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	82,00 %	76,00%	74,00 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)	
>80%	High efficacy
60-80%	Medium effacy
<60%	Low efficacy

Use of CA3301 at 0.6-0.8 l/ha against SEPTTR– Mediterranean EPPo zone

In the Mediterranean EPPO zone, a total of 7 trials evaluated the efficacy of CA3301 on durum wheat against *Zymoseptoria tritici*. 5 trials were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha (applied twice), and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 31-39 and the 2nd application was at BBCH 45-61.

Summary results are presented in Table 3.2-469.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on durum wheat against *Zymoseptoria tritici*, as disease was significantly reduced at all assessments. On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 71.90-72.88% of efficacy against *Zymoseptoria tritici* two weeks after the 2nd application and 65.14-70.80% before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 82.92-86.86% efficacy on reduction of disease severity around two weeks after the 2nd application and 78.52-76.99% before harvest. These positive effects to control *Zymoseptoria tritici* of CA3301 at 0.6-0.8 l/ha were always statistically equivalent to the reference products CA2445 and PROSARO.

In the Mediterranean EPPO zone, CA3301 at 0.6-0.8 l/ha showed high to medium efficacy in reducing the severity of *Zymoseptoria tritici* on durum wheat. The performance of the tested product at 0.6-0.8 l/ha was always equivalent to the reference products CA2445 and PROSARO. In these trials the efficacy of CA3301 at 0.6 l/ha was fairly comparable to that of the dose rate of 0.8 l/ha, however at some assessments a numerical benefit was derived from increasing the dose rate to 0.8 l/ha. Therefore, in situations with high disease pressure, historical difficulties in control of this disease or where some level of resistance is suspected, it may be appropriate to use 0.8 l/ha for control of *Zymoseptoria tritici*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Zymoseptoria tritici* on durum wheat in the Mediterranean EPP0 zone.

Table 3.2-469: Summary table – Efficacy evaluation – Durum wheat – SEPTTR – Mediterranean EPPO zone

Treatment name	UN-TREATED CHECK	CA2 445	PRO-SAR O	CA33 01	CA3 301	No of trials where CA3301				No of trials where CA3301			
Rate		0,8	1	0,6	0,8	at 0,6 l/ha is >, = or <				at 0,8 l/ha is >, = or <			
Rate unit		L/ha	L/ha	L/ha	L/ha								
Appl. Code		AB	AB	AB	AB	compared to				compared to			
% Disease severity L2 - 14-22 DA-B													
Number of values	4	4		4	4	UT C	CA2 445	PRO-SARO	CA3 301	UT C	CA2 445	PRO-SARO	CA3 301
Minimum value	8,81	4,75		0,00	0,00		0,8 l/ha	1,0 l/ha	0,8 l/ha		0,8 l/ha	1,0 l/ha	0,6 l/ha
Maximum value	56,56	11,31	-	15,88	12,69	4 >	0 >		0 >	4 >	0 >		0 >
Mean disease severity (%)	22,58	6,17		6,61	5,86	0 =	4 =	-	4 =	0 =	4 =	-	4 =
Abbott efficacy (%)	0,00%	68,37 %		71,90 %	72,88 %	0 <	0 <		0 <	0 <	0 <		0 <
% Disease severity L1 - 14-19 DA-B													

Number of values	2	2		2	2	UT	CA2	PRO-	CA3	UT	CA2	PRO-	CA3
Minimum value	7,31	0,88		1,38	1,13	C	445	SARO	301	C	445	SARO	301
Maximum value	49,06	7,31	-	7,50	5,31		0,8	1,0	0,8		0,8	1,0	0,6
Mean disease severity (%)	28,19	4,09		4,44	3,22	2 >	0 >		0 >	2 >	0 >		0 >
Abbott efficacy (%)	0,00%	86,53 %		82,92 %	86,86 %	0 =	2 =	-	2 =	0 =	2 =	-	2 =
						0 <	0 <		0 <	0 <	0 <		0 <
% Disease severity L2 - 32-37 DA-B													
Number of values	3	3	1	3	3	UT	CA2	PRO-	CA3	UT	CA2	PRO-	CA3
Minimum value	29,88	3,44	10,88	5,64	4,19	C	445	SARO	301	C	445	SARO	301
Maximum value	33,30	8,08	10,88	12,47	9,00		0,8	1,0	0,8		0,8	1,0	0,6
Mean disease severity (%)	24,97	6,42	10,88	8,76	6,96	3 >	0 >	0 >	0 >	3 >	0 >	0 >	0 >
Abbott efficacy (%)	0,00%	73,65 %	67,33 %	65,14 %	70,80 %	0 =	3 =	1 =	3 =	0 =	3 =	1 =	3 =
						0 <	0 <	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 32-37 DA-B													
Number of values	4	4	1	4	4	UT	CA2	PRO-	CA3	UT	CA2	PRO-	CA3
Minimum value	10,50	0,88	4,25	1,86	1,01	C	445	SARO	301	C	445	SARO	301
Maximum value	16,38	6,00	4,25	3,31	4,05		0,8	1,0	0,8		0,8	1,0	0,6
Mean disease severity (%)	13,84	3,39	4,25	2,84	3,06	4 >	0 >	0 >	0 >	4 >	0 >	0 >	0 >
Abbott efficacy (%)	0,00%	75,30 %	74,05 %	78,52 %	76,99 %	0 =	3 =	1 =	4 =	0 =	3 =	1 =	4 =
						0 <	0 <	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 0.6-0.8 l/ha against SEPTTR - North-Eastern East EPPO zone

In the North-Eastern EPPO zone, no trials were available for assessment of control of *Zymoseptoria tritici*. However, durum wheat and winter wheat are comparable crops, both of the genus *Triticum* and the proposed applications are the same (dose rate, application timing etc), therefore reference is made to the data presented on winter wheat in support of the proposed dose. The validity of this argumentation is supported by the fact that existing authorisations of similar prothioconazole products also have the same dose rates registered for both soft wheat and hard (durum) wheat, hence the pathogens are controlled similarly in each crop at the same dose rate.

In the North-eastern EPPO zone, 22 supportive trials demonstrated that CA3301 at 0.6-0.8 l/ha showed medium to high efficacy in reducing the severity of *Zymoseptoria tritici* on winter wheat. The performance of the tested product was overall equivalent to the reference products CA2445 and OSIRIS. Averaged across the dataset the efficacy of CA3301 at 0.6 l/ha was fairly comparable to that of the dose rate of 0.8 l/ha, however at some later assessments a statistical benefit was derived from increasing the dose rate to 0.8 l/ha. Therefore, in situations with high disease pressure, historical difficulties in control of this disease or where some level of resistance is suspected it may be appropriate to use 0.8 l/ha for control of *Zymoseptoria tritici*.

Use of CA3301 at 0.6-0.8 l/ha against SEPTTR – South-Eastern East EPPO zone

Summary results are presented in Table 3.2-470.

In the South-Eastern East EPPO zone, CA3301 at 0.6-0.8 l/ha showed high to medium efficacy in reducing the severity of *Zymoseptoria tritici* on durum wheat. The highest efficacy levels were reached 32-37 DA-B, at the most critical stage for grain filling, allowing a suitable protection of the crop during yield production. CA3301 at 0.6-0.8 l/ha was always statistically equivalent to the reference products CA2445 and PRIAXOR. Despite the low number of valid trials presented for this EPPO zone it is possible to state a statistical benefit was derived from increasing the dose rate to 0.8 l/ha for disease control, as demonstrated in the winter wheat dataset on *Zymoseptoria tritici* in South-Eastern East EPPO zone. Therefore, in situations with high disease pressure, historical difficulties in control of this disease or where some level of resistance is suspected it may be appropriate to use 0.8 l/ha for control of *Zymoseptoria tritici*.

Table 3.2-470: Summary table – Efficacy evaluation – Durum wheat – SEPTTR – South-Eastern East EPPO zone

EPTO zone											
Treatment name	UN-TREATED CHECK	CA2445	PRI-AXOR	CA3301	CA3301	No of trials where CA3301			No of trials where CA3301		
Rate		0,8	1,5	0,6	0,8	at 0,6 l/ha is >, =			at 0,8 l/ha is >, =		
Rate unit		L/ha	L/ha	L/ha	L/ha	or <			= or <		
Appl. Code		AB	AB	AB	AB	compared to			compared to		
% Disease severity L2 - 15 DA-B											
Number of values	1	1		1	1	UT C	CA24 45	CA3 301	UT C	CA24 45	CA3 301
Minimum value	11,35	3,01		4,13	1,96		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	11,35	3,01	-	4,13	1,96	1 >	0 >	0 >	1 >	0 >	1 >
Mean disease severity (%)	11,35	3,01		4,13	1,96	0 =	1 =	0 =	0 =	1 =	0 =
Abbott efficacy (%)	0,00%	73,48%		63,61%	82,73%	0 <	0 <	1 <	0 <	0 <	0 <
% Disease severity L1 - 15 DA-B											

Treatment name	UN-TREATED CHECK	CA2445	PRI-AXOR	CA3301	CA3301	No of trials where CA3301			No of trials where CA3301		
Rate		0,8	1,5	0,6	0,8	at 0,6 l/ha is >, = or <			at 0,8 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha	L/ha	compared to			compared to		
Appl. Code		AB	AB	AB	AB						
% Disease severity L2 - 15 DA-B											
Number of values	1	1		1	1	UT C	CA24 45	CA3 301	UT C	CA24 45	CA3 301
Minimum value	10,46	2,73		3,56	1,76		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	10,46	2,73	-	3,56	1,76	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	10,46	2,73		3,56	1,76	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	48,65%		65,97%	83,17%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 32-37 DA-B											
Number of values	2		2	2	2	UT C	PRI-AXOR	CA3 301	UT C	PRI-AXOR	CA3 301
Minimum value	19,35		0,41	2,08	3,59		1,5 l/ha	0,8 l/ha		1,5 l/ha	0,6 l/ha
Maximum value	22,10	-	1,81	3,33	4,63	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	20,73		1,11	2,70	4,44	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%		84,85%	87,09%	79,91%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 32 DA-B											
Number of values	1	1		1	1	UT C	CA24 45	CA3 301	UT C	CA24 45	CA3 301
Minimum value	6,87	0,10		0,09	0,06		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	6,87	0,10	-	0,09	0,06	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	6,87	0,10		0,09	0,06	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	98,54%		98,69%	99,13%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

2 valid field trials were carried out in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,6-0,8 l/ha achieved medium efficacy after 31-42 days after second application. Due to the limited number of trials, the cMSs are kindly asked to consider this use one the national level.

No efficacy trials have been submitted from **the North-East EPPO zone** or neighbouring countries for SEPTTR. This use can not be accepted because extrapolation is not possible.

4 valid field trials were conducted in **the South-East EPPO zone**. The significant higher efficacy was noted after applied at dose rate of 0,8 l/ha after 15 DA-B (82,73% on L2 and 83,17% on L1). CA3301 at dose rate of 0,6 l/ha achieved medium efficacy in the same time. Also 5 trials from the Mediterranean zone show medium level of control after second application. Taking into account of all results, it can be concluded that the test product is effective on the medium to high level. The dose rate of 0,8 l/ha should be recommended in case of

high disease pressure. The cMSs are kindly asked to consider this use on the national level.

3.2.3.37 Durum wheat (TRZDU) / *Puccinia recondita*- *Puccinia triticina* (PUCCRE-PUCCRT)

Materials and Methods – Durum wheat – PUCCRE/PUCCRT

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Puccinia recondita and *Puccinia triticina* are the causal agents of the brown rust on wheat and are considered as the same pathogen in this analysis.

Between 2017 and 2019, 1 trial was conducted in France for the Mediterranean EPPO zone and 2 trials in Hungary for the South-Eastern East EPPO zones to evaluate the efficacy of CA3301 against *Puccinia recondita* or *P. triticina* on durum wheat. The trials were carried out by certified testing institutes.

In the Mediterranean EPPO zone, 1 trial was performed in France.

In the South-Eastern East EPPO zone, 2 trials were performed in Hungary.

No trials were available in this Biological dossier for the Maritime and North-Eastern East EPPO zone.

Out of the 3 trials carried out against *Puccinia recondita* (PUCCRE) or *Puccinia triticina* (PUCCRT) on durum wheat, only one was considered valid (see Table 3.2-471):

Table 3.2-471: Presentation of trials – Durum wheat (TRZAW) / PUCCRE-PUCCRT

Crop(s) *)	Target(s)*	Country	Year s	Type of trial*	Number of trials (number of valid trials)				GEP, non- GEP, of- ficial***	Comments (any other relevant in- formation)
					Maritime zone	Mediterranean zone	North-East- ern zone	South-East- ern zone		
Durum wheat	PUCCRE/PUCC RT	France (S)	2019	MED + E	-	1 (0)-	-	-	GEP	
		Hungar y	2017 - 2018	MED + E	-	-	-	2 (1)	GEP	
TOTAL	-	-	2017 - 2019	MED + E	-	1 (0)	-	2 (1)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation

In all trials, CA3301 was compared to at least one commercial and registered fungicide used as standard reference for comparison.

Table 3.2-472: Efficacy evaluation – Presentation of reference standards used in trials –Durum wheat (TRZDU) – PUCCRE/PUCCRT – Mediterranean EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Durum Wheat	JOAO	FR (S)	2060116	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials

Table 3.2-473: Efficacy evaluation – Presentation of reference standards used in trials –Durum wheat (TRZDU) – PUCCRE/PUCCRT – South-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Durum wheat	PRO-LINE	HU	6300/1205-1/2020	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and is the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-474.

Table 3.2-474: Details on trial methodology – Durum wheat (TRZDU) – PUCCRE/PUCCRT

		Mediterranean EPPO zone	South-Eastern EPPO zone
Trials	Total number (valid number)	1 (0)	2 (1)
	Supportive trials	-	-
Guidelines	General guidelines	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)
	Specific guidelines	PP 1/26(4)	PP 1/26(4)
Experimental design	Plot design	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included
	Plot size	20 m ²	24-30 m ²
	Number of replications	4	4
Crop	Trials per crop	Durum wheat (1)	Durum wheat (2)
	Varieties per crop	Anvergur (1)	Lunadur (2)
	Sowing period	October (1)	October (2)
Application	Crop stage (BBCH)* at application	A: BBCH 36 B: BBCH 59	A: BBCH 34-37 B: BBCH 58-61
	Timing Disease stage at application	BBCH 36-59 A: PRINFC (1) B: PRINFC (1)	BBCH 34-61 A: MIXED (1), PRINFC (1), SPORUL (0)

			B: MIXED (0), PRINFC (0), SPORUL (1, N/A (1))
	Number of applications Intervals between applications	2 applications (19 days) (1)	2 applications (14-21 days) (2)
	Spray volumes	250 l/ha	200-250 l/ha
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)
	Assessment dates	0 DA-A, 12 DA-A, 19 DA-A 0 DA-B, 13 DA-B, 21 DA-B, 27 DA-B	0 DA-A, 13-15 DA-A 0 DA-B, 14-19 DA-B, 32-37 DA-B, 56 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Natural (1)	Natural (2)
	e.g. Field / Greenhouse...	Field trials	Field trials

* BBCH for weeds, pre-emergence, preventive / curative application, insect stage...

Out of the 3 trials performed on durum wheat against *Puccinia recondita*., a single trial was considered as valid.

Considering the single valid trial available on this disease the argumentation on efficacy of CA3301 for the control of brown rust on durum wheat was based also on data presented on winter wheat in the same EPPO zone and for the same disease.

This argumentation is possible since *Triticum durum* and *Triticum aestivum* have the same life cycle with the same exposure at *Puccinia recondita* or *Puccinia triticina* infection.

Triticum aestivum and *Triticum durum* belong to the same Order (Poales) and the same Family (Poaceae), are two crops with the same life cycle and are cultivated following the same agricultural practice. At the end are two crops showing a very similar sensitivity to *Puccinia recondita* (PUCCRE) or *Puccinia triticina* (PUCCRT) infection.

For these reasons, due the lack of valid trials, it is possible to refer to the data presented on winter wheat for the evaluation of the minimum effective dose in each EPPO zone.

Use of CA3301 at 2x 0.6 and 0.8 l/ha against PUCCRE/PUCCRT - Maritime EPPO zone

In the Maritime EPPO zone, no trials were available for assessment of control *Puccinia recondita*. However, durum wheat and winter wheat are comparable crops, both of the genus *Triticum* and the proposed applications are the same (dose rate, application timing etc), therefore reference is made to the data presented on winter wheat in support of the proposed dose. The validity of this argumentation is supported by the fact that existing authorisations of similar prothioconazole products also have the same dose rates registered for both soft wheat and hard (durum) wheat, hence the pathogens are controlled similarly in each crop at the same dose rate.

In the Maritime EPPO zone, 9 supportive trials carried out on winter wheat demonstrated that CA3301 at 0.6-0.8 l/ha gave equivalent or higher disease control compared to the authorised reference product CA2445. In the majority of assessments there were no statistically significant differences in disease control between the rate of 0.6 l/ha or 0.8 l/ha of CA3301. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for control of brown rust, however when conditions are conducive to heavy disease infestation the rate of 0.8 l/ha may be beneficial to further reduce disease incidence.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Puccinia recondita* or *Puccinia triticina* on durum wheat in the Maritime EPPO zone.

Use of CA3301 at 2x 0.6 and 0.8 l/ha against PUCCRE/PUCCRT – Mediterranean EPPO zone

In the Mediterranean EPPO zone, no trials were available for assessment of control *Puccinia recondita*. However, durum wheat and winter wheat are comparable crops, both of the genus *Triticum* and the proposed applications are the same (dose rate, application timing etc), therefore reference is made to the data presented on winter wheat in support of the proposed dose. The validity of this argumentation is supported by the fact that existing authorisations of similar prothioconazole products also have the same dose rates registered for both soft wheat and hard (durum) wheat, hence the pathogens are controlled similarly in each crop at the same dose rate.

17 supportive trials carried out on winter wheat demonstrated that in Mediterranean EPPO zone where warmer conditions are overall more conducive for this pathogen, the disease severity in the trials was medium-high (12-91%). With these conditions the increased 0.8 l/ha dose rate of CA3301 was more effective at reducing disease compared to the 0.6 l/ha rate, often significantly so. In addition, the performance of CA3301 at 0.8 l/ha was more comparable to the reference product CA2445 applied at the same rate of active substance. However, in some evaluations made with lower disease incidence, the 0.6 rate of CA3301 was sufficient to give comparable control. Therefore, it is proposed that the higher rate is applied when disease pressure is medium-high, and 0.6 l/ha applied in situations of lower disease pressure, with less conducive conditions for disease development.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Puccinia recondita* or *Puccinia triticina* on durum wheat in the Mediterranean EPPO zone.

Use of CA3301 at 2x 0.6 and 0.8 l/ha against PUCCRE/PUCCRT – North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, no trials were available for assessment of control *Puccinia recondita*. However, durum wheat and winter wheat are comparable crops, both of the genus *Triticum* and the proposed applications are the same (dose rate, application timing etc), therefore reference is made to the data presented on winter wheat in support of the proposed dose. The validity of this argumentation is supported by the fact that existing authorisations of similar prothioconazole products also have the same dose rates registered for both soft wheat and hard (durum) wheat, hence the pathogens are controlled similarly in each crop at the same dose rate.

In North-eastern East EPPO zone, 10 supportive trials carried out on winter wheat demonstrated that the trials had low-medium disease pressure (5.0-18.8% severity). In this data set both dose rates of CA3301 demonstrated high-medium efficacy against brown rust. In addition, both dose rates were overall comparable to the reference products in terms of disease control. Therefore, it is envisaged that a dose rate of 0.6 L/ha is appropriate for control of brown rust at this level of disease pressure. However, when disease pressure is high (as observed in trials from other EPPO zones) the increased dose rate of 0.8 L/ha with the observed marginal increase in disease reduction seen in these trials may be beneficial to maximise protection close to harvest.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Puccinia recondita* or *Puccinia triticina* on durum wheat in the North-Eastern East EPPO zone.

Use of CA3301 at 2x 0.6 and 0.8 l/ha against PUCCRE/PUCCRT – South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a single valid trial evaluated the efficacy of CA3301 at 0.6-0.8 l/ha (applied twice) on durum wheat against *Puccinia recondita* and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop BBCH stage 37 and the 2nd application was at BBCH 58.

Summary results are presented in Table 3.2-475.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the significant reduction of disease severity on durum wheat against *Puccinia recondita*. On foliar level 2, CA3301 showed 83.47-93.32% efficacy against *Puccinia recondita* around 3 weeks after the second application. In the same assessment timing on foliar level 1, CA3301 at 0.6-0.8 l/ha showed 74.07-92.72% efficacy on reduction of disease severity.

In the South-Eastern East EPPO zone, CA3301 at 0.6-0.8 l/ha showed high to medium efficacy in reducing the severity of *Puccinia recondita* on durum wheat in this trial. CA3301 at 0.6-0.8 l/ha was always equivalent to the reference product CA2445. A larger dataset regarding the same disease has been presented in the Winter wheat chapter which demonstrates that the efficacy of CA3301 0.6 l/ha was fairly comparable to that of the dose rate of 0.8 l/ha on leaves and in the same conditions of disease pressure (see **Winter wheat (TRZAW) / Puccinia recondita – Puccinia tritricina (PUCCRE-PUCCRT)**). The both dose rates gave also comparable disease control than the reference product CA2445. Therefore, it is envisaged that in situations of low disease pressure CA3301 applied at 0.6 l/ha would be sufficient to control disease, but where disease pressure is medium to high a rate of 0.8 l/ha is more appropriate.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Puccinia recondita* and *Puccinia tritricina* on durum wheat in the South-Eastern East EPPO zone.

Table 3.2-475: Summary table – Efficacy evaluation – Durum wheat – PUCCRE/ PUCCRT – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA2445 0,8 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate										
Rate unit										
Appl. Code										
% Disease severity L2 – 19 DA-B										
Number of values	1	1	1	1	UTC	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	5,99	0,75	0,99	0,4						
Maximum value	5,99	0,75	0,99	0,4	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease se- verity (%)	5,99	0,75	0,99	0,4	0 =	1 =	1 =	0 =	1 =	1 =
Abbot efficacy (%)	0,00%	87,48%	83,47%	93,32%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 – 19 DA-B										
Number of values	1	1	1	1	UTC	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	5,36	0,74	1,39	0,39						
Maximum value	5,36	0,74	1,39	0,39	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease se- verity (%)	5,36	0,74	1,39	0,39	0 =	1 =	1 =	0 =	1 =	1 =
Abbot efficacy (%)	0,00%	86,19%	74,07%	92,72%	0 <	0 <	0 <	0 <	0 <	0 <

‘>’ means CA3301 is significantly more efficient than plants treated with (treatment)
(conversely for ‘<’)

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

No efficacy trials have been submitted in **the Maritime EPPO climatic zone**. The cMSs are kindly asked to consider this use on the national level.

No efficacy trials have been submitted in **the North-East EPPO zone**. This use can not be accepted because extrapolation is not possible.

Only 1 valid trials was presented in **the South-East EPPO zone**. The high efficacy was noted after application of dose rate of 0,8 l/ha and medium to high level of control after applied of lower dose. Due to the limited number of trials, the cMSs are kindly asked to consider this use on the national level.

3.2.3.38 Durum wheat (TRZDU) / *Fusarium graminearum* (GIBBZE)

Materials and Methods – Durum wheat – GIBBZE

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2018 and 2020, 2 trials were conducted in several countries of the Mediterranean and South-Eastern ~~East~~ EPPO zones to evaluate the efficacy of CA3301 against *Fusarium graminearum*. on **durum wheat** (see Table 3.2-476). The trials were carried out by certified testing institutes.

In the Mediterranean EPPO zone, a single trial was performed in Italy.

In the South-eastern ~~East~~ EPPO zone, a single trial was performed in Hungary.

All 2 trials were considered valid.

No trials were available in this Biological dossier for the Maritime and North-Eastern ~~East~~ EPPO zones.

Table 3.2-476: Presentation of trials – Durum wheat (TRZAW) / GIBBZE

Crop(s)) *	Tar- get(s)*	Coun- try	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Durum wheat	GIBBZE	Italy	2020	MED + E		1 (1)	-	-	GEP	
		Hungary	2018	MED + E	-	-	-	1 (1)-	GEP	
TOTA L	-	-	2018 -2020	MED + E		1 (1)	-	1 (1)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

In all trials, CA3301 was compared to at least one commercial and registered fungicide used as standard reference for comparison.

Table 3.2-477: Efficacy evaluation – Presentation of reference standards used in trials –Durum wheat (TRZDU) – GIBBZE – Mediterranean EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Durum wheat	PRO-LINE	IT	013385	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials
	PRO-SARO	IT	13386	Tebuconazole + Prothioconazole	EC	125+6125 g/l	2 x 1 l/ha	2 x 1 l/ha	

Table 3.2-478: Efficacy evaluation – Presentation of reference standards used in trials –Durum wheat (TRZDU) – GIBBZE – South-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Durum wheat	PRO-LINE	HU	6300/1205-1/2020	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and is the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-479.

Table 3.2-479: Details on trial methodology – Durum wheat (TRZDU)

		Mediterranean EPPO zone	South-Eastern EPPO zone
Trials	Total number (valid number)	1 (1)	1 (1)
	Supportive trials	-	-
Guidelines	General guidelines	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)
	Specific guidelines	PP 1/26(4)	PP 1/26(4)
Experimental design	Plot design	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included
	Plot size	21 m ²	30 m ²
	Number of replications	4	4
Crop	Trials per crop	Durum wheat (1)	Durum wheat (1)
	Varieties per crop	Colombo (1)	Floradur (1)
	Sowing period	October (1)	March (1)
Application	Crop stage (BBCH)* at application	A: BBCH 31 B: BBCH 47	A: BBCH 39 B: BBCH 65

	Timing Disease stage at application	BBCH 31-47 A: PRINFC (1) B: PRINFC (1)	BBCH 39-65 A: PRINFC (1) B: PRINFC (1)
	Number of applications Intervals between applications	2 applications (29 days) (1)	2 applications (14 days) (1)
	Spray volumes	400 l/ha	300 l/ha
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)
	Assessment dates	0 DA-A, 13 DA-A, 29 DA-A 0 DA-B, 19 DA-B, 35 DA-B, 76 DA-B	0 DA-A, 14 DA-A 0 DA-B, 14 DA-B, 21 DA-B, 52 DA-B, 59 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Natural (1)	Artificial (1)
	e.g. Field / Greenhouse...	Field trial	Field trial

* BBCH for weeds, pre-emergence, preventive / curative application, insect stage...

Since a single trial was available in the Mediterranean and South-Eastern EPPO zones for this use, the argumentation on efficacy of CA3301 for the control on durum wheat was based also on data presented on winter wheat in the same EPPO zones and for the same disease.

This argumentation is possible since *Triticum durum* and *Triticum aestivum* have the same life cycle with the same exposure at *Fusarium graminearum* infection.

Triticum aestivum and *Triticum durum* belong to the same Order (Poales) and the same Family (Poaceae), are two crops with the same life cycle and are cultivated following the same agricultural practice. At the end are two crops showing a very similar sensitivity to *Fusarium graminearum* (GIBBZE).

For these reasons, due the lack of valid trials, it is possible to refer to the data presented on winter wheat for the evaluation of the minimum effective dose in all EPPO zones.

Use of CA3301 at 2x 0.6 and 0.8 l/ha against GIBBZE - Maritime EPPO zone

In the Maritime EPPO zone, no trials were available for assessment of control *Fusarium graminearum*. However, durum wheat and winter wheat are comparable crops, both of the genus *Triticum* and the proposed applications are the same (dose rate, application timing etc), therefore reference is made to the data presented on winter wheat in support of the proposed dose. The validity of this argumentation is supported by the fact that existing authorisations of similar prothioconazole products also have the same dose rates registered for both soft wheat and hard (durum) wheat, hence the pathogens are controlled similarly in each crop at the same dose rate.

In the Maritime EPPO zone, 5 supportive trials demonstrated that CA3301 at 0.6-0.8 l/ha showed medium efficacy in reducing the severity of *Fusarium graminearum* on winter wheat. At this dose rate, the tested product consistently showed efficacy to control *Fusarium graminearum* and gave always equivalent disease control to the approved reference standard. In all the assessments, there were no significant differences in disease control between the rates of 0.6 l/ha or 0.8 l/ha of CA3301. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient to control *Fusarium graminearum*, however when disease infestation is high, the rate of 0.8 l/ha may be beneficial to further reduce disease severity.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Fusarium graminearum* on durum wheat in the Maritime EPPO zone.

Use of CA3301 at 2x 0.6 and 0.8 l/ha against GIBBZE – Mediterranean EPPO zone

In the Mediterranean EPPO zone, a single trial evaluated the efficacy of CA3301 on durum wheat against *Fusarium graminearum* and enabled to evaluate the efficacy of CA3301 at 0.6-0.8 l/ha applied twice on infected ears. This trial was not inoculated with *Fusarium graminearum* at the beginning of flowering because the original purpose of this trial was the efficacy evaluation against foliar diseases. For this reason, CA3301 was first applied at crop stage BBCH 31 and the 2nd application was at BBCH 47-49. Due to the fact that no inoculation was done in this trial it is possible to determine only the efficacy on ears not inoculated (Ears NI) and damaged through natural infection. Only one assessment was performed on ears in this trial 35 DA-B that is crop stage BBCH 79.

Summary results are presented in Table 3.2-480.

Data demonstrated the positive effect of CA3301 at 0.6-0.8 l/ha for the significant reduction of disease severity on durum wheat against *Fusarium graminearum*. On ears, CA3301 at 0.6-0.8 l/ha showed 45.85-60.55% of efficacy against *Fusarium graminearum* at the last assessment before harvest which was statistically comparable to the reference products CA2445 and PROSARO.

In addition to the single trial presented above, since durum wheat and winter wheat are comparable crops, it is possible to demonstrate the efficacy of the tested product referring to the data presented on winter wheat.

On winter wheat in the Mediterranean EPPO zone, 10 trials were available. Over this supportive dataset, CA3301 at 0.6-0.8 l/ha showed medium efficacy in reducing the severity of *Fusarium graminearum* on winter wheat. In those conditions, the increased 0.8 l/ha dose rate of CA3301 was globally more effective at reducing disease compared to the 0.6 l/ha rate. In addition, the performance of CA3301 at 0.8 l/ha was more comparable to the reference products. However, in some evaluations, especially 2 weeks after application, the 0.6 rate of CA3301 was sufficient to give comparable disease control than the authorized reference products. Therefore, it is envisaged that in situations of low disease pressure CA3301 applied at 0.6 l/ha would be sufficient to control disease, but where disease pressure is medium to high a rate of 0.8 l/ha is more appropriate.

Considering all elements presented above, it is justified to claim the registration of CA3301 at 0.6-0.8 l/ha to control *Fusarium graminearum* on durum wheat in the Mediterranean EPPO zone.

Table 3.2-480: Summary table – Efficacy evaluation – Durum wheat – GIBBZE – Mediterranean EPPO zone

Treatment name	UN-TREATED CHECK	CA2 445	PRO-SAR O	CA3 301	CA3 301	No of trials where CA3301				No of trials where CA3301			
Rate		0,8	1	0,6	0,8	at 0,6 l/ha is >, = or <				at 0,8 l/ha is >, = or <			
Rate unit		L/ha	L/ha	L/ha	L/ha								
Appl. Code		AB	AB	AB	AB	compared to				compared to			
% Disease severity Ear 35 DA-B													
Number of values	1	1	1	1	1	UT C	CA2 445	PRO SAR O	CA 330 1	UT C	CA 244 5	PRO SAR O	CA 330 1
Minimum value	14,83	6,25	6,50	8,03	5,85		0,8 l/ha	1,0 l/ha	0,8 l/ha		0,8 l/ha	1,0 l/ha	0,6 l/ha
Maximum value	14,83	6,25	6,50	8,03	5,85	1 >	0 >	0 >	0 >	1 >	0 >	0 >	0 >

Mean disease severity (%)	14,83	6,25	6,50	8,03	5,85	0 =	1 =	1 =	1 =	0 =	1 =	1 =	1 =
Abbot efficacy (%)	0,00%	57,86%	56,17%	45,85%	60,55%	0 <	0 <	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbot efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 and 0.8 l/ha against GIBBZE - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, no trials were available for assessment of control *Fusarium graminearum*. However, durum wheat and winter wheat are comparable crops, both of the genus *Triticum* and the proposed applications are the same (dose rate, application timing etc), therefore reference is made to the data presented on winter wheat in support of the proposed dose. The validity of this argumentation is supported by the fact that existing authorisations of similar prothioconazole products also have the same dose rates registered for both soft wheat and hard (durum) wheat, hence the pathogens are controlled similarly in each crop at the same dose rate.

In the North-Eastern East EPPO zone, 4 supportive trials carried out on winter wheat demonstrated that the disease severity in the trials was low to relatively high (2.29-49.54%) with a limited dataset for *Fusarium graminearum*. In the majority of assessments CA3301 at 0.6-0.8 l/ha provided results statistically equivalent to the approved reference standard. Although the rate of 0.8 l/ha overall reduced disease to a greater extent than the 0.6 l/ha rate, the differences were not statistically significant in this limited dataset. Nevertheless, it is likely that in circumstances of high disease pressure the increased disease control obtained from the higher rate may be of significant benefit.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Fusarium graminearum* on durum wheat in the North-Eastern East EPPO zone.

Use of CA3301 at 2x 0.6 and 0.8 l/ha against GIBBZE – South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a single trial evaluated the efficacy of CA3301 on durum wheat against *Fusarium graminearum* and enabled to evaluate the efficacy of CA3301 at 0.6-0.8 l/ha applied twice on infected ears. This trial was inoculated with *Fusarium mix suspension* two days after application B. CA3301 was first applied at crop stage BBCH 39 and the 2nd application was at crop stage BBCH 65. In this trial the damage on ears was evaluated 14 and 21 days after the flowering stage application.

Summary results are presented in Table 3.2-481.

Data demonstrated the positive effect of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on durum wheat against *Fusarium graminearum* fully comparable to reference CA2445 at 0.8 l/ha. On ears, CA3301 at 0.6-0.8 l/ha showed 98.91-99.02% of efficacy against *Fusarium graminearum* 23 weeks after the 2nd application and 99.04- 99.1% 3 weeks after.

In addition to the single trial presented above, since durum wheat and winter wheat are comparable crops, it is possible to demonstrate the efficacy of the tested product referring to the data presented on winter wheat. In the South-Eastern East EPPO zone, 6 valid trials evaluated the efficacy of CA3301

against *Fusarium graminearum*, on winter wheat. Over this supportive dataset, the disease severity was low to medium (6.11-35.00%). In the majority of assessments CA3301 at 0.8 l/ha gave a disease control statistically equivalent or better than the authorized reference standards while the 0.6 l/ha dose rate globally provided efficacy statistically equivalent or less efficient than the reference standards. The rate of 0.8 l/ha was also statistically more efficient than the 0.6 l/ha dose rate in most of trials. Therefore, it is likely that in similar circumstances or in case of high disease pressure, CA3301 at the 0.8 l/ha dose rate would be more appropriate.

Considering all elements presented above, it is justified to claim the registration of CA3301 at 0.6-0.8 l/ha to control *Fusarium graminearum* on durum wheat in the South-Eastern East EPPO zone.

Table 3.2-481: Summary table – Efficacy evaluation – Durum wheat – GIBBZE – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA244 5 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity Inoculated Ears 14 DA-B										
Number of values	1	1	1	1	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	44,00	0,00	0,48	0,43	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	44,00	0,00	0,48	0,43	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	44,00	0,00	0,48	0,43	0 <	0 <	0 <	0 <	0 <	0 <
Abbot efficacy (%)	0,00%	100,00 %	98,91 %	99,02 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity Inoculated Ears 21 DA-B										
Number of values	1	1	1	1	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	59,15	0,57	0,57	0,53	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	59,15	0,57	0,57	0,53	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	59,15	0,57	0,57	0,53	0 <	0 <	0 <	0 <	0 <	0 <
Abbot efficacy (%)	0,00%	99,04 %	99,04 %	99,10 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)
(conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

No efficacy trials have been submitted in **the Maritime EPPO climatic zone**. The cMSs are kindly asked to consider this use on the national level.

No efficacy trials have been submitted in **the North-East EPPO zone**. This use can not be accepted because extrapolation is not possible.

Only 1 valid trials was presented in **the South-East EPPO zone**. A very high efficacy was noted after application of dose rate of 0,6-0,8 l/ha. 1 trial conducted in the Mediterranean zone show significant lower effectiveness for both doses after 35 DA-B. The disease control amounted 45,85% at dose rate of 0,6 l/ha and 60,55% at 0,8 l/ha. Due to the limited number of trials, the cMSs are kindly asked to consider this use on the national level.

3.2.3.1 Durum wheat (TRZDU) / *Fusarium spp.* (FUSASP)

Materials and Methods – Durum wheat -FUSASP

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

In 2018, a single trial was conducted in the North-Eastern EPPO zone to evaluate the efficacy of CA3301 against *Fusarium spp.* on durum wheat (see Table 3.2-482). The trial was carried out by certified testing institute but was not considered valid. Therefore no data were available to support the evaluation of CA3301 on this use.

Table 3.2-482: Presentation of trials – Durum wheat (TRZAW) / FUSASP

Crop(s)) *	Tar- get(s)*	Coun- try	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Durum wheat	FUSASP	Poland	2018	MED + E	-	-	1 (0)-	-	GEP	
TOTA L	-	-	2018	MED + E	-	-	1 (0)	-	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

In all trials, CA3301 was compared to at least one commercial and registered fungicide used as standard reference for comparison (see Table 3.2-483).

Table 3.2-483: Efficacy evaluation – Presentation of reference standards used in trials –Durum wheat (TRZDU) – FUSASP

Crop(s))	Refer- ence standard	Coun- try(ies) where the product is used ⁽¹⁾	Authoriza- tion number	Active sub- stance(s)	Formulation		Regis- tered ap- plication rate ⁽³⁾	Applica- tion rate in tri- als (per treat- ment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concentra- tion of a.s.			
Durum wheat	PRAK- TIS	PL	R-222/2019	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and is the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-484.

Table 3.2-484: Details on trial methodology – Durum wheat (TRZDU) – FUSASP

North-Eastern EPPO zone		
Trials	Total number (valid number)	1 (0)
	Supportive trials	-
Guidelines	General guidelines	PP 1/135(4)

		PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)
	Specific guidelines	PP 1/26(4)
Experimental design	Plot design	Randomized complete blocks, Untreated included
	Plot size	30 m ²
	Number of replications	4
Crop	Trials per crop	Durum wheat (1)
	Varieties per crop	Ceres (1)
	Sowing period	October (1)
Application	Crop stage (BBCH)* at application	A: BBCH 37 B: BBCH 65
	Timing Disease stage at application	BBCH 37-65 A: PRINFC (1) B: PRINFC (1)
	Number of applications Intervals between applications	2 applications (38 days) (1)
	Spray volumes	500 l/ha
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)
	Assessment dates	0 DA-A, 15 DA-A, 38 DA-A 0 DA-B, 15 DA-B, 50 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant
	e.g. Natural / artificial inoculation...	Artificial (1)
	e.g. Field / Greenhouse...	Field trial

* BBCH for weeds, pre-emergence, preventive / curative application, insect stage...

The single trial available on *Fusarium spp.* was not considered valid.

Use of CA3301 at 2x 0.6 and 0.8 l/ha against -FUSASP – all EPPO zones

In the North-Eastern EPPO zone, a single trial was performed in Poland but was not considered valid. Considering that no data were available to support the evaluation of CA3301 on this section, the argue regarding the efficacy of CA3301 for the control of *Fusarium spp.* on durum wheat was based on the extrapolation of the data presented on winter wheat for the same disease.

This extrapolation is possible since *Triticum durum* and *Triticum aestivum* have the same life cycle with the same exposure at *Fusarium spp.* infection. Moreover, *Triticum aestivum* and *Triticum durum* belong to the same Order (Poales) and the same Family (Poaceae), are two crops with the same life cycle and are cultivated following the same agricultural practice. At the end are two crops showing a very similar sensitivity to *Fusarium spp.* (FUSASP).

Over the dataset available on winter wheat, the tested product demonstrated the same trend as that for the related species *Fusarium culmorum* and *Fusarium graminearum* whereby in conditions of higher disease severity CA3301 applied at 0.8 l/ha is more effective compared to the rate of 0.6 l/ha, but at lower disease pressure, both rates can give effective control comparable to the reference standard. Furthermore the test product was demonstrated to give comparable efficacy to the authorised reference products.

Considering all elements presented above, it is justified to claim the registration of CA3301 at 0.6-0.8 l/ha to control *Fusarium spp.* on durum wheat in all EPPO zones.

Comments of zRMS:

No efficacy trials have been submitted in **the Maritime and South-East EPPO climatic zone**. Also, as support, no trials from the Mediterranean zone are available. The cMSs are kindly asked to consider this use on the national level.

No efficacy trials have been submitted in **the North-East EPPO zone**. This use can not be accepted because extrapolation is not possible.

3.2.3.2 Durum wheat (TRZDU) / *Blumeria graminis f. sp. tritici* (ERYSGR – ERYSGT)

Materials and Methods – Durum wheat – ERYSGR/ERYSGT

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Blumeria graminis and *Blumeria graminis f.sp.tritici* are the causal agents of the powdery mildew on cereals and are considered as the same pathogen in this analysis.

Between 2019 and 2020, 5 trials were conducted in the Maritime, Mediterranean and South-Eastern East EPPO zones to evaluate the efficacy of CA3301 against *Blumeria graminis* and *Blumeria graminis f.sp.tritici* on **durum wheat**. The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, 2 trials were performed in Germany.

In the Mediterranean EPPO zone, 1 trial was performed in Italy.

In the South-Eastern East EPPO zone, 2 trials were performed in Hungary.

No trials were available in this Biological dossier for the North-Eastern East EPPO zone.

Table 3.2-485: Presentation of trials – Durum wheat (TRZAW) / ERYSGR-ERYSGT

Crop(s)) *	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, offi- cial***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Durum wheat	ERYSGT	German y	2019- 2020	MED + E	2 (2)		-	-	GEP	
	ERYSGR	Italy	2019	MED + E	-	1 (1)	-	-	GEP	
	ERYSGR	Hungary	2019	MED + E				2 (2)		
TOTA L	-	-	2018 -2020	MED + E	2 (2)	1 (1)	-	2 (2)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation

In all trials, CA3301 was compared to at least one commercial and registered fungicide used as standard

reference for comparison.

Table 3.2-486: Efficacy evaluation – Presentation of reference standards used in trials –Durum wheat (TRZDU) – ERYSGR/ERYSGT - Maritime EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Durum wheat	JOAO	DE	025287-00	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

Table 3.2-487: Efficacy evaluation – Presentation of reference standards used in trials –Durum wheat (TRZDU) – ERYSGR/ERYSGT - Mediterranean EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Durum wheat	PRO-LINE	IT	013385	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

Table 3.2-488: Efficacy evaluation – Presentation of reference standards used in trials –Durum wheat (TRZDU) – ERYSGR/ERYSGT - South-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Durum wheat	PRI-AXOR	HU	04.2/2426-1/2018 04.2/4127-1/2016	Fluxapyriaxad Pyra-clostrobin	EC	225 g/l	N/A	2 x 1.5 l/ha	

CA2445 is the code name used in some trials and is the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-489.

Table 3.2-489: Details on trial methodology – Durum wheat (TRZDU) – ERYSGR/ERYSGT

		Maritime EPPO zone	Mediterranean EPPO zone	South-Eastern EPPO zone
Trials	Total number (valid number)	2 (2)	1 (1)	2 (2)
	Supportive trials	-	-	-
Guidelines	General guidelines	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)

	Specific guidelines	PP 1/26(4)	PP 1/26(4)	PP 1/26(4)
Experimental design	Plot design	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included
	Plot size	21 m ²	21 m ²	21 m ²
	Number of replications	4	4	4
October (1)	Trials per crop	Durum wheat (2)	Durum wheat (1)	Durum wheat (2)
	Varieties per crop	Wintergold (1), Duramonte (1)	Achille (1)	Wintergold (2)
	Sowing period	October (1), March (1)	November (1)	October (2)
Application	Crop stage (BBCH)* at application	A: BBCH 31 B: BBCH 53-55	A: BBCH 31 B: BBCH 51	A: BBCH 31 B: BBCH 49
	Timing Disease stage at application	BBCH 31-55 A: PRINFC (1), MIXED (1) B: PRINFC (1), MIXED (1)	BBCH 31-51 A: PRINFC (1) B: PRINFC (1)	BBCH 31-49 A: PRINFC (2) B: PRINFC (2)
	Number of applications Intervals between applications	2 applications (17 days) (2)	2 applications (24 days) (1)	2 applications (24 days) (2)
	Spray volumes	200 l/ha	400 l/ha	300 l/ha
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)
	Assessment dates	0 DA-A, 17 DA-A, 43 DA-A 0 DA-B, 14-19 DA-B, 28-33 DA-B, 39 DA-B, 51 DA-B	0 DA-A, 15 DA-A, 24 DA-A 0 DA-B, 6 DA-B, 22 DA-B, 33 DA-B, 66 DA-B	0 DA-A, 15 DA-A, 21-24 DA-A 0 DA-B, 15 DA-B, 34-37 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Natural (2)	Natural (1)	Natural (2)
	e.g. Field / Greenhouse...	Field trials	Field trials	Field trials

* BBCH for weeds, pre-emergence, preventive / curative application, insect stage...

All trials performed on durum wheat against *Blumeria graminis* and *Blumeria graminis* f.sp. *tritici*, were considered as valid.

Treatment against *Blumeria graminis* is triggered when 20% of leaves (L1 to L4 considered together) are attacked by the fungus on sensitive varieties (source ARVALIS Institut du vegetal). As a consequence, the analysis will be conducted on four foliar levels L1 to L4 with the parameter 'Disease incidence %' and 'Disease severity %', when the disease pressure was sufficient in the untreated control. In

addition, a trial was considered valid when the level of disease incidence or the disease severity was higher than 5% in the untreated control and if the reference product shows a significant difference compared to the untreated control. No trials were available in this Biological dossier for the North-Eastern EPPO zone.

Considering the low data package available on this disease on Maritime, Mediterranean and South-Eastern East EPPO zones the argumentation on minimum effective dose of CA3301 for the control against *Blumeria graminis* on durum wheat was also based on data presented on winter wheat in the same EPPO zones and for the same disease.

This argumentation is possible since *Triticum durum* and *Triticum aestivum* have the same life cycle with the same exposure at *Blumeria graminis* infection.

Triticum aestivum and *Triticum durum* belong to the same Order (Poales) and the same Family (Poaceae), are two crops with the same life cycle and are cultivated following the same agricultural practice. At the end *Triticum aestivum* and *Triticum durum* are two crops showing a very similar sensitivity to *Blumeria graminis* (ERYSGR/ERYSGT).

For these reasons, due to the lack of valid trials, it is possible to refer to the data presented on winter wheat for the evaluation of the minimum effective dose in Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones.

Use of CA3301 at 2x 0.6 and 0.8 l/ha against ERYSGR/ERYSGT – Maritime EPPO zone

In the Maritime EPPO zone, two trials were available against *Blumeria graminis* f. sp. *Tritici* on durum wheat. CA3301 was applied twice, the first application at crop stage BBCH 31 and the 2nd application was done at crop stage BBCH 53-55. Only one trial presented a sufficient infection level on severity on L2 and L1 to evaluate the CA3301 activity. However, considering that on winter wheat the incidence data were included to support the evaluation of CA3301, all 2 trials were considered valid and were included in the analysis. Therefore, data were available regarding the disease incidence on foliar levels L3, L2 and L1 and regarding the disease severity on foliar levels L2 and L1.

Summary results are presented in Table 3.2-490.

When evaluating the reduction of disease incidence, the data demonstrated that the highest fungicidal effect to control *Blumeria graminis* f. sp. *Tritici* on leaves was provided by CA3301 at 0.8 l/ha and was fully comparable to the standard CA2445 at 0.8 l/ha. On severity, the data confirmed the high efficacy control provided by CA3301 at 0.8 l/ha and at 0.6 l/ha was always statistically equivalent to the reference product CA2445.

In addition to this trial presented above, since durum wheat and winter wheat are comparable crops for several reasons, it is possible to demonstrate the efficacy of CA3301 referring to the data presented on winter wheat in the same EPPO zone. On winter wheat, a larger dataset of 14 supportive trials demonstrated that the fungicidal performance of CA3301 enabled to significantly decrease the disease incidence on leaves in most of trials, compared to the untreated control and whatever the dose rate considered. In the majority of assessments CA3301 at 0.6-0.8 l/ha provided results statistically equivalent to the authorized reference products, and on L4 statistically better results were even obtained. Although the rate of 0.8 l/ha overall reduced disease incidence to a greater extent than the 0.6 l/ha rate, the differences were not always statistically significant. Nevertheless, it is likely that in circumstances of high disease pressure the increased disease control obtained from the higher rate may be of significant benefit.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Blumeria graminis* on durum wheat in the Maritime EPPO zone.

Table 3.2-490: Summary table – Efficacy evaluation – Durum wheat – ERYSGR/ERYSGT – Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA244 5 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate										
Rate unit										
Appl. Code										
% Disease incidence L3 – 14 DA-B										
Number of values	1	1	1	1	UT C	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	95,00	13,75	25,00	16,25	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	95,00	13,75	25,00	16,25	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease incidence (%)	95,00	13,75	25,00	16,25	0 <	0 <	0 <	0 <	0 <	0 <
Abbot efficacy (%)	0,00%	85,53 %	73,68 %	82,89 %						
% Disease incidence L2 – 14-19 DA-B										
Number of values	2	2	2	2	UT C	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	47,50	0,00	0,00	0,00	2 >	0 >	0 >	2 >	0 >	0 >
Maximum value	87,50	26,25	35,00	20,00	0 =	2 =	2 =	0 =	2 =	2 =
Mean disease incidence (%)	67,50	13,13	17,50	10,00	0 <	0 <	0 <	0 <	0 <	0 <
Abbot efficacy (%)	0,00%	85,00 %	80,00 %	88,57 %						
% Disease incidence L2 – 39 DA-B										
Number of values	1	1	1	1	UT C	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	71,25	17,50	25,00	15,00	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	71,25	17,50	25,00	15,00	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease incidence (%)	71,25	17,50	25,00	15,00	0 <	0 <	0 <	0 <	0 <	0 <
Abbot efficacy (%)	0,00%	75,44 %	64,91 %	78,95 %						
% Disease incidence L1 – 39 DA-B										
Number of values	1	1	1	1	UT C	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	65,00	10,00	17,50	3,75	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	65,00	10,00	17,50	3,75	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease incidence (%)	65,00	10,00	17,50	3,75	0 <	0 <	0 <	0 <	0 <	0 <
Abbot efficacy (%)	0,00%	84,62 %	73,08 %	94,23 %						
% Disease severity L2 – 39 DA-B										
Number of values	1	1	1	1	UT C	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	9,06	0,80	1,94	0,56	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	9,06	0,80	1,94	0,56	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	9,06	0,80	1,94	0,56	0 <	0 <	0 <	0 <	0 <	0 <
Abbot efficacy (%)	0,00%	91,17 %	78,59 %	93,82 %						
% Disease severity L1 – 39 DA-B										
Number of values	1	1	1	1	UT C	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	6,94	0,40	0,75	0,19	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	6,94	0,40	0,75	0,19						

Mean disease severity (%)	6,94	0,40	0,75	0,19	0 =	1 =	1 =	0 =	1 =	1 =
Abbot efficacy (%)	0,00%	94,24 %	89,19 %	97,26 %	0 <	0 <	0 <	0 <	0 <	0 <

‘>’ means CA3301 is significantly more efficient than plants treated with (treatment)’ (conversely for ‘<’)

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 and 0.8 l/ha against ERYSGR/ERYSGT – Mediterranean EPPO zone

In the Mediterranean EPPO zone, a single valid trial evaluated the efficacy of CA3301 on durum wheat against *Blumeria graminis*. In this trial the infection on leaves appeared on foliar levels L4, L3, and L2 as well as on ears. To argue the efficacy of CA3301 at 0.6-0.8 l/ha (applied twice), and to compare it to the reference product on disease incidence and severity (%) in addition to this single trial, was considered the data package coming from trials on winter wheat on this specific EPPO zone.

CA3301 was tested at 0.6-0.8 l/ha and was compared to the reference product CA2445 on disease severity and incidence (%) (according to the supportive dataset on winter wheat). CA3301 was applied twice, the first application at crop stage BBCH 31 and the 2nd application was done at crop stage BBCH 51.

Summary results are presented in Table 3.2-491.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the significant reduction of disease severity on durum wheat against *Blumeria graminis*. On foliar level 4, CA3301 showed 98.99-93.69% efficacy against *Blumeria graminis* 6 days after second application. In the same assessment timing on foliar level 3, CA3301 at 0.6-0.8 l/ha showed 100,00-95.89% efficacy on reduction of disease severity. On ears, CA3301 at 0.6-0.8 l/ha provided 82.35-86.76% efficacy 22 days after 2nd application and 75.80-86.53% efficacy before harvest. At all assessments CA3301 gave equivalent or significantly higher disease control compared to the authorized reference CA2445.

In addition to this trial presented above, since durum wheat and winter wheat are comparable crops for several reasons, it is possible to demonstrate the efficacy of CA3301 referring to the data presented on winter wheat in the same EPPO zone. On winter wheat, a larger dataset of 7 supportive trials demonstrated that following 2 applications, the fungicidal performance of CA3301 enabled to significantly decrease the disease incidence on leaves in most of trials, compared to the untreated control and whatever the dose rate considered. The same trend was clearly observed on durum wheat on leaves and on ears. In all trials, CA3301 at 0.6-0.8 l/ha gave always comparable disease control compared to the authorized reference products, whatever the foliar level or assessment timing considered. Although the rate of 0.8 l/ha overall reduced disease incidence to a greater extent than the 0.6 l/ha rate, the differences were usually not statistically significant. Nevertheless, it is likely that in circumstances of high disease pressure the increased disease control obtained from the higher rate may be of significant benefit.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Blumeria graminis* and *Blumeria graminis* f.sp. *Tritici* on durum wheat in the Mediterranean EPPO zone.

Treatment name	UNTREATED CHECK	CA2445	CA3301	CA3301	No of trials where CA3301			No of trials where CA3301		
Rate		0,8	0,6	0,8	at 0,6 l/ha is >, = or <			at 0,8 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
% Disease incidence L4 – 6 DA-B										
Number of values	1	1	1	1	UTC	CA24 45	CA3 301	UT C	CA2 445	CA33 01
Minimum value	100,00	27,50	6,25	16,25		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	100,00	27,50	6,25	16,25	1 >	0 >	0 >	1 >	0 >	0 >
Disease incidence (%)	100,00	27,50	6,25	16,25	0 =	1 =	1 =	0 =	1 =	1 =
Abbot efficacy (%)	0,00%	72,50%	93,75%	83,75%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease incidence L3 – 6 DA-B										
Number of values	1	1	1	1	UTC	CA24 45	CA3 301	UT C	CA2 445	CA33 01
Minimum value	85,00	3,75	0,00	6,25		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	85,00	3,75	0,00	6,25	1 >	0 >	0 >	1 >	0 >	0 >
Disease incidence (%)	85,00	3,75	0,00	6,25	0 =	1 =	1 =	0 =	1 =	1 =
Abbot efficacy (%)	0,00%	85,59%	100,00%	92,65%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease incidence L2 – 6 DA-B										
Number of values	1	1	1	1	UTC	CA24 45	CA3 301	UT C	CA2 445	CA33 01
Minimum value	35,00	0,00	0,00	3,75		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	35,00	0,00	0,00	3,75	1 >	0 >	0 >	1 >	0 >	0 >
Disease incidence (%)	35,00	0,00	0,00	3,75	0 =	1 =	1 =	0 =	1 =	1 =
Abbot efficacy (%)	0,00%	100,00%	100,00%	89,29%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease incidence Ears – 22 DA-B										
Number of values	1	1	1	1	UTC	CA24 45	CA3 301	UT C	CA2 445	CA33 01
Minimum value	100,00	57,50	38,80	48,80		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	100,00	57,50	38,80	48,80	1 >	1 >	0 >	1 >	0 >	0 >
Disease incidence (%)	100,00	57,50	38,80	48,80	0 =	0 =	1 =	0 =	1 =	1 =
Abbot efficacy (%)	0,00%	42,50%	61,20%	51,20%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease incidence Ears – 33 DA-B										
Number of values	1	1	1	1	UTC	CA24 45	CA3 301	UT C	CA2 445	CA33 01
Minimum value	100,00	45,00	60,00	52,50		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	100,00	45,00	60,00	52,50	1 >	0 >	0 >	1 >	0 >	0 >
Disease incidence (%)	100,00	45,00	60,00	52,50	0 =	1 =	1 =	0 =	1 =	1 =
Abbot efficacy (%)	0,00%	55,00%	40,00%	47,50%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L4 – 6 DA-B										

Treatment name	UNTREATED CHECK	CA2445 0,8 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate										
Rate unit										
Appl. Code										
Number of values	1	1	1	1	UTC	CA24 45 0,8 l/ha	CA3 301 0,8 l/ha	UT C	CA2 445 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	37,69	2,19	0,38	2,38						
Maximum value	37,69	2,19	0,38	2,38	1 >	0 >	0 >	1 >	0 >	0 >
Disease severity (%)	37,69	2,19	0,38	2,38	0 =	1 =	1 =	0 =	1 =	1 =
Abbot efficacy (%)	0,00%	94,19%	98,99%	93,69%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L3 – 6 DA-B										
Number of values	1	1	1	1	UTC	CA24 45 0,8 l/ha	CA3 301 0,8 l/ha	UT C	CA2 445 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	15,31	0,38	0,00	0,63						
Maximum value	15,31	0,38	0,00	0,63	1 >	0 >	0 >	1 >	0 >	0 >
Disease severity (%)	15,31	0,38	0,00	0,63	0 =	1 =	1 =	0 =	1 =	1 =
Abbot efficacy (%)	0,00%	97,52%	100,00%	95,89%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity Ears – 22 DA-B										
Number of values	1	1	1	1	UTC	CA24 45 0,8 l/ha	CA3 301 0,8 l/ha	UT C	CA2 445 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	20,40	4,60	3,60	2,70						
Maximum value	20,40	4,60	3,60	2,70	1 >	1 >	0 >	1 >	0 >	0 >
Disease severity (%)	20,40	4,60	3,60	2,70	0 =	0 =	1 =	0 =	1 =	1 =
Abbot efficacy (%)	0,00%	77,45%	82,35%	86,76%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity Ears – 33 DA-B										
Number of values	1	1	1	1	UTC	CA24 45 0,8 l/ha	CA3 301 0,8 l/ha	UT C	CA2 445 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	43,80	5,90	10,60	5,90						
Maximum value	43,80	5,90	10,60	5,90	1 >	0 >	0 >	1 >	0 >	0 >
Disease severity (%)	43,80	5,90	10,60	5,90	0 =	1 =	1 =	0 =	1 =	1 =
Abbot efficacy (%)	0,00%	86,53%	75,80%	86,53%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)	
>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 and 0.8 l/ha against ERYSGR/ERYSGT - North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, no trials were available for assessment of control *Blumeria graminis*. However, durum wheat and winter wheat are comparable crops, both of the genus *Triticum* and the proposed applications are the same (dose rate, application timing etc), therefore reference is made to the

data presented on winter wheat in support of the proposed dose. The validity of this argumentation is supported by the fact that existing authorisations of similar prothioconazole products also have the same dose rates registered for both soft wheat and hard (durum) wheat, hence the pathogens are controlled similarly in each crop at the same dose rate.

In the North-~~Eastern~~ East EPPO zone, 17 supportive trials carried out on winter wheat demonstrated that in all trials, CA3301 at 0.6-0.8 l/ha gave always equivalent disease control to the approved reference standards no matter the foliar level or assessment timing considered. Although the rate of 0.8 l/ha overall reduced disease incidence to a greater extent than the 0.6 l/ha rate, the differences were usually not statistically significant. Nevertheless, it is likely that in circumstances of high disease pressure the increased disease control obtained from the higher rate may be of significant benefit.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Blumeria graminis* on durum wheat in the North-~~Eastern~~ East EPPO zone.

Use of CA3301 at 2x 0.6 and 0.8 l/ha against ERYSGR/ERYSGT– South-~~Eastern~~ East EPPO zone

In the South-~~Eastern~~ East EPPO zone, 2 trials evaluated the efficacy of CA3301 on durum wheat against *Blumeria graminis*. All 2 trials were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.8 l/ha applied twice, compared to the reference product PRIAXOR on disease severity (%).

The first application was done at crop stage BBCH 31 and the 2nd application was done at crop stage BBCH 49.

Summary results are presented in Table 3.2-492.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the significant reduction of disease severity on durum wheat against *Blumeria graminis*. On foliar level 3, CA3301 showed 64.74% -67.17% of efficacy against *Blumeria graminis* 15 days after second application.

In the same assessment timing on foliar level 2, CA3301 at 0.6-0.8 l/ha showed 77.74-82.24% efficacy on reduction of disease severity. The reference product PRIAXOR containing fluxapyroxad and pyraclostrobin was used in these trials. In one trial the test product gave equivalent efficacy at both dose rates and in one trial efficacy was lower compared to this reference.

In addition to this trial presented above, since durum wheat and winter wheat are comparable crops, it is possible to demonstrate the efficacy of CA3301 referring to the data presented on winter wheat in the South-~~Eastern~~ East EPPO zone. On winter wheat, a larger dataset of 7 supportive trials demonstrated that following 2 applications, the fungicidal performance of CA3301 enabled to significantly decrease the disease incidence on leaves in most of trials, compared to the untreated control and whatever the dose rate considered. CA3301 at 0.6-0.8 l/ha provided a control of the disease that was either statistically equivalent or less efficient than the reference product PRIAXOR in a few trials. However in the majority of trials, CA3301, especially at the 0.8 l/ha dose rate, provided a control that was statistically equivalent or even better in some trials, to the one provided by CA2445, the reference product with the same active substance at a comparable rate. Although the rate of 0.8 l/ha overall reduced disease incidence to a greater extent than the 0.6 l/ha rate, the differences were not always statistically significant. Nevertheless, it is likely that in circumstances of high disease pressure the increased disease control obtained from the higher rate may be of significant benefit.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Blumeria graminis* and *Blumeria graminis* f.sp. *Tritici* on durum wheat in the South-~~Eastern~~ East EPPO zone.

Table 3.2-492: Summary table – Efficacy evaluation – Durum wheat – ERYSGR/ERYSGT – South-East-~~East~~ EPPO zone

Treatment name	UNTREATED CHECK	PRI-AXOR 1,5 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate										
Rate unit										
Appl. Code										
% Disease severity L3 – 15 DA-B										
Number of values	2	2	2	2	UT C	PRI-AXOR 1,5 l:ha	CA33 01 0,8 l/ha	UT C	PRI-AXOR 1,5 l:ha	CA33 01 0,6 l/ha
Minimum value	49,50	11,36	12,76	10,18	2 >	0 >	0 >	2 >	0 >	1 >
Maximum value	54,75	11,59	24,50	24,69	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	52,13	11,48	18,63	17,43	0 <	1 <	1 <	0 <	1 <	0 <
Abbot efficacy (%)	0,00%	77,94%	64,74%	67,17%						
% Disease severity L2 – 15 DA-B										
Number of values	2	2	2	2	UT C	PRI-AXOR 1,5 l:ha	CA33 01 0,8 l/ha	UT C	PRI-AXOR 1,5 l:ha	CA33 01 0,6 l/ha
Minimum value	18,65	1,75	3,94	3,43	2 >	0 >	1 >	2 >	0 >	0 >
Maximum value	23,00	4,88	5,11	3,94	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	20,83	3,31	4,53	3,68	0 <	1 <	0 <	0 <	1 <	1 <
Abbot efficacy (%)	0,00%	84,70%	77,74%	82,24%						

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

2 valid trials were carried out in **the Maritime EPPO climatic zone**. Due to low disease pressure on untreated objectives, the efficacy evaluation based on PESSEV parameter was provided in 1 trial. CA3301 applied at dose rate of 0,8 l/ha achieved high efficacy and a dose rate of 0,6 l/ha presented a medium to high level. The results based on PESINC parameter confirm this trend. Because of the limited number of trials, the cMSs are kindly asked to consider this use on the national level.

No efficacy trials have been submitted in **the North-East EPPO zone**. However, the efficacy trials from Germany can support the Polish registration. The extrapolation results from trials conducted on winter wheat is possible. This use can be accepted in Poland.

2 valid field trials were presented in **the South-East EPPO zone**. CA3301 applied at dose rate of 0,8 l/ha achieved high efficacy and medium to high level at 0,6 l/ha after 15 DA-B. Also 1 trial was available in the Mediterranean zone and the test product presented high efficacy for both doses. Due to the limited number of trials, the cMSs are kindly asked to consider this use on the national level.

3.2.3.1 Durum wheat (TRZDU) / Green leaf area (%)

Materials and Methods – Durum wheat – Green leaf area

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

In all trials presented in this Biological dossier was assessed the green leaf area. The reduction of green leaf area in untreated check was a consequence of the disease infection. The green leaf area is a parameter to evaluate the CA3301 efficacy against foliar diseases.

Use of CA3301 at 2x 0.6 and 0.8 l/ha – Maritime EPPO zone

Green leaf area was recorded in the Maritime EPPO zone in four trials, but only two trials were considered as valid with a sufficient infection level for the efficacy evaluation of CA3301 against several foliar and ears disease. Green leaf area was assessed at 31-42 DA-B after two applications of CA3301 at 0.6-0.8 l/ha. In these trials, green leaf area was assessed on the entire plant.

Summary results are presented in Table 3.2-493.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the augmentation of green leaf area on durum wheat infected by foliar and ears diseases. In these trials assessing green leaf area on the whole plant, an increase of 38.87-49.82% was recorded compared to the untreated check on durum wheat.

In overall, the performance of the tested product was equivalent at the 0.8 l/ha dose rate compared to the 0.6 l/ha dose rate and at this range CA3301 was equivalent to or more efficient than the authorized reference product CA2445.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will have a positive effect on the green leaf area in durum wheat affected by a range of pathogens in the Maritime EPPO zone.

Table 3.2-493: Summary table – Efficacy evaluation – Durum wheat – Green leaf area – Maritime EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA2445 0,8 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Green leaf area plant 31-42 DA-B										
Number of val- ues	4	4	4	4	UT C	CA244 5	CA33 01	UT C	CA2 445	CA3 301
Minimum value	5,00	11,25	8,75	10,00		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	68,75	75,00	70,00	71,25	1 >	1 >	0 >	2 >	1 >	1 >
Green Leaf Area (%)	39,38	45,63	46,88	48,13	3 =	3 =	3 =	2 =	3 =	3 =
%UTC	100.00%	143.35%	138.87%	149.82%	0 <	0 <	1 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)
(conversely for '<')

Use of CA3301 at 2x 0.6 and 0.8 l/ha – Mediterranean EPPO zone

In Mediterranean EPPO zone the Green leaf area was recorded at 16-35 DA-B in 7 trials on durum wheat affected by a range of pathogens after the application of CA3301 at 0.6-0.8 l/ha (applied twice). In 6 trials, green leaf area was assessed as a percentage on the entire plant while in one trial it was assessed with the NDVI instrument with a scale 0-1.

Summary results are presented in Table 3.2-494.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the preservation of green leaf area on durum wheat affected by foliar and ears diseases.

In the 6 trials assessing green leaf area on the whole plant, an augmentation of 57.36-57.85% was recorded compared to the untreated check on durum wheat.

The performance of the tested product was overall statistically equivalent at the 0.8 l/ha and 0.6 l/ha dose rate (5 of 6 trials). In all trials it was equivalent to, or in one instance better, when applied at 0.8 l/ha than the reference products CA2445 at 0.8 l/ha, and always equivalent to PROSARO at 1 l/ha.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will have a positive effect on the green leaf area in durum wheat affected by a range of pathogens in the Mediterranean EPPO zone.

Table 3.2-494: Summary table – Efficacy evaluation – Durum wheat – Green leaf area (%) – Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA2 445	PRO- SARO	CA3 301	CA3 301	No of trials where CA3301		No of trials where CA3301	
Rate		0,8	1	0,6	0,8	at 0,6 l/ha is >, = or		at 0,8 l/ha is >, = or <	
Rate unit		L/ha	L/ha	L/ha	L/ha	<			
Appl. Code		AB	AB	AB	AB	compared to		compared to	
% Green leaf area plant 22-35 DA-B									
Number of values	6	6		6	6	UTC	CA2445 0,8 l/ha	UTC	CA2445 0,8 l/ha
Minimum value	1,25	6,25		6,25	5,00				
Maximum value	80,00	85,00	-	85,00	86,25	2 >	0 >	2 >	1 >
Mean Green leaf area (%)	53,18	54,47		57,66	58,59	4 =	6 =	4 =	5 =
%UTC	100,00%	172,4 2%		157,3 6%	157,8 5%	0 <	0 <	0 <	0 <
Number of values	2	2	2	2	2	PRO- SARO 1,0 l/ha	CA3301 0,8 l/ha	PRO- SARO 1,0 l/ha	CA3301 0,6 l/ha
Minimum value	50,00	60,00	60,00	60,00	60,00				
Maximum value	80,00	85,00	84,50	85,00	86,25	0 >	0 >	0 >	1 >
Mean Green leaf area (%)	30,00	72,50	72,25	72,25	73,13	2 =	5 =	2 =	5 =
%UTC	100,00%	113,1 3%	112,81 %	113,1 3%	113,9 1%	0 <	1 <	0 <	0 <
NDVI Green leaf area plant 16 DA-B									
Number of values	1	1		1	1	UTC	CA2445 0,8 l/ha	UTC	CA2445 0,8 l/ha
Minimum value	0,40	0,42		0,42	0,43		CA3301 0,8 l/ha		CA3301 0,6 l/ha
Maximum value	0,40	0,42	-	0,42	0,43	0 >	0 >	0 >	0 >
Green leaf area (%)	0,40	0,42		0,42	0,43	1 =	1 =	1 =	1 =
%UTC	-	-		-	-	0 <	0 <	0 <	0 <

‘>’ means CA3301 is significantly more efficient than plants treated with (treatment)’ (conversely for ‘<’)

Use of CA3301 at 2x 0.6 and 0.8 l/ha – North-Eastern East EPPO zone

The green leaf area was recorded on the entire plant at 15 DA-B in a single trial on durum wheat affected by *Fusarium spp.* and *Pyrenophora teres* following two applications of CA3301 at 0.6-0.8 l/ha.

Summary results are presented in Table 3.2-495.

Data demonstrated a slight positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the augmentation of green leaf area on durum wheat affected by foliar and ears diseases, without statistical differences between CA3301 at all tested doses and untreated check.

On North-Eastern East EPPO zone, a single trial was available to support the evaluation of CA3301 at 0.6-0.8 l/ha on green leaf area which is inadequate to evaluate the efficacy of the tested product. On winter wheat, a larger dataset of 33 supportive trials demonstrated in overall a significant increase of 40% of the green leaf area compared to the untreated control. Moreover, the performance of CA3301 at 0.8 l/ha was statistically equivalent to the 0.6 l/ha dose rate or statistically better in a few trials. In a majority of the trials, CA3301 was overall equivalent to the reference products CA2445 at 0.8 l/ha and OSIRIS at 2 l/ha.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will have a positive effect on the green leaf area in durum wheat affected by a range of pathogens in the North-Eastern East EPPO zone.

Table 3.2-495: Summary table – Efficacy evaluation – Durum wheat – Green leaf area – North-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA24 45	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or <			No of trials where CA3301 at 0,8 l/ha is >, = or <		
Rate		0,8	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
% Green leaf area plant 15 DA-B										
Number of values	1	1	1	1	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	67,50	81,25	71,25	75,00	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	67,50	81,25	71,25	75,00	0 >	0 >	0 >	0 >	0 >	0 >
Mean Green leaf area (%)	67,50	81,25	71,25	75,00	1 =	0 =	1 =	1 =	0 =	1 =
%UTC	100,00%	120,37 %	105,56 %	111,11 %	0 <	1 <	0 <	0 <	1 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 at 2x 0.6 and 0.8 l/ha – South-Eastern East EPPO zone

Green leaf area was recorded at 15-37 DA-B in 6 trials on durum wheat affected by several foliar and ears disease after two applications of CA3301 at 0.6-0.8 l/ha. In 5 trials the green leaf area was assessed on the entire plant while in one trial, the green leaf area was assessed on foliar level L1 and foliar level L2.

Summary results are presented in Table 3.2-496.

Data demonstrated a positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha on the preservation of green leaf area on durum wheat affected by foliar and ears diseases. At this dose range, the tested product provided a higher green leaf area than the untreated check and in all instances it was also comparable or more efficient compared to the authorized reference products CA2445 at 0.8 l/ha and PRIAXOR at 1.5 l/ha.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will have a positive effect on the green leaf area in durum wheat affected by a range of pathogens in the South-Eastern East EPPO zone.

Table 3.2-496: Summary table - Efficacy evaluation – Durum wheat – Green leaf area (%) Plant– South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA2 445	PRI- AXOR	CA3 301	CA3 301	No of trials where CA3301	No of trials where CA3301		
Rate		0,8	1,5	0,6	0,8	at 0,6 l/ha is >, = or	at 0,8 l/ha is >, = or		
Rate unit		L/ha	L/ha	L/ha	L/ha	<	<		
Appl. Code		AB	AB	AB	AB	compared to	compared to		
% Green leaf area plant 15-37 DA-B									
Number of values	5			5	5	UTC	CA330 1	UTC	CA33 01
Minimum value	6			7,75	8,5		0,8 l/ha		
Maximum value	48,75	-	-	70	73,75	4 >	0 >	4 >	0 >
Mean Green leaf area (%)	30,95			52,8	53,7	1 =	5 =	1 =	5 =

%UTC	100			168,0 1	171,0 9	0 <	0 <	0 <	0 <
Number of values	3	3		3	3	CA2445		CA2445	
Minimum value	6	7,75		7,75	8,5	0,8 l/ha		0,8 l/ha	
Maximum value	48,75	70	-	66,25	73,75	0 >		0 >	
Mean Green leaf area (%)	28,25	44,25		42,17	45,33	3 =		3 =	
%UTC	100	152,0 3		142,3 1	157,3 7	0 <		0 <	
Number of values	2		2	2	2	PRIAXOR		PRIAXOR	
Minimum value	40		70	67,5	62,5	1,5 l/ha		1,5 l/ha	
Maximum value	30	-	70	70	70	0 >		0 >	
Mean Green leaf area (%)	37,5		70	68,75	66,25	2 =		2 =	
%UTC	100		204,17	200	191,6 7	0 <		0 <	
% Green leaf area L2 - 32 DA-B									
Number of values	1	1		1	1	UTC	CA3 301	UTC	CA33 01
Minimum value	1,25	19,5		23,25	25,5	CA2445 0,8 l/ha	0,8 l/ha	CA2445 0,8 l/ha	0,6 l/ha
Maximum value	1,25	19,5	-	23,25	25,5	1 >	0 >	1 >	0 >
Mean Green leaf area (%)	1,25	19,5		23,25	25,5	0 =	1 =	0 =	1 =
%UTC	100	1560		1860	2040	0 <	0 <	0 <	0 <
% Green leaf area L1 - 32 DA-B									
Number of values	1	1		1	1	UTC	CA3 301	UTC	CA33 01
Minimum value	17,5	49,5		55	55,5	CA2445 0,8 l/ha	0,8 l/ha	CA2445 0,8 l/ha	0,6 l/ha
Maximum value	17,5	49,5	-	55	55,5	1 >	0 >	1 >	0 >
Mean Green leaf area (%)	17,5	49,5		55	55,5	0 =	1 =	0 =	1 =
%UTC	100	282,8 6		314,2 9	317,1 4	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)
(conversely for '<')

Comments of zRMS:

2 field trials were carried out in **the Maritime EPPO climatic zone**. CA3301 presented positive effect in assessment of green leaf area. The test product applied at dose rate 0,6 and 0,8 l/ha achieved a mean augmentation of green leaf area of 38,87% and 49,82% in trials where whole plants were observed. No significant differences between test and reference product were detected.

1 field trial was carried out in **the North-East EPPO zone**. The whole plants were observed to evaluation of green leaf area. An augmentation of green leaf area amounted 5,56% at dose rate of 0,6 l/ha and 11,11% at dose rate of 0,8 l/ha. The results from the test and reference product were comparable.

6 field trials were conducted in **the South-East EPPO zone**. The majorities trials show results from whole plants. CA3301 achieved a very positive effect in compared to untreated objectives and standards. An augmentation of green leaf area amounted 71,09 (0,8 l/ha) in case of whole plants. In 1 trial an augmentation was nearly 2000% (0,8 l/ha) on foliar L2 and 217,14% on foliar L1 after 32 days after second application. No significant differences between test and reference product were observed.

3.2.3.1 Durum wheat (TRZDU) / Conclusion Efficacy

On durum wheat, 4 foliar diseases were assessed in 18 trials across 4 EPPO zones. Disease severity was assessed and analysed on the main foliar levels 1 and 2, whereas for *Blumeria graminis* were considered all leaf foliar levels 1, 2, 3 and 4. In some instances, due the absence of appropriate level of disease the proposed number of valid trials was not fully achieved. No valid trials were presented for North-Eastern EPPO zone as this crop is rarely grown in this region and regarding the other EPPO

zone depending on the disease, the assessment timing and the crop part assessed, the dataset available was sometimes limited and so not fully representative of the efficacy of CA3301. Therefore, to get an overview of the efficacy of CA3301 at 0.6 l/ha, summary tables are presented hereunder, on foliar levels 1&2 (see Table 3.2-497 and Table 3.2-498) for SEPTTR – PUCCRE/ PUCCTR, and on all foliar levels for ERYSGT/ERYSGR (see Table 3.2-499), and on ears for GIBBZE (see Table 3.2-500).

Globally, across the 3 EPPO zones and all diseases the efficacy of CA3301 at 0.6-0.8 l/ha was acceptable to high, with some exceptions. Nevertheless, since in the fields a complex of disease is often observed instead of a single disease, it is of interest to present a summary of the efficacy of CA3301 across the diseases and EPPO zone, as well as considering the green leaf area presented above. Green leaf area not only indicates the area free of infection, but also the ability of the plant to continue effective growth and develop, enabling a longer duration of grain filling and therefore improved yield.

In many instances, a trend of decreasing disease severity when increasing the dose rates was observed with CA3301 applied at 0.6 l/ha or 0.8 l/ha. In overall the rate of 0.8 l/ha was not statistically different from 0.6 l/ha dose rate but both provided a better disease control than the lower rate of 0.48 l/ha. In circumstances of low disease pressure, the 0.6 l/ha rate may be sufficient to give comparable disease control, but due the importance of the diseases and given the possibility of resistance in some pathogens assessed the high rate may be deemed more appropriate and should be available for user according to disease development conditions, historical control and cultivar tolerance to the pathogen.

The relatively limited dataset for durum wheat is however supported by data in winter wheat since the application parameters are the same (dose rate, application timing etc) and the crop is agronomically similar. Furthermore, current authorised formulations of prothioconazole are for the same dose rate of application for both soft wheat and durum wheat, hence similar control levels are obtained for the same dose rate across these 2 crops. The same trends identified in these datasets for hard (durum) wheat are also demonstrated in the corresponding datasets for soft wheat.

In this dossier efficacy data presented is primarily from assessments where 2 applications of the test product were made. However, according to disease development conditions, a single application may provide sufficient disease control, therefore users should not be restricted to always applying twice, hence in the GAP the proposed use is for 1-2 applications. In addition, crop pathogens are commonly controlled using a programme of different fungicides with varied modes of action, therefore the choice should be available to growers to make a single application of CA3301, followed by application of a different appropriate fungicide. Prothioconazole is well established over a number of years in providing good broad spectrum efficacy across a range of common crop pathogens, with either 1 or more applications appropriate according to disease development conditions, risk of resistance development and local conditions. Current authorisations for similar products containing prothioconazole including Proline 275 and Proline/Praktis/Joao (CA2445) are for 1-2 applications at comparative rates of prothioconazole to the requested use for CA3301. Considering these elements, and that data shows comparability of CA3301 to these authorised products, registration of CA3301 at the proposed dose rate and with a number of applications of 1- 2, is requested.

It has been demonstrated in the preceding sections that the efficacy of CA3301 at 0.6-0.8 l/ha was overall equivalent to that provided by the approved reference standards used in the trials. Hence it is justified to propose that the efficacy comparable to that of the authorized products will be obtained on the pathogens where the presented data set are limited.

Considering all elements presented in the previous sections of each disease, it is justified to claim the registration of 1-2 applications of CA3301 at 0.6-0.8 l/ha to control a range of foliar and ear diseases on durum wheat.

Table 3.2-497: Summary table - Durum wheat – SEPTTR-PUCCRE/PUCCRT (Foliar level 2)

Foliar level 2			MAR		MED		NE		SE	
Disease	Assessment timing		CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB
SEPTT R	31 DA-B, 14 DA-B, 15 DA-B	Number of values Abbott efficacy (%)	1 66,62 %	1 52,49 %	4 68,20 %	4 68,95 %	-	-	1 63,61 %	1 82,73 %
	Before harvest	Number of values Abbott efficacy (%)	1 64,15 %	1 43,21 %	3 71,90 %	3 72,88 %	-	-	1 98,69 %	1 99,13 %
PUCC RE PUCC RT	19 DA-B	Number of values Abbott efficacy (%)	-	-	-	-	-	-	1 83,47 %	1 93,32 %
	Before harvest	Number of values Abbott efficacy (%)	-	-	-	-	-	-	-	-

Table 3.2-498: Summary table - Durum wheat – SEPTTR-PUCCRE/PUCCRT (Foliar level 1)

Foliar level 1			MAR		MED		NE		SE	
Disease	Assessment timing		CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB
SEPTT R	31 DA-B, 14 DA-B, 15 DA-B	Number of values Abbott efficacy (%)	-	-	2 82,92 %	2 86,86 %	-	-	1 65,97 %	1 83,17 %
	Before harvest	Number of values Abbott efficacy (%)	1 64,15 %	1 74,00 %	4 78,52 %	4 76,99 %	-	-	2 87,09 %	2 79,91 %
PUCC RE PUCC RT	2 weeks after B	Number of values Abbott efficacy (%)	-	-	-	-	-	-	1 94,97 %	1 95,98 %
	Before harvest	Number of values Abbott efficacy (%)	-	-	-	-	-	-	0 -	0 -

Table 3.2-499: Summary table - Durum wheat – ERYSGT/ERYSGR

			MAR		MED		NE		SE	
ERYSGT/ER YSGR	Assessment timing		CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB
Foliar Level 4	Incidence 6 DA-B	Number of values	-	-	1	1	-	-	-	-

		Abbott efficacy (%)			93,75 %	83,75 %				
	Severity 6 DA-B	Number of values Abbott efficacy (%)	-	-	1 98,99 %	1 93,69	-	-	-	-
Foliar Level 3	Incidence 14 DA-B, 6 DA-B	Number of values Abbott efficacy (%)	1 73,68 %	1 82,89 %	1 100%	1 92,65 %	-	-	-	-
	Severity 6 DA-B, 15 DA-B	Number of values Abbott efficacy (%)	0 -	0 -	1 100%	1 95,89 %	-	-	2 64,74 %	2 67,17 %
Foliar Level 2	Incidence 14-19 DA-B, 6 DA-B	Number of values Abbott efficacy (%)	2 80,00 %	2 88,57 %	1 100%	1 89,29 %	-	-	-	-
	Incidence 39 DA-B	Number of values Abbott efficacy (%)	1 64,91 %	1 78,95 %	-	-	-	-	-	-
	Severity 15 DA-B	Number of values Abbott efficacy (%)	-	-	-	-	-	-	2 77,74 %	2 82,24 %
	Severity 39 DA-B	Number of values Abbott efficacy (%)	1 78,59 %	1 93,82 %	-	-	-	-	-	-
Foliar Level 1	Incidence 39 DA-B	Number of values Abbott efficacy (%)	1 73,08 %	1 94,23 %	-	-	-	-	-	-
	Severity 39 DA-B	Number of values Abbott efficacy (%)	1 89,19 %	1 97,26 %	-	-	-	-	-	-

Table 3.2-500: Summary table - Durum wheat – GIBBZE

Ears NI= not Inoculated, I= Inoculated			MED (Ear NI)		SE (Ear I)	
Disease	Application timing		CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB
GIBBZE	14 DA-B	Number of values Abbott efficacy (%)	-	-	1 98,91%	1 99,02%
	35 DA-B, 21 DA-B	Number of values Abbott efficacy (%)	1 45,85%	1 60,55	1 99,04%	1 99,10%

Comments of zRMS:

It should be noted that the assessment of efficacy was provided only after second application. Due to the limited number of trials for target pests in durum wheat, the cMSs are kindly asked to consider single application of CA3301 on the national level.

3.2.3.2 Triticale (TTLWI) / *Zymoseptoria tritici* (SEPTTR)

Materials and Methods – Triticale – SEPTTR

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2017 and 2020, 21 trials were conducted in some countries of the Maritime, Mediterranean, North-Eastern East and South-Eastern East EPPO zones to evaluate the efficacy of CA3301 against *Zymoseptoria tritici* on Triticale.

In the Maritime EPPO zone, a total of 9 trials were performed in France (2), in Germany (5), in Czech Republic (1), in Denmark (1).

In the Mediterranean EPPO zone, a total of 3 trials were performed in France (1) and in Portugal (2).

In the North-Eastern East EPPO zone, a total of 5 trials were performed in Poland.

In the South-Eastern East EPPO zone, a total of 4 trials were performed in Hungary (1) and in Romania (3).

Data groupings were also made specifically for Poland evaluation and trials involved (11) were performed in the North-Eastern East EPPO zone (5), in the Czech Republic (1) and in Germany (5).

Table 3.2-501: Presentation of trials – Triticale (TTLWI) / *Zymoseptoria tritici* (SEPTTR)

Crop(s) *	Target(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mar- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Triticale	SEPTTR	France (N)	2019-2020	MED + E	2 (1)	-	-	-	GEP	
		Germany	2019-2020	MED + E	5 (3)	-	-	-	GEP	
		Czech Republic	2017	MED + E	1 (0)	-	-	-	GEP	
		Denmark	2018	MED + E	1 (0)	-	-	-	GEP	
		France (S)	2020	MED + E	-	1 (0)	-	-	GEP	
		Portugal	2018-2020	MED + E	-	2 (2)	-	-	GEP	
		Poland	2017-2019	MED + E	-	-	5 (4)	-	GEP	
		Hungary	2020	MED + E	-	-	-	1 (1)	GEP	
		Romania	2019-2020	MED + E	-	-	-	3 (2)	GEP	
TOTAL	-	-	2017-2020	MED + E	9 (4)	3 (2)	5 (4)	4 (3)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-emergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

In all trials, CA3301 was compared to at least one commercial and registered fungicide used as standard reference for comparison.

Table 3.2-502: Efficacy evaluation - Presentation of reference standards used in trials –Triticale (TTLWI) – SEPTTR – Maritime EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Triticale	JOAO	FR (N)	2060116	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in trials
	PRO-LINE	DE	025287-00	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 trials
	PRO-LINE 250 EC	CZ	4523-1	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha max	2 x 0.8 l/ha	CA2445 in trials
	PRO-LINE 250 EC	DK	18-473	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in trials

Table 3.2-503: Efficacy evaluation - Presentation of reference standards used in trials –Triticale (TTLWI) – SEPTTR – Mediterranean EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Triticale	JOAO	FR (S)	2060116	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in trials
	CA2445	PT	NA	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	
	MYS-TIC SUL	PT	7502	Tebuconazole	EW	250 g/l	2 x 1 l/ha	2 x 1 l/ha	

Table 3.2-504: Efficacy evaluation - Presentation of reference standards used in trials –Triticale (TTLWI) – SEPTTR – North-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Triticale	OSIRIS 65 EC	PL	R-87/2012	Epoxiconazole + metconazole	EC	65 g/l	1 x 1.5-2.5 l/ha	2 x 2 l/ha	

Table 3.2-505: Efficacy evaluation - Presentation of reference standards used in trials –Triticale (TTLWI) – SEPTTR – South-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Triticale	PRI-AXOR	HU	04.2/4127-1/2016	Fluxapyrixad Pyraclostrobin	EC	225 g/l	N/A	2 x 1.5 l/ha	
	PRO-LINE	RO	457PC/15.11.2018	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in trials
	PRO-LINE	HU	6300/1205-1/2020	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in trials
	NATIVO PRO 325	RO	056PC/29.09.2014	Prothioconazole + Trifloxistrobin	SC	325 g/l	2 x 1 l/ha	2 x 1 l/ha	

CA2445 is the code name used in some trials and is the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-506.

Table 3.2-506: Details on trial methodology – Triticale (TTLWI) - SEPTTR

		Maritime EPPO zone	Mediterranean EPPO zone	North-Eastern EPPO zone	South-Eastern EPPO zone	Data relevant for Poland
Trials	Total number (valid number)	9 (4)	3 (2)	5 (4)	4 (3)	11 (7)
	Supportive trials	-	-	-	-	-
Guidelines	General guidelines	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3) PP 1/225 (2) PP 1/262 (1)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)
	Specific guidelines	PP 1/26(9) PP 1/28 (2)	PP 1/26(3)	PP 1/26(4)	PP 1/26(4)	PP 1/26(4)
Experimental design	Plot design	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included
	Plot size	19,8-27 m ²	20-30 m ²	21-30 m ²	21 m ²	21-30 m ²
	Number of replications	4	4	4	4	4
Crop	Trials per crop	Triticale (9)	Triticale (3)	Triticale (5)	Triticale (4)	Triticale (11)
	Varieties per crop	Tulus (1), Tantris (1), Lombardo (2), Talento (2), Trsikell (1),	Bondadoso (1), Omeac (1), Alter (1),	Fidelio (1), Pizarro (1), Pantheon (1), Rotonondo (1), Orinoko (1)	Haiduc (2), Go-run (1), GK Sze-men (1)	Fidelio (1), Pizarro (1), Pantheon (1), Rotonondo (1), Orinoko (1), Tulus (1), Lombardo

		Temuco (1), Brehat (1)				(2), Talentro (2), Temuco (1)
	Sowing period	September (5), October (3), December (1)	October (1), De- cember (1), Janu- ary (1)	September (5)	October (4)	September (9), October (2)
Application	Crop stage (BBCH)* at application	A: BBCH 30- 39 B: BBCH 39- 65	A: BBCH 32-39 B: BBCH 39-61	A: BBCH 30-37 B: BBCH 55-61	A: BBCH 32-37 B: BBCH 39-61	A: BBCH 30-37 B: BBCH 45-61
	Timing Disease stage at application	BBCH 30-65 A: MIXED (6), N/A (2), ACTIVE (1) B: MIXED (6), N/A (2), ACTIVE (1)	BBCH 32-61 A: MIXED (1), PRINFC (2) B: MIXED (3)	BBCH 30-61 A: ACTIVE (1), MYCELI (2), N/A (2) B: ACTIVE (1), MYCELI (2), N/A (2)	BBCH 32-61 A: PRINFC (4) B: PRINFC (2), MYCELI (2)	BBCH 30-61 A: ACTIVE (1), MYCELI (2), N/A (3), MIXED (5) B: ACTIVE (1), MYCELI (2), N/A (3), MIXED (5)
	Number of applications Intervals between applications	2 applications (15-32 days) (9)	2 applications (14- 19 days) (3)	2 applications (10-47 days) (5)	2 applications (18-28 days) (4)	2 applications (10-47 days) (11)
	Spray volumes	200 l/ha	182-300 l/ha	200-300 l/ha	200-300 l/ha	200-300 l/ha
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T/HA)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T/HA)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T/HA)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T/HA)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T/HA)
	Assessment dates	0 DA-A, 13-19 DA-A 0 DA-B, 14-21 DA-B, 27-45 DA-B	0 DA-A, 14-18 DA-A, 0 DA-B, 14-15 DA-B, 21- 25 DA-B, 29-48 DA-B	0 DA-A, 13-15 DA-A, 20-30 DA-A 0 DA-B, 4-7 DA-B, 14-25 DA-B, 29-44 DA-B	0 DA-A, 13-15 DA-A, 18-28 DA-A 0 DA-B, 12-14 DA-B, 26-40 DA-B, 47-48 DA-B, 70-84 DA-B, 81-84 DA-B, 104 DA- B	0 DA-A, 13-17 DA-A, 20-32 DA-A 0 DA-B, 4-7 DA-B, 14-25 DA-B, 27-45 DA-B
Other rele- vant infor- mation	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial innoculation...	Natural (9)	Natural (3)	Natural (5)	Natural (4)	Natural (11)
	e.g. Field / Greenhouse...	Field trials	Field trials	Field trials	Field trials	Field trials

* BBCH for weeds, pre-emergence, preventive / curative application, insect stage...

Out of the 21 trials performed on triticale against *Zymoseptoria tritici*, 13 were considered valid.

Use of CA3301 at 2x 0.6-0.8 l/ha against SEPTTR – Maritime EPPO zone

In the Maritime EPPO zone, a total of 9 trials evaluated the efficacy of CA3301 on triticale against *Zymoseptoria tritici*. 4 trials were considered valid to determine the efficacy of CA3301 at 0.6-0.8 l/ha applied twice, and to compare it to the reference products on disease severity (%). The first application was performed at crop stages BBCH 30-39 and 2nd application at crop stages BBCH 39-65. Two assessments timings were selected on foliar level 2, two weeks after the 2nd application (15 DA-B) and around four weeks after 2nd application (31-42 DA-B). Only one assessment timing was selected on foliar level 1, around four weeks after 2nd application (35 DA-B).

Summary results are presented in Table 3.2-507.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha on the reduction of disease severity on triticale against *Zymoseptoria tritici*. On foliar level 2, CA3301 at 0.6-0.8 l/ha provided 61.36-44.08% efficacy around two weeks after the 2nd application and 60.09-56.42% close to harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 44.29-38.81% efficacy on reduction of disease severity close to harvest. At the proposed dose rates, CA3301 gave a significant reduction in disease severity compared to untreated plots at all assessments except 1 for the 0.6 l/ha rate and was comparable to or gave higher disease control than the reference CA2445 at all assessments.

In the Maritime EPPO zone, CA3301 at 0.6-0.8 l/ha showed medium efficacy in reducing the severity of *Zymoseptoria tritici* on triticale at 15 DA-B and 31-42 DA-B, on both main foliar levels 1 (L1) and 2 (L2). This was confirmed also in the trials presented on the closely related crop winter wheat. The performance of the tested product was overall equivalent to the reference product CA2445 applied at 0.8 l/ha. The efficacy of CA3301 at 0.6 l/ha was comparable to that of the dose rate of 0.8 l/ha, and in some assessments a statistical benefit was derived from increasing the dose rate to 0.8 l/ha. Therefore, in most instances, 0.6 l/ha dose rate will be sufficient and in situations with high disease pressure, historical difficulties in control of this disease or where some level of resistance is suspected, 0.8 l/ha dose rate may be more appropriate to control *Zymoseptoria tritici*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Zymoseptoria tritici* on triticale in the Maritime EPPO zone.

Table 3.2-507: Summary table - Efficacy evaluation – Triticale– SEPTTR - Maritime EPPO zone

Table 5.2.5.7: Summary table: Untreated table: Linearity evaluation: Plotable: SEI FFR: Marking L210 zone										
Treatment name	UNTREATED CHECK	CA24 45	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		0,8	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Disease severity L2 - 15 DA-B										
Number of values	1	1	1	1	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	5,15	1,76	1,99	2,88	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	5,15	1,76	1,99	2,88	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	5,15	1,76	1,99	2,88	0 <	0 <	0 <	0 <	0 <	0 <
Mean Abbott efficacy (%)	0,00%	65,83 %	61,36 %	44,08 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 31-42 DA-B										
Number of values	4	4	4	4	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	5,61	2,18	1,98	1,80	3 >	1 >	0 >	4 >	1 >	0 >
Maximum value	18,09	13,83	11,89	10,74	1 =	3 =	4 =	0 =	3 =	4 =
Mean disease severity (%)	10,72	6,50	4,84	4,94	0 <	0 <	0 <	0 <	0 <	0 <
Mean Abbott efficacy (%)	0,00%	44,27 %	60,09 %	56,42 %	0 <	0 <	0 <	0 <	0 <	0 <

Treatment name	UNTREATED CHECK	CA24 45	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		0,8	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Disease severity L1 - 35 DA-B										
Number of values	1	1	1	1	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	8,76	4,50	4,88	5,36	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	8,76	4,50	4,88	5,36	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	8,76	4,50	4,88	5,36	0 <	0 <	0 <	0 <	0 <	0 <
Mean Abbott efficacy (%)	0,00%	48,63 %	44,29 %	38,81 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against SEPTTR – Mediterranean EPPO zone

In the Mediterranean EPPO zone, a total of 3 trials evaluated the efficacy of CA3301 on triticale against *Zymoseptoria tritici*. Two trials were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha (applied twice), and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 32-39 and the 2nd application was at BBCH 39-61. Two main assessment timings were available: two weeks after the 2nd application (15 DA-B) and around four weeks after 2nd application (29-48 DA-B).

Summary results are presented in Table 3.2-508.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on triticale against *Zymoseptoria tritici*. On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 82.00-86.33% of efficacy two weeks after the 2nd application and 81.20-83.40% before harvest. On foliar level 1, in a single trial CA3301 at 0.6-0.8 l/ha provided 45.80-51.15% efficacy on reduction of disease severity before harvest, anyway fully comparable to the standard CA2445 at 0.8 l/ha. At the proposed dose rates, CA3301 gave a significant reduction in disease severity compared to untreated plots at all assessments except the latter one and was comparable to the reference CA2445 at all assessments.

In addition to these two valid trials it is possible to refer also to the dataset presented on winter wheat against *Zymoseptoria tritici* in Mediterranean EPPO zone where 20 trials were available (KCP 6.2.2.1 Winter wheat (TRZAW) / *Zymoseptoria tritici* (SEPTTR)). In the Mediterranean EPPO zone, CA3301 at 0.6-0.8 l/ha showed medium efficacy in reducing the severity of *Zymoseptoria tritici* on winter wheat. The performance of the tested product at 0.6-0.8 l/ha was overall equivalent to the reference products CA2445 and PROSARO, and at the rate of 0.8 l/ha CA3301 was in some instances more effective for disease control compared to the reference products. Averaged across the dataset the efficacy of CA3301 at 0.6 l/ha was fairly comparable to that of the dose rate of 0.8 l/ha, however at some assessments a statistical benefit was derived from increasing the dose rate to 0.8 l/ha. Therefore, in most instances CA3301 at 0.6 l/ha will provide sufficient disease control whereas in situations with high disease pressure, historical difficulties in control of this disease or where some level of resistance is suspected it may be appropriate to use 0.8 l/ha for control of *Zymoseptoria tritici*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Zymoseptoria tritici* on triticale in the Mediterranean EPPO zone.

Table 3.2-508: Summary table - Efficacy evaluation – Triticale – SEPTTR - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA24 45	MYSTIC SUL	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		0,8	1	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	AB						
% Disease severity L2 - 15 DA-B											
Number of values	2	2		2	2	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	5,69	0,00		0,00	0,00	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	7,50	1,40	-	2,70	2,05	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	6,59	0,70		1,35	1,03	0 =	2 =	2 =	0 =	2 =	2 =
Mean Abbott efficacy (%)	0,00%	90,67 %		82,00 %	86,33 %	0 <	0 <	0 <	0 <	0 <	0 <
Number of values	1	1	1	1	1	MYSTIC SUL			MYSTIC SUL		
Minimum value	5,69	0,00	1,94	0,00	0,00	1 l/ha			1 l/ha		
Maximum value	5,69	0,00	1,94	0,00	0,00	1 >			1 >		
Mean disease severity (%)	5,69	0,00	1,94	0,00	0,00	0 =			0 =		
Mean Abbott efficacy (%)	0,00%	100,0 0%	65,91 %	100,0 0%	100,0 0%	0 <			0 <		
% Disease severity L2 - 29-48 DA-B											
Number of values	2	2		2	2	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	10,69	0,00		0,00	0,00	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	12,50	3,90	-	4,70	4,15	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	11,59	1,95		2,35	2,08	0 =	2 =	2 =	0 =	2 =	2 =
Mean Abbott efficacy (%)	0,00%	84,40 %		81,20 %	83,40 %	0 <	0 <	0 <	0 <	0 <	0 <
Number of values	1	1	1	1	1	MYSTIC SUL			MYSTIC SUL		
Minimum value	10,69	0,00	4,50	0,00	0,00	1 l/ha			1 l/ha		
Maximum value	10,69	0,00	4,50	0,00	0,00	1 >			1 >		
Mean disease severity (%)	10,69	0,00	4,50	0,00	0,00	0 =			0 =		
Mean Abbott efficacy (%)	0,00%	100,0 0%	57,90 %	100,0 0%	100,0 0%	0 <			0 <		
% Disease severity L1 - 29 DA-B											
Number of values	1	1		1	1	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	6,55	2,00		3,55	3,20	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	6,55	2,00	-	3,55	3,20	0 >	0 >	0 >	0 >	0 >	0 >
Mean disease severity (%)	6,55	2,00		3,55	3,20	1 =	1 =	1 =	1 =	1 =	1 =
Abbott efficacy (%)	0,00%	69,47 %		45,80 %	51,15 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against SEPTTR – North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a total of 5 trials evaluated the efficacy of CA3301 on triticale against *Zymoseptoria tritici*. Four trials were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha (applied twice), and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 30-37 and the 2nd application was at BBCH 55-61. Two main assessment timings were selected: two weeks after the 2nd application (15 DA-B) on leaf level L2 and about four weeks after 2nd application (31-44 DA-B) on leaf level L2 and L1.

Summary results are presented in Table 3.2-509.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha on the reduction of disease severity on triticale against *Zymoseptoria tritici*. On foliar level 2, CA3301 at 0.6-0.8 l/ha provided 56.70-74.46% of efficacy two weeks after the 2nd application and 58.43-72.17% before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 67.62-75.65% before harvest. At the proposed dose rates, CA3301 gave a significant reduction in disease severity compared to untreated plots at all assessments and was comparable to or gave higher disease control than the reference CA2445.

In the North-Eastern East EPPO zone, CA3301 at 0.6-0.8 l/ha showed medium to high efficacy in reducing the severity of *Zymoseptoria tritici* on triticale. Applied at 0.6 l/ha, CA3301 gave higher or equivalent disease control than CA2445 applied at a higher rate of prothioconazole and was less efficient than OSIRIS 65 EC at 2,0 l/ha in 3 assessments out of 4. Applied at 0.8 l/ha, CA3301 gave in overall higher disease control than CA2445. Compared to OSIRIS, CA3301 at this dose rate was statistically equivalent except in 1 trial where it was less efficient. Across this dataset the efficacy of CA3301 at 0.6 l/ha was often comparable to that of 0.8 l/ha, however at some assessments a clear increase in the level of efficacy appeared with CA3301 applied at 0.8 l/ha. Moreover, a larger dataset was presented on the related crop-disease pair winter wheat (KCP 6.2.2.1 Winter wheat (TRZAW) / *Zymoseptoria tritici* (SEPTTR)) which supports the trends observed here. Therefore, in many instances 0.6 l/ha gave sufficient disease control but in conditions of high disease pressure, historical difficulties in control of this disease or where some level of resistance is suspected it may be appropriate to use 0.8 l/ha for control of *Zymoseptoria tritici*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Zymoseptoria tritici* on triticale in the North-Eastern East EPPO zone.

Table 3.2-509: Summary table - Efficacy evaluation – Triticale – SEPTTR – North-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA244 5	OSI- RIS 65 EC	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		0,8	2	0,6	0,8				
Rate unit		L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB				
% Disease severity L2 - 15 DA-B									
Number of values	2			2	2	UT C	CA330 1 0,8 l/ha	UT C	CA330 1 0,6 l/ha
Minimum value	5,53			2,75	1,31				
Maximum value	10,55	-	-	3,89	2,89	2 >	0 >	2 >	1 >
Mean disease severity (%)	8,04			3,32	2,10	0 =	1 =	0 =	1 =
Mean Abbott efficacy (%)	0,00%			56,70%	74,46%	0 <	1 <	0 <	0 <
Number of values	1	1		1	1	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	10,55	4,69		3,89	2,89				
Maximum value	10,55	4,69	-	3,89	2,89	0 >		1 >	
Disease severity (%)	10,55	4,69		3,89	2,89	1 =		0 =	

Treatment name	UNTREATED CHECK	CA244 5	OSI- RIS 65 EC	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		0,8	2	0,6	0,8				
Rate unit		L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB				
Mean Abbott efficacy (%)	0,00%	55,55%		63,13%	72,61%	0 <		0 <	
Number of values	1		1	1	1	OSIRIS 2 l/ha		OSIRIS 2 l/ha	
Minimum value	5,53		1,38	2,75	1,31	0 >		0 >	
Maximum value	5,53	-	1,38	2,75	1,31	0 =		1 =	
Disease severity (%)	5,53		1,38	2,75	1,31				
Mean Abbott efficacy (%)	0,00%		75,05%	50,27%	76,31%	1 <		0 <	
% Disease severity L2 - 31-41 DA-B									
Number of values	3			3	3	UT C	CA330 1 0,8 l/ha	UT C	CA330 1 0,6 l/ha
Minimum value	6,69			3,15	1,50	3 >	0 >	3 >	0 >
Maximum value	25,94	-	-	10,31	8,44				
Mean disease severity (%)	16,23			6,51	4,84	0 =	3 =	0 =	3 =
Mean Abbott efficacy (%)	0,00%			58,43%	72,17%	0 <	0 <	0 <	0 <
Number of values	1	1		1	1	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	16,05	8,70		6,08	4,58	1 >		1 >	
Maximum value	16,05	8,70	-	6,08	4,58				
Disease severity (%)	16,05	8,70		6,08	4,58	0 =		0 =	
Mean Abbott efficacy (%)	0,00%	45,79%		62,12%	71,46%	0 <		0 <	
Number of values	2		2	2	2	OSIRIS 2 l/ha		OSIRIS 2 l/ha	
Minimum value	6,69		2,35	3,15	1,50	0 >		0 >	
Maximum value	25,94	-	7,56	10,31	8,44				
Mean disease severity (%)	16,32		4,96	6,73	4,97	1 =		2 =	
Mean Abbott efficacy (%)	0,00%		67,86%	58,75%	69,54%	1 <		0 <	
% Disease severity L1 - 31-44 DA-B									
Number of values	3			3	3	UT C	CA330 1 0,8 l/ha	UT C	CA330 1 0,6 l/ha
Minimum value	11,48			3,53	2,83	3 >	0 >	3 >	1 >
Maximum value	16,69	-	-	5,08	3,50				
Mean disease severity (%)	13,26			4,26	3,17	0 =	2 =	0 =	2 =
Mean Abbott efficacy (%)	0,00%			67,62%	75,65%	0 <	1 <	0 <	0 <
Number of values	2	2		2	2	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	11,48	4,95		3,53	2,83	0 >		1 >	
Maximum value	16,69	5,01	-	5,08	3,50				
Mean disease severity (%)	14,09	4,98		4,31	3,17	2 =		1 =	
Mean Abbott efficacy (%)	0,00%	63,35%		69,44%	77,53%	0 <		0 <	
Number of values	1		1	1	1	OSIRIS 2 l/ha		OSIRIS 2 l/ha	
Minimum value	11,63		2,34	4,18	3,19	0 >		0 >	
Maximum value	11,63	-	2,34	4,18	3,19				
Disease severity (%)	11,63		2,34	4,18	3,19	0 =		0 =	
Mean Abbott efficacy (%)	0,00%		79,88%	64,06%	72,57%	1 <		1 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against SEPTTR – South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, a total of 4 trials evaluated the efficacy of CA3301 on triticale against *Zymoseptoria tritici*. 3 trials were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha (applied twice), and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 32-37 and the 2nd application was at BBCH 39-61. A main assessment timing was selected close to harvest (26-48 DA-B) and the efficacy analysis was done on both main foliar level 2 and foliar level 1.

Summary results are presented in Table 3.2-510.

Data demonstrated the acceptable effect of 2 applications of CA3301 at 0.6-0.8 l/ha on the reduction of disease severity on triticale against *Zymoseptoria tritici*. Before harvest CA3301 at 0.6-0.8 l/ha provided 96.00-96.74% of mean efficacy on foliar level 2 and 96.60-97.11% of mean efficacy on foliar level 2. CA3301 at 0.6-0.8 l/ha was overall comparable to the standard references CA2445 and NATIVO PRO. Compared to PRIAXOR which reached full control of the disease, CA3301 at 0.6-0.8 l/ha was statistically less efficient. Nevertheless, a high level of efficacy was obtained from applications of CA3301 at the proposed dose rates. At the proposed dose rates, CA3301 gave a significant reduction in disease severity compared to untreated plots at all assessments and was comparable to or gave higher disease control than the reference CA2445.

In addition to these 4 trials, it is possible to consider the dataset presented for the closely related crop winter wheat. In the South-Eastern East EPPO zone, CA3301 at 0.6-0.8 l/ha showed medium to high efficacy in reducing the severity of *Zymoseptoria tritici* on winter wheat (KCP 6.2.2.1 Winter wheat (TRZAW) / *Zymoseptoria tritici* (SEPTTR)), with the highest efficacy reached two weeks after the 2nd application on foliar level 1 with 86.6-90.1% efficacy. CA3301 at 0.6 l/ha was overall equivalent to the reference products CA2445 and PRIAXOR. At the rate of 0.8 l/ha CA3301 was more frequently comparable to or better than the reference products for disease control. Averaged across the dataset the efficacy of CA3301 at 0.6 l/ha was fairly comparable to that of the dose rate of 0.8 l/ha, however in some assessments a statistical benefit was derived from increasing the dose rate to 0.8 l/ha for disease control. Therefore, in most instances 0.6 l/ha dose rate will provide sufficient disease control and in more challenging conditions, historical difficulties in control of this disease or where some level of resistance is suspected it may be appropriate to use 0.8 l/ha for control of *Zymoseptoria tritici*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Zymoseptoria tritici* on triticale in the South-Eastern East EPPO zone.

Table 3.2-510: Summary table - Efficacy evaluation – Triticale – SEPTTR – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA24 45	NATIVO PRO 325 SC	PRIAXOR	CA33 01	CA33 01	No of trials where CA3301	No of trials where CA3301
Rate		0,8	1	1,5	0,6	0,8	at 0,6 l/ha is >, = or < compared to	at 0,8 l/ha is >, = or < compared to
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	AB	AB		
% Disease severity L2 - 26-48 DA-B								
Number of values	3				3	3	UTC	CA330 1 0,8 l/ha
Minimum value	19,50				0,19	0,15		UTC
Maximum value	33,00	-	-	-	3,43	2,80	3 >	0 >
Mean disease severity (%)	28,13				1,27	1,04	0 =	3 =
Mean Abbott efficacy (%)	0,00%				96,00 %	96,74 %	0 <	0 <
Number of values	2		2		2	2	NATIVO	NATIVO

Treatment name	UNTREATED CHECK	CA24 45	NA-TIVO PRO 325 SC	PRI-AXOR	CA33 01	CA33 01	No of trials where CA3301		No of trials where CA3301	
Rate Rate unit Appl. Code		0,8 L/ha AB	1 L/ha AB	1,5 L/ha AB	0,6 L/ha AB	0,8 L/ha AB	at 0,6 l/ha is >, = or < compared to		at 0,8 l/ha is >, = or < compared to	
Minimum value	19,50		0,17		0,19	0,15	1 l/ha		1 l/ha	
Maximum value	31,88	-	0,17	-	0,20	0,17	0 >		0 >	
Mean disease severity (%)	25,69		0,17		0,20	0,16	2 =		2 =	
Mean Abbott efficacy (%)	0,00%		99,30 %		99,20 %	99,35 %	0 <		0 <	
Number of values	1	1		1	1	1	CA24 45 0,8 l/ha	PRI-AXOR 1,5 l/ha	CA24 45 0,8 l/ha	PRI-AXOR 1,5 l/ha
Minimum value	33,00	6,16		0,00	3,43	2,80	1 >	0 >	1 >	0 >
Maximum value	33,00	6,16	-	0,00	3,43	2,80	0 =	0 =	0 =	0 =
Mean disease severity (%)	33,00	6,16		0,00	3,43	2,80	0 =	0 =	0 =	0 =
Mean Abbott efficacy (%)	0,00%	81,33 %		100,00 %	89,61 %	91,52 %	0 <	1 <	0 <	1 <
% Disease severity L1 - 26-48 DA-B										
Number of values	3				3	3	UTC	CA330 1 0,8 l/ha	UTC	CA330 1 0,6 l/ha
Minimum value	10,00				0,11	0,05	3 >	0 >	3 >	0 >
Maximum value	19,19	-	-	-	0,90	0,81	0 =	3 =	0 =	3 =
Mean disease severity (%)	16,04				0,38	0,31	0 =	3 =	0 =	3 =
Mean Abbott efficacy (%)	0,00%				96,60 %	97,11 %	0 <	0 <	0 <	0 <
Number of values	2		2		2	2	NATIVO 1 l/ha		NATIVO 1 l/ha	
Minimum value	18,93		0,06		0,11	0,05	0 >		0 >	
Maximum value	19,19	-	0,07	-	0,12	0,06	2 =		2 =	
Mean disease severity (%)	19,06		0,07		0,12	0,06	0 <		0 <	
Mean Abbott efficacy (%)	0,00%		98,25 %		99,40 %	99,72 %				
Number of values	1	1		1	1	1	CA24 45 0,8 l/ha	PRI-AXOR 1,5 l/ha	CA24 45 0,8 l/ha	PRI-AXOR 1,5 l/ha
Minimum value	10,00	0,93		0,00	0,90	0,81	0 >	0 >	0 >	0 >
Maximum value	10,00	0,93	-	0,00	0,90	0,81	1 =	0 =	1 =	0 =
Mean disease severity (%)	10,00	0,93		0,00	0,90	0,81	0 <	1 <	0 <	1 <
Mean Abbott efficacy (%)	0,00%	90,70 %		100,00 %	91,00 %	91,90 %	0 <	1 <	0 <	1 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against SEPTTR – Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-Eastern East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, a total of 9 trials evaluated the efficacy of CA3301 on triticale against *Zymoseptoria tritici*. 7 trials out of 9 were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 30-39

and the 2nd application was at BBCH 39-65. Two assessment timings were selected, one two weeks after 2nd application on foliar level 2 and one about four weeks after 2nd application (31-44 DA-B).

Summary results are presented in Table 3.2-511.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha on the reduction of disease severity on triticale against *Zymoseptoria tritici*. On foliar level 2, CA3301 at 0.6-0.8 l/ha provided 57.63-64.04% mean efficacy two weeks after the 2nd application and 57.80-63.72% before harvest. On foliar level 1, CA3301 showed 61.79-66.44% efficacy close to harvest..At the proposed dose rates, CA3301 gave a significant reduction in disease severity compared to untreated plots, with one exception for the 0.6 l/ha rate. Nevertheless, at all assessments, CA3301 was comparable to or gave higher disease control than the reference CA2445.

A representative dataset was available for the assessment of *Zymoseptoria tritici*, with disease severity ranging from relatively low to medium. Data demonstrated that at low disease severity CA3301 applied at 0.6 l/ha or at 0.8 l/ha provided comparable efficacy, however as disease progressed there was a significant benefit derived from increasing the dose rate to 0.8 l/ha. Therefore, in most instances CA3301 applied at 0.6 l/ha will provide sufficient disease control and in more challenging conditions the 0.8 l/ha dose rate may be more appropriate.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Zymoseptoria tritici* on triticale in Poland.

Table 3.2-511: Summary table - Efficacy evaluation – Triticale – SEPTTR – Data relevant for Poland

Treatment name	UNTREATED CHECK	CA244 5	OSI- RIS 65 EC	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		0,8	2	0,6	0,8				
Rate unit		L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB				
% Disease severity L2 - 15 DA-B									
Number of values	3			3	3	UT C	CA330 1 0,8 l/ha	UT C	CA330 1 0,6 l/ha
Minimum value	5,15			1,99	1,31				
Maximum value	10,55	-	-	3,89	2,89	3 >	0 >	3 >	1 >
Mean disease severity (%)	7,08			2,88	2,36	0 =	2 =	0 =	2 =
Mean Abbott efficacy (%)	0,00%			57,63%	64,04%	0 <	1 <	0 <	0 <
Number of values	2	2		2	2	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	5,15	1,76		1,99	2,88				
Maximum value	10,55	4,69	-	3,89	2,89	0 >		1 >	
Mean disease severity (%)	7,85	3,23		2,94	2,89	2 =		1 =	
Mean Abbott efficacy (%)	0,00%	60,69%		62,24%	58,34%	0 <		0 <	
Number of values	1		1	1	1	OSIRIS 2 l/ha		OSIRIS 2 l/ha	
Minimum value	5,33		1,38	2,75	1,31				
Maximum value	5,33	-	1,38	2,75	1,31	0 >		0 >	
Disease severity (%)	5,33		1,38	2,75	1,31	0 =		1 =	
Mean Abbott efficacy (%)	0,00%		74,11%	48,41%	75,42%	1 <		0 <	
% Disease severity L2 - 31-42 DA-B									
Number of values	6			6	6	UT C	CA330 1 0,8 l/ha	UT C	CA330 1 0,6 l/ha
Minimum value	5,61			1,98	2,50				
Maximum value	25,94	-	-	11,89	10,74	5 >	0 >	6 >	0 >
Mean disease severity (%)	13,52			5,94	5,01	1 =	6 =	0 =	6 =

Treatment name	UNTREATED CHECK	CA244 5	OSI- RIS 65 EC	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		0,8	2	0,6	0,8				
Rate unit		L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB				
Mean Abbott efficacy (%)	0,00%			57,80%	63,72%	0 <	0 <	0 <	0 <
Number of values	4	4		4	4	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	5,61	2,18		1,98	1,80	2 >		2 >	
Maximum value	18,09	13,83	-	11,89	10,74	2 =		2 =	
Mean disease severity (%)	12,12	7,75		5,55	5,04	2 =		2 =	
Mean Abbott efficacy (%)	0,00%	39,55%		58,40%	59,32%	0 <		0 <	
Number of values	2		2	2	2	OSIRIS 2 l/ha		OSIRIS 2 l/ha	
Minimum value	6,69		2,35	3,15	1,50	0 >		0 >	
Maximum value	25,94	-	7,56	10,31	8,44	1 =		2 =	
Mean disease severity (%)	16,32		4,96	6,73	4,97	1 <		0 <	
Mean Abbott efficacy (%)	0,00%		67,86%	56,58%	72,52%				
% Disease severity L1 - 31-44 DA-B									
Number of values	4			4	4	UT C	CA330 1 0,8 l/ha	UT C	CA330 1 0,6 l/ha
Minimum value	8,76			3,53	2,83	4 >	0 >	4 >	1 >
Maximum value	16,69	-	-	5,08	5,36	0 =	3 =	0 =	3 =
Mean disease severity (%)	12,14			4,41	3,72	0 <	1 <	0 <	0 <
Mean Abbott efficacy (%)	0,00%			61,79%	66,44%				
Number of values	3	3		3	3	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	8,76	4,50		3,53	2,83	0 >		1 >	
Maximum value	16,79	5,01	-	5,08	5,36	3 =		2 =	
Mean disease severity (%)	12,31	4,82		4,50	3,90	0 <		0 <	
Mean Abbott efficacy (%)	0,00%	58,44%		61,04%	64,40%				
Number of values	1		1	1	1	OSIRIS 2 l/ha		OSIRIS 2 l/ha	
Minimum value	11,63		2,34	4,18	3,19	0 >		0 >	
Maximum value	11,63	-	2,34	4,18	3,19	0 =		0 =	
Mean disease severity (%)	11,63		2,34	4,18	3,19	1 <		1 <	
Mean Abbott efficacy (%)	0,00%		79,88%	64,06%	72,57%				

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

4 valid field trials were carried out in the **Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,6-0,8 l/ha achieved very low (44,29% at 0,6 l/ha and 38,81% at 0,8 l/ha) to medium efficacy (61,36% at 0,6 l/ha) after 15-42 days after second application. Due to the limited number of trials, the cMSs are kindly asked to consider this use on the national level.

4 valid trials were available in the **North-East EPPO zone**. CA3301 applied at dose rate of 0,6 l/ha achieved low to medium efficacy. The use of higher dose rate caused increase of effectiveness to medium level after 15-44 DA-B. Also 3 trials from Germany have been included to the overall calculation to support Polish registration. Taking into account all results, it can be concluded that the test product is effective to control of SEPTTR but on the medium level. The dose rate of 0,8 l/ha is recommended in case of high disease pressure.

3 valid trials have been submitted in the **South-East EPPO zone**. CA3301 applied at dose rate of 0,6-0,8 l/ha achieved high efficacy after 26-48 days after second application. Also 2 trials from the Mediterranean zone confirm high level of control after applied test product in both doses. The cMSs are kindly asked to consider this use on the national level.

3.2.3.3 Triticale (TTLWI) / *Blumeria graminis* – *Blumeria graminis f.sp. tritici* (ERYSGR-ERYSGT)

Materials and Methods – Triticale – ERYSGR/ERYSGT

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Blumeria graminis and *Blumeria graminis f. sp. tritici* are the causal agents of the powdery mildew on cereals and are considered as the same pathogen in this analysis.

Between 2017 and 2020, 11 trials were conducted in different countries for the Maritime EPPO zone, North-Eastern EPPO zone and South-Eastern EPPO zone to evaluate the efficacy of CA3301 against *Blumeria graminis* on **triticale**. The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, 1 trial was performed in France, 3 trials were done in Germany and 2 trials in Czech Republic.

In the North-Eastern East EPPO zone 3 trials were performed in Poland.

In the South-Eastern East EPPO zone, 2 trials were performed in Hungary.

No trials were available in the Mediterranean EPPO zone.

Data groupings were also made specifically for Poland evaluation and trials involved (8) were performed in the North-Eastern East EPPO zone (3), in the Czech Republic (2) and in Germany (3).

Out of the 11 trials carried out against *Blumeria graminis* (ERYSGR) on triticale, 6 were considered valid (see Table 3.2-512):

Table 3.2-512: Presentation of trials – Triticale (TTLWI) / ERYSGR/ERYSGT

Crop(s) *	Tar- get(s)*	Country	Year s	Type of trial*	Number of trials (number of valid trials)				GEP, non-GEP, offi- cial***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Triticale	ERYSGR	France	2019	MED + E	1 (1)	-	-	-	GEP	
		Germany	2019 2020	MED + E	3 (1)	-	-	-	GEP	
		Czech Republic	2017 2018	MED + E	2 (1)	-	-	-	GEP	
		Poland	2017 2018	MED + E	-	-	3 (1)	-	GEP	
		Hungary	2018 2020	MED + E	-	-	-	2 (2)	GEP	
TOTAL	-	-	2017 -2020	MED + E	6 (3)	-	3 (1)	2 (2)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation

In all trials, CA3301 was compared to at least one commercial and registered fungicide used as standard reference for comparison.

Table 3.2-513: Efficacy evaluation - Presentation of reference standards used in trials –Triticale (TTLWI) – ERYSGR/ERYSGT – Maritime EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Triticale	PRO-LINE	DE	025287-00	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 trials
	PRO-LINE 250 EC	CZ	4523-1	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha max	2 x 0.8 l/ha	CA2445 in trials
	JOAO	FR	2060116	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in trials

Table 3.2-514: Efficacy evaluation - Presentation of reference standards used in trials –Triticale (TTLWI) – ERYSGR/ERYSGT – North-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Triticale	PRAKTIS	PL	R-222/2019	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in trials

Table 3.2-515: Efficacy evaluation - Presentation of reference standards used in trials –Triticale (TTLWI) – ERYSGR/ERYSGT – South-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Triticale	PRI-AXOR	HU	04.2/4127-1/2016	Fluxapyrixd Pyraclostrobin	EC	225 g/l	N/A	2 x 1.5 l/ha	
	PRO-LINE	HU	6300/1205-1/2020	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in trials

CA2445 is the code name used in some trials and is the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-516.

Table 3.2-516: Details on trial methodology – Triticale (TTLWI) – ERYSGR/ERYSGT

Maritime EPPO	North-Eastern	South-Eastern	Data relevant for
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		zone	EPPO zone	EPPO zone	Poland
Trials	Total number (valid number)	6 (3)	3 (1)	2 (2)	8 (4)
	Supportive trials	-		-	-
Guidelines	General guidelines	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)
	Specific guidelines	PP 1/26(4)	PP 1/26(4)	PP 1/26(4)	PP 1/26(4)
Experimental design	Plot design	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included
	Plot size	19.8-30 m ²	21-30 m ²	21 m ²	21-30 m ²
	Number of replications	4	4	4	4
Crop	Trials per crop	Triticale (6)	Triticale (3)	Triticale (1)	Triticale (8)
	Varieties per crop	Tulus (1), Claudius (1), Lombardo (2), Talentro (1), Trsikell (1)	Fidelio (1), Panteon (1), Twingo (1)	Unknow (1), GK Szemes (1)	Tulus (1), Claudius (1), Lombardo (2), Talentro (1), Fidelio (1), Panteon (1), Twingo (1)
	Sowing period	September (3), October (3)	September (3)	October (1), November (1)	September (6), October (2)
Application	Crop stage (BBCH)* at application	A: BBCH 30-37 B: BBCH 39-61	A: BBCH 37-39 B: BBCH 59-67	A: BBCH 31-32 B: BBCH 39-43	A: BBCH 30-39 B: BBCH 39-67
	Timing Disease stage at application	BBCH 30-61 A: PRINFC (2), MIXED (3), NA (1) B: PRINFC (3), MIXED (2), ACTIVE (1)	BBCH 37-67 A: MYCELY (1), ACTIVE (1), MIXED (1) B: MYCELY (1), ACTIVE (1), MIXED (1)	BBCH 31-43 A: PRINFC (2), B: PRINFC (2),	BBCH 30-61 A: PRINFC (2), MIXED (3), NA (1), MYCELY (1), ACTIVE (1) B: PRINFC (3), MIXED (2), ACTIVE (2), MYCELY (1)
	Number of applications Intervals between applications	2 applications (16-32 days) (6)	2 applications (10-20 days) (3)	2 applications (17-24 days) (2)	2 applications (10-32 days) (8)
	Spray volumes	200-300 l/ha	300-500 l/ha	300 l/ha	200-500 l/ha
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T/HA)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T/HA)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T/HA)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T/HA)
	Assessment dates	-1-0 DA-A, 13-17 DA-A, 0 DA-B, 14-19 DA-B, 27-42 DA-B	0 DA-A, 7-17 DA-A, 0 DA-B, 14-15 DA-B, 23-29 DA-B, 51 DA-B,	0 DA-A, 15 DA-A, -1-0 DA-B, 14-15 DA-B, 40 DA-B, 47-48 DA-B, 70-84 DA-	-1-0 DA-A, 7-17 DA-A, 0 DA-B, 14-19 DA-B, 23-51 DA-B

				B, 81-104 DA-B	
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Natural (6)	Natural (3)	Natural (2)	Natural (8)
	e.g. Field / Greenhouse...	Field trials	Field trials	Field trials	Field trials

* BBCH for weeds, pre-emergence, preventive / curative application, insect stage...

Out of the 11 trials performed on triticale against *Blumeria graminis* and *Blumeria graminis f. sp. tritici*, 6 trials were considered as valid.

Use of CA3301 at 2x 0.6-0.8 l/ha against ERYSGR/ERYSGT – Maritime EPPO zone

In the Maritime EPPO zone, 6 trials were performed between 2017 and 2020 to evaluate the efficacy of CA3301 on triticale against *Blumeria graminis* and *Blumeria graminis f. sp. tritici*. 3 trials were considered valid and enabled to evaluate the efficacy of CA3301 at 0.6-0.8 l/ha (applied twice), and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 30-37 and the 2nd application was at BBCH 39-61. Two main assessment timings were selected: around two weeks after the 2nd application (19 DA-B) on foliar level L1 and close to harvest (31-42 DA-B) on foliar level L2 and foliar level L1.

Summary results are presented in

Table 3.2-517.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha on the reduction of disease severity on triticale against *Blumeria graminis* and *Blumeria graminis f. sp. tritici*. Two weeks after second application CA3301 provided a high level of control of powdery mildew as well as in the assessments close to harvest. At all assessments CA3301 applied at the proposed dose rate significantly reduced disease severity compared to the untreated and was comparable to the reference product CA2445.

In addition to these four valid trials presented above, since triticale and winter wheat are comparable crops, it is possible to demonstrate the efficacy referring to the data presented on winter wheat (Winter wheat (TRZAW) / *Blumeria graminis* (ERYSGR-ERYSGT)). Following 2 applications, the fungicidal performance of CA3301 enabled to significantly decrease the disease pressure on leaves in most of trials, compared to the untreated control and whatever the dose rate considered. In the majority of assessments CA3301 at 0.6-0.8 l/ha gave equivalent disease control the authorised reference products. Although the rate of 0.8 l/ha overall reduced disease pressure to a greater extent than the 0.6 l/ha rate, the differences were not always significant. Nevertheless, it is likely that in circumstances of high disease pressure the increased disease control obtained from the higher rate may be of significant benefit.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Blumeria graminis* and *Blumeria graminis f. sp. tritici* on triticale in the Maritime EPPO zone.

Table 3.2-517: Summary table - Efficacy evaluation – Triticale –ERYSGR/ERYSGT – Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA244 5	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or <			No of trials where CA3301 at 0,8 l/ha is >, = or <		
Rate		0,8	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
% Disease severity L1 -19 DA-B										
Number of values	1	1	1	1	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	12,19	0,00	0,00	0,00	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	12,19	0,00	0,00	0,00	1 >	0 >	0 >	1 >	0 >	0 >
Disease severity (%)	12,19	0,00	0,00	0,00	0 =	1 =	1 =	0 =	1 =	1 =
Mean Abbott efficacy (%)	0,00%	100,00 %	100,00 %	100,00 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 -31-42 DA-B										
Number of values	2	2	2	2	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	5,46	0,00	0,00	0,00	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	11,26	0,45	0,75	0,53	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	8,36	0,23	0,38	0,26	0 =	2 =	2 =	0 =	2 =	2 =
Mean Abbott efficacy (%)	0,00%	98,00 %	96,67 %	97,65 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 42 DA-B										
Number of values	1	1	1	1	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	5,74	0,76	0,85	0,68	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	5,74	0,76	0,85	0,68	1 >	0 >	0 >	1 >	0 >	0 >
Disease severity (%)	5,74	0,76	0,85	0,68	0 =	1 =	1 =	0 =	1 =	1 =
Mean Abbott efficacy (%)	0,00%	86,76 %	85,19 %	88,15 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against ERYSGR/ERYSGT - Mediterranean EPPO zone

In the Mediterranean, no data were available to support the minimum effective dose of CA3301 against *Blumeria graminis* on triticale due to lack of disease infestation in the trials. However, the specie *Blumeria graminis* is also a pathogen agent present on wheat. It therefore seems reasonable from an agronomic perspective to assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on triticale from the robust dataset proposed for the closely related crop winter wheat. Furthermore, existing authorisations for prothioconazole products have the same dose rate for this pathogen in both winter wheat and in triticale, which also indicates that performance is comparable between the pathogen/crop pairs.

On winter wheat, a larger dataset of 7 supportive trials demonstrated that following 2 applications, the fungicidal performance of CA3301 enabled to significantly decrease the disease incidence on leaves in most of trials, compared to the untreated control and whatever the dose rate considered. The same trend was clearly observed on durum wheat on leaves and on ears. In all trials, CA3301 at 0.6-0.8 l/ha gave

always comparable disease control compared to the authorized reference products, whatever the foliar level or assessment timing considered. Although the rate of 0.8 l/ha overall reduced disease incidence to a greater extent than the 0.6 l/ha rate, the differences were usually not statistically significant. Nevertheless, it is likely that in circumstances of high disease pressure the increased disease control obtained from the higher rate may be of significant benefit.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Blumeria graminis* and *Blumeria graminis* f. sp. *tritici* on triticale wheat in the Mediterranean EPPO zone.

Use of CA3301 at 2x 0.6-0.8 l/ha against ERYSGR/ERYSGT – North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, 3 trials were performed between 2017 and 2018 to evaluate the efficacy of CA3301 on triticale against *Blumeria graminis* and *Blumeria graminis* f. sp. *tritici*. Out of 3 trials a single one was considered as valid for the efficacy evaluation. Thus to argue the efficacy of CA3301 at 0.6-0.8 l/ha (applied twice), and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 37-39 and the 2nd application was at BBCH 59-67. A single assessment timing was selected: around three weeks after the 2nd application (23 DA-B) on foliar level L2 and foliar level L1.

Summary results are presented in Table 3.2-518.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha on the reduction of disease severity on triticale against *Blumeria graminis* and *Blumeria graminis* f. sp. *tritici*. Three weeks after second application CA3301 at 0.6-0.8 l/ha provided high disease control against powdery mildew of cereals. CA3301 at 0.6-0.8 l/ha gave always equivalent disease control to the reference product CA2445 applied at 0.8 l/ha. At all assessments CA3301 applied at the proposed dose rate significantly reduced disease severity compared to the untreated.

In addition to this trial presented above, since triticale and winter wheat are comparable crops, it is possible to demonstrate the efficacy control against *Blumeria graminis* and *Blumeria graminis* f. sp. *tritici* referring to the data presented on winter wheat (KCP 6.2.2.4 Winter wheat (TRZAW) / *Blumeria graminis* (ERYSGR-ERYSGT)). Following 2 applications, the fungicidal performance of CA3301 enabled to significantly decrease the disease pressure on leaves, compared to the untreated control and whatever the dose rate considered. In all trials, CA3301 at 0.6-0.8 l/ha gave always equivalent disease control to the authorised reference products no matter the foliar level or assessment timing considered. Although the rate of 0.8 l/ha overall reduced disease incidence to a greater extent than the 0.6 l/ha rate, the differences were usually not significant. Nevertheless, it is likely that in circumstances of high disease pressure the increased disease control obtained from the higher rate may provide significant benefit.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Blumeria graminis* and *Blumeria graminis* f. sp. *tritici* on triticale wheat in the North-Eastern East EPPO zone.

Table 3.2-518: Summary table - Efficacy evaluation – Triticale –ERYSGR/ERYSGT – North-Eastern East EPPO zone

East EPTO zone										
Treatment name	UNTREATED CHECK	CA24 45	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		0,8	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Disease severity L2 23 DA-B										
Number of values	1	1	1	1	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	25,03	3,16	4,28	3,45	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha

Maximum value	25,03	3,16	4,28	3,45	1 >	0 >	0 >	1 >	0 >	0 >
Mean Disease severity (%)	25,03	3,16	4,28	3,45	0 =	1 =	1 =	0 =	1 =	1 =
Mean Abbott efficacy (%)	0,00%	87,38 %	82,90 %	86,22 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 23 DA-B										
Number of values	1	1	1	1	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	12,08	1,16	1,73	1,23	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	12,08	1,16	1,73	1,23	1 >	0 >	0 >	1 >	0 >	0 >
Mean Disease severity (%)	12,08	1,16	1,73	1,23	0 =	1 =	1 =	0 =	1 =	1 =
Mean Abbott efficacy (%)	0,00%	90,40 %	85,68 %	89,82 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against ERYSGR/ERYSGT – South - ~~Eastern~~ East EPPO zone

In the South-~~Eastern~~ East EPPO zone, only two valid trials evaluated the efficacy of CA3301 on triticale against *Blumeria graminis* and were included to support the efficacy evaluation of CA3301 at 0.6-0.8 l/ha applied twice, compared to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 31-32 and the 2nd application was at BBCH 39-43. The analysis was conducted on foliar level 1 and foliar level 2.

Summary results are presented in Table 3.2-519.

In these two valid trials CA3301 at 0.6-0.8 l/ha demonstrated high disease control comparable to that of the reference PRIAXOR. In these conditions of low to medium disease pressure, no significant differences were observed between the two tested dose rates. At all assessments CA3301 applied at the proposed dose rate significantly reduced disease severity compared to the untreated and was comparable to the reference product.

Moreover, a larger dataset has been presented for the closely related crop winter wheat (KCP 6.2.2.4 Winter wheat (TRZAW) / *Blumeria graminis* (ERYSGR-ERYSGT)) in which CA3301 enabled to significantly decrease the disease pressure on leaves in most of trials, compared to the untreated control and whatever the dose rate considered. In this dataset, CA3301 at 0.6-0.8 l/ha provided a control of the disease that was either statistically equivalent or less efficient than the reference product PRIAXOR in a few trials. However in the majority of trials, CA3301, especially at the 0.8 l/ha dose rate, provided higher or equivalent disease control, to the one provided by CA2445, the reference product with the same active substance at a comparable rate. Although the rate of 0.8 l/ha overall reduced disease pressure to a greater extent than the 0.6 l/ha rate, the differences were not always significant. Therefore, in many instances 0.6 l/ha gave sufficient disease control but in conditions of high disease pressure, historical difficulties in control of this disease or where some level of resistance is suspected it may be appropriate to use 0.8 l/ha for control of *Blumeria graminis*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Blumeria graminis* and *Blumeria graminis* f. sp. *tritici* on triticale wheat in the South-~~Eastern~~ East EPPO zone.

Table 3.2-519: Summary table - Efficacy evaluation – Triticale – ERYSGR/ERYSGT – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	PRI-AXOR	CA33 01	CA33 01	No of trials where CA3301			No of trials where CA3301		
Rate		1,5	0,6	0,8	at 0,6 l/ha is >, = or <			at 0,8 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
% Disease severity L2 40-48 DA-B										
Number of values	2	2	2	2	UT C	PRI-AXOR	CA33 01	UT C	PRI-AXOR	CA33 01
Minimum value	11,88	0,00	0,00	0,00		1,5 l/ha	0,8 l/ha		1,5 l/ha	0,6 l/ha
Maximum value	27,00	0,00	0,20	0,26	2 >	0 >	0 >	2 >	0 >	0 >
Mean Disease severity (%)	19,44	0,00	0,10	0,13	0 =	2 =	2 =	0 =	2 =	2 =
Mean Abbott efficacy (%)	0,00%	100,00%	99,63 %	99,52 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 47 DA-B										
Number of values	1	1	1	1	UT C	PRI-AXOR	CA33 01	UT C	PRI-AXOR	CA33 01
Minimum value	11,71	0,26	0,51	0,66		1,5 l/ha	0,8 l/ha		1,5 l/ha	0,6 l/ha
Maximum value	11,71	0,26	0,51	0,66	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	11,71	0,26	0,51	0,66	0 =	1 =	1 =	0 =	1 =	1 =
Mean Abbott efficacy (%)	0,00%	97,78%	95,64 %	94,36 %	0 <	0 <	0 <	0 <	0 <	0 <

> means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against ERYSGR/ERYSGT – Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-Eastern East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, a total of 8 trials evaluated the efficacy of CA3301 on triticale against *Blumeria graminis*. 4 trials out of 8 were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 30-39 and the 2nd application was at BBCH 45-67. Two assessment timings were selected, one two weeks after 2nd application (19 DA-B) and close to harvest (31-44 DA-B).

Summary results are presented in Table 3.2-520.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha on the reduction of disease severity on triticale against *Blumeria graminis*. On foliar level 2, CA3301 at 0.6-0.8 l/ha provided 91.45-93.11% mean efficacy before harvest. On foliar level 1, CA3301 showed 100.00-100.00% efficacy two weeks after the 2nd application and 85.68-89.82% close to harvest. Hence, at the proposed dose rates CA3301 provided high efficacy against *Blumeria graminis*, statistically equivalent to the reference product CA2445 at 0.8 l/ha in all assessment.

In this dataset, with disease severity ranging from relatively low to medium, data demonstrated that at low disease severity CA3301 applied at 0.6 l/ha or at 0.8 l/ha provided comparable efficacy, however as disease progressed there was a numerical benefit derived from increasing the dose rate to 0.8 l/ha.

Therefore, in most instances CA3301 applied at 0.6 l/ha will provide sufficient disease control and in more challenging conditions the 0.8 l/ha dose rate may be more appropriate.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Blumeria graminis* on triticale in Poland.

Table 3.2-520: Summary table - Efficacy evaluation – Triticale – ERYSGR / ERYSGT – Data relevant for Poland

Treatment name	UNTREATED CHECK	CA244 5 0,8 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
% Disease severity L1 - 19 DA-B										
Number of values	1	1	1	1	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	12,19	0,00	0,00	0,00	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	12,19	0,00	0,00	0,00	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	12,19	0,00	0,00	0,00	0 <	0 <	0 <	0 <	0 <	0 <
Mean Abbott efficacy (%)	0,00%	100,00 %	100,00 %	100,00 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 23-31 DA-B										
Number of values	2	2	2	2	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	5,46	0,00	0,00	0,00	2 >	0 >	0 >	2 >	0 >	0 >
Maximum value	25,03	3,16	4,28	3,45	0 =	2 =	2 =	0 =	2 =	2 =
Mean disease severity (%)	15,24	1,58	2,14	1,73	0 <	0 <	0 <	0 <	0 <	0 <
Mean Abbott efficacy (%)	0,00%	93,69 %	91,45 %	93,11 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 23 DA-B										
Number of values	1	1	1	1	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	12,08	1,16	1,73	1,23	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	12,08	1,16	1,73	1,23	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	12,08	1,16	1,73	1,23	0 <	0 <	0 <	0 <	0 <	0 <
Mean Abbott efficacy (%)	0,00%	90,40 %	85,68 %	89,82 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

3 valid trials were carried out in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,6-0,8 l/ha achieved a very high efficacy after 19-42 days after second application. Due to the limited number of trials, the cMSs are kindly asked to consider this use on the national level.

Only 1 valid trial have been submitted in **the North-East EPPO zone**. Also 2 trials from Germany and the Czech Republic have been included to the overall calculation to support of Polish registration. A high level of control was noted after use of the test product at both doses. Moreover, the extrapolation of trial results from winter wheat to winter triticale is possible and this use can be accepted in Poland. The dose rate of 0,8 l/ha can be recommended in case of high disease pressure.

2 valid trials were available in **the South-East EPPO zone**. CA3301 applied at dose rate of 0,6-0,8 l/ha achieved

a very high efficacy after 40-48 DA-B. No additional trials have been submitted from the Mediterranean zone. Due to the limited number of trials, the cMSs are kindly asked to consider this use on the national level.

3.2.3.4 Triticale (TTLWI) / *Fusarium spp* – (FUSASP)

Materials and Methods – Triticale –FUSASP

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

In 2018, a single trial was conducted in Denmark for the Maritime EPPO zone, 1 trial in Poland for the North-Eastern East EPPO zone and 1 trial in Hungary for the South-Eastern East EPPO zones to evaluate the efficacy of CA3301 against *Fusarium spp.* on **triticale**. The trials were carried out by certified testing institutes.

These 3 trials carried out against *Fusarium spp.* (FUSASP) on triticale were considered valid.

No trials were available in this Biological dossier for the Mediterranean EPPO zone.

Table 3.2-521: Presentation of trials – Triticale (TTLWI) / FUSASP

Crop(s) *	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, offi- cial***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Triticale	FUSASP	Denmark	2018	MED + E	1 (1)	-	-	-	GEP	
		Poland	2018	MED + E	-	-	1 (1)	-	GEP	
		Hungary	2018	MED + E	-	-	-	1 (1)	GEP	
TOTAL	-	-	2018	MED + E	1 (1)	-	1 (1)	1 (1)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

In all trials, CA3301 was compared to at least one commercial and registered fungicide used as standard reference for comparison.

Table 3.2-522: Efficacy evaluation - Presentation of reference standards used in trials –Triticale (TTLWI) –FUSASP – Maritime EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
	PRO-LINE 250 EC	DK	18-473	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in trials

Table 3.2-523: Efficacy evaluation - Presentation of reference standards used in trials –Triticale (TTLWI) –FUSASP – North-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
	PRAKTIS	PL	R-222/2019	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445

Table 3.2-524: Efficacy evaluation - Presentation of reference standards used in trials –Triticale (TTLWI) –FUSASP – South-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
	PRO-LINE	HU	6300/1205-1/2020	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445

CA2445 is the code name used in some trials and is the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-525.

Table 3.2-525: Details on trial methodology – Triticale (TTLWI) –FUSASP

		Maritime EPPO zone	North-Eastern EPPO zone	South-Eastern EPPO zone
Trials	Total number (valid number)	1 (1)	1 (1)	1 (1)
	Supportive trials	-	-	-
Guidelines	General guidelines	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)
	Specific guidelines	PP 1/26(4)	PP 1/26(4)	PP 1/26(4)
Experimental design	Plot design	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included

	Plot size	27 m ²	30 m ²	30 m ²
	Number of replications	4	4	4
Crop	Trials per crop	Triticale (1)	Triticale (1)	Triticale (1)
	Varieties per crop	Tantris (1)	Twingo (1)	Borwo (1)
	Sowing period	September (1)	September (1)	October(1)
Application	Crop stage (BBCH)* at application	A: BBCH 39 B: BBCH 65	A: BBCH 39 B: BBCH 67	A: BBCH 39 B: BBCH 65
	Timing Disease stage at application	BBCH 39-65 A: PRINFC (1) B: PRINFC (1)	BBCH 39-67 A: PRINFC (1) B: PRINFC (1)	BBCH 39-65 A: PRINFC (1) B: PRINFC (1)
	Number of applications Intervals between applications	2 applications (19 days) (1)	2 applications (20 days) (1)	2 applications (14 days) (1)
	Spray volumes	200-400 l/ha	300-500 l/ha	500 l/ha
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T/ha), DON (PPB), NIV (PPB)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T/ha), DON (PPB)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T/ha), DON (PPB), NIV (PPB)
	Assessment dates	0 DA-A, 19 DA-A, 0 DA-B, 15 DA-B, 30 DA-B, 63 DA-B	0 DA-A, 7 DA-A, 20 DA-A, 7 DA-B, 23 DA-B, 51 DA-B, 139 DA-B	0 DA-A, 7 DA-A, 12 DA-A, 7 DA-B, 14 DA-B, 30 DA-B, 48 DA-B, 133 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Artificial (1)	Artificial (1)	Artificial (1)
	e.g. Field / Greenhouse...	Field trial	Field trial	Field trial

* BBCH for weeds, pre-emergence, preventive / curative application, insect stage...

The 3 trials carried out against *Fusarium spp.* (FUSASP) on triticale were considered valid.

Considering the limited dataset available on this disease in Maritime, North-Eastern East and South-Eastern East EPPO zones, the argumentation on minimum effective dose of CA3301 for the control against *Fusarium spp.* on triticale was based also on data presented on winter wheat.

Use of CA3301 at 2x 0.6 and 0.8 l/ha against FUSASP – Maritime EPPO zone

In the Maritime EPPO zone, a single valid trial evaluated the efficacy of CA3301 on triticale against *Fusarium spp.* and determined the efficacy of CA3301 at 0.6-0.8 l/ha, and to compare it to the reference product on disease severity on ears (%). This trial was inoculated with *Fusarium spp.* and CA3301 was first applied at crop stages BBCH 39 and at last at BBCH 65. In this trial it was possible to determine the efficacy on inoculated ears (Ears I) and not inoculated (Ears NI). Two assessments were performed

on inoculated ears in this trial 15 DA-B, 30 DA-B and at harvest (63 DA-B) were assessed the non-inoculated ears.

Summary results are presented in Table 3.2-526.

Data demonstrated the positive effect of CA3301 at 0.6-0.8 l/ha on the reduction of disease severity on triticale against *Fusarium spp.* On inoculated ears, CA3301 at 0.6-0.8 l/ha showed 94.54-90.30% of efficacy against *Fusarium spp.* 15 days after the 2nd application and 85.39-67.34% 30 days after the 2nd application. On non-inoculated ears, a numerical higher disease control was observed for CA3301 at 0.6 l/ha.

Overall, CA3301 at 0.6-0.8 l/ha provided medium to high disease control against *Fusarium spp.* and was statistically equivalent to the reference product CA2445 applied at 0.8 l/ha. In addition, over the dataset available on winter wheat, the tested product demonstrated the same trend as that for the related species *Fusarium culmorum* and *Fusarium graminearum* whereby in conditions of higher disease severity CA3301 applied at 0.8 l/ha is more effective compared to the rate of 0.6 l/ha, but at lower disease pressure, both rates can give effective control comparable to the reference standard. Furthermore the test product was demonstrated to give comparable efficacy to the authorised reference products. Therefore, in many instances 0.6 l/ha gave sufficient disease control but in conditions of high disease pressure, historical difficulties in control of this disease it may be appropriate to use 0.8 l/ha.

Considering all elements presented above, it is justified to claim the registration of CA3301 at 0.6-0.8 l/ha to control *Fusarium spp.* on triticale in the Maritime EPPO zone.

Table 3.2-526: Summary table - Efficacy evaluation – Triticale – FUSASP – Maritime EPPO zone

Table 3.2-32b: Summary table - Efficacy evaluation – FUSARI – FUSARI – Maritime LA FIO zone										
Treatment name	UNTREATED CHECK	CA24 45	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		0,8	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Disease severity Ears I - 15 DA-B										
Number of values	1	1	1	1	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	26,19	1,66	1,43	2,54	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	26,19	1,66	1,43	2,54	1 >	0 >	0 >	1 >	0 >	0 >
Mean Disease severity (%)	26,19	1,66	1,43	2,54	0 =	1 =	1 =	0 =	1 =	1 =
Mean Abbott efficacy (%)	0,00%	93,66 %	94,54 %	90,30 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity Ears I - 30 DA-B										
Number of values	1	1	1	1	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	80,00	16,19	11,69	26,13	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	80,00	16,19	11,69	26,13	1 >	0 >	0 >	1 >	0 >	0 >
Mean Disease severity (%)	80,00	16,19	11,69	26,13	0 =	1 =	1 =	0 =	1 =	1 =
Mean Abbott efficacy (%)	0,00%	79,76 %	85,39 %	67,34 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity Ears NI - 63 DA-B										
Number of values	1	1	1	1	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	16,46	5,98	5,85	8,09	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	16,46	5,98	5,85	8,09	1 >	0 >	0 >	1 >	0 >	0 >
Mean Disease severity (%)	16,46	5,98	5,85	8,09	0 =	1 =	1 =	0 =	1 =	1 =
Mean Abbott efficacy (%)	0,00%	63,67 %	64,46 %	50,85 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 and 0.8 l/ha against FUSASP - Mediterranean EPPO zone

In the Mediterranean, no data were available to support the minimum effective dose of CA3301 against *Fusarium spp* on triticale due to lack of disease infestation in the trials. However, the specie *Fusarium spp* is also a pathogen agent present on wheat. It therefore seems reasonable from an agronomic perspective to assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on triticale from the robust dataset proposed for the closely related crop winter wheat. Furthermore, existing authorisations for prothioconazole products have the same dose rate for this pathogen in both winter wheat and in triticale, which also indicates that performance is comparable between the pathogen/crop pairs.

Over the dataset available on winter wheat, the tested product demonstrated the same trend as that for the related species *Fusarium culmorum* and *Fusarium graminearum* whereby in conditions of higher disease severity CA3301 applied at 0.8 l/ha is more effective compared to the rate of 0.6 l/ha, but at lower disease pressure, both rates can give effective control comparable to the reference standard. Furthermore the test product was demonstrated to give comparable efficacy to the authorised reference products. Therefore, in many instances 0.6 l/ha gave sufficient disease control but in conditions of high disease pressure, historical difficulties in control of this disease it may be appropriate to use 0.8 l/ha.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Fusarium spp.* on triticale in the Mediterranean EPPO zone.

Use of CA3301 at 2x 0.6 and 0.8 l/ha against FUSASP – North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a single trial in Poland evaluated the efficacy of CA3301 at 0.6-0.8 l/ha (applied twice) on triticale against *Fusarium spp* and compare it to the reference product on disease severity on inoculated ears (%). CA3301 was first applied at crop stages BBCH 39 and the 2nd application was at BBCH 67. The inoculation was done two days after each application. Only one assessment was available in this trial on inoculated ears three weeks after 2nd application (23 DA-B).

Summary results are presented in Table 3.2-527.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha with artificial inoculation on the reduction of disease severity on triticale against *Fusarium spp*. On inoculated ears, CA3301 at 0.6-0.8 l/ha provided 72.22-82.38% of efficacy three weeks after the 2nd application which was statistically equivalent to the reference standard CA2445 at 0.8 l/ha. In this trial, both dose rate were statistically equivalent but a numerical trend appeared where disease control increases with the dose rate. In addition, over the dataset available on winter wheat, the tested product demonstrated the same trend as that for the related species *Fusarium culmorum* and *Fusarium graminearum* whereby in conditions of higher disease severity CA3301 applied at 0.8 l/ha is more effective compared to the rate of 0.6 l/ha, but at lower disease pressure, both rates can give effective control comparable to the reference standard. Furthermore the test product was demonstrated to give comparable efficacy to the authorised reference products. Therefore, in many instances 0.6 l/ha gave sufficient disease control but in conditions of high disease pressure, historical difficulties in control of this disease it may be appropriate to use 0.8 l/ha. Therefore, in many instances 0.6 l/ha gave sufficient disease control but in conditions of high disease pressure, historical difficulties in control of this disease it may be appropriate to use 0.8 l/ha.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Fusarium spp.* on triticale in the North-Eastern East EPPO zone.

Table 3.2-527: Summary table - Efficacy evaluation – Triticale – FUSASP – North-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA24 45	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		0,8	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Disease severity Ear I - 23 DA-B										
Number of values	1	1	1	1	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	19,18	3,93	4,37	3,38	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	19,18	3,93	4,37	3,38	1 >	0 >	0 >	1 >	0 >	0 >
Mean Disease severity (%)	19,18	3,93	4,37	3,38	0 =	1 =	1 =	0 =	1 =	1 =
Mean Abbott efficacy (%)	0,00%	79,51 %	77,22 %	82,38 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 and 0.8 l/ha against FUSASP – South-Eastern East EPPO zone

In the South-Eastern East EPPO zone, evaluated the efficacy of CA3301 at 0.6-0.8 l/ha (applied twice) on triticale against *Fusarium spp.* and compare it to the reference product on disease severity on inoculated ears (%). This trial was inoculated two time with *Fusarium spp.* two days after each application. CA3301 was first applied at crop stages BBCH 39 and the 2nd application was at BBCH 65.

Summary results are presented in Table 3.2-528.

Data demonstrated the positive effect of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity against *Fusarium spp.* On inoculated ears, CA3301 at 0.6-0.8 l/ha showed 72.24-54.23% of efficacy against *Fusarium spp.* 14 days after the application. CA3301 at 0.8 l/ha was statistically equivalent to the reference CA2445 applied at the same dose rate and CA3301 at 0.6 l/ha was less efficient.

In addition to a single trial presented above, it is possible to demonstrate the efficacy of CA3301 referring to the data presented on winter wheat (see KCP 6.2.2.4 Winter wheat (TRZAW) / *Fusarium sp.* FUSASP). In the South-Eastern East EPPO zone a limited dataset is available for assessment of undetermined *Fusarium* species. Nevertheless, the data demonstrates the same trend as that for the related species *Fusarium culmorum* and *Fusarium graminearum* whereby in conditions of higher disease severity CA3301 applied at 0.8 l/ha is more effective compared to the rate of 0.6 l/ha, but at lower disease pressure both rates can give effective control comparable to the reference standard.

Considering all elements presented above, it is justified to claim the registration of CA3301 at 0.6-0.8 l/ha to control *Fusarium spp.* on triticale in the South-Eastern East EPPO zone.

Table 3.2-528: Summary table - Efficacy evaluation – Triticale – FUSASP – South-Eastern East EPPO zone

Treatment name	UNTREATED CHECK	CA244 5 0,8	CA330 1 0,6	CA330 1 0,8	No of trials where CA3301 at 0,6 l/ha is >, = or <		No of trials where CA3301	
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Rate unit		L/ha	L/ha	L/ha							at 0,8 l/ha is >, = or <
Appl. Code		AB	AB	AB		compared to					compared to
% Disease severity Ear I - 14 DA-B											
Number of values	1	1	1	1	UT	CA244	CA330	UT	CA244	CA330	
					C	5	1	C	5	1	
Minimum value	19,27	3,35	8,82	5,35		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha	
Maximum value	19,27	3,35	8,82	5,35	1 >	0 >	0 >	1 >	0 >	1 >	
Disease severity (%)	19,27	3,35	8,82	5,35	0 =	0 =	0 =	0 =	1 =	0 =	
Mean Abbott efficacy (%)	0,00%	82,62 %	54,23 %	72,24 %	0 <	1 <	1 <	0 <	0 <	0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

1 valid trial was carried out in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,6 l/ha achieved medium to high efficacy after 15-63 days after second application. Also the effectiveness at dose rate of 0,8 l/ha was varied and the highest result was achieved 15 days after second application (90,3%). Due to the limited number of trials, the cMSs are kindly asked to consider this use on the national level.

Only 1 valid trial have been submitted in **the North-East EPPO zone**. CA3301 applied at dose rate of 0,6 l/ha achieved medium level of control. The use of 0,8 l/ha caused increase of efficacy to high level. The extrapolation of trial results from winter wheat to winter triticale is possible and this use can be accepted in Poland. It should be noted that the test product was effective on the medium level in control of FUSASP in winter wheat in the NE. The dose rate of 0,8 l/ha can be recommended in case of high disease pressure.

1 valid trials was available in **the South-East EPPO zone**. CA3301 applied at dose rate of 0,6 l/ha achieved a low efficacy and the dose of 0,8 l/ha was effective on medium level after 14 DA-B. No additional trials have been submitted from the Mediterranean zone. Due to the limited number of trials, the cMSs are kindly asked to consider this use on the national level.

3.2.3.5 Triticale (TTLWI) / *Fusarium culmorum* – (FUSACU)

Materials and Methods – Triticale – FUSACU

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2017 and 2018, one trial was conducted in the Czech Republic for the Maritime EPPO zone, one in Portugal for the Mediterranean EPPO zone and one trial was performed in Poland for the North-Eastern ~~East~~ EPPO zone to evaluate the efficacy of CA3301 against *Fusarium culmorum* on **triticale**. The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, 1 trial was performed in the Czech Republic

In the Mediterranean EPPO zone, 1 trial was performed in Portugal.

In the North-eastern ~~East~~ EPPO zone, 1 trial was performed in Poland.

No trials were available in this Biological dossier for the South-Eastern ~~East~~ EPPO zone specifically for *Fusarium culmorum* but data on *Fusarium* spp is presented in the preceding section.

Two trials out of those three trials were considered as valid to evaluate the CA3301 efficacy.

Table 3.2-529: Presentation of trials – Triticale (TTLWI) / FUSACU

Crop(s) *	Target(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Maritime zone	Mediterranean zone	North-East- ern zone	South-East- ern zone		
Triticale	FUSACU	Czech Republic	2018	MED + E	1 (1)				GEP	
Triticale	FUSACU	Portugal	2018	MED + E	-	1 (0)	-	-	GEP	
		Poland	2017	MED + E	-	-	1 (1)	-	GEP	
TOTAL	-	-	2017-2018	MED + E	1 (1)	1 (0)	1 (1)	-	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation

In all trials, CA3301 was compared to at least one commercial and registered fungicide used as standard reference for comparison.

Table 3.2-530: Efficacy evaluation - Presentation of reference standards used in trials –Triticale (TTLWI) – FUSACU – Maritime EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Triticale	CA2445	CZ	Not registered in CZ	Prothioconazole	EC	250 g/l		2 x 0.8 l/ha	

Table 3.2-531: Efficacy evaluation - Presentation of reference standards used in trials –Triticale (TTLWI) – FUSACU – Mediterranean EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
	CA2445	PT	NA	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	

Table 3.2-532: Efficacy evaluation - Presentation of reference standards used in trials –Triticale (TTLWI) – FUSACU – North-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
	CA2445	PL	N/A	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	

CA2445 is the code name used in some trials and is the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-533.

Table 3.2-533: Details on trial methodology – Triticale (TTLWI) – FUSACU

		Maritime EPPO zone	Mediterranean EPPO zone	North-Eastern EPPO zone	South-Eastern EPPO zone
Trials	Total number (valid number)	1 (1)	1 (0)	1 (1)	No trial available on this EPPO zone
	Supportive trials	-	-	-	
Guidelines	General guidelines	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	
	Specific guidelines	PP 1/26(4)	PP 1/26(4)	PP 1/26(4)	
Experimental design	Plot design	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included	
	Plot size	30 m ²	30 m ²	21 m ²	
	Number of replications	4	4	4	
October (1)	Trials per crop	Triticale (1)	Triticale (1)	Triticale (1)	
	Varieties per crop	Talentro (1)	Fronteira (1)	Fidelio (1)	
	Sowing period	September (1)	November (1)	N/A (1)	
Application	Crop stage (BBCH)* at application	A: BBCH 37 B: BBCH 65	A: BBCH 39 B: BBCH 61	A: BBCH 37 B: BBCH 59	
	Timing Disease stage at application	BBCH 37-65 A: PRINFC (1), MIXED (1) B: PRINFC (1), MIXED (1)	BBCH 39-61 A: PRINFC (1) B: MIXED (1)	BBCH 37-59 A: PRINFC (1) B: PRINFC (1)	
	Number of applications Intervals between applications	2 applications (19 days) (1)	2 applications (19 days) (1)	2 applications (10 days) (1)	
	Spray volumes	300-500 l/ha	250 l/ha	300 l/ha	

Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (t/ha), DON (PPB), NIV (PPB)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (t/ha)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (t/ha)	
	Assessment dates	0 DA-A, 11 DA-A, 0 DA-B, 28 DA-B, 61 DA-B, 64 DA-B, 139 DA-B	0 DA-A, 14 DA-A, 18 DA-A, 0 DA-B, 15 DA-B, 21 DA-B, 25 DA-B, 29 DA-B	0 DA-A, 4 DA-C, 25 DA-B, 44 DA-B	
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant	
	e.g. Natural / artificial inoculation...	Natural (1) / Artificial (1)	Natural (1)	Natural (1)	
	e.g. Field / Greenhouse...	Field trials	Field trials	Field trials	

* BBCH for weeds, pre-emergence, preventive / curative application, insect stage...

Two trials out of three against *Fusarium culmorum* were considered as valid.

Use of CA3301 at 2x 0.6 and 0.8 l/ha against FUSACU– Maritime EPPO zone

In the Maritime EPPO zone, a single trial evaluated the efficacy of CA3301 at 0.8 l/ha and 0.6 l/ha on triticale against *Fusarium culmorum* on inoculated ears. CA3301 was applied twice, the first application at crop stage BBCH 37 and the 2nd application was done at crop stage BBCH 65. In this trial the infected ears were evaluated four weeks after 2nd application.

Summary results are presented in Table 3.2-534.

When evaluating the reduction of disease severity, the data demonstrated the medium to high fungicidal effect to control *Fusarium culmorum* on inoculated ears provided by CA3301 at 0.8 l/ha that was equivalent to the standard CA2445 at 0.8 l/ha. CA3301 at 0.6 l/ha provided medium efficacy against *Fusarium culmorum* while CA3301 at 0.8 l/ha provided high efficacy and both dose rates were statistically equivalent to the reference CA2445 applied at 0.8 l/ha. CA3301 at 0.8 l/ha appeared numerically more efficient than CA3301 at 0.6 l/ha and CA2445 at 0.8 l/ha. On inoculated ears, CA3301 at 0.6-0.8 l/ha showed 68.09-80.14% efficacy against *Fusarium culmorum* 4 weeks after the 2nd application.

Moreover, a larger dataset was presented on the closely related crop winter wheat which demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity against *Fusarium culmorum* (see Winter wheat (TRZAW) / *Fusarium culmorum* (FUSACU)). Data demonstrated that at low disease severity CA3301 applied at 0.6 l/ha or at 0.8 l/ha provided comparable efficacy, however as disease progressed there was a significant benefit derived from increasing the dose rate to 0.8 l/ha. Therefore, in many instances 0.6 l/ha gave sufficient disease control but in conditions of high disease pressure, historical difficulties in control of this disease or where some level of resistance is suspected it may be appropriate to use 0.8 l/ha.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Fusarium culmorum* on triticale in the Maritime EPPO zone.

Table 3.2-534: Summary table - Efficacy evaluation – Triticale – FUSACU – Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA24 45 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
% Disease severity Ears I - 28 DA-B						
Number of values	1	1	1	1	UT 45 C 0,8 l/ha	UT 01 C 0,8 l/ha
Minimum value	14,10	5,10	4,50	2,80	1 >	1 >
Maximum value	14,10	5,10	4,50	2,80	0 >	0 >
Mean disease severity (%)	14,10	5,10	4,50	2,80	0 =	0 =
Abbott efficacy (%)	0,00%	63,83 %	68,09 %	80,14 %	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 and 0.8 l/ha against FUSACU – North-Eastern East EPPO zone

In the North-Eastern East EPPO zone, a single trial evaluated the efficacy of CA3301 at 0.8 l/ha and 0.6 l/ha on triticale against *Fusarium culmorum* on infected not inoculated ears. CA3301 was applied twice, the first application at crop stage BBCH 37 and the 2nd application was done at crop stage BBCH 59. In this trial the infected ears were evaluated three weeks after 2nd application and close to harvest (25 DA-B and 44 DA-B).

Summary results are presented in Table 3.2-535.

When evaluating the reduction of disease severity, the data demonstrated the moderate-high fungicidal effect to control *Fusarium culmorum* on non-inoculated ears provided by CA3301 at 0.8 l/ha that was equivalent to the standard CA2445 at 0.8 l/ha. CA3301 at 0.6 l/ha provided medium efficacy against *Fusarium culmorum* and was statistically equivalent to the reference CA2445 applied at 0.8 l/ha. On non-inoculated ears, CA3301 at 0.6-0.8 l/ha showed 72.86-80.45% mean efficacy against *Fusarium culmorum* around 3 weeks after the 2nd application and 63.53-65.79% close to harvest.

Moreover, a larger dataset was presented on the closely related crop winter wheat which demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity against *Fusarium culmorum* (see KCP 6.2.2.2 Winter wheat (TRZAW) / *Fusarium culmorum* (FUSACU)). Data demonstrated that at low disease severity CA3301 applied at 0.6 l/ha or at 0.8 l/ha provided comparable efficacy, however as disease progressed there was a significant benefit derived from increasing the dose rate to 0.8 l/ha. This was particularly apparent at the second assessment of ears inoculated where in 3 trials at disease severity of 58.23-71.35% a statistical difference was recorded between the 2 dose rates. Therefore, in many instances 0.6 l/ha gave sufficient disease control but in conditions of high disease pressure, historical difficulties in control of this disease or where some level of resistance is suspected it may be appropriate to use 0.8 l/ha.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Fusarium culmorum* on triticale in the North-Eastern East EPPO zone.

Table 3.2-535: Summary table - Efficacy evaluation – Triticale – FUSACU – North-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA24 45 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
% Disease severity Ears NI- 25 DA-B						
Number of values	1	1	1	1	UT CA24 45 C 0,8 l/ha	UT CA24 45 C 0,8 l/ha
Minimum value	6,19	1,15	1,68	1,21	1 >	1 >
Maximum value	6,19	1,15	1,68	1,21	0 =	0 =
Mean Disease severity (%)	6,19	1,15	1,68	1,21	0 <	0 <
Mean Abbott efficacy (%)	0,00%	81,42 %	72,86 %	80,45 %	0 <	0 <
% Disease severity Ears NI- 44 DA-B						
Number of values	1	1	1	1	UT CA24 45 C 0,8 l/ha	UT CA24 45 C 0,8 l/ha
Minimum value	16,81	4,94	6,13	5,75	1 >	1 >
Maximum value	16,81	4,94	6,13	5,75	0 =	0 =
Mean Disease severity (%)	16,81	4,94	6,13	5,75	0 <	0 <
Mean Abbott efficacy (%)	0,00%	70,61 %	63,53 %	65,79 %	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 and 0.8 l/ha against FUSACU - All other EPPO zones

In the Mediterranean, and South-East EPPO zones, no data were available to support the efficacy evaluation of CA3301 against *Fusarium culmorum* on triticale due to lack of disease infestation in the trials. However, the specie *Fusarium culmorum* is also a pathogen agent present on wheat. It therefore seems reasonable from an agronomic perspective to assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on triticale from the robust dataset proposed for the closely related crop winter wheat. Furthermore, existing authorisations for prothioconazole products have the same dose rate for this pathogen in both winter wheat and in triticale, which also indicates that performance is comparable between the pathogen/crop pairs.

The dataset presented in - Winter wheat (TRZAW) / *Fusarium culmorum* – showed that CA3301 applied at 0.6-0.8 l/ha provided significant disease control against this fusarium species. Both dose rates gave equivalent disease control to the reference product CA2445 at 0.8 l/ha. Moreover, the level of disease control observed was medium to high with differences that were sometimes significant. Overall, a numerical trend appeared where CA3301 at 0.8 l/ha provided higher efficacy than 0.6 l/ha, particularly in case of high disease pressure.

Finally, since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.8 l/ha generally gave adequate disease control, it is supposed that the same dose range will be acceptable to control *Fusarium culmorum* on triticale in all other EPPO zones.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Fusarium culmorum* on triticale in all other EPPO zones.

Comments of zRMS:

1 valid trial was carried out in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,6 l/ha achieved medium efficacy after 28 days after second application. The use of 0,8 l/ha caused increase of effectiveness to high level. Due to the limited number of trials, the cMSs are kindly asked to consider this use on the national level.

Only 1 valid trial have been submitted in **the North-East EPPO zone**. CA3301 applied at dose rate of 0,6 l/ha achieved medium level of control. The use of 0,8 l/ha caused increase of efficacy to high level after 25 DA-B. The extrapolation of trial results from winter wheat to winter triticale is possible and this use can be accepted in Poland. It should be noted that the test product was effective on the medium level in control of FUSACU in winter wheat in the NE. The dose rate of 0,8 l/ha can be recommended in case of high disease pressure.

No dataset was available in **the South-East EPPO zone**. Also no additional trials have been submitted from the Mediterranean zone. The cMSs are kindly asked to consider this use on the national level.

3.2.3.6 Triticale (TTLWI) / *Puccinia recondita* – (PUCCRE)

Materials and Methods – Triticale – PUCCRE

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2017 and 2018, five trials were conducted between Maritime, North-Eastern East and South-Eastern East EPPO zones to evaluate the efficacy of CA3301 against *Puccinia recondita* on triticale. The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, 2 trials were performed in Czech and Denmark.

In the North-Eastern East EPPO zone, 1 trial was performed in Poland.

In the South-Eastern EPPO zone, 2 trials were performed in Hungary.

No valid trials were available in for the Mediterranean, North-Eastern and South-Eastern EPPO zone.

Out of these trials to evaluate the CA3301 efficacy against *Puccinia recondita* (PUCCRE) on triticale, 2 were considered valid (see Table 3.2-536):

Table 3.2-536: Presentation of trials – Triticale (TTLWI) / PUCCRE

Crop(s) *	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, offi- cial***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Triticale	PUCCRE	Czech Republic	2018	MED + E	1 (1)	-	-	-	GEP	
		Denmark	2018	MED + E	1 (1)	-	-	-	GEP	
		Poland	2018	MED + E	-	-	1 (0)		GEP	
		Hungary	2017-2018	MED + E	-	-	-	2 (0)	GEP	
TOTAL	-	-	2017-2018	MED + E	2 (2)	-	1 (0)	2 (0)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-

emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation

In all trials, CA3301 was compared to at least one commercial and registered fungicide used as standard reference for comparison.

Table 3.2-537: Efficacy evaluation - Presentation of reference standards used in trials –Triticale (TTLWI) – PUCCRE – Maritime EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Triticale	PRO-LINE	DE	025287-00	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in trials
	CA2445	CZ	Not registered in CZ	Prothioconazole	EC	250 g/l		2 x 0.8 l/ha	

Table 3.2-538: Efficacy evaluation - Presentation of reference standards used in trials –Triticale (TTLWI) – PUCCRE – North-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Triticale	PRAKTIS	PL	R-222/2019	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha 3 x 0.8 l/ha	CA2445 in trials

Table 3.2-539: Efficacy evaluation - Presentation of reference standards used in trials –Triticale (TTLWI) – PUCCRE – South-Eastern East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Triticale	PRO-LINE	HU	6300/1205-1/2020	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in trials

CA2445 is the code name used in some trials and is the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-540.

Table 3.2-540: Details on trial methodology – Triticale (TTLWI) – PUCCRE

		Maritime EPPO zone	Mediterranean EPPO zone	North-Eastern EPPO zone	South-Eastern EPPO zone
Trials	Total number (valid number)	2 (2)	No trials in this EPPO zone for this pest	1 (0)	2 (0)
	Supportive trials	-	-		-
Guidelines	General	PP 1/135(4)		PP 1/135(4)	PP 1/135(4)

	guidelines	PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)		PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)
	Specific guidelines	PP 1/26(4)		PP 1/26(4)	PP 1/26(4)
Experimental design	Plot design	Randomized complete blocks, Untreated included		Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included
	Plot size	27-30 m ²		27 m ²	30 m ²
	Number of replications	4		4	4
Crop	Trials per crop	Triticale (2)		Triticale (1)	Triticale (2)
	Varieties per crop	Claudius (1), Tantris (1)		Pizarro (1)	Borwo (1), GK Szemes (1)
	Sowing period	September (1), October (1),		September (1)	October (2)
Application	Crop stage (BBCH)* at application	A: BBCH 32-39 B: BBCH 59-65		A: BBCH 32 B: BBCH 61	A: BBCH 33-39 B: BBCH 61-65
	Timing Disease stage at application	BBCH 32-65 A: PRINFC (1), N/A (1) B: PRINFC (1), N/A (1)		BBCH 32-61 A: MYCELY (1) B: MYCELY (1)	BBCH 33-65 A: MYCELI (1), N/A (1) B: MIXED (1), N/A (1)
	Number of applications Intervals between applications	2 applications (19-20 days) (2)		2 applications (24 days) (1)	2 applications (14-24 days) (2)
	Spray volumes	200-400 l/ha		300 l/ha	250 - 500 l/ha
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T/HA)		Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T/HA)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T/HA)
	Assessment dates	0 DA-A, 15 DA-A, 19-20 DA-A, 0 DA-B, 14-15 DA-B, 30-31 DA-B		0 DA-A, 14 DA-A, 24 DA-A, 0 DA-B, 15 DA-B, 31 DA-B	0 DA-A, 7 DA-A, 12-16 DA-A, 21-22 DA-A, 7 DA-B, 14-19 DA-B, 27 DA-B, 55 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant		Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Natural (2)		Natural (1)	Natural (2)
	e.g. Field / Greenhouse...	Field trials		Field trials	Field trials

* BBCH for weeds, pre-emergence, preventive / curative application, insect stage...

Out of the 5 trials performed on triticale against *Puccinia recondita*, only 2 trials were considered as valid.

Use of CA3301 at 2x 0.6 and 0.8 l/ha against PUCCRE – Maritime EPPO zone

In the Maritime EPPO zone, only two valid trials were available against *Puccinia recondita* (PUCCRE), on triticale and were included to support the efficacy evaluation of CA3301 at 0.6-0.8 l/ha applied twice, compared to the reference product on disease severity (%). CA3301 was first applied at crop stages BBCH 32-39 and the 2nd application was at BBCH 59-65. The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.8 l/ha.

Summary results are presented in Table 3.2-541.

This limited dataset demonstrated the good efficacy level of CA3301 at 0.6-0.8 l/ha applied twice for the control of *Puccinia recondita* on triticale on foliar levels 2 and 1. Indeed, three weeks after 2nd application CA3301 at 0.6 l/ha showed 88.01% on foliar level 2 and 97.76% on foliar level 1. In the same assessment timing CA3301 at 0.8 l/ha achieved 95.21% on foliar level 2 and 92.43% on foliar level 1. In these trials, CA3301 at 0.6-0.8 l/ha provided high efficacy in disease reduction and was statistically equivalent to reference standard CA2445 applied at 0.8 l/ha. No statistical differences were observed between the tested dose rates.

In addition to this limited dataset, a larger dataset has been presented on the closely related crop winter wheat in which CA3301 at 0.6-0.8 l/ha showed low to high disease control (see KCP 6.2.2.2 Winter wheat (TRZAW) / *Puccinia recondita* – *Puccinia tritica* (PUCCRE-PUCCRT)). In these trials CA3301 at 0.6 l/ha and 0.8 l/ha were most of the time statistically equivalent to the standard reference CA2445 and although differences were not significant, a benefit in disease control was derived from increasing the dose rate from 0.6 l/ha to 0.8 l/ha. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for control of brown rust, however when conditions are conducive to heavy disease infestation the rate of 0.8 l/ha may be beneficial to further reduce disease incidence.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Puccinia recondita* on triticale in the Maritime EPPO zone.

Table 3.2-541: Summary table - Efficacy evaluation – Triticale –PUCCRE- Maritime EPPO zone

Table 5/2-5/17 Summary table Efficacy evaluation Product T0000E Marketing L1/L2 zone										
Treatment name	UNTREATED CHECK	CA24 45	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		0,8	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Disease severity L2 30-31 DA-B										
Number of values	2	2	2	2	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	8,96	0,31	0,13	0,19	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	10,69	2,61	2,04	0,70	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	9,83	1,46	1,08	0,44	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	83,99 %	88,01 %	95,21 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 -30 DA-B										
Number of values	1	1	1	1	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	5,81	0,25	0,13	0,44	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	5,81	0,25	0,13	0,44	1 >	0 >	0 >	1 >	0 >	0 >
Disease severity (%)	5,81	0,25	0,13	0,44	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	95,70 %	97,76 %	92,43 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 and 0.8 l/ha against PUCCRE - All other EPPO zones

In the North-East~~ern~~ EPPO zone, a single trial was conducted to assess the control of brown rust on triticale by CA3301 but it was not valid due to lack of disease infestation. In the Mediterranean and South-East~~ern~~ EPPO zone, no data were available to support the efficacy evaluation of CA3301 against *Puccinia recondita* on triticale. However, the species *Puccinia recondita* is also the causal agent of brown rust on wheat. It therefore seems reasonable from an agronomic perspective to assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on triticale from the robust dataset proposed for the closely related crop winter wheat. Furthermore, existing authorisations for prothioconazole products have the same dose rate for this pathogen in both winter wheat and in triticale, which also indicates that performance is comparable between the pathogen/crop pairs.

The dataset presented in – Winter wheat (TRZAW) / *Puccinia recondita* – *Puccinia triticina* (PUCCRE-PUCCRT)– showed that CA3301 applied at 0.6-0.8 l/ha provided significant disease control in the two main assessment timings. Both dose rates were in most instances equivalent to the references CA2445 at 0.8 l/ha and OSIRIS 65 EC applied at 2.0 l/ha. Moreover, the level of disease control observed was medium to high depending on the disease pressure. Indeed, whereas differences were not always significant, a numerical trend appeared where CA3301 at 0.8 l/ha provided higher efficacy than 0.6 l/ha dose in the most challenging conditions. Since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.8 l/ha generally gave adequate disease control, it is supposed that the same dose range will be acceptable to control brown rust on triticale in all EPPO zone.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Puccinia recondita* on triticale in all other EPPO zones.

Comments of zRMS:

2 valid trials were carried out in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,6-0,8 l/ha achieved high efficacy after 30-31 days after second application. Due to the limited number of trials, the cMSs are kindly asked to consider this use on the national level.

No valid trials have been submitted in **the North-East EPPO zone**. However, 1 trial from the Czech Republic can be use as support of Polish registration. Because an extrapolation from winter wheat to winter triticale is possible, this use can be accepted in Poland.

No dataset was available in **the South-East EPPO zone**. Also no additional trials have been submitted from the Mediterranean zone. The cMSs are kindly asked to consider this use on the national level.

3.2.3.7 Triticale (TTLWI) / *Puccinia striiformis* – *Puccinia striiformis* f. sp. *tritici* (PUCCST-PUCCSI)

Materials and Methods – Triticale – PUCCST/PUCCSI

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2018 and 2020 three trials were performed, one in the Czech Republic and one in Germany for the Maritime EPPO zone and one in Portugal for the Mediterranean EPPO zone to evaluate the efficacy

of CA3301 against *Puccinia striiformis* on **triticale**. The trials were carried out by certified testing institutes.

Two trials out of the three that were conducted to evaluate the CA3301 efficacy against *Puccinia striiformis* (PUCCST-PUCCSI) on triticale, were considered as valid (see Table 3.2-542):

Table 3.2-542: Presentation of trials – Triticale (TTLWI) / PUCCST-PUCCSI

Crop(s) *	Tar- get(s)*	Country	Year s	Type of trial*	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Triticale	PUCCSI	Czech Republic	2018	MED + E	1 (1)					
	PUCCST	Germany	2020	MED + E	1 (0)	-	-	-	GEP	
		Portugal	2018	MED + E	-	1 (1)	-	-	GEP	
TOTAL	-	-	2018 2020	MED + E	2 (1)	1 (1)	-	-	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation

Table 3.2-543: Efficacy evaluation - Presentation of reference standards used in trials –Triticale (TTLWI) – PUCCST/PUCCSI – Maritime EPPO zone

Crop(s))	Refer- ence standard	Coun- try(ies) where the product is used ⁽¹⁾	Authoriza- tion number	Active sub- stance(s)	Formulation		Regis- tered ap- plication rate ⁽³⁾	Applica- tion rate in tri- als (per treat- ment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concentra- tion of a.s.			
Triti- cale	PRO- LINE	DE	025287-00	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in trials
	CA2445	CZ	Not regis- tered in CZ	Prothiocona- zole	EC	250 g/l		2 x 0.8 l/ha	

Table 3.2-544: Efficacy evaluation - Presentation of reference standards used in trials –Triticale (TTLWI) – PUCCST/PUCCSI – Mediterranean EPPO zone

Crop(s))	Refer- ence standard	Coun- try(ies) where the product is used ⁽¹⁾	Authoriza- tion number	Active sub- stance(s)	Formulation		Regis- tered ap- plication rate ⁽³⁾	Applica- tion rate in tri- als (per treat- ment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concentra- tion of a.s.			
Triti- cale	CA2445	PT	NA	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	

CA2445 is the code name used in some trials and is the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-545.

Table 3.2-545: Details on trial methodology – Triticale (TTLWI) – Puccst/Puccsi

		Maritime EPPO zone	Mediterranean EPPO zone	North-Eastern EPPO zone	South-Eastern EPPO zone
Trials	Total number (valid number)	2 (1)	1 (1)	No trials in this EPPO zone for this pest	No trials in this EPPO zone for this pest
	Supportive trials	-	-		
Guidelines	General guidelines	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)		
	Specific guidelines	PP 1/26(4)	PP 1/26(4)		
Experimental design	Plot design	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included		
	Plot size	21-30 m ²	30 m ²		
	Number of replications	4	4		
Crop	Trials per crop	Triticale (1)	Triticale (1)		
	Varieties per crop	Talenro (2)	Fronteira (1)		
	Sowing period	September (1), October (1),	November (1)		
Application	Crop stage (BBCH)* at application	A: BBCH 31-37 B: BBCH 49-65	A: BBCH 39 B: BBCH 59		
	Timing Disease stage at application	BBCH 31-65 A: PRINFC (2), MIXED (1) B: PRINFC (2), MIXED (1)	BBCH 39-59 A: MIXED (1) B: MIXED (1)		
	Number of applications Intervals between applications	2 applications (19 days) (2)	2 applications (13 days) (1)		
	Spray volumes	200-500 l/ha	208 l/ha		
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (t/ha), DON (PPB), NIV (PPB)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (t/ha)		
	Assessment dates	0 DA-A, 19 DA-A, 0 DA-B, 28 DA-B, 61 DA-B, 64 DA-B, 139	0 DA-A, 14 DA-A, 24 DA-A, 0 DA-B, 15 DA-B, 31 DA-B		

		DA-B			
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant		
	e.g. Natural / artificial inoculation...	Natural (2) / Artificial (1)	Natural (1)		
	e.g. Field / Greenhouse...	Field trials	Field trials		

* BBCH for weeds, pre-emergence, preventive / curative application, insect stage...

Out of these three trials carried out against *Puccinia striiformis* (PUCCST-PUCCSI) on triticale two were considered as valid.

Use of CA3301 at 2x 0.6 and 0.8 l/ha against PUCCST-PUCCSI – Maritime EPPO zone

In the Maritime EPPO zone, a single valid trial was available against *Puccinia striiformis f. sp. tritici* (PUCCSI) on triticale and was included to support the efficacy evaluation of CA3301 at 0.6-0.8 l/ha applied twice, compared to the reference product on disease severity (%). CA3301 was first applied at crop stage BBCH 39 and the 2nd application was at BBCH 65.

Summary results are presented in Table 3.2-546.

On foliar level 2, when applied at 0.6 l/ha, CA3301 showed 82.48% efficacy 4 weeks after the 2nd application. On foliar level 1, at this dose rate, CA3301 showed 84.31% efficacy 4 weeks after the 2nd application.

When applied at 0.8 l/ha, on foliar level 2, CA3301 showed 84.67% efficacy 4 weeks after the 2nd application. At this dose rate on foliar level 1, CA3301 showed 88.24% efficacy 4 weeks after the 2nd application. At all assessments CA3301 applied at the proposed dose rates significantly reduced disease severity compared to the untreated and was comparable to the reference standard CA2445.

In this limited dataset, CA3301 at 0.6-0.8 l/ha provided high efficacy on reduction of disease severity. At this dose range, CA3301 was equivalent to the reference product CA2445 at 0.8 l/ha in all assessments. Differences were not significant but a numerical benefit in disease reduction was obtained from increasing dose rate from 0.6 l/ha to 0.8 l/ha. Moreover, a larger dataset was presented on the closely related crop winter wheat which demonstrated the same trends whereby applications of CA3301 resulted in medium to high efficacy comparable to that of the authorised reference products throughout the assessments (see Winter wheat (TRZAW) / *Puccinia striiformis* – *Puccinia striiformis f. sp. tritici* (PUCCST-PUCCSI)). In this dataset, the disease severity of yellow rust on winter wheat was initially low to medium, increasing to high disease severity (88-100% in some trials) as the trials progressed. Following the second application (14-19 DA-B), high efficacy was again observed from both dose rates on both leaf levels, comparable to the reference standards. At the assessment close to harvest, high efficacy was maintained for CA3301 at 0.8 l/ha at both leaf levels, and for 0.6 l/ha on L1. For this lower dose rate however, the efficacy was slightly lower (medium efficacy) on L2. Therefore, the dataset demonstrates that CA3301 applied at 0.6 l/ha can be sufficient to provide medium to high efficacy against yellow rust, but in some instances there is a benefit in increasing the dose rate to 0.8 l/ha to provide fuller control close to harvest, for example if disease pressure is high.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Puccinia striiformis* on triticale in the Maritime EPPO zone.

Table 3.2-546: Summary table - Efficacy evaluation – Triticale –PUCCSI - Maritime EPPO zone

Table 512-516: Summary table Efficacy evaluation - Efficacy - FUSC01 - Maximum L1/L2 zone										
Treatment name	UNTREATED	CA24	CA33	CA33	No of trials where			No of trials where		
Rate	CHECK	45	01	01	CA3301			CA3301		
Rate unit		0,8	0,6	0,8	at 0,6 l/ha is >, = or			at 0,8 l/ha is >, = or		
Appl. Code		L/ha	L/ha	L/ha	<			<		
		AB	AB	AB	compared to			compared to		
% Disease severity L2 - 28 DA-B										
Number of values	1	1	1	1	UT	CA24	CA33	UT	CA24	CA33
					C	45	01	C	45	01
Minimum value	13,70	2,70	2,40	2,10		0,8	0,8		0,8	0,6
Maximum value	13,70	2,70	2,40	2,10	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	13,70	2,70	2,40	2,10	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	80,29 %	82,48 %	84,67 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 28 DA-B										
Number of values	1	1	1	1	UT	CA24	CA33	UT	CA24	CA33
					C	45	01	C	45	01
Minimum value	10,20	1,70	1,60	1,20		0,8	0,8		0,8	0,6
Maximum value	10,20	1,70	1,60	1,20	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	10,20	1,70	1,60	1,20	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	83,33 %	84,31 %	88,24 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 and 0.8 l/ha against PUCGST-PUCCSI– Mediterranean EPPO zone

In the Mediterranean EPPO zone, a single trial was available against *Puccinia striiformis* (PUCGST), on triticale and was included to support the efficacy evaluation of CA3301 at 0.6-0.8 l/ha applied twice, compared to the reference product on disease severity (%). CA3301 was first applied at crop stage BBCH 39 and the 2nd application was at BBCH 59. The efficacy evaluation has been conducted focusing on CA3301 applied at 0.6 and 0.8 l/ha.

Summary results are presented in Table 3.2-547.

On foliar level 2, when applied at 0.6 l/ha, CA3301 showed 35.00% efficacy 2 weeks after the 2nd application and 35.29% 4 weeks after the 2nd application. On foliar level 1, at this dose rate, CA3301 showed 56.76% efficacy 2 weeks after the 2nd application and 59.82% 4 weeks after the 2nd application. When applied at 0.8 l/ha, on foliar level 2, CA3301 showed 35.00% efficacy 2 weeks after the 2nd application and 39.98% efficacy 4 weeks after the 2nd application. At this dose rate on foliar level 1, CA3301 showed 59.08% efficacy 2 weeks after the 2nd application and 64.29% efficacy 4 weeks after the 2nd application. At all assessments CA3301 applied at the proposed dose rates significantly reduced disease severity compared to the untreated and was comparable to the reference standard CA2445.

In this limited dataset, CA3301 at 0.6-0.8 l/ha provided low to medium efficacy on reduction of disease severity. At this dose range, CA3301 was equivalent to the reference product CA2445 at 0.8 l/ha in all assessments. Differences were not significant but a numerical benefit in disease reduction was obtained from increasing dose rate from 0.6 l/ha to 0.8 l/ha. Moreover, a larger dataset was presented on the

closely related crop winter wheat which demonstrated the same trends whereby applications of CA3301 resulted in medium to high efficacy comparable to that of the authorised reference products throughout the assessments (see KCP 6.2.2.3 Winter wheat (TRZAW) / *Puccinia striiformis* – *Puccinia striiformis* f. sp. *tritici* (PUCST-PUCSI)). In this dataset, where the majority of assessments were made in conditions of relatively low disease pressure there were no statistical differences in control of yellow rust between the dose rates of 0.6 l/ha and 0.8 l/ha, although a trend was observed for lower disease with higher dose rate. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for control of yellow rust, however when conditions are conducive to heavy disease infestation the rate of 0.8 l/ha may be beneficial to further reduce disease incidence.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Puccinia striiformis* on triticale in the Mediterranean EPPO zone.

Table 3.2-547: Summary table - Efficacy evaluation – Triticale –PUCST- Mediterranean EPPO zone

Table 3.2-3.47: Summary table - Efficacy evaluation - FIFAC - FUECSI - Mediator Fancal LPTO zone										
Treatment name	UNTREATED CHECK	CA24 45	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or <			No of trials where CA3301 at 0,8 l/ha is >, = or <		
Rate		0,8	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
% Disease severity L2 13 DA-B										
Number of values	1	1	1	1	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	58,75	32,94	38,19	38,19	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	58,75	32,94	38,19	38,19	0 =	1 =	1 =	0 =	1 =	1 =
Mean Disease severity (%)	58,75	32,94	38,19	38,19	0 <	0 <	0 <	0 <	0 <	0 <
Mean Abbott efficacy (%)	0,00%	43,93 %	35,00 %	35,00 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 13 DA-B										
Number of values	1	1	1	1	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	32,38	11,75	14,00	13,25	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	32,38	11,75	14,00	13,25	0 =	1 =	1 =	0 =	1 =	1 =
Mean Disease severity (%)	32,38	11,75	14,00	13,25	0 <	0 <	0 <	0 <	0 <	0 <
Mean Abbott efficacy (%)	0,00%	63,71 %	56,76 %	59,08 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 31 DA-B										
Number of values	1	1	1	1	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	79,88	42,13	51,69	47,94	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	79,88	42,13	51,69	47,94	0 =	1 =	1 =	0 =	1 =	1 =
Mean Disease severity (%)	79,88	42,13	51,69	47,94	0 <	0 <	0 <	0 <	0 <	0 <
Mean Abbott efficacy (%)	0,00%	47,26 %	35,29 %	39,98 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 31 DA-B										
Number of values	1	1	1	1	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	40,44	13,19	16,25	14,44	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	40,44	13,19	16,25	14,44	0 =	1 =	1 =	0 =	1 =	1 =
Mean Disease severity (%)	40,44	13,19	16,25	14,44	0 <	0 <	0 <	0 <	0 <	0 <
Mean Abbott efficacy (%)	0,00%	67,38 %	59,82 %	64,29 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6 and 0.8 l/ha against PUCST-PUCCSI - All other EPPO zones

In the North-East~~ern~~ and South-East~~ern~~ EPPO zone, no data were available to support the efficacy evaluation of CA3301 against *Puccinia striiformis* on triticale due to lack of disease infestation in the trials. However, the species *Puccinia striiformis* is also the causal agent of yellow rust on wheat. It therefore seems reasonable from an agronomic perspective to assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on triticale from the robust dataset proposed for the closely related crop winter wheat. Furthermore, existing authorisations for prothioconazole products have the same dose rate for this pathogen in both winter wheat and in triticale, which also indicates that performance is comparable between the pathogen/crop pairs.

The dataset presented in – Winter wheat (TRZAW) / *Puccinia recondita* – *Puccinia triticina* (PUCCRE-PUCCRT) and Winter wheat (TRZAW) / *Puccinia striiformis* – *Puccinia striiformis* f. sp. *tritici* (PUCST-PUCCSI) – showed that CA3301 applied at 0.6-0.8 l/ha provided significant disease control against the two different rusts. Both dose rates were equivalent to the references CA2445 at 0.8 l/ha and OSIRIS 65 EC applied at 2.0 l/ha. Moreover, the level of disease control observed was medium to high and a numerical trend appeared where CA3301 at 0.8 l/ha provided higher efficacy than 0.6 l/ha. Since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.8 l/ha generally gave adequate disease control, it is supposed that the same dose range will be acceptable to control yellow rust on triticale in all EPPO zone.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Puccinia striiformis* on triticale in all other EPPO zones.

Comments of zRMS:

Only 1 valid trial was carried out in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,6-0,8 l/ha achieved high efficacy after 28 days after second application. Due to the limited number of trials, the cMSs are kindly asked to consider this use on the national level.

No valid trials have been submitted in **the North-East EPPO zone**. However, 1 trial from the Czech Republic can be use as support of Polish registration. Despite of that, the extrapolation is not possible.

No dataset was available in **the South-East EPPO zone**. 1 trial has been submitted from the Mediterranean zone. However, CA3301 achieved very low effectiveness, either at dose rate of 0,6 and 0,8 l/ha. The cMSs are kindly asked to consider this use on the national level.

3.2.3.1 Triticale (TTLWI) / *Rhynchosporium secalis* (RHYNSE)

No data were available to support the efficacy evaluation of CA3301 against *Rhynchosporium secalis* on triticale. However, the specie *Rhynchosporium secalis* is also the causal agent of leaf blotch on barley. It therefore seems reasonable from an agronomic perspective to assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on triticale from the robust dataset proposed for the closely related crops winter and spring barley. This extrapolation is also supported by Poland national guidance extrapolation table, June 2016. Furthermore, existing authorisations for prothioconazole products (JOAO, PRAKTIS) have the same dose rate for this pathogen on barley, which also indicates that performance is comparable between the pathogen/crop pairs.

The dataset presented in – Winter barley (HORVW) / *Rhynchosporium secalis* (RHYNSE/RHYNSP) and Spring barley (HORVS) / *Rhynchosporium secalis* (RHYNSE)– showed that in conditions of disease pressure was relatively low and CA3301 gave higher or equivalent disease control compared to several authorized reference products. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient to provide acceptable control of *Rhynchosporium secalis*. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for the control of *Rhynchosporium secalis* on barley but in case of heavy infestation, 0.8 l/ha may be more adequate to obtain higher disease control on triticale.

On triticale, leaf blotch remains more occasional than on barley crops and since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.8 l/ha generally gave adequate disease control, it is supposed that the same dose range will be acceptable to control *Rhynchosporium secalis* on triticale.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Rhynchosporium secalis* on triticale in all EPPO zones.

Comments of zRMS:

No valid trials have been submitted in any EPPO climatic zone. The cMSs from the Maritime and South-East zones are kindly asked to consider this use on the national level. In the North-East zone this use can not be accepted because an extrapolation is not possible.

3.2.3.1 Triticale (TTLWI) / *Parastagonospora nodorum* (LEPTNO)

In all EPPO zone, no data were available to support the minimum effective dose of CA3301 against *Parastagonospora nodorum* on triticale. *Parastagonospora nodorum* is the causal agent of glume blotch on triticale although this disease is most closely associated with wheat. It therefore seems reasonable from an agronomic perspective to assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on triticale from the more robust dataset proposed for the closely related crop winter wheat. Furthermore, existing authorisations for prothioconazole products (JOAO, PRAKTIS) have the same dose rate for this pathogen in winter wheat, which also indicates that performance is comparable between the pathogen/crop pairs.

The dataset presented in – Winter wheat (TRZAW) / *Parastagonospora nodorum* (LEPTNO) - demonstrated that in challenging conditions of high disease pressure, CA3301 provided a low level of efficacy against *Parastagonospora nodorum* but this performance was comparable to the authorized reference product. In addition, *Zymoseptoria tritici* blotch is found commonly in the same fields and on the same plants as *Parastagonospora nodorum*, the fungi responsible of leaf (and glume) blotch of cereals, also known as Septoria nodorum blotch. When both pathogens occur together, they are referred to collectively as the Septoria blotch complex or Septoria complex. Glume blotch occurred in lesser proportion and more heterogeneous way than the Septoria species *Zymoseptoria tritici*, presented earlier in the dossier, which can also be supportive for this dataset.

Therefore with CA3301 at 0.6-0.8 l/ha it is also expected to obtain a control of glume blotch comparable to the authorised reference product. In many instances the rate of 0.6 l/ha should give acceptable control of *Parastagonospora nodorum* very comparable to that of 0.8 l/ha, nevertheless in conditions of high disease pressure the additional disease reduction obtained from the higher rate of 0.8 l/ha may be more appropriate, in particular if some level of resistance is suspected.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Parastagonospora nodorum* on triticale in all EPPO zones.

Comments of zRMS:

No valid trials have been submitted in any EPPO climatic zone. The cMSs from the Maritime and South-East zones are kindly asked to consider this use on the national level. In the North-East zone this use can not be accepted because an extrapolation is not possible.

3.2.3.1 Triticale (TTLWI) / Green leaf area (%)

Use of CA3301 at 2x 0.6 and 0.8 l/ha – Maritime EPPO zone

Green leaf area was recorded at 19-47 DA-B on triticale after two applications of CA3301 at 0.6-0.8 l/ha. In these trials, green leaf area was assessed on the entire plant.

Summary results are presented in Table 3.2-548.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the increase of green leaf area on triticale infected by foliar and ears diseases. In these trials assessing green leaf area on the whole plant, an increase of 72.26-75.48% was recorded compared to the untreated check on triticale.

The performance of the tested product was consistently equivalent to the reference product CA2445 at 0.8 l/ha.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will have a positive effect on the green leaf area in triticale affected by a range of pathogens in the Maritime EPPO zone.

Table 3.2-548: Summary table - Efficacy evaluation – Triticale – Green leaf area - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA224 5 0,8 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate										
Rate unit										
Appl. Code										
% Green leaf area plant 19-47 DA-B										
Number of values	11	11	11	11	UT C	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UT C	CA244 5 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	17,50	35,00	38,75	41,25	6 >	0 >	0 >	6 >	0 >	0 >
Maximum value	85,00	95,00	95,00	95,00	5 =	11 =	11 =	5 =	11 =	11 =
Green Leaf Area	46,98	67,50	68,25	68,07						
Abbott efficacy (%)	100,0%	172,75 %	172,26 %	175,48 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 at 2x 0.6 and 0.8 l/ha – Mediterranean EPPO zone

Green leaf area was recorded at 29-48 DA-B in 4 valid trials on triticale after two applications of CA3301 at 0.6-0.8 l/ha. In these trials the green leaf area was visually estimated as a percentage versus the untreated check.

Summary results are presented in Table 3.2-549.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the increase of green leaf area on triticale affected by foliar and ears diseases. In these 4 trials, assessing green leaf area on the whole plant, an increase of 11.47-18.95% was recorded compared to the untreated check on triticale. The numerical increase in green leaf area provided by CA3301 at 0.6-0.8 l/ha was not signifi-

cant compared to the untreated control. In conclusion, the performance of the tested product was statistically equivalent at the 0.8 l/ha and 0.6 l/ha dose rate and in all trials it was comparable to the reference product CA2445 at 0.8 l/ha.

Finally, it is possible to consider the winter wheat dataset to support the potential of CA3301 at 0.6-0.8 l/ha to increase the green leaf area. In this larger dataset, the same trends were observed. The increase in green leaf area provided by CA3301 at 0.6-0.8 l/ha was most of the time significant compared to the untreated and statistically equivalent to that provided by the references.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will have a positive effect on the green leaf area in triticale affected by a range of pathogens in the Mediterranean EPPO zone.

Table 3.2-549: Summary table - Efficacy evaluation – Triticale – Green leaf area (%) - Mediterranean EPPO zone

EFFO zone										
Treatment name	UNTREATED CHECK	CA2445	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or <			No of trials where CA3301 at 0,8 l/ha is >, = or <		
Rate		0,8	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
% Green leaf area plant 29-48 DA-B										
Number of values	4	4	4	4		CA2	CA3		CA2	CA3
Minimum value	13,75	15,00	15,00	15,00	UT	445	301	UT	445	301
Maximum value	46,50	50,00	50,00	50,00	C	0,8	0,8	C	0,8	0,6
Mean Green Leaf Area (%)	28,81	32,19	32,25	32,75	0 >	l/ha	l/ha	0 >	l/ha	l/ha
					4 =	0 >	0 >	4 =	0 >	0 >
Mean %UTC	100,00%	114,53%	111,47%	118,95%	0 <	4 =	4 =	0 <	4 =	4 =
						0 <	0 <		0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 at 2x 0.6 and 0.8 l/ha – North-Eastern EPPO zone

In the North-Eastern EPPO zone, green leaf area was recorded on the whole plant at 23-41 DA-B in four trials on triticale affected by foliar and ears diseases after two applications of CA3301 at 0.6-0.8 l/ha.

Summary results are presented in Table 3.2-550.

Data demonstrated a positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the increase of green leaf area on triticale affected by foliar and ears diseases. CA3301 at 0.6-0.8 l/ha induced an increase of green leaf area of 66.17-68.91%, and in one trial 0.8 l/ha rate provided a significant higher increase than 0.6 l/ha. The performance of the tested product was globally higher or equivalent at the 0.8 l/ha dose rate compared to the 0.6 l/ha dose rate. In a majority of trials CA3301 was overall equivalent to the reference products CA2445 at 0.8 l/ha and OSIRIS 65 EC at 2.00 l/ha except in 1 assessment for the 0.6 l/ha rate.

In addition, a larger dataset was presented on the closely related crop winter wheat in which the same trends were observed. In 33 trials assessing green leaf area on the whole plant an augmentation of 34.6-42.4% was recorded compared to the untreated check. The performance of CA3301 at 0.8 l/ha was statistically equivalent to the 0.6 l/ha dose rate or statistically better in a few trials. In a majority of the trials, CA3301 was overall equivalent to the reference products CA2445 at 0.8 l/ha and OSIRIS at 2 l/ha.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will have a positive effect on the green leaf area in triticale affected by a range of pathogens in the North-Eastern EPPO zone.

Table 3.2-550: Summary table - Efficacy evaluation – Triticale – Green leaf area – North-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA2445	OSIRIS 65 EC	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Rate		0,8	2	0,6	0,8		
Rate unit		L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	AB		
% Green leaf area plant 23-41 DA-B							
Number of values	4			4	4	UT C	CA3 301 à 0.8 l/ha
Minimum value	16,25			25,00	22,50		
Maximum value	51,25	-	-	73,75	82,50	2 >	0 >
Mean Green Leaf Area (%)	32,81			51,25	52,50	2 =	3 =
Mean % UTC	100,00%			166,17 %	168,91 %	0 <	1 <
Number of values	2	2		2	2	CA2245 à 0.8 l/ha	CA2245 à 0.8 l/ha
Minimum value	27,50	65,00		62,50	65,00		
Maximum value	51,25	81,25	-	73,75	82,50	0 >	0 >
Mean Green Leaf Area (%)	39,37	73,13		68,13	73,75	1 =	2 =
Mean % UTC	100,00%	211,14%		195,07 %	213,42 %	1 <	0 <
Number of values	2		2	2	2	OSIRIS 65 EC à 2 l/ha	OSIRIS 65 EC à 2 l/ha
Minimum value	16,25		22,50	25,00	22,50		
Maximum value	36,25	-	40,00	47,75	40,00	0 >	0 >
Mean Green Leaf Area (%)	26,25		31,25	34,37	31,25	2 =	2 =
Mean % UTC	100,0%		124,40%	137,27 %	124,40 %	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 at 2x 0.6 and 0.8 l/ha – South-Eastern EPPO zone

In the South-Eastern EPPO zone, the green leaf area was recorded in 7 trials. Among these trials, green leaf area was assessed on the whole plant in 4 trials and by foliar levels in 3 trials. These trials are presented separately.

Data demonstrated a positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the augmentation of green leaf area on triticale affected by foliar and ears diseases (see Table 3.2-551).

In trials where green leaf area was assessed on the whole plant, CA3301 provided a significantly higher increase of the green leaf area compared to the untreated control and comparable to references CA2445 at 0.8 l/ha and PRIAXOR at 1.5 l/ha except in 1 trial. In trials where green leaf area was assessed on foliar level, CA3301 at 0.6-0.8 l/ha was significantly better than untreated check and statistically equivalent to or better than CA2445. On individual foliar levels the CA3301 performance was equivalent, lower or higher than that of NATIVO PRO 365 SC at 1.5 l/ha.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will have a positive effect on the green leaf area in triticale affected by a range of pathogens in the South-East^{ern} EPPO zone.

Table 3.2-551: Summary table - Efficacy evaluation – Triticale – Green leaf area (%) Plant– South-East^{ern} EPPO zone

Treatment name	UN-TREATED CHECK	CA2445	PRI-AXOR	NATIVO PRO 365 SC	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or <		No of trials where CA3301 at 0,8 l/ha is >, = or <	
Rate		0,8	2	1	0,6	0,8				
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB	AB	compared to		compared to	
% Green leaf area plant 19-48 DA-B										
Number of values	4				4	4	UTC	CA3301 at 0.8 l/ha	UTC	CA3301 at 0.6 l/ha
Minimum value	10,00				30,00	33,75				
Maximum value	58,75	-	-	-	70,00	70,00	1 >	0 >	1 >	1 >
Mean Green Leaf Area (%)	40,63				48,75	50,94	3 =	3 =	3 =	3 =
Mean %UTC	100,00%				156,99 %	169,04 %	0 <	1 <	0 <	0 <
Number of values	3	3			3	3	CA2445 at 0.8 l/ha		CA2445 at 0.6l/ha	
Minimum value	10,00	23,75			45,00	33,75				
Maximum value	58,75	48,75	-	-	70,00	51,25	1 >		1 >	
Mean Green Leaf Area (%)	37,50	39,17			41,67	44,58	2 =		2 =	
Mean %UTC	100,00%	141.84 %			162,69 %	178,72 %	0 <		0 <	
Number of values	2		2		2	2	PRIAXOR at 2 l/ha		PRIAXOR at 2 l/ha	
Minimum value	10,00		40,00		30,00	33,75				
Maximum value	50,00	-	70,00	-	7,00	70,00	0 >		0 >	
Mean Green Leaf Area (%)	30,00		55,00		50,00	50,25	1 =		1 =	
Mean %UTC	100,0%		270,00 %		220,00 %	238,75 %	1 <		1 <	
% Green leaf area on L2 26-28 DA-B										
Number of values	3			3	3	3	UTC	CA3301 at 0.8 l/ha	UTC	CA3301 at 0.6 l/ha
Minimum value	0,00			13,75	16,25	20,75				
Maximum value	2,25	-	-	35,75	30,00	33,50	3 >	0 >	3 >	2 >
Mean Green Leaf Area (%)	0,75			25,25	23,25	25,17	0 =	1 =	0 =	1 =
Mean %UTC	100,00%			1862,96%	1769,44 %	3356,00 %	0 <	2 <	0 <	0 <
Number of values	1	1		1	1	1	CA2445 at 0.8 l/ha	NATIVO PRO at 1 l/ha	CA2445 at 0.8 l/ha	NATIVO PRO at 1 l/ha
Minimum value	2,25	30,00		37,75	30,00	33,50				
Maximum value	2,25	30,00	-	37,75	30,00	33,50	0 >	0 >	1 >	1 >

Treatment name	UN-TREATED CHECK	CA244 5	PRI-AXOR	NATIVO PRO 365 SC	CA33 01	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or <			No of trials where CA3301 at 0,8 l/ha is >, = or <		
Rate		0,8	2	1	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	AB	AB	compared to			compared to		
Mean Green Leaf Area (%)	2,25	30,00		37,75	30,00	33,50	1 =	2 =	0 =	2 =		
Mean %UTC	100,00%	1333,3 3%		1588,89%	1333,3 3%	1488,89 %	0 <	1 <	0 <	0 <		
% Green leaf area on L1 26-28 DA-B												
Number of values	3			3	3	3	U T C	NA- TIVO PRO	CA 330 1 at 0.8 l/ha	U T C	NA- TIVO PRO	CA 330 1 at 0.6 l/ha
Minimum value	11,75			35,00	48,75	50,00						
Maximum value	19,00	-	-	57,25	57,25	58,00	3 > 0 =	1 >	0 >	3 > 0 =	1 >	2 >
Mean Green Leaf Area (%)	14,17			49,08	52,00	53,92	0 =	1 =	1 =	0 =	1 =	1 =
Mean %UTC	100,00%			358,19%	388,43 %	404,74 %	0 <	1 <	2 <	0 <	1 <	0 <
Number of values	1	1		1	1	1	CA2445 at 0.8 l/ha			CA2445 at 0.8 l/ha		
Minimum value	19,00	50,00		55,00	50,00	50,00						
Maximum value	19,00	50,00	-	55,00	50,00	50,00	0 >			1 >		
Mean Green Leaf Area (%)	19,00	50,00		55,00	50,00	50,00	1 =			0 =		
Mean %UTC	100,0%	263,16 %		289,47%	263,16 %	263,16 %	0 <			0 <		

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Comments of zRMS:

11 field trials were carried out in **the Maritime EPPO climatic zone**. CA3301 presented positive effect in assessment of green leaf area. The test product achieved a mean augmentation of green leaf are of 72,26% at 0,6 l/ha and 75,48% at 0,8 l/ha in trials where whole plants were observed. No significant differences between test and reference product were detected.

4 field trials was carried out in **the North-East EPPO zone**. The whole plants were observed to evaluation of green leaf area. An augmentation of green leaf area amounted 66,17% at dose rate of 0,6 l/ha and 68,91% at dose rate of 0,8 l/ha. The results from the test and reference product were comparable.

6 field trials were conducted in **the South-East EPPO zone**. The majorities trials show results from whole plants. CA3301 achieved a very positive effect in compared to untreated objectives and standards. An augmentation of green leaf area amounted almost 70% (0,8 l/ha) in case of whole plants. In 1 trial an augmentation was over 3200% (0,8 l/ha) on foliar L2 and 300% on foliar L1 after 26-28 days after second application. Moreover, in 4 trials from the Mediterranean zone positive effect on augmentation was observed with the results of 11,47% at 0,6 l/ha and 18,95% at 0,8 l/ha. No significant differences between test and reference product were observed.

3.2.3.1 Triticale (TTLWI) / Conclusion efficacy

On triticale, 4 foliar diseases were assessed in 21 trials across 4 EPPO zones on foliar levels 1 and 2. In some instances, due the absence of appropriate level of disease the proposed number of valid trials was not fully achieved. In all EPPO zones, depending on the disease, the assessment timing and the crop part assessed, the dataset available was sometimes limited and so not fully representative of the efficacy of

CA3301. Therefore, to get an overview of the efficacy of CA3301 at 0.6 l/ha, summary tables are presented hereunder, on foliar levels 1&2 (see Table 3.2-552 & Table 3.2-553) for SEPTTR – PUCCRE/ PUCCRT - PUCCST, on all foliar levels for ERYSGT/ERYSGR (see Table 3.2-554) and on ears for FUSASP and FUSACU (see Table 3.2-555). All trials were carried out on winter triticale varieties but the same targets can attack also spring triticale varieties and consequently results can be transposable on both crops, since the dose rates and application timing in relation to the crops is the same. Spring-sown triticale is a minor crop in the cMS, therefore extrapolation is supported by EPPO guidance. Extrapolation is also supported by Poland national guidance. In addition, the same pathogens are assessed for efficacy in wheat and rye with the same dose rates and timing and these results are also supportive for the proposed dose rate range.

Globally, across the 4 EPPO zones and all diseases the efficacy of CA3301 at 0.6 l/ha was acceptable to high, with some exceptions. Nevertheless, since in the fields a complex of disease is often observed instead of a single disease, it is of interest to present a summary of the efficacy of CA3301 across the diseases and EPPO zone, as well as considering the green leaf area presented above. Green leaf area not only indicates the area free of infection, but also the ability of the plant to continue effective growth and develop, enabling a longer duration of grain filling and therefore improved yield.

In many instances, a trend of decreasing disease severity when increasing the dose rates was observed with CA3301 applied at 0.6 l/ha or 0.8 l/ha. Indeed, overall the rate of 0.8 l/ha was not statistically different from 0.6 l/ha dose rate but both provided higher disease control than the lower rate of 0.48 l/ha. In circumstances of low disease pressure, the 0.6 l/ha rate may be sufficient to give comparable disease control, but due to the importance of the diseases and given the possibility of resistance in some pathogens assessed the higher rate may be deemed more appropriate and should be available for user according to disease development conditions, historical control and cultivar tolerance to the pathogen. It has been demonstrated in the preceding sections that the efficacy of CA3301 at 0.6-0.8 l/ha was overall equivalent to that provided by the approved reference standards used in the trials. Hence it is justified to propose that the efficacy comparable to that of the authorized products will be obtained on the pathogens where the presented data set are limited.

In this dossier efficacy data presented is primarily from assessments where 2 applications of the test product were made. However, according to disease development conditions, a single application may provide sufficient disease control, therefore users should not be restricted to always applying twice, hence in the GAP the proposed use is for 1-2 applications. In addition, crop pathogens are commonly controlled using a programme of different fungicides with varied modes of action, therefore the choice should be available to growers to make a single application of CA3301, followed by application of a different appropriate fungicide. Prothioconazole is well established over a number of years in providing good broad spectrum efficacy across a range of common crop pathogens, with either 1 or more applications appropriate according to disease development conditions, risk of resistance development and local conditions. Current authorisations for similar products containing prothioconazole including Proline 275, and Proline/Praktis/Joao (CA2445) are for 1-2 applications at comparative rates of prothioconazole to the requested use for CA3301. Considering these elements, and that data shows comparability of CA3301 to these authorised products, registration of CA3301 at the proposed dose rate and with a number of applications of 1- 2, is requested.

Considering all elements presented in the previous sections of each disease, it is justified to claim the registration of 1-2 applications of CA3301 at 0.6-0.8 l/ha to control a range of foliar and ears diseases on triticale.

Table 3.2-552: Summary table - Triticale – SEPTTR-PUCCRE/PUCCST (Foliar level 2)

Foliar level 2	MAR	MED	NE	SE	POLAND GROUPING
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Disease	Assessment timing		CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB
SEPTTR	15 DA-B	Number of values Abbott efficacy (%)	1 61.36 %	1 44.08 %	2 82.00 %	2 86.33 %	2 56.70 %	2 74.46 %	-	-	3 57.63 %	3 64.04 %
	Before harvest	Number of values Abbott efficacy (%)	1 60.09 %	1 56.24 %	2 81.2% %	2 83.4% %	3 58.43 %	3 72.17 %	3 96.00 %	1 96.74 %	6 57.80 %	6 63.72 %
PUCCRE PUCCRT	13 DA-B	Number of values Abbott efficacy (%)	-	-	1 35.00 %	1 35% %	-	-	-	-	-	-
	Before harvest	Number of values Abbott efficacy (%)	2 88.01 %	2 95.21 %	1 35.29 %	1 39.98 %	-	-	-	-	-	-

Table 3.2-553: Summary table - Triticale – SEPTTR-PUCCRE/PUCCST (Foliar level 1)

Foliar level 1			MAR		MED		NE		SE		POLAND GROUPING	
Disease	Assessment timing		CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB
SEPTTR	15 DA-B	Number of values Abbott efficacy (%)	-	-	-	-	-	-	-	-	-	-
	Before harvest	Number of values Abbott efficacy (%)	1 44.29 %	1 38.81 %	1 45.80 %	1 51.15 %	3 67.62 %	3 75.65 %	3 96.60 %	3 97.11 %	4 61.79 %	4 66.44 %
PUCCRE PUCCRT	19 DA-B	Number of values Abbott efficacy (%)	-	-	1 56.76 %	1 59.08 %	-	-	-	-	-	-
	Before harvest	Number of values Abbott efficacy (%)	1 97.76 %	1 92.43 %	1 59.82 %	1 64.29 %	-	-	-	-	-	-

Table 3.2-554: Summary table - Triticale – ERYSGT/ERYSGR

			MAR		NE		SE	
ERYSGT/ERYSGR	Assessment timing		CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB
Foliar Level 2	Severity 23 DA-B	Number of values Abbott efficacy (%)	-	-	1 82.9%	1 86.22%	-	-

	Before harvest	Number of values Abbott efficacy (%)	2 96.67%	2 97.65%	-	-	2 99.63%	2 99.52%
Foliar Level 1	Severity 19 DA-B	Number of values Abbott efficacy (%)	1 100%	1 100%	-	-	-	-
	Before harvest	Number of values Abbott efficacy (%)	1 85.19%	1 88.15%	-	-	1 95.64%	1 94.36%

Table 3.2-555: Summary table - Triticale – FUSASP - FUSACU

Ears NI= not Inoculated, I= Inoculated			MAR (Ear I)		MAR (Ear NI)		SE (Ear I)		NE (Ear I)		NE (Ear NI)	
Dis-ease	Application timing		CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB
FUSASP-	15 DA-B – 14 DA-B	Number of values Abbott efficacy (%)	-	1 90.30 %	-	-	1 54.23 %	1 72.24 %	-	-	-	-
	23 DA-B, 30 DA-B	Number of values Abbott efficacy (%)	-	1 67.34 %	-	-	-	-	1 77.22 %	1 82.38 %	-	-
	63 DA-B	Number of values Abbott efficacy (%)	-	-	1 64.46 %	1 50.85 %	-	-	-	-	-	-
FUSACU	25 DA-B	Number of values Abbott efficacy (%)	-	-	-	-	-	-	-	-	1 72.86 %	1 65.79 %
	44 DA-B	Number of values Abbott efficacy (%)	-	-	-	-	-	-	-	-	1 63.53 %	1 65.79 %

Comments of zRMS:

All efficacy trials were carried out on winter triticale. The cMSs are kindly asked to consider the use of CA3301 to protection of spring triticale on the national level. Furthermore, it should be noted that the assessment of efficacy was provided only after second application. Due to the limited number of trials for target pathogens in winter triticale, the cMSs are kindly asked to consider single application of CA3301 on the national level.

3.2.3.2 Rye (SECCW) / *Zymoseptoria tritici* (SEPTTR)

Materials and Methods – Rye - SEPTTR

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2017 and 2020, a series of 17 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern and South-Eastern EPPO zones to evaluate the efficacy of CA3301 against *Zymoseptoria tritici* on rye (see Table 3.2-556). The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, a total of 4 trials were performed in the Czech Republic (2), Denmark (1) and the United Kingdom (1)

In the Mediterranean EPPO zone, a total of 3 trials were performed in Greece (1) and Portugal (2).

In the North-Eastern EPPO zone, a total of 6 trials were performed in Poland (6).

In the South-Eastern EPPO zone, a total of 4 trials were performed in Hungary (3) and Romania (1).

Data groupings were also made specifically for Poland evaluation and trials involved (8) were performed in the North-Eastern EPPO zone (6) and in the Czech Republic (2).

Table 3.2-556: Presentation of trials – Rye (SECCW)

Crop(s)) *	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Rye	SEPTTR	Czech Republic	2017- 2018	MED + E	2 (1)	-	-	-	GEP	
		Denmark	2019	MED + E	1 (0)	-	-	-	GEP	
		United King- dom	2019	MED + E	1 (1)	-	-	-	GEP	
Rye	SEPTTR	Portugal	2018	MED + E	-	2 (0)	-	-	GEP	
		Greece	2020	MED + E	-	1 (1)	-	-	GEP	
Rye	SEPTTR	Poland	2017- 2020	MED + E	-	-	6 (3)	-	GEP	
Rye	SEPTTR	Hungary	2018- 2019	MED + E	-	-	-	3 (2)	GEP	
		Romania	2019	MED + E	-	-	-	1 (1)	GEP	
TO- TAL	-	-	2017 - 2020	MED + E	4 (3)	3 (1)	6 (3)	4 (3)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

In all trials, CA3301 was compared to at least one commercial and registered fungicide used as standard reference for comparison.

Table 3.2-557: Efficacy evaluation - Presentation of reference standards used in trials – Rye (SECCW) – SEPTTR – Maritime EPPO Zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Rye	PRO-LINE 250 EC	CZ	4523-1	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha 3 x 0.6-0.8 l/ha	CA2445 in some trials
	PRO-LINE 275	UK	14790	Prothioconazole	EC	275 g/l	2 x 0.72 l/ha	2 x 0.72 l/ha	
	PRO-LINE 250 EC	DK	18-473	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

Table 3.2-558: Efficacy evaluation - Presentation of reference standards used in trials – Rye (SECCW) – SEPTTR – Mediterranean EPPO Zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Rye	PRO-LINE	GR	60838	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials
	ALTIS	GR	60512	Tebuconazole	EC	250 g/l	1 l/ha	1 l/ha	
	PRAK-TIS	PT	AV 1485	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials

Table 3.2-559: Efficacy evaluation - Presentation of reference standards used in trials – Rye (SECCW) – SEPTTR – North-Eastern EPPO Zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Rye	PRAK-TIS	PL	R-222/2019	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha 3 x 0.8 l/ha	CA2445 in some trials
	OSIRIS 65 EC	PL	R-87/2012 R-414/2018d	Epoxiconazole + metconazole	EC	65 g/l	1 x 1.5-2.5 l/ha	2 x 2 l/ha	

Table 3.2-560: Efficacy evaluation - Presentation of reference standards used in trials – Rye (SECCW) – SEPTTR – South-Eastern EPPO Zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
Rye	PRO-LINE	HU	6300/1205-1/2020	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRI-AXOR	HU	04.2/2426-1/2018	Fluxapyriaxad Pyraclostrobin	EC	225 g/l	N/A	2 x 1.5 l/ha	
	PRO-LINE	RO	457PC/15.11.2018	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-561.

Table 3.2-561: Details on trial methodology – Rye (SECCW) - SEPTTR

		Maritime EPPO zone	Mediterranean EPPO zone	North-Eastern EPPO zone	South-Eastern EPPO zone	Data relevant for Poland
Trials	Total number (valid number)	4 (3)	3 (1)	6 (3)	4 (3)	8 (5)
	Supportive trials	-	-	-	-	-
Guidelines	General guidelines	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3) PP 1/225 (2) PP 1/262 (1)	PP 1/135(4) PP 1/152(4) PP 1/181(4) PP 1/239(2) PP 1/214(3)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3) PP 1/225 (2) PP 1/262 (1)
	Specific guidelines	PP 1/26(4) PP 1/28 (3)	PP 1/26(4)	PP 1/26 (4)	PP 1/26 (4)	PP 1/26(4) PP 1/28 (3)
Experimental design	Plot design	Randomized complete blocks, Untreated included	Randomized complete blocks, Untreated included	Randomized Complete Blocks, Untreated included	Randomized Complete Blocks, Untreated included	Randomized complete blocks, Untreated included
	Plot size	20-36 m ²	21-30 m ²	21 – 30 m ²	21 – 30 m ²	21-36 m ²
	Number of replications	4	4	4	4	4
Crop	Trials per crop	SECCW (4)	SECCW (3)	SECCW (6)	SECCW (4)	SECCW (8)
	Varieties per crop	SU Santiny, Diamond, Benito, Ducato	Local landrace (2), Sito (1)	Brasetto (2), Poznanskie (1), TUR F1 (1), Tur	Dankowskie (2), Dukato (1), Suceveana (1)	SU Santiny, Ducato, Brasetto (2), Poznanskie

		Maritime EPPO zone	Mediterranean EPPO zone	North-Eastern EPPO zone	South-Eastern EPPO zone	Data relevant for Poland
				(1), Dankowskie Rubin (1)		(1), TUR F1 (1), Tur (1), Dankowskie Ru- bin (1)
	Sowing pe- riod	September (2), October (2)	November (3)	Sept (5), Oct (1)	September (3), October (1)	September (6), October (2)
Application	Crop stage (BBCH)* at application	A: BBCH 31-37 B: BBCH 39-65 C: BBCH 61	A: BBCH 37-39 B: BBCH 54-65	A: BBCH 31-39 B: BBCH 37-65 C: BBCH 59	A: BBCH 37-47 B: BBCH 41-61	A: BBCH 31-39 B: BBCH 37-65 C: BBCH 59-61
	Timing Disease stage at application	BBCH 31-65 A: MIXED (2), N/A (2) B: MIXED (2), N/A (2)	BBCH 37-65 A: PRINFC (3) B: MIXED (3)	BBCH 31-65 A: PRINFC (1), MYCELI (3), N/A (2) B: MYCELI (3), MIXED (1), N/A (2) C: MYCELI (1)	BBCH 37-61 A: PRINFC (2), MIXED (2) B: PRINFC (1), MIXED (3)	BBCH 31-65 A: PRINFC (1), MYCELI (3), N/A (2), MIXED (2) B: MYCELI (3), MIXED (3), N/A (2) C: MYCELI (1)
	Number of applications Intervals be- tween appli- cations	2 applications (14-16 days) (3) 3 applications (17 and 22 days) (1)	2 applications (16-23 days)	2 applications (15-30 days)	2 applications (9-22 days) (12)	2 applications (14-30 days) (7) 3 applications (17 and 22 days) (1)
	Spray vol- umes	200 l/ha	200-400 l/ha	200-300 l/ha	200-300 l/ha	200-300 l/ha
Assessment	Assessment types	Disease severity (%), Disease in- cidence (%), GRNARE (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease in- cidence (%), GRNARE (%), Phytotoxicity (%)	Disease severity (%), Disease in- cidence (%), GRNARE (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease in- cidence (%), GRNARE (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)	Disease severity (%), Disease in- cidence (%), GRNARE (%), Phytotoxicity (%), TKW (g), HLW (kg/ha), Moisture content (%), Yield (kg), Yield (T-MET)
	Assessment dates	0 DA-A, 14-17 DA-A, 0 DA-B, 15 DA-B, 24-53 DA-B	0 DA-A, 12-17 DA-A, 0 DA-B, 15-22 DA-B, 45 DA-B	0 DA-A, 15-16 DA-A, 0 DA-B, 15-16 DA-B, 23- 46 DA-B	0 DA-A, 9-15 DA-A, 0 DA-B, 14-15 DA-B, 25- 38 DA-Bsdint	0 DA-A, 14-17 DA-A, 0 DA-B, 15-16 DA-B, 26- 53 DA-B
Other rele- vant infor- mation	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial inoc- ulation...	Natural (4)	Natural (3)	Natural (6)	Natural (4)	Natural (8)
	e.g. Field / Greenhouse...	Field trials	Field trials	Field trials	Field trials	Field trials

Out of the 17 trials performed on rye against *Zymoseptoria tritici*, 10 were considered valid.

Use of CA3301 at 2x 0.6-0.8 l/ha against SEPTTR - Maritime EPPO zone

In the Maritime EPPO zone, a total of 4 trials evaluated the efficacy of CA3301 on rye against *Zymoseptoria tritici*. 3 trials out of 4 were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 31-33 and the 2nd application was at BBCH 39-59.

Summary results are presented in Table 3.2-562.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on rye against *Zymoseptoria tritici*, as disease was significantly reduced in all trial assessments.

On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 80.83-81.51% efficacy against *Zymoseptoria tritici* two weeks after the 2nd application and 44.45-50.82% before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 58.45-70.54% efficacy on reduction of disease severity around two weeks after the 2nd application and 76.42-65.50% before harvest.

In the Maritime EPPO zone, in a limited dataset, CA3301 at 0.6-0.8 l/ha showed high efficacy in reducing the severity of *Zymoseptoria tritici* on rye two weeks after the 2nd application on foliar level 2. At this dose range, CA3301 gave equivalent disease control compared to the authorized reference products CA2445 and PROLINE 275 at all assessments. Averaged across the dataset the efficacy of CA3301 at 0.6 l/ha was comparable to 0.8 l/ha but in some assessments a numerical increase in efficacy is observed in increasing the dose rate.

Moreover, a larger dataset was presented on the related crop-disease pair winter wheat - *Zymoseptoria tritici* which confirms the level of efficacy observed here and strengthens the numerical trend of increasing efficacy when using 0.8 l/ha dose rate compared to 0.6 l/ha.

Therefore, in many instances, and considering that *Zymoseptoria tritici* is an occasional disease on rye, 0.6 l/ha gave sufficient disease control. In conditions of high disease pressure, historical difficulties in control of this disease or where some level of resistance is suspected, it may be appropriate to use 0.8 l/ha for control of *Zymoseptoria tritici*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Zymoseptoria tritici* on rye in the Maritime EPPO zone.

Table 3.2-562: Summary table - Efficacy evaluation – Rye – SEPTTR - Maritime EPPO zone

Treatment name	UNTREATED CHECK	PROLINE 275 0,72 L/ha AB	CA24 45 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
% Disease severity L2 - 12-15 DA-B							
Number of values	2			2	2	UT C	UT C
Minimum value	16,69			1,75	1,13		
Maximum value	57,06	-	-	15,89	17,24	2 >	0 >
Mean disease severity (%)	36,88			8,82	9,18	0 =	2 =
Abbott efficacy (%)	0,00%			80,83 %	81,51 %	0 <	0 <
Number of values	1	1		1	1	PROLINE 275 0,72 l/ha	
Minimum value	57,06	15,21	-	15,89	17,24	0 >	
Maximum value	57,06	15,21		15,89	17,24	1 =	
Mean disease severity (%)	57,06	15,21		15,89	17,24	0 <	
Abbott efficacy (%)	0,00%	73,34%		72,15 %	69,79 %	0 <	
Number of values	1		1	1	1	CA2445 0,8 l/ha	
Minimum value	16,69		1,18	1,75	1,13	CA2445 0,8 l/ha	

Maximum value	16,69	-	1,18	1,75	1,13	0 >		0 >	
Mean disease severity (%)	16,69		1,18	1,75	1,13	1 =		1 =	
Abbott efficacy (%)	0,00%		92,23 %	89,51 %	93,23 %	0 <		0 <	
% Disease severity L1 - 15 DA-B									
Number of values	1	1		1	1	UT C	CA3301 0,8 l/ha	UT C	CA3301 0,6 l/ha
Minimum value	14,56	5,58		6,05	4,29		PROLINE 275		PROLINE 275
Maximum value	14,56	5,58	-	6,05	4,29	1 >	0 >	1 >	0 >
Mean disease severity (%)	14,56	5,58		6,05	4,29	0 =	1 =	0 =	1 =
Abbott efficacy (%)	0,00%	61,68%		58,45 %	70,54 %	0 <	0 <	0 <	0 <
% Disease severity L2 - 28-49 DA-B									
Number of values	2			2	2	UT C	CA3301 0,8 l/ha	UT C	CA3301 0,6 l/ha
Minimum value	14,44			9,50	6,73				
Maximum value	100,00	-	-	45,31	51,75	2 >	0 >	2 >	0 >
Mean disease severity (%)	57,22			27,41	29,24	0 =	2 =	0 =	2 =
Abbott efficacy (%)	0,00%			44,45 %	50,82 %	0 <	0 <	0 <	0 <
Number of values	1	1		1	1	PROLINE 275 0,72 l/ha		PROLINE 275 0,72 l/ha	
Minimum value	100,00	41,95		45,31	51,75				
Maximum value	100,00	41,95	-	45,31	51,75	0 >		0 >	
Mean disease severity (%)	100,00	41,95		45,31	51,75	1 =		1 =	
Abbott efficacy (%)	0,00%	58,05%		54,69 %	48,25 %	0 <		0 <	
Number of values	1		1	1	1	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	14,44		7,84	9,50	6,73				
Maximum value	14,44	-	7,84	9,50	6,73	0 >		0 >	
Mean disease severity (%)	14,44		7,84	9,50	6,73	1 =		1 =	
Abbott efficacy (%)	0,00%		45,71 %	34,21 %	53,39 %	0 <		0 <	
% Disease severity L1 - 49 DA-B									
Number of values	1	1		1	1	UT C	CA3301 0,8 l/ha	UT C	CA3301 0,6 l/ha
Minimum value	100,00	20,88		23,58	34,50		PROLINE 275		PROLINE 275
Maximum value	100,00	20,88	-	23,58	34,50	1 >	0 >	1 >	0 >
Mean disease severity (%)	100,00	20,88		23,58	34,50	0 =	1 =	0 =	1 =
Abbott efficacy (%)	0,00%	79,12%		76,42 %	65,50 %	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against SEPTTR - Mediterranean EPPO zone

In the Mediterranean EPPO zone, a total of 3 trials evaluated the efficacy of CA3301 on rye against *Zymoseptoria tritici*. 1 trial out of 3 was considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha (applied twice), and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stage BBCH 37 and the 2nd application was at BBCH 54.

Summary results are presented in Table 3.2-563.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on rye against *Zymoseptoria tritici*, as disease severity was significantly reduced at all assessments.

On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 54.16-72.72% of efficacy against *Zymoseptoria tritici* two weeks after the 2nd application and 58.82-75.93% before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 54.02-76.11% efficacy on reduction of disease severity around two weeks after the 2nd application and 42.45-73.91% before harvest.

In the Mediterranean EPPO zone, *Zymoseptoria tritici* remains an occasional disease in rye and may occur less frequently than classical rye diseases such as *Puccinia recondita* or *Rhynchosporium secalis*. Rye crop in Mediterranean EPPO zone may be less cultivated than in other EPPO zones, this is also a reason of the low dataset in this area. CA3301 at 0.6-0.8 l/ha showed low to medium efficacy in reducing the severity of *Zymoseptoria tritici* on rye. In all assessments at this dose range, CA3301 gave equivalent disease control compared to the authorized reference products CA2445 and ALTIS. Across this limited dataset, the efficacy of CA3301 at 0.6 l/ha was comparable to 0.8 l/ha, however at some assessments a clear numerical increase appears from increasing the dose rate to 0.8 l/ha. Moreover, a larger dataset was presented on the related crop-disease pair winter wheat - *Zymoseptoria tritici* which confirms the level of efficacy observed here and strengthens the numerical trend of increasing efficacy when was applied at 0.8 l/ha compared to 0.6 l/ha. Therefore, in many instances 0.6 l/ha gave sufficient disease control but in conditions of high disease pressure, historical difficulties in control of this disease or where some level of resistance is suspected it may be appropriate to use 0.8 l/ha for control of *Zymoseptoria tritici*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Zymoseptoria tritici* on rye in the Mediterranean EPPO zone.

Table 3.2-563: Summary table - Efficacy evaluation – Rye – SEPTTR - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA2 445	AL-TIS	CA3 301	CA3 301	No of trials where CA3301				No of trials where CA3301			
Rate		0,8	1	0,6	0,8	at 0,6 l/ha is >, = or <				at 0,8 l/ha is >, = or <			
Rate unit		L/ha	L/ha	L/ha	L/ha								
Appl. Code		AB	AB	AB	AB	compared to				compared to			
% Disease severity L2 -15 DA-B													
Number of values	1	1	1	1	1	U T C	CA2 445	AL-TIS	CA3 301	U T C	CA2 445	AL-TIS	CA3 301
Minimum value	17,56	7,15	7,20	8,05	4,79		0,8 l/ha	1,0 l/ha	0,8 l/ha		0,8 l/ha	1,0 l/ha	0,6 l/ha
Maximum value	17,56	7,15	7,20	8,05	4,79	1 > 0 = 0 <	0 >	0 >	0 >	1 > 0 = 0 <	0 >	0 >	0 >
Mean disease severity (%)	17,56	7,15	7,20	8,05	4,79		1 =	1 =	1 =		1 =	1 =	1 =
Abbott efficacy (%)	0,00%	59,2 8%	59,0 0%	54,1 6%	72,7 2%		0 <	0 <	0 <		0 <	0 <	0 <
% Disease severity L1 - 15 DA-B													
Number of values	1	1	1	1	1	U T C	CA2 445	AL-TIS	CA3 301	U T C	CA2 445	AL-TIS	CA3 301
Minimum value	8,33	2,44	2,84	3,83	1,99		0,8 l/ha	1,0 l/ha	0,8 l/ha		0,8 l/ha	1,0 l/ha	0,6 l/ha
Maximum value	8,33	2,44	2,84	3,83	1,99	1 > 0 = 0 <	0 >	0 >	0 >	1 > 0 = 0 <	0 >	0 >	0 >
Mean disease severity (%)	8,33	2,44	2,84	3,83	1,99		1 =	1 =	1 =		1 =	1 =	1 =
Abbott efficacy (%)	0,00%	70,7 1%	65,9 1%	54,0 2%	76,1 1%		0 <	0 <	0 <		0 <	0 <	0 <
% Disease severity L2 - 45 DA-B													
Number of values	1	1	1	1	1		CA2 445	AL-TIS	CA3 301		CA2 445	AL-TIS	CA3 301

Treatment name		CA2 445	AL- TIS	CA3 301	CA3 301	No of trials where CA3301 at 0,6 l/ha is >, = or <				No of trials where CA3301 at 0,8 l/ha is >, = or <			
Rate	UNTREATED CHECK	0,8	1	0,6	0,8								
Rate unit		L/ha	L/ha	L/ha	L/ha								
Appl. Code		AB	AB	AB	AB								
						U	0,8	1,0	0,8	U	0,8	1,0	0,6
						T	l/ha	l/ha	l/ha	T	l/ha	l/ha	l/ha
						C				C			
Minimum value	24,89	7,86	8,80	10,25	5,99	1	0 >	0 >	0 >	1	0 >	0 >	0 >
Maximum value	24,89	7,86	8,80	10,25	5,99	>				>			
Mean disease severity (%)	24,89	7,86	8,80	10,25	5,99	=	1 =	1 =	1 =	=	1 =	1 =	1 =
Abbott efficacy (%)	0,00%	68,42%	64,64%	58,82%	75,93%	<	0 <	0 <	0 <	<	0 <	0 <	0 <
% Disease severity L1 - 45 DA-B													
Number of values	1	1	1	1	1	U	CA2 445	AL- TIS	CA3 301	U	CA2 445	AL- TIS	CA3 301
Minimum value	8,74	2,81	2,55	5,03	2,28	T	0,8 l/ha	1,0 l/ha	0,8 l/ha	T	0,8 l/ha	1,0 l/ha	0,6 l/ha
Maximum value	8,74	2,81	2,55	5,03	2,28	C				C			
Mean disease severity (%)	8,74	2,81	2,55	5,03	2,28	1	0 >	0 >	0 >	1	0 >	0 >	1 >
Abbott efficacy (%)	0,00%	67,85%	70,82%	42,45%	73,91%	>				>			
						=	1 =	0 =	0 =	=	1 =	1 =	0 =
						<	0 <	1 <	1 <	<	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against SEPTTR - North-Eastern EPPO zone

In the North-Eastern EPPO zone, a total of 6 trials evaluated the efficacy of CA3301 on rye against *Zymoseptoria tritici*. 3 trials out of 6 were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha (applied twice), and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stage BBCH 37 and the 2nd application was at BBCH 57-65.

Summary results are presented in Table 3.2-564.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on rye against *Zymoseptoria tritici*, since disease severity was significantly reduced in all trial assessments.

On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 84.33-83.79% efficacy against *Zymoseptoria tritici* two weeks after the 2nd application and 75.33-82.96% before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 74.91-95.27% efficacy on reduction of disease severity two weeks after the 2nd application and 83.03-91.92% before harvest.

In the North-Eastern EPPO zone, CA3301 at 0.6-0.8 l/ha showed medium to high efficacy in reducing the severity of *Zymoseptoria tritici* on rye. In all assessments at this dose range, CA3301 gave statistically equivalent disease control compared to the authorized reference products CA2445 and OSIRIS. Although in average, CA3301 at 0.8 l/ha rate showed numerically higher efficacy levels than both reference products. Across this limited dataset the efficacy of CA3301 at 0.6 l/ha was comparable to 0.8 l/ha, however at some assessments a clear numerical increase appears with CA3301 applied at 0.8 l/ha.

Moreover, a larger dataset was presented on the related crop-disease pair winter wheat - *Zymoseptoria tritici* which supports the trends observed here.

Therefore, in many instances 0.6 l/ha gave sufficient disease control but in conditions of high disease pressure, historical difficulties in control of this disease or where some level of resistance is suspected it may be appropriate to use 0.8 l/ha for control of *Zymoseptoria tritici*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Zymoseptoria tritici* on rye in the North-East ~~EPPO~~ EPPO zone.

Table 3.2-564: Summary table - Efficacy evaluation – Rye – SEPTTR – North-East ~~EPPO~~ EPPO zone

Table 3.2-304. Summary table - Efficacy evaluation - Rye - SE1 F1R - North-East - EPTO zone													
Treatment name	UN-TREATED CHECK	CA 244 5 L/ha a AB	OSI-RIS 65 EC L/ha AB	CA 330 1 L/ha a AB	CA 330 1 L/ha a AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,6 l/ha is >, = or < compared to				
Rate		0,8	2	0,6	0,8								
Rate unit		L/ha	L/ha	L/ha	L/ha								
Appl. Code		AB	AB	AB	AB								
% Disease severity L2 - 15 DA-B													
Number of values	2	2		2	2	UTC		CA3301		UTC		CA3301	
Minimum value	5,43	1,48		1,23	1,24			0,8 l/ha				0,6 l/ha	
Maximum value	16,81	1,48	-	1,46	1,36	2 >		0 >		2 >		0 >	
Mean disease severity (%)	11,12	1,48		1,34	1,3	0 =		2 =		0 =		2 =	
Abbott efficacy (%)	0,00%	81,97%		84,33%	83,79%	0 <		0 <		0 <		0 <	
Number of values	1	1	1	1	1	CA2445		OSIRIS 65 EC		CA2445		OSIRIS 65 EC	
Minimum value	16,81	1,48	2,75	1,46	1,24	0,8 l/ha		2,0 l/ha		0,8 l/ha		2,0 l/ha	
Maximum value	16,81	1,48	2,75	1,46	1,24	0 >		0 >		0 >		0 >	
Mean disease severity (%)	16,81	1,48	2,75	1,46	1,24	2 =		1 =		2 =		1 =	
Abbott efficacy (%)	0,00%	91,20%	83,64%	91,31%	92,62%	0 <		0 <		0 <		0 <	
% Disease severity L1 - 15 DA-B													
Number of values	1	1	1	1	1	UTC	CA2445	OSI-RIS 65 EC	CA3301	UTC	CA 244 5 L/ha	OSIRIS 65 EC	CA 330 1 L/ha
Minimum value	10,56	1,14	2,40	2,65	0,50		0,8 l/ha	1,0 l/ha	0,8 l/ha		0,8 l/ha	1,0 l/ha	0,6 l/ha
Maximum value	10,56	1,14	2,40	2,65	0,50	1 >	0 >	0 >	0 >	1 >	0 >	0 >	0 >
Mean disease severity (%)	10,56	1,14	2,40	2,65	0,50	0 =	1 =	1 =	1 =	0 =	1 =	1 =	1 =
Abbott efficacy (%)	0,00%	89,20%	77,27%	74,91%	95,27%	0 <	0 <	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L2 - 26-44 DA-B													
Number of values	3	3		3	3	UTC		CA3301		UTC		CA3301	
Minimum value	9,61	1,14		1,80	0,60			0,8 l/ha				0,6 l/ha	
Maximum value	24,4	4,11	-	5,98	3,24	3 >		0 >		3 >		0 >	
Mean disease severity (%)	17,32	2,83		3,66	2,26	0 =		3 =		0 =		3 =	
Abbott efficacy (%)	0,00%	78,19%		75,33%	82,96%	0 <		0 <		0 <		0 <	
Number of values	1	1	1	1	1	CA2445		OSIRIS 65 EC		CA2445		OSIRIS 65 EC	

Treatment name	UN-TREATED CHECK	CA 244 5 0,8 L/ha a AB	OSI-RIS 65 EC 2 L/ha AB	CA 330 1 0,6 L/ha a AB	CA 330 1 0,8 L/ha a AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate									
Rate unit									
Appl. Code									
Minimum value		17,94	3,23	5,28	5,98	3,24	0,8 l/ha	2,0 l/ha	0,8 l/ha
Maximum value	17,94	3,23	5,28	5,98	3,24	0 >	0 >	0 >	0 >
Mean disease severity (%)	17,94	3,23	5,28	5,98	3,24	3 =	1 =	3 =	1 =
Abbott efficacy (%)	0,00%	82,0 0%	70,57%	66,6 7%	81,9 4%	0 <	0 <	0 <	0 <
% Disease severity L1 - 26-44 DA-B									
Number of values	2	2		2	2	UTC	CA3301	UTC	CA3301
Minimum value	8,94	0,45		0,50	0,34		0,8 l/ha		0,6 l/ha
Maximum value	15,63	2,59	-	4,43	1,93	2 >	0 >	2 >	0 >
Mean disease severity (%)	12,28	1,52		2,46	1,13	0 =	2 =	0 =	2 =
Abbott efficacy (%)	0,00%	89,2 0%		83,0 3%	91,9 2%	0 <	0 <	0 <	0 <
Number of values	1	1	1	1	1	CA2445	OSIRIS 65 EC	CA2445	OSIRIS 65 EC
Minimum value	15,63	2,59	1,83	4,43	1,93	0,8 l/ha	2,0 l/ha	0,8 l/ha	2,0 l/ha
Maximum value	15,63	2,59	1,83	4,43	1,93	0 >	0 >	0 >	0 >
Mean disease severity (%)	15,63	2,59	1,83	4,43	1,93	2 =	1 =	2 =	1 =
Abbott efficacy (%)	0,00%	83,4 3%	88,29%	71,6 6%	87,6 5%	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against SEPTTR - South-Eastern EPPO zone

In the South-Eastern EPPO zone, a total of 4 trials evaluated the efficacy of CA3301 on rye against *Zymoseptoria tritici*. 3 trials out of 4 were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha (applied twice), and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 31-37 and the 2nd application was at BBCH 59-61.

Summary results are presented in Table 3.2-565.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on rye against *Zymoseptoria tritici*, since disease severity was significantly reduced in all trial assessments.

On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 69.19-65.65% efficacy against *Zymoseptoria tritici* two weeks after the 2nd application and 83.99-91.03% before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 98.84-98.18% efficacy on reduction of disease severity before harvest.

In the South-Eastern EPPO zone, CA3301 at 0.6-0.8 l/ha showed medium to high efficacy in reducing the severity of *Zymoseptoria tritici* on rye. Highest levels of control were observed before harvest, where the timing is critical for a suitable ear filling. In all assessments at this dose range, CA3301 gave equivalent disease control compared to the authorized reference products CA2445 and PRIAXOR. Averaged across this limited dataset the efficacy of CA3301 at 0.6 l/ha was fairly comparable to 0.8 l/ha, however in some assessments a numerical benefit was derived from increasing the dose rate to 0.8 l/ha for disease control. Moreover, a larger dataset was presented on the related crop-disease pair winter wheat - *Zymoseptoria tritici* showing the same trend than observed here. Therefore, in many instances 0.6 l/ha gave sufficient disease control but in conditions of high disease pressure, historical difficulties in control of this disease or where some level of resistance is suspected, it may be appropriate to use 0.8 l/ha for control of *Zymoseptoria tritici*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Zymoseptoria tritici* on rye in the South-Eastern EPPO zone.

Table 3.2-565: Summary table - Efficacy evaluation – Rye – SEPTTR – South-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA2445 0,8 L/ha AB	PRIAXOR 1,5 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
% Disease severity L2 - 15 DA-B							
Number of values	1	1		1	1	UT C	CA3301 0,8 l/ha CA2445 0,8 l/ha
Minimum value	10,19	5,33		3,14	3,50		CA3301 0,6 l/ha CA2445 0,8 l/ha
Maximum value	10,19	5,33	-	3,14	3,50	1 >	0 >
Mean disease severity (%)	10,19	5,33		3,14	3,50	0 =	1 =
Abbott efficacy (%)	0,00%	47,69 %		69,19 %	65,65 %	0 <	0 <
% Disease severity L2 - 38 DA-B							
Number of values	1		1	1	1	UT C	CA3301 0,8 l/ha CA2445 0,8 l/ha
Minimum value	34,66		5,38	5,55	3,11		CA3301 0,6 l/ha CA2445 0,8 l/ha
Maximum value	34,66	-	5,38	5,55	3,11	1 >	0 >
Mean disease severity (%)	34,66		5,38	5,55	3,11	0 =	1 =
Abbott efficacy (%)	0,00%		84,48%	83,99 %	91,03 %	0 <	0 <
% Disease severity L1 - 25-38 DA-B							
Number of values	2			2	2	UT C	CA3301 0,8 l/ha CA3301 0,6 l/ha
Minimum value	5,88			0,01	0,02		
Maximum value	8,6	-	-	0,13	0,20	2 >	0 >
Mean disease severity (%)	7,24			0,07	0,11	0 =	2 =
Abbott efficacy (%)	0,00%			98,84 %	98,18 %	0 <	0 <
Number of values	1	1		1	1	PRIAXOR 1,5 l/ha	PRIAXOR 1,5 l/ha
Minimum value	8,60	0,05		0,01	0,02		
Maximum value	8,60	0,05	-	0,01	0,02	0 >	0 >
Mean disease severity (%)	8,60	0,05		0,01	0,02	1 =	1 =
Abbott efficacy (%)	0,00%	99,42 %		99,88 %	99,77 %	0 <	0 <
Number of values	1		1	1	1	CA2445 0,8 l/ha	CA2445 0,8 l/ha
Minimum value	5,88		0,13	0,13	0,20		
Maximum value	5,88	-	0,13	0,13	0,20	0 >	0 >
Mean disease severity (%)	5,88		0,13	0,13	0,20	1 =	1 =

Abbott efficacy (%)	0,00%		97,79%	97,79 %	96,60 %	0 <	0 <
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'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against SEPTTR - Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, a total of 8 trials from North-East EPPO zone and the neighbouring country Czech Republic evaluated the efficacy of CA3301 on rye against *Zymoseptoria tritici*. 5 trials out of 8 were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 31-39 and the 2nd application was at BBCH 37-65.

Summary results are presented in Table 3.2-566.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on rye against *Zymoseptoria tritici*, since disease severity was significantly reduced in all trial assessments.

On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 86.06-86.94% efficacy against *Zymoseptoria tritici* two weeks after the 2nd application and 65.05-75.57% before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 74.91-95.27% efficacy on reduction of disease severity two weeks after the 2nd application and 83.03-91.92% before harvest.

In Poland and neighbouring countries, CA3301 at 0.6-0.8 l/ha showed medium to high efficacy in reducing the severity of *Zymoseptoria tritici* on rye. In all assessments at this dose range, CA3301 gave statistically equivalent disease control compared to the authorized reference products CA2445 and OSIRIS 65 EC. However, in average, a numerical superiority was observed for CA3301 at 0.8 l/ha compared to both reference products. Across this limited dataset, CA3301 at 0.6 l/ha showed a comparable efficacy to 0.8 l/ha, however in some assessments a numerical benefit was derived from increasing the dose rate to 0.8 l/ha for disease control. Therefore, in many instances 0.6 l/ha gave sufficient disease control but in conditions of high disease pressure, historical difficulties in control of this disease or where some level of resistance is suspected it may be appropriate to use 0.8 l/ha for control of *Zymoseptoria tritici*.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Zymoseptoria tritici* on rye in Poland.

Table 3.2-566: Summary table - Efficacy evaluation – Rye – SEPTTR – Data relevant for Poland

Treatment name	UNTREATED CHECK	CA2 445 0,8 L/ha AB	OSIRIS 65 EC 2 L/ha AB	CA3 301 0,6 L/ha AB	CA3 301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
% Disease severity L2 - 12-15 DA-B							
Number of values	3	3		3	3	UTC	UTC
Minimum value	5,43	1,18		1,23	1,13		CA3301 0,8 l/ha
Maximum value	16,81	1,48	-	1,75	1,36	3 >	3 >
Mean disease severity (%)	12,98	1,38		1,48	1,24	0 =	0 =
Abbott efficacy (%)	0,00%	85,62 %		86,06 %	86,94 %	0 <	0 <

Treatment name	UNTREATED CHECK	CA2 445 0,8 L/ha AB	OSIRIS 65 EC 2 L/ha AB	CA3 301 0,6 L/ha AB	CA3 301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate						CA2445	OSIRIS 65 EC	CA2445	OSIRIS 65 EC
Rate unit						0,8 l/ha	2,0 l/ha	0,8 l/ha	2,0 l/ha
Appl. Code						0 >	0 >	0 >	0 >
Number of values	1	1	1	1	1	3 =	1 =	3 =	1 =
Minimum value	16,81	1,48	2,75	1,46	1,24	0 <	0 <	0 <	0 <
Maximum value	16,81	1,48	2,75	1,46	1,24				
Mean disease severity (%)	16,81	1,48	2,75	1,46	1,24				
Abbott efficacy (%)	0,00%	91,20 %	83,64%	91,31 %	92,62 %				
% Disease severity L1 - 15 DA-B									
Number of values	1	1	1	1	1	UT C	CA2 445 0,8 l/ha	OSIRIS 65 EC 1,0 l/ha	CA3 301 0,8 l/ha
Minimum value	10,56	1,14	2,40	2,65	0,50	1 >	0 >	0 >	0 >
Maximum value	10,56	1,14	2,40	2,65	0,50	0 =	1 =	1 =	1 =
Mean disease severity (%)	10,56	1,14	2,40	2,65	0,50	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	89,20 %	77,27%	74,91 %	95,27 %				
% Disease severity L2 - 26-44 DA-B									
Number of values	4	4		4	4	UTC	CA3301 0,8 l/ha	UTC	CA3301 0,6 l/ha
Minimum value	9,61	1,14		1,80	0,60	4 >	0 >	4 >	0 >
Maximum value	24,40	7,84	-	9,50	6,73	0 =	4 =	0 =	4 =
Mean disease severity (%)	16,60	4,08		5,12	3,38	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	70,07 %		65,05 %	75,57 %				
Number of values	1	1	1	1	1	CA2445	OSIRIS 65 EC	CA2445	OSIRIS 65 EC
Minimum value	17,94	3,23	5,28	5,98	3,24	0,8 l/ha	2,0 l/ha	0,8 l/ha	2,0 l/ha
Maximum value	17,94	3,23	5,28	5,98	3,24	0 >	0 >	0 >	0 >
Mean disease severity (%)	17,94	3,23	5,28	5,98	3,24	4 =	1 =	4 =	1 =
Abbott efficacy (%)	0,00%	82,00 %	70,57%	66,67 %	81,94 %	0 <	0 <	0 <	0 <
% Disease severity L1 - 26-44 DA-B									
Number of values	2	2		2	2	UTC	CA3301 0,8 l/ha	UTC	CA3301 0,6 l/ha
Minimum value	8,94	0,45		0,50	0,34	2 >	0 >	2 >	0 >
Maximum value	15,63	2,59	-	4,43	1,93	0 =	2 =	0 =	2 =
Mean disease severity (%)	12,28	1,52		2,46	1,13	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	89,20 %		83,03 %	91,92 %				
Number of values	1	1	1	1	1	CA2445	OSIRIS 65 EC	CA2445	OSIRIS 65 EC
Minimum value	15,63	2,59	1,83	4,43	1,93	0,8 l/ha	2,0 l/ha	0,8 l/ha	2,0 l/ha
Maximum value	15,63	2,59	1,83	4,43	1,93	0 >	0 >	0 >	0 >
Mean disease severity (%)	15,63	2,59	1,83	4,43	1,93	2 =	1 =	2 =	1 =
Abbott efficacy (%)	0,00%	83,43 %	88,29%	71,66 %	87,65 %	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

3 valid field trials were carried out in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,6-0,8 l/ha achieved very mixed results. The effectiveness of dose rate of 0,6 l/h amounted from low (44,45%) to high level (>80%). In the case of 0,8 l/ha was similar, the results were low (50,82%) to high (81,51%) after 12-49 days after second application. Due to the limited number of trials, the cMSs are kindly asked to consider this use on the national level.

3 valid trials were available in **the North-East EPPO zone**. CA3301 applied at dose rate of 0,6 l/ha achieved medium to high efficacy. The high level was noted after applied at 0,8 l/ha after 15-44 DA-B. The trials conducted in the Czech Republic were included to the overall calculation to support of the Polish registration. The total of 5 efficacy trials is still insufficient **to accept this use**. However, SEPTTR has local importance for winter rye in Poland and this number of trials can be accepted.

3 valid efficacy trials were carried out in **the South-East EPPO zone**. CA3301 applied at dose rate of 0,6-0,8 l/ha achieved medium to high level of control after 15-38 days after second application. Moreover, 1 field trials have been submitted from the Medoterranean zone. The significant differences were observed between 0,6 and 0,8 l/ha. The lower dose showed very low effectiveness (42,45-58,82%). The dose rate of 0,8 l/ha achieved medium level after 15-45 DA-B. Due to the limited number of trials, the cMSs are kindly asked to consider this use on the national level.

3.2.3.3 Rye (SECCW) / *Puccinia recondita* - *Puccinia recondita* f. sp. *recondita* (PUCCRE-PUCCRR)

Materials and Methods – Rye – PUCCRE/PUCCRR

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Puccinia recondita and *Puccinia recondita* f. sp. *recondita* are the causal agents of the brown rust on rye and are considered as the same pathogen in this analysis.

Between 2017 and 2020, a series of 17 trials were conducted in several countries of the Maritime, North-East~~ern~~ and South-East~~ern~~ EPPO zones to evaluate the efficacy of CA3301 against *Puccinia recondita* or *P. recondita* f. sp. *recondita* on rye (see Table 3.2-567). The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, 9 trials were performed in Czech Republic (3), Germany (2), Denmark (3) and United Kingdom (1).

In the North-Eastern EPPO zone, 6 trials were performed in Poland (5) and Latvia (1).

In the South-Eastern EPPO zone, a total of 2 trials were performed in Hungary (2).

Data groupings were also made specifically for Poland evaluation and trials involved (11) were performed in the North-Eastern EPPO zone (6), in the Czech Republic (3) and in Germany (2).

Table 3.2-567: Presentation of trials – Rye (SECCW)

Crop(s))*	Target(s)*	Country	Year s	Type of trial**	Number of trials (number of valid trials)				GEP, non- GEP, of- ficial***	Comments (any other relevant infor- mation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Rye	PUCCRE/PUCCRR	Czech Republic	2017 - 2018	MED + E	3 (3)	-	-	-	GEP	
		Denmark	2018 -	MED + E	3 (0)				GEP	

Crop(s)) *	Target(s)*	Country	Year s	Type of trial**	Number of trials (number of valid trials)				GEP, non- GEP, of- ficial***	Comments (any other relevant infor- mation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
			2019							
		Ger- many	2020	MED + E	2 (2)	-	-	-	GEP	
		United King- dom	2019	MED+ E	1 (1)				GEP	
Rye	PUCCRE/PUCC RR	Poland	2017 - 2019	MED + E	-	-	5 (3)	-	GEP	
		Latvia	2020	MED + E	-	-	1 (0)	-	GEP	
Rye	PUCCRE/PUCC RR	Hun- gary	2018 - 2019	MED + E	-	-	-	2 (1)	GEP	
TO- TAL	-	-	2017 - 2020	MED + E	9 (6)	-	6 (3)	2 (1)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation

In all trials, CA3301 was compared to at least one commercial fungicide used as standard reference for comparison.

Table 3.2-568: Efficacy evaluation - Presentation of reference standards used in trials – Rye (SECCW) – PUCCRE/PUCCRR – Maritime EPPO zone

Crop(s))	Refer- ence standard	Country(ies) where the product is used ⁽¹⁾	Authoriza- tion number	Active sub- stance(s)	Formulation		Regis- tered ap- plication rate ⁽³⁾	Applica- tion rate in tri- als (per treat- ment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concentra- tion of a.s.			
SECC W	PRO- LINE 250 EC	CZECH REPUBLIC	4523-1	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO- LINE	GER- MANY	025287-00	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO- LINE EC 250	DEN- MARK	0637	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	
	PRO- LINE 275	UNITED KINGDOM	14790	Pothiocona- zole	EC	275 g/l	2 x 0.72 l/ha	2 x 0.72 l/ha	

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-569: Efficacy evaluation - Presentation of reference standards used in trials – Rye (SECCW) – PUCCRE/PUCRR – North-East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
SECCW	OSIRIS 65 EC	POLAND	R-87/2012	Epoxiconazole + Metconazole	EC	37.5 g/l + 27.5 g/l	2.5 l/ha	2.0 l/ha	
	PRAKTIS	POLAND	R-222/2019	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials
	PRO-LINE	LATVIA	0637(LV)	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-570: Efficacy evaluation - Presentation of reference standards used in trials – Rye (SECCW) – PUCCRE/PUCRR – South-East EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
SECCW	PRO-LINE	HUNGARY	6300/1205-1/2020	Prothioconazole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials
	PRI-AXOR	HUNGARY	04.2/2426-1/2018 04.2/4127-1/2016	Fluxapyroxad + Pyraclostrobin	EC	75 g/l + 150 g/l	1.5 l/ha	1.5 l/ha	

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-571.

Table 3.2-571: Details on trial methodology – Rye (SECCW) – PUCCRE/PUCRR

		Maritime EPPO zone	North-East EPPO zone	South-East EPPO zone	Data relevant for Poland
Trials	Total number (valid number)	8 (5)	6 (3)	2 (1)	11 (8)
	Supportive trials	-	-	-	-
Guidelines	General guidelines	PP 1/152 (4) PP 1/181 (4)	PP 1/152 (4) PP 1/181 (4)	PP 1/152 (4) PP 1/181 (4)	PP 1/152 (4) PP 1/181 (4)

		PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)	PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)	PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)	PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)
	Specific guidelines	PP 1/26 (4)	PP 1/26 (4)	PP 1/26 (4)	PP 1/26 (4)
Experimental design	Plot design	Randomized Complete Blocks, Untreated included	Randomized Complete Blocks, Untreated included	Randomized Complete Blocks, Untreated included	Randomized Complete Blocks, Untreated included
	Plot size	21 - 30 m ²	21 - 30 m ²	21 - 30 m ²	21 - 30 m ²
	Number of replications	4	4	4	4
Crop	Trials per crop	SECCW (8)	SECCW (6)	SECCW (2)	SECCW (11)
	Varieties per crop	SU Santiny, Diamond, Benito, In-spektor, Palazzo, Kws Livado, Danielo, Binntto	Brasetto (2), Poznanskie (1), TUR F1 (2), KWS Serafino (1)	Dankowskie Diament (2)	Brasetto (2), Poznanskie, TUR F1, Tur, SU Santiny, Benito, Binntto, Danielo, KWS Serafino
	Sowing period	September (7), October (1)	September (5), August (1)	September (2)	August (1), September (9), October (1)
Application	Crop stage (BBCH)* at application	A: BBCH 33-37 B: BBCH 55-59	A: BBCH 31-39 B: BBCH 37-65	A: BBCH 31-37 B: BBCH 41-61	A: BBCH 31-39 B: BBCH 37-65
	Timing Pest stage at application	BBCH 31-65 A: MIXED (3), AC-TIVE (1), PRINFC (1), N/A (3) B: MIXED (2), PRINFC (2), N/A (4)	BBCH 31-61 A: MYCELI (3), MIXED (1), N/A (2) B: MYCELI (3), MIXED (1), N/A (2)	BBCH 31-61 A: N/A (1), PRINFC (1) B: N/A (1), MIXED (1)	BBCH 31-65 A: MYCELI (3), MIXED (5), N/A (3) B: MYCELI (4), MIXED (4), N/A (3)
	Number of applications Intervals between applications	2 applications (14-22 days) (4)	2 applications (16-30 days)	2 applications (14-22 days) (2)	2 applications (16-36 days)
	Spray volumes	A: 200-300 l/ha B: 200-300 l/ha	A: 200-300 l/ha B: 200-300 l/ha	A: 200-300 l/ha B: 200-300 l/ha	A: 200-300 l/ha B: 200-300 l/ha
Assessment	Assessment types	Pest severity (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg), Moisture content (%), TKW (g), HLW (kg)	Pest severity (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg/ha), TKW (g), HLW (kg/hl), MOICON (%), GRNARE (%)	Pest severity (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg), HLW (kg), TKW (g), Moisture content (%)	Pest severity (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg/ha), TKW (g), HLW (kg/hl), MOICON (%), GRNARE (%)
	Assessment dates	0 DA-A, 14-20 DA-A, 0 DA-B, 13-24 DA-B, 28-55 DA-B	0 DA-A, 14-16 DA-A, -2-0 DA-B, 14-16 DA-B, 23-39 DA-B	0 DA-A, 14-22 DA-A, 0 DA-B, 14-15 DA-B, 32-38 DA-B	0 DA-A, 14-20 DA-A, -2-0 DA-B, 13-24 DA-B, 23-55 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Natural (8)	Natural (6)	Natural (2)	Natural (11)

17 trials were carried out against *Puccinia recondita* (PUCCRE) or *Puccinia recondita* f. sp. *recondita* (PUCCRR) on rye, of which 10 were valid.

In the Maritime EPPO zone, 9 trials were available against *Puccinia recondita* (PUCCRE) or *Puccinia recondita f. sp. recondita* (PUCCRR), on rye. 6 trials out of 9 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.8 l/ha applied twice, compared to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 31-39 and the 2nd application was at BBCH 47-65.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6-0.8 l/ha to control brown rust on rye, since disease severity was significantly reduced at all trial assessments.

Overall in the Maritime EPPO zone, both dose rates of CA3301 gave equivalent disease control compared to the authorised reference products CA2445 and PROLINE 275 which both were applied at 200 g/ha of prothioconazole. In the majority of assessments, the 0.6 l/ha dose rate was comparable to 0.8 l/ha. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for control of brown rust. However, in case of very early disease infection or when climatic and cropping conditions are conducive to heavy disease infection, the rate of 0.8 l/ha may be beneficial to further reduce disease pressure.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Puccinia recondita* on rye in the Maritime EPPO zone.

[illegible]

Treatment name	UNTREATED CHECK	PROLINE 275	CA2445	CA3301	CA3301	No of trials where CA3301			No of trials where CA3301		
Rate		0,72	0,8	0,6	0,8	at 0,6 l/ha is >, = or <			at 0,8 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	AB	compared to			compared to		
						UTC	CA2445	CA3301	UTC	CA2445	CA3301
Number of values	1		1	1	1						
Minimum value	12,06		1,88	3,44	2,06	0,8 l/ha	0,8 l/ha	0,8 l/ha	0,8 l/ha	0,6 l/ha	
Maximum value	12,06	-	1,88	3,44	2,06	1 > 0 = 0 <	0 > 0 = 1 <	1 > 0 = 0 <	0 > 1 = 0 <	1 > 0 = 0 <	
Mean disease severity (%)	12,06		1,88	3,44	2,06						
Abbott efficacy (%)	0,00%		84,41%	71,48%	82,92%						
% Disease severity L2 - 28-55 DA-B											
Number of values	4			4	4	UTC	CA3301	UTC	CA3301		
Minimum value	13,68			0,50	0,28		0,8 l/ha			0,6 l/ha	
Maximum value	1000,00	-	-	16,19	20,13	4 >	0 >	4 >	1 >		
Mean disease severity (%)	38,72			7,68	6,97	0 =	3 =	0 =	3 =		
Abbott efficacy (%)	0,00%			76,70%	84,81%	0 <	1 <	0 <	0 <		
Number of values	1	1		1	1	PROLINE 275		PROLINE 275			
Minimum value	100,00	14,88		16,19	20,13	0,72 l/ha		0,72 l/ha			
Maximum value	100,00	14,88	-	16,19	20,13	0 >		0 >			
Mean disease severity (%)	100,00	14,88		16,19	20,13	1 =		1 =			
Abbott efficacy (%)	0,00%	85,12%		83,81%	79,87%	0 <		0 <			
Number of values	3		3	3	3	CA2445		CA2445			
Minimum value	13,68		0,56	0,50	0,28	0,8 l/ha		0,8 l/ha			
Maximum value	21,63	-	7,40	10,40	5,73	0 >		0 >			
Mean disease severity (%)	18,30		3,77	4,84	2,58	3 =		3 =			
Abbott efficacy (%)	0,00%		79,48%	74,33%	86,45%	0 <		0 <			
% Disease severity L1 - 35-55 DA-B											
Number of values	4			4	4	UTC	CA3301	UTC	CA3301		
Minimum value	5,38			0,20	0,13		0,8 l/ha			0,6 l/ha	
Maximum value	100,00	-	-	8,14	13,04	4 >	0 >	4 >	0 >		
Mean disease severity (%)	31,98			3,18	4,06	0 =	4 =	0 =	4 =		
Abbott efficacy (%)	0,00%			85,99%	89,25%	0 <	0 <	0 <	0 <		
Number of values	1	1		1	1	PROLINE 275		PROLINE 275			
Minimum value	100,00	14,69		8,14	13,04	0,72 l/ha		0,72 l/ha			

Treatment name	UNTREATED CHECK	PROLIN E 275	CA2445	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Rate		0,72	0,8	0,6	0,8		
Rate unit		L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	AB		
Maximum value	100,00	14,69	-	8,14	13,04	0 >	0 >
Mean disease severity (%)	100,00	14,69		8,14	13,04	1 =	1 =
Abbott efficacy (%)	0,00%	85,31%		91,86%	86,89%	0 <	0 <
Number of values	3		3	3	3	CA2445	CA2445
Minimum value	5,38		0,34	0,20	0,13	0,8 l/ha	0,8 l/ha
Maximum value	16,13	-	3,84	2,54	2,19	0 >	0 >
Mean disease severity (%)	9,32		1,96	1,52	1,07	3 =	3 =
Abbott efficacy (%)	0,00%		81,11%	84,04%	90,01%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against PUCCRE/PUCCRR - North-Eastern EPPO zone

In the North-Eastern EPPO zone, 6 trials were available against *Puccinia recondita* (PUCCRE) on rye. 3 trials out of 6 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.8 l/ha applied twice, compared to the reference products on disease severity (%). CA3301 was first applied at crop BBCH stages 32-37 and the 2nd application was at BBCH 53-65.

Summary results are presented in Table 3.2-573.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6-0.8 l/ha to control brown rust on rye, as significant reductions in disease severity were observed at all assessments.

On foliar level 2, at 0.6-0.8 l/ha, CA3301 showed 76.73-86.32% of efficacy on disease severity two weeks after the 2nd application and 83.52-85.02% before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 73.81-92.65% of efficacy on reduction of disease severity two weeks after the 2nd application and 79.79-88.22% before harvest.

In the North-Eastern EPPO zone the dataset showed low to high disease pressure (5.34-53.00% severity). In these conditions, both dose rates of CA3301 demonstrated medium to high efficacy, however in conditions of high disease pressure a significant benefit was observed with CA3301 at 0.8 l/ha compared to 0.6 l/ha, as highlighted in the trial EU19-067-63. In addition, both dose rates gave equivalent disease control compared to the authorized prothioconazole reference product. Compared to the mixture product OSIRIS 65 EC, 0.8 l/ha of CA3301 was equivalent and 0.6 l/ha was generally lower. Therefore, it is envisaged that a dose rate of 0.6 l/ha is appropriate to control brown rust in conditions of low to medium disease pressure. However, when disease pressure increases, the 0.8 l/ha dose rate may be beneficial to maximise protection and crop quality.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Puccinia recondita* on rye in the North-Eastern EPPO zone.

Table 3.2-573: Summary table - Efficacy evaluation – Rye – PUCCRE/PUCCRR – North-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA2 445	OSIRIS 65 EC	CA3 301	CA3 301	No of trials where CA3301			No of trials where CA3301		
Rate		0,8	2	0,6	0,8	at 0,6 l/ha is >, = or <			at 0,8 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	AB	compared to			compared to		
% Disease severity L2 - 15 DA-B											
Number of values	1		1	1	1	U	OSIRIS 65 EC	CA3 301	U	OSIRIS 65 EC	CA3 301
Minimum value	42,25		7,88	9,83	5,78	T	2,0 l/ha	0,8 l/ha	T	2,0 l/ha	0,6 l/ha
Maximum value	42,25	-	7,88	9,83	5,78	1	0 >	0 >	1	0 >	1 >
Mean disease severity (%)	42,25		7,88	9,83	5,78	0	0 =	0 =	0	1 =	0 =
Abbott efficacy (%)	0,00%		81,35%	76,7 3%	86,3 2%	0	1 <	1 <	0	0 <	0 <
% Disease severity L1 - 15 DA-B											
Number of values	1		1	1	1	U	OSIRIS 65 EC	CA3 301	U	OSIRIS 65 EC	CA3 301
Minimum value	16,19		2,65	4,24	1,19	T	2,0 l/ha	0,8 l/ha	T	2,0 l/ha	0,6 l/ha
Maximum value	16,19	-	2,65	4,24	1,19	1	0 >	0 >	1	1 >	1 >
Mean disease severity (%)	16,19		2,65	4,24	1,19	0	0 =	0 =	0	0 =	0 =
Abbott efficacy (%)	0,00%		83,63%	73,8 1%	92,6 5%	0	1 <	1 <	0	0 <	0 <
% Disease severity L2 - 26 DA-B											
Number of values	2	2		2	2	U	CA2445	CA3 301	U	CA2445	CA3 301
Minimum value	5,34	0,00		0,00	0,00	T	0,8 l/ha	0,8 l/ha	T	0,8 l/ha	0,6 l/ha
Maximum value	16,45	1,57	-	1,76	1,60	2	0 >	0 >	2	0 >	0 >
Mean disease severity (%)	10,90	0,78		0,88	0,80	0	2 =	2 =	0	2 =	2 =
Abbott efficacy (%)	0,00%	85.8 0%		83.5 2%	85.0 2%	0	0 <	0 <	0	0 <	0 <
% Disease severity L1 - 26-29 DA-B											
Number of values	2			2	2	UTC	CA3301		UTC	CA3301	
Minimum value	7,29			0,00	0,00		0,8 l/ha			0,8 l/ha	
Maximum value	53,00	-	-	12,1 9	7,10	2 >	0 >		2 >	1 >	
Mean disease severity (%)	30,14			6,09	3,55	0 =	1 =		0 =	1 =	
Abbott efficacy (%)	0,00%			79,7 9%	88,2 2%	0 <	1 <		0 <	0 <	
Number of values	1	1		1	1	CA2445			CA2445		
Minimum value	7,29	0,00		0,00	0,00	0,8 l/ha			0,8 l/ha		
Maximum value	7,29	0,00	-	0,00	0,00	0 >			0 >		
Mean disease severity (%)	7,29	0,00		0,00	0,00	1 =			1 =		
Abbott efficacy (%)	0,00%	100, 00%		100, 00%	100, 00%	0 <			0 <		

Number of values	1		1	1	1	OSIRIS 65 EC	OSIRIS 65 EC
Minimum value	53,00		6,70	12,19	7,10	2,0 l/ha	2,0 l/ha
Maximum value	53,00	-	6,70	12,19	7,10	0 >	0 >
Mean disease severity (%)	53,00		6,70	12,19	7,10	0 =	1 =
Abbott efficacy (%)	0,00%		87,36%	77,00%	86,60%	1 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)	
>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against PUCCRE/PUCCRR - South-Eastern EPPO zone

In the South-Eastern EPPO zone, 2 trials were available against *Puccinia recondita* (PUCCRE) or *Puccinia recondita f. sp. recondita* (PUCCRR), on rye. 1 trial out of 2 was considered valid and was included to support the efficacy evaluation of CA3301 at 0.6-0.8 l/ha applied twice, compared to the reference products on disease severity (%). CA3301 was first applied at crop stage BBCH 31 and the 2nd application was at BBCH 41. In this trial, only one assessment timing was available close to harvest (38 DA-B).

Summary results are presented in Table 3.2-574.

When evaluating the reduction of disease severity, the data demonstrated CA3301 at 0.6-0.8 l/ha allowed to completely control *P. recondita* before harvest, whatever the foliar level considered.

In the Southern-Eastern EPPO zone, in this limited dataset, disease severity was low to medium close to harvest (8.29-16.30%) depending on the foliar level. At late assessment, both rates of CA3301 gave full disease control and were comparable to the reference product. Moreover, this observation can be supported by the larger dataset provided on the closely related crop-disease pair winter wheat – *Puccinia recondita* which showed very comparable level of efficacy from both CA3301 dose rates. This larger dataset also provided information about efficacy on early assessment timing (two weeks after 2nd application) and about the benefit of increasing dose rate from 0.6 l/ha to 0.8 l/ha. Indeed, on winter wheat, data demonstrated, a numerical and statistical benefit of increasing the dose rate from 0.6 l/ha to 0.8 l/ha in late assessments to maintain crop quality until harvest.

Therefore, it is envisaged that in situations of low disease pressure, CA3301 applied at 0.6 l/ha would be sufficient to control disease, but where disease pressure is medium to high, a rate of 0.8 l/ha is more appropriate to maintain crop quality as longer as possible.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Puccinia recondita* on rye in the South-Eastern EPPO zone.

Table 3.2-574: Summary table - Efficacy evaluation – Rye – PUCCRE/PUCCRR – South-Eastern EPPO zone

Treatment name	UNTREATED CHECK	PRI-AXOR 1,5 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Rate						
Rate unit						
Appl. Code						
% Disease severity L2 - 38 DA-B						
Number of values	1	1	1	1	UT C	UT C
Minimum value	16,30	0,00	0,00	0,00	PRI-AXOR 1,5 l/ha	PRI-AXOR 1,5 l/ha
					CA3301 0,8 l/ha	CA3301 0,6 l/ha

Maximum value	16,30	0,00	0,00	0,00	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	16,30	0,00	0,00	0,00	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	100,00 %	100,00 %	100,00 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 38 DA-B										
Number of values	1	1	1	1	UT C	PRI-AXOR 1,5 l/ha	CA3 301 0,8 l/ha	UT C	PRI-AXOR 1,5 l/ha	CA3 301 0,6 l/ha
Minimum value	8,29	0,00	0,00	0,00	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	8,29	0,00	0,00	0,00	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	8,29	0,00	0,00	0,00	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	100,00 %	100,00 %	100,00 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against Puccinia recondita - Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-Eastern EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, a total of 11 trials from North-Eastern EPPO zone and the neighbouring countries Czech Republic and Germany evaluated the efficacy of CA3301 on rye against *Puccinia recondita*. 8 trials out of 11 were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha applied twice, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 31-39 and the 2nd application was at BBCH 37-65.

Summary results are presented in Table 3.2-575.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on rye against *Puccinia recondita*, since disease severity was significantly reduced at all trial assessments.

On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 74.10-84.62% efficacy against *Puccinia recondita* two weeks after the 2nd application and 78.00-85.88% before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 73.81-92.65% efficacy on reduction of disease severity two weeks after the 2nd application and 85.82-91.33% before harvest.

In Poland and neighbouring countries, CA3301 at 0.6-0.8 l/ha showed medium to high efficacy in reducing the severity of *Puccinia recondita* on rye. CA3301 at 0.6 l/ha and 0.8 l/ha were overall equivalent to the reference products CA2445 applied at 0.8 l/ha. Compared to the other reference OSIRIS 65 EC, applied at 2.0 l/ha, which has a different composition (27.5% metconazole + 37.5% epoxiconazole) and a different mode of action, CA3301 at 0.6 l/ha was statistically less efficient whereas CA3301 at 0.8 l/ha showed comparable or significantly higher control.

At most assessments (8 of 13) the efficacy of CA3301 at 0.6 l/ha was comparable to 0.8 l/ha, however in some assessments a statistical and numerical benefit was derived from increasing the dose rate to 0.8 l/ha for disease control (example of trial EU19-067-63, where the disease infection was very high from grain development stage). Considering all available data, in most instance CA3301 at 0.6 l/ha will give sufficient control of brown rust, but in situations with high disease pressure, it may be appropriate to use 0.8 l/ha.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Puccini recondita* on rye in Poland.

Table 3.2-575: Summary table - Efficacy evaluation – Rye – PUCCRE/PUCCRR – Data relevant for Poland

Treatment name	UNTREATED CHECK	CA24 45 0,8 L/ha AB	OSIRIS 65 EC 2 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to			
% Disease severity L2 - 12-15 DA-B											
Number of values	2			2	2	UTC	CA3301 0,8 l/ha	UTC	CA3301 0,6 l/ha		
Minimum value	12,06			3,44	2,06						
Maximum value	42,25	-	-	9,83	5,78	2 >	0 >	2 >	2 >		
Mean disease severity (%)	27,16			6,63	3,92	0 =	0 =	0 =	0 =		
Abbott efficacy (%)	0,00%			74,10 %	84,62 %	0 <	2 <	0 <	0 <		
Number of values	1	1		1	1	CA2445 0,8 l/ha		CA2445 0,8 l/ha			
Minimum value	12,06	1,88		3,44	2,06	0 >		0 >			
Maximum value	12,06	1,88	-	3,44	2,06						
Mean disease severity (%)	12,06	1,88		3,44	2,06	0 =		1 =			
Abbott efficacy (%)	0,00%	84,41 %		71,48 %	82,92 %	1 <		0 <			
Number of values	1		1	1	1	OSIRIS 65 EC 2,0 l/ha		OSIRIS 65 EC 2,0 l/ha			
Minimum value	42,25		7,88	9,83	5,78	0 >		0 >			
Maximum value	42,25	-	7,88	9,83	5,78						
Mean disease severity (%)	42,25		7,88	9,83	5,78	0 =		1 =			
Abbott efficacy (%)	0,00%		81,35%	76,73 %	86,32 %	1 <		0 <			
% Disease severity L1 - 15 DA-B											
Number of values	1		1	1	1	UT C	OSIRIS 65 EC 2,0 l/ha	CA33 01 0,8 l/ha	UT C	OSIRIS 65 EC 2,0 l/ha	CA33 01 0,6 l/ha
Minimum value	16,19		2,65	4,24	1,19	1 >	0 >	0 >	1 >	1 >	1 >
Maximum value	16,19	-	2,65	4,24	1,19		0 =	0 =	0 =	0 =	0 =
Mean disease severity (%)	16,19		2,65	4,24	1,19	0 =	0 =	0 =	0 =	0 =	0 =
Abbott efficacy (%)	0,00%		83,63%	73,81 %	92,65 %	0 <	1 <	1 <	0 <	0 <	0 <
% Disease severity L2 - 26-55 DA-B											
Number of values	5	5		5	5	UT C	CA2445 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA2445 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	5,34	0,00		0,00	0,00	5 >	0 >	0 >	5 >	0 >	1 >
Maximum value	21,63	7,40	-	10,40	5,73		0 =	5 =	4 =	0 =	5 =
Mean disease severity (%)	15,33	2,58		3,25	1,87	0 =	5 =	4 =	0 =	5 =	4 =
Abbott efficacy (%)	0,00%	81,81 %		78,00 %	85,88 %	0 <	0 <	1 <	0 <	0 <	0 <
% Disease severity L1 - 26-55 DA-B											
Number of values	5			5	5	UTC	CA3301 0,8 l/ha	UTC	CA3301 0,6 l/ha		
Minimum value	5,38			0,00	0,00	5 >	0 >	5 >	1 >		
Maximum value	53,00	-	-	12,19	7,10		0 =	4 =	0 =	4 =	
Mean disease severity (%)	17,65			3,35	2,06	0 =	4 =	0 =	4 =		
Abbott efficacy (%)	0,00%			85,82 %	91,33 %	0 <	1 <	0 <	0 <		
Number of values	4	4		4	4	CA2445		CA2445			

Treatment name		CA24 45 0,8 L/ha AB	OSIRIS 65 EC 2 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to 0,8 l/ha	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to 0,8 l/ha
Rate	UNTREATED CHECK						
Rate unit							
Appl. Code							
Minimum value	5,38	0,00	-	0,00	0,00	0 >	0 >
Maximum value	16,13	3,84	-	2,54	2,19	4 =	4 =
Mean disease severity (%)	8,81	1,47		1,14	0,81	0 <	0 <
Abbott efficacy (%)	0,00%	85,83 %		88,03 %	92,51 %		
Number of values	1		1	1	1	OSIRIS 65 EC 2,0 l/ha	OSIRIS 65 EC 2,0 l/ha
Minimum value	53,00		6,70	12,19	7,10	0 >	0 >
Maximum value	53,00	-	6,70	12,19	7,10	0 =	1 =
Mean disease severity (%)	53,00		6,70	12,19	7,10	1 <	0 <
Abbott efficacy (%)	0,00%		87,36%	77,00 %	86,60 %		

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

6 valid trials were carried out in **the Maritime EPPO climatic zone**. CA3301 achieved medium to high level of control after applied at dose rate of 0,6 l/ha and high efficacy at 0,8 l/ha after 12-55 days after second application.

3 valid trials were conducted in **the North-East EPPO zone**. Also 5 trials from Czech Republic and Germany have been included to the overall calculation to support of Polish registration. Taking into account all results, it can be concluded that the dose rate of 0,6 l/ha is effective on medium to high level. The high efficacy was noted after application of 0,8 l/ha.

Only 1 valid trial was available in **the South-East EPPO zone**. The very high level of control was noted after applied of CA3301 at dose rate of 0,6-0,8 l/ha (100%). No additional trials have been submitted from the Mediterranean zone. Due to the limited number of trials, the cMSs are kindly asked to consider this use on the national level.

CA3301 can be recommended to control of *Puccinia recondita* in winter rye in the Maritime and North-East EPPO zone. The dose rate of 0,8 l/ha can be use in case of high disease pressure.

3.2.3.4 Rye (SECCW) / *Rhynchosporium secalis* (RHYNSE)

Materials and Methods – Rye – RHYNSE

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2018 and 2020, a series of 6 trials were conducted in several countries of the Maritime and North-East~~EPPO~~ zones to evaluate the efficacy of CA3301 against *Rhynchosporium secalis* on **rye** (see Table 3.2-576). The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, 5 trials were performed in Denmark (3) and Germany (2).

In the North-East~~EPPO~~ EPPO zone, 1 trials was performed in Latvia.

Groupings were also made specifically for Poland and trials involved (3) were performed in the North-East~~EPPO~~ EPPO zone (1), in Latvia (1) and in the Maritime EPPO zone, in Germany (2).

Table 3.2-576: Presentation of trials – Rye (SECCW)

Crop(s)) *	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Rye	RHYNSE	Den- mark	2018- 2019	MED + E	3 (1)	-	-	-	GEP	
		Ger- many	2020	MED + E	2 (1)	-	-	-	GEP	
Rye	RHYNSE	Latvia	2020	MED + E	-	-	1 (1)	-	GEP	
TO- TAL	-	-	2018- 2020	MED + E	5 (2)	-	1 (1)	-	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation

In all trials, CA3301 was compared to at least one commercial fungicide used as standard reference for comparison.

Table 3.2-577: Efficacy evaluation - Presentation of reference standards used in trials – Rye (SECCW) – RHYNSE – Maritime EPPO zone

Crop(s))	Refer- ence standard	Coun- try(ies) where the product is used ⁽¹⁾	Authoriza- tion number	Active sub- stance(s)	Formulation		Regis- tered ap- plication rate ⁽³⁾	Applica- tion rate in tri- als (per treat- ment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concentra- tion of a.s.			
SECC W	PRO- LINE EC 250	DK	18-473	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRO- LINE	DE	025287-00	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-578: Efficacy evaluation - Presentation of reference standards used in trials – Rye (SECCW) – RHYNSE – North-Eastern EPPO zone

Crop(s)	Refer- ence stand- ard	Coun- try(ies) where the product is used ⁽¹⁾	Authoriza- tion num- ber	Active sub- stance(s)	Formulation		Regis- tered ap- plication rate ⁽³⁾	Applica- tion rate in trials (per treat- ment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concentra- tion of a.s.			
SECCW	PRO- LINE	LATVIA	0637(LV)	Prothiocona- zole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in

Table 3.2-579.

Table 3.2-579: Details on trial methodology – Rye (SECCW) – RHYNSE

		Maritime EPPO zone	North-East EPPO zone	Data relevant for Poland
Trials	Total number (valid number)	5 (2)	1 (1)	3 (2)
	Supportive trials	-	-	-
Guidelines	General guide-lines	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3) PP 1/225 (2)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)
	Specific guide-lines	PP 1/26 (4) PP 1/28 (3) PP 1/262 (1)	PP 1/26 (4)	PP 1/26 (4)
Experimental design	Plot design	Randomized Complete Blocks, Untreated included	Randomized Complete Blocks, Untreated included	Randomized Complete Blocks, Untreated included
	Plot size	18 - 30 m ²	24 m ²	21-24 m ²
	Number of replications	4	4	4
Crop	Trials per crop	SECCW (5)	SECCW (1)	SECCW (3)
	Varieties per crop	Benito, Binnitto, Kws Livado, Palazzo, Danielo	KWS Serafino	Danielo, KWS Serafino, Binnitto
	Sowing period	September (4), October (1)	August (1)	August (1), September (2)
Application	Crop stage (BBCH)* at application	A: BBCH 31-37 B: BBCH 47-69	A: BBCH 33 B: BBCH 51	A: BBCH 31-33 B: BBCH 47-51
	Timing Pest stage at application	BBCH 31-69 A: ACTIVE (1), MIXED (2), PRINFC (1), N/A (1) B: MIXED (1), PRINFC (2), N/A (2)	BBCH 33-51 A: MIXED (1) B: MIXED (1)	BBCH 31-51 A: MIXED (2), PRINFC (1) B: MIXED (2), PRINFC (1)
	Number of applications Intervals between applications	2 applications (8-20 days)	2 applications (30 days)	2 applications (19-30 days)
	Spray volumes	A: 200 l/ha B: 200 l/ha	A: 200 l/ha B: 200 l/ha	A: 200 l/ha B: 200 l/ha
Assessment	Assessment types	Pest severity (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg), Moisture content (%), TKW (g), HLW (kg)	Pest severity (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg/ha), TKW (g), HLW (kg/hl), MOICON (%), GRNARE (%)	Pest severity (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg/ha), TKW (g), HLW (kg/hl), MOICON (%), GRNARE (%)
	Assessment dates	0 DA-A, 14-20 DA-A, 0-1 DA-B, 13-24 DA-B, 29-53 DA-B	0 DA-A, 14 DA-A, -2 DA-B, 14 DA-B, 39 DA-B	0 DA-A, 14-20 DA-A, -2-0 DA-B, 14-15 DA-B, 29-55 DA-B

Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Natural (5)	Natural (1)	Natural (2)
	e.g. Field / Greenhouse...	Field trials (5)	Field trials (1)	Field trials (2)

Out of the 6 trials carried out against *Rhynchosporium secalis* (RHYNSE) on rye, 3 were considered valid:

Use of CA3301 at 2x 0.6-0.8 l/ha against RHYNSE - Maritime EPPO zone

In the Maritime EPPO zone, 5 trials were available against *Rhynchosporium secalis*, on rye. 2 trials out of 5 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.8 l/ha applied twice, compared to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 32-37 and the 2nd application was at BBCH 47-65.

Summary results are presented in Table 3.2-580.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6-0.8 l/ha to control rhynchosporiosis on rye, since disease severity was significantly reduced at all assessments.

On foliar level 2, at 0.6-0.8 l/ha, CA3301 fully controlled the disease two weeks after the 2nd application and showed 79.05-83.91% of efficacy to reduce the disease severity before harvest. On foliar level 1, CA3301 at 0.6-0.8 l/ha showed 82.47-88.26% of efficacy on reduction of disease severity before harvest.

In the Maritime EPPO zone, a limited dataset was available. At the range of 0.6-0.8 l/ha, CA3301 gave equivalent or higher disease control compared to the authorized reference product CA2445. In all the assessments, the 0.6 l/ha dose rate was comparable to 0.8 l/ha although a numerical trend was observed whereby disease control increased with the higher dose rate before harvest. Moreover, a larger dataset was presented on closely related crop-disease pair winter barley – *Rhynchosporium secalis* which supports the present data. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for control of rhynchosporiosis, however when conditions are conducive to heavy disease infestation, the rate of 0.8 l/ha may be beneficial to further reduce disease pressure.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Rhynchosporium secalis* on rye in the Maritime EPPO zone.

Table 3.2-580: Summary table - Efficacy evaluation – Rye – RHYNSE – Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA24 45	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		0,8	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Disease severity L2 - 13 DA-B										
Number of values	1	1	1	1	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	5,00	0,00	0,00	0,00	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	5,00	0,00	0,00	0,00	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease se- verity (%)	5,00	0,00	0,00	0,00	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	100,0 0%	100,0 0%	100,0 0%	0 <	0 <	0 <	0 <	0 <	0 <

% Disease severity L2 - 55 DA-B										
Number of values	1	1	1	1	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	17,09	3,89	3,58	2,75						
Maximum value	17,09	3,89	3,58	2,75	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	17,09	3,89	3,58	2,75	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	77,24 %	79,05 %	83,91 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 55 DA-B										
Number of values	1	1	1	1	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	6,73	1,83	1,18	0,79						
Maximum value	6,73	1,83	1,18	0,79	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	6,73	1,83	1,18	0,79	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	72,81 %	82,47 %	88,26 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against RHYNSE - Mediterranean EPPO zone

No data were available to support the efficacy evaluation of CA3301 against *Rhynchosporium secalis* on rye. However, the specie *Rhynchosporium secalis* is also the causal agent of leaf blotch on barley. It therefore seems reasonable from an agronomic perspective to assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on rye from the robust dataset proposed for the closely related crops winter and spring barley. Furthermore, existing authorisations for prothioconazole products (JOAO, PRAKTIS) have the same dose rate for this pathogen on barley, which also indicates that performance is comparable between the pathogen/crop pairs.

The dataset presented in – Winter barley (HORVW) / *Rhynchosporium secalis* (RHYNSE/RHYNSP) and Spring barley (HORVS) / *Rhynchosporium secalis* (RHYNSE) – showed that in conditions of disease pressure was relatively low and CA3301 gave higher or equivalent disease control compared to several authorized reference products. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient to provide acceptable control of *Rhynchosporium secalis*. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for the control of *Rhynchosporium secalis* on barley but in case of heavy infestation, 0.8 l/ha may be more adequate to obtain higher disease control on rye.

On rye, leaf blotch remains more occasional than on barley crops and since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.8 l/ha generally gave adequate disease control, it is supposed that the same dose range will be acceptable to control *Rhynchosporium secalis* on rye.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Rhynchosporium secalis* on triticale in Mediterranean EPPO zone

Use of CA3301 at 2x 0.6-0.8 l/ha against RHYNSE - North-Eastern EPPO zone

In the North-Eastern EPPO zone, 1 trial was available against *Rhynchosporium secalis* (RHYNSE) on rye. This trial was considered valid and was included to support the efficacy evaluation of CA3301 at 0.6-0.8 l/ha applied twice, compared to the reference product CA2445 on disease severity (%). CA3301 was first applied at crop BBCH stage 33 and the 2nd application was at BBCH 51.

Summary results are presented in Table 3.2-581.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6-0.8 l/ha to control rhynchosporiosis on rye, since a significant reduction in disease severity was observed. On foliar level 2, at 0.6-0.8 l/ha, CA3301 showed 74.31-75.21% of efficacy on disease severity before harvest.

In the North-Eastern EPPO zone the single trial available showed medium disease pressure (20.94% severity). In these conditions, CA3301 applied at 0.6-0.8 l/ha demonstrated medium efficacy with a slight numerical increase with 0.8 l/ha compared to 0.6 l/ha. Both dose rates gave equivalent disease control compared to CA2445. Moreover, a larger dataset was presented on closely related crops-disease pairs winter and spring barley – *Rhynchosporium secalis* can provide supportive data for the results presented here.

Therefore, it is envisaged that a dose rate of 0.6 l/ha is appropriate for control of rhynchosporiosis in conditions of low to medium disease pressure. However, when disease pressure is high, the 0.8 l/ha dose rate may be beneficial to maximise protection and crop quality.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Rhynchosporium secalis* on rye in the North-Eastern EPPO zone.

Table 3.2-581: Summary table - Efficacy evaluation – Rye – RHYNSE – North-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA24 45	CA33 01	CA33 01	No of trials where CA3301			No of trials where CA3301		
Rate		0,8	0,6	0,8	at 0,6 l/ha is >, = or			at 0,8 l/ha is >, = or		
Rate unit		L/ha	L/ha	L/ha	<			<		
Appl. Code		AB	AB	AB	compared to			compared to		
% Disease severity L2 - 39 DA-B										
Number of values	1	1	1	1	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	20,94	5,56	5,38	5,19	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	20,94	5,56	5,38	5,19	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease se- verity (%)	20,94	5,56	5,38	5,19	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	73,45 %	74,31 %	75,21 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against RHYNSE – South-Eastern EPPO zone

No data were available to support the efficacy evaluation of CA3301 against *Rhynchosporium secalis* on rye. However, the specie *Rhynchosporium secalis* is also the causal agent of leaf blotch on barley. It therefore seems reasonable from an agronomic perspective to assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on rye from the robust dataset proposed for the closely related crops winter and

spring barley. Furthermore, existing authorisations for prothioconazole products (JOAO, PRAKTIS) have the same dose rate for this pathogen on barley, which also indicates that performance is comparable between the pathogen/crop pairs.

The dataset presented in – Winter barley (HORVW) / *Rhynchosporium secalis* (RHYNSE/RHYNSP) and Spring barley (HORVS) / *Rhynchosporium secalis* (RHYNSE) – showed that in conditions of disease pressure was relatively low and CA3301 gave higher or equivalent disease control compared to several authorized reference products. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient to provide acceptable control of *Rhynchosporium secalis*. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for the control of *Rhynchosporium secalis* on barley but in case of heavy infestation, 0.8 l/ha may be more adequate to obtain higher disease control on rye.

On rye, leaf blotch remains more occasional than on barley crops and since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.8 l/ha generally gave adequate disease control, it is supposed that the same dose range will be acceptable to control *Rhynchosporium secalis* on rye.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Rhynchosporium secalis* on triticale in South-Eastern EPPO zone.

Use of CA3301 at 2x 0.6-0.8 l/ha against RHYNSE - Data relevant for Poland

Specifically for Poland, a total of 3 trials from North-Eastern EPPO zone and the neighbouring country Germany evaluated the efficacy of CA3301 on rye against *Rhynchosporium secalis*. 2 trials out of 3 were considered valid and enabled to determine the efficacy of CA3301 at 0.6-0.8 l/ha applied twice, and to compare it to the reference product on disease severity (%). CA3301 was first applied at crop stages BBCH 32-33 and the 2nd application was at BBCH 47-51.

Summary results are presented in Table 3.2-582.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the reduction of disease severity on rye against *Rhynchosporium secalis*, since disease severity was significantly reduced at all assessments

On foliar level 2, CA3301 at 0.6-0.8 l/ha showed 76.68-79.56% efficacy against *Rhynchosporium secalis* before harvest and 82.47-88.26% efficacy on foliar level 2.

In Poland and neighbouring countries, CA3301 at 0.6-0.8 l/ha showed medium to high efficacy in reducing the severity of rhynchosporiosis on rye. CA3301 at 0.6 l/ha and 0.8 l/ha were numerically more efficient but statistically equivalent to the reference product CA2445 applied at 0.8 l/ha. Across this limited dataset the efficacy of CA3301 at 0.6 l/ha was comparable to 0.8 l/ha, however in some assessments a numerical benefit was derived from increasing the dose rate to 0.8 l/ha for disease control. Moreover, a larger dataset was presented for the closely related crop-disease pair winter barley – *Rhynchosporium secalis* which supports the trends observed here and the high level of efficacy of CA3301 against this disease. According to Poland national guidance, data in winter or spring barley is supportive for rye against this pathogen.

Considering all available data, in most instances CA3301 at 0.6 l/ha will give sufficient control of rhynchosporiosis, but in situations with high disease pressure, historical difficulties in control of this disease or where some level of resistance is suspected it may be appropriate to use 0.8 l/ha.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Rhynchosporium secalis* on rye in Poland

Table 3.2-582: Summary table - Efficacy evaluation – Rye – RHYNSE – Data relevant for Poland

Treatment name	UNTREATED CHECK	CA24 45	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		0,8	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Disease severity L2 - 39-55 DA-B										
Number of values	2	2	2	2	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	17,09	3,89	3,58	2,75	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	20,94	5,56	5,38	5,19	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease se- verity (%)	19,01	4,73	4,48	3,97	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	75,34 %	76,68 %	79,56 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity L1 - 55 DA-B										
Number of values	1	1	1	1	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	6,73	1,83	1,18	0,79	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	6,73	1,83	1,18	0,79	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease se- verity (%)	6,73	1,83	1,18	0,79	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	72,81 %	82,47 %	88,26 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

2 valid trials were conducted in **the Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,6-0,8 l/ha achieved high level of control after 13-55 days after second application. Due to the limited number of trials, the cMSs are kindly asked to consider this use on the national level.

Only 1 valid trials has been submitted in **the North-East EPPO zone**. The medium efficacy was observed after applied CA3301 at dose rate of 0,6-0,8 l/ha. Also 1 trial from Germany has been included to the overall calculation to support of Polish registration. Moreover, an extrapolation of trial results is possible from winter barley to rye in Poland. The dose rate of 0,8 l/ha can be recommended in case of high disease pressure.

No data were available in **the South-East** and Mediterranean EPPO zones. The cMSs are kindly asked to consider this use on the national level.

3.2.3.5 Rye (SECCW) / *Blumeria graminis* (ERYSGR)

Materials and Methods – Rye – ERYSGR

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2018 and 2020, a series of 3 trials were conducted in several countries of the Maritime and North-East ~~EPPO~~ EPPO zones to evaluate the efficacy of CA3301 against *Blumeria graminis f. sp. secalis* on rye (ERYSGS / ERYSGR) (see Table 3.2-583). The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, 2 trials were performed in Denmark (1) and Czech Republic (1).
In the North-Eastern EPPO zone, 1 trial was performed in Latvia (1).

Out of the 3 trials carried out against *Blumeria graminis* (ERYSGS / ERYSGR) on rye, 1 was considered valid.

Table 3.2-583: Presentation of trials – Rye (SECCW)

Crop(s)) *	Tar- get(s)*	Country	Year s	Type of trial*	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
Rye	ERYSGR	Czech Republic	2018	MED + E	1 (1)	-	-	-	GEP	
		Den- mark	2019	MED + E	1 (0)	-	-	-	GEP	
Rye	ERYSGR	Latvia	2020	MED + E	-	-	1 (0)	-	GEP	
TO- TAL	-	-	2018- 2020	MED + E	2 (1)	-	1 (0)	-	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation

In all trials, CA3301 was compared to at least one commercial fungicide used as standard reference for comparison.

Table 3.2-584: Efficacy evaluation - Presentation of reference standards used in trials – Rye (SECCW) – ERYSGR – Maritime EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active sub- stance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in tri- als (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
SECCW	PROLINE	DK	18-473	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PROLINE 250 EC	CZ	4523-1	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	CA2445 in some trials

Table 3.2-585: Efficacy evaluation - Presentation of reference standards used in trials – Rye (SECCW) – ERYSGR – North-Eastern EPPO zone

Crop(s))	Refer- ence standard	Coun- try(ies) where the product is used ⁽¹⁾	Authoriza- tion number	Active sub- stance(s)	Formulation		Regis- tered ap- plication rate ⁽³⁾	Applica- tion rate in tri- als (per treat- ment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concentra- tion of a.s.			
SECC W	PRO- LINE	LV	0637(LV)	Prothiocona- zole	EC	250 g/l	0.8 l/ha	0.8 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-586.

Table 3.2-586: Details on trial methodology – Rye (SECCW) – ERYSGR

		Maritime EPPO zone	North-East EPPO zone
Trials	Total number (valid number)	2 (1)	1 (0)
	Supportive trials	-	-
Guidelines	General guidelines	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3) PP 1/225 (2)	PP 1/152 (4) PP 1/181 (4) PP 1/239 (2) PP 1/135 (4) PP 1/214 (3)
	Specific guidelines	PP 1/26 (4) PP 1/28 (3) PP 1/262 (1)	PP 1/26 (4)
Experimental design	Plot design	Randomized Complete Blocks, Un-treated included	Randomized Complete Blocks, Un-treated included
	Plot size	21 - 30 m ²	24 m ²
	Number of replications	4	4
Crop	Trials per crop	SECCW (2)	SECCW (1)
	Varieties per crop	Diamond, Benito	KWS Serafino
	Sowing period	September (1), October (1)	August (1)
Application	Crop stage (BBCH)* at application	A: BBCH 37 B: BBCH 45-65	A: BBCH 33 B: BBCH 51
	Timing Pest stage at application	BBCH 31-69 A: MIXED (1) N/A (1) B: N/A (2)	BBCH 33-51 A: MIXED (1) B: MIXED (1)
	Number of applications Intervals between applications	2 applications (14-22 days)	2 applications (30 days)
	Spray volumes	A: 200 l/ha B: 200 l/ha	A: 200 l/ha B: 200 l/ha
Assessment	Assessment types	Pest severity (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg), Moisture content (%), TKW (g), HLW (kg)	Pest severity (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 scale), Yield (kg/ha), TKW (g), HLW (kg/hl), MOICON (%), GRNARE (%)
	Assessment dates	0 DA-A, 14 DA-A, 0 DA-B, 15-24 DA-B, 28-53 DA-B	0 DA-A, 14 DA-A, -2 DA-B, 14 DA-B, 39 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Natural (2)	Natural (1)
	e.g. Field / Greenhouse...	Field trials (2)	Field trials (1)

Use of CA3301 at 2x 0.6-0.8 l/ha against ERYSGR - Maritime EPPO zone

In the Maritime EPPO zone, 2 trials were available against *Blumeria graminis* (ERYSGR), on rye. 1 trial out of 2 was considered valid and was included to support the efficacy evaluation of CA3301 at 0.6-0.8 l/ha applied twice, compared to the reference products on disease severity (%). CA3301 was first applied at crop stage BBCH 37 and the 2nd application was at BBCH 47-65.

Summary results are presented in Table 3.2-587.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6-0.8 l/ha to control powdery mildew on rye, since a significant reduction in disease severity was observed. On foliar level 2, at 0.6-0.8 l/ha, CA3301 showed 60.76-81.25% of efficacy on disease severity before harvest.

On rye, powdery mildew remains an occasional disease and depending on climatic conditions, will develop in a heterogeneous way in the crop. This explains the limited data set obtained despite the several trials implemented on rye. In this limited dataset, in the Maritime EPPO zone both dose rates of CA3301 gave equivalent disease control compared to the authorised reference product CA2445. Whereas no statistical differences were observed in this trial, a numerical trend appeared where disease control increases with the dose rate of CA3301 applied. Moreover, the species *Blumeria graminis* f. sp. *secalis* is very comparable to other *Blumeria graminis* species as f. sp. *tritici*, which causes powdery mildew on wheat. Since application details are the same, and similar prothioconazole products are registered against this pathogen at the same dose rate for wheat and rye, it seems logical from an agronomic perspective to assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on rye from the robust dataset proposed for the closely related crop winter wheat.

The dataset presented in – **Winter wheat (TRZAW) / *Blumeria graminis* (ERYSGR)** – showed that CA3301 applied at 0.6-0.8 l/ha provided significant disease control in the two main assessment timing. Both dose rates were always statistically equivalent or better than the reference products CA2445 and PROLINE 275. Moreover, the level of disease control observed was medium to high depending on the disease pressure. Indeed, whereas differences were not always significant, a clear numerical trend appeared where CA3301 at 0.8 l/ha provided better efficacy than 0.6 l/ha dose in the most challenging conditions.

Finally, since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.8 l/ha generally gave adequate disease control, and are comparable to authorised prothioconazole products, it is supposed that the same dose range will be acceptable to control powdery mildew on rye.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Blumeria graminis* on rye in the Maritime EPPO zone.

Table 3.2-587: Summary table - Efficacy evaluation – Rye – ERYSGR – Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA24	CA33	CA33	No of trials where			No of trials where		
Rate		45	01	01	CA3301			CA3301		
Rate unit		0,8	0,6	0,8	at 0,6 l/ha is >, = or			at 0,8 l/ha is >, = or <		
Appl. Code		L/ha	L/ha	L/ha	<					
		AB	AB	AB	compared to			compared to		
% Disease severity L2 - 28 DA-B										
Number of values	1	1	1	1	UT	CA24	CA330	UT	CA24	CA33
Minimum value	6,88	1,54	2,70	1,29	C	45	1	C	45	01
Maximum value	6,88	1,54	2,70	1,29		0,8	0,8 l/ha		0,8	0,6
Mean disease severity (%)	6,88	1,54	2,70	1,29		l/ha			l/ha	l/ha
					1 >	0 >	0 >	1 >	0 >	0 >
					0 =	1 =	1 =	0 =	1 =	1 =

Abbott efficacy (%)	0,00%	77,62 %	60,76 %	81,25 %	0 <	0 <	0 <	0 <	0 <	0 <
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'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)	
	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.8 l/ha against ERYSGR - Mediterranean EPPO zone

In the Mediterranean EPPO zone, no trial was conducted to assess the control of powdery mildew *Blumeria graminis* f. sp. *secalis* on rye by CA3301 due to lack of disease infection. However, the species *Blumeria graminis* f. sp. *secalis* is very comparable to other *Blumeria graminis* species as f. sp. *tritici*, which causes powdery mildew on wheat. Since application details are the same, and similar prothioconazole products are registered against this pathogen at the same dose rate for wheat and rye, it seems logical from an agronomic perspective to assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on rye from the robust dataset proposed for the closely related crop winter wheat.

The dataset presented in – **Winter wheat (TRZAW) / *Blumeria graminis* (ERYSGR)** – showed that CA3301 applied at 0.6-0.8 l/ha provided significant disease control in the two main assessment timings. Both dose rates were always statistically equivalent to the reference products CA2445 and PROSARO. Moreover, the level of disease control observed was medium to high depending on the disease pressure. Indeed, whereas differences were not always significant, a clear numerical trend appeared where CA3301 at 0.8 l/ha provided better efficacy than 0.6 l/ha dose in the most challenging conditions.

Finally, since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.8 l/ha generally gave adequate diseases control, and are comparable to authorised prothioconazole products, it is supposed that the same dose range will be acceptable to control powdery mildew on rye.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Blumeria graminis* on rye in the Mediterranean EPPO zone.

Use of CA3301 at 2x 0.6-0.8 l/ha against ERYSGR - North-East EPPO zone

In the North-East EPPO zone, a single trial was conducted to assess the control of powdery mildew *Blumeria graminis* f. sp. *secalis* on rye by CA3301 but it was not valid due to lack of disease infection. However, the species *Blumeria graminis* f. sp. *secalis* is very comparable to other *Blumeria graminis* species as f. sp. *tritici*, which causes powdery mildew on wheat. It is therefore possible to extrapolate and assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on rye from the robust dataset proposed for the closely related crop winter wheat.

The dataset presented in – **Winter wheat (TRZAW) / *Blumeria graminis* (ERYSGR)** – showed that CA3301 applied at 0.6-0.8 l/ha provided significant disease control in the two main assessment timings. Both dose rates were always statistically equivalent or better than the reference products CA2445 and OSIRIS 65 EC. Moreover, the level of disease control observed was medium to high depending on the disease pressure. Indeed, whereas differences were not always significant, a clear numerical trend appeared where CA3301 at 0.8 l/ha provided better efficacy than 0.6 l/ha dose in the most challenging conditions.

Finally, since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.8 l/ha generally gave adequate diseases control, and are comparable to authorised prothioconazole products, it is supposed that the same dose range will be acceptable to control powdery mildew on rye.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Blumeria graminis* on rye in the North-Eastern EPPO zone.

Use of CA3301 at 2x 0.6-0.8 l/ha against ERYSGR - South-Eastern EPPO zone

In the South-Eastern EPPO zone, no trial was conducted to assess the control of powdery mildew *Blumeria graminis* f. sp. *secalis* on rye by CA3301 due to lack of disease infestation. However, the species *Blumeria graminis* f. sp. *secalis* is very comparable to other *Blumeria graminis* species as f. sp. *tritici*, which causes powdery mildew on wheat. Since application details are the same, and similar prothioconazole products are registered against this pathogen at the same dose rate for wheat and rye, it seems logical from an agronomic perspective to assume the positive effects of CA3301 applied at 0.6-0.8 l/ha on rye from the robust dataset proposed for the closely related crop winter wheat.

The dataset presented in – **Winter wheat (TRZAW) / *Blumeria graminis* (ERYSGR)** – showed that CA3301 applied at 0.6-0.8 l/ha provided significant disease control in the two main assessment timings. Both dose rates were most of the time statistically equivalent to the reference products CA2445 and PRIAXOR. Moreover, the level of disease control observed was medium to high depending on the disease pressure. Indeed, whereas differences were not always significant, a clear numerical trend appeared where CA3301 at 0.8 l/ha provided better efficacy than 0.6 l/ha dose in the most challenging conditions.

Finally, since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.8 l/ha generally gave adequate diseases control, and are comparable to authorised prothioconazole products, it is supposed that the same dose range will be acceptable to control powdery mildew on rye.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Blumeria graminis* on rye in the South-Eastern EPPO zone.

Comments of zRMS:

Only 1 valid trial was carried out in the **Maritime EPPO climatic zone**. CA3301 applied at dose rate of 0,6 l/ha achieved medium efficacy after 28 after second application. The dose rate of 0,8 l/ha showed high level of control. Due to the limited number of trials, the cMSs are kindly asked to consider this use on the national level. No trials have been submitted in the North-East, South-East and Mediterranean EPPO zones. The cMSs from SE zone are kindly asked to consider this use on the national level. Because an extrapolation is not possible, this use can not be accepted in Poland.

3.2.3.6 Rye (SECCW) / *Oculimacula acuformis* (PSDCHA)

(Ramanauskiene *et al.*, Effects of fungicides on the occurrence of winter wheat eyespot caused by fungi *Oculimacula acuformis* and *O. yallundae*, Crop protection, 2016)

No data were available for assessment of control of eyespot of cereals *Oculimacula acuformis* on any crop. Although early symptoms can be confused with *Fusarium spp.*, the diseases are not related and therefore it is impossible to extrapolate from these data.

However, Ramanauskiene *et al.*, showed that 2, 3 and 4 years of prothioconazole treatments allowed to reduce the population of *O. acuformis* assessed from 2009 to 2011 on winter wheat. This positive effect was observed as early as 10 days after treatment. This pathogen infecting both winter wheat and rye, it is therefore possible to transpose these results to rye.

Moreover, prothioconazole is one of the active substances the most used as fungicide in commercial practices (*Forecasting eyespot development and yield losses in winter wheat, HGCA, 2012*). Standard reference products containing prothioconazole, such as Proline 275 are registered to control eyespot on

cereals, at the same application rates as for the other authorised pathogens, which indicates that prothioconazole controls eyespot at dose rates which are demonstrated to control the other major disease pathogens in cereals. Since the proposed dose rate for CA3301 (200-150 g/ha prothioconazole) is comparable to that of the authorised product Proline 275 (200 g/ha prothioconazole), and data shows equivalence of efficacy between these products in other pathogens, it is considered that CA3301 will also provide acceptable control of eyespot at the proposed dose rate.

Since on cereals a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the range of 0.6-0.8 l/ha gave in overall equivalent disease control compared to the authorized reference products containing prothioconazole, we assume that in most instances CA3301 at 0.6 l/ha will give sufficient control of eyespot, but in situations with high disease pressure, it may be appropriate to use 0.8 l/ha.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control *Oculimacula acufiformis* on rye in all EPPO zones.

Comments of zRMS:

No efficacy trials have been submitted in rye in any EPPO climatic zones. The cMSs from the Maritime and South-East zones are kindly asked to consider this use on the national level. This use can not be accepted in Poland because an extrapolation is not possible.

3.2.3.7 Rye (SECCWW) / Green leaf area

Use of CA3301 at 2x 0.6-0.8 l/ha in Maritime EPPO zone

Green leaf area was recorded at 12-55 DA-B in 8 valid trials on rye affected by a range of pathogens after two applications of CA3301 at 0.6-0.8 l/ha. In all 8 trials, green leaf area was assessed on the whole plant.

Summary results are presented in Table 3.2-588.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the augmentation of green leaf area on rye infected by foliar diseases. In the 8 trials assessing green leaf area on the whole plant, CA3301 at 0.6-0.8 l/ha provided an augmentation of 72.42-99.28% compared to the untreated check on rye.

The performance of the tested product was globally better or equivalent at the 0.8 l/ha dose rate compared to the 0.6 l/ha dose rate. In a majority of trials CA3301 was overall equivalent to the reference products CA2445 at 0.8 l/ha and PROLINE 275 at 0.72 l/ha except in 1 trial.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will have a positive effect on the green leaf area in rye affected by a range of pathogens in the Maritime EPPO zone.

Table 3.2-588: Summary table - Efficacy evaluation – Rye – Green leaf area - Maritime EPPO zone

Treatment name	UNTREATED CHECK	PROLINE 275	CA24 45	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Rate		0,72	0,8	0,6	0,8		
Rate unit		L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	AB		
% Green leaf area - 12-55 DA-B							
Number of values	8			8	8	UT C	CA33 01
						UT C	CA33 01

* % UTC not calculated when UTC value is zero and trial excluded from mean % UTC calculation

Green leaf area was recorded at 16-45 DA-B in 3 valid trials on rye affected by a range of pathogens after two applications of CA3301 at 0.6-0.8 l/ha. In all 3 trials, green leaf area was assessed on the whole plant.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the augmentation of green leaf area on rye affected by foliar diseases.

The performance of the tested product was statistically equivalent at the 0.8 l/ha dose rate and at the 0.6 l/ha dose rate in all trials. Also, over the dataset, CA3301 at 0.6-0.8 l/ha was statistically equivalent to standard references of the Mediterranean EPPO zone.

Table 3.2-589: Summary table - Efficacy evaluation – Rye – Green leaf area - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA244 5	AL- TIS	CA330 1	CA330 1	No of trials where CA3301	No of trials where CA3301
Rate		0,8	1	0,6	0,8	at 0,6 l/ha is > ,	at 0,8 l/ha is > ,
Rate unit		L/ha	L/ha	L/ha	L/ha	= or <	= or <
Appl. Code		AB	AB	AB	AB	compared to	compared to
% Green leaf area - 16-45 DA-B							

Number of values	3	3		3	3	UTC	CA33 01 0,8 l/ha	UTC	CA33 01 0,6 l/ha
Minimum value	49,5	53,75		50	52,5				
Maximum value	67,5	90	-	85	90	1 >	0 >	1 >	0 >
Mean Green leaf area (%)	57,25	66,17		63,17	65,08	2 =	3 =	2 =	3 =
Mean %UTC	100,00%	113,97 %		108,83 %	111,91 %	0 <	0 <	0 <	0 <
Number of values	1	1	1	1	1	CA24 45 0,8 l/ha	AL- TIS 1,0 l/ha	CA24 45 0,8 l/ha	AL- TIS 1,0 l/ha
Minimum value	67,5	90	90	85	90				
Maximum value	67,5	90	90	85	90	0 >	0 >	0 >	0 >
Mean Green leaf area (%)	67,5	90	90	85	90	3 =	1 =	3 =	1 =
Mean %UTC	100,00%	133,33 %	133,33 %	125,93 %	133,33 %	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 at 2x 0.6-0.8 l/ha in North-East ~~EPPO~~ EPPO zone

Green leaf area was recorded at 23-44 DA-B in 7 valid trials on rye affected by a range of pathogens after two applications of CA3301 at 0.6-0.8 l/ha. In all 7 trials, green leaf area was assessed on the whole plant.

Summary results are presented in Table 3.2-590.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the augmentation of green leaf area on rye affected by foliar diseases.

In the 7 trials assessing green leaf area on the whole plant, CA3301 at 0.6-0.8 l/ha provided an augmentation of 54.47-63.82% compared to the untreated check.

The performance of CA3301 at 0.8 l/ha was statistically equivalent to the 0.6 l/ha dose rate or statistically better in a few trials. In a majority of trials, CA3301 was overall equivalent to the reference products CA2445 at 0.8 l/ha and OSIRIS at 2 l/ha.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will have a positive effect on the green leaf area in rye affected by a range of pathogens in the North-East ~~EPPO~~ EPPO zone.

Table 3.2-590: Summary table - Efficacy evaluation – Rye – Green leaf area – North-East ~~EPPO~~ EPPO zone

Treatment name	UNTREATED CHECK	CA24 45	OSIRIS 65 EC	CA33 01	CA33 01	No of trials where CA3301		No of trials where CA3301	
Rate		0,8	2	0,6	0,8	at 0,6 l/ha is		at 0,8 l/ha is	
Rate unit		L/ha	L/ha	L/ha	L/ha	>, = or <		>, = or <	
Appl. Code		AB	AB	AB	AB	compared to		compared to	
% Green leaf area - 23-44 DA-B									
Number of values	7			7	7	UT	CA33 01	UT	CA33 01
Minimum value	13,00			20,00	21,25	C	0,8 l/ha	C	0,6 l/ha
Maximum value	42,50	-	-	93,75	92,50	6 >	0 >	5 >	1 >
Mean Green leaf area (%)	31,93			49,07	50,79	1 =	6 =	2 =	6 =
Mean %UTC	100,00%			154,47 %	163,82 %	0 <	1 <	0 <	0 <
Number of values	5	5		5	5	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	21,25	33,75		38,75	41,25				
Maximum value	42,50	93,75	-	93,75	92,50	0 >		2 >	

Mean Green leaf area (%)	33,85	55,00		55,70	57,85	5 =	3 =
Mean %UTC	100,00%	162,58 %		163,68 %	174,84 %	0 <	0 <
Number of values	3		3	3	3	OSIRIS 65 EC 2,0 l/ha	OSIRIS 65 EC 2,0 l/ha
Minimum value	13,00		21,25	20,00	21,25		
Maximum value	41,25	-	45,00	45,00	45,00	0 >	0 >
Mean Green leaf area (%)	27,67		35,42	34,58	35,83	3 =	3 =
Mean %UTC	100,00%		137,23%	132,57 %	138,68 %	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 at 2x 0.6-0.8 l/ha in South-East ~~EPPO~~ EPPO zone

Green leaf area was recorded at 14-38 DA-B in 4 valid trials on rye affected by a range of pathogens after two applications of CA3301 at 0.6-0.8 l/ha. In all 4 trials, green leaf area was assessed on the whole plant.

Summary results are presented in

Table 3.2-591.

Data demonstrated the positive effect of 2 applications of CA3301 at 0.6-0.8 l/ha for the augmentation of green leaf area on rye against foliar diseases.

In the 4 trials assessing green leaf area on the whole plant, CA3301 at 0.6-0.8 l/ha provided an augmentation of 55.64-67.92% compared to the untreated check on rye.

The performance of CA3301 at 0.8 l/ha was statistically equivalent to the 0.6 l/ha dose rate and was overall equivalent to the reference products CA2445 and PRIAXOR. Compared to the reference products, CA3301 at 0.6 l/ha also provided a very comparable increase in green leaf area.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will have a positive effect on the green leaf area in rye affected by a range of pathogens in the South-East ~~EPPO~~ EPPO zone.

Table 3.2-591: Summary table - Efficacy evaluation – Rye – Green leaf area – South-East ~~EPPO~~ EPPO zone

Treatment name	UNTREATED CHECK	CA24 45 0,8 L/ha AB	PRI-AXOR 1,5 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,6 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
% Green leaf area - 14-38 DA-B							
Number of values	4			4	4	UT C	CA33 01 0,8 l/ha
Minimum value	21,25			41,50	53,75		UT C
Maximum value	62,50	-	-	80,00	80,00	1 >	0 >
Mean Green leaf area (%)	44,69			63,50	65,31	3 =	4 =
Mean %UTC	100,00%			155,64 %	167,92 %	0 <	0 <
Number of values	3	3		3	3	CA2445 0,8 l/ha	CA2445 0,8 l/ha
Minimum value	21,25	52,50		41,50	53,75		
Maximum value	62,50	62,50	-	70,00	67,50	0 >	0 >
Mean Green leaf area (%)	46,25	56,00		58,00	60,42	3 =	3 =
Mean %UTC	100,00%	148,29 %		140,86 %	157,22 %	0 <	0 <
Number of values	1		1	1	1	PRIAXOR 1,5 l/ha	PRIAXOR 1,5 l/ha
Minimum value	40,00		80,00	80,00	80,00		

Maximum value	40,00	-	80,00	80,00	80,00	0 >	0 >
Mean Green leaf area (%)	40,00		80,00	80,00	80,00	1 =	1 =
Mean %UTC	100,00%		200,00%	200,00%	200,00%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Comments of zRMS:

8 field trials were carried out in **the Maritime EPPO climatic zone**. CA3301 presented positive effect in assessment of green leaf area. The test product applied at dose rate 0,6 and 0,8 l/ha achieved a mean augmentation of green leaf with results of 72,42% for lower dose and 99,28% for higher dose. The observations were provided on whole plants. No significant differences between test and reference product were detected.

7 field trial was carried out in **the North-East EPPO zone**. The whole plants were observed to evaluation of green leaf area. An augmentation of green leaf area amounted 54,47% at dose rate of 0,6 l/ha and 63,82% at dose rate of 0,8 l/ha. The results from the test and reference product were comparable.

4 field trials were conducted in **the South-East EPPO zone**. CA3301 achieved a very positive effect in compared to untreated objectives and standards. An augmentation of green leaf area amounted 67,92% (0,8 l/ha) and 55,64% (0,6 l/ha) on whole plants. Moreover in additional 3 trials from the Mediterranean zone, the test product achieved an augmentation of about 12% in case of 0,8l/ha. No significant differences between test and reference product were observed.

3.2.3.8 Rye (SECCW) / Conclusion – Efficacy tests

On rye, 4 foliar diseases were assessed in 23 trials across 4 EPPO zones. Disease severity was assessed and analysed on the main foliar levels 1 and 2. Although a comprehensive trials program was undertaken for this dossier, in some instances, due to the absence of appropriate level of diseases or other agronomic or climatic limitations, the proposed number of valid trials was not fully achieved. Hence, depending on the EPPO zone, the disease, the assessment timing and the crop part assessed, the dataset available was sometimes limited and so not fully representative of the efficacy of CA3301. Therefore, to get an overview of the efficacy of CA3301 at 0.6-0.8 l/ha, summary tables are presented hereunder, on foliar levels 1&2 (see Table 3.2-592, Table 3.2-593).

Globally, across the 4 EPPO zones and all diseases the efficacy of CA3301 was acceptable to very high. Nevertheless, since in the fields a complex of disease is often observed instead of a single disease, it is of interest to present a summary of the efficacy of CA3301 across the diseases and EPPO zones, as well as considering the green leaf area presented above. Green leaf area not only indicates the area free of infection but also the ability of the plant to continue effective growth and develop to productive stages, enabling a longer duration of grain filling and therefore improved yield quantity and quality.

In many instances, a trend of decreasing disease severity when increasing the dose rate was observed with CA3301 applied at 0.6 l/ha or 0.8 l/ha. Although the rate of 0.8 l/ha overall reduced disease to a greater extent than the 0.6 l/ha rate, the differences were not always statistically significant. However, in circumstances of high disease pressure the higher rate of 0.8 l/ha was often observed to be of significant benefit, while in circumstances of low disease pressure, the 0.6 l/ha dose rate may be sufficient to give comparable disease control. In addition, due to the importance of the diseases and given the possibility of resistance in some of the pathogens assessed, the higher rate may be deemed more appropriate and should be available for users according to disease development conditions, historical control and cultivar tolerance to the pathogens.

It has been demonstrated in the preceding sections that the efficacy of CA3301 at 0.6-0.8 l/ha was overall equivalent to that provided by the approved reference standards used in the trials. Hence it is justified to propose that efficacy comparable to that of the authorised products will be obtained on the pathogens where the presented datasets are limited. For the pathogens for which use is proposed in rye, supportive

data is also available in wheat, triticale or barley, demonstrating that efficacy is acceptable and comparable to the authorised reference standards.

In this dossier data presented for minimum effective dose is primarily from assessments where 2 applications of the test product were made. However, according to disease development conditions, a single application may provide sufficient disease control, therefore users should not be restricted to always applying twice, hence in the GAP the proposed use is for 1-2 applications. In addition, crop pathogens are commonly controlled using a programme of different fungicides with varied modes of action, therefore the choice should be available to growers to make a single application of CA3301, followed by application of a different appropriate fungicide. Prothioconazole is well established over a number of years in providing good broad spectrum efficacy across a range of common crop pathogens, with either 1 or more applications appropriate according to disease development conditions, risk of resistance development and local conditions. Current authorisations for similar products containing prothioconazole including Proline 275 and Proline/Praktis/Joao (CA2445) are for 1-2 applications at comparative rates of prothioconazole to the requested use for CA3301. Considering these elements, and that data in the efficacy section shows comparability of CA3301 to these authorised products, registration of CA3301 at the proposed minimum effective dose rate and with a number of applications of 1- 2, is requested.

Considering all elements presented in the previous sections of each disease, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.8 l/ha to control a range of foliar diseases on Rye.

Table 3.2-592: Summary table - Rye – All foliar diseases (Foliar level 2)

Foliar level 2			MAR		MED		NE		SE		Poland + CZ, DE, SK	
Disease	Applica- tion timing		CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB
SEPT TR	2 weeks af- ter B	Number of values Abbott effi- cacy (%)	2 80.83 %	2 81.51 %	1 54.16 %	1 72.72 %	2 84.33 %	2 83.79 %	1 69.19 %	1 65.65 %	3 86.06 %	3 86.94 %
	Before har- vest	Number of values Abbott effi- cacy (%)	2 44.45 %	2 50.82 %	1 58.82 %	1 75.93 %	3 75.33 %	3 82.96 %	1 83.99 %	1 91.03 %	4 65.05 %	4 75.57 %
PUCC RE PUCC RR	2 weeks af- ter B	Number of values Abbott effi- cacy (%)	1 71.48 %	1 82.92 %	-	-	1 76.73 %	1 86.32 %	-	-	2 74.10 %	2 84.62 %
	Before har- vest	Number of values Abbott effi- cacy (%)	3 74.33 %	3 86.45 %	-	-	2 91.33 %	2 92.66 %	1 100.0 0%	1 100.0 0%	5 78.00 %	5 85.88 %
RHYN SE	2 weeks af- ter B	Number of values Abbott effi- cacy (%)	1 100.0 0%	1 100.0 0%	-	-	-	-	-	-	-	-
	Before har- vest	Number of values Abbott effi- cacy (%)	1 79.05 %	1 83.91 %	-	-	1 74.31 %	1 75.21 %	-	-	2 76.68 %	2 79.56 %
ER- YSGR	Before har- vest	Number of values	1	1	-	-	-	-	-	-	-	-

		Abbott effi- cacy (%)	60.76 %	81.25 %								
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Table 3.2-593: Summary table - Rye – All foliar diseases (Foliar level 1)

Foliar level 1			MAR		MED		NE		SE		Poland + CZ, DE, SK	
Disease	Applica- tion timing		CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB
SEPTT R	2 weeks after B	Number of values Abbott effi- cacy (%)	1 58.45 %	1 70.54 %	1 54.02 %	1 76.11 %	1 74.91 %	1 95.27 %	- -	- -	1 74.91 %	1 95.27 %
	Before har- vest	Number of values Abbott effi- cacy (%)	1 76.42 %	1 65.50 %	1 42.45 %	1 73.91 %	2 83.03 %	2 91.92 %	2 98.84 %	2 98.18 %	2 83.03 %	2 91.92 %
PUCC RE PUCC RR	2 weeks after B	Number of values Abbott effi- cacy (%)	- -	- -	- -	- -	1 73.81 %	1 92.65 %	0 -	0 -	1 73.81 %	1 92.65 %
	Before har- vest	Number of values Abbott effi- cacy (%)	3 84.04 %	3 90.01 %	- -	- -	2 79.79 %	2 88.22 %	1 100.0 0%	1 100.0 0%	5 85.82 %	5 91.33 %
RHYN SE	2 weeks after B	Number of values Abbott effi- cacy (%)	- -	- -	- -	- -	- -	- -	- -	- -	- -	- -
	Before har- vest	Number of values Abbott effi- cacy (%)	1 82.47 %	1 88.26 %	- -	- -	- -	- -	- -	- -	1 82.47 %	1 88.26 %

Comments of zRMS:

All efficacy trials were conducted on winter rye and no assessments of efficacy after single application have been provided by the applicant. Moreover, the pathogen of *Puccinia coronata* was not tested in the efficacy trials in any EPPO zones. Instead, *Puccinia recondita* was included to the dataset. The eMSs are kindly asked to consider use of CA3301 to protection of spring rye and single application on the national level.

3.2.3.9 Oilseed rape (BRSNW) / *Sclerotinia sclerotiorum* (SCLESC)

Materials and Methods – Oilseed rape - SCLESC

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2017 and 2020, a total of 69 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern and South-Eastern EPPO zones to evaluate the efficacy of CA3301 against *Sclerotinia sclerotiorum* on oil seed rape (see Table 3.2-594). The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, 24 trials were performed in Czech Republic (11), Germany (9), France (3) and Denmark (1).

In the Mediterranean EPPO zone, 5 trials were performed in France (2) and Spain (3).

In the North-Eastern EPPO zone, 28 trials were performed in Poland (20), Lithuania (3) and Latvia (5).

In the South-Eastern EPPO zone, a total of 12 trials were performed in Hungary (6), Romania (4) and Slovakia (2).

Table 3.2-594: Presentation of trials – Oilseed rape (BRSNW)

Crop(s) *	Tar- get(s)*	Country	Year s	Type of trial*	Number of trials (number of valid trials)				GEP, non-GEP, offi- cial***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
BRSN W	SCLESC	Czech Republic	2017- 2019	MED + E	11 (7)	-	-	-	GEP	
		Germany	2019- 2020	MED + E	9 (9)	-	-	-	GEP	
		France	2020	MED + E	3 (3)	-	-	-	GEP	
		Denmark	2018	MED + E	1 (0)	-	-	-	GEP	
BRSN W	SCLESC	France	2019	MED + E	-	2 (0)	-	-	GEP	
		Spain	2020	MED + E	-	3 (2)	-	-	GEP	
BRSN W	SCLESC	Poland	2017- 2020	MED + E	-	-	21 (14)	-	GEP	
		Lithuani a	2019- 2020	MED + E	-	-	3 (0)	-	GEP	
		Latvia	2019- 2020	MED + E	-	-	5 (2)	-	GEP	
BRSN W	SCLESC	Hungary	2017- 2019	MED + E	-	-	-	6 (5)	GEP	
		Romania	2019- 2020	MED + E	-	-	-	4 (3)	GEP	
		Slovakia	2020	MED + E	-	-	-	2 (2)	GEP	
TOTAL	-	-	2017- 2020	MED + E	24 (19)	5 (2)	28 (16)	12 (10)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation

In all trials, CA3301 was compared to at least one commercial fungicide used as standard reference for comparison.

Table 3.2-595: Efficacy evaluation - Presentation of reference standards used in trials – Oilseed rape (BRSNW) – SCLESC – Maritime EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
BRSNW	PROLINE 250 EC	CZ	4523-1	Prothioconazole	EC	250 g/l	2 x 0.7 l/ha max	2 x 0.7 l/ha	CA2445 in some trials
	PRO-SARO	CZ	4561-2	Prothioconazole + Tebuconazole	EC	250 g/l	1 x 0.75 l/ha	2 x 0.75 l/ha	
	PROLINE	DE	025287-00	Prothioconazole	EC	250 g/l	2 x 0.7 l/ha	2 x 0.7 l/ha	CA2445 in some trials
	CA-RAMBA	DE	024487-00	Metconazole	EC	60 g/L	2 x 1.5 l/ha	2 x 1.5 l/ha	
	JOAO	FR (N)	2060116	Prothioconazole	EC	250 g/l	2 x 0.7 l/ha	2 x 0.7 l/ha	CA2445 in some trials
	BISTRO	FR (N)	2160260	Metconazole	EC	90 g/l	2 x 0.8 l/ha	2 x 0.6 l/ha	
	PROLINE EC 250	DK	18-473	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.5-0.6-0.7 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-596: Efficacy evaluation - Presentation of reference standards used in trials – Oilseed rape (BRSNW) – SCLESC – Mediterranean EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
BRSNW	JOAO	FR (S)	2060116	Prothioconazole	EC	250 g/l	2 x 0.7 l/ha	2 x 0.7 l/ha	CA2445 in some trials
	PRO-SARO	ES	25661	Prothioconazole + Tebuconazole	EC	250 g/L	2 x 1 l/ha	2 x 1 L/ha	
	CA-RAMBA	ES	25743	Metconazole	EC	9%	2 x 0.8 l/ha	2 x 0.8 l/ha	

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-597: Efficacy evaluation - Presentation of reference standards used in trials – Oilseed rape (BRSNW) – SCLESC – North-East ~~EPB~~ EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
BRSNW	PRAKTIS	PL	R-222/2019	Prothioconazole	EC	250 g/l	2 x 0.7 l/ha	2 x 0.7 l/ha	CA2445 in some trials
	TILMOR 240 EC	PL	R-23/2015	Prothioconazole + Tebuconazole	EC	240 g/l	0.75 l/ha autumn + 1 l/ha spring	1 x 0.75 l/ha + 1 x 1 l/ha	
	CA-RAMBA 60 SL	PL	R-45/2010	Metconazole	SL	60 g/l	2 x 0.7-1 l/ha	1 or 2 x 1 l/ha	
	ORIUS EXTRA	PL	R-77/2015	Tebuconazole	EW	250 g/l	1 x 1 l/ha	2 x 1 l/ha	
	PRO-SARO	LT	AS2-2F/2015	Prothioconazole + Tebuconazole	EC	250 g/l	2 x 1 l/ha	1 x 1 l/ha	
	PROLINE	LV	0637	Prothioconazole	EC	250 g/l	Not registered but standard reference at EU level	2 x 0.7 l/ha	CA2445 in some trials
	PRO-SARO	LV	0276	Prothioconazole + Tebuconazole	EC	250 g/l	2 x 1 l/ha	2 x 1 l/ha	

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-598: Efficacy evaluation - Presentation of reference standards used in trials – Oilseed rape (BRSNW) – SCLESC – South-East ~~EPB~~ EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
TRZAW	PROLINE	RO	457PC/15/11/2018	Prothioconazole	EC	250 g/l	2 x 0.7 l/ha	2 x 0.7 l/ha	CA2445 in some trials
	PROLINE	HU	6300 / 1205-1 / 2020	Prothioconazole	EC	250 g/l	Not registered but standard reference at EU level	2 x 0.7 l/ha	CA2445 in some trials
	PRO-PULSE	HU	04.2/41-1/2014	Fluoripam + Prothioconazole	SE	250 g/l	2 x 1 l/ha	2 x 1 l/ha	

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
	TILMOR	HU	04.2/7910-1/2011	Prothioconazole + Tebuconazole	EC	240 g/l	2 x 1.2 l/ha	2 x 1.2 l/ha	
	PRO-SARO	SK	06-02-0771	Prothioconazole + Tebuconazole	EC	250 g/L	2 x 0.75 l/ha	2 x 0.75 l/ha	

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-599.

Table 3.2-599: Details on trial methodology – Oilseed rape (BRSNW) – SCLESC

		Maritime EPPO zone	Mediterranean EPPO zone	North –East EPPO zone	South-Eastern EPPO zone
Trials	Total number (valid number)	24 (19)	5 (2)	28 (16)	12 (9)
	Supportive trials	-	-	-	-
Guidelines	General guidelines	PP 1/135(4) PP 1/152 (4) PP 181 (4)	PP 1/135(4) PP 1/152 (4) PP 181 (4)	PP 1/135(4) PP 1/152 (4) PP 181 (4)	PP 1/135(4) PP 1/152 (4) PP 181 (4)
	Specific guidelines	PP 1/78 (3)	PP 1/78 (3)	PP 1/78 (3)	PP 1/78 (3)
Experimental design	Plot design	Randomized Complete Blocks, Untreated included	Randomized Complete Blocks, Untreated included	Randomized Complete Blocks, Untreated included	Randomized Complete Blocks, Untreated included
	Plot size	21-45 m ²	28-45 m ²	21-48 m ²	21-42 m ²
	Number of replications	4	4	4	4
Crop	Trials per crop	BRSNW (24)	BRSNW (5)	BRSNW (28)	BRSNW (12)
	Varieties per crop	Graf (1), Archimedes (1), Atora (1), Butterfly (1), PT271 (2), KWS Digger (2), PX113 (1), DK Expression (1), Alison (1), Recordie (1), Kicker (1), Nikita (1), Hattrick (2), Avatar (2), Feliciano (1), Architect (1), Croozar (1), Expansion (2), Crome (1)	RGT Quizz (2), Imporio (1), Aquarel (1), Exception (1)	Bellevue (1), NK Technic (2), SY Polana (1), PX 113 (1), Kadore (1), Thure (2), Murphy (1), Mondit (1), Aca-pulco (2), Mercedes (2), DX Explicit (1), Absolut (1), Rohan (1), Umberto (2), PT 264 (1), Kuga (2), Exotter (1), Cult (1), Severnij (1), Einstein (1), Alabama (1), Epure (1)	Diffusion (1), DK Expression (1), Hybridrock (3), PT225 (1), Rapool Shreck (1), DK Exterior (1), PR46W21 (1), Nelson (1), Arabella (2)
	Sowing period	August (18), September (5), November (1)	September (3), October (2)	July (1), August (24), September (2), October (1)	August (6), September (4), October (2)

Application	Crop stage (BBCH)* at application	A : BBCH 51-65 or BBCH 14-19 B: BBCH 63-69	A: BBCH 53-61 B: BBCH 65-72	A: BBCH 14-26 or BBCH 33-57 B: BBCH 61-71	A: BBCH 16-18 or BBCH 38-52 B: BBCH 61-69
	Timing Pest stage at application	BBCH 14-69 A: PRINFC (21), N/A (3) B: PRINFC (20), N/A (2)	BBCH 53-72 A: PRINFC (2), MIXED (1) B: PRINFC (3), MIXED (2)	BBCH 14-71 A: PRINFC (21), N/A (5) B: PRINFC (20), MYCELI (1), MIXED (1), N/A (6)	BBCH 16-69 A: PRINFC (10), MIXED (2) B: PRINFC (9), MIXED (3)
	Number of applications Intervals between applications	1 application (2) 2 applications (11-39 or 135-225 days) (22)	1 application (2) 2 applications (34-41days) (3)	1 application (2) 2 applications (20-47 or 187-243 days) (26)	1 application (1) 2 applications (12-38 or 185 days) (11)
	Spray volumes	A: 200-400 l/ha B: 200-300 l/ha	A: 300-400 l/ha B: 300-400 l/ha	A: 200-300 l/ha B: 200-400 l/ha	A: 200-300 l/ha B: 200-300 l/ha
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10)	Disease severity (%), Disease incidence (%), Phytotoxicity (%),	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10 or %)
	Assessment dates	0 DA-A, 15-21 DA-A, 0-1 DA-B, 13-22 DA-B, 25-60 DA-B, 68-114 DA-B	0 DA-A, 20-21 DA-A, 0-3 DA-B, 19-20 DA-B, 40-50 DA-B		-1-0 DA-A, 11-21 DA-A, 0-2 DA-B, 14-22 DA-B, 33-57 DA-B 62-126 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Natural (22), Artificial (2)	Natural (5)	Natural (26), Artificial (2)	Natural (12)
	e.g. Field / Greenhouse...	Field trials	Field trials	Field trials	Field trials

In the North-Eastern EPPO zone, root infection was assessed according to the EPPO guideline PP1/78 (4). In this case, an assessment scale ranging from class 1 to class 5 was used, with class 1 corresponding to no symptoms, allowing to calculate a disease index for each treatment ranging from 0 to 100. This index was then used in the calculation of the product efficacy.

Use of CA3301 at 2x 0.6-0.7 l/ha against SCLESC with one application in autumn and one application in spring - Maritime EPPO zone

In the Maritime EPPO zone, 24 trials were available against *Sclerotinia sclerotiorum* on oilseed rape. 19 trials out of 24 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to the reference products on disease severity (%). Among these 19 trials, CA3301 was applied once in autumn and once in spring in 7 trials, first at crop stages BBCH 34-55 and the 2nd application was at BBCH 65-67. The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.7 l/ha and the analysis was conducted on stems only before harvest.

Summary results are presented in Table 3.2-600.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Sclerotinia sclerotiorum*. On stem, at this dose rate, CA3301 showed 73.79% of efficacy on disease severity before harvest.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.7 l/ha to control *S. sclerotiorum*. At this dose rate, CA3301 showed 79.54% of efficacy to control the disease on stem before harvest.

In the Maritime EPPO zone, CA3301 at 0.6-0.7 l/ha provided medium efficacy in reducing the severity of *Sclerotinia sclerotiorum* on oilseed rape on stems before harvest. The tested product gave overall equivalent disease control compared to the authorised reference products CA2445 and BISTRO and higher disease control than PROSARO and CARAMBA. Averaged across the dataset the efficacy of CA3301 at 0.6 l/ha was comparable to that of the dose rate of 0.7 l/ha. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for control of *Sclerotinia sclerotiorum*, but at high levels of infection the increased disease control from 0.7 l/ha may be of benefit.

Considering all elements presented above, it is justified to claim the registration of 2 applications, one in autumn and one in spring of CA3301 at 0.6-0.7 l/ha to control *Sclerotinia sclerotiorum* on oilseed rape in the Maritime EPPO zone.

Table 3.2-600: Summary table - Efficacy evaluation – Oilseed rape – SCLESC - Maritime EPPO zone

Treatment name		BISTRO	CA2445	PROSARO	CARAMBA	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,7 l/ha is >, = or < compared to
Rate	UNTREATED CHECK	0,6	0,7	0,75	1,5	0,6	0,7		
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	AB	AB	AB		
% Disease severity STEM - 44-84 DA-B									
Number of values	7					7	7	UT C	CA 3301 0,7 l/ha
Minimum value	6,37					0,63	0,44		UT C
Maximum value	34,00	-	-	-	-	22,25	14,13	7 >	7 >
Mean disease severity (%)	22,59					7,10	5,31	0 =	7 =
Abbott efficacy (%)	0,00%					73,79 %	79,54 %	0 <	0 <
Number of values	1	1	1			1	1	BISTRO 0,6 l/ha	BISTRO 0,6 l/ha
Minimum value	14,75	6,90	0,70			0,90	1,90		
Maximum value	14,75	6,90	0,70	-	-	0,90	1,90	0 >	0 >
Mean disease severity (%)	14,75	6,90	0,70			0,90	1,90	1 =	1 =
Abbott efficacy (%)	0,00%	53,22 %	95,25 %			93,90 %	87,12 %	0 <	0 <
Number of values	6		6			6	6	CA2445 0,7 l/ha	CA2445 0,7 l/ha
Minimum value	6,37		0,70			0,63	0,44		
Maximum value	32,81	-	20,94	-	-	22,25	14,13	0 >	0 >
Mean disease severity (%)	20,69		6,94			7,66	5,74	6 =	6 =
Abbott efficacy (%)	0,00%		69,28 %			71,26 %	74,54 %	0 <	0 <
Number of values	1			1		1	1	PRO-SARO 0,7 l/ha	PRO-SARO 0,7 l/ha
Minimum value	34,00			7,40		3,75	2,75		

Maximum value	34,00	-	-	7,40	-	3,75	2,75	1 >	1 >
Mean disease severity (%)	34,00			7,40		3,75	2,75	0 =	0 =
Abbott efficacy (%)	0,00%			78,24 %		88,97 %	91,91 %	0 <	0 <
Number of values	3		3		3	3	3	CA-RAMBA 1,5 l/ha	CA-RAMBA 1,5 l/ha
Minimum value	23,00		6,75		15,19	9,50	6,63		
Maximum value	32,81	-	20,94	-	19,19	22,25	14,13	2 >	2 >
Mean disease severity (%)	28,29		12,86		17,77	14,21	9,98	1 =	1 =
Abbott efficacy (%)	0,00%		56,46 %		36,76%	51,15 %	65,49 %	0 <	0 <

>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.7 l/ha against SCLESC with 2 applications in spring – Maritime EPPO zone

In the Maritime EPPO zone, 24 trials were available against *Sclerotinia sclerotiorum* on oilseed rape. 19 trials out of 24 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to the reference products on disease severity (%). Among these 19 trials, CA3301 was applied twice in spring in 12 trials, first at crop stages BBCH 34-55 and the 2nd application was at BBCH 63-65. The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.7 l/ha and the analysis was conducted on leaves and on stems.

Summary results are presented in Table 3.2-601.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Sclerotinia sclerotiorum*. On leaves, at this dose rate, CA3301 showed 60.32% of efficacy on disease severity 3-6 weeks after the 2nd application and 76.49% on stems before harvest. When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.7 l/ha to control *S. sclerotiorum*. On leaves, at this dose rate, CA3301 showed 64.72% of efficacy to control the disease 3-6 weeks after the 2nd application and 81.20% on stems before harvest.

In all trials in the Maritime EPPO zone CA3301 at 0.7 l/ha gave equivalent disease control compared to the authorised reference product CA2445 and at 0.6 l/ha CA3301 gave equivalent disease control in 11 trials out of 12. Moreover, in the majority of assessments there were no significant differences in disease control between the rate of 0.6 l/ha or 0.7 l/ha of CA3301 except in 2 trials with relatively high disease infection on stems (26-53%) where a benefit was derived from the dose increase. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for control of *Sclerotinia sclerotiorum*, however when conditions are conducive to heavy disease infestation the rate of 0.7 l/ha may be beneficial to further reduce disease pressure.

Considering all elements presented above, it is justified to claim the registration of 2 applications in spring of CA3301 at 0.6-0.7 l/ha to control *Sclerotinia sclerotiorum* on oilseed rape in the Maritime EPPO zone.

Table 3.2-601: Summary table - Efficacy evaluation – Oilseed rape – SCLESC - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA24 45 0,7 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to		
% Disease severity LEAF - 22-42 DA-B										
Number of values	5	5	5	5	UT C	CA24 45 0,7 l/ha	CA33 01 0,7 l/ha	UT C	CA24 45 0,7 l/ha	CA33 01 0,6 l/ha
Minimum value	7,68	1,25	1,73	1,88	5 >	0 >	0 >	5 >	0 >	0 >
Maximum value	18,00	7,78	9,20	7,63	0 =	5 =	5 =	0 =	5 =	5 =
Mean disease severity (%)	11,22	4,08	4,71	4,15	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	65,70 %	60,32 %	64,72 %						
% Disease severity STEM - 36-77 DA-B										
Number of values	12	12	12	12	UT C	CA24 45 0,7 l/ha	CA33 01 0,7 l/ha	UT C	CA24 45 0,7 l/ha	CA33 01 0,6 l/ha
Minimum value	6,25	0,00	0,13	0,00	12 >	0 >	0 >	12 >	0 >	2 >
Maximum value	53,13	14,44	15,88	12,25	0 =	11 =	10 =	0 =	12 =	10 =
Mean disease severity (%)	18,52	3,86	4,44	3,56	0 <	1 <	2 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	79,83 %	76,49 %	81,20 %						

'>' means CA3301 is significantly more efficient than plants treated with (treatment)
(conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Conclusion Maritime EPPO zone - Use of CA3301 at 2x 0.6-0.7 l/ha against SCLESC

In the Maritime EPPO zone, 24 trials were available against *Sclerotinia sclerotiorum* on oilseed rape. 19 trials out of 24 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to several authorised reference products on disease severity (%). Among these 19 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis.

In order to cover the different agricultural spraying practices of oilseed rape in Maritime EPPO zone, 2 types of spraying programs have been tested: 2 applications in spring (dedicated to spring infections of foliar, stem and pods diseases on oilseed rape) or 1 application in autumn and 1 application in spring (dedicated to both autumn and spring infections of roots, foliar, stem and pods diseases on oilseed rape). In the first group of trials, CA3301 was applied twice in spring. The data recorded were available on leaves and on stems and a single assessment timing was available for each part rated, close to harvest. When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6-0.7 l/ha to control *Sclerotinia sclerotiorum* with an average of 60.32-64.72% of efficacy on leaves and 76.49-81.20% of efficacy on stems.

In the second group of trials, CA3301 was applied once in autumn and once in spring. The data were available on stems at a single assessment before harvest. When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6-0.7 l/ha to control *Sclerotinia sclerotiorum* with a mean efficacy of 73.79-79.54% on stems.

For both application timings, CA3301 applied at 0.6-0.7 l/ha resulted in overall medium efficacy to control *Sclerotinia sclerotiorum* on leaves and on stems.

In all trials, CA3301 at 0.6-0.7 l/ha gave equivalent or higher disease control compared to the several authorised reference products. Moreover, in the majority of assessments there were no statistically significant differences in disease control between the rate of 0.6 l/ha or 0.7 l/ha of CA3301. Therefore, it is envisaged that in most instances, when low to medium levels of disease pressure are expected, applications of 0.6 l/ha will be sufficient for control of *Sclerotinia sclerotiorum* whatever the timing of application. However, in some situations a rate of 0.7 l/ha may be beneficial for improved disease control.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.7 l/ha to control *Sclerotinia sclerotiorum* on oilseed rape in the Maritime EPPO zone. Moreover, these 2 applications can be both carried out in spring or first in autumn and then the 2nd in spring.

Use of CA3301 at 2x 0.6-0.7 l/ha against SCLESC with 2 applications in spring – Mediterranean EPPO zone

In the Mediterranean EPPO zone, 5 trials were available against *Sclerotinia sclerotiorum* on oilseed rape. 2 trials out of 5 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to several authorised reference products on disease severity (%). In all 2 trials, CA3301 was applied twice in spring and no data were available in the case where CA3301 was applied once in autumn and once in spring. The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.7 l/ha and the analysis was conducted on leaves, on stems and on pods.

Summary results are presented in Table 3.2-602.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Sclerotinia sclerotiorum*. On leaves, at this dose rate, CA3301 showed 69.70% of efficacy on disease severity 3 weeks after the 2nd application and 61.43% before harvest. Moreover, the tested product showed 85.86% of efficacy on stems and 51.38% on pods before harvest.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.7 l/ha to control *Sclerotinia sclerotiorum*. On leaves, at this dose rate, CA3301 showed 78.84% of efficacy on disease severity 3 weeks after the 2nd application and 54.13% before harvest. Moreover, the tested product showed 93% of efficacy on stems and 61.28% on pods before harvest.

In the Mediterranean EPPO zone with a limited dataset for this pathogen, a consistent trend was however observed whereby CA3301 at 0.6-0.7 l/ha gave equivalent or higher disease control compared to the authorised reference products CA2445, PROSARO and CARAMBA and the data demonstrated that the best performance of the product is on stems with high efficacy. Moreover in this dataset, where the majority of assessments were made in conditions of low to medium disease pressure there were no statistical differences in disease control between the rate of 0.6 l/ha or 0.7 l/ha of CA3301. Therefore, it is likely that in instances of low to medium disease pressure, applications at 0.6 l/ha will provide sufficient control of *Sclerotinia sclerotiorum*, however, when disease pressure is high, the increased level of efficacy generally observed over the dataset from application of 0.7 l/ha may be beneficial.

Considering all elements presented above, it is justified to claim the registration of 2 applications in spring of CA3301 at 0.6-0.7 l/ha to control *Sclerotinia sclerotiorum* on oilseed rape in the Mediterranean EPPO zone.

Table 3.2-602: Summary table - Efficacy evaluation – Oilseed rape – SCLESC - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA 244 5 0,7 L/ha	CAR AMB A 0,8 L/ha	PRO SAR O 1 L/ha	CA 330 1 0,6 L/ha	CA 330 1 0,7 L/ha	No of trials where CA3301 at 0,6 l/ha is >, = or <	No of trials where CA3301 at 0,7 l/ha is >, = or <
Rate								
Rate unit								

Appl. Code		AB	AB	AB	AB	compared to		compared to		
% Disease severity LEAF - 20 DA-B										
Number of values	2	2			2	2	UTC	CA3301	UTC	CA3301
Minimum value	6,36	1,2 1			1,4 3	0,8 0		0,7 l/ha		0,6 l/ha
Maximum value	6,69	2,4 1	-	-	2,5 5	1,9 9	2 >	0 >	2 >	0 >
Mean disease severity (%)	6,52	1,8 1			1,9 9	1,4 0	0 =	2 =	0 =	2 =
Abbott efficacy (%)	0,00%	72,48 %			69,70 %	78,84 %	0 <	0 <	0 <	0 <
Number of values	1	1	1		1	1	CA244 5	CARAMBA	CA244 5	CA- RAMBA
Minimum value	6,69	2,4 1	2,46		2,5 5	1,9 9	0,7 l/ha	0,8 l/ha	0,7 l/ha	0,8 l/ha
Maximum value	6,69	2,4 1	2,46	-	2,5 5	1,9 9	0 >	0 >	0 >	0 >
Mean disease severity (%)	6,69	2,4 1	2,46		2,5 5	1,9 9	2 =	1 =	2 =	1 =
Abbott efficacy (%)	0,00%	63,98 %	63.23 %		61,88 %	70,25 %	0 <	0 <	0 <	0 <
Number of values	1	1		1	1	1	PROSARO		PROSARO	
Minimum value	6,36	1,2 1		2,00	1,4 3	0,8 0	0,7 l/ha		0,7 l/ha	
Maximum value	6,00	1,2 1	-	2,00	1,4 3	0,8 0	0 >		1 >	
Mean disease severity (%)	6,36	1,2 1		2,00	1,4 3	0,8 0	1 =		0 =	
Abbott efficacy (%)	0,00%	80,97 %		68,55 %	77,52 %	87,42 %	0 <		0 <	
% Disease severity LEAF - 41-50 DA-B										
Number of values	2	2			2	2	UTC	CA3301	UTC	CA3301
Minimum value	18,38	9,5 4			7,4 6	10,08		0,7 l/ha		0,6 l/ha
Maximum value	38,00	14,29	-	-	13,89	14,02	2 >	0 >	2 >	0 >
Mean disease severity (%)	28,19	11,91			10,68	12,05	0 =	2 =	0 =	2 =
Abbott efficacy (%)	0,00%	55,25 %			61,43 %	54,13 %	0 <	0 <	0 <	0 <
Number of values	1	1	1		1	1	CA244 5	CARAMBA	CA244 5	CA- RAMBA
Minimum value	18,38	9,5 4	8,92		7,4 6	10,08	0,7 l/ha	0,8 l/ha	0,7 l/ha	0,8 l/ha
Maximum value	18,38	9,5 4	8,92	-	7,4 6	10,08	0 >	0 >	0 >	0 >
Mean disease severity (%)	18,38	9,5 4	8,92		7,4 6	10,08	2 =	1 =	2 =	1 =
Abbott efficacy (%)	0,00%	48,10 %	51,47 %		59,41 %	45,16 %	0 <	0 <	0 <	0 <
Number of values	1	1		1	1	1	PROSARO		PROSARO	

Minimum value	38,00	14,29	-	7,23	13,89	14,02		0,7 l/ha		0,7 l/ha			
Maximum value	38,00	14,29		7,23	13,89	14,02		0 >		0 >			
Mean disease severity (%)	38,00	14,29		7,23	13,89	14,02		1 =		1 =			
Abbott efficacy (%)	0,00%	62,39%		80,97%	63,45%	63,11%		0 <		0 <			
% Disease severity STEM - 50 DA-B													
Number of values	1	1	-	1	1	1	U T C	CA3 301	CA2445 0,7 l/ha	UT C	CA3 301	CA2445 0,7 l/ha	
Minimum value	14,00	2,23		1,48	1,98	0,98		0,7 l/ha	PRO-SARO 1 l/ha		0,6 l/ha	PRO-SARO 1 l/ha	
Maximum value	14,00	2,23		1,48	1,98	0,98		1 >	0 >		0 >	1 >	0 >
Mean disease severity (%)	14,00	2,23		1,48	1,98	0,98		0 =	1 =		1 =	0 =	1 =
Abbott efficacy (%)	0,00%	84,07%		89,43%	85,86%	93,00%		0 <	0 <		0 <	0 <	0 <

Treatment name	UNTREATED CHECK	CA 2445	CAR AMB A	PROS ARO	CA3 301	CA3 301	No of trials where CA3301			No of trials where CA3301		
Rate		0,7	0,8	1	0,6	0,7	at 0,6 l/ha is >, = or <			at 0,7 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	AB	AB	compared to			compared to		
% Disease severity POD- 41 DA-B												
Number of values	1	1		1	1	1	UTC	CA 3301	CA24 45 0,7 l/ha	UTC	C A3 301	CA24 45 0,7 l/ha
Minimum value	5,45	2,62		3,57	2,65	2,11		0,7 l/ha	PRO-SARO 1 l/ha		0,6 l/ha	PRO-SARO 1 l/ha
Maximum value	5,45	2,62	-	3,57	2,65	2,11	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	5,45	2,62		3,57	2,65	2,11	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	51,93%		34,50%	51,38%	61,28%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.7 l/ha against SCLESC with one application in autumn and one application in spring - North-Eastern EPPO zone

In the North-Eastern EPPO zone, 28 trials were available against *Sclerotinia sclerotiorum* on oilseed rape. 16 trials out of 28 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to several authorised reference products on disease

Summary results are presented in Table 3.2-603.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.7 l/ha to control *Sclerotinia sclerotiorum*. On stems, at this dose rate CA3301 showed 87.31% of efficacy on disease severity 3-4 weeks after the 2nd application and 77.10% before harvest. Moreover, on roots it showed 95.24% of efficacy on disease severity 3-4 weeks after the 2nd application and 90.35% before harvest.

Considering all elements presented above, it is justified to claim the registration of 2 applications, one in autumn and one in spring of CA3301 at 0.6-0.7 l/ha to control *Sclerotinia sclerotiorum* on oilseed rape in the North-Eastern EPPO zone.

[illegible]

Number of values	1			1	1	1	UTC	CA3301 0,7 l/ha	UTC	CA33010,6 l/ha
Minimum value	15,75			1,50	0,75	0,75		TILMOR 240 EC		TILMOR 240 EC
Maximum value	15,75	-	-	1,50	0,75	0,75	1 >	0 >	1 >	0 >
Mean disease severity (%)	15,75			1,50	0,75	0,75	0 =	1 =	0 =	1 =
Abbott efficacy (%)	0,00%			90,48%	95,24 %	95,24 %	0 <	0 <	0 <	0 <
% Disease severity STEM - 34-62 DA-B										
Number of values	7	7			7	7	UTC	CA3301 0,7 l/ha	UTC	CA3301 0,6 l/ha
Minimum value	8,95	1,95			1,80	1,30				
Maximum value	26,18	6,78	-	-	8,95	5,88	7 >	0 >	7 >	4 >
Mean disease severity (%)	16,42	3,44			5,34	3,32	0 =	3 =	0 =	3 =
Abbott efficacy (%)	0,00%	78,00 %			64,95 %	77,10 %	0 <	4 <	0 <	0 <
Number of values	5	5	5		5	5	CA24 45	ORIOUS EXTRA	CA24 45	ORIOUS EXTRA
Minimum value	9,85	1,95	2,80		1,80	1,90	0,7 l/ha	1,0 l/ha	0,7 l/ha	1,0 l/ha
Maximum value	24,10	3,60	5,40	-	8,95	4,45	0 >	0 >	0 >	0 >
Mean disease severity (%)	14,07	2,98	3,89		5,80	3,21	4 =	1 =	7 =	5 =
Abbott efficacy (%)	0,00%	77,57 %	70,79%		55,77 %	74,16 %	3 <	4 <	0 <	0 <
Severity index ROOT - 38 DA-B										
Number of values	1			1	1	1	UTC	CA3301 0,7 l/ha	UTC	CA33010,6 l/ha
Minimum value	20,75			4,00	2,00	2,00		TILMOR 240 EC		TILMOR 240 EC
Maximum value	20,75	-	-	4,00	2,00	2,00	1 >	0 >	1 >	0 >
Mean disease severity (%)	20,75			4,00	2,00	2,00	0 =	1 =	0 =	1 =
Abbott efficacy (%)	0,00%			80,72%	90,35 %	90,35 %	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.7 l/ha against SCLESC with 2 applications in spring – North-Eastern EPPO zone

In the North-Eastern EPPO zone, 28 trials were available against *Sclerotinia sclerotiorum* on oilseed rape. 16 trials out of 28 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to several authorised reference products on disease severity (%). Among these 16 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis. Among the 16 valid trials, CA3301 was applied twice in spring in 7 trials, first at crop stages BBCH 33-55 and the 2nd application was at BBCH 65-69. The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.7 l/ha and the analysis was conducted on stems and on pods.

Summary results are presented in Table 3.2-604.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Sclerotinia sclerotiorum*. On stems, at this dose rate, CA3301 showed 83.73% of

efficacy on disease severity 3 weeks after the 2nd application and 79.55% before harvest. On pods, CA3301 at 0.6 l/ha showed 92.99% of efficacy before harvest.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.7 l/ha to control *S. sclerotiorum*. On stems, at this dose rate, CA3301 showed 88.21% of efficacy on disease severity 3 weeks after the 2nd application and 85.17% before harvest. On pods, CA3301 at 0.7 l/ha showed 92.61% of efficacy before harvest.

In the North-East ~~EPPO~~ EPPO zone, the disease pressure was low to medium and in overall CA3301 at 0.6-0.7 l/ha showed a high efficacy in reducing the severity of *Sclerotinia sclerotiorum* on oilseed rape, with a consistent performance until the harvest timing. CA3301 gave equivalent or higher disease control compared to the several authorised reference products. Averaged across the dataset the efficacy of CA3301 at 0.6 l/ha was fairly comparable to that of the dose rate of 0.7 l/ha, however at some later assessments a statistical benefit was derived from increasing the dose rate to 0.7 l/ha. Therefore, it is envisaged that a dose rate of 0.6 l/ha is appropriate for control of cottony rot at low to medium disease pressure while for increasing disease pressure, 0.7 l/ha may be more appropriate.

Considering all elements presented above, it is justified to claim the registration of 2 applications in spring of CA3301 at 0.6-0.7 l/ha to control *Sclerotinia sclerotiorum* on oilseed rape in the North-East ~~EPPO~~ EPPO zone.

Table 3.2-604: Summary table - Efficacy evaluation – Oilseed rape – SCLESC – North-East ~~EPPO~~ EPPO zone

Treatment name	UNTREA TED CHECK	CA2 445	PROS ARO	CARA MBA	CAR AMB A	CA3 301	CA3 301	No of trials where CA3301				No of trials where CA3301			
Rate		0,7	1	1	1	0,6	0,7	at 0,6 l/ha is >, = or <				at 0,7 l/ha is >, = or <			
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	L/ha								
Appl. Code		AB	AB	A	AB	AB	AB	compared to				compared to			
% Disease severity STEM - 21 DA-B															
Number of values	2	2			2	2	2	UTC	CA2445	CAR-AMBA	CA3301	UTC	CA2445	CAR-AMBA	CA3301
Minimum value	6,60	0,88			0,45	0,90	0,60		0,7 l/ha	1,0 l/ha (AB)	0,7 l/ha		0,7 l/ha	1,0 l/ha (AB)	0,6 l/ha
Maximum value	7,83	1,33	-	-	0,83	1,48	1,05		0 >	0 >	0 >	2 >	1 >	0 >	1 >
Mean disease severity (%)	7,21	1,10			0,64	1,19	0,83		0 =	1 =	1 =	0 =	1 =	2 =	1 =
Abbott efficacy (%)	0,00%	84,84 %			91,29 %	83,7 %	88,21 %	0 <	1 <	1 <	0 <	0 <	0 <	0 <	0 <
% Disease severity STEM - 33-56 DA-B															
Number of values	7					7	7	UTC	CA3301		UTC	CA3301			
Minimum value	4,95					0,05	0,20		0,7 l/ha			0,6 l/ha			
Maximum value	23,08	-	-	-	-	6,90	5,40		0 >			0 >			
Mean disease severity (%)	11,66					2,68	1,86		7 =			7 =			
Abbott efficacy (%)	0,00%					79,5 %	85,17 %	0 <	0 <		0 <	0 <			
Number of values	6	6				6	6	CA2445				CA2445			
Minimum value	4,95	0,00				0,05	0,20	0,7 l/ha				0,7 l/ha			
Maximum value	23,08	5,55	-	-	-	6,90	5,40	0 >				0 >			
Mean disease severity (%)	11,06	1,52				2,27	1,38	6 =				6 =			

Treatment name	UNTREATED CHECK	CA2 445	PROSARO	CARAMBA	CARAMBA	CA3 301	CA3 301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,7 l/ha is >, = or < compared to
Rate		0,7	1	1	1	0,6	0,7		
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	AB	A	AB	AB	AB		
% Disease severity STEM - 21 DA-B									
Abbott efficacy (%)	0,00%	86,46 %				82,4 3%	87,89 %	0 <	0 <
Number of values	2	2	2			2	2	PROSARO	PROSARO
Minimum value	4,95	0,00	0,00			0,05	0,20	1,0 l/ha	1,0 l/ha
Maximum value	5,45	0,33	0,05	-	-	0,60	0,60	0 >	0 >
Mean disease severity (%)	5,20	0,17	0,03			0,33	0,40	2 =	2 =
Abbott efficacy (%)	0,00%	96,97 %	99,49%			93,9 9%	92,48 %	0 <	0 <
Number of values	1			1		1	1	CARAMBA	CARAMBA
Minimum value	15,25			8,50		5,75	4,75	1,0 l/ha (A)	1,0 l/ha (A)
Maximum value	15,25	-	-	8,50	-	5,75	4,75	0 >	0 >
Mean disease severity (%)	15,25			8,50		5,75	4,75	1 =	1 =
Abbott efficacy (%)	0,00%			44,26%		62,3 0%	68,85 %	0 <	0 <
Number of values	4	4			4	4	4	CARAMBA	CARAMBA
Minimum value	5,11	0,90			1,13	0,76	0,3	1,0 l/ha (AB)	1,0 l/ha (AB)
Maximum value	23,08	5,55	-	-	5,15	6,90	5,4	0 >	1 >
Mean disease severity (%)	13,99	2,20			2,31	3,10	1,87	4 =	3 =
Abbott efficacy (%)	0,00%	81,21 %			78,79 %	76,6 5%	85,60 %	0 <	0 <
% Disease severity POD - 54 DA-B									
Number of values	1	1			1	1	1	UTC	CA 244 5
Minimum value	7,85	0,25			0,50	0,55	0,58	0,7 l/ha	CA 330 1
Maximum value	7,85	0,25	-	-	0,50	0,55	0,58	1 >	CA 244 5
Mean disease severity (%)	7,85	0,25			0,50	0,55	0,58	0 =	CA 330 1
Abbott efficacy (%)	0,00%	96,82 %			93,63 %	92,9 9%	92,61 %	0 <	CA 244 5
									CA 330 1

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Conclusion North-Eastern EPPO zone - Use of CA3301 at 2x 0.6-0.7 l/ha against SCLESC

In the North-Eastern EPPO zone, 28 trials were available against *Sclerotinia sclerotiorum* on oilseed rape. 16 trials out of 28 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to several authorised reference products on disease severity (%). Among these 16 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis.

In order to cover the different agricultural spraying practices of oilseed rape in North-Eastern EPPO zone, 2 types of spraying programs have been tested: 2 applications in spring (dedicated to spring infections of foliar, stem and pods diseases on oilseed rape) or 1 application in autumn and 1 application in spring (dedicated to both autumn and spring infections of roots, foliar, stem and pods diseases on oilseed rape). In the first group of trials, CA3301 was applied twice in spring. The data recorded were available on stems and on pods. When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6-0.7 l/ha to control *Sclerotinia sclerotiorum* with an average of 83.73-88.21 % of efficacy on stems 3 weeks after the 2nd application and 79.55-85.17% of efficacy before harvest. Moreover, CA3301 showed 92.99-92.61% of efficacy on pods before harvest.

In the second group of trials, CA3301 was applied once in autumn and once in spring. The data recorded were available on stems and on roots. When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6-0.7 l/ha to control *Sclerotinia sclerotiorum* with a mean efficacy of 80.58-87.31% on stems 2-4 weeks after the 2nd application and 64.95-77.10% before harvest. Moreover, CA3301 showed 95.24% of efficacy on pods around three weeks after the 2nd application and 90.35% before harvest.

In both cases, in overall the data demonstrate an equivalent performance on stems for the same assessment timings with a mean efficacy around 80%. This is particularly true for the 0.7 l/ha dose rate. Therefore, it is envisaged that in most instances 2 applications of CA330 in spring or one in autumn and one in spring will provide an acceptable control of *Sclerotinia sclerotiorum* whatever the timing of application as in addition efficacy was comparable to that of authorised reference products

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.7 l/ha to control *Sclerotinia sclerotiorum* on oilseed rape in the North-Eastern EPPO zone.

Use of CA3301 at 2x 0.6-0.7 l/ha against SCLESC with one application in autumn and one application in spring – South-Eastern EPPO zone

In the South-Eastern EPPO zone, 12 trials were available against *Sclerotinia sclerotiorum* on oilseed rape. 10 trials out of 12 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to several authorised reference products on disease severity (%). Among these 10 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis. CA3301 was applied once in autumn and once in spring in only one trial, first at crop BBCH 18 and the 2nd application was at BBCH 65. The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.7 l/ha. The analysis was conducted on stems only at a single assessment timing.

Summary results are presented in Table 3.2-605.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6-0.7 l/ha to control *Sclerotinia sclerotiorum* on stems and before harvest. The tested product showed 91.60% of efficacy on disease severity at 0.6 l/ha and 85.76% at 0.7 l/ha.

In the South-Eastern EPPO zone, a limited dataset was available for assessment of control of *Sclerotinia sclerotiorum* at this application timing. Nevertheless, applications of CA3301 at 0.6-0.7 l/ha demonstrated high efficacy in conditions of medium disease pressure. At this range of dosage CA3301 was

always comparable to the reference standard. A larger dataset has been presented regarding to the case where CA3301 was applied twice in spring in the South-Eastern zone, which demonstrates that efficacy of CA3301 at 0.6 l/ha was fairly comparable to that of the dose rate of 0.7 l/ha. However in some assessments a statistical benefit was derived from increasing the dose rate to 0.7 l/ha for disease control. Considering that *S. sclerotiorum* is mainly infecting oilseed rape crop at spring time during flowering period, this dataset can be supportive for the case where the first application of the product is in autumn. Therefore, it is proposed that the dose rate of 0.6 l/ha to is used for instances of low disease pressure and an increased rate of 0.7 l/ha for high disease pressure.

Considering all elements presented above, it is justified to claim the registration of 2 applications, one in autumn and one in spring of CA3301 at 0.6-0.7 l/ha to control *Sclerotinia sclerotiorum* on oilseed rape in the South-Eastern EPPO zone.

Table 3.2-605: Summary table - Efficacy evaluation – Oilseed rape – SCLESC – South-Eastern EPPO zone

Zone													
Treatment name	UNTREATED CHECK	CA24	TILM	CA330	CA33	No of trials where CA3301				No of trials where CA3301			
Rate		45	OR	1	01								
Rate unit		0,7	1,2	0,6	0,7	at 0,6 l/ha is >, = or <				at 0,7 l/ha is >, = or <			
Appl. Code		L/ha	L/ha	L/ha	L/ha	compared to				compared to			
		AB	A	AB	AB	% Disease severity STEM - 47 DA-B							
Number of values	1	1	1	1	1	UT	CA24	TIL-	CA33	UT	CA24	TIL-	CA33
Minimum value	33,35	3,00	4,45	2,80	4,75	C	45	MOR	01	C	45	MOR	01
Maximum value	33,35	3,00	4,45	2,80	4,75		0,7	1,2 l/ha	0,7		0,7	1,2 l/ha	0,6
Mean disease severity (%)	33,35	3,00	4,45	2,80	4,75	1 >	0 >	0 >	0 >	1 >	0 >	0 >	0 >
Abbott efficacy (%)	0,00%	91,00 %	86,66%	91,60, %	85,76 %	0 =	1 =	1 =	1 =	0 =	1 =	1 =	1 =
						0 <	0 <	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for

'<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.7 l/ha against SCLESC with 2 applications in spring – South-Eastern EPPO zone

In the South-Eastern EPPO zone, 12 trials were available against *Sclerotinia sclerotiorum* on oilseed rape. 10 trials out of 12 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to several authorised reference products on disease severity (%). Among these 10 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis. CA3301 was applied twice in spring in 9 trials, first at crop stages BBCH 51-55 and the 2nd application was at BBCH 65-69. The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.7 l/ha. The analysis was conducted on leaves, stems, pods and roots.

Summary results are presented in Table 3.2-606.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Sclerotinia sclerotiorum*. On leaves, at this dose rate, CA3301 showed 82.87% of efficacy on disease severity 3 weeks after the 2nd application and 65.86% before harvest. On stems, it showed 87.32% of efficacy on disease severity 3 weeks after the 2nd application and 71.67% before

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.7 l/ha to control *Sclerotinia sclerotiorum*. On leaves, at this dose rate, CA3301 showed 87.96% of efficacy on disease severity 3 weeks after the 2nd application and 72.28% before harvest. On stems, it showed 94.16% of efficacy on disease severity 3 weeks after the 2nd application and 74.97% before harvest. On pods, CA3301 at 0.7 l/ha showed 78.15% of efficacy before harvest and on roots it showed 100% of efficacy before harvest.

Considering all elements presented above, it is justified to claim the registration of 2 applications in spring of CA3301 at 0.6-0.7 l/ha to control *Sclerotinia sclerotiorum* on oilseed rape in the South-Eastern EPPZ zone.

Treatment name	UNTR	CA2	PROS	PROP	CA3	CA3301	No of trials where CA3301	No of trials where CA3301				
Rate	EATED	445	ARO	ULSE	301		at 0,6 l/ha	at 0,7 l/ha				
Rate unit	CHEC	0,7	0,75	1	0,6	0,7	is >, = or <	is >, = or <				
Appl. Code	K	L/ha	L/ha	L/ha	L/ha	L/ha	compared to	compared to				
		AB	AB	A	AB	AB						
% Disease severity LEAF - 21 DA-B												
Number of values	3	3			3	3	UTC	CA2445	CA3301	UTC	CA2445	CA3301
Minimum value	7,10	0,17			0,64	0,19		0,7 l/ha	0,7 l/ha		0,7 l/ha	0,6 l/ha
Maximum value	19,36	3,83	-	-	4,11	3,47	3 >	0 >	0 >	3 >	0 >	0 >
Mean disease severity (%)	15,27	2,44			2,95	2,22	0 =	3 =	3 =	0 =	3 =	3 =
Abbott efficacy (%)	0,00%	86,87%			82,87%	87,96%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity STEM - 21 DA-B												
Number of values	3	3			3	3	UTC	CA2445	CA3301	UTC	CA2445	CA3301

Minimum value	6,78	0,32			0,81	0,27		0,7 l/ha	0,7 l/ha		0,7 l/ha	0 1 0, 6 l/ h a
Maximum value	12,87	0,68	-	-	1,41	0,62	3 >	0 >	0 >	3 >	0 >	1 >
Mean disease severity (%)	9,76	0,50			1,12	0,50	0 =	2 =	2 =	0 =	3 =	2 =
Abbott efficacy (%)	0,00%	94,36%			87,32 %	94,16%	0 <	1 <	1 <	0 <	0 <	0 <
% Disease severity LEAF - 36-39 DA-B												
Number of values	3				3	3	UTC	CA3301		UTC	CA3301	CA3301
Minimum value	13,26				5,53	4,75		0,7 l/ha			0,6 l/ha	0,6 l/ha
Maximum value	21,43	-	-	-	6,44	5,18	3 >	0 >		3 >	0 >	0 >
Mean disease severity (%)	18,70				5,99	4,96	0 =	3 =		0 =	3 =	3 =
Abbott efficacy (%)	0,00%				65,86 %	72,28%	0 <	0 <		0 <	0 <	0 <
Number of values	2	2			2	2	CA2445		CA2445			
Minimum value	21,40	5,11			5,53	4,96	0,7 l/ha		0,7 l/ha			
Maximum value	21,43	5,24	-	-	6,00	5,18	0 >		0 >			
Mean disease severity (%)	21,42	5,17			5,77	5,07	2 =		2 =			
Abbott efficacy (%)	0,00%	75.83%			73,08 %	76,32%	0 <		0 <			
Number of values	1			1	1	1	PROPULSE		PROPULSE			
Minimum value	13,26			6,37	6,44	4,75	1,0 l/ha		1,0 l/ha			
Maximum value	13,26	-	-	6,37	6,44	4,75	0 >		0 >			
Mean disease severity (%)	13,26			6,37	6,44	4,75	1 =		1 =			
Abbott efficacy (%)	0,00%			51.96 %	51,43 %	64,18%	0 <		0 <			
% Disease severity STEM - 38-57 DA-B												
Number of values	6				6	6	UTC	CA3301		UTC	CA3301	CA3301
Minimum value	5,55				1,40	0,70		0,7 l/ha			0,6 l/ha	0,6 l/ha
Maximum value	24,70	-	-	-	7,05	10,30	6 >	0 >		6 >	2 >	2 >
Mean disease severity (%)	14,12				3,85	4,17	0 =	4 =		0 =	4 =	4 =

severity (%) Abbott efficacy (%)	0,00%				71,67 %	74,97%	0 <	2 <	0 <	0 <
Number of values	5	5			5	5	CA2445		CA2445	
Minimum value	5,55	1,20			1,40	0,70	0,7 l/ha		0,7 l/ha	
Maximum value	22,20	4,40	-	-	4,60	6,80	0 >		0 >	
Mean disease severity (%)	12,01	2,66			3,21	2,94	3 =		5 =	
Abbott efficacy (%)	0,00%	81,16%			71,72 %	78,31%	2 <		0 <	
Number of values	1	1	1		1	1	PROSARO		PROSARO	
Minimum value	5,55	1,20	0,65		1,40	0,70	0,75 l/ha		0,75 l:ha	
Maximum value	5,55	1,20	0,65	-	1,40	0,70	0 >		0 >	
Mean disease severity (%)	5,55	1,20	0,65		1,40	0,70	1 =		1 =	
Abbott efficacy (%)	0,00%	78,38%	88,29%		74,77 %	87,39%	0 <		0 <	
Number of values	2			2	2	2	PROPULSE		PROPULSE	
Minimum value	12,70			4,15	4,60	3,70	1,0 l/ha		1,0 l/ha	
Maximum value	24,70	-	-	6,10	7,05	10,30	0 >		0 >	
Mean disease severity (%)	18,70			5,13	5,83	7,00	2 =		2 =	
Abbott efficacy (%)	0,00%			71.31 %	67,62 %	64,58%	0 <		0 <	
% Disease severity POD - 39-50 DA-B										
Number of values	5				5	5	UTC	CA3301	UTC	CA3301
Minimum value	5,33				0,15	0,09		0,7 l/ha		0,6 l/ha
Maximum value	32,95	-	-	-	15,50	14,65	5 >	0 >	5 >	0 >
Mean disease severity (%)	14,52				6,41	5,13	0 =	5 =	0 =	5 =
Abbott efficacy (%)	0,00%				69,89 %	78,15%	0 <	0 <	0 <	0 <
Number of values	3	3			3	3	CA2445		CA2445	

Minimum value	5,33	0,11			0,15	0,09	0,7 l/ha			0,7 l/ha			
Maximum value	5,55	1,45	-	-	2,05	1,05	0 >			0 >			
Mean disease severity (%)	5,43	0,56			0,79	0,57	3 =			3 =			
Abbott efficacy (%)	0,00%	96,14%			85,76 %	92,33%	0 <			0 <			
Number of values	1	1	1		1	1	PROSARO			PROSARO			
Minimum value	5,55	1,45	1,05		2,05	1,05	0,75 l/ha			0,75 l:ha			
Maximum value	5,55	1,45	1,05	-	2,05	1,05	0 >			0 >			
Mean disease severity (%)	5,55	1,45	1,05		2,05	1,05	1 =			1 =			
Abbott efficacy (%)	0,00%	73,87%	81,08 %		63,06 %	81,08%	0 <			0 <			
Number of values	2			2	2	2	PROPULSE			PROPULSE			
Minimum value	23,35			7,80	14,20	9,75	1,0 l/ha			1,0 l/ha			
Maximum value	32,95	-	-	17,30	15,50	14,65	0 >			0 >			
Mean disease severity (%)	28,15			12,55	14,85	12,20	2 =			2 =			
Abbott efficacy (%)	0,00%			57,05 %	46,07 %	56,89%	0 <			0 <			
% Disease severity ROOT - 39 DA-B													
Number of values	2	2			2	2	UTC	CA2445	CA3301	UTC	CA2445	CA3301	
Minimum value	5,07	0,00			0,00	0,00		0,7 l/ha	0,7 l/ha		0,7 l/ha		
Maximum value	5,16	0,00	-	-	0,00	0,00		2 >	0 >		0 >	2 >	0 >
Mean disease severity (%)	5,11	0,00			0,00	0,00		0 =	2 =		2 =	0 =	2 =
Abbott efficacy (%)	0,00%	100,00%			100,00 %	100,00 %	0 <	0 <	0 <	0 <	0 <	0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Ab-
bott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Conclusion South-Eastern EPPO zone - Use of CA3301 at 2x 0.6-0.7 l/ha against SCLESC

In the South-Eastern EPPO zone, 12 trials were available against *Sclerotinia sclerotiorum* on oilseed rape. 10 trials out of 12 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to several authorised reference products on disease severity (%). Among these 10 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis.

In order to cover the different agricultural spraying practices of oilseed rape in South-Eastern EPPO zone, 2 types of spraying programs have been tested: 2 applications in spring (dedicated to spring infections of foliar, stem and pods diseases on oilseed rape) or 1 application in autumn and 1 application in spring (dedicated to both autumn and spring infections of roots, foliar, stem and pods diseases on oilseed rape). In the first group of trials, CA3301 was applied twice in spring. The data recorded were available on leaves, stems, pods and roots. When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6-0.7 l/ha to control *Sclerotinia sclerotiorum* with an average of 82.87-87.96% of efficacy on leaves 3 weeks after the 2nd application and 65.86-72.28% of efficacy before harvest. On stems, it showed 87.32-94.16% of efficacy 3 weeks after the 2nd application and 71.67-74.97% of efficacy before harvest. Moreover, before harvest, CA3301 showed 69.89-78.15% of efficacy on pods and 100% on roots.

In the second group of trials, CA3301 was applied once in autumn and once in spring. The data recorded were available on stems only in a single assessment, but in challenging disease infection conditions for the crop, before harvest. When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6-0.7 l/ha to control *Sclerotinia sclerotiorum* with a mean efficacy of 91.60-85.76%.

In both cases, in overall the data demonstrate medium to high efficacy on leaves, stems, pods and roots to control *Sclerotinia sclerotiorum* on oilseed rape. Although the dataset is very limited in the second group of trials, it is envisaged that in most instances 2 applications of CA330 in spring or one in autumn and one in spring will provide an acceptable control of *Sclerotinia sclerotiorum* whatever the timing of application, as in addition efficacy was comparable to authorised reference products

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.7 l/ha to control *Sclerotinia sclerotiorum* on oilseed rape in the South-Eastern EPPO zone.

Comments of zRMS:

19 valid field trials were carried out in the Maritime EPPO climatic zone. 2 applications of CA3301 in autumn and spring were used in 7 out of 19 trials. The test product applied at dose rate of 0,6-0,7 l/ha achieved medium efficacy after 44-84 DA-B. 2 applications of CA3301 in spring were used in 12 out of 19 trials. The test product at dose rate of 0,6 l/ha was effective on medium level. The higher dose achieved medium to high efficacy after 22-77 days after second application. No significant differences between the test and reference product were observed.

16 valid trials were conducted in the North-East EPPO zone. 2 applications of CA3301 in autumn and spring were used in 9 out of 16 trials. The test product applied at dose rate of 0,6-0,7 l/ha achieved medium to high level of control after 16-62 DA-B. 2 applications of CA3301 in spring were used in 7 out of 16 trials. The test

product at dose rate of 0,6 l/ha was effective in medium to high level. The dose rate of 0,7 l/ha achieved high efficacy after 21-56 days after second application. The results of test and reference products were comparable. 10 valid trials were available in **the South-East EPPO zone**. 2 applications of CA3301 in autumn and spring were used in 1 out of 10 trials. The test product at dose rate of 0,6-0,7 l/ha was effective on high level after 47 DA-B. 2 applications of CA3301 in spring were used in 9 out of 10 trials. The test product at 0,6-0,7 l/ha achieved medium to high efficacy after 21-57 days after second application. Also 2 trials (with 2 applications in spring) from the Mediterranean zone have been submitted to support of product registration in other zones. CA3301 at 0,6-0,7 l/ha showed medium to high level of control. No significant differences between the test and reference product were observed.

Taking into account all trial results, it can be concluded that CA3301 in 2 applications is effective to control of *Sclerotinia sclerotiorum* in winter barley. The dose rate of 0,7 l/ha can be recommended in case of high disease pressure.

3.2.3.10 Oilseed rape (BRSNW) / *Alternaria brassicae* (ALTEBA)

Materials and Methods – Oilseed rape – ALTEBA

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2017 and 2020, a series of 54 trials were conducted in several countries of the Maritime, Mediterranean, North-East~~EPPO~~ and South-East~~EPPO~~ EPPO zones to evaluate the efficacy of CA3301 against *Alternaria brassicae* on oilseed rape (see Table 3.2-607). The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, 12 trials were performed in Czech Republic (2), Germany (4), France (3) and Denmark (1) and United Kingdom (2).

In the Mediterranean EPPO zone, 10 trials were performed in France (5), Italy (2) and Spain (3).

In the North-East~~EPPO~~ EPPO zone, 22 trials were performed in Poland (14), Lithuania (3) and Latvia (5).

In the South-East~~EPPO~~ EPPO zone, a total of 10 trials were performed in Hungary (4), Romania (4) and Slovakia (2).

Data groupings were also made specifically for Poland evaluation and trials involved (30) were performed in the North-East~~EPPO~~ EPPO zone (22), in Czech Republic (2), in Germany (4) and in Slovakia (2).

Table 3.2-607: Presentation of trials – Oilseed rape (BRSNW)

Crop(s) *	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, offi- cial***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
BRSN W	ALTEBA	Czech Republic	2018- 2019	MED + E	2 (2)	-	-	-	GEP	

Crop(s) *	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mar- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
		Germany	2020	MED + E	4 (4)	-	-	-	GEP	
		France	2020	MED + E	3 (0)	-	-	-	GEP	
		Denmark	2018	MED + E	1 (0)	-	-	-	GEP	
		United Kingdo m	2020	MED + E	2 (1)	-	-	-	GEP	
BRSN W	ALTEBA	France	2019- 2020	MED + E	-	5 (0)	-	-	GEP	
		Spain	2020	MED + E	-	3 (3)	-	-	GEP	
		Italy	2020	MED +E	-	2 (2)	-	-		
BRSN W	ALTEBA	Poland	2017- 2020	MED + E	-	-	14 (7)	-	GEP	
		Lithuani a	2019- 2020	MED + E	-	-	3 (0)	-	GEP	
		Latvia	2019- 2020	MED + E	-	-	5 (2)	-	GEP	
BRSN W	ALTEBA	Hungary	2019- 2020	MED + E	-	-	-	4 (3)	GEP	
		Romania	2018- 2020	MED + E	-	-	-	4 (3)	GEP	
		Slovakia	2009- 2020	MED + E	-	-	-	2 (2)	GEP	
TOTAL	-	-	2018- 2020	MED + E	12 (7)	10 (5)	22 (9)	10 (8)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation

In all trials, CA3301 was compared to at least one commercial fungicide used as standard reference for comparison.

Table 3.2-608: Efficacy evaluation - Presentation of reference standards used in trials – Oilseed rape (BRSNW) –ALTEBA– Maritime EPPO zone

Crop(s))	Refer- ence standard	Coun- try(ies) where the product is used ⁽¹⁾	Authoriza- tion number	Active sub- stance(s)	Formulation		Regis- tered ap- plication rate ⁽³⁾	Applica- tion rate in tri- als (per treat- ment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concentra- tion of a.s.			
BRSN W	PRO- LINE	CZ	4523-1	Prothiocona- zole	EC	250 g/l	2 x 0.7 l/ha max	2 x 0.7 l/ha	CA2445 in some

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
	250 EC								trials
	PRO-LINE EC 250	DK	18-473	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.5-0.6-0.7 l/ha	CA2445 in some trials
	JOAO	FR (N)	2060116	Prothioconazole	EC	250 g/l	2 x 0.7 l/ha	2 x 0.7 l/ha	CA2445 in some trials
	BISTRO	FR (N)	2160260	Metconazole	EC	90 g/l	2 x 0.8 l/ha	2 x 0.6 l/ha	
	PRO-LINE	UK	12084	Prothioconazole	EC	250 g/l	2 x 0.7 l/ha	2 x 0.7 l/ha	CA2445 in some trials
	PRO-LINE	DE	025287-00	Prothioconazole	EC	250 g/l	2 x 0.7 l/ha	2 x 0.7 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-609: Efficacy evaluation - Presentation of reference standards used in trials – Oilseed rape (BRSNW) –ALTEBA– Mediterranean EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
BRSNW	JOAO	FR (S)	2060116	Prothioconazole	EC	250 g/l	2 x 0.7 l/ha	2 x 0.7 l/ha	CA2445 in some trials
	PRO-SARO	ES	25661	Prothioconazole + Tebuconazole	EC	250 g/L	2 x 1 l/ha	2 x 1 l/ha	
	ORTIVA	ES	22000	Azoxystrobin	SC	250 g/L	2 x 0.8-1 l/ha	2 x 1 l/ha	
	CA-RAMBA	IT	014101	Metconazole	EC	8.6g / 100g	2 x 0.8 l/ha	2 x 0.8 l/ha	

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-610: Efficacy evaluation - Presentation of reference standards used in trials – Oilseed rape (BRSNW) –ALTEBA– North-Eastern EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
BRSNW	PRAKTIS	PL	R-222/2019	Prothioconazole	EC	250 g/l	2 x 0.7 l/ha	2 x 0.7 l/ha	CA2445 in some trials
	TILMOR 240 EC	PL	R-23/2015	Prothioconazole + Tebuconazole	EC	240 g/l	1 x 0.75 l/ha + 1x 1 l/ha	1 x 0.75 l/ha + 1x 1 l/ha	
	CA-RAMBA 60 SL	PL	R-45/2010	Metconazole	SL	60 g/l	2 x 0.7-1 l/ha	1 or 2 x 1 l/ha	
	ORIUS EXTRA	PL	R-77/2015	Tebuconazole	EW	250 g/l	1 x 1 l/ha	2 x 1 l/ha	
	PRO-SARO	LT	AS2-2F/2015	Prothioconazole + Tebuconazole	EC	250 g/l	2 x 1 l/ha	1 x 1 l/ha	
	PRO-SARO	LV	0276	Prothioconazole + Tebuconazole	EC	250 g/la	2 x 1 l/ha	2 x 1 l/ha	

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-611: Efficacy evaluation - Presentation of reference standards used in trials – Oilseed rape (BRSNW) –ALTEBA– South-Eastern EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
BRSNW	PROLINE	RO	457PC/15/11/2018	Prothioconazole	EC	250 g/l	2 x 0.7 l/ha	2 x 0.7 l/ha	CA2445 in some trials
	PROLINE	HU	6300 / 1205-1 / 2020	Prothioconazole	EC	250 g/l	Not registered but standard reference at EU level	2 x 0.7 l/ha	CA2445 in some trials
	TILMOR	HU	04.2/7910-1/2011	Prothioconazole + Tebuconazole	EC	240 g/l	2 x 1.2 l/ha	2 x 1.2 l/ha	
	PRO-PULSE	HU	04.2/41-1/2014	Fluoripam + Prothioconazole	SE	250 g/l	2 x 1 l/ha	2 x 1 l/ha	
	ORIUS 25 EW	SK	18-00319-AU	Tebuconazole	EW	250 g/l	2 x 1 l/ha	2 x 1 l/ha	

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
	PRO-SARO	SK	06-02-0771	Prothioconazole + Tebuconazole	EC	250 g/la	2 x 0.75 l/ha	2 x 0.75 l/ha	

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-612.

Table 3.2-612: Details on trial methodology – Oilseed rape (BRSNW) – ALTEBA

		Maritime EPPO zone	Mediterranean EPPO zone	North –East EPPO zone	South-Eastern EPPO zone	Data relevant for Poland
Trials	Total number (valid number)	12 (7)	10 (5)	22 (9)	10 (8)	30 (15)
	Supportive trials	-	-	-	-	-
Guidelines	General guidelines	PP 1/135(4) PP 1/152 (4) PP 181 (4)	PP 1/135(4) PP 1/152 (4) PP 181 (4)	PP 1/135(4) PP 1/152 (4) PP 181 (4)	PP 1/135(4) PP 1/152 (4) PP 181 (4)	PP 1/135(4) PP 1/152 (4) PP 181 (4)
	Specific guidelines	PP 1/78 (3)	PP 1/78 (3)	PP 1/78 (3)	PP 1/78 (3)	PP 1/78 (3)
Experimental design	Plot design	Randomized Complete Blocks, Un-treated included	Randomized Complete Blocks, Un-treated included	Randomized Complete Blocks, Un-treated included	Randomized Complete Blocks, Un-treated included	Randomized Complete Blocks, Un-treated included
	Plot size	25-45 m ²	21-45 m ²	21-48 m ²	21-42 m ²	21-48 m ²
	Number of replications	4	4	4	4	4
Crop	Trials per crop	BRSNW (12)	BRSNW (10)	BRSNW (22)	BRSNW (10)	BRSNW (30)
	Varieties per crop	Loki (1), Butterfly (1), DK Exception (1), Nikita (2), Flamingo (1), Croozer (1), DK Expression (1), Architect (1), Expansion (2), Crome (1)	RGT Quizz (1), Aquarel (1), Imperio (1), Expansion (1), Exception (1), PR44D06 (1), Sésame (1), Amazzonite (1), Imperio (1), Arsenal (1)	Bellevue (1), NK Technic (2), Acapulco (2), Mercedes (2), DK Explicit (1), Monolit (2), Umberto (2), PT264 (1), Kuga (3), Panama (1), Cult (1), Seveernij (1), Einstein (1), Alabama (1), Epure (1)	Wyzbee (1), Mécses (3), Visby (1), Hybrirrock (1), Arabella (2), Sherpa (1), Triangle (1)	Bellevue (1), NK Technic (2), Acapulco (2), Mercedes (2), DK Explicit (1), Monolit (2), Umberto (2), PT264 (1), Kuga (3), Panama (1), Cult (1), Seveernij (1), Einstein (1), Alabama (1), Epure (1), Loki (1), DK Exception (1), Croozer (1), DK Expression (1), Expansion (2), Crome (1), Arabella (2)

	Sowing period	August (9), September (2), October (1)	August (2), September (7), October (1)	July (1), August (20), September (1)	August (7), September (2), October (1)	July (1), August (28), September (1), October (1)
Application	Crop stage (BBCH)* at application	A : BBCH 14-19 or BBCH 50-61 B: BBCH 65-69	A: BBCH 51-55 B: BBCH 65-69	A: BBCH 14-16 or BBCH 33-64 B: BBCH 65-69	A: BBCH 16-17 or BBCH 35-55 B: BBCH 65-67	A: BBCH 14-19 or BBCH 33-64 B: BBCH 65-69
	Timing Pest stage at application	BBCH 14-69 A: PRINFC (9), MIXED (2), N/A (1) B: PRINFC (7), MIXED (3), LATENT (1), N/A (1)	BBCH 51-69 A: PRINFC (2), ACTIVE (1), MIXED (2), N/A (1) B: PRINFC (3), SPORUL (1), ACTIVE (1), MIXED (4), N/A (1)	BBCH 14-69 A: PRINFC (15), MYCELI (1), MIXED (4), N/A (2) B: PRINFC (12), SPORUL (1), MIXED (6), N/A (1)	BBCH 16-67 A: PRINFC (7), SPORUL (1), MIXED (2) B: PRINFC (5), SPORUL (2), MIXED (3)	BBCH 14-69 A: PRINFC (22), MYCELI (1), MIXED (6), N/A (2) B: PRINFC (18), SPORUL (1), MIXED (9), N/A (1)
	Number of applications Intervals between applications	1 application (0) 2 applications (11-39 or 91-192 days) (12)	1 application (4) 2 applications (21-49 days) (6)	1 application (2) 2 applications (20-47 or 206-234 days) (20)	1 application (0) 2 applications (19-35 or 185-211 days) (10)	1 application (2) 2 applications (19-47 or 192-234 days) (30)
	Spray volumes	A: 200-300 l/ha B: 200-300 l/ha	A: 300-400 l/ha B: 300-400 l/ha	A: 200-400 l/ha B: 200-300 l/ha	A: 200-500 l/ha* B: 200-500 l/ha	A: 200-500 l/ha* B: 200-500 l/ha
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10)
	Assessment dates	0 DA-A, 13-48 DA-A, 169 DA-A, 0-1 DA-B, 15-28 DA-B, 50-73 DA-B, 77-108 DA-B	0 DA-A, 21 DA-A, 0 DA-B, 19-22 DA-B, 39-76 DA-B, 90 DA-B	0 DA-A, 15-21 DA-A, 42-59 DA-A, 63-203 DA-A, 0 DA-B, 15-25 DA-B, 33-50 DA-B, 54-94 DA-B	0 DA-A, 14-21 DA-A, 0-2 DA-B, 15-28 DA-B, 41-56 DA-B, 63-96 DA-B	0 DA-A, 15-28 DA-A, 42-59 DA-A, 63-203 DA-A, 0-1 DA-B, 15-28 DA-B, 33-50 DA-B, 54-97 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Natural (12)	Natural (10)	Natural (22)	Natural (10)	Natural (30)
	e.g. Field / Greenhouse...	Field trials	Field trials	Field trials	Field trials	Field trials

*In 1 trial out of 10 in the South-Eastern EPPO zone a deviation was recorded regarding the spray volume of application. In this trial 500 l/ha were applied instead of 400 l/ha maximum, which is a small difference with no impact on the validity of the trial.

Use of CA3301 at 2x 0.6-0.7 l/ha against ALTEBA with one application in autumn and one application in spring – Maritime EPPO zone

In the Maritime EPPO zone, 12 trials were available against *Alternaria brassicae* on oilseed rape. 7 trials out of 12 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to the reference products on disease severity (%). Among these

7 trials, CA3301 was applied once in autumn and once in spring in 1 trial, first at crop stage BBCH 19 and the 2nd application was at BBCH 67. The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.7 l/ha and the analysis was conducted on leaves and on pods.

Summary results are presented in Table 3.2-613.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Alternaria brassicae*. When applied at this dose rate, CA3301 showed 64.99% of efficacy to control the disease on leaves 4 weeks after the 2nd application and 63.04% of efficacy on pods before harvest.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.7 l/ha to control *Alternaria brassicae*. At 0.7 l/ha, CA3301 showed 79.48% of efficacy to control the disease on leaves 4 weeks after the 2nd application and 78.46% of efficacy on pods before harvest.

In the Maritime EPPO zone, a limited dataset was available for assessment of control *Alternaria brassicae* at this application timing. Nevertheless, applications of CA3301 at 0.6-0.7 l/ha demonstrated medium efficacy in conditions of low disease pressure. At this range of dosage CA3301 was comparable to the reference product CA2445. A larger dataset has been presented regarding to the case where CA3301 was applied twice in spring in the Maritime EPPO zone, which demonstrates that the efficacy of CA3301 at 0.6 l/ha was comparable to that of the dose rate of 0.7 l/ha. This dataset can be supportive for the case where the first application of the product is in autumn. Therefore, it is proposed that the dose rate of 0.6 l/ha is used for instances of low disease pressure and an increased rate of 0.7 l/ha for high disease pressure for control of *Alternaria brassicae*.

Considering all elements presented above, it is justified to claim the registration of 2 applications, one in autumn and one in spring of CA3301 at 0.6-0.7 l/ha to control *Alternaria brassicae* on oilseed rape in the Maritime EPPO zone.

Table 3.2-613: Summary table - Efficacy evaluation – Oilseed rape – ALTEBA - Maritime EPPO zone

Table 5.2-6.13: Summary table - Efficacy evaluation - Oncoed Rape - ATTEDA - Maritime LEAF zone										
Treatment name	UNTREATED CHECK	CA24	CA330	CA33	No of trials where			No of trials where		
Rate		45	1	01	CA3301			CA3301		
Rate unit		0,7	0,6	0,7	at 0,6 l/ha is >, = or			at 0,7 l/ha is >, = or		
Appl. Code		L/ha	L/ha	L/ha	<			<		
		AB	AB	AB	compared to			compared to		
% Disease severity LEAF - 28 DA-B										
Number of values	1	1	1	1	UT	CA24	CA33	UT	CA24	CA33
					C	45	01	C	45	01
Minimum value	8,77	1,72	3,07	1,80		0,7	0,7		0,7	0,6
						l/ha	l/ha		l/ha	l/ha
Maximum value	8,77	1,72	3,07	1,80	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	8,77	1,72	3,07	1,80	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	80,39 %	64,99 %	79,48 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity POD - 56 DA-B										
Number of values	1	1	1	1	UT	CA24	CA33	UT	CA24	CA33
					C	45	01	C	45	01
Minimum value	8,17	1,46	3,02	1,76		0,7	0,7		0,7	0,6
						l/ha	l/ha		l/ha	l/ha
Maximum value	8,17	1,46	3,02	1,76	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	8,17	1,46	3,02	1,76	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	82,13 %	63,04 %	78,46 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)
(conversely for '<')

Levels of efficacy (% Abbott efficacy)
>80% High efficacy

60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.7 l/ha against ALTEBA with 2 applications in spring – Maritime EPPO zone

In the Maritime EPPO zone, 12 trials were available against *Alternaria brassicae* on oilseed rape. 7 trials out of 12 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to the authorised reference product CA2445 on disease severity (%). Among these 7 trials, CA3301 was applied twice in spring in 6 trials, first at crop stages BBCH 50-55 and the 2nd application was at BBCH 65. The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.7 l/ha and the analysis was conducted on leaves, stems and pods.

Summary results are presented in Table 3.2-614.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Alternaria brassicae*. Before harvest, when applied at this dose rate, CA3301 showed 100% of efficacy to control the disease on total leaves, 44.83% on upper leaves, 28.26% on lower leaves, 74.56% on stems and 86.85% on pods.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.7 l/ha to control *Alternaria brassicae*. At 0.7 l/ha, CA3301 showed 100% of efficacy to control the disease on total leaves, 44.75% on upper leaves, 30.39% on lower leaves, 76.45% on stems and 91.83% on pods, before harvest.

In the Maritime EPPO zone, CA3301 at 0.6-0.7 l/ha showed in overall medium to high efficacy in reducing the severity of *Alternaria brassicae* on oilseed rape. Moreover, when applied at 0.6-0.7 l/ha, CA3301 gave statistically equivalent disease control compared to the authorised reference product CA2445 in all 6 trials, on leaves as well as on stems and pods. For all assessments there were no significant differences in disease control between the rate of 0.6 l/ha or 0.7 l/ha of CA3301. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for control of *Alternaria brassicae*, however when conditions are conducive to heavy disease infestation the rate of 0.7 l/ha may be beneficial to further reduce disease pressure.

Considering all elements presented above, it is justified to claim the registration of 2 applications in spring of CA3301 at 0.6-0.7 l/ha to control *Alternaria brassicae* on oilseed rape in the Maritime EPPO zone.

Table 3.2-614: Summary table - Efficacy evaluation – Oilseed rape – ALTEBA - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA2445 0,7 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to		
Rate										
Rate unit										
Appl. Code										
% Disease severity LEAF - 76 DA-B										
Number of values	2	2	2	2	UT	CA24	CA33	UT	CA24	CA33
					C	45	01	C	45	01
Minimum value	6,59	0,00	0,00	0,00		0,7	0,7		0,7	0,6
						l/ha	l/ha		l/ha	l/ha
Maximum value	10,03	0,00	0,00	0,00	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	8,31	0,00	0,00	0,00	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	100,00%	100,00%	100,00%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity LEAF UP - 72 DA-B										
Number of values	1	1	1	1	UT	CA24	CA33	UT	CA24	CA33
					C	45	01	C	45	01

Minimum value	23,60	12,97	13,02	13,04		0,7 l/ha	0,7 l/ha		0,7 l/ha	0,6 l/ha
Maximum value	23,60	12,97	13,02	13,04	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	23,60	12,97	13,02	13,04	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	45,04%	44,83%	44,75%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity LEAF LOW - 72 DA-B										
Number of values	1	1	1	1	UT C	CA24 45 0,7 l/ha	CA33 01 0,7 l/ha	UT C	CA24 45 0,7 l/ha	CA33 01 0,6 l/ha
Minimum value	53,08	37,13	38,08	36,95						
Maximum value	53,08	37,13	38,08	36,95	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	53,08	37,13	38,08	36,95	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	30,05%	28,26%	30,39%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity STEM - 73 DA-B										
Number of values	2	2	2	2	UT C	CA24 45 0,7 l/ha	CA33 01 0,7 l/ha	UT C	CA24 45 0,7 l/ha	CA33 01 0,6 l/ha
Minimum value	17,44	3,52	4,31	3,79						
Maximum value	18,76	4,00	4,91	4,69	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	18,10	3,76	4,61	4,24	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	79,15%	74,56%	76,45%	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity POD - 73-76 DA-B										
Number of values	3	3	3	3	UT C	CA24 45 0,7 l/ha	CA33 01 0,7 l/ha	UT C	CA24 45 0,7 l/ha	CA33 01 0,6 l/ha
Minimum value	15,42	0,00	0,00	0,00						
Maximum value	39,78	9,88	15,43	9,65	3 >	0 >	0 >	3 >	0 >	0 >
Mean disease severity (%)	26,03	3,31	5,18	3,23	0 =	3 =	3 =	0 =	3 =	3 =
Abbott efficacy (%)	0,00%	91,59%	86,85%	91,83%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)
(conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Conclusion Maritime EPPO zone - Use of CA3301 at 2x 0.6-0.7 l/ha against ALTEBA

In the Maritime EPPO zone, 12 trials were available against *Alternaria brassicae* on oilseed rape. 7 trials out of 12 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to several authorised reference product CA2445 on disease severity (%). Among these 7 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis.

In order to cover the different agricultural spraying practices of oilseed rape in Maritime EPPO zone, 2 types of spraying programs have been tested: 2 applications in spring (dedicated to spring infections of foliar, stem and pods diseases on oilseed rape) or 1 application in autumn and 1 application in spring (dedicated to both autumn and spring infections of roots, foliar, stem and pods diseases on oilseed rape).

In the first group of trials, CA3301 was applied twice in spring. The data recorded were available on leaves, on stem and on pods. A single assessment timing was available for each part rated. When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6-0.7 l/ha to control *Alternaria brassicae* with an average of 100% of efficacy to control the disease on total leaves, 44.83-44.75% on upper leaves, 28.26-30.39% on lower leaves, 74.56-76.45% on stems and 86.85-91.83% on pods before harvest.

In the second group of trials, CA3301 was applied once in autumn and once in spring. The data were available on leaves and on pods at a single assessment. When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6-0.7 l/ha to control *Alternaria brassicae* with an average 64.99-79.48% of efficacy on leaves and 63.04-78.46% on pods before harvest.

For both timings, CA3301 at 0.6-0.7 l/ha gave equivalent disease control compared to the authorised reference product CA2445. Moreover, in the assessments there were no significant differences in disease control between the rate of 0.6 l/ha or 0.7 l/ha of CA3301 in conditions of low to medium disease pressure. However, in condition of higher disease pressure (as in trial EU19-070-12 with high disease pressure on pods), the benefit of applying a higher rate of product when disease pressure is high was clearly observed. Therefore, it is envisaged that in most instances 2 applications of CA3301 in spring or one in autumn and one in spring will provide an acceptable control of *Alternaria brassicae* whatever the timing of application.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.7 l/ha to control *Alternaria brassicae* on oilseed rape in the Maritime EPPO zone. Moreover, these 2 applications can be carried out in spring or first in autumn and then the 2nd in spring.

Use of CA3301 at 2x 0.6-0.7 l/ha against ALTEBA with 2 applications in spring – Mediterranean EPPO zone

In the Mediterranean EPPO zone, in all the 5 valid trials, CA3301 was applied twice in spring, first at crop

In the Mediterranean EPPO zone, 10 trials were available against *Alternaria brassicae* on oilseed rape. 5 trials out of 10 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to the reference products on disease severity (%). In all these 5 trials, CA3301 was applied twice in spring, first at crop stages BBCH 51-55 and the 2nd application was at BBCH 65-69. The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.7 l/ha. The analysis was conducted on leaves, stems and pods. In one trial only, two different assessment timings were available on leaves. For the other parts assessed (stems and pods), a single assessment timing was available.

Summary results are presented in Table 3.2-615.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Alternaria brassicae*. When applied at 0.6 l/ha, CA3301 showed 95.70% of efficacy to control the disease on total leaves around three weeks after the 2nd application and 73.91% of efficacy on leaves, 79.30% on stems and 70.70% on pods before harvest. At 0.7 l/ha, CA3301 showed 94.15% of efficacy to control the disease on total leaves around three weeks after the 2nd application and 79.64% of efficacy on leaves, 81.99% on stems and 73.81% on pods before harvest.

In the Mediterranean EPPO zone, CA3301 at 0.6-0.7 l/ha showed in overall medium to high efficacy in reducing the severity of *Alternaria brassicae* on oilseed rape. CA3301 at 0.7 l/ha gave equivalent disease control compared to the authorised reference products CA2445, CARAMBA, PROSARO and ORTIVA in all trials and at 0.6 l/ha CA3301 gave equivalent disease control to CA2445, CARAMBA and ORTIVA in all trials. Moreover, in all assessments there were no significant differences in disease control between the rate of 0.6 l/ha or 0.7 l/ha of CA3301. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for control of *Alternaria brassicae*, however when conditions are conducive to heavy disease infestation the rate of 0.7 l/ha may be beneficial to further reduce disease pressure.

Considering all elements presented above, it is justified to claim the registration of 2 applications in spring of CA3301 at 0.6-0.7 l/ha to control *Alternaria brassicae* on oilseed rape in the Mediterranean EPPO zone.

Table 3.2-615: Summary table - Efficacy evaluation – Oilseed rape – ALTEBA - Mediterranean EPPO zone

Treatment name	UNT REA TED CHE CK	CA24 45	CAR AMB A	PRO SAR O	ORT IVA	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to				No of trials where CA3301 at 0,7 l/ha is >, = or < compared to			
Rate		0,7	0,8	1	1	0,6	0,7								
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	L/ha								
Appl. Code		AB	AB	AB	AB	AB	AB								
% Disease severity LEAF - 19 DA-B															
Number of values	1	1			1	1	1	U T C	CA 244 5	OR TIV A	CA 330 1	U T C	CA 244 5	OR TIV A	CA 330 1
Minimum value	5,81	0,62			0,45	0,25	0,34		0,7 l/ha	1,0 l/ha	0,7 l/ha		0,7 l/ha	1,0 l/ha	0,6 l/ha
Maximum value	5,81	0,62	-	-	0,45	0,25	0,34	1 > 0 = 0 <	0 >	0 >	0 >	1 > 0 = 0 <	0 >	0 >	0 >
Mean disease severity (%)	5,81	0,62			0,45	0,25	0,34		1 =	1 =	1 =		1 =	1 =	1 =
Abbott efficacy (%)	0,00 %	89,33 %			92,25 %	95,70 %	94,15 %	0 <	0 <	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity LEAF - 39-49 DA-B															
Number of values	5	5				5	5	UTC		CA3301		UTC		CA3301	
Minimum value	8,28	1,08				0,90	0,64			0,7 l/ha				0,6 l/ha	
Maximum value	62,70	12,49	-	-	-	22,43	11,97	5 >		0 >		5 >		0 >	
Mean disease severity (%)	28,43	5,26				7,70	5,20	0 =		5 =		0 =		5 =	
Abbott efficacy (%)	0,00 %	78,30 %				73,91 %	79,64 %	0 <		0 <		0 <		0 <	
Number of values	2	2	2			2	2	CA2445		CA-RAMBA		CA2445		CA-RAMBA	
Minimum value	8,28	2,80	2,70			2,94	2,85	0,7 l/ha		0,8 l/ha		0,7 l/ha		0,8 l/ha	
Maximum value	11,13	3,63	3,53	-	-	3,80	2,98	0 >		0 >		0 >		0 >	
Mean disease severity (%)	9,71	3,22	3,11			3,37	2,92	5 =		2 =		5 =		2 =	
Abbott efficacy (%)	0,00 %	66,78 %	67,84 %			65,18 %	69,20 %	0 <		0 <		0 <		0 <	
Number of values	2	2		2		2	2	PROSARO				PROSARO			
Minimum value	12,04	1,08		0,60		0,90	0,64	1,0 l/ha				1,0 l/ha			
Maximum value	62,70	12,49	-	6,75	-	22,43	11,97	0 >				0 >			
Mean disease severity (%)	37,37	6,79		3,67		11,67	6,31	1 =				2 =			
Abbott efficacy (%)	0,00 %	85,55 %		92,13 %		78,38 %	87,80 %	1 <				0 <			
Number of values	1	1			1	1	1	ORTIVA				ORTIVA			
Minimum value	48,03	6,33			9,05	8,43	7,59	1,0 l/ha				1,0 l/ha			
Maximum value	48,03	6,33	-	-	9,05	8,43	7,59	0 >				0 >			
Mean disease severity (%)	48,03	6,33			9,05	8,43	7,59	1 =				1 =			

Treatment name	UNT REATED CHECK	CA24 45	CAR AMB A	PRO SAR O	ORT IVA	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,7 l/ha is >, = or < compared to	
Rate		0,7	0,8	1	1	0,6	0,7				
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB	AB	AB				
Abbott efficacy (%)	0,00 %	86,82 %			81,16 %	82,45 %	84,20 %	0 <		0 <	
% Disease severity STEM - 39-48 DA-B											
Number of values	2	2				2	2	UTC	CA3301	UTC	CA3301
Minimum value	5,91	0,41				0,78	1,18		0,7 l/ha		0,6 l/ha
Maximum value	18,69	2,64	-	-	-	5,27	3,00	2 >	0 >	2 >	0 >
Mean disease severity (%)	12,30	1,53				3,02	2,09	0 =	2 =	0 =	2 =
Abbott efficacy (%)	0,00 %	89,47 %				79,30 %	81,99 %	0 <	0 <	0 <	0 <
Number of values	1	1		1		1	1	CA2445	PRO-SARO	CA2445	PRO-SARO
Minimum value	18,69	2,64		2,13		5,27	3,00	0,7 l/ha	1,0 l/ha	0,7 l/ha	1,0 l/ha
Maximum value	18,69	2,64	-	2,13	-	5,27	3,00	0 >	0 >	0 >	0 >
Mean disease severity (%)	18,69	2,64		2,13		5,27	3,00	2 =	0 =	2 =	1 =
Abbott efficacy (%)	0,00 %	85,87 %		88,60 %		71,80 %	83,95 %	0 <	1 <	0 <	0 <
Number of values	1	1			1	1	1	ORTIVA		ORTIVA	
Minimum value	5,91	0,41			1,22	0,78	1,18	1,0 l/ha		1,0 l/ha	
Maximum value	5,91	0,41	-	-	1,22	0,78	1,18	0 >		0 >	
Mean disease severity (%)	5,91	0,41			1,22	0,78	1,18	1 =		1 =	
Abbott efficacy (%)	0,00 %	93,06 %			79,36 %	86,80 %	80,03 %	0 <		0 <	
% Disease severity POD- 39-48 DA-B											
Number of values	3	3				3	3	UTC	CA3301	UTC	CA3301
Minimum value	7,42	1,41				2,27	1,62		0,7 l/ha		0,6 l/ha
Maximum value	25,57	4,46	-	-	-	5,61	5,43	3 >	0 >	3 >	0 >
Mean disease severity (%)	13,82	3,29				3,62	3,35	0 =	3 =	0 =	3 =
Abbott efficacy (%)	0,00 %	72,13 %				70,70 %	73,81 %	0 <	0 <	0 <	0 <
Number of values	2	2		2		2	2	CA2445	PRO-SARO	CA2445	PRO-SARO
Minimum value	7,42	1,41		1,59		2,27	1,62	0,7 l/ha	1,0 l/ha	0,7 l/ha	1,0 l/ha
Maximum value	8,48	4,00	-	3,23	-	3,00	3,01	0 >	0 >	0 >	0 >
Mean disease severity (%)	7,95	2,71		2,41		2,64	2,32	3 =	2 =	3 =	2 =
Abbott efficacy (%)	0,00 %	66,91 %		70,24 %		67,01 %	71,34 %	0 <	0 <	0 <	0 <
Number of values	1	1			1	1	1	ORTIVA		ORTIVA	
Minimum value	25,57	4,46			7,57	5,61	5,43	1,0 l/ha		1,0 l/ha	

Treatment name	UNT REA TED CHE CK	CA24 45	CAR AMB A	PRO SAR O	ORT IVA	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,7 l/ha is >, = or < compared to
Rate		0,7	0,8	1	1	0,6	0,7		
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	AB	AB	AB		
Maximum value	25,57	4,46	-	-	7,57	5,61	5,43	0 >	0 >
Mean disease severity (%)	25,57	4,46			7,57	5,61	5,43	1 =	1 =
Abbott efficacy (%)	0,00	82,56			70,39	78,06	78,76	0 <	0 <
	%	%			%	%	%		

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.7 l/ha against ALTEBA with one application in autumn and one application in spring - North-East ~~EPPO~~ EPPO zone

In the North-East ~~EPPO~~ EPPO zone, 22 trials were available against *Alternaria brassicae* on oilseed rape. 9 trials out of 22 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to the reference products on disease severity (%). Among these 9 trials, CA3301 was applied once in autumn and once in spring in 2 trials, first at crop stage BBCH 15 and the 2nd application was at BBCH 67-69. The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.7 l/ha and the analysis was conducted on pods at a single assessment timing.

Summary results are presented in Table 3.2-616.

When evaluating the reduction of disease severity, the data demonstrated the fungicidal effect against *Alternaria brassicae*, provided after two applications of CA3301 at 0.6 and 0.7 l/ha. When applied at 0.6 l/ha, CA3301 showed 74.02% of efficacy to control the disease on pods before harvest and 83.03% when applied at 0.7 l/ha.

In the North-East ~~EPPO~~ zone EPPO zone, a limited dataset was available for assessment of control of *Alternaria brassicae* at this application timing. Nevertheless, applications of CA3301 at 0.6-0.7 l/ha demonstrated high efficacy in conditions of low disease pressure. At this range of dosage, CA3301 was always comparable to the authorised reference products. A larger dataset has been presented regarding to the case where CA3301 was applied twice in spring in the North-East ~~EPPO~~ zone, which demonstrates that the efficacy of CA3301 at 0.6 l/ha was statistically comparable to that of the dose rate of 0.7 l/ha on leaves, on stems and on pods. This dataset can be supportive for the case where the first application of the product is in autumn. Therefore, it is proposed that the dose rate of 0.6 l/ha is used for instances of low disease pressure and an increased rate of 0.7 l/ha for high disease pressure.

Considering all elements presented above, it is justified to claim the registration of 2 applications, one in autumn and one in spring of CA3301 at 0.6-0.7 l/ha to control *Alternaria brassicae* on oilseed rape in the North-East ~~EPPO~~ EPPO zone.

Table 3.2-616: Summary table - Efficacy evaluation – Oilseed rape – ALTEBA – North-East ~~EPPO~~ EPPO zone

Treatment name	UNTREA TED CHECK	CA 244 5 0,7 L/h a AB	ORIOUS EXTRA 1 L/ha AB	TILMO R 240 EC 0,75-1 L/ha AB	CA3 301 0,6 L/ha AB	CA3 301 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,7 l/ha is >, = or < compared to
% Disease severity POD - 38-50 DA-B								
Number of values	2				2	2	UTC	UTC
Minimum value	5,60				1,35	0,70	CA3301 0,7 l/ha	CA3301 0,6 l/ha
Maximum value	6,75	-	-	-	1,79	1,32	2 >	2 >
Mean disease severity (%)	6,18				1,57	1,01	0 =	0 =
Abbott efficacy (%)	0,00%				74,0 2%	83,0 3%	0 <	0 <
Number of values	1	1	1		1	1	CA2 445 0,7 l/ha	ORIOUS EXTRA 1,0 l/ha
Minimum value	6,75	0,6 5	0,30		1,35	0,70	CA24 45 0,7 l/ha	ORIOUS EXTRA 1,0 l/ha
Maximum value	6,75	0,6 5	0,30	-	1,35	0,70	0 >	0 >
Mean disease severity (%)	6,75	0,6 5	0,30		1,35	0,70	1 =	1 =
Abbott efficacy (%)	0,00%	90, 37 %	95,56%		80,0 0%	89,6 3%	0 <	0 <
Number of values	1			1	1	1	TILMOR 240 EC	TILMOR 240 EC
Minimum value	5,60			1,01	1,79	1,32	0,75-1,0 l/ha	0,75-1,0 l/ha
Maximum value	5,60	-	-	1,01	1,79	1,32	0 >	0 >
Mean disease severity (%)	5,60			1,01	1,79	1,32	1 =	1 =
Abbott efficacy (%)	0,00%			81,96%	68,0 4%	76,4 3%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)	
>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.7 l/ha against ALTEBA with 2 applications in spring – North-East EPPO zone

In the North-East EPPO zone, 22 trials were available against *Alternaria brassicae* on oilseed rape. 9 trials out of 22 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to the reference products on disease severity (%). Among these 9 trials, CA3301 was applied twice in spring in 7 trials, first at crop stages BBCH 33-55 and the 2nd application was at BBCH 65-67. The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.7 l/ha and the analysis was conducted on leaves, stems and pods. On leaves, 2 different assessment timings were available whereas a single assessment timing was available for the other parts assessed (stems and pods).

Summary results are presented in Table 3.2-617.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at

0.6 l/ha to control *Alternaria brassicae*. On leaves, when applied at 0.6 l/ha, CA3301 showed 94.37% of efficacy to control the disease three weeks after the 2nd application and 73.47% before harvest. Moreover, at this dose rate CA3301 showed 82.68% of efficacy on stems and 80.33% on pods before harvest. When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.7 l/ha to *Alternaria brassicae*. When applied at 0.7 l/ha, on leaves, CA3301 showed 97.42% of efficacy to control the disease three weeks after the 2nd application and 80.92% before harvest. Moreover, at this dose rate CA3301 showed 87.19% of efficacy on stem and 87.71% on pods before harvest.

In the North-Eastern EPPO zone, the disease pressure was low to moderate and maintained to a consistent level on leaves, stems and pods. In overall CA3301 at 0.6-0.7 l/ha showed a high efficacy in reducing the severity of *Alternaria brassicae* on oilseed rape with a consistent performance until the harvest timing. CA3301 at the proposed dose rates gave equivalent disease control compared to the several authorised reference products. Averaged across the dataset the efficacy of CA3301 at 0.6 l/ha was comparable to that of the dose rate of 0.7 l/ha, in these conditions of disease pressure. Therefore, it is envisaged that a dose rate of 0.6 l/ha is appropriate for control of *Alternaria brassicae* at a low level of disease pressure while for increasing disease pressure, 0.7 l/ha may be more appropriate.

Considering all elements presented above, it is justified to claim the registration of 2 applications in spring of CA3301 at 0.6-0.7 l/ha to control *Alternaria brassicae* on oilseed rape in the North-Eastern EPPO zone.

Table 3.2-617: Summary table - Efficacy evaluation – Oilseed rape – ALTEBA – North-Eastern EPPO zone

Treatment name		CA 244 5	PRO SAR O 1	CAR AMB A 1	CAR AMB A 1	CA 330 1 0,6	CA 330 1 0,7	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,7 l/ha is >, = or < compared to
Rate	UNTREATED CHECK	0,7 L/ha	L/ha	L/ha	L/ha	L/ha	L/ha		
Rate unit		a				a	a		
Appl. Code		AB	AB	A	AB	AB	AB		
% Disease severity LEAF - 21 DA-B									
Number of values	1			1		1	1	UT C	CA3301 0,7 l/ha CA-RAMBA 1 l/ha (A)
Minimum value	14,73			0,68		0,83	0,38	UT C	CA3301 0,6 l/ha CA-RAMBA 1 l/ha (A)
Maximum value	14,73	-	-	0,68	-	0,83	0,38	1 >	0 >
Mean disease severity (%)	14,73			0,68		0,83	0,38	0 =	1 =
Abbott efficacy (%)	0,00%			95,38 %		94,37 %	97,42 %	0 <	0 <
% Disease severity LEAF - 36-50 DA-B									
Number of values	3					3	3	UT C	CA3301 0,7 l/ha
Minimum value	5,36					0,60	0,28	UT C	CA3301 0,6 l/ha
Maximum value	20,33	-	-	-	-	3,55	2,75	3 >	0 >
Mean disease severity (%)	11,08					1,75	1,16	0 =	3 =
Abbott efficacy (%)	0,00%					73,47 %	80,92 %	0 <	0 <
Number of values	2	2			2	2	2	CA 244 5 0,7 l/ha	CA-RAMBA (AB) 244 5 0,7 l/ha
Minimum value	5,36	0,35			0,33	0,60	0,28	CA 244 5 0,7 l/ha	CA-RAMBA (AB) 244 5 0,7 l/ha
Maximum value	7,55	3,46	-	-	3,04	3,55	2,75	0 >	0 >

Mean disease severity (%)	6,46	1,90			1,68	2,08	1,52	2 =	2 =	2 =	2 =
Abbott efficacy (%)	0,00%	65,4 1%			69,46 %	62,9 1%	72,4 9%	0 <	0 <	0 <	0 <
Number of values	1			1		1	1	CARAMBA (A)		CARAMBA (A)	
Minimum value	20,33			0,75		1,10	0,45	1,0 l/ha		1,0 l/ha	
Maximum value	20,33	-	-	0,75	-	1,10	0,45	0 >		0 >	
Mean disease severity (%)	20,33			0,75		1,10	0,45	1 =		1 =	
Abbott efficacy (%)	0,00%			96,31 %		94,5 9%	97,7 9%	0 <		0 <	
% Disease severity STEM - 48-54 DA-B											
Number of values	3	3				3	3	UT C	CA3301	UT C	CA3301
Minimum value	7,05	0,35				0,58	0,38		0,7 l/ha		0,6 l/ha
Maximum value	10,75	2,28	-	-	-	2,25	1,65	3 >	0 >	3 >	0 >
Mean disease severity (%)	8,80	1,45				1,57	1,17	0 =	3 =	0 =	3 =
Abbott efficacy (%)	0,00%	84,6 5%				82,6 8%	87,1 9%	0 <	0 <	0 <	0 <
Number of values	2	2	2			2	2	CA 244 5	CA- RAMBA (AB)	CA 244 5	CA- RAMBA (AB)
Minimum value	8,60	1,71	1,37			1,89	1,49	0,7 l/ha	1,0 l/ha	0,7 l/ha	1,0 l/ha
Maximum value	10,75	2,28	2,38	-	-	2,25	1,65	0 >	0 >	0 >	0 >
Mean disease severity (%)	9,68	2,00	1,87			2,07	1,57	3 =	1 =	3 =	1 =
Abbott efficacy (%)	0,00%	79,4 5%	79,79 %			78,1 3%	83,4 8%	0 <	0 <	0 <	0 <
Number of values	1	1			1	1	1	PROSARO		PROSARO	
Minimum value	7,05	0,35			0,23	0,58	0,38	1,0 l/ha		1,0 l/ha	
Maximum value	7,05	0,35	-	-	0,23	0,58	0,38	0 >		0 >	
Mean disease severity (%)	7,05	0,35			0,23	0,58	0,38	2 =		2 =	
Abbott efficacy (%)	0,00%	95,0 4%			96,74 %	91,7 7%	94,6 1%	0 <		0 <	

Treatment name	UNTREATED CHECK	CA 244 5	PROS ARO	CARA MBA	CARA MBA	CA3 301	CA3 301	No of trials where CA3301	No of trials where CA3301		
Rate		0,7	1	1	1	0,6	0,7	at 0,6 l/ha	at 0,7 l/ha		
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	L/ha	is >, = or <	is >, = or <		
Appl. Code		AB	AB	A	AB	AB	AB	compared to	compared to		
% Disease severity POD - 36-54 DA-B											
Number of values	3					3	3	UTC	CA3301	UTC	CA3301
Minimum value	5,20					0,80	0,30		0,7 l/ha		0,6 l/ha
Maximum value	21,25	-	-	-	-	2,06	1,53	3 >	0 >	3 >	0 >
Mean disease severity (%)	10,69					1,32	0,76	0 =	3 =	0 =	3 =

Abbott efficacy (%)	0,00%					80,3 3%	87,7 1%	0 <	0 <	0 <	0 <
Number of values	1	1			1	1	1	CA24 45	CA- RAMBA (AB)	CA24 45	CA- RAMBA (AB)
Minimum value	5,63	0,7 0			0,73	0,80	0,30	0,7 l/ha	1,0 l/ha	0,7 l/ha	1,0 l/ha
Maximum value	5,63	0,7 0	-	-	0,73	0,80	0,30	0 >	0 >	0 >	0 >
Mean disease severity (%)	5,63	0,7 0			0,73	0,80	0,30	1 =	1 =	1 =	1 =
Abbott efficacy (%)	0,00%	87, 57 %			87,03 %	85,7 9%	94,6 7%	0 <	0 <	0 <	0 <
Number of values	2			2		2	2	CARAMBA (A)		CARAMBA (A)	
Minimum value	5,20			0,85		1,10	0,45	1,0 l/ha		1,0 l/ha	
Maximum value	21,25	-	-	2,89	-	2,06	1,53	0 >		0 >	
Mean disease severity (%)	13,23			1,87		1,58	0,99	2 =		2 =	
Abbott efficacy (%)	0,00%			70,21 %		77,6 0%	84,2 3%	0 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Conclusion North-Eastern EPPO zone - Use of CA3301 at 2x 0.6-0.7 l/ha against ALTEBA

In the North-Eastern EPPO zone, 22 trials were available against *Alternaria brassicae* on oilseed rape. 9 trials out of 22 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to the reference products on disease severity (%). Among these 9 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis.

In order to cover the different agricultural spraying practices of oilseed rape in North-Eastern EPPO zone, 2 types of spraying programs have been tested: 2 applications in spring (dedicated to spring infections of foliar, stem and pods diseases on oilseed rape) or 1 application in autumn and 1 application in spring (dedicated to both autumn and spring infections of roots, foliar, stem and pods diseases on oilseed rape). In the first group of trials, CA3301 was applied twice in spring. The data recorded were available on leaves, on stems and on pods. On leaves, 2 different assessment timings were available whereas a single assessment timing was available for the other parts assessed (stems and pods). When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Alternaria brassicae*. On leaves, when applied at 0.6 l/ha, CA3301 showed 94.37% of efficacy to control the disease three weeks after the 2nd application and 73.47% before harvest. Moreover, at this dose rate CA3301 showed 82.68% of efficacy on stems and 80.33% on pods before harvest.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.7 l/ha to *Alternaria brassicae*. When applied at 0.7 l/ha, on leaves, CA3301 showed 97.42% of efficacy to control the disease three weeks after the 2nd application and 80.92% before harvest. Moreover, at this dose rate CA3301 showed 87.19% of efficacy on stems and 87.71% on pods before harvest.

In the second group of trials, CA3301 was applied once in autumn and once in spring. The data were available on pods at a single assessment timing. When evaluating the reduction of disease severity, the data demonstrated the fungicidal effect against *Alternaria brassicae*, provided after two applications of

CA3301 at 0.6 and 0.7 l/ha. When applied at 0.6 l/ha, CA3301 showed 74.02% of efficacy to control the disease on pods before harvest and 83.03% when applied at 0.7 l/ha.

In both cases, in overall the data demonstrate a medium to high efficacy on pods for the same assessment timings. This is particularly true for the 0.7 l/ha dose rate. In all trials, CA3301 at 0.6-0.7 l/ha gave equivalent disease control compared to the several authorised reference products. Moreover, in all assessments there were no significant differences in disease control between the rate of 0.6 l/ha or 0.7 l/ha of CA3301, although a clear numerical disease reduction was observed. Therefore, it is envisaged that in most instances 2 applications of CA3301 in spring or one in autumn and one in spring will provide an acceptable control of *Alternaria brassicae* whatever the timing of application.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.7 l/ha to control *Alternaria brassicae* on oilseed rape in the North-East ^{EPH} EPPO zone. Moreover, these 2 applications can be carried out in spring or first in autumn and then the 2nd in spring.

Use of CA3301 at 2x 0.6-0.7 l/ha against ALTEBA with one application in autumn and one application in spring - South-East ^{EPH} EPPO zone

In the South-East EPPO zone, 10 trials were available against *Alternaria brassicae* on oilseed rape. 8 trials out of 10 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to the reference products on disease severity (%). Among these 8 trials, CA3301 was applied once in autumn and once in spring in 2 trials, first at crop stage BBCH 16 and the 2nd application was at BBCH 65-67. The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.7 l/ha. The analysis was conducted on pods.

Summary results are presented in Table 3.2-618.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Alternaria brassicae*. When applied at 0.6 l/ha, CA3301 showed 78.62% of efficacy to control the disease on pods before harvest and 84.36% when applied at 0.7 l/ha.

In the South-East ^{EPH} zone EPPO zone, a limited dataset was available for assessment of control of *Alternaria brassicae* at this application timing. Nevertheless, applications of CA3301 at 0.6-0.7 l/ha demonstrated medium to high efficacy in conditions of high disease pressure. Indeed in both trials, 100% of the pods were infected with an average severity of 32.61%, inducing an harvest reduction. At 0.7 l/ha, CA3301 gave equivalent disease control compared to the authorised reference products and was comparable in 1 trial out of 2 to 0.6 l/ha. A larger dataset has been presented regarding to the case where CA3301 was applied twice in spring in the South-East ^{EPH} zone, which demonstrates that the efficacy of CA3301 at 0.6 l/ha was fairly comparable to that of the dose rate of 0.7 l/ha on leaves, on stems and on pods. This dataset can be supportive for the case where the first application of the product is in autumn. Therefore, it is proposed that the dose rate of 0.6 l/ha is used for instances of low disease pressure and an increased rate of 0.7 l/ha for high disease pressure.

Considering all elements presented above, it is justified to claim the registration of 2 applications, one in autumn and one in spring of CA3301 at 0.6-0.7 l/ha to control *Alternaria brassicae* on oilseed rape in the South-East ^{EPH} EPPO zone.

Table 3.2-618: Summary table - Efficacy evaluation – Oilseed rape – ALTEBA – South-East ^{EPH} EPPO zone

Treatment name	UNTREATED CHECK	CA244	TILMOR	CA33	CA33	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,7 l/ha is >, = or < compared to
Rate		5	240 EC	01	01		
Rate unit		0,7	1,2	0,6	0,7		
Appl. Code		L/ha	L/ha	L/ha	L/ha		
		AB	A	AB	AB		

% Disease severity POD - 37-54 DA-B									
Number of values	2		2	2	2	UTC	CA3301	UTC	CA3301
Minimum value	30,00		3,74	3,32	3,68		0,7 l/ha		0,6 l/ha
Maximum value	35,21	-	6,25	10,00	6,25	2 >	0 >	2 >	1 >
Mean disease severity (%)	32,61		5,00	6,66	4,97	0 =	1 =	0 =	1 =
Abbott efficacy (%)	0,00%		84,27%	78,62 %	84,36 %	0 <	1 <	0 <	0 <
Number of values	1	1	1	1	1	CA2 445	TILMOR 240 EC	CA24 45	TILMOR 240 EC
Minimum value	30,00	4,50	6,25	10,00	6,25	0,7 l/ha	1,2 l/ha	0,7 l/ha	1,2 l/ha
Maximum value	30,00	4,50	6,25	10,00	6,25	0 >	0 >	0 >	0 >
Mean disease severity (%)	30,00	4,50	6,25	10,00	6,25	0 =	1 =	1 =	2 =
Abbott efficacy (%)	0,00%	85,00 %	79,17%	66,67 %	79,17 %	1 <	1 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.7 l/ha against ALTEBA with 2 applications in spring – South-eastern East EPPO zone

In the South-Eastern EPPO zone, 10 trials were available against *Alternaria brassicae* on oilseed rape. 8 trials out of 10 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to the reference products on disease severity (%). Among these 8 trials, CA3301 was applied twice in spring in 6 trials, first at crop stages BBCH 35-55 and the 2nd application was at BBCH 65-67. The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.7 l/ha. The analysis was conducted on leaves, stems and pods. On leaves and stems, 2 different assessment timings were available whereas a single assessment timing was available on pods.

Summary results are presented in Table 3.2-619.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Alternaria brassicae*.

On leaves, when applied at 0.6 l/ha, CA3301 showed 85.86% of efficacy to control the disease 2-4 weeks after the 2nd application and 83.78% before harvest. On stems, CA3301 showed 94.41% of efficacy to control the disease at three weeks after the 2nd application and 80.48% before harvest. On pods, CA3301 showed 86.20% of efficacy before harvest.

On leaves, CA3301 at 0.7 l/ha showed 90.47% of efficacy to control the disease 2-4 weeks after the 2nd application and 91.83% before harvest. On stems, the tested product showed 98.88% of efficacy to control the disease at three weeks after the 2nd application and 89.13% before harvest. On pods, CA3301 showed 87.19% of efficacy before harvest.

In overall in the South-Eastern EPPO zone, disease pressure was low but reached to the pods. Indeed in some trials, disease severity appeared from low to medium level, but the infection reached 100% of the plants organs, which reveal a strong and durable infection. In these conditions, in overall CA3301 at 0.6-0.7 l/ha provided high efficacy in reducing the severity of *Alternaria brassicae* on oilseed rape with a consistent performance until the harvest timing. CA3301 at 0.7 l/ha gave equivalent disease control compared to the several authorised reference products. Moreover, in the majority of assessments, there were no significant differences in disease control between the rate of 0.6 l/ha or 0.7 l/ha. Therefore, it is

Considering all elements presented above, it is justified to claim the registration of 2 applications in spring of CA3301 at 0.6-0.7 l/ha to control *Alternaria brassicae* on oilseed rape in the South-Eastern EPPO zone.

Treatment name	UNTREATED CHECK	CA2445 L/ha AB	PROSAR O 0,75 L/ha AB	PROULSE 1 L/ha AB	ORIOUS 1 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,7 L/ha AB	No of trials where CA3301			No of trials where CA3301		
Rate								at 0,6 l/ha is >, = or <			at 0,7 l/ha is >, = or <		
Rate unit								compared to			compared to		
Appl. Code													
% Disease severity LEAF - 14-28 DA-B													
Number of values	4					4	4	UTC	CA3301		UTC	CA3301	
Minimum value	6,03					0,63	0,36		0,7 l/ha			0,6 l/ha	
Maximum value	14,81	-	-	-	-	1,95	1,18	4 >	0 <		4 >	1 >	
Mean disease severity (%)	9,83					1,26	0,75	0 =	3 =		0 =	3 =	
Abbott efficacy (%)	0,00%					85,86%	90,47%	0 <	1 <		0 <	0 <	
Number of values	3	3				3	3	CA2445			CA2445		
Minimum value	6,03	0,41				0,63	0,36	0,7 l/ha			0,7 l/ha		
Maximum value	14,81	0,82	-	-	-	1,30	1,18	0 >			0 >		
Mean disease severity (%)	9,98	0,61				1,03	0,64	2 =			3 =		
Abbott efficacy (%)	0,00%	92,68%				89,11%	91,39%	1 <			0 <		
Number of values	1				1	1	1	ORIOUS			ORIOUS		
Minimum value	8,95				2,85	1,95	1,10	1,0 l/ha			1,0 l/ha		
Maximum value	8,95	-	-	-	2,85	1,95	1,10	0 >			0 >		
Mean disease severity (%)	8,95				2,85	1,95	1,10	1 =			1 =		
Abbott efficacy (%)	0,00%				68,16%	78,21%	87,71%	0 <			0 <		
% Disease severity STEM - 21 DA-B													
Number of values	1	1				1	1	UTC	CA2445	CA3301	UTC	CA2445	CA3301

Treatment name	UNTREATED CHECK	CA2445 0,7 L/ha AB	PROSARO 0,75 L/ha AB	PROULSE 1 L/ha AB	ORIOUS 1 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to		
Rate													
Rate unit													
Appl. Code													
Minimum value	7,15	0,24				0,40	0,08		0,7 l/ha	0,7 l/ha		0,7 l/ha	0,6 l/ha
Maximum value	7,15	0,24	-	-	-	0,40	0,08	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	7,15	0,24				0,40	0,08	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	96,64 %				94,41 %	98,88 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity LEAF - 31-56 DA-B													
Number of values	5					5	5	UTC	CA3301 0,7 l/ha		UTC	CA3301 0,6 l/ha	
Minimum value	6,15					0,65	0,28						
Maximum value	21,90	-	-	-	-	4,25	2,59	5 >	0 >		5 >	2 >	
Mean disease severity (%)	13,15					2,30	1,21	0 =		3 =	0 =		3 =
Abbott efficacy (%)	0,00%					83,78 %	91,83 %	0 <		2 <	0 <		0 <
Number of values	4	4				4	4	CA2445			CA2445		
Minimum value	6,15	0,39				0,65	0,28	0,7 l/ha			0,7 l/ha		
Maximum value	21,90	2,66	-	-	-	3,75	2,59	0 >			0 >		
Mean disease severity (%)	12,57	1,09				1,82	0,97	2 =			4 =		
Abbott efficacy (%)	0,00%	92,39 %				86,58 %	93,34 %	2 <			0 <		
Number of values	1	1	1			1	1	PROSARO			PROSARO		
Minimum value	11,85	0,65	0,47			1,42	0,53	0,75 l/ha			0,75 l/ha		
Maximum value	11,85	0,65	0,47	-	-	1,42	0,53	0 >			0 >		
Mean disease severity (%)	11,85	0,65	0,47			1,42	0,53	0 =			1 =		
Abbott efficacy (%)	0,00%	94,51 %	96,03 %			88,02 %	95,53 %	1 <			0 <		
Number of values	1				1	1	1	ORIOUS			ORIOUS		
Minimum value	15,50				6,10	4,25	2,20	1,0 l/ha			1,0 l/ha		

Treatment name	UNTREATED CHECK	CA2445	PROSARO	PROULSE	ORION	CA3301	CA3301	No of trials where CA3301		No of trials where CA3301	
Rate		0,7	0,75	1	1	0,6	0,7	at 0,6 l/ha is >, = or <		at 0,7 l/ha is >, = or <	
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	L/ha				
Appl. Code		A	AB	AB	AB	AB	AB	compared to		compared to	
B											
Maximum value	15,50	-	-	-	6,10	4,25	2,20	0 >		1 >	
Mean disease severity (%)	15,50				6,10	4,25	2,20	1 =		0 =	
Abbott efficacy (%)	0,00%				60,65%	72,58%	85,81%	0 <		0 <	
% Disease severity STEM - 31-56 DA-B											
Number of values	3	3				3	3	UTC	CA3301	UTC	CA3301
Minimum value	5,74	0,28				0,63	0,48		0,7 l/ha		0,7 l/ha
Maximum value	10,73	1,43	-	-	-	2,00	0,98	3 >	0 >	3 >	1 >
Mean disease severity (%)	7,64	0,91				1,47	0,81	0 =	2 =	0 =	2 =
Abbott efficacy (%)	0,00%	87,75%				80,48%	89,13%	0 <	1 <	0 <	0 <
Number of values	1	1	1			1	1	CA2445	PRO-SARO	CA2445	PRO-SARO
Minimum value	6,45	1,43	0,20			2,00	0,98	0,7 l/ha	0,75 l/ha	0,7 l/ha	0,75 l/ha
Maximum value	6,45	1,43	0,20	-	-	2,00	0,98	0 >	0 >	0 >	0 >
Mean disease severity (%)	6,45	1,43	0,20			2,00	0,98	3 =	0 =	3 =	0 =
Abbott efficacy (%)	0,00%	77,83%	96,90%			68,99%	84,81%	0 <	1 <	0 <	1 <
% Disease severity POD - 37-56 DA-B											
Number of values	5					5	5	UTC	CA3301	UTC	CA3301
Minimum value	5,84					0,00	0,00		0,7 l/ha		0,6 l/ha
Maximum value	32,00	-	-	-	-	6,26	12,79	5 >	0 >	5 >	1 >
Mean disease severity (%)	13,02					2,33	3,05	0 =	4 =	0 =	4 =
Abbott efficacy (%)	0,00%					86,20%	87,19%	0 <	1 <	0 <	0 <
Number of values	3	3				3	3	CA2445		CA2445	
Minimum value	5,84	0,00				0,00	0,00	0,7 l/ha		0,7 l/ha	
Maximum value	14,70	2,63	-	-	-	4,00	1,65	0 >		0 >	

Treatment name	UNTREATED CHECK	CA3301 0,7 L/ha AB	PROSARO 0,75 L/ha AB	PROPULSE 1 L/ha AB	ORIOUS 1 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,7 l/ha is >, = or < compared to
Rate	8,94	0,88				1,35	0,55		
Rate unit									
Appl. Code									
Mean disease severity (%)									
Abbott efficacy (%)	0,00%	93,98%				90,72%	96,21%		
Number of values	1	1	1			1	1		
Minimum value	14,70	2,63	1,16			4,00	1,65	PROSARO 0,75 l/ha	PROSARO 0,75 l/ha
Maximum value	14,70	2,63	1,16	-	-	4,00	1,65	0 >	0 >
Mean disease severity (%)	14,70	2,63	1,16			4,00	1,65	0 =	1 =
Abbott efficacy (%)	0,00%	82,11%	92,11%			72,79%	88,78%	1 <	0 <
Number of values	1			1		1	1		
Minimum value	32,00			0,62		6,26	12,79	PROPULSE 1,0 l/ha	PROPULSE 1,0 l/ha
Maximum value	32,00	-	-	0,62	-	6,26	12,79	0 >	0 >
Mean disease severity (%)	32,00			0,62		6,26	12,79	1 =	0 =
Abbott efficacy (%)	0,00%			98,06%		80,44%	60,03%	0 <	1 <
Number of values	1				1	1	1		
Minimum value	6,30				1,96	1,36	0,80	ORIOUS 1,0 l/ha	ORIOUS 1,0 l/ha
Maximum value	6,30	-	-	-	1,96	1,36	0,80	0 >	0 >
Mean disease severity (%)	6,30				1,96	1,36	0,80	1 =	1 =
Abbott efficacy (%)	0,00%				68,89%	78,41%	87,30%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Conclusion South-Eastern EPPO zone - Use of CA3301 at 2x 0.6-0.7 l/ha against ALTEBA

In the South-Eastern EPPO zone, 10 trials were available against *Alternaria brassicae* on oilseed rape. 8 trials out of 10 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to several authorised reference products on disease severity (%). Among these 8 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis.

In order to cover the different agricultural spraying practices of oilseed rape in South-Eastern EPPO zone, 2 types of spraying programs have been tested: 2 applications in spring (dedicated to spring infections of foliar, stem and pods diseases on oilseed rape) or 1 application in autumn and 1 application in spring (dedicated to both autumn and spring infections of roots, foliar, stem and pods diseases on oilseed rape).

In the first group of trials, CA3301 was applied twice in spring. Data were available on leaves, stems and pods. On leaves and stems, 2 different assessment timings were available whereas a single assessment timing was available on pods. When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Alternaria brassicae*. On leaves, when applied at 0.6 l/ha, CA3301 showed 85.86% of efficacy to control the disease 2-4 weeks after the 2nd application and 83.78% before harvest. On stems, CA3301 showed 94.41% of efficacy to control the disease at three weeks after the 2nd application and 80.48% before harvest. On pods, CA3301 showed 86.20% of efficacy on pods before harvest.

On leaves, CA3301 at 0.7 l/ha showed 90.47% of efficacy to control the disease 2-4 weeks after the 2nd application and 91.83% before harvest. On stems, the tested product showed 98.88% of efficacy to control the disease at three weeks after the 2nd application and 89.13% before harvest. On pods, CA3301 showed 87.19% of efficacy on pods before harvest.

In the second group of trials, CA3301 was applied once in autumn and once in spring. The data were available on pods at a single assessment before harvest. When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Alternaria brassicae* under challenging disease pressure conditions. When applied at 0.6 l/ha, CA3301 showed 78.62% of efficacy to control the disease on pods before harvest and 84.36% when applied at 0.7 l/ha.

In both cases, in overall the data demonstrated a medium to high efficacy of CA3301 applied at 0.6-0.7 l/ha to reduce the disease pressure. In these datasets, CA3301 at 0.6-0.7 l/ha gave equivalent disease control compared to the several authorised reference products. Therefore, it is envisaged that in most instances 2 applications of CA3301 in spring or one in autumn and one in spring will provide an acceptable control of *Alternaria brassicae* whatever the timing of application.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.7 l/ha to control *Alternaria brassicae* on oilseed rape in the South-Eastern EPPO zone. Moreover, these 2 applications can be carried out in spring or first in autumn and then the 2nd in spring.

Use of CA3301 at 2x 0.6-0.7 l/ha against ALTEBA with one application in autumn and one application in spring - Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, a total of 3 valid trials evaluated the efficacy of CA3301 on oilseed rape against *Alternaria brassicae*. These 3 trials enabled to determine the efficacy of CA3301 at 0.6-0.7 l/ha applied once in spring and once in autumn, and to compare it to the reference products on disease severity (%). CA3301 was first applied at crop stages BBCH 15-19 and the 2nd application was at BBCH 67-69. Two assessment timings were available and the analysis was conducted on leaves and on pods.

Summary results are presented in Table 3.2-620.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Alternaria brassicae*. When applied at 0.6 l/ha, CA3301 showed 64.99% of efficacy to control the disease on leaves four weeks after the 2nd application and 70.36% on pods before harvest. CA3301 at 0.7 l/ha showed 79.48% of efficacy to control the disease on leaves four weeks after the 2nd application and 81.51% on pods before harvest.

In Poland and neighbouring countries, a limited dataset was available for assessment of control of *Alternaria brassicae* at this application timing. Nevertheless, applications of CA3301 at 0.6-0.7 l/ha demonstrated a medium to high efficacy in conditions of low disease pressure on leaves and on pods. At this range of dosage, CA3301 was always comparable to the several authorised reference products. A larger dataset has been presented regarding to the case where CA3301 was applied twice in spring in the same countries, which demonstrates that the efficacy of CA3301 at 0.6 l/ha was fairly comparable to that of the dose rate of 0.7 l/ha. However in some assessments and in challenging disease pressure conditions, a statistical benefit was derived from increasing the dose rate to 0.7 l/ha for disease control. This dataset can be supportive for the case where the first application of the product is in autumn. Therefore, it is envisaged that a dose rate of 0.6 l/ha is appropriate for control of *Alternaria brassicae* at a low level of disease pressure while for increasing disease pressure, 0,7 l/ha may be more appropriate.

Considering all elements presented above, it is justified to claim the registration of 2 applications, one in autumn and one in spring of CA3301 at 0.6-0.7 l/ha to control *Alternaria brassicae* on oilseed rape in Poland.

Table 3.2-620: Summary table - Efficacy evaluation – Oilseed rape – ALTEBA – Data relevant for Poland

Treatment name	UNTREATED CHECK	CA24 45 0,7 L/ha AB	ORIOUS EXTRA 1 L/ha AB	TILMOR 240 EC 0,75-1 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,7 l/ha is >, = or < compared to
Rate								
Rate unit								
Appl. Code								
% Disease severity LEAF - 28 DA-B								
Number of values	1	1			1	1	UT CA24 45 0,7 l/ha	UT CA24 45 0,7 l/ha
Minimum value	8,77	1,72			3,07	1,80	C 0,7 l/ha	C 0,7 l/ha
Maximum value	8,77	1,72	-	-	3,07	1,80	1 > 0 >	1 > 0 >
Mean disease severity (%)	8,77	1,72			3,07	1,80	0 = 1 =	0 = 1 =
Abbott efficacy (%)	0,00%	80,39 %			64,99 %	79,48 %	0 < 0 <	0 < 0 <
% Disease severity POD - 38-56 DA-B								
Number of values	3				3	3	UTC CA3301 0,7 l/ha	UTC CA3301 0,6 l/ha
Minimum value	5,60				0,35	0,70	0,7 l/ha	0,6 l/ha
Maximum value	8,17	-	-	-	3,02	1,76	3 > 0 >	3 > 0 >
Mean disease severity (%)	6,84				2,05	1,26	0 = 3 =	0 = 3 =
Abbott efficacy (%)	0,00%				70,36 %	81,51 %	0 < 0 <	0 < 0 <
Number of values	2	2			2	2	CA2445 0,7 l/ha	CA2445 0,7 l/ha
Minimum value	6,75	0,65			1,35	0,70	0,7 l/ha	0,7 l/ha
Maximum value	8,17	1,46	-	-	3,02	1,76	0 >	0 >
Mean disease severity (%)	7,46	1,05			2,19	1,23	2 =	2 =
Abbott efficacy (%)	0,00%	86,25 %			71,52 %	84,04 %	0 <	0 <
Number of values	1	1	1		1	1	ORIOUS EXTRA 1,0 l/ha	ORIOUS EXTRA 1,0 l/ha
Minimum value	6,75	0,65	0,30		1,35	0,70	1,0 l/ha	1,0 l/ha

Maximum value	6,75	0,65	0,30	-	1,35	0,70	0 >	0 >
Mean disease severity (%)	6,75	0,65	0,30		1,35	0,70	1 =	1 =
Abbott efficacy (%)	0,00%	90,37 %	95,56%		80,00 %	89,63 %	0 <	0 <
Number of values	1			1	1	1	TILMOR 240 EC	TILMOR 240 EC
Minimum value	5,60			1,01	1,79	0,32	0,75-1,0 l/ha	0,75-1,0 l/ha
Maximum value	5,60	-	-	1,01	1,79	1,32	0 >	0 >
Mean disease severity (%)	5,60			1,01	1,79	1,32	1 =	1 =
Abbott efficacy (%)	0,00%			81,96%	68,04 %	76,43 %	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)	
>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.7 l/ha against ALTEBA with 2 applications in spring – Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, a total of 14 valid trials evaluated the efficacy of CA3301 on oilseed rape against *Alternaria brassicae*. These trials enabled to determine the efficacy of CA3301 at 0.6-0.7 l/ha applied twice in spring on disease severity (%). CA3301 was first applied at crop stages BBCH 33-55 and the 2nd application was at BBCH 65-67. Two assessment timings were available and the analysis was conducted on leaves, on stems and on pods.

Summary results are presented in Table 3.2-621.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Alternaria brassicae*. On leaves, when applied at 0.6 l/ha, CA3301 showed 86.29% of efficacy to control the disease 3-4 weeks after the 2nd application and 83.00% before harvest. Moreover, at this dose rate CA3301 showed 77.69% of efficacy on stems and 81.60% on pods before harvest. When applied at 0.7 l/ha, on leaves, CA3301 showed 92.56% of efficacy to control the disease 3-4 weeks after the 2nd application and 89.16% before harvest. Moreover, at this dose rate CA3301 showed 83.21% of efficacy on stems and 89.34% on pods before harvest.

In Poland and neighbouring countries, a representative dataset was available for assessment of *Alternaria brassicae*, with disease pressure ranging from relatively low to medium, from leaves to pods. In overall CA3301 at 0.6-0.7 l/ha showed high efficacy in reducing the severity of *Alternaria brassicae* on oilseed rape, whatever the plant part rated. CA3301 gave equivalent disease control compared to the several authorised reference products and averaged across the dataset the efficacy of CA3301 at 0.6 l/ha was comparable to that of the dose rate of 0.7 l/ha, in these conditions of disease pressure. Therefore, it is envisaged that a dose rate of 0.6 l/ha is appropriate for control of *Alternaria brassicae* at a low level of disease pressure while for increasing disease pressure, 0,7 l/ha may be more appropriate.

Considering all elements presented above, it is justified to claim the registration of 2 applications in spring of CA3301 at 0.6-0.7 l/ha to control *Alternaria brassicae* on oilseed rape in Poland.

Table 3.2-621: Summary table - Efficacy evaluation – Oilseed rape – ALTEBA – Data relevant for Poland

Treatment name	UNTREATED CHECK	CA2445	PROSARO	PROSARO	ORIOUS	CARAMBA	CARAMBA	CA3301	CA3301	No of trials where CA3301	No of trials where CA3301
Rate		0,7	0,75	1	1	1	1	0,6	0,7	at 0,6 l/ha is	at 0,7 l/ha is
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	L/ha	L/ha	L/ha	>, = or <	>, = or <
Appl. Code		AB	AB	AB	AB	A	AB	AB	AB	compared to	compared to
% Disease severity LEAF - 21-28 DA-B											
Number of values	2							2	2	UTC	CA3301
Minimum value	8,95							0,83	0,38		0,7 l/ha
Maximum value	14,73	-	-	-	-	-	-	1,95	1,10	2 >	2 >
Mean disease severity (%)	11,84							1,39	0,74	0 =	2 =
Abbott efficacy (%)	0,00%							86,29%	92,56%	0 <	0 <
Number of values	1				1			1	1	ORIOUS	ORIOUS
Minimum value	8,95				2,85			1,95	1,10	1, 0 l/ha	1, 0 l/ha
Maximum value	8,95	-	-	-	2,85	-	-	1,95	1,10	0 >	0 >
Mean disease severity (%)	8,95				2,85			1,95	1,10	1 =	1 =
Abbott efficacy (%)	0,00%				68,16%			78,21%	87,71%	0 <	0 <
Number of values	1						1	1	1	CARAMBA	CARAMBA
Minimum value	14,73						0,68	0,83	0,38	1, 0 l/ha (AB)	1, 0 l/ha (AB)
Maximum value	14,73	-	-	-	-	-	0,68	0,83	0,38	0 >	0 >
Mean disease severity (%)	14,73						0,68	0,83	0,38	1 =	1 =
Abbott efficacy (%)	0,00%						95,38%	94,37%	97,42%	0 <	0 <
% Disease severity LEAF - 36-76 DA-B											
Number of values	7							7	7	UTC	CA3301
Minimum value	5,36							0,00	0,00		0,7 l/ha
Maximum value	20,33	-	-	-	-	-	-	4,25	2,75	7 >	7 >
Mean disease severity (%)	11,03							1,56	0,89	0 =	6 =
Abbott efficacy (%)	0,00%							83,00%	89,16%	0 <	1 <
Number of values	5	5						5	5	CA2445	CA2445
Minimum value	5,36	0,00						0,00	0,00	0,7 l/ha	0,7 l/ha
Maximum value	11,85	3,46	-	-	-	-	-	3,55	2,75	0 >	0 >
Mean disease severity (%)	8,28	0,89						1,11	0,71	4 =	5 =
Abbott efficacy (%)	0,00%	85,07%						82,77%	88,10%	1 <	0 <
Number of values	1	1	1					1	1	PROSARO	PROSARO
Minimum value	11,85	0,65	0,47					1,42	0,53	0,75 l/ha	0,75 l/ha
Maximum value	11,85	0,65	0,47	-	-	-	-	1,42	0,53	0 >	0 >
Mean disease severity (%)	11,85	0,65	0,47					1,42	0,53	0 =	1 =
Abbott efficacy (%)	0,00%	94,51%	96,03%					88,02%	95,53%	1 <	0 <
Number of values	1				1			1	1	ORIOUS	ORIOUS
Minimum value	15,50				6,10			4,25	2,20	1, 0 l/ha	1, 0 l/ha

Treatment name	UNTREATED CHECK	CA2445	PROSARO	PROSARO	ORION	CARAMBA	CARAMBA	CA3301	CA3301	No of trials where CA3301	No of trials where CA3301
Rate		0,7	0,75	1	1	1	1	0,6	0,7	at 0,6 l/ha is	at 0,7 l/ha is
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	L/ha	L/ha	L/ha	>, = or <	>, = or <
Appl. Code		AB	AB	AB	AB	A	AB	AB	AB	compared to	compared to
Maximum value	15,50	-	-	-	6,10	-	-	4,25	2,20	0 >	1 >
Mean disease severity (%)	15,50				6,10			4,25	2,20	1 =	0 =
Abbott efficacy (%)	0,00%				60,65%			72,58%	85,81%	0 <	0 <
Number of values	2	2				2		2	2	CARAMBA	CARAMBA
Minimum value	5,36	0,35				0,33		0,60	0,28	1, 0 l/ha (A)	1, 0 l/ha (A)
Maximum value	7,55	3,46	-	-	-	3,04	-	3,55	2,75	0 >	0 >
Mean disease severity (%)	6,46	1,91				1,68		2,08	1,52	2 =	2 =
Abbott efficacy (%)	0,00%	65,41%				69,46%		62,91%	72,49%	0 <	0 <
Number of values	1						1	1	1	CARAMBA	CARAMBA
Minimum value	20,33						0,75	1,10	0,45	1, 0 l/ha (AB)	1, 0 l/ha (AB)
Maximum value	20,33	-	-	-	-	-	0,75	1,10	0,45	0 >	0 >
Mean disease severity (%)	20,33						0,75	1,10	0,45	1 =	1 =
Abbott efficacy (%)	0,00%						96,31%	94,59%	97,79%	0 <	0 <
% Disease severity STEM - 48-73 DA-B											
Number of values	6	6						6	6	UTC	CA3301
Minimum value	6,45	0,35						0,58	0,38	UTC	0,7 l/ha
Maximum value	18,76	4,00	-	-	-	-	-	4,91	4,69	6 >	0 >
Mean disease severity (%)	11,51	2,21						2,66	2,16	0 =	5 =
Abbott efficacy (%)	0,00%	81,68%						77,69%	83,21%	0 <	1 <
Number of values	1	1	1					1	1	CA2445	PROSARO
Minimum value	6,45	1,43	0,20					2,00	0,98	0,7 l/ha	0,75 l/ha
Maximum value	6,45	1,43	0,20	-	-	-	-	2,00	0,98	0 >	0 >
Mean disease severity (%)	6,45	1,43	0,20					2,00	0,98	6 =	0 =
Abbott efficacy (%)	0,00%	77,83%	96,90%					68,99%	84,81%	0 <	1 <
Number of values	2	2		2				2	2	PROSARO	PROSARO
Minimum value	8,60	1,71		1,37				1,89	1,49	1,0 l/ha	1,0 l/ha
Maximum value	10,75	2,28	-	2,38	-	-	-	2,25	1,65	0 >	0 >
Mean disease severity (%)	9,68	2,00		1,87				2,07	1,57	2 =	2 =
Abbott efficacy (%)	0,00%	79,45		79,79%				78,13%	83,48%	0 <	0 <
Number of values	1	1				1		1	1	CARAMBA	CARAMBA
Minimum value	7,05	0,35				0,23		0,58	0,38	1, 0 l/ha (A)	1, 0 l/ha (A)
Maximum value	7,05	0,35	-	-	-	0,23	-	0,58	0,38	0 >	0 >
Mean disease severity (%)	7,05	0,35				0,23		0,58	0,38	1 =	1 =
Abbott efficacy (%)	0,00%	95,04%				96,74%		91,77%	94,61%	0 <	0 <

Treatment name	UNTREATE D CHECK	CA2 445	PROS ARO	PROSA RO	OR IUS	CARA MBA	CARA MBA	CA330 1	CA3 301	No of trials where CA3301	No of trials where CA3301
Rate		0,7	0,75	1	1	1	1	0,6	0,7	at 0,6 l/ha is	at 0,7 l/ha is
Rate unit		L/ha	L/ha	L/ha	L/h a	L/ha	L/ha	L/ha	L/h a	>, = or <	>, = or <
Appl. Code		AB	AB	AB	AB	A	AB	AB	AB	compared to	compared to
% Disease severity POD - 36-76 DA-B											
Number of values	8							8	8	UTC	CA3301 0,7 l/ha
Minimum value	5,20							0,00	0,00		UTC
Maximum value	39,78	-	-	-	-	-	-	15,43	9,65	8 >	0 >
Mean disease severity (%)	16,39							3,11	1,80	0 =	7 =
Abbott efficacy (%)	0,00%							81,60%	89,34%	0 <	1 <
Number of values	5	5						5	5	CA2445	CA2445
Minimum value	5,63	0,00						0,00	0,00	0,7 l/ha	0,7 l/ha
Maximum value	39,78	9,88	-	-	-	-	-	15,43	9,65	0 >	0 >
Mean disease severity (%)	19,69	2,65						4,07	2,33	4 =	5 =
Abbott efficacy (%)	0,00%	88,89%						86,42%	91,79%	1 <	0 <
Number of values	1	1	1					1	1	PROSARO	PROSARO
Minimum value	14,70	2,63	1,16					4,00	1,65	0,75 l/ha	0,75 l/ha
Maximum value	14,70	2,63	1,16	-	-	-	-	4,00	1,65	0 >	0 >
Mean disease severity (%)	14,70	2,63	1,16					4,00	1,65	0 =	1 =
Abbott efficacy (%)	0,00%	82,11%	92,11%					72,79%	88,78%	1 <	0 <
Number of values	1				1			1	1	ORIUS	ORIUS
Minimum value	6,30				1,96			1,36	0,80	1, 0 l/ha	1, 0 l/ha
Maximum value	6,30	-	-	-	1,96	-	-	1,36	0,80	0 >	0 >
Mean disease severity (%)	6,30				1,96			1,36	0,80	1 =	1 =
Abbott efficacy (%)	0,00%				68,89%			78,41%	87,30%	0 <	0 <
Number of values	1	1				1		1	1	CARAMBA	CARAMBA
Minimum value	5,63	0,70				0,73		0,80	0,30	1, 0 l/ha (A)	1, 0 l/ha (A)
Maximum value	5,63	0,70	-	-	-	0,73	-	0,80	0,30	0 >	0 >
Mean disease severity (%)	5,63	0,70				0,73		0,80	0,30	1 =	1 =
Abbott efficacy (%)	0,00%	87,57%				87,03%		85,79%	94,67%	0 <	0 <
Number of values	2						2	2	2	CARAMBA	CARAMBA
Minimum value	5,20						0,85	1,10	0,45	1, 0 l/ha (AB)	1, 0 l/ha (AB)
Maximum value	21,25	-	-	-	-	-	2,89	2,06	1,53	0 >	0 >
Mean disease severity (%)	13,23						1,87	1,58	0,99	2 =	2 =
Abbott efficacy (%)	0,00%						70,21%	77,60%	84,23%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)	
>80%	High efficacy
60-80%	Medium efficacy

Treatment name	UNTREATE D CHECK	CA2 445	PROS ARO	PROSA RO	OR IUS	CARA MBA	CARA MBA	CA330 1	CA3 301	No of trials where CA3301	No of trials where CA3301
Rate		0,7	0,75	1	1	1	1	0,6	0,7	at 0,6 l/ha	at 0,7 l/ha
Rate unit		L/ha	L/ha	L/ha	L/h a	L/ha	L/ha	L/ha	L/h a	>, = or <	>, = or <
Appl. Code		AB	AB	AB	AB	A	AB	AB	AB	compared to	compared to
<60%		Low efficacy									

Conclusion – Data relevant for Poland – Use of CA3301 at 2x 0.6-0.7 l/ha against ALTEBA

According to guidance provided by the Polish National authority, where data from the North-East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, a total of 17 valid trials were available on oilseed rape against *Alternaria brassicae* and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to the reference products on disease severity (%). Among these 17 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis.

In order to cover the different agricultural spraying practices of oilseed rape in Poland, 2 types of spraying programs have been tested: 2 applications in spring (dedicated to spring infections of foliar, stem and pods diseases on oilseed rape) or 1 application in autumn and 1 application in spring (dedicated to both autumn and spring infections of roots, foliar, stem and pods diseases on oilseed rape).

In the first group of trials, CA3301 was applied twice in spring. The data recorded were available on leaves, on stem and on pods. On leaves, 2 different assessment timings were available whereas a single assessment timing was available for the other parts assessed (stems and pods). When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Alternaria brassicae*. On leaves, when applied at 0.6 l/ha, CA3301 showed 86.29% of efficacy to control the disease 3-4 weeks after the 2nd application and 83.00% before harvest. Moreover, at this dose rate CA3301 showed 77.69% of efficacy on stems and 81.60% on pods before harvest.

When applied at 0.7 l/ha, on leaves, CA3301 showed 92.56% of efficacy to control the disease 3-4 weeks after the 2nd application and 89.16% before harvest. Moreover, at this dose rate CA3301 showed 83.21% of efficacy on stems and 89.34% on pods before harvest.

In the second group of trials, CA3301 was applied once in autumn and once in spring. The data were available on leaves and on pods at two assessment timings. When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Alternaria brassicae*. When applied at 0.6 l/ha, CA3301 showed 64.99% of efficacy to control the disease on leaves four weeks after the 2nd application and 70.36% on pods before harvest.

CA3301 showed 79.48% of efficacy to control the disease on leaves four weeks after the 2nd application and 81.51% on pods before harvest.

In both cases, in overall the data demonstrate a medium to high efficacy for the same assessment timings. This is particularly true for the 0.7 l/ha dose rate. In all trials, CA3301 at 0.6-0.7 l/ha gave equivalent disease control compared to the several authorised reference products. Moreover, in most instances there were no significant differences in disease control between the rate of 0.6 l/ha or 0.7 l/ha of CA3301, although a clear numerical disease reduction was observed. Therefore, it is envisaged that in most instances 2 applications of CA3301 in spring or one in autumn and one in spring will provide an acceptable control of *Alternaria brassicae* whatever the timing of application.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.7 l/ha to control *Alternaria brassicae* on oilseed rape in Poland. Moreover, these 2 applications can be carried out in spring or first in autumn and then the 2nd in spring.

Comments of zRMS:

7 valid field trials were carried out in **the Maritime EPPO climatic zone**. 2 applications in autumn and spring were used in 1 out of 7 trials. CA3301 applied at dose rate of 0,6-0,7 l/ha achieved medium efficacy after 28-56 DA-B. 2 applications in spring were used in 6 out of 7 trials. The test product at 0,6-0,7 l/ha achieved medium to high level of control, based on the results noted on total leaves, stem and pods.

9 valid trials were available in **the North-East EPPO zone**. 2 applications in autumn and spring were used in only 2 out of 9 trials. CA3301 applied at dose rate of 0,6 l/ha achieved medium efficacy. The higher dose rate of 0,8 l/ha caused increase of effectiveness to high level (83,03%). 2 applications in spring were used in 7 out of 9 trials. The test product at 0,6 l/ha showed medium to high level of control. The dose rate of 0,8 l/ha achieved high efficacy after 21-54 days after second applications.

8 valid trials were conducted in **the South-East EPPO zone**. 2 applications in autumn and spring were used in 2 out of 8 trials. CA3301 applied at dose rate of 0,6 l/ha achieved medium efficacy. The higher dose caused increase of effectiveness to high level (84,36%). 2 applications in spring were used in 6 out of 8 trials. The test product at 0,6-0,7 l/ha showed high efficacy after 14-56 days after second applications. 5 additional trials (with spring applications) from the Mediterranean zone have been submitted to support of product registration in other zones. CA3301 applied at dose rate of 0,6-0,7 l/ha achieved medium to high level of control.

Taking into account all trial results, it can be concluded that CA3301 in 2 applications is effective to control of *Alternaria brassicae* in winter oilseed rape. The dose rate of 0,7 l/ha can be recommended in case of high disease pressure.

3.2.3.11 Oilseed rape (BRSNW) / *Plenodomus lingam* (LEPTMA)

Materials and Methods – Oilseed rape – LEPTMA

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2018 and 2020, a total of 64 trials were conducted in several countries of the Maritime, Mediterranean, North-East~~ern~~ and South-East~~ern~~ EPPO zones to evaluate the efficacy of CA3301 against *Plenodomus lingam* on oilseed rape (see Table 3.2-622). The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, 19 trials were performed in Czech Republic (8), Germany (5), France (3), Denmark (1) and United Kingdom (2).

In the Mediterranean EPPO zone, 4 trials were performed in France (4).

In the North-East~~ern~~ EPPO zone, 27 trials were performed in Poland (22), Lithuania (3) and Latvia (2).

In the South-East~~ern~~ EPPO zone, a total of 14 trials were performed in Hungary (10) and Romania (4).

Data groupings were also made specifically for Poland evaluation and trials involved (40) were performed Poland (22), Lithuania (3), Latvia (2), Czech Republic (8) and Germany (5).

Table 3.2-622: Presentation of trials – Oilseed rape (BRSNW)

Crop(s) *	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, offi- cial***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
BRSN W	LEPTMA	Czech Republic	2018- 2020	MED + E	8 (6)	-	-	-	GEP	
		Germany	2019- 2020	MED + E	5 (5)	-	-	-	GEP	

Crop(s) *	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
		France	2020	MED + E	3 (2)	-	-	-	GEP	
		Denmark	2018	MED + E	1 (0)	-	-	-	GEP	
		United Kingdo m	2020	MED + E	2 (1)	-	-	-	GEP	
BRSN W	LEPTMA	France	2020	MED + E	-	4 (1)	-	-	GEP	
BRSN W	LEPTMA	Poland	2018- 2020	MED + E	-	-	22 (5)	-	GEP	
		Lithuani a	2019- 2020	MED + E	-	-	3 (0)	-	GEP	
		Latvia	2019- 2020	MED + E	-	-	2 (1)	-	GEP	
BRSN W	LEPTMA	Hungary	2018- 2020	MED + E	-	-	-	10 (9)	GEP	
		Romania	2020	MED + E	-	-	-	4 (3)	GEP	
TOTAL	-	-	2018- 2020	MED + E	19 (14)	4 (1)	27 (6)	14 (12)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation

In all trials, CA3301 was compared to at least one commercial fungicide used as standard reference for comparison.

Table 3.2-623: Efficacy evaluation - Presentation of reference standards used in trials – Oilseed rape (BRSNW) –LEPTMA– Maritime EPPO zone

Crop(s))	Reference standard	Coun- try(ies) where the product is used ⁽¹⁾	Authoriza- tion number	Active sub- stance(s)	Formulation		Regis- tered ap- plication rate ⁽³⁾	Applica- tion rate in trials (per treat- ment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concentra- tion of a.s.			
BRSN W	PROLINE 250 EC	CZ	4523-1	Prothiocona- zole	EC	250 g/l	2 x 0.7 l/ha max	2 x 0.7 l/ha	CA2445 in some trials
	PRO- SARO	CZ	4561-2	Prothiocona- zole + Tebu- conazole	EC	125 g/l + 125 g/l	1x 0.75-1 l/ha	2 x 0.75 l/ha	
	PROLINE EC 250	DK	18-473	Prothiocona- zole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.5- 0.6-0.7 l/ha	CA2445 in some trials

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
	JOAO	FR (N)	2060116	Prothioconazole	EC	250 g/l	2 x 0.7 l/ha	2 x 0.7 l/ha	CA2445 in some trials
	BISTRO	FR (N)	2160260	Metconazole	EC	90 g/l	2 x 0.8 l/ha	2 x 0.6 l/ha	
	PROLINE	UK	12084	Prothioconazole	EC	250 g/l	2 x 0.7 l/ha	2 x 0.7 l/ha	CA2445 in some trials
	PROLINE	DE	025287-00	Prothioconazole	EC	250 g/l	2 x 0.7 l/ha	2 x 0.7 l/ha	CA2445 in some trials
	CA-RAMBA	DE	024487-00	Metconazole	EC	60 g/l	2 x 1.5 l/a	2 x 1.5 l/ha	

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-624: Efficacy evaluation - Presentation of reference standards used in trials – Oilseed rape (BRSNW) –LEPTMA– Mediterranean EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
BRSNW	JOAO	FR (S)	2060116	Prothioconazole	EC	250 g/l	2 x 0.7 l/ha	2 x 0.7 l/ha	CA2445 in some trials
	BISTRO	FR (S)	2160260	Metconazole	EC	90 g/l	2 x 0.8 l/ha	2 x 0.6 l/ha	

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-625: Efficacy evaluation - Presentation of reference standards used in trials – Oilseed rape (BRSNW) –LEPTMA– North-Eastern EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
BRSNW	PRAKTIS	PL	R-222/2019	Prothioconazole	EC	250 g/l	2 x 0.7 l/ha	2 x 0.7 l/ha	CA2445 in some trials
	TILMOR 240 EC	PL	R-23/2015	Prothioconazole + Tebuconazole	EC	240 g/l	1 x 0.75 l/ha + 1 x 1 l/ha	1 x 0.75 l/ha + 1 x 1 l/ha	

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
	CA-RAMBA 60 SL	PL	R-45/2010	Metconazole	SL	60 g/l	2 x 0.7-1 l/ha	1 or 2 x 1 l/ha	
	ORIOUS EXTRA	PL	R-77/2015	Tebuconazole	EW	250 g/l	1 x 1 l/ha	2 x 1 l/ha	
	PRO-SARO	LT	AS2-2F/2015	Prothioconazole + Tebuconazole	EC	250 g/l	2 x 1 l/ha	1 x 1 l/ha	
	ARTINA	LT	AS2-81F(2018)	Metconazole	EC	90 g/l	1 x 0.7 l/ha	2 x 0.7 l/ha	
	PRO-SARO	LV	0276	Prothioconazole + Tebuconazole	EC	250 g/l	2 x 1 l/ha	2 x 1 l/ha	
	PROLINE	LV	0637	Prothioconazole	EC	250 g/l	2 x 0.7 l/ha	2 x 0.7 l/ha	

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-626: Efficacy evaluation - Presentation of reference standards used in trials – Oilseed rape (BRSNW) –LEPTMA– South-East ~~EPPO~~ EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
BRSNW	PROLINE	RO	457PC/15/11/2018	Prothioconazole	EC	250 g/l	2 x 0.7 l/ha	2 x 0.7 l/ha	CA2445 in some trials
	PROLINE	HU	6300 / 1205-1 / 2020	Prothioconazole	EC	250 g/l	Not registered but standat reference at EU level	2 x 0.7 l/ha	CA2445 in some trials
	TILMOR	HU	04.2/7910-1/2011	Prothioconazole + Tebuconazole	EC	240 g/l	2 x 1.2 l/ha	2 x 1.2 l/ha	
	PRO-PULSE	HU	04.2/41-1/2014	Fluoripam + Prothioconazole	SE	250 g/l	2 x 1 l/ha	2 x 1 l/ha	

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-627.

Table 3.2-627: Details on trial methodology – Oilseed rape (BRSNW) – LEPTMA

		Maritime EPPO zone	Mediterranean EPPO zone	North –East EPPO zone	South-Eastern EPPO zone	Data relevant for Poland
Trials	Total number (valid number)	19 (11)	4 (0)	27 (6)	14 (12)	40 (14)
	Supportive trials	-	-	-	-	-
Guidelines	General guidelines	PP 1/135(4) PP 1/152 (4) PP 181 (4)	PP 1/135(4) PP 1/152 (4) PP 181 (4)	PP 1/135(4) PP 1/152 (4) PP 181 (4)	PP 1/135(4) PP 1/152 (4) PP 181 (4)	PP 1/135(4) PP 1/152 (4) PP 181 (4)
	Specific guidelines	PP 1/78 (3)	PP 1/78 (3)	PP 1/78 (3)	PP 1/78 (3)	PP 1/78 (3)
Experimental design	Plot design	Randomized Complete Blocks, Un-treated included	Randomized Complete Blocks, Un-treated included	Randomized Complete Blocks, Un-treated included	Randomized Complete Blocks, Un-treated included	Randomized Complete Blocks, Un-treated included
	Plot size	22.2-45 m ²	26-39 m ²	21-48 m ²	21-42 m ²	21-48 m ²
	Number of replications	4	4	4	4	4
Crop	Trials per crop	BRSNW (19)	BRSNW (4)	BRSNW (27)	BRSNW (12)	BRSNW (27)
	Varieties per crop	KWS Factor (1), Loki (1), Alasco (1), Silver (1), Arabela (1), KWS Digger (2), PT271 (1), Advocat LG (1), Nikita (2), Flamingo (1), Picto (1), Hattrick (1), Avatar (1), Architect (1), Cortes (1), Crome (1)	Gabriella (1), Exception (1), Sésame (1), Amazonite (1)	SY Polana (1), PX113 (1), Kadore (1), Murphy (1), Tajlun F1 (2), Monolit (3), Acapulco (2), Sherpa (1), Mercedes (2), ES Cesario (1), Thure (1), Extract (1), DK Explicit (1), Rohan (2), NK Technic (1), Absolut (1), Umberto (2), PT264 (1), Kuga (1), Cult (1)	Maximu (1), Harry (2), Mécses (3), Hybrirock (3), Sherpa (1), Round (1), Exception (1), Umberto (1), PT264 (1)	SY Polana (1), PX113 (1), Kadore (1), Murphy (1), Tajlun F1 (2), Monolit (3), Acapulco (2), Sherpa (1), Mercedes (2), ES Cesario (1), Thure (1), Extract (1), DK Explicit (1), Rohan (2), NK Technic (1), Absolut (1), Umberto (2), PT264 (1), Kuga (1), Cult (1), KWS Factor (1), Loki (1), Silver (1), Arabela (1), Digger (2), PT 271 (1), Advocat (1), Hattrick (1), Avatar (2), Cortes (1), Crome (1)
	Sowing period	July (1), August (12), September (5), October (1)	September (4)	August (23), September (4)	August (9), September (5)	July (1), August (32), September (6), October (1)
Application	Crop stage (BBCH)* at application	A: BBCH 14-19 or BBCH 39-65 B: BBCH 65-69	A: BBCH 16 or BBCH 55 B: BBCH 65	A: BBCH 14-17 or BBCH 32-57 B: BBCH 57-69	A: BBCH 14-18 or BBCH 55 B: BBCH 65-67	A: BBCH 14-19 or BBCH 32-65 B: BBCH 57-69
	Timing Pest stage at application	BBCH 14-69 A: PRINFC (8), MIXED (4), N/A (3), ACTIVE (1),	BBCH 16-65 A: PRINFC (1), MIXED (1) B: PRINFC (2), MIXED (2)	BBCH 14-69 A: PRINFC (20), SPORUL (1), MIXED (3), N/A (3)	BBCH 14-67 A: PRINFC (10), MYCELI (1), MIXED (3) B: PRINFC (9),	BBCH 14-69 A: PRINFC (27), SPORUL (4), MIXED (4), N/A (5)

		SPORUL (2) B: PRINFC (8), MIXED (4), LATENT (2), N/A (4), SPORUL (1)		B: PRINFC (17), SPORUL (2), MIXED (4), N/A (4)	MIXED (5)	B: PRINFC (24), SPORUL (3), MIXED (6), N/A (7)
	Number of applications Intervals between applications	1 application (0) 2 applications (15-39 or 146-229 days) (19)	1 application (2) 2 applications (23 or 162 days) (2)	1 application (0) 2 applications (20-47 or 187-243 days) (27)	1 application (0) 2 applications (21-25 or 170-211 days) (14)	1 application (0) 2 applications (15-47 or 146-243 days) (27)
	Spray volumes	A: 200-300 l/ha B: 200-300 l/ha	A: 300 l/ha B: 300 l/ha	A: 200-300 l/ha B: 200-300 l/ha	A: 200-300 l/ha B: 200-300 l/ha	A: 200-300 l/ha B: 200-300 l/ha
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10)
	Assessment dates	0 DA-A, 13-28 DA-A, 0-1 DA-B, 15-31 DA-B, 38-64 DA-B, 69-99 DA-B	0-1 DA-A, 18-21 DA-A, -2-0 DA-B, 15-22 DA-B, 59-76 DA-B	0 DA-A, 13-28 DA-A, 32-59 DA-A, 0 DA-B, 13-27 DA-B, 28-50 DA-B, 51-94 DA-B	0 DA-A, 14-28 DA-A, 0-2 DA-B, 15-31 DA-B, 41-59 DA-B, 63-126 DA-B	0 DA-A, 13-28 DA-A, 32-59 DA-A, 0 DA-B, 13-31 DA-B, 32-50 DA-B, 51-99 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial inoculation...	Natural (19)	Natural (4)	Natural (27)	Natural (14)	Natural (40)
	e.g. Field / Greenhouse...	Field trials	Field trials	Field trials	Field trials	Field trials

For root infection caused by *Plenodomus lingam* on oilseed rape, assessments were made according the EPPO guideline PP1/78 (4). In this case, an assessment scale ranging from 0 to 5 was used, where 0 = no symptoms and 5 = fully infected. No disease index was calculated here.

Use of CA3301 at 2x 0.6-0.7 l/ha against LEPTMA with one application in autumn and one application in spring – Maritime EPPO zone

In the Maritime EPPO zone, 19 trials were available against *Plenodomus lingam* on oilseed rape. 11 trials out of 19 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to the reference products on disease severity (%). Among these 11 trials, CA3301 was applied once in autumn and once in spring in 8 trials, first at crop stages BBCH 14-19 and the 2nd application was at BBCH 65-67. The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.7 l/ha. Two assessment timings were available and the analysis was conducted on leaves, on stems and on roots.

Summary results are presented in Table 3.2-628.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Plenodomus lingam*. When applied at 0.6 l/ha, CA3301 showed 63.07% of efficacy

to control the disease on leaves around 2-4 weeks after the 2nd application and 54.27% of efficacy on stems before harvest. Moreover, CA3301 allowed to reduce the severity index from 3.20 to 2.22. When applied at 0.7 l/ha, CA3301 showed 76.06% of efficacy to control the disease on leaves around 2-4 weeks after the 2nd application and 66.46% of efficacy on stems before harvest. Moreover, CA3301 provided a reduction of the severity index from 3.20 to 2.13.

In all trials in the Maritime EPPO zone, disease pressure was medium to relatively high and in these conditions, CA3301 at 0.7 l/ha gave equivalent or higher disease control compared to the several authorised reference products, and overall equivalent control when applied at 0.6 l/ha. Moreover, in the majority of assessments there were no significant differences in disease control between the rate of 0.6 l/ha or 0.7 l/ha of CA3301. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for control of *Plenodomus lingam*, however when conditions are conducive to heavy disease infestation the rate of 0.7 l/ha may be beneficial to further reduce disease pressure, as highlighted in the trial EU20-014-08.

Considering all elements presented above, it is justified to claim the registration of 2 applications, one in autumn and one in spring of CA3301 at 0.6-0.7 l/ha to control *Plenodomus lingam* on oilseed rape in the Maritime EPPO zone.

Table 3.2-628: Summary table - Efficacy evaluation – Oilseed rape – LEPTMA - Maritime EPPO zone

ZINC														
Treatment name	UNTREATED CHECK	BISTRO	CA2445	CARAMBA	CA3301	CA3301	No of trials where CA3301			No of trials where CA3301				
Rate		0,6	0,7	1,5	0,6	0,7	at 0,6 l/ha is >, = or <			at 0,7 l/ha is >, = or <				
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha								
Appl. Code		AB	AB	AB	AB	AB	compared to			compared to				
% Disease severity LEAF - 18-28 DA-B														
Number of values	3		3		3	3	UTC	CA2445	CA3301	UTC	CA2445	CA3301		
Minimum value	5,00		1,41		1,20	1,02		0,7 l/ha	0,7 l/ha		0,7 l/ha	0,6 l/ha		
Maximum value	14,73	-	4,14	-	7,42	3,75	3 >	0 >	0 >	3 >	0 >	0 >		
Mean disease severity (%)	11,06		2,92		4,51	2,75	0 =	2 =	3 =	0 =	3 =	3 =		
Abbott efficacy (%)	0,00%		73,25%		63,07%	76,06%	0 <	1 <	0 <	0 <	0 <	0 <		
% Disease severity STEM - 56-84 DA-B														
Number of values	6		6		6	6	UTC	CA3301		UTC		CA3301		
Minimum value	17,52		3,62		8,69	4,99		0,7 l/ha				0,6 l/ha		
Maximum value	63,25	-	25,19	-	30,75	24,13	6 >	0 >		6 >		1 <		
Mean disease severity (%)	36,11		11,91		16,26	12,17	0 =	5 =		0 =		5 =		
Abbott efficacy (%)	0,00%		67,73%		54,27%	66,46%	0 <	1 <		0 <		0 <		
Number of values	1	1	1		1	1	BISTRO	CA2445		BISTRO		CA2445		
Minimum value	17,52	13,25	8,07		10,80	8,92	0,6 l/ha	0,7 l/ha		0,6 l/ha		0,7 l/ha		
Maximum value	17,52	13,25	8,07	-	10,80	8,92	0 >	0 >		0 >		0 >		
Mean disease severity (%)	17,52	13,25	8,07		10,80	8,92	1 =	5 =		1 =		6 =		
Abbott efficacy (%)	0,00%	24,37%	53,94%		38,36%	49,09%	0 <	1 <		0 <		0 <		
Number of values	3		3	3	3	3	CARAMBA			CARAMBA				
Minimum value	18,88		5,69	6,50	8,69	5,31	1,5 l/ha			1,5 l/ha				
Maximum value	46,75	-	25,19	33,94	30,75	24,13	1 >			2 >				
Mean disease severity (%)	42,96		16,15	22,77	20,50	15,77	2 =			1 =				
Abbott efficacy (%)	0,00%		64,16%	50,76%	52,72%	65,16%	0 <			0 <				
Severity index ROOT - 83 DA-B														
Number of values	1		1		1	1	UTC	CA2445	CA3301	UTC	CA2445	CA3301		
Minimum value	3,20		2,27		2,22	2,13		0,7 l/ha	0,7 l/ha		0,7 l/ha	0,6 l/ha		
Maximum value	3,20	-	2,27	-	2,22	2,13	1 >	0 >	0 >	1 >	0 >	0 >		
Mean severity index (1-5)	3,20		2,27		2,22	2,13	0 =	1 =	1 =	0 =	1 =	1 =		
Abbott efficacy (%)	-		-		-	-	0 <	0 <	0 <	0 <	0 <	0 <		

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

In the Maritime EPPO zone, 19 trials were available against *Plenodomus lingam* on oilseed rape. 11 trials out of 19 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to the reference products on disease severity (%). Among these 11 trials, CA3301 was applied twice in spring in 3 trials, first at crop stages BBCH 53-55 and the 2nd application was at BBCH 65-67. The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.7 l/ha. The analysis was conducted on leaves (39 DA-B) and on stems (51-73 DA-B).

Summary results are presented in Table 3.2-629.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Plenodomus lingam*. When applied at 0.6 l/ha, CA3301 showed 100% of efficacy to control the disease on leaves 39 days after the 2nd application and 55.58% on stems before harvest. When applied at 0.7 l/ha, CA3301 showed 100% of efficacy to control the disease on leaves 39 days after the 2nd application and 59.49% on stem before harvest.

In the Maritime EPPO zone, a limited dataset was available for assessment of control of *Plenodomus lingam* at this application timing, mainly due to the fact that fungicides are generally applied to prevent the early infection of *Plenodomus lingam* in the young stages of oilseed rape plants. Nevertheless, applications of CA3301 at 0.6-0.7 l/ha demonstrated a high efficacy on leaves in conditions of low disease pressure. At this range of dosage, CA3301 was overall comparable to the reference product CA2445. A larger dataset has been presented regarding to the case where CA3301 was applied once in autumn and once in spring in the same countries, which demonstrates that the efficacy of CA3301 at 0.6 l/ha was fairly comparable to that of the dose rate of 0.7 l/ha. However in some assessments a statistical benefit was derived from increasing the dose rate to 0.7 l/ha for disease control. This dataset can be supportive for the case where the first application of the product is in autumn. Therefore, it is envisaged that a dose rate of 0.6 l/ha is appropriate for control of *Plenodomus lingam* at a low level of disease pressure while for increasing disease pressure, 0.7 l/ha may be more appropriate.

Considering all elements presented above, it is justified to claim the registration of 2 applications in spring of CA3301 at 0.6-0.7 l/ha to control *Plenodomus lingam* on oilseed rape in the Maritime EPP0 zone.

Table 3.2-629: Summary table - Efficacy evaluation – Oilseed rape – LEPTMA - Maritime EPPO zone

Table 5.2-627: Summary table - Efficacy evaluation - Oncoed Rape - LER TMA - Maritime LPTC zone										
Treatment name	UNTREATED CHECK	CA244 5 0,7 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to		
% Disease severity LEAF - 39 DA-B										
Number of values	1	1	1	1	UT C	CA24 45 0,7 l/ha	CA33 01 0,7 l/ha	UT C	CA24 45 0,7 l/ha	CA33 01 0,6 l/ha
Minimum value	5,83	0,00	0,00	0,00	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	5,83	0,00	0,00	0,00	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	5,83	0,00	0,00	0,00	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	100,00 %	100,0 0%	100,0 0%						
% Disease severity STEM - 51-73 DA-B										

Number of values	2	2	2	2	UT C	CA24 45 0,7 l/ha	CA33 01 0,7 l/ha	UT C	CA24 45 0,7 l/ha	CA33 01 0,6 l/ha
Minimum value	11,00	2,69	4,75	3,19						
Maximum value	24,70	8,18	11,28	12,85	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	17,85	5,43	8,01	8,02	0 =	1 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	71,21%	55,58 %	59,49 %	0 <	1 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)
(conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Conclusion Maritime EPPO zone - Use of CA3301 at 2x 0.6-0.7 l/ha against LEPTMA

In the Maritime EPPO zone, 19 trials were available against *Plenodomus lingam* on oilseed rape. 11 trials out of 19 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to several authorised reference products on disease severity (%). Among these 11 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis.

In order to cover the different agricultural spraying practices of oilseed rape in Maritime EPPO zone, 2 types of spraying programs have been tested: 2 applications in spring (dedicated to spring infections of foliar, stem and pods diseases on oilseed rape) or 1 application in autumn and 1 application in spring (dedicated to both autumn and spring infections of roots, foliar, stem and pods diseases on oilseed rape). In the first group of trials, CA3301 was applied once in autumn and once in spring. The data recorded were available on leaves, on stem and on roots. When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Plenodomus lingam*. When applied at 0.6 l/ha, CA3301 showed 63.07% of efficacy to control the disease on leaves around 2-4 weeks after the 2nd application and 54.27% of efficacy on stems before harvest. Moreover, CA3301 provided a reduction of the severity index from 3.20 to 2.22.

When applied at 0.7 l/ha, CA3301 showed 76.06% of efficacy to control the disease on leaves around 2-4 weeks after the 2nd application and 66.46% of efficacy on stems before harvest. Moreover, CA3301 provided a reduction of the severity index from 3.20 to 2.13.

In the 2nd group of trials, CA3301 was applied twice in spring. Data were available on leaves and on stems. When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Plenodomus lingam*. When applied at 0.6 l/ha, CA3301 showed 100% of efficacy to control the disease on leaves 39 days after the 2nd application and 55.58% on stems before harvest.

When applied at 0.7 l/ha, CA3301 showed 100% of efficacy to control the disease on leaves 39 days after the 2nd application and 59.49% on stems before harvest.

In both cases, in overall the data demonstrate a medium efficacy in case of medium disease pressure and a high efficacy in conditions of low disease pressure.

Over the dataset, CA3301 at 0.6-0.7 l/ha gave equivalent disease control compared to the several authorised reference products. Moreover, in the majority of assessments there were no significant differences in disease control between the rate of 0.6 l/ha or 0.7 l/ha of CA3301, although a clear numerical disease reduction was observed. Therefore, it is envisaged that in most instances 2 applications of CA3301 in spring or one in autumn and one in spring will provide an acceptable control of *Plenodomus lingam* whatever the timing of application.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.7 l/ha to control *Plenodomus lingam* on oilseed rape in the Maritime EPPO zone. Moreover, these 2 applications can be carried out in spring or first in autumn and then the 2nd in spring.

Use of CA3301 at 2x 0.6-0.7 l/ha against LEPTMA – Mediterranean EPPO zone

In the Mediterranean EPPO zones, no trials were available against *Plenodomus lingam* on oilseed rape. However, other similar prothioconazole products such as Proline are authorised for use against *Plenodomus lingam* at the same dose rate of 0.7 l/ha, and since data across the various pathogens of oilseed rape has demonstrated comparability with this approved product it is anticipated that CA3301 applied at the proposed dose rates would also provide acceptable control of this pathogen. Furthermore, the data generated in the Maritime and South Eastern EPPO zones supports the minimum effective dose against *Plenodomus lingam*, and across the dataset on oilseed rape the efficacy against pathogens appears comparable regardless of the climatic zone.

Considering all elements presented above, CA3301 at 0.6-0.7 l/ha with two applications in spring or one application in autumn and one application in spring, is the minimum effective dose to control *Plenodomus lingam* on oilseed rape in the Mediterranean EPPO zone.

Use of CA3301 at 2x 0.6-0.7 l/ha against LEPTMA with one application in autumn and one application in spring – North-East~~ern~~ EPPO zone

In the North-East~~ern~~ EPPO zone, 27 trials were available against *Plenodomus lingam* on oilseed rape. 7 trials out of 27 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to the reference products on disease severity (%). Among these 7 trials, CA3301 was applied once in autumn and once in spring in 4 trials, first at crop stages BBCH 15-17 and the 2nd application was at BBCH 63-69. The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.7 l/ha. 4 assessment timings were available and the analysis was conducted on leaves, on stems, on pods and on roots.

Summary results are presented in Table 3.2-630.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Plenodomus lingam*. When applied at 0.6 l/ha, CA3301 showed 77.46% of efficacy to control the disease on leaves 4 weeks after the 2nd application and 74.59% 6 weeks after the 2nd application, full disease control on roots 5 weeks after the 2nd application, and 82.35% on stems and 85.03% on pods before harvest.

When applied at 0.7 l/ha, CA3301 showed 80.56% of efficacy to control the disease on leaves 4 weeks after the 2nd application and 82.70% 6 weeks after the 2nd application, full disease control on roots 5 weeks after the 2nd application, and 93.68% on stems and 95.08% on pods before harvest.

In the North-East~~ern~~ EPPO zone, a limited dataset was available for assessment of control of *Plenodomus lingam* at this application timing. Nevertheless, applications of CA3301 at 0.6-0.7 l/ha demonstrated a medium to high efficacy on leaves, stems, pods and roots in conditions of relatively low disease pressure. At this range of dosage, CA3301 gave equivalent disease control compared to the authorised reference products CA244, ORIUS EXTRA and TILMOR 240 EC. Moreover, there were no significant differences in disease control between the rate of 0.6 l/ha or 0.7 l/ha of CA3301. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for control of *Plenodomus lingam*, however when conditions are conducive to higher disease infestation the rate of 0.7 l/ha may be beneficial to further reduce disease pressure.

Considering all elements presented above, it is justified to claim the registration of 2 applications, one in autumn and one in spring of CA3301 at 0.6-0.7 l/ha to control *Plenodomus lingam* on oilseed rape in the North-East~~ern~~ EPPO zone.

Table 3.2-630: Summary table - Efficacy evaluation – Oilseed rape – LEPTMA – North-East-EPP zone

Treatment name	UNTREATED CHECK	CA 2445	ORIOUS EXTRA	TILMOR 240 EC	CA3301	CA 3301	No of trials where CA3301			No of trials where CA3301				
Rate		0,7	1	0,75-1	0,6	0,7	at 0,6 l/ha is >, = or <			at 0,7 l/ha is >, = or <				
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	compared to			compared to				
Appl. Code		AB	AB	AB	AB	AB								
% Disease severity LEAF- 28 DA-B														
Number of values	1	1			1	1	UT C	CA2445	CA3301	UT C	CA2445	CA3301		
Minimum value	7,10	1,70			1,60	1,38		0,7 l/ha	0,7 l/ha		0,7 l/ha	0,6 l/ha		
Maximum value	7,10	1,70	-	-	1,60	1,38	1 >	0 >	0 >	1 >	0 >	0 >		
Mean disease severity (%)	7,10	1,70			1,60	1,38	0 =	1 =	1 =	0 =	1 =	1 =		
Abbott efficacy (%)	0,00%	76,06%			77,46%	80,56%	0 <	0 <	0 <	0 <	0 <	0 <		
Severity index ROOT - 35 DA-B														
Number of values	1			1	1	1	UT C	TILMOR 240 EC	CA3301	UT C	TILMOR 240 EC	CA3301		
Minimum value	1,50			0,00	0,00	0,00		0,75-1,0 l/ha	0,7 l/ha		0,75-1,0 l/ha	0,6 l/ha		
Maximum value	1,50	-	-	0,00	0,00	0,00	1 >	0 >	0 >	1 >	0 >	0 >		
Mean severity index	1,50			0,00	0,00	0,00	0 =	1 =	1 =	0 =	1 =	1 =		
Abbott efficacy (%)	-			-	-	-	0 <	0 <	0 <	0 <	0 <	0 <		
% Disease severity LEAF - 42 DA-B														
Number of values	1	1			1	1	UT C	CA2445	CA3301	UT C	CA2445	CA3301		
Minimum value	7,40	1,43			1,88	1,28		0,7 l/ha	0,7 l/ha		0,7 l/ha	0,6 l/ha		
Maximum value	7,40	1,43	-	-	1,88	1,28	1 >	0 >	0 >	1 >	0 >	0 >		
Mean disease severity (%)	7,40	1,43			1,88	1,28	0 =	1 =	1 =	0 =	1 =	1 =		
Abbott efficacy (%)	0,00%	80,68%			74,59%	82,70%	0 <	0 <	0 <	0 <	0 <	0 <		
% Disease severity STEM - 50 DA-B														
Number of values	1	1	1		1	1	UT C	CA2445	ORIOUS EXTRA	CA3301	UT C	CA2445	ORIOUS EXTRA	CA3301
Minimum value	6,80	0,40	0,60		1,20	0,43		0,7 l/ha	1 l/ha	0,7 l/ha		0,7 l/ha	1 l/ha	0,6 l/ha
Maximum value	6,80	0,40	0,60	-	1,20	0,43	1 >	0 >	0 >	0 >	1 >	0 >	0 >	0 >
Mean disease severity (%)	6,80	0,40	0,60		1,20	0,43	0 =	1 =	1 =	1 =	0 =	1 =	1 =	1 =
Abbott efficacy (%)	0,00%	94,12%	91,18%		82,35%	93,68%	0 <	0 <	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity POD - 50 DA-B														
Number of values	1	1	1		1	1	UT C	CA2445	ORIOUS EXTRA	CA3301	UT C	CA2445	ORIOUS EXTRA	CA3301
Minimum value	9,35	0,58	0,42		1,40	0,46		0,7 l/ha	1 l/ha	0,7 l/ha		0,7 l/ha	1 l/ha	0,6 l/ha
Maximum value	9,35	0,58	0,42	-	1,40	0,46	1 >	0 >	0 >	0 >	1 >	0 >	0 >	0 >
Mean disease severity (%)	9,35	0,58	0,42		1,40	0,46	0 =	1 =	1 =	1 =	0 =	1 =	1 =	1 =
Abbott efficacy (%)	0,00%	93,80%	95,51%		85,03%	95,08%	0 <	0 <	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.7 l/ha against LEPTMA with 2 applications in spring – North-East ^{eff} EPPO zone

In the North-East ^{eff} EPPO zone, 27 trials were available against *Plenodomus lingam* on oilseed rape. 7 trials out of 27 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to the reference products on disease severity (%). Among these 7 trials, CA3301 was applied twice in spring in 3 trials, first at crop stages BBCH 36-55 and the 2nd application was at BBCH 65-69. The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.7 l/ha. The analysis was conducted on leaves (21 DA-B and 36 DA-B), on stems (24 DA-B and 54 DA-B) and on pods (36 DA-B).

Summary results are presented in

Table 3.2-631.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Plenodomus lingam*. When applied at 0.6 l/ha, CA3301 showed 98.21% of efficacy to control the disease on leaves three weeks after the second application and 95.25% six weeks after the second application. Then the tested product showed 87.80% of efficacy on stems around three weeks after the 2nd application and 58.17% before harvest. Moreover, it showed 95.02% of efficacy to reduce the disease severity on pods around 6 weeks after the 2nd application.

CA3301 at 0.7 l/ha showed 98.81% of efficacy to control the disease on leaves three weeks after the second application and 98.38% six weeks after the second application. Then the tested product showed 93.22% of efficacy on stems around three weeks after the 2nd application and 79.83% before harvest. Moreover, it showed 97.84% of efficacy to reduce the disease severity on pods around 6 weeks after the 2nd application.

In the North-East ^{eff} zone EPPO zone, a limited dataset was available for assessment of control of *Plenodomus lingam* at this application timing. Nevertheless, applications of CA3301 at 0.6-0.7 l/ha demonstrated in overall a high efficacy in conditions of 8 to 10 % of disease severity. At this range of dosage, CA3301 always gave equivalent disease control compared to the authorised reference products CA2445, PROSARO and CARAMBA. Moreover, the efficacy of CA3301 at 0.6 l/ha was statistically comparable to that of the dose rate of 0.7 l/ha on leaves, on stems and on pods. Therefore, it is proposed that the dose rate of 0.6 l/ha is used for instances of low disease pressure and an increased rate of 0.7 l/ha for high disease pressure.

Considering all elements presented above, it is justified to claim the registration of 2 applications in spring of CA3301 at 0.6-0.7 l/ha to control *Plenodomus lingam* on oilseed rape in the North-East ^{eff} EPPO zone.

Table 3.2-631: Summary table - Efficacy evaluation – Oilseed rape – LEPTMA – North-East ^{eff} EPPO zone

Treatment name	UNTREATED CHECK	CA2 445	PROSA RO	CARA MBA	CA33 01	CA33 01	No of trials where CA3301			No of trials where CA3301		
Rate		0,7	1	1	0,6	0,7	at 0,6 l/ha is >, = or <			at 0,7 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha						
Appl. Code		AB	AB	A	AB	AB	compared to			compared to		
% Disease severity LEAF - 21 DA-B												
Number of values	1			1	1	1	UTC	CA- RAMBA	CA3301	UTC	CA2445	CA3301
Minimum value	8.40			0.10	0.15	0.10		1.0 l/ha	0.7 l/ha		0.7 l/ha	0.6 l/ha

Treatment name	UNTREATED CHECK	CA2 445 0,7 L/ha AB	PROSA RO 1 L/ha AB	CARA MBA 1 L/ha A	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to				
Rate														
Rate unit														
Appl. Code														
Maximum value		8,40	-	-	0,10	0,15	0,10	1 >	0 >	0 >	1 >	0 >	0 >	
Mean disease severity (%)	8,40			0,10	0,15	0,10	0 =	1 =	1 =	0 =	1 =	1 =		
Abbott efficacy (%)	0,00%			98,81%	98,21 %	98,81 %	0 <	0 <	0 <	0 <	0 <	0 <		
% Disease severity STEM - 24 DA-B														
Number of values	1			1	1	1	UTC	CA- RAMBA 1,0 l/ha	CA3301 0,7 l/ha	UTC	CA2445 0,7 l/ha	CA3301 0,6 l/ha		
Minimum value	8,85			1,15	1,08	0,60								
Maximum value	8,85	-	-	1,15	1,08	0,60	1 >	0 >	0 >	1 >	0 >	0 >		
Mean disease severity (%)	8,85			1,15	1,08	0,60	0 =	1 =	1 =	0 =	1 =	1 =		
Abbott efficacy (%)	0,00%			87,01%	87,80 %	93,22 %	0 <	0 <	0 <	0 <	0 <	0 <		
% Disease severity LEAF - 36 DA-B														
Number of values	1			1	1	1	UTC	CA- RAMBA 1,0 l/ha	CA3301 0,7 l/ha	UTC	CA2445 0,7 l/ha	CA3301 0,6 l/ha		
Minimum value	8,00			0,15	0,38	0,13								
Maximum value	8,00	-	-	0,15	0,38	0,13	1 >	0 >	0 >	1 >	0 >	0 >		
Mean disease severity (%)	8,00			0,15	0,38	0,13	0 =	1 =	1 =	0 =	1 =	1 =		
Abbott efficacy (%)	0,00%			98,13%	95,25 %	98,38 %	0 <	0 <	0 <	0 <	0 <	0 <		
% Disease severity POD- 36 DA-B														
Number of values	1			1	1	1	UTC	CA- RAMBA 1,0 l/ha	CA3301 0,7 l/ha	UTC	CA2445 0,7 l/ha	CA3301 0,6 l/ha		
Minimum value	10,65			0,25	0,53	0,23								
Maximum value	10,65	-	-	0,25	0,53	0,23	1 >	0 >	0 >	1 >	0 >	0 >		
Mean disease severity (%)	10,65			0,25	0,53	0,23	0 =	1 =	1 =	0 =	1 =	1 =		
Abbott efficacy (%)	0,00%			97,65%	95,02 %	97,84 %	0 <	0 <	0 <	0 <	0 <	0 <		
% Disease severity STEM - 54 DA-B														
Number of values	1	1	1		1	1	UT C	CA24 45 0,7 l/ha	PRO- SARO 1,0 l/ha	CA33 01 0,7 l/ha	UT C	CA24 45 0,7 l/ha	PRO- SARO 1,0 l/ha	CA3 301 0,6 l/ha
Minimum value	9,42	2,49	2,42		3,94	1,90								
Maximum value	9,42	2,49	2,42	-	3,94	1,90	1 >	0 >	0 >	0 >	1 >	0 >	0 >	0 >
Mean disease severity (%)	9,42	2,49	2,42		3,94	1,90	0 =	1 =	1 =	1 =	0 =	1 =	1 =	1 =
Abbott efficacy (%)	0,00%	73,5 7%	74,31%		58,17 %	79,83 %	0 <	0 <	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Conclusion North-Eastern EPPO zone - Use of CA3301 at 2x 0.6-0.7 l/ha against LEPTMA

In the North-Eastern EPPO zone, 27 trials were available against *Plenodomus lingam* on oilseed rape. 7 trials out of 27 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to several authorised reference products on disease severity (%). Among these 7 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis.

In order to cover the different agricultural spraying practices of oilseed rape in North-Eastern EPPO zone, 2 types of spraying programs have been tested: 2 applications in spring (dedicated to spring infections of foliar, stem and pods diseases on oilseed rape) or 1 application in autumn and 1 application in spring (dedicated to both autumn and spring infections of roots, foliar, stem and pods diseases on oilseed rape).

In the first group of trials, CA3301 was applied once in autumn and once in spring. 4 assessment timings were available and the analysis was conducted on leaves, on stems, on pods and on roots. When applied at 0.6 l/ha, CA3301 showed 77.46% of efficacy to control the disease on leaves 4 weeks after the 2nd application and 74.59% 6 weeks after the 2nd application, 100% of efficacy on roots 5 weeks after the 2nd application, and 82.35% on stems and 85.03% on pods before harvest.

When applied at 0.7 l/ha, CA3301 showed 80.56% of efficacy to control the disease on leaves 4 weeks after the 2nd application and 82.70% 6 weeks after the 2nd application, 100% of efficacy on roots 5 weeks after the 2nd application, and 93.68% on stems and 95.08% on pods before harvest.

In the second group of trials, CA3301 was applied twice in spring. Data were available on leaves (21 DA-B and 36 DA-B), on stems (24 DA-B and 54 DA-B) and on pods (36 DA-B). When applied at 0.6 l/ha, CA3301 showed 98.21% of efficacy to control the disease on leaves three weeks after the second application and 95.25% six weeks after the second application. Then the tested product showed 87.80% of efficacy on stem around three weeks after the 2nd application and 58.17% before harvest. Moreover, it showed 95.02% of efficacy to reduce the disease severity on pods around 6 weeks after the 2nd application.

CA3301 at 0.7 l/ha showed 98.81% of efficacy to control the disease on leaves three weeks after the second application and 98.38% six weeks after the second application. Then the tested product showed 93.22% of efficacy on stems around three weeks after the 2nd application and 79.83% before harvest. Moreover, it showed 97.84% of efficacy to reduce the disease severity on pods around 6 weeks after the 2nd application.

In both cases, in overall the data demonstrated the later preventative effect of CA3301 with a medium to high efficacy to control *Plenodomus lingam* on leaves, stems, pods, and roots. In all trials, CA3301 at 0.6-0.7 l/ha gave equivalent disease control compared to the several authorised reference products. Moreover, there were no significant differences in disease control between the rate of 0.6 l/ha or 0.7 l/ha of CA3301, although a clear numerical disease reduction was observed. Therefore, it is envisaged that in most instances 2 applications of CA3301 in spring or one in autumn and one in spring will provide an acceptable control of *Plenodomus lingam* whatever the timing of application.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.7 l/ha to control *Plenodomus lingam* on oilseed rape in the North-Eastern EPPO zone. Moreover, these 2 applications can be carried out in spring or first in autumn and then the 2nd in spring.

Use of CA3301 at 2x 0.6-0.7 l/ha against LEPTMA with one application in autumn and one application in spring – South-Eastern EPPO zone

In the South-Eastern EPPO zone, 14 trials were available against *Plenodomus lingam* on oilseed rape. 12 trials out of 14 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to the reference products on disease severity (%). Among these

12 trials, CA3301 was applied once in autumn and once in spring in 9 trials, first at crop stages BBCH 14-18 and the 2nd application was at BBCH 65-67. The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.7 l/ha.

Summary results are presented in Table 3.2-632.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Plenodomus lingam*. On leaves, at this dose rate, CA3301 showed 88.04% of efficacy on disease severity 2 weeks after the 2nd application and 86.58% before harvest. On stems, CA3301 at 0.6 l/ha provided 91.46% efficacy 2 weeks after the 2nd application and 60.11% before harvest. On pods, efficacy reached 92.78% before harvest at 0.6 l/ha. On roots, CA3301 at this dose rate reduced the severity index from 2.62 to 1.35.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.7 l/ha to control *Plenodomus lingam*. On leaves, at this dose rate, CA3301 showed 90.48% of efficacy on disease severity 2 weeks after the 2nd application and 92.28% before harvest. On stems, CA3301 at 0.7 l/ha provided 95.44% efficacy 2 weeks after the 2nd application and 68.04% before harvest. On pods, efficacy reached 95.51% before harvest. On roots, CA3301 at this dose rate reduced the severity index from 2.62 to 1.14.

In all trials in the South-East ~~EPPO~~ EPPO zone CA3301 at 0.7 l/ha gave equivalent disease control compared to the authorised reference product CA2445 except in 1 assessment and at 0.6 l/ha CA3301 gave equivalent disease control in 15 assessments out of 18 recorded on leaves, stems, pods and roots. Moreover, in the majority of assessments there were no significant differences in disease control between the rate of 0.6 l/ha or 0.7 l/ha of CA3301. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for control of *Plenodomus lingam*, however when conditions are conducive to heavy disease infestation the rate of 0.7 l/ha may be beneficial to further reduce disease incidence.

Considering all elements presented above, it is justified to claim the registration of 2 applications in spring of CA3301 at 0.6-0.7 l/ha to control *Plenodomus lingam* on oilseed rape in the South-East ~~EPPO~~ EPPO zone.

Table 3.2-632: Summary table - Efficacy evaluation – Oilseed rape – LEPTMA – South-East ~~EPPO~~ EPPO zone

Treatment name	UNTREATED CHECK	CA2 445 0,7 L/ha AB	TILMOR 240 EC 1,2 L/ha A	CA33 01 0,6 L/ha AB	CA3301 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,7 l/ha is >, = or < compared to
% Disease severity LEAF- 15 DA-B							
Number of values	4			4	4	UTC	UTC
Minimum value	8,70			0,60	0,85		CA3301 0,7 l/ha
Maximum value	23,90	-	-	2,77	1,54	4 >	4 >
Mean disease severity (%)	14,36			1,76	1,26	0 =	4 =
Abbott efficacy (%)	0,00%			88,04 %	90,48 %	0 <	0 <
Number of values	3	3		3	3	CA2445 0,7 l/ha	
Minimum value	8,70	1,41		0,60	0,85	0 >	
Maximum value	12,82	2,60	-	1,93	1,54	0 >	
Mean disease severity (%)	11,18	1,86		1,42	1,21	3 =	
Abbott efficacy (%)	0,00%	82,02%		87,91 %	89,27 %	0 <	
Number of values	2		2	2	2	TILMOR 240 EC 1,2 l/ha	
Minimum value	8,70		1,75	0,60	0,85	1,2 l/ha	
Maximum value	23,90	-	2,83	2,77	1,41	0 >	

Treatment name	UNTREATED CHECK	CA2 445	TILMOR 240 EC	CA33 01	CA3 301	No of trials where CA3301			No of trials where CA3301		
Rate		0,7	1,2	0,6	0,7	at 0,6 l/ha is >, = or <			at 0,7 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha	L/ha						
Appl. Code		AB	A	AB	AB	compared to			compared to		
Mean disease severity (%)		16,30		2,29	1,69	1,13	2 =			2 =	
Abbott efficacy (%)	0,00%		84,02%	90,76 %	92,17 %	0 <			0 <		
% Disease severity STEM - 15 DA-B											
Number of values	2	2		2	2	UTC	CA2445 0,7 l/ha	CA3301 0,7 l/ha	UTC	CA2445 0,7 l/ha	CA3301 0,6 l/ha
Minimum value	6,02	0,32		0,50	0,26						
Maximum value	6,29	0,33	-	0,55	0,30	2 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	6,16	0,33		0,53	0,28	0 =	2 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	94,7 2%		91,46 %	95,44 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity LEAF - 32-49 DA-B											
Number of values	2			2	2	UTC	CA3301 0,7 l/ha		UTC	CA3301 0,6 l/ha	
Minimum value	5,62			0,83	0,61						
Maximum value	42,00	-	-	5,07	1,93	2 >	0 >		2 >	0 >	
Mean disease severity (%)	23,81			2,95	1,27	0 =	2 =		0 =	2 =	
Abbott efficacy (%)	0,00%			86,58 %	92,28 %	0 <	0 <		0 <	0 <	
Number of values	1	1		1	1	CA2445 0,7 l/ha		CA2445 0,7 l/ha			
Minimum value	5,62	0,90		0,83	0,61						
Maximum value	5,62	0,90	-	0,83	0,61	0 >		0 >			
Mean disease severity (%)	5,62	0,90		0,83	0,61	1 =		1 =			
Abbott efficacy (%)	0,00%	83,9 9%		85,23 %	89,15 %	0 <		0 <			
Number of values	1		1	1	1	TILMOR 240 EC 1,2 l/ha		TILMOR 240 EC 1,2 l/ha			
Minimum value	42,00		3,98	5,07	1,93						
Maximum value	42,00	-	3,98	5,07	1,93	0 >		0 >			
Mean disease severity (%)	42,00		3,98	5,07	1,93	1 =		1 =			
Abbott efficacy (%)	0,00%		90,52%	87,93 %	95,40 %	0 <		0 <			
% Disease severity STEM - 41-62 DA-B											
Number of values	6	6		6	6	UTC	CA3301 0,7 l/ha		UTC	CA3301 0,6 l/ha	
Minimum value	7,46	0,77		1,00	0,62						
Maximum value	76,40	18,1 5	-	43,10	33,60	6 >	0 <		6 >	1 >	
Mean disease severity (%)	31,19	8,60		16,38	11,62	0 =	5 =		0 =	5 =	
Abbott efficacy (%)	0,00%	73,8 6%		60,11 %	68,04 %	0 <	1 <		0 <	0 <	
Number of values	2	2	2	2	2	CA2445	TILMOR 240 EC	CA2445	TILMOR 240 EC		
Minimum value	53,60	13,2 0	17,30	30,15	13,30	0,7 l/ha	1,2 l/ha	0,7 l/ha	1,2 l/ha		
Maximum value	76,40	15,9 0	25,20	43,10	33,60	0 >	0 >	0 >	1 >		
Mean disease severity (%)	65,00	14,5 5	21,25	36,63	23,45	4 =	0 =	5 =	0 =		
Abbott efficacy (%)	0,00%	77,2 8%	67,37%	43,67 %	59,95 %	2 <	2 <	1 <	1 <		
% Disease severity POD - 41 DA-B											
Number of values	2	2		2	2	UTC	CA2445 0,7 l/ha	CA3301 0,7 l/ha	UTC	CA2445 0,7 l/ha	CA3301 0,6 l/ha
Minimum value	6,20	0,30		0,37	0,25						
Maximum value	6,29	0,32	-	0,53	0,31	2 >	0 >	0 >	2 >	0 >	0 >

Treatment name	UNTREATED CHECK	CA2 445	TILMOR 240 EC	CA33 01	CA3 301	No of trials where CA3301			No of trials where CA3301				
Rate		0,7	1,2	0,6	0,7	at 0,6 l/ha is >, = or <			at 0,7 l/ha is >, = or <				
Rate unit		L/ha	L/ha	L/ha	L/ha								
Appl. Code		AB	A	AB	AB	compared to			compared to				
Mean disease severity (%)		6,25	0,31		0,45	0,28	0 =	2 =	2 =	0 =	2 =	2 =	
Abbott efficacy (%)	0,00%	95,03%		92,78%	95,51%	0 <	0 <	0 <	0 <	0 <	0 <		
Severity index (1-5) ROOT- 41-62 DA-B													
Number of values	5	4	3	5	5	UT	CA24 45	TILMOR 240 EC	CA33 01	UT	CA24 45	TILMOR 240 EC	CA3 301
Minimum value	1,60	1,00	1,00	1,00	1,00	C	0,7 l/ha	1,2 l/ha	0,7 l/ha	C	0,7 l/ha	1,2 l/ha	0,6 l/ha
Maximum value	3,65	1,29	1,56	2,25	1,36	5 >	0 >	0 >	0 >	5 >	0 >	0 >	1 >
Mean severity index (1-5)	2,62	1,07	1,33	1,35	1,14	0 =	3 =	2 =	4 =	0 =	4 =	3 =	4 =
Abbott efficacy (%)	-	-	-	-	-	0 <	1 <	1 <	1 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.7 l/ha against LEPTMA with 2 applications in spring – South-Eastern EPPO zone

In the South-Eastern EPPO zone, 14 trials were available against *Plenodomus lingam* on oilseed rape. 12 trials out of 14 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to the reference products on disease severity (%). Among these 12 trials, CA3301 was applied twice in spring in 3 trials, first at crop stage BBCH 55 and the 2nd application was at BBCH 65-67. The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.7 l/ha. The analysis was conducted on leaves and on stems. Two assessment timings were available on leaves whereas a single assessment timing was available on stems.

Summary results are presented in Table 3.2-633.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Plenodomus lingam*. On leaves, at this dose rate, CA3301 showed 99.34% of efficacy on disease severity 3 weeks after the 2nd application and 61.04% before harvest. On stems, it provided 70.93% efficacy before harvest.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.7 l/ha to control *Plenodomus lingam*. On leaves, at this dose rate, CA3301 showed 98.80% of efficacy on disease severity 3 weeks after the 2nd application and 68.92% before harvest. On stems, it provided 83.58

% efficacy before harvest.

In the South-Eastern EPPO zone, CA3301 at 0.6-0.7 l/ha showed medium to high efficacy in reducing the severity of *Plenodomus lingam* on oilseed rape on leaves and stems 3 weeks after the 2nd application and before harvest. The performance of the tested product was overall equivalent to the authorised reference products CA2445 and PROPULSE except in 1 assessment where both dose rates of CA3301 gave lower disease control than the references. Averaged across the dataset the efficacy of CA3301 at 0.6 l/ha was comparable to that of the dose rate of 0.7 l/ha, however at one assessment a statistical benefit

was derived from increasing the dose rate to 0.7 l/ha. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for control of *Plenodomus lingam* and 0.7 l/ha dose rate may be useful in more challenging conditions.

Considering all elements presented above, it is justified to claim the registration of 2 applications, one in autumn and one in spring of CA3301 at 0.6-0.7 l/ha to control *Plenodomus lingam* on oilseed rape in the South-East ~~EPB~~ EPPO zone.

Table 3.2-633: Summary table - Efficacy evaluation – Oilseed rape – LEPTMA – South-East ~~EPB~~ EPPO zone

Treatment name	UNTREATED CHECK	CA24 45 0,7 L/ha AB	PROPUL SE 1 L/ha A	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,7 l/ha is >, = or < compared to
Rate							
Rate unit							
Appl. Code							
% Disease severity LEAF - 21 DA-B							
Number of values	1		1	1	1	UT C	PRO-PULSE 01 0,7 l/ha
Minimum value	24,23		0,23	0,16	0,29		1,0 l/ha
Maximum value	24,23	-	0,23	0,16	0,29	1 >	0 >
Mean disease severity (%)	24,23		0,23	0,16	0,29	0 =	1 =
Abbott efficacy (%)	0,00%		99,05%	99,34 %	98,80 %	0 <	0 <
% Disease severity LEAF - 32-46 DA-B							
Number of values	2		2	2	2	UTC	CA3301 0,7 l/ha
Minimum value	28,40		1,87	1,30	1,33		UTC
Maximum value	36,95	-	3,22	21,13	16,63	2 >	0 >
Mean disease severity (%)	32,68		2,54	11,21	8,98	0 =	1 =
Abbott efficacy (%)	0,00%		91,80%	61,04 %	68,92 %	0 <	1 <
Number of values	1	1	1	1	1	CA2445 0,7 l/ha	PRO-PULSE 01 0,6 l/ha
Minimum value	28,40	6,58	3,22	21,13	16,63		UTC
Maximum value	28,40	6,58	3,22	21,13	16,63	0 >	0 >
Mean disease severity (%)	28,40	6,58	3,22	21,13	16,63	0 =	1 =
Abbott efficacy (%)	0,00%	76,83 %	88,66%	25,60 %	41,44 %	1 <	1 <
% Disease severity STEM - 55-56 DA-B							
Number of values	2		2	2	2	UT C	PRO-PULSE 01 0,7 l/ha
Minimum value	26,30		0,40	8,68	3,70		1,0 l/ha
Maximum value	36,20	-	1,50	9,10	5,95	2 >	0 >
Mean disease severity (%)	31,25		0,95	8,89	4,83	0 =	2 =
Abbott efficacy (%)	0,00%		96,60%	70,93 %	83,58 %	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Conclusion South-Eastern EPPO zone - Use of CA3301 at 2x 0.6-0.7 l/ha against LEPTMA

In the South-East EPPO zone, 14 trials were available against *Plenodomus lingam* on oilseed rape. 12 trials out of 14 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to several authorised reference products on disease severity (%). Among these 12 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis.

In order to cover the different agricultural spraying practices of oilseed rape in South-Eastern EPPO zone, 2 types of spraying programs have been tested: 2 applications in spring (dedicated to spring infections of foliar, stem and pods diseases on oilseed rape) or 1 application in autumn and 1 application in spring (dedicated to both autumn and spring infections of roots, foliar, stem and pods diseases on oilseed rape).

In the first group of trials, CA3301 was applied once in autumn and once in spring. Two assessment timings were available and the analysis was conducted on leaves, on stems, on pods and on roots. When applied at 0.6 l/ha, CA3301 showed 88.04% of efficacy to control the disease on leaves 2 weeks after the 2nd application and 86.58% before harvest. On stems, CA3301 at 0.6 l/ha provided 91.46% efficacy 2 weeks after the 2nd application and 60.11% before harvest. On pods, it provided 92.78% efficacy before harvest.

When applied at 0.7 l/ha, CA3301 showed 90.48% of efficacy to control the disease on leaves 2 weeks after the 2nd application and 92.28% before harvest. On stems, CA3301 at 0.7 l/ha provided 95.44% efficacy 2 weeks after the 2nd application and 68.04% before harvest. On pods, it provided 95.51% efficacy before harvest.

In the second group of trials, CA3301 was applied twice in spring. Data were available on leaves (21 DA-B and 32-46 DA-B) and on stems (55-56 DA-B). When applied at 0.6 l/ha, CA3301 showed 99.34% of efficacy to control the disease on leaves three weeks after the second application and 61.04% before harvest. Then the tested product showed 70.93% of efficacy on stems before harvest.

CA3301 at 0.7 l/ha showed 98.80% of efficacy to control the disease on leaves three weeks after the second application and 68.92% before harvest. Then the tested product showed 83.58% of efficacy on stems before harvest.

In both cases, in overall the data demonstrate the later preventative effect of CA3301 with an equivalent medium level of efficacy.

In all trials, CA3301 at 0.6-0.7 l/ha gave equivalent or very comparable disease control compared to the several authorised reference products. Moreover, in the majority of assessments there were no significant differences in disease control between the rate of 0.6 l/ha or 0.7 l/ha of CA3301. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for control of *Plenodomus lingam* whatever the timing of application and that the rate of 0.7 l/ha will be useful in more challenging conditions.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.7 l/ha to control *Plenodomus lingam* on oilseed rape in the South-Eastern EPPO zone. Moreover, these 2 applications can be carried out in spring or first in autumn and then the 2nd in spring.

Use of CA3301 at 2x 0.6-0.7 l/ha against LEPTMA one application in autumn and one application in spring - Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-Eastern EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, 40 trials were available against *Plenodomus lingam* on oilseed rape. 14 trials out of 40 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to several authorised

Summary results are presented in Table 3.2-634.

In Poland and neighbouring countries, CA3301 at 0.7 l/ha gave equivalent or higher disease control compared to the authorised reference product CA2445, ORIUS EXTRA and CARAMBA and at 0.6 l/ha CA3301 always gave equivalent disease except in 2 assessments where it was less efficient than CA2445. Moreover, in the majority of assessments there were no significant differences in disease control between the rate of 0.6 l/ha or 0.7 l/ha of CA3301. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for control of *Plenodomus lingam*, however when conditions are conducive to heavy disease infestation the rate of 0.7 l/ha may be beneficial to further reduce disease pressure.

Considering all elements presented above, it is justified to claim the registration of 2 applications, one in autumn and one in spring of CA3301 at 0.6-0.7 l/ha to control *Plenodomus lingam* on oilseed rape in Poland.

Table 3.2-634: Summary table - Efficacy evaluation – Oilseed rape – LEPTMA – Data relevant for Poland

[illegible]

Number of values	6	6			6	6	UTC		CA3301		UTC		CA3301	
Minimum value	6,80	0,40			1,20	0,43			0,7 l/ha				0,6 l/ha	
Maximum value	63,25	25,19	-	-	30,75	24,13	6 >		0 >		6 >		1 >	
Mean disease severity (%)	34,32	10,63			14,66	10,75	0 =		5 =		0 =		5 =	
Abbott efficacy (%)	0,00%	74,43%			61,60%	73,89%	0 <		1 <		0 <		0 <	
Number of values	1	1	1		1	1	CA2445		ORIOUS EXTRA		CA2445		ORIOUS EXTRA	
Minimum value	6,80	0,40	0,60		1,20	0,43	0,7 l/ha		1,0 l/ha		0,7 l/ha		1,0 l/ha	
Maximum value	6,80	0,40	0,60	-	1,20	0,43	0 >		0 >		0 >		0 >	
Mean disease severity (%)	6,80	0,40	0,60		1,20	0,43	5 =		1 =		6 =		1 =	
Abbott efficacy (%)	0,00%	94,12%	91,18%		82,35%	93,68%	1 <		0 <		0 <		0 <	
Number of values	3	3		3	3	3	CARAMBA				CARAMBA			
Minimum value	18,88	5,69		6,50	8,69	5,31	1,5 l/ha				1,5 l/ha			
Maximum value	63,25	25,19	-	33,94	30,75	24,13	1 >				2 >			
Mean disease severity (%)	42,96	16,15		22,77	20,50	15,77	2 =				1 =			
Abbott efficacy (%)	0,00%	64,16%		50,76%	52,72%	66,84%	0 <				0 <			
% Disease severity POD - 50 DA-B														
Number of values	1	1	1		1	1	UTC	CA2445	ORIOUS EXTRA	CA3301	UTC	CA2445	ORIOUS EXTRA	CA3301
Minimum value	9,35	0,58	0,42		1,40	0,46		0,7 l/ha	1,0 l/ha	0,7 l/ha		0,7 l/ha	1,0 l/ha	0,6 l/ha
Maximum value	9,35	0,58	0,42	-	1,40	0,46	1 >	0 >	0 >	0 >	1 >	0 >	0 >	0 >
Mean disease severity (%)	9,35	0,58	0,42		1,40	0,46	0 =	1 =	1 =	1 =	0 =	1 =	1 =	1 =
Abbott efficacy (%)	0,00%	93,80%	95,51%		85,03%	95,08%	0 <	0 <	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.7 l/ha against LEPTMA with 2 applications in spring – Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, 40 trials were available against *Plenodomus lingam* on oilseed rape. 14 trials out of 40 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to several authorised reference products on disease severity (%). Among these 14 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis. In Poland

and the neighbouring countries, among the 14 valid trials, CA3301 was applied twice in spring in 6 trials, first at crop stages BBCH 36-55 and the 2nd application was at BBCH 65-69. 2 assessment timings were available and the analysis was conducted on leaves, on stems and on pods.

Summary results are presented in Table 3.2-635

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6-0.7 l/ha to control *Plenodomus lingam*. On leaves, when applied at 0.6 l/ha, CA3301 showed 87.80% of efficacy to control the disease 4 weeks after the 2nd application and 97.63% before harvest. Moreover, at this dose rate CA3301 showed 56.44% of efficacy on stems and 95.02% on pods before harvest. On leaves, when applied at 0.7 l/ha, CA3301 showed 93.22% of efficacy to control the disease 4 weeks after the 2nd application and 99.19% before harvest. Moreover, at this dose rate CA3301 showed 66.27% of efficacy on stems and 97.84% on pods before harvest.

In Poland and neighbouring countries, a representative dataset was available for assessment of *Plenodomus lingam*, with disease pressure ranging from relatively low to medium, from leaves to pods. In overall CA3301 at 0.6-0.7 l/ha showed high efficacy in reducing the severity of *Plenodomus lingam* on oilseed rape, whatever the plant part rated. CA3301 gave overall equivalent disease control compared to the several authorised reference products and averaged across the dataset the efficacy of CA3301 at 0.6 l/ha was comparable to that of the dose rate of 0.7 l/ha, in these conditions of disease pressure. Therefore, it is envisaged that a dose rate of 0.6 l/ha is appropriate for control of *Plenodomus lingam* at low disease pressure while for increasing disease pressure, 0,7 l/ha may be more appropriate.

Considering all elements presented above, it is justified to claim the registration of 2 applications in spring of CA3301 at 0.6-0.7 l/ha to control *Plenodomus lingam* on oilseed rape in Poland.

Table 3.2-635: Summary table - Efficacy evaluation – Oilseed rape – LEPTMA – Data relevant for Poland

Treatment name	UNTREATED CHECK	CA24 45 0,7 L/ha AB	PROSA RO 1 L/ha AB	CARAM BA 1 L/ha A	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,7 l/ha is >, = or < compared to
% Disease severity STEM - 24 DA-B								
Number of values	1			1	1	1	UT C	CA- RAMBA 1,0 l/ha
Minimum value	8,85			1,15	1,08	0,60		CA33 01 0,7 l/ha
Maximum value	8,85	-	-	1,15	1,08	0,60	1 >	UT C
Mean disease severity (%)	8,85			1,15	1,08	0,60	0 =	CA- RAMBA 1,0 l/ha
Abbott efficacy (%)	0,00%			87,01%	87,80 %	93,22 %	0 <	CA33 01 0,6 l/ha
% Disease severity LEAF - 36-39 DA-B								
Number of values	2				2	2	UTC	CA3301 0,7 l/ha
Minimum value	5,83				0,00	0,00		UTC
Maximum value	8,00	-	-	-	0,38	0,13	2 >	CA3301 0,6 l/ha
Mean disease severity (%)	6,91				0,19	0,06	0 =	
Abbott efficacy (%)	0,00%				97,63 %	99,19 %	0 <	
Number of values	1	1			1	1	PROSARO 1,0 l/ha	
Minimum value	5,83	0,00			0,00	0,00		
Maximum value	5,83	0,00	-	-	0,00	0,00	0 >	
Mean disease severity (%)	5,83	0,00			0,00	0,00	1 =	
Abbott efficacy (%)	0,00%	100,0 0%			100,00 %	100,00 %	0 <	
Number of values	1			1	1	1	CARAMBA	
							CARAMBA	

Treatment name	UNTREATED CHECK	CA24 45 0,7 L/ha AB	PROSA RO 1 L/ha AB	CARAM BA 1 L/ha A	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to 1,0 l/ha			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to 1,0 l/ha		
Rate												
Rate unit												
Appl. Code												
Minimum value	8,00			0,15	0,38	0,13						
Maximum value	8,00	-	-	0,15	0,38	0,13		0 >		0 >		
Mean disease severity (%)	8,00			0,15	0,38	0,13		1 =		1 =		
Abbott efficacy (%)	0,00%			98,13%	95,25 %	98,38 %		0 <		0 <		
% Disease severity POD- 36 DA-B												
Number of values	1			1	1	1	UT C	CA- RAMBA 1,0 l/ha	CA33 01 0,7 l/ha	UT C	CA- RAMBA 1,0 l/ha	CA33 01 0,6 l/ha
Minimum value	10,65			0,25	0,53	0,23						
Maximum value	10,65	-	-	0,25	0,53	0,23	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	10,65			0,25	0,53	0,23	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%			97,65%	95,02 %	97,84 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity STEM - 51-73 DA-B												
Number of values	3	3			3	3	UTC	CA3301 0,7 l/ha		UTC	CA3301 0,6 l/ha	
Minimum value	9,42	2,49			3,94	1,90						
Maximum value	24,70	8,18	-	-	11,28	12,85	3 >	0 >		3 >	0 >	
Mean disease severity (%)	15,04	4,45			6,66	5,98	0 =	3 =		0 =	3 =	
Abbott efficacy (%)	0,00%	72,00 %			56,44 %	66,27 %	0 <	0 <		0 <	0 <	
Number of values	1	1	1		1	1	CA2445 0,7 l/ha	PRO- SARO 1,0 l/ha		CA2445 0,7 l/ha	PRO- SARO 1,0 l/ha	
Minimum value	9,42	2,49	2,42		3,94	1,90						
Maximum value	9,42	2,49	2,42	-	3,94	1,90	0 >	0 >		0 >	0 >	
Mean disease severity (%)	9,42	2,49	2,42		3,94	1,90	2 =	1 =		3 =	1 =	
Abbott efficacy (%)	0,00%	73,57 %	74,31%		58,17 %	79,83 %	1 <	0 <		0 <	0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Conclusion Data relevant for Poland - Use of CA3301 at 2x 0.6-0.7 l/ha against LEPTMA

According to guidance provided by the Polish National authority, where data from the North-East ~~EPPO~~ EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, 40 trials were available against *Plenodomus lingam* on oilseed rape. 14 trials out of 40 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to several authorised reference products on disease severity (%). Among these 14 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis.

In order to cover the different agricultural spraying practices of oilseed rape in Poland, 2 types of spraying programs have been tested: 2 applications in spring (dedicated to spring infections of foliar, stem and pods diseases on oilseed rape) or 1 application in autumn and 1 application in spring (dedicated to both autumn and spring infections of roots, foliar, stem and pods diseases on oilseed rape).

In the first group of trials, CA3301 was applied once in autumn and once in spring. The data were available on leaves, stems and pods at two assessment timings. When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Plenodomus lingam*. When applied at 0.6 l/ha, CA3301 showed 63.55% of efficacy to control the disease on leaves four weeks after the 2nd application and 74.59% on before harvest. At this dose rate, CA3301 provided 61.60% efficacy on stem and 85.03% efficacy on pods before harvest.

When applied at 0.7 l/ha, CA3301 showed 76.39% of efficacy to control the disease on leaves four weeks after the 2nd application and 82.70% on before harvest. At this dose rate, CA3301 provided 73.89% efficacy on stems and 95.08% efficacy on pods before harvest.

In the second group of trials CA3301 was applied twice in spring. The data recorded were available on leaves, stems and pods. On stems, 2 different assessment timings were available whereas a single assessment timing was available for the other parts assessed (leaves and pods).

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6-0.7 l/ha to control *Plenodomus lingam*. On leaves, when applied at 0.6 l/ha, CA3301 showed 97.63% of efficacy to control the disease 5-6 weeks after the 2nd application. Moreover, at this dose rate CA3301 showed 87.80% of efficacy on stem 3 weeks after the 2nd application and 56.44% before harvest. On pods, CA3301 at 0.6 l/ha provided 95.02% efficacy 4 weeks after the 2nd application.

On leaves, when applied at 0.7 l/ha, CA3301 showed 99.19% of efficacy to control the disease 5-6 weeks after the 2nd application. Moreover, at this dose rate CA3301 showed 93.22% of efficacy on stems 3 weeks after the 2nd application and 66.27% before harvest. On pods, CA3301 at 0.6 l/ha provided 97.84% efficacy 4 weeks after the 2nd application.

In both cases, in overall the data demonstrate a medium to high efficacy for the same assessment timings. This is particularly true for the 0.7 l/ha dose rate. In this dataset, CA3301 at 0.6-0.7 l/ha gave overall equivalent disease control compared to the several authorised reference products. Moreover, in most instances there were no significant differences in disease control between the rate of 0.6 l/ha or 0.7 l/ha of CA3301, although a clear numerical disease reduction was observed. Therefore, it is envisaged that in most instances 2 applications of CA3301 in spring or one in autumn and one in spring will provide an acceptable control of *Plenodomus lingam* whatever the timing of application.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.7 l/ha to control *Plenodomus lingam* on oilseed rape in Poland. Moreover, these 2 applications can be carried out in spring or first in autumn and then the 2nd in spring.

Comments of zRMS:

11 valid trials were carried out in **the Maritime EPPO climatic zone**. 2 application in autumn and spring were used in 8 out of 11 trials. CA3301 applied at dose rate of 0,6 l/ha achieved low to medium efficacy. The dose rate of 0,7 l/ha caused increase of effectiveness to medium level after 18-84 DA-B. 2 applications in spring were used in 3 out of 11 trials. The results on leaves showed very high level of control after applied of the test product. CA3301 at 0,6-0,7 l/ha achieved low efficacy and it was observed on stems after 51-73 days after second application. Due to the limited number of trials for spring applications, the cMSs are kindly asked to consider this use on the national level.

7 valid trials were available in **the North-East EPPO zone**. 2 applications in autumn and spring were used in 4 out of 7 trials. CA3301 applied at dose rate of 0,6 l/ha achieved medium to high efficacy. The dose rate of 0,7 l/ha caused increase of effectiveness to high level after 28-50 days after second application. 2 applications in spring were used in 3 out of 7 trials. The test product applied at dose rate of 0,6-0,7 l/ha achieved high level of control after 21-36 DA-B. In 1 trial lower effectiveness was noted on stem after 54 days after second application. However, no significant differences between test and reference products were detected. Also results from 3 trials with spring applications and 3 trials with autumn/spring applications conducted in neighbouring countries have been included to the overall calculation to support of Polish registration. Based on all trial results, this use can be accepted in Poland.

12 valid trials were conducted in **the South-East EPPO zone**. 2 applications in autumn and spring were used in 9 out of 12 trials. In majorities trials, CA3301 applied at dose rate of 0,6-0,7 l/ha achieved high efficacy after

15-49 DA-B. In 6 trials, the test product applied at both doses presented also medium level of control on stems after 41-62 days after second application. 2 application in spring were used in 3 out of 12 trials. CA3301 applied at dose rate of 0,6-0,7 l/ha achieved medium to high efficacy after 21-56 DA-B. No additional trials from the Mediterranean zone have been submitted to support of product registration in other zones. Due to the limited number of trials for spring applications, the cMSs are kindly asked to consider this use in the national level.

3.2.3.12 Oilseed rape (BRSNW) / *Erysiphe cruciferarum* (ERYSCR)

Materials and Methods – Oilseed rape – ERYSCR

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2019 and 2020, a total of 31 trials were conducted in several countries of the Maritime, Mediterranean, North-Eastern and South-Eastern EPPO zones to evaluate the efficacy of CA3301 against *Erysiphe cruciferarum* on oilseed rape (see Table 3.2-636). The trials were carried out by certified testing institutes.

In the Maritime EPPO zone, 2 trials were performed in Czech Republic (1) and France (1).
In the Mediterranean EPPO zone, 11 trials were performed in France (8), Spain (2) and Italy (1).
In the North-Eastern EPPO zone, 3 trials were performed in Lithuania (3).
In the South-Eastern EPPO zone, a total of 15 trials were performed in Hungary (7), Slovakia (3) and Romania (5).

Data groupings were also made specifically for Poland evaluation and trials involved (7) were performed in Lithuania (2), Latvia (1), Czech Republic (1) and Slovakia (3).

Table 3.2-636: Presentation of trials – Oilseed rape (BRSNW)

Crop(s) *	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mar- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
BRSN W	ERYSCR	Czech Republic	2019	MED + E	1 (1)	-	-	-	GEP	
		France	2020	MED + E	1 (1)	-	-	-	GEP	
BRSN W	ERYSCR	France	2019- 2020	MED + E	-	8 (0)	-	-	GEP	
		Spain	2020	MED + E	-	2 (1)	-	-	GEP	
		Italy	2020	MED + E	-	1 (1)	-	-	GEP	
BRSN W	ERYSCR	Lithuani a	2019	MED + E	-	-	3 (0)	-	GEP	
BRSN W	ERYSCR	Hungary	2020	MED + E	-	-	-	7 (7)	GEP	
		Romania	2019- 2020	MED + E	-	-	-	5 (5)	GEP	

Crop(s) *	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
		Slovakia	2019- 2020	MED + E	-	-	-	3 (3)	GEP	
TOTAL	-	-	2018- 2020	MED + E	2 (2)	11 (2)	3 (0)	15 (15)	GEP	

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation

In all trials, CA3301 was compared to at least one commercial fungicide used as standard reference for comparison.

Table 3.2-637: Efficacy evaluation - Presentation of reference standards used in trials – Oilseed rape (BRSNW) – ERYSCR – Maritime EPPO zone

Crop(s))	Refer- ence standard	Coun- try(ies) where the product is used ⁽¹⁾	Authoriza- tion num- ber	Active sub- stance(s)	Formulation		Regis- tered ap- plication rate ⁽³⁾	Applica- tion rate in tri- als (per treat- ment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concentra- tion of a.s.			
BRSN W	PRO- LINE 250 EC	CZ	4523-1	Prothiocona- zole	EC	250 g/l	2 x 0.7 l/ha max	2 x 0.7 l/ha	CA2445 in some trials
	JOAO	FR (N)	2060116	Prothiocona- zole	EC	250 g/l	2 x 0.7 l/ha	2 x 0.7 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-638: Efficacy evaluation - Presentation of reference standards used in trials – Oilseed rape (BRSNW) – ERYSCR – Mediterranean EPPO zone

Crop(s))	Reference standard	Coun- try(ies) where the product is used (1)	Authoriza- tion num- ber	Active sub- stance(s)	Formulation		Regis- tered ap- plication rate ⁽³⁾	Applica- tion rate in tri- als (per treat- ment)	Re- mark ⁽⁴⁾
					Type ⁽²⁾	Concentra- tion of a.s.			
BRSN W	JOAO	FR (S)	2060116	Prothiocona- zole	EC	250 g/l	2 x 0.7 l/ha	2 x 0.8 l/ha	CA2445 in some trials
	PRAKTIS	ES	01135	Prothiocona- zole	EC	250 g/l0	2 x 0.7 l/ha	2 x 0.7 l/ha	CA2445 in some trials
	PRO- SARO	ES	25661	Prothiocona- zole + Tebu- conazole	EC	250 g/L	2 x 1 l/ha	2 x 1 L/ha	

Crop(s)	Reference standard	Country(ies) where the product is used (1)	Authorization number	Active substance(s)	Formulation		Registered application rate(3)	Application rate in trials (per treatment)	Remark(4)
					Type ⁽²⁾	Concentration of a.s.			
	CA-RAMBA	ES	25743	Metconazole	EC	90 g/l	2 x 0.8 l/ha	2 x 0.8 l/ha	
	PROLINE	IT	013385	Prothioconazole	EC	250 g/la	2 x 0.8 l/ha	2 x 0.7 l/ha	
	CA-RAMBA	IT	014101	Metconazole	EC	8.6g / 100g	2 x 0.8 l/ha	2 x 0.8 l/ha	

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-639: Efficacy evaluation - Presentation of reference standards used in trials – Oilseed rape (BRSNW) – ERYSCR – North-Eastern EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used (1)	Authorization number	Active substance(s)	Formulation		Registered application rate(3)	Application rate in trials (per treatment)	Remark(4)
					Type ⁽²⁾	Concentration of a.s.			
BRSNW	PRO-SARO	LT	AS2-2F/2015	Prothioconazole + Tebuconazole	EC	250 g/l	2 x 1 l/ha	2 x 1 l/ha	

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Table 3.2-640: Efficacy evaluation - Presentation of reference standards used in trials – Oilseed rape (BRSNW) – ERYSCR – South-Eastern EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used (1)	Authorization number	Active substance(s)	Formulation		Registered application rate(3)	Application rate in trials (per treatment)	Remark(4)
					Type ⁽²⁾	Concentration of a.s.			
BRSNW	PROLINE	RO	457PC/15/11/2018	Prothioconazole	EC	250 g/l	2 x 0.7 l/ha	2 x 0.7 l/ha	CA2445 in some trials
	PROLINE	HU	6300 / 1205-1 / 2020	Prothioconazole	EC	250 g/l	Not registered but standat reference at EU level	2 x 0.7 l/ha	CA2445 in some trials
	TILMOR	HU	04.2/7910-1/2011	Prothioconazole + Tebuconazole	EC	240 g/l	2 x 1.2 l/ha	2 x 1.2 l/ha	
	PRO-PULSE	HU	04.2/41-1/2014	Fluoripam + Prothioconazole	SE	250 g/l	2 x 1 l/ha	2 x 1 l/ha	

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
	ORIUS	SK	18-00319-AU	Tebuconazole	EW	250 g/l	2 x 1 l/ha	2 x 1 l/ha	
	PRO-SARO	SK	06-02-0771	Prothioconazole + Tebuconazole	EC	125 g/l + 125 g/l	2 x 0.75 l/ha	2 x 0.75 l/ha	
	PROLINE 250 EC	SK	06-02-0768	Prothioconazole	EC	250 g/l	Not registered for OSR but reference at Eu level	2 x 0.7 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-641.

Table 3.2-641: Details on trial methodology – Oilseed rape (BRSNW) – ERYSCR

		Maritime EPPO zone	Mediterranean EPPO zone	North –East EPPO zone	South-Eastern EPPO zone	Data relevant for Poland
Trials	Total number (valid number)	2 (2)	11 (2)	3 (0)	15 (15)	7 (4)
	Supportive trials	-	-	-	-	-
Guidelines	General guidelines	PP 1/135(4) PP 1/152 (4) PP 181 (4)	PP 1/135(4) PP 1/152 (4) PP 181 (4)	PP 1/135(4) PP 1/152 (4) PP 181 (4)	PP 1/135(4) PP 1/152 (4) PP 181 (4)	PP 1/135(4) PP 1/152 (4) PP 181 (4)
	Specific guidelines	PP 1/78 (3)	PP 1/78 (3)	PP 1/78 (3)	PP 1/78 (3)	PP 1/78 (3)
Experimental design	Plot design	Randomized Complete Blocks, Un-treated included	Randomized Complete Blocks, Un-treated included	Randomized Complete Blocks, Un-treated included	Randomized Complete Blocks, Un-treated included	Randomized Complete Blocks, Un-treated included
	Plot size	25-30.375 m ²	15-45 m ²	25 m ²	21-40.5 m ²	25-30 m ²
	Number of replications	4	4	4	4	4
Crop	Trials per crop	BRSNW (2)	BRSNW (11)	BRSNW (3)	BRSNW (15)	BRSNW (7)
	Varieties per crop	DK Exception (1), Feliciano KWS (1)	Memori CS (2), RGT Quizz (2), Exception (2), Aquarel (1), Expansion (1), Sesame (1), Amazonite (1), PR45D03 (1)	Mercedes (1), DK Explicit (1), NK Technic (1)	Extron (1), Mazari CS (1), Alicante (1), Harry (1), Hybrirrock (1), PT264 (1), Mécses (1), KWS Umberto (1), Shrek (1), Imperio (1), Es Danube (1), Compass (1),	Mercedes (1), DK Explicit (1), NK Technic (1), DK Exception (1), Alicante (1), Arabella (2)

					Arabella (2), Iowa (1)	
	Sowing period	August (2)	August (4), Sep- tember (6), Oc- tober (1)	August (3)	August (12), September (2), October (1)	August (7)
Application	Crop stage (BBCH)* at application	A: BBCH 19 or BBCH 50 B: BBCH 65-67	A: BBCH 16-33 or BBCH 53-55 B: BBCH 65-69	A: BBCH 57 B: BBCH 67	A: BBCH 14-18 or BBCH 37-55 B: BBCH 65-67	A: BBCH 37-57 B: BBCH 65-67
	Timing Pest stage at application	BBCH 19-67 A: PRINFC (1), MIXED (1), B: PRINFC (1), LATENT (1)	BBCH 16-67 A: PRINFC (6) B: PRINFC (11)	BBCH 57-67 A: SPORUL (3) B: SPORUL (3)	BBCH 14-67 A: PRINFC (13), MIXED (2) B: PRINFC (9), MIXED (6)	BBCH 537-67 A: SPORUL (3), PRINFC (4) B: SPORUL (3), PRINFC (3), MIXED (1)
	Number of applications Intervals between applications	1 application (0) 2 applications (21 or 135 days) (2)	1 application (5) 2 applications (23-41 days) (6)	1 application (0) 2 applications (20 days) (3)	1 application (0) 2 applications (21-38 or 155- 197 days) (14)	1 application (0) 2 applications (20-21 days) (7)
	Spray volumes	A: 200-225 l/ha B: 200-225 l/ha	A: 200-400 l/ha B: 200-400 l/ha	A: 300 l/ha B: 300 l/ha	A: 200-500 l/ha* B: 200-500 l/ha	A: 200-500 l/ha** B: 200-500 l/ha
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0- 10)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0- 10)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0- 10)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0- 10)	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0- 10)
	Assessment dates	0 DA-A, 15-21 DA-A, 0 DA-B, 14-21 DA-B, 42-59 DA-B, 60-73 DA-B	0-1 DA-A, 18- 26 DA-A, -2-1 DA-B, 15-23 DA-B, 41-76 DA-B	0 DA-A, 20 DA- A, 0 DA-B, 21 DA-B, 44 DA- B, 56 DA-B	0 DA-A, 14-21 DA-A, -1-0 DA- B, 15-30 DA-B, 38-76 DA-B	0 DA-A, 20-21 DA-A, 0 DA-B, 18-28 DA-B, 44-555 DA-B, 56-76 DA-B
Other rele- vant infor- mation	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant	Not relevant	Not relevant	Not relevant	Not relevant
	e.g. Natural / artificial innoculation...	Natural (2)	Natural (11)	Natural (3)	Natural (15)	Natural (7)
	e.g. Field / Greenhouse...	Field trials	Field trials	Field trials	Field trials	Field trials

*In 1 trial out of 15 in the South-Eastern EPPO zone a deviation was recorded regarding the spray volume of application. In this trial 500 l/ha were applied instead of 400 l/ha maximum, which is a small difference with no impact on the validity of the trial.

**In 1 trial out of 7 in the Poland grouping a deviation was recorded regarding the spray volume of application. In this trial 500 l/ha were applied instead of 400 l/ha maximum, which is a small difference with no impact on the validity of the trial.

Use of CA3301 at 2x 0.6-0.7 l/ha against ERYSCR with one application in autumn and one application in spring – Maritime EPPO zone

In the Maritime EPPO zone, among the 2 valid trials, CA3301 was applied once in autumn and once in spring in a single trial, first at crop stage BBCH 19 and the 2nd application was at BBCH 67. One assessment timing was available and the analysis was conducted on leaves. The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.7 l/ha.

Summary results are presented in Table 3.2-642.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Erysiphe cruciferarum*. When applied at 0.6 l/ha, CA3301 showed 33.71% of efficacy to control the disease on leaves before harvest and 28.31% at 0.7 l/ha.

In this trial in the Maritime EPPO zone, the disease pressure was challenging and the 2nd application in spring was followed by a very rainy day (24.5 mm) which may cause leaching of the products and reduced effectiveness. In addition, in this trial application timing was targeted for a different disease, hence the first application as less effective against this pathogen. In these special conditions, CA3301 at 0.6 l/ha and 0.7 l/ha gave low disease control but equivalent compared to the reference product CA2445. Moreover, there was no significant difference in disease control between the rate of 0.6 l/ha or 0.7 l/ha of CA3301. In addition both the test product and the reference product significantly reduced disease severity in this trial. However, this trial is not representative of the true behaviour of the test item and considering larger datasets presented in this dossier, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for control of *Erysiphe cruciferarum*. Finally, when conditions are conducive to heavy disease infestation the rate of 0.7 l/ha may be beneficial to further reduce disease pressure.

Considering all elements presented above, it is justified to claim the registration of 2 applications, one in autumn and one in spring of CA3301 at 0.6-0.7 l/ha to control *Erysiphe cruciferarum* on oilseed rape in the Maritime EPPO zone.

Table 3.2-642: Summary table - Efficacy evaluation – Oilseed rape – ERYSCR - Maritime EPPO zone

Table 3.2-042: Summary table - Efficacy evaluation – Onseed Rape – ERTSCR - Maritime EPTG zone										
Treatment name	UNTREATED CHECK	CA24 45	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to		
Rate		0,7	0,6	0,7						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Disease severity LEAF - 42 DA-B										
Number of values	1	1	1	1	UT C	CA24 45 0,7 l/ha	CA33 01 0,7 l/ha	UT C	CA24 45 0,7 l/ha	CA33 01 0,6 l/ha
Minimum value	26,70	19,29	17,70	19,14	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	26,70	19,29	17,70	19,14	0 =	1 =	1 =	0 =	1 =	1 =
Mean disease severity (%)	26,70	19,29	17,70	19,14	0 <	0 <	0 <	0 <	0 <	0 <
Abbott efficacy (%)	0,00%	27,75 %	33,71 %	28,31 %						

'>' means CA3301 is significantly more efficient than plants treated with (treatment)
(conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.7 l/ha against ERYSCR with 2 applications in spring - Maritime EPPO zone

In the Maritime EPPO zone, among the 2 valid trials, CA3301 was applied twice in spring in a single trial, first at crop stages BBCH 50 and the 2nd application was at BBCH 65. One assessment timing was available and the analysis was conducted on leaves. The efficacy evaluation has been focussed on CA3301 applied at 0.6 and 0.7 l/ha.

Summary results are presented in Table 3.2-643.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6-0.7 l/ha to control *Erysiphe cruciferarum*. When applied at 0.6 l/ha, CA3301 showed 49.78% of

efficacy to control the disease on leaves before harvest and 65.88% at 0.7 l/ha.

In the Maritime EPPO zone, a limited dataset was available for assessment of control of *Erysiphe cruciferarum* at this application timing. In the only one trial presented, disease pressure was challenging and data demonstrated low to medium efficacy of CA3301 to reduce disease severity. At this dose range, CA3301 was statistically comparable to the reference product CA2445 at 0.7 l/ha. Moreover, no significant difference was observed between the two tested dose rates but a clear numerical trend appeared where disease control increased with the dose rate. Considering larger datasets presented on other diseases, this trial follows the overall trend observed where in most cases 0.6 l/ha dose rate provides acceptable disease reduction and 0.7 l/ha dose rate is more appropriate in challenging conditions.

Considering all elements presented above, it is justified to claim the registration of 2 applications in spring of CA3301 at 0.6-0.7 l/ha to control *Erysiphe cruciferarum* on oilseed rape in the Maritime EPPO zone.

Table 3.2-643: Summary table - Efficacy evaluation – Oilseed rape – ERYSCR - Maritime EPPO zone

Treatment name	UNTREATED	CA24	CA33	CA33	No of trials where			No of trials where		
Rate	CHECK	45	01	01	CA3301			CA3301		
Rate unit		0,7	0,6	0,7	at 0,6 l/ha is >, = or			at 0,7 l/ha is >, = or		
Appl. Code		L/ha	L/ha	L/ha	<			<		
		AB	AB	AB	compared to			compared to		
% Disease severity LEAF - 59 DA-B										
Number of values	1	1	1	1	UT	CA24	CA33	UT	CA24	CA33
					C	45	01	C	45	01
Minimum value	30,13	10,03	15,13	10,28		0,7	0,7		0,7	0,6
						l/ha	l/ha		l/ha	l/ha
Maximum value	30,13	10,03	15,13	10,28	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	30,13	10,03	15,13	10,28	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	66,71 %	49,78 %	65,88 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Conclusion Maritime EPPO zone - Use of CA3301 at 2x 0.6-0.7 l/ha against ERYSCR

In the Maritime EPPO zone, 2 trials were available against *Erysiphe cruciferarum* on oilseed rape, were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to several authorised reference products on disease severity (%). Among these 2 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis.

In order to cover the different agricultural spraying practices of oilseed rape in Maritime EPPO zone, 2 types of spraying programs have been tested: 2 applications in spring (dedicated to spring infections of foliar, stem and pods diseases on oilseed rape) or 1 application un autumn and 1 application in spring (dedicated to both autumn and spring infections of roots, foliar, stem and pods diseases on oilseed rape).

In the first group of trials, CA3301 was applied once in autumn and once in spring and the 2nd application was followed by a very rainy day. Furthermore, in this trial application timing was targeted for a different disease, hence the first application as less effective against this pathogen. The data recorded were available on leaves. When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Erysiphe cruciferarum*. When applied at 0.6 l/ha, CA3301 showed 33.71% of efficacy to control the disease on leaves before harvest and 28.31 % at 0.7 l/ha. The efficacy

observed in this trial remained lower than for the second group of trial. This could be mainly explained by the disease cycle of ERYSCR which is most susceptible to occur in spring season / at the end of crop cycle. In this case, at disease appearance, the effect of the first application made during autumn is decreasing and a single additional application is not sufficient to control the disease. When historical pressure is known in the field site, a double application in spring is recommended.

In the 2nd group of trials, CA3301 was applied twice in spring. Data were available on leaves. When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Erysiphe cruciferarum*. When applied at 0.6 l/ha, CA3301 showed 49.78% of efficacy to control the disease on leaves before harvest and 65.88% at 0.7 l/ha.

In both cases, the dataset was limited and the disease pressure was medium to high. In both datasets also the disease control from the test product was comparable to that of the reference product. Overall, the data demonstrate a medium efficacy in case of medium disease pressure. In the two trials, CA3301 at 0.6-0.7 l/ha gave equivalent disease control compared to the authorised reference product CA2445 applied at 0.7 l/ha. Moreover, there were no significant differences in disease control between the rate of 0.6 l/ha or 0.7 l/ha of CA3301, although a clear numerical disease reduction was observed when the two applications were made in spring. Therefore, it is envisaged that in most instances 2 applications of CA3301 in spring or one in autumn and one in spring will provide an acceptable control of *Erysiphe cruciferarum* whatever the timing of application.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.7 l/ha to control *Erysiphe cruciferarum* on oilseed rape in the Maritime EPPO zone. Moreover, these 2 applications can be carried out in spring or first in autumn and then the 2nd in spring.

Use of CA3301 at 2x 0.6-0.7 l/ha against ERYSCR with 2 applications in spring - Mediterranean EPPO zone

In the Mediterranean EPPO zone, 11 trials were available against *Erysiphe cruciferarum* on oilseed rape. 2 trials out of 11 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to several authorised reference products on disease severity (%). In these 2 trials, CA3301 was applied twice in spring, first at crop stages BBCH 33-55 and the 2nd application was at BBCH 65. One assessment timing was available and the analysis was conducted on leaves, stems and pods. The efficacy evaluation has been focussed on CA3301 applied at 0.6 and 0.7 l/ha.

Summary results are presented in Table 3.2-644.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Erysiphe cruciferarum*. When applied at 0.6 l/ha, CA3301 showed 74.52% of efficacy to control the disease on leaves and 100.00% of efficacy on stems and pods around 5-6 weeks after the 2nd application.

When applied at 0.7 l/ha, CA3301 showed 72.60% of efficacy to control the disease on leaves and 100.00% of efficacy on stems and pods around 5-6 weeks after the 2nd application.

In the Mediterranean EPPO zone, a limited dataset was available for assessment of control of *Erysiphe cruciferarum* at this application timing. In the two trials presented, disease pressure was medium to high and data demonstrated medium to very high efficacy of CA3301 to reduce disease severity. At this dose range, CA3301 gave always comparable disease control to the authorised reference products CA2445 and CARAMBA.

Considering all elements presented above, it is justified to claim the registration of 2 applications in spring of CA3301 at 0.6-0.7 l/ha to control *Erysiphe cruciferarum* on oilseed rape in the Mediterranean EPPO zone.

Table 3.2-644: Summary table - Efficacy evaluation – Oilseed rape – ERYSCR - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA24 45	CARAM BA	CA330 1	CA3 301	No of trials where CA3301				No of trials where CA3301			
Rate		0,7	0,8	0,6	0,7	at 0,6 l/ha is >, = or <				at 0,7 l/ha is >, = or <			
Rate unit		L/ha	L/ha	L/ha	L/ha								
Appl. Code		AB	AB	AB	AB	compared to				compared to			
% Disease severity LEAF - 35-41 DA-B													
Number of values	2	2	2	2	2	UT C	CA24 45	CA- RAMB A	CA33 01	UT C	CA24 45	CA- RAMBA	CA3 301
Minimum value	27,13	1,20	1,90	2,68	2,40		0,7 l/ha	0,8 l/ha	0,7 l/ha		0,7 l/ha	0,8 l/ha	0,6 l/ha
Maximum value	54,93	13,73	13,41	12,50	13,6 8	2 >	0 >	0 >	0 >	2 >	0 >	0 >	0 >
Mean disease severity (%)	41,03	7,46	7,66	7,59	8,04	0 =	2 =	2 =	2 =	0 =	2 =	2 =	2 =
Abbott efficacy (%)	0,00%	73,60 %	73,56%	74,52%	72,6 0%	0 <	0 <	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity STEM - 35 DA-B													
Number of values	1	1	1	1	1	UT C	CA24 45	CA- RAMB A	CA33 01	UT C	CA24 45	CA- RAMBA	CA3 301
Minimum value	30,35	0,00	0,00	0,00	0,00		0,7 l/ha	0,8 l/ha	0,7 l/ha		0,7 l/ha	0,8 l/ha	0,6 l/ha
Maximum value	30,35	0,00	0,00	0,00	0,00	1 >	0 >	0 >	0 >	1 >	0 >	0 >	0 >
Mean disease severity (%)	30,35	0,00	0,00	0,00	0,00	0 =	1 =	1 =	1 =	0 =	1 =	1 =	1 =
Abbott efficacy (%)	0,00%	100,0 0%	100,00%	100,00 %	100, 00%	0 <	0 <	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity POD - 35 DA-B													
Number of values	1	1	1	1	1	UT C	CA24 45	CA- RAMB A	CA33 01	UT C	CA24 45	CA- RAMBA	CA3 301
Minimum value	14,50	0,00	0,00	0,00	0,00		0,7 l/ha	0,8 l/ha	0,7 l/ha		0,7 l/ha	0,8 l/ha	0,6 l/ha
Maximum value	14,50	0,00	0,00	0,00	0,00	1 >	0 >	0 >	0 >	1 >	0 >	0 >	0 >
Mean disease severity (%)	14,50	0,00	0,00	0,00	0,00	0 =	1 =	1 =	1 =	0 =	1 =	1 =	1 =
Abbott efficacy (%)	0,00%	100,0 0%	100,00%	100,00 %	100, 00%	0 <	0 <	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)	
>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.7 l/ha against ERYSCR - North-East EPPO zone

In the North-East EPPO zone, 3 trials were conducted to assess the control of powdery mildew *Erysiphe cruciferarum* on oilseed rape by CA3301 but were not valid due to lack of disease infestation. However, the dataset for this pathogen in the other climatic zones shows that CA3301 applied at the proposed dose rates of 0.6-0.7 l/ha is sufficient for control, and across the whole dataset generated on oilseed rape the efficacy of these dose rates are comparable between the different EPPO zones.

In addition, the pathogen *Erysiphe cruciferarum* is very comparable to *Blumeria graminis*/*Erysiphe graminis* specie, both of the order Erysiphales and the family Erysiphaceae, which causes powdery mildew on cereals. It is therefore possible to take into account the positive effects of CA3301 applied at 0.6-0.8 l/ha on oilseed rape from the robust dataset proposed on other crops.

The dataset presented on other crops against powdery mildew showed that CA3301 applied at 0.6-0.8 l/ha provided significant disease control in the two main assessment timing. Both dose rates were frequently better than the lower rate of 0.48 l/ha. Moreover, the level of disease control observed was medium to high depending on the disease pressure. Indeed, whereas differences were not always significant, a numerical trend appeared where CA3301 at 0.8 l/ha provided better efficacy than 0.6 l/ha dose in the most challenging conditions. Moreover, phytosanitary products formulated or co-formulated with the active substance prothioconazole (250 g/l) are commonly used and provided consistent efficacy to control powdery mildew in a large range of crops.

Finally, since in the fields a complex of disease is often observed instead of a single disease and since the datasets included in this dossier showed that the rates of 0.6-0.7 l/ha generally gave adequate disease control, it is supposed that the dose range of 0.6-0.7 will be acceptable to control powdery mildew on oilseed rape.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.7 l/ha to control *Erysiphe cruciferarum* on oilseed rape in the North-East ~~EPPO~~ EPPO zone.

Use of CA3301 at 2x 0.6-0.7 l/ha against ERYSCR with one application in autumn and one application in spring – South-East ~~EPPO~~ EPPO zone

In the South-East ~~EPPO~~ EPPO zone, among the 15 valid trials, CA3301 was applied once in autumn and once in spring in 4 trials, first at crop stages BBCH 14-16 and the 2nd application was at BBCH 65-66. Two assessment timings were available and the analysis was conducted on leaves, stems and pods. The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.7 l/ha. The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.7 l/ha.

Summary results are presented in Table 3.2-645.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Erysiphe cruciferarum*. When applied at 0.6 l/ha, CA3301 showed 69.09% of efficacy to control the disease on leaves around 5-6 weeks after the 2nd application. Before harvest, at this dose rate, CA3301 provided 55.47% efficacy on stems and 58.39% efficacy on pods.

When applied at 0.7 l/ha, CA3301 showed 78.08% of efficacy to control the disease on leaves around 5-6 weeks after the 2nd application. Before harvest, at 0.7 l/ha, CA3301 provided 63.69% efficacy on stems and 68.12% efficacy on pods.

In the South-East ~~EPPO~~ zone EPPO zone, a limited dataset was available for assessment of control of *Erysiphe cruciferarum* at this application timing. Nevertheless, applications of CA3301 at 0.6-0.7 l/ha demonstrated low to medium efficacy in conditions of challenging disease pressure. At 0.7 l/ha, CA3301 gave equivalent or higher disease control compared to the authorised reference CA2445 and was equivalent to the reference TILMOR except in 1 trial where it was less efficient. At 0.6 l/ha, CA3301 was most of the time equivalent to both references except in 1 trial (EU20-014-45) where it was less efficient in each assessments. In addition, a numerical and statistical trend appears where disease control increases with the dose rates of CA3301. Finally, a larger dataset has been presented regarding to the case where CA3301 was applied twice in spring in the South-Eastern zone, which demonstrates overall the same trends. This dataset can be supportive for the case where the first application of the product is in

autumn. Therefore, it is proposed that the dose rate of 0.6 l/ha is used for instances of low disease pressure and an increased rate of 0.7 l/ha for high disease pressure.

Considering all elements presented above, it is justified to claim the registration of 2 applications, one in autumn and one in spring of CA3301 at 0.6-0.7 l/ha to control *Erysiphe cruciferarum* on oilseed rape in the South-East ~~EPPO~~ EPPO zone.

Table 3.2-645: Summary table - Efficacy evaluation – Oilseed rape – ERYSCR – South-East ~~EPPO~~ EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA24 45 0,7 L/ha AB	TILM OR 1,2 L/ha A	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,7 l/ha is >, = or < compared to	
% Disease severity LEAF - 31-48 DA-B									
Number of values	4	4	-	4	4	UTC	CA24 45 0,7 l/ha	UTC	CA24 45 0,7 l/ha
Minimum value	11,84	2,21	-	4,06	0,46				
Maximum value	55,00	27,50	-	26,25	17,50	4 >	0 >	4 >	2 >
Mean disease severity (%)	36,71	10,39	-	10,38	7,05	0 =	3 =	0 =	2 =
Abbott efficacy (%)	0,00%	68,69 %	-	69,09 %	78,08 %	0 <	1 <	0 <	0 <
Number of values	3	3	3	3	3	TIL- MOR 1,2 l/ha	CA33 01 0,7 l/ha	TIL- MOR 1,2 l/ha	CA33 01 0,6 l/ha
Minimum value	30,00	2,21	0,00	4,06	0,46				
Maximum value	55,00	27,50	21,25	26,25	17,50	0 >	0 >	0 >	2 >
Mean disease severity (%)	45,00	11,57	8,75	11,77	7,65	2 =	2 =	2 =	2 =
Abbott efficacy (%)	0,00%	77,54 %	83,79%	76,25 %	85,55 %	1 <	2 <	1 <	0 <
% Disease severity STEM - 48-62 DA-B									
Number of values	3	3	-	3	3	UTC	CA24 45 0,7 l/ha	UTC	CA24 45 0,7 l/ha
Minimum value	10,30	5,20	-	3,46	2,98				
Maximum value	50,00	20,00	-	30,00	20,00	3 >	0 >	3 >	1 >
Mean disease severity (%)	36,77	15,07	-	17,82	14,33	0 =	2 =	0 =	2 =
Abbott efficacy (%)	0,00%	56,50 %	-	55,47 %	63,69 %	0 <	1 <	0 <	0 <
Number of values	2	2	2	2	2	TIL- MOR 1,2 l/ha	CA33 01 0,7 l/ha	TIL- MOR 1,2 l/ha	CA33 01 0,6 l/ha
Minimum value	50,00	20,00	5,00	20,00	20,00				
Maximum value	50,00	20,00	20,00	30,00	20,00	0 >	0 >	0 >	1 >
Mean disease severity (%)	50,00	20,00	12,50	25,00	20,00	1 =	2 =	1 =	2 =
Abbott efficacy (%)	0,00%	60,00 %	75,00%	50,00 %	60,00 %	1 <	1 <	1 <	0 <
% Disease severity POD - 48-62 DA-B									
Number of values	3	3	-	3	3	UTC	CA24 45 0,7 l/ha	UTC	CA24 45 0,7 l/ha
Minimum value	9,68	5,91	-	4,34	3,45				
Maximum value	50,00	20,00	-	30,00	20,00	3 >	0 >	3 >	1 >
Mean disease severity (%)	36,56	11,97	-	14,78	11,15	0 =	2 =	0 =	2 =
Abbott efficacy (%)	0,00%	59,65 %	-	58,39 %	68,12 %	0 <	1 <	0 <	0 <

Number of values	2	2	2	2	2	TIL- MOR 1,2 l/ha	CA33 01 0,7 l/ha	TIL- MOR 1,2 l/ha	CA33 01 0,6 l/ha
Minimum value	50,00	10,00	5,00	10,00	10,00	0 >	0 >	0 >	1 >
Maximum value	50,00	20,00	10,00	30,00	20,00	1 =	2 =	1 =	2 =
Mean disease severity (%)	50,00	15,00	7,50	20,00	15,00	1 <	2 <	1 <	2 <
Abbott efficacy (%)	0,00%	70,00 %	85,00%	60,00 %	70,00 %	1 <	1 <	1 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.7 l/ha against ERYSCR with 2 applications in spring - South-Eastern EPPO zone

In the South-Eastern EPPO zone, 15 trials were available against *Erysiphe cruciferarum* on oilseed rape. 15 trials out of 15 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to several authorised reference products on disease severity (%). Among the 15 valid trials, CA3301 was applied twice in spring in 11 trials, first at crop stages BBCH 37-55 and the 2nd application was at BBCH 65-69. The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.7 l/ha. The analysis was conducted on leaves, on stems and on pods. Two assessment timings were available on leaves and stems whereas a single assessment timing was available on pods.

Summary results are presented in Table 3.2-646.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6 l/ha to control *Erysiphe cruciferarum*.

Applied at 0.6 l/ha, CA3301 provided 92.74% mean efficacy on leaves and 87.54% mean efficacy on stems around 2-3 weeks after the 2nd application. At this dose rate, CA3301 showed 86.25% mean efficacy on leaves, 78.81% mean efficacy on stems and 68.64% mean efficacy on pods.

Applied at 0.7 l/ha, CA3301 provided 95.46% mean efficacy on leaves and 93.73% mean efficacy on stems around 2-3 weeks after the 2nd application. At this dose rate, CA3301 showed 90.58% mean efficacy on leaves, 84.91% mean efficacy on stems and 73.69% mean efficacy on pods.

In the South-Eastern EPPO zone, CA3301 at 0.6-0.7 l/ha showed medium to high efficacy in reducing the severity of *Erysiphe cruciferarum* on oilseed rape on leaves, stems and pods 2-3 weeks after the 2nd application and before harvest. Over the dataset, CA3301 at 0.6 l/ha was always equivalent to the references PROPULSE and ORIUS but gave lower disease control than PROSARO. Compared to CA2445 at 0.7 l/ha, CA3301 at 0.6 l/ha was most of the time statistically equivalent and sometimes less efficient. Otherwise, CA3301 at 0.7 l/ha was statistically equivalent to the four authorised reference products in all assessments. Averaged across the dataset the efficacy of CA3301 at 0.6 l/ha was comparable to that of the dose rate of 0.7 l/ha, however in some assessments close to harvest a statistical benefit was derived from increasing the dose rate to 0.7 l/ha. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for control of *Erysiphe cruciferarum* and 0.7 l/ha dose rate may be useful in more challenging conditions or when some level of resistance is suspected.

Considering all elements presented above, it is justified to claim the registration of 2 applications, one in autumn and one in spring of CA3301 at 0.6-0.7 l/ha to control *Erysiphe cruciferarum* on oilseed rape in the South-Eastern EPPO zone

Table 3.2-646: Summary table - Efficacy evaluation – Oilseed rape – ERYSCR – South-East zone

Treatment name	UNTREA TED CHECK	CA2 445	PROS ARO	PROP ULSE	ORI US	CA3 301	CA 330 1	No of trials where CA3301	No of trials where CA3301
Rate		0,7	0,75	1	1	0,6	0,7	at 0,6 l/ha is	at 0,7 l/ha is
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	L/ha	>, = or <	>, = or <
Appl. Code		AB	AB	AB	AB	AB	AB	compared to	compared to
% Disease severity LEAF - 14-21 DA-B									
Number of values	5	5				5	5	UTC	CA24 45 0,7 l/ha
Minimum value	9,76	0,00				0,00	0,00		UTC
Maximum value	50,00	2,56	-	-	-	3,73	2,32	5 >	0 >
Mean disease severity (%)	22,38	0,81				1,23	0,77	0 =	5 =
Abbott efficacy (%)	0,00%	95,34 %				92,74 %	95,4 6%	0 <	0 <
Number of values	1	1		1		1	1	PRO PUL SE 1,0 l/ha	CA33 01 0,7 l/ha
Minimum value	50,00	0,00		0,00		0,00	0,00		PRO PUL SE 1,0 l/ha
Maximum value	50,00	0,00	-	0,00	-	0,00	0,00	0 >	0 >
Mean disease severity (%)	50,00	0,00		0,00		0,00	0,00	1 =	5 =
Abbott efficacy (%)	0,00%	100,0 0%		100,00 %		100,0 0%	100, 00 %	0 <	0 <
% Disease severity STEM - 21 DA-B									
Number of values	1	1				1	1	UTC	CA24 45 0,7 l/ha
Minimum value	11,16	0,69				1,39	0,70		UTC
Maximum value	11,16	0,69	-	-	-	1,39	0,70	1 >	0 >
Mean disease severity (%)	11,16	0,69				1,39	0,70	0 =	1 =
Abbott efficacy (%)	0,00%	93,82 %				87,54 %	93,7 3%	0 <	0 <
% Disease severity LEAF - 36-54 DA-B									
Number of values	11					11	11	UTC	CA33 01 0,7 l/ha
Minimum value	19,80					1,68	1,23		UTC
Maximum value	95,48	-	-	-	-	11,70	10,0 0	11 >	0 >
Mean disease severity (%)	42,85					5,20	3,74	0 =	7 =
Abbott efficacy (%)	0,00%					86,25 %	90,5 8%	0 <	4 <
Number of values	10	10				10	10	CA2445	CA2445
Minimum value	19,80	1,77				1,68	1,23	0,7 l/ha	0,7 l/ha
Maximum value	95,48	25,18	-	-	-	11,70	10,0 0	0 >	0 >
Mean disease severity (%)	44,69	6,58				5,25	3,82	7 =	10 =
Abbott efficacy (%)	0,00%	87,07 %				86,80 %	90,8 1%	3 <	0 <
Number of values	2	2	2			2	2	PROSARO	PROSARO
Minimum value	45,00	4,65	2,70			7,05	3,95	0,75 l/ha	0,75 l/ha

Treatment name	UNTREATED CHECK	CA2 445	PROSARO	PROPULSE	ORIUS	CA3 301	CA 3301	No of trials where CA3301		No of trials where CA3301	
Rate		0,7	0,75	1	1	0,6	0,7	at 0,6 l/ha is		at 0,7 l/ha is	
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	L/ha	>, = or <		>, = or <	
Appl. Code		AB	AB	AB	AB	AB	AB	AB	compared to		compared to
Maximum value	47,50	5,90	3,80	-	-	11,70	5,20	0 >		0 >	
Mean disease severity (%)	46,25	5,28	3,25			9,38	4,58	0 =		2 =	
Abbott efficacy (%)	0,00%	88,62 %	93,00 %			79,85 %	90,14 %	2 <		0 <	
Number of values	3	3		3		3	5	PROPULSE		PROPULSE	
Minimum value	38,75	5,00		5,00		5,00	10,00	1,0 l/ha		1,0 l/ha	
Maximum value	70,00	10,00	-	10,00	-	10,00	6,67	0 >		0 >	
Mean disease severity (%)	56,25	6,67		6,67		6,67	88,16	3 =		3 =	
Abbott efficacy (%)	0,00%	88,16 %		88,16 %		88,16 %	88,16 %	0 <		0 <	
Number of values	1				1	1	1	ORIUS		ORIUS	
Minimum value	24,45				5,30	4,70	2,86	1,0 l/ha		1,0 l/ha	
Maximum value	24,45	-	-	-	5,30	4,70	2,86	0 >		0 >	
Mean disease severity (%)	24,45				5,30	4,70	2,86	1 =		1 =	
Abbott efficacy (%)	0,00%				78,32 %	80,78 %	88,30 %	0 <		0 <	
% Disease severity STEM - 36-57 DA-B											
Number of values	11					11	11	UTC	CA3301 0,7 l/ha	UTC	CA3301 0,6 l/ha
Minimum value	8,43					0,94	0,49				
Maximum value	88,82	-	-	-	-	30,00	30,00				
Mean disease severity (%)	29,67					6,14	5,21				
Abbott efficacy (%)	0,00%					78,81 %	84,91 %	0 <	4 <	0 <	0 <
Number of values	10	10				10	10	CA2445		CA2445	
Minimum value	8,43	0,74				0,94	0,49	0,7 l/ha		0,7 l/ha	
Maximum value	88,82	30,00	-	-	-	30,00	30,00	0 >		0 >	
Mean disease severity (%)	30,01	5,35				5,99	5,18	6 =		10 =	
Abbott efficacy (%)	0,00%	84,52 %				79,61 %	85,52 %	4 <		0 <	
Number of values	2	2	2			2	2	PROSARO		PROSARO	
Minimum value	13,40	1,08	0,88			3,13	0,93	0,75 l/ha		0,75 l/ha	
Maximum value	15,98	1,75	1,05	-	-	4,73	1,40	0 >		0 >	
Mean disease severity (%)	14,69	1,42	0,96			3,93	1,17	0 =		2 =	

Treatment name	UNTREATED CHECK	CA2445	PROSARO	PROPULSE	ORIUS	CA3301	CA3301	No of trials where CA3301	No of trials where CA3301
Rate		0,7	0,75	1	1	0,6	0,7	at 0,6 l/ha	at 0,7 l/ha
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	L/ha	is	is
Appl. Code		AB	AB	AB	AB	AB	AB	>, = or <	>, = or <
severity (%)								compared to	compared to
Abbott efficacy (%)	0,00%	90,49 %	93,43 %			73,52 %	92,15 %	2 <	0 <
Number of values	3	3		3		3	3	PROPULSE	PROPULSE
Minimum value	30,00	5,00		5,00		5,00	5,00	1,0 l/ha	1,0 l/ha
Maximum value	50,00	30,00	-	30,00	-	30,00	30,00	0 >	0 >
Mean disease severity (%)	43,33	15,00		15,00		15,00	15,00	3 =	3 =
Abbott efficacy (%)	0,00%	67,78 %		67,78 %		67,78 %	67,78 %	0 <	0 <
Number of values	1				1	1	1	ORIUS	ORIUS
Minimum value	26,00				7,75	7,60	5,50	1,0 l/ha	1,0 l/ha
Maximum value	26,00	-	-	-	7,75	7,60	5,50	0 >	0 >
Mean disease severity (%)	26,00				7,75	7,60	5,50	1 =	1 =
Abbott efficacy (%)	0,00%				70,19 %	70,77 %	78,85 %	0 <	0 <
% Disease severity POD - 38-57 DA-B									
Number of values	8					8	8	UTC	CA3301
Minimum value	5,60					0,00	0,00	0,7 l/ha	0,6 l/ha
Maximum value	60,00	-	-	-	-	50,00	50,00	8 >	0 >
Mean disease severity (%)	23,29					11,09	10,53	0 =	6 =
Abbott efficacy (%)	0,00%					68,64 %	73,69 %	0 <	2 >
Number of values	7	7				7	7	CA2445	CA2445
Minimum value	5,60	0,00				0,00	0,00	0,7 l/ha	0,7 l/ha
Maximum value	60,00	50,00	-	-	-	50,00	50,00	0 >	0 >
Mean disease severity (%)	25,21	11,83				12,31	11,75	5 =	7 =
Abbott efficacy (%)	0,00%	72,11 %				67,78 %	72,83 %	2 <	0 <

Treatment name	UNTREATED CHECK	CA2 445	PROSARO	PROPULSE	ORIUS	CA3 301	CA 3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,7 l/ha is >, = or < compared to
Rate		0,7	0,75	1	1	0,6	0,7		
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	AB	AB	AB		
Number of values	2	2	2			2	2	PROSARO	PROSARO
Minimum value	11,03	1,25	0,88			2,70	1,03	0,75 l/ha	0,75 l/ha
Maximum value	12,60	1,40	0,95	-	-	3,00	1,05	0 >	0 >
Mean disease severity (%)	11,82	1,33	0,91			2,85	1,04	0 =	2 =
Abbott efficacy (%)	0,00%	88,69 %	92,20 %			75,69 %	91,16 %	2 <	0 <
Number of values	3	3		3		3	3	PROPULSE	PROPULSE
Minimum value	30,00	10,00		10,00		10,00	10,00	1,0 l/ha	1,0 l/ha
Maximum value	60,00	50,00	-	50,00	-	50,00	50,00	0 >	0 >
Mean disease severity (%)	46,67	26,67		26,67		26,67	26,67	3 =	3 =
Abbott efficacy (%)	0,00%	43,33 %		43,33 %		43,33 %	43,33 %	0 <	0 <
Number of values	1				1	1	1	ORIUS	ORIUS
Minimum value	9,85				2,95	2,50	2,00	1,0 l/ha	1,0 l/ha
Maximum value	9,85	-	-	-	2,95	2,50	2,00	0 >	0 >
Mean disease severity (%)	9,85				2,95	2,50	2,00	1 =	1 =
Abbott efficacy (%)	0,00%				70,05 %	74,62 %	79,70 %	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (%)

Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Conclusion South-Eastern EPPO zone - Use of CA3301 at 2x 0.6-0.7 l/ha against ERYSCR

In the South-Eastern EPPO zone, 15 trials were available against *Erysiphe cruciferarum* on oilseed rape. 15 trials out of 15 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to several authorised reference products on disease severity (%). Among these 15 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis.

In the first group of trials, CA3301 was applied twice in spring. Two assessment timings were available on leaves and stems whereas a single assessment timing was available on pods. Applied at 0.6 l/ha,

CA3301 provided 92.74% mean efficacy on leaves and 87.54% mean efficacy on stems around 2-3 weeks after the 2nd application. At this dose rate, CA3301 showed 86.25% mean efficacy on leaves, 78.81% mean efficacy on stem and 68.64% mean efficacy on pods.

Applied at 0.7 l/ha, CA3301 provided 95.46% mean efficacy on leaves and 93.73% mean efficacy on stem around 2-3 weeks after the 2nd application. At this dose rate, CA3301 showed 90.58% mean efficacy on leaves, 84.91% mean efficacy on stem and 73.69% mean efficacy on pods.

In the second group of trials, CA3301 was applied once in autumn and once in spring. Two assessment timings were available and the analysis was conducted on leaves, stems and pods. When applied at 0.6 l/ha, CA3301 showed 69.09% of efficacy to control the disease on leaves around 5-6 weeks after the 2nd application. Before harvest, at this dose rate, CA3301 provided 55.47% efficacy on stem and 58.39% efficacy on pods.

When applied at 0.7 l/ha, CA3301 showed 78.08% of efficacy to control the disease on leaves around 5-6 weeks after the 2nd application. Before harvest, at 0.7 l/ha, CA3301 provided 63.69% efficacy on stem and 68.12% efficacy on pods.

In both cases, in overall the data demonstrate the later preventative effect of CA3301 with an equivalent medium or high level of efficacy. In all trials, CA3301 at 0.6-0.7 l/ha gave equivalent or very comparable disease control compared to the several authorised reference products. Moreover, in the majority of assessments there were no significant differences in disease control between the rate of 0.6 l/ha or 0.7 l/ha of CA3301. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for control of *Erysiphe cruciferarum* whatever the timing of application and that the rate of 0.7 l/ha will be useful in more challenging conditions.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.7 l/ha to control *Erysiphe cruciferarum* on oilseed rape in the South-Eastern EPPO zone. Moreover, these 2 applications can be carried out in spring or first in autumn and then the 2nd in spring.

Use of CA3301 at 2x 0.6-0.7 l/ha against ERYSCR with 2 applications in spring – Data relevant for Poland

According to guidance provided by the Polish National authority, where data from the North-East EPPO zone is insufficient in numbers, they will also take into account trials placed in the neighbouring countries of Germany, Czech Republic and Slovakia. In this situation, 7 trials were available against *Erysiphe cruciferarum* on oilseed rape. 4 trials out of 7 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to several authorised reference products on disease severity (%). In Poland and the neighbouring countries, among the 7 4 valid trials, CA3301 was applied twice in spring in all trials, first at crop stages BBCH 37-57 and the 2nd application was at BBCH 65-67. 2 assessment timings were available and the analysis was conducted on leaves, on stems and on pods.

Summary results are presented in

Table 3.2-647.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6-0.7 l/ha to control *Erysiphe cruciferarum*. On leaves, when applied at 0.6 l/ha, CA3301 showed 91.09% of efficacy to control the disease 4 weeks after the 2nd application and 72.57% mean efficacy before harvest. Moreover, at this dose rate CA3301 showed 72.60% of efficacy on stems and 75.33% mean efficacy on pods before harvest.

On leaves, when applied at 0.7 l/ha, CA3301 showed 95.84% of efficacy to control the disease 4 weeks after the 2nd application and 83.61% mean efficacy before harvest. Moreover, at this dose rate CA3301 showed 87.71% of efficacy on stems and 87.34% mean efficacy on pods before harvest.

Considering all elements presented above, it is justified to claim the registration of 2 applications in spring of CA3301 at 0.6-0.7 l/ha to control *Erysiphe cruciferarum* on oilseed rape in Poland.

Table 512 017 - Summary table - efficacy evaluation for PROSAR - Data relevant for Fokine										
Treatment name	UNTREATED CHECK	CA24 45 0,7 L/ha AB	PROSA RO 0,75 L/ha AB	ORI US 1 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,7 l/ha is >, = or < compared to	
% Disease severity LEAF - 28 DA-B										
Number of values	1			1	1	1	UTC	CA2445 0,7 l/ha	UTC	CA2445 0,7 l/ha
Minimum value	5,05			1,05	0,45	0,21		CA3301 0,7 l/ha		CA3301 0,6 l/ha
Maximum value	5,05	-	-	1,05	0,45	0,21	1 >	0 >	1 >	0 >
Mean disease severity (%)	5,05			1,05	0,45	0,21	0 =	1 =	0 =	1 =
Abbott efficacy (%)	0,00%			79,21 %	91,09 %	95,84 %	0 <	0 <	0 <	0 <
% Disease severity LEAF - 50-59 DA-B										
Number of values	4				4	4	UTC	CA3301 0,7 l/ha	UTC	CA3301 0,6 l/ha
Minimum value	24,45				4,70	2,86		CA3301 0,7 l/ha		CA3301 0,6 l/ha
Maximum value	47,50	-	-	-	15,13	10,28	4 >	0 >	4 >	2 >
Mean disease severity (%)	36,77				9,64	5,57	0 =	2 =	0 =	2 =
Abbott efficacy (%)	0,00%				72,57 %	83,61 %	0 <	2 <	0 <	0 <
Number of values	3	3			3	3	CA2445 0,7 l/ha		CA2445 0,7 l/ha	
Minimum value	30,13	4,65			7,05	3,95				
Maximum value	47,50	10,03	-	-	15,13	10,28	0 >		0 >	
Mean disease severity (%)	40,88	6,86			11,29	6,48	2 =		3 =	
Abbott efficacy (%)	0,00%	81,32 %			69,83 %	82,05 %	1 <		0 <	
Number of values	2	2	2		2	2	PROSARO 0,75 l/ha		PROSARO 0,75 l/ha	
Minimum value	45,00	4,65	2,70		7,05	3,95				
Maximum value	47,50	5,90	3,80	-	11,70	5,20	0 >		0 >	
Mean disease severity (%)	46,25	5,28	3,25		9,38	4,58	0 =		2 =	
Abbott efficacy (%)	0,00%	88,62 %	93,00%		79,85 %	90,14 %	2 <		0 <	
Number of values	1			1	1	1	ORIUS 1,0 l/ha		ORIUS 1,0 l/ha	
Minimum value	24,45			5,30	4,70	2,86				
Maximum value	24,45	-	-	5,30	4,70	2,86	0 >		0 >	
Mean disease severity (%)	24,45			5,30	4,70	2,86	1 =		1 =	
Abbott efficacy (%)	0,00%			78,32 %	80,78 %	88,30 %	0 <		0 <	
% Disease severity STEM - 50-53 DA-B										

Number of values	3				3	3	UTC	CA3301 0,7 l/ha	UTC	CA3301 0,6 l/ha
Minimum value	13,40				3,13	0,93				
Maximum value	26,00	-	-	-	7,60	5,50	3 >	0 >	3 >	2 >
Mean disease severity (%)	18,46				5,15	2,61	0 =	1 =	0 =	1 =
Abbott efficacy (%)	0,00%				72,60 %	87,71 %	0 <	2 <	0 <	0 <
Number of values	2	2	2		2	2	CA24 45	PROSARO	CA24 45	PROSARO
Minimum value	13,40	1,08	0,88		3,13	0,93	0,7 l/ha	0,75 l/ha	0,7 l/ha	0,75 l/ha
Maximum value	15,98	1,75	1,05	-	4,73	1,40	0 >	0 >	0 >	0 >
Mean disease severity (%)	14,69	1,41	0,96		3,93	1,17	0 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	90,49 %	93,43		73,52	92,15	2 <	2 <	0 <	0 <

Treatment name	UNTREATED CHECK	CA244 5	PROSAR O	ORIUS S	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,7 l/ha is >, = or < compared to	
Rate		0,7	0,75	1	0,6	0,7				
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB	AB				
Number of values	1			1	1	1	ORIUS 1,0 l/ha		ORIUS 1,0 l/ha	
Minimum value	26,00			7,75	7,60	5,50				
Maximum value	26,00	-	-	7,75	7,60	5,50	0 >		0 >	
Mean disease severity (%)	26,00			7,75	7,60	5,50	1 =		1 =	
Abbott efficacy (%)	0,00%			70,19 %	70,77 %	78,85 %	0 <		0 <	
% Disease severity POD - 50-53 DA-B										
Number of values	3				3	3	UTC	CA3301 0,7 l/ha	UTC	CA3301 0,6 l/ha
Minimum value	9,85				2,50	1,03				
Maximum value	12,60	-	-	-	3,00	2,00	3 >	0 >	3 >	2 >
Mean disease severity (%)	11,16				2,73	1,36	0 =	1 =	0 =	1 =
Abbott efficacy (%)	0,00%				75,33 %	87,34 %	0 <	2 <	0 <	0 <
Number of values	2	2	2		2	2	CA244 5	PRO- SARO	CA244 5	PRO- SARO
Minimum value	11,03	1,25	0,88		2,70	1,03	0,7 l/ha	0,75 l/ha	0,7 l/ha	0,75 l/ha
Maximum value	12,60	1,40	0,95	-	3,00	1,05	0 >	0 >	0 >	0 >
Mean disease severity (%)	11,82	1,33	0,91		2,85	1,04	0 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	88,69 %	92,20%		75,69 %	91,16 %	2 <	2 <	0 <	0 <
Number of values	1			1	1	1	ORIUS 1,0 l/ha		ORIUS 1,0 l/ha	
Minimum value	9,85			2,95	2,50	2,00				
Maximum value	9,85	-	-	2,95	2,50	2,00	0 >		0 >	
Mean disease severity (%)	9,85			2,95	2,50	2,00	1 =		1 =	
Abbott efficacy (%)	0,00%			70,05 %	74,62 %	79,70 %	0 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

2 valid field trials were carried out in **the Maritime EPPO climatic zone**. 2 applications in autumn and spring were used in 1 out of 2 trials. CA3301 applied at dose rate of 0,6-0,7 l/ha achieved very low efficacy (33,71% and 28,31% respectively). 2 applications in spring were used in single trial. The test product at 0,6 l/ha presented low level of control and higher effectiveness was after applied of 0,7 l/ha (65,88%). Due to the limited number of trials, the cMSs are kindly asked to consider this on the national level.

No valid trials have been submitted in **the North-East EPPO zone**. However, the results from 4 trials conducted in the Czech Republic and Slovakia have been included to the overall calculation to support of Polish registration. In spite of, the number of trials is insufficient **and no extrapolation is possible. This use can not be accepted in Poland. However, ERYSCR has local importance for winter oilseed rape in Poland and this number of trials can be accepted.**

15 valid trials were available in **the South-East EPPO zone**. 2 applications in autumn and spring were used in 4 out of 15 trials. CA3301 applied at dose rate of 0,6 l/ha achieved low to medium efficacy after 31-62 DA-B. The dose rate of 0,7 l/ha showed medium level of control after the same time. 2 applications in spring were used in 11 out of 15 trials. The test product at 0,6-0,7 l/ha showed medium to high level of control after 14-57 days after second application. 2 additional trials with 2 applications in spring have been submitted to support of product registration in other zones. The results from these trials confirmed the conclusions from the SE zone.

3.2.3.13 Oilseed rape (BRSNW) / *Pyrenopeziza brassicae* (PYRPBR)

Materials and Methods – Oilseed rape - PYRPBR

General Materials and Methods information are given in paragraph “General Materials and Methods” located in introduction of the section “3.2.3 Efficacy tests (KCP 6.2)”.

Between 2018 and 2020, a total of 5 trials were conducted in several countries of the Maritime EPPO zone to evaluate the efficacy of CA3301 against *Pyrenopeziza brassicae* on oilseed rape. The trials were carried out by certified testing institutes.

For this pathogen trials were focused on the Maritime EPPO zone where the disease is most problematic and conditions are more challenging.

In the Maritime EPPO zone, 5 trials were performed in United Kingdom (1), France (3) and Denmark (1) (see

Table 3.2-648).

Table 3.2-648: Presentation of trials – Oilseed rape (BRSNW)

Crop(s) *	Tar- get(s)*	Country	Year s	Type of trial* *	Number of trials (number of valid trials)				GEP, non-GEP, offi- cial***	Comments (any other relevant in- formation)
					Mari- time zone	Mediterra- nean zone	North- East- ern zone	South- East- ern zone		
BRSN W	PYRPBR	United kingdom	2020	MED + E	1 (0)	-	-	-	GEP	
		France	2020	MED + E	3 (3)	-	-	-	GEP	
		Denmar k	2020	MED + E	1 (0)	-	-	-	GEP	
TOTAL	-	-	2018- 2020	MED + E	5 (3)	-	-		GEP	

- * According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).
** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.
*** GEP: Good Experimental Practices. Official: carried out by a national official organisation

In all trials, CA3301 was compared to at least one commercial fungicide used as standard reference for comparison (see Table 3.2-649).

Table 3.2-649: Efficacy evaluation - Presentation of reference standards used in trials – Oilseed rape (BRSNW) – PYRPBR – Maritime EPPO zone

Crop(s)	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
BRSNW	JOAO	FR (N)	2060116	Prothioconazole	EC	250 g/l	2 x 0.7 l/ha	2 x 0.7 l/ha	CA2445 in some trials
	PRO-LINE EC 250	DK	18-473	Prothioconazole	EC	250 g/l	2 x 0.8 l/ha	2 x 0.5-0.6-0.7 l/ha	CA2445 in some trials
	PRO-LINE	UK	12084	Prothioconazole	EC	250 g/l	2 x 0.7 l/ha	2 x 0.7 l/ha	CA2445 in some trials

CA2445 is the code name used in some trials and in the analysis for all the equivalent Prothioconazole reference products at 250 g/l.

Material and Methods elements are summarized in Table 3.2-650

Table 3.2-650: Details on trial methodology – Oilseed rape (BRSNW) – PYRPBR

Maritime EPPO zone		
Trials	Total number (valid number)	5 (3)
	Supportive trials	-
Guidelines	General guidelines	PP 1/135(4) PP 1/152 (4) PP 181 (4)
	Specific guidelines	PP 1/78 (3)
Experimental design	Plot design	Randomized Complete Blocks, Untreated included
	Plot size	30-45 m ²
	Number of replications	4
Crop	Trials per crop	BRSNW (5)
	Varieties per crop	Alasco (1), Feliciano KWS (1), Architect (2), DK Expression (1)
	Sowing period	August (3), September (1), October (1)
Application	Crop stage (BBCH)* at application	A: BBCH 55 or BBCH 17-18 B: BBCH 65-69
	Timing Pest stage at application	BBCH 17-69 A: PRINFC (2), MIXED (2), N/A (1) B: MIXED (4), N/A (1)
	Number of applications Intervals between applications	1 application (0) 2 applications (25-38 or 135-198 days) (22)

	Spray volumes	A: 200-250 l/ha B: 200-250 l/ha
Assessment	Assessment types	Disease severity (%), Disease incidence (%), Green leaf area (%), Phytotoxicity (%), Vigor (0-10)
	Assessment dates	0 DA-A, 13-21 DA-A, -1-1 DA-B, 14-28 DA-B, 42-74 DA-B
Other relevant information	e.g. Soil type, pH (in case of soil active substance ...)	Not relevant
	e.g. Natural / artificial inoculation...	Natural (5)
	e.g. Field / Greenhouse...	Field trials

Use of CA3301 at 2x 0.6-0.7 l/ha against PYRPBR with one application in autumn and one application in spring - Maritime EPPO zone

In the Maritime EPPO zone, 5 trials were available against *Pyrenopeziza brassicae* on oilseed rape. 3 trials out of 5 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to several authorised reference products on disease severity (%). Among the 3 valid trials, CA3301 was applied once in autumn and once in spring in 2 trials, first at crop stages BBCH 18-19 and the 2nd application was at BBCH 65-67.

Summary results are presented in Table 3.2-651.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6-0.7 l/ha to control *Pyrenopeziza brassicae*. On leaves, applied at 0.6 l/ha, CA3301 showed 43.94% of efficacy on disease severity 2 weeks after the 2nd application and 33.04% before harvest. At this dose rate, CA3301, showed 64.88% mean efficacy on stems two weeks after the 2nd application and 47.40% before harvest.

Applied at 0.6 l/ha, CA3301 showed 64.98% of efficacy on leaves 2 weeks after the 2nd application and 37.37% before harvest. At this dose rate, CA3301 showed 70.57% mean efficacy on stems two weeks after the 2nd application and 67.92% before harvest.

In the Maritime EPPO zone, in a limited dataset, CA3301 at 0.6-0.7 l/ha showed low to medium efficacy in reducing the severity of *Pyrenopeziza brassicae* on oilseed rape on leaves and stems. To put these low levels of efficacy into perspective, it is important to notice that the 2nd application timing of EU20-014-19 was followed by a very rainy week (25.5mm) which can cause leaching of the products and increase disease pressure. The performance of the tested product was overall equivalent to the authorised reference products CA2445 applied at 0.7 l/ha except for CA3301 at 0.6 l/ha in one trial. Averaged across the dataset the efficacy of CA3301 at 0.6 l/ha was comparable to that of the dose rate of 0.7 l/ha, however at some assessments a clear numerical benefit was derived from increasing the dose rate to 0.7 l/ha. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for control of *Pyrenopeziza brassicae* and that 0.7 l/ha dose rate may be appropriate in more challenging conditions.

Considering all elements presented above, it is justified to claim the registration of 2 applications, one in autumn and one in spring of CA3301 at 0.6-0.7 l/ha to control *Pyrenopeziza brassicae* on oilseed rape in the Maritime EPPO zone.

Table 3.2-651: Summary table - Efficacy evaluation – Oilseed rape – PYRPBR - Maritime EPPO zone

Treatment name	UNTREATED	CA24	CA33	CA33	No of trials where	No of trials where
Rate	CHECK	45	01	01	CA3301	CA3301
Rate unit		0,7	0,6	0,7	at 0,6 l/ha is >, = or	at 0,7 l/ha is >, = or
Appl. Code		L/ha	L/ha	L/ha	<	<
		AB	AB	AB	compared to	compared to

% Disease severity LEAF - 14 DA-B										
Number of values	1	1	1	1	UT	CA24	CA33	UT	CA24	CA33
					C	45	01	C	45	01
Minimum value	12,45	4,01	6,98	4,36		0,7	0,7		0,7	0,6
						l/ha	l/ha		l/ha	l/ha
Maximum value	12,45	4,01	6,98	4,36	0 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	12,45	4,01	6,98	4,36	1 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	67,79 %	43,94 %	64,98 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity STEM - 14 DA-B										
Number of values	1	1	1	1	UT	CA24	CA33	UT	CA24	CA33
					C	45	01	C	45	01
Minimum value	6,15	2,07	2,16	1,81		0,7	0,7		0,7	0,6
						l/ha	l/ha		l/ha	l/ha
Maximum value	6,15	2,07	2,16	1,81	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	6,15	2,07	2,16	1,81	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	66,34 %	64,88 %	70,57 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity LEAF - 42 DA-B										
Number of values	1	1	1	1	UT	CA24	CA33	UT	CA24	CA33
					C	45	01	C	45	01
Minimum value	16,86	10,78	11,29	10,56		0,7	0,7		0,7	0,6
						l/ha	l/ha		l/ha	l/ha
Maximum value	16,86	10,78	11,29	10,56	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	16,86	10,78	11,29	10,56	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	36,06 %	33,04 %	37,37 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity STEM - 60-83 DA-B										
Number of values	2	2	2	2	UT	CA24	CA33	UT	CA24	CA33
					C	45	01	C	45	01
Minimum value	6,48	1,72	1,93	2,15		0,7	0,7		0,7	0,6
						l/ha	l/ha		l/ha	l/ha
Maximum value	15,33	2,23	11,56	4,75	1 >	0 >	0 >	2 >	0 >	0 >
Mean disease severity (%)	10,91	1,98	6,75	3,45	1 =	1 =	2 =	0 =	2 =	2 =
Abbott efficacy (%)	0,00%	79,46 %	47,40 %	67,92 %	0 <	1 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)
(conversely for '<')

Levels of efficacy (% Abbott efficacy)	
>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 2x 0.6-0.7 l/ha against PYRPBR with 2 applications in spring – Maritime EPPO zone

In the Maritime EPPO zone, 5 trials were available against *Pyrenopeziza brassicae* on oilseed rape. 3 trials out of 5 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to several authorised reference products on disease severity (%). Among these 3 valid trials, CA3301 was applied twice in spring in 1 trial, first at crop stage BBCH 55 and the 2nd application was at BBCH 69. The efficacy evaluation has been conducted focussing on CA3301 applied at 0.6 and 0.7 l/ha.

Summary results are presented in Table 3.2-652.

When evaluating the reduction of disease severity, the data demonstrated a positive effect of CA3301 at 0.6-0.7 l/ha to control *Pyrenopeziza brassicae*. On leaves, applied at 0.6 l/ha, CA3301 showed 35.94% of efficacy on disease severity 3 weeks after the 2nd application. At this dose rate, CA3301, showed 32.19% mean efficacy on stems and 42.51% on pods before harvest.

Applied at 0.7 l/ha, CA3301 showed 51.88% of efficacy on disease severity 3 weeks after the 2nd application. At this dose rate, CA3301, showed 46.52% mean efficacy on stems and 40.20% on pods before harvest.

In the Maritime EPPO zone, in a limited dataset, CA3301 at 0.6-0.7 l/ha showed low efficacy in reducing the severity of *Pyrenopeziza brassicae* on oilseed rape on leaves, stems and pods. To put these low levels of efficacy into perspective, it is important to notice that the 2nd application timing was followed by a very rainy week (33.5mm) which can cause leaching of the products and increase disease pressure. The performance of the tested product was overall equivalent to the authorised reference products CA2445 applied at 0.7 l/ha. Averaged across the dataset the efficacy of CA3301 at 0.6 l/ha was comparable to that of the dose rate of 0.7 l/ha, however at some assessments a clear numerical benefit was derived from increasing the dose rate to 0.7 l/ha. Therefore, it is envisaged that in most instances applications of 0.6 l/ha will be sufficient for control of *Pyrenopeziza brassicae* and that 0.7 l/ha dose rate may be appropriate in challenging conditions.

Considering all elements presented above, it is justified to claim the registration of 2 applications in spring of CA3301 at 0.6-0.7 l/ha to control *Pyrenopeziza brassicae* on oilseed rape in the Maritime EPPO zone.

Table 3.2-652: Summary table - Efficacy evaluation – Oilseed rape – PYRPBR - Maritime EPPO zone

Table 5.2-6.5.2: Summary table - Efficacy evaluation - Oncoed Rape - FPKI BR - Maritime LFP O Zone										
Treatment name	UNTREATED CHECK	CA24	CA33	CA33	No of trials where			No of trials where		
Rate		45	01	01	CA3301			CA3301		
Rate unit		0,7	0,6	0,7	at 0,6 l/ha is >, = or			at 0,7 l/ha is >, = or <		
Appl. Code		L/ha	L/ha	L/ha	<					
		AB	AB	AB	compared to			compared to		
% Disease severity LEAF - 21 DA-B										
Number of values	1	1	1	1	UT C	CA24 45	CA33 01	UT C	CA24 45	CA33 01
Minimum value	18,39	10,68	11,78	8,85		0,7 l/ha	0,7 l/ha		0,7 l/ha	0,6 l/ha
Maximum value	18,39	10,68	11,78	8,85	0 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	18,39	10,68	11,78	8,85	1 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	41,92 %	35,94 %	51,88 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity STEM - 57 DA-B										
Number of values	1	1	1	1	UT C	CA24 45	CA33 01	UT C	CA24 45	CA33 01
Minimum value	27,90	16,44	18,92	14,92		0,7 l/ha	0,7 l/ha		0,7 l/ha	0,6 l/ha
Maximum value	27,90	16,44	18,92	14,92	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	27,90	16,44	18,92	14,92	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	41,08 %	32,19 %	46,52 %	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity POD - 50 DA-B										
Number of values	1	1	1	1	UT C	CA24 45	CA33 01	UT C	CA24 45	CA33 01
Minimum value	13,88	8,93	7,98	8,30		0,7 l/ha	0,7 l/ha		0,7 l/ha	0,6 l/ha
Maximum value	13,88	8,93	7,98	8,30	1 >	0 >	0 >	1 >	0 >	0 >
Mean disease severity (%)	13,88	8,93	7,98	8,30	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	0,00%	35,66 %	42,51 %	40,20 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)
(conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Conclusion Maritime EPPO zone - Use of CA3301 at 2x 0.6-0.7 l/ha against PYRPBR

In the Maritime EPPO zone, 5 trials were available against *Pyrenopeziza brassicae* on oilseed rape. 3 trials out of 5 were considered valid and were included to support the efficacy evaluation of CA3301 at 0.6-0.7 l/ha applied twice, compared to several authorised reference products on disease severity (%). Among these 3 trials, CA3301 was applied according to two different timings of application and the trials were separated in two groups in the analysis.

In the first group of trials, CA3301 was applied twice in spring. The data recorded were available on leaves and stem. On leaves, applied at 0.6 l/ha, CA3301 showed 43.94% of efficacy on disease severity 2 weeks after the 2nd application and 33.04% before harvest. At this dose rate, CA3301, showed 64.88% mean efficacy on stems two weeks after the 2nd application and 47.40% before harvest. Applied at 0.7 l/ha, CA3301 showed 64.98% of efficacy on leaves 2 weeks after the 2nd application and 37.37% before harvest. At this dose rate, CA3301 showed 70.57% mean efficacy on stems two weeks after the 2nd application and 67.92% before harvest.

In the second group of trials, CA3301 was applied once in autumn and once in spring. The data recorded were available on leaves, stems and pods. On leaves, applied at 0.6 l/ha, CA3301 showed 35.94% of efficacy on disease severity 3 weeks after the 2nd application. At this dose rate, CA3301, showed 32.19% mean efficacy on stem and 42.51% on pods before harvest. Applied at 0.7 l/ha, CA3301 showed 51.88% of efficacy on disease severity 3 weeks after the 2nd application. At this dose rate, CA3301, showed 46.52% mean efficacy on stem and 40.20% on pods before harvest.

In both cases, in overall the data demonstrate a low to medium efficacy on leaves, stems, pods to control *Pyrenopeziza brassicae* on oilseed rape. To put these low levels of efficacy into perspective, it is important to notice that the 2nd application timing was followed by a very rainy week (25.5-33.5mm) in 2 trials out of 3 which can cause leaching of the products and increase disease pressure. Although the dataset is very limited in the second group of trials, it is envisaged that in most instances 2 applications of CA330 in spring or one in autumn and one in spring allowed an acceptable control of *Pyrenopeziza brassicae* whatever the timing of application. This is further supported by the fact that efficacy was comparable to reference products already authorised for this use.

Considering all elements presented above, it is justified to claim the registration of 2 applications of CA3301 at 0.6-0.7 l/ha to control *Pyrenopeziza brassicae* on oilseed rape in the Maritime EPPO zone.

Other EPPO zones

(Bush, M. N., & Flind, A. (2012). Management of *Pyrenopeziza brassicae* in oilseed rape in Northern Britain. In *The Dundee Conference. Crop Protection in Northern Britain, 2012, Dundee, UK, 28-29 February 2012* (pp. 101-105). The Association for Crop Protection in Northern Britain.)

(Oxley, S. J., & Walters, D. R. (2012). Control of light leaf spot (*Pyrenopeziza brassicae*) on winter oilseed rape (*Brassica napus*) with resistance elicitors. *Crop Protection*, 40, 59-62)

For this pathogen trials were focused on the Maritime EPPO zone where the disease is most problematic and conditions are more challenging. In the North-East^{era}, South-East^{era} and Mediterranean EPPO zones, no trials were available against *Pyrenopeziza brassicae* on oilseed rape.

However, other similar prothioconazole products such as Proline are authorised for use against *Pyrenopeziza brassicae* at the same dose rate of 0.7 l/ha, and since data across the various pathogens of oilseed rape has demonstrated comparability with this approved product it is anticipated that CA3301 applied at the proposed dose rates would also provide acceptable control of this pathogen. Furthermore, the data generated in the Maritime EPPO zone supports the use against *Pyrenopeziza brassicae*, and across the dataset on oilseed rape the efficacy against pathogens appears comparable regardless of the climatic zone.

Considering all elements presented above, it is justified to claim the registration of 2 applications in spring or 1 application in autumn and 1 in spring of CA3301 at 0.6-0.7 l/ha to control *Pyrenopeziza brassicae* on oilseed rape across all EPPO climatic zones.

Comments of zRMS:

3 valid trials were carried out in **the Maritime EPPO climatic zone**. 2 application in autumn and spring were used in 2 out of 3 trials. CA3301 applied at dose rate of 0,6-0,7 l/ha achieved low to medium efficacy after 14-83 DA-B. The significant better results was observed after used of higher dose. The single trial has been submitted for 2 applications in spring. The test product was not effective in control of PYRPBR with results amounted <50%. Due to the limited number of trials and very low effectiveness, the cMSs are kindly asked to consider this use on the national level.

No valid trials have been submitted in **the North-East and South-East EPPO zone**. The cMSs from the SE zone are kindly asked to consider this use on the national level. This use can not be accepted in Poland because an extrapolation is not possible.

3.2.3.14 Oilseed rape (BRSNW) / Green leaf area

Use of CA3301 with one application in autumn and one application in spring – Maritime EPPO zone

Green leaf area was recorded in 7 valid trials on oilseed rape after two applications of CA3301 at 0.6-0.7 l/ha. Among these 7 trials, CA3301 was applied according two different timings of application and the trials were separated in two groups in the analysis. Among the 7 valid trials, CA3301 was applied once in autumn and once in spring in 6 trials. In these trials, the green leaf area was assessed at 64-84 DA-B on the whole plant.

Summary results are presented in Table 3.2-653.

Data demonstrated a positive effect of 2 applications of CA3301 at 0.6-0.7 l/ha compared to untreated control for the increase of green leaf area on oilseed rape infected by foliar diseases. In the 6 trials assessing green leaf area on the whole plant, an augmentation of 88.83% and 62.73% was recorded with CA3301 at 0.7 l/ha and 0.6 l/ha compared to the untreated check on oilseed rape.

Considering the whole dataset, the positive effects of CA3301 at 0.6-0.7 l/ha on green leaf area were overall equivalent to those of reference standards BISTRO at 0.6 l/ha, CA2445 at 0.7 l/ha and CAMBA at 1.5 l/ha.

Therefore, it is concluded that 2 applications (one in autumn and one in spring) of CA3301 at 0.6-0.7 l/ha will have a positive effect on the green leaf area in oilseed rape affected by a range of pathogens in the Maritime EPPO zone.

Treatment name	UNTREATED CHECK	BISTR O 0,6 L/ha AB	CA244 5 0,7 L/ha AB	CARAMB A 1,5 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,7 l/ha is >, = or < compared to		
% Green leaf area - 64-84 DA-B										
Number of values	6		6		6	6	UTC	CA330 1 0,7 l/ha	UTC	CA330 1 0,6 l/ha
Minimum value	1,25		2,75		2,25	2,50				
Maximum value	71,25	-	73,75	-	75,00	72,50	3 >	0 >	3 >	0 >
Mean green leaf area (%)	20,83		26,88		27,04	28,38	3 =	6 =	3 =	6 =
Mean %UTC	100,00%		188,03 %		162,73 %	188,83 %	0 <	0 <	0 <	0 <
Number of values	1	1	1		1	1	BIS- TRO	CA244 5 0,6 l/ha	BIS- TRO	CA244 5 0,7 l/ha
Minimum value	21,50	32,50	42,50		47,50	52,50				
Maximum value	21,50	32,50	42,50	-	47,50	52,50	0 >	0 >	0 >	0 >
Mean green leaf area (%)	21,50	32,50	42,50		47,50	52,50	1 =	6 =	1 =	6 =
Mean %UTC	100,00%	152,94 %	200,00 %		223,53 %	247,06 %	0 <	0 <	0 <	0 <
Number of values	3		3	3	3	3	CARAMBA	CARAMBA		
Minimum value	1,25		2,75	2,25	2,25	2,50	1,5 l/ha	1,5 l/ha		
Maximum value	3,50	-	10,00	7,25	7,25	9,50	0 >	0 >		
Mean green leaf area (%)	2,33		5,83	4,50	4,33	5,50	3 =	3 =		
Mean %UTC	100,00%		238,94 %	188,31%	180,90 %	223,81 %	0 <	0 <		

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Green leaf area was recorded in 7 valid trials on oilseed rape after two applications of CA3301 at 0.6-0.7 l/ha and authorised reference standards. Among these 7 trials, CA3301 was applied twice in spring in 1 trial. In this trial, the green leaf area was assessed at 50 DA-B on stems and on pods.

Data demonstrated a positive effect of 2 applications of CA3301 at 0.6-0.7 l/ha compared to untreated control for the increase of green leaf area on oilseed rape infected by foliar diseases. After two applications in spring, an increase of 28.57% and 50.00% was recorded on stems and an increase of 40.00% and 52.00% was recorded on pods with CA3301 at 0.7 l/ha and 0.6 l/ha compared to the untreated check.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.7 l/ha will have a positive effect on the green leaf area in oilseed rape affected by a range of pathogens in the Maritime EPPO zone.

[illegible]

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Green leaf area was recorded in a single valid trial on oilseed rape after two applications of CA3301 at 0.6-0.7 l/ha and authorised reference standard. In this trial, CA3301 was applied once in autumn and once in spring and the green leaf area was assessed at 64 DA-B on the whole plant.

Data demonstrated a positive effect of 2 applications of CA3301 at 0.7 l/ha and 0.6 l/ha compared to untreated control for the increase of green leaf area on oilseed rape infected by foliar diseases. In this trial assessing green leaf area on the whole plant, an increase of 114.29% and 71.43% was recorded with CA3301 at 0.7 l/ha and 0.6 l/ha compared to the untreated check on oilseed rape.

In this trial, CA3301 at 0.6-0.7 l/ha was equivalent to the reference product CA2445 at 0.7 l/ha and BISTRO at 0.6 l/ha.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.7 l/ha will have a positive effect on the green leaf area in oilseed rape affected by a range of pathogens in the Mediterranean EPPO zone.

Treatment name		BISTR O	CA24 45	CA33 01	CA33 01	No of trials where CA3301	No of trials where CA3301
Rate	UNTREATED	0,6	0,7	0,6	0,7	at 0,6 l/ha is >, = or <	at 0,7 l/ha is >, = or <
Rate unit	CHECK	L/ha	L/ha	L/ha	L/ha	compared to	compared to
Appl. Code		AB	AB	AB	AB		
% Green leaf area - 14-39 64 DA-B							
Number of values	1	1	1	1	1	UT	BIS-TRO
Minimum value	8,75	8,75	15,00	15,00	18,75	C	45
Maximum value	8,75	8,75	15,00	15,00	18,75	0 >	0 >
Mean green leaf area (%)	8,75	8,75	15,00	15,00	18,75	1 =	1 =
%UTC	100,00%	100,00%	171,43%	171,43%	214,29%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 with one application in autumn and one application in spring – North-Eastern EPPO zone

Green leaf area was recorded in 5 valid trials on oilseed rape after two applications of CA3301 at 0.6-0.7 l/ha and authorised reference standards. In these trials, CA3301 was applied once in autumn and once in spring and the green leaf area was assessed at 50-62 DA-B on the whole plant.

Summary results are presented in Table 3.2-656.

Data demonstrated a positive effect of 2 applications of CA3301 at 0.6-0.7 l/ha compared to untreated control for the increase of green leaf area on oilseed rape infected by foliar diseases.

In these trials assessing green leaf area on the whole plant, an increase of 22.41% and 15.74% was recorded with CA3301 at 0.7 l/ha and 0.6 l/ha compared to the untreated check on oilseed rape.

In this limited dataset, CA3301 at 0.6-0.7 l/ha was overall equivalent to the references CA2445 at 0.7 l/ha and ORIUS EXTRA at 1.0 l/ha.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.7 l/ha will have a positive effect on the green leaf area in oilseed rape affected by a range of pathogens in the North-Eastern EPPO zone.

Table 3.2-656: Summary table - Efficacy evaluation – Oilseed rape – Green leaf area – North-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA 244 5 L/ha a AB	ORIUS EXTRA 1 L/ha AB	CA 330 1 L/ha a AB	CA 330 1 L/ha a AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to				No of trials where CA3301 at 0,7 l/ha is >, = or < compared to			
Rate		0,7	1	0,6	0,7								
Rate unit		L/h	L/ha	L/h	L/h								
Appl. Code		AB	AB	AB	AB								
% Green leaf area - 50-62 DA-B													
Number of values	5	5	5	5	5	U	CA 244 5	ORIUS EX-TRA	CA 330 1	U	CA 244 5	ORIUS EX-TRA	CA 330 1
Minimum value	15,00	21,25	25,00	18,75	21,25	C	0,7 l/ha	1,0 l/ha	0,7 l/ha	C	0,7 l/ha	1,0 l/ha	0,6 l/ha
Maximum value	75,00	97,50	96,25	90,00	100,00	2 >	0 >	0 >	0 >	2 >	0 >	0 >	1 >
Mean green leaf area (%)	59,00	71,00	71,00	67,50	70,50	3 =	5 =	5 =	4 =	3 =	5 =	5 =	4 =
Mean %UTC	100,00%	123,08 %	127,08 %	115,74 %	122,41 %	0 <	0 <	0 <	1 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 with one application in autumn and one application in spring – South – Eastern EPPO zone

Green leaf area was recorded in 8 valid trials on oilseed rape after two applications of CA3301 at 0.6-0.7 l/ha and authorised reference standards. In these trials, CA3301 was applied once in autumn and once in spring and the green leaf area was assessed at 41-79 DA-B on the whole plant.

Summary results are presented in Table 3.2-657.

Data demonstrated a positive effect of 2 applications of CA3301 at 0.7 l/ha and 0.6 l/ha compared to untreated control for the increase of green leaf area on oilseed rape infected by foliar diseases.

In these trials assessing green leaf area on the whole plant, an increase of 173.56% and 110.80% was recorded with CA3301 at 0.7 l/ha and 0.6 l/ha compared to the untreated check on oilseed rape.

Over the whole dataset, CA3301 at 0.6 l/ha was most of the time equivalent to the reference products CA2445 (0.7 l/ha) and TILMOR (1.2 l/ha), and it provided lower increase in green leaf area in some assessments. CA3301 at 0.7 l/ha provided an overall equivalent or higher increase in green leaf area compared to CA2445 and TILMOR except in 1 trial.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.7 l/ha will have a positive effect on the green leaf area in oilseed rape affected by a range of pathogens in the South-Eastern EPPO zone.

Table 3.2-657: Summary table - Efficacy evaluation – Oilseed rape – Green leaf area – South-East-EPPO zone

Treatment name	UNTREATED CHECK	CA24 45 0,7 L/ha AB	TILM OR 1,2 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,7 l/ha is >, = or < compared to
% Green leaf area - 41-79 DA-B							
Number of values	8	8		8	8	UTC	CA3301 0,7 l/ha
Minimum value	2,50	6,25		6,25	5,00		UTC
Maximum value	72,50	100,00	-	97,50	100,00	6 >	0 >
Mean green leaf area (%)	19,59	40,00		34,78	41,09	2 =	4 =
Mean %UTC	100,00%	270,28%		210,80%	273,56%	0 <	4 <
Number of values	5	5	5	5	5	CA24 45 0,7 l/ha	TIL-MOR 1,2 l/ha
Minimum value	2,50	6,25	5,00	6,25	5,00		
Maximum value	12,50	30,00	37,50	30,00	30,00	0 >	0 >
Mean green leaf area (%)	8,00	21,75	20,00	15,50	21,50	5 =	3 =
Mean %UTC	100,00%	304,00%	267,00%	217,00%	300,00%	3 <	2 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Comments of zRMS:

7 valid trials have been submitted in **the Maritime EPPO climatic zone**. The positive effect on augmentation of green leaf area was observed after application of CA3301. 2 application in autumn and spring were used in 6 out of 7 trials. The test product achieved results of 62,73% at 0,6 l/ha and 88,83% at 0,7 l/ha. 2 applications in spring were used in single trial. An augmentation of 52% (0,6 l/ha) and 40% (0,7 l/ha) was noted on pods and 50% and 28,57% in case of stem.

5 valid trials were available in **the North-East EPPO zone**. All trials were conducted with 2 applications in autumn and spring. An augmentation of green leaf area amounted 15,74% at 0,6 l/ha and 22,41% at 0,7 l/ha. The observations were provided on whole plants.

8 valid trials with 2 applications in autumn and spring were carried out in **the South-East EPPO zone**. The very positive effect was achieved after applications of CA3301. An augmentation of green leaf area amounten 110,8% at 0,6 l/ha and 173,56% at 0,7 l/ha. Also 1 additional trial from the Mediterranean zone showed a progressive trend in results. An augmentation on whole plants was 71,43% at 0,6 l/ha and 114,29% at 0,7 l/ha.

3.2.3.15 Oilseed rape (BRSNW) / Justification of the single application

In this dossier efficacy data presented were primarily from assessments where 2 applications of the test product were made. However, according to disease development conditions, a single application may provide sufficient control, therefore users should not be restricted to always applying twice, hence in the GAP the proposed use is for 1-2 applications.

In order to evaluate the efficacy of a single application of CA3301 at 0.6-0.7 l/ha, the data from early assessments (before 2nd application) of trials including two applications are presented here. One main foliar disease (*Plenodomus lingam*) with representative data was selected to justify the interest of applying CA3301 at 1 x 0.6-0.7 l/ha.

Use of CA3301 at 1 x 0.6-0.7 l/ha against *Plenodomus lingam* (LEPTMA) – Maritime EPPO Zone

In the Maritime EPPO zone, 4 valid assessments were available before the 2nd application and enabled to evaluate the efficacy of CA3301 at 0.6-0.7 l/ha applied once on Oilseed rape against *Plenodomus lingam*, and to compare it to the reference products.

Summary results are presented in Table 3.2-658.

Data demonstrated the positive effect of one application of CA3301 at 0.6-0.7 l/ha for the reduction of disease severity of *Plenodomus lingam* on oilseed rape. On leaves, CA3301 at 0.6-0.7 l/ha showed 81.49-85.53% efficacy against *Plenodomus lingam* two weeks after the 1st application and 57.63-69.53% around six months after the 1st application.

In the Maritime EPPO zone, CA3301 at 0.6-0.7 l/ha applied once showed high efficacy in reducing the severity of *Plenodomus lingam* on leaves at the assessment timing close to the application and medium efficacy after six months. Across the dataset, the performance of CA3301 at 0.6 l/ha was equivalent to CA2445 at 0.7 l/ha in 2 assessments out of 4. Moreover, the performance of CA3301 at 0.7 l/ha was always equivalent to CA2445 at 0.7 l/ha. Compared to the reference CARAMBA applied at 1.5 l/ha, both dose rate of CA3301 were statistically more efficient in the only assessment available. Therefore, a single application of CA3301 at 0.6-0.7 l/ha provides acceptable control of the disease and may be sufficient alone, depending on disease progression, or as part of a fungicide programme.

Considering all elements presented above, it is justified to claim the registration of 1 application of CA3301 at 0.6-0.7 l/ha to control *Plenodomus lingam* on oilseed rape in the Maritime EPPO zone.

Table 3.2-658: Summary table - Efficacy evaluation – 1 application – Oilseed rape – LEPTMA – Maritime EPPO zone

LEAF zone													
Treat- ment name Rate Rate unit Appl. Code	UN- TREATED CHECK	CA22 45 0,7 L/ha A	CA- RAMB A 1,5 L/ha A	CA33 01 0,6 L/ha A	CA3 301 0,7 L/ha A	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to				No of trials where CA3301 at 0,7 l/ha is >, = or < compared to			
% Disease severity LEAF - 15 DA-A													
Number of val- ues	1	1	1	1	1	UTC	CA24 45	CA- RA MB A	C A 33 01	U T C	CA 244 5	CA- RAM BA	C A 33 01
Mini- mum value	13,13	1,94	4,05	2,43	1,90		0,7 l/ha	1,5 l/ha	0, 7		0,7 l/ha	1,5 l/ha	0, 6

									l/ ha				l/ ha
Maximum value	13,13	1,94	4,05	2,43	1,90	1 >	0 >	1 >	0 >	1 >	0 >	1 <	1 >
Mean disease severity (%)	13,13	1,94	4,05	2,43	1,90	0 =	0 =	0 =	0 =	0 =	1 =	0 =	0 =
Mean Abbott efficacy (%)	0,00%	85,22 %	69,15%	81,49 %	85,53 %	0 <	1 <	0 <	1 <	0 <	0 <	0 <	0 <
% Disease severity LEAF - 149-200 DA-A													
Number of values	3	3		3	3		CA2445	CA3301		CA2445	CA3301		
Minimum value	5,70	1,33		2,60	1,56	UTC	0,7 l/ha	0,7 l/ha		0,7 l/ha	0,6 l/ha		
Maximum value	10,10	3,29	-	4,43	3,60	3 >	0 >	0 >		3 >	0 >		1 >
Mean disease severity (%)	8,62	2,29		3,60	2,67	0 =	2 =	2 =		0 =	3 =		2 =
Mean Abbott efficacy (%)	0,00%	73,88 %		57,63 %	69,53 %	0 <	1 <	1 <		0 <	0 <		0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy
(% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 1 x 0.6-0.7 l/ha against *Plenodomus lingam* (LEPTMA) – Mediterranean EPPO Zone

In the Mediterranean EPPO zone, 2 valid assessments were available before the 2nd application and enabled to evaluate the efficacy of CA3301 at 0.6-0.7 l/ha applied once on Oilseed rape against *Plenodomus lingam*, and to compare it to the reference products.

Summary results are presented in Table 3.2-659.

Data demonstrated the positive effect of 1 application of CA3301 at 0.6-0.7 l/ha for the reduction of disease severity of *Plenodomus lingam* on oilseed rape. On leaves, CA3301 at 0.6-0.7 l/ha showed 94.81-90.29% efficacy against *Plenodomus lingam* seven weeks after the 1st application and 70.70-72.97% around five months after the 1st application.

In the Mediterranean EPPO zone, CA3301 at 0.6-0.7 l/ha applied once showed high efficacy in reducing the severity of *Plenodomus lingam* on leaves seven weeks after the 1st application and medium efficacy after five months. Across the dataset, CA3301 at 0.6-0.7 l/ha was statistically equivalent to the references CA2445 at 0.7 l/ha and BISTRO at 0.6 l/ha. Therefore, a single application of CA3301 at 0.6-0.7

l/ha provides acceptable control of the disease and may be sufficient alone, depending on disease progression, or as part of a fungicide programme.

Considering all elements presented above, it is justified to claim the registration of 1 application of CA3301 at 0.6-0.7 l/ha to control *Plenodomus lingam* on oilseed rape in the Mediterranean EPPO zone.

Table 3.2-659: Summary table - Efficacy evaluation – 1 application – Oilseed rape – LEPTMA – Mediterranean EPPO zone

Treatments in the same zone													
Treatment name Rate Rate unit Appl. Code	UN-TREATED CHECK	BIS-TRO 0,6 L/ha A	CA22 45 0,7 L/ha A	CA33 01 0,6 L/ha A	CA330 1 0,7 L/ha A	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to				No of trials where CA3301 at 0,7 l/ha is >, = or < compared to			
% Disease severity LEAF - 49 DA-A													
Number of values	1	1	1	1	1	UT C	BIS-TRO	C A2 44 5	C A3 30 1	U T C	BI ST R O	C A2 44 5	C A3 30 1
Minimum value	10,40	3,28	0,85	0,54	1,01		0,6 l/ha	0,7 l/h a	0,7 l/h a		0,6 l/h a	0,7 l/h a	0,6 l/h a
Maximum value	10,40	3,28	0,85	0,54	1,01		1 >	0 >	0 >		0 >	1 >	0 >
Mean disease severity (%)	10,40	3,28	0,85	0,54	1,01	0 =	1 =	1 =	1 =	0 =	1 =	1 =	1 =
Mean Abbott efficacy (%)	0,00%	68,46 %	91,83 %	94,81 %	90,29 %	0 <	0 <	0 <	0 <	0 <	0 <	0 <	0 <
% Disease severity LEAF - 161 DA-A													
Number of values	1	1	1	1	1	UT C	BIS-TRO	C A2 44 5	C A3 30 1	U T C	BI ST R O	C A2 44 5	C A3 30 1
Minimum value	5,29	3,19	1,44	1,55	1,43		0,6 l/ha	0,7 l/h a	0,7 l/h a		0,6 l/h a	0,7 l/h a	0,6 l/h a
Maximum value	5,29	3,19	1,44	1,55	1,43		1 >	0 >	0 >		0 >	1 >	0 >
Mean disease severity (%)	5,29	3,19	1,44	1,55	1,43	0 =	1 =	1 =	1 =	0 =	1 =	1 =	1 =
Mean Abbott efficacy (%)	0,00%	39,70 %	72,78 %	70,70 %	72,97 %	0 <	0 <	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (%
Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Use of CA3301 at 1 x 0.6-0.7 l/ha against *Plenodomus lingam* (LEPTMA) – South-Eastern EPPO Zone

In the South-Eastern EPPO zone, 3 valid assessments were available before the 2nd application and enabled to evaluate the efficacy of CA3301 at 0.6-0.7 l/ha applied once on Oilseed rape against *Plenodomus lingam*, and to compare it to the reference products.

Summary results are presented in Table 3.2-660.

Data demonstrated the positive effect of 1 application of CA3301 at 0.6-0.7 l/ha for the reduction of disease severity of *Plenodomus lingam* on oilseed rape. On leaves, CA3301 at 0.6-0.7 l/ha showed 77.39-83.22% efficacy against *Plenodomus lingam* around five to six months after the 1st application.

In the South-East ~~EPPO~~ EPPO zone, CA3301 at 0.6-0.7 l/ha applied once showed medium to high efficacy in reducing the severity of *Plenodomus lingam* on leaves. Across the dataset, the performance of CA3301 at 0.6-0.7 l/ha was statistically equivalent to that provided by the reference CA2445 at 0.7 l/ha. Therefore, a single application of CA3301 at 0.6-0.7 l/ha provides acceptable control of the disease and may be sufficient alone, depending on disease progression, or as part of a fungicide programme.

Considering all elements presented above, it is justified to claim the registration of 1 application of CA3301 at 0.6-0.7 l/ha to control *Plenodomus lingam* on oilseed rape in the South-East ~~EPPO~~ EPPO zone.

Table 3.2-660: Summary table - Efficacy evaluation – 1 application – Oilseed rape – LEPTMA – South-East ~~EPPO~~ EPPO zone

East - LEAF Zone										
Treatment name	UNTREATED CHECK	CA22 45	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,7 l/ha is >, = or < compared to		
Rate		0,7	0,6	0,7						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		A	A	A						
% Disease severity LEAF - 161-185 DA-A										
Number of values	3	3	3	3	UT C	CA24 45	CA33 01	UT C	CA244 5	CA33 01
Minimum value	5,44	0,84	1,10	0,52		0,7 l/ha	0,7 l/ha		0,7 l/ha	0,6 l/ha
Maximum value	7,93	1,77	1,95	1,79	3 >	0 >	0 >	3 >	0 >	0 >
Mean disease sever- ity (%)	7,04	1,19	1,49	1,05	0 =	3 =	3 =	0 =	3 =	3 =
Mean Abbott effi- cacy (%)	0,00%	81,51 %	77,39 %	83,22 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Levels of efficacy (% Abbott efficacy)

>80%	High efficacy
60-80%	Medium efficacy
<60%	Low efficacy

Comments of zRMS:

4 valid trials were carried out to control of LEPTMA in **the Maritime EPPO climatic zone**. CA3301 applied once at dose rate of 0,6 l/ha achieved low (149-200 DA-A) and high efficacy (15 DA-A) after first application. The dose rate of 0,7 l/ha presented better results with medium to high level. Due to the limited number of trials and varied results, the cMSs are kindly asked to consider the single application on the national level.

No valid trials with single application in winter oilseed rape have been submitted in **the North-East EPPO zone**.

3 valid trials with single application were available in **the South-East EPPO zone**. CA3301 applied at dose rate of 0,6 l/ha achieved medium efficacy after 161-185 DA-A. The dose rate of 0,8 l/ha caused increase of effectiveness to high level in the same time. In 2 additional trials from the Mediterranean zone, the results showed high efficacy after 1 application after 49 DA-A and medium level after 161 DA-A. The dose rate of 0,7 l/ha can be recommended in case of high disease pressure. Due to the limited number of trials, the cMSs are kindly asked to consider the single application in winter oilseed rape on the national level.

The justification of single application was provided only for *Plenodomus lingam* in winter oilseed rape. Taking into account of varied results achieved after second application in control of other target pathogens and the

limited number of trials for some uses, the cMSs from the MAR and SE zone are kindly asked to consider the single application on the national level.

3.2.3.1 Oilseed rape (BRSNW) / Conclusion - Efficacy

On oilseed rape, 5 diseases were assessed in 128 trials across 4 EPPO zones. Among these trials, in order to cover the different agricultural spraying practices of oilseed rape, CA3301 was applied according to two different timings of application and the trials were separated in two groups in the analysis. One group was composed of trials with 2 applications in spring and the other group with trials with one application in autumn and one application in spring. Disease severity was assessed and analysed on leaves, stems, pods and roots. Depending on the EPPO zone, the disease, the assessment timing and the crop part assessed, the dataset available was sometimes limited with results not necessarily representative of the true efficacy of CA3301. Therefore, to get an overview of the efficacy of CA3301 at 0.6-0.7 l/ha, summary tables are presented hereunder, on each part assessed (see Table 3.2-661 to Table 3.2-668).

Globally, across the 4 EPPO zones and all diseases the efficacy of CA3301 at 0.6-0.7 l/ha was acceptable to very high, with some exceptions especially in case of limited dataset. Nevertheless, since in the fields a complex of disease is often observed instead of a single disease, it is of interest to look at the efficacy of CA3301 across the diseases and to not focus on a single one.

It has been shown in the previous sections that the efficacy of CA3301 at 0.6-0.7 l/ha was overall equivalent to the one provided by the approved reference standards used in the trials. In many instances, a trend of decreasing disease severity when increasing the dose rates was observed with CA3301 at 0.6-0.7 l/ha providing a better disease control than the lower rate of 0.5 l/ha. The rate of 0.6 l/ha was most of the time very comparable to the 0.7 l/ha nevertheless in some trials the differences were significant. Therefore, in circumstances of common disease pressure the rate of 0.6 l/ha will provide sufficient efficacy to maintain crop quality whereas in more challenging conditions 0.7 l/ha dose rate will be more appropriate.

Similarly, the same dose rate trends were observed for improving green leaf area in situations of infection from a single pathogen or in cases of disease complexes. Green leaf area not only indicates the area free of infection but also the ability of the plant to continue effective growth and develop to productive stages, enabling a longer duration of grain filling and therefore improved yield quantity and quality. After all, the proposed dose rate of 0.6-0.7 l/ha did not involve negative effects on the crop quality parameters observed at harvest.

In this dossier efficacy data presented is primarily from assessments where 2 applications of the test product were made. However, according to disease development conditions, a single application may provide sufficient disease control, therefore users should not be restricted to always applying twice, hence in the GAP the proposed use is for 1-2 applications. In addition, crop pathogens are commonly controlled using a programme of different fungicides with varied modes of action, therefore the choice should be available to growers to make a single application of CA3301, followed by application of a different appropriate fungicide. Prothioconazole is well established over a number of years in providing good broad spectrum efficacy across a range of common crop pathogens, with either 1 or more applications appropriate according to disease development conditions, risk of resistance development and local conditions. Current authorisations for similar products containing prothioconazole including Proline/Praktis/Joao (CA2445) are for 1-2 applications at comparative rates of prothioconazole to the requested use for CA3301. Furthermore, the data provided for a single application supports the efficacy of CA3301. Considering these elements, and that data shows comparability of CA3301 to these authorised products, registration of CA3301 at the proposed dose rate and with a number of applications of 1-2, is requested.

Table 3.2-661: Summary table – Oilseed rape – All diseases (LEAF) – Two applications in spring

[illegible]

[illegible][illegible]

Table 3.2-664: Summary table – Oilseed rape – All diseases (ROOT) – Two application in spring

[illegible]

		Abbott efficacy (%)	-	-	-	-	-	-	-	-	-	-
	Before harvest	Number of values Abbott efficacy (%)	-	-	-	-	-	-	-	-	-	-
			-	-	-	-	-	-	-	-	-	-
ERYS CR	2-5 weeks after B	Number of values Abbott efficacy (%)	-	-	-	-	-	-	-	-	-	-
	Before harvest	Number of values Abbott efficacy (%)	-	-	-	-	-	-	-	-	-	-
PYRP BR	2-5 weeks after B	Number of values Abbott efficacy (%)	-	-	-	-	-	-	-	-	-	-
	Before harvest	Number of values Abbott efficacy (%)	-	-	-	-	-	-	-	-	-	-

Table 3.2-665: Summary table – Oilseed rape – All diseases (LEAF) – On applications in autumn and one application in spring

Leaves			MAR		MED		NE		SE		Poland	
Disease	Application timing		CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB
SCLES C	2-5 weeks after B	Number of values Abbott efficacy (%)	-	-	-	-	-	-	-	-	-	-
	Before harvest	Number of values Abbott efficacy (%)	-	-	-	-	-	-	-	-	-	-
ALTE BA	2-5 weeks after B	Number of values Abbott efficacy (%)	1 64.99	1 79.48	-	-	-	-	-	-	1 64.99	1 79.48
	Before harvest	Number of values Abbott efficacy (%)	-	-	-	-	-	-	-	-	-	-
LEPT MA	2-5 weeks after B	Number of values Abbott efficacy (%)	3 63.07	3 76.06	-	-	1 77.46	1 80.56	4 88.04	4 90.48	3 63.55	3 76.39
	Before harvest	Number of values Abbott efficacy (%)	-	-	-	-	1 74.59	1 82.70	2 86.58	2 92.28	1 74.59	1 82.70
ERYS CR	2-5 weeks after B	Number of values Abbott efficacy (%)	1 33.71	1 28.31	-	-	-	-	-	-	-	-
	Before harvest	Number of values	-	-	-	-	-	-	4	4	-	-

Leaves			MAR		MED		NE		SE		Poland	
Disease	Application timing		CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB
		Abbott efficacy (%)	-	-	-	-	-	-	69.09	78.08	-	-
PYRP BR	2-5 weeks after B	Number of values	1	1	-	-	-	-	-	-	-	-
		Abbott efficacy (%)	43.94	64.98	-	-	-	-	-	-	-	-
	Before harvest	Number of values	1	1	-	-	-	-	-	-	-	-
		Abbott efficacy (%)	33.04	37.37	-	-	-	-	-	-	-	-

Table 3.2-666: Summary table – Oilseed rape – All diseases (STEM) – On applications in autumn and one application in spring

Stems			MAR		MED		NE		SE		Poland	
Disease	Application timing		CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB
SCLES C	2-5 weeks after B	Number of values	-	-	-	-	2	2	-	-	-	-
		Abbott efficacy (%)	-	-	-	-	80.58	87.31	-	-	-	-
	Before harvest	Number of values	7	7	-	-	7	7	1	1	-	-
		Abbott efficacy (%)	73.79	79.54	-	-	64.95	77.10	91.60	85.76	-	-
ALTE BA	2-5 weeks after B	Number of values	-	-	-	-	-	-	-	-	-	-
		Abbott efficacy (%)	-	-	-	-	-	-	-	-	-	-
	Before harvest	Number of values	-	-	-	-	-	-	-	-	-	-
		Abbott efficacy (%)	-	-	-	-	-	-	-	-	-	-
LEPT MA	2-5 weeks after B	Number of values	-	-	-	-	-	-	2	2	-	-
		Abbott efficacy (%)	-	-	-	-	-	-	91.46	95.44	-	-
	Before harvest	Number of values	6	6	-	-	1	1	6	6	6	6
		Abbott efficacy (%)	54.27	66.46	-	-	82.35	93.68	60.11	68.04	61.60	73.89
ERYS CR	2-5 weeks after B	Number of values	-	-	-	-	-	-	-	-	-	-
		Abbott efficacy (%)	-	-	-	-	-	-	-	-	-	-
	Before harvest	Number of values	-	-	-	-	-	-	3	3	-	-
		Abbott efficacy (%)	-	-	-	-	-	-	55.47	63.69	-	-
PYRP BR	2-5 weeks after B	Number of values	1	1	-	-	-	-	-	-	-	-

		Abbott efficacy (%)	64.88	70.57	-	-	-	-	-	-	-	-
	Before harvest	Number of values	2	2	-	-	-	-	-	-	-	-
		Abbott efficacy (%)	47.40	67.92	-	-	-	-	-	-	-	-

Table 3.2-667: Summary table – Oilseed rape – All diseases (POD) – On applications in autumn and one application in spring

Pods			MAR		MED		NE		SE		Poland	
Disease	Application timing		CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB
SCLES C	2-5 weeks after B	Number of values	-	-	-	-	-	-	-	-	-	-
		Abbott efficacy (%)	-	-	-	-	-	-	-	-	-	-
	Before harvest	Number of values	-	-	-	-	-	-	-	-	-	-
		Abbott efficacy (%)	-	-	-	-	-	-	-	-	-	-
ALTE BA	2-5 weeks after B	Number of values	-	-	-	-	-	-	-	-	-	-
		Abbott efficacy (%)	-	-	-	-	-	-	-	-	-	-
	Before harvest	Number of values	1	1	-	-	2	2	2	2	3	3
		Abbott efficacy (%)	63.04	78.46	-	-	74.02	83.03	78.62	84.36	70.36	81.51
LEPT MA	2-5 weeks after B	Number of values	-	-	-	-	-	-	-	-	-	-
		Abbott efficacy (%)	-	-	-	-	-	-	-	-	-	-
	Before harvest	Number of values	-	-	-	-	1	1	2	2	1	1
		Abbott efficacy (%)	-	-	-	-	85.03	95.08	92.78	95.51	85.03	95.08
ERYS CR	2-5 weeks after B	Number of values	-	-	-	-	-	-	-	-	-	-
		Abbott efficacy (%)	-	-	-	-	-	-	-	-	-	-
	Before harvest	Number of values	-	-	-	-	-	-	3	3	-	-
		Abbott efficacy (%)	-	-	-	-	-	-	58.39	68.12	-	-
PYRP BR	2-5 weeks after B	Number of values	-	-	-	-	-	-	-	-	-	-
		Abbott efficacy (%)	-	-	-	-	-	-	-	-	-	-
	Before harvest	Number of values	-	-	-	-	-	-	-	-	-	-
		Abbott efficacy (%)	-	-	-	-	-	-	-	-	-	-

Table 3.2-668: Summary table – Oilseed rape – All diseases (ROOT) – On applications in autumn and one application in spring

Roots	MAR	MED	NE	SE	Poland
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Disease	Application timing		CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB
SCLES C	2-5 weeks after B	Number of values Abbott efficacy (%)	-	-	-	-	1	1	-	-	-	-
	Before harvest	Number of values Abbott efficacy (%)	-	-	-	-	1	1	-	-	-	-
ALTE BA	2-5 weeks after B	Number of values Abbott efficacy (%)	-	-	-	-	-	-	-	-	-	-
	Before harvest	Number of values Abbott efficacy (%)	-	-	-	-	-	-	-	-	-	-
LEPT MA	2-5 weeks after B	Number of values Abbott efficacy (%)	-	-	-	-	-	-	-	-	-	-
	Before harvest	Number of values Abbott efficacy (%)	-	-	-	-	-	-	-	-	-	-
ERYS CR	2-5 weeks after B	Number of values Abbott efficacy (%)	-	-	-	-	-	-	-	-	-	-
	Before harvest	Number of values Abbott efficacy (%)	-	-	-	-	-	-	-	-	-	-
PYRP BR	2-5 weeks after B	Number of values Abbott efficacy (%)	-	-	-	-	-	-	-	-	-	-
	Before harvest	Number of values Abbott efficacy (%)	-	-	-	-	-	-	-	-	-	-

3.2.3.1 Spring Oilseed rape (BRSNS) - Efficacy

Oilseed rape is one of the major crop in Europe. Most of the time it is sown at the end of the summer or the beginning of the autumnal season but in marginal cases oilseed rape may be sown in the early spring. Sowing oilseed rape in spring is an alternative to produce green fodder in early summer when no other fodder is available. It is also used as replacement crop for winter sown oilseed rape after a failure of the implanting. However, spring-sown oilseed rape is more likely to be cultivated in northern countries where spring is more humid and the crop has chances to succeed.

In addition, spring sown oilseed is susceptible to face the same pathogens than winter oilseed rape and particularly powdery mildew or dark leaf spot. Considering that the profitability of this crop is not always insured, it is all the more important to protect it from disease infestation and to preserve all the yield potential.

Spring-sown oilseed rape is considered a minor crop and extrapolation of data from winter-sown oilseed rape is acceptable as indicated in EPPO extrapolation tables PP 1/257 FEET 70 (1) and PP 1/257 FEET 69 (1). This extrapolation is also supported by Poland national guidance.

It has been demonstrated in the previous sections that globally, across the 4 EPPO zones and all diseases the efficacy of CA3301 at 0.6-0.7 l/ha was overall equivalent to the authorised reference standards used in the trials on winter oilseed rape. In many instances, a trend of decreasing disease severity when increasing the dose rates was observed with CA3301 at 0.6-0.7 l/ha providing a better disease control than the lower rate of 0.5 l/ha. The rate of 0.6 l/ha was most of the time very comparable to the 0.7 l/ha nevertheless in some trials the differences were significant. Therefore, in circumstances of common disease pressure the rate of 0.6 l/ha will provide sufficient efficacy to maintain crop quality whereas in more challenging conditions 0.7 l/ha dose rate will be more appropriate. Similarly, the same dose rate trends were observed for improving green leaf area in situations of infection from a single pathogen or in cases of disease complexes. Green leaf area not only indicates the area free of infection but also the ability of the plant to continue effective growth and develop to productive stages, enabling a longer duration of grain filling and therefore improved yield quantity and quality. After all, the proposed dose rate of 0.6-0.7 l/ha did not involve negative effects on the crop quality parameters observed at harvest.

In addition, other authorised products containing prothioconazole are also approved for use in spring sown as well as winter sown oilseed rape, for example Pecari 300 EC.

Therefore, it is justified to claim the registration of one application of CA3301 at 0.6-0.7 l/ha to control a range of foliar diseases on oilseed rape.

Comments of zRMS:

Based on the GAP table, spring oilseed rape is considered according art. 51. The assessment of efficacy and phytotoxicity is not required in this case.

3.2.3.1 Other Brassicaceae (minor crops) - Efficacy

(G. Séguin-Swartz, G. *et al.*, Diseases of *Camelina sativa* (false flax) *Canadian Journal of Plant Pathology*, 2010)

The Brassicaceae family (formerly Cruciferae family) includes various *Brassica* species, representing oilseed, vegetable and fodder crops. For example, *Camelina sativa* and *Brassica juncea* are members of this genus. *Camelina sativa* (L.) Crantz (false flax) belongs to *Brassicaceae* and is generating substantial interest as an alternative oilseed crop in many regions of the world because of its potential value for food, feed, and industrial applications. This plant is known to its early maturity, high seed yield potential, drought tolerance, and its resistance to some of the common pests and diseases of Brassica oilseeds. Mustards have been consumed for centuries as vegetables, and their products used as condiments and as edible and industrial oils. The oil is commonly used for cooking and to add a hot and spicy flavor to food. As a crop, they are also one of the highest oil yielding and high protein containing oilseed species.

Because of their close genus relationship, these crops are often susceptible to the same diseases and therefore to the same diseases than winter oilseed rape.

These Brassicae crops are considered minor crops and extrapolation of data from winter-sown oilseed rape is acceptable as indicated in EPPO extrapolation tables PP 1/257 FEET 70 (1) and PP 1/257 FEET 69 (1).

It has been demonstrated in the previous sections that globally, across the 4 EPPO zones and all diseases the efficacy of CA3301 at 0.6-0.7 l/ha was overall equivalent to the authorised reference standards used in the trials. In many instances, a trend of decreasing disease severity when increasing the dose rates was observed with CA3301 at 0.6-0.7 l/ha providing a better disease control than the lower rate of 0.5

l/ha. The rate of 0.6 l/ha was most of the time very comparable to the 0.7 l/ha nevertheless in some trials the differences were significant. Therefore, in circumstances of common disease pressure the rate of 0.6 l/ha will provide sufficient efficacy to maintain crop quality whereas in more challenging conditions 0.7 l/ha dose rate will be more appropriate. Similarly, the same dose rate trends were observed for improving green leaf area in situations of infection from a single pathogen or in cases of disease complexes. Green leaf area not only indicates the area free of infection but also the ability of the plant to continue effective growth and develop to productive stages, enabling a longer duration of grain filling and therefore improved yield quantity and quality. After all, the proposed dose rate of 0.6-0.7 l/ha did not involve negative effects on the crop quality parameters observed at harvest.

Therefore, it is justified to claim the registration of 1-2 applications of CA3301 at 0.6-0.7 l/ha to control a range of foliar diseases on various seed-producing *Brassicaceae*.

Comments of zRMS:

Based on the GAP table, the various seed-producing *Brassicaceae* are considered according art. 51. The assessment of efficacy and phytotoxicity is not required in this case.

3.2.3.2 Flax (Fibre) / *Oidium lini* / *Erysiphe orontii* (ERYSP) - Efficacy

Linseed (*Linum usitatissimum* L.) varieties are two types, fiber or seed. And differ considerably in character of the plant growth. The fiber plants having tall and slender stem, produces a high amount of good quality fiber and bears seeds of poor quality oil content. Sown between March and April, 100 days are sufficient to mature and will quickly grow to reach 1 m. A mild and regularly rainy spring will ensure regular fiber growth.

Powdery mildew is an important disease of flax. The disease is caused by *Erysiphe orontii*/*Oidium lini* an obligate biotrophic ascomycete. Typical infection symptoms start with the appearance of a white powdery mass of mycelia visible as small spots that eventually spread to cover the entire leaf surface. Heavily infected leaves wither, dry up, and die. Early infections may cause severe defoliation of the flax plant and reduce the yield and quality of seed. Some flax varieties are resistant to this disease.

Flax is considered a minor crop as indicated in Table 3.2-21, therefore it is considered acceptable to extrapolate data from cereals and oilseed rape to this crop. Data generated on *Erysiphe* spp in cereals and oilseed rape indicates that the proposed dose rate of 0.6-0.8 l/ha (cereals) and 0.6-0.7 l/ha (oilseed rape) of CA3301 provides acceptable efficacy of these pathogens.

No data were available for assessment of control of Powdery mildew on flax in this dossier. However, prothioconazole is one of the active substances the most used as fungicide in commercial practices. Standard reference products containing prothioconazole, such as JOAO are registered to control powdery mildew on flax, at the same application rates as for the other authorised pathogens, which indicates that prothioconazole controls powdery mildew at dose rates which have demonstrated to control the other major disease pathogens in cereals. Since the proposed dose rate for CA3301 (200-150 g/ha prothioconazole) is comparable to that of the authorised product JOAO (200 g/ha prothioconazole), and data shows equivalence of efficacy between these products in other pathogens, it is considered that CA3301 will also provide acceptable control of powdery mildew at the proposed dose rate.

Considering all elements presented above, it is justified to claim the registration of CA3301 at 0.6-0.7 l/ha to control *Erysiphe orontii* on flax in all EPPO zones.

Comments of zRMS:

Based on the GAP table, the various seed-producing *Brassicaceae* are considered according art. 51. The assessment of efficacy and phytotoxicity is not required in this case.

3.2.3.3 Overall conclusion on efficacy

A total of 680 trials were undertaken in support of the proposed uses of CA3301 on cereals and oilseed rape in the CEU regulatory zone. In each of the crop sections CA3301 was demonstrated to provide significant reductions in disease for the target pathogens compared to untreated plots and was comparable to the efficacy provided by the authorised reference products.

Due to lack of infestation for some uses there were fewer valid trials than intended. However, in all trials, efficacy was compared to authorised reference standards, and in the majority of cases these were comparable prothioconazole EC formulations of 250 g/l. Prothioconazole has been used for many years in cereals and oilseed rape against the proposed pathogens and is well established as being effective against these diseases. In each of the cMS for this dossier, and in the relevant EPPO zones a similar formulation is already authorised for use. The efficacy of CA3301 has been demonstrated to be equivalent to that of the authorised prothioconazole formulations (in addition to other authorised fungicides) across the proposed uses in a large number of valid trials across each of the EPPO climatic zones.

Therefore, where the number of trials is limited for a particular use it is requested that the evaluator takes into account the comparability of efficacy between CA3301 and these already authorised formulations.

Information on the prothioconazole authorised reference products for the cMS and within the same EPPO zone is presented in Table 3.2-661.

For some crop/pathogen combinations a limited number of valid trials was available and reference has been made to the data on the same pathogen on a similar cereal crop. As, on the whole, current authorisations have the same dose rate approved for use on the same pathogens across different cereal crops it is considered that this extrapolation is acceptable, since prothioconazole evidently provides the same efficacy against these pathogens regardless of the type of cereal crop.

Taking into account the whole dossier, it is considered that the data supports the proposed uses for CA3301 against a range of common pathogens of cereals and oilseed rape, since significant disease reduction and comparability to authorised reference products has been demonstrated in a considerable number of trials undertaken according to appropriate EPPO standards.

Table 3.2-661: Comparable authorised prothioconazole products

Comparable authorised prothioconazole products							
Reference stand-ard	MS	Authorization number	Active sub-stance	Formulation		Crop/pathogen	Rate
				Type	Concentration of a.s.		
MARITIME EPPO ZONE							
PROLINE	AT	3771-0	Prothioconazole	EC	250 g/l	Wheat/spelt ERYSGR/SEPTTR/LEPTNO/PYRNTR/PUCCSS/FUSASP Barley ERYSGH/PUCCHD/PYRNTE/RHYNSE/PSDCHA Rye ERYSGR/PUCCSS/RHYNSE/PSDCHA Triticale SEPTTR Oilseed rape SCLESC	2 x 0.8 l/ha 2 x 0.8 l/ha 2 x 0.8 l/ha 2 x 0.8 l/ha 1 x 0.7 l/ha
PROLINE	BE	9805P/B	Prothioconazole	EC	250 g/l	Wheat SEPTTR/LEPTNO/PUCCSS/ERYSGR/FUSASP PSDCHA Barley ERYSGH /PUCCHD/PYRNTE/RHYNSE PSDCHA Rye ERYSGR/ RHYNSE Triticale SEPTTR/LEPTNO/ERYSGR/FUSASP/PUCCSS PSDCHA	2 x 0.8 l/ha 1 x 0.8 l/ha 2 x 0.8 l/ha 1 x 0.8 l/ha 2 x 0.8 l/ha 2 x 0.8 l/ha 1 x 0.8 l/ha
PROLINE 250	CZ	4523-1	Prothioconazole	EC	250 g/l	Wheat SEPTTR/LEPTNO//FUSASP/ PSDCHA ERYSGR	2 x 0.8 l/ha 1 x 0.8 l/ha

Reference stand-ard	MS	Authorization number	Active sub-stance	Formulation		Crop/pathogen	Rate
				Type	Concentration of a.s.		
						Barley RAMUCC/PUCCHD ERYSGH Rye SEPTTR/PSDCHA ERYSGR Triticale SEPTTR/PSDCHA ERYSGR Oilseed rape SCLESC	2 x 0.8 l/ha 1 x 0.8 l/ha 2 x 0.8 l/ha 1 x 0.8 l/ha 2 x 0.8 l/ha 1 x 0.8 l/ha 2 x 0.7 l/ha
PROLINE	DE	00 025287-	Prothioconazole	EC	250 g/l	Wheat ERYSGR/SEPTTR/LEPTNO/PYRNTR/PUCCSS/FUSASP/PSDCHA Barley ERYSGH/PUCCHD/PYRNTE/RHYNSE/PSDCHA Rye ERYSGR/PSDCHA/PUCCSS/ RHYNSE Triticale SEPTTR/LEPTNO Oilseed rape SCLESC	2 x 0.8 l/ha 2 x 0.8 l/ha 2 x 0.8 l/ha 2 x 0.8 l/ha 1 x 0.7 l/ha
PROLINE EC 250	DK	18-473	Prothioconazole	EC	250 g/l	Wheat ERYSGR/PSDCHA/PUCCCS/LEPTNO/SEPTTR/PYRNTR/FUSASP Barley ERYSGH/RAMUCC/PUCCHD/RHYNSE/PYRNTE Oats ERYSGA/PYRNA	2 x 0.8 l/ha 2 x 0.8 l/ha 2 x 0.8 l/ha

Reference stand-ard	MS	Authorization number	Active sub-stance	Formulation		Crop/pathogen	Rate
				Type	Concentration of a.s.		
						Triticale PUCCSS/RHYNSE/LEPTNO/SEPTTR/PSDCHA/FUSASP Rye ERYSGR/PUCCSS/RHYNSE	2 x 0.8 l/ha 2 x 0.8 l/ha
JOAO	FR	2060116	Prothioconazole	EC	250 g/l	Wheat SEPTTR/PUCCSS/ERYSGR/FUSASP PSDCHA Barley ERYSGH/FUSASP/PUCCHD/PYRNTE/RAMUCC/ RHYNSE PSDCHA Oats ERYSGA/PUCCCO PSDCHA Rye PUCCSS/RHYNSE PSDCHA Oilseed rape ALTEBA/ERYSCR/PYRPBR/SCLESC Flax ERYSP	2 x 0.8 l/ha 1 x 0.8 l/ha 2 x 0.8 l/ha 1 x 0.8 l/ha 2 x 0.8 l/ha 1 x 0.8 l/ha 2 x 0.7 l/ha 2 x 0.7 l/ha
PROLINE	NL	12725	Prothioconazole	EC	250 g/l	Wheat LEPTNO/FUSASP/PSDCHA SEPTTR/ERYSGR/PYRNTR/PUCCSS Barley ERYSGH/PYRNTE/RHYNSE/PUCCHD Triticale LEPTNO/FUSASP/PSDCHA	1 x 0.8 l/ha 2 x 0.8 l/ha 2 x 0.8 l/ha 1 x 0.8 l/ha

Reference stand-ard	MS	Authorization number	Active sub-stance	Formulation		Crop/pathogen	Rate
				Type	Concentration of a.s.		
						SEPTTR/ERYSGR/PYRNTR/PUCCSS	2 x 0.8 l/ha
PROLINE	IE	03786	Prothioconazole	EC	250 g/l	Wheat/rye/triticale ERYSGR/SEPTTR/LEPTNO/PYRNTR/PUCCSS/FUSASP/PSDCHA Barley/oats ERYSGH/PYRNTE/RHYNSE/PUCCHD/PSDCHA/FUSASP/RAMUCC Oilseed rape SCLESC/ PYRPBR/LEPTMA	3 x 0.8 l/ha 2 x 0.8 l/ha 2 x 0.7 l/ha
PROLINE EC 250	SE	4688	Prothioconazole	EC	250 g/l	Wheat/barley/rye/triticale Fungal diseases Oats Fungal diseases Oilseed rape Fungal diseases	2 x 0.6 l/ha 1 x 0.6 l/ha 1 x 0.7 l/ha
NORTH-EASTERN EPPO ZONE							
PRAKTIS	PL	R-30/020WU	Prothioconazole	EC	250 g/l	Wheat PUCCRE/SEPTTR/FUSASP Oilseed rape SCLESC	2 x 0.8 l/ha 2 x 0.7 l/ha
PROLINE	LT	AS2-6F (2018)	Prothioconazole	EC	250 g/l	Wheat/spelt ERYSGR/SEPTTR/LEPTNO/PYRNTR/PUCCSS/FUSASP/PSDCHA Barley ERYSGH/RHYNSE/PUCCHD/PYRNTE/FUSASP/PSDCHA Triticale ERYSGR/SEPTTR/LEPTNO/PUCCSS/RHYNSE/FUSASP/PSDCHA	2 x 0.8 l/ha 2 x 0.8 l/ha 2 x 0.8 l/ha

Reference stand-ard	MS	Authorization number	Active sub-stance	Formulation		Crop/pathogen	Rate
				Type	Concentration of a.s.		
						Rye ERYSGR/PUCCSS/RHYNSE/PSDCHA	2 x 0.8 l/ha
PROLINE	LV	0637	Prothioconazole	EC	250 g/l	Wheat/spelt ERYSGR/SEPTTR/LEPTNO/PYRNTR/PUCCSS/FUSASP/PSDCHA	2 x 0.8 l/ha
						Barley ERYSGH/RHYNSE/PUCCHD/PYRNTE/FUSASP/PSDCHA	2 x 0.8 l/ha
						Triticale ERYSGR/SEPTTR/LEPTNO/PUCCSS/RHYNSE/FUSASP/PSDCHA/ PYRNTR	2 x 0.8 l/ha
						Rye ERYSGR/PUCCSS/RHYNSE/ FUSASP/PSDCHA	2 x 0.8 l/ha
PROLINE	FI	2788	Prothioconazole	EC	250 g/l	Cereals ERYSGR/PUCCSS/ SEPTTR/ RAMUCC/FUSASP/ PYRNTR/PSDCHA	2 x 0.8 l/ha
						Oilseed rape ALTEBA/SCLESC	2 x 0.7 l/ha
PROLINE	EE	717/09.07.18	Prothioconazole	EC	250 g/l	Wheat ERYSGR/SEPTTR/LEPTNO/PYRNTR/PUCCSS/FUSASP/PSDCHA	2 x 0.4-0.8 l/ha
						Barley ERYSGH/RAMUCC/RHYNSE/PUCCHD/PYRNTE/FUSASP	2 x 0.4-0.8 l/ha
						Oats ERYSGR/PUCCSS/PYRNTE	2 x 0.4-0.8 l/ha
						Triticale ERYSGR/SEPTTR/LEPTNO/PUCCSS/RHYNSE/PSDCHA/PYRNTR	2 x 0.4-0.8 l/ha
						Rye ERYSGR/PUCCSS/RHYNSE	2 x 0.4-0.8 l/ha

Reference stand-ard	MS	Authorization number	Active sub-stance	Formulation		Crop/pathogen	Rate
				Type	Concentration of a.s.		
SOUTH-EASTERN EPPO ZONE							
PRAKTIS	BG	01860	Prothioconazole	EC	250 g/l	Wheat PUCCSS/ FUSASP Barley FUSASP	2 x 0.8 l/ha 2 x 0.8 l/ha
PROLINE	HU	6300/1205-1/2020	Prothioconazole	EC	250 g/l	Wheat/Rye/Triticale SEPTTR/LEPTNO/PUCCSS/PYRNTE/ERYSGR/FUSASP Barley ERYSGH/ PUCCSS/ PYRNTE	2 x 0.6-0.8 l/ha 2 x 0.6-0.8 l/ha
PROLINE 250 EC	SK	06-02-0768	Prothioconazole	EC	250 g/l	Wheat PUCCSS/ ERYSGR/ SEPTTR/PSDCHA FUSASP Barley PUCCHD/ERYSGH/RHYNSE/RAMUCC FUSASP	2 x 0.8 l/ha 2 x 0.6-0.8 l/ha 2 x 0.8 l/ha 2 x 0.6-0.8 l/ha
MEDITERRANEAN EPPO ZONE							
PROLINE	GR	60838	Prothioconazole	EC	250 g/l	Wheat ERYSGR/SEPTTR/FUSASP/LEPTNO PSDCHA Barley ERYSGH/FUSASP/PUCCHD/PYRNTE/ RHYNSE PSDCHA Oats ERYSGA/PUCCCA PSDCHA Rye PUCCSS/RHYNSE	2 x 0.8 l/ha 1 x 0.8 l/ha 2 x 0.8 l/ha 1 x 0.8 l/ha 2 x 0.8 l/ha 1 x 0.8 l/ha 2 x 0.8 l/ha

Reference stand- ard	MS	Authorization number	Active sub- stance	Formulation		Crop/pathogen	Rate
				Type	Concentration of a.s.		
						Oilseed rape ALTEBA/ERYSCR/PYRPBR/SCLESC Flax ERYSP	2 x 0.7 l/ha 2 x 0.7 l/ha
PROLINE	IT	013385	Prothioconazole	EC	250 g/l	Wheat and barley SEPTTR/PUCCSS/PYRNTE/ERYSGR/FUSASP	2 x 0.8 l/ha
PRAKTIS	IT	017751	Prothioconazole	EC	250 g/l	Wheat FUSASP/PUCCSS Barley PUCCSS	2 x 0.8 l/ha 2 x 0.8 l/ha
PRAKTIS	ES	ES-01135	Prothioconazole	EC	250 g/L	Wheat FUSASP/PUCCSS Barley PUCCSS	2 x 0.8 l/ha 2 x 0.8 l/ha
JOAO	FR	2060116	Prothioconazole	EC	250 g/l	Wheat SEPTTR/PUCCSS/ERYSGR/FUSASP PSDCHA Barley ERYSGH/FUSASP/PUCCHD/PYRNTE/RAMUCC/ RHYNSE PSDCHA Oats ERYSGA/PUCCCO PSDCHA Rye PUCCSS/RHYNSE Eyespot	2 x 0.8 l/ha 1 x 0.8 l/ha 2 x 0.8 l/ha 1 x 0.8 l/ha 2 x 0.8 l/ha 1 x 0.8 l/ha 2 x 0.8 l/ha 1 x 0.8 l/ha

Reference stand- ard	MS	Authorization number	Active sub- stance	Formulation		Crop/pathogen	Rate
				Type	Concentration of a.s.		
						Oilseed rape ALTEBA/ERYSCR/PYRPBR/SCLESC Flax ERYSP	2 x 0.7 l/ha 2 x 0.7 l/ha

3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

According to EPPO standard PP 1/213 (4) ‘Resistance risk analysis’.

According to EPPO guideline PP 1/213 “*Resistance risk analysis*”, resistance is the naturally occurring, inheritable adjustment in the ability of individuals in a population to survive a plant protection product treatment that would normally give effective control.

It is in the interest of both registration authorities and crop protection companies to protect the efficacy of plant protection products. Therefore, the development of resistance should be minimized by means of suitable management strategies which should be agreed and implemented before the product is released for full commercial use. To ensure sufficient resistance risk management strategies, a suitable resistance risk assessment should be conducted first. The resistance assessment has been undertaken according to EPPO guideline PP 1/213 “*Resistance risk analysis*”.

3.3.1 Mode of action

Prothioconazole is a member of the FRAC fungicide Group 3 (G1-3) with mode of action of Sterol biosynthesis in membranes, C14-demethylase in sterol biosynthesis (erg11/cyp51). Specifically, prothioconazole is a triazolinthione DMI-fungicide (DeMethylation Inhibitors) (SBI: Class I). Prothioconazole is a systemic fungicide molecule which acts on the endoplasmic reticulum of the cell. The mode of action is interference with the synthesis of ergosterol in the target fungi by inhibition of CYP51, which catalyses demethylation at C14 of lanosterol or 24-methylene dihydrolanosterol, leading to morphological and functional changes in the fungal cell membrane.

3.3.2 Mechanism of resistance

According to FRAC ([FRAC | Background Information](#)) there are 4 main mechanisms by which fungi can become resistant to fungicides.:

- Alteration of the target site so that sensitivity to the fungicide is reduced: By far the most common way that fungi can become resistant to a specific fungicide is via a change at the target site. As fungi grow their DNA is replicated when new cells are created. This process of replication is imperfect and errors can occur. These errors are known as mutations. Since DNA is the code used to produce enzymes in the cell, some mutations result in changes to the amino acid sequence of the target site which in turn alters the shape of the lock/target site. The fungicide/key may not fit as well anymore or may not fit at all in the target site/lock. This results in a reduction in sensitivity that may range from small to very large.
- Detoxification or metabolism of the fungicide: The fungal cell contains a vast array of metabolic machinery for normal cellular processes. This metabolic machinery may be able to modify the fungicide to a non-toxic form that is no longer harmful to the cell. Some fungicides are applied as inactive pro-fungicides which require further metabolism by the fungal cell to become the active form. If fungal metabolism is altered such that the activation step does not occur the active form of the fungicide is not produced.
- Overexpression of the target: As discussed above, the fungicide is “competing” with the natural substrate for the target site. As more and more fungicide enters the cell, it out-competes the

natural substrate for the target and as a result shuts down critical cellular processes. The production of additional target site enzyme (i.e. overexpression of the target) may increase the likelihood that enough of the fungal substrate will be able to bind with the target site enzyme such that cellular processes such as respiration can occur to some degree. Higher doses of the fungicide in in vitro experiments may restore the balance in favor of the fungicide, but higher doses may not always be practical under field conditions.

- Exclusion or expulsion from the target site: Efflux pumps exist naturally within the cell to exclude or expel foreign substances or to export endogenous substances. In fungi, the most common efflux pumps are ABC and MFS transporters. Despite these efflux pumps, most fungicides can reach effective concentrations inside the cell and inhibit cellular processes. Occasionally, these transporters are successful in expelling enough of the fungicide such that an isolate has reduced sensitivity. The fungicides expelled from the cell by a specific transporter may or may not be active at the same target site; i.e. there is not a direct relationship between the transporter that expels a specific fungicide and the target site of the fungicide. Multidrug resistance (MDR) develops when a specific transporter is able to exclude multiple fungicides from different target site groups. Application of the fungicides in question may exert enough selection pressure that isolates containing these fungicide-exporting transporters become more prevalent in the population as is the case in *Botrytis cinerea* (Kretschmer et al. 2009).

A paper by Cools *et al.*, 2013¹, gives a good overview of the mechanisms of resistance in DMI fungicides, and the following information is cited from this paper:

Triazoles and triazolinthiones form a large group of sterol 14a-demethylation inhibiting (DMI) fungicides, the most widely used class of antifungal agents for the control of pathogenic fungi. When resistance occurs, resistance levels are often low and cross-resistance between members of the azole class incomplete.

The resistance occurs through 3 primary mechanisms:

- mutations in the target-encoding CYP51 gene resulting in decreased affinity of the protein for inhibitors,
- over-expression of the target CYP51 gene most frequently caused by insertions in the predicted promoter regions,
- increased efflux caused by the over-expression of genes encoding membrane transporters.

These mechanisms can combine, and resistance levels are often determined by combinations of CYP51 amino acid alterations, CYP51 gene overexpression and/or increased efflux. In addition, some species have more than one paralogous CYP51 gene.

CYP51 alteration

Azoles inhibit sterol 14a-demethylase (CYP51). This P450 enzyme is essential for the biosynthesis of sterols, critical components of cell membranes that are considered prerequisite for the evolution of eukaryotes. Some mutations have been identified leading to resistant phenotypes in fungal pathogens of cereals:

- Y136F, in cereal powdery mildews (Delye et al., 1997, 1998; Wyand & Brown, 2005).
- Y137F, in the septoria leaf blotch pathogen *Zymoseptoria tritici* (Leroux et al., 2007; Cools et al., 2011)
- Y134F in *Puccinia triticina* (Stammler et al., 2009), the wheat brown rust pathogen.

Other CYP51 mutations confer contrasting effects on azole sensitivity. For example, in *Z. tritici* populations the sequential accumulation of CYP51 mutations has generated CYP51 variants with V136A and I381V mutations, combined or not with the substitutions D134G and/or S524T (Leroux & Walker, 2011; Cools & Fraaije, 2013). These isolates are becoming more common as they are less sensitive to the most widely used azoles epoxiconazole, prothioconazole and prochloraz.

¹ H. J. Cools, N. J. Hawkins & B. A. Fraaije. Constraints on the evolution of azole resistance in plant pathogenic fungi. Plant Pathology (2013) 62 (Suppl. 1), 36–42

Western European populations of *Z. tritici* are dominated by isolates with CYP51 variants carrying V136A and/or I381V, combined with changes at residues Y459–Y461 (Stammler et al., 2008), and different combinations of these mutations can confer decreased sensitivity to all azoles currently registered for septoria leaf blotch control (Cools et al., 2011; Cools & Fraaije, 2013).

In fungal pathogens of oilseed rape, two mutations conferring some degree of insensitivity to triazoles, G460S and S508, have been identified in the *Pyrenopeziza brassicae* population in UK (Ritchie et al., 2020). The proportion of the G460S mutation in the field reached 90% in 2019, but azoles effectiveness was not affected.

CYP51 over-expression

As a mechanism of acquired resistance to fungicides, increased expression of the target-encoding gene is unique to the azoles and with CYP51 over-expression contributes to azoleresistant phenotypes in *P. tritici* (Stammler et al., 2009) and *Z. tritici* (Cools et al., 2012).

CYP51 over-expression may offer some selective advantages in comparison to other resistance mechanisms. Unlike alterations of CYP51 primary sequence, changes in sensitivity of individuals over-expressing

CYP51 are not compound-specific, with complete cross-resistance between the azoles common. However, resistance levels are generally lower than those caused by target site alteration, and therefore higher doses or more active compounds can be effective against isolates over-expressing CYP51.

Enhanced fungicide efflux

Enhanced fungicide efflux, leading to resistance to multiple unrelated drugs, a so-called multidrug-resistant (MDR) phenotype, is caused by the over-expression of genes encoding membrane transporters (e.g. ABC transporters). For example, *Botrytis cinerea* has a genetic mechanism conferring enhanced efflux to multiple fungicides, which impacts on the performance of fungicides in the field (Kretschmer et al., 2009).

Multiple CYP51s

Multiple CYP51 paralogues have been identified in plant pathogens species such as *Fusarium* and *Rhynchosporium* (Becher et al., 2011; Hawkins et al., 2011; Liu et al., 2011). In *Fusarium graminearum*, two of the three CYP51 paralogues, CYP51A and CYP51B, are functionally redundant, both encoding sterol 14a-demethylases, but CYP51A is rapidly induced upon ergosterol depletion caused by azole treatment, and is thus responsible for the intrinsically low sensitivity of *F. graminearum* to some azole fungicides (Fan et al., 2013).

To summarise then, the so far identified mechanisms of resistance for prothioconazole and other DMI fungicides appears to comprise both target and non-target site mechanisms. These mechanisms can reduce sensitivity to those fungicides but do not necessarily result in field resistance of the pathogens, although for some pathogens this has been observed as indicated in the subsequent section.

3.3.3 Evidence of resistance

The resistance cases presented in this section relate to prothioconazole and to other fungicides with the same mode of action (Group 3). Data has been collated from a range of sources including FRAC, EPPO and also R4P for France. In 2021 EPPO launched a new resistance database (https://resistance.eppo.int/database/cases_list) collating all verified cases of resistance against plant protection products in Europe, therefore this has been used as the primary source.

EPPO database information

Specifically for prothioconazole, 5 confirmed cases of resistance are reported on the EPPO resistance database which relate to SEPTTR on wheat (1 in Belgium, 1 in Denmark) and RAMUCC on barley (1 in Germany, 1 in Denmark and 1 in Austria).

For the fungicide ~~group~~ Group 3 to which prothioconazole belongs there are 23 cases reported on the

database, although 11 of these are for pathogens on other crops such as fruit, vegetables and ornamentals which are not relevant for the use of CA3301. The 12 cases relevant for CA3301 are for FUSACU (1) on winter wheat from Belgium; powdery mildew (ERYSGR/ERYSGH) – 1 on winter wheat and 1 on barley in the UK, the 3 cases on RAMUCC on barley mentioned above for prothioconazole; and 6 cases for SEPTTR on wheat – 2 as mentioned above and 1 each from Austria, Germany, Sweden and UK. These cases are presented in Table 6.3-1.

FRAC information

The Fungicide Resistance Action Committee (FRAC) has been working for many years on monitoring of pathogens for resistance and provide annual reports on the results for each group of fungicides. These reports give information on the development of resistance over time. The most recent reports for DMI (Group 3) fungicides from the 2021 SBI working group relevant to CA3301 are summarised here:

CEREALS

- *Blumeria graminis* (ERYSGR / ERYSGH / ERYSGS/ ERYSGT): according to the FRAC, a monitoring was carried out on wheat in 2020, in various countries such as Belgium, Czech Republic, Denmark, France, Germany, Hungary, Italy, Poland, Romania, Slovakia, Spain and United Kingdom. Sensitivity data presented for 2016 to 2020 confirmed that the situation was overall stable within the range of variability detected during the last 20 years. High resistance factors have been observed only for particular DMIs especially in France, Germany and UK, but also to a lesser extent in Belgium.
On barley, monitoring was carried out in France, Germany and United Kingdom. From monitoring in 2020 and 2018 it was reported that DMI products performed well and the sensitivity of the populations stayed in the range observed for more than 15 years.
- *Fusarium graminearum* (GIBBZE): In 2020, a monitoring was carried out on wheat, in France (according to the FRAC), and a stable sensitivity situation was observed from the last 10 years.
- *Parastagonospora nodorum* (LEPTNO): According to the FRAC, a reduced monitoring was carried out in 2020, in Czech Republic and Sweden. In this monitoring on wheat, a very narrow sensitivity range with high sensitivity levels was observed.
- *Oculimacula acutiformis* (PSDCHA) and *O. yallundae* (PSDCHE): According to the FRAC, a monitoring was carried out on wheat in 2020, in various countries such as France, Germany, Latvia, Lithuania, Poland, Russia, Spain, Ukraine and United Kingdom. The same range of sensitivity, as in previous years, was observed in all countries. Between 2003 and 2012 there was no change in the sensitivity of W and R types, stable situation had been observed during that time. In 2013, some sensitivity change has been observed in the United Kingdom, but not in France or Germany. In 2014 further sensitivity decrease has been observed in the United Kingdom, and for the first time also in France and Germany. However, overall, resistance factors still remain low and performance was not affected.
- *Puccinia hordei* (PUCCHD): According to the FRAC, monitoring carried out on barley from 2014 to 2019. The observations were recorded in Denmark, France, Germany, Sweden, and United Kingdom. In the five-year interval, a very stable situation with a narrow range of sensitivity was observed.
- *Puccinia recondita* (PUCCRE) and *P. tritricina* (PUCCRT): According to the FRAC, a monitoring was carried out on wheat in 2020, in various countries such as Belgium, Czech Republic, France, Germany, Hungary, Italy, Poland, Romania, Slovakia, Spain, United Kingdom. Sensitivity data from 2020 for wheat brown rust showed that sensitivities were
- in the range of those of the last 20 years as observed in monitoring from other FRAC member companies.

- *Puccinia striiformis* (PUCCST): According to the FRAC, a monitoring was carried out in 2020, in various countries such as Belgium, Denmark, France, Germany, Italy, Poland, Portugal, Spain and United Kingdom. A high sensitivity and a low diversity of strains were recorded from 2015 to 2020.
- *Pyrenophora teres* (PYRNTE): According to the FRAC, a monitoring was carried out on barley in 2020, in various countries such as Austria, Bulgaria, Czech Republic, Denmark, France, Germany, Hungary, Ireland, Italy, Lithuania, Poland, Romania, Russia, Slovakia, Spain, Sweden, Switzerland, Ukraine and United Kingdom. Overall, the sensitivity of populations monitored in 2020 stayed in the range observed in previous years, without any major geographical differences across Europe. In 2019, like 2017 lower sensitivities have been frequently detected in major French regions and in a single location in North-Eastern Germany. In the other European regions, monitored sensitivity ranges were stable.
- *Pyrenophora tritici-repentis* (PYRNTR): According to the FRAC, a reduced monitoring was carried out in 2020, in various countries such as Czech Republic, Romania and Sweden. A stable and sensitive situation was observed concerning the response to triazoles. In addition, monitoring data from 2019 in Finland, Lithuania, and United Kingdom showed a narrow range of sensitivity in line with results from previous years.
- *Ramularia collo-cygni* (RAMUCC), according to FRAC, monitoring was carried out on barley in 2020, in various countries such as Denmark France, Germany, Hungary, Ireland, Italy, Lithuania, Poland, Slovakia, Spain, Sweden, Switzerland, and United Kingdom. Isolates were detected showing significant loss of sensitivity. Relevant CYP51-mutations explaining the effects have been identified (I325T, I328L, Y403C/Y405H).
- In 2020, the results from bioassay and molecular analysis focusing on the most relevant mutations are:
 - no to low frequencies of resistance in Italy, Switzerland, and Spain
 - no to high frequencies of resistance in France
 - moderate to high frequencies of resistance in Germany and Sweden,
 - high frequencies of resistance in Czech Republic, Denmark, France, Hungary, Ireland, Lithuania, Slovakia and United Kingdom.Isolates highly resistant to triazoles were identified as early as 2015 following monitoring carried out exclusively in Germany. The strains most resistant to prothioconazole present very high IC₅₀s, associated with a combination of mutations affecting cyp51 (I381T + I384L + Y459C or Y460H). These mutations were correlated with decreases in efficiency under controlled conditions. Other mutations (affecting codons 136, 459, 460 or 461) were also detected but have a low impact.
- *Rhynchosporium secalis* (RHYNSE): According to the FRAC, a monitoring was carried out on barley in 2020, in various countries such as Denmark, France, Germany, Hungary, Ireland, Latvia, Poland, Slovakia, Spain and United Kingdom. Field performance of DMIs was good and the sensitivity of the populations stayed in the range observed in Europe in the previous 15 years.
- *Zymoseptoria tritici* (SEPTTR): According to the FRAC, a monitoring was carried out in 2020, in various countries such as Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, France, Germany, Hungary, Ireland, Italy, Latvia, Lithuania, the Netherlands, Norway, Poland, Romania, Russia, Slovakia, Spain, Sweden, Switzerland, Turkey, Ukraine, and United Kingdom. In 2020, the sensitivity of populations was overall stable on European level with EC₅₀ sensitivity values in the range of previous years. As also reported in 2019 DMI EC₅₀ sensitivity values were higher in the UK and Ireland than observed on the European continent where a gradient can be observed from North-West to South-East.

OILSEED RAPE

- *Leptosphaeria maculans* (LEPTMA): According to FRAC, a monitoring was carried out on oilseed rape, in 2020, in various countries such as Czech Republic, Finland France, Germany, Hungary, Ireland, Latvia, Lithuania, Poland, Romania, Slovakia, Sweden and United Kingdom. A stable sensitivity was observed as well as in previous years. In addition, in 2018/19, monitoring was carried out in Czech Republic, France, Finland, Germany, Hungary, Poland, Romania, Slovakia, and United Kingdom. Data showed a stable sensitivity range as in the last 10 years.
- *Sclerotinia sclerotiorum* (SCLESC): According to FRAC, a monitoring was carried out on oilseed rape in 2020, in various countries such as Bulgaria, Czech Re-public, Denmark, France, Germany, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia, Ukraine and United Kingdom. Monitoring data has also been carried out in Europe each year since 2016. Monitoring data from the five years showed a stable and narrow sensitivity range with no geographical differences.

No monitoring has been reported from FRAC for the other target pathogens of oilseed rape ALTEBA, ERYSCR and PYRPBR. However, according to the EPPO resistance database no cases of resistance have been reported for G1-3 on these pathogens.

In addition, FRAC has published a list of first confirmed cases of plant pathogenic organisms resistant to disease control agents (revised May 2020) which lists cases for each fungicide group. Since not all of these are included in the EPPO database these cases are also presented in Table 6.3-3. Among these is a report of possible resistance development in PYRPBR for group G1-3 (DMI) fungicides

R4P – France

The R4P network in France also reports national cases of resistance ([Resistance status in France – R4P \(r4p-inra.fr\)](https://www.inrae.fr/en/themes/pest-management/plant-protection/pesticide-resistance/r4p-inra-fr)). The most recent list from July 2020 (List of cases of resistance to plant protection products detected in France, Version 3) reports various cases which are relevant for the proposed uses for CA3301 (target pathogens) as presented in Table 6.3-2. Among these cases are a report for *Rhynchosporium secalis* which is not reported on the EPPO database, although this pathogen is included in the FRAC list.

Table 3.3-1: Confirmed cases of resistance to prothioconazole and other Group 3 fungicides according to EPPO resistance database*

Case ID	Country	Active substance	Pest	Crop	Mechanism	Occurrence	Reference/source of information
22	UK	Tebuconazole	ERYSGH	HORVX	Unknown	Unknown - regional	FRAG-UK list of known UK resistant pathogens March 2012
46	UK	Tebuconazole	ERYSGR	TRZAW	Unknown	Unknown - regional	FRAG-UK list of known UK resistant pathogens March 2012
712	Belgium	Epoxiconazole, Tebuconazole	FUSACU	TRZAW	NTSR -transporter (FcABC1) upregulation	Isolated cases	Hellin, P., Scaufaire, J., Van Hese, V., Munaut, F. and Legrève, A. (2017), Sensitivity of <i>Fusarium culmorum</i> to triazoles: impact of trichothecene chemotypes, oxidative stress response and genetic diversity. Pest. Manag. Sci., 73: 1244-1252. https://doi.org/10.1002/ps.4450 ; Hellin P, King R, Urban M, Hammond-Kosack KE., Legrève A, The adaptation of <i>Fusarium culmorum</i> to DMI Fungicides Is Mediated by Major Transcriptome Modifications in Response to Azole Fungicide, Including the Overexpression of a PDR Transporter (FcABC1) Frontiers in Microbiology, 9, 2018, p. 1385 https://www.frontiersin.org/articles/10.3389/fmicb.2018.01385/full#B18
588	Austria	Prothioconazole	RAMUCC	HORVX	Both (TSR and NTSR)	Low - local	Minutes of the 2020 SBI Meeting Recommendations for 2020 - FRAC - https://www.frac.info/docs/default-source/working-groups/sbi-fungicides/group/minutes-of-the-2020-sbi-meeting-recommendations-for-2020.pdf?sfvrsn=50b499a_2
249	Denmark	Prothioconazole	RAMUCC	HORVX	Target-site resistance (TSR)	Moderate - local	FRAC
211	Germany	Prothioconazole	RAMUCC	HORVX	Both (TSR and NTSR)	Low - local	Expert knowledge meetings and FRAC
729	Sweden	Difenoconazole, Epoxiconazole, Metconazole, Propiconazole, Tebuconazole	SEPTTR	TRZAX	Target-site resistance (TSR)	High - national	Heick TM. P540 AF, Jørgensen, LN (2017) Resistance of winter wheat pathogen <i>Zymoseptoria tritici</i> to DMI and QoI fungicides in the Nordic-Baltic region – a status. European Journal of plant pathology. DOI 10.1007/s10658-017-1216-7+P547
710	Belgium	Epoxiconazole, Metconazole, Prochloraz, Prothioconazole , Tebuconazole	SEPTTR	TRZAW	Target-site resistance (TSR)	Very high - national	Curvers, K., Pycke, B., Kyndt, T. et al. Sensitivity towards DMI fungicides and haplotypic diversity of their CYP51 target in the <i>Mycosphaerella graminicola</i> population of Flanders. J Plant Dis Prot 121, 156–163 (2014). https://doi.org/10.1007/BF03356504
585	Austria	Epoxiconazole, Propiconazole, Tebuconazole	SEPTTR	TRZAX	Both (TSR and NTSR)	Moderate - national	Expert knowledge, meetings, FRAC
247	Denmark	Difenoconazole, Epoxiconazole, Metconazole,	SEPTTR	TRZAX	Target-site resistance (TSR)	High - national	Heick TM. P540 AF, Jørgensen, LN (2017) Resistance of winter wheat pathogen <i>Zymoseptoria tritici</i> to DMI and QoI fungicides in the Nordic-Baltic region – a status. European Journal of plant pathology. DOI 10.1007/s10658-017-1216-7+P547

		Prothioconazole, Tebuconazole					
208	Germany	Epoxiconazole, Propiconazole, Tebuconazole	SEPTTR	TRZAX	Both (TSR and NTSR)	High - na- tional	Expert knowledge meetings and FRAC
45	UK	Tebuconazole	SEPTTR	TRZAW	Unknown	Unknown - regional	FRAG-UK list of known UK resistant pathogens March 2012

*Accessed 17 November 2021

Table 3.3 2: Resistance cases to Group 3 fungicides in France (R4P)

Pest	Crop	Active substance	Mechanism	Occurrence	First report	Reference/source of information
ERYSGH	HORVX	Prochloraz, cyproconazole, epoxiconazole, flutriafol, metconazole, propiconazole, tebuconazole, tetraconazole, prothioconazole	TSR cyp51-Y137F +/- cyp51-K147Q	Resistance present in all regions of powdery mildew, high frequency	1990s	INRAE Grignon – A.S. Walker Walker et al, 2004; Walker et al, 2006 ; Delye et al, 1998 ; Wyand and Brown, 2005
ERYSGR	TRZAX	Prochloraz, cyproconazole, epoxiconazole, flutriafol, metconazole, propiconazole, tebuconazole, tetraconazole, prothioconazole	TSR cyp51-Y137F	Resistance present in all regions of powdery mildew, high frequency	1990s	INRAE Grignon – A.S. Walker Walker and Leroux, 2003 ; Walker et al, 2004 ; Walker et al, 2006 ; Delye et al, 1998 ; Wyand and Brown, 2005
PDCHA/E	cereals	Prochloraz epoxiconazole, propiconazole, tebuconazole, tetraconazole prothioconazole but no field resistance for prothioconazole	TSR?	Resistance present in all cereal regions, high frequency	1990s	Anses Lyon - B. Barrès, F. Rémus Leroux et al, 2006c ; Albertini et al, 2003; Durand et al, 2015 ; Leroux et Walker, 2009a ; Leroux et al, 2013
PYRNTE	HORVX	Prochloraz, cyproconazole, difenoconazole, epoxiconazole, metconazole, propiconazole, tebuconazole, prothioconazole	TSR (mutations not described)	Resistance present in cereal regions, prothioconazole seems less affected. Frequency unknown	1990s	INRAE Grignon – A.S. Walker Note commune céréales 2020; Mair et al, 2016
RAMUCC	HORVX	Prothioconazole	TSR (several combinations of mutations in cyp51 including I381T, I384L, Y459C or Y460H)	Resistance present in cereal regions, low to high frequency	2016	INRAE Grignon – A.S. Walker Strong emergence in Germany, accompanied by efficiency failures
RHYNSE	HORVX	Prochloraz, cyproconazole,	TSR	Resistance present in all cereal regions,	1990s	INRAE Grignon – A.S. Walker

		epoxiconazole, propiconazole, tebuconazole, prothioconazole		no recent information		Robbertse et al, 2001; Brunner et al, 2016
SEPTTR	TRZAX	Bromuconazole, cyproconazole, difenoconazole, epoxiconazole, flutriafol, metconazole, propiconazole, tebuconazole, tetraconazole, prothioconazole	TSR (combinations of many mutations in cyp51 + overexpression) + NTSR (efflux MDR, at least 3 genotypes)	Resistance present in all cereal regions, high frequency. Resistance affects azoles differently, according to the frequency of genotypes in populations. Uncomplete patterns of cross-resistance. In 2019, TriHR strains (high RF towards several azoles) found in 89% of the populations tests, mean frequency 46%. MDR strains found in 77% of the populations tested, mean frequency 27%.	Before1990s (2008 efflux)	INRAE Grignon – A.S. Walker Leroux et al, 2006a,b ; Leroux et al, 2007 ; Leroux et Walker, 2009a ; Leroux et Walker, 2011; Omrane et al, 2015; Note commune céréales 2020; Garnault et al, 2019.

Table 3.3 3: FRAC* cases for DMI fungicides relevant to CA3301 GAP

Pest	Crop	Reference/source of information	Remarks
ERYSGH	HORVX	Fletcher J S, Wolfe M S (1981) Insensitivity of <i>Erysiphe graminis f. sp. hordei</i> to triadimefon, triadimenol and other fungicides. Proceedings of the Brighton Crop Protection Conference, Pests & Diseases 633 – 640	Field
ERYSGR	TRZAX	De Waard M A, Kipp E M C, Horn N M, Van Nistelrooy J G M (1986). Variation in sensitivity to fungicides which inhibit ergosterol biosynthesis in wheat powdery mildew. Netherlands Journal of Plant Pathology 92, 21 – 32	Field
GIBBZE	TRZAX	Spolti, P.; Ponte, E. M. del; Dong, Y. H.; Cummings, J. A.; Bergstrom, G. C.; del Ponte, E. M. (2014) Triazole sensitivity in a contemporary population of <i>Fusarium graminearum</i> from New York wheat and competitiveness of a tebuconazole-resistant isolate. Plant Disease, Vol. 98, Number 5, pp. 607-613	Field
SEPTTR	TRZAX	<p>Metcalf R J, Shaw M W, Russell P E (2000). The effect of dose and mobility on the strength of selection for DMI fungicide resistance in inoculated field experiments. Plant Pathology 49, 546-557</p> <p>Mavroedi V I, Shaw M W (2005). Sensitivity distributions and cross resistance patterns of <i>Mycosphaerella graminicola</i> to fluquinconazole, prochloraz and azoxystrobin over a period of 9 years. Crop Protection 24, 259-266</p> <p>HGCA (2005). Wheat Disease Management Guide – 2005 Update. Home Grown Cereals Authority, London UK</p> <p>Cools H J, Fraaje B A, Lucas J A (2005). Molecular mechanisms correlated with changes in triazole sensitivity in isolates of <i>Mycosphaerella graminicola</i>. Proceedings of the BCPC International Congress, Crop Science & Technology 2005, 267-274</p>	<p>Field experiments</p> <p>Field experiments</p> <p>Field</p> <p>Laboratory</p>

PSDCHA/PSDCHE	TRZAW	Leroux P, Marchegay P (1991). Caractérisation des souches de <i>Pseudocercospora herpotrichoides</i> agent du Piétin-verse des céréales, résistantes au prochloraze, isolées en France sur blé tendre d'hiver. Agronomie 11, 767 – 776	Field
PUCCST	TRZAW	Bayles R A, Stigwood P L, Clarkson J D S (2000). Shifts in sensitivity of <i>Puccinia striiformis</i> to DMI fungicides in the UK. Acta Phytopathologica et Entomologica Hungarica 35, 381 - 382 Napier B A S, Bayles R A, Stigwood P L (2000). Sensitivity of powdery mildew and yellow rust to DMI, morpholine and strobilurin fungicides in England and Scotland. Proceedings of the BCPC Conference Pests & Diseases, 427-434	Sensitivity shift Laboratory
PYRNTE	HORVX	Sheridan J E, Grbavac N, Sheridan M H (1985). Triadimenol insensitivity in <i>Pyrenophora teres</i> . Transactions of the British Mycological Society 85, 338 – 341	Field
PYRNTR	TRZAW	Reimann S, Deising H B (2005). Inhibition of efflux mediated fungicide resistance in <i>Pyrenophora tritici-repentis</i> by a derivative of 4'-hydroxyflavone and enhancement of fungicide activity. Applied and Environmental Microbiology 71, 3269-3275	Field
RHYNSE	HORVX	Hunter T, Jordan V W, Kendall S J (1986). Fungicide sensitivity changes in <i>Rhynchosporium secalis</i> in glasshouse experiments. Proceedings of the British Crop Protection Conference, Pests & Diseases 523 – 536 Kendall S J, Hollomon D W (1990). DMI resistance and sterol 14-alpha demethylation in <i>Rhynchosporium secalis</i> . Proceedings of the British Crop Protection Conference Pests & Diseases 1129-1134 Kendall S J, Hollomon D W, Cooke L R, Jones D R (1993). Changes in sensitivity to DMI fungicides in <i>Rhynchosporium secalis</i> . Crop Protection 12, 357 – 362 Cooke L, Locke T, Lockley K D, Phillips A N, Sadiq M D S, Coll R, Black L, Taggart P J, Mercer P C (2004). The effect of fungicide programmes based on epoxyconazole on the control and DMI sensitivity of <i>Rhynchosporium secalis</i> in winter barley. Crop Protection 23, 393-406.	Glasshouse Field Field isolates Field
PYRPBR	BRSNN	Carter, H. E.; Fraaije, B. A.; West, J. S; Kelly, S. L; Mehl, A.; Shaw, M. W.; Cools, H. J. (2014). Alterations in the predicted regulatory and coding regions of the sterol 14 -demethylase gene (CYP51) confer decreased azole sensitivity in the oilseed rape pathogen <i>Pyrenopeziza brassicae</i> . Molecular Plant Pathology, 15, Number 5, pp. 513-522	Field

*List of first confirmed cases of plant pathogenic organisms resistant to disease control agents. Revised May 2020. FRAC

3.3.4 Cross-resistance

Fungicides active at the same target site (i.e. that is within the same FRAC code # on the FRAC Code List) are generally considered to be cross-resistant to each other. Cross-resistance is a phenomenon that occurs when resistance arises to one fungicide that also results in resistance to another fungicide. Occasionally, cross-resistance can occur between compounds active at different target sites (see multi-drug resistance under mechanisms of resistance below). According to the FRAC, if field resistance is known to one member of a Group, it is most likely but not exclusively valid that cross resistance to other group members will be present.

The group of fungicides that comprise the Sterol Biosynthesis Inhibitors (SBIs) inhibits the C14 demethylation step within fungal sterol biosynthesis. Prothioconazole is a Class 1 SBI known as demethylation inhibitors or DMIs (Group 3). While compounds within each of the three code groups, G1 (DMIs), G2, (amines) and G3 (KRIs), are cross-resistant with other members within the same group, there is no cross-resistance between members of different groups. Chemically, DMIs belong to different chemical groups but all DMIs inhibit fungi by interacting with the same target site, C14-demethylase (erg11/cyp51) and are therefore considered to be cross-resistant with each other.

There are big differences in the activity spectra of DMI fungicides. Generally, it is wise to accept that cross-resistance is present between DMI fungicides active against the same fungus. DMI fungicides are Sterol Biosynthesis Inhibitors (SBIs), but no cross-resistance to other SBI classes are recorded. ([FRAC Information](#)).

According to information presented in the paper by Cools et al., 2013² there are a number of cases of incomplete resistance among the DMI fungicides. Evidence of incomplete cross-resistance to prothioconazole was recorded in *Rhynchosporium secalis* on barley. In this case positive cross-resistance between propiconazole, tebuconazole, epoxiconazole has been observed but prothioconazole remained effective. In this case the pathogen contained a 2nd CYP51 target gene. Similarly for *Pseudocercospora herpotrichoides* R type and *Pseudocercospora herpotrichoides* W type, an unknown mechanism of resistance against many azoles is recorded but prothioconazole remained effective.

Nevertheless, for the purposes of maintaining efficacy in the future, resistance management strategies should be based on the proviso that cross resistance among DMI is likely.

3.3.5 Sensitivity data

Testing was undertaken in the CEU and SEU regulatory zones on the sensitivity of prothioconazole against two key pathogens - *Zymoseptoria tritici* on wheat and *Pyrenophora teres* on barley. The former is well known for the development of resistance against many fungicides including DMI fungicides. The latter has been selected as some cases are recorded for DMI fungicides, although this appears to be less established and sensitivity to prothioconazole is reportedly still maintained.

Group 3 fungicides have been in commercial use since 1970s and are widely used in Europe due to the relatively broad spectrum of activity against plant pathogens. For that reason, baseline sensitivity data is not reported here however standard isolates with DMI-sensitivity probably relatively close to the one of the unselected 'wild-type' population – were available for comparison by each of the laboratories which provided resistance testing for prothioconazole in 2020-2021.

Bioassay testing has been undertaken for prothioconazole against some of the target pathogens for which resistance has been reported. The testing was done according to the appropriate approved test methods

² H. J. Cools, N. J. Hawkins & B. A. Fraaije. Constraints on the evolution of azole resistance in plant pathogenic fungi. Plant Pathology (2013) 62 (Suppl. 1), 36–42

provided by FRAC.

CEU – Germany

In Germany testing was performed by Epilogic on *Zymoseptoria tritici* sampled from 16 locations and on *Pyrenophora teres* sampled from 10 locations in 2020 and on *Zymoseptoria tritici* sampled from 19 locations in 2021.

Zymoseptoria tritici

The data from Germany comprises results from 80 strains of *Zymoseptoria tritici* derived from the 16 sampling sites in 2020 and 76 strains from 19 locations in 2021. The test method was *in vitro* (microtiter) with test concentrations of 0.00, 0.03, 0.1, 0.3, 1.0, 3.0, 10.0, & 30.0 mg/l of prothioconazole.

Results 2020

Information on the samples and the mean, minimum and maximum EC₅₀ and EC₉₈ value are presented in Table 3.3-4. The range of EC₅₀ from the test samples was from 1.18 to 3.66 mg/l. The overall mean EC₅₀ value from all regions was 2.14 mg/l.

As shown in Figure 3.3.1 below, the majority of results were for EC₅₀ values between 1.88 and 2.18 mg/l.

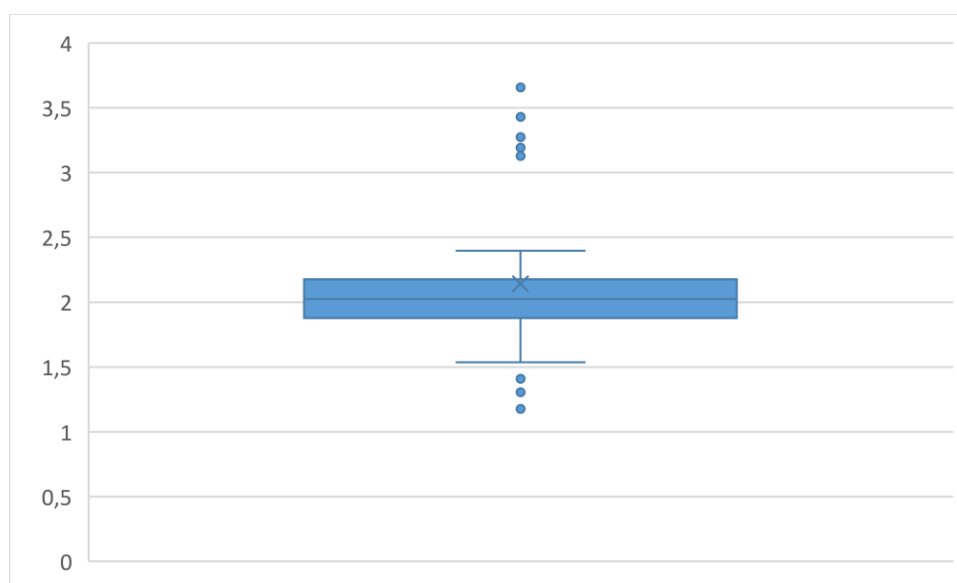


Figure 3.3 1: EC₅₀ values (mg/l) for prothioconazole on *Zymoseptoria tritici* strains sampled from Germany in 2020

The mean EC₅₀ of the reference strains known to be susceptible to DMI fungicides was reported to be 0.32 mg/l prothioconazole. This reference is therefore used as the “baseline” reference in this analysis. Clearly all samples were less sensitive to prothioconazole compared to the reference strains, however the Resistance Factor (RF) based on mean EC₅₀ values for the different regions ranged from 5.10 (Reken, Nordrhein-Westfalen) to 7.78 (Pöhl, Sachsen; variety Chevignon) which is relatively low. According to FRAC RF values of up to 10 are considered small (Fungicide resistance: The assessment of risk, FRAC Monograph No.2 second, (revised) edition). In fact, according to this paper pathogen strains with an RF value of 5 showed no difference in disease control compared to baseline populations

The diversity was low at 1.2 to 2.9 among the regions as shown in Figure 3.3.2 below.

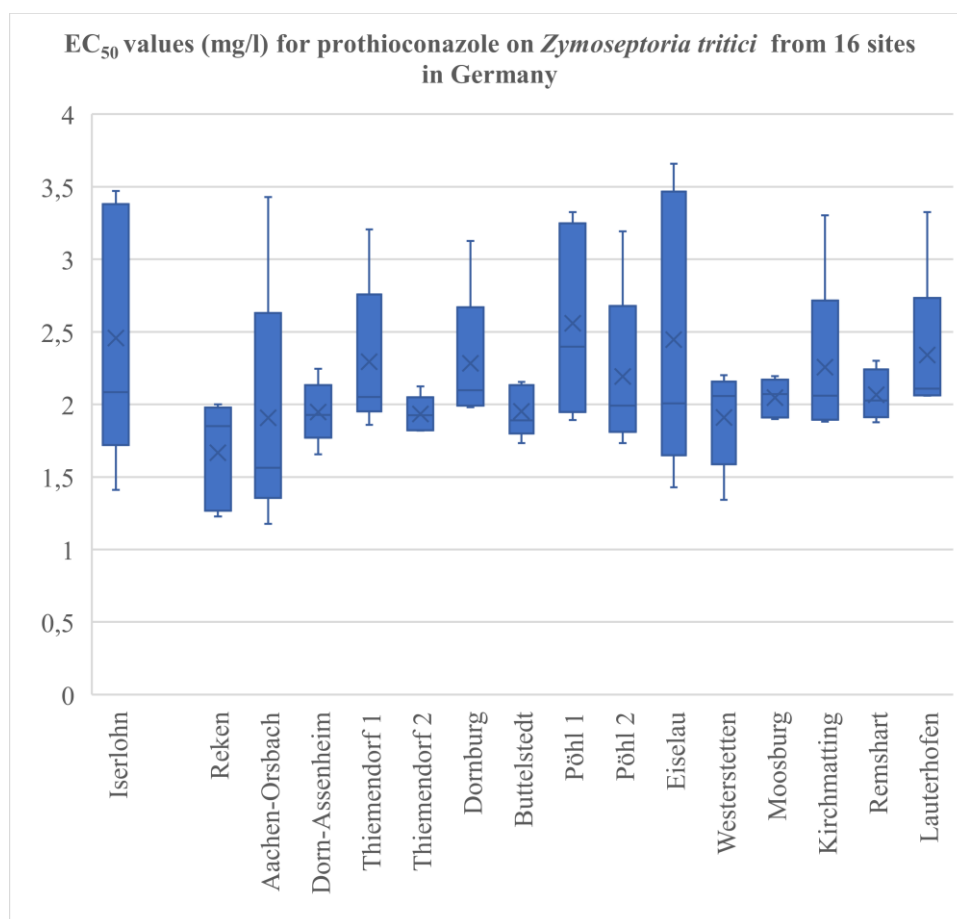


Figure 3.3.2: EC₅₀ values (mg/l) for prothioconazole on *Zymoseptoria tritici* strains sampled from Germany in 2020

Results 2021

Information on the samples and the mean, minimum and maximum EC₅₀ and EC₉₈ value are presented in Table 3.3-5. The range of EC₅₀ from the test samples was from 1.74 to 5.48 mg/l. The overall mean EC₅₀ value from all regions was 2.85 mg/l.

As shown in Figure 3.3.3 below, the majority of results were for EC₅₀ values between 2.24 and 3.42 mg/l.

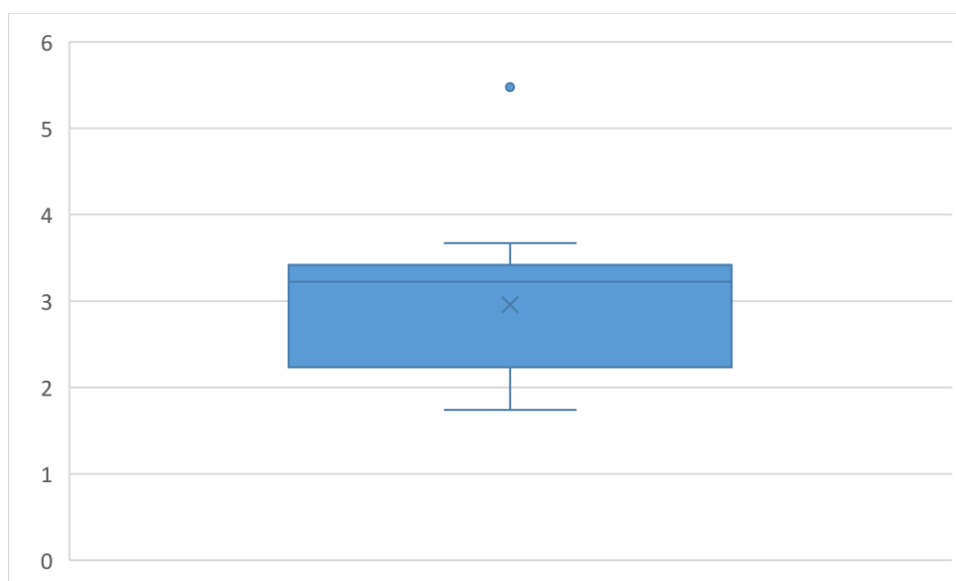


Figure 3.3.3: EC₅₀ values (mg/l) for CA3301 on *Zymoseptoria tritici* strains sampled from Germany in 2021

The mean EC₅₀ of the reference strains known to be susceptible to DMI fungicides was reported to be 0.35 mg/l prothioconazole. This reference is therefore used as the “baseline” reference in this analysis. Clearly all samples were less sensitive to prothioconazole compared to the reference strains, however the Resistance Factor (RF) based on mean EC₅₀ values for the different regions ranged from 6.3 (Damendorf) to 10.9 (Seenheim) which is relatively low.

According to FRAC RF values of up to 10 are considered small (Fungicide resistance: The assessment of risk, FRAC Monograph No.2 second, (revised) edition). In fact, according to this paper pathogen strains with an RF value of 5 showed no difference in disease control compared to baseline populations.

The diversity was low at 1.0 to 2.5 among the regions as shown in Figure 3.3.4 below.

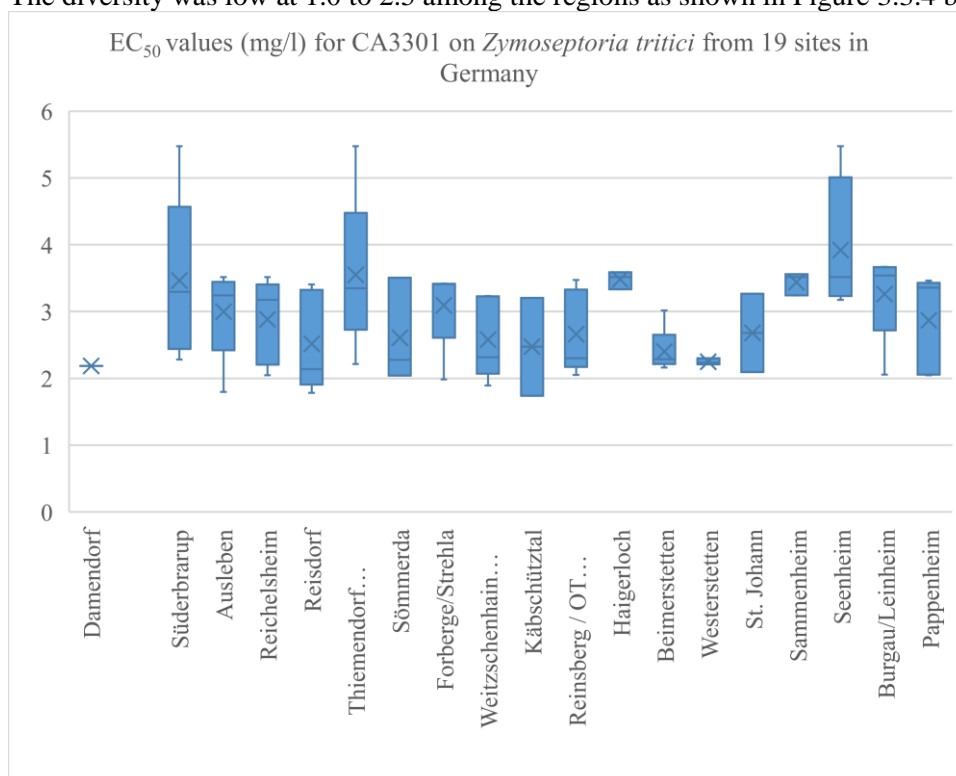


Figure 3.3.4: EC₅₀ values (mg/l) for CA3301 on *Zymoseptoria tritici* strains sampled from Germany in 2021

Conclusion on *Zymoseptoria tritici* in Germany

The data from the samples indicates that most strains of *Zymoseptoria tritici* are still sensitive to prothioconazole, indeed even the least sensitive strain in 2020 with an EC₅₀ value of 3.66 mg/l has a Resistance Factor of only 11.4, and for 2021 the least sensitive strain has an EC₅₀ value of 5.48 mg/l and an RF value of 15.7. This contrasts with some of the data reported for other DMI fungicides for example for mefentrifluconazole and tebuconazole (Kiiker *et al.*, 2021³) and for epoxiconazole and tebuconazole (Mae *et al.*, 2020⁴) in other parts of Europe, where RF values were much higher. However, in these papers also it is indicated that sensitivity of *Zymoseptoria tritici* is higher for prothioconazole than some of the other DMI fungicides.

A slight overall increase in EC₅₀ values was observed between 2020 and 2021 although in the latter results the sensitive reference strain was also higher. Resistance Factor values showed some increase compared to the previous years' samples but still remained relatively low.

In addition, the low diversity factors for the regions across both years suggest that at present the populations remain relatively stable in terms of sensitivity towards prothioconazole.

The data therefore appears to support results from the efficacy trials presented in this dossier demonstrating that prothioconazole remains effective against *Zymoseptoria tritici*.

³ Kiiker, R.; Juurik, M.; Heick, T.M.; Mäe, A. Changes in DMI, SDHI, and QoI Fungicide Sensitivity in the Estonian *Zymoseptoria tritici* Population between 2019 and 2020. *Microorganisms* 2021, 9, 81

⁴ Mae, A. ; Fillinger, S. ; Sooväli, P ; Heick, T. Fungicide Sensitivity Shifting of *Zymoseptoria tritici* in the Finnish-Baltic Region and a Novel Insertion in the MFS1 Promoter. *Front. Plant Sci.*, 15 April 2020

Table 3.3-4: Sensitivity (EC₅₀ + EC₉₈ in mg/l a.i.) of *Septoria tritici* in field samples from Germany towards prothioconazole (CA3301), 2020

Region	Variety	Date	n	MEC ₅₀	Mean RF*	EC ₅₀ min	EC ₅₀ max	Diversity factor	MEC ₉₈	EC ₉₈ min	EC ₉₈ max
Iserlohn, Nordrhein-Westfalen	Alexander	08/06/20	5	2.33	7.3	1.41	3.47	2.5	10.66	9.07	14.72
Reken, Nordrhein-Westfalen	Rubisko	10/06/20	5	1.63	5.1	1.23	2.00	1.6	10.75	9.47	13.09
Aachen-Orsbach, Nordrhein-Westfalen	Meister	18/06/20	5	1.78	5.6	1.18	3.43	2.9	8.90	7.66	10.36
Dorn-Assenheim, Hessen	Akteur	16/06/20	5	1.94	6.1	1.66	2.25	1.4	9.94	8.36	11.42
Thiemendorf, Thüringen	Compesino	07/07/20	5	2.25	7.0	1.86	3.21	1.7	10.06	8.85	12.00
Thiemendorf, Thüringen	Emmerich	07/07/20	5	1.93	6.0	1.82	2.12	1.2	9.63	8.46	10.85
Dornburg, Thüringen	Tobak	06/05/20	5	2.25	7.0	1.98	3.13	1.6	10.21	8.64	11.41
Buttelstedt, Thüringen	unknown	06/05/20	5	1.94	6.1	1.73	2.16	1.2	10.02	8.94	11.19
Pöhl, Sachsen	Chevignon	07/07/20	5	2.49	7.8	1.89	3.33	1.8	10.04	8.76	12.48
Pöhl, Sachsen	Asory	07/07/20	5	2.14	6.7	1.73	3.19	1.8	9.59	8.52	11.00
Eiselau, Baden-Württemberg	Genius	23/06/20	5	2.30	7.2	1.43	3.66	2.6	10.53	9.04	14.54
Westerstetten, Baden-Württemberg	Reform	23/06/20	5	1.88	5.9	1.34	2.20	1.6	10.81	9.43	12.95
Moosburg, Bayern	JB Asano	08/06/20	5	2.04	6.4	1.90	2.20	1.2	10.36	9.71	11.20
Kirchmatting, Bayern	JB Asano	11/06/20	5	2.20	6.9	1.88	3.30	1.8	9.97	9.11	10.77
Remshart, Bayern	Spontan	14/06/20	5	2.06	6.4	1.88	2.30	1.2	10.47	9.48	12.02
Lauterhofen, Bayern	Reform	05/07/20	5	2.30	7.2	2.06	3.33	1.6	10.32	9.17	10.85
Standard isolates											
DMI sensitive isolates	-	-	5	0.32	-	0.17	0.50	-	1.11	0.83	2.32

*RF= resistance factor: MEC₅₀/Reference EC₅₀

Diversity factor = min EC₅₀/ max EC₅₀

Table 3.3-5: Sensitivity (EC₅₀ + EC₉₈ in mg/l a.i.) of *Septoria tritici* in field samples from Germany towards prothioconazole (CA3301), 2021

Region	Variety	Date	n	MEC ₅₀	Mean RF*	EC ₅₀ min	EC ₅₀ max	Diversity factor	MEC ₉₈	EC ₉₈ min	EC ₉₈ max
Damendorf	Tobak	05/07/21	1	2.19	6.3	-	-		11.05		
Süderbrarup	unknown	07/07/21	5	3.30	9.4	2.28	5.48	2.4	9.35	7.23	11.60
Ausleben	unknown	07/07/21	5	2.91	8.3	1.79	3.52	2.0	9.03	8.44	9.68
Reichelsheim	Akteur	28/06/21	5	2.82	8.1	2.05	3.52	1.7	10.02	8.76	12.32
Reisdorf	Meister	27/04/21	5	2.43	6.9	1.78	3.40	1.9	9.73	8.78	11.14
Thiemendorf/Heideland	Akteur	30/06/21	5	3.40	9.7	2.21	5.48	2.5	9.64	8.94	11.35
Sömmerda	Akteur	09/07/21	3	2.54	7.3	2.04	3.51	1.7	10.63	9.65	11.66
Forberge/Strehla	Tobak	22/06/21	5	3.03	8.7	1.98	3.42	1.7	9.44	8.92	10.10

Weitzschenhain/Lommatzsch	Akteur	22/06/21	5	2.52	7.2	1.89	3.23	1.7	10.27	8.89	12.39
Käbschütztal	Akteur	08/07/21	2	2.36	6.7	1.74	3.21	1.8	8.89	8.85	8.93
Reinsberg / OT Hirschfeld	Asory	08/07/21	5	2.60	7.4	2.05	3.47	1.7	10.49	8.80	11.96
Haigerloch	Boss	16/07/21	3	3.48	9.9	3.33	3.59	1.1	9.57	9.19	9.87
Beimerstetten	Pep	20/07/21	5	2.39	6.8	2.16	3.02	1.4	13.28	11.06	22.24
Westerstetten	Reform	20/07/21	3	2.25	6.4	2.21	2.30	1.0	11.48	11.22	12.02
St. Johann	Jubilo	26/07/21	2	2.61	7.5	2.09	3.27	1.6	9.83	9.02	10.72
Sammenheim	Reform	04/07/21	3	3.44	9.8	3.24	3.56	1.1	9.46	8.94	9.78
Seenheim	Emerick	04/07/21	4	3.83	10.9	3.17	5.48	1.7	9.35	8.76	9.92
Burgau/Leinheim	Patras	26/07/21	5	3.19	9.1	2.05	3.67	1.8	9.95	9.31	10.64
Pappenheim	Informer	26/07/21	5	2.78	7.9	2.05	3.46	1.7	9.72	9.25	10.46
Standard isolates											
DMI sensitive isolates	-	-	4	0.35	-	0.17	0.65	-	1.70	0.81	3.26

*RF= resistance factor: MEC₅₀/Reference EC₅₀
Diversity factor = min EC₅₀/ max EC₅₀

Pyrenophora teres

The data comprises results from 49 isolates of *Pyrenophora teres* derived from the 10 sampling sites. Of these sets of data, 9 sites used airborne sampling and at 1 site field samples were taken. The test method was *in vitro* (microtiter) with test concentrations of 0.00, 0.03, 0.1, 0.3, 1.0, 3.0, 10.0, & 30.0 mg/l of prothioconazole.

Information on the samples and the mean, minimum and maximum EC₅₀ and EC₉₈ value are presented in Table 3.3-6. The range of EC₅₀ from the test samples was from 0.96 to 8.62 mg/l. The overall mean EC₅₀ value from all regions was 3.74 mg/l.

As shown in Figure 3.3.5 below, the majority of results were for EC₅₀ values between 2.07 and 5.45 mg/l.

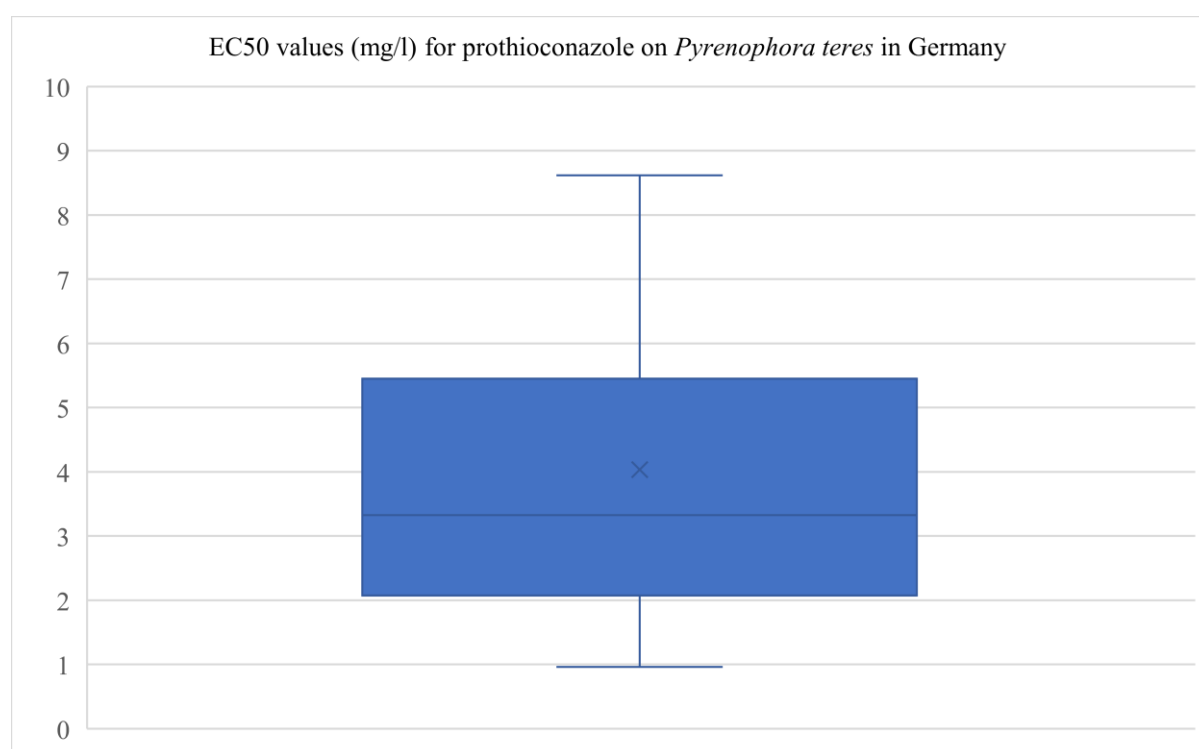


Figure 3.3.5: EC₅₀ values (mg/l) for prothioconazole on *Pyrenophora teres* strains sampled from Germany in 2020

The mean EC₅₀ of the reference strains which have no mutation and are susceptible to DMI fungicides was reported to be 0.47 mg/l. This reference is therefore used as the “baseline” reference in this analysis.

Clearly all samples were less sensitive to prothioconazole compared to the reference strains, however the Resistance Factor (RF) based on mean EC₅₀ values for the different regions ranged from 4.28 (Schweinfurt-Rothenburg) to 12.36 (Greifswald-Neubrandenburg) which is relatively low.

According to FRAC RF values of up to 10 are considered small (Fungicide resistance: The assessment of risk, FRAC Monograph No.2 second, (revised) edition). In fact, according to this paper pathogen strains with an RF value of 5 showed no difference in disease control compared to baseline populations

The diversity factor (EC₅₀ max/ EC₅₀ min) was highest in the Oldenburg i.H.-Hamburg region at 4.4, showing more variability among the samples than in other regions. In the field sample (2.7) diversity was relatively low and in the other regions also at 1.8 to 3.5. This is also presented in Figure 3.3.6 below.

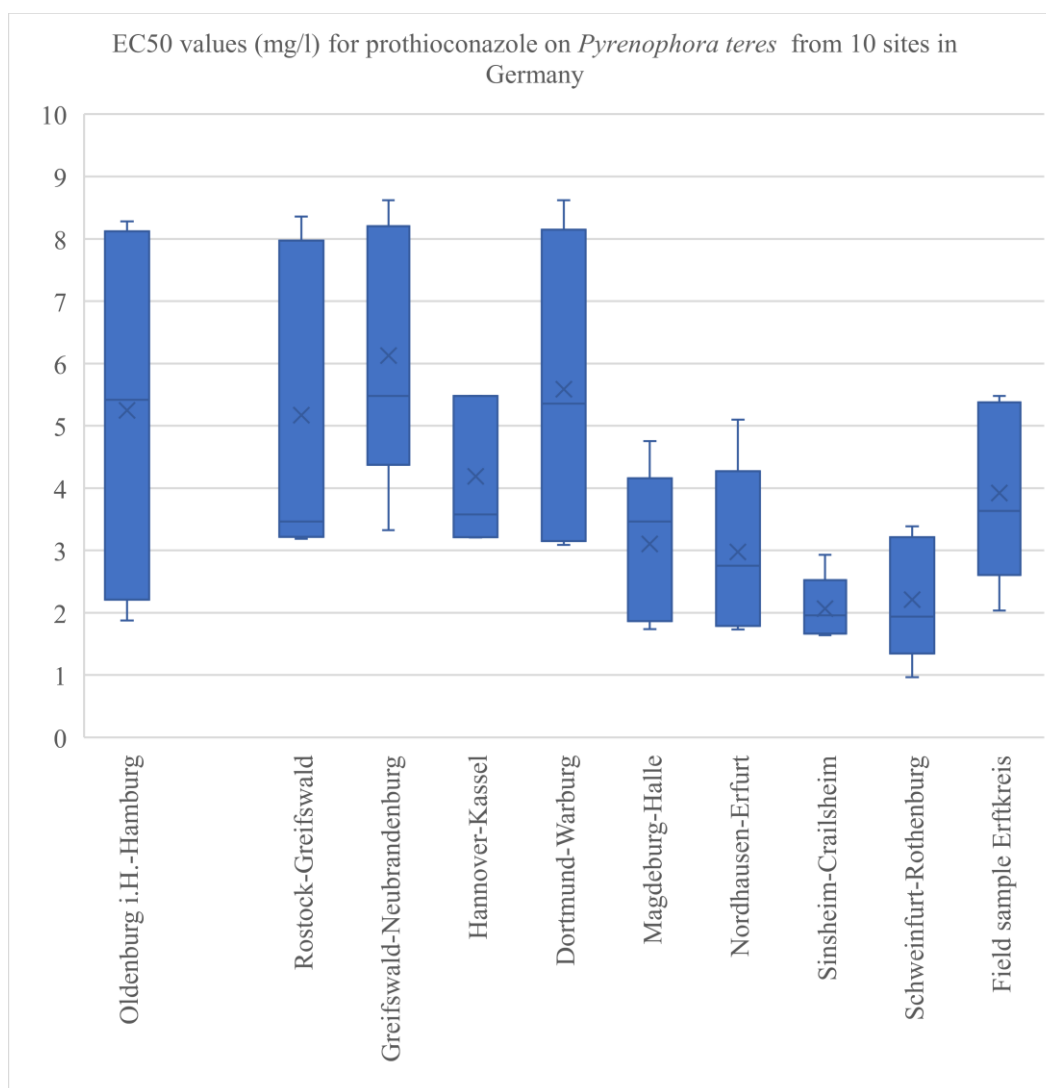


Figure 3.3.6: EC₅₀ values (mg/l) for prothioconazole on *Pyrenophora teres* strains from 10 sites in Germany in 2020

Conclusion on *Pyrenophora teres* in Germany

The data from the samples indicates that most strains of *Pyrenophora teres* are still sensitive to prothioconazole, indeed even the least sensitive strain with an EC₅₀ value of 8.62 mg/l has a Resistance Factor of only 18.3.

In addition, the low diversity factors for the regions (1.8 - 4.4) suggest that at present the populations remain relatively stable in terms of sensitivity. The data from these samples reinforces the fact that there has been very limited reporting of resistance to this pathogen for DMI fungicides and none currently recorded by EPPO for the CEU area.

The data therefore appears to support results from the efficacy trials presented in this dossier demonstrating that prothioconazole is effective against *Pyrenophora teres*.

Table 3.3-6: Sensitivity (EC₅₀ + EC₉₈ in mg/l a.i.) of *Pyrenophora teres* (net blotch in barley) in airborne samples (EpiLogic) and 1 field sample (joint/shared FRAC collection) from different cereal growing areas in Germany towards prothioconazole (CA3301), 2021

Region	Code	Date	n	MEC ₅₀	Mean RF*	EC ₅₀ min	EC ₅₀ max	Diversity factor	MEC ₉₈	EC ₉₈ min	EC ₉₈ max
Airborne samples											
Oldenburg i.H.-Hamburg	D 26	06/07/21	4	4.42	9.4	1.88	8.28	4.4	14.33	8.85	22.76
Rostock-Greifswald	D 31	07/07/21	5	4.69	10.0	3.19	8.36	2.6	12.91	8.80	22.98
Greifswald-Neubrandenburg	D 32	07/07/21	5	5.81	12.4	3.33	8.62	2.6	15.95	9.17	23.83
Hannover-Kassel	D 9	09/06/21	5	4.06	8.6	3.21	5.48	1.7	9.23	8.85	9.84
Dortmund-Warburg	D 22	06/07/21	5	5.12	10.9	3.09	8.62	2.8	19.39	8.85	25.27
Magdeburg-Halle	D 8	09/06/21	5	2.89	6.2	1.74	4.75	2.7	11.01	8.31	20.82
Nordhausen-Erfurt	D 6	09/06/21	5	2.74	5.8	1.73	5.10	2.9	10.43	7.66	21.77
Sinsheim-Crailsheim	D 15	28/06/21	5	2.02	4.3	1.64	2.93	1.8	8.93	8.00	11.13
Schweinfurt-Rothenburg	D 2	03/06/21	5	2.01	4.3	0.96	3.39	3.5	8.86	8.41	9.39
Field sample											
Erftkreis	Dt-FRAC-021	15/06/21	5	3.68	7.8	2.03	5.48	2.7	11.38	8.78	22.35
Standard isolates											
DMI sensitive isolates	EL1, EL2	-	2	0.47	-	0.46	0.49	-	5.55	5.33	5.78

*RF= resistance factor: MEC₅₀/Reference EC₅₀

Diversity factor = min EC₅₀/ max EC₅₀

3.3.6 Use pattern

The proposed use for CA3301 is for 1-2 applications against a range of pathogens in cereals and oilseed rape. These crops are usually grown in rotation. It is anticipated that CA3301 would be used in a disease control programme with other modes of action.

3.3.7 Resistance risk assessment of unrestricted use pattern

In order to evaluate the risk of pathogens to develop resistance to fungicides under specific agronomic conditions, the Fungicide Resistance Action Committee (FRAC) established a classification based on experience and reported resistance claim over the past 45 years. Information is taken from FRAC pathogen risk list 2019.

Generally, the risk increases when a pathogen undergoes many and short disease cycles per season, when the dispersal through spores over time and space is high, when sexual recombination is mandatory in the disease cycle and the competitive ability of resistant individual is at least as high as that of the wild type (in the absence of selection pressure). Furthermore the risk is considered as high when resistance evolved already after few years of product use.

Inherent risk of pathogen

According to these criteria, the FRAC defined 3 pathogen risk classes:

- High risk of resistance development: Plant pathogens from major world markets have evolved resistance to fungicides in a time span sufficiently short to be serious threat to the commercial success of more than one fungicide class.
- Medium risk of resistance development: Pathogens posing a much lower risk because resistance is not a major problem or has been slow to develop. In some cases this due to the pattern of product use.
- Low risk of resistance development: resistance occurred only to one chemical class but not to others and therefore, the pathogen is considered as low risk pathogen. Pathogens of local importance but considered as minor pathogens in commercial market terms.

Table 6.3-3 summarizes the risk of the targeted pathogens to develop a resistance to fungicides, according to the information in the FRAC pathogen risk list (2019).

Table 3.3-10: Risk of pathogens to develop a resistance to fungicides

Target disease	Target crop	Pathogen risk class
<i>Alternaria brassicae</i>	Oilseed rape	Medium risk
<i>Blumeria graminis</i>	Wheat/barley	High risk
<i>Erysiphe cruciferarum</i>	Powdery mildew	Medium risk
<i>Fusarium spp</i>	Wheat	Low risk
<i>Leptosphaeria maculans</i>	Oilseed rape	Low risk
<i>Oculimacula spp.</i>	Wheat / barley	Medium risk
<i>Parastagonospora nodorum</i>	Wheat	Low risk
<i>Puccinia spp.</i>	Wheat / barley, various	Low risk
<i>Pyrenopeziza brassicae</i>	Oilseed rape	Medium risk
<i>Pyrenophora teres</i>	Barley	Medium risk
<i>Pyrenophora tritici-repentis</i>	Wheat	Medium risk
<i>Ramularia collo-cygni</i>	Barley	High risk
<i>Rhynchosporium secalis</i>	Barley	Low risk
<i>Sclerotinia sclerotiorum</i>	Oilseed rape	Low risk
<i>Zymoseptoria tritici</i> *	Wheat	Medium risk

* EPPO standard lists this as high risk

Inherent risk of fungicide

As presented above in evidence of resistance, cases of resistance have been reported for group G1-3 (DMI) fungicides. According to the FRAC, the DMI group of fungicides belongs to the medium risk class for resistance:

Group name	Active substance risk class
DMI fungicides	Medium risk

Combined risk

The FRAC established a combined risk diagram based on inherent fungicide risk and inherent pathogen risk. The combined risk diagram for Prothioconazole versus the targeted diseases of the GAP is summarized in Table 6.3-4

Table 3.3-11: Combined resistance risk

Fungicide risk		Combined risk		
Prothioconazole	MEDIUM = 2	2 x 1 = 2	2 x 2 = 4	2 x 3 = 6
Pathogen risk		LOW = 1	MEDIUM = 2	HIGH = 3
		<i>Fusarium spp.</i> <i>Leptosphaeria maculans</i> <i>Parastagonospora nodorum</i> <i>Puccinia spp.</i> , <i>Rhynchosporium secalis</i> <i>Sclerotinia sclerotiorum</i>	<i>Alternaria brassicae</i> <i>Erysiphe cruciferarum</i> <i>Oculimacula spp.</i> <i>Pyrenopeziza brassicae</i> <i>Pyrenophora teres</i> <i>Pyrenophora tritici-repentis</i> <i>Zymoseptoria tritici</i>	<i>Blumeria graminis</i> <i>Ramularia collo-cygni</i>

Combined risk: 0.5-1.5: Low; 2-6: Medium; 9: High

Fungicide risk: 1: low / 2: medium / 3: high

Pathogen risk: 1: low / 2: medium / 3: high

According to the risk matrix for unmodified use the highest risk occurs when Prothioconazole is applied to control *Blumeria graminis* on cereals and *Ramularia collo-cygni* on-barley with a combined risk of 6. However, as EPPO considers that *Zymoseptoria tritici* is a high-risk pathogen this should also be taken into account.

3.3.8 Test methods

The resistance risk assessment has been undertaken according to the EPPO standard PP 1/213, covering all aspects indicated in this document. The evidence of resistance provided has been sourced from the EPPO resistance database with the inclusion of additional information provided by FRAC and R4P for France.

The sensitivity data was undertaken by GEP laboratories according to approved FRAC methodology on bioassay sensitivity testing.

3.3.9 Acceptability of the resistance risk

EPPO standard PP 1/213 indicates that the acceptability of the resistance risk should take into account the inherent risk of the active substance and targets and also the agronomic risk. The agronomic risk depends on a number of factors as stated in the standard:

The risk of resistance inherent in the plant protection product and the pest can be increased by certain conditions of use. This agronomic risk affects selection pressure on the development of resistance and

is influenced by the particular characteristics of the crop, the geographic area in which the product is applied and the use pattern. The factors influencing the agronomic risk may include:

- *widely grown crop with short rotations;*
- *monocropping or continuous cropping;*
- *application techniques;*
- *other cultural practices (e.g. fertilizers, cultivation);*
- *need for high numbers of applications or long exposure to obtain control, because of the features of the crop environment;*
- *use of transgenic plants with genes expressing pesticidal activity;*
- *use of cultivars susceptible to the pest(s);*
- *geographic isolation of populations preventing the re-entry of sensitive forms;*
- *environmental conditions favouring more frequent generations or higher population densities of the pest e.g. in protected crops; a greater risk of resistance has been demonstrated where fungicides are used on protected crops (defined as a crop grown in a glasshouse or polytunnel) than on outdoor crops. This is known also for insecticides.*
- *exclusive reliance on a single active substance;*
- *lack of diversity of available control measures.*

Considering the proposed uses for CA3301 the overall agronomic risk is considered low to medium since the crops are grown in rotation and grown outside rather than being in protected/isolated conditions, other active substances with different modes of action are available to use against the pathogens, resistant cultivars are available and there are cultural methods to reduce disease infestation such as removal of debris. In addition, the applications are restricted to 1 or 2 applications.

Taking into account that the inherent risk of prothioconazole is **medium**, the inherent risk of the target pathogens is **medium to high** and the agronomic risk is **low to medium**, it is considered that for some pathogens the resistance risk of unmodified use may be unacceptable, therefore a management strategy is proposed to reduce the risk of resistance development.

3.3.10 Resistance management strategy

Managing the risk of resistance for any PPP relies on using good agricultural practice and the core aspects of this are appropriate to any crop/pest pairing. The management of resistance risk involves a number of key aspects, FRAC provide the following critical recommendations for the management of resistance risk for fungicides:

- Do not use the same product exclusively
- Restrict the number of treatments applied per season
- Maintain manufacturers' recommended dose
- Avoid eradicant use
- Employ integrated disease management e.g. variety choice, rotation, crop hygiene, bio-pesticides
- Maintain chemical diversity

Specific advice is also provided by FRAC on the use of the group of fungicides to which prothioconazole belongs, and following for the use of these on cereals.

General recommendations for use of SBI (Group G) fungicides:

- Repeated application of SBI fungicides alone should not be used on the same crop in one season against a high-risk pathogen in areas of high disease pressure for that particular pathogen.
- For crop/pathogen situations where repeated spray applications (e.g. orchard crops/powdery mildew) are made during the season, alternation (block sprays or in sequence) or mixtures with an effective non cross-resistant fungicide are recommended.

- Where alternation or the use of mixtures is not feasible because of a lack of effective or compatible non cross-resistant partner fungicides, then input of SBI's should be reserved for critical parts of the season or crop growth stage.
- If the performance of SBIs should decline and sensitivity testing has confirmed the presence of less sensitive isolates, SBIs should only be used in mixture or alternation with effective non cross-resistant partner fungicides.
- The introduction of new classes of chemistry offers opportunities for more effective resistance management. The use of different modes of action should be maximized for the most effective resistance management strategies.
- Users must adhere to the manufacturers' recommendations. In many cases, reports of "resistance" have, on investigation, been attributed to cutting recommended use rates, or to poorly timed applications.
- Fungicide input is only one aspect of crop management. Fungicide use does not replace the need for resistant crop varieties, good agronomic practice, plant hygiene/sanitation, etc.
- Exclusive frequency measurements of single cyp51 mutations are not sufficient to describe the sensitivity situation towards DMIs but can help to better understand the background of sensitivity shifts

Specific recommendations for SBI fungicides on cereals (FRAC, 2021)

- Follow strictly the manufacturer's and FRAC recommendations.
- Repeated application of DMI fungicides alone should not be used on the same crop in one season against risky pathogens (e.g. cereal powdery mildews, barley net blotch, scald) in areas of high disease pressure for that particular pathogen.
- Reduced rates of DMIs can contribute to accelerate the shift to less sensitive populations. It is critical to use effective rates of DMIs in order to ensure robust disease control and effective resistance management. DMIs must provide effective disease control and be used at manufacturers recommended rates.
- When used in mixture recommended effective rates of the SBI must be maintained. Split and reduced rate programmes, using multiple repeated applications at dose rates below manufacturer's recommendations, provide continuous selection pressure and accelerate the development of resistant populations, and therefore must not be used.
- To ensure good performance and particularly resistance management in situations of even low disease pressure it is essential to adhere to dosages and spray timings as recommended by manufacturers. Curative applications should be avoided. Application timing has to be appropriate to all mix partners' characteristics. Mixing with a non-cross resistant fungicide at effective dose rates contributes to a more effective disease control and resistance management.
- The amine fungicides are effective non-cross-resistant partner fungicides for DMIs on cereals for the control of pathogens included in the label recommendation of each respective product.

Further information on managing risk in oilseed rape with emphasis also on integrated disease management is provided by AHDB in UK.

General recommendations for managing fungicide resistance in oilseed rape (AHDB):

- Use disease resistant cultivars. Where possible, varieties should be selected with good resistance ratings to the diseases of most concern on the farm. Reduced fungicide inputs may be possible on such varieties and should reflect overall disease risk.
- Target fungicides on crops where there is risk of yield loss. Seasonal variation in risk can be large, so use local guidance. Use disease forecasts, crop monitoring information and thresholds, where available.
- Ensure fungicide applications are well-timed and the appropriate dose is used.
- Avoid repeated use of the same product or fungicide having the same mode of action. It is important to follow any statutory conditions of approval, which may include a maximum number of product applications per crop or a maximum total for the active ingredient.

- Crop residues are a source of inoculum for phoma leaf spot and stem canker (*Leptosphaeria* spp), light leaf spot (*Pyrenopeziza brassicae*) and dark leaf-spot (*Alternaria* spp). Direct drilled crops may, therefore, be at greater risk than crops drilled after deep ploughing. Burying crop residues can help to decrease the production of air- or splash-borne spores. Avoid planting new crops adjacent to the previous year's stubble. Isolate new crops by 200 to 500m, if possible. Sow by late August so that plants are well-grown prior to the onset of phoma leaf spot. The disease is less damaging and easier to manage on plants with large leaves than on small plants. Early drilling, however, can increase the risk of light leaf spot, therefore all crops should be walked regularly and monitored carefully.
- Oilseed rape rotations are often shorter than ideal. The risk of soil-borne diseases such as clubroot (*Plasmodiophora brassicae*) and sclerotinia (*Sclerotinia sclerotiorum*) will be reduced by extending rotations to at least one in four and preferably longer. Trash-borne disease risk (light leaf spot and phoma) will also be reduced in extended rotations.
- Biological control with *Coniothyrium minitans* can be considered as a biological treatment as part of an integrated pest management (IPM) strategy. It works by colonising and de-activating the soil-borne sclerotia. Application may be useful after severe attacks of sclerotinia to reduce the risk of yield loss in future crops.

In conclusion the management strategy is based on ensuring that users follow label advice and good agricultural practices and consider an integrated approach to disease management.

3.3.11 Implementation of the management strategy

The resistance management strategy will be implemented through label advice, supported by local recommendations from distributors and technical advisers. Labels will clearly indicate the mode of action of the active substances.

Directions for use on the product label clearly present Good Agricultural Practice as outlined in Table 3.1-1 i.e. dose rate, application timing and number of applications. The mode of action group of the product components is clearly shown on the product label in order to enable users to rotate with different fungicide groups. A resistance statement on the label directs users to consider suitable resistance strategies. Resistance management advice will be included on Member State product labels in accordance with this strategy and national guidelines.

3.3.12 Monitoring, reporting and reaction to changes in performance

In addition to the preventive management of risk of resistance, Nufarm is committed to reporting any developments related to the efficacy of CA3301 based on resistance arising to prothioconazole to the regulatory authorities of concerned Member States according to Article 56 4 of Regulation EU 1107/2009.

Comments of zRMS:

CA3301 contains one active substance of prothioconazole belonging to DMI-fungicides (SBI: Class I) from FRAC Group 3. Currently according to EPPO resistance database, 5 confirmed cases of resistance are reported for prothioconazole which relate to SEPTTR on wheat and RAMUCC on barley in Europe. Overall for the fungicide Group 3, 12 out of 23 cases reported on the database are for FUSACU on winter wheat, ERYSGR on winter wheat and barley, RAMUCC on barley and SEPTTR on wheat. According FRAC database, 10 resistance cases for DMI fungicides are reported. The most recent reports for DMI fungicides from the 2021 SBI working group give that stable sensitivity situation was observed in Europe in case of most disease pathogens intended for CA3301 (i.a. ERYSGR, GIBBZE, PYRNTE, RHYNSE, LEPTMA, SCLESC, PUCCHD, SEPTTR). A high sensitivity and a low diversity of strains were recorded from 2015 to 2020 in case of PUCCRE. Furthermore based on R4P database, 7 resistance cases to group 3 fungicides were presented in France. It is wise to accept that cross-resistance is present between DMI fungicides active against the same fungus. DMI fungicides are SBIs, but no cross-resistance to other SBI classes are recorded. Nevertheless, for the purposes of maintaining efficacy in the future, resistance management strategies should be based on the proviso that cross resistance among DMI is likely. CA3301 is intended to use against 2 pathogens with high risk of develop a resistance: *Blumeria graminis* and *Ramularia collo-cygni*. Also 7 pathogens with medium risk are reported. Taking into account that the inherent risk of prothioconazole is medium, the inherent risk of the target pathogen is medium to high and the agronomic risk is low to medium, it can be considered that a management strategy is necessary to reduce the risk of resistance development. Based on general recommendations and specifically advice of SBI working group on FRAC website, the zRMS proposes to include below anti-resistance strategy to the product label:

As part of the prevention of the resistance of pathogens to the applied plant protection products, the following treatments are recommended:

- use CA3301 a maximum of 2 times during the growing season, in rotation with other products containing active substances belonging to other chemical groups with a different mode of action
- do not exceed the maximum recommended dose of the product
- adjust the dose of the product to the level of disease pressure on the protected crop
- use the product in the BBCH phase indicated on the label
- ~~carry out inspections to detect symptoms of ineffectiveness of the product~~ **monitor the effectiveness of the action to detect signs of resistance to the product in accordance with Integrated Pest Management**
- if possible, cultivate resistant varieties
- follow the recommendations of good agricultural practice

3.4 Adverse effects on treated crops (KCP 6.4)

Information on trials submitted (3.4: Adverse effects on treated crops)

Table 3.4-1: Presentation of trials (selectivity trials, transformation trials)

CA3301 / zRMS version	JOUST Part B – Section 3 – Core Assessment			Number of trials (number of valid trials)				GEP, non-GEP, official***	Comments (any other relevant information)
Crop(s) *	Country	Years	Type of trial**						
				Maritime zone	Mediterranean zone	North-Eastern zone	South-Eastern zone		
Winter barley	Czech Republic	2018-2019	S + Y + Q	3	-	-	-	GEP	
		2019-2020	S	2	-	-	-	GEP	
	Denmark	2018	S + Y + Q	2	-	-	-	GEP	
	France (N)	2019-2020	S + Y + Q	5	-	-	-	GEP	
		2019-2020	S	5	-	-	-	GEP	
	Germany	2019	S + Y + Q	7	-	-	-	GEP	
		2019-2020	S	4	-	-	-	GEP	
	United Kingdom	2019	S + Y + Q	4	-	-	-	GEP	
		2020	S	3	-	-	-	GEP	
Winter barley	France (S)	2019-2020	S + Y + Q	-	10	-	-	GEP	
		2019-2020	S	-	13	-	-	GEP	
	Italy	2019	S + Y + Q	-	4	-	-	GEP	
	Portugal	2018	S + Y + Q	-	3	-	-	GEP	
		2019-2020	S	-	3	-	-	GEP	
	Spain	2019-2020	S + Y + Q	-	4	-	-	GEP	
		2019-2020	S	-	8	-	-	GEP	
Winter barley	Latvia	2019	S + Y + Q	-	-	3	-	GEP	
		2019-2020	S	-	-	5	-	GEP	
	Lithuania	2019	S + Y + Q	-	-	2	-	GEP	
	Poland	2017-2019	S + Y + Q	-	-	11	-	GEP	
		2017-2020	S	-	-	18	-	GEP	
Winter barley	Bulgaria	2018-2019	S + Y + Q	-	-	-	9	GEP	
		2018	S				1	GEP	
	Hungary	2017-2019	S + Y + Q	-	-	-	7	GEP	
		2019-	S				7	GEP	

		2020							
	Romania	2019	S + Y + Q	-	-	-	2	GEP	
		2020	S	-	-	-	5	GEP	
	Slovakia	2020	S + Y + Q	-	-	-	1	GEP	
		2020	S	-	-	-	5	GEP	
TOTAL	-	-	-	35	45	39	37	GEP	
Spring barley	Czech Republic	2018-2019	S + Y + Q	4	-	-	-	GEP	
		Denmark	2018	S	1	-	-	-	GEP
		2018-2019	S + Y + Q	2	-	-	-	GEP	
	Germany	2019	S	2	-	-	-	GEP	
		2019	S + Y + Q	4	-	-	-	GEP	
	United Kingdom	2019-2020	S	4	-	-	-	GEP	
		2019-2020	S + Y + Q	6	-	-	-	GEP	
Spring barley	France (S)	2019	S	-	1	-	-	GEP	
	Italy	2020	S	-	6	-	-	GEP	
		2019-2020	S + Y + Q	-	6	-	-	GEP	
	Spain	2019-2020	S	-	9	-	-	GEP	
		2019	S + Y + Q	-	4	-	-	GEP	
	Portugal	2018	S + Y + Q	-	1	-	-	GEP	
Spring barley	Poland	2018-2020	S	-	-	18	-	GEP	
		2018-2019	S + Y + Q	-	-	5	-	GEP	
	Lithuania	2019	S	-	-	1	-	GEP	
	Latvia	2020	S	-	-	4	-	GEP	
		2019-2020	S + Y + Q	-	-	3	-	GEP	
Spring barley	Hungary	2018-2020	S	-	-	-	5	GEP	
		2019	S + Y + Q	-	-	-	2	GEP	
	Romania	2020	S	-	-	-	5	GEP	
		2018-2019	S + Y + Q	-	-	-	5	GEP	

	Slovakia	2019	S	-	-	-	2	GEP	
		2019-2020	S + Y + Q	-	-	-	5	GEP	
	Bulgaria	2018	S + Y + Q	-	-	-	1	GEP	
TOTAL	-	-	-	23	27	31	25	-	
Oat	Czech Republic	2018	S + Y + Q	1	-	-	-	GEP	
		2017-2018	S	2	-	-	-	GEP	
	Germany	2019-2020	S + Y + Q	4	-	-	-	GEP	
Oat	Italy	2020	S + Y + Q	-	1	-	-	GEP	
		2019	S	-	1	-	-	GEP	
	Portugal	2018-2020	S + Y + Q	-	3	-	-	GEP	
	Spain	2019-2020	S + Y + Q	-	2	-	-	GEP	
		2019	S	-	1	-	-	GEP	
Oat	Latvia	2019-2020	MED + E	-	-	2	-	GEP	
	Poland	2018-2020	S + Y + Q	-	-	4	-	GEP	
		2019	S	-	-	1	-	GEP	
Oat	Bulgaria	2018	S + Y + Q				1	GEP	
		2018	S + Y + Q	-	-	-	2	GEP	
	Romania	2019	S + Y + Q	-	-	-	1	GEP	
		2019	S	-	-	-	1	GEP	
TOTAL	-	-	-	7	8	7	5	GEP	
Winter wheat	Czech Republic	2018-2019	S + Y + Q	5	-	-	-	GEP	
		2017-2018	S	5	-	-	-	GEP	
	Denmark	2018	S + Y + Q	2	-	-	-	GEP	
		2018	S	1					
	France (N)	2019	S + Y + Q	3	-	-	-	GEP	
		2019-2020	S	5	-	-	-	GEP	
	Germany	2019-2020	S + Y + Q	6	-	-	-	GEP	
		2019-2020	S	6	-	-	-	GEP	
	United	2019	S + Y +	9	-	-	-	GEP	

	Kingdom		Q						
		2019-2020	S	11	-	-	-	GEP	
Winter wheat	France (S)	2019-2020	S + Y + Q	-	5	-	-	GEP	
		2019-2020	S	-	12	-	-	GEP	
	Greece	2019	S + Y + Q	-	2	-	-	GEP	
		2020	S		1	-	-	GEP	
	Italy	2020	S + Y + Q	-	3	-	-	GEP	
		2019-2020	S	-	2	-	-	GEP	
	Portugal	2018-2020	S + Y + Q	-	7	-	-	GEP	
		2018-2019	S	-	2	-	-	GEP	
	Spain	2019-2020	S + Y + Q	-	6	-	-	GEP	
		2019-2020	S	-	6	-	-	GEP	
Winter wheat	Latvia	2019	S + Y + Q	-	-	3	-	GEP	
		2019-2020	S	-	-	3	-	GEP	
	Lithuania	2019	S + Y + Q	-	-	3	-	GEP	
		2019-2020	S	-	-	2	-	GEP	
	Poland	2017-2020	S + Y + Q	-	-	16	-	GEP	
		2017-2020	S	-	-	13	-	GEP	
Winter wheat	Bulgaria	2018-2019	S + Y + Q	-	-	-	2	GEP	
		2018	S	-	-	-	1	GEP	
	Hungary	2018-2020	S + Y + Q	-	-	-	12	GEP	
		2019-2020	S	-	-	-	7	GEP	
	Romania	2018-2020	S + Y + Q	-	-	-	8	GEP	
		2019-2020	S	-	-	-	5	GEP	
	Slovakia	2020	S			-	2	GEP	
	Poland	2023	S+Y+Q	!	!	7	!	GEP	
TOTAL	-	-	-	53	46	4047	37	GEP	
Durum wheat	France (N)	2019	S	2	-	-	-	GEP	

	Germany	2019	S	1	-	-	-	GEP	
		2020	S + Y + Q	1	-	-	-	GEP	
Durum wheat	France (S)	2019	S	-	1	-	-	GEP	
		2019-2020	S	-	2	-	-	GEP	
	Italy	2019-2020	S	-	2	-	-	GEP	
		2017-2018	S	-	2	-	-	GEP	
Durum wheat	Poland	2018	S + Y + Q	-	-	1	-	GEP	
		2017-2018	S	-	-	-	2	GEP	
Durum wheat	Hungary	2018-2019	S + Y + Q	-	-	-	3	GEP	
		2020	S	-	-	-	1	GEP	
TOTAL	-	-	-	4	7	1	6	-	
Triticale	France (N)	2019	S + Y + Q	2	-	-	-	GEP	
		2019-2020	S	2	-	-	-	GEP	
	Germany	2019-2020	S + Y + Q	3	-	-	-	GEP	
		2017-2018	S + Y + Q	2	-	-	-	GEP	
	Denmark	2018	S + Y + Q	1	-	-	-	GEP	
Triticale	France (S)	2020	S + Y + Q	-	1	-	-	GEP	
		2018-2020	S + Y + Q	-	3	-	-	GEP	
Triticale	Poland	2018	S	-	-	1	-	GEP	
		2017-2019	S + Y + Q	-	-	5	-	GEP	
Triticale	Hungary	2018-2020	S + Y + Q	-	-	-	4	GEP	
		2019	S + Y + Q	-	-	-	3	GEP	
TOTAL	-	-	-	10	4	6	7	-	
Rye	Czech Republic	2017-2018	S + Y + Q	3	-	-	-	GEP	
		2018	S + Y + Q	2	-	-	-	GEP	
	Denmark	2019	S	1	-	-	-	GEP	
		2019	S + Y + Q	1	-	-	-	GEP	
	Germany	2020	S + Y + Q	2	-	-	-	GEP	

Rye	Portugal	2018	S + Y + Q	-	2	-	-	GEP	
	Greece	2020	S + Y + Q	-	1	-	-	GEP	
Rye	Poland	2017-2019	S + Y + Q	-	-	4	-	GEP	
		2019	S	-	-	1	-	GEP	
	Lithuania	2020	S + Y + Q	-	-	1	-	GEP	
	Latvia	2020	S + Y + Q	-	-	1	-	GEP	
Rye	Hungary	2018-2019	S + Y + Q	-	-	-	3	GEP	
	Romania	2019	S + Y + Q	-	-	-	1	GEP	
TOTAL	-	-	-	9	3	7	4	-	
Oilseed rape	Czech Republic	2018-2020	S	7	-	-	-	GEP	
		2018-2019	S + Y + Q	11	-	-	-	GEP	
	Germany	2020	S	9	-	-	-	GEP	
		2019-2020	S + Y + Q	3	-	-	-	GEP	
	France	2020	S	2	-	-	-	GEP	
		2020	S + Y + Q	3	-	-	-	GEP	
	Denmark	2018	S	1	-	-	-	GEP	
			S + Y + Q	1	-	-	-	GEP	
	United Kingdom	2020	S	3	-	-	-	GEP	
			S + Y + Q	1	-	-	-	GEP	
Oilseed rape	France	2020	S	-	4	-	-	GEP	
		2020	S + Y + Q	-	2	-	-	GEP	
	Spain	2020	S	-	1	-	-	GEP	
			S + Y + Q	-	4	-	-	GEP	
	Italy	2020	S	-	1	-	-	GEP	
			S + Y + Q	-	2	-	-	GEP	
Oilseed rape	Poland	2018-2020	S	-	-	15	-	GEP	
			S + Y + Q	-	-	14	-	GEP	
	Lithuania	2019-2020	S	-	-	3	-	GEP	

		2019	S + Y + Q	-	-	1	-	GEP	
	Latvia	2020	S	-	-	4	-	GEP	
		2019	S + Y	-	-	1	-	GEP	
		2019	S + Y + Q	-	-	1	-	GEP	
Oilseed rape	Hungary	2019-2020	S	-	-	-	7	GEP	
		2018-2020	S + Y + Q	-	-	-	11	GEP	
	Romania	2018-2020	S	-	-	-	6	GEP	
		2019-2020	S + Y + Q	-	-	-	10	GEP	
	Slovakia	2020	S	-	-	-	5	GEP	
		2019	S + Y + Q	-	-	-	2	GEP	
TOTAL	-	-	-	41	14	39	40	-	

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

According to the EPPO guideline PP 1/135 “Phytotoxicity assessment”

3.4.1.1 Winter barley (HORVW)

Use of CA3301 in the Maritime EPPO zone

A total of 35 trials were carried out on winter barley (HORVW) in Germany (11), France (10), the United Kingdom (7), the Czech Republic (5) and Denmark (2) on a wide-range of commercially grown varieties to assess the efficacy and crop safety of CA3301. All 35 trials included two applications of CA3301. All trials included CA2445, PROLINE 275 or MIRADOR XTRA as a reference standard.

CA3301 was applied at several dosages, from 0.48 l/ha (120 g ai/ha of Prothioconazole) up to 0.80 l/ha (200 g ai/ha of Prothioconazole).

CA3301 did not induce phytotoxicity symptoms in any of the 35 trials, whatever the dose rate or number of applications considered (see Table 3.4-2).

Considering all elements presented above, it is concluded that CA3301 applied at maximum rate of 0.6 l/ha (150 g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on winter barley in the Maritime EPPO zone.

Table 3.4-2: Summary table - Phytotoxicity – Winter barley (HORVW) – Maritime EPPO zone

Number of trials with...		35 Trials	
		CA3301	CA2445
		2x 0.6-0.8 l/ha	2x 0.8 l/ha
	0% to 5%	35	35

Number of trials with...		35 Trials	
		CA3301	CA2445
		2x 0.6-0.8 l/ha	2x 0.8 l/ha
Maximum of phytotoxicity recorded during the trials	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0
Level of symptoms at the last assessments	0% to 5%	35	35
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0

Use of CA3301 in the Mediterranean EPPO zone

A series of 45 trials were carried out on winter barley (HORVW) in France (23), Italy (4), Portugal (6) and Spain (12) on a wide-range of commercially grown varieties to assess the efficacy and crop safety of CA3301. 1 trial included CA3301 applied only once and 44 trials included two applications of CA3301. All trials included CA2445 or PROSARO as a reference standard.

CA3301 was applied at several dosages, from 0.48 l/ha (120 g ai/ha of Prothiconazole) up to 0.80 l/ha (200 g ai/ha of Prothioconazole).

CA3301 did not induce phytotoxicity symptoms in 43 trials, whatever the dose rate or number of applications considered. In the other 2 trials, minor (<4% phytotoxicity), transient and non-significant phytotoxicity symptoms were observed (see Table 3.4-3).

In one trial, on the crop variety KWS Infinity, phytotoxicity (deformation) was observed at 0 DA-B/16 DA-A with no statistical differences between the untreated check and the other treatments. Since the observed phytotoxicity was observed also in the untreated check, and at the same level as in plots treated with CA3301, the effects were clearly not related to the application of the test product. Nevertheless, the results are presented for completeness. Those symptoms were probably due to a farmer treatment applied close to the trial and at the following assessments at 1 DA-B and 15 DA-B general phytotoxicity disappeared (0% phytotoxicity) for all the treatments.

In another trial, on the crop variety Rafaela, no phytotoxicity was observed following the first application and minor (1.25%-3.75%) general phytotoxicity was observed at 18 DA-B with no statistical differences between CA3301 and the reference product treatments. Those minor symptoms were no longer discernible at the following assessment timing (32 DA-B). In addition, the variety Rafaela was used in two other trials where no phytotoxicity symptoms were observed.

Considering all elements presented above, it is concluded that CA3301 applied at maximum rate of 0.6 l/ha (150 g ai/ha of Prothioconazole) is unlikely to induce phytotoxicity symptoms on winter barley in the Mediterranean EPPO zone.

Table 3.4-3: Summary table - Phytotoxicity – Winter barley (HORVW) – Mediterranean EPPO zone

Number of trials with...		45 Trials			
		CA3301		CA2445	
		1 x 0.6-0.8 l/ha	2x 0.6-0.8 l/ha	1 x 0.8 l/ha	2x 0.8 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	1	44	1	44
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	1	44	1	44
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0

Use of CA3301 in the North-Eastern EPPO zone

A series of 39 trials were carried out on winter barley (HORVW) in Latvia (8), Lithuania (2) and Poland (29) on a wide-range of commercially grown varieties to assess the efficacy and crop safety of CA3301. 36 trials included only two applications of CA3301 and 3 trials included CA3301 applied once and twice. All trials included CA2445 or OSIRIS 65 EC as a reference standard.

CA3301 was applied at several dosages, from 0.48 l/ha (120 g ai/ha of Prothiconazole) up to 0.80 l/ha (200 g ai/ha of Prothioconazole).

CA3301 did not induce phytotoxicity symptoms in any of the 39 trials, whatever the dose rate or number of applications considered (see Table 3.4-4).

Considering all elements presented above, it is concluded that CA3301 applied at maximum rate of 0.6 l/ha (150 g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on winter barley in the North-Eastern EPPO zone.

Table 3.4-4: Summary table - Phytotoxicity – Winter barley (HORVW) – North-Eastern EPPO zone

Number of trials with...		39 Trials			
		CA3301		CA2445	
		1 x 0.6-0.8 l/ha	2x 0.6-0.8 l/ha	1 x 0.8 l/ha	2x 0.8 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	3	39	3	39
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	3	39	3	39
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0

Number of trials with...		39 Trials			
		CA3301		CA2445	
		1 x 0.6-0.8 l/ha	2x 0.6-0.8 l/ha	1 x 0.8 l/ha	2x 0.8 l/ha
	>15 %	0	0	0	0

Use of CA3301 in the South-Eastern EPPO zone

A series of 33 trials were carried out on winter barley (HORVW) Bulgaria (7), Hungary (11), Romania (9) and Slovakia (6) on a wide-range of commercially grown varieties to assess the efficacy and crop safety of CA3301. 3 trials included CA3301 applied only once, 30 trials included only two applications of CA3301, and 2 trials included CA3301 applied once and twice. All trials included CA2445, RISA 20 EC or PRIAXOR as a reference standard.

CA3301 was applied at several dosages, from 0.48 l/ha (120 g ai/ha of Prothioconazole) up to 0.80 l/ha (200 g ai/ha of Prothioconazole).

CA3301 did not induce phytotoxicity symptoms in any of the 33 trials, whatever the dose rate or number of applications considered (see Table 3.4-5).

Considering all elements presented above, it is concluded that CA3301 applied at maximum rate of 0.6 l/ha (150 g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on winter barley in the South-Eastern EPPO zone.

Table 3.4-5: Summary table - Phytotoxicity – Winter barley (HORVW) – South-Eastern EPPO zone

Number of trials with...		33 Trials			
		CA3301		CA2445	
		1 x 0.6-0.8 l/ha	2x 0.6-0.8 l/ha	1 x 0.8 l/ha	2x 0.8 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	5	30	5	30
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	5	30	5	30
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0

3.4.1.2 Spring barley (HORVS)

Use of CA3301 in the Maritime EPPO zone

A series of 23 trials were carried out on spring barley (HORVS) in Germany (6), the United Kingdom (10), the Czech Republic (4) and Denmark (3) on a wide-range of commercially grown varieties to assess the efficacy and crop safety of CA3301. All 23 trials included two applications of CA3301. All trials included CA2445 or PROLINE 275 as a reference standard.

CA3301 was applied at several dosages, from 0.36 l/ha (90 g ai/ha of Prothioconazole) up to 0.80 l/ha (200 g ai/ha of Prothioconazole).

CA3301 did not induce phytotoxicity symptoms in any of the 23 trials, whatever the dose rate or number of applications considered (see Table 3.4-6).

Considering all elements presented above, it is concluded that CA3301 applied at 100% rate of 0.6 l/ha (150g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on spring barley in the Maritime EPPO zone.

Table 3.4-6: Summary table - Phytotoxicity – Spring barley (HORVS) – Maritime EPPO zone

Number of trials with...		23 Trials	
		CA3301	CA2445
		2x 0.6-0.8 l/ha	2x 0.8 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	23	23
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0
Level of symptoms at the last assessments	0% to 5%	23	23
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0

Use of CA3301 in the Mediterranean EPPO zone

A series of 27 trials were carried out on spring barley (HORVS) in France (1), Italy (12), Portugal (1) and Spain (13) on a wide-range of commercially grown varieties to assess the efficacy and crop safety of CA3301. All 27 trials included two applications of CA3301. All trials included CA2445 or PRO-SARO as a reference standard.

CA3301 was applied at several dosages, from 0.36 l/ha (90 g ai/ha of Prothioconazole) up to 0.80 l/ha (200 g ai/ha of Prothioconazole).

CA3301 did not induce phytotoxicity symptoms in any of the 27 trials, whatever the dose rate or number of applications considered (see Table 3.4-7).

Considering all elements presented above, it is concluded that CA3301 applied at 100% rate of 0.6 l/ha (150 g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on spring barley in the Mediterranean EPPO zone.

Table 3.4-7: Summary table - Phytotoxicity – Spring barley (HORVS) – Mediterranean EPPO zone

Number of trials with...		27 Trials	
		CA3301	CA2445
		2x 0.6-0.8 l/ha	2x 0.8 l/ha
Maximum of phytotoxicity	0% to 5%	27	27

Number of trials with...		27 Trials	
		CA3301	CA2445
		2x 0.6-0.8 l/ha	2x 0.8 l/ha
recorded during the trials	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0
Level of symptoms at the last assessments	0% to 5%	27	27
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0

Use of CA3301 in the North-Eastern EPPO zone

A series of 31 trials were carried out on spring barley (HORVS) in Latvia (7), Lithuania (1) and Poland (23) on a wide range of commercially grown varieties to assess the efficacy and crop safety of CA3301. All 31 trials included two applications of CA3301. All trials included CA2445 or OSIRIS 75 EC as a reference standard.

CA3301 was applied at several dosages, from 0.36 l/ha (90 g ai/ha of Prothioconazole) up to 0.80 l/ha (200 g ai/ha of Prothioconazole).

CA3301 did not induce phytotoxicity symptoms in any of the 31 trials, whatever the dose rate considered (see Table 3.4-8).

Considering all elements presented above, it is concluded that CA3301 applied at 100% rate of 0.6 l/ha (150 g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on spring barley in the North-Eastern EPPO zone .

Table 3.4-8: Summary table - Phytotoxicity – Spring barley (HORVS) – North-Eastern EPPO zone

Number of trials with...		31 Trials	
		CA3301	CA2445
		2x 0.6-0.8 l/ha	2x 0.8 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	31	31
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0
Level of symptoms at the last assessments	0% to 5%	31	31
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0

Use of CA3301 in the South-Eastern EPPO zone

A series of 25 trials were carried out on spring barley (HORVS) in Bulgaria (1), Hungary (7), Romania (10) and Slovakia (7) on a wide-range of commercially grown varieties to assess the efficacy and crop safety of CA3301. All 25 trials included two applications of CA3301. All trials included CA2445, PRI-AXOR or BUMPER 25 EC as a reference standard.

CA3301 was applied at several dosages, from 0.36 l/ha (90 g ai/ha of Prothioconazole) up to 0.80 l/ha (200 g ai/ha of Prothioconazole).

CA3301 did not induce phytotoxicity symptoms in any of the 25 trials, whatever the dose rate considered (see Table 3.4-9).

Considering all elements presented above, it is concluded that CA3301 applied at 100% rate of 0.6 l/ha (150 g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on spring barley in the South-Eastern EPPO zone.

Table 3.4-9: Summary table - Phytotoxicity – Spring barley (HORVS) – South-Eastern EPPO zone

Number of trials with...		25 Trials	
		CA3301	CA2445
		2x 0.6-0.8 l/ha	2x 0.8 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	25	25
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0
Level of symptoms at the last assessments	0% to 5%	25	25
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0

Comments of zRMS:

No special selective trials have been submitted. The phytotoxicity assessment was provided in the efficacy trials. No negative symptoms were observed after single and double application of test product in any EPPO climatic zone. It can be concluded that CA3301 at 0,6 l/ha is safe for winter and spring barley.

3.4.1.3 Oat (AVESS/AVESA)

Use of CA3301 in the Maritime EPPO zone

A total of 7 trials were carried out on oat (AVESS/AVESA) in Germany (4), and the Czech Republic (3) on a wide-range of commercially grown varieties to assess the efficacy and crop safety of CA3301. All 7 trials included two applications of CA3301. All trials included CA2445 or TORERO as a reference standard.

CA3301 was applied at several dosages, from 0.36 l/ha (90 g ai/ha of Prothioconazole) up to 0.80 l/ha (200 g ai/ha of Prothioconazole).

CA3301 did not induce phytotoxicity symptoms in any of the 7 trials, whatever the dose rate or number of applications considered (see Table 3.4-10).

Considering all elements presented above, it is concluded that CA3301 applied at 100% rate of 0.6 l/ha (150 g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on oat in the Maritime EPPO zone.

Table 3.4-10: Summary table - Phytotoxicity – Oat (AVESS/AVESA) – Maritime EPPO zone

Number of trials with...		7 Trials	
		CA3301	CA2445
		2x 0.6-0.8 l/ha	2x 0.8 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	7	7
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0
Level of symptoms at the last assessments	0% to 5%	7	7
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0

Use of CA3301 in the Mediterranean EPPO zone

A total of 8 trials were carried out on oat (AVESS/AVESA) in Italy (2), Portugal (3) and Spain (3) on a wide-range of commercially grown varieties to assess the efficacy and crop safety of CA3301. All 8 trials included two applications of CA3301. All trials included CA2445, PROSARO, MYSTIC SUL or ORIUS P as a reference standard.

CA3301 was applied at several dosages, from 0.36 l/ha (90 g ai/ha of Prothioconazole) up to 0.80 l/ha (200 g ai/ha of Prothioconazole).

CA3301 did not induce phytotoxicity symptoms in any of the 8 trials, whatever the dose rate or number of applications considered (see Table 3.4-11).

Considering all elements presented above, it is concluded that CA3301 applied at 100% rate of 0.6 l/ha (150 g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on oat in the Mediterranean EPPO zone.

Table 3.4-11: Summary table - Phytotoxicity – Oat (AVESS/AVESA) – Mediterranean EPPO zone

Number of trials with...		8 Trials	
		CA3301	CA2445
		2x 0.6-0.8 l/ha	2x 0.8 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	8	8
	>5% to 10%	0	0
	>10% to 15%	0	0

Number of trials with...		8 Trials	
		CA3301	CA2445
		2x 0.6-0.8 l/ha	2x 0.8 l/ha
	>15 %	0	0
Level of symptoms at the last assessments	0% to 5%	8	8
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0

Use of CA3301 in the North-Eastern EPPO zone

A total of 7 trials were carried out on oat (AVESS/AVESA) in Latvia (2) and Poland (5) on a wide-range of commercially grown varieties to assess the efficacy and crop safety of CA3301. All 7 trials included two applications of CA3301. All trials included CA2445 or PROSARO as a reference standard.

CA3301 was applied at several dosages, from 0.36 l/ha (90 g ai/ha of Prothioconazole) up to 0.80 l/ha (200 g ai/ha of Prothioconazole).

CA3301 did not induce phytotoxicity symptoms in any of the 7 trials, whatever the dose rate or number of applications considered (see Table 3.4-12).

Considering all elements presented above, it is concluded that CA3301 applied at 100% rate of 0.6 l/ha (150 g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on oat in the North-Eastern EPPO zone.

Table 3.4-12: Summary table - Phytotoxicity – Oat (AVESS/AVESA) – North-Eastern EPPO zone

Number of trials with...		7 Trials	
		CA3301	CA2445
		2x 0.6-0.8 l/ha	2x 0.8 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	7	7
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0
Level of symptoms at the last assessments	0% to 5%	7	7
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0

Use of CA3301 in the South-Eastern EPPO zone

A total of 5 trials were carried out on oat (AVESS/AVESA) Bulgaria (1), Hungary (2) and Romania (2) on a wide-range of commercially grown varieties to assess the efficacy and crop safety of CA3301. All 5 trials included two applications of CA3301. All trials included CA2445 as a reference standard.

CA3301 was applied at several dosages, from 0.36 l/ha (90 g ai/ha of Prothioconazole) up to 0.80 l/ha

(200 g ai/ha of Prothioconazole).

CA3301 did not induce phytotoxicity symptoms in any of the 5 trials, whatever the dose rate or number of applications considered (see

Table 3.4-13).

Considering all elements presented above, it is concluded that CA3301 applied at 100% rate of 0.6 l/ha (150 g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on oat in the South-East^{EPPO} EPPO zone.

Table 3.4-13: Summary table - Phytotoxicity – Oat (AVESS/AVESA) – South-East^{EPPO} EPPO zone

Number of trials with...		5 Trials	
		CA3301	CA2445
		2x 0.6-0.8 l/ha	2x 0.8 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	5	5
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0
Level of symptoms at the last assessments	0% to 5%	5	5
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0

Comments of zRMS:

No special selective trials have been submitted. The phytotoxicity assessment was provided in the efficacy trials. No negative symptoms were observed after double application of test product in any EPPO climatic zone. It can be concluded that CA3301 at 0,6 l/ha is safe for spring oat.

3.4.1.4 Winter wheat (TRZAW)

Use of CA3301 in the Maritime EPPO zone

A series of 53 trials were carried out on winter wheat (TRZAW) in Germany (12), France (8), the United Kingdom (20), the Czech Republic (10) and Denmark (3) on a wide-range of commercially grown varieties to assess the efficacy and crop safety of CA3301. 3 trials included CA3301 applied only once, 45 trials included only two applications of CA3301, and 5 trials included CA3301 applied once and twice. All trials included CA2445 or PROSARO as a reference standard.

CA3301 was applied at several dosages, from 0.48 l/ha (120 g ai/ha of Prothioconazole) up to 0.80 l/ha (200 g ai/ha of Prothioconazole).

CA3301 did not induce phytotoxicity symptoms in any of the 53 trials, whatever the dose rate or number of applications considered (see Table 3.4-14).

Considering all elements presented above, it is concluded that CA3301 applied at maximum rate of 0.6-0.8 l/ha (150-200 g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on

winter wheat in Maritime EPPO Zone

Table 3.4-14: Summary table - Phytotoxicity – Winter Wheat (TRZAW) – Maritime EPPO zone

Number of trials with...		53 Trials			
		CA3301		CA2445	
		1 x 0.6-0.8 l/ha	2x 0.6-0.8 l/ha	1 x 0.6-0.8 l/ha	2x 0.6-0.8 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	8	50	8	50
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	8	50	8	50
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0

Use of CA3301 in the Mediterranean EPPO zone

A series of 46 trials were carried out on winter wheat (TRZAW) in France (17), Greece (3), Italy (5), Portugal (9) and Spain (12) on a wide-range of commercially grown varieties to assess the efficacy and crop safety of CA3301. 43 trials included only two applications of CA3301, and 3 trials included CA3301 applied once and twice. All trials included CA2445 or PROSARO as a reference standard.

CA3301 was applied at several dosages, from 0.48 l/ha (120 g ai/ha of Prothioconazole) up to 0.80 l/ha (200 g ai/ha of Prothioconazole).

CA3301 did not induce phytotoxicity symptoms in any of the 46 trials, whatever the dose rate or number of applications considered (see Table 3.4-15).

Considering all elements presented above, it is concluded that CA3301 applied at maximum rate of 0.6-0.8 l/ha (150-200 g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on winter wheat in Mediterranean EPPO zone.

Table 3.4-15: Summary table - Phytotoxicity – Winter Wheat (TRZAW) – Mediterranean EPPO zone

Number of trials with...		46 Trials			
		CA3301		CA2445	
		1 x 0.6-0.8 l/ha	2x 0.6-0.8 l/ha	1 x 0.6-0.8 l/ha	2x 0.6-0.8 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	3	46	3	46
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	3	46	3	46
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0

Number of trials with...		46 Trials			
		CA3301		CA2445	
		1 x 0.6-0.8 l/ha	2x 0.6-0.8 l/ha	1 x 0.6-0.8 l/ha	2x 0.6-0.8 l/ha
	>15 %	0	0	0	0

Use of CA3301 in the North-Eastern EPPO zone

A series of 40 trials were carried out on winter wheat (TRZAW) in Latvia (6), Lithuania (5) and Poland (29) on a wide range of commercially grown varieties to assess the efficacy and crop safety of CA3301. 34 trials included only two applications of CA3301, and 6 trials included CA3301 applied once and twice. All trials included CA2445 or OSIRIS as a reference standard.

CA3301 was applied at several dosages, from 0.48 l/ha (120 g ai/ha of Prothioconazole) up to 0.80 l/ha (200 g ai/ha of Prothioconazole).

CA3301 did not induce phytotoxicity symptoms in any of the 40 trials, whatever the dose rate or number of applications considered (see Table 3.4-16).

Considering all elements presented above, it is concluded that CA3301 applied at maximum rate of 0.6-0.8 l/ha (150-200 g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on winter wheat in North-Eastern EPPO Zone.

Table 3.4-16: Summary table - Phytotoxicity – Winter Wheat (TRZAW) – North-Eastern EPPO zone

Number of trials with...		4740 Trials				
		CA3301		Protikon 250 EC	CA2445	
		1 x 0.6-0.8 l/ha	2x 0.6-0.8 l/ha	1 x 0.6-0.8 l/ha	1 x 0.6-0.8 l/ha	2x 0.6-0.8 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	613	40	7	6	40
	>5% to 10%	0	0	0	0	0
	>10% to 15%	0	0	0	0	0
	>15 %	0	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	613	40	7	6	40
	>5% to 10%	0	0	0	0	0
	>10% to 15%	0	0	0	0	0
	>15 %	0	0	0	0	0

Use of CA3301 in the South-Eastern EPPO zone

A series of 37 trials were carried out on winter wheat (TRZAW) in Bulgaria (3), Hungary (19), Romania (13) and Slovakia (2) on a wide-range of commercially grown varieties to assess the efficacy and crop safety of CA3301. 33 trials included only two applications of CA3301, and 4 trials included CA3301 applied once and twice. All trials included CA2445, PRIAXOR or RISA 20 EC as a reference standard.

CA3301 was applied at several dosages, from 0.48 l/ha (120 g ai/ha of Prothioconazole) up to 0.80 l/ha

(200 g ai/ha of Prothioconazole).

CA3301 did not induce phytotoxicity symptoms in any of the 37 trials, whatever the dose rate or number of application considered (see Table 3.4-17).

Considering all elements presented above, it is concluded that CA3301 applied at maximum rate of 0.6-0.8 l/ha (150-200 g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on winter wheat in South-Eastern EPPO Zone.

Table 3.4-17: Summary table - Phytotoxicity – Winter Wheat (TRZAW) – South-Eastern EPPO zone

Number of trials with...		37 Trials			
		CA3301		CA2445	
		1 x 0.6-0.8 l/ha	2x 0.6-0.8 l/ha	1 x 0.6-0.8 l/ha	2x 0.6-0.8 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	4	37	4	37
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	4	37	4	37
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0

Comments of zRMS:

No special selective trials have been submitted. The phytotoxicity assessment was provided in the efficacy trials. No negative symptoms were observed after single and double application of test product in any EPPO climatic zone. It can be concluded that CA3301 at 0,6-0,8 l/ha is safe for winter wheat.

Also no negative symptoms have been observed in additional 7 efficacy trials conducted in 2023 in Poland for control PSDCHA in winter wheat.

3.4.1.5 Durum wheat (TRZDU)

Use of CA3301 in the Maritime EPPO zone

In this EPPO zone were carried out on durum wheat (TRZDU) four trials, in France (2) and in Germany (2) on 4 commercially grown varieties (Voilur – Anvergur – Wintergold – Duramonte), to assess the efficacy and crop safety of CA3301 applied twice. All trials included CA2445 as a reference standard.

CA3301 was applied at three dosages, from 0.48 l/ha (120 g ai/ha of Prothioconazole) up to 0.8 l/ha (200 g ai/ha of Prothioconazole).

CA3301 did not induce phytotoxicity symptoms in any trials, whatever the dose rate considered (see Table 3.4-18).

Considering all elements presented above, it is concluded that CA3301 applied at maximum rate of 0.6-0.8 l/ha (150-200 g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on durum wheat in Maritime EPPO zone.

Table 3.4-18: Summary table - Phytotoxicity – Durum wheat (TRZDU) – Maritime EPPO zone

Number of trials with...		4 Trials	
		CA3301	CA2445
		2x 0.6-0.8 l/ha	0.8 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	4	4
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0
Level of symptoms at the last assessments	0% to 5%	4	4
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0

Use of CA3301 in the Mediterranean EPPO zone

Seven trials were performed in the Mediterranean EPPO zone on durum wheat (TRZDU/TRZDW) in France (1), Italy (4) and in Portugal (2) on seven commercially grown varieties to assess the efficacy and crop safety of CA3301 applied twice. All trials included CA2445 or PROSARO as a reference standard.

The variety assessed were Celta, D.Ricardo, Achille, Saragolla, Anvergur, Colombo and Pharaon.

CA3301 was applied at three dosages, from 0.48 l/ha, corresponding to 120 g ai/ha of Prothioconazole, to 0.8 l/ha (200 g ai/ha of Prothioconazole).

No phytotoxicity symptoms were observed for any of CA3301 tested doses (see Table 3.4-19).

Considering all elements presented above, it is concluded that CA3301 applied at maximum rate of 0.6-0.8 l/ha (150-200 g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on durum wheat in Mediterranean EPPO zone.

Table 3.4-19: Summary table - Phytotoxicity – Durum wheat (TRZDU/TRZDW) – Mediterranean EPPO zone

Number of trials with...		7 trials		
		CA3301	CA2445	PROSARO
		2x 0.6-0.8 l/ha	0.8 l/ha	1 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	7	6	1
	>5% to 10%	0	0	0
	>10% to 15%	0	0	0
	>15 %	0	0	0
Level of symptoms at the last assessments	0% to 5%	7	6	1
	>5% to 10%	0	0	0
	>10% to 15%	0	0	0

Number of trials with...		7 trials		
		CA3301	CA2445	PROSARO
		2x 0.6-0.8 l/ha	0.8 l/ha	1 l/ha
	>15 %	0	0	0

Use of CA3301 in the North-East EPPO zone

A single trial was conducted in the North-East  EPPO zone on durum wheat (TRZDU) in Poland on variety Ceres to assess the efficacy and crop safety of CA3301 applied twice. All trials included CA2445 as a reference standard.

CA3301 was applied at four dosages, from 0.36 l/ha, corresponding to 90 g ai/ha of Prothioconazole, to 0.8 l/ha (200 g ai/ha of Prothioconazole).

No phytotoxicity symptoms were observed for any of CA3301 tested doses (see Table 3.4-20).




Considering all elements presented above, it is concluded that CA3301 applied at maximum rate of 0.6-0.8 l/ha (150-200 g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on durum wheat in North-East  EPPO zone.

Table 3.4-20: Summary table - Phytotoxicity – Durum wheat (TRZDU) – North-East  EPPO zone

Number of trials with...		1 trial	
		CA3301	CA2445
		2x 0.6-0.8 l/ha	0.8 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	1	1
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0
Level of symptoms at the last assessments	0% to 5%	1	1
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0

Use of CA3301 in the South-East EPPO zone

Six trials were conducted in the South-East  EPPO zone on durum wheat (TRZDU/TRZDW) in Hungary (5) and Romania (1) on variety Lunadur, Floradur, Wintergold and Atoudur to assess the efficacy and crop safety of CA3301 applied twice. All trials included CA2445 or PRIAXOR as a reference standard.

CA3301 was applied at four dosages in 3 trials, from 0.36 l/ha, corresponding to 90 g ai/ha of Prothioconazole, to 0.8 l/ha (200 g ai/ha of Prothioconazole), and in three dosages in the other trials from 0.48

l/ha to 0.8 l/ha.

No phytotoxicity symptoms were observed for any of CA3301 tested doses (see Table 3.4-21).

Considering all elements presented above, it is concluded that CA3301 applied at maximum rate of 0.6-0.8 l/ha (150-200 g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on durum wheat in South-East ~~EPPO~~ EPPO zone.

Table 3.4-21: Summary table - Phytotoxicity – Durum wheat (TRZDU) – South-East ~~EPPO~~ EPPO zone

Number of trials with...		6 trials		
		CA3301	CA2445	PRIAXOR
		2x 0.6-0.8 l/ha	0.8 l/ha	1.5 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	6	4	2
	>5% to 10%	0	0	0
	>10% to 15%	0	0	0
	>15 %	0	0	0
Level of symptoms at the last assessments	0% to 5%	6	4	2
	>5% to 10%	0	0	0
	>10% to 15%	0	0	0
	>15 %	0	0	0

Comments of zRMS:

No special selective trials have been submitted. The phytotoxicity assessment was provided in the efficacy trials. No negative symptoms were observed after double application of test product in any EPPO climatic zone. It can be concluded that CA3301 at 0,6-0,8 l/ha is safe for durum wheat.

3.4.1.6 Triticale (TTLWI)

Use of CA3301 in the Maritime EPPO zone

In this EPPO zone were carried out on triticale (TTLWI) 10 trials, in France (1), in Germany (5), in Denmark (1), and Czech Republic (3), on 8 commercially grown varieties to assess the efficacy and crop safety of CA3301 applied twice. All trials included CA2445 as a reference standard.

CA3301 was applied at three dose rates, from 0.48 l/ha (120 g ai/ha of Prothioconazole) up to 0.8 l/ha (200 g ai/ha of Prothioconazole).

CA3301 did not induce phytotoxicity symptoms in any trials, whatever the dose rate considered (see Table 3.4-22).

Considering all elements presented above, it is concluded that CA3301 applied at maximum rate of 0.6-0.8 l/ha (150-200 g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on triticale in Maritime EPPO zone.

Table 3.4-22: Summary table - Phytotoxicity – Triticale (TTLWI) – Maritime EPPO zone

Number of trials with...		10 Trials	
		CA3301	CA2445
		2x 0.6-0.8 l/ha	0.8 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	10	10
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0
Level of symptoms at the last assessments	0% to 5%	10	10
	>5% to 10%	0	0
	>10% to 15%	0	0
	>15 %	0	0

Use of CA3301 in the Mediterranean EPPO zone

Four trials were performed in the Mediterranean EPPO zone on triticale (TTLWI) in Portugal (3) and in France (1) on four commercially grown varieties to assess the efficacy and crop safety of CA3301 applied twice. All trials included CA2445 as a reference standard.

CA3301 was applied at three dose rates, from 0.48 l/ha, corresponding to 120 g ai/ha of Prothioconazole, to 0.8 l/ha (200 g ai/ha of Prothioconazole), in two trials the tested dose rates are from 0.36 l/ha to 0.8 l/ha.

No phytotoxicity symptoms were observed for any of CA3301 tested doses (see Table 3.4-23).

Considering all elements presented above, it is concluded that CA3301 applied at maximum rate of 0.6-0.8 l/ha (150-200 g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on triticale in Mediterranean EPPO zone.

Table 3.4-23: Summary table - Phytotoxicity – Triticale (TTLWI) – Mediterranean EPPO zone

Number of trials with...		4 trials		
		CA3301	CA2445	MYSTIC SUL
		2x 0.6-0.8 l/ha	0.8 l/ha	1 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	4	3	1
	>5% to 10%	0	0	0
	>10% to 15%	0	0	0
	>15 %	0	0	0
Level of symptoms at the last assessments	0% to 5%	4	3	1
	>5% to 10%	0	0	0
	>10% to 15%	0	0	0
	>15 %	0	0	0

Use of CA3301 in the North-Eastern EPPO zone

Six trials were conducted in the North-Eastern EPPO zone on triticale (TTLWI) in Poland on six commercial growing varieties to assess the efficacy and crop safety of CA3301 applied twice. All trials included CA2445 or OSIRIS 65 EC as a reference standard.

CA3301 was applied at four dose rates in three trials, from 0.36 l/ha, corresponding to 90 g ai/ha of Prothioconazole, to 0.8 l/ha (200 g ai/ha of Prothioconazole), and three dose rates in the other trials from 0.48 l/ha to 0.8 l/ha.

No phytotoxicity symptoms were observed for any of CA3301 tested doses (see Table 3.4-24).

Considering all elements presented above, it is concluded that CA3301 applied at maximum rate of 0.6-0.8 l/ha (150-200 g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on triticale in North-Eastern EPPO zone.

Table 3.4-24: Summary table - Phytotoxicity –Triticale (TTLWI) – North-Eastern EPPO zone

Number of trials with...		6 trials		
		CA3301	CA2445	OSIRIS 65 EC
		2x 0.6-0.8 l/ha	0.8 l/ha	2 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	6	4	2
	>5% to 10%	0	0	0
	>10% to 15%	0	0	0
	>15 %	0	0	0
Level of symptoms at the last assessments	0% to 5%	6	4	2
	>5% to 10%	0	0	0
	>10% to 15%	0	0	0
	>15 %	0	0	0

Use of CA3301 in the South-Eastern EPPO zone

Seven trials were conducted in the South-Eastern EPPO zone on Triticale (TTLWI) in Hungary (4) and Romania (3) on 4 commercially grown varieties to assess the efficacy and crop safety of CA3301 applied twice. All trials included CA2445, PRIAXOR or NATIVO PRO 365 SC as a reference standard.

CA3301 was applied at four dose rates in 2 trials, from 0.36 l/ha, corresponding to 90 g ai/ha of Prothioconazole, to 0.8 l/ha (200 g ai/ha of Prothioconazole), and in three dosage in the other trials from 0.48 l/ha to 0.8 l/ha.

No phytotoxicity symptoms were observed for any of CA3301 tested doses (see Table 3.4-25).

Considering all elements presented above, it is concluded that CA3301 applied at maximum rate of 0.6-0.8 l/ha (150-200 g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on triticale in South-Eastern EPPO zone.

Table 3.4-25: Summary table - Phytotoxicity – Triticale (TTLWI) – South-Eastern EPPO zone

Number of trials with...		7 trials			
		CA3301	CA2445	PRIAXOR	NATIVO PRO 325 SC
		2x 0.6-0.8 l/ha	0.8 l/ha	1.5 l/ha	1 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	7	3	2	3
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	7	3	2	3
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0

Comments of zRMS:

No special selective trials have been submitted. The phytotoxicity assessment was provided in the efficacy trials. No negative symptoms were observed after double application of test product in any EPPO climatic zone. It can be concluded that CA3301 at 0,6-0,8 l/ha is safe for winter triticale.

3.4.1.7 Rye (SECCW)

Use of CA3301 in the Maritime EPPO zone

A series of 9 trials were carried out on rye (SECCW) in Germany (2), the United Kingdom (1), the Czech Republic (3) and Denmark (3) on a wide-range of commercially grown varieties to assess the efficacy and crop safety of CA3301. All 9 trials included two applications of CA3301. All trials included CA2445 or PROLINE 275 as a reference standard.

CA3301 was applied at several dosages, from 0.36 l/ha (90 g ai/ha of Prothioconazole) up to 0.80 l/ha (200 g ai/ha of Prothioconazole).

CA3301 did not induce phytotoxicity symptoms in any of the 9 trials, whatever the dose rate or number of applications considered (see Table 3.4-26).

Considering all elements presented above, it is concluded that CA3301 applied at maximum rate of 0.6-0.8 l/ha (150-200 g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on rye in the Maritime EPPO zone.

Table 3.4-26: Summary table - Phytotoxicity – Rye (SECCW) – Maritime EPPO zone

Number of trials with...		9 Trials		
		CA3301	CA3301	CA2445
		2x 0.6 l/ha	2x 0.8 l/ha	2x 0.8 l/ha
Maximum of phytotoxicity recorded	0% to 5%	9	9	9
	>5% to 10%	0	0	0

Number of trials with...		9 Trials		
		CA3301	CA3301	CA2445
		2x 0.6 l/ha	2x 0.8 l/ha	2x 0.8 l/ha
during the trials	>10% to 15%	0	0	0
	>15 %	0	0	0
Level of symptoms at the last assessments	0% to 5%	9	9	9
	>5% to 10%	0	0	0
	>10% to 15%	0	0	0
	>15 %	0	0	0

Use of CA3301 in the Mediterranean EPPO zone

A series of 3 trials were carried out on rye (SECCW) in Portugal (2) and Greece (1) on a range of commercially grown varieties to assess the efficacy and crop safety of CA3301. All 3 trials included two applications of CA3301. All trials included CA2445 or ALTIS as a reference standard.

CA3301 was applied at several dosages, from 0.36 l/ha (90 g ai/ha of Prothioconazole) up to 0.80 l/ha (200 g ai/ha of Prothioconazole).

CA3301 did not induce phytotoxicity symptoms in any of the 3 trials, whatever the dose rate or number of applications considered (see Table 3.4-27).

Considering all elements presented above, it is concluded that CA3301 applied at maximum rate of 0.6-0.8 l/ha (150-200 g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on rye in the Mediterranean EPPO zone.

Table 3.4-27: Summary table - Phytotoxicity – Rye (SECCW) – Mediterranean EPPO zone

Number of trials with...		3 Trials		
		CA3301	CA3301	CA2445
		2x 0.6 l/ha	2x 0.8 l/ha	2x 0.8 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	3	3	3
	>5% to 10%	0	0	0
	>10% to 15%	0	0	0
	>15 %	0	0	0
Level of symptoms at the last assessments	0% to 5%	3	3	3
	>5% to 10%	0	0	0
	>10% to 15%	0	0	0
	>15 %	0	0	0

Use of CA3301 in the North-Eastern EPPO zone

A series of 7 trials were carried out on rye (SECCW) in Latvia (1), Lithuania (1) and Poland (5) on a wide range of commercially grown varieties to assess the efficacy and crop safety of CA3301. All 7 trials included two applications of CA3301. All trials included CA2445 or OSIRIS 65 EC as a reference standard.

CA3301 was applied at several dosages, from 0.36 l/ha (90 g ai/ha of Prothioconazole) up to 0.80 l/ha (200 g ai/ha of Prothioconazole).

CA3301 did not induce phytotoxicity symptoms in any of the 7 trials, whatever the dose rate or number of applications considered (see Table 3.4-28).

Considering all elements presented above, it is concluded that CA3301 applied at maximum rate of 0.6-0.8 l/ha (150-200 g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on rye in the North-Eastern EPPO zone.

Table 3.4-28: Summary table - Phytotoxicity – Rye (SECCW) – North-Eastern EPPO zone

Number of trials with...		7 Trials		
		CA3301	CA3301	CA2445
		2x 0.6 l/ha	2x 0.8 l/ha	2x 0.8 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	7	7	7
	>5% to 10%	0	0	0
	>10% to 15%	0	0	0
	>15 %	0	0	0
Level of symptoms at the last assessments	0% to 5%	7	7	7
	>5% to 10%	0	0	0
	>10% to 15%	0	0	0
	>15 %	0	0	0

Use of CA3301 in the South-Eastern EPPO zone

A series of 4 trials were carried out on rye (SECCW) in Hungary (3) and Romania (1) on a range of commercially grown varieties to assess the efficacy and crop safety of CA3301. All 4 trials included two applications of CA3301. All trials included CA2445 or PRIAXOR as a reference standard.

CA3301 was applied at several dosages, from 0.36 l/ha (90 g ai/ha of Prothioconazole) up to 0.80 l/ha (200 g ai/ha of Prothioconazole).

CA3301 did not induce phytotoxicity symptoms in any of the 4 trials, whatever the dose rates or number of applications considered (see Table 3.4-29).

Considering all elements presented above, it is concluded that CA3301 applied at maximum rate of 0.6-0.8 l/ha (150-200 g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on rye in the South-Eastern EPPO zone.

Table 3.4-29: Summary table - Phytotoxicity – Rye (SECCW) – South-Eastern EPPO zone

Number of trials with...		4 Trials		
		CA3301	CA3301	CA2445
		2x 0.6 l/ha	2x 0.8 l/ha	2x 0.8 l/ha
Maximum of phytotoxicity recorded	0% to 5%	4	4	4
	>5% to 10%	0	0	0

Number of trials with...		4 Trials		
		CA3301	CA3301	CA2445
		2x 0.6 l/ha	2x 0.8 l/ha	2x 0.8 l/ha
during the trials	>10% to 15%	0	0	0
	>15 %	0	0	0
Level of symptoms at the last assessments	0% to 5%	4	4	4
	>5% to 10%	0	0	0
	>10% to 15%	0	0	0
	>15 %	0	0	0

Comments of zRMS:

No special selective trials have been submitted. The phytotoxicity assessment was provided in the efficacy trials. No negative symptoms were observed after double application of test product in any EPPO climatic zone. It can be concluded that CA3301 at 0,6-0,8 l/ha is safe for winter rye.

3.4.1.8 Oilseed rape (BRSNW)

Use of CA3301 in the Maritime EPPO zone – 1 application in autumn and 1 application in spring

A total of 15 trials were carried out on oilseed rape (BRSNW) with 1 application in autumn and 1 application in spring. These trials took place in Germany (3), United Kingdom (2), Czech Republic (5), Denmark (1) and France (4) on a wide-range of commercially grown varieties to assess the efficacy and crop safety of CA3301. All trials included CA2445, BISTRO, PROSARO or CARAMBA as the reference standard.

CA3301 was applied at several dosages, from 0.5 l/ha (125 g ai/ha of Prothioconazole) up to 0.7 l/ha (175 g ai/ha of Prothioconazole). Phytotoxicity symptoms were assessed around 2 weeks after application A, at application B and at each severity assessment timing.

CA3301 applied at 0.6 l/ha and 0.7 l/ha induced minor stunting phytotoxicity symptoms (< 5%) after the first application (13 DA-A and 48 DA-A) in 1 trial out of 15 on the variety Nikita (BBCH 18). In this trial, the references BITRO and CA2445 also induced minor stunting symptoms. Stunting symptoms (>5% to 15%) were also observed 2 weeks after the application of the reference CARAMBA in 3 trials out of 15 on varieties Hatrick and Avatar (BBCH 16-18). All of these stunting symptoms disappeared at later assessment.

Furthermore, CA3301 applied at 0.6 l/ha and 0.7 l/ha induced minor discoloration symptoms (<5% to 10%) respectively in 2 and 3 trials out of 15 around 2 weeks after the application A on varieties PT271, Arabela and KWS Digger (BBACH 15-16). All of these stunting symptoms disappeared at later assessment (see Table 3.4-30).

Finally, the phytotoxicity symptoms observed did not induce significant yield loss in the 2 trials where values were available (see Table 3.4-32)

Considering all elements presented above, it is concluded that CA3301 applied at 0.6-0.7 l/ha (150-175g ai/ha of Prothioconazole) might rarely induce transient phytotoxicity symptoms on oilseed rape in the Maritime EPPO zone.

Table 3.4-30: Summary table - Phytotoxicity – Oilseed rape (BRSNW) – Maritime EPPO zone

Number of trials with...		15 Trials					
		CA3301		Standards			
		2x 0.6 l/ha (15)	2x 0.7 l/ha (15)	BISTRO (2) 2x 0.6 l/ha	CA2445 (12) 2x 0.7 l/ha	PROSARO (3) 2x 0.75 l/ha	CARAMBA (3) 2x 1.5 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	15	13	0	12	3	0
	>5% to 10%	0	2	2	0	0	1
	>10% to 15%	0	0	0	0	0	1
	>15 %	0	0	0	0	0	1
Level of symptoms at the last as- sessments	0% to 5%	15	15	2	12	3	3
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0

Data from trials in which phytotoxicity was observed.

Table 3.4-31: Phytotoxicity symptoms – Oilseed rape (BRSNW) – Maritime EPPO zone

Country	Crop Code	Variety	Crop stage	Trt-Eval Interval	Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	BISTRO 0,6 L/ha AB	CA2445 0,7 L/ha AB	PROSARO 0,75 L/ha AB	CARAMBA 1,5 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,7 L/ha AB
FR	BRSNW	Nikita	18	13 DA-A	Phytotoxicity - Stunting (%)	0,00 a	5,25 a	2,50 a			5,00 a	4,25 a
FR	BRSNW	Nikita	18	48 DA-A	Phytotoxicity - Stunting (%)	0,00 c	7,25 a	4,25 abc			4,50 ab	4,00 abc
FR	BRSNW	Nikita	65	0 DA-B	Phytotoxicity - General (%)	0,00 a	0,00 a	0,00 a			0,00 a	0,00 a
FR	BRSNW	Nikita	69	15 DA-B	Phytotoxicity - General (%)	0,00 a	0,00 a	0,00 a			0,00 a	0,00 a
FR	BRSNW	Nikita	69	64 DA-B	Phytotoxicity - General (%)	0,00 a	0,00 a	0,00 a			0,00 a	0,00 a
DE	BRSNW	Hatrick	18	15 DA-A	Phytotoxicity - Stunting (%)	0,00 b		0,00 b		17,00 a	0,00 b	0,00 b
DE	BRSNW	Hatrick	65	0 DA-B	Phytotoxicity - General (%)	0,00 a		0,00 a		0,00 a	0,00 a	0,00 a
DE	BRSNW	Hatrick	67	15 DA-B	Phytotoxicity - General (%)	0,00 a		0,00 a		0,00 a	0,00 a	0,00 a
DE	BRSNW	Hatrick	85	84 DA-B	Phytotoxicity - General (%)	0,00 a		0,00 a		0,00 a	0,00 a	0,00 a
DE	BRSNW	Avatar	16	15 DA-A	Phytotoxicity - Stunting (%)	0,00 b		0,00 b		11,75 a	0,00 b	0,00 b
DE	BRSNW	Avatar	65	0 DA-B	Phytotoxicity - General (%)	0,00 a		0,00 a		0,00 a	0,00 a	0,00 a
DE	BRSNW	Avatar	67	15 DA-B	Phytotoxicity - General (%)	0,00 a		0,00 a		0,00 a	0,00 a	0,00 a
DE	BRSNW	Avatar	85	83 DA-B	Phytotoxicity - General (%)	0,00 a		0,00 a		0,00 a	0,00 a	0,00 a
DE	BRSNW	Avatar	18	15 DA-A	Phytotoxicity - Stunting (%)	0,00 b		0,00 b		8,75 a	0,00 b	0,00 b
CZ	BRSNW	PT 271	15	15 DA-A	Phytotoxicity - Discoloration (%)	0,00 c			0,00 c		3,50 b	7,50 a
CZ	BRSNW	PT 271	35	-1 DA-B		0,00			0,00		0,00	0,00

Country	Crop Code	Variety	Crop stage	Trt-Eval Interval	Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	BISTRO 0,6 L/ha AB	CA2445 0,7 L/ha AB	PROSARO 0,75 L/ha AB	CARAMBA 1,5 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,7 L/ha AB
					Phytotoxicity - General (%)	a			a		a	a
CZ	BRSNW	PT 271	55	16 DA-B	Phytotoxicity - General (%)	0,00 a			0,00 a		0,00 a	0,00 a
CZ	BRSNW	PT 271	67	27 DA-B	Phytotoxicity - General (%)	0,00 a			0,00 a		0,00 a	0,00 a
CZ	BRSNW	PT 271	69	40 DA-B	Phytotoxicity - General (%)	0,00 a			0,00 a		0,00 a	0,00 a
CZ	BRSNW	PT 271	89	71 DA-B	Phytotoxicity - General (%)	0,00 a			0,00 a		0,00 a	0,00 a
CZ	BRSNW	Arabela	16	15 DA-A	Phytotoxicity - Discoloration (%)	0,00 a			0,00 a		0,00 a	5,00 a
CZ	BRSNW	Arabela	33	0 DA-B	Phytotoxicity - General (%)	0,00 a			0,00 a		0,00 a	0,00 a
CZ	BRSNW	Arabela	63	21 DA-B	Phytotoxicity - General (%)	0,00 a			0,00 a		0,00 a	0,00 a
CZ	BRSNW	Arabela	67	31 DA-B	Phytotoxicity - General (%)	0,00 a			0,00 a		0,00 a	0,00 a
CZ	BRSNW	Arabela	74	47 DA-B	Phytotoxicity - General (%)	0,00 a			0,00 a		0,00 a	0,00 a
CZ	BRSNW	Arabela	81	74 DA-B	Phytotoxicity - General (%)	0,00 a			0,00 a		0,00 a	0,00 a
CZ	BRSNW	KWS Digger	16	14 DA-A	Phytotoxicity - Discoloration (%)	0,00 a			0,00 a		5,00 a	10,00 a
CZ	BRSNW	KWS Digger	35	0 DA-B	Phytotoxicity - General (%)	0,00 a			0,00 a		0,00 a	0,00 a
CZ	BRSNW	KWS Digger	64	21 DA-B	Phytotoxicity - General (%)	0,00 a			0,00 a		0,00 a	0,00 a
CZ	BRSNW	KWS Digger	69	27 DA-B	Phytotoxicity - General (%)	0,00 a			0,00 a		0,00 a	0,00 a
CZ	BRSNW	KWS Digger	72	42 DA-B	Phytotoxicity - General (%)	0,00 a			0,00 a		0,00 a	0,00 a
CZ	BRSNW	KWS Digger	82	69 DA-B	Phytotoxicity - General (%)	0,00 a			0,00 a		0,00 a	0,00 a

Table 3.4-32: Relationship between phytotoxicity and yield – Oilseed rape (BRSNW) – Maritime EPPO zone

Countr y	Variet y	Treatment name Rate Rate unit Appl. Code	UNTREATE D CHECK	BISTR O 0,6 L/ha AB	CA244 5 0,7 L/ha AB	PROSAR O 0,75 L/ha AB	CARAMB A 1,5 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,7 L/ha AB	Treatment name Rate Rate unit Appl. Code	UNTREATE D CHECK	BISTR O 0,6 L/ha AB	CA244 5 0,7 L/ha AB	PROSAR O 0,75 L/ha AB	CARAMB A 1,5 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,7 L/ha AB
FR	Nikita	Maximum phytotoxicity symptoms (%)	0,00	7,25	4,25			5,00	4,25	Yield (t/ha)	2,33 a	2,48 ab	2,41 b			2,41 b	2,85 a
			a	a	abc			a	a	Yield (%UTC)	100,00 -	106,44 -	103,43 -			103,43 -	122,32 -
CZ	PT 271	Maximum phytotoxicity symptoms (%)	0,00			0,00		3,50	7,50	Yield (t/ha)	2,18 a			2,26 a		2,17 a	2,35 a
			c			c		b	a	Yield (%UTC)	100,00 -			103,67 -		99,54 -	107,80 -

*Statistical analysis was not available for UTC values of yield.

Use of CA3301 in the Maritime EPPO zone – 2 applications in spring

A total of 26 trials were carried out on Oilseed rape (BRSNW) with 2 applications in spring. These trials took place in Germany (9), United Kingdom (2), Czech Republic (13), Denmark (1) and France (1) on a wide-range of commercially grown varieties to assess the efficacy and crop safety of CA3301. All trials included CA2445 or PROLINE 275 as a reference standard.

CA3301 was applied at several dosages, from 0.5 l/ha (125 g ai/ha of Prothioconazole) up to 0.7 l/ha (175 g ai/ha of Prothioconazole).

CA3301 applied at 0.6 l/ha and 0.7 l/ha did not induce phytotoxicity symptoms in any of the 26 trials (see Table 3.4-33).

Considering all elements presented above, it is concluded that CA3301 applied at 0.6-0.7 l/ha (150-175g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on oilseed rape in the Maritime EPPO zone.

Table 3.4-33: Summary table - Phytotoxicity – Oilseed rape (BRSNW) – Maritime EPPO zone

Number of trials with...		26 Trials			
		CA3301		Standards	
		2x 0.6 l/ha (26)	2x 0.7 l/ha (26)	CA2445 (25) 2x 0.7 l/ha	PROLINE 275 (1) 2x 0.63 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	26	26	25	1
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	26	26	25	1
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0

Use of CA3301 in the Mediterranean EPPO zone – 1 application in autumn and 1 application in spring

One trial was carried out on oilseed rape (BRSNW) with 1 application in autumn and 1 application in spring. This trial took place in France (1) on a commercially grown variety to assess the efficacy and crop safety of CA3301. All trials included CA2445 or BISTRO as a reference standard.

CA3301 was applied at several dosages, from 0.5 l/ha (125 g ai/ha of Prothioconazole) up to 0.7 l/ha (175 g ai/ha of Prothioconazole).

CA3301 applied at 0.6 l/ha and 0.7 l/ha did not induce phytotoxicity symptoms in this trial (see Table 3.4-34).

Considering all elements presented above, it is concluded that CA3301 applied at 0.6-0.7 l/ha (150-175g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on oilseed rape in the Mediterranean EPPO zone.

Table 3.4-34: Summary table - Phytotoxicity – Oilseed rape (BRSNW) – Mediterranean EPPO zone

Number of trials with...		1 Trial			
		CA3301		Standards	
		2x 0.6 l/ha (1)	2x 0.7 l/ha (1)	CA2445 (1) 2x 0.7 l/ha	BISTRO (1) 2x 0.6 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	1	1	1	1
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	1	1	1	1
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0

Use of CA3301 in the Mediterranean EPPO zone – 2 applications in spring

A series of 13 trials were carried out on oilseed rape (BRSNW) with 2 applications in spring. These trials took place in Spain (5), Italy (3) and France (5) on a wide-range of commercially grown varieties to assess the efficacy and crop safety of CA3301. All trials included CA2445, CARAMBA, ORTIVA or PROSARO as a reference standard.

CA3301 was applied at several dosages, from 0.5 l/ha (125 g ai/ha of Prothioconazole) up to 0.7 l/ha (175 g ai/ha of Prothioconazole).

CA3301 applied at 0.6 l/ha and 0.7 l/ha did not induce phytotoxicity symptoms in any of the 13 trials (see Table 3.4-35).

Considering all elements presented above, it is concluded that CA3301 applied at 0.6-0.7 l/ha (150-175g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on oilseed rape in the Mediterranean EPPO zone.

Table 3.4-35: Summary table - Phytotoxicity – Oilseed rape (BRSNW) – Mediterranean EPPO zone

Number of trials with...		13 Trials					
		CA3301		Standards			
		2x 0.6 l/ha (13)	2x 0.7 l/ha (13)	CA2445 (13) 2x 0.7 l/ha	CARAMBA (4) 2x 0.8 l/ha	PROSARO (3) 2x 0.75 l/ha	ORTIVA (1) 2x 1.0 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	13	13	13	4	3	1
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	13	13	13	4	3	1
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0

Use of CA3301 in the North-Eastern EPPO zone – 1 application in autumn and 1 application in spring

A series of 13 trials were carried out on oilseed rape (BRSNW) with 1 application in autumn and 1 application in spring. These trials took place in Poland (12) and Lithuania (1) on a wide-range of commercially grown varieties to assess the efficacy and crop safety of CA3301. All trials included CA2445, ARTINA, TILMOR or ORIUS EX as a reference standard.

CA3301 was applied at several dosages, from 0.5 l/ha (125 g ai/ha of Prothioconazole) up to 0.7 l/ha (175 g ai/ha of Prothioconazole).

CA3301 applied at 0.6 l/ha and 0.7 l/ha did not induce phytotoxicity symptoms in any of the 13 trials (see

Table 3.4-36).

Considering all elements presented above, it is concluded that CA3301 applied at 0.6-0.7 l/ha (150-175g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on oilseed rape in the North-East ~~era~~ EPPO zone.

Table 3.4-36: Summary table - Phytotoxicity – Oilseed rape (BRSNW) – North-eastern East EPPO zone

Number of trials with...		13 Trials					
		CA3301		Standards			
		2x 0.6 l/ha (13)	2x 0.7 l/ha (13)	CA2445 (10) 2x 0.7 l/ha	ARTINA (1) 2x 0.7 l/ha	TILMOR (3) 0.75-1.0 l/ha (A-B)	ORIOUS EX-TRA (6) 2x 1.0 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	13	13	10	1	3	6
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	13	13	10	1	3	6
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0

Use of CA3301 in the North-Eastern EPPO zone – 2 applications in spring

A series of 26 trials were carried out on oilseed rape (BRSNW) with 2 applications in spring. These trials took place in Poland (18), Lithuania (2) and Latvia (6) on a wide-range of commercially grown varieties to assess the efficacy and crop safety of CA3301. All trials included CA2445, PROPULSE, PROSARO or CARAMBA as the reference standard.

CA3301 was applied at several dosages, from 0.5 l/ha (125 g ai/ha of Prothioconazole) up to 0.7 l/ha (175 g ai/ha of Prothioconazole). Phytotoxicity symptoms were assessed around 2 weeks after application A, at application B and at each severity assessment timing.

CA3301 applied at 0.6 l/ha induced phytotoxicity symptoms (15% volume reduction) in 1 trial out of 26 after the application B (21 DA-B and 38 DA-B) on variety Acapulco (BBCH 77-82). Moreover, applied at 0.7 l/ha, CA3301 did not induced phytotoxicity symptoms in any of the 26 trials (see Table 3.4-37). It is not clear from the trial report why the symptoms were observed, however given that these were not observed from the higher rate of application, and not observed for either rate in 25 remaining trials it is considered an unusual and possibly anomalous result.

In the trial where symptoms were observed, a numerical reduction of yield was assessed for CA3301 at 0.6 l/ha but it was not statistically significant (see Table 3.4-40).

Given the low frequency of occurrence and the level of symptoms observed, they can be considered very acceptable.

Considering all elements presented above, it is concluded that CA3301 applied at 0.6-0.7 l/ha (150-175g ai/ha of Prothioconazole) might rarely induce acceptable phytotoxicity symptoms on oilseed rape in the North-Eastern EPPO zone.

Table 3.4-37: Summary table - Phytotoxicity – Oilseed rape (BRSNW) – North-Eastern EPPO zone

Number of trials with...		26 Trials						
		CA3301		Standards				
		2x 0.6 l/ha (26)	2x 0.7 l/ha (26)	CA2445 (14) 2x 0.7 l/ha	PROPULSE (1) 2x 0.8 l/ha	PROSARO (7) 2x 1.0 l/ha	CARAMBA 60 SL (8) 1x 1.0 l/ha	CARAMBA 60 SL (6) 2x 1.0 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	25	26	14	1	7	8	6
	>5% to 10%	0	0	0	0	0	0	0
	>10% to 15%	1	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	25	26	14	1	7	8	6
	>5% to 10%	0	0	0	0	0	0	0
	>10% to 15%	1	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0	0

Data from trial in which phytotoxicity was observed.

Table 3.4-38: Phytotoxicity general – Oilseed rape (BRSNW) – North-Eastern EPPO zone

Country	Crop Code	Variety	Crop stage	Trt-Eval Interval	Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CARAMBA 1 L/ha A	CA3301 0,6 L/ha AB	CA3301 0,7 L/ha AB
PL	BRSNW	Acapulco	59	21 DA-A	Phytotoxicity - General (%)	0,00 a	0.00 a	0,00 a	0,00 a
PL	BRSNW	Acapulco	67	0 DA-B	Phytotoxicity - General (%)	0,00 a	0.00 a	0,00 a	0,00 a
PL	BRSNW	Acapulco	77	21 DA-B	Phytotoxicity - General (%)	0,00 c	0.00 c	15,00 a	0,00 c
PL	BRSNW	Acapulco	82	38 DA-B	Phytotoxicity - Gen- eral (%)	0,00 c	0.00 c	15.00 a	0.00 c

Table 3.4-39: Phytotoxicity symptoms – Oilseed rape (BRSNW) – North-Eastern EPPO zone

Country	Crop Code	Variety	Crop stage	Trt-Eval Interval	Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CARAMBA 1 L/ha A	CA3301 0,6 L/ha AB	CA3301 0,7 L/ha AB
PL	BRSNW	Acapulco	77	21 DA-B	Phytotoxicity – Volume reduction (%)	0,00 c	0.00 c	15,00 a	0.0 c
PL	BRSNW	Acapulco	82	38 DA-B	Phytotoxicity – Volume reduction (%)	0,00 c	0.00 c	15.00 a	0.00 c

Table 3.4-40: Relationship between phytotoxicity and yield – Oilseed rape (BRSNW) – Maritime EPPO zone

Country	Variety	Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CARAMBA 1 L/ha A	CA3301 0,6 L/ha AB	CA3301 0,7 L/ha AB	Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CARAMBA 1 L/ha A	CA3301 0,6 L/ha AB	CA3301 0,7 L/ha AB
PL	Acapulco	Maximum phytotoxicity symptoms (%)	0,00	0.00	15,00	0,00	Yield (t/ha)	2,66 a	2,94 ab	2,49 a	3,10 a
			c	c	a	c	Yield (%UTC)	100,00 -	110,53 -	93,61 -	116,54 -

*Statistical analysis was not available for UTC values of yield

Use of CA3301 in the South-Eastern EPPO zone – 1 application in autumn and 1 application in spring

A series of 12 trials were carried out on oilseed rape (BRSNW) with 1 application in autumn and 1 application in spring. These trials took place in Hungary (8) and Romania (4) on a wide-range of commercially grown varieties to assess the efficacy and crop safety of CA3301. All trials included CA2445 or TILMOR as a reference standard.

CA3301 was applied at several dosages, from 0.5 l/ha (125 g ai/ha of Prothioconazole) up to 0.7 l/ha (175 g ai/ha of Prothioconazole).

CA3301 applied at 0.6 l/ha and 0.7 l/ha did not induce phytotoxicity symptoms in any of the 13 trials (see Table 3.4-41).

Considering all elements presented above, it is concluded that CA3301 applied at 0.6-0.7 l/ha (150-175g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on oilseed rape in the South-Eastern EPPO zone.

Table 3.4-41: Summary table - Phytotoxicity – Oilseed rape (BRSNW) – South-Eastern EPPO zone

Number of trials with...		12 Trials			
		CA3301		Standards	
		2x 0.6 l/ha (12)	2x 0.7 l/ha (12)	CA2445 (12) 2x 0.7 l/ha	TILMOR (7) 2x 1.2 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	12	12	12	7
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	12	12	12	7
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0

Use of CA3301 in the South-Eastern EPPO zone – 2 applications in spring

A series of 29 trials were carried out on oilseed rape (BRSNW) with 2 applications in spring. These trials took place in Hungary (10), Romania (12) and Slovakia (7) on a wide-range of commercially grown varieties to assess the efficacy and crop safety of CA3301. All trials included CA2445, PRO-PULSE, PROSARO or ORIUS as a reference standard.

CA3301 was applied at several dosages, from 0.5 l/ha (125 g ai/ha of Prothioconazole) up to 0.7 l/ha (175 g ai/ha of Prothioconazole).

CA3301 applied at 0.6 l/ha and 0.7 l/ha did not induce phytotoxicity symptoms in any of the 13 trials

(see Table 3.4-42).

Considering all elements presented above, it is concluded that CA3301 applied at 0.6-0.7 l/ha (150-175g ai/ha of Prothioconazole) will not induce phytotoxicity symptoms on oilseed rape in the South-East ~~EPH~~ EPPO zone.

Table 3.4-42: Summary table - Phytotoxicity – Oilseed rape (BRSNW) – South-East ~~EPH~~ EPPO zone

Number of trials with...		29 Trials					
		CA3301		Standards			
		2x 0.6 l/ha (29)	2x 0.7 l/ha (29)	CA2445 (24) 2x 0.7 l/ha	PROSARO (5) 2x 0.75 l/ha	PROPULSE (7) 2x 1.0 l/ha	ORIUS (2) 2x 1.0 l/ha
Maximum of phytotoxicity recorded during the trials	0% to 5%	29	29	24	5	7	2
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	29	29	24	5	7	2
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0

Comments of zRMS:

No special selective trials have been submitted. The phytotoxicity assessment was provided in the efficacy trials. In the Maritime EPPO climatic zone, the negative symptoms (minor stunting and discoloration) were observed on acceptable level (<5% and 5-10%, respectively) after double application (autumn and spring) at dose rate of 0,7 l/ha. All symptoms were transient and disappeared at later assessment. In the North-East EPPO zone, volume reduction on level of 15% was detected after double application at dose rate of 0,6 l/ha. This negative symptoms was noted also at later assessment. However, the higher dose of 0,7 l/ha did not cause any phytotoxicity in submitted trials. Taking into account above results, it can be concluded that CA3301 at 0,6-0,7 l/ha is safe for winter oilseed rape but it should be noted that transient negative symptoms (stunting, discoloration, volume reduction) are possible.

3.4.2 Effect on the yield of treated plants or plant products ((KCP 6.4.2)

3.4.2.1 Winter barley (HORVW)

Use of CA3301 in the Maritime EPPO zone

Yield parameters (t/ha and the corresponding calculated %UNCK) were recorded in 21 trials implemented to evaluate the effectiveness of CA3301 at 0.6 l/ha against foliar and ear diseases in the Maritime EPPO zone.

The application of CA3301 at 0.6 l/ha had no negative impact on the yield of winter barley and had a significant positive effect in 10 trials out of 21, compared to the untreated check.

CA3301 at 0.6 l/ha increased yield by 10.43% which was always statistically equivalent to the yield increase provided by the reference products CA2445 at 0.8 l/ha, PROLINE 275 at 0.72 l/ha and MIRADOR XTRA at 0.8 l/ha (see Table 3.4-43).

Therefore, it is concluded that 2 applications of CA3301 at 0.6 l/ha will not negatively affect yield on winter barley and will have a positive effect on yield in the Maritime EPPO zone.

Table 3.4-43: Summary table – Winter barley – Yield (T/ha) - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA244 5	PROLINE 275	MIRADOR XTRA	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	0,72	0,8	0,6	
Rate unit		L/ha	L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	AB	
YIELD (T/ha) - 38-84 DA-B						
Number of values	21				21	UTC
Minimum value	5,27				5,96	
Maximum value	11,46	-	-	-	12,46	10 >
Mean Yield (T/ha)	7,63				8,36	11 =
Mean %UTC	100,00%				110,43 %	0 <
Number of values	16	16			16	CA2445
Minimum value	5,27	6,01			5,96	0,8 l/ha
Maximum value	10,55	10,37	-	-	10,21	0 >
Mean Yield (T/ha)	7,32	8,13			7,93	16 =
Mean %UTC	100,00%	112,93 %			109,56 %	0 <
Number of values	4		4		4	PROLINE 275 EC
Minimum value	7,31		7,20		7,66	0,72 l/ha
Maximum value	11,46	-	12,73	-	12,46	0 >
Mean Yield (T/ha)	8,85		10,05		10,11	4 =
Mean %UTC	100,00%		113,62%		114,57 %	0 <
Number of values	1			1	1	MYRADOR XTRA
Minimum value	7,86			8,93	8,29	0,8 l/ha
Maximum value	7,86	-	-	8,93	8,29	0 >
Mean Yield (T/ha)	7,86			8,93	8,29	1 =
Mean %UTC	100,00%			117,49%	107,84 %	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the Mediterranean EPPO zone

Yield parameters (t/ha and the corresponding calculated %UNCK) were recorded in 21 trials implemented to evaluate the effectiveness of CA3301 at 0.6 l/ha against foliar and ear diseases in the Mediterranean EPPO zone.

The application of CA3301 at 0.6 l/ha had no negative impact on the yield of winter barley and had a significant positive effect in 4 trials out of 21, compared to the untreated check.

CA3301 at 0.6 l/ha increased yield by 18.22% which was always statistically equivalent to the yield

increase provided by the reference products PROSARO at 1 l/ha and by CA2445 at 0.8 l/ha except in 1 trial where CA2445 (applied at a higher rate of prothioconazole) resulted in significantly higher yield and another trial where significantly lower yield was observed compared to CA3301 (see Table 3.4-44).

Therefore, it is concluded that 2 applications of CA3301 at 0.6 l/ha will not negatively affect yield on winter barley and will have a positive effect on yield in the Mediterranean EPPO zone.

Table 3.4-44: Summary table – Winter barley – Yield (T/ha) - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA2445	PROSARO	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	1	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
YIELD (T/ha) - 35-80 DA-B					
Number of values	21			21	UTC
Minimum value	1,25			1,87	
Maximum value	8,46	-	-	9,09	4 >
Mean Yield (T/ha)	5,09			5,66	17 =
Mean % UTC	100,00%			118,22%	0 <
Number of values	18	18		18	CA2445
Minimum value	1,25	1,65		1,87	0,8 l/ha
Maximum value	8,35	8,77	-	9,09	1 >
Mean Yield (T/ha)	4,72	5,35		5,35	16 =
Mean % UTC	100,00%	120,47%		120,29%	1 <
Number of values	4		4	4	PROSARO
Minimum value	2,02		4,48	4,34	1 l/ha
Maximum value	8,46	-	8,02	8,61	0 >
Mean Yield (T/ha)	5,98		6,57	6,85	4 =
Mean % UTC	100,00%		135,16%	137,32%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-Eastern EPPO zone

Yield parameters (t/ha and the corresponding calculated %UNCK) were recorded in 16 trials implemented to evaluate the effectiveness of CA3301 at 0.6 l/ha against foliar and ear diseases in the North-Eastern EPPO zone.

The application of CA3301 at 0.6 l/ha had no negative impact on the yield of winter barley and had a significant positive effect in 7 trials out of 16, compared to the untreated check.

CA3301 at 0.6 l/ha increased yield by 12.19% which was always statistically equivalent to the yield increase provided by the reference products OSIRIS 65 EC at 2 l/ha, and by CA2445 at 0.6-0.8 l/ha except in 1 trial where CA2445 at 0.8 l/ha (applied at a higher rate of prothioconazole) resulted in significantly higher yield. (see Table 3.4-45)

Therefore, it is concluded that 2 applications of CA3301 at 0.6 l/ha will not negatively affect yield on winter barley and will have a positive effect on yield in the North-Eastern EPPO zone.

Table 3.4-45: Summary table – Winter barley – Yield (T/ha) – North-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA2445	CA2445	OSIRIS 65 EC	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,6	0,8	2	0,6	
Rate unit		L/ha	L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	AB	
YIELD (T/ha) - 36-73 DA-B						
Number of values	16				16	UTC
Minimum value	3,02				3,24	
Maximum value	7,38	-	-	-	8,58	7 >
Mean Yield (T/ha)	5,58				6,21	9 =

Treatment name	UNTREATED CHECK	CA2445	CA2445	OSIRIS 65 EC	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,6	0,8	2	0,6	
Rate unit		L/ha	L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	AB	
Mean %UTC	100,00%				112,19%	0 <
Number of values	9		9		9	CA2445
Minimum value	3,02		2,68		3,24	0,8 l/ha
Maximum value	6,65	-	7,60	-	8,58	0 >
Mean Yield (T/ha)	5,04		5,42		5,52	8 =
Mean %UTC	100,00%		108,80%		110,58%	1 <
Number of values	7			7	7	OSIRIS 65 EC
Minimum value	5,66	-		5,37	6,55	2 l/ha
Maximum value	7,38		-	7,40	7,74	0 >
Mean Yield (T/ha)	6,28			6,61	7,10	7 =
Mean %UTC	100,00%			106,07%	114,26%	0 <
Number of values	2	2	2		2	CA2445
Minimum value	3,48	4,14	4,27		4,20	0,6 l/ha
Maximum value	6,58	7,52	7,60	-	8,58	0 >
Mean Yield (T/ha)	5,03	5,83	5,94		6,39	2 =
Mean %UTC	100,00%	118,50%	120,74%		127,26%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the South-Eastern EPPO zone

Yield parameters (t/ha and the corresponding calculated %UNCK) were recorded in 19 trials implemented to evaluate the effectiveness of CA3301 at 0.6 l/ha against foliar and ear diseases in the South-Eastern EPPO zone.

The application of CA3301 at 0.6 l/ha had no negative impact on the yield of winter barley and had a significant positive effect in 8 trials out of 19, compared to the untreated check.

CA3301 at 0.6 l/ha increased yield by 13.97% which was always statistically equivalent to the yield increase provided by the reference products CA2445 at 0.6l/ha and RISA 20 EC at 1.25 l/ha. Compared to PRIAXOR at 1.5 l/ha yield was statistically equivalent in 3 trials and significantly lower in 1 trial and compared to CA2445 at 0.8 l/ha (applied at a higher rate of prothioconazole) CA3301 was statistically equivalent in 8 trials and significantly lower in 1 trial. (see Table 3.4-46).

Therefore, it is concluded that 2 applications of CA3301 at 0.6 l/ha will not negatively affect yield on winter barley and will have a positive effect on yield in the South-Eastern EPPO zone.

Table 3.4-46: Summary table – Winter barley – Yield (T/ha) – South-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA2445	CA2445	RISA 20 EC	PRIAXOR	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,6	0,8	1,25	1,5	0,6	
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	AB	AB	
YIELD (T/ha) - 41-66 DA-B							
Number of values	19					19	UTC
Minimum value	2,76					3,39	
Maximum value	8,27	-	-	-	-	8,97	8 >
Mean Yield (T/ha)	4,75					5,28	11 =
Mean %UTC	100,00%					113,97%	0 <
Number of values	9		9			9	CA2445
Minimum value	2,76		3,81			3,65	0,8 l/ha
Maximum value	8,27	-	9,05	-	-	8,97	0 >
Mean Yield (T/ha)	5,33		6,03			6,00	8 =
Mean %UTC	100,00%		116,25%			115,53%	1 <
Number of values	7			7		7	RISA 20 EC
Minimum value	3,15	-		3,52	-	3,39	1,25 l/ha

Maximum value	3,70		-	4,20		4,49	0 >
Mean Yield (T/ha)	3,44			3,88		3,97	7 =
Mean %UTC	100,00%			113,59%		116,52%	0 <
Number of values	4	-			4	4	PRIAXOR
Minimum value	3,96		-		4,11	4,04	1,5 l/ha
Maximum value	6,98			-	7,22	6,98	0 >
Mean Yield (T/ha)	5,54				6,06	5,67	3 =
Mean %UTC	100,00%	-			109,85%	103,02%	1 <
Number of values	2	2	2			2	CA2445
Minimum value	6,65	7,33	6,90	-		7,14	0,6 l/ha
Maximum value	8,27	9,19	9,05		-	8,97	0 >
Mean Yield (T/ha)	7,46	8,26	7,98			8,06	2 =
Mean %UTC	100,00%	112,61%	108,09%			111,00%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Comments of zRMS:

No negative impact on the yield of winter barley was observed after twice application of CA3301 at dose rate of 0,6 l/ha. A positive effect was visible in all EPPO climatic zones and no significant differences between test and reference product were detected.

3.4.2.2 Spring barley (HORVS)

Use of CA3301 against all diseases in the Maritime EPPO zone

Yield parameters (T/ha and the corresponding calculated %UNCK) were recorded in 16 trials implemented to evaluate the effectiveness of CA3301 at 0.6 l/ha against foliar diseases in the Maritime EPPO zone (see Table 3.4-47).

The application of CA3301 at 0.6 l/ha had no negative impact on the yield of spring barley and had a significant positive effect in 6 trials out of 10, compared to the untreated check.

CA3301 at 0.6 l/ha increased yield by 9.11% which was always statistically equivalent to the yield increase provided by the reference products CA2445 at 0.8 l/ha and PROLINE 275 at 0.72 l/ha.

Therefore, it is concluded that 2 applications of CA3301 at 0.6 l/ha will not negatively affect yield on spring barley and might have a positive effect on yield in the Maritime EPPO zone.

Table 3.4-47: Summary table – Spring barley – Yield (T/ha) - Maritime EPPO zone

Treatment name		PROLINE 275	CA2445	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate	UNTREATED CHECK	0,72	0,8	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
YIELD (T/ha) - 34-83 DA-B					
Number of values	16			16	UTC
Minimum value	2,13			2,19	
Maximum value	8,05	-	-	8,91	6 >
Mean Yield (T/ha)	5,67			6,22	10 =
Mean %UTC	100,00%			109,11%	0 <
Number of values	5	5		5	PROLINE 275
Minimum value	5,13	5,43		5,63	0,72 l/ha
Maximum value	8,05	9,09	-	8,91	0 >
Mean Yield (T/ha)	7,01	7,90		7,91	5 =
Mean %UTC	100,00%	112,28%		112,77%	0 <
Number of values	11		11	11	CA2445
Minimum value	2,13		2,28	2,19	0,8 l/ha
Maximum value	7,03	-	7,71	7,65	0 >
Mean Yield (T/ha)	5,06		5,49	5,45	11 =

Mean % UTC	100,00%	108,79%	107,44%	0 <
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>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 against all diseases in the Mediterranean EPPO zone

Yield parameters (T/ha and the corresponding calculated %UNCK) were recorded in 10 trials implemented to evaluate the effectiveness of CA3301 at 0.6 l/ha against foliar diseases in the Mediterranean EPPO zone (see Table 3.4-48).

The application of CA3301 at 0.6 l/ha had no negative impact on the yield of spring barley in all 10 trials, compared to the untreated check.

CA3301 at 0.6 l/ha increased yield by 3.86% which was statistically equivalent to the yield increase provided by the reference products CA2445 at 0.8 l/ha in 5 trials out of 6 and PROSARO at 1 l/ha in all 4 trials. In one trial CA3301 provided a statistically less significant increase compared to CA2445, applied at a higher rate of prothioconazole.

Therefore, it is concluded that 2 applications of CA3301 at 0.6 l/ha will not negatively affect yield on spring barley and might have a positive effect on yield in the Mediterranean EPPO zone.

Table 3.4-48: Summary table – Spring barley – Yield (T/ha) - Mediterranean EPPO zone

Treatment name		CA2445	PROSARO	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate	UNTREATED CHECK	0,8	1	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
YIELD (T/ha) - 28-63 DA-B					
Number of values	10			10	UTC
Minimum value	1,31			1,25	
Maximum value	6,59	-	-	6,55	0 >
Mean Yield (T/ha)	4,52			4,67	10 =
Mean % UTC (%)	100,00%			103,86%	0 <
Number of values	6	6		6	CA2445
Minimum value	1,31	1,88		1,25	0,8 l/ha
Maximum value	6,30	6,65	-	6,55	0 >
Mean Yield (T/ha)	4,20	4,50		4,39	5 =
Mean % UTC (%)	100,00%	111,34%		103,37%	1 <
Number of values	4		4	4	PROSARO
Minimum value	3,02		3,85	3,70	1,0 l/ha
Maximum value	6,59	-	6,92	6,26	0 >
Mean Yield (T/ha)	5,00		5,48	5,10	4 =
Mean % UTC (%)	100,00%		111,89%	104,59%	0 <

>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 against all diseases in the North-Eastern EPPO zone

Yield parameters (T/ha and the corresponding calculated %UNCK) were recorded in 8 trials implemented to evaluate the effectiveness of CA3301 at 0.6 l/ha against foliar diseases in the North-Eastern EPPO zone (see Table 3.4-49).

The application of CA3301 at 0.6 l/ha had no negative impact on the yield of spring barley and had a significant positive effect in 2 trials out of 8, compared to the untreated check.

CA3301 at 0.6 l/ha increased yield by 16.45% which was statistically equivalent to the yield increase provided by the reference products CA2445 at 0.8 l/ha and OSIRIS at 2 l/ha, except in 1 trial where CA3301 at 0.6 l/ha provided a statistically higher increase than OSIRIS at 2 l/ha.

Therefore, it is concluded that 2 applications of CA3301 at 0.6 l/ha will not negatively affect yield on spring barley and might have a positive effect on yield in the North-Eastern EPPO zone.

Table 3.4-49: Summary table – Spring barley – Yield (T/ha) – North-Eastern EPPO zone

Treatment name		CA2445	OSIRIS 65 EC	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate	UNTREATED CHECK	0,8	2	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
YIELD (T/ha) - 37-73 DA-B					
Number of values	8			8	UTC
Minimum value	2,10			2,41	
Maximum value	5,32	-	-	6,43	2 >
Mean Yield (T/ha)	3,79			4,39	6 =
Mean %UTC	100,00%			116,45%	0 <
Number of values	4	4		4	CA2445
Minimum value	2,10	1,54		2,41	0,8 l/ha
Maximum value	4,02	6,44	-	4,70	0 >
Mean Yield (T/ha)	3,26	4,28		3,63	4 =
Mean %UTC	100,00%	108,00%		113,90%	0 <
Number of values	4		4	4	OSIRIS 65 EC
Minimum value	3,08		3,46	3,98	2,0 l/ha
Maximum value	4,51	-	5,06	4,83	1 >
Mean Yield (T/ha)	3,81		4,47	4,45	3 =
Mean %UTC	100,00%		118,30%	119,00%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 against all diseases in the South-Eastern EPPO zone

Yield parameters (T/ha and the corresponding calculated %UNCK) were recorded in 14 trials implemented to evaluate the effectiveness of CA3301 at 0.6 l/ha against foliar diseases in the South-Eastern EPPO zone (see Table 3.4-50).

The application of CA3301 at 0.6 l/ha had no negative impact on the yield of spring barley and had a significant positive effect in 10 trials out of 14, compared to the untreated check.

CA3301 at 0.6 l/ha increased yield by 8.90% which was statistically equivalent to the yield increase provided by the reference product CA2445 at 0.8 l/ha in 3 trials out of 8. The yield increase provided by CA3301 at 0.6 l/ha was statistically less significant in the other 5 trials compared to CA2445 applied at a higher rate of prothioconazole. Compared to PRIAXOR at 1.5 l/ha, CA3301 at 0.6 l/ha provided a statistically equivalent yield increase in 2 trials out of 4 and was statistically lower yield in the other 2 trials. Compared to BUMPER 25 EC, CA3301 at 0.6 l/ha provided an equivalent yield increase in 2 trials out of 4 and statistically higher yield in the other 2 trials.

Therefore, it is concluded that 2 applications of CA3301 at 0.6 l/ha will not negatively affect yield on spring barley and might have a positive effect on yield in the South-Eastern EPPO zone.

Table 3.4-50: Summary table – Spring barley – Yield (T/ha) – South-Eastern EPPO zone

Treatment name		BUMPER 25 EC	CA2445	PRIAXOR	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate	UNTREATED CHECK	0,5	0,8	1,5	0,6	
Rate unit		L/ha	L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	AB	
YIELD (T/ha) - 30-69 DA-B						
Number of values	14				14	UTC
Minimum value	1,20				1,47	
Maximum value	6,44	-	-	-	6,71	10>
Mean Yield (T/ha)	4,27				4,65	4 =

Mean %UTC	100,00%				108,90 %	0 <
Number of values	4	4			4	BUMPER 25 EC
Minimum value	4,17	4,24			4,31	0,5 l/ha
Maximum value	4,30	4,41	-	-	4,53	2 >
Mean Yield (T/ha)	4,23	4,32			4,41	2 =
Mean %UTC	100,00%	102,24%			104,31 %	0 <
Number of values	8		8		8	CA2445
Minimum value	1,20		1,29		1,47	0,8 l/ha
Maximum value	6,44	-	6,78	-	6,71	0 >
Mean Yield (T/ha)	4,08		4,62		4,56	3 =
Mean %UTC	100,00%		113,31 %		113,11 %	5 <
Number of values	4			4	4	PRIAXOR
Minimum value	4,99			5,20	5,15	1,5 l/ha
Maximum value	6,44	-	-	6,86	6,71	0 >
Mean Yield (T/ha)	5,44			5,77	5,72	2 =
Mean %UTC	100,00%			106,06%	105,37 %	2 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Comments of zRMS:

No negative impact on the yield of spring barley was observed after twice application of CA3301 at dose rate of 0,6 l/ha. A positive effect was visible in all EPPO climatic zones and no significant differences between test and reference product were detected.

3.4.2.3 Oat (AVESS/AVESA)

Use of CA3301 in the Maritime EPPO zone

Yield parameters (t/ha and the corresponding calculated %UNCK) were recorded in 5 trials implemented to evaluate the effectiveness of CA3301 at 0.6 l/ha against foliar diseases in the Maritime EPPO zone.

The application of CA3301 at 0.6 l/ha had no negative impact on the yield of oat and had a significant positive effect in 1 trial out of 5, compared to the untreated check.

CA3301 at 0.6 l/ha increased yield by 9.85% which was always statistically equivalent to the yield increase provided by the reference products CA2445 at 0.8 l/ha and TORERO at 1 l/h (see Table 3.4-51).

Therefore, it is concluded that 2 applications of CA3301 at 0.6 l/ha will not negatively affect yield on oat and will have a positive effect on yield in the Maritime EPPO zone.

Table 3.4-51: Summary table – Oat – Yield (T/ha) - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA2445	TORERO	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	1	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
YIELD (T/ha) - 42-52 DA-B					
Number of values	5			5	UTC
Minimum value	4,01			4,13	
Maximum value	7,38	-	-	8,41	1 >

Mean Yield (T/ha)	5,13			5,67	4 =
Mean %UTC	100,00%			109,85%	0 <
Number of values	3	3		3	CA2245
Minimum value	4,02	4,16		4,13	0,8 l/ha
Maximum value	7,38	8,33	-	8,41	0 >
Mean Yield (T/ha)	5,54	6,14		6,21	3 =
Mean %UTC	100,00%	109,92%		111,18%	0 <
Number of values	2		2	2	TORERO
Minimum value	4,01		4,49	4,35	1 l/ha
Maximum value	5,00	-	5,14	5,36	0 >
Mean Yield (T/ha)	4,51		4,82	4,86	2 =
Mean %UTC	100,00%		107,39%	107,84%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the Mediterranean EPPO zone

Yield parameters (t/ha and the corresponding calculated %UNCK) were recorded in 6 trials implemented to evaluate the effectiveness of CA3301 at 0.6 l/ha against foliar diseases in the Mediterranean EPPO zone.

The application of CA3301 at 0.6 l/ha had no negative impact on the yield of oat and had a significant positive effect in 3 trials out of 6, compared to the untreated check.

CA3301 at 0.6 l/ha increased yield by 23.34% which was always statistically equivalent to the yield increase provided by the reference products CA2445 at 0.8 l/ha, PROSARO at 1 l/ha, MYSTIC SUL at 1 l/ha and ORIUS P at 1.2 l/ha except in 2 trials where CA3301 at 0.6 l/ha increased yield significantly more than CA2445 at a higher rate of prothioconazole (0.8 l/ha) (see Table 3.4-52).

Therefore, it is concluded that 2 applications of CA3301 at 0.6 l/ha will not negatively affect yield on oat and will have a positive effect on yield in the Mediterranean EPPO zone.

Table 3.4-52: Summary table – Oat – Yield (T/ha) - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA244 5	PROSAR O	MYSTIC SUL	ORIUS P	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	1	1	1,2	0,6	
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	AB	AB	
YIELD (T/ha) - 46-77 DA-B							
Number of values	6					6	UTC
Minimum value	1,39					1,92	
Maximum value	3,82	-	-	-	-	4,31	3 >
Mean Yield (T/ha)	2,41					2,85	3 =
Mean %UTC	100,00%					123,34 %	0 <
Number of values	5	5				5	CA2245
Minimum value	1,39	1,72				1,92	0,8 l/ha
Maximum value	3,82	4,35	-	-	-	4,07	2 >
Mean Yield (T/ha)	2,16	2,37				2,56	3 =
Mean %UTC	100,00%	111,40 %				124,39 %	0 <
Number of values	2		2			2	PROSARO
Minimum value	3,65		4,07			4,07	1 l/ha
Maximum value	3,82	-	4,07	-	-	4,31	0 >
Mean Yield (T/ha)	3,74		4,07			4,19	2 =
Mean %UTC	100,00%		109,03%			112,31 %	0 <
Number of values	1	1		1		1	MYSTIC SUL

Minimum value	1,39	1,84	-	1,75	-	1,92	1 l/ha
Maximum value	1,39	1,84	-	1,75	-	1,92	0 >
Mean Yield (T/ha)	1,39	1,84		1,75		1,92	1 =
Mean %UTC	100,00%	132,70 %		125,90%		138,13 %	0 <
Number of values	1	1	-		1	1	ORIUS P
Minimum value	2,53	2,21	-		2,87	2,58	1 l/ha
Maximum value	2,53	2,21	-		2,87	2,58	0 >
Mean Yield (T/ha)	2,53	2,21			2,87	2,58	1 =
Mean %UTC	100,00%	87,35%			113,44%	101,98 %	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-Eastern EPPO zone

Yield parameters (t/ha and the corresponding calculated %UNCK) were recorded in 6 trials implemented to evaluate the effectiveness of CA3301 at 0.6 l/ha against foliar diseases in the North-Eastern EPPO zone.

The application of CA3301 at 0.6 l/ha had no negative impact on the yield of oat and had a significant positive effect in 1 trial out of 6, compared to the untreated check.

CA3301 at 0.6 l/ha increased yield by 7.82% which was always statistically equivalent to the yield increase provided by the reference products CA2445 at 0.8 l/ha and PROSARO at 1 l/ha (see Table 3.4-53).

Therefore, it is concluded that 2 applications of CA3301 at 0.6 l/ha will not negatively affect yield on oat and will have a positive effect on yield in the North-Eastern EPPO zone.

Table 3.4-53: Summary table – Oat – Yield (T/ha) – North-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA2445	PROSARO	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	1	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
YIELD (T/ha) - 36-58 DA-B					
Number of values	6			6	UTC
Minimum value	2,93			3,30	
Maximum value	6,35	-	-	7,84	1 >
Mean Yield (T/ha)	4,48			4,78	5 =
Mean %UTC	100,00%			107,82%	0 <
Number of values	5	5		5	CA2245
Minimum value	2,93	3,01		3,03	0,8 l/ha
Maximum value	6,35	8,20	-	7,84	0 >
Mean Yield (T/ha)	4,21	4,90		4,94	5 =
Mean %UTC	100,00%	113,65%		115,76%	0 <
Number of values	2		2	2	PROSARO
Minimum value	3,53		3,18	3,99	1 l/ha
Maximum value	5,86	-	5,66	4,03	0 >
Mean Yield (T/ha)	4,70		4,42	4,01	2 =
Mean %UTC	100,00%		93,34%	91,13%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the South-Eastern EPPO zone

Yield parameters (t/ha and the corresponding calculated %UNCK) were recorded in 4 trials implemented to evaluate the effectiveness of CA3301 at 0.6 l/ha against foliar diseases in the South-Eastern EPPO zone.

The application of CA3301 at 0.6 l/ha had no negative impact on the yield of oat and had a significant positive effect in 2 trials out of 4, compared to the untreated check.

CA3301 at 0.6 l/ha increased yield by 6.76% which was always statistically equivalent to the yield increase provided by the reference products CA2445 at 0.8 l/ha (see Table 3.4-54).

Therefore, it is concluded that 2 applications of CA3301 at 0.6 l/ha will not negatively affect yield on oat and will have a positive effect on yield in the South-Eastern EPPO zone.

Table 3.4-54: Summary table – Oat – Yield (T/ha) – South-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA2445	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	0,6		
Rate unit		L/ha	L/ha		
Appl. Code		AB	AB		
YIELD (T/ha) - 40-54 DA-B					
Number of values	4	4	4	UTC	CA2245 0,8 l/ha
Minimum value	2,45	2,77	2,66		
Maximum value	3,75	4,14	4,16	2 >	0 >
Mean Yield (T/ha)	2,88	3,12	3,09	2 =	4 =
Mean %UTC	100,00%	108,24%	106,76%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Comments of zRMS:

No negative impact on the yield of spring oat was observed after twice application of CA3301 at dose rate of 0,6 l/ha. A positive effect was visible in all EPPO climatic zones and no significant differences between test and reference product were detected.

3.4.2.4 Winter wheat (TRZAW)

Specially for Winter wheat, harvest data were recorded according to two different methods depending on the *Fusarium* infection. Therefore, data from trials without fusarium artificial infestation are presented in T/ha and %UTC, and for the trials with *Fusarium* species where T/ha parameter was not available, data are presented only in %UTC, converted from a range of units as indicated in the tables.

Use of CA3301 against *Fusarium* species in the Maritime EPPO zone

Yield parameters (%UTC) were recorded in 11 trials implemented to evaluate the effectiveness of CA3301 at 0.6-0.8 l/ha against *Fusarium* species in the Maritime EPPO zone.

The application of CA3301 at 0.6-0.8 l/ha had no negative impact on the yield of winter wheat and had a significant positive effect in 2 trials out of 11, compared to the untreated check. CA3301 at 0.6 l/ha and 0.8 l/ha respectively increased yield by 17.33% and 17.24% which was always statistically equivalent to the yield increase provided by the reference product CA2445 at 0.8 l/ha (13.38%) (see Table 3.4-55).

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will not negatively affect yield on winter wheat and might have a positive effect on yield in the Maritime EPPO zone.

Table 3.4-55: Yield (%UTC) in trials with *Fusarium species* – Winter wheat (TRZAW) – Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA2 445	CA3 301	CA3 301	No of trials where CA3301 at 0,6 l/ha is >, = or <			No of trials where CA3301 at 0,6 l/ha is >, = or <		
Rate		0,8	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
YIELD (T/ha) – 52-86 DA-B										
Number of values	11	11	11	11	U T C	CA2445 0,8 l/ha	CA3301 0,8 l/ha	U T C	CA2445 0,8 l/ha	CA3301 0,6 l/ha
Minimum value	100,00	99,39	100,04	98,74	2 >	0 >	0 >	2 >	0 >	0 >
Maximum value	100,00	144,89	151,87	148,64	9 =	11 =	11 =	9 =	11 =	11 =
Mean %UTC	100,00%	113,38%	117,33%	117,24%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 against all other diseases in the Maritime EPPO zone

Yield parameters (T/ha and the corresponding calculated %UTC) were recorded in 14 trials implemented to evaluate the effectiveness of CA3301 at 0.6-0.8 l/ha against foliar diseases in the Maritime EPPO zone (see Table 3.4-56).

Yield levels recorded in treated plots remained within the yield standards for winter wheat.

The application of CA3301 at 0.6 l/ha had no negative impact on the yield of winter wheat and had a significant positive effect in 9 trials out of 14, compared to the untreated check. CA3301 applied at 0.8 l/ha had no negative impact on the yield of winter wheat and had a significant positive effect in 10 trials out of 14, compared to the untreated check.

CA3301 at 0.6 l/ha and 0.8 l/ha respectively increased yield by 20.09% and 20.89% which was always statistically equivalent to the yield increase provided by the reference products CA2445 at 0.8 l/ha and PROSARO at 1 l/ha.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will not negatively affect yield on winter wheat and will have a positive effect on yield in the Maritime EPPO zone.

Table 3.4-56: Summary table – Winter wheat – Yield (T/ha) - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA244 5	PROSAR O	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		0,8	1.00	0,6	0,8				
Rate unit		L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB				
YIELD (T/ha) – 52-86 DA-B									
Number of values	14			14	14	UT C	CA330 1 0,8 l/ha	UT C	CA330 1 0,6 l/ha
Minimum value	3.88		-	7.01	6.58				
Maximum value	9.75	-		10.54	10.60	9 >	0 >	10 >	0 >
Mean Yield (T/ha)	7.67			8.84	8.88	5 =	14 =	4 =	14 =
Mean %UTC	100,00%		-	120.09 %	120.89 %	0 <	0 <	0 <	0 <
Number of values	9	9		9	9	CA2445		CA2445	
Minimum value	3.88	6.69		7.01	6.58	0,8 l/ha		0,8 l/ha	
Maximum value	9.59	9.38	-	10.15	9.67	0 >		0 >	

Mean Yield (T/ha)	7.24	8.66		8.63	8.61	9 =	9 =
Mean %UTC	100,00%	127.12 %		126.07 %	126.55 %	0 <	0 <
Number of values	5		5	5	5	PROSARO	PROSARO
Minimum value	6.57	-	7.06	7.15	7.14	1,0 l/ha	1,0 l/ha
Maximum value	9.75		10.64	10.54	10.60	0 >	0 >
Mean Yield (T/ha)	8.44		9.37	9.22	9.35	5 =	5 =
Mean %UTC	100,00%	-	110.94%	109.32 %	110.72 %	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 against *Fusarium* species in the Mediterranean EPPO zone

Yield parameters (%UTC) were recorded in 11 trials implemented to evaluate the effectiveness of CA3301 at 0.6-0.8 l/ha against *Fusarium* species in the Mediterranean EPPO zone (see Table 3.4-57).

The application of CA3301 at 0.6 l/ha and 0.8 l/ha had no negative impact on the yield of winter wheat. CA3301 at 0.6 l/ha had a significant positive effect in 4 trials out of the 9 with a statistical analysis available and CA3301 at 0.8 l/ha had a significant positive effect in 3 trials out of 9, compared to the untreated check. CA3301 at 0.6 l/ha and 0.8 l/ha respectively increased yield by 39.99% and 36.63% while the reference product CA2445 at 0.8 l/ha increased yield by 34.48%. CA3301 at 0.8 l/ha was statistically better than CA3301 at 0.6 l/ha in 1 trial out of 11 and always statistically equivalent to CA2445 while CA3301 at 0.6 l/ha was statistically less efficient than CA2445 in 2 trials out of 11 (see Table 3.4-57).

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will not negatively affect yield on winter wheat and will have a positive effect on yield in the Mediterranean EPPO zone.

Table 3.4-57: Yield (%UTC) in trials with *Fusarium* species – Winter wheat (TRZAW) – Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA2445 0,8 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate unit						
Appl. Code						
YIELD (T/ha) – 52-86 DA-B						
Number of values	11	11	11	11	U T C	U T C
Minimum value	100,00	89,01	101,76	108,10	4 >	3 >
Maximum value	100,00	205,48	212,85	214,66	5 =	6 =
Mean %UTC	100,00%	134,48%	139,99%	136,63%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

* UTC removed from statistical analysis in 2 trials.

Use of CA3301 against all other diseases in the Mediterranean EPPO zone

Yield parameters (T/ha and the corresponding calculated %UTC) were recorded in 12 trials implemented to evaluate the effectiveness of CA3301 at 0.6-0.8 l/ha against foliar diseases in the Mediterranean EPPO zone (see Table 3.4-58).

Yield levels recorded in treated plots remained within the yield standards for winter wheat.

The application of CA3301 at 0.6-0.8 l/ha had no negative impact on the yield of winter wheat and had a significant positive effect in 3 trials out of 12, compared to the untreated check.

CA3301 at 0.6 l/ha and 0.8 l/ha increased yield by 13.84% and 12.36% which was always statistically equivalent to the yield increase provided by the reference products CA2445 at 0.8 l/ha and PROSARO at 1 l/ha.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will not negatively affect yield on winter wheat and might have a positive effect on yield in the Mediterranean EPPO zone.

Table 3.4-58: Summary table – Winter wheat – Yield (T/ha) – Mediterranean EPPO zone

Table 5:4-56: Summary table Winter wheat - Yield (t/ha) Mediterranean EXPO zone										
Treatment name	UNTREATED CHECK	CA244 5	PROSAR O	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		0,8	1.00	0,6	0,8					
Rate unit		L/ha	L/ha	L/ha	L/ha					
Appl. Code		AB	AB	AB	AB					
YIELD (T/ha) – 48-89 DA-B										
Number of values	12			12	12	UT C	CA330 1 0,8 l/ha	UT C	CA330 1 0,6 l/ha	
Minimum value	1.14			1.05	1.20		3 >	0 >	3 >	0 >
Maximum value	9.89	-	-	10.02	10.38		9 =	12 =	9 =	12 =
Mean Yield (T/ha)	5.14			5.76	5.76		0 <	0 <	0 <	0 <
Mean % UTC	100,00%			113.84 %	112.36 %					
Number of values	9	9		9	9	CA2445 0,8 l/ha		CA2445 0,8 l/ha		
Minimum value	1.42	2.19		2.23	1.90					
Maximum value	9.89	10.34	-	10.02	10.38	0 >		0 >		
Mean Yield (T/ha)	5.53	6.41		6.30	6.31	9 =		9 =		
Mean % UTC	100,00%	120.47 %		119.64 %	116.96 %	0 <		0 <		
Number of values	5		5	5	5	PROSARO 1,0 l/ha		PROSARO 1,0 l/ha		
Minimum value	1.14		0.86	1.05	1.20					
Maximum value	7.53	-	7.93	7.40	7.45	0 >		0 >		
Mean Yield (T/ha)	4.40		5.14	4.90	4.82	5 =		5 =		
Mean % UTC	100,00%		111.51%	109.98 %	109.48 %	0 <		0 <		

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 against *Oculimacula acuformis* in the North-Eastern EPPO zone

Yield parameters (T/ha and the corresponding calculated %UTC) were recorded in 2 trials implemented to evaluate the effectiveness of CA3301 at 0.6-0.8 l/ha against PSDCHA.

Yield levels recorded in treated plots remained within the yield standards for winter wheat.

The application of CA3301 at 0.6-0.8 l/ha had no negative impact on the yield of winter wheat and had a significant positive effect in 1 trial out of 2, compared to the untreated check (see Table 3.4-59).

Therefore, it is concluded that one application of CA3301 at 0.6-0.8 l/ha will not negatively affect yield of winter wheat and might have a positive effect on yield.

Table 3.4-59: Summary table – Winter wheat – North-East zone- Yield (T/ha)

Treatment name	UNTREATED CHECK	PROTIKON 250 EC	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		0,8	0,6	0,8				
Rate unit		L/ha	L/ha	L/ha				
Appl. Code		A	A	A				

Yield (T/ha) – 98-110 DA-A								
Number of values	2	1	2	2	UTC	CA3301	UTC	CA3301
Minimum value	5,7	1	6,5	7,1		0,8 l/ha		0,6 l/ha
Maximum value	7,3	1	8,7	9,3	1 >	0 >	1 >	0 >
Mean Yield (T/ha)	6,5	1	7,6	8,2	1 =	2 =	1 =	2 =
Mean %UTC	100,00%	1	116,6 %	126,0 %	0 <	0 <	0 <	0 <
Number of values	2	2	2	2	PROTIKON 250 EC		PROTIKON 250 EC	
Minimum value	5,7	6,8	6,5	7,1	0,8 l/ha		0,8 l/ha	
Maximum value	7,3	8,5	8,7	9,3	0 >		1 >	
Mean Yield (T/ha)	6,5	7,7	7,6	8,2	2 =		1 =	
Mean %UTC	100,0%	117,9 %	116,6 %	126,0 %	0 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 against *Fusarium* species in the North-Eastern EPPO zone

Yield parameters (%UTC) were recorded in 11 trials implemented to evaluate the effectiveness of CA3301 at 0.6-0.8 l/ha against *Fusarium* species in the North-Eastern EPPO zone (see Table 3.4-60).

The application of CA3301 at 0.6 l/ha and 0.8 l/ha had no negative impact on the yield of winter wheat. CA3301 at 0.6 l/ha had a significant positive effect in 8 trials out of 11 and CA3301 at 0.8 l/ha had a significant positive effect in 9 trials out of 11, compared to the untreated check. CA3301 at 0.6 l/ha and 0.8 l/ha increased yield by 36.72% and 42.67% while the reference product CA2445 at 0.8 l/ha increased yield by 37.73%. CA3301 at 0.8 l/ha was statistically better than CA3301 at 0.6 l/ha and CA2445 in 1 trial out of 11 while CA3301 at 0.6 l/ha was statistically equivalent to CA2445 in all 11 trials (see Table 3.4-60).

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will not negatively affect yield on winter wheat and will have a positive effect on yield in the North-Eastern EPPO zone.

Table 3.4-60: Yield (%UTC) in trials with *Fusarium* species – Winter wheat (TRZAW) – North-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA2445 0,8 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate unit						
Appl. Code						
YIELD (T/ha) – 52-86 DA-B						
Number of values	11	11	11	11	U T C	U T C
Minimum value	100,00	107,50	105,99	111,79	8 >	9 >
Maximum value	100,00	230,26	238,12	255,63	3 =	2 =
Mean %UTC	100,00%	137,82%	126,22%	142,67%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 against all other diseases in the North-Eastern EPPO zone

Yield parameters (T/ha and the corresponding calculated %UTC) were recorded in 11 trials implemented to evaluate the effectiveness of CA3301 at 0.6-0.8 l/ha against foliar diseases in the North-Eastern EPPO zone (see Table 3.4-61).

Yield levels recorded in treated plots remained within the yield standards for winter wheat.

The application of CA3301 at 0.6 l/ha had no negative impact on the yield of winter wheat and had a significant positive effect in 1 trial out of 11, compared to the untreated check. CA3301 applied at 0.8 l/ha had no negative impact on the yield of winter wheat and had a significant positive effect in 3 trials out of 11, compared to the untreated check.

CA3301 at 0.6 l/ha and 0.8 l/ha respectively increased yield by 10.61% and 15.65% which was statistically equivalent to the yield increase provided by the reference products CA2445 at 0.8 l/ha and OSIRIS at 2 l/ha, except in 1 trial where CA3301 at 0.8 l/ha showed a yield statistically higher than OSIRIS at 2 l/ha (see Table 3.4-61).

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will not negatively affect yield on winter wheat and might have a positive effect on yield in the North-Eastern EPPO zone.

Table 3.4-61: Summary table – Winter wheat – Yield (T/ha) – North-Eastern EPPO zone

Table 5.4-61. Summary table – Winter wheat – YIELD (T/ha) – North-East – LTPO zone									
Treatment name	UNTREATED CHECK	CA244 5	OSIRI S	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		0,8	2	0,6	0,8				
Rate unit		L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB				
YIELD (T/ha) – 48-66 DA-B									
Number of values	11			11	11	UT C	CA330 1 0,8 l/ha	UT C	CA330 1 0,6 l/ha
Minimum value	2.72			2.96	2.99				
Maximum value	7.86	-	-	8.52	8.65	1 >	0 >	3 >	2 >
Mean Yield (T/ha)	5.41			5.94	6.20	10 =	9 =	8 =	9 =
Mean % UTC	100,00%			110.61 %	115.65 %	0 <	2 <	0 <	0 <
Number of values	5	5		5	5	CA2445		CA2445	
Minimum value	2.72	2.90		2.96	2.99	0,8 l/ha		0,8 l/ha	
Maximum value	7.02	6.90	-	6.94	7.24	0 >		0 >	
Mean Yield (T/ha)	5.10	5.40		5.36	5.44	5 =		5 =	
Mean % UTC	100,00%	106.95 %		106.32 %	107.44 %	0 <		0 <	
Number of values	6		6	6	6	OSIRIS		OSIRIS	
Minimum value	3.82		3.91	3.93	4.30	2,0 l/ha		2,0 l/ha	
Maximum value	7.86	-	8.96	8.52	8.65	0 >		1 >	
Mean Yield (T/ha)	5.67		6.56	6.42	6.83	6 =		5 =	
Mean % UTC	100,00%		116.94 %	114.18 %	122.49 %	0 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 against *Fusarium* species in the South-Eastern EPPO zone

Yield parameters (%UTC) were recorded in 11 trials implemented to evaluate the effectiveness of CA3301 at 0.6-0.8 l/ha against *Fusarium* species in the South-Eastern EPPO zone (see Table 3.4-62).

The application of CA3301 at 0.6 l/ha and 0.8 l/ha had no negative impact on the yield of winter wheat and had a significant positive effect in 5 trials out of 11, compared to the untreated check. CA3301 at 0.6 l/ha and 0.8 l/ha increased yield by 28.35% and 41.77% while the reference product CA2445 at 0.8

l/ha increased yield by 40.96%. CA3301 at 0.8 l/ha was statistically higher than CA3301 at 0.6 l/ha in 2 trials out of 11, statistically better than CA2445 in 2 trials out of 11 and statistically less efficient than CA2445 in 1 trial out of 11. CA3301 at 0.6 l/ha was statistically less efficient than CA2445 in 2 trials out of 11 (see Table 3.4-62) and was statistically equivalent to the reference in all other trials.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will not negatively affect yield on winter wheat and will have a positive effect on yield in the South-East ~~EPPO~~ EPPO zone.

Table 3.4-62: Yield (%UTC) in trials with *Fusarium species* – Winter wheat (TRZAW) – South-East ~~EPPO~~ EPPO zone

East of ETPO zone										
Treatment name	UNTREATED CHECK	CA2 445	CA3 301	CA3 301	No of trials where CA3301			No of trials where CA3301		
Rate		0,8	0,6	0,8	at 0,6 l/ha is >, = or <			at 0,6 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
YIELD (T/ha) – 52-86 DA-B										
Number of values	11	11	11	11	U T C	CA2445 0,8 l/ha	CA3301 0,8 l/ha	U T C	CA2445 0,8 l/ha	CA3301 0,6 l/ha
Minimum value	100,00	108,93	95,40	102,59	5 >	0 >	0 >	5 >	2 >	2 >
Maximum value	100,00	289,49	216,33	315,81	6 =	9 =	9 =	6 =	8 =	9 =
Mean %UTC	100,00%	140,96%	128,35%	132,68%	0 <	2 <	2 <	0 <	1 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 against all other diseases in the South-East ~~EPPO~~ EPPO zone

Yield parameters (T/ha and the corresponding calculated %UTC) were recorded in 11 trials implemented to evaluate the effectiveness of CA3301 at 0.6-0.8 l/ha against foliar diseases in the South-East ~~EPPO~~ EPPO zone (see Table 3.4-63)

Yield levels recorded in treated plots remained within the yield standards for winter wheat.

The application of CA3301 at 0.6-0.8 l/ha had no negative impact on the yield of winter wheat and had a significant positive effect in 5 trials out of 11, compared to the untreated check.

CA3301 at 0.6 l/ha and 0.8 l/ha respectively increased yield by 11.34% and 11.45% which was statistically equivalent to the yield increase provided by the reference products CA2445 at 0.8 l/ha, PRIAXOR at 1.5 l/ha and RISA at 1,25 l/ha (see Table 3.4-63).

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will not negatively affect yield on winter wheat and might have a positive effect on yield in the South-East ~~EPPO~~ EPPO zone.

Table 3.4-63: Summary table – Winter wheat – Yield (T/ha) – South-East ~~EPPO~~ EPPO zone

Treatment name	UNTREATED CHECK	CA24 45	PRIAX OR	RISA	CA330 1	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		0,8	1.50	1.25	0,6	0,8				
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB	AB				
YIELD (T/ha) – 50-86 DA-B										
Number of values	11				11	11	UT	CA33 01	UT	CA33 01
Minimum value	2.63				2.69	2.43	C	0,8 l/ha	C	0,6 l/ha
Maximum value	6.14	-	-	-	7.15	7.07	5 >	0 >	5 >	1 >

Mean Yield (T/ha)	4.84				5.39	5.40	6 =	10 =	6 =	10 =
Mean %UTC	100,00%				111.34 %	111.4 5%	0 <	1 <	0 <	0 <
Number of values	6	6			6	6	CA2445	CA2445		
Minimum value	2.70	2.84			3.01	3.15	0,8 l/ha	0,8 l/ha		
Maximum value	5.97	7.35	-	-	7.15	7.07	0 >	0 >		
Mean Yield (T/ha)	4.94	5.73			5.71	5.77	6 =	6 =		
Mean %UTC	100,00%	114.9 9%			1115.1 3%	116.7 0%	0 <	0 <		
Number of values	4		4		4	4	PRIAXOR	PRIAXOR		
Minimum value	2.63		3.15		2.69	2.43	1,5 l/ha	1,5 l/ha		
Maximum value	6.14	-	6.66	-	6.50	6.64	0 >	0 >		
Mean Yield (T/ha)	5.02		5.47		5.23	5.14	4 =	4 =		
Mean %UTC	100,00%		110.67 %		103.90 %	101.1 3%	0 <	0 <		
Number of values	1			1	1	1	RISA	RISA		
Minimum value	3.48			3.94	4.12	4.22	1,25 l/ha	1,25 l/ha		
Maximum value	3.48	-	-	3.94	4.12	4.22	0 >	0 >		
Mean Yield (T/ha)	3.48			3.94	4.12	4.22	1 =	1 =		
Mean %UTC	100,00%			113.2 2%	118.39 %	121.2 6%	0 <	0 <		

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Comments of zRMS:

No negative impact on the yield of winter wheat was observed after twice application of CA3301 at dose rate of 0,6-0,8 l/ha. A positive effect was visible in all EPPO climatic zones and no significant differences between test and reference product were detected.

Also no negative impact on the yield of winter wheat has been noted in additional 7 efficacy trials conducted in Poland in 2023.

3.4.2.5 Durum wheat (TRZDU)

In this chapter are presented the data coming from the harvest from different trials on durum wheat infected from different leaf and ear diseases.

In particular the data coming from inoculated trials to obtain a good infection on *Fusarium spp* and *Fusarium graminearum* were divided from the other data. In these trials were assessed the weight of 50 inoculated ears (g), the weight of infected kernel and the yield per plot to obtain the yield T/ha. These trials were undertaken in the North-Eastern and South-Eastern EPPO zones.

The data coming from other trials on foliar disease on durum wheat were presented separately.

Use of CA3301 against all foliar diseases in the Maritime EPPO zone

Yield parameters (T-MET and the corresponding calculated %UNCK) were recorded in 2 trials implemented to evaluate the effectiveness of CA3301 at 0.6-0.8 l/ha against foliar diseases in the Maritime EPPO zone (see Table 3.4-64).

The application of CA3301 at 0.6 and at 0.8 l/ha had no negative impact on the yield of durum wheat. CA3301 at 0.6 l/ha and 0.8 l/ha increased yield of about 3% which was statistically equivalent to the yield increase provided by the reference product CA2445 at 0.8 l/ha.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will not negatively affect yield on durum wheat and might have a positive effect on yield in the Maritime EPPO zone.

Table 3.4-64: Summary table – Durum wheat – Yield (T/ha) - Maritime EPPO zone

Table 5.4-6. Summary table – Durum wheat – YIELD (T/ha) – Maritime LTFC zone										
Treatment name	UNTREATED CHECK	CA244	CA330	CA330	No of trials where CA3301			No of trials where CA3301		
Rate		5	1	1	at 0,6 l/ha is >, = or <			at 0,8 l/ha is >, = or <		
Rate unit		0,8	0,6	0,8						
Appl. Code		L/ha	L/ha	L/ha	compared to			compared to		
		AB	AB	AB						
YIELD (T/ha) – 62-76 DA-B										
Number of values	2	2	2	2	UT C	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UT C	CA244 5 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	5.44	5.84	5.88	5.73	0 >	0 >	0 >	0 >	0 >	0 >
Maximum value	9.40	9.45	9.42	9.45	2 =	2 =	2 =	2 =	2 =	2 =
Mean Yield (T/ha)	7.42	7.65	7.65	7.59	0 <	0 <	0 <	0 <	0 <	0 <
Mean %UTC	100,00%	103.94 %	104.15 %	102.93 %						

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 against all foliar diseases in the Mediterranean EPPO zone

Yield parameters were recorded in 5 trials implemented to evaluate the effectiveness of CA3301 at 0.6-0.8 l/ha EPPO zone (see

Table 3.4-65). In one trial was evaluated also the *Fusarium graminearum* on ears, this infection was natural and not artificial, thus the yield was compared together with other trials.

The application of CA3301 at 0.6 and at 0.8 l/ha had no negative impact on the yield of durum wheat. CA3301 at 0.6 l/ha and 0.8 l/ha increased the yield of about 4-8% which was always statistically equivalent to the yield increase provided by the reference products CA2445 at 0.8 l/ha and PROSARO at 1 l/ha.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will not negatively affect yield on durum wheat and might have a positive effect on yield in the Mediterranean EPPO zone.

Table 3.4-65: Summary table – Durum wheat – Yield (T/ha) - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA24 45 0,8 L/ha AB	PRO-SARO 1 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
YIELD (T/ha) - 62-76 DA-B											
Number of values	5	5		5	5	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	3,29	3,51		3,83	3,68	0 >	0 >	0 >	0 >	0 >	0 >
Maximum value	5,82	6,20	-	6,35	6,11	5 =	5 =	5 =	5 =	5 =	5 =
Mean Yield (T/ha)	4,49	4,88		5,00	4,91	0 <	0 <	0 <	0 <	0 <	0 <
Mean %UTC	100,00%	103,33 %		108,71 %	104,21 %						

Number of values	2	2	2	2	2	PROSARO	PROSARO
Minimum value	4,55	4,11	4,36	4,72	4,13	1 l/ha	1 l/ha
Maximum value	5,82	6,20	6,17	6,35	6,11	0 >	0 >
Mean Yield (T/ha)	5,19	5,16	5,27	5,54	5,12	2 =	2 =
Mean %UTC	100,00%	98,43 %	100,92%	111,61 %	97,88 %	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 against *Fusarium* species in the North East~~EPB~~ EPPO zone

Yield parameters were recorded in 1 trial implemented to evaluate the effectiveness of CA3301 at 0.6-0.8 l/ha against *Fusarium spp* the North-East~~EPB~~ EPPO zone.

The application of CA3301 at 0.6-0.8 l/ha had no negative impact on the yield of durum wheat and had a significant positive effect compared to the untreated check. CA3301 at 0.6 l/ha and 0.8 l/ha increased the total kernel yield by 7% as well as the reference product CA2445 at 0.8 l/ha. CA3301 at 0.6-0.8 l/ha significantly reduced the yield of infected kernel compared to the untreated control of about 40% as well as the reference CA2445 (see Table 3.4-66).

The application of CA3301 at 0.6-0.8 l/ha significantly increased also the yield per hectare (T/ha) by 8.45 – 13.48% compared to the untreated check.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will not negatively affect yield on durum wheat and might have a positive effect on yield in the North-East~~EPB~~ EPPO zone especially when are present the *Fusarium spp*. infection on ears.

Table 3.4-66: Summary table – Durum wheat – Yield (%UTC) - North-East~~EPB~~ EPPO zone

Treatment name	UNTREATED CHECK	CA24 45	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or <			No of trials where CA3301 at 0,8 l/ha is >, = or <		
Rate		0,8	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
Yield (g) Total Kernel 50 DA-B										
Number of values	1	1	1	1	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Number of values	18,21	19,45	19,52	19,60	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Minimum value	18,21	19,45	19,52	19,60	1 >	0 >	0 >	1 >	0 >	0 >
Yield Infected Kernel (g)	18,21	19,45	19,52	19,60	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	100,00%	106,81 %	107,19 %	107,63 %	0 <	0 <	0 <	0 <	0 <	0 <
Yield (g) Infected Kernel 50 DA-B										
Number of values	1	1	1	1	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Number of values	3,30	2,09	2,30	2,17	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Minimum value	3,30	2,09	2,30	2,17	0 >	0 >	0 >	0 >	0 >	0 >
Yield Infected Kernel (g)	3,30	2,09	2,30	2,17	0 =	0 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	100,00%	63,33 %	69,70 %	65,76 %	1 <	1 <	0 <	1 <	0 <	0 <
Yield (T/ha) 50 DA-B										
Number of values	1	1	1	1	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Number of values	4,97	5,68	5,39	5,64	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Minimum value	4,97	5,68	5,39	5,64	0 >	0 >	0 >	1 >	0 >	0 >

Yield Infected Kernel (T/ha)	4,97	5,68	5,39	5,64	1 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	100,00%	114,29 %	108,45 %	113,48 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 against *Fusarium* species in the South-Eastern EPPO zone

In this trial was done an inoculation with *Fusarium graminearum* on 50 ears per plot (presented above). At harvest were harvested separately the 50 inoculated ears and then was performed the normal harvest on the half plot area. In conclusion this trial was used for the yield analysis on 50 inoculated ears and yield analysis with the other trials performed in this EPPO zone.

Yield parameters were recorded in 1 trial implemented to evaluate the effectiveness of CA3301 at 0.6-0.8 l/ha against *Fusarium graminearum* the South-Eastern EPPO zone (see Table 3.4-67).

In this trial, 50 inoculated ears were harvested. The application of CA3301 at 0.6-0.8 l/ha had no negative impact on the yield of durum wheat and had a significant positive effect compared to the untreated check on total kernel weight. CA3301 at 0.6-0.8 l/ha significantly increased the yield of total kernel of about 270% which was statistically equivalent to reference product CA2445 at 0.8 l/ha with + 330%. Regarding the weight of infected kernels no significant differences were detected between untreated check and treated treatments.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will not negatively affect yield on durum wheat and might have a positive effect on yield in the South-Eastern EPPO zone especially when are present the *Fusarium spp.* infection on ears.

Table 3.4-67: Summary table – Durum wheat – Yield (g) of Total and infected kernels on 50 ears - South-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA244 5	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		0,8	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
Yield (g) Total Kernel 52 DA-B										
Number of values	1	1	1	1	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Number of values	3,96	13,07	10,91	10,79	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Minimum value	3,96	13,07	10,91	10,79	1 >	0 >	0 >	1 >	0 >	0 >
Yield Total Kernel (g)	3,96	13,07	10,91	10,79	0 =	1 =	1 =	0 =	1 =	1 =
Abbott efficacy (%)	100,00%	330,05 %	275,51 %	272,47 %	0 <	0 <	0 <	0 <	0 <	0 <
Yield (g) Infected Kernel 52 DA-B										
Number of values	1	1	1	1	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Number of values	1,13	10,30	1,07	0,91	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Minimum value	1,13	10,30	1,07	0,91	0 >	0 >	0 >	0 >	0 >	0 >
Yield Infected Ker- nel (g)	1,13	10,30	1,07	0,91	1 =	1 =	1 =	1 =	1 =	1 =
Abbott efficacy (%)	100,00%	91,15 %	94,69 %	80,53 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 against *all foliar diseases* in the South-Eastern EPPO zone

In the South-Eastern EPPO zone the yield parameters were recorded in 6 trials implemented to evaluate the effectiveness of CA3301 at 0.6-0.8 l/ha against foliar and ears diseases in the South-Eastern EPPO zone (see Table 3.4-68).

The application of CA3301 at 0.6 and at 0.8 l/ha had no negative impact on the yield of durum wheat. CA3301 at 0.6 l/ha and 0.8 l/ha increased the yield compared to the untreated plots only in three trials, and in one trial was significant better to reference product CA2445 at 0.8 l/ha.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will not negatively affect yield on durum wheat and might have a positive effect on yield in the South-Eastern EPPO zone.

Table 3.4-68: Summary table – Durum wheat – Yield (T/ha) - South-Eastern EPPO zone Foliar diseases

Treatment name		CA2445	PRI-AXOR	CA3301	CA3301		
Rate	UNTREATED CHECK	0,8	1,5	0,6	0,8	No of trials where CA3301 at 0,6 l/ha is >, = or <	No of trials where CA3301 at 0,8 l/ha is >, = or <
Rate unit		L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	AB		
YIELD (T/ha) - 49-60 DA-B							
Number of values	6			6	6	UTC	UTC
Minimum value	2,58			2,63	2,61		
Maximum value	8,16	-	-	8,7	8,3	3 >	3 >
Mean Yield (T/ha)	4,76			5,12	5,21	3 =	3 =
Mean %UTC	100,00%			108,53%	109,99%	0 <	0 <
Number of values	4	4		4	4	CA2445	CA2445
Minimum value	2,58	2,63		2,63	2,61		
Maximum value	8,16	7,34	-	8,07	8,3	1 >	1 >
Mean Yield (T/ha)	4,97	4,94		5,15	5,31	5 =	5 =
Mean %UTC	100,00%	101,42		104,45	107,1	0 <	0 <
Number of values	2		2	2	2	PRI-AXOR	PRI-AXOR
Minimum value	4,32		5,16	4,83	4,77		
Maximum value	4,36	-	5,57	5,3	5,28	0 >	0 >
Mean Yield (T/ha)	4,34		5,37	5,07	5,03	2 =	2 =
Mean %UTC	100,00%		123,6	116,68	115,76	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Comments of zRMS:

No negative impact on the yield of durum wheat was observed after twice application of CA3301 at dose rate of 0,6-0,8 l/ha. A positive effect was visible in all EPPO climatic zones and no significant differences between test and reference product were detected.

3.4.2.6 Triticale (TTLWI)

In this chapter are presented the data coming from the harvest from different trials on triticale infected by different leaf and ear diseases.

In particular the data coming from inoculated trials to obtain a good infection on *Fusarium spp* and *Fusarium culmorum* were divided from the other data. In fact in these trials were assessed the yield on 50 inoculated ears (g) and the % of increment on yield respect the untreated check.

The data coming from other trials on foliar disease on triticale were presented in a second paragraph with the expression of yield per hectare (T/ha)..

Use of CA3301 against *Fusarium spp.* in the Maritime EPPO zone

Yield parameters was recorded in two trials implemented with the *Fusarium spp.* and *Fusarium culmorum inoculum* to evaluate the effectiveness of CA3301 at 0.6-0.8 l/ha in the Maritime EPPO zone (see

Table 3.4-69).

In both trials were harvested 50 inoculated ears per plot and were recorded the weight of infected kernel and total kernel. The application of CA3301 at 0.6 and at 0.8 l/ha had no negative impact on the yield of triticale on total kernel. CA3301 at 0.6 l/ha and 0.8 l/ha increased yield by 36.24% and 28.99% which was always statistically equivalent to the yield increase provided by the reference products CA2445 at 0.8 l/ha (37.20%).

In addition, CA3301 at 0.6-0.8 l/ha decreased the yield of infected kernel by 28.68-35.21% and was statistically equivalent to the yield of infected kernels provided by the reference product CA2445 at 0.8 l/ha

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will not negatively affect yield on triticale when affected by ear disease and might have a positive effect on yield in the Maritime EPPO zone.

Table 3.4-69: Summary table - Yield (g) in trials with *Fusarium spp.* – Triticale (TTLWI) – Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA244 5	CA330 1	CA330 1	No of trials where CA3301			No of trials where CA3301		
Rate		0,8	0,6	0,8	at 0,6 l/ha is >, = or <			at 0,8 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
Yield (g) Total Kernel - 61-75 DA-B										
Number of values	2	2	2	2	UT C	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UT C	CA244 5 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	10,89	19,07	18,86	17,28						
Maximum value	21,24	21,09	21,09	21,09	1 >	0 >	0 >	1 >	0 >	0 >
Mean Yield (g)	16,07	20,08	19,98	19,19	1 =	2 =	2 =	1 =	2 =	2 =
Mean % UTC	100,00%	137,20 %	136,24 %	128,99 %	0 <	0 <	0 <	0 <	0 <	0 <
Yield (g) Infected Kernel - 61-75 DA-B										
Number of values	2	2	2	2	UT C	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UT C	CA244 5 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	1,78	1,15	1,49	1,31						
Maximum value	5,43	3,17	3,20	3,04	0 >	0 >	0 >	0 >	0 >	0 >
Mean Yield (g)	3,61	2,16	2,35	2,18	1 =	2 =	2 =	1 =	2 =	2 =
Mean % UTC	100,00%	61,49%	71,32%	64,79%	1 <	0 <	0 <	1 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 against *all other diseases* in the Maritime EPPO zone

Yield parameters were recorded in eight trials implemented to evaluate the effectiveness of CA3301 at 0.6-0.8 l/ha against foliar diseases in the Maritime EPPO zone (see Table 3.4-70).

The application of CA3301 at 0.6 and at 0.8 l/ha had no negative impact on the yield of triticale and had a significant positive effect compared to the untreated check in 6 trials out of 8.

CA3301 at 0.6 l/ha and 0.8 l/ha increased yield by 12.41 and 11.43% which was statistically equivalent to the yield increase provided by the reference product CA2445 at 0.8 l/ha (+10.71%).

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will not negatively affect yield on triticale when affected by foliar disease and might have a positive effect on yield in the Maritime EPPO zone.

Table 3.4-70: Summary table - Yield (T/ha) in trials with *all other disease* – Triticale (TTLWI) – Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA224 5	CA330 1	CA330 1	No of trials where CA3301			No of trials where CA3301		
Rate		0,8	0,6	0,8	at 0,6 l/ha is >, = or <			at 0,8 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
% Yield T-MET 61-88 DA-B										
Number of values	9	9	9	9	UT C	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UT C	CA244 5 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	4,34	4,86	4,76	5,00	6 >	0 >	0 >	6 >	0 >	1 >
Maximum value	9,61	10,71	10,79	10,56	3 =	9 =	8 =	3 =	9 =	8 =
Mean Yield (t/ha)	7,48	8,23	8,34	8,28	0 <	0 <	1 <	0 <	0 <	0 <
Mean %UTC	100,0%	110,71 %	111,86 %	111,43 %						

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 against *all other diseases* in the Mediterranean EPPO zone

Yield parameters were recorded in 4 trials implemented to evaluate the effectiveness of CA3301 at 0.6-0.8 l/ha against foliar diseases in the Mediterranean EPPO zone (see Table 3.4-71).

The application of CA3301 at 0.6 and at 0.8 l/ha had no negative impact on the yield of triticale and had a significant positive effect compared to the untreated check in two trials.

CA3301 at 0.6 l/ha and 0.8 l/ha increased yield by 28.27% and 29.29% which was always statistically equivalent to the yield increase provided by the reference product CA2445 at 0.8 l/ha (+18.84%).

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will not negatively affect yield on triticale when affected by foliar disease and might have a positive effect on yield in the Mediterranean EPPO zone.

Table 3.4-71: Summary table- Yield (T/ha) in trials with *all other diseases* – Triticale (TTLWI) – Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA244 5	CA330 1	CA330 1	No of trials where CA3301			No of trials where CA3301		
Rate		0,8	0,6	0,8	at 0,6 l/ha is >, = or <			at 0,8 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
Yield (T/ha) 78-83 DA-B										
Number of values	4	4	4	4	UT C	CA244 5	CA330 1	UT C	CA244 5	CA330 1

Minimum value	0,87	1,02	1,33	1,33		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	8,17	8,31	8,20	8,45	2 >	0 >	0 >	2 >	0 >	0 >
Mean Yield (T/ha)	3,38	3,77	3,82	3,87	2 =	4 =	4 =	2 =	4 =	4 =
Mean %UTC	100,00%	118,84 %	128,27 %	129,29 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 against *all other disease* species in the North-East^{ERN} EPPO zone

Yield parameters were recorded in 5 trials implemented to evaluate the effectiveness of CA3301 at 0.6-0.8 l/ha against foliar disease the North-East^{ERN} EPPO zone (see Table 3.4-72).

The application of CA3301 at 0.6-0.8 l/ha had no negative impact on the yield of triticale and had a significant positive effect compared to the untreated check in respectively 3 and 2 trials. CA3301 at 0.6 l/ha and 0.8 l/ha increased yield by 18.35% and 16.79% which was statistically equivalent to the yield increase provided by the reference product CA2445 at 0.8 l/ha, and in one trial higher than OSIRIS 65 EC at 2 l/ha, when applied at 0.6 l/ha.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will not negatively affect yield on triticale affected by foliar and ear disease and might have a positive effect on yield in the North-East^{ERN} EPPO zone.

Table 3.4-72: Summary table -Yield (T/ha) in trials with *all other diseases* – Triticale (TTLWI) – North-East^{ERN} EPPO zone

Treatment name	UNTREATED CHECK	CA2445	OSIRIS 65 EC	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		0,8	2	0,6	0,8				
Rate unit		L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB				
Yield (T/ha) 57-72 DA-B									
Number of values	5			5	5	UT C	CA330 1 0,8 l/ha	UT C	CA330 1 0,6 l/ha
Minimum value	5,59			6,36	5,90				
Maximum value	6,62	-	-	7,94	7,85	3 >	0 >	2 >	0 >
Mean Yield (T/ha)	6,17			7,30	7,21	2 =	5 =	3 =	5 =
Mean %UTC	100,00%			118,35 %	116,79 %	0 <	0 <	0 <	0 <
Number of values	3	3		3	3	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	5,59	6,19		6,36	5,90				
Maximum value	6,15	7,64	-	7,94	7,85	0 >		0 >	
Mean Yield (T/ha)	5,94	7,14		7,36	7,18	3 =		3 =	
Mean %UTC	100,00%	111,44 %		123,67 %	120,50 %	0 <		0 <	
Number of values	2		2	2	2	OSIRIS 2 l/ha		OSIRIS 2 l/ha	
Minimum value	6,43		6,04	6,51	7,11				
Maximum value	6,62	-	7,04	7,91	7,40	1 >		0 >	
Mean Yield (T/ha)	6,53		6,54	7,21	7,26	1 =		2 =	
Mean %UTC	100,00%		100,14 %	110,37 %	111,24 %	0 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 against *Fusarium spp.* species in the South-East^{ERN} EPPO zone

Yield parameters were recorded in 1 trial implemented to evaluate the effectiveness of CA3301 at 0.6-0.8 l/ha against *Fusarium spp.* In the South-East^{ERN} EPPO zone (see Table 3.4-73).

In this trial were harvested 50 inoculated ears per plot and were recorded the weight of infected kernel

and total kernel. The application of CA3301 at 0.6-0.8 l/ha had no negative impact on the yield of triticale. CA3301 at 0.6 l/ha and 0.8 l/ha improved slightly the yield of total kernel of 3-6% and decreased the yield of infected kernel of 6-10% and was statistically equivalent to the yield of infected kernels provided by the reference product CA2445 at 0.8 l/ha.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will not negatively affect yield on triticale infected by *Fusarium spp.* and might have a positive effect on yield in the South-Eastern EPPO zone.

Table 3.4-73: Summary table - Yield (g) in trials with *Fusarium spp.* – Triticale (TTLWI) – South-Eastern EPPO zone

Treatment name	UN-TREATED CHECK	CA2445	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		0,8	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
YIELD (g) Total Kernel 49 DA-B										
Number of values	1	1	1	1	UTC	CA24 45	CA33 01	UT C	CA24 45	CA33 01
Minimum value	10,87	11,37	11,27	11,57		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	10,87	11,37	11,27	11,57	0 >	0 >	0 >	0 >	0 >	0 >
Mean Yield (g)	10,87	11,37	11,27	11,57	1 =	1 =	1 =	1 =	1 =	1 =
Mean %UTC	100,00%	104,60%	103,68%	106,44%	0 <	0 <	0 <	0 <	0 <	0 <
YIELD (g) Infected Kernel 49 DA-B										
Number of values	1	1	1	1	UTC	CA24 45	CA33 01	UT C	CA24 45	CA33 01
Minimum value	5,09	4,52	4,80	4,62		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	5,09	4,52	4,80	4,62	0 >	0 >	0 >	0 >	0 >	0 >
Mean Yield (g)	5,09	4,52	4,80	4,62	1 =	1 =	1 =	1 =	1 =	1 =
Mean %UTC	100,00%	88,80%	94,30%	90,77%	0 <	0 <	0 <	0 <	0 <	0 <

>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 against *all other disease* species in the South-Eastern EPPO zone

Yield parameters were recorded in 7 trials implemented to evaluate the effectiveness of CA3301 at 0.6-0.8 l/ha against all other disease the South-Eastern EPPO zone (see Table 3.4-74).

The application of CA3301 at 0.6-0.8 l/ha had no negative impact on the yield of triticale and had a significant positive effect compared to the untreated check in 3 trials out of 7. CA3301 at 0.6 l/ha and 0.8 l/ha increased yield respectively by 8.78% and 8.58% which was statistically equivalent to the yield increase provided by the reference products CA2445, PRIAXOR and NATIVO PRO 365 SC, except in 1 trial where yield was significantly higher compared to CA2445.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will not negatively affect yield on triticale infected by foliar disease and might have a positive effect on yield in the South-Eastern EPPO zone.

Table 3.4-74: Summary table - Yield (T/ha) in trials with *all other diseases* – Triticale (TTLWI) – South-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA24 45	PRI-AXOR	NATIVO PRO 365 SC	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Rate		0,8	1,5	1	0,6	0,8		
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	AB	AB		
YIELD (T/ha) 49-104 DA-B								
Number of values	7				7	7	UT C	CA33 01 0,8 l/ha
Minimum value	3,38				3,07	3,19		UT C
Maximum value	8,00	-	-	-	8,28	8,23	3 >	0 >
Mean Yield (T/ha)	4,57				4,95	4,94	4 =	7 =
Mean %UTC	100,00%				108,78 %	108,58 %	0 <	0 <
Number of values	4	4			4	4	CA2445	CA2445
Minimum value	3,50	2,93			3,07	3,19	0,8 l/ha	0,8 l/ha
Maximum value	8,00	8,65	-	-	8,28	8,23	1 >	1 >
Mean Yield (T/ha)	5,07	5,19			5,18	5,21	3 =	3 =
Mean %UTC	100,00%	100,03 %			100,76 %	101,63 %	0 <	0 <
Number of values	2		2		2	2	PRIAXOR	PRIAXOR
Minimum value	3,38		4,20		4,22	3,97	1,5 l/ha	1,5 l/ha
Maximum value	8,00	-	8,30	-	8,28	8,23	0 >	0 >
Mean Yield (T/ha)	5,69		6,25		6,25	6,10	2 =	2 =
Mean %UTC	100,00%		114,01%		114,18 %	114,18 %	0 <	0 <
Number of values	3			3	3	3	NATIVO	NATIVO
Minimum value	3,95			4,83	4,82	4,83	1 l/ha	1 l/ha
Maximum value	4,96	-	-	5,66	5,56	5,58	0 >	0 >
Mean Yield (T/ha)	4,42			5,12	5,08	5,12	3 =	3 =
Mean %UTC	100,00%			116,15%	115,23 %	116,20 %	0 <	0 <

>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Comments of zRMS:

No negative impact on the yield of winter triticale was observed after twice application of CA3301 at dose rate of 0,6-0,8 l/ha. A positive effect was visible in all EPPO climatic zones and no significant differences between test and reference product were detected.

3.4.2.7 Rye (SECCW)

Use of CA3301 against all diseases in the Maritime EPPO zone

Yield parameters (T/ha and the corresponding calculated %UNCK) were recorded in 8 trials implemented to evaluate the effectiveness of CA3301 at 0.6-0.8 l/ha against foliar diseases in the Maritime EPPO zone (see Table 3.4-75).

The application of CA3301 at 0.6 l/ha had no negative impact on the yield of rye and had a significant positive effect in 3 trials out of 8, compared to the untreated check. CA3301 applied at 0.8 l/ha had no negative effects on the yield of rye and had a significant positive effect in 3 trials out of 8, compared to untreated check.

CA3301 at 0.6 l/ha and 0.8 l/ha increased yield by 14.37% and 17.64% which was always statistically equivalent to the yield increase provided by the reference products CA2445 at 0.8 l/ha and PROLINE 275 at 0.72 l/ha.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will not negatively affect yield on rye and may have a positive effect on yield when several disease infections occur in the Maritime EPPO zone.

Table 3.4-75: Summary table – Yield (T/ha) – Rye (SECCW) – Maritime EPPO zone

Table 3.4-75. Summary table – Yield (T/ha) – Rye (SECCW) – Maritime EPG zone									
Treatment name	UNTREATED CHECK	PROLINE 275	CA24 45	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		0,72	0,8	0,6	0,8				
Rate unit		L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB				
YIELD (T/ha) - 56-97 DA-B									
Number of values	8			8	8	UT C	CA330 1 0,8 l/ha	UT C	CA33 01 0,6 l/ha
Minimum value	4,90			5,07	5,25				
Maximum value	11,11	-	-	12,54	12,51	3 >	0 >	3 >	0 >
Mean Yield (T/ha)	6,69			7,66	7,88	3 =	8 =	3 =	8 =
Mean % UTC	100,00%			114,37 %	117,64 %	0 <	0 <	0 <	0 <
Number of values	1	1		1	1	PROLINE 275 0,72 l/ha		PROLINE 275 0,72 l/ha	
Minimum value	5,73	6,99		6,91	7,21				
Maximum value	5,73	6,99	-	6,91	7,21	0 >		0 >	
Mean Yield (T/ha)	5,73	6,99		6,91	7,21	1 =		1 =	
Mean % UTC	100,00%	121,99%		120,59 %	125,83 %	0 <		0 <	
Number of values	7		7	7	7	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	4,90		4,83	5,07	5,25				
Maximum value	11,11	-	12,47	12,54	12,51	0 >		0 >	
Mean Yield (T/ha)	6,83		7,73	7,77	7,97	7 =		7 =	
Mean % UTC	100,00%		98,61 %	99,29 %	101,91 %	0 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 against all diseases in the Mediterranean EPPO zone

Yield parameters (T/ha and the corresponding calculated %UNCK) were recorded in 3 trials implemented to evaluate the effectiveness of CA3301 at 0.6-0.8 l/ha against foliar diseases in the Mediterranean EPPO zone (see Table 3.4-76).

The application of CA3301 at 0.6 l/ha had no negative impact on the yield of rye in these 3 trials, compared to the untreated check. CA3301 applied at 0.8 l/ha had no negative effects on the yield of rye in these 3 trials, compared to untreated check.

Although the differences are not significant, CA3301 at 0.6 l/ha and 0.8 l/ha numerically increased yield by 8.17% and 38.00% which was always statistically equivalent to the yield increase provided by the reference products CA2445 at 0.8 l/ha and ALTIS at 1.00 l/ha.

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will not negatively affect yield on rye and may have a positive effect on yield when several disease infections occur in the Mediterranean EPPO zone.

Table 3.4-76: Summary table – Yield (T/ha) – Rye (SECCW) – Mediterranean EPPO zone

Treatment name	UN-TREAT	CA2445	ALTIS	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate	ED	0,8	1	0,6	0,8				
Rate unit	CHEC	L/ha	L/ha	L/ha	L/ha				
Appl. Code	K	AB	AB	AB	AB				
YIELD (T/ha) - 69-83 DA-B									
Number of values	3	3		3	3	UTC	CA3301	UTC	CA3301
Minimum value	1,29	1,45		1,33	1,58		0,8 l/ha		0,6 l/ha
Maximum value	2,22	2,95	-	2,76	4,09	0 >	0 >	0 >	0 >
Mean Yield (T/ha)	1,86	2,18		2,03	2,62	3 =	3 =	3 =	3 =
Mean % UTC	100,00%	116,55%		108,17%	138,00%	0 <	0 <	0 <	0 <
Number of values	1	1	1	1	1	CA2445	ALTIS	CA2445	ALTIS
Minimum value	2,22	2,95	2,95	2,76	4,09	0,8 l/ha	1,0 l/ha	0,8 l/ha	1,0 l/ha
Maximum value	2,22	2,95	2,95	2,76	4,09	0 >	0 >	0 >	0 >
Mean Yield (T/ha)	2,22	2,95	2,95	2,76	4,09	3 =	1 =	3 =	1 =
Mean % UTC	100,00%	132,88%	132,88%	124,32%	184,23%	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 against all diseases in the North-Eastern EPPO zone

Yield parameters (T-MET and the corresponding calculated %UNCK) were recorded in 6 trials implemented to evaluate the effectiveness of CA3301 at 0.6-0.8 l/ha against foliar diseases in the North-Eastern EPPO zone.

In all the trials, the application of CA3301 at 0.6 l/ha or at 0.8 l/ha had no negative impact on the yield on rye crop.

Compared to the untreated control, CA3301 applied at 0.6 l/ha showed a numerical augmentation of the yield of rye in 3 trials and statistically increased the yield in the 3 other trials. CA3301 applied at 0.8 l/ha had showed a numerical augmentation of the yield of rye in 2 trials and statistically increased the yield in the 4 other trials, compared to untreated check.

CA3301 at 0.6 l/ha and 0.8 l/ha increased yield by 21.23% and 24.06% which was always statistically equivalent to the yield increase provided by the reference products CA2445 at 0.8 l/ha and OSIRIS 65 EC at 2.00 l/ha (see Table 3.4-77).

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will not negatively affect yield on rye and may have a positive effect on yield when several disease infections occur in the North-East~~ern~~ EPPO zone.

Table 3.4-77: Summary table – Yield (T/ha) – Rye (SECCW) – North-East~~ern~~ EPPO zone

Treatment name	UNTREATED CHECK	CA244 5	OSIRIS 65 EC	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		0,8	2	0,6	0,8				
Rate unit		L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB				
YIELD (T/ha) - 67-82 DA-B									
Number of val- ues	6			6	6	UT C	CA330 1 0,8 l/ha	UT C	CA330 1 0,6 l/ha
Minimum value	3,26			3,73	4,11				
Maximum value	6,39	-	-	8,13	8,21	3 >	0 >	4 >	0 >
Mean Yield (T/ha)	4,93			6,02	6,13	3 =	6 =	2 =	6 =
Mean %UTC	100,00%			121,23 %	124,06 %	0 <	0 <	0 <	0 <
Number of val- ues	5	5		5	5	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	3,26	4,12		3,73	4,11				
Maximum value	6,39	7,13	-	8,13	8,21	0 >		0 >	
Mean Yield (T/ha)	5,03	5,91		6,17	6,30	5 =		5 =	
Mean %UTC	100,00%	118,33 %		121,64 %	125,04 %	0 <		0 <	
Number of val- ues	2		2	2	2	OSIRIS 65 EC 2,0 l/ha		OSIRIS 65 EC 2,0 l/ha	
Minimum value	3,26		4,18	3,73	4,11				
Maximum value	4,43	-	5,11	5,28	5,28	0 >		0 >	
Mean Yield (T/ha)	3,85		4,64	4,51	4,70	2 =		2 =	
Mean %UTC	100,00%		121,79%	116,80 %	122,63 %	0 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 against all diseases in the South-East~~ern~~ EPPO zone

Yield parameters (T/ha and the corresponding calculated %UNCK) were recorded in 4 trials implemented to evaluate the effectiveness of CA3301 at 0.6 l/ha against foliar diseases in the South-East~~ern~~ EPPO zone (see Table 3.4-78).

The application of CA3301 at 0.6 l/ha had no negative impact on the yield of rye and had a significant positive effect in 2 trials out of 4, compared to the untreated check. CA3301 applied at 0.8 l/ha had no negative effects on the yield of rye in 3 trials and had a significant positive effect in 1 trial out of 4, compared to untreated check.

CA3301 at 0.6 l/ha increased yield by 7.74% which was statistically equivalent to the yield increase provided by the reference products CA2445 at 0.8 l/ha in 3 trials out of 3. Compared to PRIAXOR at 1.50 l/ha, CA3301 at 0.6 l/ha was statistically equivalent in the only trial where it was tested. CA3301 at 0.8 l/ha increased yield by 3.68% which was always statistically equivalent to the yield increase provided by CA2445 at 0.8 l/ha and PRIAXOR (see Table 3.4-78).

Therefore, it is concluded that 2 applications of CA3301 at 0.6-0.8 l/ha will not negatively affect yield on rye and may have a positive effect on yield when several disease infections occur in the South-East~~ern~~ EPPO zone.

Table 3.4-78: Summary table – Yield (T/ha) – Rye (SECCW) – South-East EPPO zone

Treatment name	UNTREATED CHECK	CA244 5	PRI- AXOR	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		0,8	1,5	0,6	0,8				
Rate unit		L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB				
YIELD (T/ha) - 47-82 DA-B									
Number of val- ues	4			4	4	UT C	CA330 1 0,8 l/ha	UT C	CA330 1 0,6 l/ha
Minimum value	0,64			0,84	0,66				
Maximum value	4,6	-	-	5,17	5,41	2 >	1 >	1 >	0 >
Mean Yield (T/ha)	2,78			2,95	3	2 =	3 =	3 =	3 =
Mean %UTC	100,00%			107,74 %	103,68 %	0 <	0 <	0 <	1 <
Number of val- ues	3	3		3	3	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	0,64	0,67		0,84	0,66				
Maximum value	3,53	4,07	-	4,07	4,08	1 >		0 >	
Mean Yield (T/ha)	2,18	2,16		2,2	2,2	2 =		3 =	
Mean %UTC	100,00%	97,90 %		106,19 %	99,03%	0 <		0 <	
Number of val- ues	1		1	1	1	PRIAXOR 1,5 l/ha		PRIAXOR 1,5 l/ha	
Minimum value	4,6		5,24	5,17	5,41				
Maximum value	4,6	-	5,24	5,17	5,41	0 >		0 >	
Mean Yield (T/ha)	4,6		5,24	5,17	5,41	1 =		1 =	
Mean %UTC	100,00%		113,91%	112,39 %	117,61 %	0 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Comments of zRMS:

No negative impact on the yield of winter rye was observed after twice application of CA3301 at dose rate of 0,6-0,8 l/ha. A positive effect was visible in all EPPO climatic zones and no significant differences between test and reference product were detected.

3.4.2.8 Oilseed rape (BRSNW)

Use of CA3301 in the Maritime EPPO zone – 1 application in autumn and 1 application in spring

Yield parameters (T/ha and the corresponding calculated %UNCK) were recorded in 7 trials implemented to evaluate the effectiveness of CA3301 at 0.6-0.7 l/ha against diseases in the Maritime EPPO zone (see Table 3.4-79).

The application of CA3301 at 0.6 l/ha and 0.7 l/ha had no negative impact on the yield of oilseed rape and had a significant positive effect respectively in 1 and 2 trials out of 7, compared to the untreated check.

CA3301 at 0.6 l/ha increased yield by 5.43% which was always statistically equivalent to the yield increase provided by the reference products CA2445 at 0.7 l/ha, PROSARO at 0.75 l/ha and BISTRO at 0.6 l/ha

Applied at 0.7 l/ha, CA3301 increased yield by 10.47% compared to the untreated check and provided a statistically higher increase in yield in 1 trial compared to CA3301 at 0.6 l/ha and CA2445 at 0.7 l/ha. Compared to the references PROSARO and BISTRO, CA3301 at 0.7 l/ha was statistically equivalent.

Therefore, it is concluded that 1 application in autumn and 1 application in spring of CA3301 at 0.6-0.7 l/ha will not negatively affect yield on oilseed rape and might have a positive effect on yield in the Maritime EPPO zone.

Table 3.4-79: Summary table – Oilseed rape – Yield (T/ha) - Maritime EPPO zone

Treatment name	UNTREATED CHECK	BIST RO	CA24 45	PROSA RO	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,7 l/ha is >, = or < compared to	
Rate		0,6	0,7	0,75	0,6	0,7				
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB	AB				
YIELD (T/ha) - 69-108 DA-B										
Number of values	7				7	7	UT C	CA33 01 0,7 l/ha	UT C	CA33 01 0,6 l/ha
Minimum value	2,18				2,17	2,35				
Maximum value	4,34	-	-	-	4,42	4,56	1 >	0 >	2 >	1 >
Mean Yield (T/ha)	3,32				3,51	3,64	6 =	6 =	5 =	6 =
Mean % UTC	100,00%				105,43 %	110,47 %	0 <	1 <	0 <	0 <
Number of values	2	2	2		2	2	BISTRO		BISTRO	
Minimum value	2,33	2,48	2,41		2,41	2,85	0,6 l/ha		0,6 l/ha	
Maximum value	4,29	4,18	4,38	-	4,41	4,56	0 >		0 >	
Mean Yield (T/ha)	3,31	3,33	3,4		3,41	3,71	2 =		2 =	
Mean % UTC	100,00%	101,94 %	102,77 %		103,12 %	114,31 %	0 <		0 <	
Number of values	6		6		6	6	CA2445		CA2445	
Minimum value	2,89		2,41		3,29	3,45	0,7 l/ha		0,7 l/ha	
Maximum value	4,34	-	4,44	-	4,42	4,56	0 >		1 >	
Mean Yield (T/ha)	3,75		3,75		3,99	4,05	6 =		5 =	
Mean % UTC	100,00%		107,29 %		106,41 %	110,92 %	0 <		0 <	
Number of values	1			1	1	1	PROSARO		PROSARO	
Minimum value	2,18			2,26	2,17	2,35	0,75 l/ha		0,75 l/ha	
Maximum value	2,18	-	-	2,26	2,17	2,35	0 >		0 >	
Mean Yield (T/ha)	2,18			2,26	2,17	2,35	1 =		1 =	
Mean % UTC	100,00%			103,67%	99,54 %	107,80 %	0 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the Maritime EPPO zone – 2 applications in spring

Yield parameters (T/ha and the corresponding calculated %UNCK) were recorded in 12 trials implemented to evaluate the effectiveness of CA3301 at 0.6-0.7 l/ha against diseases in the Maritime EPPO zone (see Table 3.4-80).

The application of CA3301 at 0.6 l/ha and 0.7 l/ha had no negative impact on the yield of oilseed rape

and both had a significant positive effect in 4 trials out of 12, compared to the untreated control.

CA3301 at 0.6 l/ha and 0.7 l/ha increased yield by 8.46% and 11.28% compared to untreated control which was always statistically equivalent to the yield increase provided by the reference products CA2445 at 0.7 l/ha (9.47%).

Therefore, it is concluded that 2 applications in spring of CA3301 at 0.6-0.7 l/ha will not negatively affect yield on oilseed rape and might have a positive effect on yield in the Maritime EPPO zone.

Table 3.4-80: Summary table – Oilseed rape – Yield (T/ha) - Maritime EPPO zone

Table 5-4-66: Summary table - Onseed type - Field (T/ha) - Maritime EPTO zone										
Treatment name	UNTREATED CHECK	CA24 45	CA33 01	CA33 01	No of trials where CA3301			No of trials where CA3301		
Rate		0,7	0,6	0,7	at 0,6 l/ha is >, = or <			at 0,7 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
YIELD (T/ha) - 67-109 DA-B										
Number of values	12	12	12	12	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	1,85	1,58	1,73	1,64	C	0,7 l/ha	0,7 l/ha	C	0,7 l/ha	0,6 l/ha
Maximum value	4,02	4,76	4,57	4,79	4 >	0 >	0 >	4 >	0 >	0 >
Mean Yield (T/ha)	2,8	3,09	3,06	3,13	8 =	12 =	12 =	8 =	12 =	12 =
Mean % UTC	100,00%	109,47 %	108,46 %	111,28 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the Mediterranean EPPO zone – 2 applications in spring

Yield parameters (T/ha and the corresponding calculated %UNCK) were recorded in 8 trials implemented to evaluate the effectiveness of CA3301 at 0.6-0.7 l/ha against diseases in the Mediterranean EPPO zone (see Table 3.4-81).

The application of CA3301 at 0.6 l/ha and 0.7 l/ha had no negative impact on the yield of oilseed rape and CA3301 at 0.6 l/ha had a significant positive effect in 1 trial out of 8, compared to the untreated check.

CA3301 at 0.6 l/ha and 0.7 l/ha provided a numerical increase in yield of 15.19% and 8.34% compared to untreated control and were always equivalent to the references CA2445 at 0.7 l/ha, CARAMBA at 0.8 l/ha, PROSARO at 1.0 l/ha and ORTIVA at 1.0 l/ha.

Therefore, it is concluded that 2 applications in spring of CA3301 at 0.6-0.7 l/ha will not negatively affect yield on oilseed rape and might have a positive effect on yield in the Mediterranean EPPO zone.


Table 3.4-81: Summary table – Oilseed rape – Yield (T/ha) - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA2 445	CARA MBA	PROS ARO	ORT IVA	CA3 301	CA3 301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,7 l/ha is >, = or < compared to	
Rate		0,7	0,8	1	1	0,6	0,7				
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB	AB	AB				
YIELD (T/ha) - 68-101 DA-B											
Number of values	8	8				8	8	UTC	CA3301	UTC	CA3301
Minimum value	2,01	2,48				2,52	2,16		0,7 l/ha		0,6 l/ha
Maximum value	4,70	5,15	-	-	-	4,82	4,78		1 >		0 >

Treatment name Rate Rate unit Appl. Code Mean Yield (T/ha) Mean %UTC	UNTREATED CHECK	CA2 445 0,7 L/ha AB	CARA MBA 0,8 L/ha AB	PROSARO 1 L/ha AB	ORTIVA 1 L/ha AB	CA3 301 0,6 L/ha AB	CA3 301 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,7 l/ha is >, = or < compared to	
	3,50 100,00%	3,91 112,72%				3,97 115,19%	3,76 108,34%	7 = 0 <	8 = 0 <	8 = 0 <	8 = 0 <
Number of values	2	2	2			2	2	CA2 445	CARAMB A	CA2 445	CARAMB A
Minimum value	2,01	2,48	2,32			2,52	2,16	0,7 l/ha	0,8 l/ha	0,7 l/ha	0,8 l/ha
Maximum value	3,01	3,29	3,22	-	-	3,42	3,48	0 >	0 >	0 >	0 >
Mean Yield (T/ha)	2,51	2,89	2,71			2,97	2,82	8 =	2 =	8 =	2 =
Mean %UTC	100,00%	116,34%	111,20 %			125,37%	107,46%	0 <	0 <	0 <	0 <
Number of values	3	3		3		3	3	PROSARO		PROSARO	
Minimum value	3,24	3,70		3,94		3,80	3,70	1,0 l/ha		1,0 l/ha	
Maximum value	4,38	5,15	-	4,89	-	4,82	4,78	0 >		0 >	
Mean Yield (T/ha)	3,74	4,42		4,56		4,47	4,21	3 =		3 =	
Mean %UTC	100,00%	118,19%		122,80 %		120,04%	112,87%	0 <		0 <	
Number of values	1	1			1	1	1	ORTIVA		ORTIVA	
Minimum value	3,15	3,60			3,45	3,79	3,38	1,0 l/ha		1,0 l/ha	
Maximum value	3,15	3,60	-	-	3,45	3,79	3,38	0 >		0 >	
Mean Yield (T/ha)	3,15	3,60			3,45	3,79	3,38	1 =		1 =	
Mean %UTC	100,00%	114,29%			109,52 %	120,32%	107,30%	0 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-East EPPO zone – 1 application in autumn and 1 application in spring

Yield parameters (T/ha and the corresponding calculated %UNCK) were recorded in 6 trials implemented to evaluate the effectiveness of CA3301 at 0.6-0.7 l/ha against diseases in the North-East  EPPO zone (see Table 3.4-82).

The application of CA3301 at 0.6 l/ha and 0.7 l/ha had no negative impact on the yield of oilseed rape and both had a significant positive effect in 3 trials out of 6, compared to the untreated check.

CA3301 at 0.6 l/ha increased yield by 15.55% compared to untreated check which was always statistically equivalent to the yield increase provided by the reference products ORIUS EXTRA at 1.0 l/ha and TILMOR 240 EC at 0.7-1.0 l/ha. Compared to CA2445 at 0.7 l/ha, CA3301 at 0.6 l/ha was statistically equivalent in 4 trials out of 5 and provided a lower increase in yield in 1 trial.

Applied at 0.7 l/ha, CA3301 increased yield by 19.65% compared to the untreated check which was always statistically equivalent to the yield increase provided by the reference products CA2445 at 0.7 l/ha, ORIUS EXTRA at 1.0 l/ha and TILMOR 240 EC at 0.7-1.0 l/ha.

Therefore, it is concluded that 1 application in autumn and 1 application in spring of CA3301 at 0.6-0.7 l/ha will not negatively affect yield on oilseed rape and might have a positive effect on yield in the North-East^{eff} EPPO zone.

Table 3.4-82: Summary table – Oilseed rape – Yield (T/ha) – North-East^{eff} EPPO zone

Treatment name	UNTREATED CHECK	CA2 445	ORIOUS EXTRA	TILMOR 240 EC	CA3 301	CA3 301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,7 l/ha is >, = or < compared to	
Rate		0,7	1	0,7-1	0,6	0,7				
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	A-B	AB	AB			
Yield (T/ha) - 59-85 DA-B										
Number of values	6				6	6	UT	CA3 301	UT	CA3 301
Minimum value	1,31				1,64	1,59	C	0,7 l/ha	C	0,6 l/ha
Maximum value	3,07	-	-	-	3,82	3,88	3 >	0 >	3 >	0 >
Mean Yield (T/ha)	2,50				2,87	2,98	3 =	6 =	3 =	6 =
Mean %UTC	100,00%				115,5 5%	119,6 5%	0 <	0 <	0 <	0 <
Number of values	5	5			5	5	CA2445		CA2445	
Minimum value	1,31	1,75			1,64	1,59	0,7 l/ha		0,7 l/ha	
Maximum value	3,07	3,71	-	-	3,82	3,88	0 >		0 >	
Mean Yield (T/ha)	2,45	2,96			2,85	2,96	4 =		5 =	
Mean %UTC	100,00%	122,1 3%			117,0 6%	121,0 2%	1 <		0 <	
Number of values	2	2	2		2	2	ORIOUS EX- TRA		ORIOUS EX- TRA	
Minimum value	1,31	1,75	1,74		1,64	1,59	1,0 l/ha		1,0 l/ha	
Maximum value	2,56	3,01	3,16	-	2,64	2,90	0 >		0 >	
Mean Yield (T/ha)	1,94	2,38	2,45		2,14	2,25	2 =		2 =	
Mean %UTC	100,00%	125,5 8%	128,13%		114,1 6%	117,3 3%	0 <		0 <	
Number of values	1			1	1	1	TILMOR 240 EC		TILMOR 240 EC	
Minimum value	2,74			2,77	2,96	3,09	0,7-1,0 l/ha		0,7-1,0 l/ha	
Maximum value	2,74	-	-	2,77	2,96	3,09	0 >		0 >	
Mean Yield (T/ha)	2,74			2,77	2,96	3,09	1 =		1 =	
Mean %UTC	100,00%			101,09%	108,0 3%	112,7 7%	0 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-East^{eff} EPPO zone – 2 applications in spring

Yield parameters (T/ha and the corresponding calculated %UNCK) were recorded in 11 trials implemented to evaluate the effectiveness of CA3301 at 0.6-0.7 l/ha against diseases in the North-East^{eff} EPPO zone (see Table 3.4-83).

The application of CA3301 at 0.6 l/ha and 0.7 l/ha had no negative impact on the yield of oilseed rape and had a significantly positive effect respectively in 1 trial and 2 trials out of 11, compared to the untreated control.

CA3301 at 0.6 l/ha and 0.7 l/ha increased yield by 6.85% and 9.64% compared to untreated control which was always statistically equivalent to the yield increase provided by the reference products CA2445 at 0.7 l/ha, PROPULSE at 0.8 l/ha and CARAMBA 60 SL at 1.0 l/ha. Moreover, CA3301 at 0.7 l/ha provided a significantly higher increase in yield compared to 0.6 l/ha dose rate in 1 trial out of 11.

In addition, compared to references PROSARO and CARAMBA at 1.0 l/ha applied once, CA3301 at 0.6-0.7 l/ha was statistically equivalent in all comparisons.

Therefore, it is concluded that 2 applications in spring of CA3301 at 0.6-0.7 l/ha will not negatively affect yield on oilseed rape and might have a positive effect on yield in the North-Eastern EPPO zone.

Table 3.4-83: Summary table – Oilseed rape – Yield (T/ha) – North-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA 2445 0,7 L/ha AB	PROPULSE 0,8 L/ha AB	PROSARO 1 L/ha A	CARAMBA 60 SL 1 L/ha A	CARAMBA 60 SL 1 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,7 l/ha is >, = or < compared to
Yield (T/ha) - 51-90 DA-B										
Number of values	11						11	11	U T C	CA 3301 0,7 l/ha
Minimum value	1,92						2,28	2,38		
Maximum value	4,05	-	-	-	-	-	4,17	4,16	1 > 10 = 0 <	2 > 9 = 0 <
Mean Yield (T/ha)	2,77						2,93	3,00		
Mean %UTC	100,00%						106,8 5%	109,6 4%		
Number of values	5	5					5	5	CA2445	CA2445
Minimum value	2,09	2,25					2,28	2,46	0,7 l/ha	0,7 l/ha
Maximum value	4,05	4,14	-	-	-	-	4,17	4,16	0 >	0 >
Mean Yield (T/ha)	2,84	2,98					2,98	3,10	5 =	5 =
Mean %UTC	100,00%	106,34 %					106,2 5%	111,2 0%	0 <	0 <
Number of values	1		1				1	1	PRO-PULSE	PRO-PULSE
Minimum value	2,80		2,90				2,95	2,84	0,8 l/ha	0,8 l/ha
Maximum value	2,80	-	2,90	-	-	-	2,95	2,84	0 >	0 >
Mean Yield (T/ha)	2,80		2,90				2,95	2,84	1 =	1 =
Mean %UTC	100,00%		103,57 %				105,3 6%	101,4 3%	0 <	0 <

Treatm ent name	UNTREA TED CHECK	CA 244 5	PROP ULSE	PROS ARO	CARAM BA 60 SL	CARAM BA 60 SL	CA330 1	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < com- pared to	No of trials where CA3301 at 0,7 l/ha is >, = or < com- pared to
Rate Rate unit		0,7 L/h a	0,8 L/ha	1 L/ha	1 L/ha	1 L/ha	0,6 L/ha	0,7 L/ha		
Appl. Code		AB	AB	A	A	AB	AB	AB		
Number of values	3	3				3	3	3	PRO- SARO	PRO- SARO
Minimu m value	2,09	2,3 8				2,43	2,28	2,54	1,0 l/ha	1,0 l/ha
Maximu m value	4,05	4,1 4	-	-	-	4,04	4,17	4,16	0 >	0 >
Mean Yield (T/ha)	2,85	3,1 2				3,05	3,07	3,20	2 =	2 =
Mean %UTC	100,00%	112 ,13 %				109,44%	110,0 3%	115,4 6%	0 <	0 <
Number of values	3				3		3	3	CA- RAMB A 1,0 l/ha (A)	CA- RAMB A 1,0 l/ha (A)
Minimu m value	1,92				2,13		2,46	2,38		
Maximu m value	3,00	-	-	-	3,47	-	3,41	3,34	0 >	0 >
Mean Yield (T/ha)	2,53				2,85		2,79	2,94	3 =	3 =
Mean %UTC	100,00%				112,38%		111,8 0%	117,2 8%	0 <	0 <
Number of values	2			2			2	2	CA- RAMB A 1,0 l/ha (AB)	CA- RAMB A 1,0 l/ha (AB)
Minimu m value	2,70			2,67			2,68	2,63		
Maximu m value	3,19	-	-	3,20	-	-	3,32	3,17	0 >	0 >
Mean Yield (T/ha)	2,95			2,94			3,00	2,90	3 =	3 =
Mean %UTC	100,00%			99,60 %			101,6 7%	98, 39 %	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the South-Eastern EPPO zone – 1 application in autumn and 1 application in spring

Yield parameters (T/ha and the corresponding calculated %UNCK) were recorded in 10 trials implemented to evaluate the effectiveness of CA3301 at 0.6-0.7 l/ha against diseases in the South-Eastern EPPO zone (see Table 3.4-84).

The application of CA3301 at 0.6 l/ha and 0.7 l/ha had no negative impact on the yield of oilseed rape and both had a significant positive effect in 2 trials out of 8, compared to the untreated check. CA3301 at 0.7 l/ha provided a significant increase in yield in 2 trials out of 8 compared to the 0.6 l/ha dose rate. CA3301 at 0.6 l/ha increased yield by 6.28% compared to untreated check which was always statistically equivalent to the yield increase provided by the reference product TILMOR at 1.2 l/ha. Compared to CA2445 at 0.7 l/ha, CA3301 at 0.6 l/ha was statistically equivalent in 7 trials out of 9 and provided a lower increase in yield in 2 trials.

Applied at 0.7 l/ha, CA3301 increased yield by 10.47% compared to the untreated check which was always statistically equivalent to the yield increase provided by the reference product TILMOR at 1.2 l/ha. Compared to CA2445 at 0.7 l/ha, CA3301 at 0.7 l/ha was statistically equivalent in 7 trials out of 9 and provided a higher increase in yield in 2 trials.

Therefore, it is concluded that 1 application in autumn and 1 application in spring of CA3301 at 0.6-0.7 l/ha will not negatively affect yield on oilseed rape and might have a positive effect on yield in the South-East ~~EP~~ EPPO zone.

Table 3.4-84: Summary table – Oilseed rape – Yield (T/ha) – South-East ~~EP~~ EPPO zone

Treatment name	UNTREATED CHECK	CA244 5	TILMO R	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,7 l/ha is >, = or < compared to	
Rate		0,7	1,2	0,6	0,7				
Rate unit		L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB				
Yield (T/ha) - 57-92 DA-B									
Number of values	10			10	10	UT	CA330 1	UT	CA330 1
Minimum value	0,41			0,48	0,57	C	0,7 l/ha	C	0,6 l/ha
Maximum value	2,91	-	-	2,99	3,07	2 >	0 >	2 >	2 >
Mean Yield (T/ha)	1,91			2,03	2,11	8 =	8 =	8 =	8 =
Mean %UTC	100,00%			106,28 %	110,47 %	0 <	2 <	0 <	0 <
Number of values	9	9		9	9	CA2445		CA2445	
Minimum value	0,41	0,62		0,48	0,57	0,7 l/ha		0,7 l/ha	
Maximum value	2,91	3,07	-	2,99	3,07	0 >		2 >	
Mean Yield (T/ha)	1,96	2,22		2,06	2,12	7 =		7 =	
Mean %UTC	100,00%	117,55 %		107,30 %	111,80 %	2 <		0 <	
Number of values	6		6	6	6	TILMOR		TILMOR	
Minimum value	0,41		0,57	0,48	0,57	1,2 l/ha		1,2 l/ha	
Maximum value	2,57	-	2,69	2,64	2,64	0 >		0 >	
Mean Yield (T/ha)	1,59		1,67	1,62	1,65	6 =		6 =	
Mean %UTC	100,00%		112,53%	106,34 %	110,36 %	0 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the South-East ~~EP~~ EPPO zone – 2 applications in spring

Yield parameters (T/ha and the corresponding calculated %UNCK) were recorded in 13 trials implemented to evaluate the effectiveness of CA3301 at 0.6-0.7 l/ha against diseases in the South-eastern ~~East~~ EPPO zone (see Table 3.4-85).

The application of CA3301 at 0.6 l/ha and 0.7 l/ha had no negative impact on the yield of oilseed rape and both had a significant positive effect in 11 out of 13, compared to the untreated check. CA3301 at 0.7 l/ha provided a significant increase in yield in 3 trials out of 13 compared to the 0.6 l/ha dose rate. CA3301 at 0.6 l/ha increased yield by 19.32% compared to untreated check which was always statistically equivalent to the yield increase provided by the reference products PROPULSE at 1.0 l/ha and ORIUS at 1.0 l/ha. Compared to CA2445 at 0.7 l/ha, CA3301 at 0.6 l/ha was statistically equivalent in 8 trials out of 9 and provided a lower increase in yield in 1 trial.

Applied at 0.7 l/ha, CA3301 increased yield by 24.01% compared to the untreated check which was always statistically equivalent to the yield increase provided by the reference products PROPULSE at 1.0 l/ha and ORIUS at 1.0 l/ha. Compared to CA2445 at 0.7 l/ha, CA3301 at 0.7 l/ha was statistically

equivalent in 7 trials out of 9 and provided a higher increase in yield in 2 trials.

Therefore, it is concluded that 2 applications in spring of CA3301 at 0.6-0.7 l/ha will not negatively affect yield on oilseed rape and might have a positive effect on yield in the South-Eastern EPPO zone.

Table 3.4-85: Summary table – Oilseed rape – Yield (T/ha) – South-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA2445	PROPULSE	ORIOUS	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,7 l/ha is >, = or < compared to	
Rate		0,7	1	1	0,6	0,7				
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB	AB				
Yield (T/ha) - 52-82 DA-B										
Number of values	13				13	13	UT C	CA3301 0,7 l/ha	UT C	CA3301 0,6 l/ha
Minimum value	1,35				1,53	1,68	11 >	0 >	11 >	3 >
Maximum value	3,62	-	-	-	3,91	3,95	2 =	10 =	2 =	10 =
Mean Yield (T/ha)	2,61				3,08	3,19	0 <	3 <	0 <	0 <
Mean % UTC	100,00%				119,32%	124,01%				
Number of values	9	9			9	9	CA2445 0,7 l/ha		CA2445 0,7 l/ha	
Minimum value	2,2	2,57			2,54	2,57	0 >		2 >	
Maximum value	3,62	3,93	-	-	3,91	3,95	8 =		7 =	
Mean Yield (T/ha)	2,7	3,39			3,31	3,44	1 <		0 <	
Mean % UTC	100,00%	126,57%			124,39%	128,66%				
Number of values	2		2		2	2	PROPULSE 1,0 l/ha		PROPULSE 1,0 l/ha	
Minimum value	1,35		1,72		1,53	1,68	0 >		0 >	
Maximum value	1,56	-	1,79	-	1,68	1,83	2 =		2 =	
Mean Yield (T/ha)	1,46		1,75		1,61	1,76	0 <		0 <	
Mean % UTC	100,00%		121,42%		111,26%	121,62%				
Number of values	2			2	2	2	ORIOUS 1,0 l/ha		ORIOUS 1,0 l/ha	
Minimum value	3,14			3,29	3,3	3,33	0 >		0 >	
Maximum value	3,51	-	-	3,62	3,65	3,68	2 =		2 =	
Mean Yield (T/ha)	3,33			3,45	3,48	3,51	0 <		0 <	
Mean % UTC	100,00%			103,96%	104,54%	105,45%				

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Comments of zRMS:

No negative impact on the yield of winter oilseed rape was observed after twice application of CA3301 at dose rate of 0,6-0,7 l/ha. A positive effect was visible in all EPPO climatic zones and no significant differences between test and reference product were detected.

3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

3.4.3.1 Winter barley (HORVW)

Moisture content

Use of CA3301 in the Maritime EPPO zone

Over 21 trials CA3301 at 0.6 l/ha did not significantly affect the moisture content compared to the untreated control, except in 2 trials where CA3301 and the reference products significantly increased moisture content.

The levels of moisture observed were in compliance with the moisture standards for barley and a faster drying of the crop in the untreated control could explain the difference observed in these 2 trials.

CA3301 at the 100% dose rate of 0.6 l/ha was statistically equivalent to the reference products CA2445 at 0.8 l/ha, PROLINE 275 at 0.72 l/ha and MIRADOR XTRA at 0.8 l/ha (see Table 3.4-86).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha is unlikely to negatively impact the moisture content in winter barley in the Maritime EPPO zone.

Table 3.4-86: Summary table – Winter barley – Moisture content (%) - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA244 5 0,8 L/ha AB	PROLINE 275 0,72 L/ha AB	MIRADOR XTRA 0,8 L/ha AB	CA330 1 0,6 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Moisture content (%) - 38-84 DA-B						
Number of values	21				21	UTC
Minimum value	9,48				9,35	
Maximum value	15,60	-	-	-	15,60	2 >
Mean Moisture content (%)	12,19				12,27	19 =
Mean %UTC	100,00%				100,82 %	0 <
Number of values	16	16			16	CA2445
Minimum value	9,48	9,30			9,35	0,8 l/ha
Maximum value	15,60	15,65	-	-	15,60	0 >
Mean Moisture content (%)	12,00	12,15			12,10	16 =
Mean %UTC	100,00%	101,47 %			101,04 %	0 <
Number of values	4		4		4	PROLINE 275 EC
Minimum value	13,03		13,20		13,13	0,72 l/ha
Maximum value	14,05	-	14,13	-	14,05	0 >
Mean Moisture content (%)	13,55		13,67		13,65	4 =
Mean %UTC	100,00%		100,88%		100,68 %	0 <
Number of values	1			1	1	MYRADOR XTRA
Minimum value	9,75			9,90	9,53	0,8 l/ha
Maximum value	9,75	-	-	9,90	9,53	0 >
Mean Moisture content (%)	9,75			9,90	9,53	1 =
Mean %UTC	100,00%			101,54%	97,74%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the Mediterranean EPPO zone

Over 21 trials, CA3301 at 0.6 l/ha did not significantly affect the moisture content compared to the untreated control.

The levels of moisture observed were in compliance with the moisture standards for barley.

CA3301 at the 100% dose rate of 0.6 l/ha was statistically equivalent to the reference products CA2445 at 0.8 l/ha and PROSARO at 1 l/ha in all trials (see Table 3.4-87).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha is unlikely to negatively impact the moisture content in winter barley in the Mediterranean EPPO zone.

Table 3.4-87: Summary table – Winter barley – Moisture content (%) - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA2445	PROSARO	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	1	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
Moisture content (%) - 35-80 DA-B					
Number of values	21			21	UTC
Minimum value	10,75			10,75	
Maximum value	15,23	-	-	14,73	0 >
Mean Moisture content (%)	12,51			12,30	21 =
Mean % UTC	100,00%			98,64%	0 <
Number of values	18	18		18	CA2445
Minimum value	10,75	10,90		10,75	0,8 l/ha
Maximum value	15,23	14,85	-	14,73	0 >
Mean Moisture content (%)	12,57	12,57		12,31	18 =
Mean % UTC	100,00%	100,21%		98,31%	0 <
Number of values	4		4	4	PROSARO
Minimum value	11,70		11,60	11,75	1 l/ha
Maximum value	12,88	-	12,93	13,00	0 >
Mean Moisture content (%)	12,27		12,18	12,19	4 =
Mean % UTC	100,00%		99,32%	99,35%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-Eastern EPPO zone

Over 16 trials, CA3301 at 0.6 l/ha did not significantly affect the moisture content compared to the untreated control.

The levels of moisture observed were always in compliance with the moisture standards at harvest for spring barley and the differences between trials may be due to difference in harvest timing and local weather variations.

CA3301 at the 100% dose rate of 0.6 l/ha was statistically equivalent to the reference products CA2445 at 0.6-0.8 l/ha and OSIRIS 65 EC at 2 l/ha in all trials (see Table 3.4-88)

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha will not negatively impact the moisture content in winter barley in the North-Eastern EPPO zone.

Table 3.4-88: Summary table – Winter barley – Moisture content (%) – North-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA2445	CA2445	OSIRIS 65 EC	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,6	0,8	2	0,6	
Rate unit		L/ha	L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	AB	
Moisture content (%) - 36-73 DA-B						
Number of values	16				16	UTC

Minimum value	7,48	-	-	-	7,48	
Maximum value	20,93	-	-	-	22,95	0 >
Mean Moisture content (%)	12,44				12,84	16 =
Mean %UTC	100,00%				102,68 %	0 <
Number of values	9		9		9	CA2445
Minimum value	11,18		11,03		10,95	0,8 l/ha
Maximum value	20,93	-	22,33	-	22,95	0 >
Mean Moisture content (%)	15,30		15,76		15,87	9 =
Mean %UTC	100,00%		102,52 %		103,09 %	0 <
Number of values	7			7	7	OSIRIS 65 EC
Minimum value	7,48			7,73	7,84	2 l/ha
Maximum value	10,35	-	-	10,15	10,70	0 >
Mean Moisture content (%)	8,76			8,92	8,96	7 =
Mean %UTC	100,00%			102,05%	102,15 %	0 <
Number of values	2	2	2		2	CA2445
Minimum value	12,46	12,84	12,91		12,75	0,6 l/ha
Maximum value	13,47	13,73	13,71	-	13,86	0 >
Mean Moisture content (%)	12,97	13,28	13,31		13,31	2 =
Mean %UTC	100,00%	102,49 %	102,70 %		102,61 %	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the South-East ~~EPB~~ EPPO zone

Over 19 trials, CA3301 at 0.6 l/ha did not significantly affect the moisture content compared to the untreated control, except in 3 trials where CA3301 significantly increased moisture content. In 2 of these trials this was also observed for the reference products and in the remaining trial there were no significant differences between CA3301 and the reference product.

The levels of moisture observed were in compliance with the moisture standards for barley and a faster drying of the crop in the untreated control could explain the difference observed in these 3 trials.

CA3301 at the 100% dose rate of 0.6 l/ha was statistically equivalent to the reference products CA2445 at 0.6-0.8 l/ha, RISA 20 EC at 1.25 l/ha and PRIAXOR at 1.5 l/ha in all trials (see Table 3.4-89).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha is unlikely to negatively impact the moisture content in winter barley in the South-East ~~EPB~~ EPPO zone.

Table 3.4-89: Summary table – Winter barley – Moisture content (%) – South-East ~~EPB~~ EPPO zone

Treatment name	UNTREATED CHECK	CA244 5	CA244 5	RISA 20 EC	PRI-AXOR	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,6	0,8	1,25	1,5	0,6	
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	AB	AB	
Moisture content (%) - 41-66 DA-B							
Number of values	19					19	UTC
Minimum value	3,34					4,07	
Maximum value	14,98	-	-	-	-	15,58	3 >
Mean Moisture content (%)	11,87					11,98	16 =
Mean %UTC	100,00%					101,43 %	0 <

Number of values	9		9			9	CA2445
Minimum value	11,25		11,38			11,25	0,8 l/ha
Maximum value	14,98	-	15,43	-	-	15,58	0 >
Mean Moisture content (%)	13,15		13,37			13,41	9 =
Mean %UTC	100,00%		101,67 %			101,97 %	0 <
Number of values	7			7		7	RISA 20 EC
Minimum value	3,34			3,60		4,07	1,25 l/ha
Maximum value	12,90	-	-	12,93	-	12,93	0 >
Mean Moisture content (%)	11,27			11,34		11,34	7 =
Mean %UTC	100,00%			101,44%		102,86 %	0 <
Number of values	4				4	4	PRIAXOR
Minimum value	8,43				8,70	7,45	1,5 l/ha
Maximum value	12,38	-	-	-	12,48	12,38	0 >
Mean Moisture content (%)	10,19				10,34	9,97	4 =
Mean %UTC	100,00%				101,60%	97,34%	0 <
Number of values	2	2	2			2	CA2445
Minimum value	13,03	13,18	13,10			13,18	0,6 l/ha
Maximum value	13,80	13,98	13,85	-	-	13,85	0 >
Mean Moisture content (%)	13,42	13,58	13,48			13,52	2 =
Mean %UTC	100,00%	101,23 %	100,45 %			100,76 %	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

HLW (Hectolitre Weight / Specific weight)

Use of CA3301 in the Maritime EPPO zone

Over 21 trials, CA3301 at 0.6 l/ha did not significantly affect the grain specific weight compared to the untreated control in 17 trials out of 21 and significantly improved the HLW in the 4 other trials.

The levels of grain specific weight observed were in accordance with the standard levels for winter barley.

At the 100% dose rate of 0.6 l/ha, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha and MIRADOR XTRA at 0.8 l/ha in all trials. Compared to PROLINE 275 at 0.72 l/ha CA3301 was statistically equivalent in 3 trials and gave significantly lower HLW in 1 trial, although the value for CA3301 was nevertheless significantly higher in this trial compared to the untreated check (see Table 3.4-90).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha will not negatively impact the grain specific weight in winter barley and might have a positive effect on the HLW in the Maritime EPPO zone.

Table 3.4-90: Summary table – Winter barley – Grain specific weight (kg/hl) - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA2445 5	PROLINE 275	MIRADOR XTRA	CA3301 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	0,72	0,8	0,6	
Rate unit		L/ha	L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	AB	
Specific Weight (kg/hl) - 38-84 DA-B						
Number of values	21				21	UTC
Minimum value	54,75				55,68	
Maximum value	68,58	-	-	-	68,93	4 >
Mean Specific Weight (kg/hl)	61,92				62,87	17 =

Mean %UTC	100,00%				101,67 %	0 <
Number of values	16	16			16	CA2445
Minimum value	54,75	55,40			55,68	0,8 l/ha
Maximum value	68,58	69,13	-	-	68,93	0 >
Mean Specific Weight (kg/hl)	62,44	63,13			63,04	16 =
Mean %UTC	100,00%	101,21 %			101,09 %	0 <
Number of values	4		4		4	PROLINE 275 EC
Minimum value	55,60		57,73		57,75	0,72 l/ha
Maximum value	67,65	-	65,53	-	68,63	0 >
Mean Specific Weight (kg/hl)	61,13		62,20		62,97	3 =
Mean %UTC	100,00%		101,96%		103,10 %	1 <
Number of values	1			1	1	MYRADOR XTRA
Minimum value	56,75			56,00	59,75	0,8 l/ha
Maximum value	56,75	-	-	56,00	59,75	0 >
Mean Specific Weight (kg/hl)	56,75			56,00	59,75	1 =
Mean %UTC	100,00%			98,68%	105,29 %	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the Mediterranean EPPO zone

Over 21 trials, CA3301 at 0.6 l/ha did not significantly affect the grain specific weight compared to the untreated control in 18 trials out of 21 and significantly improved the HLW in the 3 other trials.

The levels of grain specific weight observed were in accordance with the standard levels for winter barley.

At the 100% dose rate of 0.6 l/ha CA3301 was statistically equivalent to the reference product PROSARO at 1 l/ha in all trials. Compared to CA2445 at 0.8 l/ha CA3301 was statistically equivalent in 16 trials, gave significantly lower HLW in 1 trial, although comparable to the untreated check, and significantly higher HLW in the remaining trial. (see Table 3.4-91).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha will not negatively impact the grain specific weight in winter barley and might have a positive effect on the HLW in the Mediterranean EPPO zone.

Table 3.4-91: Summary table – Winter barley – Grain specific weight (kg/hl) - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA2445	PROSARO	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	1	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
Specific Weight (kg/hl) - 35-80 DA-B					
Number of values	21			21	UTC
Minimum value	51,33			55,68	
Maximum value	68,88	-	-	71,83	3 >
Mean Specific Weight (kg/hl)	60,14			62,34	18 =
Mean %UTC	100,00%			103,88%	0 <
Number of values	18	18		18	CA2445
Minimum value	51,33	46,70		55,68	0,8 l/ha
Maximum value	64,95	66,13	-	71,83	1 >
Mean Specific Weight (kg/hl)	59,01	60,14		61,44	16 =
Mean %UTC	100,00%	102,00%		104,33%	1 <

Number of values	4		4	4	PROSARO
Minimum value	57,18		62,40	61,15	1 l/ha
Maximum value	68,88	-	69,45	70,15	0 >
Mean Specific Weight (kg/hl)	64,51		66,27	66,11	4 =
Mean %UTC	100,00%		102,95%	102,62%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-East^{eff} EPPO zone

Over 16 trials, CA3301 at 0.6 l/ha did not significantly affect the grain specific weight compared to the untreated control in 15 trials out of 16 and significantly improved the HLW in the last trial.

The levels of grain specific weight observed were in accordance with the standard levels for winter barley.

At the 100% dose rate of 0.6 l/ha CA3301 was statistically equivalent to the reference products CA2445 at 0.6-0.8 l/ha and OSIRIS 65 EC at 2 l/ha in all trials (see Table 3.4-92).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha will not negatively impact the grain specific weight in winter barley and might have a positive effect on the HLW in the North-East^{eff} EPPO zone.

Table 3.4-92: Summary table – Winter barley – Grain specific weight (kg/hl) – North –East^{eff} EPPO zone

Treatment name	UNTREATED CHECK	CA2445	CA2445	OSIRIS 65 EC	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,6	0,8	2	0,6	
Rate unit		L/ha	L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	AB	
Specific Weight (kg/hl) - 42-96 DA-B						
Number of values	16				16	UTC
Minimum value	51,45				54,55	
Maximum value	72,19	-	-	-	73,14	1 >
Mean Specific Weight (kg/hl)	63,59				64,20	15 =
Mean %UTC	100,00%				101,06 %	0 <
Number of values	9		9		9	CA2445 0,8 l/ha
Minimum value	60,11		55,38		62,48	
Maximum value	72,19	-	71,11	-	73,14	0 >
Mean Specific Weight (kg/hl)	65,75		63,58		66,34	9 =
Mean %UTC	100,00%		96,96%		100,98 %	0 <
Number of values	7			7	7	OSIRIS 65 EC 2 l/ha
Minimum value	51,45			53,55	54,55	
Maximum value	68,77	-	-	69,77	68,15	0 >
Mean Specific Weight (kg/hl)	60,82			61,21	61,44	7 =
Mean %UTC	100,00%			100,73%	101,16 %	0 <
Number of values	2	2	2		2	CA2445 0,6 l/ha
Minimum value	60,11	62,07	58,90		62,55	
Maximum value	62,37	64,27	61,84	-	64,29	0 >
Mean Specific Weight (kg/hl)	61,24	63,17	60,37		63,42	2 =
Mean %UTC	100,00%	103,22 %	98,57%		103,57 %	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the South-Eastern EPPO zone

Over 19 trials, CA3301 at 0.6 l/ha did not significantly affect the grain specific weight compared to the untreated control in 17 trials out of 19 and significantly improved the HLW in the other 2 trials. The levels of grain specific weight observed were in accordance with the standard levels for winter barley.

At the 100% dose rate of 0.6 l/ha, CA3301 was statistically equivalent to the reference products CA2445 at 0.6-0.8 l/ha, RISA 20 EC at 1.25 l/ha and PRIAXOR at 1.5 l/ha in all trials (see Table 3.4-93).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha will not negatively impact the grain specific weight in winter barley and might have a positive effect on the HLW in the South-Eastern EPPO zone.

Table 3.4-93: Summary table – Winter barley – Grain specific weight (kg/hl) – South –Eastern EPPO zone

Treatment name	UN-TREATED CHECK	CA2445 0,6 L/ha AB	CA2445 0,8 L/ha AB	RISA 20 EC 1,25 L/ha AB	PRIAXOR 1,5 L/ha AB	CA3301 0,6 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Specific Weight (kg/hl) - 41-66 DA-B							
Number of values	19					19	UTC
Minimum value	53,95	-	-	-	-	54,33	2 >
Maximum value	80,35	-	-	-	-	80,38	17 =
Mean Specific Weight (kg/hl)	61,68					62,36	0 <
Mean %UTC	100,00%					101,10%	
Number of values	9		9			9	CA2445 0,8 l/ha
Minimum value	53,95	-	54,63	-	-	54,33	0 >
Maximum value	80,35	-	80,40	-	-	80,38	9 =
Mean Specific Weight (kg/hl)	63,40		64,46			64,23	0 <
Mean %UTC	100,00%		101,72%			101,32%	
Number of values	7			7		7	RISA 20 EC 1,25 l/ha
Minimum value	56,90	-	-	57,93	-	57,83	0 >
Maximum value	63,48	-	-	64,08	-	64,03	7 =
Mean Specific Weight (kg/hl)	60,42			61,19		61,25	0 <
Mean %UTC	100,00%			101,29%		101,38%	
Number of values	4				4	4	PRIAXOR 1,5 l/ha
Minimum value	56,12	-	-	-	55,25	55,05	0 >
Maximum value	80,35	-	-	-	80,45	80,38	4 =
Mean Specific Weight (kg/hl)	64,68				64,46	64,62	0 <
Mean %UTC	100,00%				99,59%	99,86%	
Number of values	2	2	2			2	CA2445 0,6 l/ha
Minimum value	62,83	63,08	64,38	-	-	63,83	0 >
Maximum value	65,00	65,8	66,13	-	-	65,05	2 =
Mean Specific Weight (kg/hl)	63,92	64,44	65,26			64,44	0 <
Mean %UTC	100,00%	100,81%	102,10%			100,83%	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

TKW (Thousand Kernel Weight)

Use of CA3301 in the Maritime EPPO zone

Over 19 trials, CA3301 at 0.6 l/ha did not significantly affect the thousand kernel weight compared to the untreated control in 15 trials out of 19 and significantly improved the TKW in the 4 other trials. The levels of thousand grain weight recorded in all the trial were in accordance with the standard levels for winter barley.

At the 100% dose rate of 0.6 l/ha, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha, PROLINE 275 at 0.72 l/ha and MIRADOR XTRA at 0.8 l/ha in all trials (see Table 3.4-94).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha will not negatively impact the thousand kernel weight in winter barley and might have a positive effect on the TKW in the Maritime EPPO zone.

Table 3.4-94: Summary table – Winter barley – Thousand Kernel Weight (g) - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA244 5	PROLINE 275	MIRADOR XTRA	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	0,72	0,8	0,6	
Rate unit		L/ha	L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	AB	
Thousand kernel weight (g) - 38-91 DA-B						
Number of values	19				19	UTC
Minimum value	30,97				36,38	
Maximum value	56,26	-	-	-	56,28	4 >
Mean TKW (g)	43,43				45,51	15 =
Mean %UTC	100,00%				105,48 %	0 <
Number of values	14	14			14	CA2445
Minimum value	30,97	34,43			36,38	0,8 l/ha
Maximum value	56,26	56,16	-	-	56,28	0 >
Mean TKW (g)	42,56	44,42			44,45	14 =
Mean %UTC	100,00%	105,19 %			105,40 %	0 <
Number of values	4		4		4	PROLINE 275 EC
Minimum value	43,78		46,63		47,09	0,72 l/ha
Maximum value	48,54	-	51,21	-	50,60	0 >
Mean TKW (g)	46,12		49,16		48,71	4 =
Mean %UTC	100,00%		106,69%		105,68 %	0 <
Number of values	1			1	1	MYRADOR XTRA
Minimum value	44,90			46,60	47,53	0,8 l/ha
Maximum value	44,90	-	-	46,60	47,53	0 >
Mean TKW (g)	44,90			46,60	47,53	1 =
Mean %UTC	100,00%			103,79%	105,86 %	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the Mediterranean EPPO zone

Over 18 trials, CA3301 at 0.6 l/ha did not significantly affect the thousand kernel weight compared to the untreated control in 16 trials out of 18 and significantly improved the TKW in the 2 other trials. The levels of thousand grain weight recorded in all the trial were in accordance with the standard levels for winter barley.

At the 100% dose rate of 0.6 l/ha, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha and PROSARO at 1 l/ha except in 1 trial where CA3301 gave significantly higher TKW compared to CA2445 (see Table 3.4-95).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha will not negatively impact the TKW in winter barley and might have a positive effect on the thousand kernel weight in the Mediterranean EPPO zone.

Table 3.4-95: Summary table – Winter barley – Thousand Kernel Weight (g) - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA2445	PROSARO	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	1	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
Thousand kernel weight (g) - 42-125 DA-B					
Number of values	18			18	UTC
Minimum value	33,66			37,73	
Maximum value	54,93	-	-	55,43	2 >
Mean TKW (g)	42,71			44,90	16 =
Mean % UTC	100,00%			105,82%	0 <
Number of values	15	15		15	CA2445
Minimum value	33,66	36,63		37,73	0,8 l/ha
Maximum value	54,93	55,18	-	55,43	1 >
Mean TKW (g)	42,97	44,48		45,17	14 =
Mean % UTC	100,00%	104,34%		105,95%	0 <
Number of values	4		4	4	PROSARO
Minimum value	36,98		43,56	42,06	1 l/ha
Maximum value	43,43	-	45,00	44,55	0 >
Mean TKW (g)	40,34		44,04	43,70	4 =
Mean % UTC	100,00%		109,52%	108,66%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-Eastern EPPO zone

Over 16, CA3301 at 0.6 l/ha did not significantly affect the thousand kernel weight compared to the untreated control in 15 trials out of 16 and significantly improved the TKW in the last trial.

The levels of thousand grain weight recorded in all the trial were in accordance with the standard levels for winter barley.

At the 100% dose rate of 0.6 l/ha, CA3301 was statistically equivalent to the reference products CA2445 at 0.6-0.8 l/ha and OSIRIS 65 EC at 2 l/ha in all except 1 trial where CA2445 at 0.6 l/ha and 0.8 l/ha gave significantly higher TKW (see Table 3.4-96).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha will not negatively impact the TKW in winter barley and might have a positive effect on the thousand kernel weight in the North-Eastern EPPO zone.

Table 3.4-96: Summary table – Winter barley – Thousand Kernel Weight (g) – North-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA2445	CA2445	OSIRIS 65 EC	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,6	0,8	2	0,6	
Rate unit		L/ha	L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	AB	
Thousand kernel weight (g) - 42-95 DA-B						
Number of values	16				16	UTC
Minimum value	31,50				35,72	
Maximum value	51,98	-	-	-	53,34	1 >
Mean TKW (g)	44,34				44,93	15 =

Mean %UTC	100,00%				101,60%	0 <
Number of values	9		9		9	CA2445
Minimum value	41,06		42,94		41,35	0,8 l/ha
Maximum value	51,98	-	52,41	-	53,34	0 >
Mean TKW (g)	47,28		48,00		47,55	8 =
Mean %UTC	100,00%		101,69%		100,56%	1 <
Number of values	7			7	7	OSIRIS 65 EC
Minimum value	31,50			34,08	35,72	2 l/ha
Maximum value	44,62	-	-	44,94	45,34	0 >
Mean TKW (g)	40,56			40,77	41,56	7 =
Mean %UTC	100,00%			100,81%	102,94%	0 <
Number of values	2	2	2		2	CA2445
Minimum value	41,06	46,85	46,02		42,62	0,6 l/ha
Maximum value	51,98	51,89	51,63	-	51,78	0 >
Mean TKW (g)	46,52	49,37	48,83		47,20	2 =
Mean %UTC	100,00%	106,96%	105,70%		101,71%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the South-Eastern EPPO zone

Over 19 trials, CA3301 at 0.6 l/ha did not significantly affect the thousand kernel weight compared to the untreated control in 15 trials out of 19 and significantly improved the TKW in the other 4 trials. The levels of thousand grain weight recorded in all the trial were in accordance with the standard levels for winter barley.

At the 100% dose rate of 0.6 l/ha, CA3301 was statistically equivalent to the reference products CA2445 at 0.6-0.8 l/ha, RISA 20 EC at 1.25 l/ha and PRIAXOR at 1.5 l/ha in all trials (see Table 3.4-97).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha will not negatively impact the TKW in winter barley and might have a positive effect on the thousand kernel weight in the South-Eastern EPPO zone.

Table 3.4-97: Summary table – Winter barley – Thousand Kernel Weight (g) – South-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA2445	CA2445	RISA 20 EC	PRIAXOR	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,6	0,8	1,25	1,5	0,6	
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	AB	AB	
Thousand kernel weight (g) - 42-107 DA-B							
Number of values	19					19	UTC
Minimum value	34,00					37,85	
Maximum value	49,99	-	-	-	-	50,32	4 >
Mean TKW (g)	42,85					44,11	15 =
Mean %UTC	100,00%					103,01%	0 <
Number of values	9		9			9	CA2445
Minimum value	34,00		38,30			37,85	0,8 l/ha
Maximum value	49,28	-	50,52	-	-	49,75	0 >
Mean TKW (g)	43,37		45,54			44,85	9 =
Mean %UTC	100,00%		105,19%			103,56%	0 <
Number of values	7			7		7	RISA 20 EC
Minimum value	40,15			40,98		41,18	1,25 l/ha
Maximum value	44,00	-	-	44,33	-	44,70	0 >
Mean TKW (g)	41,42			42,21		42,34	7 =
Mean %UTC	100,00%			101,94%		102,23%	0 <
Number of values	4				4	4	PRIAXOR
Minimum value	39,41				39,09	40,96	1,5 l/ha
Maximum value	49,99	-	-	-	49,88	50,32	0 >
Mean TKW (g)	45,25				45,62	46,31	4 =
Mean %UTC	100,00%				100,82%	102,46%	0 <
Number of values	2	2	2			2	CA2445

Minimum value	43,35	44,07	44,30			44,47	0,6 l/ha
Maximum value	44,83	48,21	47,92	-	-	46,45	0 >
Mean TKW (g)	44,09	46,14	46,11			45,46	2 =
Mean %UTC	100,00%	104,60%	104,54%			103,10%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Comments of zRMS:

No negative impact on the quality parameters of yield of winter barley (moisture content, HLW, thousand kernel weight) was observed after twice application of CA3301 at dose rate of 0,6 l/ha. A positive effect was visible in all EPPO climatic zones and no significant differences between test and reference product were detected.

3.4.3.2 Spring barley (HORVS)

Moisture content

Use of CA3301 in the Maritime EPPO zone

Against foliar diseases (16 trials), CA3301 at 0.6 l/ha did not significantly affect the moisture content compared to the untreated control, except in 1 trial where CA3301 significantly increased moisture content.

The levels of moisture observed were in compliance with the moisture standards for spring barley and a faster drying of the crop in the untreated control could explain the difference observed in this single trial.

At the 100% dose rate of 0.6 l/ha, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha and PROLINE 275 at 0.72 l/ha in all trials (see Table 3.4-98)

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha will not negatively impact the moisture content in spring barley in the Maritime EPPO zone.

Table 3.4-98: Summary table – Spring barley – Moisture content (%) - Maritime EPPO zone

Treatment name	UNTREATED CHECK	PROLINE 275	CA2445	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,72	0,8	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
Moisture content (%) - 34-83 DA-B					
Number of values	16			16	UTC
Minimum value	8,88			8,78	
Maximum value	16,60	-	-	17,05	1 >
Mean Moisture content (%)	13,63			13,90	15 =
Mean %UTC	100,00%			102,22%	0 <
Number of values	5	5		5	PROLINE 275
Minimum value	8,88	8,90		8,78	0,72 l/ha
Maximum value	16,60	16,85	-	17,05	0 >
Mean Moisture content (%)	14,13	14,22		14,35	5 =
Mean %UTC	100,00%	100,64%		101,40%	0 <
Number of values	11		11	11	CA2445
Minimum value	11,30		11,65	11,78	0,8 l/ha
Maximum value	15,27	-	15,45	15,43	0 >
Mean Moisture content (%)	13,41		13,60	13,71	11 =
Mean %UTC	100,00%		101,60%	102,59%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the Mediterranean EPPO zone

Against foliar diseases (10 trials), CA3301 at 0.6 l/ha did not significantly affect the moisture content compared to the untreated control.

The levels of moisture observed were always in compliance with the moisture standards at harvest for spring barley and the differences between trials may be due to difference in harvest timing and local weather variations.

At the 100% dose rate of 0.6 l/ha, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha and PROSARO at 1 l/ha respectively in all 6 and all 4 trials (see Table 3.4-99).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha is unlikely to negatively impact the moisture content in spring barley in the Mediterranean EPPO zone.

Table 3.4-99: Summary table – Spring barley – Moisture content (%) - Mediterranean EPPO zone

Treatment name		CA2445	PROSARO	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate	UNTREATED CHECK	0,8	1	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
Moisture content (%) - 28-63 DA-B					
Number of values	10			10	UTC
Minimum value	9,95			10,03	
Maximum value	14,30	-	-	14,12	0 >
Mean Moisture content (%)	11,94			11,77	10 =
Mean %UTC (%)	100,00%			99,01%	0 <
Number of values	6	6		6	CA2445
Minimum value	9,95	10,13		10,20	0,8 l/ha
Maximum value	14,30	15,05	-	14,12	0 >
Mean Moisture content (%)	12,93	12,93		12,65	6 =
Mean %UTC (%)	100,00%	100,06%		98,22%	0 <
Number of values	4		4	4	PROSARO
Minimum value	10,08		9,78	10,03	1,0 l/ha
Maximum value	11,13	-	11,28	10,90	0 >
Mean Moisture content (%)	10,45		10,48	10,47	4 =
Mean %UTC (%)	100,00%		100,32%	100,21%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-Eastern EPPO zone

Against foliar diseases (8 trials), CA3301 at 0.6 l/ha did not significantly affect the moisture content compared to the untreated control in all 8 trials.

The levels of moisture observed were in compliance with the moisture standards for spring barley, except in the trial EU19-069-98, and the differences between trials can be explain by the harvest timing and the local weather.

However, at the 100% dose rate of 0.6 l/ha, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha and OSIRIS at 2 l/ha in all trials (see Table 3.4-100).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha will not negatively impact the moisture content in spring barley in the North-Eastern EPPO zone.

Table 3.4-100: Summary table – Spring barley – Moisture content (%) – North-East^{EFF} EPPO zone

Treatment name	UNTREATED CHECK	CA2445	OSIRIS 65 EC	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	2	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
Moisture content (%) - 37-73 DA-B					
Number of values	8			8	UTC
Minimum value	7,23			8,00	
Maximum value	17,10	-	-	17,45	0 >
Mean Moisture content (%)	12,78			13,12	8 =
Mean % UTC	100,00%			103,23%	0 <
Number of values	4	4		4	CA2445
Minimum value	12,53	12,75		12,68	0,8 l/ha
Maximum value	17,10	16,88	-	17,45	0 >
Mean Moisture content (%)	14,22	14,34		14,34	4 =
Mean % UTC	100,00%	101,04%		100,83%	0 <
Number of values	4		4	4	OSIRIS 65 EC
Minimum value	7,23		7,78	8,00	2,0 l/ha
Maximum value	14,70	-	14,93	14,93	0 >
Mean Moisture content (%)	11,34		11,39	11,90	4 =
Mean % UTC	100,00%		101,35%	105,63%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the South-East^{EFF} EPPO zone

Against foliar diseases (14 trials), CA3301 at 0.6 l/ha did not significantly affect the moisture content compared to the untreated control in 12 trials out of 14 and significantly increased the moisture content in the other 2 trials, as was also observed for the reference standard.

At the 100% dose rate of 0.6 l/ha, CA3301 was statistically equivalent to the reference products, BUMPER 52 EC at 0.50 l/ha and PRIAXOR at 1.5 l/ha in all trials. Compared to the reference CA2445 at 0.8 l/ha, CA3301 at 0.6 l/ha was statistically equivalent in 4 trials out of 8 and gave statistically lower moisture content in 4 trials (see Table 3.4-101).

The levels of moisture observed were in compliance with the moisture standards for barley and a faster drying of the crop in the untreated control, could explain the difference observed in these trials.

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha will not negatively impact the moisture content in spring barley in the South-East^{EFF} EPPO zone.

Table 3.4-101: Summary table – Spring barley – Moisture content (%) – South-East^{EFF} EPPO zone

Treatment name	UNTREATED CHECK	BUMPER 25 EC	CA2445	PRIAXOR	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,5	0,8	1,5	0,6	
Rate unit		L/ha	L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	AB	
Moisture content (%) - 30-69 DA-B						
Number of values	14				14	UTC
Minimum value	11,15				11,20	
Maximum value	14,23	-	-	-	14,25	2 >
Mean Moisture content (%)	12,78				12,84	12 =
Mean % UTC	100,00%				100,47%	0 <
Number of values	4	4			4	BUMPER 25 EC
Minimum value	11,15	11,23			11,20	0,5 l/ha
Maximum value	11,75	11,78	-	-	11,83	0 >

Mean Moisture content (%)	11,51	11,56			11,57	4 =
Mean %UTC	100,00%	100,46%			100,52 %	0 <
Number of values	8		8		8	CA2445
Minimum value	12,13		12,23		12,18	0,8 l/ha
Maximum value	14,23	-	14,48	-	14,25	0 >
Mean Moisture content (%)	13,68		13,78		13,72	4 =
Mean %UTC	100,00%		100,74 %		100,27 %	4 <
Number of values	4			4	4	PRIAXOR
Minimum value	11,35			11,43	11,53	1,5 l/ha
Maximum value	13,45	-	-	13,53	13,50	0 >
Mean Moisture content (%)	12,26			12,36	12,35	4 =
Mean %UTC	100,00%			100,84%	100,80 %	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

HLW (Hectolitre Weight / Grain Specific weight)

Use of CA3301 in the Maritime EPPO zone

Against all other diseases (16 trials), CA3301 at 0.6 l/ha did not significantly affect the grain specific weight compared to the untreated control in 15 trials out of 16 and significantly improved the grain specific weight in last trial.

The levels of grain specific weight observed were in accordance with the standard levels for spring barley.

At the 100% dose rate of 0.6 l/ha, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha and PROLINE 275 at 0.72 l/ha respectively in all 11 and all 5 trials (see Table 3.4-102).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha will not negatively impact the grain specific weight in spring barley and might have a positive effect on the grain specific weight in the Maritime EPPO zone.

Table 3.4-102: Summary table – Spring barley – Grain specific weight (kg/hl) - Maritime EPPO zone

Treatment name		PROLINE 275	CA2445	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate	UNTREATED CHECK	0,72	0,8	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
Specific Weight (kg/hl) - 34-83 DA-B					
Number of values	16			16	UTC
Minimum value	52,38			52,00	1 >
Maximum value	73,51	-	-	74,00	15 =
Mean Specific Weight (kg/hl)	62,91			63,32	0 <
Mean %UTC	100,00%			100,68%	
Number of values	5	5		5	PROLINE 275
Minimum value	58,10	60,29		60,33	0,72 l/ha
Maximum value	62,63	64,20	-	63,78	0 >
Mean Specific Weight (kg/hl)	60,70	62,07		62,06	5 =
Mean %UTC	100,00%	102,04%		102,28%	0 <
Number of values	11		11	11	CA2445
Minimum value	52,38		54,50	52,00	0,8 l/ha
Maximum value	73,51	-	73,60	74,00	0 >
Mean Specific Weight (kg/hl)	63,92		63,82	63,89	11 =
Mean %UTC	100,00%		99,92%	99,96%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the Mediterranean EPPO zone

Against foliar diseases (10 trials), CA3301 at 0.6 l/ha did not significantly affect the grain specific weight compared to the untreated control in all 10 trials.

The levels of grain specific weight observed were in accordance with the standard levels for spring barley.

At the 100% dose rate of 0.6 l/ha, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha and PROSARO at 1 l/ha respectively in all 6 and all 4 trials.

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha is unlikely to negatively impact the grain specific weight in spring barley in the Mediterranean EPPO zone.

Table 3.4-103: Summary table – Spring barley – Grain specific weight (Kg/hl) - Mediterranean EPPO zone

Treatment name		CA2445	PROSARO	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate	UNTREATED CHECK	0,8	1	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
Specific weight (Kg/hl) - 28-63 DA-B					
Number of values	10			10	UTC
Minimum value	58,83			58,88	
Maximum value	69,55	-	-	68,80	0 >
Mean Specific Weight (kg/hl)	63,84			63,98	10 =
Mean %UTC (%)	100,00%			100,00%	0 <
Number of values	6	6		6	CA2445
Minimum value	58,83	58,00		58,88	0,8 l/ha
Maximum value	65,05	65,90	-	67,33	0 >
Mean Specific Weight (kg/hl)	61,87	61,00		62,73	6 =
Mean %UTC (%)	100,00%	98,60%		101,36%	0 <
Number of values	4		4	4	PROSARO
Minimum value	65,05		62,05	61,90	1,0 l/ha
Maximum value	69,55	-	70,45	68,80	0 >
Mean Specific Weight (kg/hl)	66,80		66,94	65,87	4 =
Mean %UTC (%)	100,00%		100,17%	98,59%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-Eastern EPPO zone

Against foliar diseases (8 trials), CA3301 at 0.6 l/ha did not significantly affect the grain specific weight compared to the untreated control in all 8 trials.

The levels of grain specific weight observed were in accordance with the standard levels for spring barley.

At the 100% dose rate of 0.6 l/ha, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha and OSIRIS at 2 l/ha in all trials (see Table 3.4-104).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha will not negatively impact the grain specific weight in spring barley in the North-Eastern EPPO zone.

Table 3.4-104: Summary table – Spring barley – Grain specific weight (kg/hl) – North-Eastern EPPO zone

Treatment name		CA2445	OSIRIS 65 EC	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate	UNTREATED CHECK	0,8	2	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
Specific Weight (Kg/hl) - 37-73 DA-B					

Number of values	8			8	UTC
Minimum value	61,83			62,79	0 >
Maximum value	75,00	-	-	74,03	8 =
Mean Specific Weight (kg/hl)	65,65			67,65	0 <
Mean %UTC	100,00%			102,77%	
Number of values	4	4		4	CA2445
Minimum value	61,94	56,67		62,79	0,8 l/ha
Maximum value	74,33	73,32	-	74,03	0 >
Mean Specific Weight (kg/hl)	66,79	67,34		68,91	4 =
Mean %UTC	100,00%	100,79%		103,27%	0 <
Number of values	4		4	4	OSIRIS 65 EC
Minimum value	61,83		63,35	64,52	2,0 l/ha
Maximum value	66,92	-	67,85	68,61	0 >
Mean Specific Weight (kg/hl)	64,93		66,23	66,39	4 =
Mean %UTC	100,00%		102,04%	102,28%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the South-East ~~EPF~~ EPPO zone

Against foliar diseases (13 trials), CA3301 at 0.6 l/ha did not significantly affect the grain specific weight compared to the untreated control in 9 trials out of 13 and significantly improved the grain specific weight in the other 4 trials.

The levels of grain specific weight observed were in accordance with the standard levels for spring barley.

At the 100% dose rate of 0.6 l/ha, CA3301 was statistically equivalent to the reference products BUMPER 25 EC at 0.50 l/ha and PRIAXOR at 1.5 l/ha in all trials. Compared to CA2445 at 0.8 l/ha, CA3301 at 0.6 l/ha was statistically equivalent in 4 trials and gave lower specific weight in other 4 trials, however in these trials CA3301 nevertheless significantly increased the grain specific weight compared to the untreated control (see Table 3.4-105).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha will not negatively impact the grain specific weight in spring barley and might have a positive effect on the HLW in the South-East ~~EPF~~ EPPO zone.

Table 3.4-105: Summary table – Spring barley – Grain specific weight (kg/hl) – South-East ~~EPF~~ EPPO zone

Treatment name	UNTREATED CHECK	BUMPER 25 EC	CA244 5	PRIAXO R	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,5	0,8	1,5	0,6	
Rate unit		L/ha	L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	AB	
Specific Weight (Kg/hl) - 30-83 DA-B						
Number of values	13				13	UTC
Minimum value	51,85				52,15	4 >
Maximum value	76,75	-	-	-	76,80	9 =
Mean Specific Weight (Kg/hl)	62,23				63,96	0 <
Mean %UTC	100,00%				103,16 %	
Number of values	3	3			3	BUMPER 25 EC
Minimum value	67,78	67,80			67,85	0,5 l/ha
Maximum value	69,03	69,10	-	-	69,10	0 >
Mean Specific Weight (Kg/hl)	68,22	68,27			68,32	3 =
Mean %UTC	100,00%	100,07%			100,14 %	0 <
Number of values	8		8		8	CA2445
Minimum value	51,85		51,88		52,15	0,8 l/ha
Maximum value	76,75	-	76,78	-	76,80	0 >

Mean Specific Weight (Kg/hl)	59,99		62,83		62,63	4 =
Mean %UTC	100,00%		105,24 %		104,88 %	4 <
Number of values	4			4	4	PRIAXOR
Minimum value	58,22			58,84	59,02	1,5 l/ha
Maximum value	76,75	-	-	76,85	76,80	0 >
Mean Specific Weight (Kg/hl)	68,66			69,02	68,92	4 =
Mean %UTC	100,00%			100,58%	100,43 %	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<') **TKW (Thousand Kernel Weight)**

TKW (Thousand Kernel Weight)

Use of CA3301 in the Maritime EPPO zone

Against foliar diseases (16 trials), CA3301 at 0.6 l/ha did not significantly affect the thousand kernel weight compared to the untreated control in all 16 trials.

The levels of thousand grain weight recorded in all the trial were in accordance with the standard levels for spring barley.

At the 100% dose rate of 0.6 l/ha, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha and PROLINE 275 at 0.72 l/ha respectively in all 11 and all 5 trials (see Table 3.4-106).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha will not negatively impact the thousand kernel weight in spring barley in the Maritime EPPO zone.

Table 3.4-106: Summary table – Spring barley – Thousand Kernel Weight (g) - Maritime EPPO zone

Treatment name		PROLINE 275	CA2445	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate	UNTREATED CHECK	0,72	0,8	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
Thousand kernel weight (g) - 34-83 DA-B					
Number of values	16			16	UTC
Minimum value	35,70			37,23	
Maximum value	57,46	-	-	57,78	0 >
Mean TKW (g)	47,50			48,55	16 =
Mean %UTC	100,00%			102,37%	0 <
Number of values	5	5		5	PROLINE 275
Minimum value	39,91	41,30		42,38	0,72 l/ha
Maximum value	57,46	56,93	-	57,78	0 >
Mean TKW (g)	47,34	48,62		49,00	5 =
Mean %UTC	100,00%	102,94%		103,73%	0 <
Number of values	11		11	11	CA2445
Minimum value	35,70		38,23	37,23	0,8 l/ha
Maximum value	56,82	-	56,91	57,60	0 >
Mean TKW (g)	47,53		48,37	48,35	11 =
Mean %UTC	100,00%		101,90%	101,75%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the Mediterranean EPPO zone

Against all other diseases (9 trials), CA3301 at 0.6 l/ha did not significantly affect the thousand grain weight compared to the untreated control in all 9 trials.

The levels of thousand grain weight recorded in all the trial were in accordance with the standard levels for spring barley.

At the 100% dose rate of 0.6 l/ha, CA3301 was statistically equivalent to the reference products CA2445

at 0.8 l/ha and PROSARO at 1 l/ha respectively in all 5 and all 4 trials.

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha will not negatively impact the thousand kernel weight in spring barley in the Mediterranean EPPO zone.

Table 3.4-107: Summary table – Spring barley – Thousand Kernel Weight (g) - Mediterranean EPPO zone

Treatment name		CA2445	PROSARO	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate	UNTREATED CHECK	0,8	1	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
TKW (g) - 28-63 DA-B					
Number of values	9			9	UTC
Minimum value	36,83			38,35	
Maximum value	61,03	-	-	62,27	0 >
Mean TKW (g)	48,82			49,91	9 =
Mean % UTC	100,00%			102,12%	0 <
Number of values	5	5		5	CA2445
Minimum value	36,83	38,35		38,43	0,8 l/ha
Maximum value	61,03	60,31	-	62,27	0 >
Mean TKW (g)	49,33	49,47		50,61	5 =
Mean % UTC	100,00%	100,57%		102,70%	0 <
Number of values	4		4	4	PROSARO
Minimum value	40,46		35,94	38,35	1,0 l/ha
Maximum value	53,14	-	55,01	56,14	0 >
Mean TKW (g)	48,19		48,70	49,03	4 =
Mean % UTC	100,00%		100,42%	101,39%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-Eastern EPPO zone

Against foliar diseases (8 trials), CA3301 at 0.6 l/ha did not significantly affect the thousand kernel weight compared to the untreated control in 5 trials out of 8 and significantly improved the thousand kernel weight in the other 3 trials.

The levels of thousand grain weight recorded in all the trial were in accordance with the standard levels for spring barley.

At the 100% dose rate of 0.6 l/ha, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha and OSIRIS at 2 l/ha in all trials (see Table 3.4-108).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha in spring barley will not negatively impact the thousand grain weight and in contrast might have a positive effect in the North-Eastern EPPO zone.

Table 3.4-108: Summary table – Spring barley – Thousand Kernel Weight (g) – North-Eastern EPPO zone

Treatment name		CA2445	OSIRIS 65 EC	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate	UNTREATED CHECK	0,8	2	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
Thousand kernel weight (g) - 40-96 DA-B					
Number of values	8			8	UTC
Minimum value	31,89			36,91	
Maximum value	51,84	-	-	51,48	3 >
Mean TKW (g)	43,12			45,19	5 =
Mean % UTC	100,00%			105,63%	0 <
Number of values	4	4		4	CA2445
Minimum value	31,89	36,12		36,91	0,8 l/ha

Treatment name		CA2445	OSIRIS 65 EC	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate	UNTREATED CHECK	0,8	2	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
Maximum value	51,84	51,98	-	51,48	0 >
Mean TKW (g)	42,27	44,30		44,38	4 =
Mean % UTC	100,00%	105,53%		105,90%	0 <
Number of values	4		4	4	OSIRIS 65 EC
Minimum value	39,97		43,52	42,44	2,0 l/ha
Maximum value	47,81	-	48,81	49,21	0 >
Mean TKW (g)	43,75		45,74	46,00	4 =
Mean % UTC	100,00%		104,79%	105,35%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the South-Eastern EPPO zone

Against foliar diseases (14 trials), CA3301 at 0.6 l/ha did not significantly affect the thousand kernel weight compared to the untreated control in 9 trials out of 14 and significantly improved the TKW in the other 5 trials.

CA3301 at 0.6 l/ha was statistically equivalent to the reference products BUMPER 25 EC at 0.50 l/ha. Compared to CA2445 at 0.8 l/ha and PRIAXOR 1.50 l/ha, CA3301 at 0.6 l/ha was statistically equivalent in 2 trials and gave lower thousand kernel weight respectively in 5 and 2 trials. However in all but one of these trials CA3301 nevertheless significantly increased TKW compared to the untreated control, and was comparable in the other trial (see Table 3.4-109).

The levels of thousand grain weight recorded in all the trial were in accordance with the standard levels for spring barley.

The differences observed in thousand kernel weight could be at least partially explain by the closely related differences in moisture content. However, despite being significant, the numerical differences are very limited.

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha will not negatively impact the thousand kernel weight in spring barley and might have a positive effect on the thousand kernel weight in the South-Eastern EPPO zone.

Table 3.4-109: Summary table – Spring barley – Thousand Kernel Weight (g) – South-Eastern EPPO zone

Treatment name		BUMPER 25 EC	CA2445	PRIAXOR	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate	UNTREATED CHECK	0,5	0,8	1,5	0,6	
Rate unit		L/ha	L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	AB	
TKW (g)- 30-83 DA-B						
Number of values	14				14	UTC
Minimum value	33,58				33,84	
Maximum value	46,70	-	-	-	46,80	5 >
Mean TKW (g)	41,53				43,03	9 =
Mean % UTC	100,00%				103,71 %	0 <
Number of values	4	4			4	BUMPER 25 EC
Minimum value	42,08	42,12			42,22	0,5 l/ha
Maximum value	43,48	43,56	-	-	43,64	0 >
Mean TKW (g)	42,77	42,82			42,89	4 =
Mean % UTC	100,00%	100,14%			100,29 %	0 <
Number of values	8		8		8	CA2445
Minimum value	33,58		34,00		33,84	0,8 l/ha

Maximum value	46,70	-	47,14	-	46,80	0 >
Mean TKW (g)	40,52		43,79		42,97	2 =
Mean % UTC	100,00%		108,10 %		106,06 %	5 <
Number of values	4			4	4	PRIAXOR
Minimum value	33,58			34,49	33,84	1,5 l/ha
Maximum value	44,78	-	-	45,92	45,31	0 >
Mean TKW (g)	41,14			41,74	41,58	2 =
Mean % UTC	100,00%			101,56%	101,07 %	2 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Comments of zRMS:

No negative impact on the quality parameters of yield of spring barley (moisture content, HLW, thousand kernel weight) was observed after twice application of CA3301 at dose rate of 0,6 l/ha. A positive effect was visible in all EPPO climatic zones and no significant differences between test and reference product were detected.

3.4.3.3 Oat (AVESS/AVESA)

Moisture content

Use of CA3301 in the Maritime EPPO zone

In 5 trials where it was recorded, CA3301 at 0.6 l/ha did not significantly affect the moisture content compared to the untreated control. The levels of moisture observed were in compliance with the moisture standards for oat.

CA3301 at 0.6 l/ha was statistically equivalent to the reference products CA2445 at 0.8 l/ha and TORERO at 1 l/ha in all trials (see Table 3.4-110).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha is unlikely to negatively impact the moisture content in oat in the Maritime EPPO zone.

Table 3.4-110: Summary table – Oat – Moisture content (%) - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA2445	TORERO	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	1	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
Moisture content (%) - 42-52 DA-B					
Number of values	5			5	UTC
Minimum value	11,15			11,18	
Maximum value	16,10	-	-	16,37	0 >
Mean Moisture content (%)	12,70			12,87	5 =
Mean % UTC	100,00%			101,13%	0 <
Number of values	3	3		3	CA2245
Minimum value	11,15	11,15		11,20	0,8 l/ha
Maximum value	13,53	14,10	-	14,28	0 >
Mean Moisture content (%)	11,99	12,23		12,26	3 =
Mean % UTC	100,00%	101,85%		102,06%	0 <
Number of values	2		2	2	TORERO
Minimum value	11,43		11,13	11,18	1 l/ha
Maximum value	16,10	-	16,29	16,37	0 >
Mean Moisture content (%)	13,77		13,71	13,78	2 =
Mean % UTC	100,00%		99,28%	99,74%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the Mediterranean EPPO zone

In 6 trials where it was recorded, CA3301 at 0.6 l/ha did not significantly affect the moisture content compared to the untreated control. The levels of moisture observed were in compliance with the moisture standards for oat.

CA3301 at 0.6 l/ha was statistically equivalent to the reference products CA2445 at 0.8 l/ha, PROSARO at 1 l/ha, MYSTIC SUL at 1 l/ha and ORIUS P at 1.2 l/ha in all trials (see Table 3.4-111).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha is unlikely to negatively impact the moisture content in oat in the Mediterranean EPPO zone.

Table 3.4-111: Summary table – Oat – Moisture content (%) – Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA244 5	PROSAR O	MYSTIC SUL	ORIUS P	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	1	1	1,2	0,6	
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	AB	AB	
Moisture content (%) - 46-77 DA-B							
Number of values	6					6	UTC
Minimum value	9,15					9,13	
Maximum value	19,20	-	-	-	-	21,03	0 >
Mean Moisture content (%)	14,37					15,12	6 =
Mean %UTC	100,00%					103,99 %	0 <
Number of values	5	5				5	CA2245
Minimum value	10,03	10,05				9,90	0,8 l/ha
Maximum value	19,20	21,05	-	-	-	21,03	0 >
Mean Moisture content (%)	15,42	16,42				16,32	5 =
Mean %UTC	100,00%	105,65 %				104,83 %	0 <
Number of values	2		2			2	PROSARO
Minimum value	9,15		9,30			9,13	1 l/ha
Maximum value	10,03	-	10,03	-	-	9,90	0 >
Mean Moisture content (%)	9,59		9,66			9,52	2 =
Mean %UTC	100,00%		100,82%			99,24%	0 <
Number of values	1	1		1		1	MYSTIC SUL
Minimum value	15,40	16,28		16,20		16,35	1 l/ha
Maximum value	15,40	16,28	-	16,20	-	16,35	0 >
Mean Moisture content (%)	15,40	16,28		16,20		16,35	1 =
Mean %UTC	100,00%	105,71 %		105,19%		106,17 %	0 <
Number of values	1	1			1	1	ORIUS P
Minimum value	13,27	13,68	-		13,65	13,30	1 l/ha
Maximum value	13,27	13,68		-	13,65	13,30	0 >
Mean Moisture content (%)	13,27	13,68			13,65	13,30	1 =
Mean %UTC	100,00%	103,09 %			102,86 %	100,23 %	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-Eastern EPPO zone

In 6 trials where it was recorded, CA3301 at 0.6 l/ha did not significantly affect the moisture content

compared to the untreated control, except in 1 trial where CA3301 significantly increased moisture content from 11.33% in the untreated to 11.98%. However, in this trial CA3301 was comparable with the reference product at 11.55% moisture content.

The levels of moisture observed were in compliance with the moisture standards for oat and a faster drying of the crop in the untreated control could explain the difference observed in this trial.

CA3301 at 0.6 l/ha was statistically equivalent to the reference products CA2445 at 0.8 l/ha and PRO-SARO at 1 l/ha in all trials (see Table 3.4-112).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha will not negatively impact the moisture content in oat in the North-Eastern EPPO zone.

Table 3.4-112: Summary table – Oat – Moisture content (%) – North-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA2445	PROSARO	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	1	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
Moisture content (%) - 36-58 DA-B					
Number of values	6			6	UTC
Minimum value	10,75			10,60	
Maximum value	18,63	-	-	18,85	1 >
Mean Moisture content (%)	13,11			13,28	5 =
Mean % UTC	100,00%			101,31%	0 <
Number of values	5	5		5	CA2245
Minimum value	10,75	11,55		10,60	0,8 l/ha
Maximum value	13,18	13,58	-	13,52	0 >
Mean Moisture content (%)	12,01	12,54		12,17	5 =
Mean % UTC	100,00%	104,74%		101,34%	0 <
Number of values	2		2	2	PROSARO
Minimum value	12,55		12,38	12,55	1 l/ha
Maximum value	18,63	-	17,30	18,85	0 >
Mean Moisture content (%)	15,59		14,84	15,70	2 =
Mean % UTC	100,00%		95,75%	100,59%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the South-Eastern EPPO zone

In 4 trials where it was recorded, CA3301 at 0.6 l/ha did not significantly affect the moisture content compared to the untreated control. The levels of moisture observed were in compliance with the moisture standards for oat.

CA3301 at 0.6 l/ha was statistically equivalent to the reference product CA2445 at 0.8 l/ha in all trials (see Table 3.4-113)

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha is unlikely to negatively impact the moisture content in oat in the South-Eastern EPPO zone.

Table 3.4-113: Summary table – Oat – Moisture content (%) – South-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA2445	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	0,6	
Rate unit		L/ha	L/ha	
Appl. Code		AB	AB	
Moisture content (%) - 40-54 DA-B				
Number of values	4	4	4	UTC
Minimum value	8,70	9,35	9,38	
Maximum value	15,83	15,78	15,63	0 >
				CA2245
				0,8 l/ha

Mean Moisture content (%)	12,12	12,27	12,27	4 =	4 =
Mean %UTC	100,00%	101,79%	101,91%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

HLW (Hectolitre Weight / Grain Specific weight)

Use of CA3301 in the Maritime EPPO zone

In 5 trials where it was recorded, CA3301 at 0.6 l/ha did not significantly affect the grain specific weight compared to the untreated control in all 5 trials.

The levels of grain specific weight observed were in compliance with the standards for oat.

CA3301 at 0.6 l/ha was statistically equivalent to the reference products CA2445 at 0.8 l/ha and TORERO at 1 l/ha in all trials (see Table 3.4-114).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha will not negatively impact the grain specific weight in oat in the Maritime EPPO zone.

Table 3.4-114: Summary table – Oat – Grain specific weight (kg/hl) - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA2445	TORERO	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	1	0,6	
Rate unit		L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	
Specific Weight (kg/hl) - 48-65 DA-B					
Number of values	5			5	UTC
Minimum value	34,73			34,94	
Maximum value	52,95	-	-	53,13	0 >
Mean Specific Weight (kg/hl)	43,42			44,05	5 =
Mean %UTC	100,00%			101,56%	0 <
Number of values	3	3		3	CA2245
Minimum value	44,13	44,23		45,68	0,8 l/ha
Maximum value	52,95	52,93	-	53,13	0 >
Mean Specific Weight (kg/hl)	48,76	48,79		49,42	3 =
Mean %UTC	100,00%	100,00%		101,45%	0 <
Number of values	2		2	2	TORERO
Minimum value	34,73		34,01	34,94	1 l/ha
Maximum value	36,11	-	35,48	37,05	0 >
Mean Specific Weight (kg/hl)	35,42		34,74	36,00	2 =
Mean %UTC	100,00%		98,17%	101,72%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the Mediterranean EPPO zone

In 6 trials where it was recorded, CA3301 at 0.6 l/ha did not significantly affect the grain specific weight compared to the untreated control in all 6 trials. The levels of grain specific weight observed were in compliance with the standards for oat. CA3301 at 0.6 l/ha was statistically equivalent to the reference products, PROSARO at 1 l/ha, MYSTIC SUL at 1 l/ha and ORIUS P at 1.2 l/ha in all trials. Compared to CA2445 at 0.8 l/ha CA3301 at 0.6 l/ha significantly increased the grain specific weight compared in 2 trials and was equivalent in the remaining 3 trials (see Table 3.4-115).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha will not negatively impact the grain specific weight in oat in the Mediterranean EPPO zone.

Table 3.4-115: Summary table – Oat – Grain specific weight (kg/hl) - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA2445	PROSARO	MYSTIC SUL	ORIUS P	CA3301	No of trials where CA3301
		5	O	SUL	P	1	

Rate Rate unit Appl. Code		0,8 L/ha AB	1 L/ha AB	1 L/ha AB	1,2 L/ha AB	0,6 L/ha AB	at 0,6 l/ha is >, = or < compared to
Specific Weight (kg/hl) - 46-87DA-B							
Number of values	6					6	UTC
Minimum value	31,05					32,90	
Maximum value	52,67	-	-	-	-	52,22	0 >
Mean Specific Weight (kg/hl)	40,64					41,30	6 =
Mean %UTC	100,00%					101,97 %	0 <
Number of values	5	5				5	CA2245
Minimum value	31,05	33,38				32,90	0,8 l/ha
Maximum value	52,67	52,29	-	-	-	52,22	2 >
Mean Specific Weight (kg/hl)	40,73	40,14				41,63	3 =
Mean %UTC	100,00%	98,81%				102,62 %	0 <
Number of values	2		2			2	PROSARO
Minimum value	40,18		39,38			39,65	1 l/ha
Maximum value	42,33	-	42,53	-	-	42,45	0 >
Mean Specific Weight (kg/hl)	41,26		40,95			41,05	2 =
Mean %UTC	100,00%		99,24%			99,48%	0 <
Number of values	1	1		1		1	MYSTIC SUL
Minimum value	31,05	33,38		32,88		32,90	1 l/ha
Maximum value	31,05	33,38	-	32,88	-	32,90	0 >
Mean Specific Weight (kg/hl)	31,05	33,38		32,88		32,90	1 =
Mean %UTC	100,00%	107,50 %		105,89%		105,96 %	0 <
Number of values	1	1			1	1	ORIOUS P
Minimum value	52,67	52,29	-		52,04	52,22	1 l/ha
Maximum value	52,67	52,29		-	52,04	52,22	0 >
Mean Specific Weight (kg/hl)	52,67	52,29			52,04	52,22	1 =
Mean %UTC	100,00%	99,28%			98,80%	99,15%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-Eastern EPPO zone

In 6 trials where it was recorded, CA3301 at 0.6 l/ha did not significantly affect the grain specific weight compared to the untreated control in 5 trials out of 6 and significantly increased it in the last trial.

The levels of grain specific weight observed were in compliance with the standards for oat.

CA3301 at 0.6 l/ha was statistically equivalent to the reference products CA2445 at 0.8 l/ha and PROSARO at 1 l/ha in all trials in which both were tested (see Table 3.4-116).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha will not negatively impact the grain specific weight in oat and might have a positive effect in the North-Eastern EPPO zone.

Table 3.4-116: Summary table – Oat – Grain specific weight (kg/hl) – North-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA2445	PROSARO	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate Rate unit Appl. Code		0,8 L/ha AB	1 L/ha AB	0,6 L/ha AB	
Specific Weight (kg/hl) - 36-58 DA-B					
Number of values	6			6	UTC
Minimum value	36,48			34,00	

Maximum value	61,75	-	-	67,38	1 >
Mean Specific Weight (kg/hl)	54,32			55,64	5 =
Mean %UTC	100,00%			101,87%	0 <
Number of values	5	5		5	CA2245
Minimum value	36,48	31,40		34,00	0,8 l/ha
Maximum value	61,75	66,50	-	67,38	0 >
Mean Specific Weight (kg/hl)	54,05	55,08		55,52	5 =
Mean %UTC	100,00%	100,74%		102,04%	0 <
Number of values	2		2	2	PROSARO
Minimum value	55,69		55,52	56,26	1 l/ha
Maximum value	59,10	-	59,00	58,20	0 >
Mean Specific Weight (kg/hl)	57,40		57,26	57,23	2 =
Mean %UTC	100,00%		99,76%	99,75%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the South-East^{eff} EPPO zone

In 4 trials where it was recorded, CA3301 at 0.6 l/ha did not significantly affect the grain specific weight compared to the untreated control in all 4 trials. The levels of grain specific weight observed were in compliance with the standards for oat.

CA3301 at 0.6 l/ha was statistically equivalent to the reference product CA2445 at 0.8 l/ha in all 4 trials (see Table 3.4-117).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha will not negatively impact the Grain specific weight in oat in the South-East^{eff} EPPO zone.

Table 3.4-117: Summary table – Oat – Grain specific weight (kg/hl) – South-East^{eff} EPPO zone

Treatment name	UNTREATED CHECK	CA2445	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	0,6		
Rate unit		L/ha	L/ha		
Appl. Code		AB	AB		
Specific Weight (kg/hl) - 40-63 DA-B					
Number of values	4	4	4	UTC	CA2245
Minimum value	41,73	41,85	42,13		0,8 l/ha
Maximum value	63,62	64,16	64,32	0 >	0 >
Mean Specific Weight (kg/hl)	50,38	50,72	50,93	4 =	4 =
Mean %UTC	100,00%	100,65%	101,10%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

TKW (Thousand Kernel Weight)

Use of CA3301 in the Maritime EPPO zone

In 5 trials where it was recorded, CA3301 at 0.6 l/ha did not significantly affect the thousand kernel weight compared to the untreated control in all 5 trials.

The levels of thousand grain weight observed were in compliance with the standards for oat.

CA3301 at 0.6 l/ha was statistically equivalent to the reference products CA2445 at 0.8 l/ha and TORERO at 1 l/ha in all trials in which both were tested (see Table 3.4-118).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha will not negatively impact the thousand kernel weight on oat in the Maritime EPPO zone.

Table 3.4-118: Summary table – Oat – Thousand Kernel Weight (g) - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA2445	TORERO	CA3301	No of trials where CA3301
Rate		0,8	1	0,6	

Rate unit		L/ha	L/ha	L/ha	at 0,6 l/ha is >, = or < compared to
Appl. Code		AB	AB	AB	
Thousand kernel weight (g) - 48-65 DA-B					
Number of values	5			5	UTC
Minimum value	22,58			23,88	
Maximum value	36,65	-	-	36,70	0 >
Mean TKW (g)	29,55			29,31	5 =
Mean %UTC	100,00%			99,34%	0 <
Number of values	3	3		3	CA2245 0,8 l/ha
Minimum value	30,55	30,75		29,35	
Maximum value	36,65	37,05	-	36,70	0 >
Mean TKW (g)	32,82	32,97		32,59	3 =
Mean %UTC	100,00%	100,44%		99,24%	0 <
Number of values	2		2	2	TORERO 1 l/ha
Minimum value	22,58		23,93	23,88	
Maximum value	26,71	-	26,36	24,90	0 >
Mean TKW (g)	24,65		25,14	24,39	2 =
Mean %UTC	100,00%		102,33%	99,49%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the Mediterranean EPPO zone

In 4 trials where it was recorded, CA3301 at 0.6 l/ha did not significantly affect the thousand kernel weight compared to the untreated control in all 4 trials.

The levels of thousand grain weight observed were in compliance with the standards for oat.

CA3301 at 0.6 l/ha was statistically equivalent to the reference products CA2445 at 0.8 l/ha, PROSARO at 1 l/ha, MYSTIC SUL at 1 l/ha and ORIOUS P at 1.2 l/ha in all trials in which both were tested (see Table 3.4-119).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha will not negatively impact the thousand kernel weight in oat in the Mediterranean EPPO zone.

Table 3.4-119: Summary table – Oat – Thousand Kernel Weight (g) - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA2445	PROSAR O	MYSTIC SUL	ORIOUS P	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Rate		0,8	1	1	1,2	0,6	
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	
Appl. Code		AB	AB	AB	AB	AB	
Thousand kernel weight (g) - 46-77 DA-B							
Number of values	4					4	UTC
Minimum value	20,35					22,35	
Maximum value	41,77	-	-	-	-	43,43	0 >
Mean TKW (g)	30,04					32,13	4 =
Mean %UTC	100,00%					104,00 %	0 <
Number of values	3	3				3	CA2245 0,8 l/ha
Minimum value	20,35	22,03				22,35	
Maximum value	41,77	42,91	-	-	-	43,43	0 >
Mean TKW (g)	31,13	32,57				33,08	3 =
Mean %UTC	100,00%	105,28 %				106,95 %	0 <
Number of values	2		2			2	PROSARO 1 l/ha
Minimum value	30,76		31,60			29,27	
Maximum value	31,26	-	33,31	-	-	33,46	0 >
Mean TKW (g)	31,01		32,46			31,30	2 =

Mean %UTC	100,00%		104,64%			101,10%	0 <
Number of values	1	1		1		1	MYSTIC SUL 1 l/ha
Minimum value	20,35	22,03		22,25		22,35	
Maximum value	20,35	22,03	-	22,25	-	22,35	0 >
Mean TKW (g)	20,35	22,03		22,25		22,35	1 =
Mean %UTC	100,00%	108,26%		109,34%		109,83%	0 <
Number of values	1	1			1	1	ORIOUS P 1 l/ha
Minimum value	41,77	42,91	-		42,68	43,43	
Maximum value	41,77	42,91		-	42,68	43,43	0 >
Mean TKW (g)	41,77	42,91			42,68	43,43	1 =
Mean %UTC	100,00%	102,73%			102,18%	103,97%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-Eastern EPPO zone

In 6 trials where it was recorded, CA3301 at 0.6 l/ha did not significantly affect the thousand kernel weight compared to the untreated control in 5 trials out of 6 and significantly increased it in the last trial.

The levels of thousand grain weight observed were in compliance with the standards for oat.

CA3301 at 0.6 l/ha was statistically equivalent to the reference products CA2445 at 0.8 l/ha and PROSARO at 1 l/ha in all trials in which both were tested (see Table 3.4-120).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha will not negatively impact the thousand kernel weight in oat and might have a positive effect in the North-Eastern EPPO zone.

Table 3.4-120: Summary table – Oat – Thousand Kernel Weight (g) – North-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA2445 0,8 L/ha AB	PROSARO 1 L/ha AB	CA3301 0,6 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to
Thousand kernel weight (g) - 36-97 DA-B					
Number of values	6			6	UTC
Minimum value	30,80			34,71	
Maximum value	44,90	-	-	42,43	1 >
Mean TKW (g)	39,29			38,98	5 =
Mean %UTC	100,00%			99,84%	0 <
Number of values	5	5		5	CA2445 0,8 l/ha
Minimum value	30,80	33,92		34,71	
Maximum value	44,90	42,99	-	42,43	0 >
Mean TKW (g)	38,92	38,91		38,91	5 =
Mean %UTC	100,00%	100,73%		100,68%	0 <
Number of values	2		2	2	PROSARO 1 l/ha
Minimum value	39,10		36,58	36,63	
Maximum value	41,17	-	38,22	39,37	0 >
Mean TKW (g)	40,14		37,40	38,00	2 =
Mean %UTC	100,00%		93,30%	94,66%	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the South-Eastern EPPO zone

In 4 trials where it was recorded, CA3301 at 0.6 l/ha did not significantly affect the thousand kernel weight compared to the untreated control in 3 trials out of 4 and significantly increased it in the last trial.

The levels of thousand grain weight observed were in compliance with the standards for oat.

CA3301 at 0.6 l/ha was statistically equivalent to the reference product CA2445 at 0.8 l/ha in all 4 trials (see Table 3.4-121).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6 l/ha will not negatively impact the thousand kernel weight in oat and might have a positive effect in the South-Eastern EPPO zone.

Table 3.4-121: Summary table – Oat – Thousand Kernel Weight (g) – South-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA2445	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	
Rate		0,8	0,6		
Rate unit		L/ha	L/ha		
Appl. Code		AB	AB		
Thousand kernel weight (g) - 40-63 DA-B					
Number of values	4	4	4	UTC	CA2245
Minimum value	31,58	31,75	31,93		0,8 l/ha
Maximum value	33,3	34.19	33,78	1 >	0 >
Mean TKW (g)	32,21	33,16	32,98	3 =	4 =
Mean % UTC	100,00%	102,95%	102,41%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Comments of zRMS:

No negative impact on the quality parameters of yield of spring oat (moisture content, HLW, thousand kernel weight) was observed after twice application of CA3301 at dose rate of 0,6 l/ha. A positive effect was visible in all EPPO climatic zones and no significant differences between test and reference product were detected.

3.4.3.4 Winter wheat (TRZAW)

Moisture content

Use of CA3301 in the Maritime EPPO zone

Against *Fusarium* species (11 trials), CA3301 at 0.6-0.8 l/ha did not significantly affect the moisture content compared to the untreated control.

Whatever the dose rate considered, CA3301 was statistically equivalent to the reference product CA2445 at 0.8 l/ha.

Against all other diseases (14 trials), CA3301 at 0.6-0.8 l/ha did not significantly affect the moisture content compared to the untreated control, except in 2 trials where CA3301 and the reference product significantly increased moisture content.

The levels of moisture observed were in compliance with the moisture standards for wheat and a faster drying of the crop in the untreated control could explain the difference observed in these 2 trials.

Whatever the dose rate considered, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha and PROSARO at 1 l/ha.

Summary results are presented in Table 3.4-122.

Considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the moisture content in winter wheat in Maritime EPPO zone

Table 3.4-122: Summary table – Winter wheat – Moisture content (%) - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA2445	PROSARO	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or <		No of trials where CA3301 at 0,8 l/ha is >, = or <	
Rate		0,8	1.00	0,6	0,8				
Rate unit		L/ha	L/ha	L/ha	L/ha				

Appl. Code		AB	AB	AB	AB	compared to	compared to
Moisture content – <i>Fusarium</i> trials (%) – 30-78 DA-B							
Number of values	11	11		11	11	UT C	CA3301 0,8 l/ha
Minimum value	7.70	8.00		8.00	7.73		CA2445 0,8 l/ha
Maximum value	17.42	17.42	-	17.42	17.42	0 >	0 >
Mean Moisture content (%)	14.47	14.37		14.44	15.52	11 =	11 =
Mean %UTC	100,00%	99.62 %		99.96 %	100.3 4%	0 <	0 <
Moisture content – Foliar diseases trials – 58-86 DA-B							
Number of values	14			14	14	UT C	CA3301 0,8 l/ha
Minimum value	10.68			10.81	10.95		CA2445 0,8 l/ha
Maximum value	18.00	-	-	18.00	18.00	2 >	0 >
Mean Moisture content (%)	13.64			13.73	13.74	12 =	14 =
Mean %UTC	100,00%			100.6 5%	100.7 1%	0 <	0 <
Number of values	9	9		9	9		CA2445 0,8 l/ha
Minimum value	10.68	10.95		10.81	10.95		CA2445 0,8 l/ha
Maximum value	16.20	16.73	-	16.68	16.85	0 >	0 >
Mean Moisture content (%)	12.77	12.94		12.90	12.92	9 =	9 =
Mean %UTC	100,00%	101.7 5%		100.9 8%	101.0 9%	0 <	0 <
Number of values	5		5	5	5		PROSARO 1,0 l/ha
Minimum value	13.30		13.35	13.35	13.35		PROSARO 1,0 l/ha
Maximum value	18.00	-	18.00	18.00	18.00	0 >	0 >
Mean Moisture content (%)	15.23		15.23	15.23	15.22	5 =	5 =
Mean %UTC	100,00%		100.07 %	100.0 5%	100.0 3%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the Mediterranean EPPO zone

Against *Fusarium* species (11 trials), CA3301 at 0.6 l/ha did not significantly affect the moisture content compared to the untreated control in 10 trials out of 11 and significantly increased the moisture content in the last trial. CA3301 at 0.8 l/ha did not significantly affect the moisture content compared to the untreated control in 8 trials out of 11, and significantly increased the moisture content in 1 trial, and significantly decreased the moisture content in the last 2 trials. These trends were also observed for the reference standard CA2445.

CA3301 at 0.8 l/ha was statistically equivalent to the reference product CA2445 at 0.8 l/ha in 8 trials out of 11. The tested product provided a statistically lower moisture content than CA2445 in 1 trial and showed a significant higher moisture content in 2 trials. CA3301 at 0.6 l/ha was statistically equivalent to CA2445 in 9 trials and provided a statistically higher moisture content in the last 2 trials.

Against all other diseases (12 trials), CA3301 at 0.6-0.8 l/ha did not significantly affect the moisture content compared to the untreated control.

Whatever the dose rate considered, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha and PROSARO at 1 l/ha.

Summary results are presented in Table 3.4-123.

Considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha is unlikely to negatively impact the moisture content in winter wheat in Mediterranean EPPO zone.

Table 3.4-123: Summary table – Winter wheat – Moisture content (%) - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA2 445 0,8 L/ha AB	PROS ARO 1.00 L/ha AB	CA3 301 0,6 L/ha AB	CA3 301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to				No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Moisture content – Fusarium trials (%) – 37-83 DA-B												
Number of values	11	11		11	11	U T C	CA24 45 0,8 l/ha	CA3 301 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA3 301 0,6 l/ha	
Minimum value	8.78	9.05		9.73	9.65							
Maximum value	17.73	15.18	-	18.33	15.78	1 > 10 = 0 <	2 >	2 >	1 >	1 >	0 >	
Mean Moisture content (%)	12.86	12.33		13.12	12.57		9 =	9 =	8 =	8 =	9 =	
Mean %UTC	100,00%	97.43 %		102.3 2%	99.27 %		0 <	0 <	2 <	2 <	2 <	
Moisture content – Foliar diseases trials – 33-89 DA-B												
Number of values	12			12	12	UTC	CA3301 0,8 l/ha		UTC	CA3301 0,6 l/ha		
Minimum value	10.63			10.70	10.75							
Maximum value	16.75	-	-	17.00	17.13	0 >	0 >		0 >	0 >		
Mean Moisture content (%)	12.41			12.49	12.54	12 =	12 =		12 =	12 =		
Mean %UTC	100,00%			100.6 4%	100.9 4%	0 <	0 <		0 <	0 <		
Number of values	9	9		9	9	CA2445 0,8 l/ha			CA2445 0,8 l/ha			
Minimum value	10.63	10.65		10.70	10.75							
Maximum value	16.75	17.30	-	17.00	17.13	0 >			0 >			
Mean Moisture content (%)	12.28	12.42		12.35	12.39	9 =			9 =			
Mean %UTC	100,00%	101.1 3%		100.5 5%	100.8 5%	0 <			0 <			
Number of values	5		5	5	5	PROSARO 1,0 l/ha			PROSARO 1,0 l/ha			
Minimum value	10.63		10.98	11.03	10.90							
Maximum value	14.13	-	14.08	13.98	14.13	0 >			0 >			
Mean Moisture content (%)	12.42		12.59	12.57	12.59	5 =			5 =			
Mean %UTC	100,00%		101.50 %	101.4 1%	101.4 6%	0 <			0 <			

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-Eastern EPPO zone

Against *Fusarium* species (11 trials), CA3301 at 0.6-0.8 l/ha did not significantly affect the moisture content compared to the untreated control.

Whatever the dose rate considered, CA3301 was statistically equivalent to the reference product CA2445 at 0.8 l/ha.

Against all other diseases (11 trials), CA3301 at 0.6-0.8 l/ha did not significantly affect the moisture content compared to the untreated control except in 1 trial where both CA3301 and the reference standard significantly increased moisture content.

The levels of moisture observed were in compliance with the moisture standards for wheat and a faster drying of the crop in the untreated control could explain the difference observed in this trial.

Whatever the dose rate considered, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha and OSIRIS at 2 l/ha.

Against *Oculimacula acufornis* (1 trial), CA3301 at 0.6-0.8 l/ha did not significantly affect the moisture content compared to the untreated control. Reference product also did not significantly increase moisture content.

Summary results are presented in Table 3.4-124 and Table 3.4-125.

Considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the moisture content in winter wheat in North-Eastern EPPO zone.

Table 3.4-124: Summary table – Winter wheat – Moisture content (%) – North-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA2 445 0,8 L/ha AB	OSI RIS 2.00 L/ha AB	CA3 301 0,6 L/ha AB	CA3 301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Moisture content – Fusarium trials (%) – 41-100 DA-B											
Number of values	11	11		11	11	U TC	CA24 45 0,8 l/ha	CA3 301 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA3 301 0,6 l/ha
Minimum value	11.78	11.84		11.95	11.87	0 > 11 = 0 <	0 >	0 >	0 >	0 >	0 >
Maximum value	14.03	14.00	-	14.15	14.48		11 =	11 =	11 =	11 =	11 =
Mean Moisture content (%)	12.73	12.72		12.79	12.79		11 =	11 =	11 =	11 =	11 =
Mean %UTC	100,00%	99.90 %		100.4 4%	100.4 4%		0 <	0 <	0 <	0 <	0 <
Moisture content – Foliar diseases trials – 48-66 DA-B											
Number of values	11			11	11	UTC	CA3301 0,8 l/ha		UTC	CA3301 0,6 l/ha	
Minimum value	10.48			10.98	11.10						
Maximum value	16.98	-	-	17.10	17.85	1 >	0 >		1 >	0 >	
Mean Moisture content (%)	12.89			13.08	13.06	10 =	11 =		10 =	11 =	
Mean %UTC	100,00%			101.7 6%	101.4 1%	0 <	0 <		0 <	0 <	
Number of values	5	5		5	5	CA2445 0,8 l/ha		CA2445 0,8 l/ha			
Minimum value	12.51	12.51		12.51	12.73						
Maximum value	16.98	18.10	-	17.10	17.85	0 >		0 >			
Mean Moisture content (%)	14.29	14.51		14.31	14.47	5 =		5 =			
Mean %UTC	100,00%	101.3 3%		100.1 5%	101.1 1%	0 <		0 <			
Number of values	6		6	6	6	OSIRIS 2,0 l/ha		OSIRIS 2,0 l/ha			
Minimum value	10.48		10.63	10.98	11.10						
Maximum value	13.48	-	13.50	13.58	13.35	0 >		0 >			
Mean Moisture content (%)	11.73		11.87	12.06	11.88	6 =		6 =			
Mean %UTC	100,00%		101.3 2%	103.1 0%	101.6 6%	0 <		0 <			

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Table 3.4-125: Summary table – Winter wheat – Moisture content (%) – North-Eastern EPPO zone

Treatment name	UNTREATED CHECK	Protikon 250	CA330	CA33	No of trials		No of trials	
Rate		EC	1	01	where CA3301	where CA3301		
Rate unit		0,8	0,6	0,8	at 0,6 l/ha is	at 0,8 l/ha is		
Appl. Code		L/ha	L/ha	L/ha	>, = or <	>, = or <		
		A	A	A	compared to	compared to		
Moisture content- Eyespot disease- 110 DA-A								
Number of values	12	1	12	12		CA33		CA33
Minimum value	10,4	1	10,4	10,6	UTC	01 0,8 l/ha	UTC	01 0,6 l/ha
Maximum value	10,4 14,5	1	10,4 14,6	10,6 14,5	0 >	0 >	0 >	0 >

Mean Moisture content (%)	10,4 12,5	-	10,4 12,5	10,6 12,6	± 2 =	± 2 =	± 2 =	± 2 =
Mean %UTC	100,00%	-	100,00%	101,9%	0 <	0 <	0 <	0 <
Number of values	± 2	± 2	± 2	± 2	Protikon 250 EC		Protikon 250 EC	
Minimum value	10,4	10,6	10,4	10,6	0,8 l/ha		0,8 l/ha	
Maximum value	14,5	14,7	14,6	14,5	0 >		0 >	
Mean Moisture content (%)	10,4 12,5	10,6 12,7	10,4 12,5	10,6 12,6	± 2 =		± 2 =	
Mean %UTC	100,00%	101,9 101,6%	100,00%	101,9 100,8%	0 <		0 <	

Use of CA3301 in the South-Eastern EPPO zone

Against *Fusarium* species (11 trials), CA3301 at 0.6-0.8 l/ha did not significantly affect the moisture content compared to the untreated control.

Whatever the dose rate considered, CA3301 was statistically equivalent to the reference product CA2445 at 0.8 l/ha.

Against all other diseases (11 trials), CA3301 at 0.6-0.8 l/ha did not significantly affect the moisture content compared to the untreated control in 7 trials out of 11 and significantly increased the moisture content in the other 4 trials, as was also observed for the reference standard. The levels of moisture observed were in compliance with the moisture standards for wheat and a faster drying of the crop in the untreated control, could explain the difference observed in this trial.

Whatever the dose rate considered, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha, RISA at 1.25 l/ha and PRIAXOR at 1.5 l/ha except in 1 trial where CA3301 at 0.8 l/ha gave statistically higher moisture content than CA2445 at 0.8 l/ha.

Summary results are presented in Table 3.4-126.

Considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the moisture content in winter wheat in South-Eastern EPPO zone.

Table 3.4-126: Summary table – Winter wheat – Moisture content (%) – South-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA2 445	PRIAXOR	RISA	CA3 301	CA3 301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Rate	0,8	0,8	1,5	1,25	0,6	0,8		
Rate unit	L/ha	L/ha	L/ha	L/ha	L/ha	L/ha		
Appl. Code	AB	AB	AB	AB	AB	AB		
Moisture content (%) – <i>Fusarium</i> trials – 46-109 DA-B								
Number of values	11	11			11	11	U T C	U T C
Minimum value	11.00	10.98			10.98	10.93	CA3301 0,8 l/ha	CA3301 0,6 l/ha
Maximum value	14.03	14.25	-	-	13.83	14.10	CA2445 0,8 l/ha	CA2445 0,8 l/ha
Mean Moisture content (%)	12.84	12.81			12.78	12.76	0 >	0 >
Mean %UTC	100.00%	99.81%			99.52%	99.38%	11 =	11 =
							0 <	0 <
Moisture content (%) – Foliar diseases trials – 50-76 DA-B								
Number of values	11				11	11	U T C	U T C
Minimum value	5.10				5.13	5.13	CA3301 0,8 l/ha	CA3301 0,6 l/ha

Maximum value	14.15	-	-	-	14.55	14.48	4 > 7 = 0 <	0 > 10 = 1 <	4 > 7 = 0 <	1 > 10 = 0 <
Mean Moisture content (%)	12.41				12.55	12.56				
Mean %UTC	100,00%				101.0 2%	101.1 6%				
Number of values	6	6			6	6	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	11.81	11.97			11.92	11.93	0 >		0 >	
Maximum value	14.15	14.55	-	-	14.55	14.48	6 =		6 =	
Mean Moisture content (%)	13.25	13.52			13.48	13.51	0 <		0 <	
Mean %UTC	100,00%	102.0 0%			101.6 6%	101.9 2%				
Number of values	4		4		4	4	PRIAXOR 1,5 l/ha		PRIAXOR 1,5 l/ha	
Minimum value	5.10		5.28		5.13	5.13	0 >		0 >	
Maximum value	13.98	-	13.95	-	13.95	13.95	4 =		4 =	
Mean Moisture content (%)	11.12		11.29		11.17	11.15	0 <		0 <	
Mean %UTC	100,00%		101.90 %		100.5 3%	100.3 3%				
Number of values	1			1	1	1	RISA 1,25 l/ha		RISA 1,25 l/ha	
Minimum value	12.60			12.60	12.50	12.58	0 >		0 >	
Maximum value	12.60	-	-	12.60	12.50	12.58	1 =		1 =	
Mean Moisture content (%)	12.60			12.60	12.50	12.58	0 <		0 <	
Mean %UTC	100,00%			100.0 0%	99.21 %	99.84 %				

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

HLW (Hectolitre Weight / Specific weight)

Use of CA3301 in the Maritime EPPO zone

Against *Fusarium* species (9 trials), CA3301 at 0.6-0.8 l/ha did not significantly affect the HLW compared to the untreated control in 8 trials out of 9 and significantly improved the HLW in the last trial.

Whatever the dose rate considered, CA3301 was statistically equivalent to the reference product CA2445 at 0.8 l/ha.

Against all other diseases (14 trials), CA3301 at 0.6-0.8 l/ha did not significantly affect the HLW compared to the untreated control in 7 trials out of 14 and significantly improved the HLW in the 7 other trials.

Whatever the dose rate considered, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha and PROSARO at 1 l/ha.

Specific grain weight levels recorded in the trials remained within the standards for winter wheat.

Summary results are presented in Table 3.4-127.

Considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the HLW in winter wheat and might have a positive effect on the HLW in Maritime EPPO zone

Table 3.4-127: Summary table – Winter wheat – Specific weight (kg/hl) - Maritime EPPO zone

Treatment name	UNTRE ATED CHECK	CA2445	PROSA RO	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or <	No of trials where CA3301 at 0,8 l/ha is >, = or <
Rate		0,8	1.00	0,6	0,8		
Rate unit		L/ha	L/ha	L/ha	L/ha		

Appl. Code		AB	AB	AB	AB	compared to	compared to
Specific weight (kg/hl) – <i>Fusarium</i> trials – 30-72 DA-B							
Number of values	9	9		9	9	UTC	CA330 1 0,8 l/ha
Minimum value	58.80	60.35		61.08	58.10	UTC	CA244 5 0,8 l/ha
Maximum value	81.75	82.75	-	82.75	83.25	1 >	0 >
Mean Specific weight (kg/hl)	68.92	70.81		70.93	71.38	8 =	9 =
Mean %UTC	100,00%	102,95%		103,05%	103,74%	0 <	0 <
Specific weight (kg/hl) – Foliar diseases trials – 52-100 DA-B							
Number of values	14			14	14	UTC	CA330 1 0,8 l/ha
Minimum value	68.95			70.30	69.00		UTC
Maximum value	81.85	-	-	83.71	83.45	7 >	0 >
Mean Specific weight (kg/hl)	75.01			78.37	76.98	7 =	14 =
Mean %UTC	100,00%			102,71%	102,66%	0 <	0 <
Number of values	9	9		9	9	CA2445 0,8 l/ha	CA2445 0,8 l/ha
Minimum value	70.98	70.75		73.00	72.75		
Maximum value	81.85	82.30	-	83.71	83.45	0 >	0 >
Mean Specific weight (kg/hl)	76.12	77.92		78.37	78.52	9 =	9 =
Mean %UTC	100,00%	102,44%		103,03%	103,24%	0 <	0 <
Number of values	5		5	5	5	PROSARO 1,0 l/ha	PROSARO 1,0 l/ha
Minimum value	68.95		70.30	70.30	69.00		
Maximum value	76.05	-	77.50	77.75	77.73	0 >	0 >
Mean Specific weight (kg/hl)	73.04		74.92	74.59	74.22	5 =	5 =
Mean %UTC	100,00%		102,03%	102,12%	101,60%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the Mediterranean EPPO zone

Against *Fusarium* species (11 trials), CA3301 at 0.6 l/ha did not significantly affect the HLW compared to the untreated control in 8 trials out of 11 and significantly improved the HLW in the other 3 trials. CA3301 at 0.8 l/ha did not significantly affect the HLW compared to the untreated control in 6 trials out of 11, significantly improved the HLW in 4 trials and significantly decreased the HLW in the last trial.

CA3301 at 0.8 l/ha was statistically equivalent to the reference product CA2445 at 0.8 l/ha in all 11 trials while CA3301 at 0.6 l/ha was statistically equivalent in 10 trials and statistically higher in the last trial compared to CA2445.

Against all other diseases (12 trials), CA3301 at 0.6-0.8 l/ha did not significantly affect the HLW compared to the untreated control in 9 trials out of 12 and significantly improved the HLW in the 3 other trials.

Whatever the dose rate considered, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha and PROSARO at 1 l/ha.

Specific grain weight levels recorded in treated plots remained within the standards for winter wheat.

Summary results are presented in Table 3.4-128.

Considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha is unlikely to negatively impact the HLW in winter wheat and might have a positive effect on the HLW in Mediterranean EPPO zone

Table 3.4-128: Summary table – Winter wheat – Specific weight (kg/hl) - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA2 445 0,8 L/ha AB	PROS ARO 1.00 L/ha AB	CA3 301 0,6 L/ha AB	CA3 301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Specific weight (kg/hl) – Fusarium trials – 37-83 DA-B											
Number of values	11	11		11	11	U T C	CA24 45 0,8 l/ha	CA3 301 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA3 301 0,6 l/ha
Minimum value	17.73	14.4 8		18.3 3	14.9 0						
Maximum value	246.25	253. 9	-	262. 15	245. 03	3 >	1 >	2 >	4 >	0 >	0 >
Mean Specific weight (kg/hl)	85.46	90.0 9		90.3 5	89.9 7	8 =	10 =	9 =	6 =	11 =	9 =
Mean %UTC	100.00%	104. 21		104. 76	105. 23	0 <	0 <	0 <	1 <	0 <	2 <
Specific weight (kg/hl) – Foliar diseases trials – 33-96 DA-B											
Number of values	12			12	12	UTC	CA3301 0,8 l/ha		UTC	CA3301 0,6 l/ha	
Minimum value	33.08			35.8 8	39.5 8						
Maximum value	84.43	-	-	84.6 5	84.6 5	3 >	0 >		3 >	0 >	
Mean Specific weight (kg/hl)	68.36			69.8 3	68.9 0	9 =	12 =		9 =	12 =	
Mean %UTC	100,00%			102. 70%	101. 75%	0 <	0 <		0 <	0 <	
Number of values	9	9		9	9	CA2445 0,8 l/ha		CA2445 0,8 l/ha			
Minimum value	33.08	39.4 8		35.8 8	39.5 8						
Maximum value	84.43	84.4 8	-	84.6 5	84.6 5	0 >		0 >			
Mean Specific weight (kg/hl)	66.53	68.2 4		67.9 0	67.0 3	9 =		9 =			
Mean %UTC	100,00%	103. 92%		102. 80%	102. 04%	0 <		0 <			
Number of values	5		5	5	5	PROSARO 1,0 l/ha		PROSARO 1,0 l/ha			
Minimum value	33.08		42.59	40.3 3	39.5 8						
Maximum value	77.68	-	78.98	79.1 0	78.7 3	0 >		0 >			
Mean Specific weight (kg/hl)	65.24		67.82	68.1 0	67.1 7	5 =		5 =			
Mean %UTC	100,00%		106.68 %	106. 28%	104. 77%	0 <		0 <			

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-Eastern EPPO zone

Against *Fusarium* species (9 trials), CA3301 at 0.6 l/ha did not significantly affect the HLW compared to the untreated control in 2 trials out of 9 and significantly improved the HLW in the other 7 trials. CA3301 at 0.8 l/ha did not significantly affect the HLW compared to the untreated control in 1 trial out of 9 and significantly improved the HLW in the other 8 trials.

Whatever the dose rate considered, CA3301 was statistically equivalent to the reference product CA2445 at 0.8 l/ha in all the trials.

Against all other diseases (11 trials), CA3301 at 0.6-0.8 l/ha did not significantly affect the HLW compared to the untreated control in 9 trials out of 11 and significantly improved the HLW in the other 2 trials.

Whatever the dose rate considered, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha and OSIRIS at 2 l/ha in all the trials.

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')
*weight of 100L tr

Treatment name		CA2 445	PRIA XOR	RIS A	CA3 301	CA3 301	No of trials where CA3301	No of trials where CA3301
Rate	UNTREATED CHECK	0,8	1.5	1.25	0,6	0,8	at 0,6 l/ha is >, =	at 0,8 l/ha is >, =
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	or <	or <
Appl. Code		AB	AB	AB	AB	AB	compared to	compared to
Specific weight (kg/hl) – Fusarium trials – 46-109 DA-B								
Number of values	11	11			11	11	CA24 45	CA3 301

Minimum value	37.95	45.7 0			41.5 8	44.7 0	U T C	0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	79.85	81.9 0	-	-	80.5 5	80.2 5	2 >	0 >	0 >	2 >	0 >	0 >
Mean Specific weight (kg/hl)	65.12	68.9 0			68.2 7	68.2 9	9 =	10 =	11 =	9 =	10 =	11 =
Mean %UTC	100.00%	107. 01%			105. 64%	106. 00%	0 <	1 <	0 <	0 <	1 <	0 <
Specific weight (kg/hl) – Foliar diseases trials – 50-86 DA-B												
Number of values	11				11	11	UTC	CA3301		UTC		CA3301
Minimum value	69.03				70.6 0	70.6 3		0,8 l/ha				0,6 l/ha
Maximum value	83.73	-	-	-	84.0 0	83.6 5	4 >	0 >		4 >		1 >
Mean Specific weight (kg/hl)	74.24				75.2 6	75.3 0	7 =	10 =		7 =		10 =
Mean %UTC	100.00%				101. 44%	101. 50%	0 <	1 <		0 <		0 <
Number of values	6	6			6	6	CA2445		CA2445			
Minimum value	69.05	72.4 0			71.9 3	72.3 0	0,8 l/ha		0,8 l/ha			
Maximum value	74.10	74.2 8	-	-	73.9 3	73.9 0	0 >		0 >			
Mean Specific weight (kg/hl)	71.26	72.9 6			72.6 6	72.8 5	6 =		6 =			
Mean %UTC	100.00%	102. 44%			102. 01%	102. 27%	0 <		0 <			
Number of values	4		4		4	4	PRIAXOR		PRIAXOR			
Minimum value	75.39		76.35		75.5 4	75.0 6	1,5 l/ha		1,5 l/ha			
Maximum value	83.73	-	84.15	-	84.0 0	83.6 5	0 >		0 >			
Mean Specific weight (kg/hl)	80.02		80.64		80.3 3	80.1 5	4 =		4 =			
Mean %UTC	100.00%		100.7 8%		100. 38%	100. 15%	0 <		0 <			
Number of values	1			1	1	1	RISA		RISA			
Minimum value	69.03			70.1 3	70.6 0	70.6 3	1,25 l/ha		1,25 l/ha			
Maximum value	69.03	-	-	70.1 3	70.6 0	70.6 3	0 >		0 >			
Mean Specific weight (kg/hl)	69.03			70.1 3	70.6 0	70.6 3	1 =		1 =			
Mean %UTC	100.00%			101. 59%	102. 27%	102. 32%	0 <		0 <			

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

TKW (Thousand Kernel Weight)

Use of CA3301 in the Maritime EPPO zone

Against *Fusarium* species (11 trials), CA3301 at 0.6-0.8 l/ha did not significantly affect the TKW compared to the untreated control in 9 trials out of 11 and significantly improved the TKW in the last 2 trials.

Whatever the dose rate considered, CA3301 was statistically equivalent to the reference product CA2445 at 0.8 l/ha in all trials.

Against all other diseases (13 trials), CA3301 at 0.6 l/ha did not significantly affect the TKW compared to the untreated control in 10 trials out of 13 and significantly improved the TKW in the other 3 trials. CA3301 at 0.8 l/ha did not significantly affect the TKW compared to the untreated control in 9 trials out of 13 and significantly improved the TKW in the other 4 trials.

Whatever the dose rate considered, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha and PROSARO at 1 l/ha except in 1 trial where CA3301 at 0.6 l/ha was statistically lower than CA2445 at 0.8 l/ha.

Thousand grain weight levels recorded in treated plots remained within the standards for winter wheat.

Summary results are presented in Table 3.4-132.

Considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the TKW in winter wheat and might have a positive effect on the TKW in Maritime EPPO zone

Table 3.4-132: Summary table – Winter wheat – Thousand kernel weight (g) - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA24 45 0,8 L/ha AB	PROSA RO 1.00 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Rate							
Rate unit							
Appl. Code							
Thousand kernel weight (g) – Fusarium trials – 30-78 DA-B							
Number of values	11	11		11	11	UT C	CA3301 0,8 l/ha
Minimum value	27.94	19.91		21.41	19.24	C	CA2445 0,8 l/ha
Maximum value	48.84	49.77	-	49.50	50.00	2 >	0 >
Mean TKW (g)	39.85	40.01		40.84	40.41	9 =	11 =
Mean %UTC	100,00%	99.96 %		102.00 %	100.7 9%	0 <	0 <
Thousand kernel weight (g) – Foliar diseases trials – 52-86 DA-B							
Number of values	13			13	13	UT C	CA3301 0,8 l/ha
Minimum value	35.95			37.18	38.61	C	CA3301 0,6 l/ha
Maximum value	49.00	-	-	55.14	52.86	3 >	0 >
Mean TKW (g)	41.53			44.11	44.39	10 =	12 =
Mean %UTC	100,00%			106.46 %	107.2 4%	0 <	1 <
Number of values	8	8		8	8	CA2445 0,8 l/ha	
Minimum value	35.95	38.01		37.18	38.61	0 >	
Maximum value	45.93	46.23	-	46.18	47.28	8 =	
Mean TKW (g)	39.88	43.04		42.41	43.39	1 <	
Mean %UTC	100,00%	108.5 2%		106.79 %	109.3 1%	0 <	
Number of values	5		5	5	5	PROSARO 1,0 l/ha	
Minimum value	40.22		43.07	43.64	39.73	0 >	
Maximum value	49.00	-	55.05	55.14	52.86	0 >	

Mean TKW (g)	44.18		47.40	46.84	45.99	5 =	5 =
Mean %UTC	100,00%		107.13%	105.94 %	103.9 3%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the Mediterranean EPPO zone

Against *Fusarium* species (7 trials), CA3301 at 0.6 l/ha did not significantly affect the TKW compared to the untreated control in 4 trials out of 7 and significantly improved the TKW in the other 3 trials. CA3301 at 0.8 l/ha did not significantly affect the TKW compared to the untreated control in 2 trials out of 7 and significantly improved the TKW in the other 5 trials.

Whatever the dose rate considered, CA3301 was statistically equivalent to the reference product CA2445 at 0.8 l/ha in all trials.

Against all other diseases (12 trials), CA3301 at 0.6-0.8 l/ha did not significantly affect the TKW compared to the untreated control in 9 trials out of 12 and significantly improved the TKW in the other 3 trials.

Whatever the dose rate considered, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha and PROSARO at 1 l/ha except in 1 trial where CA3301 at 0.6 l/ha was statistically less efficient than CA2445 at 0.8 l/ha.

Thousand grain weight levels recorded in treated plots remained within the standards for winter wheat.

Summary results are presented in Table 3.4-133.

Considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the TKW in winter wheat and might have a positive effect on the TKW in Mediterranean EPPO zone.

Table 3.4-133: Summary table – Winter wheat – Thousand kernel weight (g) - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA24 45	PROS ARO	CA33 01	CA33 01	No of trials where CA3301			No of trials where CA3301			
Rate		0,8	1.00	0,6	0,8	at 0,6 l/ha is >, = or			at 0,8 l/ha is >, = or			
Rate unit		L/ha	L/ha	L/ha	L/ha	<			<			
Appl. Code		AB	AB	AB	AB	compared to			compared to			
Thousand kernel weight (g) – Fusarium trials – 56-83 DA-B												
Number of values	7	7		7	7	UT C	CA24 45	CA3 301	UT C	CA24 45	CA3 301	
Minimum value	27.92	33.70		34.63	32.98		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha	
Maximum value	39.85	45.48	-	43.01	44.50		3 >	0 >		0 >	5 >	0 >
Mean TKW (g)	34.24	37.95		38.08	38.37		4 =	7 =		7 =	2 =	7 =
Mean %UTC	100,00%	111.5 4%		111.9 2%	112.8 8	0 <	0 <	0 <	0 <	0 <	0 <	
Thousand kernel weight (g) – Foliar diseases trials – 33-118 DA-B												
Number of values	12			12	12	UTC	CA3301		UTC	CA3301		
Minimum value	29.56			29.83	28.36		0,8 l/ha			0,6 l/ha		
Maximum value	67.80	-	-	72.80	73.78		3 >	0 >		3 >	1 >	
Mean TKW (g)	40.58			42.26	42.80		9 =	11 =		9 =	11 =	
Mean %UTC	100,00%			104.1 1%	105.4 1%	0 <	1 <		0 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Against *Fusarium* species (11 trials), CA3301 at 0.6 l/ha did not significantly affect the TKW compared to the untreated control in 6 trials out of 11 and significantly improved the TKW in the other 5 trials. CA3301 at 0.8 l/ha did not significantly affect the TKW compared to the untreated control in 5 trials out of 11 and significantly improved the TKW in the other 6 trials.

Against all other diseases (11 trials), CA3301 at 0.6-0.8 l/ha did not significantly affect the TKW compared to the untreated control in 8 trials out of 11 and significantly improved the TKW in the other 3 trials.

Against *Oculimacula acutiformis* (1 trial), CA3301 at 0.6-0.8 l/ha and reference product showed significantly higher values of TKW in comparison to untreated control. TKW value for CA3301 at 0.6 l/ha was significantly lower in comparison to reference product and CA3301 in dose rate 0,8 l/ha (see Table 3.4-135).

Thousand grain weight levels recorded in treated plots remained within the standards for winter wheat.

Summary results are presented in Table 3.4-134.

Considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the TKW in winter wheat and might have a positive effect on the TKW in North-Eastern EPPO zone.

Treatment name	UNTREATED CHECK	CA24 45	OSIR IS	CA33 01	CA33 01	No of trials where CA3301	No of trials where CA3301
Rate		0,8	2,00	0,6	0,8	at 0,6 l/ha is >, = or	at 0,8 l/ha is >, = or <
Rate unit		L/ha	L/ha	L/ha	L/ha	<	
Appl. Code		AB	AB	AB	AB	compared to	compared to
Thousand kernel weight (g) – <i>Fusarium</i> trials – 41-100 DA-B							

Number of values	11	11		11	11	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	16.28	25.93		26.38	25.68						
Maximum value	46.80	48.13	-	49.60	49.10	5 >	0 >	0 >	6 >	0 >	1 >
Mean TKW (g)	32.57	37.70		37.34	37.81	6 =	10 =	10 =	5 =	11 =	10 =
Mean %UTC	100.00%	120.8 6%		119.5 7%	121.0 7%	0 <	1 <	1 <	0 <	0 <	0 <
Thousand kernel weight (g) – Foliar diseases trials – 55-99 DA-B											
Number of values	11			11	11	UTC	CA3301		UTC		CA3301
Minimum value	29.15			27.82	31.82		0,8 l/ha				0,6 l/ha
Maximum value	58.78	-	-	59.64	58.51	3 >	0 >		3 >		0 >
Mean TKW (g)	40.47			41.61	42.32	8 =	11 =		8 =		11 =
Mean %UTC	100,00%			103.1 7%	105.1 2%	0 <	0 <		0 <		0 <
Number of values	5	5		5	5	CA2445		CA2445			
Minimum value	39.34	40.43		36.52	40.44	0,8 l/ha		0,8 l/ha			
Maximum value	58.78	58.51	-	59.64	58.51	0 >		0 >			
Mean TKW (g)	47.30	48.14		47.05	48.13	5 =		5 =			
Mean %UTC	100,00%	101.7 9%		99.21 %	101.8 3%	0 <		0 <			
Number of values	6		6	6	6	OSIRIS		OSIRIS			
Minimum value	29.15		30.43	27.82	31.82	2,0 l/ha		2,0 l/ha			
Maximum value	41.96	-	46.10	45.21	44.75	0 >		0 >			
Mean TKW (g)	34.79		37.58	37.08	37.48	6 =		6 =			
Mean %UTC	100,00%		108.0 2%	106.4 8%	107.8 7%	0 <		0 <			

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Table 3.4-135: Summary table – Winter wheat – Thousand kernel weight (g) – North-East EPPO zone

Treatment name		Protikon 250	CA3301	CA33	No of trials where CA3301		No of trials where CA3301	
Rate	UNTREATED	EC	0,6	01	at 0,6 l/ha is >		at 0,8 l/ha is >	
Rate unit	CHECK	L/ha	L/ha	L/ha	= or <		= or <	
Appl. Code		A	A	A	compared to		compared to	
Thousand kernel weight (g) – Eyespot disease 110 DA-A								
Number of values	12	12	12	12	UT	CA3301	UT	CA3301
Minimum value	36,9	36,9	39,9	41,8	C	0,8 l/ha	C	0,6 l/ha
Maximum value	36,9 45,0	36,9	39,9 46,2	41,8 47,7	12 >	0 >	12 >	12 >
Mean TKW* (g)	36,9 41,0	36,9	39,9 43,1	41,8 44,8	0 =	0 =	0 =	0 =
Mean %UTC	100,00%	100,00%	108,1 105,1%	113,3 109,3%	0 <	12 <	0 <	0 <
Number of values	12	12	12	12	Protikon 250		Protikon 250	
		EC			EC		EC	

Minimum value	36,9	42,2	39,9	41,8	0,8 l/ha	0,8 l/ha
Maximum value	36,9	42,2 45,8	39,9 46,2	41,8 47,7	0 >	0 >
Mean TKW* (g)	36,9 41,0	42,2 44,0	39,9 46,2	41,8 44,8	0 =	1 =
Mean % UTC	100,00%	114,4 107,3%	108,1 105,1%	113,3 109,3%	1 <	0 <

> means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')
* thousand kernel weight

Use of CA3301 in the South-Eastern EPPO zone

Against *Fusarium* species (11 trials), CA3301 at 0.6 l/ha did not significantly affect the TKW compared to the untreated control in 7 trials out of 11 and significantly improved the TKW in the other 3 trials. CA3301 at 0.8 l/ha did not significantly affect the TKW compared to the untreated control in 8 trials out of 11 and significantly improved the TKW in the other 2 trials. In the last trial, the UTC was excluded from the statistical analysis, however a considerable numerical increase was observed from treatment applications.

Whatever the dose rate considered, CA3301 was statistically equivalent to the reference product CA2445 at 0.8 l/ha in 10 trials out of 11 and statistically lower in the last trial.

Against all other diseases (11 trials), CA3301 at 0.6-0.8 l/ha did not significantly affect the TKW compared to the untreated control in 6 trials out of 11 and significantly improved the TKW in the other 5 trials.

CA3301 at 0.6 l/ha was statistically equivalent to the reference products CA2445 at 0.8 l/ha, RISA at 1.25 l/ha and PRIAXOR at 1.5 l/ha except in 1 trial where CA2445 at 0.8 l/ha was statistically higher and another trial where CA2445 at 0.8 l/ha was statistically lower. CA3301 at 0.8 l/ha was statistically equivalent to the reference products CA2445 at 0.8 l/ha, RISA at 1.25 l/ha and PRIAXOR at 1.5 l/ha except in 1 trial where CA3301 at 0.8 l/ha was statistically higher than CA2445 at 0.8 l/ha.

Thousand grain weight levels recorded in treated plots remained within standards for winter wheat.

Summary results are presented in Table 3.4-136.

Considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the TKW in winter wheat and might have a positive effect on the TKW in South-Eastern EPPO zone

Table 3.4-136: Summary table – Winter wheat – Thousand kernel weight (g) – South-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA2 445	PRIA XOR	RIS A	CA3 301	CA3 301	No of trials where CA3301			No of trials where CA3301		
Rate		0,8	1.5	1.25	0,6	0,8	at 0,6 l/ha is >, = or			at 0,8 l/ha is >, = or		
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	<			<		
Appl. Code		AB	AB	AB	AB	AB	compared to			compared to		
Thousand kernel weight (g) – Fusarium trials – 46-109 DA-B												
Number of values	11	11			11	11	U T C	CA24 45	CA3 301	UT	CA24 45	CA3 301
Minimum value	18.53	25.86			26.05	27.98		0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	48.83	50.67	-	-	50.56	50.84	3 > 7 =	0 >	0 >	2 >	0 >	0 >
Mean TKW (g)	36.25	39.93			39.30	39.66		10 =	11 =	8 =	10 =	11 =

Mean %UTC	100.00%	113.6 2%			111.5 1%	113.1 4%	0 <	1 <	0 <	0 <	1 <	0 <
Thousand kernel weight (g) – Foliar diseases trials – 50-86 DA-B												
Number of values	11				11	11	UTC	CA3301	UTC	CA3301		
Minimum value	38.11				34.39	40.02		0,8 l/ha		0,6 l/ha		
Maximum value	49.00	-	-	-	46.90	47.05	5 >	1 >	5 >	1 >		
Mean TKW (g)	41.78				43.03	43.76	6 =	9 =	6 =	9 =		
Mean %UTC	100,00%				103.2 0%	104.9 4%	0 <	1 <	0 <	1 <		
Number of values	6	6			6	6	CA2445	CA2445				
Minimum value	39.56	42.45			42.70	41.83	0,8 l/ha	0,8 l/ha				
Maximum value	41.93	46.45	-	-	46.90	46.43	1 >	1 >				
Mean TKW (g)	40.85	44.46			44.52	44.17	4 =	5 =				
Mean %UTC	100,00%	108.8 4%			109.0 0%	108.1 3%	1 <	0 <				
Number of values	4		4		4	4	PRIAXOR	PRIAXOR				
Minimum value	38.11		39.65		34.39	40.02	1,5 l/ha	1,5 l/ha				
Maximum value	49.00	-	47.00	-	45.45	47.05	0 >	0 >				
Mean TKW (g)	43.23		43.39		40.89	43.45	4 =	4 =				
Mean %UTC	100,00%		100.63 %		94.71 %	100.8 0%	0 <	0 <				
Number of values	1			1	1	1	RISA	RISA				
Minimum value	41.63			41.5 8	42.63	42.60	1,25 l/ha	1,25 l/ha				
Maximum value	41.63	-	-	41.5 8	42.63	42.60	0 >	0 >				
Mean TKW (g)	41.63			41.5 8	42.63	42.60	1 =	1 =				
Mean %UTC	100,00%			99.8 8%	102.4 0%	102.3 3%	0 <	0 <				

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

*In 1 trial UTC was excluded from the statistical analysis

Lodging area and lodging angle (*Oculimacula acufiformis*)

Lodging area was assessed in 7 trials conducted in Poland. Additionally, in two trials lodging angle was assessed. In any of the conducted trials, whatever the dose rate of application considered, no significant impact on lodging area and lodging angle was observed.

Summary results are presented in Table 3.4-137 and Table 3.4-138.

Considering presented data, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact lodging in winter wheat.

Table 3.4-137: Summary table – Winter wheat - lodging area- North-East EPPO

Treatment name	UNTREATED CHECK	Protikon 250 EC	CA330 1	CA330 1	No of trials where CA3301	No of trials where CA3301
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Rate		0,8	0,6	0,8	at 0,6 l/ha is >, = or <		at 0,8 l/ha is >, = or <	
Rate unit		L/ha	L/ha	L/ha				
Appl. Code		A	A	A	compared to		compared to	
lodging area 61-80 DA-A								
Number of values	7	-	7	7	UT	CA3301	UT	CA3301
Minimum value	0	-	0	0	C	0,8 l/ha	C	0,6 l/ha
Maximum value	35	-	2,5	23,87	0 >	0 >	0 >	0 >
Lodging area (%)	9,1	-	0,5	3,4	7 =	7 =	7 =	7 =
		-			0 <	0 <	0 <	0 <
Number of values	7	7	7	7	Protikon 250		Protikon 250	
Minimum value	0	0	0	0	EC		EC	
Maximum value	35	2,5	2,5	23,87	0,8 l/ha		0,8 l/ha	
Lodging area (%)	9,1	0,4	0,5	3,4	7 =		7 =	
					0 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Table 3.4-138: Summary table – Winter wheat- lodging angle- North-East EPPO

Treatment name	UNTREATED CHECK	Protikon 250	CA33	CA33	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		EC	01	01				
Rate unit		0,8	0,6	0,8				
Appl. Code		L/ha	L/ha	L/ha				
lodging angle 61-80 DA-A								
Number of values	2	-	2	2	UT	CA3301	UT	CA3301
Minimum value	45,0	-	6,3	0	C	0,8 l/ha	C	0,6 l/ha
Maximum value	51,3	-	6,3	26,3	0 >	0 >	0 >	0 >
Lodging angle (0-90)	48,2	-	6,3	13,2	2 =	2 =	2 =	2 =
		-			0 <	0 <	0 <	0 <
Number of values	2	2	2	2	Protikon 250		Protikon 250	
Minimum value	45,0	0	6,3	0	EC		EC	
Maximum value	51,3	6,3	6,3	26,3	0,8 l/ha		0,8 l/ha	
Lodging angle (0-90)	48,2	3,2	6,3	13,2	0 >		0 >	
					2 =		2 =	
					0 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Mycotoxins (*Fusarium* species)

Detection levels from mycotoxins DON (Deoxynivalenol), NIV (Nivalenol), T-2 and HT-2 lab analysis were available in several trials on winter wheat. Only trials where the presence of mycotoxins was detected in untreated controls were considered valids and included.

Use of CA3301 in the Maritime EPPO zone

DON (10 trials)

Detection levels from mycotoxin (DON) lab analysis were very variable but CA3301 at 0.6 l/ha significantly reduced the DON level in 1 trial out of 9 compared to the untreated check and CA3301 at 0.8 l/ha significantly reduced it in 2 trials out of 9. In 1 trial out of 10, statistical analysis was not available.

No clear differences among treated samples were observed as CA3301 at 0.6 l/ha, CA3301 at 0.8 l/ha and CA2445 at 0.8 l/ha were always statistically equivalent. After application of CA3301 at 0.6-0.8 l/ha, 7 trials out of 10 had DON levels lower than the threshold of 1250 PPB (or 1.25 PPM) recommended by the Commission Regulation (EC) No 1881/2006 on soft winter wheat.

NIV (3 trials)

Detection levels from mycotoxin (NIV) lab analysis showed no significant differences between treatments in all 3 trials. NIV mycotoxins reached 85 to 150 PPB in the untreated check in the 3 trials. In one trial, CA3301 at 0.8 l/ha allowed a numerical reduction of the NIV level from 150 PPB in the untreated to 0 PPB, while 0.6 l/ha did not reduce the NIV level.

T-2, HT-2 (2 trials)

Detection levels from mycotoxin (T-2 and HT-2) lab analysis showed no significant differences among treated or untreated samples in these 2 trials. T-2 and HT-2 mycotoxins reached 150 PPB in all treatments, which is above the level of 100 PPB recommended by the European Commission (2013/165/EU) on unprocessed cereals.

Summary results are presented in Table 3.4-139.

Considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the mycotoxins levels in winter wheat in Maritime EPPO zone.

Table 3.4-139: Summary table – Winter wheat – Mycotoxins - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA2445	CA3301	CA3301	No of trials where CA3301			No of trials where CA3301		
Rate		0,8	0,6	0,8	at 0,6 l/ha is >, = or			at 0,8 l/ha is >, = or		
Rate unit		L/ha	L/ha	L/ha	<			<		
Appl. Code		AB	AB	AB	compared to			compared to		
DON (PPB) – 62-188 DA-B										
Number of values	10		10	10	UTC	CA3301		UTC		CA3301
Minimum value DON	97.50		0.00	0.00		0,8 l/ha		0,6 l/ha		
Maximum value DON	376750.00	-	107515.01	77195.01	1 >	0 >		2 >		0 >
Mean DON (PPB)	16850.22		13467.74	10122.84	8 =	8 =		7 =		8 =
Mean %UTC	100,00%		50.23 79.93%	52.61 60.08%	0 <	0 <		0 <		0 <
Number of values	9	9	9	9	CA2445			CA2445		
Minimum value DON	97.50	0.00	0.00	0.00	0,8 l/ha			0,8 l/ha		
Maximum value DON	376750.00	100437.51	107515.01	77.195.01	0 >			0 >		
Mean DON (PPB)	18816.40	14231.16	15124.77	11351.55	8 =			8 =		
Mean %UTC	100,00%	55.58 75.63%	48.49 80.38%	48.31 60.33%	0 <			0 <		
NIV (PPB) – 101-182 DA-B										
Number of values	3	3	3	3	UT	CA24	CA3	UT	CA24	CA3
Minimum value NIV	85.00	0.00	150.00	0.00	C	45 0,8 l/ha	301 0,8 l/ha	C	45 0,8 l/ha	301 0,6 l/ha
Maximum value NIV	150.00	150.00	197.50	150.00	0 >	0 >	0 >	0 >	0 >	0 >
Mean NIV (PPB)	128.33	100.00	165.83	100.00	3 =	3 =	3 =	3 =	3 =	3 =

Mean %UTC	100,00%	66.67 77.92%	144.12 129.22%	66.67 77.92 %	0 <	0 <	0 <	0 <	0 <	0 <
HT-2 (PPB) – 173-182 DA-B										
Number of values	2	2	2	2	UT	CA24 45	CA3 301	UT	CA24 45	CA3 301
Minimum value HT-2	150.00	150.00	150.00	150.0 0	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value HT-2	150.00	150.00	150.00	150.0 0	0 >	0 >	0 >	0 >	0 >	0 >
Mean HT-2 (PPB)	150.00	150.00	150.00	150.0 0	2 =	2 =	2 =	2 =	2 =	2 =
Mean %UTC	100,00%	100,00%	100,00%	100,0 0%	0 <	0 <	0 <	0 <	0 <	0 <
T-2 (PPB) – 52-86 DA-B										
Number of values	2	2	2	2	UT	CA24 45	CA3 301	UT	CA24 45	CA3 301
Minimum value T-2	150.00	150.00	150.00	150.0 0	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value T-2	150.00	150.00	150.00	150.0 0	0 >	0 >	0 >	0 >	0 >	0 >
Mean T-2 (PPB)	150.00	150.00	150.00	150.0 0	2 =	2 =	2 =	2 =	2 =	2 =
Mean %UTC	100,00%	100,00%	100,00%	100,0 0%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the Mediterranean EPPO zone

DON (7 trials)

Detection levels from mycotoxin (DON) lab analysis were very variable but CA3301 at 0.6-0.8 l/ha significantly reduced the DON level in 2 trials out of 7 compared to the untreated check.

No clear differences among treated samples were observed as CA3301 at 0.6 l/ha, CA3301 at 0.8 l/ha and CA2445 at 0.8 l/ha were always statistically equivalent. After application of CA3301 at 0.6-0.8 l/ha, 4 trials out of 7 had DON levels lower than the threshold of 1250 PPB recommended by the Commission Regulation (EC) No 1881/2006 on unprocessed soft winter wheat.

NIV (1 trial)

Detection levels from mycotoxin (NIV) lab analysis showed no significant differences between treatments in this trial. NIV mycotoxins reached 150 PPB in all the treatments.

T-2, HT-2 (1 and 2 trials)

Detection levels from mycotoxin (T-2 and HT-2) lab analysis showed no significant differences among treated or untreated samples in all valid trials.

HT-2 mycotoxins were under the threshold detection level (of 50 PPB) in 5 trials. These trials were removed from the analysis.

In the first trial HT-2 level reached 150 PPB in all treatments which is above the level of 100 PPB for the sum of HT-2 and T-2 recommended by the European Commission (2013/165/EU) on unprocessed cereal. In the last trial, HT-2 level reached 14.50, 0.25 and 15.25 PPB in the UTC, CA3301 at 0.6 l/ha and CA3301 at 0.8 l/ha respectively. It was below the recommended level of 100 PPB for the sum of HT-2 and T-2 since T-2 levels reached 0 PPB for this trial.

T-2 mycotoxins were under the threshold detection level (of 50 PPB) in 5 trials. These trials were removed from the analysis. In the last trial, T-2 level reached 150 PPB in all treatments which is above the level of 100 PPB recommended for the sum of HT-2 and T-2 by the European Commission (2013/165/EU) on unprocessed cereals.

Summary results are presented in Table 3.4-140.

Considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the mycotoxins levels in winter wheat in Mediterranean EPPO zone.

Table 3.4-140: Summary table – Winter wheat – Mycotoxins - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA2445	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		0,8	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
DON (PPB) – 52-141 DA-B										
Number of values	7	7	7	7	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value DON	119.00	94.25	89.50	71.75	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value DON	34213.25	28429.50	25362.75	23494.00	2 >	0 >	0 >	2 >	0 >	0 >
Mean DON (PPB)	7037.11	5024.36	4497.32	4249.25	5 =	7 =	7 =	5 =	7 =	7 =
Mean % UTC	100.00%	58.23 71.40%	49.01 63.91%	47.69 60.38%	0 <	0 <	0 <	0 <	0 <	0 <
NIV (PPB) – 52 DA-B										
Number of values	1	1	1	1	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value NIV	150.00	150.00	150.00	150.00	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value NIV	150.00	150.00	150.00	150.00	0 >	0 >	0 >	0 >	0 >	0 >
Mean NIV (PPB)	150.00	150.00	150.00	150.00	1 =	1 =	1 =	1 =	1 =	1 =
Mean % UTC	100.00%	100.00%	100.00%	100.00%	0 <	0 <	0 <	0 <	0 <	0 <
HT-2 (PPB)– 52-96 DA-B										
Number of values	2	2	2	2	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value HT-2	14.50	0.00	0.25	15.25	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value HT-2	150.00	150.00	150.00	150.00	0 >	0 >	0 >	0 >	0 >	0 >
Mean HT-2 (PPB)	82.25	75.00	75.13	82.63	2 =	2 =	2 =	2 =	2 =	2 =
Mean % UTC	100,00%	50.00 91.19%	50.86 91.34%	102.59 100.46%	0 <	0 <	0 <	0 <	0 <	0 <
T-2 (PPB)– 52 DA-B										
Number of values	1	1	1	1	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value T-2	150.00	150.00	150.00	150.00	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value T-2	150.00	150.00	150.00	150.00	0 >	0 >	0 >	0 >	0 >	0 >
Mean T-2 (PPB)	150.00	150.00	150.00	150.00	1 =	1 =	1 =	1 =	1 =	1 =
Mean % UTC	100,00%	100,00%	100,00%	100,00%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-Eastern EPPO zone

DON (8 trials)

Detection levels from mycotoxin (DON) lab analysis were very variable but CA3301 at 0.6 l/ha significantly reduced the DON level in 3 trials out of 8 compared to the untreated check and CA3301 at 0.8 l/ha reduced it in 4 trials out of 8.

No clear differences among treated samples were observed as CA3301 at 0.6 l/ha, CA3301 at 0.8 l/ha and CA2445 at 0.8 l/ha were always statistically equivalent. After application of CA3301 at 0.6-0.8 l/ha, 2 trials out of 8 had DON levels lower than the threshold of 1250 PPB recommended by the Commission Regulation (EC) No 1881/2006 on unprocessed soft winter wheat.

NIV (0 trial)

Mycotoxin (NIV) lab analysis was performed in 5 trials but were not detected in any of the 5 trials. Therefore these trials are not presented here.

T-2, HT-2 (1 trial)

T-2 mycotoxins were not detected in 1 trial with a value of 0 PPB, and under the threshold detection level of 50 PPB in 4 trials. These trials are not presented here.

HT-2 mycotoxins were not detected in 1 trial with a value of 0 PPB, and were not detectable or under the threshold detection level (of 50 PPB) in 3 trials.

In the last trial, HT-2 level reached 34.50, 1.00 and 13.25 PPB in the UTC, CA3301 at 0.6 l/ha and CA3301 at 0.8 l/ha respectively. It was below the level of 100 PPB for the sum of HT-2 and T-2 recommended by the European Commission (2013/165/EU) on unprocessed cereals with all treatments and untreated control.

Summary results are presented in Table 3.4-141.

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the mycotoxins levels in winter wheat in North-East ~~EPPO~~ EPPO zone.

Table 3.4-141: Summary table – Winter wheat – Mycotoxins – North-East ~~EPPO~~ EPPO zone

Treatment name	UNTREATED CHECK	CA2445	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		0,8	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
DON (PPB) – 55-176 DA-B										
Number of values	8	8	8	8	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value DON	56.61	40.45	0.00	0.00	3 >	0 >	0 >	4 >	0 >	0 >
Maximum value DON	100694.01	23629.13	30983.75	24093.25	5 =	8 =	8 =	3 =	8 =	8 =
Mean DON (PPB)	28235.40	8790.89	10725.40	8180.04	0 <	0 <	0 <	0 <	0 <	0 <
Mean %UTC	100.00%	48.65 31.13%	38.23 37.99%	33.11 28.97%						
HT-2 (PPB)– 116 DA-B										
Number of values	1	1	1	1	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value HT-2	34.50	7.13	1.00	13.25	0 >	0 >	0 >	0 >	0 >	0 >
Maximum value HT-2	34.50	7.13	1.00	13.25	1 =	1 =	1 =	1 =	1 =	1 =
Mean HT-2 (PPB)	34.50	7.13	1.00	13.25	0 <	0 <	0 <	0 <	0 <	0 <
Mean %UTC	100.00%	20.67%	2.90%	38.41 %						

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the South-Eastern EPPO zone

DON (11 trials)

Detection levels from mycotoxin (DON) lab analysis were very variable but CA3301 at 0.6 l/ha significantly reduced the DON level in 4 trials out of 11 compared to the untreated check and CA3301 at 0.8 l/ha reduced it in 6 trials out of 11.

No clear differences among treated samples were observed as CA3301 at 0.6 l/ha, CA3301 at 0.8 l/ha and CA2445 at 0.8 l/ha were always statistically equivalent. After application of CA3301 at 0.6-0.8 l/ha, respectively 3 trials out of 11 and 4 trials out of 11 had DON levels lower than the threshold of 1250 PPB recommended by the Commission Regulation (EC) No 1881/2006 on unprocessed soft winter wheat.

NIV (0 trial)

Mycotoxin (NIV) lab analysis was performed in 6 trials but were not detected in any of the 6 trials. Therefore these trials are not presented here.

T-2, HT-2 (0 trial)

T-2 and HT-2 mycotoxins were not detected in 2 trials with a value of 0 PPB, and not detectable or under the threshold level (of 50 PPB) in 3 trials. Therefore these trials are not presented here.

Summary results are presented Table 3.4-142.

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the mycotoxins levels in winter wheat.

Table 3.4-142: Summary table – Winter wheat – Mycotoxins – South-Eastern EPPO zone

Table 3-4-142. Summary table – Winter wheat – Mycotoxins – South-East – LAFC zone										
Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA2445 0,8 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
DON (PPB) – 87-211 DA-B										
Number of values	11	11	11	11	UT	CA24	CA33	UT	CA24	CA33
Minimum value DON	457.50	235.75	246.75	504.75	C	45 0,8 l/ha	01 0,8 l/ha	C	45 0,8 l/ha	01 0,6 l/ha
Maximum value DON	40856.53	8507.50	7687.50	10345.00	4 >	0 >	0 >	6 >	0 >	0 >
Mean DON (PPB)	9335.74	3616.12	3872.17	4077.92	7 =	11 =	11 =	5 =	11 =	11 =
Mean %UTC	100.00%	52.83 38.73%	56.70 41.48%	65.28 43.68%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Comments of zRMS:

No negative impact on the quality parameters of yield of winter wheat (moisture content, HLW, thousand kernel weight, mycotoxins) was observed after twice application of CA3301 at dose rate of 0,6-0,8 l/ha. A positive effect was visible in all EPPO climatic zones and no significant differences between test and reference product were detected. Also no adverse effect has been noted for moisture content, HLW, thousand kernel weight and lodging in additional efficacy trials conducted in 2023 in Poland.

3.4.3.5 Durum wheat (TRZDU)

Moisture content

Use of CA3301 in the Maritime EPPO zone

In the Maritime EPPO zone were harvested two trials on durum wheat established for the efficacy evaluation of CA3301 at 0.6-0.8 l/ha for the control of several foliar and ears diseases.

In these two trials CA3301 at 0.6-0.8 l/ha did not significantly affect the moisture content compared to the untreated control and was statistically equivalent to the reference product CA2445 at 0.8 l/ha (see Table 3.4-143). Moisture content in treated plots remained within the moisture standards for durum wheat.

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the moisture content in durum wheat in the Maritime EPPO zone.

Table 3.4-143: Summary table – Durum wheat – Moisture content – Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA244 5 0,8 L/ha AB	CA330 1 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Moisture content (%) – 62-71 DA-B										
Number of values	2	2	2	2	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	10,30	10,43	10,38	10,58	0 >	0 >	0 >	0 >	0 >	0 >
Maximum value	16,09	16,15	17,05	15,50	2 =	2 =	2 =	2 =	2 =	2 =
Mean Moisture content (%)	13,19	13,29	13,71	13,04	0 <	0 <	0 <	0 <	0 <	0 <
Mean %UTC	100,00%	100,82 %	103,37 %	99,53 %						

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the Mediterranean EPPO zone

In the Mediterranean EPPO zone were harvested five trial on durum wheat established for the efficacy evaluation of CA3301 at 0.6-0.8 l/ha for the control of several foliar and ears diseases.

In the majority of these trials CA3301 at 0.6-0.8 l/ha did not significantly affect the moisture content compared to the untreated control and was statistically equivalent to the reference product CA2445 at 0.8 l/ha and PROSARO at 1 l/ha, except for one trial were CA3301 at 0.6-0.8 l/ha showed kernel more dry respect the reference CA2445 at 0.8 l/ha (see Table 3.4-144). Moisture content in treated plots remained within the moisture standards for durum wheat.

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the moisture content in durum wheat in the Mediterranean EPPO zone

Table 3.4-144: Summary table – Durum wheat – Moisture content – Mediterranean EPPO zone

Table 3.4.14: Summary table – Barani wheat – Moisture content – Moisture content (%) – 62-76 DA-B											
Treatment name	UNTREATED CHECK	CA24 45	PRO- SARO	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		0,8	1	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	AB						
Moisture content (%) – 62-76 DA-B											
Number of values	5	5		5	5	UT C	CA24 45	CA33 01	UT C	CA24 45	CA33 01

Minimum value	10,41	10,75		10,22	9,94		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	15,83	16,05	-	15,87	16,16	0 >	0 >	0 >	0 >	0 >	0 >
Mean Moisture content (%)	12,08	12,35		11,99	11,97	5 =	4 =	5 =	5 =	4 =	5 =
Mean %UTC	100,00%	102,2 7%		99,12 %	98,70 %	0 <	1 <	0 <	0 <	1 <	0 <
Number of values	2	2	2	2	2	PROSARO 1 l/ha		PROSARO 1 l/ha			
Minimum value	10,86	10,75	11,01	10,79	10,94	0 >		0 >			
Maximum value	12,86	13,25	12,85	12,81	12,82	2 =		2 =			
Mean Moisture content (%)	11,86	12,00	11,93	11,80	11,88	0 <		0 <			
Mean %UTC	100,00%	101,0 1%	100,65%	99,48 %	100,2 1%						

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-East^{eff} EPPO zone

In the North-East^{eff} EPPO zone was set up one trial on durum wheat to evaluate the efficacy of CA3301 at 0.6-0.8 l/ha against *Fusarium spp.* In this trial was performed a *Fusarium spp.* inoculum on five groups of 10 ears per plot. At harvest were harvested 50 inoculated ears and then was harvested the half plot surface not inoculated. The data below present the moisture content values obtained for both types of harvest.

In this trial CA3301 at 0.6-0.8 l/ha did not significantly affect the moisture content compared to the untreated control and was statistically equivalent to the reference product CA2445 in both types of harvest, not inoculated kernel and inoculated kernels (see Table 3.4-145). Moisture content in treated plots remained within the moisture standards for durum wheat.

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the moisture content in durum wheat in the North-East^{eff} EPPO zone

Table 3.4-145: Summary table – Durum wheat – Moisture content – North-East^{eff} EPPO zone

Treatment name	UNTREATED CHECK	CA244 5	CA330 1	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to				No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		0,8	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
Moisture content (%) – Uninfected ears– 50 DA-B										
Number of values	1	1	1	1	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	13,20	13,15	12,88	13,05	0 >	0 >	0 >	0 >	0 >	0 >
Maximum value	13,20	13,15	12,88	13,05	1 =	1 =	1 =	1 =	1 =	1 =
Mean Moisture content (%)	13,20	13,15	12,88	13,05	1 =	1 =	1 =	1 =	1 =	1 =
Mean %UTC	100,00%	99,62 %	97,58 %	98,86 %	0 <	0 <	0 <	0 <	0 <	0 <
Moisture content (%) – Infected ears– 50 DA-B										
Number of values	1	1	1	1	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	12,18	12,23	12,18	12,08	0 >	0 >	0 >	0 >	0 >	0 >
Maximum value	12,18	12,23	12,18	12,08	1 =	1 =	1 =	1 =	1 =	1 =
Mean Moisture content (%)	12,18	12,23	12,18	12,08	1 =	1 =	1 =	1 =	1 =	1 =
Mean %UTC	100,00%	100,41 %	100,00 %	99,18 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the South-Eastern EPPO zone

In the South-Eastern EPPO zone were harvested six trials on durum wheat established for the efficacy evaluation of CA3301 at 0.6-0.8 l/ha for the control of several foliar and ears diseases.

In the majority of these trials CA3301 at 0.6-0.8 l/ha did not significantly affect the moisture content compared to the untreated control and was statistically equivalent to the reference product CA2445 at 0.8 l/ha and PRIAXOR at 1.5 l/ha, except for one trial where CA3301 at 0.6-0.8 l/ha showed kernel more dry respect the untreated check (see Table 3.4-146). Moisture content in treated plots remained within the moisture standards for durum wheat.

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the moisture content in durum wheat in the South-Eastern EPPO zone.

Table 3.4-146: Summary table – Durum wheat – Moisture content – South-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA244 5	PRI- AXOR	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		0,8	1,5	0,6	0,8				
Rate unit		L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB				
Moisture content (%) 49-60 DA-B									
Number of values	6			6	6	UT C	CA330 1 0,8 l/ha	UT C	CA330 1 0,6 l/ha
Minimum value	11,65			11,80	11,85	1 >	0 >	1 >	0 >
Maximum valeu	17,00	-	-	16,50	16,43	5 =	6 =	5 =	6 =
Mean Moisture content (%)	13,51			13,64	13,51	5 =	6 =	5 =	6 =
Mean % UTC	100,00%			101,03 %	100,19 %	0 <	0 <	0 <	0 <
Number of values	4	4		4	4	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	11,65	11,80		11,80	11,80	0 >		0 >	
Maximum valeu	17,00	16,28	-	16,50	16,43	4 =		4 =	
Mean Moisture content (%)	13,73	13,66		13,88	13,70	4 =		4 =	
Mean % UTC	100,00%	99,90 %		101,45 %	100,07 %	0 <		0 <	
Number of values	2		2	2	2	PROSARO 1 l/ha		PROSARO 1 l/ha	
Minimum value	12,95		12,98	12,98	12,90	1 l/ha		1 l/ha	
Maximum valeu	13,23	-	13,35	13,25	13,40	0 >		0 >	
Mean Moisture content (%)	13,09		13,16	13,12	13,15	2 =		2 =	
Mean % UTC	100,00%		100,60%	100,19 %	100,45 %	0 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

HLW (Hectolitre Weight / Grain specific weight)

Use of CA3301 in the Maritime EPPO zone

In the Maritime EPPO zone were harvested two trials on durum wheat established for the efficacy evaluation of CA3301 at 0.6-0.8 l/ha for the control of several foliar and ears diseases.

The levels of grain specific weight observed were in compliance with the standards for durum wheat.

In these two trials CA3301 at 0.6-0.8 l/ha did not significantly affect the grain specific weight compared to the untreated control and was statistically equivalent to the reference product CA2445 at 0.8 l/ha (see Table 3.4-147).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at

a rate of 0.6-0.8 l/ha will not negatively impact the grain specific weight in durum wheat in the Maritime EPPO zone.

Table 3.4-147: Summary table – Durum wheat – HLW (kg/hL) – Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA24 45	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, =, or < compared to			No of trials where CA3301 at 0,8 l/ha is >, =, or < compared to		
Rate		0,8	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
Grain Specific Weight (kg/hl) – 62-71 DA-B										
Number of values	2	2	2	2	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	72,41	70,51	73,25	73,13	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	78,75	81,08	80,35	80,70	0 >	0 >	0 >	0 >	0 >	0 >
Mean Specific Weight (kg/hl)	75,56	74,69	76,33	76,83	2 =	2 =	2 =	2 =	2 =	2 =
Mean %UTC	100,00%	101,41 %	99,77 %	101,12 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the Mediterranean EPPO zone

In the Mediterranean EPPO zone were harvested five trials on durum wheat established for the efficacy evaluation of CA3301 at 0.6-0.8 l/ha against several foliar and ears diseases.

The levels of grain specific weight observed were in compliance with the standards for durum wheat.

In two trials, CA3301 at 0.6-0.8 l/ha statistically improved the grain specific weight as well as the reference CA2445 at 0.8 l/ha compared to the untreated control. In the other three trials CA3301 at 0.6-0.8 l/ha did not significantly affect the grain specific weight compared to the untreated control and was statistically equivalent to the reference product CA2445 at 0.8 l/ha and PROSARO at 1 l/ha (see Table 3.4-148).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the grain specific weight in durum wheat and might have a positive effect on the HLW in the Mediterranean EPPO zone.

Table 3.4-148: Summary table – Durum wheat – HLW (kg/hL) – Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA24 45	PRO- SARO	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		0,8	1	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	AB						
Grain Specific Weight (kg/hl) – 62-76 DA-B											
Number of values	5	5		5	5	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	72,41	70,51		73,13	73,54	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	78,75	81,08	-	80,70	81,10	2 >	0 >	0 >	2 >	0 >	0 >
Mean Specific Weight (kg/hl)	75,56	74,69		76,83	77,03	3 =	5 =	5 =	3 =	5 =	5 =
Mean %UTC	100,00%	98,85 %		101,6 8%	101,9 3%	0 <	0 <	0 <	0 <	0 <	0 <
Number of values	2	2	2	2	2	PROSARO			PROSARO		
Minimum value	73,98	70,51	76,18	75,80	75,20	1 l/ha			1 l/ha		
Maximum value	77,03	70,83	76,65	76,68	77,30	0 >			0 >		
Mean Specific Weight (kg/hl)	75,51	70,67	76,42	76,24	76,25	2 =			2 =		
Mean %UTC	100,00%	93,64 %	101,24%	101,0 0%	101,0 0%	0 <			0 <		

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

In the North-Eastern EPPO zone was set up one trial on durum wheat to evaluate the efficacy of CA3301 at 0.6-0.8 l/ha against *Fusarium spp.* In this trial was performed a *Fusarium spp.* inoculum on five groups of 10 ears per plot. At harvest were harvested 50 inoculated ears and then was harvested the half plot surface not inoculated.

The levels of grain specific weight observed were in compliance with the standards for durum wheat. CA3301 at 0.6-0.8 l/ha did not significantly affect the grain specific weight compared to the untreated control and was statistically equivalent to the reference product CA2445 at 0.8 l/ha (see Table 3.4-149).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the grain specific weight in durum wheat in the North-East EPPZ zone.

Treatment name	UNTREATED CHECK	CA24 45	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or <				No of trials where CA3301 at 0,8 l/ha is >, = or <		
Rate		0,8	0,6	0,8							
Rate unit		L/ha	L/ha	L/ha							
Appl. Code		AB	AB	AB	compared to				compared to		
Grain Specific Weight (kg/hl) – 50 DA-B											
Number of values	1	1	1	1	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01	
Minimum value	74,18	71,70	72,53	73,50	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha	
Maximum value	74,18	71,70	72,53	73,50	0 >	0 >	0 >	0 >	0 >	0 >	
Mean Specific Weight (kg/hl)	74,18	71,70	72,53	73,50	1 =	1 =	1 =	1 =	1 =	1 =	
Mean %UTC	100,00%	96,66 %	97,78 %	99,08 %	0 <	0 <	0 <	0 <	0 <	0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

The grain specific weight was recorded in 1 trial implemented to evaluate the effectiveness of CA3301 at 0.6-0.8 l/ha against *Fusarium graminearum* the South-Eastern EPPO zone.

In this trial, 50 inoculated ears were harvested. The application of CA3301 at 0.6-0.8 l/ha had no negative impact on the grain specific weight of durum wheat and had a significant positive effect compared to the untreated check on infected kernel with an augmentation of 11.14-15.88% equivalent to the standard CA2445 at 0.8 l/ha with 18.05%. Also on uninoculated kernel was observed a light augmentation of grain specific weight even if no significant differences appeared versus the untreated check (see Table 3.4-150).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the grain specific weight in durum wheat when affected by *Fusarium graminearum* and might have a positive effect on the HLW in the South-Eastern EPPo zone.

South-Eastern ETPG Zone						
Treatment name	UNTREATED CHECK	CA24	CA33	CA33	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Rate		0,8	0,6	0,8		
Rate unit		L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB		
Grain Specific Weight (kg/hl) 59 DA-B Uninfected kernel						

Number of values	1	1	1	1	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	70,73	70,88	75,70	73,48						
Maximum value	73,73	70,88	75,70	73,48	0 >	0 >	0 >	0 >	0 >	0 >
Mean Specific Weight (kg/hl)	70,73	70,88	75,70	73,48	1 =	1 =	1 =	1 =	1 =	1 =
Mean % UTC	100,00%	100,21 %	107,03 %	103,89 %	0 <	0 <	0 <	0 <	0 <	0 <
Grain Specific Weight (kg/hl) 59 DA-B Infected kernel										
Number of values	1	1	1	1	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value	63,28	74,70	70,33	73,33						
Maximum value	63,28	74,70	70,33	73,33	0 >	0 >	0 >	1 >	0 >	0 >
Mean Specific Weight (kg/hl)	63,28	74,70	70,33	73,33	1 =	1 =	1 =	0 =	1 =	1 =
Mean % UTC	100,00%	118,05 %	111,14 %	115,88 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 against **all other disease** in the South-Eastern EPPO zone

The grain specific weight was recorded also in five trials implemented to evaluate the effectiveness of CA3301 at 0.6-0.8 l/ha against foliar disease in the South-Eastern EPPO zone.

The levels of grain specific weight observed were in compliance with the standards for durum wheat. In two trials, CA3301 at 0.6-0.8 l/ha statistically improved the grain specific weight as well as the reference CA2445 at 0.8 l/ha and PRIAXOR at 1.5 l/ha compared to the untreated control. In the other three trials CA3301 at 0.6-0.8 l/ha did not significantly affect the grain specific weight compared to the untreated control and was statistically equivalent to the reference product CA2445 at 0.8 l/ha and PRIAXOR at 1.5 l/ha (see Table 3.4-151).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the grain specific weight in durum wheat when affected by foliar diseases and might have a positive effect on the HLW in the South-Eastern EPPO zone.

Table 3.4-151: Summary table – Durum wheat – HLW (kg/hL) in all other disease trials South-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA244 5	PRI- AXOR	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		0,8	1,5	0,6	0,8				
Rate unit		L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB				
Grain Specific Weight (kg/100L) 56-74									
Number of values	5			5	5	UT C	CA330 1 0,8 l/ha	UT C	CA330 1 0,6 l/ha
Minimum value	76,65	-	-	75,70	76,75				
Maximum value	81,63			82,43	82,50	2 >	0 >	2 >	0 >
Mean Specific Weight (kg/hl)	80,11			80,42	80,76	3 =	5 =	3 =	5 =
Mean % UTC	100,00%			100,32 %	100,17 %	0 <	0 <	0 <	0 <
Number of values	3	3	-	3	3	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	76,65	76,65	-	76,20	75,50				
Maximum value	81,63	81,73		82,43	82,50	0 >		0 >	
Mean Specific Weight (kg/hl)	80,57	79,79		80,08	79,96	3 =		3 =	

Mean % UTC	100,00%	99,97 %		100,32 %	100,17 %	0 <	0 <
Number of values	2		2	2	2	PROSARO 1 l/ha	PROSARO 1 l/ha
Minimum value	80,04	-	81,15	80,86	81,33		
Maximum value	81,09		81,55	81,52	81,56	0 >	0 >
Mean Specific Weight (kg/hl)	80,57		81,35	81,19	81,45	2 =	2 =
Mean % UTC	100,00%		100,98%	100,78 %	101,10 %	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

TKW (Thousand Kernel Weight)

Use of CA3301 in the Maritime EPPO zone

In the Maritime EPPO zone were harvested two trial on durum wheat established for the efficacy evaluation of CA3301 at 0.6-0.8 l/ha for the control of several foliar and ear diseases.

The levels of thousand grain weight observed were in compliance with the standards for durum wheat. In these two trials CA3301 at 0.6-0.8 l/ha did not significantly affect the thousand kernel weight compared to the untreated control and was statistically equivalent to the reference product CA2445 at 0.8 l/ha (see Table 3.4-152).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the thousand grain weight in durum wheat in the Maritime EPPO zone.

Table 3.4-152: Summary table – Durum wheat – TKW (g/1000 grains) – Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA244 5	CA330 1	CA330 1	No of trials where CA3301			No of trials where CA3301		
Rate		0,8	0,6	0,8	at 0,6 l/ha is >, = or <			at 0,8 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
Thousand kernel weight (g) – 51-77 DA-B										
Number of values	2	2	2	2	UT C	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UT C	CA244 5 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	44,90	46,30	45,16	45,15						
Maximum value	50,39	51,54	50,98	51,24	0 >	0 >	0 >	0 >	0 >	0 >
Mean TKW (g)	47,65	48,92	48,07	48,19	2 =	2 =	2 =	2 =	2 =	2 =
Mean %UTC	100,00%	102,70 %	100,87 %	101,31 %	0 <	0 <	0 <	0 <	0 <	0 <

Use of CA3301 in the Mediterranean EPPO zone

In the Mediterranean EPPO zone five trials were harvested on durum wheat after the efficacy evaluation of CA3301 at 0.6-0.8 l/ha for the control of several foliar and ear diseases.

The levels of thousand grain weight observed were in compliance with the standards for durum wheat. Only in one trial CA3301 at 0.6l/ha improved significantly the thousand kernel weight, compared to untreated plots, but was comparable to other treated plots. In the other four trials CA3301 at 0.6-0.8 l/ha did not significantly affect this quality parameter compared to the untreated control and was statistically equivalent to the reference product CA2445 at 0.8 l/ha and PROSARO at 1 l/ha (see Table 3.4-153).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the thousand grain weight and might have a positive effect in durum wheat in the Mediterranean EPPO zone.

Table 3.4-153: Summary table – Durum wheat – TKW (g/1000 grains) – Mediterranean EPPO zone

Treatment name	UN-TREATED CHECK	CA2445	PRO-SARO	CA3301	CA3301	No of trials where CA3301	No of trials where CA3301
Rate		0,8	1	0,6	0,8	at 0,6 l/ha is >, = or	at 0,8 l/ha is >, = or
Rate unit		L/ha	L/ha	L/ha	L/ha	<	<
Appl. Code		AB	AB	AB	AB	compared to	compared to
Thousand kernel weight (g) – 70-87 DA-B							
Number of values	5	5		5	5	UTC	UTC
Minimum value	35,78	37,67	-	37,63	37,22	CA2 445 0,8 l/ha	CA3 301 0,8 l/ha
Maximum value	47,20	46,82		49,31	48,74	1 >	1 >
Mean TKW (g/)	43,38	44,40		45,20	44,53	4 =	4 =
Mean % UTC	100,00%	102,56%		104,27%	102,75%	0 <	0 <
Number of values	2	2	2	2	2	PROSARO	
Minimum value	47,04	46,37	47,29	48,09	46,57	1 l/ha	
Maximum value	47,20	46,82	49,52	49,31	48,74	0 >	
Mean TKW (g/)	47,12	46,60	48,41	48,70	47,66	2 =	
Mean % UTC	100,00%	98,89%	102,73%	102,87%	101,14%	0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-East EPPO zone

In the North-East EPPO zone was undertaken one trial on durum wheat to evaluate the efficacy of CA3301 at 0.6-0.8 l/ha against *Fusarium spp.* In this trial was performed a *Fusarium spp* inoculum on five groups of 10 ears per plot. At harvest were harvested 50 inoculated ears and then was harvested the half plot surface not inoculated.

The levels of thousand grain weight observed were in compliance with the standards for durum wheat. In this trial the thousand kernel weight was recorded on uninfected kernel and infected kernel. CA3301 at 0.6-0.8 l/ha did not significantly affect this quality parameter compared to the untreated control and was statistically equivalent to the reference product CA2445 at 0.8 l/ha (see Table 3.4-154).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the thousand grain weight on durum wheat in the North-East EPPO zone.

Table 3.4-154: Summary table – Durum wheat – TKW (g/1000 grains) – North-East EPPO zone

Treatment name	UNTREATED CHECK	CA2445	CA3301	CA3301	No of trials where CA3301	No of trials where CA3301
Rate		0,8	0,6	0,8	at 0,6 l/ha is >, = or <	at 0,8 l/ha is >, = or <
Rate unit		L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	compared to	compared to
Thousand kernel weight (g) – Uninfected ears - 50 DA-B						
Number of values	1	1	1	1	UT C	UT C
Minimum value	48,20	48,83	49,08	48,93	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha
Maximum value	48,20	48,83	49,08	48,93	0 >	0 >
Mean TKW (g)	48,20	48,83	49,08	48,93	1 =	1 =
Mean % UTC	100,00%	101,31 %	101,83 %	101,51 %	0 <	0 <
Thousand kernel weight (g) – Infected ears - 50 DA-B						
Number of values	1	1	1	1	UT C	UT C
Minimum value	40,95	39,85	43,18	41,18	CA244 5 0,8 l/ha	CA330 1 0,6 l/ha

Maximum value	49,95	39,85	43,18	41,18	0 >	0 >	0 >	0 >	0 >	0 >
Mean TKW (g)	40,95	39,85	43,18	41,18	1 =	1 =	1 =	1 =	1 =	1 =
Mean % UTC	100,00%	97,31%	105,45 %	100,56 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 against *Fusarium graminearum* in the South-Eastern EPPO zone

The thousand kernel weight was recorded in 1 trial implemented to evaluate the effectiveness of CA3301 at 0.6-0.8 l/ha against *Fusarium graminearum* the South-Eastern EPPO zone.

In this trial, 50 inoculated ears were harvested. The application of CA3301 at 0.6-0.8 l/ha had no negative impact on the thousand grain weight of durum wheat and had a significant positive effect compared to the untreated check on infected kernel with an augmentation of 11.05-15.46% equivalent to the standard CA2445 at 0.8 l/ha with 17.28%. Also on uninoculated kernel was observed a light augmentation of thousand grain weight even if no significant differences appeared versus the untreated check (see Table 3.4-155).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the thousand grain weight and might have a positive effect in durum wheat when infected by *Fusarium graminearum* in the South-Eastern EPPO zone.

Table 3.4-155: Summary table – Durum wheat – TKW (g/1000 grains) – *Fusarium graminearum* trial in South-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA244 5	CA330 1	CA330 1	No of trials where CA3301			No of trials where CA3301		
Rate		0,8	0,6	0,8	at 0,6 l/ha is >, = or <			at 0,8 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
Thousand Kernel Weight (g) 59 DA-B Uninfected kernel										
Number of values	1	1	6	6	UT C	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UT C	CA244 5 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	46,18	49,30	53,08	53,03						
Maximum value	46,18	49,30	53,08	53,03	0 >	0 >	0 >	0 >	0 >	0 >
TKW (g)	46,18	49,30	53,08	53,03	1 =	1 =	1 =	1 =	1 =	1 =
Mean % UTC	100,00%	106,76 %	114,94 %	114,83 %	0 <	0 <	0 <	0 <	0 <	0 <
Thousand kernel weight (g) 59 DA-B Infected kernel										
Number of values	1	1	1	1	UT C	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UT C	CA244 5 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	40,10	47,03	44,53	46,30						
Maximum value	40,10	47,03	44,53	46,30	0 >	0 >	0 >	1 >	0 >	0 >
TKW (g)	40,10	47,03	44,53	46,30	1 =	1 =	1 =	0 =	1 =	1 =
Mean % UTC	100,00%	117,28 %	111,05 %	115,46 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 against all other disease in the South-Eastern EPPO zone

The thousand grain weight was recorded also in five trials implemented to evaluate the effectiveness of CA3301 at 0.6-0.8 l/ha against foliar disease in the South-Eastern EPPO zone.

The levels of thousand grain weight observed were in compliance with the standards for durum wheat. In two trials CA3301 at 0.6-0.8 l/ha improved significantly the thousand kernel weight, compared to untreated plots and equivalent to reference products. In the other four trials CA3301 at 0.6-0.8 l/ha did

not significantly affect this quality parameter compared to the untreated control and was statistically equivalent to the reference product CA2445 at 0.8 l/ha and PRIAXOR at 1.5 l/ha (see Table 3.4-156).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the thousand grain weight and might have a positive effect in durum wheat affected by foliar diseases in the South-East^{err} EPPO zone.

Table 3.4-156: Summary table – Durum wheat – TKW (g) in all other disease trials South-East^{err} EPPO zone

Treatment name	UNTREATED CHECK	CA24 45	PRI-AXOR	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		0,8	1,5	0,6	0,8				
Rate unit		L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB				
Thousand kernel weight (g) – 56-74 DA-B									
Number of values	5			5	5	UT	CA33 01	UT	CA33 01
Minimum value	39,93	-	-	38,35	39,75	C	0,8 l/ha	C	0,6 l/ha
Maximum valeu	47,02			49,78	49,95	2 >	0 >	2 >	0 >
Mean Thousand kernel weight (g)	44,38			45,35	45,63	3 =	5 =	3 =	5 =
Mean % UTC	100,00%			101,97 %	102,70 %	0 <	0 <	0 <	0 <
Number of values	3	3		3	3	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	39,93	36,70	-	38,35	39,75	0 >		0 >	
Maximum valeu	47,02	49,11		49,70	49,26	3 =		3 =	
Mean Thousand kernel weight (g)	43,14	42,88		43,43	44,07	0 <		0 <	
Mean % UTC	100,00%	99,06 %		100,40 %	102,01 %				
Number of values	2		2	2	2	PROSARO 1 l/ha		PROSARO 1 l/ha	
Minimum value	46,20	-	48,27	46,68	45,96	0 >		0 >	
Maximum valeu	46,27		50,31	49,78	49,95	2 =		2 =	
Mean Thousand kernel weight (g)	46,24		49,29	48,23	47,96	0 <		0 <	
Mean % UTC	100,00%		106,61%	104,32 %	103,72 %				

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Mycotoxins (Fusarium species)

Detection levels from mycotoxins DON (Deoxynivalenol) and NIV (Nivalenol) lab analysis were available only in two trials on durum wheat, one trial performed in Poland in 2018 for the North-East^{err} EPPO zone and one trial performed in Hungary in 2018 for the South-East^{err} EPPO zone.

Use of CA3301 in the North-East^{err} EPPO zone

DON (Deoxynivalenol)

Detection levels from mycotoxin (DON) lab analysis on infected kernel in the trial did not notice any statistical differences on DON content on inoculated ears between treated or untreated plots, but CA3301 at 0.6-0.8 l/ha and the reference CA2445 significantly reduced the DON level but not under the legal limit on durum wheat (1750 PPB Reg. EU 2016/239).

Obviously, this tendency was more evident in uninfected kernels where all treatments and untreated were acceptable because DON levels were under the legal limits (see Table 3.4-157). In this trial was evident the efficacy of CA3301 at 0.6-0.8 l/ha as well as the reference product CA2445 at 0.8 l/ha for the reduction on DON levels on durum wheat compared to the untreated check, as all treatments significantly reduced DON levels and were statistically comparable to each other .

NIV (Nivalenol)

Detection levels from mycotoxin (NIV) lab analysis showed no significant differences between treatments and untreated control but CA3301 at 0.8 l/ha allowed a reduction of the NIV level from 202.5 PPB in the untreated to 27.5 PPB, while 0.6 l/ha reduced the NIV level only until 155 PPB on infected kernels, which was comparable to the reference product CA2445 at 165 PPB (see Table 3.4-157). On uninfected kernels CA3301 at 0.6-0.8 l/ha provided a complete absence of NIV level as well as reference CA2445 at 0.8 l/ha versus 27.5 PPB in untreated check.

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the mycotoxins levels in durum wheat but might have a positive effect, in the North-Eastern EPPO zone.

Table 3.4-157: Summary table – Durum wheat – Mycotoxins – North-Eastern EPPO zone

Table 3-4-137. Summary table – Durum wheat – Mycotoxins – North-East – ETCO zone										
Treatment name	UNTREATED CHECK	CA244 5	CA330 1	CA330 1	No of trials where CA3301			No of trials where CA3301		
Rate		0,8	0,6	0,8	at 0,6 l/ha is >, = or <			at 0,8 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
DON (PPB)- Infected ears – 50 DA-B										
Number of values	1	1	1	1	UT	CA244	CA330	UT	CA244	CA330
Minimum value DON	20342,50	15942,5 0	12547,5 0	12625,0 0	C	5 0,8 l/ha	1 0,8 l/ha	C	5 0,8 l/ha	1 0,6 l/ha
Maximum value DON	20342,50	15942,5 0	12547,5 0	12625,0 0	0 >	0 >	0 >	0 >	0 >	0 >
Mean DON (PPB)	20342,50	15942,5 0	12547,5 0	12625,0 0	1 =	1 =	1 =	1 =	1 =	1 =
Mean %UTC	100,00%	78,37%	61,68%	62,06%	0 <	0 <	0 <	0 <	0 <	0 <
DON (PPB) – Uninfected ears – 50 DA-B										
Number of values	1	1	1	1	UT	CA244	CA330	UT	CA244	CA330
Minimum value DON	257,50	0,00	0,00	0,00	C	5 0,8 l/ha	1 0,8 l/ha	C	5 0,8 l/ha	1 0,6 l/ha
Maximum value DON	257,50	0,00	0,00	0,00	1 >	0 >	0 >	1 >	0 >	0 >
Mean DON (PPB)	257,50	0,00	0,00	0,00	0 =	1 =	1 =	0 =	1 =	1 =
Mean %UTC	100,00%	0,00%	0,00%	0,00%	0 <	0 <	0 <	0 <	0 <	0 <
NIV (PPB)- Infected ears – 50 DA-B										
Number of values	1	1	1	1	UT	CA244	CA330	UT	CA244	CA330
Minimum value NIV	202,50	165,00	155,00	27,50	C	5 0,8 l/ha	1 0,8 l/ha	C	5 0,8 l/ha	1 0,6 l/ha
Maximum value NIV	202,50	165,00	155,00	27,50	0 >	0 >	0 >	0 >	0 >	0 >
Mean NIV (PPB)	202,50	165,00	155,00	27,50	1 =	1 =	1 =	1 =	1 =	1 =
Mean %UTC	100,00%	81,48%	76,54%	13,58%	0 <	0 <	0 <	0 <	0 <	0 <
NIV (PPB)- Uninnfected ears – 50 DA-B										
Number of values	1	1	1	1	UT	CA244	CA330	UT	CA244	CA330
Minimum value NIV	27,50	0,00	0,00	0,00	C	5 0,8 l/ha	1 0,8 l/ha	C	5 0,8 l/ha	1 0,6 l/ha
Maximum value NIV	27,50	0,00	0,00	0,00	0 >	0 >	0 >	0 >	0 >	0 >
Mean NIV (PPB)	27,50	0,00	0,00	0,00	1 =	1 =	1 =	1 =	1 =	1 =
Mean %UTC	100,00%	0,00%	0,00%	0,00%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the South-Eastern EPPO zone

DON (Deoxynivalenol)

Detection levels from mycotoxin (DON) lab analysis on infected kernel in the trial EU18-040-13 showed the acceptable efficacy of CA3301 at 0.6-0.8 l/ha for the reduction of DON levels on durum wheat. CA3301 at 0.6-0.8 l/ha reduced significantly the DON levels under the threshold both for infected kernels and uninfected kernels, compared to the untreated check, and was comparable to the reference product CA2445 at 0.8 l/ha (see Table 3.4-158).

In addition, no Nivalenol (NIV) was detected in this trial.

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the mycotoxins levels in durum wheat but might have a positive effect in the South-Eastern EPPO zone.

Table 3.4-158: Summary table – Durum wheat – Mycotoxins – South-Eastern EPPO zone

Table 3.4-136. Summary table – Durum wheat – Mycotoxins – South-Eastern EU zone										
Treatment name	UNTREATED CHECK	CA244 5	CA330 1	CA330 1	No of trials where CA3301			No of trials where CA3301		
Rate		0,8	0,6	0,8	at 0,6 l/ha is >, = or <			at 0,8 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
DON (PPB)- Infected ears – 59 DA-B										
Number of values	1	1	1	1	UT C	CA244 5	CA330 1	UT C	CA244 5	CA330 1
Minimum value DON	12287,50	1015,0 0	2052,5 0	1535,0 0		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value DON	12287,50	1015,0 0	2052,5 0	1535,0 0	1 >	0 >	0 >	1 >	0 >	0 >
Mean DON (PPB)	12287,50	1015,0 0	2052,5 0	1535,0 0	0 =	1 =	1 =	0 =	1 =	1 =
Mean %UTC	100,00%	8,26%	16,70 %	12,49 %	0 <	0 <	0 <	0 <	0 <	0 <
DON (PPB) – Uninfected ears – 59 DA-B										
Number of values	1	1	1	1	UT C	CA244 5	CA330 1	UT C	CA244 5	CA330 1
Minimum value DON	6545,00	347,50	850,00	517,50		0,8 l/ha	0,8 l/ha		0,8 l/ha	0,6 l/ha
Maximum value DON	6545,00	347,50	850,00	517,50	1 >	0 >	0 >	1 >	0 >	0 >
Mean DON (PPB)	6545,00	347,50	850,00	517,50	0 =	1 =	1 =	0 =	1 =	1 =
Mean %UTC	100,00%	5,31%	12,99 %	7,91%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Comments of zRMS:

No negative impact on the quality parameters of yield of durum wheat (moisture content, HLW, thousand kernel weight, mycotoxins) was observed after twice application of CA3301 at dose rate of 0,6-0,8 l/ha. A positive effect was visible in all EPPO climatic zones and no significant differences between test and reference product were detected.

3.4.3.6 Triticale (TTLWI)

Moisture content

Use of CA3301 in the Maritime EPPO zone

In the Maritime EPPO zone were harvested nine trials on triticale established for the efficacy evaluation of CA3301 at 0.6-0.8 l/ha for the control of several foliar and ear diseases.

In these nine trials CA3301 at 0.6-0.8 l/ha did not significantly affect the moisture content compared to the untreated control and was statistically equivalent to the reference product CA2445 at 0.8 l/ha (see Table 3.4-159).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the moisture content in triticale in the Maritime EPPO zone.

Table 3.4-159: Summary table - Moisture content– Triticale (TTLWI) – Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA224 5	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate		0,8	0,6	0,8						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB						
% Moisture content 61-88 DA-B										
Number of values	9	9	9	9	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	7,60	7,78	7,60	7,78	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	15,96	16,10	15,98	16,13	0 >	0 >	0 >	0 >	0 >	0 >
Mean Moisture content (%)	11,06	11,19	11,15	11,15	9 =	9 =	9 =	9 =	9 =	9 =
Mean %UTC	100,0%	101,30 %	100,89 %	100,90 %	0 <	0 <	0 <	0 <	0 <	0 <

Use of CA3301 in the Mediterranean EPPO zone

In the Mediterranean EPPO zone were harvested four trials on triticale established for the efficacy evaluation of CA3301 at 0.6-0.8 l/ha for the control of several foliar and ear diseases.

In all trials CA3301 at 0.6-0.8 l/ha did not significantly affect the moisture content compared to the untreated control and was statistically equivalent to the reference product CA2445 (see Table 3.4-160).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the moisture content in triticale in the Mediterranean EPPO zone.

Table 3.4-160: Summary table - Moisture content– Triticale (TTLWI) – Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA24 45 0,8 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate										
Rate unit										
Appl. Code										
Moistue content (%) - 78-84 DA-B										
Number of values	4	4	4	4	UT	CA24 45	CA33 01	UT	CA24 45	CA33 01
Minimum value	10,58	10,93	10,90	10,91	C	0,8 l/ha	0,8 l/ha	C	0,8 l/ha	0,6 l/ha
Maximum value	17,23	16,80	16,68	16,08	0 >	0 >	0 >	0 >	0 >	0 >
Mean Moisture content (%)	13,78	13,32	13,54	12,98	4 =	4 =	4 =	4 =	4 =	4 =
Mean %UTC	100,00%	97,05 %	98,70 %	94,89 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-Eastern EPPO zone

In the North-Eastern EPPO zone were set up six trials on triticale to evaluate the efficacy of CA3301 at 0.6-0.8 l/ha against foliar and ear diseases. Five trials were harvested to determine the yield and the quality of grains.

In these trials CA3301 at 0.6-0.8 l/ha did not significantly affect the moisture content compared to the untreated control and was statistically equivalent to the reference product CA2445 at 0.8 l/ha, and compared to OSIRIS 65 EC at 2 l/ha except 1 trial where CA3301 at 0.6 l/ha gave significantly higher moisture content (see Table 3.4-161).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the moisture content in triticale in the North-East^{eff} EPPO zone.

Table 3.4-161: Summary table - Moisture content– Triticale (TTLWI) – North-East^{eff} EPPO zone

Treatment name	UNTREATED CHECK	CA2445	OSIRIS 65 EC	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or <		No of trials where CA3301 at 0,8 l/ha is >, = or <	
Rate		0,8	2	0,6	0,8				
Rate unit		L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB	compared to		compared to	
Moistue content (%) - 57-72 DA-B									
Number of values	5			5	5	UT C	CA3301 at 0.8 l/ha	UT C	CA3301 at 0.6 l/ha
Minimum value	10,18			10,40	10,55				
Maximum value	12,98	-	-	12,85	12,95	0 >	0 >	0 >	0 >
Mean Moisture content (%)	11,64			11,72	11,59	5 =	5 =	5 =	5 =
Mean %UTC	100,00%			100,76%	99,66%	0 <	0 <	0 <	0 <
Number of values	3	3		3	3	CA2445 at 0.8 l/ha		CA2445 at 0.8 l/ha	
Minimum value	11,88	11,95		11,78	11,65				
Maximum value	12,98	12,70	-	12,85	12,95	0 >		0 >	
Mean Moisture content (%)	12,38	12,32		12,40	12,28	3 =		3 =	
Mean %UTC	100,00%	99,34%		100,15%	99,20%	0 <		0 <	
Number of values	2		2	2	2	OSIRIS at 2 l/ha		OSIRIS at 2 l/ha	
Minimum value	10,18		9,75	10,40	10,55				
Maximum value	10,90	-	10,33	11,03	10,58	1 >		0 >	
Mean Moisture content (%)	10,54		10,04	10,72	10,57	1 =		2 =	
Mean %UTC	100,00%		95,46%	101,68%	100,36 %	0 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the South-East^{eff} EPPO zone

In the South-East^{eff} EPPO zone were set up seven trials on triticale to evaluate the efficacy of CA3301 at 0.6-0.8 l/ha against *foliar and ear* diseases.

In 4 trials out of 7, CA3301 at 0.6-0.8 l/ha did not significantly affect the moisture content compared to the untreated control and in three trials the untreated showed more dry grain than treated treatments because the disease symptoms may have induced early drying. In all trials the moisture content of plots treated with CA3301 was statistically equivalent to the reference products CA2445, PRIAXOR and NATIVO PRO 365 SC (see Table 3.4-162).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at

a rate of 0.6-0.8 l/ha will not negatively impact the moisture content in triticale in the South-East-~~ern~~ EPPO zone.

Table 3.4-162: Summary table - Moisture content -Triticale (TTLWI) – South-East~~ern~~ EPPO zone

Treatment name	UNTREATED CHECK	CA24 45	PRI-AXOR	NATIVO PRO 365 SC	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		0,8	1,5	1	0,6	0,8				
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB	AB				
Moistue content (%) - 48-84 DA-B										
Number of values	7				7	7	UT C	CA33 01 0,8 l/ha	UT C	CA33 01 0,6 l/ha
Minimum value	10,83				10,93	10,90				
Maximum value	13,98	-	-	-	14,45	14,40	3 >	0 >	3 >	0 >
Mean Moisture (%)	12,83				12,99	12,97	4 =	7 =	4 =	7 =
Mean %UTC	100,00%				102,7 2%	102,4 6%	0 <	0 <	0 <	0 <
Number of values	4	4			4	4	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	12,28	12,30			12,28	12,13				
Maximum value	13,33	13,50	-	-	13,63	13,60	0 >		0 >	
Mean Moisture (%)	12,84	12,86			12,88	12,87	4 =		4 =	
Mean %UTC	100,00%	100,1 3%			100,2 9%	100,2 2%	0 <		0 <	
Number of values	2		2		2	2	PRIAXOR 1,5 l/ha		PRIAXOR 1,5 l/ha	
Minimum value	10,83		10,80		10,93	10,90				
Maximum value	12,95	-	13,08	-	12,78	13,13	0 >		0 >	
Mean Moisture (%)	11,89		11,94		11,86	12,02	2 =		2 =	
Mean %UTC	100,00%		100,36 %		99,81 %	101,0 2%	0 <		0 <	
Number of values	3			3	3	3	NATIVO 1 l/ha		NATIVO 1 l/ha	
Minimum value	13,33			13,68	13,63	13,60				
Maximum value	13,98	-	-	14,48	14,45	14,40	0 >		0 >	
Mean Moisture (%)	13,66			14,03	14,04	14,00	3 =		3 =	
Mean %UTC	100,00%			102,68%	102,9 6%	102,6 7%	0 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

HLW (Hectolitre Weight / Grain Specific weight)

Use of CA3301 in trial with *Fusarium spp.* trials in the Maritime EPPO zone

In the Maritime EPPO zone one trial was inoculated with *Fusarium spp.* to evaluate the efficacy of CA3301 at 0.6-0.8 l/ha on ears disease. In this trial 50 inoculated ears were harvested.

In thois trials CA3301 at 0.6-0.8 l/ha did not significantly affect the grain specific weight compared to the untreated control and was statistically equivalent to the reference product CA2445 at 0.8 l/ha (see Table 3.4-163).

The grain specific weight values recorded in the trial were in accordance with the standards for triticale.

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact and might have a positive effect on the Grain Specific weight in triticale affected by *Fusarium spp.* in the Maritime EPPO zone.

Table 3.4-163: Summary table - Grain specific weight (kg/hl) – Triticale (TTLWI) on *Fusarium spp.* – Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA244 5 0,8 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
HLW (kg/hl) Infected kernel										
Number of values	1	1	1	1	UT C	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UT C	CA244 5 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	67,35	75,62	78,02	77,81						
Maximum value	67,35	75,62	78,02	77,81	0 >	0 >	0 >	0 >	0 >	0 >
Mean HLW (kg/hl)	67,35	75,62	78,02	77,81	1 =	1 =	1 =	1 =	1 =	1 =
Mean %UTC	100,0%	112,28 %	115,84 %	115,53 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in trial with **all other disease** in the Maritime EPPO zone

In the Maritime EPPO zone were harvested nine trials on triticale established for the efficacy evaluation of CA3301 at 0.6-0.8 l/ha for the control of several foliar and ears disease.

In these nine trials CA3301 at 0.6-0.8 l/ha did not significantly affect the Grain Specific weight compared to the untreated control and was statistically equivalent to the reference product CA2445 at 0.8 l/ha (see Table 3.4-164). The grain specific weight values recorded in these trials were in accordance with the standards for triticale.

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the Grain Specific weight in triticale in the Maritime EPPO zone.

Table 3.4-164: Summary table - Grain specific weight (kg/hl) – Triticale (TTLWI) on **all other disease – Maritime EPPO zone**

Treatment name	UNTREATED CHECK	CA224 5	CA330 1	CA330 1	No of trials where CA3301			No of trials where CA3301		
Rate		0,80	0,60	0,80	at 0,6 l/ha is >, = or <			at 0,8 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
%HLW (kg/ha) 61-88 DA-B										
Number of values	8	8	8	8	UT C	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UT C	CA244 5 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	64,99	66,39	66,14	65,80						
Maximum value	80,10	80,18	80,35	80,18	0 >	0 >	0 >	0 >	0 >	0 >
Mean HLW (kg/ha)	71,76	72,61	72,53	72,78	9 =	9 =	9 =	9 =	9 =	9 =
Mean %UTC	100,0%	101,03 %	101,09 %	101,45 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the Mediterranean EPPO zone

In the Mediterranean EPPO zone were harvested four trials on triticale established for the efficacy evaluation of CA3301 at 0.6-0.8 l/ha for the control of several foliar and ear diseases. CA3301 at 0.6-0.8

l/ha did not significantly increase the grain specific weight compared to the untreated control and was always statistically equivalent to the reference products CA2445 at 0.8 l/ha (see Table 3.4-165). The grain specific weight values recorded in these trials were in accordance with the standards for triticale.

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the grain specific weight in triticale and might have a positive effect on triticale in the Mediterranean EPPO zone.

Table 3.4-165: Summary table - Grain specific weight (kg/ha) – Triticale (TTLWI) – Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA244 5 0,8 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
Rate										
Rate unit										
Appl. Code										
HLW (kg/ha) 78-84 DA-B										
Number of values	4	4	4	4	UT C	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UT C	CA244 5 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	54,68	61,8	61,8	60,5	0 >	0 >	0 >	0 >	0 >	0 >
Maximum value	71,8	71,85	71,05	72,35	4 =	4 =	4 =	4 =	4 =	4 =
Mean HLW (kg/ha)	65,4	67,59	66,82	67,79	0 <	0 <	0 <	0 <	0 <	0 <
Mean %UTC	100,00%	103,85 %	102,73 %	104,03 %						

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-Eastern EPPO zone

In the North-Eastern EPPO zone were set up six trials on triticale to evaluate the efficacy of CA3301 at 0.6-0.8 l/ha against foliar and ear diseases. Five trials were harvested to determine the yield and the quality of grains.

CA3301 at 0.6-0.8 l/ha increased the grain specific weight in two trials compared to the untreated control and was always statistically equivalent to the reference products CA2445 at 0.8 l/ha and OSIRIS 65 EC at 2 l/ha (see Table 3.4-166).

The grain specific weight values recorded in these trials were in accordance with the standards for triticale.

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the grain specific weight in triticale in the North-Eastern EPPO zone.

Table 3.4-166: Summary table - Grain specific weight (kg/ha) – Triticale (TTLWI) – North-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA2445 0,8 L/ha AB	OSIRIS 65 EC 2 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate									
Rate unit									
Appl. Code									
HLW (kg/ha) 57-109 DA-B									
Number of values	5			5	4	UT C	CA330 1 0,8 l/ha	UT C	CA330 1 0,6 l/ha
Minimum value	57,25			62,50	62,83	2 >	0 >	2 >	1 >
Maximum value	75,44	-	-	75,57	77,65	3 =	4 =	3 =	4 =
Mean HLW (kg/ha)	67,06			68,46	69,32	0 <	1 <	0 <	0 <
Mean %UTC	100,00%			102,45 %	103,57 %				
Number of values	3	3		3	3	CA2445		CA2445	

Treatment name	UNTREATED CHECK	CA2445	OSIRIS 65 EC	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Rate		0,8	2	0,6	0,8		
Rate unit		L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	AB		
HLW (kg/ha) 57-109 DA-B							
Minimum value	57,25	62,88		62,50	62,83	0,8 l/ha	0,8 l/ha
Maximum value	64,20	67,43	-	67,03	67,15	0 >	0 >
Mean HLW (kg/ha)	61,75	65,20		64,65	64,32	3 =	3 =
Mean %UTC	100,00%	105,78 %		104,84 %	104,36 %	0 <	0 <
Number of values	2		2	2	2	OSIRIS 2 l/ha	OSIRIS 2 l/ha
Minimum value	74,63		74,73	72,78	75,99	0 >	0 >
Maximum value	75,44	-	75,51	75,57	77,65	0 >	0 >
Mean HLW (kg/ha)	75,04		75,12	74,18	76,82	2 =	2 =
Mean %UTC	100,00%		100,11 %	98,85%	102,39 %	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the South-Eastern EPPO zone

In the South-Eastern EPPO zone were set up seven trials on triticale to evaluate the efficacy of CA3301 at 0.6-0.8 l/ha against *foliar and ear* diseases.

CA3301 at 0.6-0.8 l/ha significantly increased the grain specific weight compared to the untreated control in three trials and was always statistically equivalent to the reference products PRIAXOR at 2 l/ha and NATIVO PRO 365 SC at 1 l/ha. Compared to CA2445 CA3301 applied at 0.6 l/ha was equivalent in all trials and applied at 0.8 l/ha was equivalent in 3 trials and significantly higher in 1 trial (see Table 3.4-167).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact and might improve the grain specific weight in triticale in the South-Eastern EPPO zone.

Table 3.4-167: Summary table - Grain specific weight (kg/ha) – Triticale (TTLWI) – South-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA2445	PRIAXOR	NATIVO PRO 365 SC	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Rate		0,8	2	1	0,6	0,8		
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	AB	AB		
HLW (kg/ha) - 48-104 DA-B								
Number of values	7				7	7	UT C	CA3301 0,8 l/ha
Minimum value	66,86				67,53	67,28		
Maximum value	74,88	-	-	-	75,33	75,48	3 >	0 >
Mean HLW (kg/ha)	70,95				71,35	71,26	4 =	7 =
Mean %UTC	100,00%				100,59 %	100,45 %	0 <	0 <
Number of values	4	4			4	4	CA2445	CA2445
Minimum value	67,70	67,45			67,53	67,28	0,8 l/ha	0,8 l/ha
Maximum value	74,88	75,23	-	-	75,33	75,48	0 >	1 >

Treatment name	UNTREATED CHECK	CA24 45	PRI-AXOR	NATIVO PRO 365 SC	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Rate		0,8	2	1	0,6	0,8		
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	AB	AB		
Mean HLW (kg/ha)	72,21	72,33			72,21	72,25	4 =	3 =
Mean %UTC	100,00%	100,16 %			100,00 %	100,04 %	0 <	0 <
Number of values	2		2		2	2	PRIAXOR	PRIAXOR
Minimum value	66,86		68,48		68,53	67,72	1,5 l/ha	1,5 l/ha
Maximum value	73,60	-	72,50	-	73,00	73,40	0 >	0 >
Mean HLW (kg/ha)	70,23		70,49		70,77	70,56	2 =	2 =
Mean %UTC	100,50%		100,46%		100,84 %	100,51 %	0 <	0 <
Number of values	3			3	3	3	NATIVO	NATIVO
Minimum value	69,40			70,08	70,00	70,08	1 l/ha	1 l/ha
Maximum value	74,88	-	-	75,53	75,33	75,48	0 >	0 >
Mean HLW (kg/ha)	71,94			72,51	72,48	72,55	3 =	3 =
Mean %UTC	100,00%			100,79%	100,82 %	100,86 %	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

TKW (Thousand Kernel Weight)

Use of CA3301 in *Fusarium spp.* trial in the Maritime EPPO zone

In the Maritime EPPO zone two trials was inoculated with *Fusarium spp.* and *Fusarium culmorum* to evaluate the efficacy of CA3301 at 0.6-0.8 l/ha on ears disease. In those trials 50 inoculated ears were harvested.

In those trials CA3301 at 0.6-0.8 l/ha significantly increased the thousand kernel weight compared to the untreated control in 1 trial out of 2 and was statistically equivalent to the reference product CA2445 at 0.8 l/ha (see Table 3.4-168).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact and might have a positive effect on the thousand kernel weight in triticale on Maritime EPPO zone.

Table 3.4-168: Summary Table - Thousand Kernel Weight (g) – Triticale (TTLWI) on *Fusarium spp.* and *Fusarium culmorum* – Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA224 5	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		0,8	0,6	0,8				
Rate unit		L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB				
TKW (g) 61-75 DA-B Infected Kernel								
Number of values	2	2	2	2	UT	CA24 45	CA33 01	UT
Minimum value	27,58	36,23	36,21	34,93	C	0,8 l/ha	0,8 l/ha	C
Maximum value	34,47	43,32	42,52	38,86	1 >	0 >	0 >	1 >
Mean TKW (g)	31,03	39,78	39,37	36,90	1 =	2 =	2 =	1 =

Mean %UTC	100,0%	131,09 %	129,61 %	121,12 %	0 <	0 <	0 <	0 <	0 <	0 <
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'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in trial with **all other disease** in the Maritime EPPO zone

In the Maritime EPPO zone were harvested nine trials on triticale established for the efficacy evaluation of CA3301 at 0.6-0.8 l/ha for the control of several foliar and ear diseases.

CA3301 at 0.6-0.8 l/ha significantly increased the thousand kernel weight compared to the untreated control in 1 trial out of 9 and was always statistically equivalent to the reference product CA2445 at 0.8 l/ha (see Table 3.4-169).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the thousand kernel weight and might have a positive effect in triticale in the Maritime EPPO zone.

Table 3.4-169: Summary table - Thousand Kernel Weight (g) – Triticale (TTLWI) – Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA224 5 0,8 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to			No of trials where CA3301 at 0,8 l/ha is >, = or < compared to		
TKW (g) 61-88 DA-B										
Number of values	9	9	9	9	UT C	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UT C	CA244 5 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value	31,69	31,98	31,48	31,03	1 >	0 >	0 >	1 >	0 >	0 >
Maximum value	53,41	55,20	55,32	56,08	8 =	9 =	9 =	8 =	9 =	9 =
Mean HLW (kg/100l)	42,23	43,06	42,73	43,41						
Abbott efficacy (%)	100,0%	101,84 %	101,00 %	102,50 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the Mediterranean EPPO zone

In the Mediterranean EPPO zone were harvested four trials on triticale established for the efficacy evaluation of CA3301 at 0.6-0.8 l/ha for the control of several foliar and ear diseases. In one trial this quality parameter was not assessed.

In the other three trials CA3301 at 0.6-0.8 l/ha did not significantly affect the thousand kernel weight compared to the untreated control and was statistically equivalent to the reference product CA2445 at 0.8 l/ha (see Table 3.4-170).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the thousand kernel weight and might have a positive effect in triticale in the Mediterranean EPPO zone.

Table 3.4-170: Summary table - Thousand Kernel Weight (g) – Triticale (TTLWI) – Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA244 5	CA330 1	CA330 1	No of trials where CA3301			No of trials where CA3301		
Rate		0,8	0,6	0,8	at 0,6 l/ha is >, = or <			at 0,8 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
TKW (g) 78-117 DA-B										
Number of values	3	3	3	3	UT	CA244 5	CA330 1	UT	CA244 5	CA330 1
Minimum value	32.3	33.9	32.7	35.13	C	0.8 l/ha	0.8 l/ha	C	0.8 l/ha	0.6 l/ha

Maximum value	35,68	39,25	39,88	39,38	0 >	0 >	0 >	0 >	0 >	0 >
Mean TKW (g)	33,78	35,92	36,38	36,87	3 =	3 =	3 =	3 =	3 =	3 =
Mean % UTC	100,00%	106,37 %	107,78 %	109,27 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-Eastern EPPO zone

In the North-Eastern EPPO zone were set up six trials on triticale to evaluate the efficacy of CA3301 at 0.6-0.8 l/ha against foliar and ear diseases. Five trial were harvested to determine the yield and quality of grains.

In two trials CA3301 at 0.6-0.8 l/ha significantly increased TKW compared to the untreated control and in one trial were also statistically better than CA2445 at 0.8 l/ha. In two trials CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha and OSIRIS 65 EC at 2 l/ha (see Table 3.4-171).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact and might have a positive effects on the thousand kernel weight on triticale in the North-Eastern EPPO zone.

Table 3.4-171: Summary table - Thousand Kernel Weight (g) – Triticale (TTLWI) – North-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA2445 0,8 L/ha AB	OSIRIS 65 EC 2 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
TKW (g) 57-109 DA-B							
Number of values	5			5	5	UTC	CA3301 0,8 l/ha
Minimum value	30,37			29,26	33,28		
Maximum value	50,81	-	-	52,34	53,01	2 >	0 >
Mean TKW (g)	38,25			40,19	41,57	3 =	5 =
Mean % UTC	100,00%			105,06%	109,30%	0 <	0 <
Number of values	3	3		3	3	CA2445 0,8 l/ha	CA2445 0,8 l/ha
Minimum value	62,98	35,68		35,72	62,83		
Maximum value	41,53	42,50	-	44,88	67,15	1 >	1 >
Mean TKW (g)	36,69	39,77		39,78	64,32	2 =	2 =
Mean % UTC	100,00%	106,24%		108,64%	104,36%	0 <	0 <
Number of values	2		2	2	2	OSIRIS 2 l/ha	OSIRIS 2 l/ha
Minimum value	30,37		29,20	29,26	33,28		
Maximum value	50,81	-	51,77	52,34	53,01	0 >	0 >
Mean TKW (g)	40,59		40,48	40,80	43,15	2 =	2 =
Mean % UTC	100,00%		99,02%	99,88%	106,96%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the South-Eastern EPPO zone

In the South-Eastern EPPO zone were set up seven trials on triticale to evaluate the efficacy of CA3301 at 0.6-0.8 l/ha against foliar and ear diseases. I

In three trials CA3301 at 0.6-0.8 l/ha significantly increased TKW compared to the untreated control and were overall statistically equivalent than standards CA2445 at 0.8 l/ha, PRIAXOR at 2 l/ha and NATIVO PRO 365 SC at 1 l/ha, except in 1 trial where CA3301 at 0.8 l/ha gave significantly higher TKW compared to CA2445 and 1 trial where CA3301 at 0.6 l/ha gave significantly lower TKW compared to NATIVO PRO 365 SC (see Table 3.4-172).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact and might have a positive effects on the thousand kernel weight on triticale in the South-Eastern EPPO zone.

Table 3.4-172: Summary table - Thousand Kernel Weight (g) – Triticale (TTLWI) – South-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA24 45	PRI-AXOR	NATIVO PRO 365 SC	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		0,8	2	1	0,6	0,8				
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB	AB				
TKW (g) - 49-104 DA-B										
Number of values	7				7	7	UT C	CA33 01 0,8 l/ha	UT C	CA33 01 0,6 l/ha
Minimum value	34,55				34,24	32,90				
Maximum value	47,61	-	-	-	49,44	49,68	3 >	0 >	3 >	0 >
Mean TKW (g)	39,83				41,50	41,24	4 =	7 =	4 =	7 =
Mean %UTC	100,00%				104,08 %	103,28 %	0 <	0 <	0 <	0 <
Number of values	4	4			4	4	CA2445		CA2445	
Minimum value	34,55	34,48			34,92	32,90	0,8 l/ha		0,8 l/ha	
Maximum value	47,61	49,14	-	-	49,27	49,68	0 >		1 >	
Mean TKW (g)	40,72	40,86			41,33	41,23	4 =		3 =	
Mean %UTC	100,00%	100,22 %			101,28 %	100,81 %	0 <		0 <	
Number of values	2		2		2	2	PRIAXOR		PRIAXOR	
Minimum value	37,40		37,21		38,41	36,66	1,5 l/ha		1,5 l/ha	
Maximum value	43,85	-	44,35	-	44,75	45,60	0 >		0 >	
Mean TKW (g)	40,63		40,78		41,58	41,13	2 =		2 =	
Mean %UTC	100,00%		100,32%		102,38 %	101,01 %	0 <		0 <	
Number of values	3			3	3	3	NATIVO		NATIVO	
Minimum value	38,56			41,84	41,70	42,06	1 l/ha		1 l/ha	
Maximum value	47,61	-	-	49,87	49,44	49,68	0 >		0 >	
Mean TKW (g)	42,06			45,53	45,40	45,60	2 =		3 =	
Mean %UTC	100,00%			108,47%	110,37 %	110,84 %	1 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Mycotoxins (*Fusarium* species)

Detection levels from mycotoxins DON and NIV lab analysis were available only on four trials on triticale in 2018, one trial performed in Denmark for the Maritime EPPO zone, one in Portugal for the Mediterranean EPPO zone, one in Poland for the North-Eastern EPPO zone and one in Hungary for the South-Eastern EPPO zone.

Use of CA3301 in the Maritime EPPO zone

DON (2 trials)

Mycotoxin (DON) lab analysis was performed on infected kernel in 2 trials. In one trial CA3301 at 0.6-

Treatment name	UN-TREATED CHECK	CA2445	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or <	No of trials where CA3301 at 0,8 l/ha is >, = or <
Rate		0,8	0,6	0,8		
Rate unit		L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	compared to	compared to

Number of values	1	1	1	1	UT C	CA24 45 0,8 l/ha	CA33 01 0,8 l/ha	UT C	CA24 45 0,8 l/ha	CA33 01 0,6 l/ha
Minimum value DON	115,00	0,00	55,00	0,00						
Maximum value DON	115,00	0,00	55,00	0,00	1 >	0 >	0 >	1 >	0 >	0 >
Mean DON (PPB)	115,00	0,00	55,00	0,00	0 =	1 =	1 =	0 =	1 =	1 =
% UTC	100,00%	0,00%	47,83%	0,00%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-East **EPPO** zone

DON (1 trial)

In the North-East **EPPO** zone, DON mycotoxin levels were analysed in 1 trial and detected in infected kernels. CA3301 at 0.6-0.8 l/ha provided a significant reduction of DON level compared to the untreated control but not under the legal limit on triticale (1250 PPB). Moreover, compared to the reference product CA2445 at 0.8 l/ha, CA3301 at 0.6-0.8 l/ha provided a statistically equivalent DON level reduction (see Table 3.4-175).

NIV mycotoxin levels were not assessed in the North-East **EPPO** zone.

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the mycotoxins levels in triticale but might have a positive effect, in the North-East **EPPO** zone.

Table 3.4-175: Summary Table – Mycotoxin – Triticale (TTLWI) – North-East **EPPO zone**

Treatment name	UNTREATED CHECK	CA244 5 0,8 L/ha AB	CA330 1 0,6 L/ha AB	CA330 1 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to			
DON (PPB) Infected Kernel 139 DA-B										
Number of values	1	1	1	1	UT C	CA244 5 0,8 l/ha	CA330 1 0,8 l/ha	UT C	CA244 5 0,8 l/ha	CA330 1 0,6 l/ha
Minimum value DON	7484,25	2025,7 5	1897,0 0	1617,0 0						
Maximum value DON	7484,25	2025,7 5	1897,0 0	1617,0 0	1 >	0 >	0 >	1 >	0 >	0 >
DON (PPB)	7484,25	2025,7 5	1897,0 0	1617,0 0	0 =	1 =	1 =	0 =	1 =	1 =
(%) UTC	100,00%	27,07 %	25,35 %	21,61 %	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the South-East **EPPO** zone

DON & NIV (1 trial)

In the South-East **EPPO** zone, mycotoxins (DON and NIV) analysis were performed in 1 trial but no mycotoxins were detected on both infected kernels and non-infected kernels. Therefore, data are not presented here.

Comments of zRMS:

No negative impact on the quality parameters of yield of winter triticale (moisture content, HLW, thousand kernel weight, mycotoxins) was observed after twice application of CA3301 at dose rate of 0,6-0,8 l/ha. A positive effect was visible in all EPPO climatic zones and no significant differences between test and reference

product were detected.

3.4.3.7 Rye (SECCW)

Moisture content

Use of CA3301 in the Maritime EPPO zone

Against foliar diseases (8 trials), CA3301 at 0.6-0.8 l/ha did not significantly affect the moisture content compared to the untreated control in all 8 trials.

Whatever the dose rate considered, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha and PROLINE 275 at 0.72 l/ha (see Table 3.4-176).

The levels of moisture observed were in compliance with the moisture standards for rye and local ripening or harvesting conditions could explain the differences among trials.

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the moisture content in rye in the Maritime EPPO zone.

Table 3.4-176: Summary table - Moisture content (%) – Rye (SECCW) – Maritime EPPO zone

Treatment name	UNTREATED CHECK	PROLINE 275	CA24 45	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Rate		0,72	0,8	0,6	0,8		
Rate unit		L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	AB		
Moisture content (%) - 56-97 DA-B							
Number of values	8			8	8	UT C	CA33 01 0,8 l/ha
Minimum value	11,30			11,28	11,33		
Maximum value	14,99	-	-	14,79	14,99	0 >	0 >
Mean Moisture content (%)	13,16			13,25	13,29	8 =	8 =
Mean %UTC	100,00%			100,7 0%	101,0 3%	0 <	0 <
Number of values	1	1		1	1	PROLINE 275 0,72 l/ha	PROLINE 275 0,72 l/ha
Minimum value	13,35	13,35		13,43	13,20		
Maximum value	13,35	13,35	-	13,43	13,20	0 >	0 >
Mean Moisture content (%)	13,35	13,35		13,43	13,20	1 =	1 =
Mean %UTC	100,00%	100,00%		100,6 0%	98,88 %	0 <	0 <
Number of values	7		7	7	7	CA2445 0,8 l/ha	CA2445 0,8 l/ha
Minimum value	11,30		11,38	11,28	11,33		
Maximum value	14,99	-	14,70	14,79	14,99	0 >	0 >
Mean Moisture content (%)	13,13		13,20	13,22	13,30	7 =	7 =
Mean %UTC	100,00%		100,6 7%	100,7 2%	101,3 3%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the Mediterranean EPPO zone

Against foliar diseases (3 trials), CA3301 at 0.6-0.8 l/ha did not significantly affect the moisture content compared to the untreated control.

Whatever the dose rate considered, CA3301 was statistically equivalent to the reference product CA2445 at 0.8 l/ha in 2 trials out of 3 and decreased the moisture content in the third trial. Compared to ALTIS at 1 l/ha, CA3301 at 0.6-0.8 l/ha was statistically equivalent in a single trial (see Table 3.4-177).

The levels of moisture observed were in compliance with the moisture standards for rye and differences observed within trials are not necessary negative as decreasing moisture content is an important parameter for grain storage.

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha is unlikely to negatively impact the moisture content in rye in the Mediterranean EPPO zone.

Table 3.4-177: Summary table – Moisture content (%) – Rye (SECCW) – Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA24 45	AL- TIS	CA33 01	CA33 01	No of trials where CA3301		No of trials	
Rate		0,8	1	0,6	0,8	at 0,6 l/ha is		at 0,8 l/ha is	
Rate unit		L/ha	L/ha	L/ha	L/ha	>, = or <		>, = or <	
Appl. Code		AB	AB	AB	AB	compared to		compared to	
Moisture content (%) - 69-83 DA-B									
Number of values	3	3		3	3	UTC	CA33 01 0,8 l/ha	UTC	CA33 01 0,6 l/ha
Minimum value	11,75	12,01		11,78	11,94				
Maximum value	14,53	15,85	-	14,68	15,35		0 >		0 >
Mean Moisture content (%)	12,88	13,80		13,02	13,10	3 =	3 =	3 =	3 =
Mean %UTC	100,00%	107,1 6%		101,0 8%	101,4 5%	0 <	0 <	0 <	0 <
Number of values	1	1	1	1	1	CA24 45 0,8 l/ha	AL- TIS 1,0 l/ha	CA24 45 0,8 l/ha	AL- TIS 1,0 l/ha
Minimum value	14,53	15,85	15,18	14,68	15,35				
Maximum value	14,53	15,85	15,18	14,68	15,35	0 >	0 >	0 >	0 >
Mean Moisture content (%)	14,53	15,85	15,18	14,68	15,35	2 =	1 =	2 =	1 =
Mean %UTC	100,00%	109,0 8%	104,4 7%	101,0 3%	105,6 4%	1 <	0 <	1 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-Eastern EPPO zone

Against foliar diseases (6 trials), CA3301 at 0.6-0.8 l/ha did not significantly affect the moisture content compared to the untreated control.

Whatever the dose rate considered, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha and OSIRIS 65 EC at 2.0 l/ha respectively in 5 trials and 1 trial (see Table 3.4-178). The levels of moisture observed were in compliance with the moisture standards for rye and differences observed among trials could be explained by local ripening or harvesting conditions.

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha is unlikely to negatively impact the moisture content in rye in the North-Eastern EPPO zone.

Table 3.4-178: Summary table – Moisture content (%) – Rye (SECCW) – North-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA24 45 0,8	OSIRIS 65 EC 2	CA33 01 0,6	CA33 01 0,8	No of trials where CA3301	No of trials where CA3301
Rate							

Rate unit		L/ha	L/ha	L/ha	L/ha	at 0,6 l/ha	at 0,8 l/ha
Appl. Code		AB	AB	AB	AB	is >, = or < compared to	is >, = or < compared to
Moisture content (%) - 67-82 DA-B							
Number of values	6			6	6	UT C	CA33 01
Minimum value	10,09			9,68	10,27	0,8 l/ha	0,6 l/ha
Maximum value	14,05	-	-	14,68	14,58	0 >	0 >
Mean Moisture content (%)	12,19			12,25	12,31	6 =	6 =
Mean %UTC	100,00%			100,24 %	100,87 %	0 <	0 <
Number of values	5	5		5	5	CA2445 0,8 l/ha	CA2445 0,8 l/ha
Minimum value	10,09	10,17		9,68	10,27	0 >	0 >
Maximum value	14,05	14,95	-	14,68	14,58	5 =	5 =
Mean Moisture content (%)	12,21	12,49		12,28	12,40	0 <	0 <
Mean %UTC	100,00%	102,04 %		100,29 %	101,46 %		
Number of values	2		2	2	2	OSIRIS 65 EC 2,0 l/ha	OSIRIS 65 EC 2,0 l/ha
Minimum value	11,99		11,88	11,94	11,85	0 >	0 >
Maximum value	12,10	-	12,08	12,10	11,96	2 =	2 =
Mean Moisture content (%)	12,05		11,98	12,02	11,91	0 <	0 <
Mean %UTC	100,00%		99,46%	99,79 %	98,84 %		

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the South-East^{err} EPPO zone

Against foliar diseases (4 trials), CA3301 at 0.6-0.8 l/ha did not significantly affect the moisture content compared to the untreated control except in 1 trial where both dose rates increased or maintained moisture content.

Whatever the dose rate considered, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha and PRIAXOR at 1.5 l/ha (see Table 3.4-179).

Although an increase in moisture content was observed in 1 trial in treated modalities, the levels of moisture were overall in compliance with the moisture standards for rye and a faster drying of the crop in the untreated due to higher disease infestation could explain the difference observed in this trial.

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha is unlikely to negatively impact the moisture content in rye in the South-East^{err} EPPO zone.

Table 3.4-179: Summary table – Moisture content (%) – Rye (SECCW) – South-East^{err} EPPO zone

Treatment name	UNTREATED CHECK	CA24 45	PRI- AXOR	CA33 01	CA33 01	No of trials where CA3301	No of trials where CA3301
Rate		0,8	1,5	0,6	0,8	at 0,6 l/ha is	at 0,8 l/ha is
Rate unit		L/ha	L/ha	L/ha	L/ha	>, = or <	>, = or <
Appl. Code		AB	AB	AB	AB	compared to	compared to
Moisture content (%) - 47-82 DA-B							
Number of values	4			4	4	UT C	CA33 01
Minimum value	12,08			12,08	12,08	0,8 l/ha	0,6 l/ha
Maximum value	13,48	-	-	14,03	13,90	1 >	1 >
Mean Moisture content (%)	12,84			13,00	13,01	3 =	4 =

Mean %UTC	100,00%			101,19 %	101,22 %	0 <	0 <	0 <	0 <
Number of values	3	3		3	3	CA2445		CA2445	
Minimum value	12,08	12,00		12,08	12,08	0,8 l/ha		0,8 l/ha	
Maximum value	13,48	13,93	-	14,03	13,90	0 >		0 >	
Mean Moisture content (%)	12,94	13,13		13,10	13,08	3 =		3 =	
Mean %UTC	100,00%	101,47 %		101,18 %	101,04 %	0 <		0 <	
Number of values	1		1	1	1	PRIAXOR		PRIAXOR	
Minimum value	12,58		12,73	12,73	12,80	1,5 l/ha		1,5 l/ha	
Maximum value	12,58	-	12,73	12,73	12,80	0 >		0 >	
Mean Moisture content (%)	12,58		12,73	12,73	12,80	1 =		1 =	
Mean %UTC	100,00%		101,19%	101,19 %	101,75 %	0 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

HLW (Hectolitre Weight / Grain Specific weight)

Use of CA3301 in the Maritime EPPO zone

Against foliar diseases (8 trials), CA3301 at 0.6-0.8 l/ha did not significantly affect the HLW compared to the untreated control in all 8 trials.

The levels of specific weight were overall in compliance with standards for rye and whatever the dose rate considered, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha and PROLINE 275 at 0.72 l/ha in all 8 trials (see Table 3.4-180).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the grain specific weight in rye in the Maritime EPPO zone.

Table 3.4-180: Summary table – Grain specific weight – Rye (SECCW) – Maritime EPPO zone

Treatment name	UNTREATED CHECK	PROLINE 275	CA244 5	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		0,72	0,8	0,6	0,8				
Rate unit		L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB				
Specific weight (kg/hl) - 56-97 DA-B									
Number of values	8			8	8	UT C	CA33 01 0,8 l/ha	UT C	CA33 01 0,6 l/ha
Minimum value	69,40			68,90	69,40	0 >	0 >	0 >	0 >
Maximum value	83,10	-	-	82,09	82,61	8 =	8 =	8 =	8 =
Mean HLW (kg/hl)	75,50			75,71	75,83	0 <	0 <	0 <	0 <
Mean %UTC	100,00%			100,29 %	100,45 %				
Number of values	1	1		1	1	PROLINE 275 0,72 l/ha		PROLINE 275 0,72 l/ha	
Minimum value	69,40	68,58		68,90	69,40	0 >		0 >	
Maximum value	69,40	68,58	-	68,90	69,40	1 =		1 =	
Mean HLW (kg/hl)	69,40	68,58		68,90	69,40	0 <		0 <	
Mean %UTC	100,00%	98,82%		99,28 %	100,00 %				
Number of values	7		7	7	7	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	73,40		73,50	73,20	73,75	0 >		0 >	
Maximum value	83,10	-	81,69	82,09	82,61				

Mean HLW (kg/ha)	76,37		76,87	76,69	76,75	7 =	7 =
Mean %UTC	100,00%		100,68 %	100,44 %	100,51 %	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the Mediterranean EPPO zone

Against all foliar diseases (3 trials), CA3301 at 0.6-0.8 l/ha did not significantly affect the grain specific weight compared to the untreated control in all 3 trials.

The levels of grain specific weight were overall in compliance with standards for rye and whatever the dose rate considered, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha and ALTIS at 1.00 l/ha respectively in 3 trials and 1 trial (see Table 3.4-181).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the grain specific weight in rye in the Mediterranean EPPO zone.

Table 3.4-181: Summary table – Grain specific weight (kg/ha) – Rye (SECCW) – Mediterranean EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA24 45 0,8 L/ha AB	AL- TIS 1 L/ha AB	CA330 1 0,6 L/ha AB	CA33 01 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Specific weight (kg/ha) - 69-83 DA-B							
Number of values	3	3		3	3	UTC	CA33 01 0,8 l/ha
Minimum value	70,13	69,63		70,38	69,03		UTC
Maximum value	77,00	75,26	-	78,58	75,70	0 >	0 >
Mean HLW (kg/ha)	74,33	71,81		74,49	72,82	3 =	3 =
Mean %UTC	100,00%	96,75 %		100,21 %	98,00 %	0 <	0 <
Number of values	1	1	1	1	1	CA24 45 0,8 l/ha	AL- TIS 1,0 l/ha
Minimum value	77,00	69,63	79,03	78,58	73,75		CA24 45 0,8 l/ha
Maximum value	77,00	69,63	79,03	78,58	73,75	0 >	0 >
Mean HLW (kg/ha)	77,00	69,63	79,03	78,58	73,75	3 =	1 =
Mean %UTC	100,00%	90,43 %	102,64 %	102,05 %	95,78 %	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-Eastern EPPO zone

Against all foliar diseases (6 trials), CA3301 at 0.6-0.8 l/ha did not significantly affect the grain specific weight compared to the untreated control in all 6 trials.

The levels of grain specific weight were overall in compliance with standards for rye and whatever the dose rate considered, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha and OSIRIS 65 EC at 2.0 l/ha respectively in 5 and 2 trials (see Table 3.4-182).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the grain specific weight in rye in the North-Eastern EPPO zone.

Table 3.4-182: Summary table – Grain specific weight (kg/hl) – Rye (SECCW) – North-East^{eff} EPPO zone

Treatment name	UNTREATED CHECK	CA244 5	OSIRIS 65 EC	CA33 01	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		0,8	2	0,6	0,8				
Rate unit		L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB				
Specific weight (kg/hl) - 67-87 DA-B									
Number of val- ues	6			6	6	UT C	CA33 01 0,8 l/ha	UT C	CA33 01 0,6 l/ha
Minimum value	65,06			65,55	64,90				
Maximum value	80,28	-	-	79,40	80,10	0 >	0 >	0 >	0 >
Mean HLW (kg/hl)	71,79			71,42	72,30	6 =	6 =	6 =	6 =
Mean %UTC	100,00%			99,49 %	100,76 %	0 <	0 <	0 <	0 <
Number of val- ues	5	5		5	5	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	65,06	65,85		65,55	64,90				
Maximum value	80,28	79,40	-	79,40	80,10	0 >		0 >	
Mean HLW (kg/hl)	71,41	72,27		71,19	72,06	5 =		5 =	
Mean %UTC	100,00%	101,40 %		99,70 %	100,98 %	0 <		0 <	
Number of val- ues	2		2	2	2	OSIRIS 65 EC 2,0 l/ha		OSIRIS 65 EC 2,0 l/ha	
Minimum value	73,73		72,70	72,58	73,50				
Maximum value	80,28	-	78,30	79,40	80,10	0 >		0 >	
Mean HLW (kg/hl)	77,01		75,50	75,99	76,80	2 =		2 =	
Mean %UTC	100,00%		98,07%	98,67 %	99,73 %	0 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the South-East^{eff} EPPO zone

Against all foliar diseases (4 trials), CA3301 at 0.6-0.8 l/ha did not significantly affect the grain specific weight compared to the untreated control except in 1 trial where both dose rates increased the grain specific weight. In this trial, the increase in specific weight is closely related to the higher moisture content and the variation remained lower than 2% compared to the untreated control.

The levels of grain specific weight were overall in compliance with standards for rye and whatever the dose rate considered, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha and PRIAXOR at 1.5 l/ha respectively in 3 trials and 1 trial (see Table 3.4-183).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the grain specific weight in rye in the South-East^{eff} EPPO zone.

Table 3.4-183: Summary table – Grain specific weight (kg/hl) – Rye (SECCW) – South-East^{eff} EPPO zone

LTP Zone									
Treatment name	UNTREATED CHECK	CA244 5	PRI-AXOR	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		0,8	1,5	0,6	0,8				
Rate unit		L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB				
Specific weight (kg/hl) - 47-89 DA-B									
Number of values	4			4	4	UT C	CA330 1	UT C	CA330 1

Minimum value	70,78			70,83	70,88		0,8 l/ha		0,6 l/ha
Maximum value	73,30	-	-	73,60	73,13	1 >	0 >	1 >	0 >
Mean HLW (kg/ha)	71,82			72,05	72,11	3 =	4 =	3 =	4 =
Mean %UTC	100,00%			100,32 %	100,42 %	0 <	0 <	0 <	0 <
Number of values	3	3		3	3	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	70,78	70,63		70,83	70,88	0 >		0 >	
Maximum value	73,30	72,05	-	73,60	73,13	3 =		3 =	
Mean HLW (kg/ha)	71,64	73,50		71,96	71,96	0 <		0 <	
Mean %UTC	100,00%	100,59 %		100,45 %	100,46 %				
Number of values	2		1	1	1	PRIAXOR 1,5 l/ha		PRIAXOR 1,5 l/ha	
Minimum value	72,36		72,34	72,31	72,56	0 >		0 >	
Maximum value	72,36	-	72,34	72,31	72,56	1 =		1 =	
Mean HLW (kg/ha)	72,36		72,34	72,31	72,56	0 <		0 <	
Mean %UTC	100,00%		99,97%	99,93 %	100,28 %				

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

TKW (Thousand Kernel Weight)

Use of CA3301 in the Maritime EPPO zone

Against foliar diseases (7 trials), CA3301 at 0.6-0.8 l/ha did not significantly affect the thousand kernel weight compared to the untreated control in all 7 trials.

The levels of thousand kernel weight for rye were overall in compliance with standards and whatever the dose rate considered, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha and PROLINE 275 at 0.72 l/ha respectively in 6 trials and 1 trial (see Table 3.4-184).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the thousand kernel weight in rye in the Maritime EPPO zone.

Table 3.4-184: Summary table – Thousand kernel weight (g) – Rye (SECCW) – Maritime EPPO zone

Treatment name	UNTREATED CHECK	PROLINE 275	CA244 5	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Rate		0,72	0,8	0,6	0,8		
Rate unit		L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	AB		
Thousand kernel weight (g) - 56-106 DA-B							
Number of values	7			7	7	UT C	CA33 01
Minimum value	27,04			26,99	27,08		0,8 l/ha
Maximum value	39,45	-	-	40,43	40,42	0 >	0 >
Mean TKW (g)	32,29			32,57	32,99	7 =	7 =
Mean %UTC	100,00%			100,99 %	102,01 %	0 <	0 <
Number of values	1	1		1	1	PROLINE 275	PROLINE 275

Minimum value	39,45	40,58		40,43	40,42	0,72 l/ha	0,72 l/ha
Maximum value	39,45	40,58	-	40,43	40,42	0 >	0 >
Mean TKW (g)	39,45	40,58		40,43	40,42	1 =	1 =
Mean %UTC	100,00%	102,86%		102,48 %	102,46 %	0 <	0 <
Number of values	6		6	6	6	CA2445	CA2445
Minimum value	27,04		28,75	26,99	27,08	0,8 l/ha	0,8 l/ha
Maximum value	34,76	-	35,48	37,04	37,54	0 >	0 >
Mean TKW (g)	31,10		31,36	31,27	31,76	6 =	6 =
Mean %UTC	100,00%		101,16 %	100,74 %	101,94 %	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the Mediterranean EPPO zone

Against foliar diseases (3 trials), CA3301 at 0.6-0.8 l/ha did not significantly affect the thousand kernel weight compared to the untreated control in all 3 trials.

The levels of thousand kernel weight for rye were overall in compliance with standards and whatever the dose rate considered, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha and ALTIS at 1.00 l/ha respectively in 3 trials and 1 trial (see Table 3.4-185).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the thousand kernel weight in rye in the Mediterranean EPPO zone.

Table 3.4-185: Summary table – Thousand kernel weight (g) – Rye (SECCW) – Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA2445 0,8 L/ha AB	ALTIS 1 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Thousand kernel weight (g) - 69-83 DA-B							
Number of values	3	3		3	3	UTC	CA3301 0,8 l/ha
Minimum value	24,56	23,28		23,82	24,11	UTC	UTC
Maximum value	28,44	29,79	-	29,58	31,60	0 >	0 >
Mean TKW (g)	26,13	26,17		26,59	27,10	3 =	3 =
Mean %UTC	100,00%	99,87 %		101,60 %	103,34 %	0 <	0 <
Number of values	1	1	1	1	1	CA2445 0,8 l/ha	CA2445 0,8 l/ha
Minimum value	28,44	29,79	29,90	29,58	31,60	ALTIS 1,0 l/ha	ALTIS 1,0 l/ha
Maximum value	28,44	29,79	29,90	29,58	31,60	0 >	0 >
Mean TKW (g)	28,44	29,79	29,90	29,58	31,60	3 =	1 =
Mean %UTC	100,00%	104,75 %	105,13 %	104,01 %	111,11 %	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-Eastern EPPO zone

Against foliar diseases (6 trials), CA3301 at 0.6-0.8 l/ha did not significantly affect the thousand kernel weight compared to the untreated control in all 6 trials.

The levels of thousand kernel weight for rye were overall in compliance with standards and whatever the dose rate considered, CA3301 was statistically equivalent to the reference products CA2445 at 0.8 l/ha and OSIRIS 65 EC at 2.0 l/ha respectively in 5 and 2 trials (see Table 3.4-186).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the thousand kernel weight in rye in the North-Eastern EPPO zone.

Table 3.4-186: Summary table – Thousand kernel weight (g) – Rye (SECCW) – North-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA2445 0,8 L/ha AB	OSIRIS 65 EC 2 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,8 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,8 l/ha is >, = or < compared to
Thousand kernel weight (g) - 72-102 DA-B							
Number of values	6			6	6	UT C	CA3301 0,8 l/ha
Minimum value	24,44			24,68	21,35		
Maximum value	30,78	-	-	31,99	32,37	0 >	0 >
Mean TKW (g)	28,20			28,46	27,52	6 =	6 =
Mean %UTC	100,00%			100,83 %	97,26 %	0 <	0 <
Number of values	5	5		5	5	CA2445	CA2445
Minimum value	26,45	25,12		24,85	25,67	0,8 l/ha	0,8 l/ha
Maximum value	30,78	31,65	-	31,99	32,37	0 >	0 >
Mean TKW (g)	28,95	28,47		29,22	28,76	5 =	5 =
Mean %UTC	100,00%	98,22 %		100,80 %	99,24 %	0 <	0 <
Number of values	2		2	2	2	OSIRIS 65 EC	OSIRIS 65 EC
Minimum value	24,44		22,01	24,68	21,35	2,0 l/ha	2,0 l/ha
Maximum value	30,78	-	32,10	31,99	32,27	0 >	0 >
Mean TKW (g)	27,61		27,06	28,34	26,86	2 =	2 =
Mean %UTC	100,00%		97,17%	102,46 %	96,26 %	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the South-Eastern EPPO zone

Against foliar diseases (4 trials), CA3301 at 0.6-0.8 l/ha did not significantly affect the thousand kernel weight compared to the untreated control except in 1 trial where both dose rate increased the thousand kernel weight. In this trial, the increase in thousand kernel weight is closely related to the higher moisture content.

The levels of thousand kernel weight for rye were overall in compliance with standards and whatever the dose rate considered, CA3301 was statistically equivalent to the reference products CA2445 at 0.8

l/ha and PRIAXOR at 1.5 l/ha respectively in 3 trials and 1 trial (see Table 3.4-187).

Consequently, considering elements previously presented, it is concluded that CA3301 applied at a rate of 0.6-0.8 l/ha will not negatively impact the thousand kernel weight in rye in the South-East ~~EP~~ EPPO zone.

Table 3.4-187: Summary table – Thousand kernel weight (g) – Rye (SECCW) – South-East ~~EP~~ EPPO zone

LPTO ZONE									
Treatment name	UNTREATED CHECK	CA244 5	PRI- AXOR	CA330 1	CA330 1	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,8 l/ha is >, = or < compared to	
Rate		0,8	1,5	0,6	0,8				
Rate unit		L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB				
Thousand kernel weight (g) - 47-89 DA-B									
Number of values	4			4	4	UT C	CA330 1 0,8 l/ha	UT C	CA330 1 0,6 l/ha
Minimum value	25,78			26	22,32				
Maximum value	29,3	-	-	31,79	31,74	1 >	0 >	1 >	0 >
Mean TKW (g)	26,9			27,88	26,66	3 =	4 =	3 =	4 =
Mean %UTC	100,00%			103,48 %	98,85%	0 <	0 <	0 <	0 <
Number of values	3	3		3	3	CA2445 0,8 l/ha		CA2445 0,8 l/ha	
Minimum value	25,78	25,88		26	25,98				
Maximum value	29,3	31,67	-	31,79	31,74	0 >		0 >	
Mean TKW (g)	27,16	27,99		28,04	28,11	3 =		3 =	
Mean %UTC	100,00%	102,88 %		103,03 %	103,32 %	0 <		0 <	
Number of values	1		1	1	1	PRIAXOR 1,5 l/ha		PRIAXOR 1,5 l/ha	
Minimum value	26,13		28,38	27,39	22,32				
Maximum value	26,13	-	28,38	27,39	22,32	0 >		0 >	
Mean TKW (g)	26,13		28,38	27,39	22,32	1 =		1 =	
Mean %UTC	100,00%		108,61%	104,82 %	85,42%	0 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Comments of zRMS:

No negative impact on the quality parameters of yield of winter rye (moisture content, HLW, thousand kernel weight) was observed after twice application of CA3301 at dose rate of 0,6-0,8 l/ha. A positive effect was visible in all EPPO climatic zones and no significant differences between test and reference product were detected.

3.4.3.8 Oilseed rape (BRSNW)

Moisture content (%)

Use of CA3301 in the Maritime EPPO zone – 1 application in autumn and 1 application in spring

Applied against a range of diseases (7 trials), CA3301 at 0.6-0.7 l/ha did not significantly affect the moisture content compared to the untreated control, except in 1 trial where CA3301 at 0.6 l/ha significantly increased moisture content.

At the dose rates of 0.6 l/ha and 0.7 l/ha, CA3301 was statistically equivalent to the reference products CA2445 at 0.7 l/ha, PROSARO at 0.75 l/ha and BISTRO at 0.6 l/ha (see Table 3.4-188).

The levels of moisture observed were in compliance with the moisture standards for oilseed rape and differences between trials may be due to differences in harvest timings and local weather variations.

Consequently, considering elements previously presented, it is concluded that CA3301 applied in autumn and in spring at a rate of 0.6-0.7 l/ha will not negatively impact the moisture content in oilseed rape in Maritime EPPO zone.

Table 3.4-188: Summary table – Oilseed rape – Moisture content (%) - Maritime EPPO zone

Treatment name	UNTREATED CHECK	BIST RO	CA24 45	PROSA RO	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,7 l/ha is >, = or < compared to	
Rate		0,6	0,7	0,75	0,6	0,7				
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB	AB				
Moisture content (%) - 69-111 DA-B										
Number of values	7				7	7	UT	CA33 01	UT	CA33 01
Minimum value	4,73				4,43	4,78	C	0,7 l/ha	C	0,6 l/ha
Maximum value	10,83	-	-	-	11,03	10,80	1 >	0 >	0 >	0 >
Mean Moicon (%)	7,80				8,15	8,02	6 =	7 =	7 =	7 =
Mean %UTC	100,00%				103,72 %	102,52 %	0 <	0 <	0 <	0 <
Number of values	2	2	2		2	2	BISTRO		BISTRO	
Minimum value	5,78	5,75	5,38		5,55	5,43	0,6 l/ha		0,6 l/ha	
Maximum value	7,83	8,30	8,93	-	9,68	9,03	0 >		0 >	
Mean Moicon (%)	6,81	7,03	7,16		7,62	7,23	2 =		2 =	
Mean %UTC	100,00%	102,74 %	103,56 %		109,82 %	104,64 %	0 <		0 <	
Number of values	6		6		6	6	CA2445		CA2445	
Minimum value	5,78		5,38		5,55	5,43	0,7 l/ha		0,7 l/ha	
Maximum value	10,83	-	10,75	-	11,03	10,80	0 >		0 >	
Mean Moicon (%)	8,42		8,58		8,60	8,47	6 =		6 =	
Mean %UTC	100,00%		102,92 %		105,39 %	102,76 %	0 <		0 <	
Number of values	1			1	1	1	PROSARO		PROSARO	
Minimum value	4,73			4,48	4,43	4,78	0,75 l/ha		0,75 l/ha	
Maximum value	4,73	-	-	4,48	4,43	4,78	0 >		0 >	
Mean Moicon (%)	4,73			4,48	4,43	4,78	1 =		1 =	
Mean %UTC	100,00%			94,71%	93,66 %	101,06 %	0 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the Maritime EPPO zone – 2 applications in spring

Applied against a range of diseases (12 trials), CA3301 at 0.6-0.7 l/ha did not significantly affect the moisture content compared to the untreated control.

At the dose rates of 0.6 l/ha and 0.7 l/ha, CA3301 was statistically equivalent to the reference product CA2445 at 0.7 l/ha (see Table 3.4-189.)

The levels of moisture observed were in compliance with the moisture standards for oilseed rape and differences between trials may be due to differences in harvest timings and local weather variations.

Consequently, considering elements previously presented, it is concluded that CA3301 applied twice in spring at a rate of 0.6-0.7 l/ha will not negatively impact the moisture content in oilseed rape in Maritime EPPO zone.

Table 3.4-189: Summary table – Oilseed rape – Moisture content (%) - Maritime EPPO zone

Treatment name	UNTREATED CHECK	CA24 45 0,7 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,7 l/ha is >, = or < compared to	
Rate								
Rate unit								
Appl. Code								
Moisture content (%) - 67-109 DA-B								
Number of values	12	12	12	12	UT C	CA24 45 0,7 l/ha	CA33 01 0,7 l/ha	UT C
Minimum value	4,58	4,53	4,58	4,33				
Maximum value	9,65	9,45	9,48	9,68				
Mean Moisture content (%)	6,66	6,69	6,60	6,66	0 > 12 =	0 > 12 =	0 > 12 =	0 > 12 =
Mean %UTC	100,00%	100,6 7%	99,35 %	99,86 %	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the Mediterranean EPPO zone – 2 applications in spring

Applied against a range of diseases (8 trials), CA3301 at 0.6-0.7 l/ha did not significantly affect the moisture content compared to the untreated control.

At the dose rates of 0.6 l/ha and 0.7 l/ha, CA3301 was statistically equivalent to the reference products CA2445 at 0.7 l/ha, CARAMBA at 0.8 l/ha, PROSARO at 1.0 l/ha and ORTIVA at 1.0 l/ha (see Table 3.4-190).

The levels of moisture observed were in compliance with the moisture standards for oilseed rape and differences between trials may be due to differences in harvest timings and local weather variations.

Consequently, considering elements previously presented, it is concluded that CA3301 applied twice in spring at a rate of 0.6-0.7 l/ha will not negatively impact the moisture content in oilseed rape in Mediterranean EPPO zone.

Table 3.4-190: Summary table – Oilseed rape – Moisture content (%) - Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA2 445 0,7 L/ha AB	CARA MBA 0,8 L/ha AB	PROS ARO 1 L/ha AB	ORT IVA 1 L/ha AB	CA3 301 0,6 L/ha AB	CA3 301 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,7 l/ha is >, = or < compared to	
Rate											
Rate unit											
Appl. Code											
Moisture content (%) - 68-101 DA-B											
Number of values	8	8				8	8	UT C	CA330 1 0,7 l/ha	UT C	CA3 301 0,6 l/ha
Minimum value	6,20	5,87				6,07	5,97				
Maximum value	13,20	12,8 8	-	-	-	13,4 8	14,3 0	0 >	0 >	0 >	0 >

Mean Moisture content (%)	9,78	9,76				9,99	9,97	8 =	8 =	8 =	8 =
Mean % UTC	100,00%	99,91%				102,09%	101,38%	0 <	0 <	0 <	0 <
Number of values	2	2	2			2	2	CA2445	CA-RAMBA	CA2445	CA2445
Minimum value	6,20	5,87	6,13			6,07	5,97	0,7 l/ha	0,8 l/ha	0,7 l/ha	0,7 l/ha
Maximum value	13,20	12,88	14,03	-	-	13,48	14,30	0 >	0 >	0 >	0 >
Mean Moisture content (%)	9,70	9,38	10,64			9,78	10,14	8 =	2 =	8 =	2 =
Mean % UTC	100,00%	96,13%	102,58%			100,01%	102,31%	0 <	0 <	0 <	0 <
Number of values	3	3		3		3	3	PROSARO		PROSARO	
Minimum value	9,73	10,08		9,45		9,85	9,55	1,0 l/ha		1,0 l/ha	
Maximum value	10,93	11,50	-	12,05	-	11,98	11,50	0 >		0 >	
Mean Moisture content (%)	10,33	10,58		10,49		10,66	10,48	3 =		3 =	
Mean % UTC	100,00%	102,36%		101,33%		103,09%	101,28%	0 <		0 <	
Number of values	1	1			1	1	1	ORTIVA		ORTIVA	
Minimum value	8,18	8,45			8,43	8,55	8,33	1,0 l/ha		1,0 l/ha	
Maximum value	8,18	8,45	-	-	8,43	8,55	8,33	0 >		0 >	
Mean Moisture content (%)	8,18	8,45			8,43	8,55	8,33	1 =		1 =	
Mean % UTC	100,00%	103,30%			103,06%	104,52%	101,83%	0 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-East ^{EFF} EPPO zone – 1 application in autumn and 1 application in spring

Applied against a range of diseases (6 trials), CA3301 at 0.6-0.7 l/ha did not significantly affect the moisture content compared to the untreated control.

At the dose rates of 0.6 l/ha and 0.7 l/ha, CA3301 was statistically equivalent to the reference products CA2445 at 0.7 l/ha and ORIUS EXTRA at 1.0 l/ha respectively in 5 and 6 trials out of 7. In the remaining trial CA3301 at 0,6 l/ha showed a higher moisture content than CA2445. Compared to TILMOR 240 EC, both dose rates of CA3301 provided a statistically lower moisture content in 1 trial out of 1 (see Table 3.4-191).

The levels of moisture observed were in compliance with the moisture standards for oilseed rape and differences between trials may be due to differences in harvest timings and local weather variations.

Consequently, considering elements previously presented, it is concluded that CA3301 applied in autumn and in spring at a rate of 0.6-0.7 l/ha will not negatively impact the moisture content in oilseed rape in North-East ^{EFF} EPPO zone.

Table 3.4-191: Summary table – Oilseed rape – Moisture content (%) – North-East ^{EFF} EPPO zone

Treatment name	UNTREATED CHECK	CA2445	ORIUS EXTRA	TILMOR 240 EC	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,7 l/ha is >, = or < compared to
Rate		0,7	1	0,70-1,00	0,6	0,7		
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	AB	A-B	AB	AB		

Moisture content (%) - 59-85 DA-B										
Number of values	6				6	6	UTC	CA33 01 0,7 l/ha	UTC	CA33 01 0,6 l/ha
Minimum value	7,50				7,53	7,65				
Maximum value	13,53	-	-	-	16,03	14,85	1 >	0 >	0 >	0 >
Mean Moisture content (%)	9,70				10,21	10,15	5 =	6 =	6 =	6 =
Mean %UTC	100,00%				104,07 %	104,37 %	0 <	0 <	0 <	0 <
Number of values	5	5			5	5	CA2445 0,7 l/ha		CA2445 0,7 l/ha	
Minimum value	7,50	7,55			7,53	7,65				
Maximum value	11,53	11,34	-	-	11,61	11,52	0 >		0 >	
Mean Moisture content (%)	8,94	9,35			10,15	9,22	5 =		5 =	
Mean %UTC	100,00%	104,98 %			101,19 %	103,29 %	0 <		0 <	
Number of values	2	2	2		2	2	ORIUS EX- TRA 1,0 l/ha		ORIUS EX- TRA 1,0 l/ha	
Minimum value	8,58	10,22	10,00		8,68	9,55				
Maximum value	11,53	11,34	11,52	-	11,61	11,52	0 >		0 >	
Mean Moisture content (%)	10,06	10,78	10,76		10,15	10,54	2 =		2 =	
Mean %UTC	100,00%	108,73 %	108,23%		100,93 %	105,61 %	0 <		0 <	
Number of values	1			1	1	1	TILMOR 240 EC		TILMOR 240 EC	
Minimum value	13,53			20,20	16,03	14,85	0,70-1,0 l/ha		0,70-1,0 l/ha	
Maximum value	13,53	-	-	20,20	16,03	14,85	0 >		0 >	
Mean Moisture content (%)	13,53			20,20	16,03	14,85	0 =		0 =	
Mean %UTC	100,00%			149,30%	118,48 %	109,75 %	1 <		1 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-Eastern EPPO zone – 2 applications in spring

Applied against a range of diseases (10 trials), CA3301 at 0.6-0.7 l/ha did not significantly affect the moisture content compared to the untreated control.

At the dose rates of 0.6 l/ha and 0.7 l/ha, CA3301 was statistically equivalent to the reference products CA2445 at 0.7 l/ha and CARAMBA 60 SL at 1.0 l/ha respectively in 5 trials and 3 trials.

In addition, compared to the references PROSARO and CARAMBA at 1.0 l/ha applied once, CA3301 at 0.6-0.7 l/ha provided statistically equivalent moisture levels in all comparisons (see Table 3.4-192).

The levels of moisture observed were in compliance with the moisture standards for oilseed rape and differences between trials may be due to differences in harvest timings and local weather variations.

Consequently, considering elements previously presented, it is concluded that CA3301 applied twice in spring at a rate of 0.6-0.7 l/ha will not negatively impact the moisture content in oilseed rape in North-Eastern EPPO zone.

Table 3.4-192: Summary table – Oilseed rape – Moisture content (%) – North-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA 2445	PROSARO	CARAMBA 60 SL	CARAMBA 60 SL	CA 3301	CA 3301	No of trials where CA3301 is >, = or <	No of trials where CA3301 is >, = or <
Rate		0,7 L/ha	1 L/ha	1 L/ha	1 L/ha	0,6 L/ha	0,7 L/ha	at 0,6 l/ha	at 0,7 l/ha
Rate unit		a	L/ha	L/ha	L/ha	a	a	is >, = or <	is >, = or <

Appl. Code		AB	A	A	A-B	AB	AB	compared to	compared to
Moisture content (%) - 51-90 DA-B									
Number of values	10					10	10	UT C	CA 330 1 0,7 l/ha
Minimum value	6,55					6,63	6,93		UT C
Maximum value	20,66	-	-	-	-	20,73	22,36	0 >	0 >
Mean Moisture content (%)	9,60					9,71	10,11	10 =	10 =
Mean %UTC	100,00%					101,18%	104,38%	0 <	0 <
Number of values	5	5				5	5	CA2445 0,7 l/ha	CA2445 0,7 l/ha
Minimum value	6,55	6,40				6,63	6,93		
Maximum value	20,66	21,99	-	-	-	20,73	22,36	0 >	0 >
Mean Moisture content (%)	10,07	10,34				10,17	10,62	5 =	5 =
Mean %UTC	100,00%	101,26%				101,23%	104,57%	0 <	0 <
Number of values	3	3			3	3	3	PROSARO 1,0 l/ha	PROSARO 1,0 l/ha
Minimum value	8,00	8,08			8,15	8,10	8,13		
Maximum value	20,66	21,99	-	-	18,47	20,73	22,36	0 >	0 >
Mean Moisture content (%)	12,25	12,77			11,63	12,39	12,92	2 =	2 =
Mean %UTC	100,00%	103,10%			97,83%	101,64%	104,03%	0 <	0 <
Number of values	3			3		3	3	CA-RAMBA 60 SL 1,0 l/ha (A)	CA-RAMBA 60 SL 1,0 l/ha (A)
Minimum value	7,53			7,43		7,50	7,53		
Maximum value	9,05	-	-	8,93	-	9,58	9,10	0 >	0 >
Mean Moisture content (%)	8,23			8,13		8,35	8,21	3 =	3 =
Mean %UTC	100,00%			98,83%		101,33%	99,77%	0 <	0 <
Number of values	2		2			2	2	CA-RAMBA 60 SL 1,0 l/ha (AB)	CA-RAMBA 60 SL 1,0 l/ha (AB)
Minimum value	8,18		8,43			8,20	8,83		
Maximum value	12,80	-	13,28	-	-	12,98	14,55	0 >	0 >
Mean Moisture content (%)	10,49		10,86			10,59	11,69	3 =	3 =
Mean %UTC	100,00%		103,40%			100,83%	110,81%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the South-Eastern EPPO zone – 1 application in autumn and 1 application in spring

Against diseases (10 trials), CA3301 at 0.6-0.7 l/ha did not significantly affect the moisture content compared to the untreated control in 8 trials out of 10 and provided a significant increase in 2 trials. In these trials moisture content increased from 10.25% in the untreated to 11.33% for both rates and in the other trial from 10.33% in the untreated to 11.35% for both rates. In addition, in both of the trials the authorised reference product also demonstrated the same increase and was statistically comparable to CA3301 applied at both rates.

At the dose rates of 0.6 l/ha and 0.7 l/ha, CA3301 was statistically equivalent to the reference products

CA2445 at 0.7 l/ha and TILMOR at 1.2 l/ha respectively in all 9 trials and all 6 trials (see Table 3.4-193).

The levels of moisture observed were in compliance with the moisture standards for oilseed rape and differences between trials may be due to differences in harvest timings and local weather variations.

Consequently, considering elements previously presented, it is concluded that CA3301 applied in autumn and in spring at a rate of 0.6-0.7 l/ha will not negatively impact the moisture content in oilseed rape in South-Eastern EPPO zone.

Table 3.4-193: Summary table – Oilseed rape – Moisture content (%) – South-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA24 45	TILM OR	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,7 l/ha is >, = or < compared to
Rate		0,7	1,2	0,6	0,7		
Rate unit		L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	AB	AB	AB		
Moisture content (%) - 57-92 DA-B							
Number of values	10			10	10	UT C	CA33 01 0,7 l/ha
Minimum value	4,78			4,80	5,43		
Maximum value	11,08	-	-	11,45	11,53	2 >	0 >
Mean Moisture content (%)	8,67			8,95	9,22	8 =	10 =
Mean %UTC	100,00%			102,79 %	106,77 %	0 <	0 <
Number of values	9	9		9	9	CA2445 0,7 l/ha	CA2445 0,7 l/ha
Minimum value	4,78	6,63		4,80	6,41		
Maximum value	11,08	12,55	-	11,45	11,53	0 >	0 >
Mean Moisture content (%)	9,03	9,91		9,34	9,56	9 =	9 =
Mean %UTC	100,00%	111,03 %		103,10 %	107,52 %	0 <	0 <
Number of values	6		6	6	6	TILMOR 1,2 l/ha	TILMOR 1,2 l/ha
Minimum value	4,78		5,28	4,80	5,43		
Maximum value	11,08	-	14,63	11,45	11,53	0 >	0 >
Mean Moisture content (%)	8,33		9,24	8,48	8,74	6 =	6 =
Mean %UTC	100,00%		110,86 %	101,84 %	107,43 %	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the South-Eastern EPPO zone – 2 applications in spring

Against diseases (13 trials), CA3301 at 0.6 l/ha and 0.7 l/ha did not significantly affect the moisture content compared to the untreated control respectively in 6 and 5 trials, and provided a significant increase respectively in 7 and 8 trials. In all except 2 of these trials a significant increase compared to the untreated was also observed from the authorised reference product. In 1 of these neither the 0.6 l/ha rate of CA3301 or CA2445 increased moisture compared to the untreated but were also not statistically different to the 0.7 l/ha rate. In the other trial the rate of 0.7 l/ha was comparable to CA2445 and to 0.6 l/ha of CA3301, but the latter was not comparable to CA2445.

At the dose rates of 0.6 l/ha and 0.7 l/ha, CA3301 was statistically equivalent to the reference products PROPULSE at 1.0 l/ha and ORIUS at 1.0 l/ha. Compared to CA2445 at 0.7 l/ha, CA3301 at 0.6-0.7 l/ha was equivalent in 8 trials and provided a significant increase in 1 trial (see Table 3.4-194).

The levels of moisture observed were in compliance with the moisture standards for oilseed rape and a faster drying of the crop in the untreated control could explain the differences observed in this dataset.

Consequently, considering elements previously presented, it is concluded that CA3301 applied twice in spring at a rate of 0.6-0.7 l/ha will not negatively impact the moisture content in oilseed rape in South-East ~~EPPO~~ EPPO zone.

Table 3.4-194: Summary table – Oilseed rape – Moisture content (%) – South-East ~~EPPO~~ EPPO zone

Treatment name	UNTREATED CHECK	CA2445 0,7 L/ha AB	PROPULS E 1 L/ha AB	ORIOUS 1 L/ha AB	CA3301 0,6 L/ha AB	CA3301 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,7 l/ha is >, = or < compared to
Moisture content (%) - 52-82 DA-B								
Number of values	13				13	13	UT C	CA3301 1 0,7 l/ha
Minimum value	5,08				4,98	5,33	7 >	0 >
Maximum value	10,40	-	-	-	11,58	11,40	8 >	2 >
Mean Moisture content (%)	8,90				9,53	9,54	6 =	11 =
Mean %UTC	100,00%				106,03 %	106,58 %	0 <	2 <
Number of values	9	9			9	9	CA2445 0,7 l/ha	CA2445 0,7 l/ha
Minimum value	8,60	8,80			8,78	8,88	1 >	1 >
Maximum value	10,40	11,43	-	-	11,58	11,40	8 =	8 =
Mean Moisture content (%)	9,98	10,78			10,91	10,85	0 <	0 <
Mean %UTC	100,00%	107,84 %			109,18 %	108,61 %		
Number of values	2		2		2	2	PROPULSE 1,0 l/ha	PROPULSE 1,0 l/ha
Minimum value	5,08		5,75		4,98	5,33	0 >	0 >
Maximum value	5,25	-	6,00	-	5,10	5,35	2 =	2 =
Mean Moisture content (%)	5,17		5,88		5,04	5,34	0 <	0 <
Mean %UTC	100,00%		113,74%		97,59%	103,41 %		
Number of values	2			2	2	2	ORIOUS 1,0 l/ha	ORIOUS 1,0 l/ha
Minimum value	7,58			7,60	7,60	7,63	0 >	0 >
Maximum value	8,00	-	-	8,03	8,03	8,05	2 =	2 =
Mean Moisture content (%)	7,79			7,81	7,82	7,84	0 <	0 <
Mean %UTC	100,00%			100,32 %	100,32 %	100,64 %		

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Oil content (%)

Use of CA3301 in the Maritime EPPO zone – 1 application in autumn and 1 application in spring

Among trials conducted in the Maritime EPPO zone with 1 application in autumn and 1 application in spring of CA3301 at 0.6-0.7 l/ha, oil content (%) was analysed in 3 trials.

In these trials, CA3301 at 0.6 l/ha did not significantly affect oil content compared to the untreated control and provided statistically equivalent oil content compared to the references CA2445 at 0.7 l/ha and PROSARO at 0.75 l/ha.

Applied at 0.7 l/ha, CA3301 provided a significant increase in oil content in 1 trial out of 3 compared to the untreated control and was equivalent in the remaining trials. Compared to the references CA2445 at 0.7 l/ha and PROSARO at 0.75 l/ha, CA3301 at 0.7 l/ha provided statistically equivalent oil content in all trials (see Table 3.4-195).

The levels of oil content observed were overall in compliance with the oil content standards for oilseed rape and differences between trials may be due to differences in harvest timings, local growth conditions

and crop varieties.

Consequently, considering elements previously presented, it is concluded that CA3301 applied in autumn and in spring at a rate of 0.6-0.7 l/ha will not negatively impact the oil content and might have a positive effect in oilseed rape in Maritime EPPO zone.

Table 3.4-195: Summary table – Oilseed rape – Oil content (%) - Maritime EPPO zone

Table 5-4-13: Summary table - Onseed rape - Oil content (%) - Maritime LFO zone									
Treatment name	UNTREATED CHECK	CA2445	PROSAR O	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,7 l/ha is >, = or < compared to	
Rate		0,7	0,75	0,6	0,7				
Rate unit		L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB				
Oil content (%) - 69-72 DA-B									
Number of values	3			3	3	UT	CA3301	UT	CA3301
Minimum value	41,25			40,55	40,93	C	0,7 l/ha	C	0,6 l/ha
Maximum value	48,65	-	-	48,50	48,65	0 >	0 >	1 >	1 >
Mean Oilcon (%)	45,13			44,85	45,47	3 =	2 =	2 =	2 =
Mean %UTC	100,00%			99,47 99%	100,73 100,75%	0 <	1 <	0 <	0 <
Number of values	2	2		2	2	CA2445		CA2445	
Minimum value	41,25	40,93		40,55	40,93	0,7 l/ha		0,7 l/ha	
Maximum value	48,65	49,28	-	48,50	48,65	0 >		0 >	
Mean Oilcon (%)	44,95	45,10		44,53	44,79	2 =		2 =	
Mean %UTC	100,00%	100,26 100,33%		99,00 99,07%	99,61 99,64%	0 <		0 <	
Number of values	1		1	1	1	PROSARO		PROSARO	
Minimum value	45,48		45,95	45,67	46,83	0,75 l/ha		0,75 l/ha	
Maximum value	45,48	-	45,95	45,67	46,83	0 >		0 >	
Mean Oilcon (%)	45,48		45,95	45,67	46,83	1 =		1 =	
Mean %UTC	100,00%		45,95 101,03%	100,42%	102,97%	0 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the Maritime EPPO zone – 2 applications in spring

Among trials conducted in the Maritime EPPO zone with 2 applications in spring of CA3301 at 0.6-0.7 l/ha, oil content (%) was analysed in 12 trials.

In these trials, CA3301 at 0.6 l/ha did not significantly affect oil content compared to the untreated control, except in 1 trial where it provided an increase in oil content and was comparable to the reference product CA2445. At this dose rate, CA3301 provided a statistically equivalent oil content compared to the reference CA2445 at 0.7 l/ha in all 12 trials.

Applied at 0.7 l/ha, CA3301 did not significantly affect oil content compared to the untreated control in the 12 trials. Compared to the reference CA2445 at 0.7 l/ha, CA3301 at 0.7 l/ha provided a statistically equivalent oil content in 11 trials and a lower oil content in the last trial, although in that trial CA3301 was comparable to the untreated (see Table 3.4-196).

Consequently, considering elements previously presented, it is concluded that CA3301 applied twice in spring at a rate of 0.6-0.7 l/ha will not negatively impact the oil content in oilseed rape in Maritime Eppo zone.

Treatment name	UNTRE ATED CHECK	CA2445	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or <			No of trials where CA3301 at 0,7 l/ha is >, = or <		
Rate		0,7	0,6	0,7						
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
Oil content (%) - 67-133 DA-B										
Number of values	12	12	12	12	UTC	CA24 45	CA33 01	UTC	CA24 45	CA33 01
Minimum value	38,27	38,61	38,01	37,5		0,7 l/ha	0,7 l/ha		0,7 l/ha	0,6 l/ha
Maximum value	48,88	49,48	49,28	48,98	1 >	0 >	0 >	0 >	0 >	0 >
Mean Oil content (%)	43,64	44,18	43,96	43,69	11 =	12 =	12 =	12 =	11 =	12 =
Mean %UTC	100,00%	101,15% 101,24%	100,58% 100,73%	99,98% 100,11%	0 <	0 <	0 <	0 <	1 <	0 <

Use of CA3301 in the Mediterranean EPPO zone – 2 applications in spring

In these trials, CA3301 at 0.6 l/ha did not significantly affect oil content compared to the untreated control in all 8 trials. At this dose rate, CA3301 provided a statistically equivalent oil content compared to the references CA2445 at 0.7 l/ha, CARAMBA at 0.8 l/ha, PROSARO at 1.0 l/ha and ORTIVA at 1.0 l/ha.

Applied at 0.7 l/ha, CA3301 did not significantly affect oil content compared to the untreated control in all 8 trials. Compared to the references CA2445 at 0.7 l/ha, CARAMBA at 0.8 l/ha, PROSARO at 1.0 l/ha and ORTIVA at 1.0 l/ha, CA3301 at 0.7 l/ha provided a statistically equivalent oil content in all the trials (see Table 3.4-197).

The levels of oil content observed were in compliance with the oil content standards for oilseed rape and differences between trials may be due to differences in harvest timings, local growth conditions and crop varieties.

Consequently, considering elements previously presented, it is concluded that CA3301 applied twice in spring at a rate of 0.6-0.7 l/ha will not negatively impact the oil content in oilseed rape in Mediterranean EPPO zone.

Table 3-4-15: Summary table - Unseed rape - Oil content (%) - Mediterranean ETO zone									
Treatment name	UNTREATED CHECK	CA24 45	CARA MBA	PROS ARO	ORTI VA	CA3 301	CA33 01	No of trials where CA3301	No of trials where CA3301
Rate		0,7	0,8	1	1	0,6	0,7	at 0,6 l/ha	at 0,7 l/ha
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	L/ha	is >, = or <	is >, = or <
Appl. Code		AB	AB	AB	AB	AB	AB	compared to	compared to
Oil content (%) - 68-103 DA-R									

Number of values	8	8				8	8	UTC	CA3301 0,7 l/ha	UTC	CA3301 0,6 l/ha
Minimum value	41,00	42,14				42,16	42,33				
Maximum value	50,73	51,73	-	-	-	50,93	51,05	0 >	0 >	0 >	0 >
Mean Oil content (%)	45,67	46,15				46,00	46,30	6 =	6 =	6 =	6 =
Mean %UTC	100,00%	100,54%				100,59%	100,80%	0 <	0 <	0 <	0 <
Number of values	2	2	2			2	2	CA2445 0,7 l/ha	CA-RAMBA 0,8 l/ha	CA2445 0,7 l/ha	CA2445 0,7 l/ha
Minimum value	50,40	50,53	48,30			49,23	49,63				
Maximum value	50,73	51,73	50,68	-	-	50,93	51,05	0 >	0 >	0 >	0 >
Mean Oil content (%)	50,57	51,13	49,66			50,08	50,34	6 =	2 =	6 =	2 =
Mean %UTC	100,00%	101,11%	97,87%			99,04%	99,55%	0 <	0 <	0 <	0 <
Number of values	3	3		3		3	3	PROSARO		PROSARO	
Minimum value	41,00	42,14		42,74		42,16	42,33	1,0 l/ha		1,0 l/ha	
Maximum value	45,80	46,25	-	46,86	-	47,10	47,26	0 >		0 >	
Mean Oil content (%)	43,40	44,07		44,45		44,08	44,50	3 =		3 =	
Mean %UTC	100,00%	101,56%		102,45%		101,56%	102,54%	0 <		0 <	
Number of values	1	1			1	1	1	ORTIVA		ORTIVA	
Minimum value	43,93	44,20			45,30	44,61	45,21	1,0 l/ha		1,0 l/ha	
Maximum value	43,93	44,20	-	-	45,30	44,61	45,21	0 >		0 >	
Mean Oil content (%)	43,93	44,20			45,30	44,61	45,21	1 =		1 =	
Mean %UTC	100,00%	100,61%			103,12%	101,55%	102,91%	0 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

* 2 trials without statistical analysis

Use of CA3301 in the North-Eastern EPPO zone – 1 application in autumn and 1 application in spring

Among trials conducted in the North-eastern East EPPO zone with 1 application in autumn and 1 application in spring of CA3301 at 0.6-0.7 l/ha, oil content (%) was analysed in 4 trials.

In these trials, CA3301 at 0.6 l/ha provided significantly lower oil content compared to the untreated control in 1 trial out of 4 and was equivalent in the other 3 trials. At this dose rate, CA3301 provided statistically equivalent oil content compared to the references CA2445 at 0.7 l/ha and TILMOR 240 EC at 0.7-1.0 l/ha.

Applied at 0.7 l/ha, CA3301 provided significantly lower oil content compared to the untreated control in 1 trial out of 4 and was equivalent in the other 3 trials. At this dose rate, CA3301 provided statistically equivalent oil content compared to the references CA2445 at 0.7 l/ha and TILMOR 240 EC at 0.7-1.0 l/ha (see Table 3.4-198).

The levels of oil content observed were overall in compliance with the oil content standards for oilseed rape except in 1 trial where it reached 68.05% in the untreated control and was higher than in all treated modalities. Moreover differences between trials may be due to differences in harvest timings, local growth conditions and crop varieties.

Consequently, considering elements previously presented, it is concluded that CA3301 applied in autumn and in spring at a rate of 0.6-0.7 l/ha will not negatively impact the oil content in oilseed rape in North-Eastern EPPO zone.

Table 3.4-198: Summary table – Oilseed rape – Oil content (%) – North-Eastern EPPO zone

Treatment name	UNTREATED CHECK	CA24 45	TILMOR 240 EC	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,7 l/ha is >, = or < compared to
Rate		0,7	0,7-1	0,6	0,7		
Rate unit		L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	A-B	AB	AB		
Oil content (%) - 90-126 DA-B							
Number of values	4			4	4	UTC	CA33 01 0,7 l/ha
Minimum value	37,93			39,18	38,80		
Maximum value	68,05	-	-	49,08	49,38	0 >	0 >
Mean Oil content (%)	49,86			44,93	45,43	3 =	4 =
Mean %UTC	100,00%			93,16 %	93,91 %	1 <	0 <
Number of values	3	3		3	3	CA2445 0,7 l/ha	CA2445 0,7 l/ha
Minimum value	37,93	39,55		39,18	38,80		
Maximum value	49,75	49,30	-	49,08	49,38	0 >	0 >
Mean Oil content (%)	43,80	44,55		44,21	44,34	3 =	3 =
Mean %UTC	100,00%	101,9 4%		101,1 5%	101,3 7%	0 <	0 <
Number of values	1		1	1	1	TILMOR 240 EC 0,70-1,0 l/ha	TILMOR 240 EC 0,70-1,0 l/ha
Minimum value	68,05		45,70	47,10	48,68		
Maximum value	68,05	-	45,70	47,10	48,68	0 >	0 >
Mean Oil content (%)	68,05		45,70	47,10	48,68	1 =	1 =
Mean %UTC	100,00%		67,16%	69,21 %	71,54 %	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-Eastern EPPO zone – 2 applications in spring

Among trials conducted in the North-Eastern EPPO zone with 2 applications in spring of CA3301 at 0.6-0.7 l/ha, oil content (%) was analysed in 11 trials.

In these trials, CA3301 at 0.6 l/ha provided significantly lower oil content compared to the untreated control in 1 trial and a higher oil content in 1 trial out of 11, although comparable to the reference products in these 2 trials. In the other 9 trials, CA3301 at 0.6 l/ha did not affect the oil content compared to the untreated control. At this dose rate, CA3301 provided statistically equivalent oil content compared to the references CA2445 at 0.7 l/ha, PROPULSE at 0.8 l/ha and CARAMBA 60 SL at 1.0 l/ha.

Applied at 0.7 l/ha, CA3301 did not affect the oil content compared to the untreated control. At this dose rate, CA3301 provided statistically equivalent oil content compared to the references CA2445 at 0.7 l/ha, PROPULSE at 0.8 l/ha and CARAMBA 60 SL at 1.0 l/ha (see Table 3.4-199).

In addition, compared to references PROSARO and CARAMBA at 1.0 l/ha applied once, CA3301 at 0.6-0.7 l/ha provided statistically equivalent oil content in all comparisons.

The levels of oil content observed were in compliance with the oil content standards for oilseed rape and differences between trials may be due to differences in harvest timings, local growth conditions and crop varieties.

Consequently, considering elements previously presented, it is concluded that CA3301 applied twice in spring at a rate of 0.6-0.7 l/ha will not negatively impact the oil content in oilseed rape in North-East^{eff} EPPO zone.

Table 3.4-199: Summary table – Oilseed rape – Oil content (%) – North-East^{eff} EPPO zone

Treatment name	UNTREATED CHECK	CA 2445	PROPULSE	PROSARO	CARAMBA 60 SL	CARAMBA 60 SL	CA 3301	CA 3301	No of trials where CA3301 is >, = or < compared to	No of trials where CA3301 is >, = or < compared to
Rate		0,7 L/ha	0,8 L/ha	1 L/ha	1 L/ha	1 L/ha	0,6 L/ha	0,7 L/ha		
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha	L/ha	L/ha		
Appl. Code		AB	AB	A	A	AB	AB	AB		
Oil content (%) - 55-112 DA-B										
Number of values	11						11	11	UT C	CA 3301 0,7 l/ha
Minimum value	40,93						37,90	40,90		
Maximum value	49,75	-	-	-	-	-	48,95	49,15	1 >	0 >
Mean Oil content (%)	45,14						44,52	45,08	9 =	11 =
Mean %UTC	100,00%						98,60%	99,90%	1 <	0 <
Number of values	5	5					5	5	CA2445 0,7 l/ha	CA2445 0,7 l/ha
Minimum value	40,93	39,50					37,90	40,90		
Maximum value	47,10	47,80	-	-	-	-	47,20	47,10	0 >	0 >
Mean Oil content (%)	44,07	43,79					43,27	44,28	5 =	5 =
Mean %UTC	100,00%	99,26%					98,06%	100,47%	0 <	0 <
Number of values	1		1				1	1	PRO-PULSE 0,8 l/ha	PRO-PULSE 0,8 l/ha
Minimum value	45,30		45,78				46,13	45,50		
Maximum value	45,30	-	45,78	-	-	-	46,13	45,50	0 >	0 >
Mean Oil content (%)	45,30		45,78				46,13	45,50	1 =	1 =
Mean %UTC	100,00%		101,06%				101,83%	100,44%	0 <	0 <

Treatment name	UNTREATED CHECK	CA 244 5 0,7 L/ha AB	PRO PULS E 0,8 L/ha AB	PRO SAR O 1 L/ha A	CARAM BA 60 SL 1 L/ha A	CARAM BA 60 SL 1 L/ha AB	CA 330 1 0,6 L/ha AB	CA 330 1 0,7 L/ha AB	No of trials where CA3301 is >, = or < compared to	No of trials where CA3301 is >, = or < compared to
Number of values	3	3				3	3	3	PRO-SARO 1,0 l/ha	PRO-SARO 1,0 l/ha
Minimum value	41,00	39,50				40,20	37,90	40,90		
Maximum value	47,10	47,80	-	-	-	47,80	47,20	47,10	0 >	0 >
Mean Oil content (%)	44,90	44,63				44,03	43,87	44,80	2 =	2 =
Mean %UTC	100,00%	99,28 %				98,06%	97,48 %	99,78 %	0 <	0 <
Number of values	3				3		3	3	CA-RAMBA 60 SL 1,0 l/ha (A)	CA-RAMBA 60 SL 1,0 l/ha (A)
Minimum value	47,23				46,23		44,25	45,75		
Maximum value	49,75	-	-	-	49,45	-	48,95	49,15	0 >	0 >
Mean Oil content (%)	48,41				48,09		47,17	47,77	3 =	3 =
Mean %UTC	100,00%				99,32%		99,51 %	98,66 %	0 <	0 <
Number of values	2			2			2	2	CA-RAMBA 60 SL 1,0 l/ha (AB)	CA-RAMBA 60 SL 1,0 l/ha (AB)
Minimum value	42,35			42,33			42,43	42,53		
Maximum value	43,30	-	-	43,63	-	-	43,33	43,20	0 >	0 >
Mean Oil content (%)	42,83			42,98			42,88	4,87	3 =	3 =
Mean %UTC	100,00%			100,36 %			100,13 %	100,10 %	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the South-Eastern EPPO zone – 1 application in autumn and 1 application in spring

Among trials conducted in the South-Eastern EPPO zone with 1 application in autumn and 1 application in spring of CA3301 at 0.6-0.7 l/ha, oil content (%) was analysed in 3 trials.

In these trials, CA3301 at 0.6 l/ha did not significantly affect oil content compared to the untreated control and provided statistically equivalent oil content compared to the references CA2445 at 0.7 l/ha and TILMOR at 1.2 l/ha.

Applied at 0.7 l/ha, CA3301 did not significantly affect oil content compared to the untreated control and provided statistically equivalent oil content compared to the references CA2445 at 0.7 l/ha and TILMOR at 1.2 l/ha (see Table 3.4-200).

The levels of oil content observed were in compliance with the oil content standards for oilseed rape and differences between trials may be due to differences in harvest timings, local growth conditions and

crop varieties.

Consequently, considering elements previously presented, it is concluded that CA3301 applied in autumn and in spring at a rate of 0.6-0.7 l/ha will not negatively impact the oil content in oilseed rape in South-East ~~EPF~~ EPPO zone.

Table 3.4-200: Summary table – Oilseed rape – Oil content (%) – South-East ~~EPF~~ EPPO zone

Treatment name	UNTREATED CHECK	CA2445	TILMOR	CA3301	CA3301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,7 l/ha is >, = or < compared to	
Rate		0,7	1,2	0,6	0,7				
Rate unit		L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB				
Oil content (%) - 61-70 DA-B									
Number of values	3			3	3	UT C	CA3301 0,7 l/ha	UT C	CA3301 0,6 l/ha
Minimum value	44,53			44,50	44,61				
Maximum value	46,98	-	-	46,98	46,33	0 >	0 >	0 >	0 >
Mean Oil content (%)	45,59			45,35	45,31	3 =	3 =	3 =	3 =
Mean %UTC	100,00%			99,47 %	99,41 %	0 <	0 <	0 <	0 <
Number of values	2	2		2	2	CA2445 0,7 l/ha		CA2445 0,7 l/ha	
Minimum value	44,53	44,66		44,50	44,61	0 >		0 >	
Maximum value	45,25	45,75	-	44,56	45,00	2 =		2 =	
Mean Oil content (%)	44,89	45,21		44,53	44,81	0 <		0 <	
Mean %UTC	100,00%	100,70 %		99,20 %	99,81 %				
Number of values	1		1	1	1	TILMOR 1,2 l/ha		TILMOR 1,2 l/ha	
Minimum value	46,98		47,33	46,98	46,33	0 >		0 >	
Maximum value	46,98	-	47,33	46,98	46,33	1 =		1 =	
Mean Oil content (%)	46,98		47,33	46,98	46,33	0 <		0 <	
Mean %UTC	100,00%		100,74 %	100,00 %	98,62 %				

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the South-East ~~EPF~~ EPPO zone – 2 applications in spring

Among trials conducted in the South-East ~~EPF~~ EPPO zone with 2 applications in spring of CA3301 at 0.6-0.7 l/ha, oil content (%) was analysed in 12 trials.

In these trials, CA3301 at 0.6 l/ha provided significantly higher oil content compared to the untreated control in 7 trials out of 12, which was also observed for the reference products. In the other 5 trials, CA3301 at 0.6 l/ha did not affect the oil content. At this dose rate, CA3301 provided statistically equivalent oil content compared to the references PROPULSE at 1.0 l/ha and ORIUS at 1.0 l/ha. Compared to CA2445, CA3301 at 0.6 l/ha provided significantly lower oil content in 5 trials out of 8, although still significantly higher than the untreated, and was equivalent in the other 3 trials.

Applied at 0.7 l/ha, CA3301 provided significantly higher oil content compared to the untreated control in 8 trials out of 12, which was also observed for the reference products. In the other 4 trials, CA3301 at 0.7 l/ha did not affect the oil content. At this dose rate, CA3301 provided statistically equivalent oil content compared to the references PROPULSE at 1.0 l/ha and ORIUS at 1.0 l/ha. Compared to CA2445, CA3301 at 0.7 l/ha provided significantly higher oil content in 5 trials out of 8 and was equivalent in the other 3 trials.

Moreover, CA3301 at 0.7 l/ha provided a significantly higher oil content compared to 0.6 l/ha dose rate in 6 trials (see Table 3.4-201).

The levels of oil content observed were in compliance with the oil content standards for oilseed rape and differences between trials may be due to differences in harvest timings, local growth conditions and crop varieties.

Consequently, considering elements previously presented, it is concluded that CA3301 applied twice in spring at a rate of 0.6-0.7 l/ha will not negatively impact the oil content and might have positive effects in oilseed rape in South-East ~~EPPO~~ EPPO zone.

Table 3.4-201: Summary table – Oilseed rape – Oil content (%) – South-East ~~EPPO~~ EPPO zone

Treatment name	UNTREATED CHECK	CA24 45	PROPU LSE	ORIU S	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,7 l/ha is >, = or < compared to	
Rate		0,7	1	1	0,6	0,7				
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB	AB				
Oil content (%) - 52-126 DA-B										
Number of values	12				12	12	UT C	CA33 01 0,7 l/ha	UT C	CA33 01 0,6 l/ha
Minimum value	42,11				44,58	44,68				
Maximum value	49,35	-	-	-	49,98	50,33	7 >	0 >	8 >	6 >
Mean Oil content (%)	44,59				46,98	47,56	5 =	6 =	4 =	6 =
Mean %UTC	100,00%				105,5 5%	106,8 5%	0 <	6 <	0 <	0 <
Number of values	8	8			8	8	CA2445 0,7 l/ha		CA2445 0,7 l/ha	
Minimum value	42,11	47,29			46,97	47,61				
Maximum value	49,35	50,4	-	-	49,98	50,33	0 >		5 >	
Mean Oil content (%)	43,95	48			47,56	48,29	3 =		3 =	
Mean %UTC	100,00%	109,3 6%			108,3 6%	110,0 4%	5 <		0 <	
Number of values	2		2		2	2	PROPULSE 1,0 l/ha		PROPULSE 1,0 l/ha	
Minimum value	46,6		47,35		46,83	46,95				
Maximum value	47,38	-	47,7	-	46,83	47,55	0 >		0 >	
Mean Oil content (%)	46,99		47,53		46,83	47,25	2 =		2 =	
Mean %UTC	100,00%		101,15%		99,67 %	100,5 5%	0 <		0 <	
Number of values	2			2	2	2	ORIUS 1,0 l/ha		ORIUS 1,0 l/ha	
Minimum value	44,43			44,53	44,58	44,68				
Maximum value	45,08	-	-	45,15	45,13	45,18	0 >		0 >	
Mean Oil content (%)	44,76			44,84	44,86	44,93	2 =		2 =	
Mean %UTC	100,00%			100,1 9%	100,2 2%	100,3 9%	0 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

HLW (Hectolitre Weight / Grain Specific weight)

Use of CA3301 in the Maritime EPPO zone – 1 application in autumn and 1 application in spring

Among trials conducted in the Maritime EPPO zone with 1 application in autumn and 1 application in spring of CA3301 at 0.6-0.7 l/ha, grain specific weight (kg/hl) was recorded in 1 trial.

In this trial, CA3301 at 0.6-0.7 l/ha did not affect significantly the grain specific weight compared to the untreated control. Compared to the references CA2445 at 0.7 l/ha and BISTRO at 0.6 l/ha, CA3301 at 0.6-0.7 l/ha provided statistically equivalent grain specific weight (see Table 3.4-202).

The levels of grain specific weight recorded in this trial was in accordance with the standard levels for oilseed rape.

Consequently, considering elements previously presented, it is concluded that CA3301 applied in autumn and in spring at a rate of 0.6-0.7 l/ha will not negatively impact the grain specific weight in oilseed rape in Maritime EPPO zone.

Table 3.4-202: Summary table – Oilseed rape – Grain specific weight (kg/hl) – Maritime EPPO zone

Treatment name		BIS TRO	CA2 445	CA3 301	CA3 301	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to				No of trials where CA3301 at 0,7 l/ha is >, = or < compared to			
Rate	UNTREATED CHECK	0,6 L/ha	0,7 L/ha	0,6 L/ha	0,7 L/ha								
Rate unit		L/ha	L/ha	L/ha	L/ha								
Appl. Code		AB	AB	AB	AB								
HLW (Kg/ha) - 111 DA-B													
Number of values	1	1	1	1	7	U T C	BIS-TRO 0,6 l/ha	CA2 445 l/ha	CA3 301 l/ha	U T C	BIS-TRO 0,6 l/ha	CA2 445 l/ha	CA3 301 l/ha
Minimum value	57,30	57,5 5	55,9 8	56,5 5	54,8 8	0 >	0 >	0 >	0 >	0 >	0 >	0 >	0 >
Maximum value	57,30	57,5 5	55,9 8	56,5 5	54,8 8	1 =	1 =	1 =	1 =	1 =	1 =	1 =	1 =
Mean HLW (kg/ha)	57,30	57,5 5	55,9 8	56,5 5	54,8 8	0 <	0 <	0 <	0 <	0 <	0 <	0 <	0 <
Mean %UTC	100,00%	100, 44%	97,7 0%	98,6 9%	95,7 8%								

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the Mediterranean EPPO zone – 2 applications in spring

Among trials conducted in the Mediterranean EPPO zone with 2 applications in spring of CA3301 at 0.6-0.7 l/ha, grain specific weight (kg/hl) was recorded in 4 trials.

In these trials, CA3301 at 0.6-0.7 l/ha did not affect significantly the grain specific weight compared to the untreated control. Compared to the references CA2445 at 0.7 l/ha, PROSARO at 1.0 l/ha and ORTIVA at 1.0 l/ha, CA3301 at 0.6-0.7 l/ha provided statistically equivalent grain specific weight (see Table 3.4-203).

The levels of grain specific weight recorded in all the trials were in accordance with the standard levels for oilseed rape.

Consequently, considering elements previously presented, it is concluded that CA3301 applied twice in spring at a rate of 0.6-0.7 l/ha will not negatively impact the grain specific weight in oilseed rape in Mediterranean EPPO zone.

Table 3.4-203: Summary table – Oilseed rape – Grain specific weight (kg/hl) – Mediterranean EPPO zone

Treatment name	UNTREATED CHECK	CA2 445	PROS ARO	ORTI VA	CA33 01	CA33 01	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,7 l/ha is >, = or < compared to	
Rate		0,7	1	1	0,6	0,7				
Rate unit		L/ha	L/ha	L/ha	L/ha	L/ha				
Appl. Code		AB	AB	AB	AB	AB				
HLW (kg/ha) - 74-101 DA-B										
Number of values	4	4			4	4	UTC	CA330 1	UTC	CA330 1

Treatment name	UNTREATED CHECK	CA2 445 0,7 L/ha AB	PROS ARO 1 L/ha AB	ORTI VA 1 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,7 l/ha is >, = or < compared to	
Rate										
Rate unit										
Appl. Code										
Minimum value	63,88	63,15			63,36	63,12		0,7 l/ha		0,6 l/ha
Maximum value	65,88	65,27	-	-	66,27	66,78	0 >	0 >	0 >	0 >
Mean HLW (kg/hl)	64,83	64,36			65,14	64,96	4 =	4 =	4 =	4 =
Mean % UTC	100,00%	99,31 %			100,5 0%	100,2 0%	0 <	0 <	0 <	0 <
Number of values	3	3	3		3	3	CA2 445 0,7 l/ha	PRO-SARO 1,0 l/ha	CA2 445 0,7 l/ha	PRO-SARO 1,0 l/ha
Minimum value	63,88	63,15	62,71		63,36	63,12				
Maximum value	65,88	65,27	67,05	-	66,27	66,78	0 >	0 >	0 >	0 >
Mean HLW (kg/hl)	64,56	64,27	64,94		65,10	65,02	4 =	3 =	4 =	3 =
Mean % UTC	100,00%	99,56 %	100,58 %		100,8 4%	100,7 1%	0 <	0 <	0 <	0 <
Number of values	1	1		1	1	1	ORTIVA 1,0 l/ha		ORTIVA 1,0 l/ha	
Minimum value	65,62	64,67		64,89	65,27	64,76				
Maximum value	65,62	64,67	-	64,89	65,27	64,76	0 >		0 >	
Mean HLW (kg/hl)	65,62	64,67		64,89	65,27	64,76	1 =		1 =	
Mean % UTC	100,00%	98,55 %		98,89 %	99,47 %	98,69 %	0 <		0 <	

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-Eastern EPPO zone – 2 applications in spring

Among trials conducted in the North-Eastern EPPO zone with 2 applications in spring of CA3301 at 0.6-0.7 l/ha, grain specific weight (kg/hl) was recorded in 1 trial.

In this trial, CA3301 at 0.6-0.7 l/ha did not affect significantly the grain specific weight compared to the untreated control. Compared to the reference PROPULSE at 0.8 l/ha, CA3301 at 0.6-0.7 l/ha provided statistically equivalent grain specific weight (see Table 3.4-204).

The levels of grain specific weight recorded in this trial was in accordance with the standard levels for oilseed rape.

Consequently, considering elements previously presented, it is concluded that CA3301 applied twice in spring at a rate of 0.6-0.7 l/ha will not negatively impact the grain specific weight in oilseed rape in North-Eastern EPPO zone.

Table 3.4-204: Summary table – Oilseed rape – Grain specific weight (kg/hl) – North-Eastern EPPO zone

Treatment name	UNTREATED CHECK	PROPU LSE	CA33 01	CA33 01	No of trials where CA3301			No of trials where CA3301		
Rate		0,8	0,6	0,7	at 0,6 l/ha is >, = or <			at 0,7 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		AB	AB	AB	compared to			compared to		
HLW (Kg/ha) - 60 DA-B										
Number of values	1	1	1	1	UT C	PRO- PU LSE	CA33 01	UT C	PRO- PU LSE	CA33 01

Minimum value	73,42	76,29	72,72	74,61		0,8 l/ha	0,7 l/ha		0,8 l/ha	0,6 l/ha
Maximum value	73,42	76,29	72,72	74,61	0 >	0 >	0 >	0 >	0 >	0 >
Mean HLW (Kg/ha)	73,42	76,29	72,72	74,61	1 =	1 =	1 =	1 =	1 =	1 =
Mean %UTC	100,00%	103,91%	99,05 %	101,6 2%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

TKW (Thousand Kernel Weight)

Use of CA3301 in the Mediterranean EPPO zone – 2 applications in spring

Among trials conducted in the Mediterranean EPPO zone with 1 application in autumn and 1 application in spring of CA3301 at 0.6-0.7 l/ha, thousand kernel weight (g) was recorded in 4 trials.

In these trials, CA3301 at 0.6-0.7 l/ha did not affect significantly the thousand kernel weight compared to the untreated control. Compared to the references CA2445 at 0.7 l/ha, PROSARO at 1.0 l/ha and ORTIVA at 1.0 l/ha, CA3301 at 0.6-0.7 l/ha provided statistically equivalent thousand kernel weight (see Table 3.4-205).

The levels of thousand kernel weight recorded in all the trials were in accordance with the standard levels for oilseed rape.

Consequently, considering elements previously presented, it is concluded that CA3301 applied twice in spring at a rate of 0.6-0.7 l/ha will not negatively impact the thousand kernel weight in oilseed rape in Mediterranean EPPO zone.

Table 3.4-205: Summary table – Oilseed rape – Thousand kernel weight (g) – Mediterranean EPPO zone

Treatment name Rate Rate unit Appl. Code	UNTREATED CHECK	CA24 45 0,7 L/ha AB	PRO- SARO 1 L/ha AB	ORTI VA 1 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to		No of trials where CA3301 at 0,7 l/ha is >, = or < compared to	
TKW (g) - 74-101 DA-B										
Number of values	4	4			4	4	UTC	CA330 1	UTC	CA330 1
Minimum value	4,71	5,04			4,93	5,03		0,7 l/ha		0,6 l/ha
Maximum value	5,03	5,24	-	-	5,55	5,20	0 >	0 >	0 >	0 >
Mean TKW (g)	4,89	5,13			5,19	5,14	4 =	4 =	4 =	4 =
Mean %UTC	100,00%	104,9 9%			106,1 4%	105,2 1%	0 <	0 <	0 <	0 <
Number of values	3	3	3		3	3	CA2 445 0,7 l/ha	PRO- SARO 1,0 l/ha	CA2 445 0,7 l/ha	PRO- SARO 1,0 l/ha
Minimum value	4,71	5,04	4,83		4,98	5,03	0 >	0 >	0 >	0 >
Maximum value	5,03	5,24	5,15	-	5,55	5,20				
Mean TKW (g)	4,91	5,16	5,01		5,28	5,14	4 =	3 =	4 =	3 =
Mean %UTC	100,00%	104,9 9%	102,05 %		107,3 6%	104,6 6%	0 <	0 <	0 <	0 <
Number of values	1	1		1	1	1	ORTIVA		ORTIVA	

Treatment name	UNTREATED CHECK	CA24 45 0,7 L/ha AB	PRO-SARO 1 L/ha AB	ORTI VA 1 L/ha AB	CA33 01 0,6 L/ha AB	CA33 01 0,7 L/ha AB	No of trials where CA3301 at 0,6 l/ha is >, = or < compared to	No of trials where CA3301 at 0,7 l/ha is >, = or < compared to
Minimum value	4,81	5,05		4,90	4,93	5,14	1,0 l/ha	1,0 l/ha
Maximum value	4,81	5,05	-	4,90	4,93	5,14	0 >	0 >
Mean TKW (g)	4,81	5,05		4,90	4,93	5,14	1 =	1 =
Mean %UTC	100,00%	104,9 9%		101,87 %	102,4 9%	106,8 6%	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Use of CA3301 in the North-Eastern EPPO zone – 2 applications in spring

Among trials conducted in the North-Eastern EPPO zone with 2 applications in spring of CA3301 at 0.6-0.7 l/ha, thousand kernel weight (g) was recorded in 2 trials.

In these trials, CA3301 at 0.6-0.7 l/ha did not affect significantly the thousand kernel weight compared to the untreated control. Compared to the reference PROSARO at 1.0 l/ha, CA3301 at 0.6-0.7 l/ha provided statistically equivalent thousand kernel weight (see Table 3.4-206).

The levels of thousand kernel weight recorded in all the trials were in accordance with the standard levels for oilseed rape.

Consequently, considering elements previously presented, it is concluded that CA3301 applied twice in spring at a rate of 0.6-0.7 l/ha will not negatively impact the thousand kernel weight in oilseed rape in North-Eastern EPPO zone.

Table 3.4-206: Summary table – Oilseed rape – Thousand kernel weight (g) – North-Eastern EPPO zone

Treatment name	UNTREATED CHECK	PROSARO	CA33 01	CA33 01	No of trials where CA3301			No of trials where CA3301		
Rate		1	0,6	0,7	at 0,6 l/ha is >, = or <			at 0,7 l/ha is >, = or <		
Rate unit		L/ha	L/ha	L/ha						
Appl. Code		A	AB	AB	compared to			compared to		
TKW (g) - 100 DA-B										
Number of values	2	2	2	2	UT C	PRO-SARO	CA33 01	UT C	PRO-SARO	CA33 01
Minimum value	5,07	5,08	4,97	5,13		1,0 l/ha	0,7 l/ha		1,0 l/ha	0,6 l/ha
Maximum value	5,08	5,1	5,2	5,22	0 >	0 >	0 >	0 >	0 >	0 >
Mean TKW (g)	5,07	5,09	5,08	5,17	2 =	2 =	2 =	2 =	2 =	2 =
Mean %UTC	100,00%	100,30%	100,19%	101,97%	0 <	0 <	0 <	0 <	0 <	0 <

'>' means CA3301 is significantly more efficient than plants treated with (treatment)' (conversely for '<')

Comments of zRMS:

No negative impact on the quality parameters of yield of winter oilseed rape (moisture content, HLW, thousand kernel weight, oil content) was observed after twice application of CA3301 at dose rate of 0,6-0,7 l/ha. A positive effect was visible in all EPPO climatic zones and no significant differences between test and reference product were detected.

3.4.4 Effects on transformation processes (KCP 6.4.4)

No specific studies investigating the effects of CA3301 on transformation processes were implemented. However, considering that CA3301 did not induce phytotoxicity symptoms it is logically expected that CA3301 sprayed at maximum 0.8 l/ha ~~according~~ according the application timing claimed will not negatively impact transformation processes.

Comments of zRMS:

No trials for effects on transformation processes have been submitted. CA3301 contains active substance of prothioconazole, which has been known for many years. No reports of negative impact on this parameter have been noted. According to the EPPO guideline PP 1/243 (2), the main crops which may be subjected to transformation processes include grapevine (winemaking), cereals (baking and brewing) and hop (brewing). However, if the applicant can demonstrate that residues are undetectable, or that any residues will not affect yeasts, a reasoned case may be sufficient to address these requirements.

3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

The impact of CA3301 on treated plants or plant products used for propagation was not specifically investigated. However, considering that CA3301 did not induce phytotoxicity symptoms and did not negatively impact treated plants and plant products, it is assumed that the test product will not negatively affect plants or plant products used for propagation.

Comments of zRMS:

Accepted.

3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

No specific trials were carried out on cereals to assess the possible impact of CA3301 applications on succeeding crops. The absence of phytotoxicity and adverse effects on the yield, quality of plant products and processing operations allow to conclude that no negative impact on succeeding crops is expected if CA3301 is applied according the recommended conditions in this dossier.

Comments of zRMS:

Accepted.

3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

No specific trials were carried out on cereals to assess the possible impact of CA3301 applications on adjacent crops. The absence of phytotoxicity and adverse effects on the yield, quality of plant products and processing operations allow to conclude that no negative impact on adjacent crops is expected if CA3301 is applied according the recommended conditions in this dossier.

Comments of zRMS:

Accepted.

3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in Part B; Section 9 (Ecotoxicology). No specific assessments of beneficials and non target organisms were taken in the efficacy trials; however, no adverse effects were noted when visual observations were made within these field trial sites.

Comments of zRMS:

Accepted.

3.6 Other/special studies

No other/special studies are presented in this dossier.

3.7 List of test facilities including the corresponding certificates

3.7.1 Winter barley (HORVW)

Table 3.7-1: List of test facilities - HORVW

Maritime EPPO zone

Test facility	Address	Certificate (Yes or No)
SynTech Research Czech Republic s.r.o.	Semčice 245 294 46 Semčice, CZECH REPUBLIC	YES
Agrolab A/S	Røjleskovvej 18 5500 Middelfart DENMARK	YES
QUINTUS GMBH	Liepen 7 17194 Hohen Wangelin OT Liepen GERMANY	YES
Oxford Agricultural Trials Limited	West Farm Barns – Launton Road - Stratton Audley – Bicester OXON - OX279AS UNITED KINGDOM	YES
ANADIAG FRANCE	13, rue de la Bourbre 38300 Ruy FRANCE	YES (2017)
ANADIAG CZECH REPUBLIC	517 54 Chleny 47 CZECH REPUBLIC	YES
ANADIAG DEUTSCHLAND	Lebacherstrasse 4 D-66113 Saarbrücken	YES

Test facility	Address	Certificate (Yes or No)
	GERMANY	
ANADIAG SAS	174 impasse du Plan d'Eau, 38300 Ruy-Montceau FRANCE	YES (2019)

Test facility	Address	Certificate (Yes or No)
SynTech Research Czech Republic s.r.o.	Semčice 245 294 46 Semčice, CZECH REPUBLIC	YES

ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

Odbor přípravků na ochranu rostlin

Zemědělská 1a, Brno, PSČ 613 00

Příloha rozhodnutí č.j.: UKZUZ 033034/2017 ze dne 12. 4. 2017

OSVĚDČENÍ

GEP/SYT/2017

o způsobilosti k provádění zkoušek
v souladu se zásadami správné pokusnické praxe

Official Recognition Certificate / GEP - Certificate

právnícká osoba: **SynTech Research Czech s.r.o.**

sidlo právnické osoby: Žitná 562/10, Nové Město (Praha 2), 120 00 Praha

IČ právnické osoby: 04601351

je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe podle § 45 odst. 1 zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, v platném znění, v návaznosti na Směrnici 91/414/EHS.

oblasti zkoušení / categories of official recognition:

- polní plodiny a zelenina / *field crops and vegetables*
- moření osiva / *seed treatment*
- laboratorní testy a analýzy / *laboratory tests and analyses*

Ústřední kontrolní a zkušební ústav zemědělský
Ředitelství zemědělských vstupů
Odbor přípravků na ochranu rostlin
613 00 Brno, Zemědělská 1a
-1-



Ing. Pavel Minář, Ph.D.
ředitel odboru

Test facility	Address	Certificate (Yes or No)
Agrolab A/S	Røjleskovvej 18 5500 Middelfart DENMARK	YES



Certifikat

for GEP-anerkendelse tildeles herved

Forsøgsenheden: Agrolab A/S
Røjleskovvej 18
DK-5500 Middelfart

Anerkendelsen gælder udførelsen af GEP-effektivitetsforsøg for bekæmpelsesmidler inden for

Forsøgsområderne: Markforsøg

GEP Anerkendelses Enheden ved Nationalt Center for Fødevarer og Jordbrug, Aarhus Universitet, kontrollerer organisation, personale, lokaler, forsøgsarealer, forsøgsudstyr samt standardforskrifter og forsøgsrapporter. Forsøgsenheden er underkastet løbende kontrol og inspektion.

Certifikatet for anerkendelse er gyldigt for en periode på 6 år.

Anerkendelsesdato: 1. januar 2014

Underskrevet: 16. december 2013


Nina Sørup Hansen
Miljøstyrelsen


Ulla Fosgerau Salomonsen
Aarhus Universitet


Peter Kryger Jensen
Aarhus Universitet

Forordning 1107/2009 om plantebeskyttelsesmidler og Miljøministeriets bekendtgørelse nr.1088 af 6. september 2013 anfører, at undersøgelser af plantebeskyttelsesmidlers effektivitet, der er udført i Danmark med henblik på godkendelse, skal være foretaget af forsøgsenheder, der er anerkendt hertil af Nationalt Center for Fødevarer og Jordbrug, Aarhus Universitet.

Test facility	Address	Certificate (Yes or No)
QUINTUS GMBH	Liepen 7 17194 Hohen Wangelin OT Liepen GERMANY	YES

GEP AGREEMENT

Anerkennungsbescheinigung

Die Versuchseinrichtung Quintus GmbH

mit Hauptsitz in Liepen 7
17194 Hohen Wangelin

und organisatorisch zugehörigen Arbeitseinheiten in 08393 Schönberg
Breitenbacher Straße 21
74595 Langenburg-
Nesselbach
Orlacher Straße 16
27796 Hude
Wieselweg 6

ist auf Antrag vom 2016-02-01

und nach durchgeführter Besichtigung durch Herrn Dr. S. Goltermann
Landesamt für Landwirtschaft,
Lebensmittelsicherheit und
Verbraucherschutz MV
2016-04-11

am

in den Versuchskategorien Acker-, Obst-, Gemüse-, Zier-
pflanzenbau, Haus- und
Kleingarten
agriculture, horticulture, home
and garden

als Einrichtung für die Prüfung der Wirksamkeit von Pflanzenschutzmitteln im Sinne des § 8 Abs. 6 der Pflanzenschutzmittelverordnung und gemäß Verordnung (EU) Nr. 284/2013 für 5 Jahre amtlich anerkannt worden.

Recognition Certificate

The testing facility

with headquarter in

and subsidiary testing units in

on application from

and after inspection

by from

on

in the trial categories

has been officially recognised as an organisation for efficacy testing facility of plant protection products according to § 8 par. 6 of the Plant Protection Products Ordinance and the Commission Regulation (EU) No 284/2013 for 5 years.

11.04.2016 

Datum date

Unterschrift signature

Landesamt für Landwirtschaft,
Lebensmittelsicherheit und
Verbraucherschutz MV,
Thierfelderstr. 16, 18059 Rostock

Adresse der anerkennenden Behörde
address of the recognising authority



Test facility	Address	Certificate (Yes or No)
Oxford Agricultural Trials Limited	West Farm Barns – Launton Road - Stratton Audley – Bicester OXON - OX279AS UNITED KINGDOM	YES



Certificate of

Official Recognition of Efficacy Testing Facilities or Organisations in the United Kingdom

This certifies that

Oxford Agricultural Trials Limited

complies with the minimum standards laid down in
Regulation (EC) 1107/2009 for efficacy testing.

The above Facility/Organisation has been officially
recognised as being competent to carry out efficacy trials/tests
in the United Kingdom in the following categories:

**Agriculture/Horticulture
Biologicals and Semiochemicals
Stored Crops**

Date of issue: 9 January 2018
Effective date: 1 January 2018
Expiry date: 31 December 2022

Signature


Authorised signatory

Certification Number

ORETO 385



Chemicals Regulation Division



Department of
**Agriculture and
Rural Development**

Test facility	Address	Certificate (Yes or No)
ANADIAG FRANCE	13, rue de la Bourbre 38300 Ruy FRANCE	YES (2017)



MINISTÈRE DE L'AGRICULTURE ET DE L'ALIMENTATION

**DÉCISION D'AGRÈMENT POUR RÉALISER
DES ESSAIS OFFICIELLEMENT RECONNUS**

Conformément à l'article R. 253-38 du code rural et de la pêche maritime et à l'article 6 de l'arrêté du 26 avril 2007 relatif aux essais officiels et officiellement reconnus pour l'évaluation des produits mentionnés à l'article L. 253-1 du code rural et de la pêche maritime,

Vu la convention passée avec le Cofrac n° 4609,

Vu le rapport d'évaluation réalisé par le Cofrac, en date du 27 juillet 2017,

L'agrément pour réaliser des essais officiellement reconnus est renouvelé, à l'organisme :

ANADIAG France
13 rue de la Bourbre
38300 RUY

sous le numéro : **BPE - 105**

ET POUR LE PÉRIMÈTRE SUIVANT :

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
ANADIAG France 13 rue de la Bourbre 38300 RUY (unité centrale)	- Traitement des semences : grandes cultures
UE 01 – Harnes (UE 62) ZI la Motte au Bois 62440 HARNES	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Zones non agricoles
UE 03 – Saint Pierre du Bû (UE 14) Couvigny 14700 SAINT PIERRE DU BU	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum
UE 03 – Cintré (UE 35) Rue du puisatier ZA du moulin à vent 35310 CINTRE	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Zones non agricoles
UE 06 – Varois et Chaignot (UE 21) 8 route de Gray 21490 VAROIS ET CHAIGNOT	- Grandes cultures - Vigne - Zones non agricoles
UE 08 – Saint Barthélémy (UE 38) 700 route de Pisieu 38270 SAINT BARTHELEMY	- Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
UE 10 – Saint Etienne de Fougères (UE 47) ZA Bel Air 47380 SAINT ETIENNE DE FOUGERES	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles - Désinfections et désinsectisation des sols, des matériels et des locaux de culture et de stockage des végétaux
UE 12– Saint Germain des Près (UE 49) ZA la Poterie 49170 SAINT GERMAIN DES PRES	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur
UE 13 – Castillon du Gard (UE 30) ZA les codes bas 3 30210 CASTILLON DU GARD	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles
UE 15 – Haguenau (UE 67) 16 rue Ampère 67500 HAGUENAU	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Processus de transformation : <ul style="list-style-type: none"> - Vinification - Transformation de pomme de terre - Transformation de fruits (compote, jus de fruit, nectar, fruit au sirop, confiture, fruits séchés) - Transformation de légumes (jus, concentré de tomates, conserve de légumes, ketchup, choucroute) - Extraction d'huile
UE 16 – Thorée les Pins (UE 72) La Belle Métairie 72800 THOREE LES PINS	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture
UE 17 – Toulouse (UE 31) 75 voie de TOEC Bâtiment entreprise 2 31076 TOULOUSE	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture

Cet agrément est délivré pour une durée de cinq ans à compter du 09/10/2017 jusqu'au 08/10/2022. En application de l'article 5 de l'arrêté susmentionné, une nouvelle évaluation aura lieu dans un délai compris entre vingt-quatre et trente-six mois à compter du 09/10/2017.

Date : 03 OCT. 2017

Le sous directeur de la qualité, de la santé
et de la protection des végétaux

Alain TRIDON

Test facility	Address	Certificate (Yes or No)
ANADIAG CZECH REPUBLIC	517 54 Chleny 47 CZECH REPUBLIC	YES

ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

Odbor přípravků na ochranu rostlin

Zemědělská 1a, Brno, PSČ 613 00

Příloha rozhodnutí č.j.: UKZUZ 035705/2015 ze dne 30. 4. 2015

OSVĚDČENÍ

GEP/AHC/2015

o způsobilosti k provádění zkoušek
v souladu se zásadami správné pokusnické praxe

Official Recognition Certificate / GEP - Certificate

právníká osoba: **Anadiag SA, CZ organizační složka podniku**

sídlo právnické osoby: Chleny 46, 517 45 Chleny

IČ právnické osoby: 27518604

je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe podle § 45 odst. 1 zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, v platném znění, v návaznosti na Směrnici 91/414/EHS.

oblasti zkoušení / categories of official recognition:

- polní plodiny a zelenina / *field crops and vegetables*
- trvalé kultury / *high crops*
- skleníky a jiné kryté prostory / *protected areas and storage rooms*

Ústřední kontrolní a zkušební ústav zemědělský
Sekce zemědělských vstupů
Odbor přípravků na ochranu rostlin
613 00 Brno, Zemědělská 1a
- 1 -




Ing. Pavel Minář, Ph.D.
ředitel odboru


Test facility	Address	Certificate (Yes or No)
ANADIAG DEUTSCHLAND	Lebacherstrasse 4 D-66113 Saarbrücken GERMANY	YES

* Ministerium für
Umwelt und
Verbraucherschutz

SAARLAND



GEP-Anerkennungs-Zertifikat / Recognition Certificate

 <p>Anerkennungsbescheinigung</p> <p>Die Versuchseinrichtung</p> <p>mit Hauptsitz in</p> <p>und organisatorisch zugehörigen Arbeitseinheiten in</p> <p>ist auf Antrag vom und nach durchgeführter Besichtigung</p> <p>durch</p> <p>vom</p> <p>am</p> <p>in den Versuchskategorien</p> <p>bis zum</p>	<p>Anadiag Deutschland GmbH Versuchsstation Bondorf Haitinger Höfe 4 D-71149 Bondorf</p> <p>Lebacherstraße 4 D-66113 Saarbrücken</p> <p>./.</p> <p>30.06.2017</p> <p>Dr. Friedrich Merz und Frank Mohr</p> <p>Regierungspräsidium Stuttgart und Ministerium für Umwelt und Verbraucherschutz Saarland</p> <p>22.09.2017</p> <p>Ackerbau, Gemüsebau, Weinbau, Obstbau und Sonstige (Nichtkulturland: Rasen, Gleisanlagen, Wege und Plätze)</p> <p>21.09.2022</p>	<p>Recognition Certificate</p> <p>The testing facility</p> <p>with headquarters in</p> <p>and subsidiary testing units in</p> <p>on application from and after inspection</p> <p>by</p> <p>dated</p> <p>on</p> <p>in the trial categories</p> <p>until</p>
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als Einrichtung für die Prüfung der
Wirksamkeit von Pflanzenschutzmitteln
im Sinne des § 8 Abs. 6 der
Pflanzenschutzmittelverordnung
und gemäß Verordnung (EU) Nr. 284/2013
für 5 Jahre amtlich anerkannt worden.

has been officially recognised
as an organisation for efficacy
testing facility of plant protection
products according to § 8 par. 6
of the Plant Protection Products
Ordinance and the Commission
Regulation (EU) No 284/2013
for 5 years.

18.12.2017

Datum
date

Frank Meyer

Unterschrift
sign

Ministerium für Umwelt und Verbraucherschutz
Referat B/2
Keplerstraße 18
D-66 117 Saarbrücken

Adresse der anerkennenden Behörde
address of the recognising authority



Stempel
stamp

Test facility	Address	Certificate (Yes or No)
ANADIAG SAS	174 impasse du Plan d'Eau, 38300 Ruy-Montceau FRANCE	YES (2019)



MINISTÈRE DE L'AGRICULTURE ET DE L'ALIMENTATION

**DÉCISION D'AGRÈMENT POUR RÉALISER
DES ESSAIS OFFICIELLEMENT RECONNUS**

Annule et remplace les courriers du 7/02/2020

Conformément à l'article R. 253-38 du code rural et de la pêche maritime et à l'article 6 de l'arrêté du 26 avril 2007 relatif aux essais officiels et officiellement reconnus pour l'évaluation des produits mentionnés à l'article L. 253-1 du code rural et de la pêche maritime,

Vu la convention passée avec le Cofrac n° 4609,

Vu le rapport d'évaluation réalisé par le Cofrac, en date du 26/11/2019,

L'agrément pour réaliser des essais officiellement reconnus est maintenu et étendu, à l'organisme :

Anadiag France
174 impasse du plan d'eau
38300 RUY MONTCEAU

sous le numéro : **BPE - 105**

ET POUR LE PÉRIMÈTRE SUIVANT :

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
ANADIAG FRANCE 174 impasse du plan d'eau 38300 RUY MONTCEAU (unité centrale)	- Traitement des semences : grandes cultures
UE 01 – Harnes (UE 62) ZI la Motte au Bois 62440 HARNES	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Zones non agricoles
UE 03 – Saint Pierre du Bû (UE 14) Couvigny 14700 SAINT PIERRE DU BU	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Zones non agricoles
UE 04 – Cintré (UE 35) Rue du puisatier ZA du moulin à vent 35310 CINTRE	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Zones non agricoles
UE 06 – Varois et Chaignot (UE 21) 8 route de gray 21490 VAROIS ET CHAIGNOT	- Grandes cultures - Vigne - Cultures fruitières et arboriculture - Zones non agricoles

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
UE 08 – Saint Barthélemy (UE 38) 700 route de Pisieu 38270 SAINT BARTHELEMY	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles
UE 10 – Saint Etienne de Fougères (UE 47) ZA Bel Air 47380 SAINT ETIENNE DE FOUGERES	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles - Désinfection et désinsectisation des sols, des matériels et des locaux de culture et de stockage des végétaux
UE 12 – Saint Germain des Prés (UE 49) ZA la Potherie 49170 SAINT GERMAIN DES PRES	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles
UE 13 – Castillon du Gard (UE 30) ZA les Codes Bas 3 30210 CASTILLON DU GARD	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles
UE 15 – Haguenau (UE 67) 16 rue Ampère 67500 HAGUENAU	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Zones non agricoles - Processus de transformation : <ul style="list-style-type: none"> Vinification Transformation de pomme de terre Transformation de fruits (compote, jus de fruit, nectar, fruit au sirop, confiture, fruits séchés) Transformation de légumes (jus, concentré de tomates, conserve de légumes, ketchup, choucroute) Extraction d'huile

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
UE 16 – Thorée les Pins (UE 72) La Belle Métairie 72800 THOREE LES PINS	<ul style="list-style-type: none">- Grandes cultures- Vigne- Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum- Cultures fruitières et arboriculture- Zones non agricoles
UE 17 – Toulouse (UE 31) 75 voie du TOEC Bâtiment entreprise 2 31076 TOULOUSE Cedex 3	<ul style="list-style-type: none">- Grandes cultures- Vigne- Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum- Cultures fruitières et arboriculture- Zones non agricoles

Cet agrément est valable jusqu'au 08/10/2022. La prochaine évaluation de votre organisme est prévue au planning sur septembre / octobre 2020.

Date : 07/02/2020

La sous directrice de la qualité,
de la santé et de la protection
des végétaux

Anne-Cécile COTILLON

Mediterranean EPPO zone

Test facility	Address	Certificate (Yes or No)
SynTech Research Portugal	Rua António Oliveira, 21 Lote 16 B - Armazém L Zona Industrial de Caldas da Rainha Freguesia de Santo Onofre 2500-916 Caldas da Rainha PORTUGAL	YES
ANADIAG IBÉRICA, SL	c/ Falgueres s/n 17460 Celrà (Girona) SPAIN	YES
ANADIAG PORTUGAL	Rua dos Olivais 3, R/C Direito Fracção B 3780-229 ANADIA, PORTUGAL	YES

Test facility	Address	Certificate (Yes or No)
SynTech Research Portugal	Rua António Oliveira, 21 Lote 16 B - Armazém L Zona Industrial de Caldas da Rainha Freguesia de Santo Onofre 2500-916 Caldas da Rainha PORTUGAL	YES



REPÚBLICA
PORTUGUESA

SECRETARIA-GERAL
DO AGRICULTURA E
DESENVOLVIMENTO RURAL



dgav
Direção-Geral
de Alimentação
e Veterinária

CERTIFICADO

ORGANIZAÇÃO OFICIALMENTE RECONHECIDA PARA A REALIZAÇÃO DE
ENSAIOS DE EFICÁCIA DE PRODUTOS FITOFARMACÊUTICOS

Certifica-se que a **SYNTECH Research Portugal** é reconhecida como Organização Oficialmente Reconhecida, em Portugal, para a realização de ensaios de eficácia de produtos fitofarmacêuticos, segundo a Boa Prática Experimental, n.º 35, da Portaria n.º 396/2000, de 14 de Julho, que concretiza os princípios estabelecidos no Regulamento (UE) N.º 284/2013 da Comissão de 1 de março de 2013, em conformidade com o Regulamento (CE) N.º 1107/2009 do Parlamento Europeu e de acordo com o respetivo pedido.

- **Certificado n.º 30 (trinta)**
- **Data de entrada em vigor do reconhecimento: 29 de maio de 2018**
- **Termo do prazo do reconhecimento: 29 de maio de 2023**
- **Condições / Limitações: ---**

Lisboa, 10 julho de 2018.

A Subdiretora Geral

ANA PAULA DE
ALMEIDA CRUZ DE
CARVALHO

Assinado de forma digital por ANA
PAULA DE ALMEIDA CRUZ DE
CARVALHO
Dados: 2018.07.10 21:15:18 +01'00'

SEDE: CAMPO GRANDE, 50 – 1700-092 LISBOA TEL/F, 21 323 96 99 FAX, 21 323 96 01

Test facility	Address	Certificate (Yes or No)
ANADIAG IBÉRICA, SL	c/ Falgueres s/n 17460 Celrà (Girona) SPAIN	YES



MINISTERIO
DE AGRICULTURA Y PESCA,
ALIMENTACIÓN Y MEDIO AMBIENTE

SECRETARÍA GENERAL DE
AGRICULTURA Y ALIMENTACIÓN

DIRECCIÓN GENERAL DE SANIDAD
DE LA PRODUCCIÓN AGRARIA

ASUNTO: Renovación Acreditación Nº EOR 20/97

De acuerdo con lo establecido en el artículo 19 de la Orden de 11 de diciembre de 1995 por el que se establecen las disposiciones relativas a las renovaciones de autorizaciones de ensayos y experiencias con productos fitosanitarios, esta Dirección General ha resuelto, previo informe favorable de la Comisión de Evaluación de Productos Fitosanitarios, renovar la acreditación Nº EOR 20/97 concedida a su empresa, para realizar ensayos oficialmente reconocidos.

La validez de esta acreditación queda ampliada hasta el 18 de julio del año 2022, salvo que sea revisada o revocada antes de la conclusión de dicho plazo si se determina que ha dejado de cumplirse alguno de los requisitos exigidos para su autorización o de las obligaciones establecidas por la Orden Ministerial de 11 de diciembre de 1995.

Madrid 18 de julio de 2017

EL DIRECTOR GENERAL DE SANIDAD
DE LA PRODUCCIÓN AGRARIA

Fdo.: Valentín Almaraz de Lara

ANADIAG IBERICA, S.L.
GIRONA
JCS/amg

Test facility	Address	Certificate (Yes or No)
ANADIAG PORTUGAL	Rua dos Olivais 3, R/C Direito Fracção B 3780-229 ANADIA, PORTUGAL	YES



AGRICULTURA, ALIMENTAÇÃO
E AMBIENTE RURAL



CERTIFICADO

ORGANIZAÇÃO OFICIALMENTE RECONHECIDA PARA A REALIZAÇÃO DE ENSAIOS DE EFICÁCIA DE PRODUTOS FITOFARMACÊUTICOS

Certifica-se que é reconhecida como Organização Oficialmente Reconhecida, em Portugal, a **ANADIAG Portugal** para a realização de ensaios de eficácia de produtos fitofarmacêuticos, segundo a Boa Prática Experimental, n.º 35, da Portaria n.º 396/2000, de 14 de Julho, que concretiza os princípios estabelecidos no Regulamento (UE) N.º 284/2013 da Comissão de 1 de março de 2013, em conformidade com o Regulamento (CE) N.º 1107/2009 do Parlamento Europeu e do Conselho, de 21 de outubro, de acordo com o respetivo pedido.

- **Certificado n.º 19 (dezanove)**
- **Data de entrada em vigor do reconhecimento: 20 de abril de 2017**
- **Termo do prazo do reconhecimento: 20 de abril de 2022**
- **Condições / Limitações: —**

Oeiras, 27 de fevereiro de 2018

A Subdiretora Geral

ANA PAULA DE
ALMEIDA CRUZ DE
CARVALHO

Assinado de forma digital
por ANA PAULA DE ALMEIDA
CRUZ DE CARVALHO
Dados: 2018.02.27 13:52:02 Z

North-Eastern EPPO zone

Test facility	Address	Certificate (Yes or No)
Staphyt	Station Dabrowa 15 63-23 Jaraczewo POLAND	YES
ANADIAG POLSKA	Ul. Sadowa 16/22, 95-100 Zgierz POLAND	YES
SIA Agrolab Baltic	Ozoli, Kursisi pagast LV-3890 LATVIA	YES
LRCAF, Institute of Agriculture	Instituto al. 1, LT-58344 Akademija LITHUANIA	YES

Test facility	Address	Certificate (Yes or No)
Staphyt	Station Dabrowa 15 63-23 Jaraczewo POLAND	YES

**GLÓWNY INSPEKTOR
OCHRONY ROŚLIN I NASIENNICTWA**

Tadeusz Kłos

WO-505- 14 /2012

Warszawa, 09.09.2012 r.

DECYZJA Nr 7/2012

Na podstawie art. 155 ustawy z dnia 14 czerwca 1960 r. Kodeks postępowania administracyjnego (Dz.U. z 2000 r. Nr 98, poz. 1071 ze zm.) i art. 40 ust. 1 ustawy z dnia 18 grudnia 2003 r. o ochronie roślin (Dz.U. z 2008 r. Nr 133, poz. 849 ze zm.), po rozpatrzeniu wniosku z dnia 6 września 2012 r., zmieniam decyzję Nr 9/2005 z dnia 1 maja 2005 r., zmienioną decyzjami: Nr 3/2006 z dnia 5 maja 2006 r., Nr 8/2006 z dnia 11 grudnia 2006 r., Nr 2/2009 z dnia 18 lutego 2009 r., Nr 12/2011 z dnia 31 marca 2011 r. oraz Nr 4/2012 z dnia 4 kwietnia 2012 r.

Rozstrzygnięciu decyzji nadaję następujące brzmienie:

upoważniam

STAPHYT Sp. z o.o.

ul. Ziębicka 2; 60-164 Poznań

do prowadzenia badań skuteczności działania środka ochrony roślin

z grupy fungicydów, herbicydów, insektycydów, moluskocydów, akaricydów, regulatorów wzrostu, zapraw nasiennych oraz do łącznego stosowania środków ochrony roślin w uprawach polowych: zbóż, kukurydzy, rzepaku, buraków cukrowych, słonecznika, ziemniaków, warzyw, w uprawach sadowniczych (jabłoni, gruszy, porzeczek, truskawek, pestkówek), w magazynach i przechowalniach, a także na trawnikach oraz w uprawach roślin ozdobnych w polu i pod osłonami.

Uzasadnienie

W dniu 6 września 2012 r. Staphyt Sp. z o.o. (ul. Ziębicka 2; 60-164 Poznań) zwróciła się z wnioskiem o rozszerzenie zakresu decyzji Głównego Inspektora Ochrony Roślin i Nasiennictwa upoważniającej do prowadzenia badań skuteczności działania środków ochrony roślin Nr 9/2005 z dnia 1 maja 2005 r.,


zmienionej decyzjami: Nr 3/2006 z dnia 5 maja 2006 r., Nr 8/2006 z dnia 11 grudnia 2006 r., Nr 2/2009 z dnia 18 lutego 2009 r. oraz Nr 4/2012 z dnia 4 kwietnia 2012 r. Wniosek dotyczył możliwości prowadzenia badań w magazynach i przechowalniach.

Staphyt Sp. z o.o. spełnia warunki organizacyjno-techniczne, zwane „Zasadami Dobrej Praktyki Eksperymentalnej” (Good Experimental Practice - GEP), zapewniające prawidłowe przeprowadzanie badań skuteczności działania środka ochrony roślin.

Mając na uwadze powyższe, postanowiono jak w rozstrzygnięciu decyzji.

Pouczenie

Od niniejszej decyzji odwołanie nie przysługuje. Jednakże strona niezadowolona z decyzji może zwrócić się do Głównego Inspektora Ochrony Roślin i Nasiennictwa z wnioskiem o ponowne rozpatrzenie sprawy w terminie 14 dni od dnia doręczenia decyzji, zgodnie z art. 127 § 3 Kodeksu postępowania administracyjnego.

 GŁÓWNY INSPEKTOR
Tadeusz Kłos

Test facility	Address	Certificate (Yes or No)
ANADIAG POLSKA	Ul. Sadowa 16/22, 95-100 Zgierz POLAND	YES

SWORN TRANSLATOR
MARTA TRAWCZYŃSKA

ul. Św. Wojciecha 3/3a lok. 1, 10-038 Olsztyn
T + 48 665 240 339, F + 48 89/ 512 00 99

CERTIFIED TRANSLATION FROM THE POLISH LANGUAGE

[Any remarks in square brackets are the translator's. The translated document consists of two (2) pages.]

[national emblem of the Republic of Poland]
MAIN INSPECTOR
OF PLANT HEALTH AND SEED PROTECTION

Andrzej Chodkowski

Warsaw, dated 12 October 2018

BORiT.541.11.2018.1

DECISION No. 10/2018

Pursuant to Article 155 of the Act of 14 June 1960 Administrative Procedure Code (Dz.U. *[Polish Official Journal of Laws]* of 2017, item 1257 as amended), having examined the application filed by Anadiag SAS Branch Office in Poland dated 3 October 2018, I vary the decision No. 7/2007 dated 28 May 2007, varied by decisions No. 1/2010 dated 18 March 2010, No. 18/2011 dated 18 August 2011, No. 1/2012 dated 13 January 2012 and No. 3/2014 dated 16 April 2014 to grant authorization to conduct research of the efficiency of plant health products in such a manner that the decision shall read as follows:

"I authorize

Anadiag SAS Branch Office in Poland

ul. Sadowa 16/22, 95-100 Zgierz

to conduct research of the efficiency of plant health products from the group of acaricides, bacteriocides, fungicides, herbicides, insecticides, molluscicides, rodenticides, pheromones and growth regulators in outdoor crops, orchard crops, under covers, in edible mushrooms cultivations, in meadows and pastures. The research shall be conducted in cereal, root and oil crops, vegetables, orchard and ornamental plants, legumes, grass and special plants, in storage rooms and rooms for cultivation of edible mushrooms, in lawns and in non-agricultural lands."

No reasoning for this decision has been prepared as the decision grants the application of the Party in its entirety (Article 107(4) of the Administrative Procedure Code *[hereinafter referred to as "APC"]*).



Marta Trawczyńska

Instruction

This decision may not be appealed against. A Party unsatisfied with this decision may file an application to the Main Inspector of Plant Health and Seed Protection requesting a re-examination of the case, within 14 days of being served with this decision, pursuant to Article 127(3) APC.

Until the time-limit to apply for re-examination of the case has expired, a Party may waive this right towards the public administration authority which issued the decision. On the day when the Main Inspector of Plant Health and Seed Protection receives the waiver of the right to apply for re-examination of the case, the decision becomes final and non-appealable, which means that the decision shall be enforced immediately and it may not be appealed against to the Voivodeship Administration Court.

If a Party does not believe that the decision grants the Party's application but does not wish to exercise its right to apply for re-examination of the case, the Party may file to the Voivodeship Administration Court in Warsaw a complaint against the decision within 30 days of being served with the decision. The complaint shall be filed through the Main Inspector of Plant Health and Seed Protection.

Pursuant to section 2(1)(2) of the Regulation of the Council of Ministers of 16 December 2003 on the amount and detailed rules for collecting charges in proceedings before administrative courts (Dz.U. [Polish Official Journal of Laws] No. 221, item 2193 as amended) a fixed charge, which is independent of the subject-matter of the act appealed against or activities in cases regarding complaints against acts or public administration activities regarding rights or duties specified by the law, shall amount to PLN 200.

At the request of a Party made before court proceedings are instituted or in the course of such proceedings, the Party may be granted legal aid consisting of full or partial exemption from court costs and having an attorney-at-law or a legal advisor appointed for such Party, if the Party substantiates that they are unable to bear any costs of the proceedings or full costs thereof.

To be served upon:

1. [REDACTED]
Anadiag SAS Branch Office in Poland
ul. Sadowa 16/22
95-100 Zgierz
2. file

[round official seal with the national emblem of the Republic of Poland in its midst and the following circumscription: MAIN INSPECTOR OF PLANT HEALTH AND SEED PROTECTION]

[rectangular stamp reading: P.p. / MAIN INSPECTOR / Tadeusz Łęczyński; illegible signature]

I, duly commissioned sworn translator of the English language (TP/101/2013) in Olsztyn, hereby certify that the above translation is a true and complete version of the document in Polish presented to me.

Reg. No. 222/2018

Olsztyn, dated 29s October 2018



Marta Trzcynin

Test facility	Address	Certificate (Yes or No)
SIA Agrolab Baltic	Ozoli, Kursisi pagast LV-3890 LATVIA	YES



Valsts augu aizsardzības dienests

SERTIFIKĀTS

Nr. 30

Izsniegts **SIA „AgroLab Baltic”**

(komersanta nosaukums, reģistrācijas numurs, juridiskā adrese)

Reģ. Nr. 44103075387

Elizabetes iela 45/47, Rīga, LV-1010

par tiesībām veikt normatīvajos aktos par augu aizsardzības līdzekļu reģistrāciju noteiktos
efektivitātes pārbaudes izmēģinājumus:

Lauks- graudaugi-fungicīdi, insekticīdi, kodnes, **lauks-** rapsis- insekticīdi, **lauks-** dārzeņi- insekticīdi,
lauks- graudaugi-limacīdi, **lauks** -rapsis- limacīdi.

Sertifikāts izsniegts: 08.01.2019.
(datums)

Sertifikāts derīgs līdz: 07.01.2024.
(datums)

Valsts augu aizsardzības dienests

Augu aizsardzības līdzekļu

reģistrācijas daļas vadītāja

(amats, paraksts un tā atšifrējums)



Z.V.

R.Čūdere


Test facility	Address	Certificate (Yes or No)
LRCAF, Institute of Agriculture	Instituto al. 1, LT-58344 Akademija LITHUANIA	YES

<div><div></div><div><p>VALSTYBINĖ AUGALININKYSTĖS TARNYBA PRIE ŽEMĖS ŪKIO MINISTERIJOS</p><p>GEROS AUGALŲ APSAUGOS PRODUKTŲ VEIKSMINGUMO IR (ARBA) ATRANKUMO BANDYMŲ PRAKTIKOS SERTIFIKATAS</p><p>2013-12-12 Nr. AS4 – 13/02 Vilnius</p><p>Patvirtinama, kad Lietuvos agrarinių ir miškų mokslų centro filialas Žemdirbystės institutas, į.k. 302474007, Instituto al. 1, Akademija, 58344 Kėdainių r., laikosi geros augalų apsaugos produktų veiksmingumo ir (arba) atrankumo bandymų praktikos ir turi teisę atlikti šiuos tyrimus:</p><p>lauko bandymai; vegetaciniai bandymai.</p><p>Sertifikatas galioja iki 2019 m. gruodžio 12 d.</p><div><div>Direktorius</div><div></div><div>Evaldas Zigmas Čijauskas</div></div></div></div>

South-Eastern EPPO zone


Test facility	Address	Certificate (Yes or No)
Staphyt	Station Kecskemet HUNGARY	YES
Staphyt	Station Kecskemet HUNGARY	YES
SynTech Research Hungary Kft.	Török Ignác u. 30. 9700 Szombathely, HUNGARY	YES
SAGEA OOD	Street 10, N°4 9000 Varna BULGARIA	YES
ANADIAG BULGARIA LTD	Bul. Vasil levski № 244 4000 Plovdiv BULGARIA	YES
ANADIAG HUNGARY Kft.	H2921, Komárom, Petőfi Sándor 67 HUNGARY	YES
ANADIAG ROMANIA SRL	Piata Montreal no. 10, World Trade Centre, Entrance F, 1st Floor 011469, Bucharest, ROMANIA	YES
GEMERPRODUKT VALICE OVD	Okružná 3771/116, 979 01 Rimavská Sobota, SLOVAKIA	YES

Test facility	Address	Certificate (Yes or No)
Staphyt (JS Agrotest Kft.)	Zemplen Gyozo u. 7/B 8800 Nagykanizsa HUNGARY	YES



n é b i h
Termőföldtől az asztalig

National Food Chain Safety Office
President



H-1026 Budapest, Keleti Károly u. 24.
Hungary
Tel: 36/1/336-9100 Fax: 36/1/336-9099
E-mail: info@nabih.gov.hu
www.nabih.gov.hu

Your ref.: -

Our ref.: 04.2/8942-7/2015

9 December 2015

Subject: Certificate of Official Recognition of Efficacy Testing Facilities or Organisations in Hungary

Having received the application submitted by the **JS Agrotest Kft. (H-8800 Nagykanizsa, Zemplén Győző u. 7/B, Hungary)**, the client, for completing a certification procedure of first instance concerning the Official Recognition of Efficacy Testing Facilities/Organisations, i.e. Good Experimental Practices (*hereinafter: GEP*), I, acting as the food chain control body, has made the following

DECISION:

I issue the client's GEP certificate for its premises at Szolnok, Piroskai út 2, for carrying out efficacy trials for authorisation purposes. The GEP certificate is effective for 2 years from the entry into force of this Decision.

The client's GEP certificate is given for the following categories of products and cultivation:

- product categories:** herbicides, fungicides and bactericides, zoocides, growth regulators and yield enhancing substances, additives;
- cultivation categories:** field crops, vegetables, fruits, grapevines, ornamentals, forest, public area, others.

I inform you that the present certification is without prejudice to either the licences concerning the operation/follow-up of activity laid down in other provisions of legislation or the client's obligation for obtaining them.

The client is obliged to notify the competent authority, within 15 days, of any important changes concerning the certified activity of the testing facility.

I call your attention that respect of the provisions laid down in the legislation on GEP certification and in this Decision shall be randomly controlled by my competent authority. If during the official inspection it is stated that the testing facility does not meet the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate.

If during the official inspection it is found that some details are missing in relation to a particular trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization.

The fee of the present procedure is 500.000 HUF (i.e. five hundred thousand Hungarian Forints) paid by the client.

No further complaint shall be lodged against the present Decision, effective by its publication, through state administration, though with reference to infringement of law, judicial review of the Decision may be requested at the Capital Administrative and Employment Court. The claim note shall be submitted to my competent authority within 30 days of the communication of the Decision.

I inform you that the court shall judge the case out of court, but shall carry on a lawsuit at the request of any of the parties. The client may ask for carrying on a lawsuit, but in default of so doing, no verification is accepted. Submission of the claim note has no delaying force on the implementation of this Decision.

J U S T I F I C A T I O N

In its application of 10 October 2015, the client submitted an application to the competent authority for a procedure of GEP certification.

As a follow-up to this application, the competent authority made a local inspection at the client's facilities of Szolnok, Piroskai út 2 on 4 November 2015. Statements made during the local inspection are reported in the protocol Nr. 04.2/8942-3/2015. Based on the results of the local inspection the competent authority concluded that the client's testing facility does not meet the requirements concerning the efficacy trials specified in Article 22 of the Decree 89/2004 (V. 15.) FVM on the authorization of placing on the market and use, as well as on the packaging, labelling, storage and transport of plant protection products (hereinafter: Decree 89/2004) and in the Decision Nr. 04.2/8942-4/2015 it calls the client to fill the data gap.

Article 22(5) of Decree 89/2004 - Based on request, the competent authority shall make local inspections at the testing facility and decide on the GEP qualification of the testing facility. The decision shall include the product categories and the cultivation categories for which the testing facility obtained the GEP-certificate.

(6) The validity of GEP-certification is 2 years in case of the first request and maximum 3 years in case of renewal of the certification.

(7) A fee laid down in specific legislation shall be paid for the GEP-certification procedure.

(8) The testing facility having GEP-certification shall notify the competent authority, within 15 days, about any important changes concerning the certified activity of the testing facility.

(9) The competent authority shall randomly control the testing facility having GEP-certification. If it is found that the testing facility does not meet the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate. If during the official inspection it is established that some details are missing in relation to a trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization."

Client filled the missing data gap and reported on it in the letter of 25 November 2015, therefore I made the Decision as specified in the first part. Therefore I stated that conditions for issuing the certificate specified above are met, so I made the Decision as specified in the first part.

The fee of the present procedure is HUF 500.000 and was established in accordance with point 8.19.1 of Annex 1 to the Decree 63/2012. (VII. 2.) FVM on the extent of administrative servicing fees due for the procedures by the agricultural administrative bodies of the National Food Chain Safety Office and the county government offices and on the rules of paying the administrative servicing fees. The client paid the fee.

I made this Decision within my jurisdiction laid down in Article 3 paragraph (1) and Article 5 point c) of Government Decree 22/2012. (II. 29.) concerning the National Food Chain Safety Office, Article 3, Article 22 paragraph (1) of Decree 89/2004 and in compliance with Articles 71 paragraph (1) and Article 72 paragraph (1) of Act CXL of 2004 on general rules of administrative official procedure and service (hereinafter: Act CXL of 2004).

I excluded the possibility of appeal in compliance with Article 100 paragraph (1) point e) of Act CXL of 2004 and provided the possibility of judicial review in compliance with Article 109 paragraph (1) of Act CXL of 2004 and Article 330 paragraph (2) of Act III of 1952 on Civil Procedure.



dr. Márton Oravecz
president

Decision is made in two copies:

- Client (with acknowledgement of receipt)
- Archives



n é b i h
Termőföldtől az asztalig

Nemzeti Élelmiszerlánc-biztonsági Hivatal
Elnök



1024 Budapest, Keleti Károly u. 24
Tel: 06/1/336-9100 Fax: 06/1/336-9099
E-mail: elnoktitkarsag@nebih.gov.hu
www.nebih.gov.hu

Ikt.sz.: 04.2/8942-7/2015.
Tárgy: GEP minősítés
Ügyintéző: dr. Ripka Géza
Elérhetőség: 309-1032
Melléklet(ek): -
Hiv. szám: -

A JS Agrotest Kft. (8800 Nagykanizsa, Zemplén Győző u. 7/B.) ügyfél (a továbbiakban: Ügyfél) által előterjesztett, Helyes Kísérleti Gyakorlatra (a továbbiakban: GEP minősítés) vonatkozó minősítés lefolytatása iránti kérelem alapján indult elsőfokú eljárásban, élelmiszerlánc-felügyeleti szervként eljárva (továbbiakban: engedélyező hatóság), meghoztam az alábbi

H A T Á R O Z A T O T :

Ügyfél engedélyezési célú biológiai hatásvizsgálatok elvégzésére vonatkozó GEP minősítését Szolnok, Piroskai út 2. szám alatti telephelyére kiadom. A GEP minősítés a határozatom jogerőre emelkedésétől számított 2 évig érvényes.

Ügyfél GEP minősítése az alábbi minősítési kategóriákra és művelési ágakra kerül kiadásra:

- **minősítési kategória:** herbicidek, fungicidek és baktericidek, zoocidok, növekedésszabályozó és termésnövelő készítmények, adalékanyagok;
- **művelési ág:** szántóföld, zöldség, gyümölcs és szőlő, dísnövény, erdő, közterület, egyéb (rezisztencia, dózis vizsgálat, talajfertőtlenítő szerek).

Jelen minősítés nem érinti a működéssel/tevékenység folytatásával kapcsolatos egyéb jogszabályban előírt engedélyeket, illetve Ügyfélnek az azok beszerzésére vonatkozó kötelezettségét.

Ügyfél a vizsgálóhely minősített tevékenységét érintő jelentős változásról 15 napon belül köteles értesíteni az eljáró hatóságot.

A GEP minősítéssel kapcsolatos jogszabályokban és a jelen határozatban foglaltak betartását hatóságom szűrőpróbaszerűen ellenőrzi. Amennyiben az ellenőrzés során megállapítást nyer, hogy a vizsgálóhely nem tartja be a rá vonatkozó GEP-követelményeket, akkor az eljáró hatóság a határozatban feltüntetett minősített területre vonatkozó tevékenység végzését legfeljebb 2 hónapra felfüggesztheti, illetve a kiadott GEP minősítését visszavonhatja.

Ha az ellenőrzés során egy adott kísérlettel kapcsolatban hiányosságok kerülnek megállapításra, a kísérletet a hiányosságok mértékétől függően az eljáró hatóság kizárhatja az engedélyezésnél elfogadhatók közül.

Jelen eljárás díja 500.000.- Ft (azaz Ötszázezer forint), amelyet az Ügyfél megfizetett.

Jelen, a közléssel jogerős határozatom ellen közigazgatási úton további jogorvoslatnak helye nincs, bírósági felülvizsgálata jogszabálysértésre hivatkozással kérhető a Fővárosi Közigazgatási és Munkaügyi Bíróságtól. A keresetlevelet hatóságomhoz kell benyújtani a felülvizsgálni kért határozat közlésétől számított harminc napon belül.

A bíróság a pert tárgyaláson kívül bírálja el, a felek bármelyikének kérelmére azonban tárgyalást tart. Tárgyalás tartását a keresetlevélben kérheti, ennek elmulasztása miatt igazolásnak nincs helye. A keresetlevél benyújtásának a döntés végrehajtására halasztó hatálya nincs.

I N D O K O L Á S

Ügyfél 2015. október 10-én kelt kérelmében GEP minősítés iránti kérelmet nyújtott be hatóságomnál.

A kérelem nyomán az eljáró hatóság 2015. november 4-én helyszíni ellenőrzést folytatott le Ügyfél Szolnok, Piroskai út 2. szám alatti telephelyén, amelynek megállapításait a 04.2/8942-3/2015. számú jegyzőkönyvben rögzítette.

A helyszíni ellenőrzés során az eljáró hatóság megállapította, hogy a növényvédő szerek forgalomba hozatalának és felhasználásának engedélyezéséről, valamint a növényvédő szerek csomagolásáról, jelöléséről, tárolásáról és szállításáról szóló 89/2004. (V. 15.) FVM rendelet (továbbiakban: Rendelet) 22. §-ában foglalt biológiai hatékonysági vizsgálatokkal kapcsolatos előírásoknak Ügyfél vizsgálóhelye nem felel meg hiánytalanul, és a 04.2/8942-4/2015. számú végzésben a hiányosság megszüntetésére hívta fel.

A Rendelet 22. §. (5) Kérelem alapján az engedélyező hatóság helyszíni ellenőrzést folytat le a vizsgálóhelyen, majd határozatban dönt a vizsgálóhely GEP-minősítéséről. A határozatnak ki kell terjednie arra, hogy a vizsgálóhely milyen kategóriákra, illetve művelési ágakra szerezte meg a GEP-minősítést.

(6) A GEP-minősítés érvényességi ideje első tanúsítás esetén 2 év, a tanúsítás megújítását követően legfeljebb 5 év.

(7) A GEP-minősítési eljárásért a külön jogszabályban meghatározott díjat kell fizetni.

(8) A GEP-minősítéssel rendelkező vizsgálóhely minden, a minősített tevékenységét érintő jelentős változásról 15 napon belül köteles értesíteni az engedélyező hatóságot.

(9) Az engedélyező hatóság szűrőpróbaszerűen ellenőrzi a GEP-minősítéssel rendelkező vizsgálóhelyeket. Amennyiben megállapítást nyer, hogy a vizsgálóhely nem tartja be a rá vonatkozó GEP-követelményeket, a hatóság a határozatban feltüntetett minősített területre vonatkozó tevékenységet legfeljebb 2 hónapra felfüggesztheti, illetve a kiadott GEP-minősítést visszavonhatja. Ha az ellenőrzés során egy adott kísérlettel kapcsolatban hiányosságok kerülnek megállapításra, a kísérletet a hiányosságok mértékétől függően az engedélyező hatóság kizárhatja az engedélyezésnél elfogadhatók közül."

Ügyfél a hiányosságot megszüntette, amit az eljáró hatóságnak 2015. november 25-én érkezett levelében jelentett be, amelynek értékelése során megállapítottam, hogy a GEP-minősítés fentiek szerinti feltételei fennállnak, így a rendelkező részben foglaltak szerint döntöttem.

Jelen eljárás díja a Nemzeti Élelmiszerlánc-biztonsági Hivatal, valamint a megyei kormányhivatalok mezőgazdasági szakigazgatási szervei előtt kezdeményezett eljárásokban fizetendő igazgatási szolgáltatási díjak mértékéről, valamint az igazgatási szolgáltatási díj fizetésének szabályairól szóló 63/2012. (VII. 2.) VM rendelet 1. sz. mellékletének 8.19.1. pontja szerint 500.000.- Ft, amelyet Ügyfél megfizetett.

Határozatomat a Nemzeti Élelmiszerlánc-biztonsági Hivatalról szóló 22/2012. (II. 29.) Korm. rendelet 3. § (1) bekezdésében és 5. § c) pontjában, a Rendelet 3. §-ában illetve 22. § (1) bekezdésében biztosított jogkörben eljárva, a közigazgatási hatósági eljárás és szolgáltatás általános szabályairól szóló 2004. évi CXL. törvény (továbbiakban: Ket.) 71. § (1) bekezdésének és 72. § (1) bekezdésének megfelelően hoztam meg.

A fellebbezést a Ket. 100. § (1) bekezdés e) pontja alapján zártam ki, a bírósági felülvizsgálat lehetőségéről a Ket. 109. § (1) bekezdése, valamint a Polgári Perrendtartásról szóló 1952. évi III. törvény 330. § (2) bekezdése alapján adtam tájékoztatást.

Budapest, 2015. december „9.”



Határozat készült 2 példányban, kapiák:

- Ügyfél (tértivevényel)
- Irattár

Test facility	Address	Certificate (Yes or No)
SynTech Research Hungary Kft.	Török Ignác u. 30. 9700 Szombathely, HUNGARY	YES



Your ref.: -

Our ref.: 04.2/4838-7/2016

15 August 2016

Subject: Certificate of Official Recognition of Efficacy Testing Facilities or Organisations in Hungary

Having received the application submitted by the **SynTech Research Hungary Kft. (H-9700 Szombathely, Török Ignác u. 30, Hungary)**, the client, for completing a certification procedure of first instance concerning the Official Recognition of Efficacy Testing Facilities/Organisations, i.e. Good Experimental Practices (*hereinafter: GEP*), I, acting as the food chain control body, has made the following

DECISION:

I issue the client's GEP certificate for its premises at Szombathely, Török Ignác u. 30 for carrying out efficacy trials for authorisation purposes. The GEP certificate is effective for 5 years from the entry into force of this Decision.

The client's GEP certificate is given for the following categories of products and cultivation:

- product categories:** herbicides, fungicides and bactericides, zoocides, growth regulators and yield enhancing substances, additives;
- cultivation categories:** field crops, vegetables, fruits, grapevines, ornamentals, forest, others.

I inform you that the present certification is without prejudice to either the licences concerning the operation/follow-up of activity laid down in other provisions of legislation or the client's obligation for obtaining them.

The client is obliged to notify the competent authority, within 15 days, of any important changes concerning the certified activity of the testing facility.

I call your attention that respect of the provisions laid down in the legislation on GEP certification and in this Decision shall be randomly controlled by my competent authority. If during the official inspection it is stated that the testing facility does not meet the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate.

If during the official inspection it is found that some details are missing in relation to a particular trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization.

The fee of the present procedure is 250.000 HUF (i.e. two hundred and fifty thousand Hungarian Forints) paid by the client.

No further complaint shall be lodged against the present Decision, effective by its publication, through state administration, though with reference to infringement of law, judicial review of the Decision may be requested at the Capital Administrative and Employment Court. The claim note shall be submitted to my competent authority within 30 days of the communication of the Decision.

I inform you that the court shall judge the case out of court, but shall carry on a lawsuit at the request of any of the parties. The client may ask for carrying on a lawsuit, but in default of so doing, no verification is accepted. Submission of the claim note has no delaying force on the implementation of this Decision.

J U S T I F I C A T I O N

In its application of 7 July 2016, the client submitted an application to the competent authority for a procedure of GEP certification.

As a follow-up to this application, the competent authority made a local inspection at the client's facility of Szombathely, Török Ignác u. 30 on 12 July 2016. Statements made during the local inspection are reported in the protocol Nr. 04.2/4838-4/2016. Based on the results of the local inspection the competent authority concluded that the client's testing facility does not meet the requirements concerning the efficacy trials specified in Article 22 of the Decree 89/2004 (V. 15.) FVM on the authorization of placing on the market and use, as well as on the packaging, labelling, storage and transport of plant protection products (hereinafter: Decree 89/2004) and in the Decision Nr. 04.2/4838-5/2016 it calls the client to fill the data gaps.

Article 22(5) of Decree 89/2004 - Based on request, the competent authority shall make local inspections at the testing facility and decide on the GEP qualification of the testing facility. The decision shall include the product categories and the cultivation categories for which the testing facility obtained the GEP-certificate.

(6) The validity of GEP-certification is 2 years in case of the first request and maximum 5 years in case of renewal of the certification.

(7) A fee laid down in specific legislation shall be paid for the GEP-certification procedure.

(8) The testing facility having GEP-certification shall notify the competent authority, within 15 days, about any important changes concerning the certified activity of the testing facility.

(9) The competent authority shall randomly control the testing facility having GEP-certification. If it is found that the testing facility does not meet the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate. If during the official inspection it is established that some details are missing in relation to a trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization."

Client filled the missing data gaps and reported on it in the letter of 12 August 2016, therefore I made the Decision as specified in the first part. Therefore I stated that conditions for issuing the certificate specified above are met, so I made the Decision as specified in the first part.

The fee of the present procedure is HUF 250,000 and was established in accordance with point 8.19.2 of Annex 1 to the Decree 63/2012, (VII. 2.) VM on the extent of administrative servicing fees due for the procedures by the agricultural administrative bodies of the National Food Chain Safety Office and the county government offices and on the rules of paying the administrative servicing fees. The client paid the fee.

I made this Decision within my jurisdiction laid down in Article 3 paragraph (1) and Article 5 point c) of Government Decree 22/2012, (II. 29.) concerning the National Food Chain Safety Office, Article 3, Article 22 paragraph (1) of Decree 89/2004 and in compliance with Articles 71 paragraph (1) and Article 72 paragraph (1) of Act CXL of 2004 on general rules of administrative official procedure and service (hereinafter: Act CXL of 2004).

I excluded the possibility of appeal in compliance with Article 100 paragraph (1) point e) of Act CXL of 2004 and provided the possibility of judicial review in compliance with Article 109 paragraph (1) of Act CXL of 2004 and Article 330 paragraph (2) of Act III of 1952 on Civil Procedure.

on behalf of
dr. Márton Oravecz
president

László Jordán
director

Test facility	Address	Certificate (Yes or No)
SAGEA OOD	Street 10, N°4 9000 Varna BULGARIA	YES



РЕПУБЛИКА БЪЛГАРИЯ
Министерство на земеделието, храните и горите
Българска агенция по безопасност на храните

СЕРТИФИКАТ

№006
София, 06.10.18 г.

На основание чл. 75 от Закона за защита на растенията и чл. 23 от Наредба № 19 от 8 ноември 2016 г. за биологично изпитване на продукти за растителна защита (обн., ДВ. бр.90 от 15.11.2016 г.) и Заповед № РД 11-1909 от 20.09.2017 г. на изпълнителния директор на Българската агенция по безопасност на храните

ИЗДАВАМ:

настоящия сертификат, в уверение на това, че база „Саджеа“ ООД със седалище и адрес на управление: с.Стъргел 2135, общ. Горна Малина, обл. София, кьща 22, с места за изпитване: гр. Пловдив 4000, бул. „България“ № 6, бл. 18, етаж партерен и гр. Варна 9000, район „Приморски“, ул. „10-та“ № 4 одобрена за извършване на биологично изпитване на продукти за растителна защита на територията на Република България за следните групи култури:

1. Полски култури
2. Трайни насаждение
3. Зеленчукови култури
4. Оранжевийни култури

Сертификатът удостоверява осигурено качество при провеждане на опити за ефикасност на продукти за растителна защита, съответстващо на Добрата експериментална практика и стандартите за изпитване за ефикасност на ПРЗ, определени от Европейската и средиземноморската организация по растителна защита (EPPO).

Сертификатът е валиден до 20.09.2027 г.


Д-Р ДАМЯН ИЛИЕВ
Изпълнителен директор на
Българската агенция по безопасност на храните

Test facility	Address	Certificate (Yes or No)
ANADIAG BULGARIA LTD	Bul. Vasil levski № 244 4000 Plovdiv BULGARIA	YES

	<p>РЕПУБЛИКА БЪЛГАРИЯ Министерство на земеделието, храните и горите Българска агенция по безопасност на храните</p>
<p>СЕРТИФИКАТ №003 Издание: 31.12.11.2018 г. София, 22.11.2018 г.</p>	
<p>На основание чл. 75 от Закона за защита на растенията и чл. 23 от Наредба № 19 от 8 ноември 2016 г. за биологично изпитване на продукти за растителна защита (обн., ДВ. бр.90 от 15.11.2016 г.) и Заповед № РД 11-2394 от 26.11.2018 г. на изпълнителния директор на Българската агенция по безопасност на храните</p>	
<p>ИЗДАВАМ:</p>	
<p>настоящия сертификат, в уверение на това, че база „Анадиаг България“ ЕООД със седалище и адрес на управление: град София 1142, бул. „Патриарх Евтимий“ № 21, вх. В, ет. 3, ап. 52 с ЕИК: 202022346 с места за изпитване: гр. Пловдив 4000, ул. „Васил Левски“ № 244 (зад сградата на Агроцентър) и гр. Плевен 5800, местност „Чаира“, ул. „Чаталджа“ № 59 е одобрена за извършване на биологично изпитване на продукти за растителна защита на територията на Република България за следните групи култури:</p>	
<p>1. Полски култури 2. Трайни насаждение 3. Зеленчукови култури 4. Оранжеви култури</p>	
<p>Сертификатът удостоверява осигурено качество при провеждане на опити за ефикасност на продукти за растителна защита, съответстващо на Добрата експериментална практика и стандартите за изпитване за ефикасност на ПРЗ, определени от Европейската и средиземноморската организация по растителна защита (EPPO).</p>	
<p>Сертификатът е валиден до 26.11.2028 г.</p>	
<p>Д-Р ДАМЯН ИЛИЕВ Изпълнителен директор на Българската агенция по безопасност на храните</p>	

Test facility	Address	Certificate (Yes or No)
ANADIAG HUNGARY Kft.	H2921, Komárom, Petőfi Sándor 67 HUNGARY	YES

n é b i h
Termőföldszőlő az asztalig

National Food Chain Safety Office
Directorate of Plant Protection, Soil Conservation
and Agri-environment

H-1125 Budapest, Budaiúti út 141-143.
Hungary
Tel: 36/1/309-1060 Fax: 36/1/246-2942
E-mail: nc@nebih.gov.hu
www.nebih.gov.hu

Your ref.: -
Our ref.: 04.2/6149-7/2016
7 October 2016

Subject: Certificate of Official Recognition of Efficacy Testing Facilities or Organisations in Hungary

Having received the application submitted by the **Anadiag Hungary Mezőgazdasági Szolgáltató Kft. (H-2921 Komárom, Petőfi Sándor út 67, Hungary)**, the client, for completing a certification procedure of first instance concerning the Official Recognition of Efficacy Testing Facilities/Organisations, i.e. Good Experimental Practices (*hereinafter: GEP*), I, acting as the food chain control body, has made the following

D E C I S I O N :

I issue the client's GEP certificate for its premises at Komárom, Petőfi Sándor út 67 for carrying out efficacy trials for authorisation purposes. The GEP certificate is effective for 5 years from the entry into force of this Decision.

The client's GEP certificate is given for the following categories of products and cultivation:

- product categories:** herbicides, fungicides and bactericides, zoocides, growth regulators and yield enhancing substances, additives;
- cultivation categories:** field crops, vegetables, fruits, grapevines, ornamentals, others.

I inform you that the present certification is without prejudice to either the licences concerning the operation-follow-up of activity laid down in other provisions of legislation or the client's obligation for obtaining them.

The client is obliged to notify the competent authority, within 15 days, of any important changes concerning the certified activity of the testing facility.

I call your attention that respect of the provisions laid down in the legislation on GEP certification and in this Decision shall be randomly controlled by my competent authority. If during the official inspection it is stated that the testing facility does not meet the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate.

If during the official inspection it is found that some details are missing in relation to a particular trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization.

The fee of the present procedure is 250.000 HUF (i.e. two hundred and fifty thousand Hungarian Forints) paid by the client.

No further complaint shall be lodged against the present Decision, effective by its publication, through state administration, though with reference to infringement of law, judicial review of the Decision may be requested at the Capital Administrative and Employment Court. The claim note shall be submitted to my competent authority within 30 days of the communication of the Decision.

I inform you that the court shall judge the case out of court, but shall carry on a lawsuit at the request of any of the parties. The client may ask for carrying on a lawsuit, but in default of so doing, no verification is accepted. Submission of the claim note has no delaying force on the implementation of this Decision.

J U S T I F I C A T I O N

In its application of 29 August 2016, the client submitted an application to the competent authority for a procedure of GEP certification.

As a follow-up to this application, the competent authority made a local inspection at the client's facility of Komárom, Petőfi Sándor út 67 on 31 August 2016. Statements made during the local inspection are reported in the protocol Nr. 04.2/6149-4/2016. Based on the results of the local inspection the competent authority concluded that the client's testing facility does not meet the requirements concerning the efficacy trials specified in Article 22 of the Decree 89/2004 (V. 15.) FVM on the authorization of placing on the market and use, as well as on the packaging, labelling, storage and transport of plant protection products (hereinafter: Decree 89/2004) and in the Decision Nr. 04.2/6149-5/2016 it calls the client to fill the data gaps.

Article 22(5) of Decree 89/2004 - Based on request, the competent authority shall make local inspections at the testing facility and decide on the GEP qualification of the testing facility. The decision shall include the product categories and the cultivation categories for which the testing facility obtained the GEP-certificate.

(6) The validity of GEP-certification is 2 years in case of the first request and maximum 5 years in case of renewal of the certification.

(7) A fee laid down in specific legislation shall be paid for the GEP-certification procedure.

(8) The testing facility having GEP-certification shall notify the competent authority, within 15 days, about any important changes concerning the certified activity of the testing facility.

(9) The competent authority shall randomly control the testing facility having GEP-certification. If it is found that the testing facility does not meet the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate. If during the official inspection it is established that some details are missing in relation to a trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization."

Client filled the missing data gaps and reported on it in the letter of 20 September 2016, therefore I made the Decision as specified in the first part. Therefore I stated that conditions for issuing the certificate specified above are met, so I made the Decision as specified in the first part.

The fee of the present procedure is HUF 250.000 and was established in accordance with point 8.19.2 of Annex 1 to the Decree 63/2012. (VII. 2.) VM on the extent of administrative servicing fees due for the procedures by the agricultural administrative bodies of the National Food Chain Safety Office and the county government offices and on the rules of paying the administrative servicing fees. The client paid the fee.

I made this Decision within my jurisdiction laid down in Article 3 paragraph (1) and Article 5 point c) of Government Decree 22/2012. (II. 29.) concerning the National Food Chain Safety Office, Article 3, Article 22 paragraph (1) of Decree 89/2004 and in compliance with Articles 71 paragraph (1) and Article 72 paragraph (1) of Act CXL of 2004 on general rules of administrative official procedure, and service (hereinafter: Act CXL of 2004).

I excluded the possibility of appeal in compliance with Article 100 paragraph (1) point e) of Act CXL of 2004 and provided the possibility of judicial review in compliance with Article 109 paragraph (1) of Act CXL of 2004 and Article 330 paragraph (2) of Act III of 1952 on Civil Procedure.

on behalf of
dr. Márton Oravecz
president


László Jordán
director

Test facility	Address	Certificate (Yes or No)
ANADIAG ROMANIA SRL	Piata Montreal no. 10, World Trade Centre, Entrance F, 1st Floor 011469, Bucharest, ROMANIA	YES

MINISTERUL AGRICULTURII ȘI DEZVOLTĂRII RURALE	MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT
Autoritatea Națională Fitosanitară	National Phytosanitary Authority
Comisia Națională de Omologare a Produselor de Protecție a Plantelor	National Commission for Registration of Plant Protection Products

Certificat de recunoaștere oficială a testelor de eficacitate biologică în conformitate cu bunele practici experimentale/Certificate of official recognition of the efficacy biological tests according to the good experimental practices

Se acordă: SC ANADIAG ROMANIA SRL
It is granted to: SC ANADIAG ROMANIA SRL
cu sediul: Str. Gen. C. Budisteanu, nr.28-C;010775, Bucuresti
with headquarter: Gen. C. Budisteanu Street, no. 28-C, 010775, Bucharest
pentru domeniul/
domeniile de activitate: Culturi agricole de câmp și pajisti; Pomicultură; Viticultură; Legumicultură; Floricultură; Silvicultură; Plante ornamentale și de interior; Zone non agricole
for the domain/
domains of activity: Crops fields and meadows; Fruit tree growing; Viticulture; Vegetable crops; Floriculture; Aromatic and medicinal plants; Ornamental and indoor plants; Silviculture; Non agricultural zones

Prezentul certificat se eliberează în conformitate cu prevederile Ordinului ministrului agriculturii și dezvoltării rurale, al ministrului sănătății și al ministrului mediului și schimbărilor climatice nr.60/512/1258/2013 și prevederile Procedurii naționale de omologare a produselor de protecție a plantelor care conțin substanțe active notificate și pentru care nu s-a luat încă o decizie de includere în lista cu substanțe active autorizate în Uniunea Europeană, aprobată prin Ordinul ministrului agriculturii,

pădurilor și dezvoltării rurale, al ministrului sănătății și al ministrului mediului și gospodăririi apelor nr. 134/197/412/2006, cu modificările și completările ulterioare.

This certificate is issued according to the provisions of the Order of the ministry of agriculture and rural development, of the ministry of health and of the ministry of environment and climate change no. 60/512/1258/2013 and the provisions of the National Procedure for Registration of Plant Protection Products which contain notified active substances and for which isn't taken yet a decision for inclusion in European Union list of authorised active substances, approved by the Order of the ministry of agriculture, forests and rural development, of the ministry of health and of the ministry of environment and waters husbandry no. 134/197/412/2006, with subsequent amendments and completions.

Data emiterii certificatului: 20.08.2015

Issuance date of the certificate

Data expirării certificatului: 20.08.2020

Expiry date of the certificate

PREȘEDINTE/CHAIRMAN,

Elena LEAOTA



Test facility	Address	Certificate (Yes or No)
GEMERPRODUKT VALICE OVD	Okružná 3771/116, 979 01 Rimavská Sobota, SLOVAKIA	YES

Central Controlling and Testing Institute in Agriculture in Bratislava
Matúškova 21, 833 16 Bratislava

GEP CERTIFICATE
No. 03/C - 06/2019

Issued in accordance with § 28 of the Act No. 405/2011 Coll. on Plant Care, Amending and Supplementing Act of the National Council of the Slovak Republic No. 145/1995 Coll. on Administrative Fees as Amended and § 3 of the Regulation of the Ministry of Agriculture and Rural Development of the Slovak Republic No 486/2011 Coll. laying down details of the conditions, procedures and deadlines to implement the provisions of the tests of biological efficacy, applications, principles of good experimental practice, audits and issuing certificate, extension of the certificate, recertification (hereinafter "Regulation")

for

GEMERPRODUKT VALICE,
ovocinársko-vinohradnícke družstvo
Okružná 3771
979 01 Rimavská Sobota

Identification number: 36059005

which has demonstrated implementation of principles of Good experimental practice (GEP) in accordance with the requirements of the Regulation in the following categories

Categories of crops	Categories of plant protection products and their adverse effects on crops.
cereals	fungicides; fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides; zoocides - seed treatment; growth regulators; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides; zoocides - seed treatment; growth regulators
maize	fungicides; fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides; zoocides - seed treatment; growth regulators; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides; zoocides - seed treatment; growth regulators
legumes	fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides - seed treatment; growth regulators; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides; zoocides - seed treatment; growth regulators
oil plants	fungicides; fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides; zoocides - seed treatment; growth regulators; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides; zoocides - seed treatment; growth regulators
technical plants	fungicides - seed treatment; zoocides - seed treatment; growth regulators; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides; zoocides; zoocides - seed treatment; growth regulators

root crops	fungicides; fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides; zoocides - seed treatment; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides; zoocides - seed treatment
vegetables and root vegetables	fungicides; fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides; zoocides - seed treatment; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides; zoocides - seed treatment
grape, fruit and stocks	fungicides; fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides; zoocides - seed treatment; growth regulators; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides; zoocides - seed treatment; growth regulators

Date of issue: 28.05.2019
Date of expiry: 12.04.2021




Ing. Peter Rusňák, PhD.
General Director

This certificate includes also appendix.
By issuing this certificate, certificate No. 03/C 05/2019 expires.

3.7.2 Spring barley (HORSV)

Table 3.7-2: List of test facilities - HORVS

Maritime EPPO zone

Test facility	Address	Certificate (Yes or No)
ANADIAG SA, CZ osp.	51754 Chleny 47 CZECH REPUBLIC	YES
SYNTECH RESEARCH Czech Republic s.r.o	Semčice 245 294 46 Semčice, CZECH REPUBLIC	YES
Zkusebni Stanice Nechanice, s.r.o	Stolbova 319, 503 19 Nechanice, CZECH REPUBLIC	YES
QUINTUS Gmbh GERMANY	QUINTUS GmbH, Liepen 7, 17194 Hohen wangelin OT Liepen, GERMANY	YES
AGROLAB A/S DENMARK	AGROLAB A/S Røjleskovvej 18 5500 Middelfart DENMARK	YES
OXFORD AGRICULTURE TRIALS Ltd UK	OATS Ltd West farm barns, Stratton Audley, Oxon, UNITED KINGDOM	YES

Test facility	Address	Certificate (Yes or No)
ANADIAG SA, CZ osp.	51754 Chleny 47 CZECH REPUBLIC	YES

ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

Odbor přípravků na ochranu rostlin

Zemědělská 1a, Brno, PSČ 613 00

Příloha rozhodnutí č.j.: UKZUZ 035705/2015 ze dne 30. 4. 2015

OSVĚDČENÍ

GEP/AHC/2015

o způsobilosti k provádění zkoušek
v souladu se zásadami správné pokusnické praxe

Official Recognition Certificate / GEP - Certificate

právnícká osoba: **Anadiag SA, CZ organizační složka podniku**

sídlo právnické osoby: Chleny 46, 517 45 Chleny

IČ právnické osoby: 27518604

je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe podle § 45 odst. 1 zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, v platném znění, v návaznosti na Směrnici 91/414/EHS.

oblasti zkoušení / categories of official recognition:

- polní plodiny a zelenina / field crops and vegetables
- trvalé kultury / high crops
- skleníky a jiné kryté prostory / protected areas and storage rooms

Ústřední kontrolní a zkušební ústav zemědělský
Sekce zemědělských vstupů
Odbor přípravků na ochranu rostlin
613 00 Brno, Zemědělská 1a
- 1 -


Ing. Pavel Minář, Ph.D.
ředitel odboru

Test facility	Address	Certificate (Yes or No)
SYNTECH RESEARCH Czech Republic s.r.o	Semčice 245 294 46 Semčice, CZECH REPUBLIC	YES

ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

Odbor přípravků na ochranu rostlin

Zemědělská 1a, Brno, PSČ 613 00

Příloha rozhodnutí č.j.: UKZUZ 033034/2017 ze dne 12. 4. 2017

OSVĚDČENÍ

GEP/SYT/2017

o způsobilosti k provádění zkoušek
v souladu se zásadami správné pokusnické praxe

Official Recognition Certificate / GEP - Certificate

právnícká osoba: **SynTech Research Czech s.r.o.**

sídlo právnické osoby: Žitná 562/10, Nové Město (Praha 2), 120 00 Praha

IČ právnické osoby: 04601351

je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe podle § 45 odst. 1 zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, v platném znění, v návaznosti na Směrnici 91/414/EHS.

oblasti zkoušení / categories of official recognition:

- polní plodiny a zelenina / *field crops and vegetables*
- moření osiva / *seed treatment*
- laboratorní testy a analýzy / *laboratory tests and analyses*

Ústřední kontrolní a zkušební ústav zemědělský
Se sídlem zemědělských vstupů
Odbor přípravků na ochranu rostlin
613 00 Brno, Zemědělská 1a
- 1 -


Ing. Pavel Minář, Ph.D.
ředitel odboru

Test facility	Address	Certificate (Yes or No)
Zkusební Stanice Nechanice, s.r.o	Stolbova 319, 503 19 Nechanice, CZECH REPUBLIC	YES

ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

Odbor přípravků na ochranu rostlin

Zemědělská 1a, Brno, PSČ 613 00

Příloha rozhodnutí č.j.: UKZUZ 073241/2016 ze dne 28. 6. 2016

OSVĚDČENÍ

GEP/NEC/2016

o způsobilosti k provádění zkoušek
v souladu se zásadami správné pokusnické praxe

Official Recognition Certificate / GEP - Certificate

právnícká osoba: **ZKUŠEBNÍ STANICE NECHANICE, s.r.o.**

sídlo právnické osoby: Štolbova 319, 503 15 Nechanice


IČ právnické osoby: 25283669

je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe podle § 45 odst. 1 zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, v platném znění, v návaznosti na Směrnici 91/414/EHS.

oblasti zkoušení / categories of official recognition:

- polní plodiny a zelenina / field crops and vegetables
- trvalé kultury / high crops
- skleníky a jiné kryté prostory / protected areas and storage rooms

Ústřední kontrolní a zkušební ústav zemědělský
Sekce zemědělských vstupů
Odbor přípravků na ochranu rostlin
613 00 Brno, Zemědělská 1a
- 1 -


Ing. Pavel Minář, Ph.D.
ředitel odboru

Test facility	Address	Certificate (Yes or No)
QUINTUS GmbH GERMANY	QUINTUS GmbH, Liepen 7, 17194 Hohen wangelin OT Liepen, GERMANY	YES

GEP AGREEMENT

Anerkennungsbescheinigung

Die Versuchseinrichtung

mit Hauptsitz in

und organisatorisch
zugehörigen
Arbeitseinheiten in

ist auf Antrag vom

und nach durchgeführter
Besichtigung
durch
vom

am

in den Versuchskategorien

als Einrichtung für die Prüfung
der Wirksamkeit von
Pflanzenschutzmitteln im
Sinne des § 8 Abs. 6 der
Pflanzenschutzmittelverordnu
ng und gemäß
Verordnung (EU) Nr. 284/2013
für 5 Jahre amtlich anerkannt
worden.

Quintus GmbH

Liepen 7
17194 Hohen Wangelin

08393 Schönberg
Breitenbacher Straße 21

74595 Langenburg-
Nesselbach
Orlacher Straße 16

27798 Hude
Wieselweg 6

2016-02-01

Herrn Dr. S. Goltermann
Landesamt für Landwirtschaft,
Lebensmittelsicherheit und
Verbraucherschutz MV
2016-04-11

Acker-, Obst-, Gemüse-, Zier-
pflanzenbau, Haus- und
Kleingarten

agriculture, horticulture, home
and garden

Recognition Certificate

The testing facility

with headquarter in

and subsidiary testing
units in

on application from

and after inspection

by
from

on

in the trial categories

has been officially
recognised as an
organisation for efficacy
testing facility of plant
protection products
according to § 8 par. 6 of
the Plant Protection
Products Ordinance and
the Commission
Regulation (EU) No
284/2013 for 5 years.

11.04.2016

Datum
date

Unterschrift
signature

Landesamt für Landwirtschaft,
Lebensmittelsicherheit und
Verbraucherschutz MV,
Thierfelderstr. 18, 18059 Rostock
Adresse der anerkennenden Behörde
address of the recognising authority



Test facility	Address	Certificate (Yes or No)
AGROLAB A/S DENMARK	AGROLAB A/S Røjleskovvej 18 5500 Middelfart DENMARK	YES



Certifikat

for GEP-anerkendelse tildeles herved

Forsøgsenheden: Agrolab A/S
Røjleskovvej 18
DK-5500 Middelfart

Anerkendelsen gælder udførelsen af GEP-effektivitetsforsøg for bekæmpelsesmidler inden for

Forsøgsområderne: Markforsøg

GEP Anerkendelses Enheden ved Nationalt Center for Fødevarer og Jordbrug, Aarhus Universitet, kontrollerer organisation, personale, lokaler, forsøgsarealer, forsøgsudstyr samt standardforskrifter og forsøgsrapporter. Forsøgsenheden er underkastet løbende kontrol og inspektion.

Certifikatet for anerkendelse er gyldigt for en periode på 6 år.

Anerkendelsesdato: 1. januar 2014

Underskrevet: 16. december 2013


Nina Sørup Hansen
Miljøstyrelsen


Ulla Fosgerau Salomonsen
Aarhus Universitet


Peter Kryger Jensen
Aarhus Universitet

Forordning 1107/2009 om plantebeskyttelsesmidler og Miljøministeriets bekendtgørelse nr.1088 af 6. september 2013 anfører, at undersøgelser af plantebeskyttelsesmidlers effektivitet, der er udført i Danmark med henblik på godkendelse, skal være foretaget af forsøgsenheder, der er anerkendt hertil af Nationalt Center for Fødevarer og Jordbrug, Aarhus Universitet.

Test facility	Address	Certificate (Yes or No)
OXFORD AGRICULTURE TRIALS Ltd UK	OATS Ltd West farm barns, Stratton Audley, Oxon, UNITED KINGDOM	YES



Certificate of

Official Recognition of Efficacy Testing Facilities or Organisations in the United Kingdom

This certifies that

Oxford Agricultural Trials Limited

complies with the minimum standards laid down in
Regulation (EC) 1107/2009 for efficacy testing.

The above Facility/Organisation has been officially
recognised as being competent to carry out efficacy trials/tests
in the United Kingdom in the following categories:

**Agriculture/Horticulture
Biologicals and Semiochemicals
Stored Crops**

Date of issue: 9 January 2018
Effective date: 1 January 2018
Expiry date: 31 December 2022

Signature 
Authorised signatory

Certification Number
ORETO 385



HSE
Chemicals Regulation Division



Department of
**Agriculture and
Rural Development**

Mediterranean EPPO zone

Test facility	Address	Certificate (Yes or No)
ANADIAG ITALIA SRL	Strada Savonesa 9, Tortona 15057 ITALY	YES
ANADIAG FRANCE	ZA Bel air 47380 Saint-Etienne de Fougères FRANCE	YES
ANADIAG IBERICA, SL	ANADIAG IBERICA, SL C/ Falgueres s/n Celrà, Girona 17460 SPAIN	YES
SYNTECH RESEARCH POR- TUGAL	Rua Antonio de Oliveira 21, Caldas Da Rainha 2500-916 PORTUGAL	YES

Test facility	Address	Certificate (Yes or No)
ANADIAG ITALIA SRL	Strada Savonesa 9, Tortona 15057 ITALY	YES

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DECRETO 30 luglio 2018.

Riconoscimento dell'idoneità al Centro «Anadiag Italia S.r.l.» ad effettuare prove ufficiali di campo, finalizzate alla produzione di dati di efficacia e alla determinazione dell'entità dei residui di prodotti fitosanitari.

**IL DIRETTORE GENERALE
DELLO SVILUPPO RURALE**

Visto il decreto legislativo del 17 marzo 1995, n. 194 che, in attuazione della direttiva 91/414/CEE, disciplina l'immissione in commercio dei prodotti fitosanitari;

Visti in particolare i commi 5, 6, 7 e 8 dell'art. 4 del predetto decreto legislativo n. 194/95;

Visto il decreto del Ministro della sanità del 28 settembre 1995 che modifica gli allegati II e III del suddetto decreto legislativo n. 194/95;

Visto il decreto interministeriale 27 novembre 1996 che, in attuazione del citato decreto legislativo n. 194/95, disciplina i principi delle buone pratiche per l'esecuzione delle prove di campo e definisce i requisiti necessari al riconoscimento ufficiale dell'idoneità a condurre prove di campo finalizzate alla registrazione dei prodotti fitosanitari;

Vista l'istanza presentata in data 10 gennaio 2018 dal Centro «Anadiag Italia S.r.l.», con sede legale in fraz. Rivalta Scrivia - Strada Savonesa, 9 - 15050 Tortona (AL);

Visto l'esito favorevole della verifica della conformità ad effettuare prove di campo a fini registrativi, finalizzate alla produzione di dati di efficacia e alla determinazione dell'entità dei residui di prodotti fitosanitari effettuata in data 23 giugno 2018 presso il Centro «Anadiag Italia S.r.l.»;

Visto il decreto legislativo 30 luglio 1999, n. 300, di riforma dell'organizzazione di Governo a norma dell'art. 11 della legge 15 marzo 1997, n. 59;

Visto il decreto legislativo 30 marzo 2001, n. 165, relativo alle «norme generali sull'ordinamento del lavoro alle dipendenze delle amministrazioni pubbliche», in particolare l'art. 4, commi 1 e 2 e l'art. 16, comma 1;

Visto il decreto del Presidente del Consiglio dei ministri 27 febbraio del 2013, n. 105, recante il Regolamento di organizzazione del Ministero delle politiche agricole alimentari e forestali, a norma dell'art. 2, comma 10-ter, del decreto-legge 6 luglio 2012, n. 95, convertito, con modificazioni, dalla legge 7 agosto 2012, n. 135, così come modificato dal decreto del Presidente del Consiglio dei ministri 17 luglio 2017, n. 143;

Visto il decreto del Ministro delle politiche agricole alimentari e forestali del 7 marzo 2018, Registrato alla Corte dei conti il 3 aprile 2018 al n. 191, recante individuazione degli Uffici dirigenziali di livello non generale;

Considerato che il suddetto Centro ha dichiarato di possedere i requisiti prescritti dalla normativa vigente, a far data dal 10 gennaio 2018, a fronte di apposita documentazione presentata;

Decreta:

Art. 1.

1. Il Centro «Anadiag Italia S.r.l.», con sede legale in fraz. Rivalta Scrivia - Strada Savonesa, 9 - 15050 Tortona (AL), è riconosciuto idoneo a proseguire nelle prove ufficiali di campo con prodotti fitosanitari volte ad ottenere le seguenti informazioni:

efficacia dei prodotti fitosanitari (di cui all'Allegato III, punto 6.2 del decreto legislativo n. 194/95);

dati sulla comparsa o eventuale sviluppo di resistenza (di cui all'Allegato III, punto 6.3 del decreto legislativo n. 194/95);

incidenza sulla resa quantitativa e/o qualitativa (di cui all'Allegato III, punto 6.4 del decreto legislativo n. 194/95);

fitotossicità nei confronti delle piante e prodotti vegetali bersaglio (di cui all'Allegato III, punto 6.5 del decreto legislativo n. 194/95);

osservazioni riguardanti gli effetti collaterali indesiderabili (di cui all'Allegato III, punto 6.6 del decreto legislativo n. 194/95);

individuazione dei prodotti di degradazione e di reazione dei metaboliti in piante o prodotti trattati (di cui all'allegato II, punto 6.1 del decreto legislativo n. 194/95);



valutazione del comportamento dei residui delle sostanze attive e dei suoi metaboliti a partire dall'applicazione fino al momento della raccolta o della commercializzazione dei prodotti immagazzinati (di cui all'allegato II, punto 6.2 del decreto legislativo n. 194/95);

definizione del bilancio generale dei residui delle sostanze attive (di cui all'allegato II, punto 6.3 del decreto legislativo n. 194/95);

prove relative agli effetti della lavorazione industriale e/o preparazione domestica sulla natura e sull'entità dei residui (di cui all'allegato II, punto 6.6 del decreto legislativo n. 194/95);

prove su destino e comportamento nel suolo (di cui all'allegato II, punto 7.1 del decreto legislativo n. 194/95);

prove su destino e comportamento nell'acqua e nell'aria (di cui all'allegato II, punto 7.2 del decreto legislativo n. 194/95);

studi ecotossicologici relativi agli effetti su organismi non bersaglio (di cui all'allegato II, punto 8.3 del decreto legislativo n. 194/95);

determinazione dei residui in o su prodotti trattati, alimenti per l'uomo o per gli animali (di cui all'allegato III, punto 8.1 del decreto legislativo n. 194/95);

prove relative agli effetti della lavorazione industriale e/o preparazione domestica sulla natura e sull'entità dei residui (Allegato III, Punto 8.2 del decreto legislativo n. 194/95);

effetti sull'aspetto, l'odore, il gusto o altri aspetti qualitativi dovuti ai residui nei o sui prodotti freschi o lavorati (Allegato III, Punto 8.3 del decreto legislativo n. 194/95);

valutazione dei dati sui residui nelle colture successive o di rotazione (di cui all'allegato III, punto 8.5 del decreto legislativo n. 194/95);

individuazione dei tempi di carenza per impieghi in pre-raccolta o post-raccolta (di cui all'allegato III, punto 8.6 del decreto legislativo n. 194/95);

prove su destino e comportamento ambientale (di cui all'allegato III, punti 9.1, 9.2 e 9.3 del decreto legislativo n. 194/95);

studi ecotossicologici relativi agli effetti su organismi non bersaglio (di cui all'allegato III, punto 10.3 del decreto legislativo n. 194/95).

2. Il riconoscimento di cui al comma 1, riguarda le prove di campo di efficacia e le prove di campo finalizzate alla determinazione dell'entità dei residui di prodotti fitosanitari nei seguenti settori di attività:

aree non agricole;
colture arboree;
colture erbacee;
colture forestali;
colture medicinali ed aromatiche;
colture ornamentali;
colture orticole;
concia sementi;
conservazione post-raccolta;
colture in vivaio;

prove di semicampo in ambiente controllato;

diserbo;

entomologia;

microbiologia agraria;

nematologia;

patologia vegetale;

zoologia agraria;

produzione sementi;

vertebrati dannosi;

fitoregolatori, attivatori e coadiuvanti;

vinificazione.

Art. 2.

1. Il mantenimento dell'idoneità di cui all'articolo precedente è subordinato alla verifica biennale in loco del possesso dei requisiti prescritti, da parte degli ispettori iscritti nell'apposita lista nazionale di cui all'art. 4, comma 8, del citato decreto legislativo 194/95.

2. Il Centro «Anadiag Italia S.r.l.» è tenuto a comunicare a questo Ministero l'indicazione precisa delle tipologie delle prove che andrà ad eseguire, nonché la loro localizzazione territoriale.

3. Il citato Centro è altresì tenuto a comunicare ogni eventuale variazione che interverrà rispetto a quanto dalla stessa dichiarato nell'istanza di riconoscimento, nonché a quanto previsto dal presente decreto.

Art. 3.

1. Il presente decreto ha la validità di mesi 24 dalla data di ispezione effettuata in data 23 giugno 2018.

2. Il Centro «Anadiag Italia S.r.l.», qualora intenda confermare o variare gli ambiti operativi di cui al presente decreto, potrà inoltrare apposita istanza, almeno sei mesi prima della data di scadenza, corredata dalla relativa documentazione comprovante il possesso dei requisiti richiesti.

Il presente decreto, ai sensi dell'art. 13 del decreto legislativo n. 196/2003, sarà oggetto di pubblicazione in ottemperanza agli obblighi di legge previsti dal decreto legislativo n. 33/2013.

Il presente decreto sarà pubblicato nella *Gazzetta Ufficiale* della Repubblica italiana.

Roma, 30 luglio 2018

Il direttore generale: GATTO

18A05349



Test facility	Address	Certificate (Yes or No)
ANADIAG FRANCE	ZA Bel air 47380 Saint-Etienne de Fougères FRANCE	YES



MINISTÈRE DE L'AGRICULTURE ET DE L'ALIMENTATION

**DÉCISION D'AGRÈMENT POUR RÉALISER
DES ESSAIS OFFICIELLEMENT RECONNUS**

Conformément à l'article R. 253-38 du code rural et de la pêche maritime et à l'article 6 de l'arrêté du 26 avril 2007 relatif aux essais officiels et officiellement reconnus pour l'évaluation des produits mentionnés à l'article L. 253-1 du code rural et de la pêche maritime,

Vu la convention passée avec le Cofrac n° 4609,

Vu le rapport d'évaluation réalisé par le Cofrac, en date du 27 juillet 2017,

L'agrément pour réaliser des essais officiellement reconnus est renouvelé, à l'organisme :

ANADIAG France
13 rue de la Bourbre
38300 RUY

sous le numéro : **BPE - 105**

ET POUR LE PÉRIMÈTRE SUIVANT :

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
ANADIAG France 13 rue de la Bourbre 38300 RUY (unité centrale)	- Traitement des semences : grandes cultures
UE 01 – Harnes (UE 62) ZI la Motte au Bois 62440 HARNES	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Zones non agricoles
UE 03 – Saint Pierre du Bû (UE 14) Couvrigny 14700 SAINT PIERRE DU BU	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum
UE 03 – Cintré (UE 35) Rue du puisatier ZA du moulin à vent 35310 CINTRE	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Zones non agricoles
UE 06 – Varois et Chaignot (UE 21) 8 route de Gray 21490 VAROIS ET CHAIGNOT	- Grandes cultures - Vigne - Zones non agricoles
UE 08 – Saint Barthélémy (UE 38) 700 route de Pisieu 38270 SAINT BARTHELEMY	- Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
UE 10 – Saint Etienne de Fougères (UE 47) ZA Bel Air 47380 SAINT ETIENNE DE FOUGERES	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles - Désinfections et désinsectisation des sols, des matériels et des locaux de culture et de stockage des végétaux
UE 12– Saint Germain des Prés (UE 49) ZA la Poterie 49170 SAINT GERMAIN DES PRES	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur
UE 13 – Castillon du Gard (UE 30) ZA les codes bas 3 30210 CASTILLON DU GARD	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles
UE 15 – Haguenau (UE 67) 16 rue Ampère 67500 HAGUENAU	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Processus de transformation : <ul style="list-style-type: none"> - Vinification - Transformation de pomme de terre - Transformation de fruits (compote, jus de fruit, nectar, fruit au sirop, confiture, fruits séchés) - Transformation de légumes (jus, concentré de tomates, conserve de légumes, ketchup, choucroute) - Extraction d'huile
UE 16 – Thorée les Pins (UE 72) La Belle Métairie 72800 THOREE LES PINS	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture
UE 17 – Toulouse (UE 31) 75 voie de TOEC Bâtiment entreprise 2 31076 TOULOUSE	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture

Cet agrément est délivré pour une durée de cinq ans à compter du 09/10/2017 jusqu'au 08/10/2022. En application de l'article 5 de l'arrêté susmentionné, une nouvelle évaluation aura lieu dans un délai compris entre vingt-quatre et trente-six mois à compter du 09/10/2017.

Date : 03 OCT. 2017

Le sous directeur de la qualité, de la santé
et de la protection des végétaux

Alain TRIDON

Test facility	Address	Certificate (Yes or No)
ANADIAG IBERICA, SL	ANADIAG IBERICA, SL C/ Falgueres s/n Celrà, Girona 17460 SPAIN	YES



MINISTERIO
DE AGRICULTURA Y PESCA,
ALIMENTACION Y MEDIO AMBIENTE

SECRETARÍA GENERAL DE
AGRICULTURA Y ALIMENTACIÓN

DIRECCIÓN GENERAL DE SANIDAD
DE LA PRODUCCIÓN AGRARIA

ASUNTO: Renovación Acreditación N° EOR 20/97

De acuerdo con lo establecido en el artículo 19 de la Orden de 11 de diciembre de 1995 por el que se establecen las disposiciones relativas a las renovaciones de autorizaciones de ensayos y experiencias con productos fitosanitarios, esta Dirección General ha resuelto, previo informe favorable de la Comisión de Evaluación de Productos Fitosanitarios, renovar la acreditación N° EOR 20/97 concedida a su empresa, para realizar ensayos oficialmente reconocidos.

La validez de esta acreditación queda ampliada hasta el 18 de julio del año 2022, salvo que sea revisada o revocada antes de la conclusión de dicho plazo si se determina que ha dejado de cumplirse alguno de los requisitos exigidos para su autorización o de las obligaciones establecidas por la Orden Ministerial de 11 de diciembre de 1995.

Madrid 18 de julio de 2017

EL DIRECTOR GENERAL DE SANIDAD
DE LA PRODUCCIÓN AGRARIA

Fdo.: Valentin Almansa de Lara

ANADIAG IBERICA, S.L.
GIRONA
JCS/amg

Test facility	Address	Certificate (Yes or No)
SYNTECH RESEARCH PORTUGAL	Rua Antonio de Oliveira 21, Caldas Da Rainha 2500-916 PORTUGAL	YES



REPÚBLICA
PORTUGUESA



INSTITUTO NACIONAL
DE MEDICINA VETERINÁRIA



dgav
Direção-Geral
de Veterinária

CERTIFICADO

ORGANIZAÇÃO OFICIALMENTE RECONHECIDA PARA A REALIZAÇÃO DE
ENSAIOS DE EFICÁCIA DE PRODUTOS FITOFARMACÊUTICOS

Certifica-se que a **SYNTECH Research Portugal** é reconhecida como Organização Oficialmente Reconhecida, em Portugal, para a realização de ensaios de eficácia de produtos fitofarmacêuticos, segundo a Boa Prática Experimental, n.º 35, da Portaria n.º 396/2000, de 14 de Julho, que concretiza os princípios estabelecidos no Regulamento (UE) N.º 284/2013 da Comissão de 1 de março de 2013, em conformidade com o Regulamento (CE) N.º 1107/2009 do Parlamento Europeu e de acordo com o respetivo pedido.

- **Certificado n.º 30 (trinta)**
- **Data de entrada em vigor do reconhecimento: 29 de maio de 2018**
- **Termo do prazo do reconhecimento: 29 de maio de 2023**
- **Condições / Limitações: —**

Lisboa, 10 julho de 2018.

A Subdiretora Geral

ANA PAULA DE
ALMEIDA CRUZ DE
CARVALHO

Assinado de forma digital por ANA
PAULA DE ALMEIDA CRUZ DE
CARVALHO.
Dados: 2018.07.10 21:15:18 +01'00'

SEDE: CAMPO GRANDE, 90 – 1700-083 LISBOA. TEL: 31 221 95 00 FAX: 31 221 95 91

North-Eastern EPPO zone

Test facility	Address	Certificate (Yes or No)
ANADIAG POLSKA	Ul. Sadowa 16/22, 95-100 Zgierz, POLAND	YES
SYNTECH RESEARCH POLAND	69/1 Jagiellonska 85-027 Bydgoszcz, POLAND	YES
LRCAF Institute of Agriculture LITHUANIA	Akademija, Kedainiai LT-58344 LITHUANIA	YES
SIA Agrolab Baltic LATVIA	“Ozoli” Kursisu parish, LV-3890 Kursisi, LATVIA	YES

Test facility	Address	Certificate (Yes or No)
ANADIAG POLSKA	Ul. Sadowa 16/22, 95-100 Zgierz, POLAND	YES

SWORN TRANSLATOR
MARTA TRAWCZYŃSKA

ul. Św. Wojciecha 3/3a lok. 1, 10-038 Olsztyn
T +48 665 240 339, F +48 89/ 512 00 99

CERTIFIED TRANSLATION FROM THE POLISH LANGUAGE

[Any remarks in square brackets are the translator's. The translated document consists of two (2) pages.]

[national emblem of the Republic of Poland]

MAIN INSPECTOR
OF PLANT HEALTH AND SEED PROTECTION

Andrzej Chodkowski

Warsaw, dated 12 October 2018

BORIT.541.11.2018.1

DECISION No. 10/2018

Pursuant to Article 155 of the Act of 14 June 1960 Administrative Procedure Code (Dz.U. [Polish Official Journal of Laws] of 2017, item 1257 as amended), having examined the application filed by Anadiag SAS Branch Office in Poland dated 3 October 2018, I vary the decision No. 7/2007 dated 28 May 2007, varied by decisions No. 1/2010 dated 18 March 2010, No. 18/2011 dated 18 August 2011, No. 1/2012 dated 13 January 2012 and No. 3/2014 dated 16 April 2014 to grant authorization to conduct research of the efficiency of plant health products in such a manner that the decision shall read as follows:

"I authorize

Anadiag SAS Branch Office in Poland

ul. Sadowa 16/22, 95-100 Zgierz

to conduct research of the efficiency of plant health products from the group of acaricides, bacteriocides, fungicides, herbicides, insecticides, molluscicides, rodenticides, pheromones and growth regulators in outdoor crops, orchard crops, under covers, in edible mushrooms cultivations, in meadows and pastures. The research shall be conducted in cereal, root and oil crops, vegetables, orchard and ornamental plants, legumes, grass and special plants, in storage rooms and rooms for cultivation of edible mushrooms, in lawns and in non-agricultural lands."

No reasoning for this decision has been prepared as the decision grants the application of the Party in its entirety (Article 107(4) of the Administrative Procedure Code [hereinafter referred to as "APC"]).



Marta Trawczyńska

Test facility	Address	Certificate (Yes or No)
SYNTECH RESEARCH POLAND	69/1 Jagiellonska 85-027 Bydgoszcz, POLAND	YES



**GLÓWNY INSPEKTOR
OCHRONY ROŚLIN I NASIENNICTWA**

Tadeusz Klos

WO-505-8/15

Warszawa, 27.04.2015 r.

DECYZJA Nr 6/2015

Na podstawie art. 17 ust. 2 i ust. 8 pkt 2 w związku z art. 79 ust. 3 ustawy z dnia 8 marca 2013 r. o środkach ochrony roślin (Dz.U. z 2013 r. poz. 455 z późn. zm.) oraz art. 104 ustawy z dnia 14 czerwca 1960 r. Kodeks postępowania administracyjnego (Dz.U. z 2013 r. poz. 267 z późn.zm.), po rozpatrzeniu wniosku z dnia 30 marca 2015 r., rozszerzam zakres upoważnienia do prowadzenia badań skuteczności działania środka ochrony roślin wydanego w drodze decyzji Nr 5/2013 z dnia 25 marca 2013 r., zmienionej decyzją Nr 2/2014 z dnia 7 marca 2014 r., w zakresie prowadzenia badań skuteczności działania środka ochrony roślin z użyciem akaricydów i nematocydów w uprawach warzyw w polu i pod osłonami.

Rozstrzygnięciu decyzji nadaję następujące brzmienie:

Upoważniam

SynTech Research Poland Sp. z o.o.

ul. Jagiellońska 69/1; 85-027 Bydgoszcz

do prowadzenia badań skuteczności działania środka ochrony roślin

z grupy akaricydów, fungicydów, herbicydów, insektycydów, nematocydów i regulatorów wzrostu w uprawach polowych (zboża, kukurydza, rzepak, burak cukrowy, ziemniak, warzywa kapustne, pomidor, ogórek, sałata, marchew, pietruszka, cebula, fasola, papryka, burak), w uprawach sadowniczych (jabłoni, wiśnia, czereśnia, śliwa, morela, brzoskwinia, grusza, malina, truskawka, porzeczka, orzech), w uprawach chmielu, traw łąkowych i pastwiskowych oraz na terenach nieużytkowanych rolniczo.

Uzasadnienie

Pismem z dnia 30 marca 2015 r. Spółka z o.o. SynTech Research Poland zwróciła się z prośbą o rozszerzenie zakresu upoważnienia Nr 5/2013 wydanego przez Głównego Inspektora Ochrony Roślin i Nasiennictwa w dniu 25 marca 2013 r., zmienionej decyzją Nr 2/2014 z dnia 7 marca 2014 r., umożliwiające Spółce prowadzenie badań skuteczności działania środka ochrony roślin. Wnioskowana zmiana dotyczy prowadzenia badań z użyciem środków ochrony roślin z grupy akaricydów i nematocydów oraz stosowania badanych środków w uprawach marchwi, pietruszki, cebuli, fasoli, papryki, buraka, truskawki, porzeczki, gruszy, orzecha, moreli, brzoskwini, winorośli i chmielu, traw łąkowych i pastwiskowych oraz na terenach nieużytkowanych rolniczo.

Test facility	Address	Certificate (Yes or No)
LRCAF Institute of Agriculture LITHUANIA	Akademija, Kedainiai LT-58344 LITHUANIA	YES

<div><p>VALSTYBINĖ AUGALININKYSTĖS TARNYBA PRIE ŽEMĖS ŪKIO MINISTERIJOS</p><p>GEROS AUGALŲ APSAUGOS PRODUKTŲ VEIKSMINGUMO IR (ARBA) ATRANKUMO BANDYMŲ PRAKTIKOS SERTIFIKATAS</p><p>2013-12-12 Nr. AS4 – 13/02 Vilnius</p><p>Patvirtinama, kad Lietuvos agrarinių ir miškų mokslų centro filialas Žemdirbystės institutas, į.k. 302474007, Instituto al. 1, Akademija, 58344 Kėdainių r., laikosi geros augalų apsaugos produktų veiksmingumo ir (arba) atrankumo bandymų praktikos ir turi teisę atlikti šiuos tyrimus:</p><p>lauko bandymai; vegetaciniai bandymai.</p><p>Sertifikatas galioja iki 2019 m. gruodžio 12 d.</p><div><div>Direktorius</div><div></div><div>Evaldas Zigmas Čijauskas</div></div></div>

Test facility	Address	Certificate (Yes or No)
SIA Agrolab Baltic LATVIA	“Ozoli” Kursisu parish, LV-3890 Kursisi, LATVIA	YES



Valsts augu aizsardzības dienests

SERTIFIKĀTS

Nr. 30

Izsniegts **SIA „AgroLab Baltic”**

(komersanta nosaukums, reģistrācijas numurs, juridiskā adrese)

Reģ. Nr. 44103075387

Elizabetes iela 45/47, Rīga, LV-1010

par tiesībām veikt normatīvajos aktos par augu aizsardzības līdzekļu reģistrāciju noteiktos
efektivitātes pārbaudes izmēģinājumus:

Lauks- graudaugi-fungicīdi, insekticīdi, kodnes, lauks- rapsis- insekticīdi, lauks- dārzeņi- insekticīdi,
lauks- graudaugi-limacīdi, lauks- rapsis- limacīdi.

Sertifikāts izsniegts: 08.01.2019.
(datums)

Sertifikāts derīgs līdz: 07.01.2024.
(datums)

Valsts augu aizsardzības dienests

Augu aizsardzības līdzekļu

reģistrācijas daļas vadītāja

(amats, paraksts un tā atšifrējums)



R.Čūdere

South-Eastern EPPO zone

Test facility	Address	Certificate (Yes or No)
GEMERPRODUKT VALICE - OVD	Ovocinársko-vinohradnicke družstvo Okružná 3771, Rimavská Sobota 979 01, SLOVAKIA	YES
ANADIAG HUNGARY	ANADIAG HUNGARY Petofi Sandor utca 67, Komarom 2921, HUNGARY	YES
ANADIAG ROMANIA	ANADIAG ROMANIA SRL, Str. Piata Montreal, nr°10, WTC, 011469 Bucharest, ROMANIA	YES
SAGEA OOD	SAGEA OOD Boulevard Bulgaria, 6 4000 Plovdiv BULGARIA	YES

Test facility	Address	Certificate (Yes or No)
GEMERPRODUKT VALICE - OVD	Ovocinársko-vinohradnícke družstvo Okružná 3771, Rimavská Sobota 979 01, SLOVAKIA	YES

Central Controlling and Testing Institute in Agriculture in Bratislava
Matiškova 21, 833 16 Bratislava

GEP CERTIFICATE
No. 03/C - 06/2019

issued in accordance with § 28 of the Act No. 405/2011 Coll. on Plant Care, Amending and Supplementing Act of the National Council of the Slovak Republic No. 145/1995 Coll. on Administrative Fees as Amended and § 3 of the Regulation of the Ministry of Agriculture and Rural Development of the Slovak Republic No 486/2011 Coll. laying down details of the conditions, procedures and deadlines to implement the provisions of the tests of biological efficacy, applications, principles of good experimental practice, audits and issuing certificate, extension of the certificate, recertification (hereinafter "Regulation")

for

GEMERPRODUKT VALICE,
ovocinársko-vinohradnícke družstvo
Okružná 3771
979 01 Rimavská Sobota

Identification number: 36059005

which has demonstrated implementation of principles of Good experimental practice (GEP) in accordance with the requirements of the Regulation in the following categories

Categories of crops	Categories of plant protection products and their adverse effects on crops.
cereals	fungicides; fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides; zoocides - seed treatment; growth regulators; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides; zoocides - seed treatment; growth regulators
maize	fungicides; fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides; zoocides - seed treatment; growth regulators; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides; zoocides - seed treatment; growth regulators
legumes	fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides - seed treatment; growth regulators; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides; zoocides - seed treatment; growth regulators
oil plants	fungicides; fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides; zoocides - seed treatment; growth regulators; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides; zoocides - seed treatment; growth regulators
technical plants	fungicides - seed treatment; zoocides - seed treatment; growth regulators; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides; zoocides; zoocides - seed treatment; growth regulators

root crops	fungicides; fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides; zoocides - seed treatment; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides; zoocides - seed treatment
vegetables and root vegetables	fungicides; fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides; zoocides - seed treatment; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides; zoocides - seed treatment
grape, fruit and stocks	fungicides; fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides; zoocides - seed treatment; growth regulators; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides; zoocides - seed treatment; growth regulators


Date of issue: 28.05.2019
Date of expiry: 12.04.2021




Ing. Peter Rusňák, PhD.
General Director

This certificate includes also appendices.
By issuing this certificate, certificate No. 03/AC-05/2019 expires.

Test facility	Address	Certificate (Yes or No)
ANADIAG HUNGARY	ANADIAG HUNGARY Petofi Sandor utca 67, Komarom 2921, HUNGARY	YES



n é b i h
Termőföldül az állatig

National Food Chain Safety Office
Directorate of Plant Protection, Soil Conservation
and Agri-environment

H-1118 Budapest, Bartók út 143-145,
Hungary
Tel: 36/1/309-3300 Fax: 36/1/336-2942
E-mail: nt@neh.gov.hu
www.nebih.gov.hu

Your ref.: -

Our ref.: 04.2/6149-7/2016

7 October 2016

Subject: Certificate of Official Recognition of Efficacy Testing Facilities or Organisations in Hungary

Having received the application submitted by the **Anadiag Hungary Mezőgazdasági Szolgáltató Kft. (H-2921 Komárom, Petőfi Sándor út 67, Hungary)**, the client, for completing a certification procedure of first instance concerning the Official Recognition of Efficacy Testing Facilities/Organisations, i.e. Good Experimental Practices (hereinafter: GEP), I, acting as the food chain control body, has made the following

DECISION:

I issue the client's GEP certificate for its premises at Komárom, Petőfi Sándor út 67 for carrying out efficacy trials for authorisation purposes. The GEP certificate is effective for 5 years from the entry into force of this Decision.

The client's GEP certificate is given for the following categories of products and cultivation:

- **product categories:** herbicides, fungicides and bactericides, zoocides, growth regulators and yield enhancing substances, additives;
- **cultivation categories:** field crops, vegetables, fruits, grapevines, ornamentals, others.

I inform you that the present certification is without prejudice to either the licences concerning the operation/follow-up of activity laid down in other provisions of legislation or the client's obligation for obtaining them.

The client is obliged to notify the competent authority, within 15 days, of any important changes concerning the certified activity of the testing facility.

I call your attention that respect of the provisions laid down in the legislation on GEP certification and in this Decision shall be randomly controlled by my competent authority. If during the official inspection it is stated that the testing facility does not meet the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate.

If during the official inspection it is found that some details are missing in relation to a particular trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization.

The fee of the present procedure is 250.000 HUF (i.e. two hundred and fifty thousand Hungarian Forints) paid by the client.

No further complaint shall be lodged against the present Decision, effective by its publication, through state administration, though with reference to infringement of law, judicial review of the Decision may be requested at the Capital Administrative and Employment Court. The claim note shall be submitted to my competent authority within 30 days of the communication of the Decision.

I inform you that the court shall judge the case out of court, but shall carry on a lawsuit at the request of any of the parties. The client may ask for carrying on a lawsuit, but in default of so doing, no verification is accepted. Submission of the claim note has no delaying force on the implementation of this Decision.

J U S T I F I C A T I O N

In its application of 29 August 2016, the client submitted an application to the competent authority for a procedure of GEP certification.

As a follow-up to this application, the competent authority made a local inspection at the client's facility of Komárom, Petőfi Sándor út 67 on 31 August 2016. Statements made during the local inspection are reported in the protocol Nr. 04.2/6149-4/2016. Based on the results of the local inspection the competent authority concluded that the client's testing facility does not meet the requirements concerning the efficacy trials specified in Article 22 of the Decree 89/2004 (V. 15.) FVM on the authorization of placing on the market and use, as well as on the packaging, labelling, storage and transport of plant protection products (hereinafter: Decree 89/2004) and in the Decision Nr. 04.2/6149-5/2016 it calls the client to fill the data gaps.

Article 22(5) of Decree 89/2004 - Based on request, the competent authority shall make local inspections at the testing facility and decide on the GEP qualification of the testing facility. The decision shall include the product categories and the cultivation categories for which the testing facility obtained the GEP-certificate.

(6) The validity of GEP-certification is 2 years in case of the first request and maximum 3 years in case of renewal of the certification.

(7) A fee laid down in specific legislation shall be paid for the GEP-certification procedure.

(8) The testing facility having GEP-certification shall notify the competent authority, within 15 days, about any important changes concerning the certified activity of the testing facility.

(9) The competent authority shall randomly control the testing facility having GEP-certification. If it is found that the testing facility does not meet the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate. If during the official inspection it is established that some details are missing in relation to a trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization."

Client filled the missing data gaps and reported on it in the letter of 20 September 2016, therefore I made the Decision as specified in the first part. Therefore I stated that conditions for issuing the certificate specified above are met, so I made the Decision as specified in the first part.

The fee of the present procedure is HUF 250.000 and was established in accordance with point 8.19.2 of Annex 1 to the Decree 63/2012. (VII. 2.) FVM on the extent of administrative servicing fees due for the procedures by the agricultural administrative bodies of the National Food Chain Safety Office and the county government offices and on the rules of paying the administrative servicing fees. The client paid the fee.

I made this Decision within my jurisdiction laid down in Article 3 paragraph (1) and Article 5 point e) of Government Decree 22/2012. (II. 29.) concerning the National Food Chain Safety Office, Article 3, Article 22 paragraph (1) of Decree 89/2004 and in compliance with Articles 71 paragraph (1) and Article 72 paragraph (1) of Act CXL of 2004 on general rules of administrative official procedure and service (hereinafter: Act CXL of 2004).

I excluded the possibility of appeal in compliance with Article 100 paragraph (1) point e) of Act CXL of 2004 and provided the possibility of judicial review in compliance with Article 109 paragraph (1) of Act CXL of 2004 and Article 330 paragraph (2) of Act III of 1952 on Civil Procedure.

on behalf of
dr. Márton Oravecz
president


László Jordán
director

Test facility	Address	Certificate (Yes or No)
ANADIAG ROMANIA	ANADIAG ROMANIA SRL, Str. Piata Montreal, nr°10, WTC, 011469 Bucharest, ROMANIA	YES

GEP AGREEMENT

MINISTERUL AGRICULTURII ȘI DEZVOLTĂRII RURALE	MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT
Autoritatea Națională Fitosanitară	National Phytosanitary Authority
Comisia Națională de Omologare a Produselor de Protecție a Plantelor	National Commission for Registration of Plant Protection Products

**Certificat de recunoaștere oficială a testelor de eficacitate biologică în
conformitate cu bunele practici experimentale/Certificate of official
recognition of the efficacy biological tests according to the good
experimental practices**

Se acordă: SC ANADIAG ROMANIA SRL
It is granted to: SC ANADIAG ROMANIA SRL
cu sediul: Str. Gen. C. Budisteanu, nr.28-C;010775, Bucuresti
with headquarter: Gen. C. Budisteanu Street, no. 28-C, 010775, Bucharest
pentru domeniul/
domeniile de activitate: Culturi agricole de câmp și pajiști; Pomicultură;
Viticultură; Legumicultură; Floricultură; Silvicultură; Plante ornamentale și de
interior; Zone non agricole
for the domain/
domains of activity: Crops fields and meadows; Fruit tree growing; Viticulture;
Vegetable crops; Floriculture; Aromatic and medicinal plants; Ornamental and indoor
plants; Silviculture; Non agricultural zones

Prezentul certificat se eliberează în conformitate cu prevederile Ordinului ministrului
agriculturii și dezvoltării rurale, al ministrului sănătății și al ministrului mediului și
schimbărilor climatice nr.60/512/1258/2013 și prevederile Procedurii naționale de
omologare a produselor de protecție a plantelor care conțin substanțe active
notificate și pentru care nu s-a luat încă o decizie de includere în lista cu substanțe
active autorizate în Uniunea Europeană, aprobată prin Ordinul ministrului agriculturii,

pădurilor și dezvoltării rurale, al ministrului sănătății și al ministrului mediului și gospodăririi apelor nr.134/197/412/2006, cu modificările și completările ulterioare.

This certificate is issued according to the provisions of the Order of the ministry of agriculture and rural development, of the ministry of health and of the ministry of environment and climate change no.60/512/1258/2013 and the provisions of the National Procedure for Registration of Plant Protection Products which contain notified active substances and for which isn't taken yet a decision for inclusion in European Union list of authorised active substances, approved by the Order of the ministry of agriculture, forests and rural development, of the ministry of health and of the ministry of environment and waters husbandry no.134/197/412/2006, with subsequent amendments and completions.

Data emiterii certificatului: 20.08.2015

Issuance date of the certificate

Data expirării certificatului: 20.08.2020

Expiry date of the certificate

PREȘEDINTE/CHAIRMAN,

Elena LEAOTA



Test facility	Address	Certificate (Yes or No)
SAGEA OOD	SAGEA OOD Boulevard Bulgaria, 6 4000 Plovdiv BULGARIA	YES



РЕПУБЛИКА БЪЛГАРИЯ
Министерство на земеделието, храните и горите
Българска агенция по безопасност на храните

СЕРТИФИКАТ

№006

София, 06.10.17 г.

На основание чл. 75 от Закона за защита на растенията и чл. 23 от Наредба № 19 от 8 ноември 2016 г. за биологично изпитване на продукти за растителна защита (обн., ДВ, бр.90 от 15.11.2016 г.) и Заповед № РД 11-1909 от 20.09.2017 г. на изпълнителния директор на Българската агенция по безопасност на храните

ИЗДАВАМ:

настоящия сертификат, в уверение на това, че база „Салжеа“ ООД със седалище и адрес на управление: с.Стъргел 2135, общ. Горна Малина, обл. София, къща 22, е места за изпитване: гр. Пловдив 4000, бул. „България“ № 6, бл. 18, етаж партерен и гр. Варна 9000, район „Приморски“, ул. „10-та“ № 4 одобрена за извършване на биологично изпитване на продукти за растителна защита на територията на Република България за следните групи култури:

1. Полеки култури
2. Трайни насаждение
3. Зеленчукови култури
4. Оранжерийни култури

Сертификатът удостоверява осигурено качество при провеждане на опити за ефикасност на продукти за растителна защита, съответстващо на Добрата експериментална практика и стандартите за изпитване за ефикасност на ПРЗ, определени от Европейската и средиземноморската организация по растителна защита (EPPO).

Сертификатът е валиден до 20.09.2027 г.

Д-Р ДАМЯН ИЛЧЕВ

Изпълнителен директор на
Българската агенция по безопасност на храните



3.7.3 Oat (AVESS/AVESA)

Table 3.7-3: List of test facilities –AVESS/AVESA

Maritime EPPO zone

Test facility	Address	Certificate (Yes or No)
STAPHYT	Menin 569 66457 Menin GERMANY	YES
ZS Nechanice	Štolbova 319, 503 15 Nechanice, CZECH REPUBLIC	YES
QUINTUS GMBH	LIEPEN 7 17194 Hohen Wangelin OT Liepen GERMANY	YES
SynTech Research Portugal	Rua Antonio de Oliveira 21 - Freguesia Santo Onofre Caldas da Rainha 2500-916 PORTUGAL	YES (2019)

Test facility	Address	Certificate (Yes or No)
STAPHYT	Menin 569 66457 Menin GERMANY	YES



ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

STAPHYT s.r.o.
Měnin 569
664 57 Měnin

Útvar: Odbor přípravků na ochranu rostlin
Adresa: Zemědělská 1a, 613 00 Brno

Sp.zn: SZ UKZUZ 032225/2016/06857 Č.j.: UKZUZ 057138/2016 Datum: 18. 5. 2016
Vyřizuje: ing. Míňářová Tel.: 545 110 444 E-mail: ivana.minarova@ukzuz.cz

ROZHODNUTÍ

Ústřední kontrolní a zkušební ústav zemědělský (dále jen „ÚKZÚZ“), Hroznová 2, 656 06 Brno, jako věcně příslušný správní orgán podle § 72 odst. 1 písm. c) zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, ve znění pozdějších předpisů (dále jen „zákon“) a v návaznosti na čl. 54 odst. 4 Nařízení Evropského parlamentu a Rady (ES) č. 1107/2009, o uvádění přípravků na ochranu rostlin na trh a o zrušení směrnice Rady 79/117/EHS a 91/414/EHS, v platném znění, v provedení § 45 odst. 1 zákona, v řízení o způsobilosti k provádění pokusů a zkoušek s přípravky nebo dalšími prostředky na základě žádosti společnosti **STAPHYT s.r.o.**, Měnin 569, 664 57 Měnin, IČ 29210917 dále jen „společnost STAPHYT s.r.o.“ a to:

žádosti o prodloužení platnosti rozhodnutí o způsobilosti k provádění zkoušek podle § 45 odst. 1 zákona ze dne 24. 3. 2016, doručené ÚKZÚZ dne 24. 3. 2016, č.j. UKZUZ 032225/2016

rozhodl takto:

společnost STAPHYT s.r.o. je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe.

právnícká osoba: **STAPHYT s.r.o.**

sídlo právnické osoby: Měnin 569, 664 57 Měnin

IČ právnické osoby: 29210917

GEP kód: **GEP/SHT/2016**

oblasti zkoušení: **polní plodiny a zelenina**
trvalé kultury
skleníky a jiné kryté prostory
moření osiva

rozhodnutí se vydává s účinností od 1. 9. 2016

dobu účinnosti rozhodnutí: 5 let

Tímto rozhodnutím se k datu nabytí jeho účinnosti zrušuje rozhodnutí č.j. SRS 026758/2010 ze dne 2. 7. 2010.

Odůvodnění:

Řízení ve věci uznání osoby za způsobilou provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe bylo zahájeno na základě žádosti ze dne 24. 3. 2016, doručené UKZÚZ dne 24. 3. 2016.

Rozhodnutí o způsobilosti k provádění pokusů a zkoušek v souladu s požadavky správné pokusnické praxe bylo vydáno na základě kontroly předložené dokumentace pracoviště STAPHYT s.r.o., Příručky jakosti, Standardních operačních postupů a Metrologického řádu, kterou bylo UKZÚZ prokázáno, že žadatel splnil požadavky stanovené v § 45 odst. 12 a 13 zákona v návaznosti na § 4 odst. 2 vyhlášky č. 32/2012 Sb., o přípravcích a dalších prostředcích na ochranu rostlin, ve znění pozdějších předpisů.

Vzhledem k výše uvedeným skutečnostem bylo rozhodnuto tak, jak je stanoveno ve výrokové části tohoto rozhodnutí.

Správní poplatek podle zákona č. 634/2004 Sb., o správních poplatcích, ve znění pozdějších předpisů, podle Sazebníku, Položky 86 písm. b) „Přijetí žádosti o vydání osvědčení o způsobilosti k provádění zkoušek pro účely povolení“ ve výši 100,- Kč, k žádosti doručené UKZÚZ dne 24. 3. 2016, č.j. UKZUZ 032225/2016, byl uhrazen dne 24. 3. 2016 formou kolkové známky.

Poučení:

Proti tomuto rozhodnutí lze podat odvolání do 15 dnů ode dne jeho doručení, nejpozději však do 15 dnů po uplynutí desátého dne ode dne, kdy bylo nedoručené a uložené rozhodnutí připraveno k vyzvednutí, a to k Ministerstvu zemědělství České republiky, odbor rostlinných komodit, prostřednictvím Ústředního kontrolního a zkušebního ústavu zemědělského, sekce zemědělských vstupů, odboru přípravků na ochranu rostlin, Zemědělská 1a, 613 00 Brno.

Otisk úředního razítka

Ing. Pavel Minář, Ph.D.
ředitel odboru

2

UKZÚZ
Hroznová 2
656 06 BRNO

Telefon: +420 543 548 111
Fax: +420 543 211 148
E-mail: podatelna@ukzuz.cz

IČ: 00020338
DIČ: CZ00020338

www.ukzuz.cz
ID DS: ugbaiq7

Test facility	Address	Certificate (Yes or No)
ZS Nechanice	Štolbova 319, 503 15 Nechanice, Czech Republic	YES

ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

Odbor přípravků na ochranu rostlin

Zemědělská 1a, Brno, PSČ 613 00

Příloha rozhodnutí č.j.: UKZUZ 073241/2016 ze dne 28. 6. 2016

OSVĚDČENÍ

GEP/NEC/2016

o způsobilosti k provádění zkoušek
v souladu se zásadami správné pokusnické praxe

Official Recognition Certificate / GEP - Certificate

právnícká osoba: **ZKUŠEBNÍ STANICE NECHANICE, s.r.o.**

sídlo právnické osoby: Štolbova 319, 503 15 Nechanice

IČ právnické osoby: 25283669

je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe podle § 45 odst. 1 zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, v platném znění, v návaznosti na Směrnici 91/414/EHS.

oblasti zkoušení / categories of official recognition:

- polní plodiny a zelenina / *field crops and vegetables*
- trvalé kultury / *high crops*
- skleníky a jiné kryté prostory / *protected areas and storage rooms*

Ústřední kontrolní a zkušební ústav zemědělský
Sekce zemědělských vstupů
Odbor přípravků na ochranu rostlin
613 00 Brno, Zemědělská 1a
- 1 -


Ing. Pavel Minář, Ph.D.
ředitel odboru

Test facility	Address	Certificate (Yes or No)
QUINTUS GMBH	LIEPEN 7 17194 Hohen Wange- lin OT Liepen GERMANY	YES

Anerkennungsbescheinigung

Die Versuchseinrichtung

Quintus GmbH

mit Hauptsitz in

Liepen 7
17194 Hohen Wangelin

und organisatorisch
zugehörigen
Arbeitseinheiten in

08393 Schönberg
Breitenbacher Straße 21

74595 Langenburg-
Nesselbach
Orlacher Straße 16

27798 Hude
Wieselweg 6

ist auf Antrag vom

2016-02-01

und nach durchgeführter
Besichtigung
durch
vom

Herrn Dr. S. Goltermann
Landesamt für Landwirtschaft,
Lebensmittelsicherheit und
Verbraucherschutz MV
2016-04-11

am

in den Versuchskategorien

Acker-, Obst-, Gemüse-, Zier-
pflanzenbau, Haus- und
Kleingarten

agriculture, horticulture, home
and garden

als Einrichtung für die Prüfung
der Wirksamkeit von
Pflanzenschutzmitteln im
Sinne des § 8 Abs. 6 der
Pflanzenschutzmittelverordnu
ng und und gemäß
Verordnung (EU) Nr. 284/2013
für 5 Jahre amtlich anerkannt
worden.

Recognition Certificate

The testing facility

with headquarter in

and subsidiary testing
units in

on application from

and after inspection

by
from

on

in the trial categories

has been officially
recognised as an
organisation for efficacy
testing facility of plant
protection products
according to § 8 par. 6 of
the Plant Protection
Products Ordinance and
the Commission
Regulation (EU) No
284/2013 for 5 years.

11.04.2016 
Datum date Unterschrift signature
Landesamt für Landwirtschaft,
Lebensmittelsicherheit und
Verbraucherschutz MV,
Thierfelderstr. 18, 18059 Rostock
Adresse der anerkennenden Behörde
address of the recognising authority



Mediterranean EPPO zone

Test facility	Address	Certificate (Yes or No)
SynTech Research Portugal	Rua Antonio de Oliveira 21 - Freguesia Santo Onofre Caldas da Rainha 2500-916 PORTUGAL	YES (2019)
ANADIAG IBÉRICA, SL	c/ Falgueres s/n 17460 Celrà (Girona - SPAIN)	YES
ANADIAG ITALIA SRL	S.da Savonesa, 9 15050 Fraz. Rivalta S. Tortona (AL) ITALY	YES
SynTech Research Portugal	Rua Antonio de Oliveira 21 - Freguesia Santo Onofre Caldas da Rainha 2500-916 PORTUGAL	YES (2020)

Test facility	Address	Certificate (Yes or No)
SynTech Research Portugal	Rua Antonio de Oliveira 21 - Freguesia Santo Onofre Caldas da Rainha 2500-916 PORTUGAL	YES (2019)



REPÚBLICA
PORTUGUESA



GOVERNO PORTUGUÊS



dgav
Direção-Geral
de Alimentação
e Veterinária

CERTIFICADO

ORGANIZAÇÃO OFICIALMENTE RECONHECIDA PARA A REALIZAÇÃO DE
ENSAIOS DE EFICÁCIA DE PRODUTOS FITOFARMACÊUTICOS

Certifica-se que a **SYNTECH Research Portugal** é reconhecida como Organização Oficialmente Reconhecida, em Portugal, para a realização de ensaios de eficácia de produtos fitofarmacêuticos, segundo a Boa Prática Experimental, n.º 35, da Portaria n.º 396/2000, de 14 de Julho, que concretiza os princípios estabelecidos no Regulamento (UE) N.º 284/2013 da Comissão de 1 de março de 2013, em conformidade com o Regulamento (CE) N.º 1107/2009 do Parlamento Europeu e de acordo com o respetivo pedido.

- **Certificado n.º 30 (trinta)**
- **Data de entrada em vigor do reconhecimento: 29 de maio de 2018**
- **Termo do prazo do reconhecimento: 29 de maio de 2023**
- **Condições / Limitações: ---**

Lisboa, 10 julho de 2018.

A Subdiretora Geral

ANA PAULA DE
ALMEIDA CRUZ DE
CARVALHO

Assinado de forma digital por ANA
PAULA DE ALMEIDA CRUZ DE
CARVALHO
Dados: 2018.07.10 21:15:18 +01'00'

SEDE: CAMPO GRANDE, 50 – 1700-460 LISBOA. TELEF. 21 323 95 00 FAX. 21 323 95 01

Test facility	Address	Certificate (Yes or No)
ANADIAG IBÉ- RICA, SL	c/ Falgueres s/n 17460 Celrà (Girona) SPAIN	YES



MINISTERIO
DE AGRICULTURA Y PESCA,
ALIMENTACIÓN Y MEDIO AMBIENTE

SECRETARÍA GENERAL DE
AGRICULTURA Y ALIMENTACIÓN

DIRECCIÓN GENERAL DE SANIDAD
DE LA PRODUCCIÓN AGRARIA

ASUNTO: Renovación Acreditación Nº EOR 20/97

De acuerdo con lo establecido en el artículo 19 de la Orden de 11 de diciembre de 1995 por el que se establecen las disposiciones relativas a las renovaciones de autorizaciones de ensayos y experiencias con productos fitosanitarios, esta Dirección General ha resuelto, previo informe favorable de la Comisión de Evaluación de Productos Fitosanitarios, renovar la acreditación Nº EOR 20/97 concedida a su empresa, para realizar ensayos oficialmente reconocidos.

La validez de esta acreditación queda ampliada hasta el 18 de julio del año 2022, salvo que sea revisada o revocada antes de la conclusión de dicho plazo si se determina que ha dejado de cumplirse alguno de los requisitos exigidos para su autorización o de las obligaciones establecidas por la Orden Ministerial de 11 de diciembre de 1995.

Madrid 18 de julio de 2017

EL DIRECTOR GENERAL DE SANIDAD
DE LA PRODUCCIÓN AGRARIA

Fdo.: Valentia Almansa de Lara

ANADIAG IBERICA, S.L.
GIRONA
JCS/amg

Test facility	Address	Certificate (Yes or No)
ANADIAG ITA-LIA SRL	S.da Savonesa, 9 15050 Fraz. Rivalta S. Tortona (AL) ITALY	YES

DECRETO 30 luglio 2018.

Riconoscimento dell'idoneità al Centro «Anadiag Italia S.r.l.» ad effettuare prove ufficiali di campo, finalizzate alla produzione di dati di efficacia e alla determinazione dell'entità dei residui di prodotti fitosanitari.

IL DIRETTORE GENERALE
DELLO SVILUPPO RURALE

Visto il decreto legislativo del 17 marzo 1995, n. 194 che, in attuazione della direttiva 91/414/CEE, disciplina l'immissione in commercio dei prodotti fitosanitari;

Visti in particolare i commi 5, 6, 7 e 8 dell'art. 4 del predetto decreto legislativo n. 194/95;

Visto il decreto del Ministro della sanità del 28 settembre 1995 che modifica gli allegati II e III del suddetto decreto legislativo n. 194/95;

Visto il decreto interministeriale 27 novembre 1996 che, in attuazione del citato decreto legislativo n. 194/95, disciplina i principi delle buone pratiche per l'esecuzione delle prove di campo e definisce i requisiti necessari al riconoscimento ufficiale dell'idoneità a condurre prove di campo finalizzate alla registrazione dei prodotti fitosanitari;

Vista l'istanza presentata in data 10 gennaio 2018 dal Centro «Anadiag Italia S.r.l.», con sede legale in fraz. Rivalta Scrivia - Strada Savonesa, 9 - 15050 Tortona (AL);

Visto l'esito favorevole della verifica della conformità ad effettuare prove di campo a fini registrati, finalizzate alla produzione di dati di efficacia e alla determinazione dell'entità dei residui di prodotti fitosanitari effettuata in data 23 giugno 2018 presso il Centro «Anadiag Italia S.r.l.»;

Visto il decreto legislativo 30 luglio 1999, n. 300, di riforma dell'organizzazione di Governo a norma dell'art. 11 della legge 15 marzo 1997, n. 59;

Visto il decreto legislativo 30 marzo 2001, n. 165, relativo alle «norme generali sull'ordinamento del lavoro alle dipendenze delle amministrazioni pubbliche», in particolare l'art. 4, commi 1 e 2 e l'art. 16, comma 1;

Visto il decreto del Presidente del Consiglio dei ministri 27 febbraio del 2013, n. 105, recante il Regolamento di organizzazione del Ministero delle politiche agricole alimentari e forestali, a norma dell'art. 2, comma 10-ter, del decreto-legge 6 luglio 2012, n. 95, convertito, con modificazioni, dalla legge 7 agosto 2012, n. 135, così come modificato dal decreto del Presidente del Consiglio dei ministri 17 luglio 2017, n. 143;

Visto il decreto del Ministro delle politiche agricole alimentari e forestali del 7 marzo 2018, Registrato alla Corte dei conti il 3 aprile 2018 al n. 191, recante individuazione degli Uffici dirigenziali di livello non generale;

Considerato che il suddetto Centro ha dichiarato di possedere i requisiti prescritti dalla normativa vigente, a far data dal 10 gennaio 2018, a fronte di apposita documentazione presentata;

Decreta:

Art. 1.

1. Il Centro «Anadiag Italia S.r.l.», con sede legale in fraz. Rivalta Scrivia - Strada Savonesa, 9 - 15050 Tortona (AL), è riconosciuto idoneo a proseguire nelle prove ufficiali di campo con prodotti fitosanitari volte ad ottenere le seguenti informazioni:

- efficacia dei prodotti fitosanitari (di cui all'Allegato III, punto 6.2 del decreto legislativo n. 194/95);
- dati sulla comparsa o eventuale sviluppo di resistenza (di cui all'Allegato III, punto 6.3 del decreto legislativo n. 194/95);
- incidenza sulla resa quantitativa e/o qualitativa (di cui all'Allegato III, punto 6.4 del decreto legislativo n. 194/95);
- fitotossicità nei confronti delle piante e prodotti vegetali bersaglio (di cui all'Allegato III, punto 6.5 del decreto legislativo n. 194/95);
- osservazioni riguardanti gli effetti collaterali indesiderabili (di cui all'Allegato III, punto 6.6 del decreto legislativo n. 194/95);
- individuazione dei prodotti di degradazione e di reazione dei metaboliti in piante o prodotti trattati (di cui all'allegato II, punto 6.1 del decreto legislativo n. 194/95);

valutazione del comportamento dei residui delle sostanze attive e dei suoi metaboliti a partire dall'applicazione fino al momento della raccolta o della commercializzazione dei prodotti immagazzinati (di cui all'allegato II, punto 6.2 del decreto legislativo n. 194/95);

definizione del bilancio generale dei residui delle sostanze attive (di cui all'allegato II, punto 6.3 del decreto legislativo n. 194/95);

prove relative agli effetti della lavorazione industriale e/o preparazione domestica sulla natura e sull'entità dei residui (di cui all'allegato II, punto 6.6 del decreto legislativo n. 194/95);

prove su destino e comportamento nel suolo (di cui all'allegato II, punto 7.1 del decreto legislativo n. 194/95);

prove su destino e comportamento nell'acqua e nell'aria (di cui all'allegato II, punto 7.2 del decreto legislativo n. 194/95);

studi ecotossicologici relativi agli effetti su organismi non bersaglio (di cui all'allegato II, punto 8.3 del decreto legislativo n. 194/95);

determinazione dei residui in o su prodotti trattati, alimenti per l'uomo o per gli animali (di cui all'allegato III, punto 8.1 del decreto legislativo n. 194/95);

prove relative agli effetti della lavorazione industriale e/o preparazione domestica sulla natura e sull'entità dei residui (Allegato III, Punto 8.2 del decreto legislativo n. 194/95);

effetti sull'aspetto, l'odore, il gusto o altri aspetti qualitativi dovuti ai residui nei o sui prodotti freschi o lavorati (Allegato III, Punto 8.3 del decreto legislativo n. 194/95);

valutazione dei dati sui residui nelle colture successive o di rotazione (di cui all'allegato III, punto 8.5 del decreto legislativo n. 194/95);

individuazione dei tempi di carenza per impieghi in pre-raccolta o post-raccolta (di cui all'allegato III, punto 8.6 del decreto legislativo n. 194/95);

prove su destino e comportamento ambientale (di cui all'allegato III, punti 9.1, 9.2 e 9.3 del decreto legislativo n. 194/95);

studi ecotossicologici relativi agli effetti su organismi non bersaglio (di cui all'allegato III, punto 10.3 del decreto legislativo n. 194/95).

2. Il riconoscimento di cui al comma 1, riguarda le prove di campo di efficacia e le prove di campo finalizzate alla determinazione dell'entità dei residui di prodotti fitosanitari nei seguenti settori di attività:

aree non agricole;
colture arboree;
colture erbacee;
colture forestali;
colture medicinali ed aromatiche;
colture ornamentali;
colture orticole;
concia sementi;
conservazione post-raccolta;
colture in vivaio;

prove di semicampo in ambiente controllato;

diserbo;

entomologia;

microbiologia agraria;

nematologia;

patologia vegetale;

zoologia agraria;

produzione sementi;

vertebrati dannosi;

fitoregolatori, attivatori e coadiuvanti;

vinificazione.

Art. 2.

1. Il mantenimento dell'idoneità di cui all'articolo precedente è subordinato alla verifica biennale in loco del possesso dei requisiti prescritti, da parte degli ispettori iscritti nell'apposita lista nazionale di cui all'art. 4, comma 8, del citato decreto legislativo 194/95.

2. Il Centro «Anadiag Italia S.r.l.» è tenuto a comunicare a questo Ministero l'indicazione precisa delle tipologie delle prove che andrà ad eseguire, nonché la loro localizzazione territoriale.

3. Il citato Centro è altresì tenuto a comunicare ogni eventuale variazione che interverrà rispetto a quanto dalla stessa dichiarato nell'istanza di riconoscimento, nonché a quanto previsto dal presente decreto.

Art. 3.

1. Il presente decreto ha la validità di mesi 24 dalla data di ispezione effettuata in data 23 giugno 2018.

2. Il Centro «Anadiag Italia S.r.l.», qualora intenda confermare o variare gli ambiti operativi di cui al presente decreto, potrà inoltrare apposita istanza, almeno sei mesi prima della data di scadenza, corredata dalla relativa documentazione comprovante il possesso dei requisiti richiesti.

Il presente decreto, ai sensi dell'art. 13 del decreto legislativo n. 196/2003, sarà oggetto di pubblicazione in ottemperanza agli obblighi di legge previsti dal decreto legislativo n. 33/2013.

Il presente decreto sarà pubblicato nella *Gazzetta Ufficiale* della Repubblica italiana.

Roma, 30 luglio 2018

Il direttore generale: GATTO

18A05349



Test facility	Address	Certificate (Yes or No)
SynTech Re- search Portugal	Rua Antonio de Oliveira 21 - Fre- guesia Santo Onofre Caldas da Rainha 2500-916 PORTUGAL	YES (2020)



CERTIFICADO

ORGANIZAÇÃO OFICIALMENTE RECONHECIDA PARA A REALIZAÇÃO DE ENSAIOS DE EFICÁCIA DE PRODUTOS FITOFARMACÊUTICOS

Certifica-se que é reconhecida como Organização Oficialmente Reconhecida, em Portugal, a **ANADIAG Portugal** para a realização de ensaios de eficácia de produtos fitofarmacêuticos, segundo a Boa Prática Experimental, n.º 35, da Portaria n.º 396/2000, de 14 de Julho, que concretiza os princípios estabelecidos no Regulamento (UE) N.º 284/2013 da Comissão de 1 de março de 2013, em conformidade com o Regulamento (CE) N.º 1107/2009 do Parlamento Europeu e do Conselho, de 21 de outubro, de acordo com o respetivo pedido.

- **Certificado n.º 19 (dezanove)**
- **Data de entrada em vigor do reconhecimento: 20 de abril de 2017**
- **Termo do prazo do reconhecimento: 20 de abril de 2022**
- **Condições / Limitações: ---**

Oeiras, 27 de fevereiro de 2018

A Subdiretora Geral

ANA PAULA DE
ALMEIDA CRUZ DE
CARVALHO

Assinado de forma digital
por ANA PAULA DE ALMEIDA
CRUZ DE CARVALHO
Dados: 2018.02.27 13:52:02 Z

North-Eastern EPPO zone

Test facility	Address	Certificate (Yes or No)
SynTech Research Poland Sp. z o.o.	Jagiellońska 69/1 Bydgoszcz 85-027 POLAND	YES
ANADIAG POLSKA	Ul. Sadowa 16/22, 95-100 Zgierz, POLAND	YES
Agrolab Baltic	Bugenių km. LT-89452 Mažeikių raj. LITHUANIA	YES

Test facility	Address	Certificate (Yes or No)
SynTech Re- search Poland Sp. z o.o.	Jagiellońska 69/1 Bydgoszcz 85-027 Poland	YES



GLÓWNY INSPEKTOR
OCHRONY ROŚLIN I NASIENICTWA

Tadeusz Klos

WO-505-B/15

Warszawa, 27.04.2015 r.

DECYZJA Nr 6/2015

Na podstawie art. 17 ust. 2 i ust. 8 pkt 2 w związku z art. 79 ust. 3 ustawy z dnia 8 marca 2013 r. o środkach ochrony roślin (Dz.U. z 2013 r. poz. 455 z późn. zm.) oraz art. 104 ustawy z dnia 14 czerwca 1960 r. Kodeks postępowania administracyjnego (Dz.U. z 2013 r. poz. 267 z późn.zm.), po rozpatrzeniu wniosku z dnia 30 marca 2015 r., rozszerzam zakres upoważnienia do prowadzenia badań skuteczności działania środka ochrony roślin wydanego w drodze decyzji Nr 5/2013 z dnia 25 marca 2013 r., zmienionego decyzją Nr 2/2014 z dnia 7 marca 2014 r., w zakresie prowadzenia badań skuteczności działania środka ochrony roślin z użyciem akarycydów i nematocydów w uprawach warzyw w polu i pod osłonami.

Rozstrzygnięciu decyzji nadaje następujące brzmienie:

Upoważniam

SynTech Research Poland Sp. z o.o.

ul. Jagiellońska 69/1; 85-027 Bydgoszcz

do prowadzenia badań skuteczności działania środka ochrony roślin

z grupy akarycydów, fungicydów, herbicydów, insektycydów, nematocydów i regulatorów wzrostu w uprawach polowych (zboża, kukurydza, rzepak, burak cukrowy, ziemniak, warzywa kapustne, pomidor, ogórek, sałata, marchew, pietruszka, cebula, fasola, papryka, burak), w uprawach sadowniczych (jabłoni, wiśnia, czereśnia, śliwa, morela, brzoskwinia, grusza, malina, truskawka, porzeczka, winorośl, orzech), w uprawach chmielu, traw łąkowych i pastwiskowych oraz na terenach nieużytkowanych rolniczo.

Uzasadnienie

Pismem z dnia 30 marca 2015 r. Spółka z o.o. SynTech Research Poland zwróciła się z prośbą o rozszerzenie zakresu upoważnienia Nr 5/2013 wydanego przez Głównego Inspektora Ochrony Roślin i Nasiennictwa w dniu 25 marca 2013 r., zmienionego decyzją Nr 2/2014 z dnia 7 marca 2014 r., umożliwiającego Spółce prowadzenie badań skuteczności działania środka ochrony roślin. Wnioskowana zmiana dotyczy prowadzenia badań z użyciem środków ochrony roślin z grupy akarycydów i nematocydów oraz stosowania badanych środków w uprawach marchwi, pietruszki, cebuli, fasoli, papryki, buraka, truskawki, porzeczki, gruszy, orzecha, moreli, brzoskwini, winorośli i chmielu, traw łąkowych i pastwiskowych oraz na terenach nieużytkowanych rolniczo.

/TRANSLATION FROM THE POLISH LANGUAGE/

/state emblem of the Republic of Poland/

Tadeusz Kloz

Chief Inspector of the Plant and Seed Protection Service

WO-505-S/15

Warsaw, 27 April 2015

Decision No 6/2015

Acting pursuant to Article 17 section 2 and section 8 point 2 in conjunction with Article 79 section 3 of the Act of 8 March 2013 – on the plant protection products (Journal of Laws of 2013, item 455) in connection with Article 104 of the Act of 14 June 1960 Code of Administrative Procedures (Journal of Laws of 2013, item 267, as amended), after having examined the motion of 30 March 2015, I expand the scope of authorization to investigate the performance of the plant protection product released by the decision No 5/2013 of 25 March 2013 as amended by decision No 2/2014 of 7 March 2014, in terms of investigating the performance of plant protection products with use of acaricides and nematocides in field and protected conditions in vegetable cultivation.

The decision shall have the following wording:

I hereby authorize
SynTech Research Poland Sp. z o.o.
ul. Jagiellońska 69/1, 85-027 Bydgoszcz

to investigate the performance of the plant protection product

of the following groups: acaricides, fungicide, herbicide, insecticide, nematocides, growth regulators, on field crops (cereals, maize, oilseed rape, sugar beet, potato, cabbage, tomato, cucumber, lettuce, carrot, parsley, onion, bean, paprika, beetroot) and fruit plants (apples, cherries, plums, apricots, peaches, pears, raspberries, strawberries, currants, grapes and nuts), on hops, meadow and pasture grass and on fallow lands.

Grounds

On 30 March 2015 SynTech Research Poland Sp. z o.o. applied to for extending the scope of authorization No 5/2013 issued by Chief Inspector of the Plant and Seed Protection Service on 25 March 2013, as amended and complemented by decision No 2/2014 of 7 March 2014 allowing to investigate the performance of the plant protection product. The Company asked, inter alia, to be granted the right to investigate the performance of growth regulators and for increasing the range of crops, in which will be able to be performed the study, ie field crops (cereals, maize, oilseed rape, sugar beet, potato, cabbage, tomato, cucumber, lettuce, carrot, parsley, onion, bean, paprika, beetroot) and fruit plants (apples, cherries, plums, apricots, peaches, pears, raspberries, strawberries, currants, grapes and nuts), on hops, meadow and pasture grass and on fallow lands.

SynTech Research Poland Sp. z o.o. meets the requirements of good experimental practice within the meaning of Article 3 point 20 of Regulation No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection product on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p.1 as amendment).

Taking this into consideration, it has been decided as stated above

Information

No appeal may be brought against the decision. Nevertheless, a dissatisfied party may ask the Chief Inspector of the Plant and Seed Protection Service to review the case within 14 days from the day the decision is delivered, pursuant to Article 127 §3 of the Code of Administrative Proceedings.

Procedures relating to the issue of this decision shall be subject to a registration fee 1000 PLN, pursuant to Article 3 of the Act of 16 November 2006 on stamp duty (Journal of Laws of 2012, item 1282 as amended) Malgorzata Kukula - Chief Specialist of the Plant and Seed Protection Service

[Seal with the polish emblem in the middle and the following circumscription]: Chief Inspector of the Plant and Seed Protection Service

[rectangular stamp]: Chief Inspector Tadeusz Klos

[illegible signature]

Test facility	Address	Certificate (Yes or No)
ANADIAG POL- SKA	Ul. Sadowa 16/22, 95- 100 Zgierz, POLAND	YES

SWORN TRANSLATOR
MARTA TRAWCZYŃSKA
ul. Św. Wojciecha 3/3a lok. 1, 10-038 Olsztyn
T + 48 665 240 339, F + 48 89/ 512 00 99

CERTIFIED TRANSLATION FROM THE POLISH LANGUAGE

*[Any remarks in square brackets are the translator's. The translated document consists of two
(2) pages.]*

[national emblem of the Republic of Poland]
MAIN INSPECTOR
OF PLANT HEALTH AND SEED PROTECTION

Andrzej Chodkowski

Warsaw, dated 12 October 2018

BORIT.541.11.2018.1

DECISION No. 10/2018

Pursuant to Article 155 of the Act of 14 June 1960 Administrative Procedure Code (Dz.U. *[Polish Official Journal of Laws]* of 2017, item 1257 as amended), having examined the application filed by Anadiag SAS Branch Office in Poland dated 3 October 2018, I vary the decision No. 7/2007 dated 28 May 2007, varied by decisions No. 1/2010 dated 18 March 2010, No. 18/2011 dated 18 August 2011, No. 1/2012 dated 13 January 2012 and No. 3/2014 dated 16 April 2014 to grant authorization to conduct research of the efficiency of plant health products in such a manner that the decision shall read as follows:

"I authorize

Anadiag SAS Branch Office in Poland
ul. Sadowa 16/22, 95-100 Zgierz

to conduct research of the efficiency of plant health products from the group of acaricides, bacteriocides, fungicides, herbicides, insecticides, molluscicides, rodenticides, pheromones and growth regulators in outdoor crops, orchard crops, under covers, in edible mushrooms cultivations, in meadows and pastures. The research shall be conducted in cereal, root and oil crops, vegetables, orchard and ornamental plants, legumes, grass and special plants, in storage rooms and rooms for cultivation of edible mushrooms, in lawns and in non-agricultural lands."

No reasoning for this decision has been prepared as the decision grants the application of the Party in its entirety (Article 107(4) of the Administrative Procedure Code *[hereinafter referred to as "APC"]*).



Marta Trawczyńska

Instruction

This decision may not be appealed against. A Party unsatisfied with this decision may file an application to the Main Inspector of Plant Health and Seed Protection requesting a re-examination of the case, within 14 days of being served with this decision, pursuant to Article 127(3) APC.


Until the time-limit to apply for re-examination of the case has expired, a Party may waive this right towards the public administration authority which issued the decision. On the day when the Main Inspector of Plant Health and Seed Protection receives the waiver of the right to apply for re-examination of the case, the decision becomes final and non-appealable, which means that the decision shall be enforced immediately and it may not be appealed against to the Voivodeship Administration Court.

If a Party does not believe that the decision grants the Party's application but does not wish to exercise its right to apply for re-examination of the case, the Party may file to the Voivodeship Administration Court in Warsaw a complaint against the decision within 30 days of being served with the decision. The complaint shall be filed through the Main Inspector of Plant Health and Seed Protection.

Pursuant to section 2(1)(2) of the Regulation of the Council of Ministers of 16 December 2003 on the amount and detailed rules for collecting charges in proceedings before administrative courts (Dz.U. [Polish Official Journal of Laws] No. 221, item 2193 as amended) a fixed charge, which is independent of the subject-matter of the act appealed against or activities in cases regarding complaints against acts or public administration activities regarding rights or duties specified by the law, shall amount to PLN 200.

At the request of a Party made before court proceedings are instituted or in the course of such proceedings, the Party may be granted legal aid consisting of full or partial exemption from court costs and having an attorney-at-law or a legal advisor appointed for such Party, if the Party substantiates that they are unable to bear any costs of the proceedings or full costs thereof.

To be served upon:

1. 
Anadiag SAS Branch Office in Poland
ul. Sadowa 16/22
95-100 Zgierz
2. file

(round official seal with the national emblem of the Republic of Poland in its midst and the following circumscription: MAIN INSPECTOR OF PLANT HEALTH AND SEED PROTECTION)

(rectangular stamp reading: P.p. / MAIN INSPECTOR / Tadeusz Łęczyński; illegible signature)

I, duly commissioned sworn translator of the English language (TP/101/2013) in Olsztyn, hereby certify that the above translation is a true and complete version of the document in Polish presented to me.

Reg. No. 222/2018

Olsztyn, dated 29s October 2018



Marta Trawczyn

Test facility	Address	Certificate (Yes or No)
Agrolab Baltic	Bugenių km. LT-89452 Mažeikių raj. Lithuania	YES



Valsts augu aizsardzības dienests

SERTIFIKĀTS

Nr. 30

Izsniegts **SIA „AgroLab Baltic”**
(komersanta nosaukums, reģistrācijas numurs, juridiskā adrese)

Reģ. Nr. 44103075387

Elizabetes iela 45/47, Rīga, LV-1010

par tiesībām veikt normatīvajos aktos par augu aizsardzības līdzekļu reģistrāciju noteiktos
efektivitātes pārbaudes izmēģinājumus:

Lauks- graudaugi-fungicīdi, insekticīdi, kodnes, lauks- rapsis- insekticīdi, lauks- dārzeni- insekticīdi,
lauks- graudaugi-limacīdi, lauks- rapsis- limacīdi.

Sertifikāts izsniegts: 08.01.2019.
(datums)

Sertifikāts derīgs līdz: 07.01.2024.
(datums)

Valsts augu aizsardzības dienests
Augu aizsardzības līdzekļu
reģistrācijas daļas vadītāja
(amats, paraksts un tā atšifrējums)



Z.V.



R.Čūdere

South-Eastern EPPO zone

Test facility	Address	Certificate (Yes or No)
Syntech Research Hungary	Török Ignác u. 30 Szombathely 9700 HUNGARY	YES
SynTech Research Hungary Kft.	Török Ignác u. 30. 9700 Szombathely, HUNGARY	YES
SAGEA OOD	Boulevard Bulgaria, 6 4000 Plovdiv BULGARIA	YES
ANADIAG ROMANIA SRL	Piata Montreal no. 10, World Trade Centre, Entrance F, 1st Floor 011469, Bucharest, ROMANIA	YES

Test facility	Address	Certificate (Yes or No)
Syntech Research Hungary	Török Ignác u. 30 Szombathely 9700 Hungary	YES

ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

Odbor přípravků na ochranu rostlin

Zemědělská 1a, Brno, PSČ 613 00

Příloha rozhodnutí č.j.: UKZUZ 033034/2017 ze dne 12. 4. 2017

OSVĚDČENÍ

GEP/SYT/2017

o způsobilosti k provádění zkoušek
v souladu se zásadami správné pokusnické praxe

Official Recognition Certificate / GEP - Certificate

právnícká osoba: **SynTech Research Czech s.r.o.**

sidlo právnické osoby: Žitná 562/10, Nové Město (Praha 2), 120 00 Praha

IČ právnické osoby: 04601351

Je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe podle § 45 odst. 1 zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, v platném znění, v návaznosti na Směrnici 91/414/EHS.

oblasti zkoušení / categories of official recognition:

- polní plodiny a zelenina / *field crops and vegetables*
- moření osiva / *seed treatment*
- laboratorní testy a analýzy / *laboratory tests and analyses*

Ústřední kontrolní a zkušební ústav zemědělský
Seznam zemědělských vstupů
Odbor přípravků na ochranu rostlin
613 00 Brno, Zemědělská 1a

-1-

Ing. Pavel Minář, Ph.D.
ředitel odboru

Test facility	Address	Certificate (Yes or No)
SynTech Research Hungary Kft.	Török Ignác u. 30. 9700 Szombathely HUNGARY	YES



n é b i h
Termőföldtől az asztalig

National Food Chain Safety Office
Directorate of Plant Protection, Soil Conservation
and Agri-environment



H-1118 Budapest, Budaörsi út 141-145.
Hungary
Tel: 36/1/309-1000 Fax: 36/1/246-2942
E-mail: nti@nebih.gov.hu
www.nebih.gov.hu

Your ref.: -

Our ref.: 04,2/4838-7/2016

15 August 2016

Subject: Certificate of Official Recognition of Efficacy Testing Facilities or Organisations in Hungary

Having received the application submitted by the **SynTech Research Hungary Kft. (H-9700 Szombathely, Török Ignác u. 30, Hungary)**, the client, for completing a certification procedure of first instance concerning the Official Recognition of Efficacy Testing Facilities/Organisations, i.e. Good Experimental Practices (*hereinafter: GEP*). I, acting as the food chain control body, has made the following

DECISION:

I issue the client's GEP certificate for its premises at Szombathely, Török Ignác u. 30 for carrying out efficacy trials for authorisation purposes. The GEP certificate is effective for 5 years from the entry into force of this Decision.

The client's GEP certificate is given for the following categories of products and cultivation:

- **product categories:** herbicides, fungicides and bactericides, zoocides, growth regulators and yield enhancing substances, additives;
- **cultivation categories:** field crops, vegetables, fruits, grapevines, ornamentals, forest, others.

I inform you that the present certification is without prejudice to either the licences concerning the operation/follow-up of activity laid down in other provisions of legislation or the client's obligation for obtaining them.

The client is obliged to notify the competent authority, within 15 days, of any important changes concerning the certified activity of the testing facility.

I call your attention that respect of the provisions laid down in the legislation on GEP certification and in this Decision shall be randomly controlled by my competent authority. If during the official inspection it is stated that the testing facility does not meet the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate.

If during the official inspection it is found that some details are missing in relation to a particular trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization.

The fee of the present procedure is 250.000 HUF (i.e. two hundred and fifty thousand Hungarian Forints) paid by the client.

No further complaint shall be lodged against the present Decision, effective by its publication, through state administration, though with reference to infringement of law, judicial review of the Decision may be requested at the Capital Administrative and Employment Court. The claim note shall be submitted to my competent authority within 30 days of the communication of the Decision.

I inform you that the court shall judge the case out of court, but shall carry on a lawsuit at the request of any of the parties. The client may ask for carrying on a lawsuit, but in default of so doing, no verification is accepted. Submission of the claim note has no delaying force on the implementation of this Decision.

J U S T I F I C A T I O N

In its application of 7 July 2016, the client submitted an application to the competent authority for a procedure of GEP certification.

As a follow-up to this application, the competent authority made a local inspection at the client's facility of Szombathely, Török Ignác u. 30 on 12 July 2016. Statements made during the local inspection are reported in the protocol Nr. 04.2/4838-4/2016. Based on the results of the local inspection the competent authority concluded that the client's testing facility does not meet the requirements concerning the efficacy trials specified in Article 22 of the Decree 89/2004 (V. 15.) FVM on the authorization of placing on the market and use, as well as on the packaging, labelling, storage and transport of plant protection products (hereinafter: Decree 89/2004) and in the Decision Nr. 04.2/4838-5/2016 it calls the client to fill the data gaps.

Article 22(3) of Decree 89/23004 - Based on request, the competent authority shall make local inspections at the testing facility and decide on the GEP qualification of the testing facility. The decision shall include the product categories and the cultivation categories for which the testing facility obtained the GEP-certificate.

(6) The validity of GEP-certification is 2 years in case of the first request and maximum 5 years in case of renewal of the certification.

(7) A fee laid down in specific legislation shall be paid for the GEP-certification procedure.

(8) The testing facility having GEP-certification shall notify the competent authority, within 15 days, about any important changes concerning the certified activity of the testing facility.

(9) The competent authority shall randomly control the testing facility having GEP-certification. If it is found that the testing facility does not meet the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate. If during the official inspection it is established that some details are missing in relation to a trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization."

Client filled the missing data gaps and reported on it in the letter of 12 August 2016, therefore I made the Decision as specified in the first part. Therefore I stated that conditions for issuing the certificate specified above are met, so I made the Decision as specified in the first part.

The fee of the present procedure is HUF 250.000 and was established in accordance with point 8.19.2 of Annex 1 to the Decree 63/2012. (VII. 2.) VM on the extent of administrative servicing fees due for the procedures by the agricultural administrative bodies of the National Food Chain Safety Office and the county government offices and on the rules of paying the administrative servicing fees. The client paid the fee.

I made this Decision within my jurisdiction laid down in Article 3 paragraph (1) and Article 5 point c) of Government Decree 22/2012. (II. 29.) concerning the National Food Chain Safety Office, Article 3, Article 22 paragraph (1) of Decree 89/2004 and in compliance with Articles 71 paragraph (1) and Article 72 paragraph (1) of Act CXL of 2004 on general rules of administrative official procedure and service (hereinafter: Act CXL of 2004).

I excluded the possibility of appeal in compliance with Article 100 paragraph (1) point e) of Act CXL of 2004 and provided the possibility of judicial review in compliance with Article 109 paragraph (1) of Act CXL of 2004 and Article 330 paragraph (2) of Act III of 1952 on Civil Procedure.

on behalf of
dr. Márton Oravecz
president



László Jordán 55.
director

Test facility	Address	Certificate (Yes or No)
SAGEA OOD	Boulevard Bulgaria, 6 4000 Plovdiv BULGARIA	YES

 РЕПУБЛИКА БЪЛГАРИЯ
Министерство на земеделието, храните и горите
Българска агенция по безопасност на храните

СЕРТИФИКАТ
№006
София, 26.10.17 г.

На основание чл. 75 от Закона за защита на растенията и чл. 23 от Наредба № 19 от 8 ноември 2016 г. за биологично изпитване на продукти за растителна защита (обн., ДВ, бр.90 от 15.11.2016 г.) и Заповед № РД 11-1909 от 20.09.2017 г. на изпълнителния директор на Българската агенция по безопасност на храните

ИЗДАВАМ:

настоящия сертификат, в уверение на това, че база „Саджеа“ ООД със седалище и адрес на управление: с.Стъргел 2135, общ. Горна Малина, обл. София, къща 22, с места за изпитване: гр. Пловдив 4000, бул. „България“ № 6, бл. 18, етаж партерен и гр. Варна 9000, район „Приморски“, ул. „10-та“ № 4 олобрена за извършване на биологично изпитване на продукти за растителна защита на територията на Република България за следните групи култури:

1. Полски култури
2. Трайни насаждение
3. Зеленчукови култури
4. Оранжеви култури

Сертификатът удостоверява осигурено качество при провеждане на опити за ефикасност на продукти за растителна защита, съответстващо на Добрата експериментална практика и стандартите за изпитване за ефикасност на ПРЗ, определени от Европейската и средиземноморската организация по растителна защита (EPPO).

Сертификатът е валиден до 20.09.2027 г.


Д-Р ДАМЯН ИЛИЕВ
Изпълнителен директор на
Българската агенция по безопасност на храните

Test facility	Address	Certificate (Yes or No)
ANADIAG RO-MANIA SRL	Piata Montreal no. 10, World Trade Centre, Entrance F, 1st Floor 011469, Bucharest, ROMANIA	YES

MINISTERUL AGRICULTURII ȘI DEZVOLTĂRII RURALE	MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT
Autoritatea Națională Fitosanitară	National Phytosanitary Authority
Comisia Națională de Omologare a Produselor de Protecție a Plantelor	National Commission for Registration of Plant Protection Products

Certificat de recunoaștere oficială a testelor de eficacitate biologică în conformitate cu bunele practici experimentale/Certificate of official recognition of the efficacy biological tests according to the good experimental practices

Se acordă: SC ANADIAG ROMANIA SRL
It is granted to: SC ANADIAG ROMANIA SRL
cu sediul: Str. Gen. C. Budisteanu, nr.28-C;010775, Bucuresti
with headquarter: Gen. C. Budisteanu Street, no. 28-C, 010775, Bucharest
pentru domeniul/
domeniile de activitate: Culturi agricole de câmp si pajisti; Pomicultură; Viticultură; Legumicultură; Floricultură; Silvicultură; Plante ornamentale și de interior; Zone non agricole
for the domain/
domains of activity: Crops fields and meadows; Fruit tree growing; Viticulture; Vegetable crops; Floriculture; Aromatic and medicinal plants; Ornamental and indoor plants; Silviculture; Non agricultural zones

Prezentul certificat se eliberează în conformitate cu prevederile Ordinului ministrului agriculturii și dezvoltării rurale, al ministrului sănătății și al ministrului mediului și schimbărilor climatice nr.60/512/1258/2013 și prevederile Procedurii naționale de omologare a produselor de protecție a plantelor care conțin substanțe active notificate și pentru care nu s-a luat încă o decizie de includere în lista cu substanțe active autorizate în Uniunea Europeană, aprobată prin Ordinul ministrului agriculturii,

pădurilor și dezvoltării rurale, al ministrului sănătății și al ministrului mediului și gospodăririi apelor nr. 134/197/412/2006, cu modificările și completările ulterioare.

This certificate is issued according to the provisions of the Order of the ministry of agriculture and rural development, of the ministry of health and of the ministry of environment and climate change no. 60/512/1258/2013 and the provisions of the National Procedure for Registration of Plant Protection Products which contain notified active substances and for which isn't taken yet a decision for inclusion in European Union list of authorised active substances, approved by the Order of the ministry of agriculture, forests and rural development, of the ministry of health and of the ministry of environment and waters husbandry no. 134/197/412/2006, with subsequent amendments and completions.

Data emiterii certificatului: 20.08.2015

Issuance date of the certificate

Data expirării certificatului: 20.08.2020

Expiry date of the certificate

PREȘEDINTE/CHAIRMAN,

Elena LEAOTA



3.7.4 Winter wheat (TRZAW)

Table 3.7-4: List of test facilities - TRZAW

Maritime EPPO zone

Test facility	Address	Certificate (Yes or No)
Staphyt	Menin 569 664 57 Menin CZECH REPUBLIC	YES
Staphyt (ATC Agro Trial Center GmbH)	Blatnicka 179 68724 Uhersky Ostroh CZECH REPUBLIC	YES
InTec AGRO TRIALS, s.r.o	Blatnicka 179 Uhersky Ostroh 687 24 CZECH REPUBLIC	YES
Agrolab	Rojleskovvej 18 DK-5500 Middelfart DENMARK	YES
SynTech Research Czech s.r.o	Zitna 562/10, Nové Mesto (Praha 2), 12000 Praha CZECH REPUBLIC	YES
ANADIAG Deutschland	Lebacherstrasse 4 D-66113 Saarbrücken GERMANY	YES
Quintus GmbH	LIEPEN 7 17194 Hohen Wangelin OT Liepen GERMANY	YES
Oxford Agricultural Trials Limited	West Farm Barns, Launton Road – Stratton Audley – Bicester OXON OX279AS UNITED KINGDOM	YES
ANADIAG France	13, rue de la Bourbre 38300 Ruy FRANCE	YES (2017)
ANADIAG SA	Chelny 46 517 54 Chleny CZECH REPUBLIC	YES
SynTech Research Germany	Industriestrasse 3, Preetz 24211 Schleswig-Holstein GERMANY	YES
SynTech Research France	613 route du Bois de Loyse 71570 La Chapelle de Guinchay FRANCE	YES (2018)
ANADIAG SAS	174, impasse du Plan d'eau 380300 Ruy-Montceau FRANCE	YES (2020)
SynTech Research Germany	Loofter Str. 9, 25593 Christinenthal GERMANY	YES
SynTech Research UK	2 Old Hall Farm Barns Thurston Road, Pakenham Bury St Edmunds Suffolk IP31 2NG UNITED KINGDOM	YES

Test facility	Address	Certificate (Yes or No)
Staphyt	Menín 569 664 57 Menín CZECH REPUBLIC	YES



ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

STAPHYT s.r.o.
Měnín 569
664 57 Měnín

Útvar: Odbor přípravků na ochranu rostlin
Adresa: Zemědělská 1a, 613 00 Brno

Sp.zn: SZ UKZUZ 032225/2016/06857 Č.j.: UKZUZ 057138/2016 Datum: 18. 5. 2016
Vyřizuje: ing. Míňářová Tel.: 545 110 444 E-mail: ivana.minarova@ukzuz.cz

ROZHODNUTÍ

Ústřední kontrolní a zkušební ústav zemědělský (dále jen „ÚKZÚZ“), Hroznová 2, 656 06 Brno, jako věcně příslušný správní orgán podle § 72 odst. 1 písm. c) zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, ve znění pozdějších předpisů (dále jen „zákon“) a v návaznosti na čl. 54 odst. 4 Nařízení Evropského parlamentu a Rady (ES) č. 1107/2009, o uvádění přípravků na ochranu rostlin na trh a o zrušení směrnic Rady 79/117/EHS a 91/414/EHS, v platném znění, v provedení § 45 odst. 1 zákona, v řízení o způsobilosti k provádění pokusů a zkoušek s přípravky nebo dalšími prostředky na základě žádosti společnosti **STAPHYT s.r.o.**, Měnín 569, 664 57 Měnín, IČ 29210917 dále jen „společnost STAPHYT s.r.o.“ a to:

žádosti o prodloužení platnosti rozhodnutí o způsobilosti k provádění zkoušek podle § 45 odst. 1 zákona ze dne 24. 3. 2016, doručené ÚKZÚZ dne 24. 3. 2016, č.j. UKZUZ 032225/2016

rozhodl takto:

společnost STAPHYT s.r.o. je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe.

právnícká osoba: **STAPHYT s.r.o.**

sídlo právnické osoby: Měnín 569, 664 57 Měnín

IČ právnické osoby: 29210917

GEP kód: **GEP/SHT/2016**

oblasti zkoušení: **polní plodiny a zelenina**
trvalé kultury
skleníky a jiné kryté prostory
moření osiva

rozhodnutí se vydává s účinností od 1. 9. 2016

doba účinnosti rozhodnutí: 5 let

Tímto rozhodnutím se k datu nabytí jeho účinnosti zrušuje rozhodnutí č.j. SRS 026758/2010 ze dne 2. 7. 2010.

Odůvodnění:

Řízení ve věci uznání osoby za způsobilou provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe bylo zahájeno na základě žádosti ze dne 24. 3. 2016, doručené ÚKZÚZ dne 24. 3. 2016.

Rozhodnutí o způsobilosti k provádění pokusů a zkoušek v souladu s požadavky správné pokusnické praxe bylo vydáno na základě kontroly předložené dokumentace pracoviště STAPHYT s.r.o., Příručky jakosti, Standardních operačních postupů a Metrologického řádu, kterou bylo ÚKZÚZ prokázáno, že žadatel splnil požadavky stanovené v § 45 odst. 12 a 13 zákona v návaznosti na § 4 odst. 2 vyhlášky č. 32/2012 Sb., o přípravcích a dalších prostředcích na ochranu rostlin, ve znění pozdějších předpisů.

Vzhledem k výše uvedeným skutečnostem bylo rozhodnuto tak, jak je stanoveno ve výrokové části tohoto rozhodnutí.

Správní poplatek podle zákona č. 634/2004 Sb., o správních poplatcích, ve znění pozdějších předpisů, podle Sazebníku, Položky 86 písm. b) „Přijetí žádosti o vydání osvědčení o způsobilosti k provádění zkoušek pro účely povolení“ ve výši 100,- Kč, k žádosti doručené ÚKZÚZ dne 24. 3. 2016, č.j. UKZUZ 032225/2016, byl uhrazen dne 24. 3. 2016 formou kolkové známky.

Poučení:

Proti tomuto rozhodnutí lze podat odvolání do 15 dnů ode dne jeho doručení, nejpozději však do 15 dnů po uplynutí desátého dne ode dne, kdy bylo nedoručené a uložené rozhodnutí připraveno k vyzvednutí, a to k Ministerstvu zemědělství České republiky, odbor rostlinných komodit, prostřednictvím Ústředního kontrolního a zkušebního ústavu zemědělského, sekce zemědělských vstupů, odboru přípravků na ochranu rostlin, Zemědělská 1a, 613 00 Brno.

Otisk úředního razítka

Ing. Pavel Minář, Ph.D.
ředitel odboru

Test facility	Address	Certificate (Yes or No)
Staphyt (ATC Agro Trial Center GmbH)	Blatnická 179 68724 Uherský Os- troh CZECH REPUBLIC	YES



ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

ATC Agro Trial Center GmbH, organizační
složka
Blatnická 179
68724 Uherský Ostroh

Útvar: Odbor přípravků na ochranu rostlin
Adresa: Zemědělská 1a, 613 00 Brno

Sp.zn: SZ UKZUZ 055894/2016/15869 Č.j.: UKZUZ 073735/2016 Datum: 1. 7. 2016
Vyřizuje: mg. Mlnářová Tel.: 545 110 444 E-mail: tvana.minarova@ukzuz.cz

ROZHODNUTÍ

Ústřední kontrolní a zkušební ústav zemědělský (dále jen „ÚKZÚZ“), Hroznová 2, 656 06 Brno, jako věcně příslušný správní orgán podle § 72 odst. 1 písm. c) zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, ve znění pozdějších předpisů (dále jen „zákon“) a v návaznosti na čl. 54 odst. 4 Nařízení Evropského parlamentu a Rady (ES) č. 1107/2009, o uvádění přípravků na ochranu rostlin na trh a o zrušení směrnic Rady 79/117/EHS a 91/414/EHS, v platném znění, v provedení § 45 odst. 1 zákona, v řízení o způsobilosti k provádění pokusů a zkoušek s přípravky nebo dalšími prostředky na základě žádosti společnosti **ATC Agro Trial Center GmbH, organizační složka**, Blatnická 179, 68724 Uherský Ostroh, IČ 29220351 dále jen „společnost ATC Agro Trial Center GmbH, organizační složka“ a to:

žádosti o prodloužení platnosti rozhodnutí o způsobilosti k provádění zkoušek podle § 45 odst. 1 zákona ze dne 13. 5. 2016, doručené ÚKZÚZ dne 16. 5. 2016, č.j. UKZUZ 055894/2016

rozhodl takto:

ATC Agro Trial Center GmbH, organizační složka, je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe.

právnícká osoba: **ATC Agro Trial Center GmbH, organizační složka**

sídlo právnické osoby: Blatnická 179, 68724 Uherský Ostroh

IČ právnické osoby: 29220351

GEP kód: **GEP/ATC/2016**

oblasti zkoušení: **polní plodiny a zelenina**
trvalé kultury
skleníky a jiné kryté prostory

rozhodnutí se vydává s účinností od 1. 9. 2016

dobu účinnosti rozhodnutí: 5 let

Tímto rozhodnutím se k datu nabytí jeho účinnosti zrušuje rozhodnutí č.j. SRS 018365/2011 ze dne 21. 2. 2011.

Odůvodnění:

Řízení ve věci uznání osoby za způsobilou provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe bylo zahájeno na základě žádosti ze dne 13. 5. 2016, doručené UKZÚZ dne 16. 5. 2016.

Rozhodnutí o způsobilosti k provádění pokusů a zkoušek v souladu s požadavky správné pokusnické praxe bylo vydáno na základě kontroly předložené dokumentace pracoviště ATC Agro Trial Center GmbH, organizační složka, Příručky jakosti, Standardních operačních postupů a Metrologického řádu, kterou bylo UKZÚZ prokázáno, že žadatel splnil požadavky stanovené v § 45 odst. 12 a 13 zákona v návaznosti na § 4 odst. 2 vyhlášky č. 32/2012 Sb., o přípravcích a dalších prostředcích na ochranu rostlin, ve znění pozdějších předpisů.

Vzhledem k výše uvedeným skutečnostem bylo rozhodnuto tak, jak je stanoveno ve výrokové části tohoto rozhodnutí.

Správní poplatek podle zákona č. 634/2004 Sb., o správních poplatcích, ve znění pozdějších předpisů, podle Sazebníku, Položky 86 písm. b) „Přijetí žádosti o vydání osvědčení o způsobilosti k provádění zkoušek pro účely povolení“ ve výši 100,- Kč, k žádosti doručené UKZÚZ dne 16. 5. 2016, č.j. UKZUZ 055894/2016, byl uhrazen dne 16. 5. 2016 formou kolkové známky.

Poučení:

Proti tomuto rozhodnutí lze podat odvolání do 15 dnů ode dne jeho doručení, nejpozději však do 15 dnů po uplynutí desátého dne ode dne, kdy bylo nedoručené a uložené rozhodnutí připraveno k vyzvednutí, a to k Ministerstvu zemědělství České republiky, odbor rostlinných komodit, prostřednictvím Ústředního kontrolního a zkušebního ústavu zemědělského, sekce zemědělských vstupů, odboru přípravků na ochranu rostlin, Zemědělská 1a, 613 00 Brno.

Otisk úředního razítka

Ing. Pavel Minář, Ph.D.
ředitel odboru

Test facility	Address	Certificate (Yes or No)
InTec AGRO TRIALS, s.r.o.	Blatnická 179 Uherský Ostroh 687 24 CZECH REPUBLIC	YES



ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

Hroznová 2
656 06 Brno

www.ukzuz.cz
ID DS: ughaiq7

IČO: 00020338
DIČ: CZ00020338

InTec Agro Trials, spol. s r.o.
Blatnická 179
687 24 Uherský Ostroh
IČO: 06774512

Útvar: OPOR
Vytizuje: Ing. Ivana Minářová
E-mail: ivana.minarova@ukzuz.cz
Telefon: +420 545 110 444
Adresa: Zemědělská 1a, 613 00 Brno

Spisová zn.: SZ UKZUZ 010368/2018/01399
Č. j.: UKZUZ 013294/2018

Datum: 7. 2. 2018

ROZHODNUTÍ

Ústřední kontrolní a zkušební ústav zemědělský (dále jen „ÚKZÚZ“), Hroznová 2, 656 06 Brno, jako věcně příslušný správní orgán podle § 72 odst. 1 písm. c) a v návaznosti na čl. 54 odst. 4 Nařízení Evropského parlamentu a Rady (ES) č. 1107/2009, o uvádění přípravků na ochranu rostlin na trh a o zrušení směrnic Rady 79/117/EHS a 91/414/EHS, v platném znění, v provedení § 45 odst. 1 zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, ve znění pozdějších předpisů (dále jen „zákon“), v řízení o způsobilosti k provádění pokusů a zkoušek s přípravky nebo dalšími prostředky na základě žádosti společnosti **InTec Agro Trials, s.r.o.**, a to:

žádosti o uznání osoby za způsobilou k provedení zkoušek podle § 45 odst. 1 zákona ze dne 24. 1. 2018, doručené ÚKZÚZ dne 26. 1. 2018, č.j. UKZUZ 010368/2018

rozhodl takto:

Společnost InTec Agro Trials, s.r.o. je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe.

právnícká osoba: **InTec Agro Trials, s.r.o.**

sídlo právnické osoby: Blatnická 179, Ostrožské Předměstí, 687 24 Uherský Ostroh

IČ právnické osoby: 06774512

GEP kód: GEP/ITU/2018

oblasti zkoušení: **polní plodiny a zelenina**
trvalé kultury
skleníky a jiné kryté prostory

dobu platnosti rozhodnutí: 5 let ode dne nabytí účinnosti tohoto rozhodnutí

Odůvodnění:

Řízení ve věci uznání osoby za způsobilou provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe bylo zahájeno na základě žádosti ze dne 24. 1. 2018, doručené ÚKZÚZ dne 26. 1. 2018.

Do firmy InTec Agro Trials, s.r.o. přechází původní personální obsazení a zařízení firmy ATC – Agro Trial Center GmbH, organizační složky, původního držitele povolení č.j. UKZUZ 073735/2016 ze dne 1. 7. 2016. Nedošlo ke změnám v oblasti personálního obsazení, v prostorách, v nichž je činnost realizována, na pozemcích, na nichž je činnost prováděna a změnám v základní dokumentaci.

Rozhodnutí o způsobilosti k provádění pokusů a zkoušek v souladu s požadavky správné pokusnické praxe bylo vydáno na základě předložené dokumentace, Příručky jakosti, Standardních operačních postupů a Metrologického řádu, kterou bylo ÚKZÚZ prokázáno, že žadatel splnil požadavky stanovené v § 45 odst. 12 a 13 zákona v návaznosti na § 4 odst. 2 vyhlášky č. 32/2012 Sb., o přípravcích a dalších prostředcích na ochranu rostlin, ve znění pozdějších předpisů.

Vzhledem k výše uvedeným skutečnostem bylo rozhodnuto tak, jak je stanoveno ve výrokové části tohoto rozhodnutí.

Správní poplatek podle zákona č. 634/2004 Sb., o správních poplatcích, ve znění pozdějších předpisů, podle Sazebníku, Položky 86 písm. b) „Přijetí žádosti o vydání osvědčení o způsobilosti k provádění zkoušek pro účely povolení“ ve výši 100,- Kč, k žádosti doručené ÚKZÚZ dne 26. 1. 2018, č.j. UKZUZ 010368/2018, byl uhrazen dne 26. 1. 2018 formou kolkové známky.

Poučení o odvolání:

Proti tomuto rozhodnutí lze podat odvolání do 15 dnů ode dne jeho doručení, nejpozději však do 15 dnů po uplynutí desátého dne ode dne, kdy bylo nedoručené a uložené rozhodnutí připraveno k vyzvednutí, a to k Ministerstvu zemědělství České republiky, odbor rostlinných komodit, prostřednictvím Ústředního kontrolního a zkušebního ústavu zemědělského, sekce zemědělských vstupů, odboru přípravků na ochranu rostlin, Zemědělská 1a, 613 00 Brno.

Ing. Pavel Minář, Ph.D.
ředitel OPOR

Test facility	Address	Certificate (Yes or No)
Agrolab	Røjleskovvej 18 DK-5500 Middelfart DENMARK	YES



Certifikat

for **GEP-anerkendelse** tildeles herved

Forsøgsenheden: Agrolab A/S
Røjleskovvej 18
DK-5500 Middelfart

Anerkendelsen gælder udførelsen af GEP-effektivitetsforsøg for bekæmpelsesmidler inden for

Forsøgsområderne: Markforsøg



GEP Anerkendelses Enheden ved Nationalt Center for Fødevarer og Jordbrug, Aarhus Universitet, kontrollerer organisation, personale, lokaler, forsøgsarealer, forsøgsudstyr samt standardforskrifter og forsøgsrapporter. Forsøgsenheden er underkastet løbende kontrol og inspektion.

Certifikatet for anerkendelse er gyldigt for en periode på 6 år.

Anerkendelsesdato: 1. januar 2014

Underskrevet: 16. december 2013


Nina Sørup Hansen
Miljøstyrelsen


Ulla Fosgerau Salomonsen
Aarhus Universitet


Peter Kryger Jensen
Aarhus Universitet

Forordning 1107/2009 om plantebeskyttelsesmidler og Miljøministeriets bekendtgørelse nr.1088 af 6. september 2013 anfører, at undersøgelser af plantebeskyttelsesmidlers effektivitet, der er udført i Danmark med henblik på godkendelse, skal være foretaget af forsøgsenheder, der er anerkendt hertil af Nationalt Center for Fødevarer og Jordbrug, Aarhus Universitet.

Test facility	Address	Certificate (Yes or No)
SynTech Re- search Czech s.r.o	Zitna 562/10, Nové Mesto (Praha 2), 12000 Praha CZECH REPUBLIC	YES

ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

Odbor přípravků na ochranu rostlin

Zemědělská 1a, Brno, PSČ 613 00

Příloha rozhodnutí č.j.: UKZUZ 033034/2017 ze dne 12. 4. 2017

OSVĚDČENÍ

GEP/SYT/2017

**o způsobilosti k provádění zkoušek
v souladu se zásadami správné pokusnické praxe**

Official Recognition Certificate / GEP - Certificate

právnícká osoba: **SynTech Research Czech s.r.o.**

sídlo právnické osoby: Žitná 562/10, Nové Město (Praha 2), 120 00 Praha

IČ právnické osoby: 04601351

Je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe podle § 45 odst. 1 zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, v platném znění, v návaznosti na Směrnici 91/414/EHS.

oblasti zkoušení / categories of official recognition:

- polní plodiny a zelenina / *field crops and vegetables*
- moření osiva / *seed treatment*
- laboratorní testy a analýzy / *laboratory tests and analyses*

Ústřední kontrolní a zkušební ústav zemědělský
Sešce zemědělských vstupů
Odbor přípravků na ochranu rostlin
613 00 Brno, Zemědělská 1a

-1-

Ing. Pavel Minář, Ph.D.
ředitel odboru

Test facility	Address	Certificate (Yes or No)
ANADIAG Deutschland	Lebacherstrasse 4 D-66113 Saarbrücken GERMANY	YES

* Ministerium für
Umwelt und
Verbraucherschutz

SAARLAND



GEP-Anerkennungs-Zertifikat / Recognition Certificate



Anerkennungsbescheinigung

Recognition Certificate

Die Versuchseinrichtung

**Anadiag Deutschland GmbH
Versuchsstation Bondorf
Haitinger Höfe 4
D-71149 Bondorf**

The testing facility

mit Hauptsitz in

**Lebacherstraße 4
D-66113 Saarbrücken**

with headquarters in

und organisatorisch
zugehörigen Arbeitseinheiten
in

./.

and subsidiary testing
units in

ist auf Antrag vom und nach
durchgeführter Besichtigung

30.06.2017

on application from and
after inspection

durch

**Dr. Friedrich Merz und
Frank Mohr**

by

vom

**Regierungspräsidium Stuttgart
und Ministerium für Umwelt und
Verbraucherschutz Saarland**

dated

am

22.09.2017

on

in den Versuchskategorien

**Ackerbau, Gemüsebau, Weinbau,
Obstbau und Sonstige
(Nichtkulturland: Rasen,
Gleisanlagen, Wege und Plätze)**

in the trial categories

bis zum

21.09.2022

until

als Einrichtung für die Prüfung der
Wirksamkeit von Pflanzenschutzmitteln
im Sinne des § 8 Abs. 6 der
Pflanzenschutzmittelverordnung
und gemäß Verordnung (EU) Nr. 284/2013
für 5 Jahre amtlich anerkannt worden.

has been officially recognised
as an organisation for efficacy
testing facility of plant protection
products according to § 8 par. 6
of the Plant Protection Products
Ordinance and the Commission
Regulation (EU) No 284/2013
for 5 years.

18.12.2017

Datum
date

Frank Mely

Unterschrift
sign

Ministerium für Umwelt und Verbraucherschutz
Referat B/2
Keplerstraße 18
D-66 117 Saarbrücken

Adresse der anerkennenden Behörde
address of the recognising authority



Stempel
stamp

Test facility	Address	Certificate (Yes or No)
Quintus GmbH	LIEPEN 7 17194 Hohen Wangelin OT Liepen GERMANY	YES

Anerkennungsbescheinigung

Die Versuchseinrichtung

Quintus GmbH

mit Hauptsitz in

Liepen 7
17194 Hohen Wangelin

und organisatorisch
zugehörigen
Arbeitseinheiten in

08393 Schönberg
Breitenbacher Straße 21

74595 Langenburg-
Nesselbach
Orlacher Straße 16

27798 Hude
Wieselweg 6

ist auf Antrag vom

2016-02-01

und nach durchgeführter
Besichtigung
durch
vom

Herrn Dr. S. Goltermann
Landesamt für Landwirtschaft,
Lebensmittelsicherheit und
Verbraucherschutz MV
2016-04-11

am

in den Versuchskategorien

Acker-, Obst-, Gemüse-, Zier-
pflanzenbau, Haus- und
Kleingarten

agriculture, horticulture, home
and garden

als Einrichtung für die Prüfung
der Wirksamkeit von
Pflanzenschutzmitteln im
Sinne des § 8 Abs. 6 der
Pflanzenschutzmittelverordnu
ng und und gemäß
Verordnung (EU) Nr. 284/2013
für 5 Jahre amtlich anerkannt
worden.

Recognition Certificate

The testing facility

with headquarter in

and subsidiary testing
units in

on application from

and after inspection

by
from

on

in the trial categories

has been officially
recognised as an
organisation for efficacy
testing facility of plant
protection products
according to § 8 par. 6 of
the Plant Protection
Products Ordinance and
the Commission
Regulation (EU) No
284/2013 for 5 years.

11.04.2016

Datum
date

Unterschrift
signature

Landesamt für Landwirtschaft,
Lebensmittelsicherheit und
Verbraucherschutz MV,
Thierfelderstr. 18, 18059 Rostock
Adresse der anerkennenden Behörde
address of the recognising authority



Test facility	Address	Certificate (Yes or No)
Oxford Agricultural Trials Limited	West Farm Barns, Launton Road – Stratton Audley – Bicester OXON OX279AS UNITED KING- DOM	YES



Certificate of

Official Recognition of Efficacy Testing Facilities or Organisations in the United Kingdom

This certifies that

Oxford Agricultural Trials Limited

**complies with the minimum standards laid down in
Regulation (EC) 1107/2009 for efficacy testing.**

**The above Facility/Organisation has been officially
recognised as being competent to carry out efficacy trials/tests
in the United Kingdom in the following categories:**

**Agriculture/Horticulture
Biologicals and Semiochemicals
Stored Crops**

Date of issue: 9 January 2018
Effective date: 1 January 2018
Expiry date: 31 December 2022

Signature


Authorised signatory

Certification Number

ORETO 385



Chemicals Regulation Division



Department of
**Agriculture and
Rural Development**

Test facility	Address	Certificate (Yes or No)
ANADIAG France	13, rue de la Bourbre 38300 Ruy FRANCE	YES



MINISTÈRE DE L'AGRICULTURE ET DE L'ALIMENTATION

**DÉCISION D'AGRÈMENT POUR RÉALISER
DES ESSAIS OFFICIELLEMENT RECONNUS**

Conformément à l'article R. 253-38 du code rural et de la pêche maritime et à l'article 6 de l'arrêté du 26 avril 2007 relatif aux essais officiels et officiellement reconnus pour l'évaluation des produits mentionnés à l'article L. 253-1 du code rural et de la pêche maritime,

Vu la convention passée avec le Cofrac n° 4609,

Vu le rapport d'évaluation réalisé par le Cofrac, en date du 27 juillet 2017,

L'agrément pour réaliser des essais officiellement reconnus est renouvelé, à l'organisme :

ANADIAG France
13 rue de la Bourbre
38300 RUY

sous le numéro : **BPE - 105**

ET POUR LE PÉRIMÈTRE SUIVANT :

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
ANADIAG France 13 rue de la Bourbre 38300 RUY (unité centrale)	- Traitement des semences : grandes cultures
UE 01 – Harnes (UE 62) ZI la Motte au Bois 62440 HARNES	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Zones non agricoles
UE 03 – Saint Pierre du Bû (UE 14) Couvrigny 14700 SAINT PIERRE DU Bû	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum
UE 03 – Cintré (UE 35) Rue du puisatier ZA du moulin à vent 35310 CINTRE	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Zones non agricoles
UE 06 – Varois et Chaignot (UE 21) 8 route de Gray 21490 VAROIS ET CHAIGNOT	- Grandes cultures - Vigne - Zones non agricoles
UE 08 – Saint Barthélémy (UE 38) 700 route de Pisieu 38270 SAINT BARTHELEMY	- Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
UE 10 – Saint Etienne de Fougères (UE 47) ZA Bel Air 47380 SAINT ETIENNE DE FOUGERES	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles - Désinfections et désinsectisation des sols, des matériels et des locaux de culture et de stockage des végétaux
UE 12– Saint Germain des Prés (UE 49) ZA la Poterie 49170 SAINT GERMAIN DES PRES	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur
UE 13 – Castillon du Gard (UE 30) ZA les codes bas 3 30210 CASTILLON DU GARD	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles
UE 15 – Haguenau (UE 67) 16 rue Ampère 67500 HAGUENAU	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Processus de transformation : <ul style="list-style-type: none"> - Vinification - Transformation de pomme de terre - Transformation de fruits (compote, jus de fruit, nectar, fruit au sirop, confiture, fruits séchés) - Transformation de légumes (jus, concentré de tomates, conserve de légumes, ketchup, choucroute) - Extraction d'huile
UE 16 – Thorée les Pins (UE 72) La Belle Métairie 72800 THOREE LES PINS	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture
UE 17 – Toulouse (UE 31) 75 voie de TOEC Bâtiment entreprise 2 31076 TOULOUSE	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture

Cet agrément est délivré pour une durée de cinq ans à compter du 09/10/2017 jusqu'au 08/10/2022. En application de l'article 5 de l'arrêté susmentionné, une nouvelle évaluation aura lieu dans un délai compris entre vingt-quatre et trente-six mois à compter du 09/10/2017.

Date : 03 OCT. 2017

Le sous directeur de la qualité, de la santé
et de la protection des végétaux

Alain TRIDON

Test facility	Address	Certificate (Yes or No)
ANADIAG SA	Chelny 46 517 54 Chleny CZECH REPUBLIC	YES

ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

Odbor přípravků na ochranu rostlin

Zemědělská 1a, Brno, PSČ 613 00

Příloha rozhodnutí č.j.: UKZUZ 035705/2015 ze dne 30. 4. 2015

OSVĚDČENÍ

GEP/AHC/2015

o způsobilosti k provádění zkoušek
v souladu se zásadami správné pokusnické praxe

Official Recognition Certificate / GEP - Certificate

právnícká osoba: **Anadiag SA, CZ organizační složka podniku**

sídlo právnické osoby: Chleny 46, 517 45 Chleny

IČ právnické osoby: 27518604

je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe podle § 45 odst. 1 zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, v platném znění, v návaznosti na Směrnici 91/414/EHS.

oblasti zkoušení / categories of official recognition:

- polní plodiny a zelenina / field crops and vegetables
- trvalé kultury / high crops
- skleníky a jiné kryté prostory / protected areas and storage rooms

Ústřední kontrolní a zkušební ústav zemědělský
Sekce zemědělských vstupů
Odbor přípravků na ochranu rostlin
613 00 Brno, Zemědělská 1a
- 1 -



Ing. Pavel Minář, Ph.D.
ředitel odboru

Test facility	Address	Certificate (Yes or No)
SynTech Research Germany	Industriestrasse 3, Preetz 24211 Schleswig-Holstein GERMANY	YES

GEP-Anerkennungs-Zertifikat

Anerkennungsbescheinigung

Die Versuchseinrichtung
mit Hauptsitz in
und organisatorisch zugehörigen
Arbeitseinheiten in
und
ist auf Antrag vom
und durchgeführter Besichtigung
durch
vom
in den Versuchskategorien

als Einrichtung für die Prüfung der
Wirksamkeit von Pflanzenschutzmitteln
im Sinne des § 8 Abs. 6 der
Pflanzenschutzmittelverordnung
und gemäß Verordnung (EU) 284/2013
für 5 Jahre bis zum 02.08.2021
amtlich anerkannt worden.

SynTech Research
Germany GmbH
Industriestrasse 3
24211 Preetz
85416 Langenbach
74199 Untergruppenbach
07.05.2016
Landwirtschaftskammer
Schleswig-Holstein
07.05.2016
Ackerbau und Grünland,
Gemüsebau, Obstbau,
Weinbau, Hopfenbau,
Zierpflanzenbau und Forst

Recognition Certificate

The testing facility
with headquarter in
and subsidiary testing
units in
and
on application from
and inspection
by
from the
in the trial categories

has been officially recognised
as an organisation for efficacy
testing facility of plant protection
products according to § 8 par. 6
of the Plant Protection Products
Ordinance and the Commission
Regulation (EU) 284/2013 for
5 years until 2nd of August 2021.

Datum
date
10.08.2017

Unterschrift
sign

Adresse der anerkennenden Behörde
address of the recognising authority

Stempel
stamp

P. Leiden Johansen

Landwirtschaftskammer Schleswig-Holstein
(Chamber of Agriculture Schleswig-Holstein)
Grüner Kamp 15-17
24768 Rendsburg



Test facility	Address	Certificate (Yes or No)
SynTech Research France	613 route du Bois de Loyse 71570 La Chapelle de Guinchay FRANCE	YES



MINISTÈRE DE L'AGRICULTURE ET DE L'ALIMENTATION

**DÉCISION D'AGRÈMENT POUR RÉALISER
DES ESSAIS OFFICIELLEMENT RECONNUS**

Conformément à l'article R. 253-38 du code rural et de la pêche maritime et à l'article 6 de l'arrêté du 26 avril 2007 relatif aux essais officiels et officiellement reconnus pour l'évaluation des produits mentionnés à l'article L. 253-1 du code rural et de la pêche maritime,

Vu la convention passée avec le Cofrac n° 3004,

Vu le rapport d'évaluation réalisé par le Cofrac, en date du 03/02/2018,

L'agrément pour réaliser des essais officiellement reconnus est maintenu, à l'organisme :

SYNTECH RESEARCH France SAS
1095 chemin du Bachas
30000 NIMES

sous le numéro : **BPE - 059**

ET POUR LE PÉRIMÈTRE SUIVANT :

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
UE 01 – Unité Région Centre-Est SYNTECH RESEARCH France SAS 613 route du Bois de Loyse 71570 LA CHAPELLE GUINCHAY	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles
UE 02 – Unité Région Centre-Ouest SYNTECH RESEARCH France SAS 17 rue du Château-d'Eau 37360 ROUZIERES DE TOURAINE	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Zones non agricoles
UE 03 – Unité Région Sud-Est SYNTECH RESEARCH France SAS 1095 chemin du Bachas 30000 NIMES	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
UE 04 – Unité Région Sud-Ouest SYNTECH RESEARCH France SAS 29 rue Motta Di Livenza 32600 L'ISLE JOURDAIN	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Zones non agricoles
UE 05 – Unité Région Nord SYNTECH RESEARCH France SAS 6 route d'Oresmaux 80160 SAINT SAUFLIEU	<ul style="list-style-type: none"> - Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Zones non agricoles
UE 06 – Unité Région Centre SYNTECH RESEARCH France SAS 13 rue du Cinq Mars 63260 EFFIAT	<ul style="list-style-type: none"> - Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Traitement des semences (grandes cultures)
UE 08 – Unité Région Nord-Ouest SYNTECH RESEARCH France SAS 4 rue du Manoir 27490 AUTHEUIL AUTHOUILLET	<ul style="list-style-type: none"> - Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Zones non agricoles

Cet agrément est valable jusqu'au 29/10/2019. L'évaluation de renouvellement devra impérativement avoir lieu 5 mois avant cette échéance.

Date : 16 JUIL. 2018

Le sous directrice de la
qualité, de la santé et de la
protection des végétaux



Anne-Cécile COTILLON

Test facility	Address	Certificate (Yes or No)
ANADIAG SAS	174, impasse du Plan d'eau 380300 Ruy- Montceau FRANCE	YES



MINISTÈRE DE L'AGRICULTURE ET DE L'ALIMENTATION

**DÉCISION D'AGRÈMENT POUR RÉALISER
DES ESSAIS OFFICIELLEMENT RECONNUS**

Annule et remplace les courriers du 7/02/2020

Conformément à l'article R. 253-38 du code rural et de la pêche maritime et à l'article 6 de l'arrêté du 26 avril 2007 relatif aux essais officiels et officiellement reconnus pour l'évaluation des produits mentionnés à l'article L. 253-1 du code rural et de la pêche maritime,

Vu la convention passée avec le Cofrac n° 4609,

Vu le rapport d'évaluation réalisé par le Cofrac, en date du 26/11/2019,

L'agrément pour réaliser des essais officiellement reconnus est maintenu et étendu, à l'organisme :

Anadiag France
174 impasse du plan d'eau
38300 RUY MONTCEAU

sous le numéro : **BPE - 105**

ET POUR LE PÉRIMÈTRE SUIVANT :

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
ANADIAG FRANCE 174 impasse du plan d'eau 38300 RUY MONTCEAU (unité centrale)	- Traitement des semences : grandes cultures
UE 01 – Harnes (UE 62) ZI la Motte au Bois 62440 HARNES	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Zones non agricoles
UE 03 – Saint Pierre du Bû (UE 14) Couvigny 14700 SAINT PIERRE DU BU	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Zones non agricoles
UE 04 – Cintré (UE 35) Rue du puisatier ZA du moulin à vent 35310 CINTRE	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Zones non agricoles
UE 06 – Varois et Chaignot (UE 21) 8 route de gray 21490 VAROIS ET CHAIGNOT	- Grandes cultures - Vigne - Cultures fruitières et arboriculture - Zones non agricoles

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
UE 08 – Saint Barthélémy (UE 38) 700 route de Pisieu 38270 SAINT BARTHELEMY	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles
UE 10 – Saint Etienne de Fougères (UE 47) ZA Bel Air 47380 SAINT ETIENNE DE FOUGERES	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles - Désinfection et désinsectisation des sols, des matériels et des locaux de culture et de stockage des végétaux
UE 12 – Saint Germain des Prés (UE 49) ZA la Potherie 49170 SAINT GERMAIN DES PRES	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles
UE 13 – Castillon du Gard (UE 30) ZA les Codes Bas 3 30210 CASTILLON DU GARD	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles
UE 15 – Haguenau (UE 67) 16 rue Ampère 67500 HAGUENAU	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Zones non agricoles - Processus de transformation : <ul style="list-style-type: none"> Vinification Transformation de pomme de terre Transformation de fruits (compote, jus de fruit, nectar, fruit au sirop, confiture, fruits séchés) Transformation de légumes (jus, concentré de tomates, conserve de légumes, ketchup, choucroute) Extraction d'huile

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
UE 16 – Thorée les Pins (UE 72) La Belle Métairie 72800 THOREE LES PINS	<ul style="list-style-type: none">- Grandes cultures- Vigne- Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum- Cultures fruitières et arboriculture- Zones non agricoles
UE 17 – Toulouse (UE 31) 75 voie du TOEC Bâtiment entreprise 2 31076 TOULOUSE Cedex 3	<ul style="list-style-type: none">- Grandes cultures- Vigne- Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum- Cultures fruitières et arboriculture- Zones non agricoles

Cet agrément est valable jusqu'au 08/10/2022. La prochaine évaluation de votre organisme est prévue au planning sur septembre / octobre 2020.

Date : 07/02/2020

La sous directrice de la qualité,
de la santé et de la protection
des végétaux



Anne-Cécile COTILLON

Test facility	Address	Certificate (Yes or No)
SynTech Research Germany	Loofter Str. 9, 25593 Christinenthal GERMANY	YES

GEP-Anerkennungs-Zertifikat

Anerkennungsbescheinigung

Die Versuchseinrichtung
mit Hauptsitz in
und organisatorisch zugehörigen
Arbeitseinheiten in
und
ist auf Antrag vom
und durchgeführter Besichtigung
durch
vom
in den Versuchskategorien

als Einrichtung für die Prüfung der
Wirksamkeit von Pflanzenschutzmitteln
im Sinne des § 8 Abs. 6 der
Pflanzenschutzmittelverordnung
und gemäß Verordnung (EU) 284/2013
vom 01.07.2020 bis zum 02.08.2021
amtlich anerkannt worden.

SynTech Research
Germany GmbH

Loofter Str. 9
25593 Christinenthal

74199 Untergruppenbach,
85368 Moosburg an der Isa
37081 Göttingen

22.06.2020

Landwirtschaftskammer
Schleswig-Holstein

07.05.2016

Ackerbau und Grünland,
Gemüsebau, Obstbau,
Weinbau, Hopfenbau,
Zierpflanzenbau und Forst

Recognition Certificate

The testing facility
with headquarter in
and subsidiary testing
units in
and
on application from
and inspection
by
from the
in the trial categories

has been officially recognised
as an organisation for efficacy
testing facility of plant protection
products according to § 8 par. 6
of the Plant Protection Products
Ordinance and the Commission
Regulation (EU) 284/2013 from
1st of July 2020 to
2nd of August 2021.

Datum
date

24.06.2020

Unterschrift
sign



Adresse der anerkennenden Behörde
address of the recognising authority

Landwirtschaftskammer Schleswig-Holstein
(Chamber of Agriculture Schleswig-Holstein)
Grüner Kamp 15-17
24768 Rendsburg

Stempel
stamp



Test facility	Address	Certificate (Yes or No)
SynTech Research UK	2 Old Hall Farm Barns Thurston Road, Pakenham Bury St Edmunds Suffolk IP31 2NG UNITED KINGDOM	YES



Certificate of

Official Recognition of Efficacy Testing Facilities or Organisations in the United Kingdom

This certifies that

SynTech Research UK

complies with the minimum standards laid down in
Regulation (EC) 1107/2009 for efficacy testing.

The above Facility/Organisation has been officially
recognised as being competent to carry out efficacy trials/tests
in the United Kingdom in the following categories:

Agriculture/Horticulture

Date of issue: 8 June 2020
Effective date: 3 April 2020
Expiry date: 2 April 2025

Signed by: rachel.brown@hse.gov.uk
Signing time Monday, June 8 2020, 9:31:19 GMT
Location: CRD York
Reason to sign: For the Health and Safety Executive

HSE Digital Signature

Certification Number

ORETO 425

Mediterranean EPPO zone

Test facility	Address	Certificate (Yes or No)
Agricultura y Ensayo S.L.	2 Rua Dr. Osar da Costa Neves 2080-130 Almeirim PORTUGAL	YES
SynTech Research Portugal	21 Rua Antonio Oliveira 2500-916 Caldas da Rainha PORTUGAL	YES
ANADIAG IBERICA SL	c/ Falgueres s/n 17460 Celrà SPAIN	YES
ANADIAG HELLAS LTD	New Ring Road Verias – Thessalonikis & N. Mandilara, PO Box 71 59100 Veria GREECE	YES
ANADIAG Portugal	Rua dos Olivais 3, R/C Direito Fracção B 3780-229 ANADIA, PORTUGAL	YES
SynTech Research Spain, S.L	Camino de los Huertos, s/n E-46210 (Picanya) Valencia SPAIN	YES
Agricola 2000 S.C.p.A	Via Trieste, 9 Tribiano 20067 ITALY	YES
ANADIAG ITALIA SRL	9 S. da Savonesa Frazione Rivalta Scrivia 15050 Tortona ITALY	YES

Test facility	Address	Certificate (Yes or No)
Agricultura y Ensayo S.L.	2 Rua Dr. Osar da Costa Neves 2080-130 Almeirim PORTUGAL	YES



REPUBLICA PORTUGUESA



CERTIFICADO

ORGANIZAÇÃO OFICIALMENTE RECONHECIDA PARA A REALIZAÇÃO DE ENSAIOS DE EFICÁCIA DE PRODUTOS FITOFARMACÊUTICOS

Certifica-se que foi reconhecida como Organização Oficialmente Reconhecida, em Portugal, a **AGRICULTURA Y ENSAYO S.L.** – Sucursal em Portugal, para a realização de ensaios de eficácia de produtos fitofarmacêuticos, segundo a Boa Prática Experimental, n.º 35, da Portaria n.º 396/2000, de 14 de Julho, que concretiza os princípios estabelecidos no Regulamento (UE) N.º 284/2013 da Comissão de 1 de março de 2013, em conformidade com o Regulamento (CE) N.º 1107/2009 do Parlamento Europeu e de acordo com o respetivo pedido.

- **Certificado n.º 25**
- **Data de entrada em vigor do reconhecimento: 26 de julho de 2016**
- **Termo do prazo do reconhecimento: 26 de julho de 2021**
- **Condições / Limitações: ---**

Oeiras, 20 de setembro de 2016.

A Subdiretora Geral

Ana Paula de Almeida
Cruz de Carvalho

Assinado de forma digital por Ana
Paula de Almeida Cruz de Carvalho
Dados: 2017.04.03 08:44:10 +01'00'

Test facility	Address	Certificate (Yes or No)
SynTech Re- search Portugal	21 Rua Antonio Oliveira 2500-916 Caldas da Rainha PORTUGAL	YES



CERTIFICADO

ORGANIZAÇÃO OFICIALMENTE RECONHECIDA PARA A REALIZAÇÃO DE ENSAIOS DE EFICÁCIA DE PRODUTOS FITOFARMACÊUTICOS

Certifica-se que a **SYNTECH Research Portugal** é reconhecida como Organização Oficialmente Reconhecida, em Portugal, para a realização de ensaios de eficácia de produtos fitofarmacêuticos, segundo a Boa Prática Experimental, n.º 35, da Portaria n.º 396/2000, de 14 de Julho, que concretiza os princípios estabelecidos no Regulamento (UE) N.º 284/2013 da Comissão de 1 de março de 2013, em conformidade com o Regulamento (CE) N.º 1107/2009 do Parlamento Europeu e de acordo com o respetivo pedido.

- **Certificado n.º 30 (trinta)**
- **Data de entrada em vigor do reconhecimento: 29 de maio de 2018**
- **Termo do prazo do reconhecimento: 29 de maio de 2023**
- **Condições / Limitações: ---**

Lisboa, 10 julho de 2018.

A Subdiretora Geral

ANA PAULA DE
ALMEIDA CRUZ DE
CARVALHO

Assinado de forma digital por ANA
PAULA DE ALMEIDA CRUZ DE
CARVALHO
Dados: 2018.07.10 21:15:18 +01'00'

Test facility	Address	Certificate (Yes or No)
ANADIAG IBERICA SL	c/ Falgueres s/n 17460 Celrà SPAIN	YES



MINISTERIO
DE AGRICULTURA Y PESCA,
ALIMENTACION Y MEDIO AMBIENTE

SECRETARÍA GENERAL DE
AGRICULTURA Y ALIMENTACIÓN

DIRECCIÓN GENERAL DE SANIDAD
DE LA PRODUCCIÓN AGRARIA

ASUNTO: Renovación Acreditación N° EOR 20/97

De acuerdo con lo establecido en el artículo 19 de la Orden de 11 de diciembre de 1995 por el que se establecen las disposiciones relativas a las renovaciones de autorizaciones de ensayos y experiencias con productos fitosanitarios, esta Dirección General ha resuelto, previo informe favorable de la Comisión de Evaluación de Productos Fitosanitarios, renovar la acreditación N° EOR 20/97 concedida a su empresa, para realizar ensayos oficialmente reconocidos.

La validez de esta acreditación queda ampliada hasta el 18 de julio del año 2022, salvo que sea revisada o revocada antes de la conclusión de dicho plazo si se determina que ha dejado de cumplirse alguno de los requisitos exigidos para su autorización o de las obligaciones establecidas por la Orden Ministerial de 11 de diciembre de 1995.

Madrid 18 de julio de 2017

EL DIRECTOR GENERAL DE SANIDAD
DE LA PRODUCCIÓN AGRARIA

Fdo.: Valentín Almansa de Lara



ANADIAG IBERICA, S.L.
GIRONA
JCS/amg

Test facility	Address	Certificate (Yes or No)
ANADIAG HEL- LAS LTD	New Ring Road Ve- rias – Thessalonikis & N. Mandilara, PO Box 71 59100 Veria GREECE	YES



HELLENIC REPUBLIC
MINISTRY OF RURAL DEVELOPMENT & FOOD
GENERAL DIRECTORATE OF SUSTAINABLE PLANT PRODUCE
DIRECTORATE OF PLANT PRODUCE PROTECTION
DEPARTMENT OF PLANT PROTECTION PRODUCTS & BIOCIDES
150 SYGROU AV., 17671 ATHENS
TEL: 0030 210 938 7337
FAX: 0030 210 92 12 090
E-MAIL: apapamichail@minagric.gr

Date: July 2017

RECOGNITION CERTIFICATE
OF TESTING FACILITY FOR GEP BIOLOGICAL TRIALS
*(In accordance with the provisions of Article 54 of the
Regulation(EC) 1107/2009)*

ANADIAG Hellas L.t.d.

Headquarters: Ring road Verlas – Thessalonikis & N. Mandilara str., Verla, Imathia

Branch1: 8 Elusas str., P.C. 71409, Heraklion Crete

Branch2: Old Nat. Road of Patras – Pyrgou, P.C. 27300, Kavasila Pyrgos Ilias

Is recognized in accordance to the Ministerial Decision No. 183351/7-4-2010 for
conducting biological tests and trials in:

- a) open fields
- b) controlled environment (e.g. greenhouses, warehouses)

With:

RECOGNITION CODE
ANA/02/2020

Decision number and date of first recognition: **129499/29-12-2015**

Decision number and date of first renewal of the recognition:

6966/71619/26-06-2012

Decision number and date of second renewal of the recognition:

7871/716211/12-07-2017

Expiring date of the validity of this certificate: 31-12-2020

This certificate remains valid until further notice and provided that the company
continues to meet the requirements of the Ministerial Decision 183351/7-4-2010, as
applicable.



The Head of the
Directorate:

ΣΗ. ΖΩΓΡΑΦΟΣ

Revision 3

ANA/02/2020

Page 1/1

Test facility	Address	Certificate (Yes or No)
ANADIAG Portugal	Rua dos Olivais 3, R/C Direito Fracção B 3780-229 ANADIA, PORTUGAL	YES



AGRICULTURA, FLORESTAS
E DESENVOLVIMENTO RURAL



CERTIFICADO

ORGANIZAÇÃO OFICIALMENTE RECONHECIDA PARA A REALIZAÇÃO DE ENSAIOS DE EFICÁCIA DE PRODUTOS FITOFARMACÊUTICOS

Certifica-se que é reconhecida como Organização Oficialmente Reconhecida, em Portugal, a **ANADIAG Portugal** para a realização de ensaios de eficácia de produtos fitofarmacêuticos, segundo a Boa Prática Experimental, n.º 35, da Portaria n.º 396/2000, de 14 de Julho, que concretiza os princípios estabelecidos no Regulamento (UE) N.º 284/2013 da Comissão de 1 de março de 2013, em conformidade com o Regulamento (CE) N.º 1107/2009 do Parlamento Europeu e do Conselho, de 21 de outubro, de acordo com o respetivo pedido.

- **Certificado n.º 19 (dezanove)**
- **Data de entrada em vigor do reconhecimento: 20 de abril de 2017**
- **Termo do prazo do reconhecimento: 20 de abril de 2022**
- **Condições / Limitações: ---**

Oeiras, 27 de fevereiro de 2018

A Subdiretora Geral

ANA PAULA DE
ALMEIDA CRUZ DE
CARVALHO

Assinado de forma digital
por ANA PAULA DE ALMEIDA
CRUZ DE CARVALHO
Dados: 2018.02.27 13:52:02 Z

Test facility	Address	Certificate (Yes or No)
SynTech Re- search Spain, S.L	Camino de los Huertos, s/n E-46210 (Picanya) Valencia SPAIN	YES



MINISTERIO
DE AGRICULTURA Y PESCA,
ALIMENTACION Y MEDIO AMBIENTE

SECRETARÍA GENERAL DE
AGRICULTURA Y ALIMENTACION

DIRECCIÓN GENERAL DE SANIDAD
DE LA PRODUCCIÓN AGRARIA

ASUNTO: Renovación Acreditación Nº EOR 2/96

De acuerdo con lo establecido en el artículo 19 de la Orden de 11 de diciembre de 1995 por el que se establecen las disposiciones relativas a las renovaciones de autorizaciones de ensayos y experiencias con productos fitosanitarios, esta Dirección General ha resuelto, previo informe favorable de la Comisión de Evaluación de Productos Fitosanitarios, renovar la acreditación Nº EOR 2/96 concedida a su empresa, para realizar ensayos oficialmente reconocidos.

La validez de esta acreditación queda ampliada hasta el 22 de febrero del año 2022, salvo que sea revisada o revocada antes de la conclusión de dicho plazo si se determina que ha dejado de cumplirse alguno de los requisitos exigidos para su autorización o de las obligaciones establecidas por la Orden Ministerial de 11 de diciembre de 1995.

Madrid 22 de febrero de 2017

EL DIRECTOR GENERAL DE SANIDAD
DE LA PRODUCCIÓN AGRARIA

Fdo.: Valentín Almansa de Lara

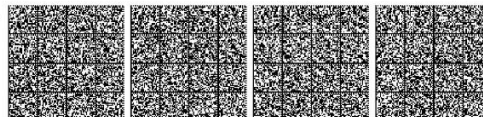
RECERCA AGRICOLA/SYNTECH RESEARCH SPAIN S.L.
VALENCIA
IBD/me

Test facility	Address	Certificate (Yes or No)
Agricola 2000 S.C.p.A	Via Trieste, 9 Tribiano 20067 ITALY	YES

Serie generale - n. 144

Visto il decreto legislativo 30 luglio 1999, n. 300, di riforma dell'organizzazione di governo a norma dell'art. 11 della legge 15 marzo 1997, n. 59:

Prove relative agli effetti della lavorazione industriale e/o preparazione domestica sulla natura e sull'enti-



23-6-2018

GAZZETTA UFFICIALE DELLA REPUBBLICA ITALIANA

Serie generale - n. 144

tà dei residui (di cui all'allegato II, punto 6.6 del decreto legislativo 194/95);

Prove di campo ambientali ed eco tossicologiche atte alla valutazione del destino e comportamento nell'ambiente delle sostanze attive e dei suoi metaboliti (di cui all'allegato II, parte A, punti 7.1, 7.2 e 8.3 del decreto legislativo 194/95);

Determinazione dei residui in o su prodotti trattati, alimenti per l'uomo o per gli animali (di cui all'Allegato III, punto 8.1 del decreto legislativo 194/95);

Prove relative agli effetti della lavorazione industriale e/o preparazione domestica sulla natura e sull'entità dei residui (Allegato III, Punto 8.2 del decreto legislativo 194/95);

Valutazione dei dati sui residui nelle colture successive o di rotazione (di cui all'Allegato III, punto 8.5 del decreto legislativo 194/95);

Individuazione dei tempi di carenza per impieghi in pre-raccolta o post-raccolta (di cui all'Allegato III, punto 8.6 del decreto legislativo 194/95);

Prove su destino e comportamento ambientale (di cui all'Allegato III, punti 9.1, 9.2 e 9.3 del decreto legislativo 194/95 e successive modifiche);

Studi ecotossicologici relativi agli effetti su altri organismi non bersaglio (di cui all'Allegato III, punti 10.3, 10.4, 10.5, 10.6, 10.7 del decreto legislativo 194/95).

2. Il riconoscimento di cui al comma 1, riguarda le prove di campo di efficacia e le prove di campo finalizzate alla determinazione dell'entità dei residui di prodotti fitosanitari nei seguenti settori di attività:

Aree acquatiche;
Aree non agricole;
Colture arboree;
Colture erbacee;
Colture forestali;
Colture medicinali ed aromatiche;
Colture ornamentali;
Colture orticole;
Colture tropicali;
Concia sementi;
Conservazione post-raccolta;
Diserbo;
Entomologia;
Microbiologia agraria;
Nematologia;
Patologia vegetale;
Zoologia agraria;
Produzione sementi;
Vertebrati dannosi.

Art. 2.

1. Il mantenimento dell'idoneità di cui all'articolo precedente è subordinato alla verifica biennale in loco del possesso dei requisiti prescritti, da parte degli ispettori iscritti nell'apposita lista nazionale di cui all'art. 4, comma 8, del citato decreto legislativo 194/95.

2. Il Centro «Agricola 2000 S.c.p.a.» è tenuto a comunicare a questo Ministero l'indicazione precisa delle tipologie delle prove che andrà ad eseguire, nonché la loro localizzazione territoriale.

3. Il citato Centro è altresì tenuto a comunicare ogni eventuale variazione che interverrà rispetto a quanto dalla stessa dichiarato nell'istanza di riconoscimento, nonché a quanto previsto dal presente decreto.

Art. 3.

1. Il presente decreto ha la validità di mesi 24 dalla data di ispezione effettuata in data 4-5 maggio 2018.

2. Il Centro «Agricola 2000 S.c.p.a.», qualora intenda confermare o variare gli ambiti operativi di cui al presente decreto, potrà inoltrare apposita istanza, almeno sei mesi prima della data di scadenza, corredata dalla relativa documentazione comprovante il possesso dei requisiti richiesti.

Il presente decreto, ai sensi dell'art. 13 del decreto legislativo 196/2003, sarà oggetto di pubblicazione in ottemperanza agli obblighi di legge previsti dal decreto legislativo 33/2013.

Il presente decreto sarà pubblicato nella *Gazzetta Ufficiale* della Repubblica italiana.

Roma, 11 giugno 2018

Il direttore generale: GATTO

18A04333

MINISTERO DELLO SVILUPPO ECONOMICO

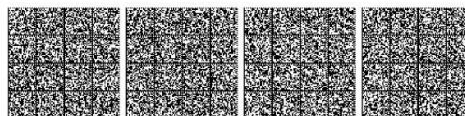
DECRETO 23 marzo 2018.

Ulteriori modifiche al decreto 9 dicembre 2014 in materia di contratti di sviluppo.

IL MINISTRO DELLO SVILUPPO ECONOMICO

Visto l'art. 43 del decreto-legge 25 giugno 2008, n. 112, convertito, con modificazioni, dalla legge 6 agosto 2008, n. 133, relativo alla semplificazione degli strumenti di attrazione degli investimenti e di sviluppo d'impresa;

Visto l'art. 3 del decreto-legge 21 giugno 2013, n. 69, convertito, con modificazioni, dalla legge 9 agosto 2013, n. 98, concernente il rifinanziamento dei contratti di sviluppo, che prevede che il Ministro dello sviluppo economico, con proprio decreto, provvede a ridefinire le modalità e i criteri per la concessione delle agevolazioni e la realizzazione degli interventi di cui all'art. 43 del decreto-legge 25 giugno 2008, n. 112, convertito, con modificazioni, dalla legge 6 agosto 2008, n. 133, anche al fine di accelerare le procedure per la concessione delle agevolazioni, di favorire la rapida realizzazione dei programmi d'investimento e di prevedere specifiche priorità in favore dei programmi che ricadono nei territori oggetto



Test facility	Address	Certificate (Yes or No)
ANADIAG ITA-LIA SRL	9 S. da Savonesa Frazione Rivalta Scrivia 15050 Tortona ITALIA	YES

Serie generale - n. 187

— 12 —



13-8-2018

GAZZETTA UFFICIALE DELLA REPUBBLICA ITALIANA

Serie generale - n. 187

18A05348

DECRETO 30 luglio 2018.

Riconoscimento dell'idoneità al Centro «Anadiag Italia S.r.l.» ad effettuare prove ufficiali di campo, finalizzate alla produzione di dati di efficacia e alla determinazione dell'entità dei residui di prodotti fitosanitari.

IL DIRETTORE GENERALE
DELLO SVILUPPO RURALE

Visto il decreto legislativo del 17 marzo 1995, n. 194 che, in attuazione della direttiva 91/414/CEE, disciplina l'immissione in commercio dei prodotti fitosanitari;

Visti in particolare i commi 5, 6, 7 e 8 dell'art. 4 del predetto decreto legislativo n. 194/95;

Visto il decreto del Ministro della sanità del 28 settembre 1995 che modifica gli allegati II e III del suddetto decreto legislativo n. 194/95;

Visto il decreto interministeriale 27 novembre 1996 che, in attuazione del citato decreto legislativo n. 194/95, disciplina i principi delle buone pratiche per l'esecuzione delle prove di campo e definisce i requisiti necessari al riconoscimento ufficiale dell'idoneità a condurre prove di campo finalizzate alla registrazione dei prodotti fitosanitari;

Vista l'istanza presentata in data 10 gennaio 2018 dal Centro «Anadiag Italia S.r.l.», con sede legale in fraz. Rivalta Scrivia - Strada Savonesa, 9 - 15050 Tortona (AL);

Visto l'esito favorevole della verifica della conformità ad effettuare prove di campo a fini registrativi, finalizzate alla produzione di dati di efficacia e alla determinazione dell'entità dei residui di prodotti fitosanitari effettuata in data 23 giugno 2018 presso il Centro «Anadiag Italia S.r.l.»;

Visto il decreto legislativo 30 luglio 1999, n. 300, di riforma dell'organizzazione di Governo a norma dell'art. 11 della legge 15 marzo 1997, n. 59;

Visto il decreto legislativo 30 marzo 2001, n. 165, relativo alle «norme generali sull'ordinamento del lavoro alle dipendenze delle amministrazioni pubbliche», in particolare l'art. 4, commi 1 e 2 e l'art. 16, comma 1;

Visto il decreto del Presidente del Consiglio dei ministri 27 febbraio del 2013, n. 105, recante il Regolamento di organizzazione del Ministero delle politiche agricole alimentari e forestali, a norma dell'art. 2, comma 10-ter, del decreto-legge 6 luglio 2012, n. 95, convertito, con modificazioni, dalla legge 7 agosto 2012, n. 135, così come modificato dal decreto del Presidente del Consiglio dei ministri 17 luglio 2017, n. 143;

Visto il decreto del Ministro delle politiche agricole alimentari e forestali del 7 marzo 2018, Registrato alla Corte dei conti il 3 aprile 2018 al n. 191, recante individuazione degli Uffici dirigenziali di livello non generale;

Considerato che il suddetto Centro ha dichiarato di possedere i requisiti prescritti dalla normativa vigente, a far data dal 10 gennaio 2018, a fronte di apposita documentazione presentata;

Decreta:

Art. 1.

1. Il Centro «Anadiag Italia S.r.l.», con sede legale in fraz. Rivalta Scrivia - Strada Savonesa, 9 - 15050 Tortona (AL), è riconosciuto idoneo a proseguire nelle prove ufficiali di campo con prodotti fitosanitari volte ad ottenere le seguenti informazioni:

efficacia dei prodotti fitosanitari (di cui all'Allegato III, punto 6.2 del decreto legislativo n. 194/95);

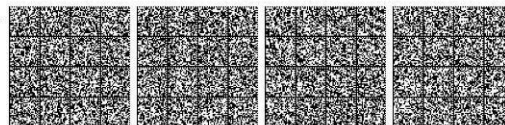
dati sulla comparsa o eventuale sviluppo di resistenza (di cui all'Allegato III, punto 6.3 del decreto legislativo n. 194/95);

incidenza sulla resa quantitativa e/o qualitativa (di cui all'Allegato III, punto 6.4 del decreto legislativo n. 194/95);

fitotossicità nei confronti delle piante e prodotti vegetali bersaglio (di cui all'Allegato III, punto 6.5 del decreto legislativo n. 194/95);

osservazioni riguardanti gli effetti collaterali indesiderabili (di cui all'Allegato III, punto 6.6 del decreto legislativo n. 194/95);

individuazione dei prodotti di degradazione e di reazione dei metaboliti in piante o prodotti trattati (di cui all'allegato II, punto 6.1 del decreto legislativo n. 194/95);



North-Eastern EPPO zone

Test facility	Address	Certificate (Yes or No)
STAPHYT	Ul. Ziebicka 2 60-164 Poznan POLAND	YES
ANADIAG POLSKA	Ul. Sadowa 16/22 95-100 Zgierz POLAND	YES
LRCAF, Institute of Agriculture	Instituto al. 1, Akademija, 58344 Kedainiu r. LITHUANIA	YES (2013)
Agrolab Baltic	Elizabetes iela 45/47, Riga LV-1010 LATVIA	YES
LRCAF, Institute of Agriculture	Instituto al. 1, Akademija, 58344 Kedainiu r. LITHUANIA	YES (2019)
SynTech Research Poland Sp. z o.o.	85-027 Bydgoszcz POLAND	YES
Latvian Plant Protection Rese- arch Center Ltd	Struktoru iela 14a Riga LV-1039 LATVIA	YES

Test facility	Address	Certificate (Yes or No)
STAPHYT	Ul. Ziebiga 2 60-164 Poznań POLAND	YES

**GLÓWNY INSPEKTOR
OCHRONY ROŚLIN I NASIENICTWA**

Tadeusz Kłos

WO-505- 14 /2012

Warszawa, 25.09.2012 r.

DECYZJA Nr 7/2012

Na podstawie art. 155 ustawy z dnia 14 czerwca 1960 r. Kodeks postępowania administracyjnego (Dz.U. z 2000 r. Nr 98, poz. 1071 ze zm.) i art. 40 ust. 1 ustawy z dnia 18 grudnia 2003 r. o ochronie roślin (Dz.U. z 2008 r. Nr 133, poz. 849 ze zm.), po rozpatrzeniu wniosku z dnia 6 września 2012 r., zmieniam decyzję Nr 9/2005 z dnia 1 maja 2005 r., zmienioną decyzjami: Nr 3/2006 z dnia 5 maja 2006 r., Nr 8/2006 z dnia 11 grudnia 2006 r., Nr 2/2009 z dnia 18 lutego 2009 r., Nr 12/2011 z dnia 31 marca 2011 r. oraz Nr 4/2012 z dnia 4 kwietnia 2012 r.

Rozstrzygnięciu decyzji nadaję następujące brzmienie:

upoważniam

STAPHYT Sp. z o.o.

ul. Ziebiga 2; 60-164 Poznań

do prowadzenia badań skuteczności działania środka ochrony roślin

z grupy fungicydów, herbicydów, insektycydów, moluskocydów, akarycydów, regulatorów wzrostu, zapraw nasiennych oraz do łącznego stosowania środków ochrony roślin w uprawach polowych: zbóż, kukurydzy, rzepaku, buraków cukrowych, słonecznika, ziemniaków, warzyw, w uprawach sadowniczych (jabłoni, gruszy, porzeczki, truskawki, pestkowe), w magazynach i przechowalniach, a także na trawnikach oraz w uprawach roślin ozdobnych w polu i pod osłonami.

Uzasadnienie

W dniu 6 września 2012 r. Staphyt Sp. z o.o. (ul. Ziebiga 2; 60-164 Poznań) zwróciła się z wnioskiem o rozszerzenie zakresu decyzji Głównego Inspektora Ochrony Roślin i Nasiennictwa upoważniającej do prowadzenia badań skuteczności działania środków ochrony roślin Nr 9/2005 z dnia 1 maja 2005 r.,

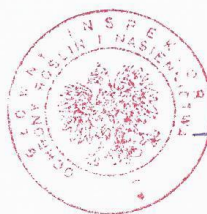
zmienionej decyzjami: Nr 3/2006 z dnia 5 maja 2006 r., Nr 8/2006 z dnia 11 grudnia 2006 r., Nr 2/2009 z dnia 18 lutego 2009 r. oraz Nr 4/2012 z dnia 4 kwietnia 2012 r. Wniosek dotyczył możliwości prowadzenia badań w magazynach i przechowalniach.

Staphyt Sp. z o.o. spełnia warunki organizacyjno-techniczne, zwane „Zasadami Dobrej Praktyki Eksperymentalnej” (Good Experimental Practice - GEP), zapewniające prawidłowe przeprowadzanie badań skuteczności działania środka ochrony roślin.

Mając na uwadze powyższe, postanowiono jak w rozstrzygnięciu decyzji.

Pouczenie

Od niniejszej decyzji odwołanie nie przysługuje. Jednakże strona niezadowolona z decyzji może zwrócić się do Głównego Inspektora Ochrony Roślin i Nasiennictwa z wnioskiem o ponowne rozpatrzenie sprawy w terminie 14 dni od dnia doręczenia decyzji, zgodnie z art. 127 § 3 Kodeksu postępowania administracyjnego.



GŁÓWNY INSPEKTOR

Tadeusz Kłos

Test facility	Address	Certificate (Yes or No)
ANADIAG POL- SKA	Ul. Sadowa 16/22 95-100 Zgierz POLAND	YES

SWORN TRANSLATOR
MARTA TRAWCZYŃSKA
ul. Św. Wojciecha 3/3a lok. 1, 10-038 Olsztyn
T +48 665 240 339, F +48 89/ 512 00 99

CERTIFIED TRANSLATION FROM THE POLISH LANGUAGE

[Any remarks in square brackets are the translator's. The translated document consists of two (2) pages.]

[national emblem of the Republic of Poland]

MAIN INSPECTOR
OF PLANT HEALTH AND SEED PROTECTION

Andrzej Chodkowski

Warsaw, dated 12 October 2018

BORiT.541.11.2018.1

DECISION No. 10/2018

Pursuant to Article 155 of the Act of 14 June 1960 Administrative Procedure Code (Dz.U. *[Polish Official Journal of Laws]* of 2017, item 1257 as amended), having examined the application filed by Anadiag SAS Branch Office in Poland dated 3 October 2018, I vary the decision No. 7/2007 dated 28 May 2007, varied by decisions No. 1/2010 dated 18 March 2010, No. 18/2011 dated 18 August 2011, No. 1/2012 dated 13 January 2012 and No. 3/2014 dated 16 April 2014 to grant authorization to conduct research of the efficiency of plant health products in such a manner that the decision shall read as follows:

"I authorize

Anadiag SAS Branch Office in Poland
ul. Sadowa 16/22, 95-100 Zgierz

to conduct research of the efficiency of plant health products from the group of acaricides, bactericides, fungicides, herbicides, insecticides, molluscicides, rodenticides, pheromones and growth regulators in outdoor crops, orchard crops, under covers, in edible mushrooms cultivations, in meadows and pastures. The research shall be conducted in cereal, root and oil crops, vegetables, orchard and ornamental plants, legumes, grass and special plants, in storage rooms and rooms for cultivation of edible mushrooms, in lawns and in non-agricultural lands."

No reasoning for this decision has been prepared as the decision grants the application of the Party in its entirety (Article 107(4) of the Administrative Procedure Code *[hereinafter referred to as "APC"]*).



Marta Trawczyńska

Instruction

This decision may not be appealed against. A Party unsatisfied with this decision may file an application to the Main Inspector of Plant Health and Seed Protection requesting a re-examination of the case, within 14 days of being served with this decision, pursuant to Article 127(3) APC.

Until the time-limit to apply for re-examination of the case has expired, a Party may waive this right towards the public administration authority which issued the decision. On the day when the Main Inspector of Plant Health and Seed Protection receives the waiver of the right to apply for re-examination of the case, the decision becomes final and non-appealable, which means that the decision shall be enforced immediately and it may not be appealed against to the Voivodeship Administration Court.

If a Party does not believe that the decision grants the Party's application but does not wish to exercise its right to apply for re-examination of the case, the Party may file to the Voivodeship Administration Court in Warsaw a complaint against the decision within 30 days of being served with the decision. The complaint shall be filed through the Main Inspector of Plant Health and Seed Protection.

Pursuant to section 2(1)(2) of the Regulation of the Council of Ministers of 16 December 2003 on the amount and detailed rules for collecting charges in proceedings before administrative courts (Dz.U. [Polish Official Journal of Laws] No. 221, item 2193 as amended) a fixed charge, which is independent of the subject-matter of the act appealed against or activities in cases regarding complaints against acts or public administration activities regarding rights or duties specified by the law, shall amount to PLN 200.

At the request of a Party made before court proceedings are instituted or in the course of such proceedings, the Party may be granted legal aid consisting of full or partial exemption from court costs and having an attorney-at-law or a legal advisor appointed for such Party, if the Party substantiates that they are unable to bear any costs of the proceedings or full costs thereof.

To be served upon:

1

Anadiag SAS Branch Office in Poland
ul. Sadowa 16/22
95-100 Zgierz

2. file

[round official seal with the national emblem of the Republic of Poland in its midst and the following circumscription: MAIN INSPECTOR OF PLANT HEALTH AND SEED PROTECTION]

[rectangular stamp reading: P.p. / MAIN INSPECTOR / Tadeusz Łaczyński; illegible signature]

I, duly commissioned sworn translator of the English language (TP/101/2013) in Olsztyn, hereby certify that the above translation is a true and complete version of the document in Polish presented to me.

Reg. No. 222/2018

Olsztyn, dated 29s October 2018



Marta Trawczyńska

Test facility	Address	Certificate (Yes or No)
LRCAF, Institute of Agriculture	Instituto al. 1, Akad- emija, 58344 Kedainiu r. LITHUANIA	YES (2013)

<div><p>VALSTYBINĖ AUGALININKYSTĖS TARNYBA PRIE ŽEMĖS ŪKIO MINISTERIJOS</p><p>GEROS AUGALŲ APSAUGOS PRODUKTŲ VEIKSMINGUMO IR (ARBA) ATRANKUMO BANDYMŲ PRAKTIKOS SERTIFIKATAS</p><p>2013-12-12 Nr. AS4 – 13/02 Vilnius</p><p>Patvirtinama, kad Lietuvos agrarinių ir miškų mokslų centro filialas Žemdirbystės institutas, į.k. 302474007, Instituto al. 1, Akademija, 58344 Kėdainių r., laikosi geros augalų apsaugos produktų veiksmingumo ir (arba) atrankumo bandymų praktikos ir turi teisę atlikti šiuos tyrimus:</p><p>lauko bandymai; vegetaciniai bandymai.</p><p>Sertifikatas galioja iki 2019 m. gruodžio 12 d.</p><div><div>Direktorius</div><div></div><div>Evaldas Zigmantas Čijauskas</div></div></div>
--

Test facility	Address	Certificate (Yes or No)
Agrolab Baltic	Elizabetes iela 45/47, Rīga LV-1010 LATVIA	YES



Valsts augu aizsardzības dienests

SERTIFIKĀTS

Nr. 30

Izsniegts **SIA „AgroLab Baltic”**
(komersanta nosaukums, reģistrācijas numurs, juridiskā adrese)

Reģ. Nr. 44103075387

Elizabetes iela 45/47, Rīga, LV-1010

par tiesībām veikt normatīvajos aktos par augu aizsardzības līdzekļu reģistrāciju noteiktos
efektivitātes pārbaudes izmēģinājumus:

Lauks- graudaugi-fungicīdi, insekticīdi, kodnes, **lauks-** rapsis- insekticīdi, **lauks-** dārzeņi- insekticīdi,
lauks- graudaugi-limacīdi, **lauks** -rapsis- limacīdi.

Sertifikāts izsniegts: 08.01.2019.
(datums)

Sertifikāts derīgs līdz: 07.01.2024.
(datums)


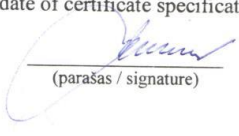
Valsts augu aizsardzības dienests
Augu aizsardzības līdzekļu
reģistrācijas daļas vadītāja
(amats, paraksts un tā atšifrējums)



Z.V.

 R.Čūdere

Test facility	Address	Certificate (Yes or No)
LRCAF, Institute of Agriculture	Instituto al. 1, Akad- emija, 58344 Kedainiu r. LITHUANIA	YES (2019)

<div><p>VALSTYBINĖ AUGALININKYSTĖS TARNYBA PRIE ŽEMĖS ŪKIO MINISTERIJOS / STATE PLANT SERVICE UNDER THE MINISTRY OF AGRICULTURE</p><p>GEROSIOS AUGALŲ APSAUGOS PRODUKTŲ VEIKSMINGUMO BANDYMŲ PRAKTIKOS SERTIFIKATAS / CERTIFICATE OF GOOD EXPERIMENTAL PRACTICE</p><p><u>2019 m. gruodžio 6 d. Nr. AS4-02(2019)</u> (data) <u>Vilnius</u> (vieta)</p><p>Šiuo sertifikatu patvirtinama, kad / This is to certify that <u>Lietuvos agrarinių ir miškų mokslo centro filialas Žemdirbystės institutas</u> (juridinio asmens pavadinimas, teisinė forma arba fizinio asmens vardas, pavardė / name, type of legal entity or name, surname of natural person)</p><p><u>302474007</u> (juridinio arba fizinio asmens kodas / code of legal entity or natural person)</p><p><u>Instituto al. 1, Akademija, 58344 Kedainių r.</u> (juridinio asmens buveinės adresas arba fizinio asmens adresas / address of legal entity or natural person)</p><p>laikosi gerosios augalų apsaugos produktų veiksmingumo bandymų praktikos ir turi teisę atlikti augalų apsaugos produktų veiksmingumo bandymus šioje (šiose) srityje (srityse) / complies with the requirements of good experimental practice and has the right to perform plant protection product efficacy testing in the following field (fields): <u>lauko augalai (išskyrus daržoves)</u></p><p>Sertifikatas patikslintas / date of certificate specification: _____</p><div><div><u>Direktorius</u> (pareigos / office)</div><div> (parašas / signature)</div><div><u>Sergejus Fedotovas</u> (vardas, pavardė / name, surname)</div></div></div>

Test facility	Address	Certificate (Yes or No)
SynTech Research Poland Sp. z o.o.	85-027 Bydgoszcz POLAND	YES



GLÓWNY INSPEKTOR
OCHRONY ROŚLIN I NASIENICTWA

Tadeusz Kłos

WO-505-8/15

Warszawa, 27.04.2015 r.

DECYZJA Nr 6/2015

Na podstawie art. 17 ust. 2 i ust. 8 pkt 2 w związku z art. 79 ust. 3 ustawy z dnia 8 marca 2013 r. o środkach ochrony roślin (Dz.U. z 2013 r. poz. 455 z późn. zm.) oraz art. 104 ustawy z dnia 14 czerwca 1960 r. Kodeks postępowania administracyjnego (Dz.U. z 2013 r. poz. 267 z późn.zm.), po rozpatrzeniu wniosku z dnia 30 marca 2015 r., rozszerzam zakres upoważnienia do prowadzenia badań skuteczności działania środka ochrony roślin wydanego w drodze decyzji Nr 5/2013 z dnia 25 marca 2013 r., zmienionego decyzją Nr 2/2014 z dnia 7 marca 2014 r., w zakresie prowadzenia badań skuteczności działania środka ochrony roślin z użyciem akarycydów i nematocydów w uprawach warzyw w polu i pod osłonami.

Rozstrzygnięciu decyzji nadaję następujące brzmienie:

Upoważniam

SynTech Research Poland Sp. z o.o.

ul. Jagiellońska 69/1; 85-027 Bydgoszcz

do prowadzenia badań skuteczności działania środka ochrony roślin

z grupy akarycydów, fungicydów, herbicydów, insektycydów, nematocydów i regulatorów wzrostu w uprawach polowych (zboża, kukurydza, rzepak, burak cukrowy, ziemniak, warzywa kapustne, pomidor, ogórek, sałata, marchew, pietruszka, cebula, fasola, papryka, burak), w uprawach sadowniczych (jabłoni, wiśnia, czereśnia, śliwa, morela, brzoskwinia, grusza, malina, truskawka, porzeczka, winorośl, orzech), w uprawach chmielu, traw łąkowych i pastwiskowych oraz na terenach nieużytkowanych rolniczo.

Uzasadnienie

Pismem z dnia 30 marca 2015 r. Spółka z o.o. SynTech Research Poland zwróciła się z prośbą o rozszerzenie zakresu upoważnienia Nr 5/2013 wydanego przez Głównego Inspektora Ochrony Roślin i Nasiennictwa w dniu 25 marca 2013 r., zmienionego decyzją Nr 2/2014 z dnia 7 marca 2014 r., umożliwiającą Spółce prowadzenie badań skuteczności działania środka ochrony roślin. Wnioskowana zmiana dotyczy prowadzenia badań z użyciem środków ochrony roślin z grupy akarycydów i nematocydów oraz stosowania badanych środków w uprawach marchwi, pietruszki, cebuli, fasoli, papryki, buraka, truskawki, porzeczki, gruszy, orzecha, moreli, brzoskwini, winorośli i chmielu, traw łąkowych i pastwiskowych oraz na terenach nieużytkowanych rolniczo.

SynTech Research Poland Sp. z o.o. spełnia wymagania dobrej praktyki doświadczalnej w rozumieniu art. 3 pkt 20 rozporządzenia Parlamentu Europejskiego i Rady (WE) nr 1107/2009 z dnia 21 października 2009 r. dotyczącego wprowadzania do obrotu środków ochrony roślin i uchylającego dyrektywy Rady 79/117/EWG i 91/414/EWG (Dz.Urz. UE L 309 z 24.11.2009 r., str. 1 z późn. zm.).

Mając na uwadze powyższe, postanowiono jak w rozstrzygnięciu decyzji.

Pouczenie

Od niniejszej decyzji odwołanie nie przysługuje. Jednakże strona niezadowolona z decyzji może zwrócić się do Głównego Inspektora Ochrony Roślin i Nasiennictwa z wnioskiem o ponowne rozpatrzenie sprawy w terminie 14 dni od dnia doręczenia decyzji, zgodnie z art. 127 § 3 Kodeksu postępowania administracyjnego.

Pobrano opłatę skarbową zgodnie z częścią I ust. 36c załącznika do ustawy z dnia 16 listopada 2006 r. o opłacie skarbowej (Dz.U. z 2012 r. poz. 1282 z późn. zm.) w wysokości 1000 zł.

Małgorzata Kukula – gł. specjalista w Głównym Inspektoracie Ochrony Roślin i Nasiennictwa

Otrzymują:

- 1) SynTech Research Poland Sp. z o.o.
ul. Jagiellońska 69/1
85-027 Bydgoszcz
- 1) a/a



Z-ca GŁÓWNEGO INSPEKTORA

up. Wivade
Dariusz Wiraszka

Test facility	Address	Certificate (Yes or No)
Latvian Plant Protection Rese- arch Center Ltd	Struktoru iela 14a Rīga LV-1039 LATVIA	YES



Valsts augu aizsardzības dienests

SERTIFIKĀTS

Nr. 20

Izsniegts: **SIA „Latvijas Augu aizsardzības pētniecības centrs”**
(komersanta nosaukums, reģistrācijas numurs, juridiskā adrese)

Reģ. Nr. 40003033658

Struktoru iela 14a, Rīga, LV- 1039

par tiesībām veikt normatīvajos aktos par augu aizsardzības līdzekļu reģistrāciju noteiktos
efektivitātes pārbaudes izmēģinājumus:

Lauks- graudaugi -herbicīdi, kodnes, fungicīdi, insekticīdi; **lauks- kartupeļi**- kodnes, herbicīdi, fungicīdi, insekticīdi; **lauks- dārzeņi**- fungicīdi; **lauks- rapsis**- kodnes, herbicīdi, fungicīdi, insekticīdi, limacīdi; **lauks- pākšaugi**- fungicīdi, limacīdi; **lauks- neluksaimnieciska rakstura platības**- herbicīdi; **lauks- lopbarības augi**- fungicīdi, herbicīdi; **siltumnīca- dārzeņi**- insekticīdi; **auglaugu stādījumi- augļu koki**- fungicīdi, insekticīdi.

Sertifikāts izsniegts: 28.09.2016.
(datums)

Sertifikāts derīgs līdz: 27.09.2021.
(datums)

Valsts augu aizsardzības dienests
Augu aizsardzības līdzekļu
reģistrācijas daļas vadītāja
(amats, paraksts un tā atšifrējums)

R.Čūdere



South-Eastern EPPO zone

Test facility	Address	Certificate (Yes or No)
STAPHYT Station	Kecskemet KECSKEMET HUNGARY	YES
STAPHYT	Ul. 5-ta., No 54, Stopanski dvor. 4212 Zlatitrap Plovdiv district BULGARIA	YES
SynTech Research Hungary Kft.	Török Ignac u.30 9700 Szombathely HUNGARY	YES (2016)
ANADIAG HUNGARY Kft	H2921, Komarom, Petofi Sandor 67 HUNGARY	YES
ANADIAG ROMANIA SRL	Piata Montreal no. 10 World Trade Centre 011469, Bucharest ROMANIA	YES
ANADIAG Bulgaria Ltd	Bul. Vasil levskiN244 4000 Plovdiv BULGARIA	YES
SynTech Research Agrico SRL	Str. Marchus Aurelius NR.6 Arad, Jud. ARAD 310209 ROMANIA	YES
GEMERPRODUKT VALICE OVD	Okružná 3771/116, 979 01 Rimavská Sobota SLOVAKIA	YES
SynTech Research Hungary Kft.	Török Ignac u.30 Szombathely HUNGARY	YES (2020)

Test facility	Address	Certificate (Yes or No)
STAPHYT Station	Kecskemet KECSKEMET HUNGARY	YES



PEST MEGYEI
KORMÁNYHIVATAL

Ügyirat-szám: PE/NT/0045-7/2018

Ügyintéző: Dr. Cs. Tóth Attila

Telefon: 06-1/236-3926

E-mail: cs.totha@pest.gov.hu

Tárgy: Staphyt Hungary Kft. (5000

Szolnok, Piroskai u. 2.)

vizsgálóhelyének GEP tanúsítása

Melléklet:-

A Pest Megyei Kormányhivatal (továbbiakban: engedélyező hatóság) a Staphyt Hungary Kft. (székhely: 5000 Szolnok, Piroskai u. 2., a továbbiakban: Ügyfél) vizsgálóhelyének Helyes Kísérleti Gyakorlat (továbbiakban: GEP) szerinti inspekciója és elismerése iránti kérelme alapján indult elsőfokú eljárásban meghozta az alábbi

H A T Á R O Z A T O T :

Engedélyezési célú biológiai hatásvizsgálatok végzéséhez az Ügyfél vizsgálóhelyének GEP-minősítését kiadom.

A GEP-minősítés 5 évig érvényes határozatom jogerőre emelkedésétől számítva.

A vizsgálóhely GEP-minősítés az alábbi minősítési kategóriákra és művelési ágakra kerül kiadásra:

- **minősítési kategória:** herbicidek, fungicidek és baktericidek, zoocidok, növekedésszabályozó és terménynövelő készítmények, adalékanyagok
- **művelési ág:** szántóföld, zöldség, gyümölcs, szőlő, dísznövény, erdő, közterület és egyéb (rezisztencia, dózis vizsgálat, talajfertőtlenítő szerek)

Jelen minősítés nem érinti a működéssel/tevékenység folytatásával kapcsolatos egyéb jogszabályban előírt engedélyeket, illetve Ügyfélnek azok beszerzésére vonatkozó kötelezettségét.

Az Ügyfél a vizsgálóhelyeinek minősített tevékenységét érintő jelentős változásról 15 napon belül köteles értesíteni az engedélyező hatóságot.

A GEP-minősítéssel kapcsolatos jogszabályokban és a jelen határozatban foglaltak betartását hatóságom szűrőpróbaszerűen ellenőrzi. Amennyiben az ellenőrzés során megállapítást nyer, hogy a vizsgálóhely nem tartja be a rá vonatkozó GEP - követelményeket, akkor az engedélyező hatóság a határozatban feltüntetett minősített területre vonatkozó tevékenység végzését legfeljebb 2 hónapra felfüggesztheti, illetve a kiadott GEP-minősítését visszavonhatja.

Ha az ellenőrzés során egy adott kísérlettel kapcsolatban hiányosságok kerülnek megállapításra, a kísérletet a hiányosságok mértékétől függően az engedélyező hatóság kizárhatja az engedélyezésnél elfogadhatók közül.

A vizsgálóhely GEP szerinti inspekciója és elismerése eljárás díjköteles, amely a Nemzeti Élelmiszerlánc-biztonsági Hivatal, valamint a megyei kormányhivatalok mezőgazdasági szakigazgatási szervei előtt kezdeményezett eljárásokban fizetendő igazgatási szolgáltatási díjak mértékéről, valamint az igazgatási szolgáltatási díj fizetésének szabályairól szóló 63/2012. (VII. 2.) VM rendelet 1. sz. mellékletének 8.19.2. pontja szerint: **250.000.- Ft, amelyet az Ügyfél megfizetett.**

Élelmiszerlánc- biztonsági, Földhivatali, Növény- és Talajvédelmi, Erdészeti Főosztály

Cím: 1135 Budapest, Lehel u. 43-47.;

Telefon: 06-1/236-3034 Fax: 06-1/350-6117

E-mail: pmkh-nto@pest.gov.hu Honlap: www.kormanyhivatal.hu/hu/pest

Jelen határozat ellen közigazgatási per indítható a Fővárosi Közigazgatási és Munkaügyi Bíróságnál a határozatot hozó Élelmiszerlánc-biztonsági Földhivatali, Növény- és Talajvédelmi, Erdészeti Főosztály Növény- és Talajvédelmi Osztály elleni kereset indításával. A keresetlevelet a felülvizsgálni kért határozat közlésétől számított harminc napon belül, az engedélyező hatósághoz elektronikus úton kell benyújtani.

INDOKOLÁS

Az Ügyfél 2018. január 17-én érkezett levelében vizsgálóhelyének GEP szerinti minősítésének felülvizsgálatát és a minősítés megújítását kérte a Pest Megyei Kormányhivatal, Élelmiszerlánc-biztonsági, Földhivatali, Növény- és Talajvédelmi Erdészeti Főosztály, Növény- és Talajvédelmi Osztályától.

Az engedélyező hatóság 2018. március 8-án az Ügyfél székhelyén helyszíni ellenőrzést tartott, amelyeknek megállapításait a PE/NT/0045-3/2018. számú jegyzőkönyvben rögzítette.

A helyszíni ellenőrzés során az engedélyező hatóság megállapította, hogy a növényvédő szerek forgalomba hozatalának és felhasználásának engedélyezéséről, valamint a növényvédő szerek csomagolásáról, jelöléséről, tárolásáról és szállításáról szóló 99/2004. (V. 15.) FVM rendelet (továbbiakban: Rendelet) 22. §-ban foglalt biológiai hatásvizsgálatokkal kapcsolatos előírásoknak a vizsgálóhely nem felelt meg hiánytalanul, és az ügyfelet a PE/NT/0045-5/2018. számú végzésben a hiányosságok megszüntetésére szólította fel.

Az Ügyfél a hiányosságokat megszüntette és annak bizonyításáról szóló dokumentációt az engedélyező hatóságnak 2018. április 30-án megküldte.

A fentiek alapján megállapítottam, hogy a GEP-minősítés megadásának feltételei teljesültek, ennek megfelelően döntöttem a rendelkező részben foglaltak szerint.

A Rendelet 22. §-a értelmében „(5) Kérelem alapján az engedélyező hatóság helyszíni ellenőrzést folytat le a vizsgálóhelyen, majd határozatban dönt a vizsgálóhely GEP-minősítéséről. A határozatnak ki kell terjednie arra, hogy a vizsgálóhely milyen kategóriákra, illetve művelési ágakra szerezte meg a GEP-minősítést.

(6) A GEP-minősítés érvényességi ideje első tanúsítás esetén 2 év, a tanúsítás megújítását követően legfeljebb 5 év.

(7) A GEP-minősítési eljárásért a külön jogszabályban meghatározott díjat kell fizetni

(8) A GEP-minősítéssel rendelkező vizsgálóhely minden, a minősített tevékenységét érintő jelentős változásról 15 napon belül köteles értesíteni az engedélyező hatóságot.

(9) Az engedélyező hatóság szűrőpróbaszerűen ellenőrzi a GEP-minősítéssel rendelkező vizsgálóhelyeket. Amennyiben megállapítást nyer, hogy a vizsgálóhely nem tartja be a rá vonatkozó GEP-követelményeket, a hatóság a határozatban feltüntetett minősített területre vonatkozó tevékenységet legfeljebb 2 hónapra felfüggesztheti, illetve a kiadott GEP-minősítést visszavonhatja. Ha az ellenőrzés során egy adott kísérlettel kapcsolatban hiányosságok kerülnek megállapításra, a kísérletet a hiányosságok mértékétől függően az engedélyező hatóság kizárhatja az engedélyezésnél elfogadhatók közül.”

Az engedélyező hatóság a határozatát a földművelésügyi hatósági és igazgatási feladatokat ellátó szervek kijelöléséről szóló 383/2016. (XII.2.) Kormányrendelet 19. § a) pontjában és az élelmiszerláncról és hatósági felügyeletéről szóló 2008. évi XLVI. törvény 33. § e) pontjában

biztosított jogkörében, valamint a központi hivatalok felülvizsgálatával és a járási (fővárosi kerületi) hivatalok megerősítésével összefüggő egyes törvények módosításáról, valamint egyes költségvetési szervek feladatainak átadásáról szóló 2016. évi CIV. törvény 136. §. (1) bekezdésében foglaltaknak megfelelően hozta.

Határozatomat az *általános közigazgatási rendtartásról* szóló 2016. évi CL. törvény (a továbbiakban: Ákr.) 80. § (1) bekezdésének és 81. § (1) és (4) bekezdésének megfelelően adtam ki.

A jelen határozat elleni fellebbezés lehetősége az Ákr. 114. § (1) bekezdése alapján került kizárásra. A bírósági felülvizsgálat lehetőségéről szóló tájékoztatás a közigazgatási perrendtartásról szóló 2017. évi I. törvény 13. § (1), 38.§ (1), 39. § (1) bekezdésein alapul.

Budapest, 2018. május 14.

Dr. Tarnai Richárd kormány megbízott
névében és megbízásából

Tóth Ágoston
osztályvezető

A határozatot kapiák:

1. Ügyfél
2. Irattár

Test facility	Address	Certificate (Yes or No)
STAPHYT	Ul. 5-ta., No 54, Stopanski dvor. 4212 Zlatitrap Plovdiv district BULGARIA	YES

 **РЕПУБЛИКА БЪЛГАРИЯ**
Министерство на земеделието, храните и горите
Българска агенция по безопасност на храните

СЕРТИФИКАТ
№007
София, 20.10.2017 г.

На основание чл. 75 от Закона за защита на растенията и чл. 23 от Наредба № 19 от 8 ноември 2016 г. за биологично изпитване на продукти за растителна защита (обн., ДВ, бр.90 от 15.11.2016 г.) и Заповед № РД 11-1967 от 06.10.2017 г. на изпълнителния директор на Българската агенция по безопасност на храните

ИЗДАВАМ:

настоящия сертификат, в уверение на това, че база „Стафит България“ ЕООД със седалище и адрес на управление: гр. София 1303, обл. София, община Столична, район Възраждане, бул. „Александър Стамболийски“ № 84-86, ет. 2, ап.4 с ЕИК:204461025 с места за изпитване: град Добрич 9300, кв. „Рилци“, стопанския двор и село Златитрап 4208, община „Родопи“, Пловдивска област, стопанския двор одобрена за извършване на биологично изпитване на продукти за растителна защита на територията на Република България за следните групи култури:

1. Полски култури
2. Трайни насаждения
3. Зеленчукови култури

Сертификатът удостоверява осигурено качество при провеждане на опити за ефикасност на продукти за растителна защита, съответстващо на Добрата експериментална практика и стандартите за изпитване за ефикасност на ПРЗ, определени от Европейската и средиземноморската организация по растителна защита (EPPO).

Сертификатът е валиден до 06.10.2027 г.

Д-Р ДАМЯН ИЛНЕВ
Изпълнителен директор на
Българската агенция по безопасност на храните



Test facility	Address	Certificate (Yes or No)
SynTech Re- search Hungary Kft.	Török Ignác u.30 Szombathely HUNGARY	YES



n é b i h
Termőföldtől az asztalig

National Food Chain Safety Office
Directorate of Plant Protection, Soil Conservation
and Agri-environment



H-1118 Budapest, Budabörsi út 141-145.
Hungary
Tel: 36/1/309-1009 Fax: 36/1/246-2942
E-mail: nti@nebih.gov.hu
www.nebih.gov.hu

Your ref.: -

Our ref.: 04.2/4838-7/2016

15 August 2016

Subject: Certificate of Official Recognition of Efficacy Testing Facilities or Organisations in Hungary

Having received the application submitted by **the SynTech Research Hungary Kft. (H-9700 Szombathely, Török Ignác u. 30, Hungary), the client**, for completing a certification procedure of first instance concerning the Official Recognition of Efficacy Testing Facilities/Organisations, i.e. Good Experimental Practices (*hereinafter: GEP*), I, acting as the food chain control body, has made the following

DECISION:

I issue the client's GEP certificate for its premises at Szombathely, Török Ignác u. 30 for carrying out efficacy trials for authorisation purposes. The GEP certificate is effective for 5 years from the entry into force of this Decision.

The client's GEP certificate is given for the following categories of products and cultivation:

- **product categories:** herbicides, fungicides and bactericides, zoocides, growth regulators and yield enhancing substances, additives;
- **cultivation categories:** field crops, vegetables, fruits, grapevines, ornamentals, forest, others.

I inform you that the present certification is without prejudice to either the licences concerning the operation/follow-up of activity laid down in other provisions of legislation or the client's obligation for obtaining them.

The client is obliged to notify the competent authority, within 15 days, of any important changes concerning the certified activity of the testing facility.

I call your attention that respect of the provisions laid down in the legislation on GEP certification and in this Decision shall be randomly controlled by my competent authority. If during the official inspection it is stated that the testing facility does not meet the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate.

If during the official inspection it is found that some details are missing in relation to a particular trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization.

The fee of the present procedure is 250.000 HUF (i.e. two hundred and fifty thousand Hungarian Forints) paid by the client.

No further complaint shall be lodged against the present Decision, effective by its publication, through state administration, though with reference to infringement of law, judicial review of the Decision may be requested at the Capital Administrative and Employment Court. The claim note shall be submitted to my competent authority within 30 days of the communication of the Decision.

I inform you that the court shall judge the case out of court, but shall carry on a lawsuit at the request of any of the parties. The client may ask for carrying on a lawsuit, but in default of so doing, no verification is accepted. Submission of the claim note has no delaying force on the implementation of this Decision.

J U S T I F I C A T I O N

In its application of 7 July 2016, the client submitted an application to the competent authority for a procedure of GEP certification.

As a follow-up to this application, the competent authority made a local inspection at the client's facility of Szombathely, Török Ignác u. 30 on 12 July 2016. Statements made during the local inspection are reported in the protocol Nr. 04.2/4838-4/2016. Based on the results of the local inspection the competent authority concluded that the client's testing facility does not meet the requirements concerning the efficacy trials specified in Article 22 of the Decree 89/2004 (V. 15.) FVM on the authorization of placing on the market and use, as well as on the packaging, labelling, storage and transport of plant protection products (hereinafter: Decree 89/2004) and in the Decision Nr. 04.2/4838-5/2016 it calls the client to fill the data gaps.

Article 22(5) of Decree 89/23004 - Based on request, the competent authority shall make local inspections at the testing facility and decide on the GEP qualification of the testing facility. The decision shall include the product categories and the cultivation categories for which the testing facility obtained the GEP-certificate.

(6) The validity of GEP-certification is 2 years in case of the first request and maximum 5 years in case of renewal of the certification.

(7) A fee laid down in specific legislation shall be paid for the GEP-certification procedure.

(8) The testing facility having GEP-certification shall notify the competent authority, within 15 days, about any important changes concerning the certified activity of the testing facility.

(9) The competent authority shall randomly control the testing facility having GEP-certification. If it is found that the testing facility does not meet the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate. If during the official inspection it is established that some details are missing in relation to a trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization."

Client filled the missing data gaps and reported on it in the letter of 12 August 2016, therefore I made the Decision as specified in the first part. Therefore I stated that conditions for issuing the certificate specified above are met, so I made the Decision as specified in the first part.

The fee of the present procedure is HUF 250.000 and was established in accordance with point 8.19.2 of Annex I to the Decree 63/2012. (VII. 2.) VM on the extent of administrative servicing fees due for the procedures by the agricultural administrative bodies of the National Food Chain Safety Office and the county government offices and on the rules of paying the administrative servicing fees. The client paid the fee.



I made this Decision within my jurisdiction laid down in Article 3 paragraph (1) and Article 5 point c) of Government Decree 22/2012. (II. 29.) concerning the National Food Chain Safety Office, Article 3, Article 22 paragraph (1) of Decree 89/2004 and in compliance with Articles 71 paragraph (1) and Article 72 paragraph (1) of Act CXL of 2004 on general rules of administrative official procedure and service (hereinafter: Act CXL of 2004).

I excluded the possibility of appeal in compliance with Article 100 paragraph (1) point e) of Act CXL of 2004 and provided the possibility of judicial review in compliance with Article 109 paragraph (1) of Act CXL of 2004 and Article 330 paragraph (2) of Act III of 1952 on Civil Procedure.

on behalf of
dr. Márton Oravecz
president

László Jordán SS.
director

Test facility	Address	Certificate (Yes or No)
ANADIAG HUNGARY Kft	H2921, Komárom, Petöfi Sándor 67 HUNGARY	YES

	n é b i h Termőföldtől az asztalig	National Food Chain Safety Office Directorate of Plant Protection, Soil Conservation and Agri-environment		H-1118 Budapest, Budaörsi út 141-145. Hungary Tel: 36/1/309-1000 Fax: 36/1/246-2942 E-mail: nt@nebih.gov.hu www.nebih.gov.hu
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Your ref.: -

Our ref.: 04.2/6149-7/2016

7 October 2016

Subject: Certificate of Official Recognition of Efficacy Testing Facilities or Organisations in Hungary

Having received the application submitted by the **Anadiag Hungary Mezőgazdasági Szolgáltató Kft. (H-2921 Komárom, Petöfi Sándor út 67, Hungary)**, the client, for completing a certification procedure of first instance concerning the Official Recognition of Efficacy Testing Facilities/Organisations, i.e. Good Experimental Practices (*hereinafter*: GEP), I, acting as the food chain control body, has made the following

D E C I S I O N :

I issue the client's GEP certificate for its premises at Komárom, Petöfi Sándor út 67 for carrying out efficacy trials for authorisation purposes. The GEP certificate is effective for 5 years from the entry into force of this Decision.

The client's GEP certificate is given for the following categories of products and cultivation:

- product categories:** herbicides, fungicides and bactericides, zoocides, growth regulators and yield enhancing substances, additives;
- cultivation categories:** field crops, vegetables, fruits, grapevines, ornamentals, others.

I inform you that the present certification is without prejudice to either the licences concerning the operation/follow-up of activity laid down in other provisions of legislation or the client's obligation for obtaining them.

The client is obliged to notify the competent authority, within 15 days, of any important changes concerning the certified activity of the testing facility.

I call your attention that respect of the provisions laid down in the legislation on GEP certification and in this Decision shall be randomly controlled by my competent authority. If during the official inspection it is stated that the testing facility does not meet the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate.

If during the official inspection it is found that some details are missing in relation to a particular trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization.

The fee of the present procedure is 250.000 HUF (i.e. two hundred and fifty thousand Hungarian Forints) paid by the client.

No further complaint shall be lodged against the present Decision, effective by its publication, through state administration, though with reference to infringement of law, judicial review of the Decision may be requested at the Capital Administrative and Employment Court. The claim note shall be submitted to my competent authority within 30 days of the communication of the Decision.

I inform you that the court shall judge the case out of court, but shall carry on a lawsuit at the request of any of the parties. The client may ask for carrying on a lawsuit, but in default of so doing, no verification is accepted. Submission of the claim note has no delaying force on the implementation of this Decision.

J U S T I F I C A T I O N

In its application of 29 August 2016, the client submitted an application to the competent authority for a procedure of GEP certification.

As a follow-up to this application, the competent authority made a local inspection at the client's facility of Komárom, Petőfi Sándor út 67 on 31 August 2016. Statements made during the local inspection are reported in the protocol Nr. 04.2/6149-4/2016. Based on the results of the local inspection the competent authority concluded that the client's testing facility does not meet the requirements concerning the efficacy trials specified in Article 22 of the Decree 89/2004 (V. 15.) FVM on the authorization of placing on the market and use, as well as on the packaging, labelling, storage and transport of plant protection products (hereinafter: Decree 89/2004) and in the Decision Nr. 04.2/6149-5/2016 it calls the client to fill the data gaps.

Article 22(5) of Decree 89/23004 - Based on request, the competent authority shall make local inspections at the testing facility and decide on the GEP qualification of the testing facility. The decision shall include the product categories and the cultivation categories for which the testing facility obtained the GEP-certificate.

(6) The validity of GEP-certification is 2 years in case of the first request and maximum 5 years in case of renewal of the certification.

(7) A fee laid down in specific legislation shall be paid for the GEP-certification procedure.

(8) The testing facility having GEP-certification shall notify the competent authority, within 15 days, about any important changes concerning the certified activity of the testing facility.

(9) The competent authority shall randomly control the testing facility having GEP-certification. If it is found that the testing facility does not meet the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate. If during the official inspection it is established that some details are missing in relation to a trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization."


Client filled the missing data gaps and reported on it in the letter of 20 September 2016, therefore I made the Decision as specified in the first part. Therefore I stated that conditions for issuing the certificate specified above are met, so I made the Decision as specified in the first part.

The fee of the present procedure is HUF 250.000 and was established in accordance with point 8.19.2 of Annex 1 to the Decree 63/2012. (VII. 2.) VM on the extent of administrative servicing fees due for the procedures by the agricultural administrative bodies of the National Food Chain Safety Office and the county government offices and on the rules of paying the administrative servicing fees. The client paid the fee.

I made this Decision within my jurisdiction laid down in Article 3 paragraph (1) and Article 5 point c) of Government Decree 22/2012. (II. 29.) concerning the National Food Chain Safety Office, Article 3, Article 22 paragraph (1) of Decree 89/2004 and in compliance with Articles 71 paragraph (1) and Article 72 paragraph (1) of Act CXL of 2004 on general rules of administrative official procedure and service (hereinafter: Act CXL of 2004).

I excluded the possibility of appeal in compliance with Article 100 paragraph (1) point e) of Act CXL of 2004 and provided the possibility of judicial review in compliance with Article 109 paragraph (1) of Act CXL of 2004 and Article 330 paragraph (2) of Act III of 1952 on Civil Procedure.

on behalf of
dr. Márton Oravecz
president


László Jordán
director

Test facility	Address	Certificate (Yes or No)
ANADIAG ROMANIA SRL	Piata Montreal no. 10 World Trade Centre 011469, Bucharest ROMANIA	YES

MINISTERUL AGRICULTURII ȘI DEZVOLTĂRII RURALE	MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT
Autoritatea Națională Fitosanitară	National Phytosanitary Authority
Comisia Națională de Omologare a Produselor de Protecție a Plantelor	National Commission for Registration of Plant Protection Products

Certificat de recunoaștere oficială a testelor de eficacitate biologică în conformitate cu bunele practici experimentale/Certificate of official recognition of the efficacy biological tests according to the good experimental practices

Se acordă: SC ANADIAG ROMANIA SRL
It is granted to: SC ANADIAG ROMANIA SRL
cu sediul: Str. Gen. C. Budisteanu, nr.28-C;010775, Bucuresti
with headquarter: Gen. C. Budisteanu Street, no. 28-C, 010775, Bucharest
pentru domeniul/
domeniile de activitate: Culturi agricole de câmp si pajisti; Pomicultură;
Viticultură; Legumicultură; Floricultură; Silvicultură; Plante ornamentale și de interior; Zone non agricole
for the domain/
domains of activity: Crops fields and meadows; Fruit tree growing; Viticulture;
Vegetable crops; Floriculture; Aromatic and medicinal plants; Ornamental and indoor plants; Silviculture; Non agricultural zones

Prezentul certificat se eliberează în conformitate cu prevederile Ordinului ministrului agriculturii și dezvoltării rurale, al ministrului sănătății și al ministrului mediului și schimbărilor climatice nr.60/512/1258/2013 și prevederile Procedurii naționale de omologare a produselor de protecție a plantelor care conțin substanțe active notificate și pentru care nu s-a luat încă o decizie de includere în lista cu substanțe active autorizate în Uniunea Europeană, aprobată prin Ordinul ministrului agriculturii,

pădurilor și dezvoltării rurale, al ministrului sănătății și al ministrului mediului și gospodăririi apelor nr.134/197/412/2006, cu modificările și completările ulterioare.

This certificate is issued according to the provisions of the Order of the ministry of agriculture and rural development, of the ministry of health and of the ministry of environment and climate change no.60/512/1258/2013 and the provisions of the National Procedure for Registration of Plant Protection Products which contain notified active substances and for which isn't taken yet a decision for inclusion in European Union list of authorised active substances, approved by the Order of the ministry of agriculture, forests and rural development, of the ministry of health and of the ministry of environment and waters husbandry no.134/197/412/2006, with subsequent amendments and completions.

Data emiterii certificatului: 20.08.2015

Issuance date of the certificate

Data expirării certificatului: 20.08.2020

Expiry date of the certificate

PREȘEDINTE/CHAIRMAN,

Elena LEAOTA



Test facility	Address	Certificate (Yes or No)
ANADIAG Bulgaria Ltd	Bul. Vasil levskiN244 4000 Plovdiv BULGARIA	YES



РЕПУБЛИКА БЪЛГАРИЯ
Министерство на земеделието, храните и горите
Българска агенция по безопасност на храните

СЕРТИФИКАТ

№003

Издание: 3/29.11.2018г.

София, 29.11.2018г.

На основание чл. 75 от Закона за защита на растенията и чл. 23 от Наредба № 19 от 8 ноември 2016 г. за биологично изпитване на продукти за растителна защита (обн., ДВ. бр. 90 от 15.11.2016 г.) и Заповед № РД 11-2394 от 26.11.2018 г. на изпълнителния директор на Българската агенция по безопасност на храните

ИЗДАВАМ:

настоящия сертификат, в уверение на това, че база „Анадиаг България“ ЕООД със седалище и адрес на управление: град София 1142, бул. „Патриарх Евтимий“ № 21, вх. В, ет. 3, ап. 52 с ЕИК: 202022346 с места за изпитване: гр. Пловдив 4000, ул. „Васил Левски“ № 244 (зад сградата на Агроцентър) и гр. Плевен 5800, местност „Чаира“, ул. „Чаталджа“ № 59 е одобрена за извършване на биологично изпитване на продукти за растителна защита на територията на Република България за следните групи култури:

1. Полски култури
2. Трайни насаждение
3. Зеленчукови култури
4. Оранжерийни култури

Сертификатът удостоверява осигурено качество при провеждане на опити за ефикасност на продукти за растителна защита, съответстващо на Добрата експериментална практика и стандартите за изпитване за ефикасност на ПРЗ, определени от Европейската и средиземноморската организация по растителна защита (EPPO).

Сертификатът е валиден до 26.11.2028 г.

Д-Р ДАМЯН ИЛИЕВ

Изпълнителен директор на
Българската агенция по безопасност на храните



Test facility	Address	Certificate (Yes or No)
SynTech Research Agrico SRL	Str. Marchus Aurelius NR.6 Arad, Jud. ARAD 310209 ROMANIA	YES

MINISTERUL AGRICULTURII ȘI DEZVOLTĂRII RURALE Autoritatea Națională Fitosanitară Comisia Națională de Omologare a Produselor de Protecție a Plantelor	MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT National Phytosanitary Authority National Commission for Registration of Plant Protection Products
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Nr.inreg. 34/F/09.01.2018

Certificat de recunoaștere oficială a testelor de eficacitate biologică
în conformitate cu bunele practici experimentale / Certificate of official
recognition of the efficacy biological tests according to the good
experimental practices

Se acordă: **SC SYNTECH RESEARCH AGRICO SRL**
It is granted to: **SC SYNTECH RESEARCH AGRICO SRL**
cu sediul: **Strada Marcus Aurelius, nr. 6, cod postal 310209, Arad, judetul Arad**
with headquarters: **Marcus Aurelius street, no. 6, postal code 310209, Arad, Arad county**

domeniile de activitate: culturi agricole de câmp și pajiști, pomicultură, viticultură, legumicultură, floricultură, plante ornamentale și de interior
domains of activity: Crops fields and meadows, fruit growing, viticulture, vegetable growing, floriculture, ornamental and indoor plants


Prezentul certificat se eliberează în conformitate cu prevederile Ordinului ministrului agriculturii și dezvoltării rurale, al ministrului sănătății și al ministrului mediului și schimbărilor climatice nr. 60/512/1258/2013 și prevederile Procedurii naționale de omologare a produselor de protecție a plantelor care conțin substanțe active notificate și pentru care nu s-a luat încă o decizie de includere în lista cu substanțe active autorizate în Uniunea Europeană, aprobată prin ordinul ministrului agriculturii, pădurilor și dezvoltării rurale, al ministrului sănătății și al ministrului mediului și gospodăririi apelor nr. 134/197/412/2006, cu modificările și completările ulterioare.

This certificate is issued according to the provisions of the Order of the ministry of agriculture and rural development, of the ministry of health and of the ministry of environment and climate change no. 60/512/1258/2013 and the provisions of the National Procedure for Registration of Plant Protection Products which contain notified active substances and for which isn't taken yet a decision for inclusion in European Union list of authorized active substances, approved by the Order of the ministry of agriculture, forests and rural development, of the ministry of health and of the ministry of environment and waters husbandry no. 134/197/412/2006, with subsequent amendments and completions.

Data emiterii certificatului: 08.01.2018
Issuance date of the certificate

Data expirării certificatului: 08.01.2022
Expiry date of the certificate

PREȘEDINTE/CHAIRMAN,
Doina BAICULESCU



Test facility	Address	Certificate (Yes or No)
GE-MERPRODUKT VALICE OVD	Okružná 3771/116, 979 01 Rimavská Sobota SLOVAKIA	YES

Central Controlling and Testing Institute in Agriculture in Bratislava
Matúškova 21, 833 16 Bratislava

GEP CERTIFICATE
No. 03/C - 06/2019

issued in accordance with § 28 of the Act No. 405/2011 Coll. on Plant Care, Amending and Supplementing Act of the National Council of the Slovak Republic No. 145/1995 Coll. on Administrative Fees as Amended and § 3 of the Regulation of the Ministry of Agriculture and Rural Development of the Slovak Republic No 486/2011 Coll. laying down details of the conditions, procedures and deadlines to implement the provisions of the tests of biological efficacy, applications, principles of good experimental practice, audits and issuing certificate, extension of the certificate, recertification (hereinafter "Regulation")

for

GEMERPRODUKT VALICE,
ovocinársko-vinohradnícke družstvo
Okružná 3771
979 01 Rimavská Sobota

Identification number: 36059005

which has demonstrated implementation of principles of Good experimental practice (GEP) in accordance with the requirements of the Regulation in the following categories

Categories of crops	Categories of plant protection products and their adverse effects on crops.
cereals	fungicides; fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides; zoocides - seed treatment; growth regulators; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides; zoocides - seed treatment; growth regulators
maize	fungicides; fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides; zoocides - seed treatment; growth regulators; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides; zoocides - seed treatment; growth regulators
legumes	fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides - seed treatment; growth regulators; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides; zoocides - seed treatment; growth regulators
oil plants	fungicides; fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides; zoocides - seed treatment; growth regulators; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides; zoocides - seed treatment; growth regulators
technical plants	fungicides - seed treatment; zoocides - seed treatment; growth regulators; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides; zoocides; zoocides - seed treatment; growth regulators

root crops	fungicides; fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides; zoocides - seed treatment; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides; zoocides - seed treatment
vegetables and root vegetables	fungicides; fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides; zoocides - seed treatment; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides; zoocides - seed treatment
grape, fruit and stocks	fungicides; fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides; zoocides - seed treatment; growth regulators; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides; zoocides - seed treatment; growth regulators

Date of issue: 28.05.2019
Date of expire: 12.04.2021




Ing. Peter Rusňák, PhD.
General Director

This certificate includes also appendix.
By issuing this certificate, certificate No. 03/C-05/2019 expire.

Test facility	Address	Certificate (Yes or No)
SynTech Research Hungary Kft.	Török Ignác u.30 9700 Szombathely HUNGARY	YES

Aláíró: dr. Brandenburg Tamás (2020.04.09. 10:41:45)



PEST MEGYEI
KORMÁNYHIVATAL

Ügyirat-szám: PE/NT/00150-2/2020

Ügyintéző: Tóth Ágoston

Telefon: 06-1/236-4161

Tárgy: **CPR Europe Kft.** vizsgáló-helyének

GEP tanúsítása

Melléklet: -

A **Pest Megyei Kormányhivatal** (a továbbiakban: engedélyező hatóság) **CPR Europe Kft.** (székhely: 9700 Szombathely Török Ignác u. 30. továbbiakban: Ügyfél) vizsgálóhely „Jó Kísérleti Gyakorlat (GEP)” szerinti inspekcója és elismerése tárgyában benyújtott kérelme alapján indult közigazgatási hatósági eljárásban meghozta az alábbi

H A T Á R O Z A T O T :

Engedélyezési célú biológiai hatásvizsgálatok végzéséhez az Ügyfél vizsgálóhelyének GEP-minősítését kiadom.

A GEP - minősítés 2022. szeptember 20.-áig érvényes. Egyúttal visszavonom a PE/NT/00636-14/2017 sz. határozatban szereplő engedélyt.

A vizsgálóhely GEP - minősítés az alábbi minősítési kategóriákra és művelési ágakra kerül kiadásra:

- **minősítési kategória:** herbicidek, fungicidek és baktericidek, zoocidok, növekedésszabályozó és terménynövelő készítmények, adalékanyagok
- **művelési ág:** szántóföld, zöldség, gyümölcs, szőlő, dísznövény, erdő, közterület és egyéb

Jelen minősítés nem érinti a működéssel/tevékenység folytatásával kapcsolatos egyéb jogszabályban előírt engedélyeket, illetve Ügyfélnek azok beszerzésére vonatkozó kötelezettségét.

Az Ügyfél a vizsgálóhelyeinek minősített tevékenységét érintő jelentős változásról 15 napon belül köteles értesíteni az engedélyező hatóságot.

A GEP - minősítéssel kapcsolatos jogszabályokban és a jelen határozatban foglaltak betartását hatóságom szűrőpróbaszerűen ellenőrzi. Amennyiben az ellenőrzés során megállapítást nyer, hogy a vizsgálóhely nem tartja be a rá vonatkozó GEP - követelményeket, akkor az engedélyező hatóság a határozatban feltüntetett minősített területre vonatkozó tevékenység végzését legfeljebb 2 hónapra felfüggesztheti, illetve a kiadott GEP - minősítését visszavonhatja.

Ha az ellenőrzés során egy adott kísérlettel kapcsolatban hiányosságok kerülnek megállapításra, a kísérletet a hiányosságok mértékétől függően az engedélyező hatóság kizárhatja az engedélyezésnél elfogadhatók közül.

A vizsgálóhely GEP szerinti felülvizsgálata és az elismerés meghosszabbítása eljárás díjköteles, amely a Nemzeti Élelmiszerlánc-biztonsági Hivatal, valamint a megyei kormányhivatalok mezőgazdasági szakigazgatási szervei előtt kezdeményezett eljárásokban fizetendő igazgatási

szolgáltatási díjak mértékéről, valamint az igazgatási szolgáltatási díj fizetésének szabályairól szóló 63/2012. (VII. 2.) VM rendelet 1. sz. mellékletének 8.19.2. pontja szerint: 250.000,- Ft, amelyet az Ügyfél megfizetett.

Döntésem közléssel végleges.

Jelen határozat ellen közigazgatási per indítható a Fővárosi Törvényszéknél a határozatot hozó Élelmiszerlánc-biztonsági, Állategészségügyi, Növény- és Talajvédelmi Főosztály Növény- és Talajvédelmi Osztály elleni kereset indításával. A keresetlevelet a felülvizsgálni kért határozat közlésétől számított harminc napon belül, az engedélyező hatósághoz elektronikus úton kell benyújtani.

I N D O K O L Á S

Az Ügyfél az engedélyező hatósághoz 2020. 03. 30.-án kérelmet nyújtott be a PE/NT/00636-14/2017 számú határozat módosítása iránt. Indoklasként cégnév-változást jelölt meg, mely nem érint működési kérdéseket (személyi állomány, tárgyi eszközök, dokumentációkezelés, archiválás). Igazolásként benyújtotta a Szombathelyi Törvényszék Cégbírósága által 2020. 03. 26.-án kiállított Cg. 18-09-106748/101 sz. végzését, melyben a Cégbíróság a névváltozást bejegyezte.

A fentiek alapján megállapítottam, hogy a GEP-minősítés feltételei nem változtak, ennek megfelelően döntöttem a rendelkező részben foglaltak szerint.

A Rendelet 22. §-a értelmében „(5) Kérelem alapján az engedélyező hatóság helyszíni ellenőrzést folytat le a vizsgálóhelyen, majd határozatban dönt a vizsgálóhely GEP-minősítéséről. A határozatnak ki kell terjednie arra, hogy a vizsgálóhely milyen kategóriákra, illetve művelési ágakra szerezte meg a GEP-minősítést.

(6) A GEP-minősítés érvényességi ideje első tanúsítás esetén 2 év, a tanúsítás megújítását követően legfeljebb 5 év.

(7) A GEP-minősítési eljárásért a külön jogszabályban meghatározott díjat kell fizetni.

(8) A GEP-minősítéssel rendelkező vizsgálóhely minden, a minősített tevékenységét érintő jelentős változásról 15 napon belül köteles értesíteni az engedélyező hatóságot.

(9) Az engedélyező hatóság szűrőpróbaszerűen ellenőrzi a GEP-minősítéssel rendelkező vizsgálóhelyeket. Amennyiben megállapítást nyer, hogy a vizsgálóhely nem tartja be a rá vonatkozó GEP-követelményeket, a hatóság a határozatban feltüntetett minősített területre vonatkozó tevékenységet legfeljebb 2 hónapra felfüggesztheti, illetve a kiadott GEP-minősítést visszavonhatja. Ha az ellenőrzés során egy adott kísérlettel kapcsolatban hiányosságok kerülnek megállapításra, a kísérletet a hiányosságok mértékétől függően az engedélyező hatóság kizárhatja az engedélyezésnél elfogadhatók közül.”

Az engedélyező hatóság a határozatát a földművelésügyi hatósági és igazgatási feladatokat ellátó szervek kijelöléséről szóló 383/2016. (XII.2.) Kormányrendelet 19. § a) pontjában és az élelmiszerláncról és hatósági felügyeletéről szóló 2008. évi XLVI. törvény 33. § e) pontjában biztosított jogkörében foglaltaknak megfelelően hozta.

A bírósági felülvizsgálatról és a kereset benyújtásának lehetőségéről és szabályairól az általános közigazgatási rendtartásról szóló 2016. évi CL. törvény (a továbbiakban: Ákr.) 112. § (1)-(2) bekezdése, a 113. § (1) bekezdés a) pontja és 114. §-a, továbbá a közigazgatási perrendtartásról szóló 2017. évi I.

törvény 13. § (1) bekezdése b) pontja, a 28. § (1)-(2) bekezdése, 29. § (1), 38. §-a, 39. §-a, 50. §, 52. §, 77. § 157. §. (1) bekezdése, a bíróságok szervezetéről és igazgatásáról szóló 2011. évi CLXI. törvény 21. § (6) bekezdése, a bíróságok elnevezéséről, székhelyéről és illetékességi területének meghatározásáról szóló 2010. évi CLXXXIV. törvény 4. melléklet 1. pontja, a Polgári perrendtartásról szóló 2016. évi CXXX. törvény 605. §-a, valamint az *elektronikus ügyintézés és a bizalmi szolgáltatások általános szabályairól* szóló 2015. évi CCXXII. törvény 9. § (1) bekezdése rendelkezik.

Budapest, 2020. április 9.

Dr. Tarnai Richárd kormány megbízott
névében és megbízásából

Dr. Brandenburg Tamás
főosztályvezető

1. Ügyfél
2. Irattár

3.7.5 Durum wheat (TRZDU)

Table 3.7-5: List of test facilities - TRZDU

Maritime EPPO zone

Test facility Durum Wheat	Address	Certificate (Yes or No)
ANADIAG France	13, rue de la Bourbre 38300 RUY FRANCE	YES
Quintus GMBH	LIEPEN 7 17194 Hohen Wange- lin OT LIEPEN GERMANY	YES

Test facility	Address	Certificate (Yes or No)
ANADIAG France	13, rue de la Bourbre 38300 RUY FRANCE	YES



MINISTÈRE DE L'AGRICULTURE ET DE L'ALIMENTATION

**DÉCISION D'AGRÈMENT POUR RÉALISER
DES ESSAIS OFFICIELLEMENT RECONNUS**

Conformément à l'article R. 253-38 du code rural et de la pêche maritime et à l'article 6 de l'arrêté du 26 avril 2007 relatif aux essais officiels et officiellement reconnus pour l'évaluation des produits mentionnés à l'article L. 253-1 du code rural et de la pêche maritime,

Vu la convention passée avec le Cofrac n° 4609,

Vu le rapport d'évaluation réalisé par le Cofrac, en date du 27 juillet 2017,

L'agrément pour réaliser des essais officiellement reconnus est renouvelé, à l'organisme :

ANADIAG France
13 rue de la Bourbre
38300 RUY

sous le numéro : **BPE - 105**

ET POUR LE PÉRIMÈTRE SUIVANT :

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
ANADIAG France 13 rue de la Bourbre 38300 RUY (unité centrale)	- Traitement des semences : grandes cultures
UE 01 – Harnes (UE 62) ZI la Motte au Bois 62440 HARNES	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Zones non agricoles
UE 03 – Saint Pierre du Bû (UE 14) Couvrigny 14700 SAINT PIERRE DU BU	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum
UE 03 – Cintré (UE 35) Rue du puisatier ZA du moulin à vent 35310 CINTRE	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Zones non agricoles
UE 06 – Varois et Chaignot (UE 21) 8 route de Gray 21490 VAROIS ET CHAIGNOT	- Grandes cultures - Vigne - Zones non agricoles
UE 08 – Saint Barthélémy (UE 38) 700 route de Pisieu 38270 SAINT BARTHELEMY	- Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
UE 10 – Saint Etienne de Fougères (UE 47) ZA Bel Air 47380 SAINT ETIENNE DE FOUGERES	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles - Désinfections et désinsectisation des sols, des matériels et des locaux de culture et de stockage des végétaux
UE 12– Saint Germain des Prés (UE 49) ZA la Poterie 49170 SAINT GERMAIN DES PRES	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur
UE 13 – Castillon du Gard (UE 30) ZA les codes bas 3 30210 CASTILLON DU GARD	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles
UE 15 – Haguenau (UE 67) 16 rue Ampère 67500 HAGUENAU	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Processus de transformation : <ul style="list-style-type: none"> - Vinification - Transformation de pomme de terre - Transformation de fruits (compote, jus de fruit, nectar, fruit au sirop, confiture, fruits séchés) - Transformation de légumes (jus, concentré de tomates, conserve de légumes, ketchup, choucroute) - Extraction d'huile
UE 16 – Thorée les Pins (UE 72) La Belle Métairie 72800 THOREE LES PINS	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture
UE 17 – Toulouse (UE 31) 75 voie de TOEC Bâtiment entreprise 2 31076 TOULOUSE	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture

Cet agrément est délivré pour une durée de cinq ans à compter du **09/10/2017** jusqu'au **08/10/2022**. En application de l'article 5 de l'arrêté susmentionné, une nouvelle évaluation aura lieu dans un délai compris entre vingt-quatre et trente-six mois à compter du **09/10/2017**.

Date :

03 OCT. 2017

Le sous directeur de la qualité, de la santé
et de la protection des végétaux

Alain TRIDON

Test facility	Address	Certificate (Yes or No)
Quintus GMBH	LIEPEN 7 17194 Hohen Wangelin OT LIEPEN GERMANY	YES

Anerkennungsbescheinigung

Recognition Certificate

Die Versuchseinrichtung	Quintus GmbH	The testing facility
mit Hauptsitz in	Liepen 7 17194 Hohen Wangelin	with headquarter in
und organisatorisch zugehörigen Arbeitseinheiten in	08393 Schönberg Breitenbacher Straße 21 74595 Langenburg- Nesselbach Orlacher Straße 16 27798 Hude Wieselweg 6	and subsidiary testing units in
ist auf Antrag vom	2016-02-01	on application from
und nach durchgeführter Besichtigung durch vom	Herrn Dr. S. Goltermann Landesamt für Landwirtschaft, Lebensmittelsicherheit und Verbraucherschutz MV 2016-04-11	by from
am		on
in den Versuchskategorien	Acker-, Obst-, Gemüse-, Zier- pflanzenbau, Haus- und Kleingarten agriculture, horticulture, home and garden	in the trial categories
als Einrichtung für die Prüfung der Wirksamkeit von Pflanzenschutzmitteln im Sinne des § 8 Abs. 6 der Pflanzenschutzmittelverordnu ng und und gemäß Verordnung (EU) Nr. 284/2013 für 5 Jahre amtlich anerkannt worden.		has been officially recognised as an organisation for efficacy testing facility of plant protection products according to § 8 par. 6 of the Plant Protection Products Ordinance and the Commission Regulation (EU) No 284/2013 for 5 years.

11.04.2016 
Datum date
Unterschrift signature
Landesamt für Landwirtschaft,
Lebensmittelsicherheit und
Verbraucherschutz MV,
Thierfelderstr. 18, 18059 Rostock
Adresse der anerkennenden Behörde
address of the recognising authority



Mediterranean EPPO zone

Test facility Durum Wheat	Address	Certificate (Yes or No)
STAPHYT Agricultura y Ensayo S.L. Sucursal em Portugal	Rua Dr. Oscar da Costa Neves, n°2 Almeirim 2080-130 PORTUGAL	YES
ANADIAG ITA- LIA SRL	Strada Savonesa 9 15057 Tortona ITALY	YES

Test facility	Address	Certificate (Yes or No)
STAPHYT Agricultura y Ensayo S.L. Sucursal em Portugal	Rua Dr. Oscar da Costa Neves, nº2 Almeirim 2080-130 PORTUGAL	YES



ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

STAPHYT s.r.o.
Měnin 569
664 57 Měnin

Útvar: Odbor přípravků na ochranu rostlin
Adresa: Zemědělská 1a, 613 00 Brno

Sp.zn: SZ UKZUZ 032225/2016/06857 Č.j.: UKZUZ 057138/2016 Datum: 18. 5. 2016
Vyřizuje: ing. Minářová Tel.: 545 110 444 E-mail: ivana.minarova@ukzuz.cz

ROZHODNUTÍ

Ústřední kontrolní a zkušební ústav zemědělský (dále jen „ÚKZÚZ“), Hroznová 2, 656 06 Brno, jako věcně příslušný správní orgán podle § 72 odst. 1 písm. c) zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, ve znění pozdějších předpisů (dále jen „zákon“) a v návaznosti na čl. 54 odst. 4 Nařízení Evropského parlamentu a Rady (ES) č. 1107/2009, o uvádění přípravků na ochranu rostlin na trh a o zrušení směrnic Rady 79/117/EHS a 91/414/EHS, v platném znění, v provedení § 45 odst. 1 zákona, v řízení o způsobilosti k provádění pokusů a zkoušek s přípravky nebo dalšími prostředky na základě žádosti společnosti **STAPHYT s.r.o.**, Měnin 569, 664 57 Měnin, IČ 29210917 dále jen „společnost STAPHYT s.r.o.“ a to:

žádosti o prodloužení platnosti rozhodnutí o způsobilosti k provádění zkoušek podle § 45 odst. 1 zákona ze dne 24. 3. 2016, doručené ÚKZÚZ dne 24. 3. 2016, č.j. UKZUZ 032225/2016

rozhodl takto:

společnost STAPHYT s.r.o. je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe.

právnícká osoba: **STAPHYT s.r.o.**

sídlo právnické osoby: Měnin 569, 664 57 Měnin

IČ právnické osoby: 29210917

GEP kód: **GEP/SHT/2016**

oblasti zkoušení: **polní plodiny a zelenina**
trvalé kultury
skleníky a jiné kryté prostory
moření osiva

rozhodnutí se vydává s účinností od 1. 9. 2016

dobu účinnosti rozhodnutí: 5 let

Tímto rozhodnutím se k datu nabytí jeho účinnosti zrušuje rozhodnutí č.j. SRS 026758/2010 ze dne 2. 7. 2010.

Odůvodnění:

Řízení ve věci uznání osoby za způsobilou provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe bylo zahájeno na základě žádosti ze dne 24. 3. 2016, doručené UKZÚZ dne 24. 3. 2016.

Rozhodnutí o způsobilosti k provádění pokusů a zkoušek v souladu s požadavky správné pokusnické praxe bylo vydáno na základě kontroly předložené dokumentace pracoviště STAPHYT s.r.o., Příručky jakosti, Standardních operačních postupů a Metrologického řádu, kterou bylo UKZÚZ prokázáno, že žadatel splnil požadavky stanovené v § 45 odst. 12 a 13 zákona v návaznosti na § 4 odst. 2 vyhlášky č. 32/2012 Sb., o přípravcích a dalších prostředcích na ochranu rostlin, ve znění pozdějších předpisů.

Vzhledem k výše uvedeným skutečnostem bylo rozhodnuto tak, jak je stanoveno ve výrokové části tohoto rozhodnutí.

Správný poplatek podle zákona č. 634/2004 Sb., o správních poplatcích, ve znění pozdějších předpisů, podle Sazebníku, Položky 86 písm. b) „Přijetí žádosti o vydání osvědčení o způsobilosti k provádění zkoušek pro účely povolení“ ve výši 100,- Kč, k žádosti doručené UKZÚZ dne 24. 3. 2016, č.j. UKZUZ 032225/2016, byl uhrazen dne 24. 3. 2016 formou kolkové známky.

Poučení:

Proti tomuto rozhodnutí lze podat odvolání do 15 dnů ode dne jeho doručení, nejpozději však do 15 dnů po uplynutí desátého dne ode dne, kdy bylo nedoručené a uložené rozhodnutí připraveno k vyzvednutí, a to k Ministerstvu zemědělství České republiky, odbor rostlinných komodit, prostřednictvím Ústředního kontrolního a zkušebního ústavu zemědělského, sekce zemědělských vstupů, odboru přípravků na ochranu rostlin, Zemědělská 1a, 613 00 Brno.

Otisk úředního razítka

Ing. Pavel Minář, Ph.D.
ředitel odboru

2

UKZÚZ
Hroznová 2
656 06 BRNO

Telefon: +420 543 548 111
Fax: +420 543 211 148
E-mail: podatelna@ukzuz.cz

IČ: 00020338
DIČ: CZ00020338
www.ukzuz.cz
ID DS: ugbaiq7

Test facility	Address	Certificate (Yes or No)
ANADIAG ITA-LIA SRL	Strada Savonesa 9 15057 Tortona ITALY	YES

<p>DECRETO 30 luglio 2018.</p> <p>Riconoscimento dell'idoneità al Centro «Anadiag Italia S.r.l.» ad effettuare prove ufficiali di campo, finalizzate alla produzione di dati di efficacia e alla determinazione dell'entità dei residui di prodotti fitosanitari.</p> <p>IL DIRETTORE GENERALE DELLO SVILUPPO RURALE</p> <p>Visto il decreto legislativo del 17 marzo 1995, n. 194 che, in attuazione della direttiva 91/414/CEE, disciplina l'immissione in commercio dei prodotti fitosanitari;</p> <p>Visti in particolare i commi 5, 6, 7 e 8 dell'art. 4 del predetto decreto legislativo n. 194/95;</p> <p>Visto il decreto del Ministro della sanità del 28 settembre 1995 che modifica gli allegati II e III del suddetto decreto legislativo n. 194/95;</p> <p>Visto il decreto interministeriale 27 novembre 1996 che, in attuazione del citato decreto legislativo n. 194/95, disciplina i principi delle buone pratiche per l'esecuzione delle prove di campo e definisce i requisiti necessari al riconoscimento ufficiale dell'idoneità a condurre prove di campo finalizzate alla registrazione dei prodotti fitosanitari;</p>	<p>Vista l'istanza presentata in data 10 gennaio 2018 dal Centro «Anadiag Italia S.r.l.», con sede legale in fraz. Rivalta Scrivia - Strada Savonesa, 9 - 15050 Tortona (AL);</p> <p>Visto l'esito favorevole della verifica della conformità ad effettuare prove di campo a fini registrati, finalizzate alla produzione di dati di efficacia e alla determinazione dell'entità dei residui di prodotti fitosanitari effettuata in data 23 giugno 2018 presso il Centro «Anadiag Italia S.r.l.»;</p> <p>Visto il decreto legislativo 30 luglio 1999, n. 300, di riforma dell'organizzazione di Governo a norma dell'art. 11 della legge 15 marzo 1997, n. 59;</p> <p>Visto il decreto legislativo 30 marzo 2001, n. 165, relativo alle «norme generali sull'ordinamento del lavoro alle dipendenze delle amministrazioni pubbliche», in particolare l'art. 4, commi 1 e 2 e l'art. 16, comma 1;</p> <p>Visto il decreto del Presidente del Consiglio dei ministri 27 febbraio del 2013, n. 105, recante il Regolamento di organizzazione del Ministero delle politiche agricole alimentari e forestali, a norma dell'art. 2, comma 10-ter, del decreto-legge 6 luglio 2012, n. 95, convertito, con modificazioni, dalla legge 7 agosto 2012, n. 135, così come modificato dal decreto del Presidente del Consiglio dei ministri 17 luglio 2017, n. 143;</p> <p>Visto il decreto del Ministro delle politiche agricole alimentari e forestali del 7 marzo 2018, Registrato alla Corte dei conti il 3 aprile 2018 al n. 191, recante individuazione degli Uffici dirigenziali di livello non generale;</p> <p>Considerato che il suddetto Centro ha dichiarato di possedere i requisiti prescritti dalla normativa vigente, a far data dal 10 gennaio 2018, a fronte di apposita documentazione presentata;</p> <p>Decreta:</p> <p>Art. 1.</p> <p>1. Il Centro «Anadiag Italia S.r.l.», con sede legale in fraz. Rivalta Scrivia - Strada Savonesa, 9 - 15050 Tortona (AL), è riconosciuto idoneo a proseguire nelle prove ufficiali di campo con prodotti fitosanitari volte ad ottenere le seguenti informazioni:</p> <p>efficacia dei prodotti fitosanitari (di cui all'Allegato III, punto 6.2 del decreto legislativo n. 194/95);</p> <p>dati sulla comparsa o eventuale sviluppo di resistenza (di cui all'Allegato III, punto 6.3 del decreto legislativo n. 194/95);</p> <p>incidenza sulla resa quantitativa e/o qualitativa (di cui all'Allegato III, punto 6.4 del decreto legislativo n. 194/95);</p> <p>fitotossicità nei confronti delle piante e prodotti vegetali bersaglio (di cui all'Allegato III, punto 6.5 del decreto legislativo n. 194/95);</p> <p>osservazioni riguardanti gli effetti collaterali indesiderabili (di cui all'Allegato III, punto 6.6 del decreto legislativo n. 194/95);</p> <p>individuazione dei prodotti di degradazione e di reazione dei metaboliti in piante o prodotti trattati (di cui all'allegato II, punto 6.1 del decreto legislativo n. 194/95);</p>
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valutazione del comportamento dei residui delle sostanze attive e dei suoi metaboliti a partire dall'applicazione fino al momento della raccolta o della commercializzazione dei prodotti immagazzinati (di cui all'allegato II, punto 6.2 del decreto legislativo n. 194/95);

definizione del bilancio generale dei residui delle sostanze attive (di cui all'allegato II, punto 6.3 del decreto legislativo n. 194/95);

prove relative agli effetti della lavorazione industriale e/o preparazione domestica sulla natura e sull'entità dei residui (di cui all'allegato II, punto 6.6 del decreto legislativo n. 194/95);

prove su destino e comportamento nel suolo (di cui all'allegato II, punto 7.1 del decreto legislativo n. 194/95);

prove su destino e comportamento nell'acqua e nell'aria (di cui all'allegato II, punto 7.2 del decreto legislativo n. 194/95);

studi ecotossicologici relativi agli effetti su organismi non bersaglio (di cui all'Allegato II, punto 8.3 del decreto legislativo n. 194/95);

determinazione dei residui in o su prodotti trattati, alimenti per l'uomo o per gli animali (di cui all'Allegato III, punto 8.1 del decreto legislativo n. 194/95);

prove relative agli effetti della lavorazione industriale e/o preparazione domestica sulla natura e sull'entità dei residui (Allegato III, Punto 8.2 del decreto legislativo n. 194/95);

effetti sull'aspetto, l'odore, il gusto o altri aspetti qualitativi dovuti ai residui nei o sui prodotti freschi o lavorati (Allegato III, Punto 8.3 del decreto legislativo n. 194/95);

valutazione dei dati sui residui nelle colture successive o di rotazione (di cui all'Allegato III, punto 8.5 del decreto legislativo n. 194/95);

individuazione dei tempi di carenza per impieghi in pre-raccolta o post-raccolta (di cui all'Allegato III, punto 8.6 del decreto legislativo n. 194/95);

prove su destino e comportamento ambientale (di cui all'Allegato III, punti 9.1, 9.2 e 9.3 del decreto legislativo n. 194/95);

studi ecotossicologici relativi agli effetti su organismi non bersaglio (di cui all'Allegato III, punto 10.3 del decreto legislativo n. 194/95).

2. Il riconoscimento di cui al comma 1, riguarda le prove di campo di efficacia e le prove di campo finalizzate alla determinazione dell'entità dei residui di prodotti fitosanitari nei seguenti settori di attività:

aree non agricole;
colture arboree;
colture erbacee;
colture forestali;
colture medicinali ed aromatiche;
colture ornamentali;
colture orticole;
concia sementi;
conservazione post-raccolta;
colture in vivaio;

prove di semicampo in ambiente controllato;

diserbo;

entomologia;

microbiologia agraria;

nematologia;

patologia vegetale;

zoologia agraria;

produzione sementi;

vertebrati dannosi;

fitoregolatori, attivatori e coadiuvanti;

vinificazione.

Art. 2.

1. Il mantenimento dell'idoneità di cui all'articolo precedente è subordinato alla verifica biennale in loco del possesso dei requisiti prescritti, da parte degli ispettori iscritti nell'apposita lista nazionale di cui all'art. 4, comma 8, del citato decreto legislativo 194/95.

2. Il Centro «Anadiag Italia S.r.l.» è tenuto a comunicare a questo Ministero l'indicazione precisa delle tipologie delle prove che andrà ad eseguire, nonché la loro localizzazione territoriale.

3. Il citato Centro è altresì tenuto a comunicare ogni eventuale variazione che interverrà rispetto a quanto dalla stessa dichiarato nell'istanza di riconoscimento, nonché a quanto previsto dal presente decreto.

Art. 3.

1. Il presente decreto ha la validità di mesi 24 dalla data di ispezione effettuata in data 23 giugno 2018.

2. Il Centro «Anadiag Italia S.r.l.», qualora intenda confermare o variare gli ambiti operativi di cui al presente decreto, potrà inoltrare apposita istanza, almeno sei mesi prima della data di scadenza, corredata dalla relativa documentazione comprovante il possesso dei requisiti richiesti.

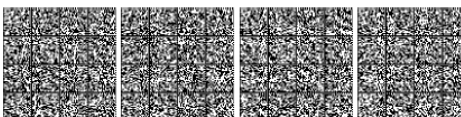
Il presente decreto, ai sensi dell'art. 13 del decreto legislativo n. 196/2003, sarà oggetto di pubblicazione in ottemperanza agli obblighi di legge previsti dal decreto legislativo n. 33/2013.

Il presente decreto sarà pubblicato nella *Gazzetta Ufficiale* della Repubblica italiana.

Roma, 30 luglio 2018

Il direttore generale: GATTO


18A05349



North-Eastern EPPO zone

Test facility Durum Wheat	Address	Certificate (Yes or No)
SynTech Re- search Poland Sp. z o.o.	69/1 Jagiellonska 85-027 Bydgoszcz POLAND	YES

Test facility	Address	Certificate (Yes or No)
SynTech Re- search Poland Sp. z o.o.	69/1 Jagiellonska 85-027 Bydgoszcz POLAND	YES


**GŁÓWNY INSPEKTOR
OCHRONY ROŚLIN I NASIENICTWA**
Tadeusz Kłos

WO-505-8/15 Warszawa, 27.04.2015 r.

DECYZJA Nr 6/2015

Na podstawie art. 17 ust. 2 i ust. 8 pkt 2 w związku z art. 79 ust. 3 ustawy z dnia 8 marca 2013 r. o środkach ochrony roślin (Dz.U. z 2013 r. poz. 455 z późn. zm.) oraz art. 104 ustawy z dnia 14 czerwca 1960 r. Kodeksu postępowania administracyjnego (Dz.U. z 2013 r. poz. 267 z późn.zm.), po rozpatrzeniu wniosku z dnia 30 marca 2015 r., rozszerzam zakres upoważnienia do prowadzenia badań skuteczności działania środka ochrony roślin wydanego w drodze decyzji Nr 5/2013 z dnia 25 marca 2013 r., zmienionego decyzją Nr 2/2014 z dnia 7 marca 2014 r., w zakresie prowadzenia badań skuteczności działania środka ochrony roślin z użyciem akaricydów i nematocydów w uprawach warzyw w polu i pod osłonami.

Rozstrzygnięciu decyzji nadaje następujące brzmienie:

Upoważniam
SynTech Research Poland Sp. z o.o.
ul. Jagiellońska 69/1; 85-027 Bydgoszcz
do prowadzenia badań skuteczności działania środka ochrony roślin

z grupy akaricydów, fungicydów, herbicydów, insektycydów, nematocydów i regulatorów wzrostu w uprawach polowych (zboża, kukurydza, rzepak, burak cukrowy, ziemniak, warzywa kapustne, pomidor, ogórek, sałata, marchew, pietruszka, cebula, fasola, papryka, buraki), w uprawach sadowniczych (jabłoni, wiśnia, czereśnia, śliwa, morela, brzoskwinia, grusza, malina, truskawka, porzeczka, winorośl, orzech), w uprawach chmielu, traw łąkowych i pastwiskowych oraz na terenach nieużytkowanych rolniczo.


Uzasadnienie

Pismem z dnia 30 marca 2015 r. Spółka z o.o. SynTech Research Poland zwróciła się z prośbą o rozszerzenie zakresu upoważnienia Nr 5/2013 wydanego przez Głównego Inspektora Ochrony Roślin i Nasiennictwa w dniu 25 marca 2013 r., zmienionego decyzją Nr 2/2014 z dnia 7 marca 2014 r., umożliwiającą Spółce prowadzenie badań skuteczności działania środka ochrony roślin. Wnikskowana zmiana dotyczy prowadzenia badań z użyciem środków ochrony roślin z grupy akaricydów i nematocydów oraz stosowania badanych środków w uprawach marchwi, pietruszki, cebuli, łaski, papryki, buraka, truskawki, porzeczki, gruszy, orzecha, moreli, brzoskwinii, winorośli i chmielu, traw łąkowych i pastwiskowych oraz na terenach nieużytkowanych rolniczo.

South-Eastern EPPO zone


Test facility Durum Wheat	Address	Certificate (Yes or No)
Staphyt Hungary Kft. (JS Agrotest Kft.)	Zemplen Gyozo u. 7/B 8800 Nagykanizsa HUNGARY	YES (2015)
Staphyt Hungary Kft.	Piroskai u. 2 5000 Szolnok HUNGARY	YES (2018)
SynTech Research Hungary Kft.	Török Ignác u. 30 9700 Szombathely, HUNGARY	YES
ANADIAG HUNGARY Kft.	H2921, Komárom, Petőfi Sándor 67 HUNGARY	YES
ANADIAG ROMANIA SRL	Piata Montreal no. 10, World Trade Centre, Entrance F, 1st Floor 011469, Bucharest, ROMANIA	YES

Test facility	Address	Certificate (Yes or No)
STAPHYT (JS Agrotest Kft.)	Zemplen Gyozo u. 7/B 8800 Nagykanizsa HUNGARY	YES



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Termőföldtől az asztalig

Nemzeti Élelmiszerlánc-biztonsági Hivatal
Elnök



1024 Budapest, Keleti Károly u. 24
Tel: 06/1/336-9100 Fax: 06/1/336-9099
E-mail: elnokitikarsag@nebih.gov.hu
www.nebih.gov.hu

Ikt.sz.: 04.2/8942-7/2015.
Tárgy: GEP minősítés
Ügyintéző: dr. Ripka Géza
Elérhetőség: 309-1032
Melléklet(ek): -
Hiv. szám: -

A JS Agrotest Kft. (8800 Nagykanizsa, Zemplén Győző u. 7/B.) ügyfél (a továbbiakban: Ügyfél) által előterjesztett, Helyes Kísérleti Gyakorlatra (a továbbiakban: GEP minősítés) vonatkozó minősítés lefolytatása iránti kérelem alapján indult elsőfokú eljárásban, élelmiszerlánc-felügyeleti szervként eljárva (továbbiakban: engedélyező hatóság), meghoztam az alábbi

H A T Á R O Z A T O T :

Ügyfél engedélyezési célú biológiai hatásvizsgálatok elvégzésére vonatkozó GEP minősítését Szolnok, Piroskai út 2. szám alatti telephelyére kiadom. A GEP minősítés a határozatom jogerőre emelkedésétől számított 2 évig érvényes.

Ügyfél GEP minősítése az alábbi minősítési kategóriákra és művelési ágakra kerül kiadásra:

- **minősítési kategória:** herbicidek, fungicidek és baktericidek, zoocidok, növekedésszabályozó és termésmnövelő készítmények, adalékanyagok;
- **művelési ág:** szántóföld, zöldség, gyümölcs és szőlő, dísznövény, erdő, közterület, egyéb (rezisztencia, dózis vizsgálat, talajfertőtlenítő szerek).

Jelen minősítés nem érinti a működéssel/tevékenység folytatásával kapcsolatos egyéb jogszabályban előírt engedélyeket, illetve Ügyfélnek az azok beszerzésére vonatkozó kötelezettségét.

Ügyfél a vizsgálóhely minősített tevékenységét érintő jelentős változásról 15 napon belül köteles értesíteni az eljáró hatóságot.

A GEP minősítéssel kapcsolatos jogszabályokban és a jelen határozatban foglaltak betartását hatóságom szűrőpróbaszerűen ellenőrzi. Amennyiben az ellenőrzés során megállapítást nyer, hogy a vizsgálóhely nem tartja be a rá vonatkozó GEP-követelményeket, akkor az eljáró hatóság a határozatban feltüntetett minősített területre vonatkozó tevékenység végzését legfeljebb 2 hónapra felfüggesztheti, illetve a kiadott GEP minősítését visszavonhatja.

Ha az ellenőrzés során egy adott kísérlettel kapcsolatban hiányosságok kerülnek megállapításra, a kísérletet a hiányosságok mértékétől függően az eljáró hatóság kizárhatja az engedélyezésnél elfogadhatók közül.

Jelen eljárás díja 500.000.- Ft (azaz Ötszázezer forint), amelyet az Ügyfél megfizetett.

Jelen, a közléssel jogerős határozatom ellen közigazgatási úton további jogorvoslatnak helye nincs, bírósági felülvizsgálata jogszabálysértésre hivatkozással kérhető a Fővárosi Közigazgatási és Munkaügyi Bíróságtól. A keresetlevelet hatóságomhoz kell benyújtani a felülvizsgálni kért határozat közlésétől számított harminc napon belül.

A bíróság a pert tárgyaláson kívül bírálja el, a felek bármelyikének kérelmére azonban tárgyalást tart. Tárgyalás tartását a keresetlevélben kérheti, ennek elmulasztása miatt igazolásnak nincs helye. A keresetlevél benyújtásának a döntés végrehajtására halasztó hatálya nincs.

I N D O K O L Á S

Ügyfél 2015. október 10-én kelt kérelmében GEP minősítés iránti kérelmet nyújtott be hatóságomnál.

A kérelem nyomán az eljáró hatóság 2015. november 4-én helyszíni ellenőrzést folytatott le Ügyfél Szolnok, Piroskai út 2. szám alatti telephelyén, amelynek megállapításait a 04.2/8942-3/2015. számú jegyzőkönyvben rögzítette.

A helyszíni ellenőrzés során az eljáró hatóság megállapította, hogy a növényvédő szerek forgalomba hozatalának és felhasználásának engedélyezéséről, valamint a növényvédő szerek csomagolásáról, jelöléséről, tárolásáról és szállításáról szóló 89/2004. (V. 15.) FVM rendelet (továbbiakban: Rendelet) 22. §-ában foglalt biológiai hatékonysági vizsgálatokkal kapcsolatos előírásoknak Ügyfél vizsgálóhelye nem felel meg hiánytalanul, és a 04.2/8942-4/2015. számú végzésben a hiányosság megszüntetésére hívta fel.

A Rendelet 22. § „(5) Kérelem alapján az engedélyező hatóság helyszíni ellenőrzést folytat le a vizsgálóhelyen, majd határozatban dönt a vizsgálóhely GEP-minősítéséről. A határozatnak ki kell terjednie arra, hogy a vizsgálóhely milyen kategóriákra, illetve művelési ágakra szerezte meg a GEP-minősítést.

(6) A GEP-minősítés érvényességi ideje első tanúsítás esetén 2 év, a tanúsítás megújítását követően legfeljebb 5 év.

(7) A GEP-minősítési eljárásért a külön jogszabályban meghatározott díjat kell fizetni.

(8) A GEP-minősítéssel rendelkező vizsgálóhely minden, a minősített tevékenységét érintő jelentős változásról 15 napon belül köteles értesíteni az engedélyező hatóságot.

(9) Az engedélyező hatóság szűrőpróbaszerűen ellenőrzi a GEP-minősítéssel rendelkező vizsgálóhelyeket. Amennyiben megállapítást nyer, hogy a vizsgálóhely nem tartja be a rá vonatkozó GEP-követelményeket, a hatóság a határozatban feltüntetett minősített területre vonatkozó tevékenységet legfeljebb 2 hónapra felfüggesztheti, illetve a kiadott GEP-minősítést visszavonhatja. Ha az ellenőrzés során egy adott kísérlettel kapcsolatban hiányosságok kerülnek megállapításra, a kísérletet a hiányosságok mértékétől függően az engedélyező hatóság kizárhatja az engedélyezésnél elfogadhatók közül.”

Ügyfél a hiányosságot megszüntette, amit az eljáró hatóságnak 2015. november 25-én érkezett levelében jelentett be, amelynek értékelése során megállapítottam, hogy a GEP-minősítés fentiek szerinti feltételei fennállnak, így a rendelkező részben foglaltak szerint döntöttem.

Jelen eljárás díja a Nemzeti Élelmiszerlánc-biztonsági Hivatal, valamint a megyei kormányhivatalok mezőgazdasági szakigazgatási szervei előtt kezdeményezett eljárásokban fizetendő igazgatási szolgáltatási díjak mértékéről, valamint az igazgatási szolgáltatási díj fizetésének szabályairól szóló 63/2012. (VII. 2.) VM rendelet 1. sz. mellékletének 8.19.1. pontja szerint 500.000.- Ft, amelyet Ügyfél megfizetett.

Határozatomat a Nemzeti Élelmiszerlánc-biztonsági Hivatalról szóló 22/2012. (II. 29.) Korm. rendelet 3. § (1) bekezdésében és 5. § c) pontjában, a Rendelet 3. §-ában illetve 22. § (1) bekezdésében biztosított jogkörben eljárva, a közigazgatási hatósági eljárás és szolgáltatás általános szabályairól szóló 2004. évi CXL. törvény (továbbiakban: Ket.) 71. § (1) bekezdésének és 72. § (1) bekezdésének megfelelően hoztam meg.

A fellebbezést a Ket. 100. § (1) bekezdés e) pontja alapján zártam ki, a bírósági felülvizsgálat lehetőségéről a Ket. 109. § (1) bekezdése, valamint a Polgári Perrendtartásról szóló 1952. évi III. törvény 330. § (2) bekezdése alapján adtam tájékoztatást.

Budapest, 2015. december „9.”



Határozat készült 2 példányban, kapják:

- Ügyfél (tértivevényvel)
- Irattár



n é b i h
Termőföldtől az asztalig

National Food Chain Safety Office
President



H-1024 Budapest, Keleti Károly u. 24.
Hungary
Tel: 36/1/336-9100 Fax: 36/1/336-9099
E-mail: elnokititkarsag@nebih.gov.hu
www.nebih.gov.hu

Your ref.: -

Our ref.: 04.2/8942-7/2015

9 December 2015

Subject: Certificate of Official Recognition of Efficacy Testing Facilities or Organisations in Hungary

Having received the application submitted by **the JS Agrotest Kft. (H-8800 Nagykanizsa, Zemplén Győző u. 7/B, Hungary)**, **the client**, for completing a certification procedure of first instance concerning the Official Recognition of Efficacy Testing Facilities/Organisations, i.e. Good Experimental Practices (*hereinafter*: GEP), I, acting as the food chain control body, has made the following

DECISION:

I issue the client's GEP certificate for its premises at Szolnok, Piroskai út 2, for carrying out efficacy trials for authorisation purposes. **The GEP certificate is effective for 2 years from the entry into force of this Decision.**

The client's GEP certificate is given for the following categories of products and cultivation:

- product categories:** herbicides, fungicides and bactericides, zoocides, growth regulators and yield enhancing substances, additives;
- cultivation categories:** field crops, vegetables, fruits, grapevines, ornamentals, forest, public area, others.

I inform you that the present certification is without prejudice to either the licences concerning the operation/follow-up of activity laid down in other provisions of legislation or the client's obligation for obtaining them.

The client is obliged to notify the competent authority, within 15 days, of any important changes concerning the certified activity of the testing facility.

I call your attention that respect of the provisions laid down in the legislation on GEP certification and in this Decision shall be randomly controlled by my competent authority. If during the official inspection it is stated that the testing facility does not meet the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate.

If during the official inspection it is found that some details are missing in relation to a particular trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization.

The fee of the present procedure is 500.000 HUF (i.e. five hundred thousand Hungarian Forints) paid by the client.

No further complaint shall be lodged against the present Decision, effective by its publication, through state administration, though with reference to infringement of law, judicial review of the Decision may be requested at the Capital Administrative and Employment Court. The claim note shall be submitted to my competent authority within 30 days of the communication of the Decision.

I inform you that the court shall judge the case out of court, but shall carry on a lawsuit at the request of any of the parties. The client may ask for carrying on a lawsuit, but in default of so doing, no verification is accepted. Submission of the claim note has no delaying force on the implementation of this Decision.

J U S T I F I C A T I O N

In its application of 10 October 2015, the client submitted an application to the competent authority for a procedure of GEP certification.

As a follow-up to this application, the competent authority made a local inspection at the client's facilities of Szolnok, Piroskai út 2 on 4 November 2015. Statements made during the local inspection are reported in the protocol Nr. 04.2/8942-3/2015. Based on the results of the local inspection the competent authority concluded that the client's testing facility does not meet the requirements concerning the efficacy trials specified in Article 22 of the Decree 89/2004 (V. 15.) FVM on the authorization of placing on the market and use, as well as on the packaging, labelling, storage and transport of plant protection products (hereinafter: Decree 89/2004) and in the Decision Nr. 04.2/8942-4/2015 it calls the client to fill the data gap.

Article 22(5) of Decree 89/23004 - Based on request, the competent authority shall make local inspections at the testing facility and decide on the GEP qualification of the testing facility. The decision shall include the product categories and the cultivation categories for which the testing facility obtained the GEP-certificate.

(6) The validity of GEP-certification is 2 years in case of the first request and maximum 5 years in case of renewal of the certification.

(7) A fee laid down in specific legislation shall be paid for the GEP-certification procedure.

(8) The testing facility having GEP-certification shall notify the competent authority, within 15 days, about any important changes concerning the certified activity of the testing facility.

(9) The competent authority shall randomly control the testing facility having GEP-certification. If it is found that the testing facility does not meet the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate. If during the official inspection it is established that some details are missing in relation to a trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization."

Client filled the missing data gap and reported on it in the letter of 25 November 2015, therefore I made the Decision as specified in the first part. Therefore I stated that conditions for issuing the certificate specified above are met, so I made the Decision as specified in the first part.

The fee of the present procedure is HUF 500.000 and was established in accordance with point 8.19.1 of Annex 1 to the Decree 63/2012. (VII. 2.) VM on the extent of administrative servicing fees due for the procedures by the agricultural administrative bodies of the National Food Chain Safety Office and the county government offices and on the rules of paying the administrative servicing fees. The client paid the fee.

I made this Decision within my jurisdiction laid down in Article 3 paragraph (1) and Article 5 point c) of Government Decree 22/2012. (II. 29.) concerning the National Food Chain Safety Office, Article 3, Article 22 paragraph (1) of Decree 89/2004 and in compliance with Articles 71 paragraph (1) and Article 72 paragraph (1) of Act CXL of 2004 on general rules of administrative official procedure and service (hereinafter: Act CXL of 2004).

I excluded the possibility of appeal in compliance with Article 100 paragraph (1) point e) of Act CXL of 2004 and provided the possibility of judicial review in compliance with Article 109 paragraph (1) of Act CXL of 2004 and Article 330 paragraph (2) of Act III of 1952 on Civil Procedure.



dr. Márton Óravec
president

Decision is made in two copies:

- Client (with acknowledgement of receipt)
- Archives

Test facility	Address	Certificate (Yes or No)
Staphyt Hungary Kft	Piroskai u. 2 5000 Szolnok HUNGARY	YES



**PEST MEGYEI
KORMÁNYHIVATAL**

Ügyirat-szám: PE/NT/0045-7/2018

Ügyintéző: Dr. Cs. Tóth Attila

Telefon: 06-1/236-3926

E-mail: cs.totha@pest.gov.hu

Tárgy: Staphyt Hungary Kft. (5000

Szolnok, Piroskai u. 2.)

vizsgálóhelyének GEP tanúsítása

Melléklet:-

A Pest Megyei Kormányhivatal (továbbiakban: engedélyező hatóság) a Staphyt Hungary Kft. (székhely: 5000 Szolnok, Piroskai u. 2., a továbbiakban: Ügyfél) vizsgálóhelyének Helyes Kísérleti Gyakorlat (továbbiakban: GEP) szerinti inspekcója és elismerése iránti kérelme alapján indult elsőfokú eljárásban meghozta az alábbi

H A T Á R O Z A T O T :

Engedélyezési célú biológiai hatásvizsgálatok végzéséhez az Ügyfél vizsgálóhelyének GEP-minősítését kiadom.

A GEP-minősítés 5 évig érvényes határozatom jogerőre emelkedésétől számítva.

A vizsgálóhely GEP-minősítés az alábbi minősítési kategóriákra és művelési ágakra kerül kiadásra:

- **minősítési kategória:** herbicidek, fungicidek és baktericidek, zoocidok, növekedésszabályozó és termésnövelő készítmények, adalékanyagok
- **művelési ág:** szántóföld, zöldség, gyümölcs, szőlő, dísznövény, erdő, közterület és egyéb (rezisztencia, dózis vizsgálat, talajfertőtlenítő szerek)

Jelen minősítés nem érinti a működéssel/tevékenység folytatásával kapcsolatos egyéb jogszabályban előírt engedélyeket, illetve Ügyfélnek azok beszerzésére vonatkozó kötelezettségét.

Az Ügyfél a vizsgálóhelyeinek minősített tevékenységét érintő jelentős változásról 15 napon belül köteles értesíteni az engedélyező hatóságot.

A GEP-minősítéssel kapcsolatos jogszabályokban és a jelen határozatban foglaltak betartását hatóságom szűrőpróbaszerűen ellenőrzi. Amennyiben az ellenőrzés során megállapítást nyer, hogy a vizsgálóhely nem tartja be a rá vonatkozó GEP - követelményeket, akkor az engedélyező hatóság a határozatban feltüntetett minősített területre vonatkozó tevékenység végzését legfeljebb 2 hónapra felfüggesztheti, illetve a kiadott GEP-minősítését visszavonhatja.

Ha az ellenőrzés során egy adott kísérlettel kapcsolatban hiányosságok kerülnek megállapításra, a kísérletet a hiányosságok mértékétől függően az engedélyező hatóság kizárhatja az engedélyezésnél elfogadhatók közül.

A vizsgálóhely GEP szerinti inspekcója és elismerése eljárás díjköteles, amely a **Nemzeti Élelmiszerlánc-biztonsági Hivatal, valamint a megyei kormányhivatalok mezőgazdasági szakigazgatási szervei előtt kezdeményezett eljárásokban fizetendő igazgatási szolgáltatási díjak mértékéről, valamint az igazgatási szolgáltatási díj fizetésének szabályairól** szóló 63/2012. (VII. 2.) VM rendelet 1. sz. mellékletének 8.19.2. pontja szerint: **250.000,- Ft, amelyet az Ügyfél megfizetett.**

Élelmiszerlánc- biztonsági, Földhivatali, Növény- és Talajvédelmi, Erdészeti Főosztály

Cím: 1135 Budapest, Lehel u. 43-47.;

Telefon: 06-1/236-3934 Fax: 06-1/350-6117

E-mail: pmkh-nto@pest.gov.hu Honlap: www.kormanyhivatal.hu/hu/pest

Jelen határozat ellen közigazgatási per indítható a Fővárosi Közigazgatási és Munkaügyi Bíróságnál a határozatot hozó Élelmiszerlánc-biztonsági Földhivatali, Növény- és Talajvédelmi, Erdészeti Főosztály Növény- és Talajvédelmi Osztály elleni kereset indításával. A keresetlevelet a felülvizsgálni kért határozat közlésétől számított harminc napon belül, az engedélyező hatósághoz elektronikus úton kell benyújtani.

INDOKOLÁS

Az Ügyfél 2018. január 17-én érkezett levelében vizsgálóhelyének GEP szerinti minősítésének felülvizsgálatát és a minősítés megújítását kérte a Pest Megyei Kormányhivatal, Élelmiszerlánc-biztonsági, Földhivatali, Növény- és Talajvédelmi Erdészeti Főosztály, Növény- és Talajvédelmi Osztályától.

Az engedélyező hatóság 2018. március 8-án az Ügyfél székhelyén helyszíni ellenőrzést tartott, amelyeknek megállapításait a PE/NT/0045-3/2018. számú jegyzőkönyvben rögzítette.

A helyszíni ellenőrzés során az engedélyező hatóság megállapította, hogy a növényvédő szerek forgalomba hozatalának és felhasználásának engedélyezéséről, valamint a növényvédő szerek csomagolásáról, jelöléséről, tárolásáról és szállításáról szóló 89/2004. (V. 15.) FVM rendelet (továbbiakban: Rendelet) 22. §-ban foglalt biológiai hatásvizsgálatokkal kapcsolatos előírásoknak a vizsgálóhely nem felelt meg hiánytalanul, és az ügyfelet a PE/NT/0045-5/2018. számú végzésben a hiányosságok megszüntetésére szólította fel.

Az Ügyfél a hiányosságokat megszüntette és annak bizonyításáról szóló dokumentációt az engedélyező hatóságnak 2018. április 30-án megküldte.

A fentiek alapján megállapítottam, hogy a GEP-minősítés megadásának feltételei teljesültek, ennek megfelelően döntöttem a rendelkező részben foglaltak szerint.

A Rendelet 22. §-a értelmében „(5) Kérelem alapján az engedélyező hatóság helyszíni ellenőrzést folytat le a vizsgálóhelyen, majd határozatban dönt a vizsgálóhely GEP-minősítéséről. A határozatnak ki kell terjednie arra, hogy a vizsgálóhely milyen kategóriákra, illetve művelési ágakra szerezte meg a GEP-minősítést.

(6) A GEP-minősítés érvényességi ideje első tanúsítás esetén 2 év, a tanúsítás megújítását követően legfeljebb 5 év.


(7) A GEP-minősítési eljárásért a külön jogszabályban meghatározott díjat kell fizetni.

(8) A GEP-minősítéssel rendelkező vizsgálóhely minden, a minősített tevékenységét érintő jelentős változásról 15 napon belül köteles értesíteni az engedélyező hatóságot.

(9) Az engedélyező hatóság az újrapróbához ellenőrző a GEP-minősítéssel rendelkező vizsgálóhelyeket. Amennyiben megállapítást nyer, hogy a vizsgálóhely nem tartja be a rá vonatkozó GEP-követelményeket, a hatóság a határozatban feltüntetett minősített területre vonatkozó tevékenységet legfeljebb 2 hónapra felfüggesztheti, illetve a kiadott GEP-minősítést visszavonhatja. Ha az ellenőrzés során egy adott kísérlettel kapcsolatban hiányosságok kerülnek megállapításra, a kísérletet a hiányosságok mértékétől függően az engedélyező hatóság kizárhatja az engedélyezésnél elfogadhatók közül.”


Az engedélyező hatóság a határozatát a földművelésügyi hatósági és igazgatási feladatokat ellátó szervek kijelöléséről szóló 383/2016. (XII.2.) Kormányrendelet 19. § a) pontjában és az élelmiszerláncról és hatósági felügyeletről szóló 2008. évi XLVI. törvény 33. § e) pontjában

Test facility	Address	Certificate (Yes or No)
SynTech Re- search Hungary Kft.	Török Ignác u. 30 9700 Szombathely, HUNGARY	YES



n é b i h
 Nemzeti Élelmiszerlánc-biztonsági Hivatal
 Termékbiztonsági és állategészségügyi hatóság

National Food Chain Safety Office
 Directorate of Plant Protection, Soil Conservation
 and Agri-environment



H-2133 Budapest, Budavári út 149-145.
 Hungary
 Tel: 36/1/949-1000 Fax: 36/1/265-1042
 E-mail: info@neh.gov.hu
www.nebih.gov.hu

Your ref.: -

Our ref.: 04.2/4838-7/2016

15 August 2016

Subject: Certificate of Official Recognition of Efficacy Testing Facilities or Organisations in Hungary

Having received the application submitted by the **SynTech Research Hungary Kft. (H-9700 Szombathely, Török Ignác u. 30, Hungary)**, the client, for completing a certification procedure of first instance concerning the Official Recognition of Efficacy Testing Facilities/Organisations, i.e. Good Experimental Practices (*hereinafter: GEP*), I, acting as the food chain control body, has made the following

DECISION:

I issue the client's GEP certificate for its premises at Szombathely, Török Ignác u. 30 for carrying out efficacy trials for authorisation purposes. The GEP certificate is effective for 5 years from the entry into force of this Decision.

The client's GEP certificate is given for the following categories of products and cultivation:

- product categories:** herbicides, fungicides and bactericides, zoocides, growth regulators and yield enhancing substances, additives;
- cultivation categories:** field crops, vegetables, fruits, grapevines, ornamentals, forest, others.

I inform you that the present certification is without prejudice to either the licences concerning the operation/follow-up of activity laid down in other provisions of legislation or the client's obligation for obtaining them.

The client is obliged to notify the competent authority, within 15 days, of any important changes concerning the certified activity of the testing facility.

I call your attention that respect of the provisions laid down in the legislation on GEP certification and in this Decision shall be randomly controlled by my competent authority. If during the official inspection it is stated that the testing facility does not meet the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate.

If during the official inspection it is found that some details are missing in relation to a particular trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization.

The fee of the present procedure is 250.000 HUF (i.e. two hundred and fifty thousand Hungarian Forints) paid by the client.

No further complaint shall be lodged against the present Decision, effective by its publication, through state administration, though with reference to infringement of law, judicial review of the Decision may be requested at the Capital Administrative and Employment Court. The claim note shall be submitted to my competent authority within 30 days of the communication of the Decision.

I inform you that the court shall judge the case out of court, but shall carry on a lawsuit at the request of any of the parties. The client may ask for carrying on a lawsuit, but in default of so doing, no verification is accepted. Submission of the claim note has no delaying force on the implementation of this Decision.

J U S T I F I C A T I O N

In its application of 7 July 2016, the client submitted an application to the competent authority for a procedure of GEP certification.

As a follow-up to this application, the competent authority made a local inspection at the client's facility of Szecsbathely, Török Ignác u. 20 on 12 July 2016. Statements made during the local inspection are reported in the protocol Nr. 04.2.4838-4/2016. Based on the results of the local inspection the competent authority concluded that the client's testing facility does not meet the requirements concerning the efficacy trials specified in Article 22 of the Decree 89/2004 (V. 15.) FVM on the authorization of placing on the market and use, as well as on the packaging, labelling, storage and transport of plant protection products (hereinafter: Decree 89/2004) and in the Decision Nr. 04.2.4838-5/2016 it calls the client to fill the data gaps.

Article 22(3) of Decree 89/2004 - Based on request, the competent authority shall make local inspections at the testing facility and decide on the GEP qualification of the testing facility. The decision shall include the product categories and the cultivation categories for which the testing facility obtained the GEP-certificate.

(6) The validity of GEP-certification is 2 years in case of the first request and maximum 5 years in case of renewal of the certification.

(7) A fee laid down in specific legislation shall be paid for the GEP-certification procedure.

(8) The testing facility having GEP-certification shall notify the competent authority, within 15 days, about any important changes concerning the certified activity of the testing facility.

(9) The competent authority shall randomly control the testing facility having GEP-certification. If it is found that the testing facility does not meet the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate. If during the official inspection it is established that some details are missing in relation to a trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization."

Client filled the missing data gaps and reported on it in the letter of 12 August 2016, therefore I made the Decision as specified in the first part. Therefore I stated that conditions for issuing the certificate specified above are met, so I made the Decision as specified in the first part.

The fee of the present procedure is HUF 250,000 and was established in accordance with point 8.19.2 of Annex 1 to the Decree 63/2012. (VI. 2.) PM on the extent of administrative servicing fees due for the procedures by the agricultural administrative bodies of the National Food Chain Safety Office and the county government offices and on the rules of paying the administrative servicing fees. The client paid the fee.



I made this Decision within my jurisdiction laid down in Article 3 paragraph (1) and Article 5 point c) of Government Decree 22/2012. (II. 29.) concerning the National Food Chain Safety Office, Article 3, Article 22 paragraph (1) of Decree 89/2004 and in compliance with Articles 71 paragraph (1) and Article 72 paragraph (1) of Act CXL of 2004 on general rules of administrative official procedure and service (hereinafter: Act CXL of 2004).

I excluded the possibility of appeal in compliance with Article 100 paragraph (1) point c) of Act CXL of 2004 and provided the possibility of judicial review in compliance with Article 109 paragraph (1) of Act CXL of 2004 and Article 330 paragraph (2) of Act III of 1952 on Civil Procedure.

on behalf of
dr. Márton Graveler
president

László József
director

Test facility	Address	Certificate (Yes or No)
ANADIAG HUNGARY Kft.	H2921, Komárom, Petőfi Sándor 67 HUNGARY	YES

	n é b i h Termőföldtől az asztalig	National Food Chain Safety Office Directorate of Plant Protection, Soil Conservation and Agri-environment	 H-1118 Budapest, Budaörsi út 141-145. Hungary Tel: 36/1/309-1000 Fax: 36/1/246-2942 E-mail: nti@nebih.gov.hu www.nebih.gov.hu
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Your ref.: -

Our ref.: 04.2/6149-7/2016

7 October 2016

Subject: Certificate of Official Recognition of Efficacy Testing Facilities or Organisations in Hungary

Having received the application submitted by **the Anadiag Hungary Mezőgazdasági Szolgáltató Kft. (H-2921 Komárom, Petőfi Sándor út 67, Hungary)**, the client, for completing a certification procedure of first instance concerning the Official Recognition of Efficacy Testing Facilities/Organisations, i.e. Good Experimental Practices (*hereinafter*: GEP), I, acting as the food chain control body, has made the following

DECISION:

I issue the client's GEP certificate for its premises at Komárom, Petőfi Sándor út 67 for carrying out efficacy trials for authorisation purposes. The GEP certificate is effective for 5 years from the entry into force of this Decision.

The client's GEP certificate is given for the following categories of products and cultivation:

- product categories:** herbicides, fungicides and bactericides, zoocides, growth regulators and yield enhancing substances, additives;
- cultivation categories:** field crops, vegetables, fruits, grapevines, ornamentals, others.

I inform you that the present certification is without prejudice to either the licences concerning the operation/follow-up of activity laid down in other provisions of legislation or the client's obligation for obtaining them.

The client is obliged to notify the competent authority, within 15 days, of any important changes concerning the certified activity of the testing facility.

I call your attention that respect of the provisions laid down in the legislation on GEP certification and in this Decision shall be randomly controlled by my competent authority. If during the official inspection it is stated that the testing facility does not meet the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate.

If during the official inspection it is found that some details are missing in relation to a particular trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization.

The fee of the present procedure is 250.000 HUF (i.e. two hundred and fifty thousand Hungarian Forints) paid by the client.

No further complaint shall be lodged against the present Decision, effective by its publication, through state administration, though with reference to infringement of law, judicial review of the Decision may be requested at the Capital Administrative and Employment Court. The claim note shall be submitted to my competent authority within 30 days of the communication of the Decision.

I inform you that the court shall judge the case out of court, but shall carry on a lawsuit at the request of any of the parties. The client may ask for carrying on a lawsuit, but in default of so doing, no verification is accepted. Submission of the claim note has no delaying force on the implementation of this Decision.

J U S T I F I C A T I O N

In its application of 29 August 2016, the client submitted an application to the competent authority for a procedure of GEP certification.

As a follow-up to this application, the competent authority made a local inspection at the client's facility of Komárom, Petőfi Sándor út 67 on 31 August 2016. Statements made during the local inspection are reported in the protocol Nr. 04.2/6149-4/2016. Based on the results of the local inspection the competent authority concluded that the client's testing facility does not meet the requirements concerning the efficacy trials specified in Article 22 of the Decree 89/2004 (V. 15.) FVM on the authorization of placing on the market and use, as well as on the packaging, labelling, storage and transport of plant protection products (hereinafter: Decree 89/2004) and in the Decision Nr. 04.2/6149-5/2016 it calls the client to fill the data gaps.

Article 22(5) of Decree 89/23004 - Based on request, the competent authority shall make local inspections at the testing facility and decide on the GEP qualification of the testing facility. The decision shall include the product categories and the cultivation categories for which the testing facility obtained the GEP-certificate.

(6) The validity of GEP-certification is 2 years in case of the first request and maximum 5 years in case of renewal of the certification.

(7) A fee laid down in specific legislation shall be paid for the GEP-certification procedure.

(8) The testing facility having GEP-certification shall notify the competent authority, within 15 days, about any important changes concerning the certified activity of the testing facility.

(9) The competent authority shall randomly control the testing facility having GEP-certification. If it is found that the testing facility does not meet the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate. If during the official inspection it is established that some details are missing in relation to a trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization."


Client filled the missing data gaps and reported on it in the letter of 20 September 2016, therefore I made the Decision as specified in the first part. Therefore I stated that conditions for issuing the certificate specified above are met, so I made the Decision as specified in the first part.

The fee of the present procedure is HUF 250.000 and was established in accordance with point 8.19.2 of Annex 1 to the Decree 63/2012. (VII. 2.) VM on the extent of administrative servicing fees due for the procedures by the agricultural administrative bodies of the National Food Chain Safety Office and the county government offices and on the rules of paying the administrative servicing fees. The client paid the fee.

I made this Decision within my jurisdiction laid down in Article 3 paragraph (1) and Article 5 point c) of Government Decree 22/2012. (II. 29.) concerning the National Food Chain Safety Office, Article 3, Article 22 paragraph (1) of Decree 89/2004 and in compliance with Articles 71 paragraph (1) and Article 72 paragraph (1) of Act CXL of 2004 on general rules of administrative official procedure and service (hereinafter: Act CXL of 2004).

I excluded the possibility of appeal in compliance with Article 100 paragraph (1) point e) of Act CXL of 2004 and provided the possibility of judicial review in compliance with Article 109 paragraph (1) of Act CXL of 2004 and Article 330 paragraph (2) of Act III of 1952 on Civil Procedure.

on behalf of
dr. Márton Oravecz
president


László Jordán
director

Test facility	Address	Certificate (Yes or No)
ANADIAG RO- MANIA SRL	Piata Montreal no. 10, World Trade Centre, Entrance F, 1st Floor 011469, Bucharest, ROMANIA	YES

MINISTERUL AGRICULTURII ȘI DEZVOLTĂRII RURALE Autoritatea Națională Fitosanitară Comisia Națională de Omologare a Produselor de Protecție a Plantelor	MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT National Phytosanitary Authority National Commission for Registration of Plant Protection Products
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**Certificat de recunoaștere oficială a testelor de eficacitate biologică în
conformitate cu bunele practici experimentale/Certificate of official
recognition of the efficacy biological tests according to the good
experimental practices**

Se acordă: SC ANADIAG ROMANIA SRL
It is granted to: SC ANADIAG ROMANIA SRL
cu sediul: Str. Gen. C. Budisteanu, nr.28-C;010775, Bucuresti
with headquarter: Gen. C. Budisteanu Street, no. 28-C, 010775, Bucharest
pentru domeniul/
domeniile de activitate: Culturi agricole de câmp si pajisti; Pomicultură;
Viticultură; Legumicultură; Floricultură; Silvicultură; Plante ornamentale și de
interior; Zone non agricole
for the domain/
domains of activity: Crops fields and meadows; Fruit tree growing; Viticulture;
Vegetable crops; Floriculture; Aromatic and medicinal plants; Ornamental and indoor
plants; Silviculture; Non agricultural zones

Prezentul certificat se eliberează în conformitate cu prevederile Ordinului ministrului
agriculturii și dezvoltării rurale, al ministrului sănătății și al ministrului mediului și
schimbărilor climatice nr.60/512/1258/2013 și prevederile Procedurii naționale de
omologare a produselor de protecție a plantelor care conțin substanțe active
notificate și pentru care nu s-a luat încă o decizie de includere în lista cu substanțe
active autorizate în Uniunea Europeană, aprobată prin Ordinul ministrului agriculturii,

pădurilor și dezvoltării rurale, al ministrului sănătății și al ministrului mediului și gospodăririi apelor nr.134/197/412/2006, cu modificările și completările ulterioare.

This certificate is issued according to the provisions of the Order of the ministry of agriculture and rural development, of the ministry of health and of the ministry of environment and climate change no.60/512/1258/2013 and the provisions of the National Procedure for Registration of Plant Protection Products which contain notified active substances and for which isn't taken yet a decision for inclusion in European Union list of authorised active substances, approved by the Order of the ministry of agriculture, forests and rural development, of the ministry of health and of the ministry of environment and waters husbandry no.134/197/412/2006, with subsequent amendments and completions.

Data emiterii certificatului: 20.08.2015

Issuance date of the certificate

Data expirării certificatului: 20.08.2020

Expiry date of the certificate

PREȘEDINTE/CHAIRMAN,

Elena LEAOTĂ



3.7.6 Triticale (TTLWI)

Table 3.7-6: List of test facilities - TTLWI

Maritime EPPO zone

Test facility	Address	Certificate (Yes or No)
STAPHYT	Langenburger Str. 35 BLAUFELDEN 74572 GERMANY	Yes
InTec Agro Trials, s.r.o.	Blatnicka 179 Uhersky Ostroh, Czech Republic 687 24 CZECH REPUBLIC	Yes
Agrolab A/S	Røjleskovvej 18 Middelfart 5500 DENMARK	Yes
Quintus GMBH LIEPEN 7	17194 Hohen Wangelin OT LIEPEN GERMANY	Yes
ANADIAG FRANCE	13 rue de la Bourbre RUY 38300 FRANCE	Yes

Test facility	Address	Certificate (Yes or No)
STAPHYT	Langenburger Str. 35 BLAUFELDEN 74572 GERMANY	Yes



ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

STAPHYT s.r.o.
Měnin 569
664 57 Měnin

Útvar: Odbor přípravků na ochranu rostlin
Adresa: Zemědělská 1a, 613 00 Brno

Sp.zn: SZ UKZÚZ 032225/2016/06857 Č.j.: UKZUZ 057138/2016 Datum: 18. 5. 2016
Vyřizuje: ing. Minářová Tel.: 545 110 444 E-mail: ivana.minarova@ukzuz.cz

ROZHODNUTÍ

Ústřední kontrolní a zkušební ústav zemědělský (dále jen „ÚKZÚZ“), Hroznová 2, 656 06 Brno, jako věcně příslušný správní orgán podle § 72 odst. 1 písm. c) zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, ve znění pozdějších předpisů (dále jen „zákon“) a v návaznosti na čl. 54 odst. 4 Nařízení Evropského parlamentu a Rady (ES) č. 1107/2009, o uvádění přípravků na ochranu rostlin na trh a o zrušení směrnice Rady 79/117/EHS a 91/414/EHS, v platném znění, v provedení § 45 odst. 1 zákona, v řízení o způsobilosti k provádění pokusů a zkoušek s přípravky nebo dalšími prostředky na základě žádosti společnosti **STAPHYT s.r.o.**, Měnin 569, 664 57 Měnin, IČ 29210917 dále jen „společnost STAPHYT s.r.o.“ a to:

žádosti o prodloužení platnosti rozhodnutí o způsobilosti k provádění zkoušek podle § 45 odst. 1 zákona ze dne 24. 3. 2016, doručené ÚKZÚZ dne 24. 3. 2016, č.j. UKZUZ 032225/2016

rozhodl takto:

společnost STAPHYT s.r.o. je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe.

právníká osoba: **STAPHYT s.r.o.**

sídlo právnické osoby: Měnin 569, 664 57 Měnin

IČ právnické osoby: 29210917

GEP kód: **GEP/SHT/2016**

oblasti zkoušení: **polní plodiny a zelenina**
trvalé kultury
skleníky a jiné kryté prostory
moření osiva

rozhodnutí se vydává s účinností od 1. 9. 2016

dobu účinnosti rozhodnutí: 5 let

Tímto rozhodnutím se k datu nabytí jeho účinnosti zrušuje rozhodnutí č.j. SRS 026758/2010 ze dne 2. 7. 2010.

Odůvodnění:

Řízení ve věci uznání osoby za způsobilou provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe bylo zahájeno na základě žádosti ze dne 24. 3. 2016, doručené UKZÚZ dne 24. 3. 2016.

Rozhodnutí o způsobilosti k provádění pokusů a zkoušek v souladu s požadavky správné pokusnické praxe bylo vydáno na základě kontroly předložené dokumentace pracoviště STAPHYT s.r.o., Příručky jakosti, Standardních operačních postupů a Metrologického řádu, kterou bylo UKZÚZ prokázáno, že žadatel splnil požadavky stanovené v § 45 odst. 12 a 13 zákona v návaznosti na § 4 odst. 2 vyhlášky č. 32/2012 Sb., o přípravcích a dalších prostředcích na ochranu rostlin, ve znění pozdějších předpisů.

Vzhledem k výše uvedeným skutečnostem bylo rozhodnuto tak, jak je stanoveno ve výrokové části tohoto rozhodnutí.

Správní poplatek podle zákona č. 634/2004 Sb., o správních poplatcích, ve znění pozdějších předpisů, podle Sazebníku, Položky 86 písm. b) „Přijetí žádosti o vydání osvědčení o způsobilosti k provádění zkoušek pro účely povolení“ ve výši 100,- Kč, k žádosti doručené UKZÚZ dne 24. 3. 2016, č.j. UKZUZ 032225/2016, byl uhrazen dne 24. 3. 2016 formou kolkové známky.

Poučení:

Proti tomuto rozhodnutí lze podat odvolání do 15 dnů ode dne jeho doručení, nejpozději však do 15 dnů po uplynutí desátého dne ode dne, kdy bylo nedoručeno a uloženo rozhodnutí připraveno k vyzvednutí, a to k Ministerstvu zemědělství České republiky, odbor rostlinných komodit, prostřednictvím Ústředního kontrolního a zkušebního ústavu zemědělského, sekce zemědělských vstupů, odboru přípravků na ochranu rostlin, Zemědělská 1a, 613 00 Brno.

Otisk úředního razítka

Ing. Pavel Minář, Ph.D.
ředitel odboru

2

UKZÚZ
Hroznová 2
656 06 BRNO

Telefon: +420 543 548 111
Fax: +420 543 211 148
E-mail: podatelna@ukzuz.cz

IČ: 00020338
DIČ: CZ00020338
www.ukzuz.cz
ID DS: ugbaiq7

Test facility	Address	Certificate (Yes or No)
InTec Agro Trials, s.r.o.	Blatnická 179 Uherský Ostroh, Czech Republic 687 24 CZECH REPUBLIC	Yes



ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

Hroznová 2
656 06 Brno

www.ukzuz.cz
ID DS: ugbaiaq7

IČO: 00020338
DIČ: CZ00020338

InTec Agro Trials, spol. s r.o.
Blatnická 179
687 24 Uherský Ostroh
IČO: 06774512

Útvar: OPOR
Vyrizuje: Ing. Ivana Minářová
E-mail: ivana.minarova@ukzuz.cz
Telefon: +420 545 110 444
Adresa: Zemědělská 1a, 613 00 Brno

Spisová zn.: SZ UKZUZ 010368/2018/01399
Č. j.: UKZUZ 013294/2018
Datum: 7. 2. 2018

ROZHODNUTÍ

Ústřední kontrolní a zkušební ústav zemědělský (dále jen „ÚKZÚZ“), Hroznová 2, 656 06 Brno, jako věcně příslušný správní orgán podle § 72 odst. 1 písm. c) a v návaznosti na čl. 54 odst. 4 Nařízení Evropského parlamentu a Rady (ES) č. 1107/2009, o uvádění přípravků na ochranu rostlin na trh a o zrušení směrnic Rady 79/117/EHS a 91/414/EHS, v platném znění, v provedení § 45 odst. 1 zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, ve znění pozdějších předpisů (dále jen „zákon“), v řízení o způsobilosti k provádění pokusů a zkoušek s přípravky nebo dalšími prostředky na základě žádosti společnosti **InTec Agro Trials, s.r.o.**, a to:

žádosti o uznání osoby za způsobilou k provedení zkoušek podle § 45 odst. 1 zákona ze dne 24. 1. 2018, doručené ÚKZÚZ dne 26. 1. 2018, č.j. UKZUZ 010368/2018

rozhodl takto:

Společnost InTec Agro Trials, s.r.o. je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe.

právníká osoba: **InTec Agro Trials, s.r.o.**

sídlo právnické osoby: Blatnická 179, Ostrožské Předměstí, 687 24 Uherský Ostroh

IČ právnické osoby: 06774512

GEP kód: GEP/ITU/2018

oblasti zkoušení: **polní plodiny a zelenina
trvalé kultury
skleníky a jiné kryté prostory**

dobu platnosti rozhodnutí: 5 let ode dne nabytí účinnosti tohoto rozhodnutí

Odůvodnění:

Řízení ve věci uznání osoby za způsobilou provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe bylo zahájeno na základě žádosti ze dne 24. 1. 2018, doručené ÚKZÚZ dne 26. 1. 2018.

Do firmy InTec Agro Trials, s.r.o. přechází původní personální obsazení a zařízení firmy ATC – Agro Trial Center GmbH, organizační složky, původního držitele povolení č.j. UKZUZ 073735/2016 ze dne 1. 7. 2016. Nedošlo ke změnám v oblasti personálního obsazení, v prostorách, v nichž je činnost realizována, na pozemcích, na nichž je činnost prováděna a změnám v základní dokumentaci.

Rozhodnutí o způsobilosti k provádění pokusů a zkoušek v souladu s požadavky správné pokusnické praxe bylo vydáno na základě předložené dokumentace, Příručky jakosti, Standardních operačních postupů a Metrologického řádu, kterou bylo ÚKZÚZ prokázáno, že žadatel splnil požadavky stanovené v § 45 odst. 12 a 13 zákona v návaznosti na § 4 odst. 2 vyhlášky č. 32/2012 Sb., o přípravcích a dalších prostředcích na ochranu rostlin, ve znění pozdějších předpisů.

Vzhledem k výše uvedeným skutečnostem bylo rozhodnuto tak, jak je stanoveno ve výrokové části tohoto rozhodnutí.

Správní poplatek podle zákona č. 634/2004 Sb., o správních poplatcích, ve znění pozdějších předpisů, podle Sazebníku, Položky 86 písm. b) „Přijetí žádosti o vydání osvědčení o způsobilosti k provádění zkoušek pro účely povolení“ ve výši 100,- Kč, k žádosti doručené ÚKZÚZ dne 26. 1. 2018, č.j. UKZUZ 010368/2018, byl uhrazen dne 26. 1. 2018 formou kolkové známky.

Poučení o odvolání:

Proti tomuto rozhodnutí lze podat odvolání do 15 dnů ode dne jeho doručení, nejpozději však do 15 dnů po uplynutí desátého dne ode dne, kdy bylo nedoručené a uložené rozhodnutí připraveno k vyzvednutí, a to k Ministerstvu zemědělství České republiky, odbor rostlinných komodit, prostřednictvím Ústředního kontrolního a zkušebního ústavu zemědělského, sekce zemědělských vstupů, odboru přípravků na ochranu rostlin, Zemědělská 1a, 613 00 Brno.

Ing. Pavel Minář, Ph.D.
ředitel OPOR

Test facility	Address	Certificate (Yes or No)
Agrolab A/S	Røjleskovvej 18 Middelfart 5500 DENMARK	Yes



Certifikat

for GEP-anerkendelse tildeles herved

Forsøgsenheden: Agrolab A/S
Røjleskovvej 18
DK-5500 Middelfart

Anerkendelsen gælder udførelsen af GEP-effektivitetsforsøg for bekæmpelsesmidler inden for

Forsøgsområderne: Markforsøg

GEP

GEP Anerkendelses Enheden ved Nationalt Center for Fødevarer og Jordbrug, Aarhus Universitet, kontrollerer organisation, personale, lokaler, forsøgsarealer, forsøgsudstyr samt standardforskrifter og forsøgsrapporter. Forsøgsenheden er underkastet løbende kontrol og inspektion.

Certifikatet for anerkendelse er gyldigt for en periode på 6 år.

Anerkendelsesdato: 1. januar 2014

Underskrevet: 16. december 2013


Nina Sørup Hansen
Miljøstyrelsen


Ulla Fosgerau Salomonsen
Aarhus Universitet


Peter Kryger Jensen
Aarhus Universitet

Forordning 1107/2009 om plantebeskyttelsesmidler og Miljøministeriets bekendtgørelse nr.1088 af 6. september 2013 anfører, at undersøgelser af plantebeskyttelsesmidlers effektivitet, der er udført i Danmark med henblik på godkendelse, skal være foretaget af forsøgsenheder, der er anerkendt hertil af Nationalt Center for Fødevarer og Jordbrug, Aarhus Universitet.

Test facility	Address	Certificate (Yes or No)
Quintus GMBH LIEPEN 7	17194 Hohen Wangelin OT LIEPEN GERMANY	Yes

Anerkennungsbescheinigung

Die Versuchseinrichtung

mit Hauptsitz in

und organisatorisch
zugehörigen
Arbeitseinheiten in

ist auf Antrag vom

und nach durchgeführter
Besichtigung
durch
vom

am

in den Versuchskategorien

als Einrichtung für die Prüfung
der Wirksamkeit von
Pflanzenschutzmitteln im
Sinne des § 8 Abs. 6 der
Pflanzenschutzmittelverordnu
ng und gemäß
Verordnung (EU) Nr. 284/2013
für 5 Jahre amtlich anerkannt
worden.

Quintus GmbH

Liepen 7
17194 Hohen Wangelin

08393 Schönberg
Breitenbacher Straße 21

74595 Langenburg-
Nesselbach
Orlacher Straße 16

27798 Hude
Wieselweg 6

2016-02-01

Herrn Dr. S. Goltermann
Landesamt für Landwirtschaft,
Lebensmittelsicherheit und
Verbraucherschutz MV
2016-04-11

Acker-, Obst-, Gemüse-, Zier-
pflanzenbau, Haus- und
Kleingarten

agriculture, horticulture, home
and garden

Recognition Certificate

The testing facility

with headquarter in

and subsidiary testing
units in

on application from

and after inspection

by
from

on

in the trial categories

has been officially
recognised as an
organisation for efficacy
testing facility of plant
protection products
according to § 8 par. 6 of
the Plant Protection
Products Ordinance and
the Commission
Regulation (EU) No
284/2013 for 5 years.

11.04.2016

Datum
date

Unterschrift
signature

Landesamt für Landwirtschaft,
Lebensmittelsicherheit und
Verbraucherschutz MV,
Thierfelderstr. 18, 18059 Rostock

Adresse der anerkennenden Behörde
address of the recognising authority



Test facility	Address	Certificate (Yes or No)
ANADIAG FRANCE	13 rue de la Bourbre RUY 38300 FRANCE	Yes



MINISTÈRE DE L'AGRICULTURE ET DE L'ALIMENTATION

**DÉCISION D'AGRÈMENT POUR RÉALISER
DES ESSAIS OFFICIELLEMENT RECONNUS**

Conformément à l'article R. 253-38 du code rural et de la pêche maritime et à l'article 6 de l'arrêté du 26 avril 2007 relatif aux essais officiels et officiellement reconnus pour l'évaluation des produits mentionnés à l'article L. 253-1 du code rural et de la pêche maritime,

Vu la convention passée avec le Cofrac n° 4609,

Vu le rapport d'évaluation réalisé par le Cofrac, en date du 27 juillet 2017,

L'agrément pour réaliser des essais officiellement reconnus est renouvelé, à l'organisme :

ANADIAG France
13 rue de la Bourbre
38300 RUY

sous le numéro : **BPE - 105**

ET POUR LE PÉRIMÈTRE SUIVANT :

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
ANADIAG France 13 rue de la Bourbre 38300 RUY (unité centrale)	- Traitement des semences : grandes cultures
UE 01 – Harnes (UE 62) ZI la Motte au Bois 62440 HARNES	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Zones non agricoles
UE 03 – Saint Pierre du Bû (UE 14) Couvigny 14700 SAINT PIERRE DU BU	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum
UE 03 – Cintré (UE 35) Rue du puisatier ZA du moulin à vent 35310 CINTRE	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Zones non agricoles
UE 06 – Varois et Chaignot (UE 21) 8 route de Gray 21490 VAROIS ET CHAIGNOT	- Grandes cultures - Vigne - Zones non agricoles
UE 08 – Saint Barthélémy (UE 38) 700 route de Pisieu 38270 SAINT BARTHELEMY	- Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
UE 10 – Saint Etienne de Fougères (UE 47) ZA Bel Air 47380 SAINT ETIENNE DE FOUGERES	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles - Désinfections et désinsectisation des sols, des matériels et des locaux de culture et de stockage des végétaux
UE 12– Saint Germain des Prés (UE 49) ZA la Poterie 49170 SAINT GERMAIN DES PRES	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur
UE 13 – Castillon du Gard (UE 30) ZA les codes bas 3 30210 CASTILLON DU GARD	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles
UE 15 – Haguenau (UE 67) 16 rue Ampère 67500 HAGUENAU	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Processus de transformation : <ul style="list-style-type: none"> - Vinification - Transformation de pomme de terre - Transformation de fruits (compote, jus de fruit, nectar, fruit au sirop, confiture, fruits séchés) - Transformation de légumes (jus, concentré de tomates, conserve de légumes, ketchup, choucroute) - Extraction d'huile
UE 16 – Thorée les Pins (UE 72) La Belle Métairie 72800 THOREE LES PINS	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture
UE 17 – Toulouse (UE 31) 75 voie de TOEC Bâtiment entreprise 2 31076 TOULOUSE	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture

Cet agrément est délivré pour une durée de cinq ans à compter du **09/10/2017** jusqu'au **08/10/2022**. En application de l'article 5 de l'arrêté susmentionné, une nouvelle évaluation aura lieu dans un délai compris entre vingt-quatre et trente-six mois à compter du **09/10/2017**.

Date : 03 OCT. 2017

Le sous directeur de la qualité, de la santé
et de la protection des végétaux

Alain TRIDON

Mediterranean EPPO zone

Test facility	Address	Certificate (Yes or No)
Agricultura y Ensayo S.L. Sucursal em Portugal	Rua Dr. Oscar da Costa Neves, n°2 Almeirim 2080-130 PORTUGAL	Yes
SynTech Research Portugal	Rua António Oliveira, 21 Lote 16 B - Armazém L Zona Industrial de Caldas da Rainha Freguesia de Santo Onofre 2500-916 Caldas da Rainha- PORTUGAL	Yes
ANADIAG France	13 rue de la Bourbre RUY 38300 FRANCE	Yes
ANADIAG Portugal	Rua dos Olivais 3, R/C Direito Fracção B 3780-229 ANADIA PORTUGAL	Yes

Test facility	Address	Certificate (Yes or No)
Agricultura y Ensayo S.L. Sucursal em Portugal	Rua Dr. Oscar da Costa Neves, n.º Almeirim 2080-130 PORTUGAL	Yes



CERTIFICADO

ORGANIZAÇÃO OFICIALMENTE RECONHECIDA PARA A REALIZAÇÃO DE ENSAIOS DE EFICÁCIA DE PRODUTOS FITOFARMACÊUTICOS

Certifica-se que foi reconhecida como Organização Oficialmente Reconhecida, em Portugal, a **AGRICULTURA Y ENSAYO S.L. – Sucursal em Portugal**, para a realização de ensaios de eficácia de produtos fitofarmacêuticos, segundo a Boa Prática Experimental, n.º 35, da Portaria n.º 396/2000, de 14 de Julho, que concretiza os princípios estabelecidos no Regulamento (UE) N.º 284/2013 da Comissão de 1 de março de 2013, em conformidade com o Regulamento (CE) N.º 1107/2009 do Parlamento Europeu e de acordo com o respetivo pedido.

- **Certificado n.º 25**
- **Data de entrada em vigor do reconhecimento: 26 de julho de 2016**
- **Termo do prazo do reconhecimento: 26 de julho de 2021**
- **Condições / Limitações: ---**

Oeiras, 20 de setembro de 2016.

A Subdiretora Geral

Ana Paula de Almeida
Cruz de Carvalho

Assinado de forma digital por Ana
Paula de Almeida Cruz de Carvalho
Dados: 2017.04.03 08:44:10 +01'00'

Test facility	Address	Certificate (Yes or No)
SynTech Research Portugal	Rua António Oliveira, 21 Lote 16 B - Armazém L Zona Industrial de Caldas da Rainha Freguesia de Santo Onofre 2500-916 Caldas da Rainha- PORTUGAL	Yes



AKKREDITÁLÁSI OKIRAT

ACCREDITATION CERTIFICATE

A NEMZETI AKKREDITÁLÓ HATÓSÁG

The National Accreditation Authority

a 2015. évi CXXIV. törvény és a 424/2015. (XII.23.) Kormányrendeletben foglalt
felhatalmazás alapján elismeri, hogy a
authorized by Act No. CXXIV of 2015 and Government Decree No. 424/2015. (XII.23.),
recognizes, that

SynTech Research Hungary Kft.
Analitikai Laboratórium
1045 Budapest, Berliini utca 47-49.

megfelel az MSZ EN ISO/IEC 17025:2005 szabvány követelményeinek és a
complies with criteria of Standard MSZ EN ISO/IEC 17025:2005 as

vizsgálólaboratórium
TESTING LABORATORY
kategóriába az alábbi számon bejegyzi
and has been assigned registration number

NAH-1-1846/2018

Az akkreditálás területét az akkreditálási határozat tartalmazza.
The scope of accreditation is specified in the accreditation decision.

Az akkreditált státusz kezdetének napja:
Start date of the accredited status
2018. augusztus 30.

Az akkreditált státusz lejáratának napja:
Expiry date of the accredited status
2023. augusztus 30.

Budapest, 2018. augusztus 30.



Devecz Miklós
A Nemzeti Akkreditáló Hatóság főigazgatója
Director General of the National Accreditation Authority

A NAH ebben a kategóriában aláírja az Európai Akkreditálási Együttműködés (EA) megállapodásának.
The NAH is a signatory in this field of the European co-operation for Accreditation (EA) Multilateral Agreement (MLA) for accreditation.

Test facility	Address	Certificate (Yes or No)
ANADIAG France	13 rue de la Bourbre RUY 38300 FRANCE	Yes



MINISTÈRE DE L'AGRICULTURE ET DE L'ALIMENTATION

**DÉCISION D'AGRÈMENT POUR RÉALISER
DES ESSAIS OFFICIELLEMENT RECONNUS**

Annule et remplace les courriers du 7/02/2020

Conformément à l'article R. 253-38 du code rural et de la pêche maritime et à l'article 6 de l'arrêté du 26 avril 2007 relatif aux essais officiels et officiellement reconnus pour l'évaluation des produits mentionnés à l'article L. 253-1 du code rural et de la pêche maritime,

Vu la convention passée avec le Cofrac n° 4609,

Vu le rapport d'évaluation réalisé par le Cofrac, en date du 26/11/2019,

L'agrément pour réaliser des essais officiellement reconnus est maintenu et étendu, à l'organisme :

Anadiag France
174 impasse du plan d'eau
38300 RUY MONTCEAU

sous le numéro : **BPE - 105**

ET POUR LE PÉRIMÈTRE SUIVANT :

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
ANADIAG FRANCE 174 impasse du plan d'eau 38300 RUY MONTCEAU (unité centrale)	- Traitement des semences : grandes cultures
UE 01 – Harnes (UE 62) ZI la Motte au Bois 62440 HARNES	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Zones non agricoles
UE 03 – Saint Pierre du Bû (UE 14) Couvrigny 14700 SAINT PIERRE DU BU	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Zones non agricoles
UE 04 – Cintré (UE 35) Rue du puisatier ZA du moulin à vent 35310 CINTRE	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Zones non agricoles
UE 06 – Varois et Chaignot (UE 21) 8 route de gray 21490 VAROIS ET CHAIGNOT	- Grandes cultures - Vigne - Cultures fruitières et arboriculture - Zones non agricoles

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
UE 08 – Saint Barthélémy (UE 38) 700 route de Pisieu 38270 SAINT BARTHELEMY	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles
UE 10 – Saint Etienne de Fougères (UE 47) ZA Bel Air 47380 SAINT ETIENNE DE FOUGERES	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles - Désinfection et désinsectisation des sols, des matériels et des locaux de culture et de stockage des végétaux
UE 12 – Saint Germain des Prés (UE 49) ZA la Potherie 49170 SAINT GERMAIN DES PRES	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles
UE 13 – Castillon du Gard (UE 30) ZA les Codes Bas 3 30210 CASTILLON DU GARD	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles
UE 15 – Haguenau (UE 67) 16 rue Ampère 67500 HAGUENAU	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Zones non agricoles - Processus de transformation : <ul style="list-style-type: none"> Vinification Transformation de pomme de terre Transformation de fruits (compote, jus de fruit, nectar, fruit au sirop, confiture, fruits séchés) Transformation de légumes (jus, concentré de tomates, conserve de légumes, ketchup, choucroute) Extraction d'huile

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
UE 16 – Thorée les Pins (UE 72) La Belle Métairie 72800 THOREE LES PINS	<ul style="list-style-type: none">- Grandes cultures- Vigne- Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum- Cultures fruitières et arboriculture- Zones non agricoles
UE 17 – Toulouse (UE 31) 75 voie du TOEC Bâtiment entreprise 2 31076 TOULOUSE Cedex 3	<ul style="list-style-type: none">- Grandes cultures- Vigne- Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum- Cultures fruitières et arboriculture- Zones non agricoles

Cet agrément est valable jusqu'au 08/10/2022. La prochaine évaluation de votre organisme est prévue au planning sur septembre / octobre 2020.

Date : 07/02/2020

La sous directrice de la qualité,
de la santé et de la protection
des végétaux



Anne-Cécile COTILLON

Test facility	Address	Certificate (Yes or No)
ANADIAG Portugal	Rua dos Olivais 3, R/C Direito Fracção B 3780-229 ANADIA, PORTUGAL	Yes



CERTIFICADO

ORGANIZAÇÃO OFICIALMENTE RECONHECIDA PARA A REALIZAÇÃO DE ENSAIOS DE EFICÁCIA DE PRODUTOS FITOFARMACÊUTICOS

Certifica-se que é reconhecida como Organização Oficialmente Reconhecida, em Portugal, a **ANADIAG Portugal** para a realização de ensaios de eficácia de produtos fitofarmacêuticos, segundo a Boa Prática Experimental, n.º 35, da Portaria n.º 396/2000, de 14 de Julho, que concretiza os princípios estabelecidos no Regulamento (UE) N.º 284/2013 da Comissão de 1 de março de 2013, em conformidade com o Regulamento (CE) N.º 1107/2009 do Parlamento Europeu e do Conselho, de 21 de outubro, de acordo com o respetivo pedido.

- **Certificado n.º 19 (dezanove)**
- **Data de entrada em vigor do reconhecimento: 20 de abril de 2017**
- **Termo do prazo do reconhecimento: 20 de abril de 2022**
- **Condições / Limitações: —**

Oeiras, 27 de fevereiro de 2018

A Subdiretora Geral

ANA PAULA DE
ALMEIDA CRUZ DE
CARVALHO

Assinado de forma digital
por ANA PAULA DE ALMEIDA
CRUZ DE CARVALHO
Dados: 2018.02.27 13:52:02 Z

North-Eastern EPPO zone

Test facility	Address	Certificate (Yes or No)
STAPHYT	Langenburger Str. 35 BLAUFELDEN 74572 GERMANY	Yes
ANADIAG POLSKA	Ul. Sadowa 16/22, 95-100 Zgierz, POLAND	Yes

Test facility	Address	Certificate (Yes or No)
STAPHYT	Langenburger Str. 35 BLAUFELDEN 74572 GERMANY	Yes

**GLÓWNY INSPEKTOR
OCHRONY ROŚLIN I NASIENICTWA**

Tadeusz Kłos

WO-505- 14 /2012

Warszawa, 26.09.2012 r.

DECYZJA Nr 7/2012

Na podstawie art. 155 ustawy z dnia 14 czerwca 1960 r. Kodeks postępowania administracyjnego (Dz.U. z 2000 r. Nr 98, poz. 1071 ze zm.) i art. 40 ust. 1 ustawy z dnia 18 grudnia 2003 r. o ochronie roślin (Dz.U. z 2008 r. Nr 133, poz. 849 ze zm.), po rozpatrzeniu wniosku z dnia 6 września 2012 r., zmieniając decyzję Nr 9/2005 z dnia 1 maja 2005 r., zmienioną decyzjami: Nr 3/2006 z dnia 5 maja 2006 r., Nr 8/2006 z dnia 11 grudnia 2006 r., Nr 2/2009 z dnia 18 lutego 2009 r., Nr 12/2011 z dnia 31 marca 2011 r. oraz Nr 4/2012 z dnia 4 kwietnia 2012 r.

Rozstrzygnięciu decyzji nadaję następujące brzmienie:

upoważniam

STAPHYT Sp. z o.o.

ul. Ziębicka 2; 60-164 Poznań

do prowadzenia badań skuteczności działania środka ochrony roślin

z grupy fungicydów, herbicydów, insektycydów, moluskocydów, akarycydów, regulatorów wzrostu, zapraw nasiennych oraz do łącznego stosowania środków ochrony roślin w uprawach polowych: zbóż, kukurydzy, rzepaku, buraków cukrowych, słonecznika, ziemniaków, warzyw, w uprawach sadowniczych (jabłoni, gruszy, porzeczki, truskawki, pestkowe), w magazynach i przechowalniach, a także na trawnikach oraz w uprawach roślin ozdobnych w polu i pod osłonami.

Uzasadnienie

W dniu 6 września 2012 r. Staphyt Sp. z o.o. (ul. Ziębicka 2; 60-164 Poznań) zwróciła się z wnioskiem o rozszerzenie zakresu decyzji Głównego Inspektora Ochrony Roślin i Nasiennictwa upoważniającej do prowadzenia badań skuteczności działania środków ochrony roślin Nr 9/2005 z dnia 1 maja 2005 r.,

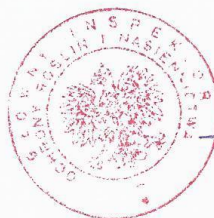
zmienionej decyzjami: Nr 3/2006 z dnia 5 maja 2006 r., Nr 8/2006 z dnia 11 grudnia 2006 r., Nr 2/2009 z dnia 18 lutego 2009 r. oraz Nr 4/2012 z dnia 4 kwietnia 2012 r. Wniosek dotyczył możliwości prowadzenia badań w magazynach i przechowalniach.

Staphyt Sp. z o.o. spełnia warunki organizacyjno-techniczne, zwane „Zasadami Dobrej Praktyki Eksperymentalnej” (Good Experimental Practice - GEP), zapewniające prawidłowe przeprowadzanie badań skuteczności działania środka ochrony roślin.

Mając na uwadze powyższe, postanowiono jak w rozstrzygnięciu decyzji.

Pouczenie

Od niniejszej decyzji odwołanie nie przysługuje. Jednakże strona niezadowolona z decyzji może zwrócić się do Głównego Inspektora Ochrony Roślin i Nasiennictwa z wnioskiem o ponowne rozpatrzenie sprawy w terminie 14 dni od dnia doręczenia decyzji, zgodnie z art. 127 § 3 Kodeksu postępowania administracyjnego.



GŁÓWNY INSPEKTOR

Tadeusz Kłos

Test facility	Address	Certificate (Yes or No)
ANADIAG POLSKA	Ul. Sadowa 16/22, 95-100 Zgierz, POLAND	Yes

SWORN TRANSLATOR
MARTA TRAWCZYŃSKA

ul. Św. Wojciecha 3/3a lok. 1, 10-038 Olsztyn
T + 48 665 240 339, F +48 89/ 512 00 99

CERTIFIED TRANSLATION FROM THE POLISH LANGUAGE

[Any remarks in square brackets are the translator's. The translated document consists of two (2) pages.]

[national emblem of the Republic of Poland]
MAIN INSPECTOR
OF PLANT HEALTH AND SEED PROTECTION

Andrzej Chodkowski

Warsaw, dated 12 October 2018

BORIT.541.11.2018.1

DECISION No. 10/2018

Pursuant to Article 155 of the Act of 14 June 1960 Administrative Procedure Code (Dz.U. *[Polish Official Journal of Laws]* of 2017, item 1257 as amended), having examined the application filed by Anadiag SAS Branch Office in Poland dated 3 October 2018, I vary the decision No. 7/2007 dated 28 May 2007, varied by decisions No. 1/2010 dated 18 March 2010, No. 18/2011 dated 18 August 2011, No. 1/2012 dated 13 January 2012 and No. 3/2014 dated 16 April 2014 to grant authorization to conduct research of the efficiency of plant health products in such a manner that the decision shall read as follows:

"I authorize

Anadiag SAS Branch Office in Poland
ul. Sadowa 16/22, 95-100 Zgierz

to conduct research of the efficiency of plant health products from the group of acaricides, bacteriocides, fungicides, herbicides, insecticides, molluscicides, rodenticides, pheromones and growth regulators in outdoor crops, orchard crops, under covers, in edible mushrooms cultivations, in meadows and pastures. The research shall be conducted in cereal, root and oil crops, vegetables, orchard and ornamental plants, legumes, grass and special plants, in storage rooms and rooms for cultivation of edible mushrooms, in lawns and in non-agricultural lands."

No reasoning for this decision has been prepared as the decision grants the application of the Party in its entirety (Article 107(4) of the Administrative Procedure Code *[hereinafter referred to as "APC"]*).



Marta Trawczyńska

Instruction

This decision may not be appealed against. A Party unsatisfied with this decision may file an application to the Main Inspector of Plant Health and Seed Protection requesting a re-examination of the case, within 14 days of being served with this decision, pursuant to Article 127(3) APC.

Until the time-limit to apply for re-examination of the case has expired, a Party may waive this right towards the public administration authority which issued the decision. On the day when the Main Inspector of Plant Health and Seed Protection receives the waiver of the right to apply for re-examination of the case, the decision becomes final and non-appealable, which means that the decision shall be enforced immediately and it may not be appealed against to the Voivodeship Administration Court.

If a Party does not believe that the decision grants the Party's application but does not wish to exercise its right to apply for re-examination of the case, the Party may file to the Voivodeship Administration Court in Warsaw a complaint against the decision within 30 days of being served with the decision. The complaint shall be filed through the Main Inspector of Plant Health and Seed Protection.

Pursuant to section 2(1)(2) of the Regulation of the Council of Ministers of 16 December 2003 on the amount and detailed rules for collecting charges in proceedings before administrative courts (Dz.U. [Polish Official Journal of Laws] No. 221, item 2193 as amended) a fixed charge, which is independent of the subject-matter of the act appealed against or activities in cases regarding complaints against acts or public administration activities regarding rights or duties specified by the law, shall amount to PLN 200.

At the request of a Party made before court proceedings are instituted or in the course of such proceedings, the Party may be granted legal aid consisting of full or partial exemption from court costs and having an attorney-at-law or a legal advisor appointed for such Party, if the Party substantiates that they are unable to bear any costs of the proceedings or full costs thereof.

To be served upon:

1. Mr Jacek Jateczak
Anadiag SAS Branch Office in Poland
ul. Sadowa 16/22
95-100 Zgierz
2. file

[round official seal with the national emblem of the Republic of Poland in its midst and the following circumscription: MAIN INSPECTOR OF PLANT HEALTH AND SEED PROTECTION]

[rectangular stamp reading: P.p. / MAIN INSPECTOR / Tadeusz Łączyński; illegible signature]

I, duly commissioned sworn translator of the English language (TP/101/2013) in Olsztyn, hereby certify that the above translation is a true and complete version of the document in Polish presented to me.

Reg. No. 222/2018

Olsztyn, dated 29s October 2018



Marta Trawczyńska

South-Eastern EPPO zone

Test facility	Address	Certificate (Yes or No)
STAPHYT	Station Kecskemet, KECSKEMET HUNGARY	Yes
ANADIAG HUNGARY Kft.	H2921, Komárom, Petőfi Sándor 67 HUNGARY	Yes
ANADIAG ROMANIA SRL	Piata Montreal no. 10, World Trade Centre, Entrance F, 1st Floor 011469, Bucharest, ROMANIA	Yes

Test facility	Address	Certificate (Yes or No)
STAPHYT	Station Kecskemet, KECSKEMET HUNGARY	Yes



PEST MEGYEI
KORMÁNYHIVATAL

Ügyirat-szám: PE/NT/0045-7/2018

Ügyintéző: Dr. Cs. Tóth Attila

Telefon: 06-1/236-3928

E-mail: cs.totha@pest.gov.hu

Tárgy: Staphyt Hungary Kft. (5000

Szolnok, Piroskai u. 2.)

vizsgálóhelyének GEP tanúsítása

Melléklet:-

A Pest Megyei Kormányhivatal (továbbiakban: engedélyező hatóság) a Staphyt Hungary Kft. (székhely: 5000 Szolnok, Piroskai u. 2., a továbbiakban: Ügyfél) vizsgálóhelyének Helyes Kísérleti Gyakorlat (továbbiakban: GEP) szerinti inspekciója és elismerése iránti kérelme alapján indult elsőfokú eljárásban meghozta az alábbi

H A T Á R O Z A T O T :

Engedélyezési célú biológiai hatásvizsgálatok végzéséhez az Ügyfél vizsgálóhelyének GEP-minősítését kiadom.

A GEP-minősítés 5 évig érvényes határozatom jogerőre emelkedésétől számítva.

A vizsgálóhely GEP-minősítés az alábbi minősítési kategóriákra és művelési ágakra kerül kiadásra:

- minősítési kategória:** herbicidek, fungicidek és baktericidek, zoocidok, növekedésszabályozó és terménynövelő készítmények, adalékanyagok
- művelési ág:** szántóföld, zöldség, gyümölcs, szőlő, dísznövény, erdő, közterület és egyéb (rezisztencia, dózis vizsgálat, talajfertőtlenítő szerek)

Jelen minősítés nem érinti a működéssel/tevékenység folytatásával kapcsolatos egyéb jogszabályban előírt engedélyeket, illetve Ügyfélnek azok beszerzésére vonatkozó kötelezettségét.

Az Ügyfél a vizsgálóhelyeinek minősített tevékenységét érintő jelentős változásról 15 napon belül köteles értesíteni az engedélyező hatóságot.

A GEP-minősítéssel kapcsolatos jogszabályokban és a jelen határozatban foglaltak betartását hatóságom szűrőpróbaszerűen ellenőrzi. Amennyiben az ellenőrzés során megállapítást nyer, hogy a vizsgálóhely nem tartja be a rá vonatkozó GEP - követelményeket, akkor az engedélyező hatóság a határozatban feltüntetett minősített területre vonatkozó tevékenység végzését legfeljebb 2 hónapra felfüggesztheti, illetve a kiadott GEP-minősítését visszavonhatja.

Ha az ellenőrzés során egy adott kísérlettel kapcsolatban hiányosságok kerülnek megállapításra, a kísérletet a hiányosságok mértékétől függően az engedélyező hatóság kizárhatja az engedélyezésnél elfogadhatók közül.

A vizsgálóhely GEP szerinti inspekciója és elismerése eljárás díjköteles, amely a Nemzeti Élelmiszerlánc-biztonsági Hivatal, valamint a megyei kormányhivatalok mezőgazdasági szakigazgatási szervei előtt kezdeményezett eljárásokban fizetendő igazgatási szolgáltatási díjak mértékéről, valamint az igazgatási szolgáltatási díj fizetésének szabályairól szóló 63/2012. (VII. 2.) VM rendelet 1. sz. mellékletének 8.19.2. pontja szerint: **250.000.- Ft, amelyet az Ügyfél megfizetett.**

Élelmiszerlánc- biztonsági, Földhivatali, Növény- és Talajvédelmi, Erdészeti Főosztály

Cím: 1135 Budapest, Lehel u. 43-47.;

Telefon: 06-1/236-3934 Fax: 06-1/350-0117

E-mail: pmkh-nto@pest.gov.hu Honlap: www.kormanyhivatal.hu/hu/pest

Jelen határozat ellen közigazgatási per indítható a Fővárosi Közigazgatási és Munkaügyi Bíróságnál a határozatot hozó Élelmiszerlánc-biztonsági Földhivatali, Növény- és Talajvédelmi, Erdészeti Főosztály Növény- és Talajvédelmi Osztály elleni kereset indításával. A keresetlevelet a felülvizsgálni kért határozat közlésétől számított harminc napon belül, az engedélyező hatósághoz elektronikus úton kell benyújtani.

INDOKOLÁS

Az Ügyfél 2018. január 17-én érkezett levelében vizsgálóhelyének GEP szerinti minősítésének felülvizsgálatát és a minősítés megújítását kérte a Pest Megyei Kormányhivatal, Élelmiszerlánc-biztonsági, Földhivatali, Növény- és Talajvédelmi Erdészeti Főosztály, Növény- és Talajvédelmi Osztályától.

Az engedélyező hatóság 2018. március 8-án az Ügyfél székhelyén helyszíni ellenőrzést tartott, amelyeknek megállapításait a PE/NT/0045-3/2018. számú jegyzőkönyvben rögzítette.

A helyszíni ellenőrzés során az engedélyező hatóság megállapította, hogy a növényvédő szerek forgalomba hozatalának és felhasználásának engedélyezéséről, valamint a növényvédő szerek csomagolásáról, jelöléséről, tárolásáról és szállításáról szóló 89/2004. (V. 15.) FVM rendelet (továbbiakban: Rendelet) 22. §-ban foglalt biológiai hatásvizsgálatokkal kapcsolatos előírásoknak a vizsgálóhely nem felelt meg hiánytalanul, és az ügyfelet a PE/NT/0045-5/2018. számú végzésben a hiányosságok megszüntetésére szólította fel.

Az Ügyfél a hiányosságokat megszüntette és annak bizonyításáról szóló dokumentációt az engedélyező hatóságnak 2018. április 30-án megküldte.

A fentiek alapján megállapítottam, hogy a GEP-minősítés megadásának feltételei teljesültek, ennek megfelelően döntöttem a rendelkező részben foglaltak szerint.

A Rendelet 22. §-a értelmében „(5) Kérelem alapján az engedélyező hatóság helyszíni ellenőrzést folytat le a vizsgálóhelyen, majd határozatban dönt a vizsgálóhely GEP-minősítéséről. A határozatnak ki kell terjednie arra, hogy a vizsgálóhely milyen kategóriákra, illetve művelési ágakra szerezte meg a GEP-minősítést.

(6) A GEP-minősítés érvényességi ideje első tanúsítás esetén 2 év, a tanúsítás megújítását követően legfeljebb 5 év.

(7) A GEP-minősítési eljárásért a külön jogszabályban meghatározott díjat kell fizetni

(8) A GEP-minősítéssel rendelkező vizsgálóhely minden, a minősített tevékenységét érintő jelentős változásról 15 napon belül köteles értesíteni az engedélyező hatóságot.

(9) Az engedélyező hatóság szűrőpróbaszerűen ellenőrzi a GEP-minősítéssel rendelkező vizsgálóhelyeket. Amennyiben megállapítást nyer, hogy a vizsgálóhely nem tartja be a rá vonatkozó GEP-követelményeket, a hatóság a határozatban feltüntetett minősített területre vonatkozó tevékenységet legfeljebb 2 hónapra felfüggesztheti, illetve a kiadott GEP-minősítést visszavonhatja. Ha az ellenőrzés során egy adott kísérlettel kapcsolatban hiányosságok kerülnek megállapításra, a kísérletet a hiányosságok mértékétől függően az engedélyező hatóság kizárhatja az engedélyezésnél elfogadhatók közül.”

Az engedélyező hatóság a határozatát a földművelésügyi hatósági és igazgatási feladatokat ellátó szervek kijelöléséről szóló 383/2016. (XII.2.) Kormányrendelet 19. § a) pontjában és az élelmiszerláncról és hatósági felügyeletéről szóló 2008. évi XLVI. törvény 33. § e) pontjában

biztosított jogkörében, valamint a központi hivatalok felülvizsgálatával és a járási (fővárosi kerületi) hivatalok megerősítésével összefüggő egyes törvények módosításáról, valamint egyes költségvetési szervek feladatainak átadásáról szóló 2016. évi CIV. törvény 136. §. (1) bekezdésében foglaltaknak megfelelően hozta.

Határozatomat az *általános közigazgatási rendtartásról* szóló 2016. évi CL. törvény (a továbbiakban: Ákr.) 80. § (1) bekezdésének és 81. § (1) és (4) bekezdésének megfelelően adtam ki.

A jelen határozat elleni fellebbezés lehetősége az Ákr. 114. § (1) bekezdése alapján került kizárásra. A bírósági felülvizsgálat lehetőségéről szóló tájékoztatás a közigazgatási perrendtartásról szóló 2017. évi I. törvény 13. § (1), 38.§ (1), 39. § (1) bekezdésein alapul.

Budapest, 2018. május 14.



Dr. Tarnai Richárd kormány megbízott
névében és megbízásából

Tóth Ágoston
osztályvezető

A határozatot kapják:

1. Ügyfél
2. Irattár

Test facility	Address	Certificate (Yes or No)
ANADIAG HUNGARY Kft.	H2921, Komárom, Petőfi Sándor 67 HUNGARY	Yes

	n é b i h Termőföldtől az asztalig	National Food Chain Safety Office Directorate of Plant Protection, Soil Conservation and Agri-environment	 H-1118 Budapest, Budaörsi út 141-145. Hungary Tel: 36/1/309-1000 Fax: 36/1/246-2942 E-mail: nti@nebih.gov.hu www.nebih.gov.hu
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Your ref.: -

Our ref.: 04.2/6149-7/2016

7 October 2016

Subject: Certificate of Official Recognition of Efficacy Testing Facilities or Organisations in Hungary

Having received the application submitted by the **Anadiag Hungary Mezőgazdasági Szolgáltató Kft. (H-2921 Komárom, Petőfi Sándor út 67, Hungary)**, the client, for completing a certification procedure of first instance concerning the Official Recognition of Efficacy Testing Facilities/Organisations, i.e. Good Experimental Practices (*hereinafter*: GEP), I, acting as the food chain control body, has made the following

DECISION:

I issue the client's GEP certificate for its premises at Komárom, Petőfi Sándor út 67 for carrying out efficacy trials for authorisation purposes. The GEP certificate is effective for 5 years from the entry into force of this Decision.

The client's GEP certificate is given for the following categories of products and cultivation:

- product categories:** herbicides, fungicides and bactericides, zoocides, growth regulators and yield enhancing substances, additives;
- cultivation categories:** field crops, vegetables, fruits, grapevines, ornamentals, others.

I inform you that the present certification is without prejudice to either the licences concerning the operation/follow-up of activity laid down in other provisions of legislation or the client's obligation for obtaining them.

The client is obliged to notify the competent authority, within 15 days, of any important changes concerning the certified activity of the testing facility.

I call your attention that respect of the provisions laid down in the legislation on GEP certification and in this Decision shall be randomly controlled by my competent authority. If during the official inspection it is stated that the testing facility does not meet the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate.

If during the official inspection it is found that some details are missing in relation to a particular trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization.

The fee of the present procedure is 250.000 HUF (i.e. two hundred and fifty thousand Hungarian Forints) paid by the client.

No further complaint shall be lodged against the present Decision, effective by its publication, through state administration, though with reference to infringement of law, judicial review of the Decision may be requested at the Capital Administrative and Employment Court. The claim note shall be submitted to my competent authority within 30 days of the communication of the Decision.

I inform you that the court shall judge the case out of court, but shall carry on a lawsuit at the request of any of the parties. The client may ask for carrying on a lawsuit, but in default of so doing, no verification is accepted. Submission of the claim note has no delaying force on the implementation of this Decision.

J U S T I F I C A T I O N

In its application of 29 August 2016, the client submitted an application to the competent authority for a procedure of GEP certification.

As a follow-up to this application, the competent authority made a local inspection at the client's facility of Komárom, Petőfi Sándor út 67 on 31 August 2016. Statements made during the local inspection are reported in the protocol Nr. 04.2/6149-4/2016. Based on the results of the local inspection the competent authority concluded that the client's testing facility does not meet the requirements concerning the efficacy trials specified in Article 22 of the Decree 89/2004 (V. 15.) FVM on the authorization of placing on the market and use, as well as on the packaging, labelling, storage and transport of plant protection products (hereinafter: Decree 89/2004) and in the Decision Nr. 04.2/6149-5/2016 it calls the client to fill the data gaps.

Article 22(5) of Decree 89/23004 - Based on request, the competent authority shall make local inspections at the testing facility and decide on the GEP qualification of the testing facility. The decision shall include the product categories and the cultivation categories for which the testing facility obtained the GEP-certificate.

(6) The validity of GEP-certification is 2 years in case of the first request and maximum 5 years in case of renewal of the certification.

(7) A fee laid down in specific legislation shall be paid for the GEP-certification procedure.

(8) The testing facility having GEP-certification shall notify the competent authority, within 15 days, about any important changes concerning the certified activity of the testing facility.

(9) The competent authority shall randomly control the testing facility having GEP-certification. If it is found that the testing facility does not meet the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate. If during the official inspection it is established that some details are missing in relation to a trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization."

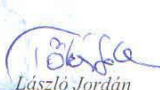
Client filled the missing data gaps and reported on it in the letter of 20 September 2016, therefore I made the Decision as specified in the first part. Therefore I stated that conditions for issuing the certificate specified above are met, so I made the Decision as specified in the first part.

The fee of the present procedure is HUF 250.000 and was established in accordance with point 8.19.2 of Annex 1 to the Decree 63/2012. (VII. 2.) VM on the extent of administrative servicing fees due for the procedures by the agricultural administrative bodies of the National Food Chain Safety Office and the county government offices and on the rules of paying the administrative servicing fees. The client paid the fee.

I made this Decision within my jurisdiction laid down in Article 3 paragraph (1) and Article 5 point c) of Government Decree 22/2012. (II. 29.) concerning the National Food Chain Safety Office, Article 3, Article 22 paragraph (1) of Decree 89/2004 and in compliance with Articles 71 paragraph (1) and Article 72 paragraph (1) of Act CXL of 2004 on general rules of administrative official procedure and service (hereinafter: Act CXL of 2004).

I excluded the possibility of appeal in compliance with Article 100 paragraph (1) point e) of Act CXL of 2004 and provided the possibility of judicial review in compliance with Article 109 paragraph (1) of Act CXL of 2004 and Article 330 paragraph (2) of Act III of 1952 on Civil Procedure.

on behalf of
dr. Márton Oravecz
president


László Jordán
director

Test facility	Address	Certificate (Yes or No)
ANADIAG ROMANIA SRL	Piata Montreal no. 10, World Trade Centre, Entrance F, 1st Floor 011469, Bucharest, ROMANIA	Yes

MINISTERUL AGRICULTURII ȘI DEZVOLTĂRII RURALE	MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT
Autoritatea Națională Fitosanitară	National Phytosanitary Authority
Comisia Națională de Omologare a Produselor de Protecție a Plantelor	National Commission for Registration of Plant Protection Products

Certificat de recunoaștere oficială a testelor de eficacitate biologică în conformitate cu bunele practici experimentale/Certificate of official recognition of the efficacy biological tests according to the good experimental practices

Se acordă: SC ANADIAG ROMANIA SRL
It is granted to: SC ANADIAG ROMANIA SRL
cu sediul: Str. Gen. C. Budisteanu, nr.28-C;010775, Bucuresti
with headquarter: Gen. C. Budisteanu Street, no. 28-C, 010775, Bucharest
pentru domeniul/
domeniile de activitate: Culturi agricole de câmp si pajisti; Pomicultură;
Viticultură; Legumicultură; Floricultură; Silvicultură; Plante ornamentale și de interior; Zone non agricole
for the domain/
domains of activity: Crops fields and meadows; Fruit tree growing; Viticulture;
Vegetable crops; Floriculture; Aromatic and medicinal plants; Ornamental and indoor plants; Silviculture; Non agricultural zones

Prezentul certificat se eliberează în conformitate cu prevederile Ordinului ministrului agriculturii și dezvoltării rurale, al ministrului sănătății și al ministrului mediului și schimbărilor climatice nr.60/512/1258/2013 și prevederile Procedurii naționale de omologare a produselor de protecție a plantelor care conțin substanțe active notificate și pentru care nu s-a luat încă o decizie de includere în lista cu substanțe active autorizate în Uniunea Europeană, aprobată prin Ordinul ministrului agriculturii,

pădurilor și dezvoltării rurale, al ministrului sănătății și al ministrului mediului și gospodăririi apelor nr.134/197/412/2006, cu modificările și completările ulterioare.

This certificate is issued according to the provisions of the Order of the ministry of agriculture and rural development, of the ministry of health and of the ministry of environment and climate change no.60/512/1258/2013 and the provisions of the National Procedure for Registration of Plant Protection Products which contain notified active substances and for which isn't taken yet a decision for inclusion in European Union list of authorised active substances, approved by the Order of the ministry of agriculture, forests and rural development, of the ministry of health and of the ministry of environment and waters husbandry no.134/197/412/2006, with subsequent amendments and completions.

Data emiterii certificatului: 20.08.2015

Issuance date of the certificate

Data expirării certificatului: 20.08.2020

Expiry date of the certificate

PREȘEDINTE/CHAIRMAN,

Elena LEAOTA



3.7.7 Rye (SECCW)

Table 3.7-7: List of test facilities - SECCW

Maritime EPPO zone

Test facility	Address	Certificate (Yes or No)
STAPHYT	Station Sokolnice - Menín 569 MENÍN 569 - 664 52 Czech Republic	YES
InTec Agro Trials, s.r.o.	Blatnicka 179 Uhersky Ostroh, 687 24 Czech Republic	YES
Agrolab A/S	Røjleskovvej 18 5500 Middelfart Denmark	YES
Oxford Agricultural Trials Limited	West Farm Barns – Launton Road - Stratton Audley – Bicester OXON - OX279AS – UNITED KINGDOM	YES
QUINTUS GMBH	LIEPEN 7 17194 Hohen Wangelin OT Liepen GERMANY	YES

Test facility	Address	Certificate (Yes or No)
STAPHYT	Station Sokolnice - Menín 569 MENÍN 569 - 664 52 Czech Republic	YES



ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

STAPHYT s.r.o.
Měnín 569
664 57 Měnín



Útvar: Odbor přípravků na ochranu rostlin
Adresa: Zemědělská 1a, 613 00 Brno

Sp.zn: SZ UKZUZ 032225/2016/06857 Č.j.: UKZUZ 057138/2016 Datum: 18. 5. 2016
Vyřizuje: ing. Minářová Tel.: 545 110 444 E-mail: ivana.minarova@ukzuz.cz

ROZHODNUTÍ

Ústřední kontrolní a zkušební ústav zemědělský (dále jen „ÚKZÚZ“), Hroznová 2, 656 06 Brno, jako věcně příslušný správní orgán podle § 72 odst. 1 písm. c) zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, ve znění pozdějších předpisů (dále jen „zákon“) a v návaznosti na čl. 54 odst. 4 Nařízení Evropského parlamentu a Rady (ES) č. 1107/2009, o uvádění přípravků na ochranu rostlin na trh a o zrušení směrnic Rady 79/117/EHS a 91/414/EHS, v platném znění, v provedení § 45 odst. 1 zákona, v řízení o způsobilosti k provádění pokusů a zkoušek s přípravky nebo dalšími prostředky na základě žádosti společnosti **STAPHYT s.r.o.**, Měnín 569, 664 57 Měnín, IČ 29210917 dále jen „společnost STAPHYT s.r.o.“ a to:

žádosti o prodloužení platnosti rozhodnutí o způsobilosti k provádění zkoušek podle § 45 odst. 1 zákona ze dne 24. 3. 2016, doručené ÚKZÚZ dne 24. 3. 2016, č.j. UKZUZ 032225/2016

rozhodl takto:

společnost STAPHYT s.r.o. je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe.

právníká osoba: **STAPHYT s.r.o.**

sídlo právnické osoby: Měnín 569, 664 57 Měnín

IČ právnické osoby: 29210917

GEP kód: **GEP/SHT/2016**

oblasti zkoušení: **polní plodiny a zelenina**
trvalé kultury
skleníky a jiné kryté prostory
moření osiva

rozhodnutí se vydává s účinností od 1. 9. 2016

doba účinnosti rozhodnutí: 5 let

Tímto rozhodnutím se k datu nabytí jeho účinnosti zrušuje rozhodnutí č.j. SRS 026758/2010 ze dne 2. 7. 2010.

Odůvodnění:

Řízení ve věci uznání osoby za způsobilou provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe bylo zahájeno na základě žádosti ze dne 24. 3. 2016, doručené UKZÚZ dne 24. 3. 2016.

Rozhodnutí o způsobilosti k provádění pokusů a zkoušek v souladu s požadavky správné pokusnické praxe bylo vydáno na základě kontroly předložené dokumentace pracoviště STAPHYT s.r.o., Příručky jakosti, Standardních operačních postupů a Metrologického řádu, kterou bylo ÚKZÚZ prokázáno, že žadatel splnil požadavky stanovené v § 45 odst. 12 a 13 zákona v návaznosti na § 4 odst. 2 vyhlášky č. 32/2012 Sb., o přípravcích a dalších prostředcích na ochranu rostlin, ve znění pozdějších předpisů.

Vzhledem k výše uvedeným skutečnostem bylo rozhodnuto tak, jak je stanoveno ve výrokové části tohoto rozhodnutí.

Správní poplatek podle zákona č. 634/2004 Sb., o správních poplatcích, ve znění pozdějších předpisů, podle Sazebníku, Položky 86 písm. b) „Přijetí žádosti o vydání osvědčení o způsobilosti k provádění zkoušek pro účely povolení“ ve výši 100,- Kč, k žádosti doručené UKZÚZ dne 24. 3. 2016, č.j. UKZUZ 032225/2016, byl uhrazen dne 24. 3. 2016 formou kolkové známky.

Poučení:

Proti tomuto rozhodnutí lze podat odvolání do 15 dnů ode dne jeho doručení, nejpozději však do 15 dnů po uplynutí desátého dne ode dne, kdy bylo nedoručené a uložené rozhodnutí připraveno k vyzvednutí, a to k Ministerstvu zemědělství České republiky, odbor rostlinných komodit, prostřednictvím Ústředního kontrolního a zkušebního ústavu zemědělského, sekce zemědělských vstupů, odboru přípravků na ochranu rostlin, Zemědělská 1a, 613 00 Brno.

Otisk úředního razítka

Ing. Pavel Minář, Ph.D.
ředitel odboru

Test facility	Address	Certificate (Yes or No)
InTec Agro Trials, s.r.o.	Blatnická 179 Uherský Ostroh, 687 24 Czech Republic	YES



ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

Hroznová 2
656 06 Brno

www.ukzuz.cz
ID DS: ugbaq7

IČO: 00020338
DIČ: CZ00020338

InTec Agro Trials, spol. s r.o.
Blatnická 179
687 24 Uherský Ostroh
IČO: 06774512

Útvar:	OPOR	Spisová zn.:	SZ UKZUZ 010368/2018/01399
Vyřizuje:	Ing. Ivana Minářová	C. j.:	UKZUZ 013294/2018
E-mail:	ivana.minarova@ukzuz.cz		
Telefon:	+420 545 110 444		
Adresa:	Zemědělská 1a, 613 00 Brno	Datum:	7. 2. 2018

ROZHODNUTÍ

Ústřední kontrolní a zkušební ústav zemědělský (dále jen „ÚKZÚZ“), Hroznová 2, 656 06 Brno, jako věcně příslušný správní orgán podle § 72 odst. 1 písm. c) a v návaznosti na čl. 54 odst. 4 Nařízení Evropského parlamentu a Rady (ES) č. 1107/2009, o uvádění přípravků na ochranu rostlin na trh a o zrušení směrnic Rady 79/117/EHS a 91/414/EHS, v platném znění, v provedení § 45 odst. 1 zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, ve znění pozdějších předpisů (dále jen „zákon“), v řízení o způsobilosti k provádění pokusů a zkoušek s přípravky nebo dalšími prostředky na základě žádosti společnosti **InTec Agro Trials, s.r.o.**, a to:

žádosti o uznání osoby za způsobilou k provedení zkoušek podle § 45 odst. 1 zákona ze dne 24. 1. 2018, doručené ÚKZÚZ dne 26. 1. 2018, č.j. UKZUZ 010368/2018

rozhodl takto:

Společnost InTec Agro Trials, s.r.o. je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe.

právníká osoba: **InTec Agro Trials, s.r.o.**

sídlo právnické osoby: Blatnická 179, Ostrožské Předměstí, 687 24 Uherský Ostroh

IČ právnické osoby: 06774512

GEP kód: GEP/ITU/2018

oblasti zkoušení: **polní plodiny a zelenina**
trvalé kultury
skleníky a jiné kryté prostory

dobu platnosti rozhodnutí: 5 let ode dne nabytí účinnosti tohoto rozhodnutí

Odůvodnění:

Řízení ve věci uznání osoby za způsobilou provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe bylo zahájeno na základě žádosti ze dne 24. 1. 2018, doručené ÚKZÚZ dne 26. 1. 2018.

Do firmy InTec Agro Trials, s.r.o. přechází původní personální obsazení a zařízení firmy ATC – Agro Trial Center GmbH, organizační složky, původního držitele povolení č.j. UKZUZ 073735/2016 ze dne 1. 7. 2016. Nedošlo ke změnám v oblasti personálního obsazení, v prostorách, v nichž je činnost realizována, na pozemcích, na nichž je činnost prováděna a změnám v základní dokumentaci.

Rozhodnutí o způsobilosti k provádění pokusů a zkoušek v souladu s požadavky správné pokusnické praxe bylo vydáno na základě předložené dokumentace, Příručky jakosti, Standardních operačních postupů a Metrologického řádu, kterou bylo ÚKZÚZ prokázáno, že žadatel splnil požadavky stanovené v § 45 odst. 12 a 13 zákona v návaznosti na § 4 odst. 2 vyhlášky č. 32/2012 Sb., o přípravcích a dalších prostředcích na ochranu rostlin, ve znění pozdějších předpisů.

Vzhledem k výše uvedeným skutečnostem bylo rozhodnuto tak, jak je stanoveno ve výrokové části tohoto rozhodnutí.

Správní poplatek podle zákona č. 634/2004 Sb., o správních poplatcích, ve znění pozdějších předpisů, podle Sazebníku, Položky 86 písm. b) „Přijetí žádosti o vydání osvědčení o způsobilosti k provádění zkoušek pro účely povolení“ ve výši 100,- Kč, k žádosti doručené ÚKZÚZ dne 26. 1. 2018, č.j. UKZUZ 010368/2018, byl uhrazen dne 26. 1. 2018 formou kolkové známky.

Poučení o odvolání:

Proti tomuto rozhodnutí lze podat odvolání do 15 dnů ode dne jeho doručení, nejpozději však do 15 dnů po uplynutí desátého dne ode dne, kdy bylo nedoručené a uložené rozhodnutí připraveno k vyzvednutí, a to k Ministerstvu zemědělství České republiky, odbor rostlinných komodit, prostřednictvím Ústředního kontrolního a zkušebního ústavu zemědělského, sekce zemědělských vstupů, odboru přípravků na ochranu rostlin, Zemědělská 1a, 613 00 Brno.

Ing. Pavel Minář, Ph.D.
ředitel OPOR

Test facility	Address	Certificate (Yes or No)
Agrolab A/S	Røjleskovvej 18 5500 Middelfart Denmark	YES



Certifikat

for **GEP-ankendelse** tildeles herved

Forsøgsenheden: **Agrolab A/S**
Røjleskovvej 18
DK-5500 Middelfart

Anerkendelsen gælder udførelsen af GEP-effektivitetsforsøg for bekæmpelsesmidler inden for

Forsøgsområderne: **Markforsøg**



GEP Anerkendelses Enheden ved Nationalt Center for Fødevarer og Jordbrug, Aarhus Universitet, kontrollerer organisation, personale, lokaler, forsøgsarealer, forsøgsudstyr samt standardforskrifter og forsøgsrapporter. Forsøgsenheden er underkastet løbende kontrol og inspektion.

Certifikatet for anerkendelse er gyldigt for en periode på 6 år.

Anerkendelsesdato: 1. januar 2014

Underskrevet: 16. december 2013


Nina Sørup Hansen
Miljøstyrelsen


Ulla Fosgerau Salomonsen
Aarhus Universitet


Peter Kryger Jensen
Aarhus Universitet

Forordning 1107/2009 om plantebeskyttelsesmidler og Miljøministeriets bekendtgørelse nr.1088 af 6. september 2013 anfører, at undersøgelser af plantebeskyttelsesmidlers effektivitet, der er udført i Danmark med henblik på godkendelse, skal være foretaget af forsøgsenheder, der er anerkendt hertil af Nationalt Center for Fødevarer og Jordbrug, Aarhus Universitet.

Test facility	Address	Certificate (Yes or No)
Oxford Agricultural Trials Limited	West Farm Barns – Launton Road - Stratton Audley – Bicester OXON - OX279AS – UNITED KINGDOM	YES



Certificate of

Official Recognition of Efficacy Testing Facilities or Organisations in the United Kingdom

This certifies that

Oxford Agricultural Trials Limited

complies with the minimum standards laid down in
Regulation (EC) 1107/2009 for efficacy testing.

The above Facility/Organisation has been officially
recognised as being competent to carry out efficacy trials/tests
in the United Kingdom in the following categories:

**Agriculture/Horticulture
Biologicals and Semiochemicals
Stored Crops**

Date of issue: 9 January 2018
Effective date: 1 January 2018
Expiry date: 31 December 2022

Signature


Alison Richardson
Authorised signatory

Certification Number

ORETO 385



Chemicals Regulation Division



Department of
**Agriculture and
Rural Development**

Test facility	Address	Certificate (Yes or No)
QUINTUS GMBH	LIEPEN 7 17194 Hohen Wangelin OT Liepen GERMANY	YES

Anerkennungsbescheinigung

Recognition Certificate

Die Versuchseinrichtung

Quintus GmbH

The testing facility

mit Hauptsitz in

Liepen 7
17194 Hohen Wangelin

with headquarter in

und organisatorisch
zugehörigen
Arbeitseinheiten in

08393 Schönberg
Breitenbacher Straße 21

74595 Langenburg-
Nesselbach
Orlacher Straße 16

27798 Hude
Wieselweg 6

and subsidiary testing
units in

ist auf Antrag vom

2016-02-01

on application from

und nach durchgeführter
Besichtigung
durch
vom

Herrn Dr. S. Goltermann
Landesamt für Landwirtschaft,
Lebensmittelsicherheit und
Verbraucherschutz MV
2016-04-11

and after inspection

by
from

am

on

in den Versuchskategorien

Acker-, Obst-, Gemüse-, Zier-
pflanzenbau, Haus- und
Kleingarten

agriculture, horticulture, home
and garden

in the trial categories

als Einrichtung für die Prüfung
der Wirksamkeit von
Pflanzenschutzmitteln im
Sinne des § 8 Abs. 6 der
Pflanzenschutzmittelverordnu
ng und gemäß
Verordnung (EU) Nr. 284/2013
für 5 Jahre amtlich anerkannt
worden.

has been officially
recognised as an
organisation for efficacy
testing facility of plant
protection products
according to § 8 par. 6 of
the Plant Protection
Products Ordinance and
the Commission
Regulation (EU) No
284/2013 for 5 years.

11.04.2016

Goltermann

Landesamt für Landwirtschaft,
Lebensmittelsicherheit und
Verbraucherschutz MV,
Thierfelderstr. 18, 18059 Rostock

Datum
date

Unterschrift
signature

Adresse der anerkennenden Behörde
address of the recognising authority



Mediterranean EPPO zone

Test facility	Address	Certificate (Yes or No)
AGRICULTURA Y ENSAYO S.L.	Sucursal em Portugal Rua Dr. Oscar da Costa Neves, nº2 Almeirim 2080-130 PORTUGAL	YES
ANADIAG HELLAS LTD	New Ring Road Verias – Thessalonikis & N. Mandilara, PO Box 71, 59100 Veria, Greece	YES

Test facility	Address	Certificate (Yes or No)
AGRICULTURA Y ENSAYO S.L.	Sucursal em Portugal Rua Dr. Oscar da Costa Neves, n°2 Almeirim 2080-130 PORTUGAL	YES



CERTIFICADO

ORGANIZAÇÃO OFICIALMENTE RECONHECIDA PARA A REALIZAÇÃO DE ENSAIOS DE EFICÁCIA DE PRODUTOS FITOFARMACÊUTICOS

Certifica-se que foi reconhecida como Organização Oficialmente Reconhecida, em Portugal, a **AGRICULTURA Y ENSAYO S.L.** – Sucursal em Portugal, para a realização de ensaios de eficácia de produtos fitofarmacêuticos, segundo a Boa Prática Experimental, n.º 35, da Portaria n.º 396/2000, de 14 de Julho, que concretiza os princípios estabelecidos no Regulamento (UE) N.º 284/2013 da Comissão de 1 de março de 2013, em conformidade com o Regulamento (CE) N.º 1107/2009 do Parlamento Europeu e de acordo com o respetivo pedido.

- **Certificado n.º 25**
- **Data de entrada em vigor do reconhecimento: 26 de julho de 2016**
- **Termo do prazo do reconhecimento: 26 de julho de 2021**
- **Condições / Limitações: ---**

Oeiras, 20 de setembro de 2016.

A Subdiretora Geral

Ana Paula de Almeida
Cruz de Carvalho

Assinado de forma digital por Ana
Paula de Almeida Cruz de Carvalho
Dados: 2017.04.03 08:44:10 +01'00'

Test facility	Address	Certificate (Yes or No)
ANADIAG HELLAS LTD	New Ring Road Verias – Thessalonikis & N. Mandilara, PO Box 71, 59100 Veria, GREECE	YES



HELLENIC REPUBLIC
MINISTRY OF RURAL DEVELOPMENT & FOOD
GENERAL DIRECTORATE OF SUSTAINABLE PLANT PRODUCE
DIRECTORATE OF PLANT PRODUCE PROTECTION
DEPARTMENT OF PLANT PROTECTION PRODUCTS & BIOCIDES
150 SYGROU AV., 17671 ATHENS
TEL: 0030 210 979 7337
FAX: 0030 210 92 12 090
E-MAIL: apapamichal@minagric.gr

Date: July 2017

RECOGNITION CERTIFICATE
OF TESTING FACILITY FOR GEP BIOLOGICAL TRIALS
*(in accordance with the provisions of Article 54 of the
Regulation (EC) 1107/2009)*

ANADIAG Hellas L.t.d.

Headquarters: Ring road Verias – Thessalonikis & N. Mandilara str., Veria, Imathia

Branch1: 8 Elusas str., P.C. 71409, Heraklion Crete

Branch2: Old Nat. Road of Patras – Pyrgou, P.C. 27300, Kavalita Pyrgos Ilias

Is recognized in accordance to the Ministerial Decision No. 183351/7-4-2010 for
conducting biological tests and trials in:

- a) open fields
- b) controlled environment (e.g. greenhouses, warehouses)

With:

RECOGNITION CODE

ANA/02/2020

Decision number and date of first recognition: **120400/20-12-2015**

Decision number and date of first renewal of the recognition:

6966/71619/26-06-2012

Decision number and date of second renewal of the recognition:

7871/716211/12-07-2017

Expiring date of the validity of this certificate: 31-12-2020

This certificate remains valid until further notice and provided that the company
continues to meet the requirements of the Ministerial Decision 183351/7-4-2010, as
applicable.



The Head of the
Directorate:

[Signature]
ΣΤ. ΖΩΓΡΑΦΟΣ

Revision 3

ANA/02/2020

Page 1/1

North-Eastern EPPO zone

Test facility	Address	Certificate (Yes or No)
STAPHYT	Station Dabrowa 15 Jaraczewo 63-233 POLAND	YES
ANADIAG POLSKA	Ul. Sadowa 16/22, 95-100 Zgierz, POLAND	YES
AGROLAB BALTIC	Bugenių km. LT-89452 Mažeikių raj. LITHUANIA	YES

Test facility	Address	Certificate (Yes or No)
STAPHYT	Station Dabrowa 15 Jaraczewo 63-233 POLAND	YES

**GLÓWNY INSPEKTOR
OCHRONY ROŚLIN I NASIENICTWA**

Tadeusz Kłos

WO-505- 14 /2012

Warszawa, 09.09.2012 r.

DECYZJA Nr 7/2012

Na podstawie art. 155 ustawy z dnia 14 czerwca 1960 r. Kodeks postępowania administracyjnego (Dz.U. z 2000 r. Nr 98, poz. 1071 ze zm.) i art. 40 ust. 1 ustawy z dnia 18 grudnia 2003 r. o ochronie roślin (Dz.U. z 2008 r. Nr 133, poz. 849 ze zm.), po rozpatrzeniu wniosku z dnia 6 września 2012 r., zmieniam decyzję Nr 9/2005 z dnia 1 maja 2005 r., zmienioną decyzjami: Nr 3/2006 z dnia 5 maja 2006 r., Nr 8/2006 z dnia 11 grudnia 2006 r., Nr 2/2009 z dnia 18 lutego 2009 r., Nr 12/2011 z dnia 31 marca 2011 r. oraz Nr 4/2012 z dnia 4 kwietnia 2012 r.

Rozstrzygnięciu decyzji nadaję następujące brzmienie:

upoważniam

STAPHYT Sp. z o.o.

ul. Ziębicka 2; 60-164 Poznań

do prowadzenia badań skuteczności działania środka ochrony roślin

z grupy fungicydów, herbicydów, insektycydów, moluskocydów, akaricydów, regulatorów wzrostu, zapraw nasiennych oraz do łącznego stosowania środków ochrony roślin w uprawach polowych: zbóż, kukurydzy, rzepaku, buraków cukrowych, słonecznika, ziemniaków, warzyw, w uprawach sadowniczych (jabłoni, gruszy, porzeczek, truskawek, pestkówek), w magazynach i przechowalniach, a także na trawnikach oraz w uprawach roślin ozdobnych w polu i pod osłonami.

Uzasadnienie

W dniu 6 września 2012 r. Staphyt Sp. z o.o. (ul. Ziębicka 2; 60-164 Poznań) zwróciła się z wnioskiem o rozszerzenie zakresu decyzji Głównego Inspektora Ochrony Roślin i Nasiennictwa upoważniającej do prowadzenia badań skuteczności działania środków ochrony roślin Nr 9/2005 z dnia 1 maja 2005 r.,

zmienionej decyzjami: Nr 3/2006 z dnia 5 maja 2006 r., Nr 8/2006 z dnia 11 grudnia 2006 r., Nr 2/2009 z dnia 18 lutego 2009 r. oraz Nr 4/2012 z dnia 4 kwietnia 2012 r. Wniosek dotyczył możliwości prowadzenia badań w magazynach i przechowalniach.

Staphyt Sp. z o.o. spełnia warunki organizacyjno-techniczne, zwane „Zasadami Dobrej Praktyki Eksperymentalnej” (Good Experimental Practice - GEP), zapewniające prawidłowe przeprowadzanie badań skuteczności działania środka ochrony roślin.

Mając na uwadze powyższe, postanowiono jak w rozstrzygnięciu decyzji.

Pouczenie

Od niniejszej decyzji odwołanie nie przysługuje. Jednakże strona niezadowolona z decyzji może zwrócić się do Głównego Inspektora Ochrony Roślin i Nasiennictwa z wnioskiem o ponowne rozpatrzenie sprawy w terminie 14 dni od dnia doręczenia decyzji, zgodnie z art. 127 § 3 Kodeksu postępowania administracyjnego.

 **GLÓWNY INSPEKTOR**
Tadeusz Kłos



GŁÓWNY INSPEKTORAT OCHRONY ROŚLIN I NASIENNICTWA

Al. Jana Pawła II 11, 00-828 Warszawa
tel. 22 652 92 90, fax 22 654 52 21
www.piorin.gov.pl, e-mail: gi@piorin.gov.pl

WO-505-14/2012

Warszawa, 25.09.2012 r.

Pani Magdalena Zaręba
Staphyt Sp. z o.o.
ul. Ziębicka 2
60-164 Poznań

Główny Inspektorat Ochrony Roślin i Nasiennictwa przesyła decyzję nr 7/2012 z dnia 25 września 2012 r. zmieniającą decyzję Nr 9/2005 z dnia 1 maja 2005 r., zmienioną decyzjami: Nr 3/2006 z dnia 5 maja 2006 r., Nr 8/2006 z dnia 11 grudnia 2006 r., Nr 2/2009 z dnia 18 lutego 2009 r., Nr 12/2011 z dnia 31 marca 2011 r. oraz Nr 4/2012 z dnia 4 kwietnia 2012 r., upoważniającą do prowadzenia badań skuteczności działania środka ochrony roślin.

Zmiana zakresu upoważnienia dla jednostki organizacyjnej upoważnionej do przeprowadzania badań skuteczności działania środka ochrony roślin podlega opłacie w wysokości 1.000 zł (*rozporządzenie Ministra Rolnictwa i Rozwoju Wsi z dnia 31 maja 2005 r. w sprawie wysokości opłat rejestrowych za czynności związane z wydaniem decyzji dotyczących środków ochrony roślin i substancji aktywnych oraz trybu ich uiszczania - Dz. U. Nr 99, poz. 833, ze zm.*). Opłatę rejestrową należy wnieść, w terminie 7 dni od dnia doręczenia decyzji, na rachunek bankowy Głównego Inspektoratu Ochrony Roślin i Nasiennictwa – NBP O/O Warszawa - 57 1010 1010 0083 4122 3100 0000.

Tadeusz Kłos
Główny Inspektor

Test facility	Address	Certificate (Yes or No)
ANADIAG POLSKA	Ul. Sadowa 16/22, 95-100 Zgierz, POLAND	YES

SWORN TRANSLATOR
MARTA TRAWCZYŃSKA
ul. Św. Wojciecha 3/3a lok. 1, 10-038 Olsztyn
T +48 665 240 339, F +48 89/ 512 00 99

CERTIFIED TRANSLATION FROM THE POLISH LANGUAGE

[Any remarks in square brackets are the translator's. The translated document consists of two (2) pages.]

[national emblem of the Republic of Poland]
MAIN INSPECTOR
OF PLANT HEALTH AND SEED PROTECTION

Andrzej Chodkowski

Warsaw, dated 12 October 2018

BORiT.541.11.2018.1

DECISION No. 10/2018

Pursuant to Article 155 of the Act of 14 June 1960 Administrative Procedure Code (Dz.U. *[Polish Official Journal of Laws]* of 2017, item 1257 as amended), having examined the application filed by Anadiag SAS Branch Office in Poland dated 3 October 2018, I vary the decision No. 7/2007 dated 28 May 2007, varied by decisions No. 1/2010 dated 18 March 2010, No. 18/2011 dated 18 August 2011, No. 1/2012 dated 13 January 2012 and No. 3/2014 dated 16 April 2014 to grant authorization to conduct research of the efficiency of plant health products in such a manner that the decision shall read as follows:

"I authorize

Anadiag SAS Branch Office in Poland
ul. Sadowa 16/22, 95-100 Zgierz

to conduct research of the efficiency of plant health products from the group of acaricides, bacteriocides, fungicides, herbicides, insecticides, molluscicides, rodenticides, pheromones and growth regulators in outdoor crops, orchard crops, under covers, in edible mushrooms cultivations, in meadows and pastures. The research shall be conducted in cereal, root and oil crops, vegetables, orchard and ornamental plants, legumes, grass and special plants, in storage rooms and rooms for cultivation of edible mushrooms, in lawns and in non-agricultural lands."

No reasoning for this decision has been prepared as the decision grants the application of the Party in its entirety (Article 107(4) of the Administrative Procedure Code *[hereinafter referred to as "APC"]*).



Marta Trawczyńska

Test facility	Address	Certificate (Yes or No)
AGROLAB BALTIC	Bugenių km. LT-89452 Mažeikių raj. LITHUANIA	YES



Valsts augu aizsardzības dienests

SERTIFIKĀTS

Nr. 30

Izsniegts **SIA „AgroLab Baltic”**
(komersanta nosaukums, reģistrācijas numurs, juridiskā adrese)

Reģ. Nr. 44103075387

Elizabetes iela 45/47, Rīga, LV-1010

par tiesībām veikt normatīvajos aktos par augu aizsardzības līdzekļu reģistrāciju noteiktos
efektivitātes pārbaudes izmēģinājumus:

Lauks- graudaugi-fungicīdi, insekticīdi, kodnes, **lauks-** rapsis- insekticīdi, **lauks-** dārzeņi- insekticīdi,
lauks- graudaugi-limacīdi, **lauks-** rapsis- limacīdi.

Sertifikāts izsniegts: 08.01.2019.
(datums)

Sertifikāts derīgs līdz: 07.01.2024.
(datums)

Valsts augu aizsardzības dienests
Augu aizsardzības līdzekļu
reģistrācijas daļas vadītāja
(amats, paraksts un tā atšifrējums)



 R.Čūdere

South-Eastern EPPO zone

Test facility	Address	Certificate (Yes or No)
STAPHYT	Station Kecskemet, KECSKEMET HUNGARY	YES
ANADIAG HUNGARY Kft.	H2921, Komárom, Petőfi Sándor 67 HUNGARY	YES
ANADIAG ROMANIA SRL	Piata Montreal no. 10, World Trade Centre, Entrance F, 1st Floor 011469, Bucharest, ROMANIA	YES

Test facility	Address	Certificate (Yes or No)
STAPHYT	Station Kecskemet, KECSKEMET HUNGARY	YES



PEST MEGYEI
KORMÁNYHIVATAL

Ügyirat-szám: PE/NT/0045-7/2018

Ügyintéző: Dr. Cs. Tóth Attila

Telefon: 06-1/238-3928

E-mail: cs.totha@pest.gov.hu

Tárgy: Staphyt Hungary Kft. (5000

Szolnok, Piroskai u. 2.)

vizsgálóhelyének GEP tanúsítása

Melléklet:-

A Pest Megyei Kormányhivatal (továbbiakban: engedélyező hatóság) a Staphyt Hungary Kft. (székhely: 5000 Szolnok, Piroskai u. 2., a továbbiakban: Ügyfél) vizsgálóhelyének Helyes Kísérleti Gyakorlat (továbbiakban: GEP) szerinti inspekcója és elismerése iránti kérelme alapján indult elsőfokú eljárásban meghozta az alábbi

H A T Á R O Z A T O T :

Engedélyezési célú biológiai hatásvizsgálatok végzéséhez az Ügyfél vizsgálóhelyének GEP-minősítését kiadom.

A GEP-minősítés 5 évig érvényes határozatom jogerőre emelkedésétől számítva.

A vizsgálóhely GEP-minősítés az alábbi minősítési kategóriákra és művelési ágakra kerül kiadásra:

- minősítési kategória:** herbicidek, fungicidek és baktericidek, zoocidok, növekedésszabályozó és termésnövelő készítmények, adalékanyagok
- művelési ág:** szántóföld, zöldség, gyümölcs, szőlő, dísznövény, erdő, közterület és egyéb (rezisztencia, dózis vizsgálat, talajfertőtlenítő szerek)

Jelen minősítés nem érinti a működéssel/tevékenység folytatásával kapcsolatos egyéb jogszabályban előírt engedélyeket, illetve Ügyfélnek azok beszerzésére vonatkozó kötelezettségét.

Az Ügyfél a vizsgálóhelyeinek minősített tevékenységét érintő jelentős változásról 15 napon belül köteles értesíteni az engedélyező hatóságot.

A GEP-minősítéssel kapcsolatos jogszabályokban és a jelen határozatban foglaltak betartását hatóságom szűrőpróbaszerűen ellenőrzi. Amennyiben az ellenőrzés során megállapítást nyer, hogy a vizsgálóhely nem tartja be a rá vonatkozó GEP - követelményeket, akkor az engedélyező hatóság a határozatban feltüntetett minősített területre vonatkozó tevékenység végzését legfeljebb 2 hónapra felfüggesztheti, illetve a kiadott GEP-minősítését visszavonhatja.

Ha az ellenőrzés során egy adott kísérlettel kapcsolatban hiányosságok kerülnek megállapításra, a kísérletet a hiányosságok mértékétől függően az engedélyező hatóság kizárhatja az engedélyezésnél elfogadhatók közül.

A vizsgálóhely GEP szerinti inspekcója és elismerése eljárás díjköteles, amely a Nemzeti Élelmiszerlánc-biztonsági Hivatal, valamint a megyei kormányhivatalok mezőgazdasági szakigazgatási szervei előtt kezdeményezett eljárásokban fizetendő igazgatási szolgáltatási díjak mértékéről, valamint az igazgatási szolgáltatási díj fizetésének szabályairól szóló 63/2012. (VII. 2.) VM rendelet 1. sz. mellékletének 8.19.2. pontja szerint: **250.000.- Ft, amelyet az Ügyfél megfizetett.**

Élelmiszerlánc- biztonsági, Földhivatali, Növény- és Talajvédelmi, Erdészeti Főosztály

Cím: 1135 Budapest, Lehel u. 43-47.;

Telefon: 06-1/230-3934 Fax: 06-1/350-0117

E-mail: pmkh-nto@pest.gov.hu Honlap: www.kormanyhivatal.hu/hu/pest

Jelen határozat ellen közigazgatási per indítható a Fővárosi Közigazgatási és Munkaügyi Bíróságnál a határozatot hozó Élelmiszerlánc-biztonsági Földhivatali, Növény- és Talajvédelmi, Erdészeti Főosztály Növény- és Talajvédelmi Osztály elleni kereset indításával. A keresetlevelet a felülvizsgálni kért határozat közlésétől számított harminc napon belül, az engedélyező hatósághoz elektronikus úton kell benyújtani.

INDOKOLÁS

Az Ügyfél 2018. január 17-én érkezett levelében vizsgálóhelyének GEP szerinti minősítésének felülvizsgálatát és a minősítés megújítását kérte a Pest Megyei Kormányhivatal, Élelmiszerlánc-biztonsági, Földhivatali, Növény- és Talajvédelmi Erdészeti Főosztály, Növény- és Talajvédelmi Osztályától.

Az engedélyező hatóság 2018. március 8-án az Ügyfél székhelyén helyszíni ellenőrzést tartott, amelyeknek megállapításait a PE/NT/0045-3/2018. számú jegyzőkönyvben rögzítette.

A helyszíni ellenőrzés során az engedélyező hatóság megállapította, hogy a növényvédő szerek forgalomba hozatalának és felhasználásának engedélyezéséről, valamint a növényvédő szerek csomagolásáról, jelöléséről, tárolásáról és szállításáról szóló 89/2004. (V. 15.) FVM rendelet (továbbiakban: Rendelet) 22. §-ban foglalt biológiai hatásvizsgálatokkal kapcsolatos előírásoknak a vizsgálóhely nem felelt meg hiánytalanul, és az ügyfelet a PE/NT/0045-5/2018. számú végzésben a hiányosságok megszüntetésére szólította fel.

Az Ügyfél a hiányosságokat megszüntette és annak bizonyításáról szóló dokumentációt az engedélyező hatóságnak 2018. április 30-án megküldte.

A fentiek alapján megállapítottam, hogy a GEP-minősítés megadásának feltételei teljesültek, ennek megfelelően döntöttem a rendelkező részben foglaltak szerint.

A Rendelet 22. §-a értelmében „(5) Kérelem alapján az engedélyező hatóság helyszíni ellenőrzést folytat le a vizsgálóhelyen, majd határozatban dönt a vizsgálóhely GEP-minősítéséről. A határozatnak ki kell terjednie arra, hogy a vizsgálóhely milyen kategóriákra, illetve művelési ágakra szerezte meg a GEP-minősítést.

(6) A GEP-minősítés érvényességi ideje első tanúsítás esetén 2 év, a tanúsítás megújítását követően legfeljebb 5 év.

(7) A GEP-minősítési eljárásért a külön jogszabályban meghatározott díjat kell fizetni.

(8) A GEP-minősítéssel rendelkező vizsgálóhely minden, a minősített tevékenységét érintő jelentős változásról 15 napon belül köteles értesíteni az engedélyező hatóságot.

(9) Az engedélyező hatóság szűrőpróbaszerűen ellenőrzi a GEP-minősítéssel rendelkező vizsgálóhelyeket. Amennyiben megállapítást nyer, hogy a vizsgálóhely nem tartja be a rá vonatkozó GEP-követelményeket, a hatóság a határozatban feltüntetett minősített területre vonatkozó tevékenységet legfeljebb 2 hónapra felfüggesztheti, illetve a kiadott GEP-minősítést visszavonhatja. Ha az ellenőrzés során egy adott kísérlettel kapcsolatban hiányosságok kerülnek megállapításra, a kísérletet a hiányosságok mértékétől függően az engedélyező hatóság kizárhatja az engedélyezésnél elfogadhatók közül.”

Az engedélyező hatóság a határozatát a földművelésügyi hatósági és igazgatási feladatokat ellátó szervek kijelöléséről szóló 383/2016. (XII.2.) Kormányrendelet 19. § a) pontjában és az élelmiszerláncról és hatósági felügyeletéről szóló 2008. évi XLVI. törvény 33. § e) pontjában

biztosított jogkörében, valamint a központi hivatalok felülvizsgálatával és a járási (fővárosi kerületi) hivatalok megerősítésével összefüggő egyes törvények módosításáról, valamint egyes költségvetési szervek feladatainak átadásáról szóló 2016. évi CIV. törvény 136. §. (1) bekezdésében foglaltaknak megfelelően hozta.

Határozatomat az *általános közigazgatási rendtartásról* szóló 2016. évi CL. törvény (a továbbiakban: Ákr.) 80. § (1) bekezdésének és 81. § (1) és (4) bekezdésének megfelelően adtam ki.

A jelen határozat elleni fellebbezés lehetősége az Ákr. 114. § (1) bekezdése alapján került kizárásra. A bírósági felülvizsgálat lehetőségéről szóló tájékoztatás a közigazgatási perrendtartásról szóló 2017. évi I. törvény 13. § (1), 38. § (1), 39. § (1) bekezdésein alapul.

Budapest, 2018. május 14.

Dr. Tarnai Richárd kormány megbízott
névében és megbízásából

Tóth Ágoston
osztályvezető

A határozatot kapiák:

1. Ügyfél
2. Irattár

Test facility	Address	Certificate (Yes or No)
ANADIAG HUNGARY Kft.	H2921, Komárom, Petőfi Sándor 67 HUNGARY	YES

n é b i h
Tudásfeldolgozó és szolgáltató

National Food Chain Safety Office
Directorate of Plant Protection, Soil Conservation
and Agri-environment

H-1138 Budapest, Budafoki út 143-145.
Hungary
Tel: 36/1/509-3308 Fax: 36/1/590-2942
E-mail: ef@neh.gov.hu
www.nebih.gov.hu

Your ref.: -
Our ref.: 04.2/6149-7/2016
7 October 2016

Subject: Certificate of Official Recognition of Efficacy Testing Facilities or Organisations in Hungary

Having received the application submitted by the **Anadiag Hungary Mezőgazdasági Szolgáltató Kft. (H-2921 Komárom, Petőfi Sándor út 67, Hungary)**, the client, for completing a certification procedure of first instance concerning the Official Recognition of Efficacy Testing Facilities/Organisations, i.e. Good Experimental Practices (*hereinafter: GEP*), I, acting as the food chain control body, has made the following

DECISION:

I issue the client's GEP certificate for its premises at Komárom, Petőfi Sándor út 67 for carrying out efficacy trials for authorisation purposes. The GEP certificate is effective for 5 years from the entry into force of this Decision.

The client's GEP certificate is given for the following categories of products and cultivation:

- product categories:** herbicides, fungicides and bactericides, zoocides, growth regulators and yield enhancing substances, additives;
- cultivation categories:** field crops, vegetables, fruits, grapevines, ornamentals, others.

I inform you that the present certification is without prejudice to either the licences concerning the operation/follow-up of activity laid down in other provisions of legislation or the client's obligation for obtaining them.

The client is obliged to notify the competent authority, within 15 days, of any important changes concerning the certified activity of the testing facility.

I call your attention that respect of the provisions laid down in the legislation on GEP certification and in this Decision shall be randomly controlled by my competent authority. If during the official inspection it is stated that the testing facility does not meet the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate.

If during the official inspection it is found that some details are missing in relation to a particular trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization.

The fee of the present procedure is 250.000 HUF (i.e. two hundred and fifty thousand Hungarian Forints) paid by the client.

No further complaint shall be lodged against the present Decision, effective by its publication, through state administration, though with reference to infringement of law, judicial review of the Decision may be requested at the Capital Administrative and Employment Court. The claim note shall be submitted to my competent authority within 30 days of the communication of the Decision.

I inform you that the court shall judge the case out of court, but shall carry on a lawsuit at the request of any of the parties. The client may ask for carrying on a lawsuit, but in default of so doing, no verification is accepted. Submission of the claim note has no delaying force on the implementation of this Decision.

J U S T I F I C A T I O N

In its application of 29 August 2016, the client submitted an application to the competent authority for a procedure of GEP certification.

As a follow-up to this application, the competent authority made a local inspection at the client's facility of Komárom, Petőfi Sándor út 67 on 31 August 2016. Statements made during the local inspection are reported in the protocol Nr. 04.2/6149-4/2016. Based on the results of the local inspection the competent authority concluded that the client's testing facility does not meet the requirements concerning the efficacy trials specified in Article 22 of the Decree 89/2004 (V. 15.) FVM on the authorization of placing on the market and use, as well as on the packaging, labelling, storage and transport of plant protection products (hereinafter: Decree 89/2004) and in the Decision Nr. 04.2/6149-5/2016 it calls the client to fill the data gaps.

Article 22(5) of Decree 89/2004 - Based on request, the competent authority shall make local inspections at the testing facility and decide on the GEP qualification of the testing facility. The decision shall include the product categories and the cultivation categories for which the testing facility obtained the GEP-certificate.

(6) The validity of GEP-certification is 2 years in case of the first request and maximum 3 years in case of renewal of the certification.

(7) A fee laid down in specific legislation shall be paid for the GEP-certification procedure.

(8) The testing facility having GEP-certification shall notify the competent authority, within 15 days, about any important changes concerning the certified activity of the testing facility.

(9) The competent authority shall randomly control the testing facility having GEP-certification. If it is found that the testing facility does not meet the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate. If during the official inspection it is established that some details are missing in relation to a trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization."

Client filled the missing data gaps and reported on it in the letter of 20 September 2016, therefore I made the Decision as specified in the first part. Therefore I stated that conditions for issuing the certificate specified above are met, so I made the Decision as specified in the first part.

The fee of the present procedure is HUF 250.000 and was established in accordance with point 8.19.2 of Annex 1 to the Decree 63/2012. (VII. 2.) FVM on the extent of administrative servicing fees due for the procedures by the agricultural administrative bodies of the National Food Chain Safety Office and the county government offices and on the rules of paying the administrative servicing fees. The client paid the fee.

I made this Decision within my jurisdiction laid down in Article 3 paragraph (1) and Article 5 point e) of Government Decree 22/2012. (II. 29.) concerning the National Food Chain Safety Office, Article 3, Article 22 paragraph (1) of Decree 89/2004 and in compliance with Articles 71 paragraph (1) and Article 72 paragraph (1) of Act CXL of 2004 on general rules of administrative official procedure and service (hereinafter: Act CXL of 2004).

I excluded the possibility of appeal in compliance with Article 100 paragraph (1) point e) of Act CXL of 2004 and provided the possibility of judicial review in compliance with Article 109 paragraph (1) of Act CXL of 2004 and Article 330 paragraph (2) of Act III of 1952 on Civil Procedure.

on behalf of
dr. Márton Oravecz
president


László Jordán
director

Test facility	Address	Certificate (Yes or No)
ANADIAG ROMANIA	ANADIAG ROMANIA SRL, Str. Piata Montreal, nr°10, WTC, 011469 Bucharest, ROMANIA	YES

GEP AGREEMENT

MINISTERUL AGRICULTURII ȘI DEZVOLTĂRII RURALE	MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT
Autoritatea Națională Fitosanitară	National Phytosanitary Authority
Comisia Națională de Omologare a Produselor de Protecție a Plantelor	National Commission for Registration of Plant Protection Products

Certificat de recunoaștere oficială a testelor de eficacitate biologică în conformitate cu bunele practici experimentale/Certificate of official recognition of the efficacy biological tests according to the good experimental practices

Se acordă: SC ANADIAG ROMANIA SRL
It is granted to: SC ANADIAG ROMANIA SRL
cu sediul: Str. Gen. C. Budisteanu, nr.28-C;010775, Bucuresti
with headquarter: Gen. C. Budisteanu Street, no. 28-C, 010775, Bucharest
pentru domeniul/
domeniile de activitate: Culturi agricole de câmp și pajiști; Pomicultură;
Viticultură; Legumicultură; Floricultură; Silvicultură; Plante ornamentale și de interior; Zone non agricole
for the domain/
domains of activity: Crops fields and meadows; Fruit tree growing; Viticulture;
Vegetable crops; Floriculture; Aromatic and medicinal plants; Ornamental and indoor plants; Silviculture; Non agricultural zones

Prezentul certificat se eliberează în conformitate cu prevederile Ordinului ministrului agriculturii și dezvoltării rurale, al ministrului sănătății și al ministrului mediului și schimbărilor climatice nr.60/512/1258/2013 și prevederile Procedurii naționale de omologare a produselor de protecție a plantelor care conțin substanțe active notificate și pentru care nu s-a luat încă o decizie de includere în lista cu substanțe active autorizate în Uniunea Europeană, aprobată prin Ordinul ministrului agriculturii,

pădurilor și dezvoltării rurale, al ministrului sănătății și al ministrului mediului și gospodăririi apelor nr.134/197/412/2006, cu modificările și completările ulterioare.

This certificate is issued according to the provisions of the Order of the ministry of agriculture and rural development, of the ministry of health and of the ministry of environment and climate change no.60/512/1258/2013 and the provisions of the National Procedure for Registration of Plant Protection Products which contain notified active substances and for which isn't taken yet a decision for inclusion in European Union list of authorised active substances, approved by the Order of the ministry of agriculture, forests and rural development, of the ministry of health and of the ministry of environment and waters husbandry no.134/197/412/2006, with subsequent amendments and completions.

Data emiterii certificatului: 20.08.2015

Issuance date of the certificate

Data expirării certificatului: 20.08.2020

Expiry date of the certificate

PREȘEDINTE/CHAIRMAN,

Elena LEAOTA



3.7.8 Oilseed rape (BRSNW)

Table 3.7-8: List of test facilities - BRSNW

Maritime EPPO zone

Test facility	Address	Certificate (Yes or No)
STAPHYT	Station Sokolnice – Menin 569 MENIN 569-66452 CZECH REPUBLIC	Yes
ATC - Agro Trial Center GmbH, organizacni slozka	Blatnicka 179 68724 Uhersky Ostroh CZECH REPUBLIC	Yes
SynTech Research CZ s.r.o.	Semcice 245 294 46 Semcice CZECH REPUBLIC	Yes
VKST Field Trials	Soren Moller Kongstedvej 4 4100 Ringsted DENMARK	Yes
ANADIAG SA, CZ osp.	514 54 Chleny 47 CZECH REPUBLIC	Yes
Agrolab A/S	Rojleskovvej 18 5500 Middelfart DENMARK	Yes
BioChem agrar GmbH	Meierei 1 Ebrach 96157 GERMANY	Yes
Agriculture research Insitute, Ltd.	ZVU Kromeriz 767 01 CZECH REPUBLIC	Yes
InTec AgroTrials, s.r.o.	Blatnicka 179 687 24 Uhersky Ostroh CZECH REPUBLIC	Yes
Zkusebni Stanice Nechanice	Stolbova 319 503 15 Nechanice CZECH REPUBLIC	Yes
ANADIAG France	174, impasse du Plan d'Eau 38 300 Ruy-Montceau FRANCE	Yes
Oxford Agricultural Trials Limited	West Farm Barns Lauton Road- Statton Adley Bicester OXON – OX279AS UNITED KINGDOM	Yes

Test facility	Address	Certificate (Yes or No)
Trialtec GMBH	Kampenredder 5 24363 Haby GERMANY	Yes

Test facility	Address	Certificate (Yes or No)
STAPHYT	Station Sokolnice – Menin 569 MENIN 569-66452 CZECH REPUBLIC	Yes



ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

STAPHYT s.r.o.
Měnin 569
664 57 Měnin

Útvar: Odbor přípravků na ochranu rostlin
Adresa: Zemědělská 1a, 613 00 Brno

Sp.zn: SZ UKZUZ 032225/2016/06857 Č.j.: UKZUZ 057138/2016 Datum: 18. 5. 2016
Vyřizuje: ing. Míňářová Tel.: 545 110 444 E-mail: ivana.minarova@ukzuz.cz

ROZHODNUTÍ

Ústřední kontrolní a zkušební ústav zemědělský (dále jen „ÚKZÚZ“), Hroznová 2, 656 06 Brno, jako věcně příslušný správní orgán podle § 72 odst. 1 písm. c) zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, ve znění pozdějších předpisů (dále jen „zákon“) a v návaznosti na čl. 54 odst. 4 Nařízení Evropského parlamentu a Rady (ES) č. 1107/2009, o uvádění přípravků na ochranu rostlin na trh a o zrušení směrnic Rady 79/117/EHS a 91/414/EHS, v platném znění, v provedení § 45 odst. 1 zákona, v řízení o způsobilosti k provádění pokusů a zkoušek s přípravky nebo dalšími prostředky na základě žádosti společnosti **STAPHYT s.r.o.**, Měnin 569, 664 57 Měnin, IČ 29210917 dále jen „společnost STAPHYT s.r.o.“ a to:

žádosti o prodloužení platnosti rozhodnutí o způsobilosti k provádění zkoušek podle § 45 odst. 1 zákona ze dne 24. 3. 2016, doručené ÚKZÚZ dne 24. 3. 2016, č.j. UKZUZ 032225/2016

rozhodl takto:

společnost STAPHYT s.r.o. je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe.

právnícká osoba: **STAPHYT s.r.o.**

sídlo právnické osoby: Měnin 569, 664 57 Měnin

IČ právnické osoby: 29210917

GEP kód: **GEP/SHT/2016**

oblasti zkoušení: **polní plodiny a zelenina**
trvalé kultury
skleníky a jiné kryté prostory
moření osiva

rozhodnutí se vydává s účinností od 1. 9. 2016

doba účinnosti rozhodnutí: 5 let

Tímto rozhodnutím se k datu nabytí jeho účinnosti zrušuje rozhodnutí č.j. SRS 026758/2010 ze dne 2. 7. 2010.

Odůvodnění:

Řízení ve věci uznání osoby za způsobilou provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe bylo zahájeno na základě žádosti ze dne 24. 3. 2016, doručené UKZÚZ dne 24. 3. 2016.

Rozhodnutí o způsobilosti k provádění pokusů a zkoušek v souladu s požadavky správné pokusnické praxe bylo vydáno na základě kontroly předložené dokumentace pracoviště STAPHYT s.r.o., Příručky jakosti, Standardních operačních postupů a Metrologického řádu, kterou bylo UKZÚZ prokázáno, že žadatel splnil požadavky stanovené v § 45 odst. 12 a 13 zákona v návaznosti na § 4 odst. 2 vyhlášky č. 32/2012 Sb., o přípravcích a dalších prostředcích na ochranu rostlin, ve znění pozdějších předpisů.

Vzhledem k výše uvedeným skutečnostem bylo rozhodnuto tak, jak je stanoveno ve výrokové části tohoto rozhodnutí.

Správní poplatek podle zákona č. 634/2004 Sb., o správních poplatcích, ve znění pozdějších předpisů, podle Sazebníku, Položky 86 písm. b) „Přijetí žádosti o vydání osvědčení o způsobilosti k provádění zkoušek pro účely povolení“ ve výši 100,- Kč, k žádosti doručené UKZÚZ dne 24. 3. 2016, č.j. UKZUZ 032225/2016, byl uhrazen dne 24. 3. 2016 formou kolkové známky.

Poučení:

Proti tomuto rozhodnutí lze podat odvolání do 15 dnů ode dne jeho doručení, nejpozději však do 15 dnů po uplynutí desátého dne ode dne, kdy bylo nedoručené a uložené rozhodnutí připraveno k vyzvednutí, a to k Ministerstvu zemědělství České republiky, odbor rostlinných komodit, prostřednictvím Ústředního kontrolního a zkušebního ústavu zemědělského, sekce zemědělských vstupů, odboru přípravků na ochranu rostlin, Zemědělská 1a, 613 00 Brno.

Otisk úředního razítka

Ing. Pavel Minář, Ph.D.
ředitel odboru

2

ÚKZÚZ
Hroznová 2
656 06 BRNO

Telefon: +420 543 548 111
Fax: +420 543 211 148
E-mail: podatelna@ukzuz.cz

IČ: 00020338
DIČ: CZ00020338
www.ukzuz.cz
ID DS: ugbaiq7

Test facility	Address	Certificate (Yes or No)
ATC - Agro Trial Center GmbH, organizační složka	Blatnická 179 68724 Uherský Ostroh CZECH REPUBLIC	Yes



ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

ATC Agro Trial Center GmbH, organizační
složka
Blatnická 179
68724 Uherský Ostroh

Útvar: Odbor přípravků na ochranu rostlin
Adresa: Zemědělská 1a, 613 00 Brno

Sp.zn: SZ UKZUZ 055894/2016/15869 Č.j.: UKZUZ 073735/2016 Datum: 1. 7. 2016
Vyřizuje: ing. Minářová Tel.: 545 110 444 E-mail: ivana.minarova@ukzuz.cz

ROZHODNUTÍ

Ústřední kontrolní a zkušební ústav zemědělský (dále jen „ÚKZÚZ“), Hroznová 2, 656 06 Brno, jako věcně příslušný správní orgán podle § 72 odst. 1 písm. c) zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, ve znění pozdějších předpisů (dále jen „zákon“) a v návaznosti na čl. 54 odst. 4 Nařízení Evropského parlamentu a Rady (ES) č. 1107/2009, o uvádění přípravků na ochranu rostlin na trh a o zrušení směrnic Rady 79/117/EHS a 91/414/EHS, v platném znění, v provedení § 45 odst. 1 zákona, v řízení o způsobilosti k provádění pokusů a zkoušek s přípravky nebo dalšími prostředky na základě žádosti společnosti **ATC Agro Trial Center GmbH, organizační složka**, Blatnická 179, 68724 Uherský Ostroh, IČ 29220351 dále jen „společnost ATC Agro Trial Center GmbH, organizační složka“ a to:

žádosti o prodloužení platnosti rozhodnutí o způsobilosti k provádění zkoušek podle § 45 odst. 1 zákona ze dne 13. 5. 2016, doručené ÚKZÚZ dne 16. 5. 2016, č.j. UKZUZ 055894/2016

rozhodl takto:

ATC Agro Trial Center GmbH, organizační složka, je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe.

právníká osoba: **ATC Agro Trial Center GmbH, organizační složka**

sídlo právnické osoby: Blatnická 179, 68724 Uherský Ostroh

IČ právnické osoby: 29220351

GEP kód: **GEP/ATC/2016**

oblasti zkoušení: **polní plodiny a zelenina**
trvalé kultury
skleníky a jiné kryté prostory

rozhodnutí se vydává s účinností od 1. 9. 2016

dobu účinnosti rozhodnutí: 5 let

Tímto rozhodnutím se k datu nabytí jeho účinnosti zrušuje rozhodnutí č.j. SRS 018365/2011 ze dne 21. 2. 2011.

Odůvodnění:

Řízení ve věci uznání osoby za způsobilou provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe bylo zahájeno na základě žádosti ze dne 13. 5. 2016, doručené UKZÚZ dne 16. 5. 2016.

Rozhodnutí o způsobilosti k provádění pokusů a zkoušek v souladu s požadavky správné pokusnické praxe bylo vydáno na základě kontroly předložené dokumentace pracoviště ATC Agro Trial Center GmbH, organizační složka, Příručky jakosti, Standardních operačních postupů a Metrologického řádu, kterou bylo UKZÚZ prokázáno, že žadatel splnil požadavky stanovené v § 45 odst. 12 a 13 zákona v návaznosti na § 4 odst. 2 vyhlášky č. 32/2012 Sb., o přípravcích a dalších prostředcích na ochranu rostlin, ve znění pozdějších předpisů.

Vzhledem k výše uvedeným skutečnostem bylo rozhodnuto tak, jak je stanoveno ve výrokové části tohoto rozhodnutí.

Správní poplatek podle zákona č. 634/2004 Sb., o správních poplatcích, ve znění pozdějších předpisů, podle Sazebníku, Položky 86 písm. b) „Přijetí žádosti o vydání osvědčení o způsobilosti k provádění zkoušek pro účely povolení“ ve výši 100,- Kč, k žádosti doručené UKZÚZ dne 16. 5. 2016, č.j. UKZUZ 055894/2016, byl uhrazen dne 16. 5. 2016 formou kolkové známky.

Poučení:

Proti tomuto rozhodnutí lze podat odvolání do 15 dnů ode dne jeho doručení, nejpozději však do 15 dnů po uplynutí desátého dne ode dne, kdy bylo nedoručené a uložené rozhodnutí připraveno k vyzvednutí, a to k Ministerstvu zemědělství České republiky, odbor rostlinných komodit, prostřednictvím Ústředního kontrolního a zkušebního ústavu zemědělského, sekce zemědělských vstupů, odboru přípravků na ochranu rostlin, Zemědělská 1a, 613 00 Brno.

Otisk úředního razítka

Ing. Pavel Minář, Ph.D.
ředitel odboru

Test facility	Address	Certificate (Yes or No)
SynTech Research CZ s.r.o.	Semcice 245 294 46 Semcice CZECH REPUBLIC	Yes

ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

Odbor přípravků na ochranu rostlin

Zemědělská 1a, Brno, PSČ 613 00

Příloha rozhodnutí č.j.: UKZUZ 033034/2017 ze dne 12. 4. 2017

OSVĚDČENÍ

GEP/SYT/2017

o způsobilosti k provádění zkoušek
v souladu se zásadami správné pokusnické praxe

Official Recognition Certificate / GEP - Certificate

právnícká osoba: **SynTech Research Czech s.r.o.**

sídlo právnické osoby: Žitná 562/10, Nové Město (Praha 2), 120 00 Praha

IČ právnické osoby: 04601351

je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe podle § 45 odst. 1 zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, v platném znění, v návaznosti na Směrnici 91/414/EHS.

oblasti zkoušení / categories of official recognition:

- polní plodiny a zelenina / *field crops and vegetables*
- moření osiva / *seed treatment*
- laboratorní testy a analýzy / *laboratory tests and analyses*

Ústřední kontrolní a zkušební ústav zemědělský
Sekce zemědělských vstupů
Odbor přípravků na ochranu rostlin
613 00 Brno, Zemědělská 1a
-1-


Ing. Pavel Minář, Ph.D.
ředitel odboru

Test facility	Address	Certificate (Yes or No)
VKST Field Trials	Soren Moller Kongstedvej 4 4100 Ringsted DENMARK	Yes



Certificate

GEP approval is granted to

Testing unit: **VKST Field Trials**
Eulbyvej 15
DK-4180 Sorø

The approval applies to the execution of GEP efficacy trials of pesticides within

Testing areas: **Field Trials**

GEP

The GEP Recognition Unit at the Danish Centre for Food and Agriculture, Aarhus University, controls organisation, staff, premises, trial fields, trial equipment, standard operation procedures and trial reports. The testing unit is subject to continuous control and inspection.

The certificate is valid for a period of 6 years.

Date of approval: 1 January 2014

Signed: 20 April 2017


Henrik Frølich Bredsgaard
Danish Environmental
Protection Agency


Else Thordahl Meyer
Aarhus University


Peter Kryger Jensen
Aarhus University

Regulation 1107/2009 concerning plant protection products and ministerial order no. 1088 dated 6th September 2013 from Danish Ministry of the Environment states that investigations of the efficacy of plant protection products carried out in Denmark for registration purposes must be performed by testing units which have been approved to carry out these investigations by the Danish Centre for Food and Agriculture, Aarhus University.

Test facility	Address	Certificate (Yes or No)
ANADIAG SA, CZ osp.	514 54 Chleny 47 CZECH REPUBLIC	Yes

ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

Odbor přípravků na ochranu rostlin

Zemědělská 1a, Brno, PSČ 613 00

Příloha rozhodnutí č.j.: UKZUZ 035705/2015 ze dne 30. 4. 2015

OSVĚDČENÍ

GEP/AHC/2015

o způsobilosti k provádění zkoušek
v souladu se zásadami správné pokusnické praxe

Official Recognition Certificate / GEP - Certificate

právnícká osoba: **Anadiag SA, CZ organizační složka podniku**

sídlo právnické osoby: Chleny 46, 517 45 Chleny


IČ právnické osoby: 27518604

je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe podle § 45 odst. 1 zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, v platném znění, v návaznosti na Směrnici 91/414/EHS.

oblasti zkoušení / categories of official recognition:

- polní plodiny a zelenina / field crops and vegetables
- trvalé kultury / high crops
- skleníky a jiné kryté prostory / protected areas and storage rooms

Ústřední kontrolní a zkušební ústav zemědělský
Sekce zemědělských vstupů
Odbor přípravků na ochranu rostlin
613 00 Brno, Zemědělská 1a
- 1 -


Ing. Pavel Minář, Ph.D.
ředitel odboru

Test facility	Address	Certificate (Yes or No)
Agrolab	Røjleskovvej 18 5500 Middelfart DENMARK	Yes



Certifikat

for **GEP-ankendelse** tildeles herved

Forsøgsenheden: Agrolab A/S
Røjleskovvej 18
DK-5500 Middelfart

Anerkendelsen gælder udførelsen af GEP-effektivitetsforsøg for bekæmpelsesmidler inden for

Forsøgsområderne: Markforsøg

GEP Anerkendelses Enheden ved Nationalt Center for Fødevarer og Jordbrug, Aarhus Universitet, kontrollerer organisation, personale, lokaler, forsøgsarealer, forsøgsudstyr samt standardforskrifter og forsøgsrapporter. Forsøgsenheden er underkastet løbende kontrol og inspektion.

Certifikatet for anerkendelse er gyldigt for en periode på 6 år.

Anerkendelsesdato: 1. januar 2014

Underskrevet: 16. december 2013


Nina Sørup Hansen
Miljøstyrelsen


Ulla Fosgerau Salomonsen
Aarhus Universitet


Peter Kryger Jensen
Aarhus Universitet

Forordning 1107/2009 om plantebeskyttelsesmidler og Miljøministeriets bekendtgørelse nr.1088 af 6. september 2013 anfører, at undersøgelser af plantebeskyttelsesmidlers effektivitet, der er udført i Danmark med henblik på godkendelse, skal være foretaget af forsøgsenheder, der er anerkendt hertil af Nationalt Center for Fødevarer og Jordbrug, Aarhus Universitet.

Test facility	Address	Certificate (Yes or No)
BioChem agrar GmbH	Meierei 1 Ebrach 96157 GERMANY	Yes

Anerkennungsbescheinigung

Die Versuchseinrichtung BioChem agrar GmbH
mit Hauptsitz in D-04827 Machern OT Gerichshain, Kupferstr. 6
und organisatorisch zugehörigen Arbeitseinheiten in Blankenhagen, Tützpatz, Oderbruch,
Prignitz, Neugattersleben, Motterwitz, Trossin, Gerichshain und Ebrach
ist auf Antrag vom 08.02.2019
und nach durchgeführter Besichtigung vom 14.03.2019
durch Herrn Dittrich, Frau Petrick und Herrn Pfüller
vom Sächsischen Landesamt für Umwelt, Landwirtschaft und Geologie am 21.03.2019
in den Versuchskategorien Ackerbau, Grünland, Gemüsebau, Obstbau, Zierpflanzenbau, Forst,
Hopfenbau, Weinbau, Nichtkulturland, Sonderkulturen und Vorratsschutz
für 5 Jahre amtlich anerkannt worden als Einrichtung für die Prüfung der Wirksamkeit von
Pflanzenschutzmitteln im Sinne des § 8 Absatz 6 der Pflanzenschutzmittelverordnung und gemäß
Verordnung (EU) Nr. 284/2013.

Recognition Certificate

The testing facility BioChem agrar GmbH
with headquarters in D-04827 Machern OT Gerichshain, Kupferstr. 6
and subsidiary testing units in Blankenhagen, Tützpatz, Oderbruch, Prignitz, Neugattersleben,
Motterwitz, Trossin, Gerichshain und Ebrach
has been officially recognized for 5 years as an organisation for efficacy testing facility of plant
protection products according to paragraph (6) of Article 8 of the Plant Protection Products
Ordinance and the Commission Regulation (EU) Nr. 284/2013 following its application
dated 2019-02-08
and after inspection of 2019-03-14
by Herrn Dittrich, Frau Petrick and Herrn Pfüller
from the Sächsisches Landesamt für Umwelt, Landwirtschaft und Geologie on 2019-03-21
in the trial categories agriculture, grassland, vegetable gardening, fruit-growing, ornamental plant
growing, forestry, hop growing, viticulture, non-cultivated areas, specialised crops and storage
protection.

21.03.2019

Datum
date


Unterschrift
sign

Sächsisches Landesamt für Umwelt,
Landwirtschaft und Geologie
Pillnitzer Platz 3
D-01326 Dresden

Adresse der anerkennenden Behörde
address of the recognizing authority



Test facility	Address	Certificate (Yes or No)
Agriculture research Institute, Ltd.	ZVU Kromeriz 767 01 CZECH REPUBLIC	Yes

ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

Odbor přípravků na ochranu rostlin

Zemědělská 1a, Brno, PSČ 613 00

Příloha rozhodnutí č.j.: UKZUZ 062941/2016 ze dne 31. 5. 2016

OSVĚDČENÍ

GEP/KRO/2016

o způsobilosti k provádění zkoušek
v souladu se zásadami správné pokusnické praxe

Official Recognition Certificate / GEP - Certificate

právníká osoba: **Zemědělský výzkumný ústav Kroměříž, s.r.o.**

sídlo právnické osoby: Havlíčkova 2787/121, 767 01 Kroměříž

IČ právnické osoby: 46904841

je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe podle § 45 odst. 1 zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, v platném znění, v návaznosti na Směrnici 91/414/EHS.

oblasti zkoušení / categories of official recognition:

- polní plodiny a zelenina / *field crops and vegetables*
- trvalé kultury / *high crops*
- moření osiva / *seed treatment*
- laboratorní testy a analýzy / *laboratory tests and analyses*

Ústřední kontrolní a zkušební ústav zemědělský
Sekce zemědělských vstupů
Odbor přípravků na ochranu rostlin
613 00 Brno, Zemědělská 1a
- 1 -



Ing. Pavel Minář, Ph.D.
ředitel odboru

Test facility	Address	Certificate (Yes or No)
InTec AgroTrials, s.r.o.	Blatnická 179 687 24 Uherský Ostroh CZECH REPUBLIC	Yes



ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

Hroznová 2
656 06 Brno

www.ukzuz.cz
ID DS: ugbaiaq7

IČO: 00020338
DIČ: CZ00020338

InTec Agro Trials, spol. s r.o.
Blatnická 179
687 24 Uherský Ostroh
IČO: 06774512

Utvar:	OPOR	Spisová zn.:	SZ UKZUZ 010368/2018/01399
Vyřizuje:	Ing. Ivana Minářová	Č. j.:	UKZUZ 013294/2018
E-mail:	ivana.minarova@ukzuz.cz		
Telefon:	+420 545 110 444		
Adresa:	Zemědělská 1a, 613 00 Brno	Datum:	7. 2. 2018

ROZHODNUTÍ

Ústřední kontrolní a zkušební ústav zemědělský (dále jen „ÚKZÚZ“), Hroznová 2, 656 06 Brno, jako věcně příslušný správní orgán podle § 72 odst. 1 písm. c) a v návaznosti na čl. 54 odst. 4 Nařízení Evropského parlamentu a Rady (ES) č. 1107/2009, o uvádění přípravků na ochranu rostlin na trh a o zrušení směrnic Rady 79/117/EHS a 91/414/EHS, v platném znění, v provedení § 45 odst. 1 zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, ve znění pozdějších předpisů (dále jen „zákon“), v řízení o způsobilosti k provádění pokusů a zkoušek s přípravky nebo dalšími prostředky na základě žádosti společnosti **InTec Agro Trials, s.r.o.**, a to:

žádosti o uznání osoby za způsobilou k provedení zkoušek podle § 45 odst. 1 zákona ze dne 24. 1. 2018, doručené ÚKZÚZ dne 26. 1. 2018, č.j. UKZUZ 010368/2018

rozhodl takto:

Společnost InTec Agro Trials, s.r.o. je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe.

právníká osoba: **InTec Agro Trials, s.r.o.**

sídlo právnické osoby: Blatnická 179, Ostrožské Předměstí, 687 24 Uherský Ostroh

IČ právnické osoby: 06774512

GEP kód: GEP/ITU/2018

oblasti zkoušení: **polní plodiny a zelenina**
trvalé kultury
skleníky a jiné kryté prostory

dobu platnosti rozhodnutí: 5 let ode dne nabytí účinnosti tohoto rozhodnutí

Odůvodnění:

Řízení ve věci uznání osoby za způsobilou provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe bylo zahájeno na základě žádosti ze dne 24. 1. 2018, doručené ÚKZÚZ dne 26. 1. 2018.

Do firmy InTec Agro Trials, s.r.o. přechází původní personální obsazení a zařízení firmy ATC – Agro Trial Center GmbH, organizační složky, původního držitele povolení č.j. UKZUZ 073735/2016 ze dne 1. 7. 2016. Nedošlo ke změnám v oblasti personálního obsazení, v prostorách, v nichž je činnost realizována, na pozemcích, na nichž je činnost prováděna a změnám v základní dokumentaci.

Rozhodnutí o způsobilosti k provádění pokusů a zkoušek v souladu s požadavky správné pokusnické praxe bylo vydáno na základě předložené dokumentace, Příručky jakosti, Standardních operačních postupů a Metrologického řádu, kterou bylo ÚKZÚZ prokázáno, že žadatel splnil požadavky stanovené v § 45 odst. 12 a 13 zákona v návaznosti na § 4 odst. 2 vyhlášky č. 32/2012 Sb., o přípravcích a dalších prostředcích na ochranu rostlin, ve znění pozdějších předpisů.

Vzhledem k výše uvedeným skutečnostem bylo rozhodnuto tak, jak je stanoveno ve výrokové části tohoto rozhodnutí.

Správní poplatek podle zákona č. 634/2004 Sb., o správních poplatcích, ve znění pozdějších předpisů, podle Sazebníku, Položky 86 písm. b) „Přijetí žádosti o vydání osvědčení o způsobilosti k provádění zkoušek pro účely povolení“ ve výši 100,- Kč, k žádosti doručené ÚKZÚZ dne 26. 1. 2018, č.j. UKZUZ 010368/2018, byl uhrazen dne 26. 1. 2018 formou kolkové známky.

Poučení o odvolání:

Proti tomuto rozhodnutí lze podat odvolání do 15 dnů ode dne jeho doručení, nejpozději však do 15 dnů po uplynutí desátého dne ode dne, kdy bylo nedoručené a uložené rozhodnutí připraveno k vyzvednutí, a to k Ministerstvu zemědělství České republiky, odbor rostlinných komodit, prostřednictvím Ústředního kontrolního a zkušebního ústavu zemědělského, sekce zemědělských vstupů, odboru přípravků na ochranu rostlin, Zemědělská 1a, 613 00 Brno.

Ing. Pavel Minář, Ph.D.
ředitel OPOR

Test facility	Address	Certificate (Yes or No)
Zkusebni Stanice Nechanice	Stolbova 319 503 15 Nechanice CZECH REPUBLIC	Yes

ÚSTŘEDNÍ KONTROLNÍ A ZKUŠEBNÍ ÚSTAV ZEMĚDĚLSKÝ

Odbor přípravků na ochranu rostlin

Zemědělská 1a, Brno, PSČ 613 00

Příloha rozhodnutí č.j.: UKZUZ 073241/2016 ze dne 28. 6. 2016

OSVĚDČENÍ

GEP/NEC/2016

o způsobilosti k provádění zkoušek
v souladu se zásadami správné pokusnické praxe

Official Recognition Certificate / GEP - Certificate

právnícká osoba: **ZKUŠEBNÍ STANICE NECHANICE, s.r.o.**

sídlo právnické osoby: Štolbova 319, 503 15 Nechanice

IČ právnické osoby: 25283669

je způsobilá provádět pokusy a zkoušky v souladu s požadavky správné pokusnické praxe podle § 45 odst. 1 zákona č. 326/2004 Sb., o rostlinolékařské péči a o změně některých souvisejících zákonů, v platném znění, v návaznosti na Směrnici 91/414/EHS.

oblasti zkoušení / categories of official recognition:

- polní plodiny a zelenina / field crops and vegetables
- trvalé kultury / high crops
- skleníky a jiné kryté prostory / protected areas and storage rooms

Ústřední kontrolní a zkušební ústav zemědělský
Sekce zemědělských vstupů
Odbor přípravků na ochranu rostlin
613 00 Brno, Zemědělská 1a
- 1 -

Ing. Pavel Minář, Ph.D.
ředitel odboru

Test facility	Address	Certificate (Yes or No)
ANADIAG France	174, impasse du Plan d'Eau 38 300 Ruy-Montceau FRANCE	Yes



MINISTÈRE DE L'AGRICULTURE ET DE L'ALIMENTATION

**DÉCISION D'AGRÈMENT POUR RÉALISER
DES ESSAIS OFFICIELLEMENT RECONNUS**

Annule et remplace les courriers du 7/02/2020

Conformément à l'article R. 253-38 du code rural et de la pêche maritime et à l'article 6 de l'arrêté du 26 avril 2007 relatif aux essais officiels et officiellement reconnus pour l'évaluation des produits mentionnés à l'article L. 253-1 du code rural et de la pêche maritime,

Vu la convention passée avec le Cofrac n° 4609,

Vu le rapport d'évaluation réalisé par le Cofrac, en date du 26/11/2019,

L'agrément pour réaliser des essais officiellement reconnus est maintenu et étendu, à l'organisme :

Anadiag France
174 impasse du plan d'eau
38300 RUY MONTCEAU

sous le numéro : **BPE - 105**

ET POUR LE PÉRIMÈTRE SUIVANT :

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
ANADIAG FRANCE 174 impasse du plan d'eau 38300 RUY MONTCEAU (unité centrale)	- Traitement des semences : grandes cultures
UE 01 – Harnes (UE 62) ZI la Motte au Bois 62440 HARNES	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Zones non agricoles
UE 03 – Saint Pierre du Bû (UE 14) Couvigny 14700 SAINT PIERRE DU BU	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Zones non agricoles
UE 04 – Cintré (UE 35) Rue du puisatier ZA du moulin à vent 35310 CINTRE	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Zones non agricoles
UE 06 – Varois et Chaignot (UE 21) 8 route de gray 21490 VAROIS ET CHAIGNOT	- Grandes cultures - Vigne - Cultures fruitières et arboriculture - Zones non agricoles

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
UE 08 – Saint Barthélémy (UE 38) 700 route de Pisieu 38270 SAINT BARTHELEMY	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles
UE 10 – Saint Etienne de Fougères (UE 47) ZA Bel Air 47380 SAINT ETIENNE DE FOUGERES	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles - Désinfection et désinsectisation des sols, des matériels et des locaux de culture et de stockage des végétaux
UE 12 – Saint Germain des Prés (UE 49) ZA la Potherie 49170 SAINT GERMAIN DES PRES	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles
UE 13 – Castillon du Gard (UE 30) ZA les Codes Bas 3 30210 CASTILLON DU GARD	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles
UE 15 – Haguenau (UE 67) 16 rue Ampère 67500 HAGUENAU	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Zones non agricoles - Processus de transformation : <ul style="list-style-type: none"> <i>Vinification</i> <i>Transformation de pomme de terre</i> <i>Transformation de fruits (compote, jus de fruit, nectar, fruit au sirop, confiture, fruits séchés)</i> <i>Transformation de légumes (jus, concentré de tomates, conserve de légumes, ketchup, choucroute)</i> <i>Extraction d'huile</i>

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
UE 16 – Thorée les Pins (UE 72) La Belle Métairie 72800 THOREE LES PINS	<ul style="list-style-type: none">- Grandes cultures- Vigne- Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum- Cultures fruitières et arboriculture- Zones non agricoles
UE 17 – Toulouse (UE 31) 75 voie du TOEC Bâtiment entreprise 2 31076 TOULOUSE Cedex 3	<ul style="list-style-type: none">- Grandes cultures- Vigne- Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum- Cultures fruitières et arboriculture- Zones non agricoles

Cet agrément est valable jusqu'au 08/10/2022. La prochaine évaluation de votre organisme est prévue au planning sur septembre / octobre 2020.

Date : 07/02/2020

La sous directrice de la qualité,
de la santé et de la protection
des végétaux



Anne-Cécile COTILLON

Test facility	Address	Certificate (Yes or No)
Oxford Agricultural Trials Limited	West Farm Barns Lauton Road- Statton Adley Bicester OXON – OX279AS UNITED KINGDOM	Yes



Certificate of

Official Recognition of Efficacy Testing Facilities or Organisations in the United Kingdom

This certifies that

Oxford Agricultural Trials Limited

complies with the minimum standards laid down in
Regulation (EC) 1107/2009 for efficacy testing.

The above Facility/Organisation has been officially
recognised as being competent to carry out efficacy trials/tests
in the United Kingdom in the following categories:

**Agriculture/Horticulture
Biologicals and Semiochemicals
Stored Crops**

Date of issue: 9 January 2018
Effective date: 1 January 2018
Expiry date: 31 December 2022

Signature


Authorised signatory

Certification Number

ORETO 385



Chemicals Regulation Division



Department of
**Agriculture and
Rural Development**

Test facility	Address	Certificate (Yes or No)
Trialtec GMBH	Kampenredder 5 24363 Haby GERMANY	Yes

GEP-Anerkennungs-Zertifikat

Anerkennungsbescheinigung

Recognition Certificate

Die Versuchseinrichtung
trial-tec: GmbH
mit Hauptsitz in
Kampenredder 5
24363 Haby
ist auf Antrag vom
07.09.2017
und durchgeführter Besichtigung
durch
Landwirtschaftskammer
Schleswig-Holstein
vom
23.04.2018
in den Versuchskategorien
Ackerbau und Grünland,
Gemüsebau, Obstbau,
Zierpflanzenbau und
Nichtkulturland

The testing facility
with headquarter in
on application from
and inspection
by
from the
in the trial categories

als Einrichtung für die Prüfung der
Wirksamkeit von Pflanzenschutzmitteln
im Sinne des § 8 Abs. 6 der
Pflanzenschutzmittelverordnung
und gemäß Verordnung (EU) 284/2013
für 5 Jahre bis zum 22.04.2023
amtlich anerkannt worden.

has been officially recognised
as an organisation for efficacy
testing facility of plant protection
products according to § 8 par. 6
of the Plant Protection Products
Ordinance and the Commission
Regulation (EU) 284/2013 for
5 years until 22nd of April 2023.

Datum
date

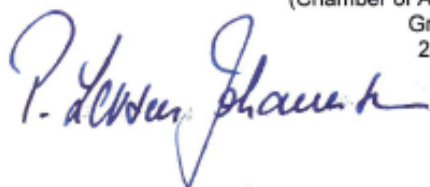
Unterschrift
sign

Adresse der anerkennenden Behörde
address of the recognising authority

Stempel
stamp

08.05.2019

Landwirtschaftskammer Schleswig-Holstein
(Chamber of Agriculture Schleswig-Holstein)
Grüner Kamp 15-17
24768 Rendsburg



Mediterranean EPPO zone

Test facility	Address	Certificate (Yes or No)
ANADIAG France	13, rue de la Bourbre 38300 Ruy FRANCE	Yes
ANADIAG Iberica, SL	C/ Falgueres, 15 17400 Celra (Girona) SPAIN	Yes
ANADIAG Italia SRL	S. da Savonesa, 9 15050 Fraz Rivalta S. Tortona ITALY	Yes

Test facility	Address	Certificate (Yes or No)
ANADIAG France	13, rue de la Bourbre 38300 Ruy FRANCE	Yes



MINISTÈRE DE L'AGRICULTURE ET DE L'ALIMENTATION

**DÉCISION D'AGRÉMENT POUR RÉALISER
DES ESSAIS OFFICIELLEMENT RECONNUS**

Conformément à l'article R. 253-38 du code rural et de la pêche maritime et à l'article 6 de l'arrêté du 26 avril 2007 relatif aux essais officiels et officiellement reconnus pour l'évaluation des produits mentionnés à l'article L. 253-1 du code rural et de la pêche maritime,

Vu la convention passée avec le Cofrac n° 4609,

Vu le rapport d'évaluation réalisé par le Cofrac, en date du 27 juillet 2017,

L'agrément pour réaliser des essais officiellement reconnus est renouvelé, à l'organisme :

ANADIAG France
13 rue de la Bourbre
38300 RUY

sous le numéro : **BPE - 105**

ET POUR LE PÉRIMÈTRE SUIVANT :

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
ANADIAG France 13 rue de la Bourbre 38300 RUY (unité centrale)	- Traitement des semences : grandes cultures
UE 01 – Harnes (UE 62) ZI la Motte au Bois 62440 HARNES	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Zones non agricoles
UE 03 – Saint Pierre du Bû (UE 14) Couvigny 14700 SAINT PIERRE DU BU	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum
UE 03 – Cintré (UE 35) Rue du puisatier ZA du moulin à vent 35310 CINTRE	- Grandes cultures - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Zones non agricoles
UE 06 – Varois et Chaignot (UE 21) 8 route de Gray 21490 VAROIS ET CHAIGNOT	- Grandes cultures - Vigne - Zones non agricoles
UE 08 – Saint Barthélémy (UE 38) 700 route de Pisieu 38270 SAINT BARTHELEMY	- Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticolas et plantes d'intérieur

UNITÉ(S)	SECTEUR(S) D'ACTIVITÉ
UE 10 – Saint Etienne de Fougères (UE 47) ZA Bel Air 47380 SAINT ETIENNE DE FOUGERES	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles - Désinfections et désinsectisation des sols, des matériels et des locaux de culture et de stockage des végétaux
UE 12– Saint Germain des Prés (UE 49) ZA la Poterie 49170 SAINT GERMAIN DES PRES	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur
UE 13 – Castillon du Gard (UE 30) ZA les codes bas 3 30210 CASTILLON DU GARD	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Productions horticoles et plantes d'intérieur - Zones non agricoles
UE 15 – Haguenau (UE 67) 16 rue Ampère 67500 HAGUENAU	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture - Processus de transformation : <ul style="list-style-type: none"> - Vinification - Transformation de pomme de terre - Transformation de fruits (compote, jus de fruit, nectar, fruit au sirop, confiture, fruits séchés) - Transformation de légumes (jus, concentré de tomates, conserve de légumes, ketchup, choucroute) - Extraction d'huile
UE 16 – Thorée les Pins (UE 72) La Belle Métairie 72800 THOREE LES PINS	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture
UE 17 – Toulouse (UE 31) 75 voie de TOEC Bâtiment entreprise 2 31076 TOULOUSE	<ul style="list-style-type: none"> - Grandes cultures - Vigne - Cultures légumières, plantes aromatiques, médicinales, condimentaires et à parfum - Cultures fruitières et arboriculture

Cet agrément est délivré pour une durée de cinq ans à compter du **09/10/2017 jusqu'au 08/10/2022**. En application de l'article 5 de l'arrêté susmentionné, une nouvelle évaluation aura lieu dans un délai compris entre vingt-quatre et trente-six mois à compter du **09/10/2017**.

Date : 03 OCT. 2017

Le sous directeur de la qualité, de la santé
et de la protection des végétaux

Alain TRIDON

Test facility	Address	Certificate (Yes or No)
ANADIAG Iberica, SL	C/ Falgueres, 15 17400 Celra (Girona) SPAIN	Yes

GEP AGREEMENT



MINISTERIO
DE AGRICULTURA Y PESCA,
ALIMENTACION Y MEDIO AMBIENTE

SECRETARÍA GENERAL DE
AGRICULTURA Y ALIMENTACIÓN

DIRECCIÓN GENERAL DE SANIDAD
DE LA PRODUCCIÓN AGRARIA

ASUNTO: Renovación Acreditación N° EOR 20/97

De acuerdo con lo establecido en el artículo 18 de la Orden de 11 de diciembre de 1995 por el que se establecen las disposiciones relativas a las renovaciones de autorizaciones de ensayos y experiencias con productos fitosanitarios, esta Dirección General ha resuelto, previo informe favorable de la Comisión de Evaluación de Productos Fitosanitarios, renovar la acreditación N° EOR 20/97 concedida a su empresa, para realizar ensayos oficialmente reconocidos.

La validez de esta acreditación queda ampliada hasta el 18 de julio del año 2022, salvo que sea revisada o revocada antes de la conclusión de dicho plazo si se determina que ha dejado de cumplirse alguno de los requisitos exigidos para su autorización o de las obligaciones establecidas por la Orden Ministerial de 11 de diciembre de 1995.

Madrid 18 de julio de 2017

EL DIRECTOR GENERAL DE SANIDAD
DE LA PRODUCCIÓN AGRARIA

Fdo.: Valentin Almanza de Lara



Test facility	Address	Certificate (Yes or No)
ANADIAG Italia SRL	S. da Savonesa, 9 15050 Fraz Rivalta S. Tortona ITALY	Yes

Serie generale - n. 187

DECRETO 30 luglio 2018.

IL DIRETTORE GENERALE
DELLO SVILUPPO RURALE

Visto il decreto interministeriale 27 novembre 1996 che, in attuazione del citato decreto legislativo n. 194/95, disciplina i principi delle buone pratiche per l'esecuzione delle prove di campo e definisce i requisiti necessari al riconoscimento ufficiale dell'idoneità a condurre prove di campo finalizzate alla registrazione dei prodotti fitosanitari:

Considerato che il suddetto Centro ha dichiarato di possedere i requisiti prescritti dalla normativa vigente, a far data dal 10 gennaio 2018, a fronte di apposita documentazione presentata;

Decreta:

Art. 1.

1. Il Centro «Anadiag Italia S.r.l.», con sede legale in fraz. Rivalta Scrivia - Strada Savonese, 9 - 15050 Tortona (AL), è riconosciuto idoneo a proseguire nelle prove ufficiali di campo con prodotti fitosanitari volte ad ottenere le seguenti informazioni:

efficacia dei prodotti fitosanitari (di cui all'Allegato III, punto 6.2 del decreto legislativo n. 194/95);

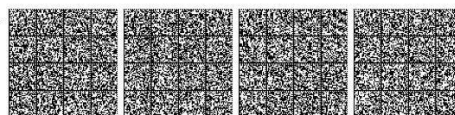
dati sulla comparsa o eventuale sviluppo di resistenza (di cui all'Allegato III, punto 6.3 del decreto legislativo n. 194/95):

incidenza sulla resa quantitativa e/o qualitativa (di cui all'Allegato III, punto 6.4 del decreto legislativo n. 194/95);

fitotossicità nei confronti delle piante e prodotti vegetali bersaglio (di cui all'Allegato III, punto 6.5 del decreto legislativo n. 194/95);

osservazioni riguardanti gli effetti collaterali indesiderabili (di cui all'Allegato III, punto 6.6 del decreto legislativo n. 194/95);

individuazione dei prodotti di degradazione e di reazione dei metaboliti in piante o prodotti trattati (di cui all'allegato II, punto 6.1 del decreto legislativo n. 194/95);



valutazione del comportamento dei residui delle sostanze attive e dei suoi metaboliti a partire dall'applicazione fino al momento della raccolta o della commercializzazione dei prodotti immagazzinati (di cui all'allegato II, punto 6.2 del decreto legislativo n. 194/95);

definizione del bilancio generale dei residui delle sostanze attive (di cui all'allegato II, punto 6.3 del decreto legislativo n. 194/95);

prove relative agli effetti della lavorazione industriale e/o preparazione domestica sulla natura e sull'entità dei residui (di cui all'allegato II, punto 6.6 del decreto legislativo n. 194/95);

prove su destino e comportamento nel suolo (di cui all'allegato II, punto 7.1 del decreto legislativo n. 194/95);

prove su destino e comportamento nell'acqua e nell'aria (di cui all'allegato II, punto 7.2 del decreto legislativo n. 194/95);

studi ecotossicologici relativi agli effetti su organismi non bersaglio (di cui all'Allegato II, punto 8.3 del decreto legislativo n. 194/95);

determinazione dei residui in o su prodotti trattati, alimenti per l'uomo o per gli animali (di cui all'Allegato III, punto 8.1 del decreto legislativo n. 194/95);

prove relative agli effetti della lavorazione industriale e/o preparazione domestica sulla natura e sull'entità dei residui (Allegato III, Punto 8.2 del decreto legislativo n. 194/95);

effetti sull'aspetto, l'odore, il gusto o altri aspetti qualitativi dovuti ai residui nei o sui prodotti freschi o lavorati (Allegato III, Punto 8.3 del decreto legislativo n. 194/95);

valutazione dei dati sui residui nelle colture successive o di rotazione (di cui all'Allegato III, punto 8.5 del decreto legislativo n. 194/95);

individuazione dei tempi di carenza per impieghi in pre-raccolta o post-raccolta (di cui all'Allegato III, punto 8.6 del decreto legislativo n. 194/95);

prove su destino e comportamento ambientale (di cui all'Allegato III, punti 9.1, 9.2 e 9.3 del decreto legislativo n. 194/95);

studi ecotossicologici relativi agli effetti su organismi non bersaglio (di cui all'Allegato III, punto 10.3 del decreto legislativo n. 194/95).

2. Il riconoscimento di cui al comma 1, riguarda le prove di campo di efficacia e le prove di campo finalizzate alla determinazione dell'entità dei residui di prodotti fitosanitari nei seguenti settori di attività:

aree non agricole;
colture arboree;
colture erbacee;
colture forestali;
colture medicinali ed aromatiche;
colture ornamentali;
colture orticole;
concia sementi;
conservazione post-raccolta;
colture in vivaio;

prove di semicampo in ambiente controllato;

diserbo;

entomologia;

microbiologia agraria;

nematologia;

patologia vegetale;

zoologia agraria;

produzione sementi;

vertebrati dannosi;

fitoregolatori, attivatori e coadiuvanti;

vinificazione.

Art. 2.

1. Il mantenimento dell'idoneità di cui all'articolo precedente è subordinato alla verifica biennale in loco del possesso dei requisiti prescritti, da parte degli ispettori iscritti nell'apposita lista nazionale di cui all'art. 4, comma 8, del citato decreto legislativo 194/95.

2. Il Centro «Anadiag Italia S.r.l.» è tenuto a comunicare a questo Ministero l'indicazione precisa delle tipologie delle prove che andrà ad eseguire, nonché la loro localizzazione territoriale.

3. Il citato Centro è altresì tenuto a comunicare ogni eventuale variazione che interverrà rispetto a quanto dalla stessa dichiarato nell'istanza di riconoscimento, nonché a quanto previsto dal presente decreto.

Art. 3.

1. Il presente decreto ha la validità di mesi 24 dalla data di ispezione effettuata in data 23 giugno 2018.

2. Il Centro «Anadiag Italia S.r.l.», qualora intenda confermare o variare gli ambiti operativi di cui al presente decreto, potrà inoltrare apposita istanza, almeno sei mesi prima della data di scadenza, corredata dalla relativa documentazione comprovante il possesso dei requisiti richiesti.

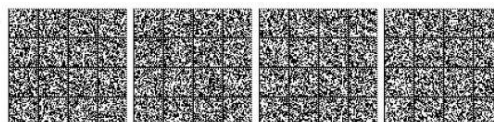
Il presente decreto, ai sensi dell'art. 13 del decreto legislativo n. 196/2003, sarà oggetto di pubblicazione in ottemperanza agli obblighi di legge previsti dal decreto legislativo n. 33/2013.

Il presente decreto sarà pubblicato nella *Gazzetta Ufficiale* della Repubblica italiana.

Roma, 30 luglio 2018

Il direttore generale: GATTO

18A05349



North-Eastern EPPO zone

Test facility	Address	Certificate (Yes or No)
STAPHYT	Station Dabrowa 15 Jaraczewo 63-233 POLAND	Yes
SynTech Research Poland Sp. Z.o.o.	69/1 Jagiellonska 85-027 Bydgoszcz POLAND	Yes
ANADIAG Polska	Ul. Sadowa 16/22 95-100 Zgierz POLAND	Yes
ANADIAG Polska	Ul. Sadowa 16/22 95-100 Zgierz POLAND	Yes
Institute of Agriculture, LAMMC	Instituto al. 1 Kedainai LT-58 344 LITHUANIA	Yes
Institute of Agriculture, LAMMC	Instituto al. 1 Kedainai LT-58 344 LITHUANIA	Yes
Agrolab Baltic	Agrolab Baltic Bugeniu km. LT-89452 Mazeikiu raj LITHUANIA	Yes

Test facility	Address	Certificate (Yes or No)
STAPHYT	Station Dabrowa 15 Jaraczewo 63-233 POLAND	Yes

**GŁÓWNY INSPEKTOR
OCHRONY ROŚLIN I NASIENICTWA**

Tadeusz Kłos

WO-505- 14 /2012

Warszawa, 26.09.2012 r.

DECYZJA Nr 7/2012

Na podstawie art. 155 ustawy z dnia 14 czerwca 1960 r. Kodeks postępowania administracyjnego (Dz.U. z 2000 r. Nr 98, poz. 1071 ze zm.) i art. 40 ust. 1 ustawy z dnia 18 grudnia 2003 r. o ochronie roślin (Dz.U. z 2008 r. Nr 133, poz. 849 ze zm.), po rozpatrzeniu wniosku z dnia 6 września 2012 r., zmieniam decyzję Nr 9/2005 z dnia 1 maja 2005 r., zmienioną decyzjami: Nr 3/2006 z dnia 5 maja 2006 r., Nr 8/2006 z dnia 11 grudnia 2006 r., Nr 2/2009 z dnia 18 lutego 2009 r., Nr 12/2011 z dnia 31 marca 2011 r. oraz Nr 4/2012 z dnia 4 kwietnia 2012 r.

Rozstrzygnięciu decyzji nadaję następujące brzmienie:

upoważniam

STAPHYT Sp. z o.o.

ul. Ziębicka 2; 60-164 Poznań

do prowadzenia badań skuteczności działania środka ochrony roślin

z grupy fungicydów, herbicydów, insektycydów, moluskocydów, akarycydów, regulatorów wzrostu, zapraw nasiennych oraz do łącznego stosowania środków ochrony roślin w uprawach polowych: zbóż, kukurydzy, rzepaku, buraków cukrowych, słonecznika, ziemniaków, warzyw, w uprawach sadowniczych (jabłoni, gruszy, porzeczek, truskawek, pestkówek), w magazynach i przechowalniach, a także na trawnikach oraz w uprawach roślin ozdobnych w polu i pod osłonami.

Uzasadnienie

W dniu 6 września 2012 r. Staphyt Sp. z o.o. (ul. Ziębicka 2; 60-164 Poznań) zwróciła się z wnioskiem o rozszerzenie zakresu decyzji Głównego Inspektora Ochrony Roślin i Nasiennictwa upoważniającej do prowadzenia badań skuteczności działania środków ochrony roślin Nr 9/2005 z dnia 1 maja 2005 r.,

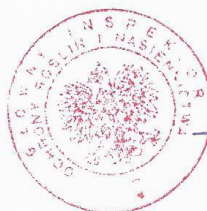
zmienionej decyzjami: Nr 3/2006 z dnia 5 maja 2006 r., Nr 8/2006 z dnia 11 grudnia 2006 r., Nr 2/2009 z dnia 18 lutego 2009 r. oraz Nr 4/2012 z dnia 4 kwietnia 2012 r. Wniosek dotyczył możliwości prowadzenia badań w magazynach i przechowalniach.

Staphyt Sp. z o.o. spełnia warunki organizacyjno-techniczne, zwane „Zasadami Dobrej Praktyki Eksperymentalnej” (Good Experimental Practice - GEP), zapewniające prawidłowe przeprowadzanie badań skuteczności działania środka ochrony roślin.

Mając na uwadze powyższe, postanowiono jak w rozstrzygnięciu decyzji.

Pouczenie

Od niniejszej decyzji odwołanie nie przysługuje. Jednakże strona niezadowolona z decyzji może zwrócić się do Głównego Inspektora Ochrony Roślin i Nasiennictwa z wnioskiem o ponowne rozpatrzenie sprawy w terminie 14 dni od dnia doręczenia decyzji, zgodnie z art. 127 § 3 Kodeksu postępowania administracyjnego.



GŁÓWNY INSPEKTOR

Tadeusz Kłos

Test facility	Address	Certificate (Yes or No)
SynTech Research Poland Sp. Z.o.o.	69/1 Jagiellonska 85-027 Bydgoszcz POLAND	Yes



GLÓWNY INSPEKTOR
OCHRONY ROŚLIN I NASIENICTWA

Tadeusz Klos

WO-505-8/15

Warszawa, 27.04.2015 r.

DECYZJA Nr 6/2015

Na podstawie art. 17 ust. 2 i ust. 8 pkt 2 w związku z art. 79 ust. 3 ustawy z dnia 8 marca 2013 r. o środkach ochrony roślin (Dz.U. z 2013 r. poz. 455 z późn. zm.) oraz art. 104 ustawy z dnia 14 czerwca 1960 r. Kodeks postępowania administracyjnego (Dz.U. z 2013 r. poz. 267 z późn. zm.), po rozpatrzeniu wniosku z dnia 30 marca 2015 r., rozszerzam zakres upoważnienia do prowadzenia badań skuteczności działania środka ochrony roślin wydanego w drodze decyzji Nr 5/2013 z dnia 25 marca 2013 r., zmienionego decyzją Nr 2/2014 z dnia 7 marca 2014 r., w zakresie prowadzenia badań skuteczności działania środka ochrony roślin z użyciem akaricydów i nematocydów w uprawach warzyw w polu i pod osłonami.

Rozstrzygnięciu decyzji nadaję następujące brzmienie:

Upoważniam

SynTech Research Poland Sp. z o.o.

ul. Jagiellońska 69/1; 85-027 Bydgoszcz

do prowadzenia badań skuteczności działania środka ochrony roślin

z grupy akaricydów, fungicydów, herbicydów, insektycydów, nematocydów i regulatorów wzrostu w uprawach polowych (zboża, kukurydza, rzepak, burak cukrowy, ziemniak, warzywa kapustne, pomidor, ogórek, sałata, marchew, pietruszka, cebula, fasola, papryka, burak), w uprawach sadowniczych (jabłoni, wiśni, czereśni, śliwa, morela, brzoskwinia, grusza, malina, truskawka, porzeczka, winorośl, orzech), w uprawach chmielu, traw łąkowych i pastwiskowych oraz na terenach nieużytkowanych rolniczo.

Uzasadnienie

Pismem z dnia 30 marca 2015 r. Spółka z o.o. SynTech Research Poland zwróciła się z prośbą o rozszerzenie zakresu upoważnienia Nr 5/2013 wydanego przez Głównego Inspektora Ochrony Roślin i Nasiennictwa w dniu 25 marca 2013 r., zmienionego decyzją Nr 2/2014 z dnia 7 marca 2014 r., umożliwiającego Spółce prowadzenie badań skuteczności działania środka ochrony roślin. Wnioskowana zmiana dotyczy prowadzenia badań z użyciem środków ochrony roślin z grupy akaricydów i nematocydów oraz stosowania badanych środków w uprawach marchwi, pietruszki, cebuli, fasoli, papryki, buraka, truskawki, porzeczki, gruszy, orzecha, moreli, brzoskwini, winorośli i chmielu, traw łąkowych i pastwiskowych oraz na terenach nieużytkowanych rolniczo.

Test facility	Address	Certificate (Yes or No)
ANADIAG Polska	Ul. Sadowa 16/22 95-100 Zgierz POLAND	Yes

***Certified translation from Polish
of two pages of the document***

[embossed seal bearing the national emblem of the Republic of Poland] -/-

**GŁÓWNY INSPEKTOR OCHRONY ROŚLIN I NASIENNICTWA -/-
(CHIEF PLANT AND SEED HEALTH INSPECTOR) -/-
Tadeusz Klos -/-**

WO-505-5/14 -/-

-/- Warsaw, on 16 April, 2014.

-/- DECISION no. 3/2014 -/-

Pursuant to section 17(1) and (2) of the Act of 8 March, 2013 on Plant Protection Products (in Journal of Laws of 2013, item 455) and to section 104 of the Act of 14 June, 1960 – Administrative Procedure Code (in Journal of Laws of 2013, item 267), having considered the request of 14 January, 2014 and the request of 14 February, 2014, as amended by letter of 4 April, 2014, I hereby amend decision no. 7/2007 of 28 May, 2007, as amended by decisions no. 1/2010 of 18 March, 2010, no. 18/2011 of 18 August, 2011 and no. 1/2012 of 13 January, 2012. -/-

The ruling of the decision is hereby amended to read as follows: -/-

-/- I hereby authorize -/-

**-/- Anadiag S.A. Oddział w Polsce -/-
-/- (Anadiag public limited company, Branch in Poland) -/-**

-/- ul. Sadowa 16/22, 95-100 Zgierz -/-

-/- to conduct studies evaluating the efficacy of plant protection product -/-

from the group of acaricides, bactericides, fungicides, herbicides, insecticides, molluscicides, rodenticides, pheromones and growth regulators in open field crops, orchard crops, shelter crops, in edible mushrooms crops, on meadows and pastures. The research will also be conducted on grains crops, root crops, oilseeds crops, vegetable crops, orchard plants crops and ornamental plants crops, legumes crops, grass crops and crops of plants used in specific fields, on warehouse premises and on premises intended for cultivation of edible mushrooms, on lawns and in areas not used for agriculture. -/-

-/- Justification -/-

By way of letter executed under no. APL-4-2014 of 14 January, 2014, Mr. Jacek Jatczak, a representative of Anadiag S.A. Oddział w Polsce, submitted a request for change of the company's registered office in the authorization issued by the Chief Plant and Seed Health



Inspector to conduct studies evaluating efficacy of plant protection product. Transfer of the company's all and any activities from Skierniewice (ul. Trzcińska 6) to Zgierz (ul. Sadowa 16/22) had been notified to the Chief Plant and Seed Health Inspector by Mr. Jatczak by way of letter executed under no. APL-1-2014 of 9 January, 2014. -/-

Subsequently, on 14 February, 2014, by way of latter executed under no. APL-5-2014, Mr. Jacek Jatczak submitted a request for extension of the aforesaid authorization issued by the Chief Plant and Seed Health Inspector to include additional groups of plant protection products (pheromones, rodenticides, viroides, nematocides), crops (crops of edible mushrooms, meadows and pastures) and locations where studies are conducted (nurseries, warehouse premises and premises intended for cultivation of edible mushrooms, lawns and recreation areas, areas not used of agriculture). Said request was subsequently modified by the party concerned on 4 April, 2014 (letter executed under no. APL-8-2014) so as to limit the requested changes to the following: in the group of plant protection products – to pheromones and rodenticides; and with regard to locations where studies are conducted – to warehouse premises and premises intended for cultivation of edible mushrooms, lawns and areas not used of agriculture. -/-

Following an inspection carried out at the new registered office of Anadiag S.A. Oddział w Polsce with regard to meeting the requirements of good laboratory practice within the meaning of article 3 paragraph 20 of the Regulation (EC) no. 1107/2009 of the European Parliament and of the Council of 21 October, 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009 p.1, as later amended), the Chief Plant and Seed Health Inspector granted the requested changes. -/-

In the light of the above, it was decided as stated. -/-

-/- Instructions -/-

The present decision cannot be appealed against. However, a party objecting to the present decision has the right to request that the Chief Plant and Seed Health Inspector reconsider the case, such request to be filed within 14 days of the service hereof, pursuant to section 127 §3 of Administrative Procedure Code. -/-

Stamp duty fee has been collected in accordance with part I, item 36c of Appendix to the Act of 16 November, 2006 on Stamp Duty Fee (Journal of Laws of 2012, item 1282, as later amended) in the amount of PLN 1000. -/-

Małgorzata Kukuła – chief specialist in the Chief Plant and Seed Health Inspectorate -/-

[official round seal bearing the national emblem of the Republic of Poland: Chief Plant and Seed Health Inspector] -/-



CHIEF INSPECTOR -/-

Tadeusz Kłos -/-

[illegible signature] -/-

I hereby confirm the accordance of this translation with the document in Polish submitted to me.

Magdalena Zytek

Sworn translator of English,

entered under no. TP/3341/05 in the register of sworn translators of the Minister of Justice

Address: 91-312 Łódź, ul. Urzędnicza 39 m. 67

tel. 507 096 361

characters: 4802 (5 standardized pages)

fee: statutory

Register no.: 262/2015

date: 17/12/2015



[Handwritten signature]

Test facility	Address	Certificate (Yes or No)
ANADIAG Polska	Ul. Sadowa 16/22 95-100 Zgierz POLAND	Yes

SWORN TRANSLATOR
MARTA TRAWCZYŃSKA
ul. Św. Wojciecha 3/3a lok. 1, 10-038 Olsztyn
T + 48 665 240 339, F +48 89/ 512 00 99

CERTIFIED TRANSLATION FROM THE POLISH LANGUAGE

[Any remarks in square brackets are the translator's. The translated document consists of two (2) pages.]

[national emblem of the Republic of Poland]
MAIN INSPECTOR
OF PLANT HEALTH AND SEED PROTECTION

Andrzej Chodkowski

Warsaw, dated 12 October 2018

BORiT.541.11.2018.1

DECISION No. 10/2018

Pursuant to Article 155 of the Act of 14 June 1960 Administrative Procedure Code (Dz.U. *[Polish Official Journal of Laws]* of 2017, item 1257 as amended), having examined the application filed by Anadiag SAS Branch Office in Poland dated 3 October 2018, I vary the decision No. 7/2007 dated 28 May 2007, varied by decisions No. 1/2010 dated 18 March 2010, No. 18/2011 dated 18 August 2011, No. 1/2012 dated 13 January 2012 and No. 3/2014 dated 16 April 2014 to grant authorization to conduct research of the efficiency of plant health products in such a manner that the decision shall read as follows:

"I authorize

Anadiag SAS Branch Office in Poland
ul. Sadowa 16/22, 95-100 Zgierz

to conduct research of the efficiency of plant health products from the group of acaricides, bacteriocides, fungicides, herbicides, insecticides, molluscicides, rodenticides, pheromones and growth regulators in outdoor crops, orchard crops, under covers, in edible mushrooms cultivations, in meadows and pastures. The research shall be conducted in cereal, root and oil crops, vegetables, orchard and ornamental plants, legumes, grass and special plants, in storage rooms and rooms for cultivation of edible mushrooms, in lawns and in non-agricultural lands."

No reasoning for this decision has been prepared as the decision grants the application of the Party in its entirety (Article 107(4) of the Administrative Procedure Code *[hereinafter referred to as "APC"]*).



Marta Trawczyńska

Instruction

This decision may not be appealed against. A Party unsatisfied with this decision may file an application to the Main Inspector of Plant Health and Seed Protection requesting a re-examination of the case, within 14 days of being served with this decision, pursuant to Article 127(3) APC.

Until the time-limit to apply for re-examination of the case has expired, a Party may waive this right towards the public administration authority which issued the decision. On the day when the Main Inspector of Plant Health and Seed Protection receives the waiver of the right to apply for re-examination of the case, the decision becomes final and non-appealable, which means that the decision shall be enforced immediately and it may not be appealed against to the Voivodeship Administration Court.

If a Party does not believe that the decision grants the Party's application but does not wish to exercise its right to apply for re-examination of the case, the Party may file to the Voivodeship Administration Court in Warsaw a complaint against the decision within 30 days of being served with the decision. The complaint shall be filed through the Main Inspector of Plant Health and Seed Protection.

Pursuant to section 2(1)(2) of the Regulation of the Council of Ministers of 16 December 2003 on the amount and detailed rules for collecting charges in proceedings before administrative courts (Dz.U. [Polish Official Journal of Laws] No. 221, item 2193 as amended) a fixed charge, which is independent of the subject-matter of the act appealed against or activities in cases regarding complaints against acts or public administration activities regarding rights or duties specified by the law, shall amount to PLN 200.

At the request of a Party made before court proceedings are instituted or in the course of such proceedings, the Party may be granted legal aid consisting of full or partial exemption from court costs and having an attorney-at-law or a legal advisor appointed for such Party, if the Party substantiates that they are unable to bear any costs of the proceedings or full costs thereof.

To be served upon:

1. [REDACTED]
Anadiag SAS Branch Office in Poland
ul. Sadowa 16/22
95-100 Zgierz
2. file

[round official seal with the national emblem of the Republic of Poland in its midst and the following circumscription: MAIN INSPECTOR OF PLANT HEALTH AND SEED PROTECTION]

[rectangular stamp reading: P.p. / MAIN INSPECTOR / Tadeusz Łęczyński; illegible signature]

I, duly commissioned sworn translator of the English language (TP/101/2013) in Olsztyn, hereby certify that the above translation is a true and complete version of the document in Polish presented to me.

Reg. No. 222/2018

Olsztyn, dated 29s October 2018


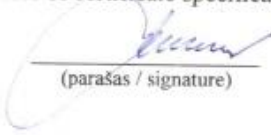


Małgorzata Trawczyńska

Test facility	Address	Certificate (Yes or No)
Institute of Agriculture, LAMMC	Instituto al. 1 Kedainai LT-58 344 LITHUANIA	Yes

<div><p>VALSTYBINĖ AUGALININKYSTĖS TARNYBA PRIE ŽEMĖS ŪKIO MINISTERIJOS</p><p>GEROS AUGALŲ APSAUGOS PRODUKTŲ VEIKSMINGUMO IR (ARBA) ATRANKUMO BANDYMŲ PRAKTIKOS SERTIFIKATAS</p><p>2013-12-12 Nr. AS4 – 13/02 Vilnius</p><p>Patvirtinama, kad Lietuvos agrarinių ir miškų mokslų centro filialas Žemdirbystės institutas, į.k. 302474007, Instituto al. 1, Akademija, 58344 Kėdainių r., laikosi geros augalų apsaugos produktų veiksmingumo ir (arba) atrankumo bandymų praktikos ir turi teisę atlikti šiuos tyrimus:</p><p>lauko bandymai; vegetaciniai bandymai.</p><p>Sertifikatas galioja iki 2019 m. gruodžio 12 d.</p><div><div>Direktorius</div><div></div><div>Evaldas Zigmas Čijauskas</div></div></div>

Test facility	Address	Certificate (Yes or No)
Institute of Agriculture, LAMMC	Instituto al. 1 Kedainai LT-58 344 LITHUANIA	Yes

<div><p>VALSTYBINĖ AUGALININKYSTĖS TARNYBA PRIE ŽEMĖS ŪKIO MINISTERIJOS / STATE PLANT SERVICE UNDER THE MINISTRY OF AGRICULTURE</p><p>GEROSIOS AUGALŲ APSAUGOS PRODUKTŲ VEIKSMINGUMO BANDYMŲ PRAKTIKOS SERTIFIKATAS / CERTIFICATE OF GOOD EXPERIMENTAL PRACTICE</p><p><u>2019 m. gruodžio 6 d. Nr. AS4-02(2019)</u> (data)</p><p><u>Vilnius</u> (vieta)</p><p>Šiuo sertifikatu patvirtinama, kad / This is to certify that <u>Lietuvos agrarinių ir miškų mokslo centro filialas Žemdirbystės institutas</u> (juridinio asmens pavadinimas, teisinė forma arba fizinio asmens vardas, pavardė / name, type of legal entity or name, surname of natural person)</p><p><u>302474007</u> (juridinio arba fizinio asmens kodas / code of legal entity or natural person)</p><p><u>Instituto al. 1, Akademija, 58344 Kėdainių r.</u> (juridinio asmens buveinės adresas arba fizinio asmens adresas / address of legal entity or natural person)</p><p>laikosi gerosios augalų apsaugos produktų veiksmingumo bandymų praktikos ir turi teisę atlikti augalų apsaugos produktų veiksmingumo bandymus šioje (šiose) srityje (srityse) / complies with the requirements of good experimental practice and has the right to perform plant protection product efficacy testing in the following field (fields): <u>lauko augalai (išskyrus daržoves)</u></p><p>Sertifikatas patikslintas / date of certificate specification: _____</p><div><div><u>Direktorius</u> (pareigos / office)</div><div> (parašas / signature)</div><div><u>Sergejus Fedotovas</u> (vardas, pavardė / name, surname)</div></div></div>

Test facility	Address	Certificate (Yes or No)
Agrolab Baltic	Agrolab Baltic Bugeniu km. LT-89452 Mazeikiu raj LITHUANIA	Yes



Valsts augu aizsardzības dienests

SERTIFIKĀTS

Nr. 16

Izsniegts **SIA „AgroLab Baltic”**
(komersanta nosaukums, reģistrācijas numurs, juridiskā adrese)

Reģ. Nr. 44103075387

Valmieras iela 20A, Cēsis, LV- 4101

par tiesībām veikt normatīvajos aktos par augu aizsardzības līdzekļu reģistrāciju noteiktos
efektivitātes pārbaudes izmēģinājumus:

Lauks- rapsis- herbicīdi, fungicīdi, kodnes, **lauks- kartupeļi-** insekticīdi.

Sertifikāts izsniegts: 09.03.2015.
(datums)

Sertifikāts derīgs līdz: 08.03.2020.
(datums)

Valsts augu aizsardzības dienests
Augu aizsardzības līdzekļu
reģistrācijas daļas vadītāja
(amats, paraksts un tā atšifrējums)



R.Čūdere

South-Eastern EPPO zone

Test facility	Address	Certificate (Yes or No)
STAPHYT	Station Kecskemet KECSKEMET HUNGARY	Yes
ANADIAG Hungary K.f.t	H2921 Komarom Petofi Sandor 67 HUNGARY	Yes
ANADIAG Romania SRL	ANADIAG Romania SRL Piata Montreal n°10 World Trade Centre 011469 Bucharest ROMANIA	Yes
Gemerprodukt Valice OVD	Okruzna Rimovska Sobota 3771 SLOVAKIA	Yes

Test facility	Address	Certificate (Yes or No)
STAPHYT	Station Kecskemet KECSKEMET HUNGARY	Yes



**GŁÓWNY INSPEKTOR
OCHRONY ROŚLIN I NASIENICTWA**

Tadeusz Kłos

WO-505- 14 /2012

Warszawa, 26.09.2012 r.

DECYZJA Nr 7/2012

Na podstawie art. 155 ustawy z dnia 14 czerwca 1960 r. Kodeks postępowania administracyjnego (Dz.U. z 2000 r. Nr 98, poz. 1071 ze zm.) i art. 40 ust. 1 ustawy z dnia 18 grudnia 2003 r. o ochronie roślin (Dz.U. z 2008 r. Nr 133, poz. 849 ze zm.), po rozpatrzeniu wniosku z dnia 6 września 2012 r., zmieniając decyzję Nr 9/2005 z dnia 1 maja 2005 r., zmienioną decyzjami: Nr 3/2006 z dnia 5 maja 2006 r., Nr 8/2006 z dnia 11 grudnia 2006 r., Nr 2/2009 z dnia 18 lutego 2009 r., Nr 12/2011 z dnia 31 marca 2011 r. oraz Nr 4/2012 z dnia 4 kwietnia 2012 r.

Rozstrzygnięciu decyzji nadaję następujące brzmienie:

upoważniam

STAPHYT Sp. z o.o.

ul. Ziębicka 2; 60-164 Poznań

do prowadzenia badań skuteczności działania środka ochrony roślin

z grupy fungicydów, herbicydów, insektycydów, moluskocydów, akarycydów, regulatorów wzrostu, zapraw nasiennych oraz do łącznego stosowania środków ochrony roślin w uprawach polowych: zbóż, kukurydzy, rzepaku, buraków cukrowych, słonecznika, ziemniaków, warzyw, w uprawach sadowniczych (jabłoni, gruszy, porzeczek, truskawek, pestkówek), w magazynach i przechowalniach, a także na trawnikach oraz w uprawach roślin ozdobnych w polu i pod osłonami.

Uzasadnienie

W dniu 6 września 2012 r. Staphyt Sp. z o.o. (ul. Ziębicka 2; 60-164 Poznań) zwróciła się z wnioskiem o rozszerzenie zakresu decyzji Głównego Inspektora Ochrony Roślin i Nasiennictwa upoważniającej do prowadzenia badań skuteczności działania środków ochrony roślin Nr 9/2005 z dnia 1 maja 2005 r.,

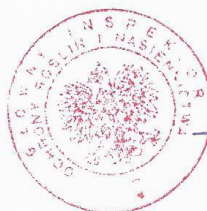
zmienionej decyzjami: Nr 3/2006 z dnia 5 maja 2006 r., Nr 8/2006 z dnia 11 grudnia 2006 r., Nr 2/2009 z dnia 18 lutego 2009 r. oraz Nr 4/2012 z dnia 4 kwietnia 2012 r. Wniosek dotyczył możliwości prowadzenia badań w magazynach i przechowalniach.

Staphyt Sp. z o.o. spełnia warunki organizacyjno-techniczne, zwane „Zasadami Dobrej Praktyki Eksperymentalnej” (Good Experimental Practice - GEP), zapewniające prawidłowe przeprowadzanie badań skuteczności działania środka ochrony roślin.

Mając na uwadze powyższe, postanowiono jak w rozstrzygnięciu decyzji.

Pouczenie

Od niniejszej decyzji odwołanie nie przysługuje. Jednakże strona niezadowolona z decyzji może zwrócić się do Głównego Inspektora Ochrony Roślin i Nasiennictwa z wnioskiem o ponowne rozpatrzenie sprawy w terminie 14 dni od dnia doręczenia decyzji, zgodnie z art. 127 § 3 Kodeksu postępowania administracyjnego.



GŁÓWNY INSPEKTOR

Tadeusz Kłos

Test facility	Address	Certificate (Yes or No)
ANADIAG Hungary K.f.t	H2921 Komarom Petofi Sandor 67 HUNGARY	Yes



n é b i h
Termőföldtől az asztalig

National Food Chain Safety Office
Directorate of Plant Protection, Soil Conservation
and Agri-environment



H-1118 Budapest, Budaörsi út 141-145.
Hungary
Tel: 36/1/309-1000 Fax: 36/1/246-2942
E-mail: nti@nebih.gov.hu
www.nebih.gov.hu

Your ref.: -

Our ref.: 04.2/6149-7/2016

7 October 2016

Subject: Certificate of Official Recognition of Efficacy Testing Facilities or Organisations in Hungary

Having received the application submitted by the **Anadiag Hungary Mezőgazdasági Szolgáltató Kft. (H-2921 Komárom, Petőfi Sándor út 67, Hungary)**, the client, for completing a certification procedure of first instance concerning the Official Recognition of Efficacy Testing Facilities/Organisations, i.e. Good Experimental Practices (*hereinafter*: GEP), I, acting as the food chain control body, has made the following

DECISION:

I issue the client's GEP certificate for its premises at Komárom, Petőfi Sándor út 67 for carrying out efficacy trials for authorisation purposes. The GEP certificate is effective for 5 years from the entry into force of this Decision.

The client's GEP certificate is given for the following categories of products and cultivation:

- **product categories:** herbicides, fungicides and bactericides, zoocides, growth regulators and yield enhancing substances, additives;
- **cultivation categories:** field crops, vegetables, fruits, grapevines, ornamentals, others.

I inform you that the present certification is without prejudice to either the licences concerning the operation/follow-up of activity laid down in other provisions of legislation or the client's obligation for obtaining them.

The client is obliged to notify the competent authority, within 15 days, of any important changes concerning the certified activity of the testing facility.

I call your attention that respect of the provisions laid down in the legislation on GEP certification and in this Decision shall be randomly controlled by my competent authority. If during the official inspection it is stated that the testing facility does not meet the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate.

If during the official inspection it is found that some details are missing in relation to a particular trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization.

The fee of the present procedure is 250.000 HUF (i.e. two hundred and fifty thousand Hungarian Forints) paid by the client.

No further complaint shall be lodged against the present Decision, effective by its publication, through state administration, though with reference to infringement of law, judicial review of the Decision may be requested at the Capital Administrative and Employment Court. The claim note shall be submitted to my competent authority within 30 days of the communication of the Decision.

I inform you that the court shall judge the case out of court, but shall carry on a lawsuit at the request of any of the parties. The client may ask for carrying on a lawsuit, but in default of so doing, no verification is accepted. Submission of the claim note has no delaying force on the implementation of this Decision.

J U S T I F I C A T I O N

In its application of 29 August 2016, the client submitted an application to the competent authority for a procedure of GEP certification.

As a follow-up to this application, the competent authority made a local inspection at the client's facility of Komárom, Petőfi Sándor út 67 on 31 August 2016. Statements made during the local inspection are reported in the protocol Nr. 04.2/6149-4/2016. Based on the results of the local inspection the competent authority concluded that the client's testing facility does not meet the requirements concerning the efficacy trials specified in Article 22 of the Decree 89/2004 (V. 15.) FVM on the authorization of placing on the market and use, as well as on the packaging, labelling, storage and transport of plant protection products (hereinafter: Decree 89/2004) and in the Decision Nr. 04.2/6149-5/2016 it calls the client to fill the data gaps.

Article 22(5) of Decree 89/2004 - Based on request, the competent authority shall make local inspections at the testing facility and decide on the GEP qualification of the testing facility. The decision shall include the product categories and the cultivation categories for which the testing facility obtained the GEP-certificate.

(6) The validity of GEP-certification is 2 years in case of the first request and maximum 5 years in case of renewal of the certification.

(7) A fee laid down in specific legislation shall be paid for the GEP-certification procedure.

(8) The testing facility having GEP-certification shall notify the competent authority, within 15 days, about any important changes concerning the certified activity of the testing facility.

(9) The competent authority shall randomly control the testing facility having GEP-certification. If it is found that the testing facility does not meet the relevant GEP requirements, the competent authority may suspend the activity related to the category specified in this Decision for maximum 2 months or may revoke the GEP-certificate. If during the official inspection it is established that some details are missing in relation to a trial, the competent authority responsible for authorization may exclude the trial, depending on the extent of missing data, from those that may be accepted for authorization."

Client filled the missing data gaps and reported on it in the letter of 20 September 2016, therefore I made the Decision as specified in the first part. Therefore I stated that conditions for issuing the certificate specified above are met, so I made the Decision as specified in the first part.

The fee of the present procedure is HUF 250.000 and was established in accordance with point 8.19.2 of Annex 1 to the Decree 63/2012. (VII. 2.) VM on the extent of administrative servicing fees due for the procedures by the agricultural administrative bodies of the National Food Chain Safety Office and the county government offices and on the rules of paying the administrative servicing fees. The client paid the fee.

I made this Decision within my jurisdiction laid down in Article 3 paragraph (1) and Article 5 point e) of Government Decree 22/2012. (II. 29.) concerning the National Food Chain Safety Office, Article 3, Article 22 paragraph (1) of Decree 89/2004 and in compliance with Articles 71 paragraph (1) and Article 72 paragraph (1) of Act CXL of 2004 on general rules of administrative official procedure and service (hereinafter: Act CXL of 2004).

I excluded the possibility of appeal in compliance with Article 100 paragraph (1) point e) of Act CXL of 2004 and provided the possibility of judicial review in compliance with Article 109 paragraph (1) of Act CXL of 2004 and Article 330 paragraph (2) of Act III of 1952 on Civil Procedure.

on behalf of
dr. Márton Oravecz
president


László Jordán
director

Test facility	Address	Certificate (Yes or No)
ANADIAG Romania SRL	ANADIAG Romania SRL Piata Montreal n°10 World Trade Centre 011469 Bucharest ROMANIA	Yes

MINISTERUL AGRICULTURII ȘI DEZVOLTĂRII RURALE	MINISTRY OF AGRICULTURE AND RURAL DEVELOPMENT
Autoritatea Națională Fitosanitară	National Phytosanitary Authority
Comisia Națională de Omologare a Produselor de Protecție a Plantelor	National Commission for Registration of Plant Protection Products

Certificat de recunoaștere oficială a testelor de eficacitate biologică în conformitate cu bunele practici experimentale/Certificate of official recognition of the efficacy biological tests according to the good experimental practices

Se acordă: SC ANADIAG ROMANIA SRL
It is granted to: SC ANADIAG ROMANIA SRL
cu sediul: Str. Gen. C. Budisteanu, nr.28-C;010775, Bucuresti
with headquarter: Gen. C. Budisteanu Street, no. 28-C, 010775, Bucharest
pentru domeniul/
domeniile de activitate: Culturi agricole de câmp si pajisti; Pomicultură;
Viticultură; Legumicultură; Floricultură; Silvicultură; Plante ornamentale și de interior; Zone non agricole
for the domain/
domains of activity: Crops fields and meadows; Fruit tree growing; Viticulture;
Vegetable crops; Floriculture; Aromatic and medicinal plants; Ornamental and indoor plants; Silviculture; Non agricultural zones

Prezentul certificat se eliberează în conformitate cu prevederile Ordinului ministrului agriculturii și dezvoltării rurale, al ministrului sănătății și al ministrului mediului și schimbărilor climatice nr.60/512/1258/2013 și prevederile Procedurii naționale de omologare a produselor de protecție a plantelor care conțin substanțe active notificate și pentru care nu s-a luat încă o decizie de includere în lista cu substanțe active autorizate în Uniunea Europeană, aprobată prin Ordinul ministrului agriculturii,

pădurilor și dezvoltării rurale, al ministrului sănătății și al ministrului mediului și gospodăririi apelor nr.134/197/412/2006, cu modificările și completările ulterioare.

This certificate is issued according to the provisions of the Order of the ministry of agriculture and rural development, of the ministry of health and of the ministry of environment and climate change no.60/512/1258/2013 and the provisions of the National Procedure for Registration of Plant Protection Products which contain notified active substances and for which isn't taken yet a decision for inclusion in European Union list of authorised active substances, approved by the Order of the ministry of agriculture, forests and rural development, of the ministry of health and of the ministry of environment and waters husbandry no.134/197/412/2006, with subsequent amendments and completions.

Data emiterii certificatului: 20.08.2015

Issuance date of the certificate

Data expirării certificatului: 20.08.2020

Expiry date of the certificate

PREȘEDINTE/CHAIRMAN,

Elena LEAOTĂ



Test facility	Address	Certificate (Yes or No)
Gemerprodukt Valice OVD	Okružna Rimovská Sobota 3771 SLOVAKIA	Yes

Central Controlling and Testing Institute in Agriculture in Bratislava
Matúškova 21, 833 16 Bratislava

GEP CERTIFICATE

No. 03/C - 06/2019

issued in accordance with § 28 of the Act No. 405/2011 Coll. on Plant Care, Amending and Supplementing Act of the National Council of the Slovak Republic No. 145/1995 Coll. on Administrative Fees as Amended and § 3 of the Regulation of the Ministry of Agriculture and Rural Development of the Slovak Republic No 486/2011 Coll. laying down details of the conditions, procedures and deadlines to implement the provisions of the tests of biological efficacy, applications, principles of good experimental practice, audits and issuing certificate, extension of the certificate, recertification (hereinafter "Regulation")

for

GEMERPRODUKT VALICE,
ovocinársko-vinohradnícke družstvo
Okružná 3771
979 01 Rimavská Sobota

Identification number: 36059005

which has demonstrated implementation of principles of Good experimental practice (GEP) in accordance with the requirements of the Regulation in the following categories

Categories of crops	Categories of plant protection products and their adverse effects on crops.
cereals	fungicides; fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides; zoocides - seed treatment; growth regulators; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides; zoocides - seed treatment; growth regulators
maize	fungicides; fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides; zoocides - seed treatment; growth regulators; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides; zoocides - seed treatment; growth regulators
legumes	fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides - seed treatment; growth regulators; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides; zoocides - seed treatment; growth regulators
oil plants	fungicides; fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides; zoocides - seed treatment; growth regulators; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides; zoocides - seed treatment; growth regulators
technical plants	fungicides - seed treatment; zoocides - seed treatment; growth regulators; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliant, drying agents; zoocides; zoocides; zoocides - seed treatment; growth regulators

root crops	fungicides; fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides; zoocides - seed treatment; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides; zoocides - seed treatment
vegetables and root vegetables	fungicides; fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides; zoocides - seed treatment; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides; zoocides - seed treatment
grape, fruit and stocks	fungicides; fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides; zoocides - seed treatment; growth regulators; phytotoxicity - fungicides; fungicides - seed treatment; herbicides, defoliants, drying agents; zoocides; zoocides - seed treatment; growth regulators

Date of issue: 28.05.2019
Date of expire: 12.04.2021



Ing. Peter Rusňák, PhD.
General Director

This certificate includes also appendix.
By issuing this certificate, certificate No. 03/C-05/2019 expire.

Appendix 1 Lists of data considered in support of the evaluation

A 1.1 Winter barley (HORVW)

Maritime EPPO zone

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – Maritime EPPO zone					
KCP 6.2 KCP 6.4	S. KRÍŽEK	2018	REG: Efficacy of CA3301 on Winter Barley (Foliar diseases) SynTech Research Czech Republic s.r.o. EU18-041-01 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	M. SPRINGER	2018	REG: Efficacy of CA3301 on Winter Barley (Foliar diseases) SynTech Research Czech Republic s.r.o. EU18-041-02 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	R. BESANA	2018	REG: Efficacy of CA3301 on Winter Barley (Foliar diseases) Agrolab A/S EU18-041-07 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	R. BESANA	2018	REG: Efficacy of CA3301 on Winter Barley (Foliar diseases) Agrolab A/S EU18-041-08 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. HUET-TENRAUCH	2019	REG: EFFICACY of CA3301 & CA3642 on winter barley (Foliar diseases) QUINTUS EU19-069-03 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. HUET-TENRAUCH	2019	REG: EFFICACY of CA3301 & CA3642 on winter barley (Foliar diseases) QUINTUS EU19-069-04 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	L. STOKES	2019	REG: EFFICACY of CA3301 & CA3642 on winter barley (Foliar diseases) Oxford Agriculture Trials Limited EU19-069-05 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. STOKES	2019	REG: EFFICACY of CA3301 & CA3642 on winter barley (Foliar diseases) Oxford Agriculture Trials Limited EU19-069-06 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. DUCROT	2019	REG: EFFICACY of CA3301 & CA3642 on winter barley (Foliar diseases) ANADIAG FRANCE EU19-069-07 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. DUCROT	2019	REG: EFFICACY of CA3301 & CA3642 on winter barley (Foliar diseases) ANADIAG FRANCE EU19-069-08 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. HUET-TENRAUCH	2019	REG: EFFICACY of CA3301 & CA3642 on winter barley (Foliar diseases) QUINTUS EU19-069-09 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. HUET-TENRAUCH	2019	REG: EFFICACY of CA3301 & CA3642 on winter barley (Foliar diseases) QUINTUS EU19-069-10 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I. SIMEK	2019	REG: EFFICACY of CA3301 & CA3642 on winter barley (foliar diseases) ANADIAG CZECH REPUBLIC EU19-069-11 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. STOKES	2019	REG: EFFICACY of CA3301 & CA3642 on winter barley (Foliar diseases) Oxford Agriculture Trials Limited EU19-069-12 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	J. HUET-TENRAUCH	2019	REG: EFFICACY of CA3301 & CA3642 on winter barley (Foliar diseases) QUINTUS EU19-069-13 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. HUET-TENRAUCH	2019	REG: EFFICACY of CA3301 & CA3642 on winter barley (Foliar diseases) QUINTUS EU19-069-14 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. DUCROT	2019	REG: EFFICACY of CA3301 & CA3642 on winter barley (Foliar diseases) ANADIAG FRANCE EU19-069-15 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. DUCROT	2019	REG: EFFICACY of CA3301 & CA3642 on winter barley (Foliar diseases) ANADIAG FRANCE EU19-069-16 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. DUCROT	2019	REG: EFFICACY of CA3301 & CA3642 on winter barley (Foliar diseases) ANADIAG FRANCE EU19-069-17 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. HUET-TENRAUCH	2019	REG: EFFICACY of CA3301 & CA3642 on winter barley (Foliar diseases) QUINTUS EU19-069-19 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A. MEYER	2019	REG: EFFICACY of CA3301 & CA3642 on winter barley (Foliar diseases) ANADIAG DEUTSCHLAND EU19-069-20 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I. SIMEK	2019	REG: EFFICACY of CA3301 & CA3642 on winter barley (foliar diseases) ANADIAG CZECH REPUBLIC EU19-069-21 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	L. STOKES	2019	REG: EFFICACY of CA3301 & CA3642 on winter barley (Foliar diseases) Oxford Agriculture Trials Limited EU19-069-22 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. FRIEDRICH	2020	REG: EFFICACY of CA3301 & CA3642 on winter barley (Foliar diseases) QUINTUS EU20-037-01 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. FRIEDRICH	2020	REG: EFFICACY of CA3301 & CA3642 on winter barley (Foliar diseases) QUINTUS EU20-037-02 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. FRIEDRICH	2020	REG: EFFICACY of CA3301 & CA3642 on winter barley (Foliar diseases) QUINTUS EU20-037-03 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	H. ERB	2020	REG: EFFICACY of CA3301 & CA3642 on winter barley (Foliar diseases) Oxford Agriculture Trials Limited EU20-037-05 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. DUCROT	2020	REG: EFFICACY of CA3301 & CA3642 on winter barley (Foliar diseases) ANADIAG SAS EU20-037-06 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. DUCROT	2020	REG: EFFICACY of CA3301 & CA3642 on winter barley (Foliar diseases) ANADIAG SAS EU20-037-07 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	H. ERB	2020	REG: EFFICACY of CA3301 & CA3642 on winter barley (Foliar diseases) Oxford Agriculture Trials Limited EU20-037-08 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	S. DUCROT	2020	REG: EFFICACY of CA3301 & CA3642 on winter barley (Foliar diseases) ANADIAG SAS EU20-037-10 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. DUCROT	2020	REG: EFFICACY of CA3301 & CA3642 on winter barley (Foliar diseases) ANADIAG SAS EU20-037-11 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	H. ERB	2020	REG: EFFICACY of CA3301 & CA3642 on winter barley (Foliar diseases) Oxford Agriculture Trials Limited EU20-037-13 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I. SIMEK	2020	REG: EFFICACY of CA3301 & CA3642 on winter barley (foliar diseases) ANADIAG CZECH REPUBLIC EU20-037-14 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. DUCROT	2020	REG: EFFICACY of CA3301 & CA3642 on winter barley (Foliar diseases) ANADIAG SAS EU20-037-16 GEP; Unpublished	Y	NUFARM

Mediterranean EPPO zone

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – Mediterranean EPPO zone					
KCP 6.2 KCP 6.4	L. MARTINEZ	2018	REG: Efficacy of CA3301 on Winter Barley (Foliar diseases) – Portugal - 2018 SynTech Research Portugal EU18-041-34 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	L. MARTINEZ	2018	REG: Efficacy of CA3301 on Winter Barley (Foliar diseases) – Portugal - 2018 SynTech Research Portugal EU18-041-35 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. MARTINEZ	2018	REG: Efficacy of CA3301 on Winter Barley (Foliar diseases) – Portugal - 2018 SynTech Research Portugal EU18-041-37 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. VILLETON	2019	REG: EFFICACY of CA3301 and CA3642 on Winter Barley (Foliar diseases) ANADIAG FRANCE EU19-069-39 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. VILLETON	2019	REG: EFFICACY of CA3301 and CA3642 on Winter Barley (Foliar diseases) ANADIAG FRANCE EU19-069-41 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	M. DELPERO	2019	REG: EFFICACY of CA3301 and CA3642 on Winter Barley (Foliar diseases) ANADIAG ITALIA SRL EU19-069-42 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. VILLETON	2019	REG: EFFICACY of CA3301 and CA3642 on Winter Barley (Foliar diseases) ANADIAG FRANCE EU19-069-43 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. VILLETON	2019	REG: EFFICACY of CA3301 and CA3642 on Winter Barley (Foliar diseases) ANADIAG FRANCE EU19-069-44 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	M. DELPERO	2019	REG: EFFICACY of CA3301 and CA3642 on Winter Barley (Foliar diseases) ANADIAG ITALIA SRL EU19-069-45 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	C. VILLETON	2019	REG: EFFICACY of CA3301 and CA3642 on Winter Barley (Foliar diseases) ANADIAG FRANCE EU19-069-47 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. VILLETON	2019	REG: EFFICACY of CA3301 and CA3642 on Winter Barley (Foliar diseases) ANADIAG FRANCE EU19-069-48 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. MASDE-VALL	2019	REG: EFFICACY of CA3301 and CA3642 on Winter Barley (Foliar diseases) ANADIAG IBERICA SL EU19-069-49 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. MASDE-VALL	2019	REG: EFFICACY of CA3301 and CA3642 on Winter Barley (Foliar diseases) ANADIAG IBERICA SL EU19-069-50 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	M. DELPERO	2019	REG: EFFICACY of CA3301 and CA3642 on Winter Barley (Foliar diseases) ANADIAG ITALIA SRL EU19-069-51 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. VILLETON	2019	REG: EFFICACY of CA3301 and CA3642 on Winter Barley (Foliar diseases) ANADIAG FRANCE EU19-069-52 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. VILLETON	2019	REG: EFFICACY of CA3301 and CA3642 on Winter Barley (Foliar diseases) ANADIAG FRANCE EU19-069-53 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	M. DELPERO	2019	REG: EFFICACY of CA3301 and CA3642 on Winter Barley (Foliar diseases) ANADIAG ITALIA SRL EU19-069-54 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	L. MASDEVALL	2019	REG: EFFICACY of CA3301 and CA3642 on Winter Barley (Foliar diseases) ANADIAG IBERICA SL EU19-069-55 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. MASDEVALL	2019	REG: EFFICACY of CA3301 and CA3642 on Winter Barley (Foliar diseases) ANADIAG IBERICA SL EU19-069-56 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. RODRIGUES	2019	REG: EFFICACY of CA3301 and CA3642 on Winter Barley (Foliar diseases) ANADIAG PORTUGAL EU19-069-57 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. VILLETON	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG SAS EU20-037-31 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. VILLETON	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG SAS EU20-037-32 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. VILLETON	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG SAS EU20-037-33 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. VILLETON	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG SAS EU20-037-34 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A. SPAGNOLO	2020	REG: EFFICACY of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG SAS EU20-037-35 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	A. SPAGNOLO	2020	REG: EFFICACY of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG SAS EU20-037-37 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A. SPAGNOLO	2020	REG: EFFICACY of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG SAS EU20-037-38 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A. SPAGNOLO	2020	REG: EFFICACY of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG SAS EU20-037-39 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A. SPAGNOLO	2020	REG: EFFICACY of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG SAS EU20-037-40 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. MASDE- VALL	2020	REG: EFFICACY of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG IBERICA SL EU20-037-41 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	M. ADARNIUS BLANCH	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG IBERICA SL EU20-037-42 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. MASDE- VALL	2020	REG: EFFICACY of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG IBERICA SL EU20-037-43 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. VILLETON	2020	REG: EFFICACY of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG SAS EU20-037-45 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	C. VILLETON	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG SAS EU20-037-46 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. VILLETON	2020	REG: EFFICACY of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG SAS EU20-037-47 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. MASDEVALL	2020	REG: EFFICACY of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG IBERICA SL EU20-037-48 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. MASDEVALL	2020	REG: EFFICACY of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG IBERICA SL EU20-037-49 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. MASDEVALL	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG IBERICA SL EU20-037-50 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. RODRIGUES	2020	REG: EFFICACY of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG PORTUGAL EU20-037-51 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. RODRIGUES	2020	REG: EFFICACY of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG PORTUGAL EU20-037-52 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A. SPAGNOLO	2020	REG: EFFICACY of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG SAS EU20-037-53 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	A. SPAGNOLO	2020	REG: EFFICACY of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG SAS EU20-037-54 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A. SPAGNOLO	2020	REG: EFFICACY of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG SAS EU20-037-55 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. MASDE-VALL	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG IBERICA SL EU20-037-56 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. MASDE-VALL	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG IBERICA SL EU20-037-57 GEP; Unpublished	Y	NUFARM

North-Eastern EPPO zone

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – North-Eastern EPPO zone					
KCP 6.2 KCP 6.4	L. KMIĘCIAK	2017	EVAL: Efficacy of CA3301 on Winter barley GEP Trial, POLAND, 2017 STAPHYT EU17-055-01 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. KMIĘCIAK	2017	EVAL: Efficacy of CA3301 on Winter barley GEP Trial, POLAND, 2017 STAPHYT EU17-055-02 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	L. KMIECIAK	2017	EVAL: Efficacy of CA3301 on Winter barley GEP Trial, POLAND, 2017 STAPHYT EU17-055-05 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	G. DABROWSKI	2018	REG: Efficacy of CA3301 on Winter Barley (Foliar diseases) SynTech Research Poland Sp. z o.o. EU18-041-13 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	M. CWIEK	2018	REG: Efficacy of CA3301 on Winter Barley (Foliar diseases) SynTech Research Poland Sp. z o.o. EU18-041-14 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2019	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG POLSKA EU19-069-74 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2019	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG POLSKA EU19-069-75 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2019	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG POLSKA EU19-069-76 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A. M. FIRERE	2019	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) Agrolab Baltic EU19-069-77 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2019	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG POLSKA EU19-069-78 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	J. JATCZAK	2019	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG POLSKA EU19-069-79 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2019	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG POLSKA EU19-069-80 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A. M. FIRERE	2019	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) Agrolab Baltic EU19-069-81 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	K. VERI-KAITE	2019	Efficacy of CA3301 & CA3642 on Winter Barley LRCAF, Institute of Agriculture EU19-069-82 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2019	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG POLSKA EU19-069-83 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2019	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG POLSKA EU19-069-84 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2019	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG POLSKA EU19-069-85 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A. M. FIRERE	2019	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) Agrolab Baltic EU19-069-86 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	A. M. FIRERE	2019	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) Agrolab Baltic EU19-069-87 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2019	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG POLSKA EU19-069-88 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2019	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG POLSKA EU19-069-89 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2019	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG POLSKA EU19-069-90 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A. M. FIRERE	2019	Efficacy of CA3301 & CA3642 on Winter Barley in Latvia, 2019 Agrolab Baltic EU19-069-91 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	K. VERI-KAITE	2019	Efficacy of CA3301 & CA3642 on Winter Barley LRCAF, Institute of Agriculture EU19-069-92 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG POLSKA EU20-037-79 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG POLSKA EU20-037-80 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	J. JATCZAK	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG POLSKA EU20-037-81 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG POLSKA EU20-037-82 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG POLSKA EU20-037-83 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A. M. FIRERE	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) Agrolab Baltic EU20-037-85 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A. M. FIRERE	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) Agrolab Baltic EU20-037-86 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG POLSKA EU20-037-91 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG POLSKA EU20-037-92 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A. M. FIRERE	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG POLSKA EU20-037-93 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	J. JATCZAK	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG POLSKA EU20-037-95 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG POLSKA EU20-037-96 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG POLSKA EU20-037-98 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG POLSKA EU20-037-99 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley (Foliar diseases) ANADIAG POLSKA EU20-037-100 GEP; Unpublished	Y	NUFARM
KCP 6.2	A.M. FIRERE	2021	REG: Efficacy of CA3301&CA3642 on Winter Barley (Foliar diseases) SIA Agrolab Baltic EU21-020-54 DEP; Unpublished	Y	NUFARM
KCP 6.2	A.M. FIRERE	2021	REG: Efficacy of CA3301&CA3642 on Winter Barley (Foliar diseases) SIA Agrolab Baltic EU21-020-53 GEP; Unpublished	Y	NUFARM
KCP 6.2	G. CARDIET	2021	REG: Efficacy of CA3301&CA3642 on Winter Barley (Foliar diseases) REG - EFF - CA3301 & CA3642 LRCAF, Institute of Agriculture EU21-020-52 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2	G. CARDIET	2021	REG: Efficacy of CA3301&CA3642 on Winter Barley (foliar diseases) ANADIAG POLSKA EU21-020-49 GEP; Unpublished	Y	NUFARM

South-Eastern EPPO zone

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – South-Eastern EPPO zone					
KCP 6.2 KCP 6.4	M. VILLANYI	2017	EVAL: Efficacy of CA3301 on Winter barley. GEP Trial, HUNGARY, 2017 STAPHYT EU17-055-03 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	M. VILLANYI	2017	EVAL: Efficacy of CA3301 on Winter barley. GEP Trial, HUNGARY, 2017 STAPHYT EU17-055-04 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. NEMETH	2018	REG: EFFICACY OF CA3301 ON WINTER BARLEY (FOLIAR DISEASES) IN HUNGARY, IN 2018 SynTech Research Hungary Kft. EU18-041-19 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A. VARGA	2018	Efficacy of CA3301 on Winter Barley (Foliar diseases) SynTech Research Hungary Kft. EU18-041-20 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. RINALDI	2018	REG: Efficacy of CA3301 on Winter Barley (Foliar diseases) SynTech Research Hungary Kft. EU18-041-29 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	D. RINALDI	2018	REG: Efficacy of CA3301 on Winter Barley (Foliar diseases) SynTech Research Hungary Kft. EU18-041-30 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. RINALDI	2018	REG: Efficacy of CA3301 on Winter Barley / on Spring Barley / on Spring Oat (Foliar diseases) SynTech Research Hungary Kft. EU18-041-31 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. VOURKOS	2019	REG: EFFICACY of CA3301 and CA3642 on WINTER BARLEY ANADIAG BULGARIA LTD EU19-069-109 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2019	REG: EFFICACY of CA3301 and CA3642 on WINTER BARLEY ANADIAG HUNGARY Kft. EU19-069-110 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2019	REG: EFFICACY of CA3301 and CA3642 on WINTER BARLEY ANADIAG HUNGARY Kft. EU19-069-111 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. VOURKOS	2019	REG: EFFICACY of CA3301 and CA3642 on WINTER BARLEY ANADIAG BULGARIA LTD EU19-069-112 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. VOURKOS	2019	REG: EFFICACY of CA3301 and CA3642 on WINTER BARLEY ANADIAG BULGARIA LTD EU19-069-113 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I. ENE	2019	REG: EFFICACY of CA3301 and CA3642 on WINTER BARLEY ANADIAG ROMANIA SRL EU19-069-114 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	I. ENE	2019	REG: EFFICACY of CA3301 and CA3642 on WINTER BARLEY ANADIAG ROMANIA SRL EU19-069-115 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2019	REG: EFFICACY of CA3301 and CA3642 on WINTER BARLEY ANADIAG HUNGARY Kft. EU19-069-116 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2019	REG: EFFICACY of CA3301 and CA3642 on WINTER BARLEY ANADIAG HUNGARY Kft. EU19-069-117 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. VOURKOS	2019	REG: EFFICACY of CA3301 and CA3642 on WINTER BARLEY ANADIAG BULGARIA LTD EU19-069-120 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. VOURKOS	2019	REG: EFFICACY of CA3301 and CA3642 on WINTER BARLEY ANADIAG BULGARIA LTD EU19-069-121 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2019	REG: EFFICACY of CA3301 and CA3642 on WINTER BARLEY ANADIAG HUNGARY Kft. EU19-069-122 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2019	REG: EFFICACY of CA3301 and CA3642 on WINTER BARLEY ANADIAG HUNGARY Kft. EU19-069-123 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. VOURKOS	2019	REG: EFFICACY of CA3301 and CA3642 on WINTER BARLEY ANADIAG BULGARIA LTD EU19-069-124 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	F. VOURKOS	2019	REG: EFFICACY of CA3301 and CA3642 on WINTER BARLEY ANADIAG BULGARIA LTD EU19-069-125 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley against <i>Ramularia collo-cygni</i> ANADIAG HUNGARY Kft. EU20-037-124 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I. ENE	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley against <i>Ramularia collo-cygni</i> ANADIAG ROMANIA SRL EU20-037-128 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I. ENE	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley against <i>Ramularia collo-cygni</i> ANADIAG ROMANIA SRL EU20-037-131 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. TOTH	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley against <i>Ramularia collo-cygni</i> GEMERPRODUKT VALICE OVD EU20-037-132 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. TOTH	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley against <i>Ramularia collo-cygni</i> GEMERPRODUKT VALICE OVD EU20-037-133 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. TOTH	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley against <i>Ramularia collo-cygni</i> GEMERPRODUKT VALICE OVD EU20-037-134 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley against <i>Puccinia hordei</i> ANADIAG HUNGARY Kft. EU20-037-136 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	I. ENE	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley against <i>Puccinia hordei</i> ANADIAG ROMANIA SRL EU20-037-137 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I. ENE	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley against <i>Puccinia hordei</i> ANADIAG ROMANIA SRL EU20-037-138 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. TOTH	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley against <i>Puccinia hordei</i> GEMERPRODUKT VALICE OVD EU20-037-139 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I. ENE	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley against <i>Rhynchosporium secalis</i> ANADIAG ROMANIA SRL EU20-037-144 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I. ENE	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley against <i>Rhynchosporium secalis</i> ANADIAG ROMANIA SRL EU20-037-145 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I. ENE	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley against <i>Rhynchosporium secalis</i> ANADIAG ROMANIA SRL EU20-037-146 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. TOTH	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley against <i>Rhynchosporium secalis</i> GEMERPRODUKT VALICE OVD EU20-037-147 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. TOTH	2020	REG: Efficacy of CA3301 & CA3642 on Winter Barley against <i>Rhynchosporium secalis</i> GEMERPRODUKT VALICE OVD EU20-037-148 GEP; Unpublished	Y	NUFARM

A 1.2 Spring Barley (HORVS)

Maritime EPPO zone

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – Maritime EPPO Zone					
KCP 6.2 KCP 6.4	Jan CAP	2018	EFFICACY OF CA3301 ON SPRING BARLEY (FOLIAR DISEASES) Zkusebni stanice NECHANICE, s.r.o EU18-041-03 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Michal SPRINGER	2018	EFFICACY OF CA3301 ON SPRING BARLEY (FOLIAR DISEASES) SynTech Research Czech Republic s.r.o EU18-041-04 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Steffen BROCKSTEDT	2018	EFFICACY OF CA3301 and CA3581 ON SPRING BARLEY (FOLIAR DISEASES) AGROLAB A/S EU18-041-09 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Steffen BROCKSTEDT	2018	EFFICACY OF CA3301 and CA3581 ON SPRING BARLEY (FOLIAR DISEASES) AGROLAB A/S EU18-041-10 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Juliane HÜTTENRAUCH	2019	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Quintus Gmbh EU19-069-23 GEP, unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Steffen BROCKSTEDT	2019	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY IN DENMARK, 2019 AGROLAB A/S EU19-069-24 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Julie DENUELLE	2019	EFFICACY OF CA3301 & CA342 ON SPRING BARLEY (FOLIAR DISEASES) OATS Ltd EU19-069-25 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	Julie DENUELLE	2019	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) OATS Ltd EU19-069-26 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Julie DENUELLE	2019	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) OATS Ltd EU19-069-27 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Juliane HÜT- TENRAUCH	2019	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Quintus Gmbh EU19-069-28 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Julie DENUELLE	2019	EFFICACY OF CA3301 & CA642 ON SPRING BARLEY (FOLIAR DISEASES) Oxford Agricultural Trials Limited (Oat Ltd) EU19-069-29 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Juliane HÜT- TENRAUCH	2019	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) QUINTUS GmbH EU19-069-30 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Julie DENUELLE	2019	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) OATS Ltd EU19-069-31 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Julie DENUELLE	2019	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) OATS Ltd EU19-069-32 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Iva SIMEK	2019	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag SA, CZ osp. EU19-069-33 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	Juliane HÜTTENRAUCH	2019	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) QUINTUS GmbH EU19-069-34 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Iva SIMEK	2019	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) ANADIAG SA, Cz osp. EU19-069-35 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Pierre FERRAN-TER-RATS	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) QUTINS GmbH EU20-037-17 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Pierre FERRAN-TER-RATS	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) OATS Ltd EU20-037-18 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Pierre FERRAN-TER-RATS	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) OATS Ltd EU20-037-19 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Pierre FERRAN-TER-RATS	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) OATS Ltd EU20-037-21 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Pierre FERRAN-TER-RATS	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) QUINTUS GmbH EU20-037-25 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Pierre FERRAN-TER-RATS	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) OATS Ltd EU20-037-27 GEP, Unpublished	Y	NUFARM

Mediterranean EPPO zone

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – Mediterranean EPPO Zone					
KCP 6.2 KCP 6.4	Luis MARTINEZ	2018	EFFICACY OF CA3301 ON WINTER BARLEY (FOLIAR DISEASES) Syntech Research Portugal EU18-041-36 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Manuela DELPERO	2019	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Italia SRL EU19-069-40 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Manuela DELPERO	2019	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Italia SRL EU19-069-58 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Cécile VILLETON	2019	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag France EU19-069-59 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Manuela DELPERO	2019	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag France EU19-069-60 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Manuela DELPERO	2019	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Italia SRL EU19-069-61 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Laura MASDEVALL	2019	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY (FOLIAR DISEASES) ANADIAG Iberica, SL EU19-069-62 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Laura MASDEVALL	2019	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY (FOLIAR DISEASES) ANADIAG Iberica, SL EU19-069-63 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	Laura MASDEVALL	2019	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Iberica, SL EU19-069-64 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Laura MASDEVALL	2019	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Iberica, SL EU19-069-65 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Manuela DELPERO	2019	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY (FOLIAR DISEASES) ANADIAG Italia, SRL EU19-069-67 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Laura MASDEVALL	2019	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Iberica, SL EU19-069-68 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Laura MASDEVALL	2019	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Iberica, SL EU19-069-69 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Laura MASDEVALL	2019	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Iberica, SL EU19-069-70 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Laura MASDEVALL	2019	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Iberica, SL EU19-069-71 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Cyndel BER- GER	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Italia SRL EU20-037-58 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No.	Data protection claimed Y/N	Owner
			GLP or GEP, Published or Unpublished		
KCP 6.2 KCP 6.4	Cyndel BER-GER	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Italia SRL EU20-037-59 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Cyndel BER-GER	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Italia SRL EU20-037-60 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Cyndel BER-GER	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Italia, SRL EU20-037-62 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Cyndel BER-GER	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Italia, SRL EU20-037-63 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Magali ADARNIUS	2020	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Iberica, SL EU20-037-64 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Magali ADARNIUS	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Italia, SRL EU20-037-65 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Magali ADARNIUS	2020	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Iberica, SL EU20-037-67 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Magali ADARNIUS	2020	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Iberica, SL EU20-037-68 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title	Data protection claimed Y/N	Owner
			Company Report No. GLP or GEP, Published or Unpublished		
KCP 6.2 KCP 6.4	Cyndel BERGER	2020	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Italia, SRL EU20-037-69 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Pierre FERRAN-TER-RATS	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Italia, SRL EU20-037-70 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Magali ADARNIUS	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Iberica, SL EU20-037-73 GEP, Unpublished	Y	NUFARM

North-Eastern EPPO zone

Annex Point	Author	Year	Title	Data protection claimed Y/N	Owner
			Company Report No.		
			GLP or GEP, Published or Unpublished		
Field trials – North-East EPPO Zone					
KCP 6.2 KCP 6.4	Eliza POTOCKA	2018	EFFICACY OF CA3301 ON SPRING BARLEY (FOLIAR DISEASES) Syntech Research Poland, Sp. z o.o. EU18-041-15 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Mateusz SWITKOWSKI	2018	EFFICACY OF CA3301 ON SPRING BARLEY (FOLIAR DISEASES) Syntech Research Poland, Sp. z o.o. EU18-041-16 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Pierre FERRAN-TER-RATS	2019	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Polska, EU19-069-93 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	Pierre FER-RAN-TER-RATS	2019	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Polska, EU19-069-94 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Pierre FER-RAN-TER-RATS	2019	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Polska, EU19-069-95 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Pierre FER-RAN-TER-RATS	2019	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Polska, EU19-069-96 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Pierre FER-RAN-TER-RATS	2019	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Polska EU19-069-97 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Pierre FER-RAN-TER-RATS	2019	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Polska EU19-069-98 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Pierre FER-RAN-TER-RATS	2019	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Polska EU19-069-99 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Anna Marija FIRERE	2019	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) SIA Agrolab Baltic, LV EU19-069-100 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Karolina VERI-KAITE	2019	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY LRCAF, Institute of Agriculture, Lithuania EU19-069-102 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	Pierre FER-RAN-TER-RATS	2019	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Polska, EU19-069-103 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Pierre FER-RAN-TER-RATS	2019	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Polska, EU19-069-104 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Pierre FER-RAN-TER-RATS	2019	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Polska, EU19-069-105 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Guillaume CARDIET	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Polska EU20-037-103 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Guillaume CARDIET	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Polska EU20-037-105 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Guillaume CARDIET	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Polska EU20-037-106 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Antanina USINSKIENE	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Agrolab Baltic EU20-037-107 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Ruta ZITKUTE	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Agrolab Baltic EU20-037-108 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	Guillaume CARDIET	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Polska EU20-037-109 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Guillaume CARDIET	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Polska EU20-037-110 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Guillaume CARDIET	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Polska EU20-037-111 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Ruta ZITKUTE	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Agrolab Baltic EU20-037-112 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Guillaume CARDIET	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Polska EU20-037-113 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Guillaume CARDIET	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Polska EU20-037-114 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Guillaume CARDIET	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Polska EU20-037-115 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Guillaume CARDIET	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Polska EU20-037-116 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title	Data protection claimed Y/N	Owner
			Company Report No. GLP or GEP, Published or Unpublished		
KCP 6.2 KCP 6.4	Anna Marija FIRERE	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Agrolab Baltic EU20-037-117 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Anna Marija FIRERE	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Agrolab Baltic EU20-037-118 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Guillaume CARDIET	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) Anadiag Polska EU20-037-119 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Karolina VERI-KAITE	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY (FOLIAR DISEASES) LRCAF, Institute of Agriculture, LT EU20-037-120 GEP, Unpublished	Y	NUFARM

South-Eastern EPPO zone

Annex Point	Author	Year	Title	Data protection claimed Y/N	Owner
			Company Report No.		
			GLP or GEP, Published or Unpublished		
Field trials – South-East EPPO Zone					
KCP 6.2 KCP 6.4	Zsolt VADASZ	2018	EFFICACY OF CA3301 ON SPRING BARLEY (FOLIAR DISEASES) Syntech Research Hungary Kft. EU18-041-21 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Andrei-Ionut COCA	2018	EFFICACY OF CA3301 ON SPRING BARLEY (FOLIAR DISEASES) Syntech Research Agrico, Ro EU18-041-26 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	Dario RINALDI	2018	EFFICACY OF CA3301 ON SPRING BARLEY (FOLIAR DISEASES) Syntech Research Hungary Kft. / Sagea OOD Bulgaria EU18-041-33 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	David BLASKO	2019	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY Anadiag Hungary Kft. EU19-069-126 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	David BLASKO	2019	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY Anadiag Hungary Kft. EU19-069-127 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Ján BALOG	2019	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY GEMERPRODUKT Valice - OVD EU19-069-130 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Jan BALOG	2019	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY Gemerprodukt Valice - OVD EU19-069-131 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Jan BALOG	2019	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY Gemerprodukt Valice - OVD EU19-069-132 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Iulian ENE	2019	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY ANADIAG ROMANIA SRL EU19-069-133 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Guillaume CARDIET	2019	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY ANADIAG ROMANIA SRL EU19-069-134 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	Ján BALOG	2019	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY GEMERPRODUKT Valice - OVD EU19-069-135 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Iulian ENE	2019	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY Anadiag Romania SRL EU19-069-136 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Iulian ENE	2019	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY Anadiag Romania SRL EU19-069-137 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Jen BALOG	2019	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY Gemerprodukt Valice OVD EU19-069-138 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	David BLASKO	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY AGAINST <i>Ramularia collo-cygni</i> Anadiag Hungary Kft. EU20-037-149 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	David BLASKO	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY AGAINST <i>Ramularia collo-cygni</i> Anadiag Hungary Kft EU20-037-150 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Iulian ENE	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY AGAINST <i>Ramularia collo-cygni</i> ANADIAG ROMANIA SRL EU20-037-151 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Iulian ENE	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY AGAINST <i>Ramularia collo-cygni</i> ANADIAG ROMANIA SRL EU20-037-152 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	Frantisek TOTH	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY AGAINST <i>Ramularia collo-cygni</i> GEMERPRODUKT Valice - OVD EU20-037-153 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	David BLASKO	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY AGAINST <i>Ramularia collo-cygni</i> Anadiag Hungary Kft EU20-037-154 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Iulian ENE	2020	EFFICACY OF CA3301 AND CA3642 ON SPRING BARLEY AGAINST <i>Rhynchosporium secalis</i> ANADIAG ROMANIA SRL EU20-041-155 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Iulian ENE	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY AGAINST <i>Rhynchosporium secalis</i> ANADIAG ROMANIA SRL EU20-041-156 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Iulian ENE	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY AGAINST <i>Rhynchosporium secalis</i> ANADIAG ROMANIA SRL EU20-041-157 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	David BLASKO	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY AGAINST <i>Rhynchosporium secalis</i> ANADIAG ROMANIA SRL EU20-041-158 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Frantisek TOTH	2020	EFFICACY OF CA3301 & CA3642 ON SPRING BARLEY AGAINST <i>Pyrenophora teres</i> Gemerprodukt Valice OVD EU20-037-160 GEP, Unpublished	Y	NUFARM

A 1.3 Oat (AVESS/AVESA)

Maritime EPPO zone

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – Maritime EPPO Zone					
KCP 6.2 KCP 6.4	N. EBERLE	2017	EVAL: Efficacy of CA3301 on Oat GEP Trial, CZECH REPUBLIC, 2017 STAPHYT EU17-054-01 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. MOLNAR	2018	REG: Efficacy of CA3301 on Spring Oat (Foliar diseases) ZS NECHANICE, EU18-041-05 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. MOLNAR	2018	REG: Efficacy of CA3301 on Spring Oat (Foliar diseases) SYNTECH EU18-041-06 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. DENUELLE	2019	REG: EFFICACY of CA3301 & CA3642 on spring oat (Foliar diseases) Quintus GMBH EU19-069-01 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. DENUELLE	2019	REG: EFFICACY of CA3301 & CA3642 on spring oat (Foliar diseases) Quintus GMBH EU19-069-02 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. FRIE- DRICH	2020	REG: EFFICACY of CA3301 & CA3642 on Spring Oat (Foliar diseases) Quintus GMBH EU20-037-28 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. FRIE- DRICH	2020	REG: EFFICACY of CA3301 & CA3642 on Spring Oat (Foliar diseases) Quintus GMBH EU20-037-29 GEP, Unpublished	Y	NUFARM

Mediterranean EPPO zone

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – Mediterranean EPPO Zone					
KCP 6.2 KCP 6.4	F. MOLNAR	2018	REG: Efficacy of CA3301 on Spring Oat (Foliar diseases) - Portugal – 2018 SYNTECH RESEARCH EU18-041-38 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. MOLNAR	2018	REG: Efficacy of CA3301 on Oat (Foliar diseases) - Portugal – 2018 SYNTECH RESEARCH EU18-041-39 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A DELLA	2019	REG: EFFICACY of CA3301 and CA3642 on SPRING OAT (foliar diseases) ANADIAG EU19-069-36 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A DELLA	2019	REG: EFFICACY of CA3301 and CA3642 on Spring Oat (Foliar diseases) ANADIAG EU19-069-37 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A DELLA	2019	REG: EFFICACY of CA3301 and CA3642 on Spring Oat (Foliar diseases) ANADIAG EU19-069-38 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	P. FERRAN-TERRATS	2020	REG: EFFICACY of CA3301&CA3642 on Spring Oat (Foliar diseases) ANADIAG EU20-037-76 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	P. FERRAN-TERRATS	2020	REG: Efficacy of CA3301&CA3642 on Spring Oat (Foliar diseases) ANADIAG EU20-037-77 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	P. FERRAN-TERRATS	2020	REG : EFFICACY of CA3301 & CA3642 on Spring Oat (Foliar diseases) ANADIAG EU20-037-78 GEP, Unpublished	Y	NUFARM

North-East ~~EPH~~ EPPO zone

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – North-East EPPO Zone					
KCP 6.2 KCP 6.4	F. MOLNAR	2018	REG: Efficacy of CA3301 on Spring Oat (Foliar diseases) SYNTHECH RESEARCH EU18-041-17 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. MOLNAR	2018	REG: Efficacy of CA3301 on Spring Oat (Foliar diseases) SYNTHECH RESEARCH EU18-041-18 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	P. FERRAN-TERRATS	2019	REG: Efficacy of CA3301&CA3642 on Spring Oat (Foliar diseases) ANADIAG EU19-069-72 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	P. FERRAN-TERRATS	2019	REG: Efficacy of CA3301&CA3642 on Spring Oat (Foliar diseases) AGROLAB EU19-069-73 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	G. CARDIET	2020	REG: Efficacy of CA3301&CA3642 on Spring Oat (foliar diseases) ANADIAG EU20-037-121 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	G. CARDIET	2020	REG: Efficacy of CA3301&CA3642 on Spring Oat (foliar diseases) ANADIAG EU20-037-122 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	G. CARDIET	2020	REG: Efficacy of CA3301&CA3642 on Spring Oat (Foliar diseases) AGROLAB EU20-037-123 GEP, Unpublished	Y	NUFARM
KCP 6.2	G. CARDIET	2021	REG: Efficacy of CA3301&CA3642 on oat (foliar diseases) ANADIAG POLSKA EU21-020-44 GEP; Unpublished	Y	NUFARM

South-Eastern EPPO zone

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – South-East EPPO Zone					
KCP 6.2 KCP 6.4	T. BARASITS	2018	REG: Efficacy of CA3301 on Spring Oat (Foliar diseases) SYNTHECH RESEARCH EU18-041-22 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. MOLNAR	2018	REG: Efficacy of CA3301 on Spring Oat (Foliar diseases) SYNTHECH RESEARCH EU18-041-23 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. MOLNAR	2018	REG: Efficacy of CA3301 on Spring Oat (Foliar diseases) SAGEA OOD EU18-041-32 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	G. CARDIET	2019	REG: EFFICACY of CA3301 and CA3642 on SPRING OAT ANADIAG EU19-069-106 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	G. CARDIET	2019	REG: EFFICACY of CA3301 and CA3642 on SPRING OAT ANADIAG EU19-069-107 GEP, Unpublished	Y	NUFARM

A 1.4 Winter wheat (TRZAW)

Maritime EPPO zone

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – Maritime EPPO zone					
KCP 6.2 KCP 6.4	V. DOSTAL	2017	Efficacy of CA3301 on Winter wheat STAPHYT EU17-028-01 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	V. DOSTAL	2017	Efficacy of CA3301 on Winter wheat STAPHYT EU17-028-02 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	V. DOSTAL	2017	EFFICACY OF CA3301 ON WINTER WHEAT. STAPHYT EU17-056-03 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	T. BAUER	2017	EFFICACY OF CA3301 ON WINTER WHEAT. ATC / STAPHYT EU17-056-04 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protec- tion claimed Y/N	Owner
			Field trials – Maritime EPPO zone		
KCP 6.2 KCP 6.4	V. KRSICKOVA	2018	EFFICACY OF CA3301 ON WINTER WHEAT (FOLIAR DISEASES). STAPHYT EU18-039-01 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	V. GEZOVA	2018	EFFICACY OF CA3301 ON WINTER WHEAT (FOLIAR DISEASES). InToc Agro Trials, s.r.o EU18-039-02 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. BROCK- STED	2018	Efficacy of CA3301 on Winter Wheat (Foliar dis- eases) Agrolab EU18-039-06 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. BROCK- STED	2018	Efficacy of CA3301 on Winter Wheat (Foliar dis- eases) Agrolab EU18-039-07 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. KRIZEK	2018	EFFICACY OF CA3301 ON WINTER WHEAT AGAINST FUSARIUM SP. (FUSASP). SynTech Research Czech Republic, s.r.o EU18-040-01 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	M. SPRINGER	2018	EFFICACY OF CA3301 ON WINTER WHEAT AGAINST FUSARIUM SSP. (FUSASP). SynTech Research Czech Republic s.r.o. EU18-040-02 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. BROCK- STED	2018	Efficacy of CA3301 on Winter Wheat against Fusarium spp (FUSASP) Agrolab EU18-040-05 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A. MEYER	2019	EFFICACY of CA3301 & CA3642 on winter wheat (Foliar diseases) ANADIAG Deutschland EU19-067-01 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title	Data protec- tion claimed Y/N	Owner
			Company Report No.		
			GLP or GEP, Published or Unpublished		
Field trials – Maritime EPPO zone					
KCP 6.2 KCP 6.4	J. HUET- TENRAUCH	2019	EFFICACY OF CA3301 & CA3642 ON WIN- TER WHEAT (FOLIAR DISEASES). Quintus GmbH EU19-067-02 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. STOKES	2019	EFFICACY of CA3301 & CA3642 on winter wheat (Foliar diseases) Oxford Agricultural Trials Limited EU19-067-03 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. DUCROT	2019	EFFICACY OF CA3301 & CA3642 ON WIN- TER WHEAT (FOLIAR DISEASES). ANADIAG France EU19-067-04 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. DUCROT	2019	EFFICACY OF CA3301 & CA3642 ON WIN- TER WHEAT (FOLIAR DISEASES). ANADIAG France EU19-067-05 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. STOKES	2019	EFFICACY of CA3301 & CA3642 on winter wheat (Foliar diseases) Oxford Agricultural Trials Limited EU19-067-06 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A. MEYER	2019	EFFICACY OF CA3301 & CA3642 ON WIN- TER WHEAT (FOLIAR DISEASES). ANADIAG Deutschland EU19-067-07 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. HUET- TENRAUCH	2019	EFFICACY of CA3301 & CA3642 on winter wheat (Foliar diseases) Quintus GmbH EU19-067-08 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. DUCROT	2019	EFFICACY OF CA3301 & CA3642 ON WIN- TER WHEAT (FOLIAR DISEASES). ANADIAG France EU19-067-09 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
			Field trials – Maritime EPPO zone		
KCP 6.2 KCP 6.4	L. STOKES	2019	EFFICACY of CA3301 & CA3642 on winter wheat (Foliar diseases). Oxford Agrigultural Trials Limited EU19-067-10 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. STOKES	2019	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FOLIAR DISEASES). Oxford Agrigultural Trials Limited EU19-067-11 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. STOKES	2019	EFFICACY of CA3301 & CA3642 on winter wheat (Foliar diseases) Oxford Agrigultural Trials Limited EU19-067-12 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. STOKES	2019	EFFICACY of CA3301 & CA3642 on winter wheat (Foliar diseases) Oxford Agrigultural Trials Limited EU19-067-13 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. DUCROT	2019	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FOLIAR DISEASES). ANADIAG France EU19-067-14 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. DUCROT	2019	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FOLIAR DISEASES). ANADIAG France EU19-067-15 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. HUET-TENRAUCH	2019	EFFICACY of CA3301 & CA3642 on winter wheat (Foliar diseases) Quintus GmbH EU19-067-16 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I. SIMEK	2019	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FOLIAR DISEASES)) ANADIAG SA, CZ EU19-067-17 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protec- tion claimed Y/N	Owner
			Field trials – Maritime EPPO zone		
KCP 6.2 KCP 6.4	K. LAWINSKI	2019	EFFICACY OF CA3301&CA3642 ON WIN- TER WHEAT (FUSASP) SynTech Research Germany EU19-068-01 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	M. JOVIC	2019	EFFICACY OF CA3301&CA3642 ON WIN- TER WHEAT (FUSASP) SynTech Research Germany GmbH EU19-068-02 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. KRIZEK	2019	EFFICACY OF CA3301 & CA3642 ON WIN- TER WHEAT (FUSASP). SynTech Research Czech Republic, s.r.o EU19-068-03 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. MCEWAN	2019	EFFICACY OF CA3301&CA3642 ON WIN- TER WHEAT (FUSASP) SynTech Research UK EU19-068-04 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. GAYOT	2019	EFFICACY OF CA3301&CA3642 ON WIN- TER WHEAT (FUSASP) SynTech Research France EU19-068-05 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. DUCROT	2020	EFFICACY OF CA3301 & CA3642 ON WIN- TER WHEAT (FOLIAR DISEASES). ANADIAG SAS EU20-035-02 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	H. ERB	2020	EFFICACY of CA3301 & CA3642 on Winter Wheat (Foliar diseases) Oxford Agricultural Trials Limited EU20-035-03 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	H. ERB	2020	EFFICACY of CA3301 & CA3642 on Winter Wheat (Foliar diseases) Oxford Agricultural Trials Limited EU20-035-04 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – Maritime EPPO zone					
KCP 6.2 KCP 6.4	H. ERB	2020	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FOLIAR DISEASES). Oxford Agricultural Trials Limited EU20-035-05 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	H. ERB	2020	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FOLIAR DISEASES). Oxford Agricultural Trials Limited EU20-035-06 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	H. ERB	2020	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FOLIAR DISEASES). Oxford Agricultural Trials Limited EU20-035-07 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	H. ERB	2020	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FOLIAR DISEASES). Oxford Agricultural Trials Limited EU20-035-08 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	H. ERB	2020	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FOLIAR DISEASES). Oxford Agricultural Trials Limited EU20-035-09 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	H. ERB	2020	EFFICACY of CA3301 & CA3642 on Winter Wheat (Foliar diseases) Oxford Agricultural Trials Limited EU20-035-10 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	H. ERB	2020	EFFICACY of CA3301 & CA3642 on Winter Wheat (Foliar diseases) Oxford Agricultural Trials Limited EU20-035-11 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	H. ERB	2020	EFFICACY of CA3301 & CA3642 on Winter Wheat (Foliar diseases) Oxford Agricultural Trials Limited EU20-035-12 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title	Data protec- tion claimed Y/N	Owner
			Company Report No.		
			GLP or GEP, Published or Unpublished		
Field trials – Maritime EPPO zone					
KCP 6.2 KCP 6.4	H. ERB	2020	EFFICACY of CA3301 & CA3642 on Winter Wheat (Foliar diseases) Oxford Agricultural Trials Limited EU20-035-13 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. FREDRICH	2020	EFFICACY OF CA3301 & CA3642 on winter wheat (Foliar Diseases). Quintus GmbH EU20-035-15 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. FREDRICH	2020	EFFICACY OF CA3301 & CA3642 on winter wheat (Foliar Diseases). Quintus GmbH EU20-035-16 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. DUCROT	2020	EFFICACY OF CA3301 & CA3642 ON Winter Wheat (FOLIAR DISEASES). ANADIAG SAS EU20-035-21 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	M. MILAN-KOVIC	2020	EFFICACY OF CA3301 ON WINTER WHEAT (FUSASP) SynTech Research Germany EU20-036-01 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. STRBAC	2020	EFFICACY OF CA3301 ON WINTER WHEAT (FUSASP). SynTech Research Company EU20-036-03 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. MCEWAN	2020	EFFICACY OF CA3301 ON WINTER WHEAT (FUSASP) SynTech Research UK EU20-036-04 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. MCEWAN	2020	EFFICACY OF CA3301 ON WINTER WHEAT (FUSASP) SynTech Research UK EU20-036-06 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – Maritime EPPO zone					
KCP 6.2 KCP 6.4	S. STRBAC	2020	EFFICACY OF CA3301 ON WINTER WHEAT (FUSASP) SynTech Research Germany EU20-036-26 GEP, Unpublished	Y	NUFARM

Mediterranean EPPO zone

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – Mediterranean EPPO zone					
KCP 6.2 KCP 6.4	D. DUARTE	2018	Efficacy of CA3301 on Winter wheat (Foliar diseases) GEP Trial, PORTUGAL, 2018 Agricultura y Ensayo S.L. EU18-039-22 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. DUARTE	2018	Efficacy of CA3301 on Winter wheat (Foliar diseases) GEP Trial, PORTUGAL, 2018 Agricultura y Ensayo S.L. EU18-039-23 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. MARTINEZ	2018	REG: Efficacy CA3301 on Winter wheat against <i>Fusarium spp</i> (FUSASP) – Portugal – 2018 SynTech Research Portugal EU18-040-17 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. MARTINEZ	2018	REG: Efficacy CA3301 on Winter wheat against <i>Fusarium spp</i> (FUSASP) – Portugal – 2018 SynTech Research Portugal EU18-040-18 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. MARTINEZ	2018	Efficacy of CA3301 on Winter Wheat against <i>Fusarium spp</i> (FUSASP) SynTech Research Portugal EU18-040-19 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – Mediterranean EPPO zone					
KCP 6.2 KCP 6.4	L. MASDEVALL	2019	REG: EFFICACY of CA3301 and CA3642 on Winter Soft Wheat ANADIAG IBERICA SL EU19-067-26 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. MASDEVALL	2019	REG: EFFICACY of CA3301 and CA3642 on Winter Soft Wheat ANADIAG IBERICA SL EU19-067-27 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BOURAS	2019	REG: EFFICACY of CA3301 and CA3642 on Winter Soft Wheat ANADIAG HELLAS LTD EU19-067-28 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BOURAS	2019	REG: EFFICACY of CA3301 and CA3642 on Winter Soft Wheat ANADIAG HELLAS LTD EU19-067-29 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. VILLETON	2019	REG: EFFICACY of CA3301 and CA3642 on Winter Soft Wheat ANADIAG FRANCE EU19-067-30 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. VILLETON	2019	REG: EFFICACY of CA3301 and CA3642 on Winter Soft Wheat ANADIAG FRANCE EU19-067-31 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. VILLETON	2019	EFFICACY OF CA3301 & CA3642 ON WINTER SOFT WHEAT. ANADIAG France EU19-067-32 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. VILLETON	2019	EFFICACY OF CA3301 & CA3642 ON WINTER SOFT WHEAT. ANADIAG France EU19-067-33 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – Mediterranean EPPO zone					
KCP 6.2 KCP 6.4	L. MASDEVALL	2019	EFFICACY OF CA3301 & CA3642 ON WINTER SOFT WHEAT. ANADIAG Iberica, SL EU19-067-34 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. MASDEVALL	2019	EFFICACY OF CA3301 & CA3642 ON WINTER SOFT WHEAT. ANADIAG Iberica, SL EU19-067-35 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. VILLETON	2019	REG: EFFICACY of CA3301 and CA3642 on Winter Soft Wheat ANADIAG FRANCE EU19-067-36 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. VILLETON	2019	REG: EFFICACY of CA3301 and CA3642 on Winter Soft Wheat ANADIAG France EU19-067-37 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. MASDEVALL	2019	REG: EFFICACY of CA3301 and CA3642 on Winter Soft Wheat ANADIAG Iberica EU19-067-38 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. MASDEVALL	2019	REG: EFFICACY of CA3301 and CA3642 on Winter Soft Wheat ANADIAG Iberica EU19-067-39 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. RODRIGUES	2019	REG: EFFICACY of CA3301 and CA3642 on Winter Soft Wheat ANADIAG Iberica EU19-067-40 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. GAYOT	2019	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FUSASP). SynTech Research France EU19-068-06 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – Mediterranean EPPO zone					
KCP 6.2 KCP 6.4	S. GAYOT	2019	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FUSASP). SynTech Research France EU19-068-07 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	V. CORTS	2019	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FUSASP). SynTech Research Spain EU19-068-08 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J.J. MARTINEZ	2019	REG: Efficacy of CA3301 & CA3642 on Winter Wheat (FUSASP) SynTech Research Spain EU19-068-09 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	N. PATI	2019	REGISTRATION: EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FUSASP) Agricola 2000 S.C.p.A EU19-068-10 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. MARTINEZ	2019	REG: Efficacy of CA3301 & CA3642 on Winter Wheat (FUSASP) – Portugal - 2019 SynTech Research Portugal EU19-068-11 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	P. FERRAN-TERRATS	2020	REG: Efficacy of CA3301 & CA3642 on Winter Wheat (Foliar diseases) ANADIAG SAS EU20-035-30 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	P. FERRAN-TERRATS	2020	REG: Efficacy of CA3301 & CA3642 on Winter Wheat (Foliar diseases) ANADIAG SAS EU20-035-31 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. BERGER	2020	REG: Efficacy of CA3301 & CA3642 on Winter Wheat (Foliar diseases) ANADIAG ITALIA SRL EU20-035-32 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
			Field trials – Mediterranean EPPO zone		
KCP 6.2 KCP 6.4	P. FERRAN- TERRATS	2020	REG: Efficacy of CA3301 & CA3642 on Winter Wheat (Foliar diseases) ANADIAG SAS EU20-035-34 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	P. FERRAN- TERRATS	2020	REG: Efficacy of CA3301 & CA3642 on Winter Wheat (Foliar diseases) ANADIAG SAS EU20-035-35 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. BERGER	2020	REG: Efficacy of CA3301 & CA3642 on Winter Wheat (Foliar diseases) ANADIAG SAS EU20-035-36 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	M. ADARNIUS	2020	REG: EFFICACY of CA3301 & CA3642 on Winter Wheat (Foliar diseases) ANADIAG IBERICA SL EU20-035-37 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. MASDE- VALL	2020	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FOLIAR DISEASES). ANADIAG Iberica EU20-035-38 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. VILLETON	2020	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FOLIAR DISEASES). ANADIAG SAS EU20-035-39 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	P. FERRAN- TERRATS	2020	REG: EFFICACY of CA3301 & CA3642 on Winter Wheat (Foliar diseases) ANADIAG SAS EU20-035-41 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. VILLETON	2020	REG: Efficacy of CA3301 & CA3642 on Winter Wheat (Foliar diseases) ANADIAG SAS EU20-035-42 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – Mediterranean EPPO zone					
KCP 6.2 KCP 6.4	L. MASDEVALL	2020	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FOLIAR DISEASES). ANADIAG Iberica EU20-035-44 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BOURAS	2020	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FOLIAR DISEASES). ANADIAG Hellas LTD EU20-035-45 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. BERGER	2020	REG: Efficacy of CA3301 & CA3642 on Winter Wheat (Foliar diseases) ANADIAG ITALIA SRL EU20-035-47 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. GAYOT	2020	REG: EFFICACY OF CA3301 ON WINTER WHEAT (FUSASP) FRANCE, EPPOMED – SPRING 2020 SynTech Research France EU20-036-08 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	N. PATI	2020	REG: EFFICACY OF CA3301 ON WINTER WHEAT (FUSASP). ITALY – 2020 Agricola 2000 S.C.p.A EU20-036-11 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	N. PATI	2020	EFFICACY OF CA3301 ON WINTER WHEAT (FUSASP). Agricola 200 S.C.p.A EU20-036-12 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. MARTINEZ	2020	REG: EFFICACY OF CA3301 ON WINTER WHEAT (FUSASP). Portugal – 2020 SynTech Research Portugal EU20-036-13 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. MARTINEZ	2020	REG: EFFICACY OF CA3301 ON WINTER WHEAT (FUSASP). Portugal – 2020 SynTech Research Portugal EU20-036-14 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – Mediterranean EPPO zone					
KCP 6.2 KCP 6.4	V. CORTS	2020	EFFICACY OF CA3301 WINTER WHEAT (FUSASP). SynTech Research Spain S.L. EU20-036-16 GEP, Unpublished	Y	NUFARM

North-East ~~EPPO~~ EPPO zone

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials –North-East EPPO EPPO zone					
KCP 6.2 KCP 6.4	L. KMIECIAK	2017	Efficacy of CA3301 on Winter wheat STAPHYT EU17-028-03 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. KMIECIAK	2017	Efficacy of CA3301 on Winter wheat STAPHYT EU17-028-04 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. KMIECIAK	2017	Efficacy of CA3301 on Winter wheat STAPHYT EU17-056-01 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. KMIECIAK	2017	Efficacy of CA3301 on Winter wheat STAPHYT EU17-056-02 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	E. POTOCKA	2018	EFFICACY OF CA3301 ON WINTER WHEAT AGAINST FUSARIUM SP. (FUSASP). SynTech Reasearch Poland Sp. Z o. o. EU18-040-07 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	G. PI-OTROWSKI	2018	EFFICACY OF CA3301 ON WINTER WHEAT AGAINST FUSARIUM SP. (FUSASP). SynTech Reasearch Poland Sp. Z o. o. EU18-040-08 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials –North-East EPPO zone					
KCP 6.2 KCP 6.4	J. JATCZAK	2019	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FOLIAR DISEASES). ANADIAG Polska EU19-067-48 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2019	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FOLIAR DISEASES). ANADIAG Polska EU19-067-49 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2019	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FOLIAR DISEASES). ANADIAG Polska EU19-067-50 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. RAMA-NAUSKIENE	2019	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT LRCAF, Institute of Agriculture EU19-067-51 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. RAMA-NAUSKIENE	2019	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT LRCAF, Institute of Agriculture EU19-067-52 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. RAMA-NAUSKIENE	2019	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT LRCAF, Institute of Agriculture EU19-067-53 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2019	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FOLIAR DISEASES). ANADIAG Polska EU19-067-54 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2019	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FOLIAR DISEASES). ANADIAG Polska EU19-067-55 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
			Field trials –North-East*** EPPO zone		
KCP 6.2 KCP 6.4	A. USIN- SKIENE	2019	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FOLIAR DISEASES). Agrolab Baltic EU19-067-56 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2019	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FOLIAR DISEASES). ANADIAG Polska EU19-067-57 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2019	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FOLIAR DISEASES). ANADIAG Polska EU19-067-58 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A. USIN- SKIENE	2019	Efficacy of CA3301&CA3642 on Winter Wheat (Foliar diseases) Agrolab Baltic EU19-067-59 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. RAMA- NAUSKIENE	2019	EFFICACY OF CA3301&CA3642 ON WINTER WHEAT LRCAF, Institute of Agriculture EU19-067-60 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	E. POTOCKA	2019	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FUSASP). SynTech Research Poland Sp. Z o.o. EU19-068-12 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	M. SPRINGER	2019	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FUSASP). SynTech Research Poland Sp. Z o.o. EU19-068-13 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	M. WEEK	2019	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FUSASP). SynTech Research Poland Sp. Z o.o. EU19-068-14 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials –North-East EPPO zone					
KCP 6.2 KCP 6.4	O. TREIKALE	2019	EFFICACY OF CA3301 ON WINTER WHEAT (FUSASP). Latvian Plant Protection Research Centre, Ltd EU19-068-15 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	O. TREIKALE	2019	EFFICACY OF CA3301 ON WINTER WHEAT (FUSASP). Latvian Plant Protection Research Centre, Ltd EU19-068-16 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2020	Efficacy of CA3301&CA3642 on Winter Wheat (foliar diseases) ANADIAG Polska EU20-035-56 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2020	Efficacy of CA3301&CA3642 on Winter Wheat (foliar diseases) ANADIAG Polska EU20-035-57 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. RAMA-NAUSKIENE	2020	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT LRCAF, Institute of Agriculture EU20-035-58 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2020	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FOLIAR DISEASES). ANADIAG Polska EU20-035-59 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2020	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FOLIAR DISEASES). ANADIAG Polska EU20-035-60 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2020	Efficacy of CA3301&CA3642 on Winter Wheat (foliar diseases) ANADIAG Polska EU20-035-61 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials –North-East EPPO zone					
KCP 6.2 KCP 6.4	J. JATCZAK	2020	Efficacy of CA3301&CA3642 on Winter Wheat (foliar diseases) ANADIAG Polska EU20-035-62 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2020	Efficacy of CA3301&CA3642 on Winter Wheat (foliar diseases) ANADIAG Polska EU20-035-63 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2020	Efficacy of CA3301&CA3642 on Winter Wheat (foliar diseases) ANADIAG Polska EU20-035-64 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2020	Efficacy of CA3301&CA3642 on Winter Wheat (foliar diseases) ANADIAG Polska EU20-035-65 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A. USIN-SKIENE	2020	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FOLIAR DISEASES) Agrolab Baltic EU20-035-66 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A. USIN-SKIENE	2020	Efficacy of CA3301&CA3642 on Winter Wheat (Foliar disease) Agrolab Baltic EU20-035-67 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. KO-ZLOWSKI	2020	EFFICACY OF CA3301 ON WINTER WHEAT (FUSASP) SynTech Research Poland EU20-036-17 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	M. CWIEK	2020	Efficacy of CA3301 on Winter Wheat (FUSASP) SynTech Research Poland EU20-036-18 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials –North-East*** EPPO zone					
KCP 6.2 KCP 6.4	Z. JASKOLSKI	2020	EFFICACY OF CA3301 ON WINTER WHEAT (FUSACU) SynTech Research Poland Sp. Z o.o. EU20-036-19 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	M. KASPEREK	2020	EFFICACY OF CA3301 ON WINTER WHEAT (FUSASP) SynTech Research Agrico SRL EU20-036-20 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	JATCZAK J.	2023	EU23-150 REG:CA3301 Eyespot on wheat LEX ANADIAG SAS POLSKA, Report No: EU23-150-01 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	JATCZAK J.	2023	EU23-150 REG:CA3301 Eyespot on wheat LEX ANADIAG SAS POLSKA, Report No: EU23-150-02 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	JATCZAK J.	2023	EU23-150 REG:CA3301 Eyespot on wheat LEX ANADIAG SAS POLSKA, Report No: EU23-150-03 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	JATCZAK J.	2023	EU23-150 REG:CA3301 Eyespot on wheat LEX ANADIAG SAS POLSKA, Report No: EU23-150-04 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	JATCZAK J.	2023	EU23-150 REG:CA3301 Eyespot on wheat LEX ANADIAG SAS POLSKA, Report No: EU23-150-05 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	JATCZAK J.	2023	EU23-150 REG:CA3301 Eyespot on wheat LEX ANADIAG SAS POLSKA, Report No: EU23-150-06 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	JATCZAK J.	2023	EU23-150 REG:CA3301 Eyespot on wheat LEX ANADIAG SAS POLSKA, Report No: EU23-150-07 GEP; Unpublished	Y	NUFARM

South-East* EPPO zone**

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – South-Eastern EPPO zone					
KCP 6.2 KCP 6.4	M. VILLANYI	2018	EFFICACY OF CA3301 ON WINTER WHEAT (FOLIAR DISEASES). STAPHYT EU18-039-15 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	G. KOLEV	2018	Efficacy of CA3301 on Winter wheat (Foliar diseases) STAPHYT EU18-039-21 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	G. LOR-INCZNE IZSANYI	2018	EFFICACY OF CA3301 ON WINTER WHEAT AGAINST FUSARIUM SPP (FUSASP) SynTech Research Hungary EU18-040-11 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	T. HALMAGYI	2018	EFFICACY OF CA3301 ON WINTER WHEAT AGAINST FUSARIUM SP (FUSASP). SynTech Research Hungary Kft. EU18-040-12 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A. COCA	2018	EFFICACY OF CA3301 ON WINTER WHEAT (FUSASP) SynTech Research Agrico SRL EU18-040-15 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. RINALDI	2018	Efficacy of CA3301 on Winter Wheat against Fusarium spp. (FUSASP) SAGEA OOD EU18-040-16 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2019	EFFICACY of CA3301 and CA3642 on SORFT WINTER WHEAT ANADIAG Hungary EU19-067-65 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2019	EFFICACY of CA3301 and CA3642 on SORFT WINTER WHEAT ANADIAG Hungary EU19-067-66 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – South-Eastern EPPO zone					
KCP 6.2 KCP 6.4	I. ENE	2019	EFFICACY of CA3301 and CA3642 on SORFT WINTER WHEAT ANADIAG Romania EU19-067-67 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I. ENE	2019	EFFICACY of CA3301 and CA3642 on SORFT WINTER WHEAT ANADIAG Romania EU19-067-68 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2019	EFFICACY of CA3301 and CA3642 on SORFT WINTER WHEAT ANADIAG Hungary EU19-067-69 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2019	EFFICACY OF CA3301 and CA3642 on SOFT WINTER WHEAT. ANADIAG Hungary Kft. EU19-067-70 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I. ENE	2019	EFFICACY OF CA3301 & CA3642 ON SOFT WINTER WHEAT. ANADIAG Romania srl EU19-067-71 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I. ENE	2019	EFFICACY OF CA3301 and CA3642 on SOFT WINTER WHEAT. ANADIAG Romania EU19-067-72 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2019	EFFICACY OF CA3301 and CA3642 on SOFT WINTER WHEAT. ANADIAG Hungary EU19-067-73 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2019	REG: EFFICACY of CA3301 and CA3642 on SOFT WINTER WHEAT ANADIAG Hungary EU19-067-74 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – South-Eastern EPPO zone					
KCP 6.2 KCP 6.4	I. ENE	2019	EFFICACY of CA3301 and CA3642 on Soft Winter Wheat ANADIAG Romania EU19-067-75 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I. ENE	2019	EFFICACY of CA3301 and CA3642 on Soft Winter Wheat ANADIAG Romania EU19-067-76 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. VOURKOS	2019	EFFICACY OF CA3301 & CA3642 ON SOFT WINTER WHEAT. ANADIAG Bulgaria Ltd. EU19-067-77 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I. MAKO	2019	Efficacy of CA3301&CA3642 on Winter Wheat (FUSASP) SynTech Research Hungary EU19-068-17 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	G. LOR-INCZNE IZSANYI	2019	Efficacy of CA3301&CA3642 on Winter Wheat (FUSASP) SynTech Research Hungary EU19-068-18 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A-I. COCA	2019	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FUSASP). SynTech Research Agrico EU19-068-19 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	M. COMAN	2019	EFFICACY OF CA3301 & CA3642 ON WINTER WHEAT (FUSASP) SynTech Research Agrico EU19-068-20 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	G. SOMODY	2019	Efficacy if CA3301&CA3642 on Winter Wheat (FUSASP) SynTech Research Hungary EU19-068-21 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – South-Eastern EPPO zone					
KCP 6.2 KCP 6.4	D. BLASKO	2020	Efficacy of CA3301&CA3642 on Winter Soft Wheat against <i>Puccinia recondita</i> ANADIAG Hungary EU20-035-70 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2020	Efficacy of CA3301&CA3642 on Winter Soft Wheat against <i>Puccinia recondita</i> ANADIAG Hungary EU20-035-71 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I. ENE	2020	EFFICACY OF CA3301 & CA3642 ON WINTER SOFT WHEAT AGAINST PUCCINIA RECONDITA. ANADIAG Romania SRL EU20-035-72 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2020	Efficacy of CA3301&CA3642 on Winter Soft Wheat against powdery mildew ANADIAG Hungary EU20-035-73 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2020	Efficacy of CA3301&CA3642 on Winter Soft Wheat against powdery mildew ANADIAG Hungary EU20-035-74 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2020	Efficacy of CA3301&CA3642 on Winter Soft Wheat against powdery mildew ANADIAG Hungary EU20-035-75 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. ENE	2020	REG: Efficacy of CA3301&CA3642 on Winter Soft Wheat against powdery mildew ANADIAG Romania EU20-035-79 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. ENE	2020	REG: Efficacy of CA3301&CA3642 on Winter Soft Wheat against powdery mildew ANADIAG Romania EU20-035-80 GEP; Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – South-Eastern EPPO zone					
KCP 6.2 KCP 6.4	F. TOTH	2020	REG: Efficacy of CA3301&CA3642 on Winter Soft Wheat against powdery mildew GEMERPRODUKT VALICE OVD EU20-035-81 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. TOTH	2020	REG: Efficacy of CA3301&CA3642 on Winter Soft Wheat against powdery mildew GEMERPRODUKT VALICE OVD EU20-035-82 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I. MAKO	2020	Efficacy of CA3301 on Winter Wheat (FUSASP) CPR Europe Kft EU20-036-21 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	Z. NAGY	2020	REG: Efficacy of CA3301 on Winter Wheat (FUSASP) CPR Europe Kft EU20-036-22 GEP; Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A-I. COCA	2020	EFFICACY OF CA3301 ON WINTER WHEAT (FUSASP) SynTech Research Agrico EU20-036-23 GEP; Unpublished	Y	NUFARM

A 1.5 Winter Durum Wheat (TRZDW/TRZDU)

Maritime EPPO zone

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – Maritime EPPO Zone					
KCP 6.2 KCP 6.4	S. DUCROT	2021	Efficacy of CA3301 & CA3642 on winter durum wheat (Foliar diseases) ANADIAG France EU19-067-18 GEP, Unpublished	Y	NUFARM


Annex Point	Author	Year	Title Company Report No.	Data protection claimed Y/N	Owner
			GLP or GEP, Published or Unpublished		
KCP 6.2 KCP 6.4	S. DUCROT	2021	Efficacy of CA3301 & CA3642 on winter durum wheat (Foliar diseases) ANADIAG France EU19-067-19 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. HUET-TENRAUCH	2019	Efficacy of CA3301 & CA3642 on winter durum wheat (Foliar diseases) Quintus GMBH EU19-067-20 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. FRIEDRICH	2020	Efficacy of CA3301 & CA3642 on Durum Wheat (Foliar diseases) Quintus GMBH EU20-035-23 GEP, Unpublished	Y	NUFARM

Mediterranean EPPO zone

Annex Point	Author	Year	Title	Data protection claimed Y/N	Owner
			Company Report No.		
GLP or GEP, Published or Unpublished					
Field trials – Mediterranean EPPO Zone					
KCP 6.2 KCP 6.4	C. FERNÁN-DEZ	2018	Efficacy of CA3301 on Winter durum wheat (Foliar diseases) GEP Trial, PORTUGAL, 2018 STAPHYT EU18-039-24 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A. DELLA	2019	EFFICACY of CA3301 and CA3642 on Winter Durum Wheat ANADIAG ITALIA SRL EU19-067-41 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A. DELLA	2019	EFFICACY of CA3301 and CA3642 on Winter Durum Wheat ANADIAG ITALIA SRL EU19-067-42 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	A. DELLA	2019	EFFICACY of CA3301 and CA3642 on Winter Durum Wheat ANADIAG FRANCE EU19-067-43 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	P. FERRAN-TERRATS	2020	EFFICACY of CA3301 and CA3642 on Winter Durum Wheat ANADIAG ITALIA SRL EU20-035-49 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	P. FERRAN-TERRATS	2020	EFFICACY of CA3301 and CA3642 on Winter Durum Wheat ANADIAG ITALIA SRL EU20-035-50 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	N. EBERLE	2017	EVAL: Efficacy of CA3301 on Winter durum wheat GEP Trial, PORTUGAL, 2017 STAPHYT EU 17-028-05 GEP, Unpublished	Y	NUFARM

North-East EPPO zone

Annex Point	Author	Year	Title	Data protection claimed Y/N	Owner
			Company Report No.		
			GLP or GEP, Published or Unpublished		
Field trials – North-East  EPPO Zone					
KCP 6.2 KCP 6.4	A. GARBOWSKI	2018	Efficacy of CA3301 on Winter Durum Wheat against Fuarium spp. (FUSASP) SynTech Research EU18-040-09 GEP, Unpublished	Y	NUFARM

South-East EPPO zone

Annex Point	Author	Year	Title	Data protection claimed Y/N	Owner
			Company Report No.		
			GLP or GEP, Published or Unpublished		
Field trials – South-East EPPO Zone					

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	N. EBERLE	2017	EVAL: Efficacy of CA3301 on Winter wheat GEP Trial, HUNGARY, 2017 Staphyt Hungary Kft. (JS Agotest Kft.) EU17-026-06 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. FERNÁN-DEZ	2018	Efficacy of CA3301 on Winter durum wheat (Foliar diseases) GEP Trial, HUNGARY, 2018 Staphyt Hungary Kft. EU18-039-19 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	M. FERENC	2018	REG: Efficacy of CA3301 on Spring Durum Wheat against Fusarium spp (FUSASP) SYNTECH Research Hungary Kft. EU18-040-13 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	G. CARDIET	2019	REG: EFFICACY of CA3301 and CA3642 on WINTER DURUM WHEAT ANADIAG EU19-067-78 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	G. CARDIET	2019	REG: EFFICACY of CA3301 and CA3642 on WINTER DURUM WHEAT ANADIAG EU19-067-79 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A. DELLA	2020	REG: Efficacy of CA3301&CA3642 on Winter Durum Wheat against Zymoseptoria tritici ANADIAG EU20-035-84 GEP, Unpublished	Y	NUFARM

A 1.6 Triticale (TILWI)

Maritime EPPO zone

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – Maritime EPPO Zone					

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	N. EBERLE	2017	EVAL: Efficacy of CA3301 on triticales GEP Trial, CZECH REPUBLIC, 2017 STAPHYT EU17-052-01 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. FERNÁN- DEZ	2018	Efficacy of CA3301 on Winter Triticale (Foliar diseases) GEP Trial, CZECH REPUBLIC, 2018 INTEC AGRO TRIAL EU18-039-03 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. KRIZEK	2018	REG: EFFICACY OF CA3301 ON WINTER TRITICALE AGAINST FUSARIUM SPP. (FUSASP) SynTech Reserch Czech Republic s.r.o EU18-040-03 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. MOLNAR	2018	REG: Efficacy of CA3301 on Winter Triticale against Fusarium spp (FUSASP) AGROLAB EU18-040-06 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. HUET- TENRAUCH	2019	REG: EFFICACY of CA3301 & CA3642 on winter triticales (Foliar diseases) Quintus GMBH EU19-067-21 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. HUET- TENRAUCH	2019	REG: EFFICACY of CA3301 & CA3642 on winter triticales (Foliar diseases) Quintus GMBH EU19-067-22 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. DENUELLE	2019	REG: EFFICACY of CA3301 & CA3642 on winter triticales (Foliar diseases) ANADIAG EU19-067-23 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. FRIEDRICH	2020	REG: EFFICACY of CA3301 & CA3642 on Triticale (Foliar diseases) QUINTUS EU20-035-24 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	F. FRIEDRICH	2020	REG: EFFICACY of CA3301 & CA3642 on Triticale (Foliar diseases) QUINTUS EU20-035-25 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. FRIEDRICH	2020	REG: EFFICACY of CA3301 & CA3642 on winter wheat (Foliar diseases) QUINTUS EU20-035-26 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	P. FERRAN-TERRATS	2020	REG: EFFICACY of CA3301 & CA3642 on Triticale (Foliar diseases) ANADIAG EU20-035-27 GEP, Unpublished	Y	NUFARM

Mediterranean EPPO zone

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – Mediterranean EPPO Zone					
KCP 6.2 KCP 6.4	C. FERNÁNDEZ	2018	Efficacy of CA3301 on Winter triticale (Foliar diseases) GEP Trial, PORTUGAL, 2018 STAPHYT EU18-039-25 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. MOLNAR	2018	REG: Efficacy of CA3301 on Winter Triticale against Fusarium spp (FUSASP) - Portugal – 2018 SYNTECH EU18-040-20 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	P. FERRAN-TERRATS	2020	REG: Efficacy of CA3301 & CA3642 on Winter Triticale (Foliar diseases) ANADIAG EU20-035-51 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	P. FERRAN-TERRATS	2020	REG: Efficacy of CA3301&CA3642 on WinterTriticale (Foliar diseases) ANADIAG EU20-035-52 GEP, Unpublished	Y	NUFARM

North-East ~~ern~~ EPPO zone

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – North-East EPPO Zone					
KCP 6.2 KCP 6.4	N. EBERLE	2017	EVAL: Efficacy of CA3301 on triticales GEP Trial, POLAND, 2017 STAPHYT EU17-052-02 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. FERNÁN-DEZ	2018	Efficacy of CA3301 on Winter triticales (Foliar diseases) GEP Trial, Poland, 2018) STAPHYT EU18-039-11 GEP, Unpublished	Y	NUFARM
KCP 6.4	C. FERNÁN-DEZ	2018	Efficacy of CA3301 on Winter triticales (Foliar diseases) GEP Trial, POLAND, 2018 STAPHYT EU18-039-14 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. MOLNAR	2018	REG: EFFICACY OF CA3301 ON TRITICALE AGAINST FUSARIUM SPP. (FUSASP) SYNTECH EU18-040-10 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	P. ERRAN-TERRATS	2019	REG: Efficacy of CA3301&CA3642 on Winter Triticale (Foliar diseases) ANADIAG EU19-067-61 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	P. ERRAN-TERRATS	2019	REG: Efficacy of CA3301&CA3642 on Winter Triticale (Foliar diseases) ANADIAG EU19-067-62 GEP, Unpublished	Y	NUFARM

South-East EPPO zone

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – South-East EPPO Zone					
KCP 6.2 KCP 6.4	C. FERNÁNDEZ	2018	Efficacy of CA3301 on Winter Triticale (Foliar diseases) GEP Trial, HUNGARY, 2018 STAPHYT EU18-039-16 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. MOLNAR	2018	REG: EFFICACY OF CA3301 ON WINTERTRITICALE AGAINST FUSARIUM SPP (FUSASP). SYNTECH EU18-040-14 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	G. CARDIET	2019	REG: EFFICACY of CA3301 and CA3642 on WINTER TRITICALE ANADIAG EU19-067-80 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	G. CARDIET	2019	REG: EFFICACY of CA3301 and CA3642 on WINTER TRITICALE ANADIAG EU19-067-81 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	G. CARDIET	2019	REG: EFFICACY of CA3301 and CA3642 on WINTER TRITICALE ANADIAG EU19-067-82 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	A DELLA	2020	REG: Efficacy of CA3301&CA3642 on Winter Triticale against Zymoseptoria tritici ANADIAG EU20-035-85 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A DELLA	2020	REG: Efficacy of CA3301&CA3642 on Winter Triticale against Zymoseptoria tritici ANADIAG EU20-035-86 GEP, Unpublished	Y	NUFARM

A 1.7 Rye (SECCW)

Maritime EPPO zone

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – Maritime EPPO Zone					
KCP 6.2 KCP 6.4	N. EBERLE	2017	EVAL: Efficacy of CA3301 on Rye GEP Trial, CZECH REPUBLIC, 2017 STAPHYT, EU17-053-01 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. FERNÁN-DEZ	2018	Efficacy of CA3301 on Winter Rye (Foliar diseases) GEP Trial, CZECH REPUBLIC, 2018 STAPHYT EU18-039-04 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. FERNÁN-DEZ	2018	Efficacy of CA3301 on rye (Foliar diseases) GEP Trial, CZECH REPUBLIC, 2018 InTec Agro Trials, s.r.o. EU18-039-05 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. FERNÁN-DEZ	2018	Efficacy of CA3301 on Winter Rye (Foliar diseases) GEP Trial, DENMARK, 2018 AGROLAB EU18-039-09 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.4	C. FERNÁN-DEZ	2018	Efficacy of CA3301 on Winter rye (Foliar diseases) GEP Trial, DENMARK, 2018 AGROLAB EU18-039-10 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A. Ušinskienė	2019	Efficacy of CA3301&CA3642 on Winter rye in Denmark, 2019 AGROLAB EU19-067-24 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. STOKES	2019	REG: EFFICACY of CA3301 & CA3642 on winter rye (Foliar diseases) Oxford Agricultural Trials Limited EU19-067-25 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. FRIEDRICH	2020	REG: EFFICACY of CA3301 & CA3642 on winter rye (Foliar diseases) QUINTUS EU20-035-28 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. FRIEDRICH	2020	REG: EFFICACY of CA3301 & CA3642 on winter rye (Foliar diseases) QUINTUS EU20-035-29 GEP, Unpublished	Y	NUFARM

Mediterranean EPPO zone

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – Mediterranean EPPO Zone					
KCP 6.2 KCP 6.4	C. FERNÁN-DEZ	2018	Efficacy of CA3301 on Winter rye (Foliar diseases) GEP Trial, PORTUGAL, 2018 Agricultura y Ensayo S.L., EU18-039-26 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	C. FERNÁN-DEZ	2018	Efficacy of CA3301 on Winter rye (Foliar diseases) GEP Trial, PORTUGAL, 2018 Agricultura y Ensayo S.L., EU18-039-27 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BOURAS	2020	REG: Efficacy of CA3301&CA3642 on Winter Rye (Foliar diseases) ANADIAG HELLAS LTD EU20-035-54 GEP, Unpublished	Y	NUFARM

North-East ~~EPPO~~ EPPO zone

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – Maritime North-East EPPO Zone					
KCP 6.2 KCP 6.4	N. EBERLE	2017	EVAL: Efficacy of CA3301 on Rye GEP Trial, POLAND, 2017 STAPHYT, EU17-053-02 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. FERNÁN-DEZ	2018	Efficacy of CA3301 on Winter rye (Foliar diseases) GEP Trial, POLAND, 2018 STAPHYT EU18-039-12 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. FERNÁN-DEZ	2018	Efficacy of CA3301 on Winter rye (Foliar diseases) GEP Trial, POLAND, 2018 STAPHYT EU18-039-13 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	P. FERRAN-TERRATS	2019	REG: Efficacy of CA3301&CA3642 on Winter Rye (Foliar diseases) ANADIAG POLSKA EU19-067-63 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	P. FERRAN-TERRATS	2019	REG: Efficacy of CA3301&CA3642 on Winter Rye (Foliar diseases) ANADIAG POLSKA EU19-067-64 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	G. CARDIET	2020	REG: Efficacy of CA3301&CA3642 on Winter Rye (foliar diseases) ANADIAG POLSKA EU20-035-68 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A. Ušinskienė	2020	REG: Efficacy of CA3301&CA3642 on Winter Rye (Foliar diseases) AGROLAB EU20-035-69 GEP, Unpublished	Y	NUFARM

South-East ~~EPH~~ EPPO zone

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – South-East EPPO Zone					
KCP 6.2 KCP 6.4	C. FERNÁN-DEZ	2018	Efficacy of CA3301 on Winter rye (Foliar diseases) GEP Trial, HUNGARY, 2018 STAPHYT EU18-039-17 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. FERNÁN-DEZ	2018	Efficacy of CA3301 on Winter rye (Foliar diseases) GEP Trial, HUNGARY, 2018 STAPHYT EU18-039-18 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	G. CARDIET	2019	REG: EFFICACY of CA3301 and CA3642 on WINTER RYE ANADIAG HUNGARY Kft. EU19-067-83 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	G. CARDIET	2019	REG: EFFICACY of CA3301 and CA3642 on WINTER RYE ANADIAG ROMANIA SRL EU19-067-84 GEP, Unpublished	Y	NUFARM

A 1.8 Oilseed rape (BRSNW)

Maritime EPPO zone

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – Maritime EPPO Zone					
KCP 6.2 KCP 6.4	V. DOSTAL	2017	Efficacy of CA3301 on winter OSR. ATC EU17-057-03 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	T. BAUER	2017	Efficacy of CA3301 on winter OSR. ATC EU17-057-04 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. KRIZEK	2018	PTZ autumn efficacy trials on OSR with focus on LEPTMA & PYRPBR. SynTech Research CZ EU18-021-01 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. KRIZEK	2018	PTZ autumn efficacy trials on OSR with focus on LEPTMA & PYRPBR. SynTech Research CZ EU18-021-02 GEP, Unpublished	Y	NUFARM
KCP 6.4	F. MOLNAR	2018	PTZ autumn efficacy trials on OSR with focus on LEPTMA & PYRPBR. VKST Field Trials EU18-021-05 GEP, Unpublished	Y	NUFARM
KCP 6.4	I. SIMEK	2018	PTZ spring efficacy on OSR with focus on SCLESC, ALTEBA, ERYSCR ANADIAG SA, CZ osp. EU18-022-01 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I. SIMEK	2018	PTZ spring efficacy on OSR with focus on SCLESC, ALTEBA, ERYSCR ANADIAG SA, CZ osp. EU18-022-02 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.4	I. SIMEK	2018	PTZ spring efficacy on OSR with focus on SCLESC, ALTEBA, ERYSCR ANADIAG SA, CZ osp. EU18-022-03 GEP, Unpublished	Y	NUFARM
KCP 6.4	S. BROCKSTEDT	2018	PTZ spring efficacy on OSR with focus on SCLESC, ALTEBA, ERYSCR Agrolab EU18-022-04 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I. SIMEK	2019	PTZ autumn efficacy trials on OSR with focus on LEPTMA & PYRPBR ANADIAG SA, CZ osp. EU19-003-01 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I. SIMEK	2019	PTZ autumn efficacy trials on OSR with focus on LEPTMA & PYRPBR ANADIAG SA, CZ osp. EU19-003-02 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I. SIMEK	2019	PTZ autumn efficacy trials on OSR with focus on LEPTMA & PYRPBR ANADIAG SA, CZ osp. EU19-003-05 GEP, Unpublished	Y	NUFARM
KCP 6.4	B. LORENZ	2019	Efficacy of CA3301 and CA3642 on wOSR in spring BioChem agrar GmbH EU19-070-01 GEP, Unpublishes	Y	NUFARM
KCP 6.2 KCP 6.4	I. SIMEK	2019	Efficacy of CA3301 and CA3642 on winter OSR in spring. ANADIAG SA, CZ osp. EU19-070-03 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I. SIMEK	2019	Efficacy of CA3301 and CA3642 on winter OSR in spring. ANADIAG SA, CZ osp. EU19-070-07 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Un-published	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	I. SIMEK	2019	Efficacy of CA3301 and CA3642 on winter OSR in spring. ANADIAG SA, CZ osp. EU19-070-08 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	U. ZICKART	2019	Efficacy of CA3301 and CA3642 on wOSR in spring. BioChem agrar GmbH EU19-070-11 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	T. SPITZER	2019	Efficacy of CA3301 & CA3642 on winter OSR in spring. Agriculture Research Institute Ltd EU19-070-12 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I. SIMEK	2019	Efficacy of CA3301 and CA3642 on winter OSR in spring. ANADIAG SA, CZ osp. EU19-070-17 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	T. BAUER	2019	Efficacy of CA3301 and CA3642 on wOSR in spring. InTec Agro Trials EU19-070-18 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. REISZOVA	2019	Efficacy of CA3301 & CA3642 on wOSR in spring. Zkusebni stanice Nechanice EU19-070-19 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. REISZOVA	2019	Efficacy of CA3301 & CA3642 on wOSR in spring. Zkusebni stanice Nechanice EU19-070-24 GEP, Unpublished	Y	NUFARM
KCP 6.4	I. SIMEK	2019	Efficacy of CA3301 and CA3642 on winter OSR in spring. ANADIAG SA, CZ osp. EU19-070-27 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Un-published	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	S. LEFEVRE	2020	PTZ autumn efficacy trials on OSR with focus on LEPTMA ANADIAG France EU20-014-01 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. LEFEVRE	2020	PTZ autumn efficacy trials on OSR with focus on LEPTMA ANADIAG France EU20-014-02 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	H. ERB	2020	PTZ autumn efficacy trials on OSR with focus on LEPTMA OAT Limited EU20-014-05 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	H. ERB	2020	PTZ autumn efficacy trials on OSR with focus on LEPTMA OAT Limited EU20-014-06 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. ROHR	2020	PTZ autumn efficacy trials on OSR with focus on LEPTMA Trialtec GMBH EU20-014-07 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. ROHR	2020	PTZ autumn efficacy trials on OSR with focus on LEPTMA Trialtec GMBH EU20-014-08 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. ROHR	2020	PTZ autumn efficacy trials on OSR with focus on LEPTMA Trialtec GMBH EU20-014-09 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. LEFEVRE	2020	PTZ autumn efficacy trials on OSR with focus on PYRPBR ANADIAG FRANCE EU20-014-19 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Un-published	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	S. LEFEVRE	2020	PTZ autumn efficacy trials on OSR with focus on PYRPBR ANADIAG FRANCE EU20-014-20 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. ROHR	2020	Efficacy of CA3301 & CA3642 on wOSR in spring. Trialtec GMBH EU20-038-01 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J.ROHR	2020	Efficacy of CA3301 & CA3642 on wOSR in spring. Trialtec GMBH EU20-038-02 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	H. ERB	2020	Efficacy of CA3301 & CA3642 on wOSR in spring. OAT Limited EU20-038-03 GEP, Unpublished	Y	NUFARM
KCP 6.4	I. SIMEK	2020	Efficacy of CA3301 & CA3642 on wOSR in spring ANADIAG CZ EU20-038-08 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I. SIMEK	2020	Efficacy of CA3301 & CA3642 on wOSR in spring. ANADIAG CZ EU20-038-13 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. DUCROT	2020	Efficacy of CA3301 & CA3642 on wOSR in spring. ANADIAG SAS EU20-038-14 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. ROHR	2020	Efficacy of CA3301 & CA3642 on wOSR in spring. Trialtec GMBH EU20-038-17 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	J. ROHR	2020	Efficacy of CA3301 & CA3642 on wOSR in spring. Trialtec GMBH EU20-038-18 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. ROHR	2020	Efficacy of CA3301 & CA3642 on wOSR in spring. Trialtec GMBH EU20-038-19 GEP, Unpublished	Y	NUFARM

Mediterranean EPPO zone

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – Mediterranean EPPO Zone					
KCP 6.4	C. VILLETTON	2019	Efficacy of CA3301 and CA3642 on winter OSR in spring. ANADIAG France EU19-070-14 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. VILLETTON	2019	Efficacy of CA3301 and CA3642 on winter OSR in spring. ANADIAG France EU19-070-15 GEP, Unpublished	Y	NUFARM
KCP 6.4	C. VILLETTON	2019	Efficacy of CA3301 and CA3642 on winter OSR in spring. ANADIAG France EU19-070-16 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	S. LEFEVRE	2020	PTZ autumn efficacy trials on OSR with focus on LEPTMA ANADIAG France EU20-014-21 GEP, Unpublished	Y	NUFARM
KCP 6.4	A. SPAGNOLO	2020	Efficacy of CA3301 and CA3642 on wOSR in spring. ANADIAG France EU20-038-22 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.4	A. SPAGNOLO	2020	Efficacy of CA3301 and CA3642 on wOSR in spring. ANADIAG France EU20-038-25 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. MASDE- VALL	2020	Efficacy of CA3301 and CA3642 on wOSR in spring. ANADIAG Iberica EU20-038-27 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. MASDE- VALL	2020	Efficacy of CA3301 and CA3642 on wOSR in spring. ANADIAG Iberica EU20-038-28 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. MASDE- VALL	2020	Efficacy of CA3301 and CA3642 on wOSR in spring. ANADIAG Iberica EU20-038-29 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. VILLETON	2020	Efficacy of CA3301 and CA3642 on wOSR in spring. ANADIAG SAS EU20-038-33 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	C. VILLETON	2020	Efficacy of CA3301 and CA3642 on wOSR in spring. ANADIAG SAS EU20-038-34 GEP, Unpublished	Y	NUFARM
KCP 6.4	C. VILLETON	2020	Efficacy of CA3301 and CA3642 on wOSR in spring. ANADIAG SAS EU20-038-35 GEP, Unpublished	Y	NUFARM
KCP 6.4	C. VILLETON	2020	Efficacy of CA3301 and CA3642 on wOSR in spring. ANADIAG SAS EU20-038-36 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.4	L. MASDEVALL	2020	Efficacy of CA3301 and CA3642 on wOSR in spring. ANADIAG Iberica EU20-038-37 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	M. DELPERO	2020	Efficacy of CA3301 and CA3642 on wOSR in spring. ANADIAG Italia SRL EU20-038-39 GEP, Unpublished	Y	NUFARM
KCP 6.4	C. VILLETTON	2020	Efficacy of CA3301 and CA3642 on wOSR in spring. ANADIAG SAS EU20-038-43 GEP, Unpublished	Y	NUFARM
KCP 6.4	C. VILLETTON	2020	Efficacy of CA3301 and CA3642 on wOSR in spring. ANADIAG SAS EU20-038-44 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. MASDEVALL	2020	Efficacy of CA3301 and CA3642 on wOSR in spring. ANADIAG Iberica EU20-038-46 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	M. DELPERO	2020	Efficacy of CA3301 and CA3642 on wOSR in spring. ANADIAG Italia SRL EU20-038-47 GEP, Unpublished	Y	NUFARM
KCP 6.4	M. DELPERO	2020	Efficacy of CA3301 and CA3642 on wOSR in spring. ANADIAG Italia SRL EU20-038-48 GEP, Unpublished	Y	NUFARM

North-East ~~EPB~~ EPPO zone

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – North-East EPB EPPO Zone					

Annex Point	Author	Year	Title Company Report No.	Data protection claimed Y/N	Owner
			GLP or GEP, Published or Unpublished		
KCP 6.2 KCP 6.4	L. KMIECIAK	2017	Efficacy of CA3301 on winter OSR. STAPHYT EU17-057-01 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L. KMIECIAK	2017	Efficacy of CA3301 on winter OSR. STAPHYT EU17-057-02 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	M. CWIEK	2018	PTZ autumn efficacy trials on winter OSR with focus on LEPTMA & PYRPBR SynTech Research Poland EU18-021-06 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A. GARBOWSKI	2018	PTZ autumn efficacy trials on winter OSR with focus on LEPTMA & PYRPBR SynTech Research Poland EU18-021-07 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	M. SWITKOWSKI	2018	PTZ autumn efficacy trials on winter OSR with focus on LEPTMA & PYRPBR SynTech Research Poland EU18-021-08 GEP, Unpublished	Y	NUFARM
KCP 6.4	J. JATCZAK	2018	PTZ spring efficacy trials on winter OSR with focus on SCLESC, ALTEBA, ER-YSCR. ANADIAG Polska EU18-022-05 GEP, Unpublished	Y	NUFARM
KCP 6.4	J. JATCZAK	2018	PTZ spring efficacy trials on winter OSR with focus on SCLESC, ALTEBA, ER-YSCR. ANADIAG Polska EU18-022-06 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2019	PTZ autumn efficacy trials on winter OSR with focus on LEPTMA & PYRPBR ANADIAG Polska EU19-003-06 GEP, Unpublished	Y	NUFARM


Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	J. JATCZAK	2019	PTZ autumn efficacy trials on winter OSR with focus on LEPTMA & PYRPBR ANADIAG Polska EU19-003-07 GEP, Unpublished	Y	NUFARM
KCP 6.4	J. JATCZAK	2019	PTZ autumn efficacy trials on winter OSR with focus on LEPTMA & PYRPBR ANADIAG Polska EU19-003-08 GEP, Unpublished	Y	NUFARM
KCP 6.4	J. JATCZAK	2019	Efficacy of CA3301 and CA3642 on winter OSR in spring ANADIAG Polska EU19-070-28 GEP, Unpublished	Y	NUFARM
KCP 6.4	J. JATCZAK	2019	Efficacy of CA3301 and CA3642 on winter OSR in spring ANADIAG Polska EU19-070-29 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2019	Efficacy of CA3301 and CA3642 on winter OSR in spring ANADIAG Polska EU19-070-30 GEP, Unpublished	Y	NUFARM
KCP 6.4	R. SEMASKIENE	2019	Efficacy of CA3301 and CA3642 on wOSR in spring LRCAF, Institute of Agriculture EU19-070-31 GEP, Unpublished	Y	NUFARM
KCP 6.4	J. JATCZAK	2019	Efficacy of CA3301 and CA3642 on winter OSR in spring ANADIAG Polska EU19-070-32 GEP, Unpublished	Y	NUFARM
KCP 6.4	J. JATCZAK	2019	Efficacy of CA3301 and CA3642 on winter OSR in spring ANADIAG Polska EU19-070-33 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.4	J. JATCZAK	2019	Efficacy of CA3301 and CA3642 on winter OSR in spring ANADIAG Polska EU19-070-34 GEP, Unpublished	Y	NUFARM
KCP 6.4	R. SEMASKIENE	2019	Efficacy of CA3301 and CA3642 on wOSR in spring LRCAF, Institute of Agriculture EU19-070-36 GEP, Unpublished	Y	NUFARM
KCP 6.4	J. JATCZAK	2019	Efficacy of CA3301 and CA3642 on winter OSR in spring ANADIAG Polska EU19-070-37 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2019	Efficacy of CA3301 and CA3642 on winter OSR in spring ANADIAG Polska EU19-070-38 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A. USINSKIENE	2019	Efficacy of CA3301 and CA3642 on winter OSR in spring Agrolab Baltic EU19-070-40 GEP, Unpublished	Y	NUFARM
KCP 6.4	R. SEMASKIENE	2019	Efficacy of CA3301 and CA3642 on wOSR in spring LRCAF, Institute of Agriculture EU19-070-41 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2020	Autumn efficacy trials on OSR with focus on LEPTMA ANADIAG Polska EU20-014-32 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2020	Autumn efficacy trials on OSR with focus on LEPTMA ANADIAG Polska EU20-014-33 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title	Data protection claimed Y/N	Owner
			Company Report No.		
KCP 6.2 KCP 6.4	J. JATCZAK	2020	GLP or GEP, Published or Unpublished Autumn efficacy trials on OSR with focus on LEPTMA ANADIAG Polska EU20-014-34 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2020	Autumn efficacy trials on OSR with focus on LEPTMA ANADIAG Polska EU20-014-35 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2020	PTZ autumn efficacy trials on OSR with focus on LEPTMA ANADIAG Polska EU20-014-36 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2020	PTZ autumn efficacy trials on OSR with focus on LEPTMA ANADIAG Polska EU20-014-40 GEP, Unpublished	Y	NUFARM
KCP 6.4	R. SEMASKIENE	2020	The efficacy of CA3301 and CA3642 against <i>Leptosphaeria maculans</i> on wOSR. LRCAF, Institute of Agriculture EU20-014-41 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2020	Efficacy of CA3301 & CA3642 on wOSR in spring. ANADIAG Polska EU20-038-49 GEP, Unpublished	Y	NUFARM
KCP 6.4	J. JATCZAK	2020	Efficacy of CA3301 & CA3642 on wOSR in spring. ANADIAG Polska EU20-038-52 GEP, Unpublished	Y	NUFARM
KCP 6.4	A. USINSKIENE	2020	Efficacy of CA3301 & CA3642 on winter Oilseed rape (Foliar diseases). Agrolab Baltic EU20-038-53 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	A. USINSKIENE	2020	Efficacy of CA3301 & CA3642 on winter Oilseed rape (Foliar diseases). Agrolab Baltic EU20-038-54 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2020	Efficacy of CA3301 & CA3642 on wOSR in spring. ANADIAG Polska EU20-038-55 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	A. USINSKIENE	2020	Efficacy of CA3301 & CA3642 on winter Oilseed rape (Foliar diseases). Agrolab Baltic EU20-038-60 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2020	Efficacy of CA3301 & CA3642 on wOSR in spring. ANADIAG Polska EU20-038-64 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2020	Efficacy of CA3301 & CA3642 on wOSR in spring. ANADIAG Polska EU20-038-65 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	J. JATCZAK	2020	Efficacy of CA3301 & CA3642 on wOSR in spring. ANADIAG Polska EU20-038-66 GEP, Unpublished	Y	NUFARM
KCP 6.4	A. USINSKIENE	2020	Efficacy of CA3301 & CA3642 on winter Oilseed rape (Foliar diseases). Agrolab Baltic EU20-038-69 GEP, Unpublished	Y	NUFARM

South-East EPPO zone

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
Field trials – South-East  EPPO Zone					

Annex Point	Author	Year	Title Company Report No.	Data protection claimed Y/N	Owner
			GLP or GEP, Published or Unpublished		
KCP 6.2 KCP 6.4	M. VILLANYI	2017	Efficacy of CA3301 on winter OSR. STAPHYT EU17-057-05 GEP, Unpublished	Y	NUFARM
KCP 6.4	G. LORINCZNE	2018	PTZ autumn efficacy trials on OSR with focus on LEPTMA & PYRPBR in Hungary, 2018 Syntech Research hungary Kft. EU18-021-03 GEP, Unpublished	Y	NUFARM
KCP 6.4	T. BARASITS	2018	PTZ autumn efficacy trials on OSR with focus on LEPTMA & PYRPBR Syntech Research hungary Kft. EU18-021-04 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2018	PTZ spring efficacy trials on OSR with focus on SCLESC, ALTEBA, ERYSCR. ANADIAG Hungary EU18-022-09 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	L-A. STEFAN	2018	PTZ spring efficacy trials on OSR with focus on SCLESC, ALTEBA, ERYSCR. ANADIAG Romania EU18-022-11 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2019	PTZ autumn efficacy trials on OSR with focus on LEPTMA & PYRPBR. ANADIAG Hungary EU19-003-03 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2019	Efficacy of CA3301 & CA3642 on winter OSR in spring. ANADIAG Hungary EU19-070-42 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2019	Efficacy of CA3301 & CA3642 on winter OSR in spring. ANADIAG Hungary EU19-070-43 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.4	H. GALY	2019	Efficacy of CA3301 & CA3642 on winter OSR in spring. ANADIAG Romania EU19-070-44 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	H. GALY	2019	Efficacy of CA3301 & CA3642 on winter OSR in spring. ANADIAG Romania EU19-070-45 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	H. GALY	2019	Efficacy of CA3301 & CA3642 on winter OSR in spring. ANADIAG Romania EU19-070-47 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	H. GALY	2019	Efficacy of CA3301 & CA3642 on winter OSR in spring. ANADIAG Romania EU19-070-48 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. TOTH	2019	Efficacy of CA3301 & CA3642 on winter OSR in spring, Slovakia 2019 GemerproduktValice, OVD EU19-070-50 GEP, Unpublished	Y	NUFARM
KCP 6.4	H. GALY	2019	Efficacy of CA3301 & CA3642 on winter OSR in spring. ANADIAG Romania EU19-070-51 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	H. GALY	2019	Efficacy of CA3301 & CA3642 on winter OSR in spring. ANADIAG Romania EU19-070-52 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. TOTH	2019	Efficacy of CA3301 & CA3642 on winter OSR in spring. Gemerprodukt Valice OVD EU19-070-53 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	D. BASKO	2019	Efficacy of CA3301 & CA3642 on winter OSR in spring. ANADIAG Hungary EU19-070-54 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2020	PTZ autumn efficacy trials on OSR with focus on LEPTMA. ANADIAG Hungary EU20-014-42 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2020	PTZ autumn efficacy trials on OSR with focus on LEPTMA. ANADIAG Hungary EU20-014-43 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2020	PTZ autumn efficacy trials on OSR with focus on LEPTMA. ANADIAG Hungary EU20-014-44 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2020	PTZ autumn efficacy trials on OSR with focus on LEPTMA. ANADIAG Hungary EU20-014-45 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2020	PTZ autumn efficacy trials on OSR with focus on LEPTMA. ANADIAG Hungary EU20-014-46 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I.ENE	2020	PTZ autumn efficacy trials on OSR with focus on LEPTMA. ANADIAG Romania EU20-014-47 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I.ENE	2020	PTZ autumn efficacy trials on OSR with focus on LEPTMA. ANADIAG Romania EU20-014-48 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	I.ENE	2020	PTZ autumn efficacy trials on OSR with focus on LEPTMA. ANADIAG Romania EU20-014-49 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I.ENE	2020	PTZ autumn efficacy trials on OSR with focus on LEPTMA. ANADIAG Romania EU20-014-50 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2020	Efficacy of CA3301 & CA3642 on winter OSR in spring against <i>Erysiphe crucifearum</i> . ANADIAG Hungary EU20-038-71 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2020	Efficacy of CA3301 & CA3642 on winter OSR in spring against <i>Sclerotinia sclerotiorum</i> . ANADIAG Hungary EU20-038-72 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I. ENE	2020	Efficacy of CA3301 & CA3642 on winter OSR in spring against <i>Sclerotinia sclerotiorum</i> . ANADIAG Romania EU20-038-74 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I.ENE	2020	Efficacy of CA3301 & CA3642 on winter OSR in spring against <i>Sclerotinia sclerotiorum</i> . ANADIAG Romania EU20-038-75 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. TOTH	2020	Efficacy of CA3301 & CA3642 on winter OSR in spring against <i>Sclerotinia sclerotiorum</i> . Gemerprodukt Valice OVD EU20-038-76 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	F. TOTH	2020	Efficacy of CA3301 & CA3642 on winter OSR in spring against <i>Sclerotinia sclerotiorum</i> . Gemerprodukt Valice OVD EU20-038-77 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	D. BLASKO	2020	Efficacy of CA3301 & CA3642 on winter OSR in spring against <i>Erysiphe crucifearum</i> and <i>Plenodomus lingam</i> ANADIAG Hungary EU20-038-78 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I.ENE	2020	Efficacy of CA3301 & CA3642 on winter OSR in spring against <i>Erysiphe crucifearum</i> . ANADIAG Romania EU20-038-79 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I.ENE	2020	Efficacy of CA3301 & CA3642 on winter OSR in spring against <i>Erysiphe crucifearum</i> . ANADIAG Romania EU20-038-80 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I.ENE	2020	Efficacy of CA3301 & CA3642 on winter OSR in spring against <i>Erysiphe crucifearum</i> . ANADIAG Romania EU20-038-81 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. TOTH	2020	Efficacy of CA3301 & CA3642 on winter OSR in spring against <i>Erysiphe crucifearum</i> . Gemerprodukt Valice OVD EU20-038-82 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. TOTH	2020	Efficacy of CA3301 & CA3642 on winter OSR in spring against <i>Erysiphe crucifearum</i> . Gemerprodukt Valice OVD EU20-038-83 GEP, Unpublished	Y	NUFARM

Annex Point	Author	Year	Title Company Report No. GLP or GEP, Published or Unpublished	Data protection claimed Y/N	Owner
KCP 6.2 KCP 6.4	D. BLASKO	2020	Efficacy of CA3301 & CA3642 on winter OSR in spring against <i>Erysiphe crucifearum</i> ANADIAG Hungary EU20-038-84 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	I.ENE	2020	Efficacy of CA3301 & CA3642 on winter OSR in spring against <i>Alternaria brassicae</i> . ANADIAG Romania EU20-038-86 GEP, Unpublished	Y	NUFARM
KCP 6.2 KCP 6.4	F. TOTH	2020	Efficacy of CA3301 & CA3642 on winter OSR in spring against <i>Alternaria brassicae</i> . Gemerprodukt Valice OVD EU20-038-87 GEP, Unpublished	Y	NUFARM