REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product name: Telaron Alpha / Patton Alpha

Product code: FGF11

Chemical active substances:

azoxystrobin, 160 g/L

prothioconazole, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT
(new Authorisation)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: November 2024, update January 2025, January 2026

MS Finalisation date: March 2025 (initial Core Assessment) update August 2025, February 2026, March 2026, April 2026 (final Core Assessment)

Version history

When	What
November 2024	Initial version
January 2025	V2 - Revised version from Applicant following request from evaluator. All changes are highlighted in green.
March 2025	Initial zRMS assessment The report in the dRR format has been 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. Following the evaluation and before sending the document for commenting, all coloured highlighting was removed, from the parts updated by the Applicant, for better legibility.
August 2025	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. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.
January 2026	V3 – Revised version from Applicant. In response to zRMS comments, additional summaries are presented for selected uses to show efficacy from assessments after the first application (and therefore representative of a single application). All updates are highlighted turquoise.
February 2026	zRMS assessment (Core Assessment updated following the addition of the new summaries for selected uses to show efficacy from assessments after the first application) Additional assessments included by the zRMS in the report are highlighted in green. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.
March 2026	Final report (Core Assessment updated following the commenting period). No additional information or assessments after the commenting period.
April 2026	Final report (Core Assessment updated following the comments received from Polish Ministry of Agriculture) Additional information/assessments included by the zRMS in the report in response to comments received from Polish Ministry of Agriculture are highlighted in red. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency. An exception is made for the GAP table (column 15), where the assessment conclusions are indicated by color coding. For the better clarity, updates to the conclusions related to the efficacy section have been implemented in a non-visible manner. The revisions concern the introduction of conditional approvals for uses 1 (PL), 3 (PL), and 5 (PL).

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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 zRMS:

This application has been submitted for the authorization of new product FGF11 (Patton Alpha) in Austria, Belgium, Czech Republic, Germany, Hungary, Ireland, Netherlands, Poland, Romania, Slovenia, Slovakia and France (belonging to the Maritime EPPO climatic zone). FGF11 contains two active substances: azoxystrobin (160 g/L) and prothioconazole (200 g/L). This product is applied at dose rate of 1 l/ha once per growing season for the protection of spring and winter cereals and oilseed rape against disease pathogens.

MED
The applicant has submitted limited number of trials with the results after 1 application. However, some uses have been accepted in the assessment provided by the zRMS. The final conclusions have been presented below in chapter 'Efficacy'. FGF11 applied at dose rate of 1 l/ha once per growing season can be determined as the minimum effective dose for the control of *Zymoseptoria tritici* on winter wheat and winter triticale, *Pyrenophora teres* on winter barley (only in the SE zone), *Sclerotinia sclerotiorum* on winter oilseed rape and *Fusasrium* spp. on winter wheat (only in the NE and SE zone).

Efficacy
According to the GAP table, the intended maximum number of applications for all uses is one, both per use and per crop/season. However, the test product FGF11 was applied twice per growth season in wheat and triticale crops, rye and barley crops. All these trials have been accepted, but considered the authorization aimed by the applicant only efficacy results from assessments after the first application (A) were respected and taken into account for efficacy calculation. As both actives of the test product are translocated in plant, including newly developing organs, one cannot exclude some fungicidal activity in these tissues, from which the leaves F and F-1 origin, even though these leaves are not yet developed at 0 DA-A. This activity, preceding the second application, may reduce the level of infestation that is recorded in these leaves at 0 DA-B, as much as during the period following the second application. Consequently, the final efficacy concluded at xx DA-B should may be, in part, the result of the fungicidal activity, of the test item, that can be traced back to the dose delivered in application A. It cannot be judicioiusly called "efficacy after single application".
Additional tables by crop species requested have been added below the tables provided by the applicant, either in chapter 3.2.2 and 3.2.3. The average effectiveness after 1 and 2 applications is presented separately. Due to limited number of trials with results after 1 application, the number of trials may not be sufficient in most cases to accept the intended uses. However, given the low pest severity after the first application, additional results after the second application may be supportive. Finally, the below uses have been accepted by the zRMS:

- SEPTTR/TRZAW: all EPPO zones
- ~~SEPTTR/TRZAS: the NE zone~~
- SEPTTR/TTLWI: the NE zone
- PYRNTE/HORVW: the SE zone
- SCLESC/BRSNW: all EPPO zones
- FUSASP/TRZAW: the NE and SE zones

The below uses have not been accepted:

- SEPTTR/TRZAS,TRZDU,TRZSP,TTLSO: the NE zone
- PUCCST/~~TRZAW,~~TRZAS,~~TTLWI,TTLSO,~~TRZDU,TRZSP: the NE zone

- PUCCRE/~~TRZAW,TTLWI,~~TRZAS,TTLSO,TRZDU,TRZSP: the NE zone
- PUCCRR/SECCW,SECCS: the NE zone
- PYRNTE/HORVW,HORVS: the NE zone
- PUCCHD/~~HORVW,~~HORVS: the NE zone
- RAMUCC/HORVW,HORVS: the NE zone
- RHYNSE/HORVW,HORVS: the NE zone
- SCLESC/BRSNS: the NE zone
- FUSASP/TRZAS,TRZDU,TRZSP: the NE zone

The cMSs belonging to the Maritime and South-East zone are kindly asked to consider the below uses at the national level*:

- SEPTTR/TRZAS,TRZDU,TRZSP,TTLWI,TTLSO
- PUCCST/~~TRZAW,TRZAS,~~TRZDU,TRZSP,~~TTLWI,TTLSO~~
- PUCCST/TTLWI: the MAR zone
- PUCCST/TTLSO
- PUCCRE/ ~~TRZAW,TRZAS~~,TRZDU,TRZSP,~~TTLWI,TTLSO~~
- PUCCRE/TTLSO
- PUCCRR/SECCW,SECCS: the MAR zone
- PUCCRR/SECCS: the SE zone
- ~~PYRNTE/HORVW,HORVS: the MAR zone~~
- ~~PYRNTE/HORVS: the SE zone~~
- PUCCHD/HORVW,HORVS
- RAMUCC/HORVW,HORVS
- RHYNSE/HORVW,HORVS
- SCLESC/BRSNS
- FUSASP/TRZAW,TRZAS,TRZDU,TRZSP: the MAR zone
- FUSASP/TRZAS,TRZDU,TRZSP: the SE zone

In respons to zRMS comments, the applicant included additional summaries presented for selected uses to show efficacy from assessments after the first application (and therefore representative of a single application) and argumentation to justify the use of data from assessments after the second application as being supportive of the proposed use of a single application. Taking into account above information, some uses were re-evaluated, resulting in the following approvals:

- PUCCST/TRZAW, TRZAS: the ~~NE,~~ SE, MAR zones
- PUCCST/TRZAW: the NE zone
- PUCCST/TTLWI: the NE and SE zones
- PUCCST/TTLSO: the NE zone
- PUCCRE/TRZAW, TTLWI, TRZAS: the ~~NE,~~ SE, MAR zone
- PUCCRE/TRZAW: the NE zone
- PUCCRE/TTLWI: the NE zone
- PUCCRR/SECCW: the SE zone
- PYRNTE/HORVW, HORVS: the SE, ~~NE~~ and MAR zone
- PUCCHD/HORVW, ~~HORVS~~: the NE zone

~~BBCH stage~~

~~Based on a limited number of efficacy trials after 1 application used for the overall calculation, BBCH stages for the accepted uses were shortened. The BBCH stage proposed by the applicant in the GAP tabel are the result of 2 applications and therefore, in the opinion of zRMS, should be modified. BBCH stages with 1 application in the efficacy trials used for the evaluation provided by zRMS are below:~~

~~Maritime~~	~~North-East~~	~~South-East~~
~~Spring barley~~		
~~32~~	~~30-34~~	~~31-33~~
~~Winter barley~~		
~~31-32~~	~~31-33~~	~~30-33~~
~~Spring wheat~~		
~~32-33~~	-	~~31-34~~
~~Winter wheat~~		
~~31-33~~	~~31-33~~	~~31-41~~
~~Durum wheat~~		
~~31-32~~	-	~~31-35~~

Spelt		
32-33	-	-
Winter triticale		
31-37	31-37	31-35
Spring triticale		
-	31-32	-

However, the final decision about on modification of BBCH stages is left to the cMSs at the national level.

Selectivity
No phytotoxicity symptoms have been noted, either in low disease trials and the efficacy trials. No special selectivity trials were conducted in any crops. Furthermore, no adverse effect was observed in case of quantity and quality parameters of crop yields. In general, FGF11 applied at dose rate of 1 l/ha once per growing season is safe for wheat and triticale crops, winter and spring barley, winter rye and winter oilseed rape if applied according to the recommendations in the product label.

Resistance risk
The resistance management strategy for FGF11 is based on a limited number of applications (max 1 application per season/crop) and use of alternation with products containing actives with different MoA. The general anti-resistance recommendations are presented in chapter 3.3.

*Please note, that where a particular use is marked blue in the GAP table, it means that taking individual decision on that use by the respective cMS is welcome. It should not be meant as an off-loading, of the decision-taking, by the zRMS to the cMS. Instead, it aims at allowing the cMSs to take decisions different from that taken by zRMS for their own country, in recognition of the cMSs` different national requirements or preferences. Bearing that in mind, zRMS has discussed, in the commenting boxes, any doubtful issues, highlighting positive efficacy results where relevant, while also sharing with cMSs the reasons for which taking different decisions may be justified in different zones.
In case of the draft Registration Report there is still time for any cMS to express their view and argue, in favour or against the authorization in their country. That is why the zRMS is kindly asking the cMSs to not only take their decisions, but also to share the underlying information with the zRMS PL, within the commenting period framework. Only then will the zRMS be able to complete the GAP table unambiguously, in the final Registration Report, for all the EPPO zones and for all the concerned Member States, for which the present dossier has been submitted.

Table 3.1-1: GAP table

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**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	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
1	~~CEU (~~AT ~~-BE, CZ, DE, HU, IE, NL, PL, RO, SL, SK)~~	Winter wheat, spring wheat, durum wheat, spelt TRZAW, TRZAS, ~~TRSDU~~ TRZDU, TRZSP	F	Septoria leaf blotch (*Zymoseptoria tritici*) [SEPTTR]; Yellow rust (*Puccinia striiformis*) [PUCCST]; Brown rust (*Puccinia recondita*) [PUCCRE]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A TRZAW (SEPTTR, PUCCST, PUCCRE) TRZAS (PUCCST, PUCCRE) C ~~TRZAW (PUCCST, PUCCRE)~~ TRZAS (SEPTTR) TRZDU TRZSP
1	BE	Winter wheat, spring wheat, durum wheat, spelt TRZAW, TRZAS, ~~TRSDU~~ TRZDU, TRZSP	F	Septoria leaf blotch (*Zymoseptoria tritici*) [SEPTTR]; Yellow rust (*Puccinia striiformis*) [PUCCST]; Brown rust (*Puccinia recondita*) [PUCCRE]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A TRZAW (SEPTTR, PUCCST, PUCCRE) TRZAS (PUCCST, PUCCRE) C ~~TRZAW (PUCCST, PUCCRE)~~ TRZAS (SEPTTR) TRZDU TRZSP
1	CZ	Winter wheat, spring wheat, durum wheat, spelt TRZAW, TRZAS, ~~TRSDU~~ TRZDU, TRZSP	F	Septoria leaf blotch (*Zymoseptoria tritici*) [SEPTTR]; Yellow rust (*Puccinia striiformis*) [PUCCST]; Brown rust (*Puccinia recondita*) [PUCCRE]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A TRZAW (SEPTTR, PUCCST, PUCCRE) TRZAS (PUCCST, PUCCRE) C ~~TRZAW (PUCCST, PUCCRE)~~ TRZAS (SEPTTR) TRZDU TRZSP

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**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	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
1	DE	Winter wheat, spring wheat, durum wheat, spelt TRZAW, TRZAS, ~~TRSDU~~ TRZDU, TRZSP	F	Septoria leaf blotch (*Zymoseptoria tritici*) [SEPTTR]; Yellow rust (*Puccinia striiformis*) [PUCCST]; Brown rust (*Puccinia recondita*) [PUCCRE]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A TRZAW (SEPTTR, PUCCST, PUCCRE) TRZAS (PUCCST, PUCCRE) C ~~TRZAW (PUCCST, PUCCRE)~~ TRZAS (SEPTTR) TRZDU TRZSP
1	HU	Winter wheat, spring wheat, durum wheat, spelt TRZAW, TRZAS, ~~TRSDU~~ TRZDU, TRZSP	F	Septoria leaf blotch (*Zymoseptoria tritici*) [SEPTTR]; Yellow rust (*Puccinia striiformis*) [PUCCST]; Brown rust (*Puccinia recondita*) [PUCCRE]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A TRZAW (SEPTTR, PUCCST, PUCCRE) TRZAS (PUCCST, PUCCRE) C ~~TRZAW (PUCCST, PUCCRE)~~ TRZAS (SEPTTR) TRZDU TRZSP
~~1~~	~~HU~~	~~Winter wheat, spring wheat, durum wheat, spelt TRZAW, TRZAS, TRSDU, TRZSP~~	~~F~~	~~Septoria leaf blotch (*Zymoseptoria tritici*) [SEPTTR]; Yellow rust (*Puccinia striiformis*) [PUCCST]; Brown rust (*Puccinia recondita*) [PUCCRE]~~	~~Spray~~	~~BBCH 30-69~~	~~a) 1 b) 1~~	~~-~~	~~a) 1.0 b) 1.0~~	~~a) 160+200 b) 160+200~~	~~100-400~~	~~35~~		
1	IE	Winter wheat, spring wheat, durum wheat, spelt TRZAW, TRZAS, ~~TRSDU~~ TRZDU, TRZSP	F	Septoria leaf blotch (*Zymoseptoria tritici*) [SEPTTR]; Yellow rust (*Puccinia striiformis*) [PUCCST];	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A TRZAW (SEPTTR, PUCCST, PUCCRE) TRZAS (PUCCST, PUCCRE)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**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	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
				Brown rust (*Puccinia recondita*) [PUCCRE]										C ~~TRZAW (PUCCST, PUCCRE)~~ TRZAS (SEPTTR) TRZDU TRZSP
1	NL	Winter wheat, spring wheat, durum wheat, spelt TRZAW, TRZAS, ~~TRSDU~~ TRZDU, TRZSP	F	Septoria leaf blotch (*Zymoseptoria tritici*) [SEPTTR]; Yellow rust (*Puccinia striiformis*) [PUCCST]; Brown rust (*Puccinia recondita*) [PUCCRE]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A TRZAW (SEPTTR, PUCCST, PUCCRE) TRZAS (PUCCST, PUCCRE) C ~~TRZAW (PUCCST, PUCCRE)~~ TRZAS (SEPTTR) TRZDU TRZSP
1	PL	Winter wheat, spring wheat, durum wheat, spelt TRZAW, TRZAS, ~~TRSDU~~ TRZDU, TRZSP	F	Septoria leaf blotch (*Zymoseptoria tritici*) [SEPTTR]; Yellow rust (*Puccinia striiformis*) [PUCCST]; Brown rust (*Puccinia recondita*) [PUCCRE]	Spray	BBCH 30-69 ~~30-33~~	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A TRZAW, (SEPTTR, PUCCST, PUCCRE) R TRZAS/PUCCST TRZAS/PUCCRE TRZAS/SEPTTR- in PL only conditional registration is possible - **(final decision is left at the Authority discretion)** N TRZDU TRZSP Durum wheat and spelt- possible authorization based on the art. 51-minor uses
1	RO	Winter wheat, spring wheat, durum wheat, spelt TRZAW, TRZAS, ~~TRSDU~~	F	Septoria leaf blotch (*Zymoseptoria tritici*) [SEPTTR]; Yellow rust (*Puccinia*	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A TRZAW (SEPTTR, PUCCST, PUCCRE) TRZAS

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**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	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
		TRZDU, TRZSP		*striiformis*) [PUCCST]; Brown rust (*Puccinia recondita*) [PUCCRE]										(PUCCST, PUCCRE) C ~~TRZAW (PUCCST, PUCCRE)~~ TRZAS (SEPTTR) TRZDU TRZSP
1	SL	Winter wheat, spring wheat, durum wheat, spelt TRZAW, TRZAS, ~~TRSDU~~ TRZDU, TRZSP	F	Septoria leaf blotch (*Zymoseptoria tritici*) [SEPTTR]; Yellow rust (*Puccinia striiformis*) [PUCCST]; Brown rust (*Puccinia recondita*) [PUCCRE]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A TRZAW (SEPTTR, PUCCST, PUCCRE) TRZAS (PUCCST, PUCCRE) TRZAS (PUCCST, PUCCRE) C ~~TRZAW (PUCCST, PUCCRE)~~ TRZAS (SEPTTR) TRZDU TRZSP
1	SK	Winter wheat, spring wheat, durum wheat, spelt TRZAW, TRZAS, ~~TRSDU~~ TRZDU, TRZSP	F	Septoria leaf blotch (*Zymoseptoria tritici*) [SEPTTR]; Yellow rust (*Puccinia striiformis*) [PUCCST]; Brown rust (*Puccinia recondita*) [PUCCRE]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A TRZAW (SEPTTR, PUCCST, PUCCRE) TRZAS (PUCCST, PUCCRE) C ~~TRZAW (PUCCST, PUCCRE)~~ TRZAS (SEPTTR) TRZDU TRZSP

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**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	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
1	FR Maritime	Winter wheat, spring wheat, durum wheat, spelt TRZAW, TRZAS, ~~TRSDU~~ TRZDU, TRZSP	F	Septoria leaf blotch (*Zymoseptoria tritici*) [SEPTTR]; Yellow rust (*Puccinia striiformis*) [PUCCST]; Brown rust (*Puccinia recondita*) [PUCCRE]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A TRZAW (SEPTTR, PUCCST, PUCCRE) TRZAS (PUCCST, PUCCRE) C ~~TRZAW (PUCCST, PUCCRE)~~ TRZAS (SEPTTR) TRZDU TRZSP
2	~~CEU (AT, BE, CZ, DE, HU, IE, NL, PL, RO, SL, SK)~~	Winter triticale, spring triticale TTLWI, TTLSO	F	Septoria leaf blotch (*Zymoseptoria tritici*) [SEPTTR]; Yellow rust (*Puccinia striiformis*) [PUCCST]; Brown rust (*Puccinia recondita*) [PUCCRE]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A TTLWI (PUCCRE) C TTLWI (SEPTTR, PUCCST) TTLSO
2	BE	Winter triticale, spring triticale TTLWI, TTLSO	F	Septoria leaf blotch (*Zymoseptoria tritici*) [SEPTTR]; Yellow rust (*Puccinia striiformis*) [PUCCST]; Brown rust (*Puccinia recondita*) [PUCCRE]	Spray	BBCH 30-69	c) 1 d) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A TTLWI (PUCCRE) C TTLWI (SEPTTR, PUCCST) TTLSO
2	CZ	Winter triticale, spring triticale TTLWI, TTLSO	F	Septoria leaf blotch (*Zymoseptoria tritici*) [SEPTTR]; Yellow rust (*Puccinia striiformis*) [PUCCST]; Brown rust (*Puccinia recondita*) [PUCCRE]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A TTLWI (PUCCRE) C TTLWI (SEPTTR, PUCCST) TTLSO

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**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	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
2	DE	Winter triticale, spring triticale TTLWI, TTLSO	F	Septoria leaf blotch (*Zymoseptoria tritici*) [SEPTTR]; Yellow rust (*Puccinia striiformis*) [PUCCST]; Brown rust (*Puccinia recondita*) [PUCCRE]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A TTLWI (PUCCRE) C TTLWI (SEPTTR, PUCCST) TTLSO
2	HU	Winter triticale, spring triticale TTLWI, TTLSO	F	Septoria leaf blotch (*Zymoseptoria tritici*) [SEPTTR]; Yellow rust (*Puccinia striiformis*) [PUCCST]; Brown rust (*Puccinia recondita*) [PUCCRE]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A TTLWI (PUCCST, PUCCRE) C TTLWI (SEPTTR) TTLSO
2	IE	Winter triticale, spring triticale TTLWI, TTLSO	F	Septoria leaf blotch (*Zymoseptoria tritici*) [SEPTTR]; Yellow rust (*Puccinia striiformis*) [PUCCST]; Brown rust (*Puccinia recondita*) [PUCCRE]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A TTLWI (PUCCRE) C TTLWI (SEPTTR, PUCCST) TTLSO
2	NL	Winter triticale, spring triticale TTLWI, TTLSO	F	Septoria leaf blotch (*Zymoseptoria tritici*) [SEPTTR]; Yellow rust (*Puccinia striiformis*) [PUCCST]; Brown rust (*Puccinia recondita*) [PUCCRE]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A TTLWI (PUCCRE) C TTLWI (SEPTTR, PUCCST) TTLSO
2	PL	Winter triticale, spring triticale TTLWI, TTLSO	F	Septoria leaf blotch (*Zymoseptoria tritici*) [SEPTTR]; Yellow rust (*Puccinia*	Spray	BBCH 30-69 ~~30-37~~	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A TTLWI (SEPTTR, PUCCST, PUCCRE)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**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	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
				striiformis) [PUCCST]; Brown rust (*Puccinia recondita*) [PUCCRE]										TTLSO (PUCCST) N TTLSO (PUCCRE, SEPTTR)
2	RO	Winter triticale, spring triticale TTLWI, TTLSO	F	Septoria leaf blotch (*Zymoseptoria tritici*) [SEPTTR]; Yellow rust (*Puccinia striiformis*) [PUCCST]; Brown rust (*Puccinia recondita*) [PUCCRE]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A TTLWI (PUCCST, PUCCRE) C TTLWI (SEPTTR) TTLSO
2	SL	Winter triticale, spring triticale TTLWI, TTLSO	F	Septoria leaf blotch (*Zymoseptoria tritici*) [SEPTTR]; Yellow rust (*Puccinia striiformis*) [PUCCST]; Brown rust (*Puccinia recondita*) [PUCCRE]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A TTLWI (PUCCST, PUCCRE) C TTLWI (SEPTTR) TTLSO
2	SK	Winter triticale, spring triticale TTLWI, TTLSO	F	Septoria leaf blotch (*Zymoseptoria tritici*) [SEPTTR]; Yellow rust (*Puccinia striiformis*) [PUCCST]; Brown rust (*Puccinia recondita*) [PUCCRE]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A TTLWI (PUCCST, PUCCRE) C TTLWI (SEPTTR) TTLSO
2	FR Maritime	Winter triticale, spring triticale TTLWI, TTLSO	F	Septoria leaf blotch (*Zymoseptoria tritici*) [SEPTTR];	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A TTLWI (PUCCRE)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**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	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
				Yellow rust (*Puccinia striiformis*) [PUCCST]; Brown rust (*Puccinia recondita*) [PUCCRE]										C TTLWI (SEPTTR, PUCCST) TTLSO
3	~~CEU (~~AT~~, BE, CZ, DE, HU, IE, NL, PL, RO, SI, SK)~~	Winter barley, spring barley HORVW, HORVS	F	Net blotch (*Pyrenophora teres*) [PYRNTE]; Ramularia (*Ramularia collo-cygni*) [RAMUCC]; Leaf blotch (*Rhynchosporium secali*) [RHYNSE]; Rust (*Puccinia hordeii*) [PUCCHD]	Spray	BBCH 30-59	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A (PYRNTE) C (PUCCHD, RAMUCC, RHYNSE)
3	BE	Winter barley, spring barley HORVW, HORVS	F	Net blotch (*Pyrenophora teres*) [PYRNTE]; Ramularia (*Ramularia collo-cygni*) [RAMUCC]; Leaf blotch (*Rhynchosporium secali*) [RHYNSE]; Rust (*Puccinia hordeii*) [PUCCHD]	Spray	BBCH 30-59	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A (PYRNTE) C (PUCCHD, RAMUCC, RHYNSE)
3	CZ	Winter barley, spring barley HORVW, HORVS	F	Net blotch (*Pyrenophora teres*) [PYRNTE]; Ramularia (*Ramularia collo-cygni*) [RAMUCC]; Leaf blotch (*Rhynchosporium secali*) [RHYNSE]; Rust (*Puccinia hordeii*) [PUCCHD]	Spray	BBCH 30-59	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A (PYRNTE) C (PUCCHD, RAMUCC, RHYNSE)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**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	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
3	DE	Winter barley, spring barley HORVW, HORVS	F	Net blotch (*Pyrenophora teres*) [PYRNTE]; Ramularia (*Ramularia collo-cygni*) [RAMUCC]; Leaf blotch (*Rhynchosporium secali*) [RHYNSE]; Rust (*Puccinia hordeii*) [PUCCHD]	Spray	BBCH 30-59	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A (PYRNTE) C (PUCCHD, RAMUCC, RHYNSE)
3	HU	Winter barley, spring barley HORVW, HORVS	F	Net blotch (*Pyrenophora teres*) [PYRNTE]; Ramularia (*Ramularia collo-cygni*) [RAMUCC]; Leaf blotch (*Rhynchosporium secali*) [RHYNSE]; Rust (*Puccinia hordeii*) [PUCCHD]	Spray	BBCH 30-59	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A ~~HORVW~~ (PYRNTE) C ~~HORVW~~ (PUCCHD, RAMUCC, RHYNSE) ~~HORVS~~
3	IE	Winter barley, spring barley HORVW, HORVS	F	Net blotch (*Pyrenophora teres*) [PYRNTE]; Ramularia (*Ramularia collo-cygni*) [RAMUCC]; Leaf blotch (*Rhynchosporium secali*) [RHYNSE]; Rust (*Puccinia hordeii*) [PUCCHD]	Spray	BBCH 30-59	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A (PYRNTE) C (PUCCHD, RAMUCC, RHYNSE)
3	NL	Winter barley, spring barley HORVW, HORVS	F	Net blotch (*Pyrenophora teres*) [PYRNTE]; Ramularia (*Ramularia collo-cygni*)	Spray	BBCH 30-59	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A (PYRNTE)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**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	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			C (PUCCHD, RAMUCC, RHYNSE)
				[RAMUCC]; Leaf blotch (*Rhynchosporium secali*) [RHYNSE]; Rust (*Puccinia hordeii*) [PUCCHD]										
3	PL	Winter barley, spring barley HORVW, HORVS	F	Net blotch (*Pyrenophora teres*) [PYRNTE]; Ramularia (*Ramularia collo-cygni*) [RAMUCC]; Leaf blotch (*Rhynchosporium secali*) [RHYNSE]; Rust (*Puccinia hordeii*) [PUCCHD]	Spray	BBCH 30-59	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A HORVW (PUCCHD) R HORVS/PUCCHD HORVS/PYRNTE HORVW/PYRNTE - in PL only conditional registration is possible - **(final decision is left at the Authority discretion)** N RAMUCC, RHYNSE
3	RO	Winter barley, spring barley HORVW, HORVS	F	Net blotch (*Pyrenophora teres*) [PYRNTE]; Ramularia (*Ramularia collo-cygni*) [RAMUCC]; Leaf blotch (*Rhynchosporium secali*) [RHYNSE]; Rust (*Puccinia hordeii*) [PUCCHD]	Spray	BBCH 30-59	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A HORVW (PYRNTE) C HORVW (PUCCHD, RAMUCC, RHYNSE) HORVS

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**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	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
3	SI	Winter barley, spring barley HORVW, HORVS	F	Net blotch (*Pyrenophora teres*) [PYRNTE]; Ramularia (*Ramularia collo-cygni*) [RAMUCC]; Leaf blotch (*Rhynchosporium secali*) [RHYNSE]; Rust (*Puccinia hordeii*) [PUCCHD]	Spray	BBCH 30-59	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A ~~HORVW~~ (PYRNTE) C ~~HORVW~~ (PUCCHD, RAMUCC, RHYNSE) ~~HORVS~~
3	SK	Winter barley, spring barley HORVW, HORVS	F	Net blotch (*Pyrenophora teres*) [PYRNTE]; Ramularia (*Ramularia collo-cygni*) [RAMUCC]; Leaf blotch (*Rhynchosporium secali*) [RHYNSE]; Rust (*Puccinia hordeii*) [PUCCHD]	Spray	BBCH 30-59	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A ~~HORVW~~ (PYRNTE) C ~~HORVW~~ (PUCCHD, RAMUCC, RHYNSE) ~~HORVS~~
3	FR Maritime	Winter barley, spring barley HORVW, HORVS	F	Net blotch (*Pyrenophora teres*) [PYRNTE]; Ramularia (*Ramularia collo-cygni*) [RAMUCC]; Leaf blotch (*Rhynchosporium secali*) [RHYNSE]; Rust (*Puccinia hordeii*) [PUCCHD]	Spray	BBCH 30-59	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A (PYRNTE) C (PUCCHD, RAMUCC, RHYNSE)
4	~~CEU~~ (AT, ~~BE, CZ, DE,~~	Winter oilseed rape, spring oilseed rape BRSNW, BRSNS	F	Cottony rot (*Sclerotinia sclerotiorum*) [SCLESC]	Spray	BBCH 61-73	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A BRSNW

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**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	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			C BRSNS
4	BE	Winter oilseed rape, spring oilseed rape BRSNW, BRSNS	F	Cottony rot (*Sclerotinia sclerotiorum*) [SCLESC]	Spray	BBCH 61-73	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A BRSNW C BRSNS
4	CZ	Winter oilseed rape, spring oilseed rape BRSNW, BRSNS	F	Cottony rot (*Sclerotinia sclerotiorum*) [SCLESC]	Spray	BBCH 61-73	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A BRSNW C BRSNS
4	DE	Winter oilseed rape, spring oilseed rape BRSNW, BRSNS	F	Cottony rot (*Sclerotinia sclerotiorum*) [SCLESC]	Spray	BBCH 61-73	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A BRSNW C BRSNS
4	HU	Winter oilseed rape, spring oilseed rape BRSNW, BRSNS	F	Cottony rot (*Sclerotinia sclerotiorum*) [SCLESC]	Spray	BBCH 61-73	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A BRSNW C BRSNS
4	IE	Winter oilseed rape, spring oilseed rape BRSNW, BRSNS	F	Cottony rot (*Sclerotinia sclerotiorum*) [SCLESC]	Spray	BBCH 61-73	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A BRSNW C BRSNS
4	NL	Winter oilseed rape, spring oilseed rape BRSNW, BRSNS	F	Cottony rot (*Sclerotinia sclerotiorum*) [SCLESC]	Spray	BBCH 61-73	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A BRSNW C BRSNS
4	PL	Winter oilseed rape, spring oilseed rape BRSNW, BRSNS	F	Cottony rot (*Sclerotinia sclerotiorum*) [SCLESC]	Spray	BBCH 61-73 61-67 69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A BRSNW N BRSNS Spring oilseed rape-possible authorization based on the art. 51-minor uses
4	RO	Winter oilseed rape, spring oilseed rape BRSNW, BRSNS	F	Cottony rot (*Sclerotinia sclerotiorum*) [SCLESC]	Spray	BBCH 61-73	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A BRSNW C BRSNS
4	SI		F		Spray		a) 1	-	a) 1.0	a) 160+200	100-400	35		A BRSNW

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**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	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
		Winter oilseed rape, spring oilseed rape BRSNW, BRSNS		Cottony rot (*Sclerotinia sclerotiorum*) [SCLESC]		BBCH 61-73	b) 1		b) 1.0	b) 160+200			Applications are growth stage re-stricted	C BRSNS
4	SK	Winter oilseed rape, spring oilseed rape BRSNW, BRSNS	F	Cottony rot (*Sclerotinia sclerotiorum*) [SCLESC]	Spray	BBCH 61-73	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A BRSNW C BRSNS
4	FR Maritime	Winter oilseed rape, spring oilseed rape BRSNW, BRSNS	F	Cottony rot (*Sclerotinia sclerotiorum*) [SCLESC]	Spray	BBCH 61-73	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A BRSNW C BRSNS
5	~~CEU (~~AT ~~-BE, CZ, DE, HU, IE, NL PL, RO, SI, SK)~~	Winter rye, spring rye SECCW, SECCS	F	Brown rust (*Puccinia recondita*) [PUCCRR]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	C
5	BE	Winter rye, spring rye SECCW, SECCS	F	Brown rust (*Puccinia recondita*) [PUCCRR]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	C
5	CZ	Winter rye, spring rye SECCW, SECCS	F	Brown rust (*Puccinia recondita*) [PUCCRR]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	C
5	DE	Winter rye, spring rye SECCW, SECCS	F	Brown rust (*Puccinia recondita*) [PUCCRR]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	C
5	HU	Winter rye, spring rye SECCW, SECCS	F	Brown rust (*Puccinia recondita*) [PUCCRR]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A SECCW C SECCS
5	IE	Winter rye, spring rye SECCW, SECCS	F	Brown rust (*Puccinia recondita*) [PUCCRR]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**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	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
5	NL	Winter rye, spring rye SECCW, SECCS	F	Brown rust (*Puccinia recondita*) [PUCCRR]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	C
5	PL	Winter rye, spring rye SECCW, SECCS	F	Brown rust (*Puccinia recondita*) [PUCCRR]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	N SECCS Spring rye- possible authorization based on the art. 51-minor uses R SECCW/PUCCRR - in PL only conditional registration is possible - **(final decision is left at the Authority discretion)**
5	RO	Winter rye, spring rye SECCW, SECCS	F	Brown rust (*Puccinia recondita*) [PUCCRR]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A SECCW C SECCS
5	SI	Winter rye, spring rye SECCW, SECCS	F	Brown rust (*Puccinia recondita*) [PUCCRR]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A SECCW C SECCS
5	SK	Winter rye, spring rye SECCW, SECCS	F	Brown rust (*Puccinia recondita*) [PUCCRR]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A SECCW C SECCS
5	FR Maritime	Winter rye, spring rye SECCW, SECCS	F	Brown rust (*Puccinia recondita*) [PUCCRR]	Spray	BBCH 30-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	C
6	~~CEU (~~AT~~, BE, CZ, DE, HU, IE, NL PL, RO, SI, SK)~~	Winter wheat, spring wheat, durum wheat, spelt TRZAW, TRZAS, ~~TRSDU~~ TRZDU, TRZSP	F	Fusarium (*Fusarium species*) FUSASP	Spray	BBCH 59-69	a) 1 a) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**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	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
6	BE	Winter wheat, spring wheat, durum wheat, spelt TRZAW, TRZAS, ~~TRSDU~~ TRZDU, TRZSP	F	Fusarium (*Fusarium species*) FUSASP	Spray	BBCH 59-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	C
6	CZ	Winter wheat, spring wheat, durum wheat, spelt TRZAW, TRZAS, ~~TRSDU~~ TRZDU, TRZSP	F	Fusarium (*Fusarium species*) FUSASP	Spray	BBCH 59-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	C
6	DE	Winter wheat, spring wheat, durum wheat, spelt TRZAW, TRZAS, ~~TRSDU~~ TRZDU, TRZSP	F	Fusarium (*Fusarium species*) FUSASP	Spray	BBCH 59-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	C
6	HU	Winter wheat, spring wheat, durum wheat, spelt TRZAW, TRZAS, ~~TRSDU~~ TRZDU, TRZSP	F	Fusarium (*Fusarium species*) FUSASP	Spray	BBCH 59-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A TRZAW C TRZAS, TRZDU, TRZSP
6	IE	Winter wheat, spring wheat, durum wheat, spelt TRZAW, TRZAS, ~~TRSDU~~ TRZDU, TRZSP	F	Fusarium (*Fusarium species*) FUSASP	Spray	BBCH 59-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	C
6	NL	Winter wheat, spring wheat, durum wheat, spelt TRZAW, TRZAS, ~~TRSDU~~ TRZDU, TRZSP	F	Fusarium (*Fusarium species*) FUSASP	Spray	BBCH 59-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	C
6	PL	Winter wheat, spring wheat, durum wheat, spelt	F	Fusarium (*Fusarium species*) FUSASP	Spray	BBCH 59-69	a) 1 b) 1	-	a) 1.0	a) 160+200	100-400	35		A TRZAW

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**FG or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**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	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
		TRZAW, TRZAS, ~~TRSDU~~ TRZDU, TRZSP							b) 1.0	b) 160+200			Applications are growth stage re-stricted	N TRZAS, TRZDU, TRZSP Durum wheat and spelt - possible authorization based on the art. 51-minor uses
6	RO	Winter wheat, spring wheat, durum wheat, spelt TRZAW, TRZAS, ~~TRSDU~~ TRZDU, TRZSP	F	Fusarium (*Fusarium species*) FUSASP	Spray	BBCH 59-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A TRZAW C TRZAS, TRZDU, TRZSP
6	SI	Winter wheat, spring wheat, durum wheat, spelt TRZAW, TRZAS, ~~TRSDU~~ TRZDU, TRZSP	F	Fusarium (*Fusarium species*) FUSASP	Spray	BBCH 59-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A TRZAW C TRZAS, TRZDU, TRZSP
6	SK	Winter wheat, spring wheat, durum wheat, spelt TRZAW, TRZAS, ~~TRSDU~~ TRZDU, TRZSP	F	Fusarium (*Fusarium species*) FUSASP	Spray	BBCH 59-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	A TRZAW C TRZAS, TRZDU, TRZSP
6	FR Maritime	Winter wheat, spring wheat, durum wheat, spelt TRZAW, TRZAS, ~~TRSDU~~ TRZDU, TRZSP	F	Fusarium (*Fusarium species*) FUSASP	Spray	BBCH 59-69	a) 1 b) 1	-	a) 1.0 b) 1.0	a) 160+200 b) 160+200	100-400	35	Applications are growth stage re-stricted	C

Remarks table:

(1) Numeration necessary to allow references
(2) Use official codes/nomenclatures of EU
(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.*, fumigation of a structure)
(4) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(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
(8) The minimum and maximum number of application possible under practical conditions of use must be provided
(9) Minimum interval (in days) between applications of the same product.
(10) For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products
(11) If water volume range depends on application equipments (e.g., ULVA or LVA) it should be mentioned under "application: method/kind".

fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named

(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

(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

(12) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).

(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 new plant protection product FGF11 containing azoxystrobin and prothioconazole, a product which is being registered in the Central registration zone according to Article 33 of Regulation (EC) No. 1107/2009.

Azoxystrobin was included into Annex I of Council Directive 91/414/EEC (Directive 98/47/EC, 25th June 1998) and approved in accordance with Regulation (EC) No. 1107/2009 by Commission Implementing Regulation (EU) No. 540/2011 (25th May 2011) and renewed by Commission Implementing Regulation (EU) No. 703/2011 (21st July 2011), with the current approval extended until 31st December 2024 by Commission Implementing Regulation (EU) No. 2019/291 (19th February 2019).

Prothioconazole was included into Annex I of Council Directive 91/414/EEC on 1st August 2008 (Directive 2008/44/EC, 4th April 2008) and approved in accordance with Regulation (EC) No. 1107/2009 by Commission Implementing Regulation (EU) No. 540/2011 (25th May 2011), with renewal extended until 15th August 2025 by Commission Implementing Regulation (EU) No. 2023/918 (4th May 2023).

The conclusions on the peer review of the pesticide risk assessment for the active substance azoxystrobin and final renewal report (SANCO/11027/2011 rev. 3 – 20 March 2015) is considered to provide a summary of the relevant review information or a reference to where such information can be found

The conclusions on the peer review of the pesticide risk assessment for the active substance prothioconazole and final renewal report (SANCO/3923/07 final – 26 January 2021) is considered to provide a summary of the relevant review information or a reference to where such information can be found

The Annex I of the Inclusion Directives for azoxystrobin (703/2011/EC) and prothioconazole (2008/44/EC) provides specific provisions 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:

Only uses as fungicides may be authorised.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on azoxystrobin and prothioconazole and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 10th December 2007 and 10th March 2015 shall be taken into account.

There are no specific additional points that Member States need to pay particular attention to with regard to granting of authorisations of plant protection products containing azoxystrobin or prothioconazole relating to efficacy or other Section 3 data requirements.

The objective of this document is to provide data on the efficacy, crop safety and other Section 3 data points in support of the registration of FGF11, a suspension concentrate (SC) formulation containing 160 g/L azoxystrobin and 200 g/L prothioconazole in the EU Central Registration zone with Poland acting as zRMS. cMS are Austria, Belgium, Czech Republic, Germany, Hungary, Ireland, the Netherlands, Romania, Slovakia and Slovenia. Separate registrations will also be requested in the EU Southern Registration zone and the United Kingdom (Great Britain). FGF11 is intended for use as a fungicide for control of foliar and ear diseases (SEPTTR, PUCCST, PUCCRE, PUCCRR, PUCCHD, PYRNTE, RAMUCC, RHYNSE and/or FUSASP) in cereals and SCLESC in oilseed rape.

In response to zRMS comments, this updated version includes additional summaries presented for selected uses to show efficacy from assessments after the first application (and therefore representative of a single application). These new summaries are presented in Section *3.2.3 (Efficacy tests)*.

Additional argumentation is also included to justify the use of data from assessments after the second application as being supportive of the proposed use of a single application. This justification is included in section *Information on trials submitted (3.2 Efficacy data)- Assessment methods*.

All updates are highlighted blue.

The GAP table for the intended uses of FGF11 is included in Table 3.1-1 of this document.

Information on the detailed composition of FGF11 can be found in the confidential dossier of this submission (Registration Report - Part C).

Description of active substances

azoxystrobin

Azoxystrobin, first introduced in 1998, is a systemic and translaminar, broad-spectrum fungicide belonging to the class of methoxy acrylates from the strobilurin chemical family.

Azoxystrobin is readily absorbed by plant foliage and systemic movement following uptake leads to an even distribution of azoxystrobin via the xylem throughout the leaves with no evidence for accumulation at either leaf tips or margins. As a broad spectrum systemic, translaminar, preventative and protectant fungicide, azoxystrobin inhibits spore germination and development, mycelial growth and sporulation.

Products containing azoxystrobin, as straight formulation or in mixture with other fungicides, are registered in the EU for use in arable crops, vegetables, orchards, hops and ornamentals.

prothioconazole

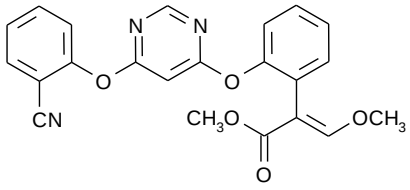
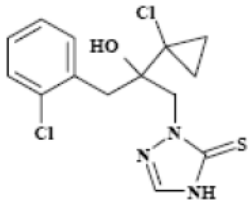
Prothioconazole is a triazolinthione substance with fungicide activity that was developed and introduced by Bayer and first approved in the EU in 2002.

Prothioconazole is a systemic fungicide with long-lasting preventative, curative and eradicative activity, which is quickly absorbed into plant tissue and then moves up through the plant.

A range of commercially available products containing prothioconazole are currently approved and widely used in EU countries for application as foliar applied sprays or as seed treatments for broad spectrum control of fungal pathogens in cereals and oilseed rape.

Table 3.2-1: Details of the active substances

Active substance(s)	azoxystrobin	prothioconazole
Concentration (Unit: g/kg or g/L...)	160 g/L	200 g/L
Chemical name (IUPAC)	Methyl (E)-2-{2[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate	(RS)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3-thione
Chemical name (CA)	Methyl E-2-{2[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy}-α-(methoxymethylene)benzeneacetate	2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1,2-dihydro-3H-1,2,4-triazole-3-thione
CAS no.	131860-33-8	178928-70-6
Molecular formula	C_{22} H_{17} N_3 O_5	C_{14} H_{15} Cl_2 N_3 O_5
Molecular mass	403.40 g/mol	344.26 g/mol

Active substance(s)	azoxystrobin	prothioconazole
Structural formula		
Chemical group	Methoxy-acrylates	Triazolinthiones
Mode of action	Inhibition of mitochondrial respiration (Quinone outside Inhibitor=QoI) working at the level of Complex III of respiratory chain, located in inner mitochondrial membrane, the site Qo. Against pathogens from the Ascomycetes, Basidiomycetes, Deuteromycetes i (QoI fungicide) Inhibition of spore germination, mycelial growth and sporulation	Interference with the synthesis of ergostero. Affected hyphal growth and germ tuve elongation. Inclued diseases caused by Ascomycetes, Basidiomycetes and Deuteromycetes (DMI fungicide)
Plant translocation	Systemic, translaminar	Systemic
Biological action	Preventative, with curative and eradicant properties	Preventative, curative and eradicative

Mode of action

azoxystrobin

Azoxystrobin is a methoxy acrylate that belongs to the FRAC Mode of Action group C3. The mode of action is that of a Quinone outside inhibitor (QoI) that disrupts the mitochondrial respiration of fungi by binding to the Quinol outer binding site of the cytochrome bc1 complex. The subsequent interference with electron flow through the electron transport chain causes the inhibition of ATP formation, a fundamental biochemical process in all classes of fungi. Deprivation of ATP hinders cellular processes requiring energy, such as spore germination and mycelial growth.

prothioconazole

Prothioconazole belongs to the DMI (demethylation-inhibiting) fungicides in FRAC Mode of Action group G1. The mode of action of prothioconazole and other DMI fungicides is to block sterol biosynthesis by inhibiting the Cytochrome P450-dependent C-14 demethylase reaction leading to a reduction in the normal sterol pathway end products and an accumulation of abnormal sterols. This includes effects on the synthesis of ergosterol, an important structural component of many fungal cell membranes, thereby interfering with synthesis of new membranes needed for cell growth. It is not clear which of the two effects (reduction in sterol production or accumulation of abnormal sterols) is primarily responsible for the impairment of membrane function and limitation of fungal growth.

Description of the plant protection product

FGF11, formulated as a suspension concentrate (SC) containing 160 g azoxystrobin/L and 200 g prothioconazole/L, is intended for use as a fungicide for the control of multiple fungal pathogens in cereals and oilseed rape.

In the EU, several products containing azoxystrobin and prothioconazole, are already on the market.

The proposed label rate of FGF11 is 1.0 L product/ha, with a maximum of 1 application per season made when the cereal crops are within the growth stage range of BBCH 30 or 59 until 59 or 69, and when oilseed rape is within the growth stage range of BBCH 61-73; and applications made in water volumes of 100-400 L/ha.

Table 3.2-2: Simplified table of registered and requested uses for FGF11

Uses		Member States	Currently registered rates	Requested rate	Comments
Crops	**Targets**				
TRZAW, TRZAS, TRSDU, TRZSP	SEPTTR	PL, AT, BE, CZ, DE, HU, IE, NL, RO, SI, SK	-	1.0 L/ha	1 application BBCH 30-69 100-400 L/ha
	PUCCST				
	PUCCRE				
	FUSASP				1 application BBCH 59-69 100-400 L/ha
TTLWI, TTLSO	SEPTTR	PL, AT, BE, CZ, DE, HU, IE, NL, RO, SI, SK	-	1.0 L/ha	1 application BBCH 30-69 100-400 L/ha
	PUCCST				
	PUCCRE				
HORVW, HORVS	PYRNTE	PL, AT, BE, CZ, DE, HU, IE, NL, RO, SI, SK	-	1.0 L/ha	1 application BBCH 30-59 100-400 L/ha
	RAMUCC				
	RHYNSE				
	PUCCHD				
SECCW, SECCS	PUCCRE	PL, AT, BE, CZ, DE, HU, IE, NL, RO, SI, SK	-	1.0 L/ha	1 application BBCH 30-69 100-400 L/ha
	PUCCRR				
BRSNW, BRSNS	SCLESC	PL, AT, BE, CZ, DE, HU, IE, NL, RO, SI, SK	-	1.0 L/ha	1 application BBCH 61-73 100-400 L/ha

Description of the target pests

Table 3.2-3: Glossary of pathogens mentioned in the dossier

EPPO code	Scientific name	Common name
SEPTTR	*Zymoseptoria tritici*	Septoria leaf blotch
PUCCST	*Puccinia striiformis*	Yellow rust
PUCCRE	*Puccinia recondita*	Brown rust
FUSASP	*Fusarium species*	Fusarium
PYRNTE	*Pyrenophora teres*	Net blotch
RAMUCC	*Ramularia collo-cygni*	Ramularia leaf spot
RHYNSE	*Rhynchosporium secali*	Leaf blotch
PUCCHD	*Puccinia hordei*	Brown rust of barley
PUCCRR	*Puccinia recondite f. sp. recondita*	Brown rust of rye
SCLESC	*Sclerotinia sclerotiorum*	Cottony rot

A detailed description of each pathogen can be found below.

Septoria leaf spot (*Zymoseptoria tritici*: SEPTTR)

Zymoseptoria tritici (anamorph; teleomorph is *Mycosphaerella graminicola*) is the primary causative fungal agent of Leaf spot in wheat and occasionally affects other cereals including spelt and triticale. It is a disease that occurs worldwide wherever wheat is grown and has a major economic impact in terms yield losses, which can exceed 50% on susceptible varieties under favourably wet conditions.

Zymoseptoria tritici infects the leaf of both hexaploid and tetraploid wheat, although it can also infect spikes. Sources of inoculum that cause new infection include wheat stubble, volunteer plants, susceptible

grasses and infected seed, and it is the air-borne ascospores that primarily infect lower leaves of winter-sown crops. Germination of *Zymoseptoria tritici* by apical cell elongation or budding, which requires temperatures of 15-25°C in wet conditions and can occur at any stage of plant growth, is initiated on the wet leaf surface and germ tubes enter the leaf tissue through stomata or directly through epidermal tissue extending into mesophyll tissue. After a period of biotrophic growth there is a switch to necrotrophic growth and lesions develop around the points of infection. Lesions initially appearing as small yellowish flecks mainly on lower leaves, expanding longitudinally along the veins into irregular red-brown lesions with black pycnidia becoming visible in substomatal cavities as the lesions develop. The ascospores are produced following bipolar heterothallic mating that requires both mating types for sexual reproduction and gather in pseudotheca underneath the host epidermis within necrotic lesions. Secondary spread onto uninfected upper leaves or nearby plants occurs as a result of contact with infected tissue, by rain splash of pycnidia that are released when the leaf has been wet for at least 30 minutes, or by ascospore release. Conidia germinate within 12 hours of leaf contact in high humidity and hyphae penetrate the leaf primarily through the stomata and proliferate in the mesophyll, with the development of yellow to reddish-brown or greyish-white to brown blotches on all above ground parts of the plant.

The overall levels that develop of Septoria leaf spot disease are determined largely by weather conditions during stem extension, rather than by the period of exposure to ascospore distribution.

Brown rust (*Puccinia recondita*: PUCCRE, *Puccinia recondita f. sp. recondita*: PUCCRR)

Brown rust caused by the rust fungus *Puccinia recondita* is a serious fungal disease affecting wheat, triticale and spelt, while *Puccinia recondite f. sp. recondita* is causing the disease on rye.

The life cycle and susceptibility to fungicides of all pathotypes causing Brown rust on cereals are virtually identical. This is the most prevalent of all rust diseases affecting wheat and occurs in almost all areas where the crop is grown. Warm and moist conditions promote the development of the disease.

Brown rust appears as small circular to oval brown pustules on the upper surface of the leaf. These pustules are scattered across the leaves randomly or may group into patches in serious cases. Spores develop on the leaves and leaf sheaths but do not form on the upper stem or ears. Under favourable environmental conditions, rust spores germinate and penetrate the leaf and approximately 10-14 days after infection, the fungi will begin to sporulate and the symptoms become visible on the leaves. *Puccinia recondita* has both an asexual and sexual life cycle. A second host (*Thalictrum* spp.) on which the fungi overwinters is necessary in order to complete the sexual life cycle and where these do not grow the pathogen will only undergo the asexual life cycle over-wintering as mycelium or uredinia.

With warm temperatures favouring infection, the disease develops more rapidly when temperatures are above 15°C, so typically later in the season on more mature crops. However, when the disease develops quickly under favourable conditions, yield losses of between 5 and 20% are normal, but can reach up to 60% in severe cases. In addition to losses in yield, high levels of infection on the leaves can also affect quality by causing grain to shrivel.

Yellow rust (*Puccinia striiformis*: PUCCST)

There are two distinct pathotypes of the Yellow rust basidiomycete fungus that can infect cereals, but by far the most common is that affecting wheat and occasionally triticale (*Puccinia striiformis* f.sp. *tritici*), with that affecting barley (*Puccinia striiformis* f.sp. *hordei*) far less common and rarely of economic importance in Europe.

Epidemics generally occur on susceptible wheat varieties in seasons where a mild winter is followed by a cool moist spring, with *Puccinia striiformis* infection and spread being inhibited by temperatures of 20°C and above. The disease therefore most commonly occurs in Europe in regions with maritime climates or at higher altitudes with cooler temperatures. Under favourable conditions, sexual reproduction occurs and *Puccinia striiformis* can rapidly produce new genetic variants or races that can infect previously resistant varieties, with the disease capable of causing yield losses of up to 40-50% on susceptible varieties and under conditions favourable to disease development.

Puccinia striiformis requires living plant material in order to survive but can withstand very low temperatures as dormant mycelium in overwintering volunteers or early autumn-sown crops. Symptoms develop under cool moist conditions and in early spring small patches or foci of infection appear, with yellow to orange coloured pustules known as uredia seen on leaves. Yellow rust lesions typically spread as a yellow band moving ahead of the pustules across the upper surface of young leaves and on older leaves the pustules occur in obvious stripes. Pustules erupt releasing the asexual urediniospores that are spread by contact with uninfected leaves on the same or nearby plants and by wind dispersal. Germination of the urediniospores is optimal at temperatures of 10-15°C and with high relative humidity, when the germ tubes will extend and penetrate stomata. Once inside the plant, haustoria penetrate into the mesophyll cells and mycelium spread longitudinally between the veins of mature leaves producing hyphal pustules. High levels of infection affects the plants by haustoria extracting nutrients and disrupting the epidermis, which leads to a loss of water retention in the leaves and ultimately to leaf desiccation. Severe attacks give rise to chlorosis and necrosis and in some cases, infection occurs on the ears, with the formation of spore masses between the lemma and the glume.

At the end of the summer, black telia may form on the underside of necrotic leaf tissue giving rise to teliospores and recent research suggests that these may have alternative hosts outside the agricultural environment. Teliospores have the potential to develop into basidia and basidiospores.

Fusarium ear blight (*Fusarium* species: FUSASP)

In addition to causing seedling blight and foot rot at earlier stages of plant development, there are a number of Fusarium species that cause ear blight on many grasses and the majority of cereal types, including wheat, triticale, spelt. The most prevalent species that cause seedling blight symptoms on the ear are *Fusarium culmorum* and *Fusarium graminearum* and others that occur on cereals are *Fusarium poae*, *Fusarium graminum*, *Fusarium sambucinum* and *Microdochium nivale*. Multiple species commonly occur on a cereal crop in the field, with combinations prevalence and relative proportions of the different species varying by area and from year to year dependent on climatic conditions.

Whilst seed-borne infection is a main source of transmission, these Fusarium pathogens are common in the soil and most have competitive saprophytic abilities that allow them to colonise debris and stubble. Warm and dry conditions in the spring promote the production of spores, with high rainfall in June then resulting in water droplet transfer of the spores onto the ears. Whilst optimum conditions for disease development differ slightly between species, infection occurs under warm and humid conditions mainly during flowering and continuation of these conditions together with high rainfall favour further spread and development of the disease on the ears during ripening.

Early symptoms of infection are of small, brown, water-soaked lesions on the outer glumes of florets and under favourable conditions the florets or whole spikelets become infected leading to premature bleaching of spikelets or whole ears. For some species, salmon pink or orange sporodochia become visible on the rachis at the base of infected spikelets under humid conditions and purplish-brown perithecia may also develop on the bracts.

Although, Fusarium ear blight generally has a higher impact on grain quality than on yield and the difficulty of accurately assessing impact on yield, severe and early occurring infections of *Fusarium culmorum* and *Fusarium graminearum* can cause direct losses in yield of up to 30%, with *Microdochium nivale* capable of causing losses of up to 10%. By affecting a spikelet further down the ear, disease infection prevents nutrients and water reaching uninfected spikelets above this point and thereby prevents grain formation or reduces grain fill resulting in the production of small and shrivelled grain.

Another important impact on grain quality caused by Fusarium ear blight infection is that all causal species, with the exception of *Microdochium nivale*, produce mycotoxins that are toxic to both humans and animals. The most significant of these are DON (deoxynivalenol) and ZON (zearalenone) both of which are produced by *Fusarium culmorum* and *Fusarium graminearum* and have stringent permitted tolerance levels set in grain products within the EU.

Leaf blotch (*Rhynchosporium secalis*: RHYNSE) in barley

Leaf blotch is one of the most important diseases of barley crops, particularly in seasons and areas where periods of mild temperatures, high rainfall and humidity occur, favouring disease development. Also occurring in rye, triticale and some wild grasses, *Rhynchosporium secalis* is one of the most destructive pathogens of barley worldwide, commonly causing yield losses of 1-10%, but capable of causing more serious reductions in yield of up to 40% when conditions are highly conducive to disease development and when infection develops between first node detectable and boot-swollen growth stages in both winter and spring barley. As with other foliar diseases, it is the reduction in photosynthetic leaf area that leads to poorly filled grain and reductions in grain yield and quality.

Rhynchosporium secalis is a polycyclic disease, normally involving several generations of the pathogen during a growing season. The fungus overwinters on stubble, debris and infected volunteer plants, and autumn-sown crops can quickly become infected via conidia dispersal onto healthy plant tissue. Unusually, *Rhynchosporium secalis* produces conidia directly from the vegetative hyphae growing under the cuticle, without the formation of conidiophores or other structures, and the initial visual symptoms of disease can appear after sporulation. Although most conidia are dispersed only short distances in splash droplets, some may travel further in small air-borne droplets[1]. Whilst it is known that seed-borne infection is possible, this mode of transmission is not well understood.

The pathogen causes characteristic scald-like lesions on leaves, leaf sheaths and ears, with symptoms first appearing as grey, water-soaked lesions approximately 10 days after infection. These lesions can become dry with a pale green/grey colour, or more generally develop into oval lesions that acquire a dark brown necrotic margin as they age, with the centre of the lesion remaining pale green or straw-coloured. As the disease develops, lesions can coalesce to form large areas of leaf yellowing and with infection also occurring in the leaf axil this can eventually lead to leaf mortality.

Net blotch (*Pyrenophora teres*: PYRNTE) in barley

Net blotch is an important disease in barley and although it can occur in a wide range of grasses, the forms on barley are specific to that crop and do not affect other cereals or grasses. There are two distinct forms of *Pyrenophora. teres* that cause the net form (*Pyrenophora teres* f. *teres*) and the spot form (*Pyrenophora teres* f. *maculate*) of the disease. When occurring at high levels and not effectively controlled, net blotch can cause reductions in grain quality and high losses in yield of up to 40%, particularly in winter barley when disease develops through the winter and into the early spring, to produce an early epidemic as the crop develops.

Net blotch can be seed-borne, in which case mycelium will infect the coleoptile and then the first leaf as it emerges, with the disease then able to spread to other leaves and surrounding plants. However, the main source of inoculum is usually from the pathogen over-wintering in infected stubble and crop debris which is then spread by water splash on to new plants in the next season. Although there are suggestions of long distance spread or ascospores from over-wintering pseudothecia the role of these is not thought to be as important as trash-borne inoculum.

Ramularia leaf spot (*Ramularia collo-cygni* RAMUCC)

Ramularia leaf spot is an important pathogen of barley and can cause extensive damage to the upper leaves in both spring and winter barley once crops have finished flowering, leading to losses in yield, of up to 1 tonne/ha in susceptible varieties, and also reductions in grain quality.

The disease is caused by the fungal pathogen *Ramularia collo-cygni*. The main source of disease spread is from seed-borne infection and a number of studies have shown that *Ramularia collo-cygni* spreads from infected seed into developing plant tissue[2], although secondary infections also occur during the season from air-borne spores released from infected barley crops or volunteers and also host grasses.

The first symptoms appear as small irregular brown ‘pepper-pot’ like lesions on the leaf surface, on lower leaves during tillering or on top leaves at the onset of flowering. These early lesions quickly

[1] Fitt BDL, McCartney HA, Walklate PJ, 1989. The role of rain in dispersal of pathogen inoculum. Annual Review of Phytopathology 27, pp241–70.

[2] Havis ND, et al., 2015. Ramularia collo-cygni – An Emerging Pathogen of Barley Crops. Disease Control and Pest Management, July 2015, Volume 105, Number 7, pp895-904

develop into more typical Ramularia lesions which are rectangular, dark brown, 2mm x 0.5mm in size and with straight vertical edges in line with leaf ridges and irregular horizontal edges. These lesions are surrounded with yellow chlorotic leaf tissue giving a halo like appearance. The disease typically occurs relatively late in the season, causing premature leaf senescence, leading to loss of green leaf area and subsequent yield reductions.

Infection of young seedlings with net blotch can look very similar to leaf stripe infection, with the first leaf often having a single brown stripe extending the whole length of the leaf. However, later leaves do not usually show striped symptoms, with leaves infected by splash-borne spores typically showing short brown stripes or blotches with a network of darker lines at random on the leaves. The disease tends to produce 'stripe' symptoms or 'netting' symptoms which are distinctly different in appearance. There is also another, less common symptom which is termed 'spot blotch' where lesions are more oval in appearance. Leaves frequently have yellowing associated with all types of lesion, particularly when the symptoms are severe. The glumes and awns can also be affected, producing dark brown flecking and striping.

Brown rust of barley (*Puccinia hordei*: PUCCHD)

The main *Pucciniaceae* species that causes Brown rust in barley is *Puccinia hordei* and this is by far the most common of the leaf rusts that affect barley. The disease is present wherever barley is grown and often develops later in the season, commonly occurring on the flag leaf with increased potential to adversely affect grain development. Under optimum conditions for infection and spread, the disease can cause yield losses of 15-50% without the use of an effective fungicide treatment.

Puccinia hordei requires green plant material in order to survive and dormant mycelium or uredia can overwinter on living volunteer barley plants or autumn-sown barley crops. *Puccinia hordei* has both an asexual and sexual life cycle and a second host (*Ornithogalum umbellatum*) on which the fungi overwinters is necessary in order to complete the sexual life cycle. Within this alternative host, teliospores can undergo a sexual cycle to produce aeciospores with the potential to re-infect barley.

The symptoms of *Puccinia hordei* on barley are very similar to those of *Puccinia triticina* on wheat in that small, oval to circular brown-orange spore containing pustules develop mainly on the upper leaf surface, but also occurring on the lower leaves and the leaf sheaths, and these are surrounded by light green or yellow chlorotic halos. Infection can also spread to the stem, glume, and awn if sporulation continues late in the season and under severe disease pressure leaves may die off prematurely. Brown rust on barley develops rapidly under damp conditions and at optimum temperatures within the range of 15-22ºC, when new pustules and spores may be produced within 8 days of infection. Germination of urediniospores is facilitated by night dew and these spores can be dispersed over potentially long distances by the wind. Later in the season, small black thick-walled teliospores develop on the underside of the leaves either within uredial sori or within separate telial sori that can persist between crops.

Cottony rot *(Sclerotinia sclerotiorum:* SCLESC)

Sclerotinia sclerotiorum is the causal agent of Cottony rot affecting a wide range of crops. SCLESC is a soil born disease surviving in the soil by the mean of sclerotia, black dots of 1-10 mm size which can rest for 10 years in the soil.

In the spring, sclerotia can germinate (soil moisture and temperatures >10°C), produce apothecia and when mature these apothecia release spores which contaminate the plant surface, particularly petals. Petal contamination is essential in the spread of the disease as it sticks to the leaf of stem surface and provides a growing medium allowing spores to germinate and penetrate the plant.

Rapidly the first symptoms, pale brown patches, develop but the symptoms more typical of the disease appear later in the season: large white lesions on stems sometimes with black sclerotia visible on the surface and plenty more sclerotia in the stem or root cavity. These lesions cause premature ripening of the pod by disruption of nutrient and water supply. The sclerotia produced during the crop cycle represent a new source of contamination for the soil and of other crop by contamination of the harvest. Conditions favouring the disease are a history of soil contamination, sufficient temperature and showery

conditions to allow the petals to stick during the contamination period. The critical period for the protection of the crop against sclerotinia is the early to mid-flowering.

In the United Kingdom (GB), the economic threshold for intervention was estimated at 10% plants contaminated. The importance of this disease is also growing in other countries of Europe like France or Germany and is directly linked to the intensive cultivation and limited crop rotation. In the coastal region of the northeast of Germany (Mecklenburg-Western Pomerania), up to 30% yield loss can occur.

Table 3.2-4: Major / minor status* of intended uses (for all cMS and zRMS)

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	minor
TRZAW	PL, AT, BE, CZ, DE, HU, IE, NL, RO, SI, SK	-	SEPTTR	PL, AT, BE, CZ, DE, HU, IE, NL, RO, SI, SK	
			PUCCST	PL, AT, BE, CZ, DE, HU, IE, NL, RO, SI, SK	
			PUCCRE	PL, AT, BE, CZ, DE, IE, NL, RO, SI, SK	HU
			FUSASP	PL, AT, BE, CZ, DE, HU, IE, NL, RO, SI, SK	
TRZAS	PL, AT, CZ, DE, HU, NL, RO, SI, SK	BE, IE	SEPTTR	PL, AT, CZ, DE, HU, NL, RO, SI, SK	BE, IE
			PUCCST	PL, AT, CZ, DE, HU, NL, RO, SI, SK	BE, IE
			PUCCRE	PL, AT, CZ, DE, NL, RO, SI, SK	BE, HU, IE
			FUSASP	PL, AT, CZ, DE, HU, NL, RO, SI, SK	BE, IE
TRZDU	AT, DE, HU, SI, SK	PL, BE, CZ, IE, NL, RO	SEPTTR	AT, SI, SK	PL, BE, CZ, DE, HU, IE, NL, RO
			PUCCST	AT, SI, SK	PL, BE, CZ, DE, HU, IE, NL, RO
			PUCCRE	AT, SI, SK	PL, BE, CZ, DE, HU, IE, NL, RO
			FUSASP	AT, SI, SK	PL, BE, CZ, DE, HU, IE, NL, RO
TRZSP	AT, DE	PL, BE, CZ, HU, IE, NL, RO, SI, SK	SEPTTR	AT, DE	PL, BE, CZ, HU; IE, NL, RO, SI, SK
			PUCCST	AT, DE	PL, BE, CZ, HU; IE, NL, RO, SI, SK
			PUCCRE	AT, DE	PL, BE, CZ, HU; IE, NL, RO, SI, SK
			FUSASP	AT, DE	PL, BE, CZ, HU; IE, NL, RO, SI, SK
TTLWI	PL, AT, CZ, DE, HU, RO, SI, SK	BE, IE, NL	SEPTTR	PL, AT, CZ, DE, HU, RO, SI, SK	BE, IE, NL

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	minor
			PUCCST	PL, AT, CZ, DE, HU, RO, SI, SK	BE, IE, NL
			PUCCRE	PL, AT, CZ, DE, RO, SI, SK	BE, HU, IE, NL

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	minor
TTLSO	PL, CZ	AT, BE, DE, IE, HU; NL, RO, SI, SK	SEPTTR	PL, AT, CZ	BE, DE, HU, IE, NL, RO, SI, SK
			PUCCRE	PL, AT, CZ	BE, DE, HU, IE, NL, RO, SI, SK
			PUCCST	AT, CZ	BE, PL, DE, HU, IE, NL, RO, SI, SK
HORVW	PL, AT, BE, CZ, DE, HU, IE, NL, RO, SI, SK	-	RAMUCC	PL, AT, BE, CZ, DE, IE, NL, RO, SI, SK	HU
			RHYNSE	PL, AT, BE, CZ, DE, IE, NL, RO, SI, SK	HU
			PYRNTE	PL, AT, BE, CZ, DE, HU, IE, NL, RO, SI, SK	
			PUCCHD	PL, AT, BE, CZ, DE, HU, IE, NL, RO, SI, SK	
HORVS	PL, AT, CZ, DE, HU, IE, NL, RO, SI, SK	BE	RAMUCC	PL, AT, CZ, DE, IE, NL, RO, SI, SK	BE, HU
			RHYNSE	PL, AT, CZ, DE, IE, NL, RO, SI, SK	BE, HU
			PYRNTE	PL, AT, CZ, DE, HU, IE, NL, RO, SI, SK	BE
			PUCCHD	PL, AT, CZ, DE, HU, IE, NL, RO, SI, SK	BE
SECCW	PL, AT, CZ, DE, HU, SK	BE, IE, NL, RO, SI	PUCCRE	PL, AT, CZ, SK	BE, DE, HU, IE, NL, RO, SI
			PUCCRR	PL, AT, CZ, DE, HU, SK,	BE, IE, NL, RO, SI
SECCS	CZ, HU	PL, AT, BE, DE, IE, NL, RO, SI, SK	PUCCRE	PL, CZ	AT, BE, DE, HU, IE, NL, RO, SI, SK
			PUCCRR	PL, CZ, HU	AT, BE, DE, IE, NL, RO, SI, SK
BRSNW	PL, AT, BE, CZ, DE, HU, IE, RO, SI, SK	NL	SCLESC	PL, AT, BE, CZ, DE, HU, RO, SI, SK	IE, NL
BRSNS	BE, CZ, HU, RO	PL, AT, DE, IE, NL, SI, SK	SCLESC	PL, BE, CZ, HU, RO	AT, DE, IE, NL, SI, SK

*minor/major status according to national guidance on the European Union Minor Uses Database EUMUDA where available. Missing status information was added based on expert judgement

Comments of zRMS:

The cMSs are kindly asked to verify the major / minor status of the intended uses. ZRMS would appreciate it.

Supporting information from earlier formulations of the active substances or similar active substances

All data summarised within this dossier have been generated with the same suspension concentrate (SC) formulation containing 160 g/L azoxystrobin and 200 g/L prothioconazole, which has been identified in trials reports using the name FGF11.

Compliance with the Uniform Principles

All efficacy and crop safety data summarised in this draft registration report have been generated and presented in accordance with the Uniform Principles for evaluation and authorisation of chemical plant protection products, as provided for in Article 29(6) of Regulation (EC) No. 1107/2009 and set out in Commission Regulation (EU) No. 546/2011 (10th June 2011). In compliance with both the general and specific Uniform Principles relating to the evaluation of Efficacy Data and Information for FGF11, trials were carried out according to GEP by testing facilities that have been officially authorised and accredited at national level or have been carried out by professional facilities using SOPs and methods based on Good Experimental Practice. Copies of the GEP certificates for these testing facilities are included in Section 3.7.

In addition, all trials were conducted according to the most current EPPO standard guidelines, with any deviations from these guidelines being described where they have occurred, and justification given for the inclusion of any resulting data in this dRR. The design, analysis of results and reporting of all trials were carried out in accordance with guidelines set out in EPPO standards PP1/152(4) Design and analysis of efficacy evaluation trials and PP1/181(4) Conduct and reporting of efficacy evaluation trials. The conduct of the field work was commensurate with 'Good Agricultural Practice' and in accordance with general guidelines in EPPO standard PP1/135(4) Phytotoxicity assessment, and specific guidelines relevant to the crop.

Justification for data outside countries of submission

Justification for the use of biological efficacy data included in this dossier is made according to EPPO PP 1/241(2) "Guidance on comparable climates".

Efficacy trials from which data are summarized in this dossier were carried out in the following EPPO climatic zones:

Maritime: France, Germany, United Kingdom, Ireland

North-east: Lithuania, Poland, Finland

South-east: Bulgaria, Hungary, Romania

Trials carried out in the Maritime EPPO climatic zone have been conducted in areas where climatic conditions are representative of those in Austria, Belgium, Czech Republic, Germany, Ireland, Netherlands and Great Britain. Data generated in these trials are therefore fully supportive towards demonstrating the efficacy of FGF11 in the EU Central Registration zone with respect to these countries.

Trials carried out in the North-East EPPO climatic zone have been conducted in areas where climatic conditions are representative of those in Poland. Data generated in these trials are therefore fully supportive towards demonstrating the efficacy of FGF11 in the EU Central Registration zone with respect to this country.

Trials carried out in the South-east EPPO climatic zone have been conducted in areas where climatic conditions are representative of those in Romania, Hungary, Slovakia and Slovenia. Data generated in these trials are therefore fully supportive towards demonstrating the efficacy of FGF11 in the EU Central Registration zone with respect to these countries.

Information on trials submitted (3.2 Efficacy data)

Table 3.2-5: 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)
					Mar. zone	Med. zone	N-E zone	S-E zone		
TRZAW	SEPTTR	Germany	2022-2023	MED, E	3 (3)	-	-	-	GEP	
				MED, E, Y, Q	5 (5)	-	-	-	GEP	
		France	2022-2023	MED, E, Y, Q	6 (6)	-	-	-	GEP	
			2022	MED, E	1 (1)	-	-	-	GEP	
		Great Britain	2022	MED, E	2 (2)	-	-	-	GEP	
			2022-2023	MED, E, Y, Q	3 (3)	-	-	-	GEP	
			2024	P	1 (1)	-	-	-	GEP	Greenhouse trial
		Ireland	2022	MED, E, Y, Q	3 (3)	-	-	-	GEP	
		Poland	2022-2023	MED, E	-	-	4 (4)	-	GEP	
				MED, E, Y, Q	-	-	7 (7)	-	GEP	
		Lithuania	2022-2023	MED, E, Y, Q	-	-	4 (4)	-	GEP	
		Hungary	2022-2023	MED, E	-	-	-	4 (4)	GEP	
			2022	MED, E, Y, Q	-	-	-	1 (1)	GEP	
		Bulgaria	2022-2023	MED, E	-	-	-	2 (2)	GEP	
			2022	MED, E, Y, Q	-	-	-	2 (2)	GEP	
		Romania	2022	MED, E	-	-	-	1 (1)	GEP	
			2023	MED, E, Y, Q	-	-	-	4 (4)	GEP	
		Spain	2023-2024	P	-	1 (1)	-	-	GEP	Greenhouse trial
	PUCCST/ PUCCSI	Germany	2022-2023	MED, E	2 (2)	-	-	-	GEP	
			2022	MED, E, Y, Q	2 (2)	-	-	-	GEP	
		France	2022	MED, E, Y, Q	2 (2)	-	-	-	GEP	
		Ireland	2022-2023	MED, E, Y, Q	2 (2)	-	-	-	GEP	
		Poland	2022	MED, E	-	-	2 (2)	-	GEP	
			2023	MED, E, Y, Q	-	-	2 (2)	-	GEP	
		Bulgaria	2022	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)
					Mar. zone	Med. zone	N-E zone	S-E zone		
				Y, Q						
			2023	MED, E	-	-	-	2 (2)	GEP	
		Romania	2023	MED, E	-	-	-	2 (2)	GEP	
	PUCCRE/ PUCCRT	Germany	2022-2023	MED, E, Y, Q	4 (4)	-	-	-	GEP	
		France	2023	MED, E, Y, Q	3 (3)	-	-	-	GEP	
		Great Britain	2022-2023	MED, E, Y, Q	3 (3)	-	-	-	GEP	
		Poland	2022-2023	MED, E	-	-	4 (4)	-	GEP	
			2023	MED, E, Y, Q	-	-	3 (3)	-	GEP	
		Hungary	2022	MED, E, Y, Q	-	-	-	1 (1)	GEP	
			2022-2023	MED, E	-	-	-	3 (3)	GEP	
		Bulgaria	2022	MED, E, Y, Q	-	-	-	1 (1)	GEP	
			2023	MED, E	-	-	-	1 (1)	GEP	
		Romania	2023	MED, E, Y, Q	-	-	-	1 (1)	GEP	
TRZAW (continued)	FUSASP	Germany	2023	MED, E	1 (1)	-	-	-	GEP	
				E	1 (1)	-	-	-	GEP	
		Denmark	2023	E	1 (1)	-	-	-	GEP	
		France	2023	E	3 (3)	-	-	-	GEP	
		Great Britain	2023	MED, E	1 (1)	-	-	-	GEP	
		Ireland	2023	E	2 (2)	-	-	-	GEP	
				MED, E	1 (1)	-	-	-	GEP	
		Poland	2023	E	-	-	6 (6)	-	GEP	
				MED, E	-	-	6 (6)	-	GEP	
		Lithuania	2023	E	-	-	1 (1)	-	GEP	
		Latvia	2023	E	-	-	2 (2)	-	GEP	
		Bulgaria	2023	E	-	-	-	4 (4)	GEP	
				MED, E	-	-	-	1 (1)	GEP	
		Hungary	2023	E	-	-	-	2 (2)	GEP	
				MED, E	-	-	-	2 (2)	GEP	
		Romania	2023	E	-	-	-	4 (4)	GEP	
				MED, E	-	-	-	2 (2)	GEP	
TOTAL	**-**		**2022-2024**		**52 (52)**	**1 (1)**	**41 (41)**	**41 (41)**		

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)
					Mar. zone	Med. zone	N-E zone	S-E zone		
TRZAS	SEPTTR	Germany	2022	MED, E	1 (1)	-	-	-	GEP	
		Germany	2022	MED, E, Y, Q	1 (1)	-	-	-	GEP	
		Denmark	2023	MED, E	1 (1)	-	-	-	GEP	
		Great Britain	2023	MED, E	1 (1)	-	-	-	GEP	
		Ireland	2022	MED, E	1 (1)	-	-	-	GEP	
		Poland	2022	MED, E	-	-	1 (1)	-	GEP	
			2023	MED, E, Y, Q	-	-	1 (1)	-	GEP	
		Romania	2022-2023	MED, E, Y, Q	-	-	-	2 (2)	GEP	
	PUCCSI/ PUCCST	Germany	2023	MED, E	1 (1)	-	-	-	GEP	
		Great Britain	2022-2023	MED, E	2 (2)	-	-	-	GEP	
			2022	MED, E, Y, Q	1 (1)	-	-	-	GEP	
		Poland	2023	MED, E, Y, Q	-	-	2 (2)	-	GEP	
	PUCCRE/ PUCCRT	Poland	2022-2023	MED, E, Y, Q	-	-	2 (2)	-	GEP	
		Romania	2023	MED; E	-	-	-	1 (1)	GEP	
		Hungary	2023	MED, E, Y, Q	-	-	-	1 (1)	GEP	
TOTAL	**-**		**2022-2023**		**9 (9)**	**-**	**6 (6)**	**4 (4)**		
TRZDW/ TRZDU	SEPTTR	Germany	2022-2023	MED, E, Y, Q	3 (3)	-	-	-	GEP	
		Bulgaria	2022	MED, E	-	-	-	1 (1)	GEP	
			2022-2023	MED, E, Y, Q	-	-	-	2 (2)	GEP	
		Romania	2022-2023	MED, E	-	-	-	2 (2)	GEP	
	PUCCSI/ PUCCST	Germany	2023	MED, E, Y, Q	1 (1)	-	-	-	GEP	
		Romania	2022	MED, E	-	-	-	1 (1)	GEP	
	PUCCRE	Germany	2022	MED, E, Y, Q	1 (1)	-	-	-	GEP	
		Romania	2022	MED, E	-	-	-	1 (1)	GEP	
		Bulgaria	2022	MED, E, Y, Q	-	-	-	1 (1)	GEP	
TOTAL	**-**		**2022-2023**		**5 (5)**	**-**	**-**	**8 (8)**		

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)
					Mar. zone	Med. zone	N-E zone	S-E zone		
TRZSP	SEPTTR	Germany	2023	MED, E	1 (1)	-	-	-	GEP	
			2022	MED, E, Y, Q	3 (3)	-	-	-	GEP	
		Hungary	2023	MED, E, Y, Q	-	-	-	1 (1)	GEP	
	PUCCSI/ PUCCST	Germany	2022	MED, E, Y, Q	2 (2)	-	-	-	GEP	
		Bulgaria	2023	MED, E	-	-	-	1 (1)	GEP	
		Romania	2023	MED, E	-	-	-	1 (1)	GEP	
	PUCCRE/ PUCCRT	Germany	2022	MED, E, Y, Q	3 (3)	-	-	-	GEP	
			2023	MED, E	1 (1)	-	-	-	GEP	
TOTAL	-		**2022-2023**		**10 (10)**	-	-	**3 (3)**		
TTLWI	SEPTTR	Germany	2022-2023	MED, E	2 (2)	-	-	-	GEP	
			2023	MED, E, Y, Q	2 (2)	-	-	-	GEP	
		Great Britain	2023	MED, E	1 (1)	-	-	-	GEP	
		Poland	2022-2023	MED, E, Y, Q	4 (4)	-	-	-	GEP	
		Hungary	2023	MED, E, Y, Q	-	-	-	1 (1)	GEP	
		Romania	2022-2023	MED, E	-	-	-	3 (3)	GEP	
	PUCCSI/ PUCCST	Poland	2022-2023	MED, E	-	-	2 (2)	-	GEP	
		Romania	2023	MED, E	-	-	-	1 (1)	GEP	
				MED, E, Y, Q	-	-	-	1 (1)	GEP	
	PUCCRE/ PUCCRT	Germany	2023	MED, E	1 (1)	-	-	-	GEP	
		Poland	2023	MED, E	-	-	2 (2)	-	GEP	
		Hungary	2023	MED, E, Y, Q	-	-	-	2 (2)	GEP	
		Romania	2022	MED, E, Y, Q	-	-	-	1 (1)	GEP	
			2023	MED, E	-	-	-	1 (1)	GEP	
TOTAL	-		**2022-2023**		**10 (10)**	-	**4 (4)**	**10 (10)**		
TTLSO	PUCCST	Poland	2023	MED, E	-	-	1 (1)	-	GEP	
TOTAL	-		**2023**		-	-	**1 (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)
					Mar. zone	Med. zone	N-E zone	S-E zone		
SECCW	PUCCRE/ PUCCRT	Germany	2023	MED, E, Y, Q	1 (1)	-	-	-	GEP	
		France	2022	MED, E	2 (2)	-	-	-	GEP	
		Great Britain	2022	MED, E	2 (2)	-	-	-	GEP	
		Ireland	2023	MED, E, Y, Q	1 (1)	-	-	-	GEP	
		Poand	2022	MED, E, Y, Q	-	-	2 (2)	-	GEP	
			2023	MED, E	-	-	1 (1)	-	GEP	
		Bulgaria	2022	MED, E, Y, Q	-	-	-	1 (1)	GEP	
		Hungary	2023	MED, E, Y, Q	-	-	-	2 (2)	GEP	
		Romania	2022-2023	MED, E	-	-	-	2 (2)	GEP	
TOTAL	-		**2022-2023**		**6 (6)**	-	**3 (3)**	**5 (5)**		
HORVW	PYRNTE	France	2023	MED, E, Y, Q	1 (1)	-	-	-	GEP	
		Great Britain	2022-2023	MED, E	2 (2)	-	-	-	GEP	
			2023	MED, E, Y, Q	1 (1)	-	-	-	GEP	
		Poland	2023	MED, E	-	-	1 (1)	-	GEP	
				MED, E, Y, Q	-	-	3 (3)	-	GEP	
		Bulgaria	2022	MED, E, Y, Q	-	-	-	1 (1)	GEP	
			2023	MED, E	-	-	-	2 (2)	GEP	
		Hungary	2022-2023	MED, E	-	-	-	2 (2)	GEP	
			2023	MED, E, Y, Q	-	-	-	1 (1)	GEP	
		Romania	2022-2023	MED, E	-	-	-	3 (3)	GEP	
	PUCCHD	Germany	2022-2023	MED, E, Y, Q	2 (2)	-	-	-	GEP	
		France	2023	MED, E	1 (1)	-	-	-	GEP	
		Poland	2022	MED, E	-	-	1 (1)	-	GEP	
			2023	MED, E, Y, Q	-	-	3 (3)	-	GEP	
	RAMUCC	Germany	2022-2023	MED, E, Y, Q	2 (2)	-	-	-	GEP	
		France	2023	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)
					Mar. zone	Med. zone	N-E zone	S-E zone		
				Y, Q						
			2022-2023	MED, E	3 (3)	-	-	-	GEP	
	RHYNSE	Germany	2023	MED, E, Y, Q	1 (1)	-	-	-	GEP	
		France	2023	MED, E	1 (1)	-	-	-	GEP	
				MED, E, Y, Q	1 (1)	-	-	-	GEP	
		Great Britain	2022	MED, E	1 (1)	-	-	-	GEP	
				MED, E, Y, Q	1 (1)	-	-	-	GEP	
TOTAL	-		**2022-2023**		**18 (18)**		**8 (8)**	**9 (9)**		
HORVS	PYRNTE	Great Britain	2022	MED, E	1 (1)	-	-	-	GEP	
		Ireland	2023	MED, E, Y, Q	1 (1)	-	-	-	GEP	
		Finland	2022-2023	MED, E, Y, Q	-	-	2 (2)	-	GEP	
		Lithuania	2022	MED, E, Y, Q	-	-	1 (1)	-	GEP	
		Poland	2023	MED, E	-	-	1 (1)	-	GEP	
		Bulgaria	2023	MED, E	-	-	-	1 (1)	GEP	
		Hungary	2023	MED, E, Y, Q	-	-	-	1 (1)	GEP	
		Romania	2023	MED, E	-	-	-	1 (1)	GEP	
	PUCCHD	Poland	2023	MED, E	-	-	1 (1)	-	GEP	
	RAMUCC	Ireland	2023	MED, E, Y, Q	1 (1)	-	-	-	GEP	
TOTAL	-		**2022-2023**		**3 (3)**		**5 (5)**	**3 (3)**		
BRSNW	SCLESC	Germany	2022-2023	MED, E, Y, Q	3 (3)	-	-	-	GEP	
		France	2023	MED, E	2 (2)	-	-	-	GEP	
		Great Britain	2022-2023	MED, E, Y, Q	2 (2)	-	-	-	GEP	
			2022	MED, E	1 (1)	-	-	-	GEP	
		Lithuania	2022	MED, E	-	-	1 (1)	-	GEP	
		Poland	2023	MED, E	-	-	2 (2)	-	GEP	
				MED, E, Y, Q	-	-	2 (2)	-	GEP	
		Bulgaria	2022	MED, E, Y, Q	-	-	-	1 (1)	GEP	
			2023	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)
					Mar. zone	Med. zone	N-E zone	S-E zone		
		Hungary	2022	MED, E	-	-	-	2 (2)	GEP	
			2023	MED, E, Y, Q	-	-	-	3 (3)	GEP	
		Romania	2023	MED, E, Y, Q	-	-	-	3 (3)	GEP	
TOTAL	**-**	**-**	**2022-2023**	**-**	**8 (8)**	**-**	**5 (5)**	**10 (10)**	**-**	

* According to the GAP table
** P = preliminary trial, MED = minimum effective dose, E = efficacy trial, Y = trial with yield assessment in presence of target(s), Q = trial with quality assessment in presence of target(s)
*** GEP: Good Experimental Practices. Official: carried out by a national official organisation

Extrapolation

According to the EPPO guideline PP1/257, regarding fungicides, an extrapolation can be considered as valid if:

- The crop, botanical family, cropping system, growth pattern can be considered as comparable. All cereals (winter and spring wheat, durum wheat, spelt, triticale, winter and spring barley, and winter and spring rye) can be considered as comparable crops. All oilseed rape crops (winter and spring oilseed rape) can also be considered comparable crops.
- The taxonomic relationship, biology, life cycle, behaviour, plant parts attacked, damage caused by diseases can be considered as comparable. Leaf spot, *Zymoseptoria tritici* (SEPTTR), Brown rust, *Puccinia recondita* (PUCCRE/PUCCRR), Yellow rust, *Puccinia striiformis* (PUCCSI), Net blotch, *Pyrenophora teres* (PYRNTE), Ramularia, *Ramularia collo-cygni* (RAMUCC), Leaf blotch, *Rhynchosporium secali* (RHYNSE), Rust, *Puccinia hordeii* (PUCCHD), Cottony rot, *Sclerotinia sclerotiorum* (SCLESC), and Fusarium, *Fusarium* species (FUSASP) can be considered as comparable whatever the cereal crops.
- The growing conditions (field or protected) and cultivation techniques, growing systems, soil type can be considered as comparable. All cereals (winter and spring wheat, durum wheat, spelt, triticale, winter and spring barley, and winter and spring rye) can be considered as agronomic comparable, and all oilseed rape crops (winter and spring oilseed rape) can also be considered comparable.

All data against *Zymoseptoria tritici* (SEPTTR) in winter and spring wheat, durum wheat, spelt, and triticale can be considered as comparable and merged in efficacy section.

All data against *Puccinia striiformis* (PUCCSI) in winter and spring wheat, durum wheat, spelt, and triticale can be considered as comparable and merged in efficacy section.

All data against *Puccinia recondita* (PUCCRE/PUCCRR) in winter and spring wheat, durum wheat, spelt, rye and triticale can be considered as comparable and merged in efficacy section (rye is presented separately).

All data against *Pyrenophora teres* (PYRNTE) in winter and spring barley can be considered as comparable and merged in efficacy section.

All data against *Ramularia collo-cygni* (RAMUCC) in winter and spring barley can be considered as comparable and merged in efficacy section.

All data against *Puccinia hordeii* (PUCCHD) in winter and spring barley can be considered as comparable and merged in efficacy section.

These extrapolations are confirmed by Dutch authorities document[3], SANCO extrapolation document D3/SI2.395857[4], EPPO Standard PP 1/257[5], Guidance on efficacy requirements from CRD Data requirements handbook[6], CRD Efficacy Guideline 407[7] and Polish national extrapolation guidance[8].

Overview of materials and methods for efficacy trials

Information on material and methods for all uses can be found in 3.2.3

Products included in all efficacy trials carried out in cereals and oilseed rape are listed in Table 3.2-6. Details and data for additional candidate formulations included in trials, which are not relevant to this application for the authorisation of FGF11, have not been summarised or included in this dossier but are in the individual trial reports.

Table 3.2-6: Presentation of reference standards used in trials (efficacy trials)

Crop(s)	Product	Country(ies) where the product is registered[1]	Authorisation number	Active substance(s)	Formulation		Registered appl'n rate[3]	Appl'n rate in trials (per treatment)	Remark[4]
					Type[2]	Concentration of a.s.			
Test product									
TRZAW, TRZAS, TRZDU, TRZSP, TTLWI, SECCW, HORVW, HORVS, BRSNW	FGF11	-	-	azoxystrobrin + prothioconazole	EC	160 + 200 g/L	-	0.5 L/ha 0.75 L/ha 1.0 L/ha	
Standard reference products									
TRZAW	Proline*	DE	025287-00	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
		IE	3786				0.8 L/ha	0.8 L/ha	
		LT	AS2-6F(2018)				0.8 L/ha	0.8 L/ha	
		BG	-				-*	0.8 L/ha	
		HU	6300/1205-1/2020				0.6-0.8 L/ha	0.8 L/ha	
		RO	457PC/15.11.2018				0.8 L/ha	0.8 L/ha	
	Melvar	BG	02061-1/31.01.2023	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
	Joao	FR	2060116	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
	Praktis	BG	01860- ПР3-1/10.07.2020 г	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
	Curbatur	DE	025287-60	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
		LT	AS2-80F(2018)				0.8 L/ha	0.8 L/ha	

[3] Appendices Dutch extrapolation document in English EM v2.1
[4] Sanco Technical Report: Proposals for extending and harmonizing efficacy and crop safety extrapolations to reduce the need for efficacy trials on minor crops (SANCO/D3/SI2.395857)
[5] EPPO PP1 - PP1/257(2) - Efficacy and crop safety extrapolations for minor uses
[6] CRD Data Requirements Handbook: Chapter 8: Guidance on Efficacy Requirements
[7] CRD EFFICACY GUIDELINE 407: CEREAL and MAIZE PESTS (Version 1.0, March 2019)
[8] Skuteczność działania środków ochrony roślin - Tabela ekstrapolacji dla sekcji skuteczność PL (aktualizacja 15.09.2023)

Crop(s)	Product	Country(ies) where the product is registered[1]	Authorisation number	Active substance(s)	Formulation		Registered appl'n rate[3]	Appl'n rate in trials (per treatment)	Remark[4]
					Type[2]	Concentration of a.s.			
	Promino 300 EC	PL	R-211/2019	prothioconazole	EC	300 g/L	0.33-0.65 L/ha	0.65 L/ha	for FUSASP only max rate
	Protendo 300 EC	PL	R-224/2019	prothioconazole	EC	300 g/L	0.33-0.65 L/ha	0.65 L/ha	registered against SEPTTR, PUCCSI, FUSASP, for FUSASP only max rate,
	Verben	BG	02062-1/31.01.2023	prothioconazole + proquinazid	EC	200 + 50 g/L	1.0 L/ha	1.0 L/ha	
	Prosaro	BG	05676428, 81782423	prothioconazole + tebuconazole	EC	125 + 125 g/L	1.0 L/ha	1.0 L/ha	
	Elatus Era	FR	2160959	prothioconazole + benzovindiflupyr	EC	150 + 75 g/L	1.0 L/ha	1.0 L/ha	
	Input Classic	DE	025625-00	prothioconazole + spiroxamine	EC	160 + 300 g/L	1.25 L/ha	1.25 L/ha	
TRZAS	Proline	DE	025287-00	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
		DK	18-473				0.8 L/ha	0.8 L/ha	
		IE	3786				0.8 L/ha	0.8 L/ha	
		HU	6300/1205-1/2020				0.6-0.8 L/ha	0.8 L/ha	
		RO	457PC/15.11.2018				0.8 L/ha	0.8 L/ha	
	Promino 300 EC	PL	R-211/2019	prothioconazole	EC	300 g/L	0.33-0.65 L/ha	0.65 L/ha	
	Curbatur	DE	025287-60	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
	Ascra Xpro	DE	008219-00	prothioconazole + fluopyram + bixafen	EC	130 + 65 + 65 g/L	1.5 L/ha	1.5 L/ha	
TRZDW/TRZDU	Proline*	DE	025287-00	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
		BG	-				-*	0.8 L/ha	
		RO	457PC/15.11.2018				0.8 L/ha	0.8 L/ha	
TRZSP	Proline	DE	025287-00	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
		BG*	-				-*	0.8 L/ha	

Crop(s)	Product	Country(ies) where the product is registered[1]	Authorisation number	Active substance(s)	Formulation		Registered appl'n rate[3]	Appl'n rate in trials (per treatment)	Remark[4]
					Type[2]	Concentration of a.s.			
		HU	6300/1205-1/2020				0.6-0.8 L/ha	0.8 L/ha	
		RO	457PC/15.11.2018				0.8 L/ha	0.8 L/ha	
	Curbatur	DE	025287-60	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
	Melvar	BG	02061-1/31.01.2023	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
	Ascra Xpro	DE	008219-00	prothioconazole + fluopyram + bixafen	EC	130 + 65 + 65 g/L	1.5 L/ha	1.2 L/ha	used in 1 trial, lower rate used for low disease pressure
	Fandango	DE	025315-00	prothioconazole + fluoxastrobin	EC	100 + 100 g/L	1.5 L/ha	1.5 L/ha	
TTLWI	Proline*	DE	025287-00	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	registered only against Septoria spp.
		HU	6300/1205-1/2020				0.6-0.8 L/ha	0.8 L/ha	
		RO	457PC/15.11.2018				0.8 L/ha	0.8 L/ha	
	Promino 300 EC	PL	R-211/2019	prothioconazole	EC	300 g/L	0.33-0.65 L/ha	0.65 L/ha	registered in SEPTTR only
	Protendo 300 EC	PL	R-224/2019	prothioconazole	EC	300 g/L	0.33-0.65 L/ha	0.65 L/ha	Registered against SEPTTR only
	Input Classic	DE	025625-00	prothioconazole + spiroxamine	EC	160 + 300 g/L	1.25 L/ha	0.8 L/ha	used in 1 trial, lower rate used for low disease pressure
	Input Triple	DE	008930-00	prothioconazole + proquinazid + spiroxamine	EC	160 + 40 + 200 g/L	1.25 L/ha	1.25 L/ha	

Crop(s)	Product	Country(ies) where the product is registered[1]	Authorisation number	Active substance(s)	Formulation		Registered appl'n rate[3]	Appl'n rate in trials (per treatment)	Remark[4]
					Type[2]	Concentration of a.s.			
SECCE/ SECCW	Proline	DE	025287-00	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
		IE	3786				0.8 L/ha	0.8 L/ha	
		HU	6300/1205-1/2020				0.6-0.8 L/ha	0.8 L/ha	
		RO	457PC/15.11.2018				0.8 L/ha	0.8 L/ha	
	Joao	FR	2060116	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
	Promino 300 EC	PL	R-211/2019	prothioconazole	EC	300 g/L	0.33-0.65 L/ha	0.65 L/ha	
	Prosaro	BG	05676428, 81782423	prothioconazole + tebuconazole	EC	125 + 125 g/L	0.8 L/ha	0.8 L/ha	
HORVW	Proline*	DE	025287-00	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
		BG	-				-*	0.8 L/ha	
		HU	6300/1205-1/2020				0.8 L/ha	0.8 L/ha	
		RO	457PC/15.11.2018				0.8 L/ha	0.8 L/ha	
	Promino 300 EC	PL	R-211/2019	prothioconazole	EC	300 g/L	0.33-0.65 L/ha	0.65 L/ha	
	Protendo 300 EC	PL	R-224/2019	prothioconazole	EC	300 g/L	0.33-0.65 L/ha	0.65 L/ha	
	Melvar	BG	02061-1/31.01.2023	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
	Joao	FR	2060116	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
	Praktis	BG	01860- ПР3-1/10.07.2020 г	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
	Elatus Era	FR	2160959	prothioconazole + benzovindiflupyr	EC	150 + 75 g/L	1.0 L/ha	1.0 L/ha	
	Ascra Xpro	DE	008219-00	prothioconazole + fluopyram + bixafen	EC	130 + 65 + 65 g/L	1.2 L/ha	1.0 L/ha	in trials used in tank mix with Input triple
	Input Triple	DE	008930-00	prothioconazole + proquinazid + spiroxamine	EC	160 + 40 + 200 g/L	1.25 L/ha	0.8 L/ha 1.25 L/ha	in the trials, the lower rate was used in tank mix with Ascra

Crop(s)	Product	Country(ies) where the product is registered[1]	Authorisation number	Active substance(s)	Formulation		Registered appl'n rate[3]	Appl'n rate in trials (per treatment)	Remark[4]
					Type[2]	Concentration of a.s.			
									Xpro
HORVS	Proline*	IE	3786	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
		FI	3082				0.8 L/ha	0.8 L/ha	
		LT	AS2-6F(2018)				0.8 L/ha	0.8 L/ha	registered in TRZAW only*
		BG	-				-*	0.8 L/ha	
		HU	6300/1205-1/2020				0.6-0.8 L/ha	0.8 L/ha	
		RO	457PC/15.11.2018				0.8 L/ha	0.8 L/ha	
	Curbatur	LT	AS2-80F(2018)	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	Registered in TRZAW only*
	Promino 300 EC	PL	R-211/2019	prothioconazole	EC	300 g/L	0.33-0.65 L/ha	0.65 L/ha	
	Protendo 300 EC	PL	R-224/2019	prothioconazole	EC	300 g/L	0.33-0.65 L/ha	0.65 L/ha	
	Melvar	BG	02061-1/31.01.2023	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
	Praktis	BG	01860- ПРЗ-1/10.07.2020 г	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
BRSNW	Proline*	DE	025287-00	prothioconazole	EC	250 g/L	0.7 L/ha	0.7 L/ha 0.8 L/ha	
		FR	-				-*	0.7 L/ha 0.8 L/ha	
		LT	AS2-6F(2018)				0.8 L/ha	0.8 L/ha	Registered in TRZAW only*
		BG	-				-*	0.8 L/ha	
		HU	6300/1205-1/2020				0.8 L/ha	0.8 L/ha	Registered in cereals only*
		RO	457PC/15.11.2018				0.8 L/ha	0.8 L/ha	
	Melvar	BG	02061-1/31.01.2023	prothioconazole	EC	250 g/L	-*	0.8 L/ha	
	Protendo 300 EC	HU	6300/731-1/2021	prothioconazole	EC	300 g/L	0.3-0.6 L/ha	0.6 L/ha	
	Proceed 300	HU	6300/1775-2/2021	prothioconazole	EC	300 g/L	0.3-0.6 L/ha	0.6 L/ha	

Crop(s)	Product	Country(ies) where the product is registered[1]	Authorisation number	Active substance(s)	Formulation		Registered appl'n rate[3]	Appl'n rate in trials (per treatment)	Remark[4]
					Type[2]	Concentration of a.s.			
	Joao	FR	2060116	prothioconazole	EC	250 g/L	0.7 L/ha	0.7 L/ha	
	Prosaro	BG	05676428, 81782423	prothioconazole + tebuconazole	EC	125 + 125 g/L	1.0 L/ha	1.0 L/ha	
	Pictor 400 SC	PL	R-65/2010	boscalid + dimoxystrobin	SC	200+200 g/L	0.5 L/ha	0.5 L/ha	

(1) only on use(s) applied for (with the test product)
(2) e.g. WP (wettable powder), EC (emulsifiable concentrate), etc.
(3) dose(s) / dose range authorized on that use in the country
(4) Other relevant information (e.g. uses, number of applications, spray volume, method of application, etc.)
*In countries where Proline (or equivalent) is not registered but was used in the trials as a zonal transversal reference, a locally registered reference product was used in addition

Assessment methods

For target diseases occurring on leaves and stems in oilseed rape, disease severity was determined by visual estimation of percentage area of the leaf/stem with disease infection on 25 leaves/stems per plot. Disease incidence on the leaves and stems were also recorded.

For target diseases occurring on the leaves in cereals, disease severity was determined by visual estimation of percentage area of the leaf with disease infection symptoms at individual leaf levels on 10 leaves per plot. Disease incidence on the leaves was also recorded.

For target diseases occurring on the ears in cereals, disease severity was determined by visual estimation of percentage area of the ear with disease infection symptoms on 50 ears per plot. Disease incidence on the ears was also recorded.

On some of the trials that generated data on efficacy against FUSASP, laboratory analysis of mycotoxin levels in the grain was determined from samples taken at commercial harvest and bulked across replicates.

Where assessed, green leaf area was determined by visual estimation at individual leaf levels or plants on an overall plot basis.

Where determined, crop yield was evaluated at normal commercial harvest using small plot combines to harvest crop from a fixed area per plot and weighing the amount of grain collected. Moisture content of the grain was also determined, and yield calculated in tonnes/hectare, corrected to moisture content according to national standard. Various seed quality parameters (thousand grain weight, hectolitre weight, oil content) were determined on samples of seed collected from each plot at harvest.

Crop phytotoxicity was assessed at regular intervals throughout the duration of the trials by visual assessments for signs of chlorosis, necrosis or other adverse effects on growth and development, using a percentage scale, where 0=no toxicity and 100=complete plant destruction.

Use of data from assessments after the second application

The Applicant considers that assessment data from after the second application in all relevant trials is supportive of the proposed GAP of a single application. Based upon the new summary tables provided at the end of the subsections for selected uses, for assessments after the first application, it can be seen that levels of efficacy are generally comparable to assessments from after the second application; therefore indicating that data from these later assessments is also supportive of a single application. As the assessments after the second applications were later in the season, disease pressure was greater, so

represents more challenging conditions, and a larger dataset of valid data. The first application in most trials targeted lower leaves on plants where disease levels were lower, and natural senescence often occurred before disease could develop significantly; the lower leaves generally act as a source of infection for upper leaves, on which disease typically develop greater.

It is considered that the second application in all relevant trials targeted different leaf levels and disease populations than the first application. Therefore, it is considered that assessments from after the second application are also representative of a single application. Since Application B targeted upper leaves (L1, L2, L3) at a T2 timing (approximately BBCH 37-45), and it is these leaves which contribute most to yield, it is considered that efficacy from this application is a better demonstration of product efficacy; Application A targeted lower leaves at a T1 timing (approximately BBCH 30-33). It should also be noted that all reference products were applied according to their registered use, including 2 applications.

Generally, many foliar fungicides are only considered to be effective and provide a period of disease protection of 14-21 days. A study by Fang et al., 2023 found that prothioconazole dissipates in wheat leaves by 94-96% within 12 days. Many solo formulated products containing azoxystrobin recommend repeated application in the case of high pressure after 14 days (AMISTAR UK, AMISTAR DE). Therefore, although at the T2 application (B) there may be some residual prothioconazole or azoxystrobin remaining in plants from the T1 application (A), it is considered that the fungicidal effect will be negligible, and that assessments after the second application are representative of the second application, therefore a single application.

The use of assessment data after a T2 application to support a single application use in trials which received T1 and T2 applications, is also supported by the Registration Reports from zRMS Poland, for other cereal foliar fungicides. For registered product **GRETEG** [R171-2021] (product code A7402T) containing 250 g/L difenoconazole, submitted by Syngenta in 2020, an overspray of undefined local registered products was made earlier in the season before the test product was applied at a T2 timing. The exact products used are not described in detail or considered comparable in all trials, yet the data from assessments after the T2 application was accepted by the PL evaluator to support a single application. In the case of FGF11, it could be considered that the T1 application acted as a coverspray, and since it was the same product in all trials, it is considered a better scenario than for A7402T.
For registered product **SORATEL** [R156-2023] (product code ADM.03500.F.2.B / MCW-2075) containing 250 g/L prothioconazole, submitted by Adama in 2021, T1 and T2 applications of the test product were made, and assessments after the second application were considered supportive of a single application. Although data was also presented from assessments preceding the second application, the PL evaluator acknowledged that the interval between both application was usually greater than 14 days, and therefore any remaining effects of the first application was not considered significant, and the evaluator accepts the use of data from assessments after the second application. In the case of FGF11, the interval between application was also usually greater than 14 days (14-36 days for wheat and triticale in EPPO-NE), so it is considered that any potential effects from the first application are negligible at the later assessments.
Therefore, the Applicant requests that the assessment criteria and understanding used by PL evaluators for the registration of **GRETEG** and **SORATEL** is also considered for FGF11.

Numerical and statistical analysis

For all data, the following analysis of variance (ANOVA) assumptions (i) homogeneity of variance and (ii) normality of data were tested. The homogeneity of variance assumption was tested by Bartlett's or Levene's test, whilst the normality of data assumption was tested by Shapiro-Wilks, Skewness and Kurtosis tests. Where assumptions were not met, raw data were transformed appropriately to increase the homogeneity and/or normality of data. In these cases, and depending on the trial, means were reported as de-transformed averages, transformed averages or raw averages with the statistical analysis of the transformed data. If still no homogeneity of variance and/or normality of data was obtained by the transformation, this transformation was cancelled, and the statistical analysis should be treated with caution.

ANOVA was performed on untransformed and transformed data at 95% confidence level. Student Newman-Keuls' (SNK) Post-Hoc multiple comparison test was applied to separate any treatment differences that may be implied by the ANOVA test, and these are indicated by a letter test; treatment means with no letters in common are significantly different according to the SNK test.

Wherever Bartlett's/Levene's test indicated no homogeneity of variance and/or Shapiro-Wilks/Skewness/Kurtosis tests indicated no normality of data, the statistical analysis should be treated with caution.

3.2.1 Preliminary tests (KCP 6.1)

FGF11 is a new product for control of various fungal diseases in wheat (winter, spring, durum), spelt, triticale (winter and spring), rye (winter and spring), barley (winter and spring) and oilseed rape (winter and spring) containing an association of azoxystrobin (160 g/L) and prothioconazole (200 g/L) as a ready mixed co-formulation. Products containing azoxystrobin or prothioconazole, either as the sole active substance or in co-formulations with other active substances, have been authorised for use as fungicides in cereals and oilseed rape in EU countries for a number of years for which effective rates and efficacy against target diseases in cereals and oilseed rape have been widely researched and demonstrated by studies and submitted data supporting current registrations of these products and also proven in commercial practice.

Two (2) preliminary studies conducted in greenhouses between 2023 and 2024 included a comparison to authorised products containing azoxystrobin and prothioconazole alone and applied at rates of active substance matching that delivered by FGF11 applied at the proposed label rate of 1.0 L product/ha. Additionally, the same studies included tank mixtures of approved azoxystrobin and prothioconazole products applied at rates representing different ratios of the 2 active substances. Both studies are presented in this section to provide justification of the combination and the ratio of the two active substances in the co-formulation.

The 2 greenhouse studies were conducted in winter wheat against SEPTTR (*Zymoseptoria tritici*) as target. SEPTTR in winter wheat represents a major significant crop-disease combination and was therefore chosen for the formulation development of FGF11. Once the best formulation was determined, the efficacy of FGF11 against other diseases in various cereals and against SCLESC in oilseed rape was tested and the results are presented in Section 3.2.2 (Minimum effective dose) and Section 3.2.3 (Efficacy tests).

Table 3.2-7: Details on trial methodology (preliminary studies on wheat)

Guidelines	General guidelines	EPPO PP1/152 (4), EPPO PP1/181 (4), EPPO PP1/135 (4), EPPO PP1/214 (4)
	Specific guidelines	EPPO PP1/26 (4)
Experimental design	Plot design	RCBD (2)
	Plot size	0.25-6 m² (2)
	Number of replications	3 (1), 4 (1)
Crop	Trials per crop	Winter wheat (TRZAW) (2)
	Varieties per crop	**TRZAW:** Barrel (1), Tejada (1)
	Sowing period	**TRZAW:** September (1), November (1)
Targets	Target diseases	SEPTTR (2)
Application	Crop stage (BBCH) at application	**TRZAW:** A1: from 29-30 to 31-33 (BBCH) (2), A2: from 32-33 to 39 (BBCH) (2)
	Application period	**TRZAW:** A1: December (1), March (1), A2: January (1), April (1)
	Number of applications	2 (2) with intervals of 24 or 28 days
	Spray volumes	200 L/ha (1), 300 L/ha (1)
Assessments	Assessment types	% disease severity on leaves
	Assessment dates	between 0 and 35 or 45 DA-A2
Other relevant information	e.g. Natural / artificial inoculation	Artificial (2)

	e.g. Field / Greenhouse	Greenhouse (2)

Studies were carried out by ~~organisations~~ organizations that are officially ~~recognised~~ recognized as competent to carry out efficacy testing in accordance with Regulation (EU) 284/2013 by the authorities in the relevant countries.

Links to copies of the GEP certificates for both trials ~~organisations~~ organizations are included in Section 3.7.

On 1 of the 2 studies, 2 applications of the treatments were made on crops growth stage representative of the ones proposed for the application of FGF11. On the other 1 study, a first application was done at crop growth stage of 29-30 (BBCH) and therefore only slightly outside of the GAP crop growth stage. However as second application was done at crop growth stage of 32-33 (BBCH), it is considered that this slight deviation at first application had no negative impact on the efficacy of the product and therefore study is still considered as valid to justify the combination and the ratio of the active substances contained in FGF11.

Although only 1 application is claimed for FGF11, studies with 2 applications are considered as fully valid. The 2nd application targeted new infections on the leaves, therefore assessments after the 2nd application is indicative of a single application.

On both studies applications of the treatments were made in water volumes representative of the ones proposed for the application of FGF11.

Data are summarised in this dossier from assessment timings where mean levels of disease in the untreated control reached ≥5% severity at individual leaf levels following application.

Efficacy data are summarised across studies for disease on the upper leaves (1-3) and/or lower leaves (4) from representative assessment timings in this Section.

Whilst in one of the studies, prothioconazole was applied at 110 or 220 g/ha at first application timing (either alone or in tank mixture) and at 100 or 200 g/ha at second application timing, the difference between 110 or 220 g prothioconazole/ha rates and these of 100 or 200 g/ha is = 10%, with a total difference of 5% taking into account both application timings. Therefore, data from this trial are considered as representative of the efficacy of prothioconazole applied at 100 or 200 g/ha and are presented together with these rates in the summary below.

3.2.1.1.1 Justification of the combination of the active substances in the co-formulation

The efficacy of a tank mixture of azoxystrobin and prothioconazole products at rates of 160 g azoxystrobin/ha + 200 g prothioconazole/ha therefore at rates matching those delivered by FGF11 applied at the proposed label rate of 1.0 L product/ha was compared to equivalent rates of the azoxystrobin and prothioconazole products applied alone on 2 studies carried out under controlled greenhouse conditions. These studies generated data on efficacy against SEPTTR in winter wheat. Of these preliminary greenhouse studies, 1 was carried out in Spain and 1 was carried out in the United Kingdom.

An overall summary of the efficacy of the tank mixture of azoxystrobin and prothioconazole products applied at rates of 160 g azoxystrobin/ha + 200 g prothioconazole/ha with that of the same rates of azoxystrobin and prothioconazole applied alone against SEPTTR in winter wheat at final assessment timings (35-45 DA-A2) across studies is given in Table 3.2-8.

Table 3.2-8: Component justification; comparison of mean overall percentage efficacy of the tank mixture of azoxystrobin and prothioconazole products applied at rates of 160 g azoxystrobin/ha + 200 g prothioconazole/ha to that of azoxystrobin and prothioconazole applied alone at equivalent rates against SEPTTR on winter wheat at final assessment timings (35-45 DA-A2)

No. of trials (no. of data points)	*Untreated*		azoxystrobin		prothioconazole		azoxystrobin + prothioconazole		Statistical comparison of 160 g azoxystrobin/ha + 200 g prothioconazole/ha to#	
			160 g/ha		200 g/ha		160 + 200 g/ha			
	Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max	160 g azoxystrobin/ha	200 g prothioconazole/ha
2 (3)	***64.6***	*28.7-93.3*	**56.9**	32.6-80.0	**62.6**	33.4-86.0	**82.9**	56.9-98.1	> (2), = (1)	> (2), = (1)

No. of data points where >, = or <, based on statistically significant differences at 95% confidence level

Data generated in the greenhouse preliminary studies clearly show the efficacy of the tank mixture of azoxystrobin and prothioconazole products applied at rates of 160 g azoxystrobin/ha + 200 g prothioconazole/ha therefore at rates matching those delivered by FGF11 applied at the proposed label rate of 1.0 L product/ha to be higher and more consistent compared to that given by the same rates of azoxystrobin and prothioconazole applied alone.

FGF11 combines the complementary activity of two active ingredients with different modes of action target sites to give effective preventative, curative and eradicative control of various fungal diseases, therefore is an important part of management strategy in reducing of resistance risk.

Additionally, the use of the combination of azoxystrobin and prothioconazole in FGF11 give effective diseases control with the use of only a single product, whereas the application of more than one alternative product either in tank mixture or applied separately may be less practical and economical.

Furthermore, addition of azoxystrobin in FGF11 have a positive effect on green leaf maintenance – delay in leaf yellowing have potential effect on yield increasing.

Based on the above, the combination of the two active substances in FGF11 and at the amounts delivered when applied at the proposed label rate of 1.0 L product/ha is fully justified.

Comments of zRMS:

2 greenhouse trials have been submitted to justify the combination of the active substances contained in FGF11. Both trials were conducted in winter wheat between 2023 and 2024 in UK and Spain. The tank mixture shows the effect of 98,13% on L1 and 93,53% on L2-4 after 45 DA-A2 against SEPTTR in the trial from Spain. The tank mixture of azoxystrobin and prothioconazole products applied at rates of 160 g azoxystrobin/ha and 200 g prothioconazole/ha achieved superior results compared to azoxystrobin (80% and 58,13%) and prothioconazole (85,97% and 68,58%) applied alone. Significant differences were visible also in the other trial from UK where the tank mixture achieved the mean percentage efficacy of 56,89% on L4. Lower results were on the objects treated of azoxystrobin (32,56%) and prothioconazole (33,39%) applied alone.
Based on the results from greenhouse trials, it can be concluded that the combination of the active substances contained in FGF11 is justified.

3.2.1.1.2 Justification of the ratio of the active substances in the co-formulation

A total of 2 studies carried out in greenhouses between 2023 and 2024 have generated data on the efficacy azoxystrobin and prothioconazole products applied together in tank mixture at rates representing different ratios of the 2 active substances (80 g + 200 g a.i./ha [0.5N+1N], 160 g + 100 g a.i./ha [1N+0.5N] and 160 g + 200 g a.i./ha [1N+1N]). These studies generated data on efficacy against SEPTTR in winter wheat. Of these preliminary greenhouse studies, 1 was carried out in Spain and 1 was carried out in Great Britain.

An overall summary of the efficacy of the tank mixture of azoxystrobin and prothioconazole products applied together in tank mixtures at rates of giving different ratios of the 2 active substances against SEPTTR in winter wheat at final assessment timings (35-45 DA-A2) across studies is given in Table 3.2-9.

Table 3.2-9: Ratio justification; comparison of mean overall percentage efficacy of the tank mixture of azoxystrobin and prothioconazole products at different ratios against SEPTTR on wheat at final assessment timings (35-45 DA-A2)

No. of trials (no. of data points)	*Untreated*		azoxystrobin + prothioconazole						Statistical comparison of 160 g azoxystrobin/ha + 200 g prothioconazole/ha to#	
			80 + 200 g/ha		160 + 100 g/ha		160 + 200 g/ha			
	Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max	80 g azoxystrobin/ha + 200 g prothioconazole/ha	160 g azoxystrobin/ha + 100 g prothioconazole/ha
2 (3)	***64.6***	*28.7-93.3*	**66.3**	40.8-88.9	**69.7**	44.8-92.1	**82.9**	56.9-98.1	> (2), = (1)	> (2), = (1)

No. of data points where >, = or <, based on statistically significant differences at 95% confidence level

Data generated in the greenhouse preliminary studies clearly show the efficacy of the tank mixture of azoxystrobin and prothioconazole products applied at ratio of 160 g azoxystrobin/ha + 200 g prothioconazole/ha therefore at ratio in FGF11 when applied at the proposed label rate of 1.0 L product/ha to be higher and more consistent compared to ratios containing reduced amounts of azoxystrobin or prothioconazole.

Based on the data from these 2 studies, the ratio of 160 g azoxystrobin/ha + 200 g prothioconazole/ha in FGF11 when applied at the proposed label rate of 1.0 L product/ha is fully justified.

Comments of zRMS:

Both greenhouse trials presented significant differences between dose rates of the tank mixture. The mean percentage efficacy of the claimed ratio of 160 g azoxystrobin/ha and 200 g prothioconazole/ha was 98,13% on L1 and 93,53% on L2-4 in the trial from Spain. Lower doses achieved inferior results of 80-85,97% on L1 and 58-13-68,58% on L2-4. In the trial conducted in UK, the claimed ratio achieved moderate efficacy (56,89%) and the lower doses had significant inferior results with the difference about 20%.
Based on the results from greenhouse trials, it can be concluded that the ratios of active substances contained in FGF11 are justified.

3.2.2 Minimum effective dose (KCP 6.2)

3.2.2.1 Minimum effective dose for control of target foliar diseases in winter wheat, spring wheat, durum wheat, spelt, winter triticale and spring triticale

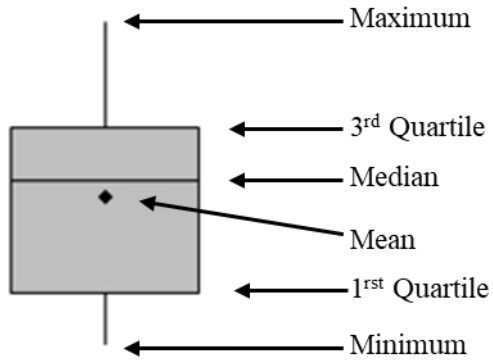
One hundred and twenty two (122) of the 123 trials carried out between 2022 and 2023 generated data on the efficacy of FGF11 applied at a range of rates against target foliar diseases in wheat (winter, spring, durum), spelt and triticale (winter and spring). The data from these trials are summarised in support of justification of the minimum effective dose rate for control of target disease in wheat (winter, spring, durum), spelt and triticale (winter and spring) by FGF11.

The materials and methods used in the efficacy trials from which data are summarized to justify minimum effective dose for control of target foliar diseases in wheat (winter, spring, durum), spelt and triticale (winter and spring) are given in Section 3.2.3.1.

Data are summarised in this dossier from assessment timings where mean levels of disease in the untreated control reached ≥5% severity at individual leaf levels following application.

Only data with ≥6 data points per EPPO climatic zone are presented as a Box-Whisker plot.

The Box-Whisker plot indicate the following values of the relevant summarised aggregated data:



Efficacy data are summarised across trials for disease on the upper leaves (1-3) from representative assessment timings in this Section.

3.2.2.1.1 Minimum effective dose for control of Septoria leaf spot (*Zymoseptoria tritici*: SEPTTR)

A total of 86 trials carried out between 2022 and 2023 generated data on the efficacy of FGF11 applied at a range of rates (0.5 L, 0.75 L and 1.0 L product/ha) against SEPTTR in winter wheat (51 trials), spring wheat (9 trials), durum wheat (8 trials), spelt (5 trials) and winter triticale (13 trials).

Of these trials, 40 were carried out in the Maritime EPPO climatic zone (21 in Germany, 1 in Denmark, 4 in Ireland, 7 in the United Kingdom, 7 in France), 20 were carried out in the North-east EPPO climatic zone (3 in Lithuania, 17 in Poland) and 26 were carried out in the South-east EPPO climatic zone (7 in Bulgaria, 7 in Hungary, 12 in Romania).

Disease developed on all 86 trials and was assessed as percentage severity on the upper leaves (1-3).

Across trials, the efficacy of FGF11 has been evaluated under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in wheat, spelt and triticale crops growing regions across EU Central Registration zone countries.

An overall summary of mean percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against SEPTTR in wheat and triticale at 14 DA-A1 / 12-57 DA-A2 across trials and leaf levels with valid data in each of the EPPO climatic zones is given in Table 3.2-10, with data presented as a Box-Whisker plot in Figure 3.2-1, Figure 3.2-2 and Figure 3.2-3.

Table 3.2-10: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against SEPTTR across trials on wheat and triticale in all climatic zones at 14-15 DA-A1 / 12-57 DA-A2

Registration or EPPO climatic zone	No. of trials (no. of data points)	*Untreated*		FGF11						Statistical comparison of 1.0 L/ha to#	
				0.5 L/ha		0.75 L/ha		1.0 L/ha			
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max	0.5 L/ha	0.75 L/ha
CEU	86 (173)	***16.7***	*5.0-100*	**64.3**	0.0-100	**73.9**	12.5-100	**80.7**	12.5-100	> (78), = (95)	> (27), = (146)
EPPO MAR	40 (74)	***23.4***	*5.0-100*	**59.4**	0.0-100	**69.0**	12.5-100	**75.2**	12.5-100	> (20), = (54)	> (4), = (70)
EPPO NE	20 (42)	***14.3***	*5.1-48.8*	**67.3**	16.7-100	**77.7**	41.4-100	**83.8**	54.4-100	> (25), = (17)	> (12), = (30)
EPPO SE	26 (57)	***9.8***	*5.0-25.0*	**68.4**	31.8-100	**77.6**	40.1-100	**85.4**	51.8-100	> (33), = (24)	> (11), = (46)

No. of data points where >, = or <, based on statistically significant differences at 95% confidence level

Table 3.2-10a: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against SEPTTR across trials on winter wheat in all climatic zones after 1 application

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L2									
North-East (+trials conducted in Germany)	1 trial	***4,1***	-	**66,3**	-	**80,5**	-	**90,0**	-
South-East	1 trial	***4,13***	-	**72,72**	-	**75,15**	-	**88,19**	-
L3									
Maritime	1 trial	***7,48***	-	**36,68**	-	**80,1**	-	**66,54**	-
North-East (+ trials conducted in Germany)	1 trial	***5,2***	-	**63,3**	-	**80,8**	-	**87,2**	-
South-East	4 trials	***6,6***	*5,0-9,23*	**72,2**	67,68-76,3	**80,4**	76,37-84,53	**87,8**	81,94-100
L4									
Maritime	3 trials	***21,5***	*5,0-30,75*	**34,6**	30,0-42,02	**38,97**	35,0-41,31	**43,0**	29,76-50,0
North-East (+trials conducted in Germany)	4 trials	***6,3***	*5,0-7,4*	**54,9**	30,0-66,5	**61,9**	35,0-78,1	**69,3**	50,0-85,4

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
South-East	4 trials	***9,4***	*5,08-11,13*	**59,7**	29,42-73,62	**64,5**	30,71-76,36	**71,8**	37,63-84,08
L5									
Maritime	4 trials	***32,1***	*5,0-83,75*	**56,7**	19,9-100	**65,5**	41,87-100	**69,5**	60,75-100
North-East (+trials conducted in Germany)	5 trials	***9,2***	*4,79-19,5*	**68,1**	39,9-100	**70,3**	48,7-100	**70,3**	43,6-100
South-East	2 trials	***11,99***	*5,85-18,13*	**77,1**	76,41-77,82	**82,7**	79,89-85,51	**90,0**	85,22-94,81

Table 3.2-10b: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against SEPTTR across trials on spring wheat in all climatic zones after 1 application

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L3									
South-East	1 trial	***5,4***	-	**55,1**	-	**62,3**	-	**64,6**	-
L4									
Maritime	1 trial	***5,6***	-	**86,57**	-	**87,84**	-	**99,46**	-
L5									
South-East	1 trial	***5,75***	-	**75,13**	-	**83,96**	-	**90,51**	-

Table 3.2-10c: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against SEPTTR across trials on durum wheat in all climatic zones after 1 application

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L2									
Maritime	1 trial	***5,0***	-	**100**	-	**100**	-	**100**	-

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L3									
South-East	1 trial	***4,1***	-	**65,57**	-	**73,98**	-	**82,7**	-
L4									
Maritime	1 trial	***10,0***	-	**100**	-	**100**	-	**100**	-
South-East	1 trial	***5,2***	-	**88,42**	-	**100**	-	**100**	-

Table 3.2-10d: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against SEPTTR across trials on spelt in all climatic zones after 1 application

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L4									
Maritime	1 trial	***5,75***	-	**100**	-	**100**	-	**100**	-
L5									
Maritime	2 trials	***9,3***	*6,25-12,25*	**69,3**	53,21-85,42	**72,4**	57,38-87,5	**76,1**	61,43-90,83

Table 3.2-10e: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against SEPTTR across trials on winter triticale in all climatic zones after 1 application

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L2									
Maritime	1 trial	***6,9***	-	**53,0**	-	**100**	-	**100**	-
North-East (+trials conducted in Germany)	1 trial	***6,9***	-	**53,0**	-	**100**	-	**100**	-
L3									

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
Maritime	2 trials	***12,7***	*10,4-15,0*	**72,0**	63,3-80,7	**94,9**	89,7-100	**96,4**	92,7-100
North-East (+ trials conducted in Germany)	2 trials	***12,7***	*10,4-15,0*	**72,0**	63,3-80,7	**94,9**	89,7-100	**96,4**	92,7-100
L4									
Maritime	1 trial	***14,1***	-	**58,9**	-	**70,6**	-	**80,9**	-
North-East (+trials conducted in Germany)	2 trials	***10,7***	*7,3-14,1*	**67,1**	58,9-75,2	**75,9**	70,6-81,1	**83,3**	80,9-85,6
South-East	1 trial	***4,4***	-	**45,8**	-	**52,4**	-	**62,8**	-
L5									
North-East (+trials conducted in Germany)	1 trial	***5,5***	-	**79,4**	-	**86,3**	-	**87,7**	-
South-East	2 trials		*5,15-8,5*		68,2-79,49		86,23-87,1		92,81-94,0
L6									
South-East	1 trial	***19,8***	-	**78,0**	-	**84,8**	-	**81,2**	-

Table 3.2-10f: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against SEPTTR across trials on winter wheat in all climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L1									
Maritime	12 trials	***31,3***	*5,6-100*	**54,7**	25,97-93,75	**65,3**	40,48-93,75	**73,8**	46,73-93,75
North-East	6 trials	***21,5***	*6,73-48,75*	**60,4**	16,69-92,03	**77,3**	46,54-97,17	**83,5**	55,17-99,32
South-East	8 trials	***6,9***	*5,12-10,0*	**72,4**	60,45-83,24	**83,8**	71,11-100	**91,2**	75,19-100
L2									

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L1									
Maritime	20 trials	***24,4***	*5,0-61,25*	**61,3**	31,14-100	**71,9**	38,5-100	**77,3**	52,08-100
North-East	13 trials	***14,4***	*5,08-33,25*	**61,2**	31,56-84,81	**72,5**	46,25-93,28	**79,5**	55,44-100
South-East	14 trials	***10,99***	*5,08-22,25*	**66,6**	45,74-75,18	**75,2**	56,08-85,84	**84,8**	67,26-90,33
L3									
Maritime	19 trials	***24,1***	*5,25-61,25*	**53,9**	16,08-93,5	**59,1**	24,6-100	**65,4**	32,19-100
North-East	12 trials	***14,8***	*5,28-34,0*	**66,8**	35,86-100	**73,3**	41,36-100	**79,99**	54,36-100
South-East	13 trials	***11,0***	*6,08-20,75*	**63,7**	31,82-85,8	**72,7**	40,05-100	**80,5**	51,77-100

Table 3.2-10g: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against SEPTTR across trials on durum wheat in all climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L1									
Maritime	2 trials	***37,2***	*6,88-67,5*	**44,5**	12,19-76,85	**79,2**	64,56-93,87	**95,8**	94,66-96,96
South-East	3 trials	***6,8***	*6,25-7,25*	**81,98**	79,99-83,26	**93,5**	88,12-97,22	**100**	100-100
L2									
Maritime	3 trials	***6,6***	*5,0-9,53*	**54,1**	16,66-100	**70,5**	42,82-100	**80,3**	54,45-100
South-East	3 trials	***6,1***	*5,25-7,38*	**92,1**	76,26-100	**94,95**	84,87-100	**97,2**	91,7-100
L3									
South-East	2 trials	***8,1***	*7,0-9,25*	**72,1**	65,38-78,81	**78,9**	71,81-86,01	**85,6**	78,48-92,8

Table 3.2-10h: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against SEPTTR across trials on spring wheat in all climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L1									
Maritime	2 trials	***7,1***	*6,25-7,98*	**46,3**	0,00-92,61	**71,2**	47,5-94,83	**70,7**	42,5-98,83
South-East	1 trial	***7,13***	-	**76,67**	-	**83,55**	-	**87,42**	-
L2									
Maritime	2 trials	***29,9***	*7,5-52,25*	**26,1**	12,5-39,76	**30,3**	12,5-48,15	**38,7**	12,5-64,86
North-East	1 trial	***5,5***	-	**76,94**	-	**100**	-	**100**	-
South-East	1 trial	***5,25***	-	**78,64**	-	**83,41**	-	**85,91**	-
L3									
Maritime	4 trials	***7,5***	*5,5-9,95*	**69,3**	40,24-100	**72,6**	40,0-88,33	**88,1**	81,06-100
North-East	1 trial	***5,9***	-	**82,86**	-	**91,89**	-	**93,84**	-
South-East	2 trials	***7,8***	*5,3-10,3*	**73,4**	69,5-77,24	**82,5**	78,1-86,8	**87,95**	81,6-94,3

Table 3.2-10i: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against SEPTTR across trials on spelt in all climatic zones after 2 applications

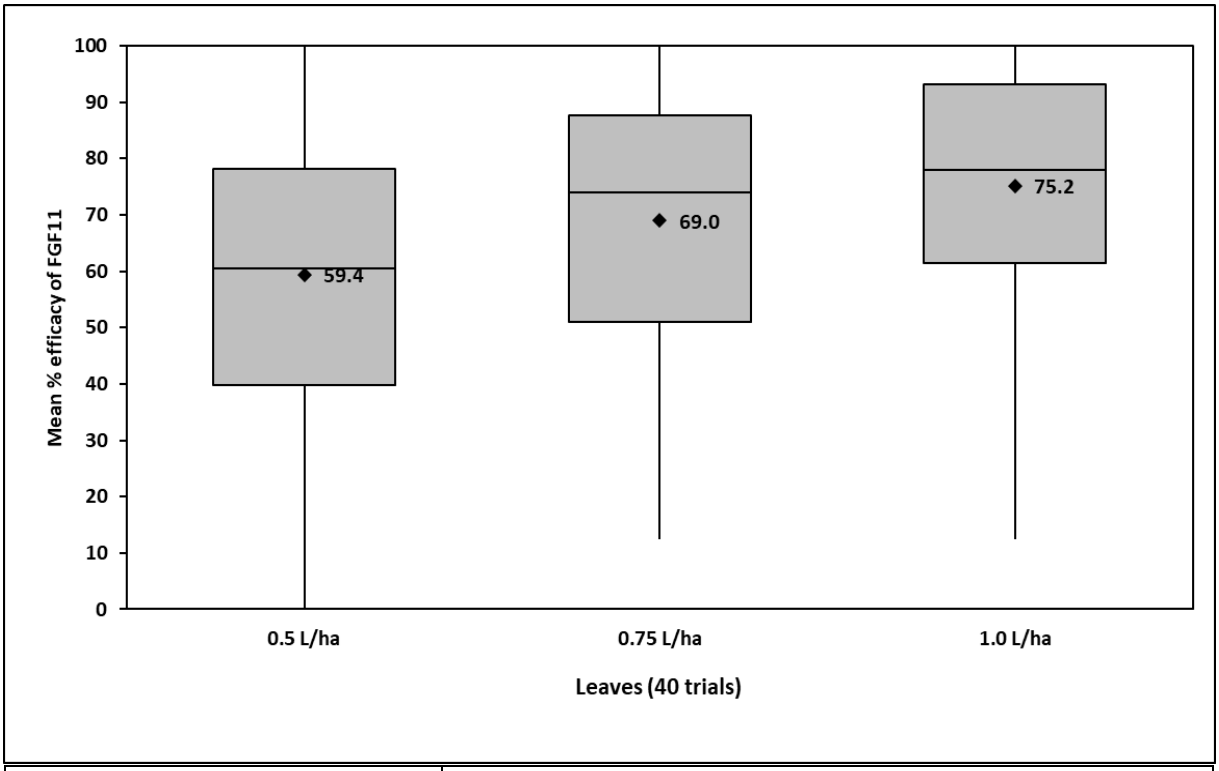
Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L1									
South-East	1 trial	***18,6***	-	**61,73**	-	**69,73**	-	**79,41**	-
L2									
Maritime	1 trial	***5,25***	-	**100**	-	**100**	-	**100**	-
L3									
Maritime	3 trials	***15,6***	*5,18-35,0*	**72,1**	51,58-87,33	**73,7**	58,01-82,92	**73,9**	60,15-83,34

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L1									
South-East	1 trial	***16,3***	-	**61,22**	-	**69,72**	-	**71,03**	-

Table 3.2-10j: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against SEPTTR across trials on winter triticale in all climatic zones after 2 applications

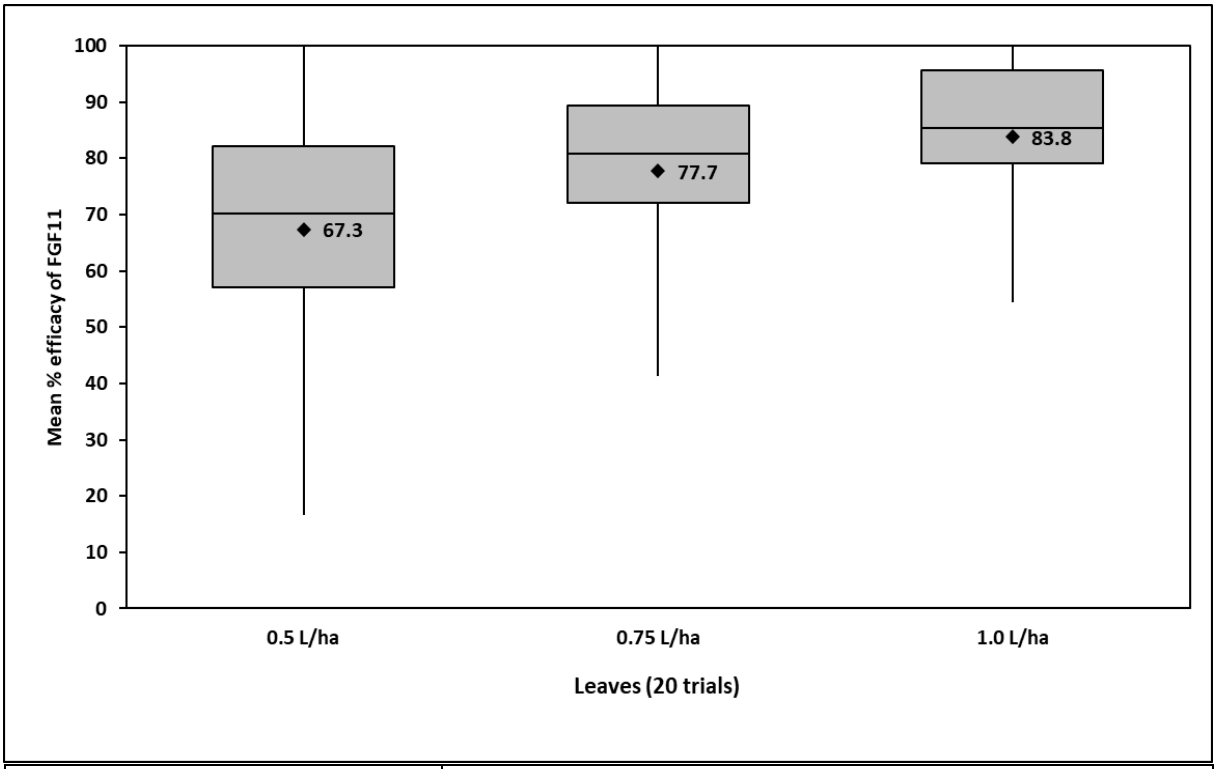
Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L1									
North-East	2 trials	***9,6***	*7,63-11,48*	**78,9**	76,98-80,99	**92,7**	85,39-100	**95,1**	90,18-100
South-East	1 trial	***5,0***	-	**45,49**	-	**66,33**	-	**76,53**	-
L2									
Maritime	2 trials	***18,99***	*16,13-21,85*	**62,2**	57,45-66,87	**100**	100-100	**100**	100-100
North-East	4 trials	***9,1***	*5,16-14,63*	**81,7**	73,99-90,64	**86,3**	81,84-91,4	**92,9**	85,39-100
South-East	2 trials	***17,6***	*10,13-25,0*	**55,1**	41,03-69,1	**66,8**	55,55-77,95	**78,3**	71,32-85,32
L3									
Maritime	5 trials	***26,1***	*9,18-37,1*	**88,3**	75,37-100	**94,7**	89,46-100	**93,3**	75,0-100
North-East	3 trials	***13,9***	*6,14-23,5*	**74,4**	61,3-87,87	**85,4**	82,17-90,65	**89,4**	85,44-95,91
South-East	4 trials	***11,0***	*6,3-17,63*	**64,2**	56,03-78,94	**74,2**	64,18-89,32	**86,3**	77,56-96,13

Figure 3.2-1: Dose justification; mean efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against SEPTTR across 40 trials on wheat and triticale, Maritime EPPO climatic zone



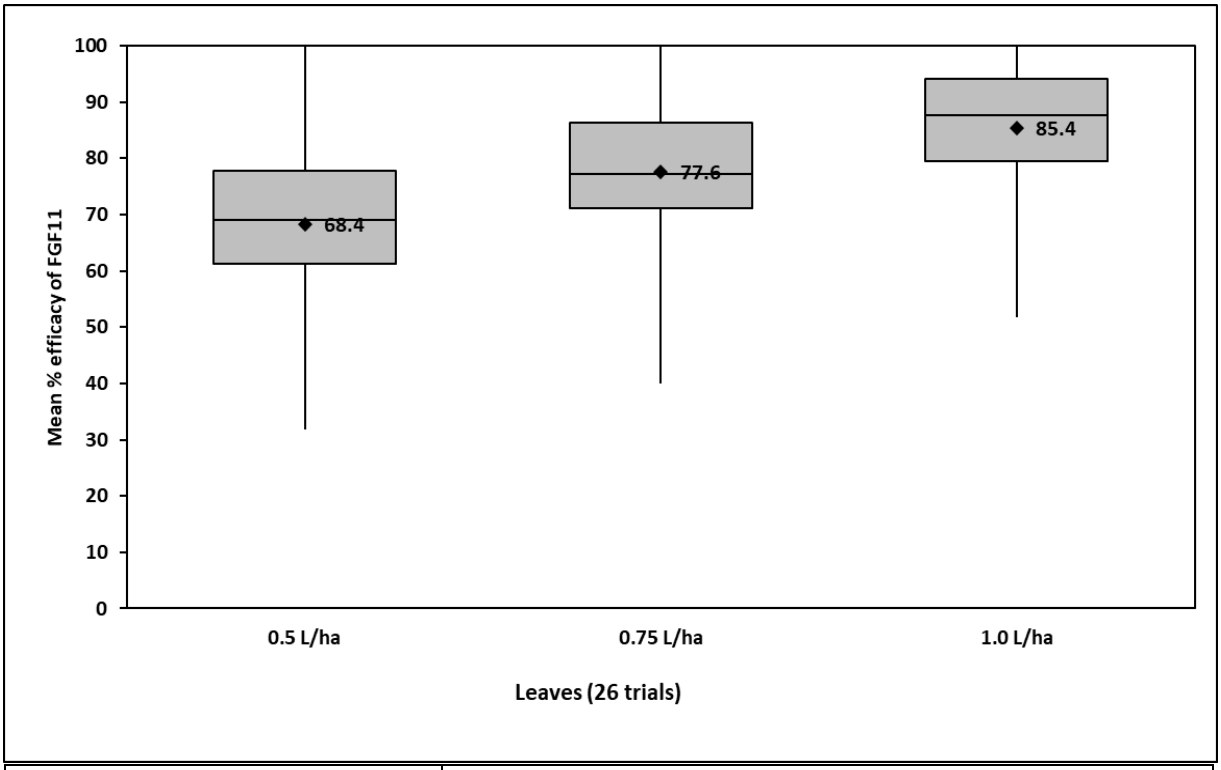
	Mean % efficacy of FGF11		
	0.5 L/ha	**0.75 L/ha**	**1.0 L/ha**
No. of trials (no. of data points)	40 (74)	40 (74)	40 (74)
Mean	**59.4**	**69.0**	**75.2**
S.D.	25.3	22.3	20.4
Q1	39.9	51.0	61.4
Median	60.5	74.0	77.9
Q3	78.2	87.7	93.2

Figure 3.2-2: Dose justification; mean efficacy (based on disease severity on the leaves 1-3) of FGF11 applied at a range of rates against SEPTTR across 20 trials on wheat and triticale, North-east EPPO climatic zone



	Mean % efficacy of FGF11		
	0.5 L/ha	**0.75 L/ha**	**1.0 L/ha**
No. of trials (no. of data points)	20 (42)	20 (42)	20 (42)
Mean	**67.3**	**77.7**	**83.8**
S.D.	18.1	15.6	14.0
Q1	57.1	72.0	79.0
Median	70.2	80.7	85.4
Q3	82.1	89.5	95.6

Figure 3.2-3: Dose justification; mean efficacy (based on disease severity on the leaves 1-3) of FGF11 applied at a range of rates against SEPTTR across 26 trials on wheat and triticale, South-east EPPO climatic zone



	Mean % efficacy of FGF11		
	0.5 L/ha	**0.75 L/ha**	**1.0 L/ha**
No. of trials (no. of data points)	26 (57)	26 (57)	26 (57)
Mean	**68.4**	**77.6**	**85.4**
S.D.	13.4	13.2	12.1
Q1	61.2	71.1	79.5
Median	69.1	77.2	87.6
Q3	77.8	86.4	94.0

Data generated in trials carried out in Maritime, North-east and South-east EPPO climatic zones clearly show the efficacy of FGF11 applied at 1.0 L product/ha against SEPTTR in wheat and triticale to be higher and more consistent compared to that of lower rates (0.75 L and 0.5 L product/ha).

Whilst no or limited data have been generated in support of justifying the minimum effective dose of FGF11 for control of SEPTTR in spring wheat, durum wheat, spelt, winter and/or spring triticale in some of the EPPO climatic zones, the susceptibility of the crops to this fungal pathogen, disease development pressure and development patterns, agronomy of the crops and areas in which the crops are grown in the Central Registration zone and Great Britain can be considered to be sufficiently similar between different cereal crops for the data generated in trials in winter wheat to also provide justification of the same rate with respect to efficacy against SEPTTR in spring wheat, durum wheat, spelt, winter and spring triticale.

Furthermore, products containing prothioconazole and azoxystrobin straight and as mixture are already registered against SEPTTR in the different cereal types mentioned above throughout Europe. The registered rate is generally the same for spring, winter and durum wheat, spelt and winter and spring triticale. The minimum effective dose of FGF11 against SEPTTR was extensively proven in winter wheat and was confirmed by trials in other cereal types. It can therefore be considered that the minimum effective dose of FGF11 for all types of wheat, spelt and triticale is the same.

It is therefore reasonable to conclude that the proposed label rate of 1.0 L product/ha is fully justified as the minimum effective dose for the control of SEPTTR in wheat (winter, spring, durum), spelt and triticale (winter and spring) by FGF11.

Comments of zRMS:

1 application

Winter wheat

A total of 16 efficacy trials have been submitted to determine the minimum effective dose for the control of *Zymoseptoria tritici* (SEPTTR) in winter wheat after 1 application.

In the Maritime EPPO climatic zone, 6 trials were conducted in 2022. FGF11 applied at dose rate of 1 l/ha achieved medium level of control with the results of 66,54% on L3 and 69,5% on L5. Significant inferior effectiveness was visible at lower dose rates of 0,75 l/ha and 0,5 l/ha.

In the North-East zone, 4 trials were conducted between 2022 and 2023. Also 3 trials from Germany can ~~be~~ support ~~for~~ the Polish registration. The test product at claimed dose presented medium level of control on L4 (69,3%) and L5 (70,3%). Good efficacy with the results of 90% on L2, 87,2% on L3 was in 1 out of 7 trials. Slight inferior results was noted at the lower dose of 0,75 l/ha.

In the South-East zone, 6 trials were conducted between 2022 and 2023. FGF11 at 1 l/ha presented good control with the results of 88,19% on L2, 87,8% on L3 and 90% on L5. Significant inferior effectiveness was observed at the lower doses.

Taking into account all zones, the dose rate of 1 l/ha can be determined as the minimum effective dose for the control of SEPTTR in winter wheat.

Spring wheat

A total of 3 efficacy trials have been submitted to determine the minimum effective dose for the control of *Zymoseptoria tritici* (SEPTTR) in spring wheat after 1 application.

In the Maritime EPPO climatic zone, only 1 trial was conducted in 2022. FGF11 at dose rate of 1 l/ha achieved high level of control with the result of 99,46% on L4. Slight inferior efficacy was observed at the lower doses of 0,75 l/ha and 0,5 l/ha. Due to limited number of trials in spring wheat and the opportunities of extrapolation from winter wheat, the claimed dose of 1 l/ha is justified as MED. However, the final decision to accept this use is left to the cMSs.

In the South-East zone, 2 trials were carried out between 2022 and 2023. The test product at claimed dose rate presented good efficacy on L5 (90,51%) and medium level of control on L3 (64,6%). Due to limited number of trials in spring wheat and the opportunities of extrapolation from winter wheat, the claimed dose of 1 l/ha is justified as MED. However, the final decision to accept this use is left to the cMSs.

No results after 1 application were available in the North-East EPPO zone. This use cannot be accepted in Poland. ~~However, 2 trials with 2 applications have been submitted and extrapolation from winter wheat is possible for this use.~~

Taking into account the Maritime and South-East zone, the dose rate of 1 l/ha can be determined as the minimum effective dose for the control of SEPTTR in spring wheat.

Durum wheat

A total of 3 efficacy trials have been submitted to determine the minimum effective dose for the control of *Zymoseptoria tritici* (SEPTTR) in durum wheat after 1 application.

In the Maritime EPPO climatic zone, only 1 trial was conducted in 2022. FGF11 at dose rate of 1 l/ha achieved full effectiveness on L2 and L4. Comparable effect was visible at the lower doses of 0,75 l/ha and 0,5 l/ha. Due to limited number of trials in durum wheat and the opportunities of extrapolation from winter wheat, the claimed dose of 1 l/ha is justified as MED. However, the final decision to accept this use is left to the cMSs.

In the South-East zone, 2 trials were carried out between 2022 and 2023. The test product at the claimed dose rate presented good level of control with the results of 82,7% on L3 and 100% on L4. Significant differences between the dose rate of 1 l/ha and the lower doses were observed on L3. Due to limited number of trials in durum wheat and the opportunities of extrapolation from winter wheat, the claimed dose of 1 l/ha is justified as MED. However, the final decision to accept this use is left to the cMSs.

No results after 1 application were available in the North-East zone. This use cannot be accepted in Poland. Durum wheat is minor crop in Poland and the registration under art. 51 is possible in this case.

Taking into account the Maritime and South-East zone, the dose rate of 1 l/ha can be determined as the minimum effective dose for the control of SEPTTR in durum wheat.

Spelt

Only 2 efficacy trials have been submitted to determine the minimum effective dose for the control of *Zymoseptoria tritici* (SEPTTR) in spelt after 1 application. Both trials were conducted in 2022 in the Maritime EPPO climatic zone. FGF11 at dose rate of 1 l/ha achieved full control on L4 and medium efficacy on L5 (76,1%). Due to limited number of trials in spelt and the opportunities of extrapolation from winter wheat, the claimed dose of 1 l/ha is justified as MED. However, the final decision to accept this use is left to the cMSs.
No results after 1 application were available in the North-East and South-East EPPO zone. This use cannot be accepted in Poland. Spelt is minor crop in Poland and the registration under art. 51 is possible in this case. The cMSs belonging to the SE zone are kindly asked to consider this use at the national level.
Taking into account the Maritime zone, the dose rate of 1 l/ha can be determined as the minimum effective dose for the control of SEPTTR in spelt.

Winter triticale
A total of 8 efficacy trials have been submitted to determine the minimum effective dose for the control of *Zymospetoria tritici* (SEPTTR) in winter triticale after 1 application.
In the Maritime EPPO climatic zone, 3 trials were conducted in 2023. FGF11 applied at dose rate of 1 l/ha achieved good control with the results of 100% on L2, 96,4% on L3 and 80,9% on L4. Similar effect was observed on L2 and L3 and significant inferior efficacy on L4 at lower dose of 0,75 l/ha. Due to limited number of trials in spelt and the opportunities of extrapolation from winter wheat, the claimed dose of 1 l/ha is justified as MED. However, the final decision to accept this use is left to the cMSs.
In the North-East zone, 2 trials were carried out in 2023. Also 3 trials from Germany can be support for the Polish registration. The test product at the claimed dose rate presented good efficacy with the results of 100% on L2, 96,4% on L3, 83,3% on L4 and 87,7% on L5. Comparable effect was visible at the lower dose of 0,75 l/ha on L2, L3 and L5 and medium efficacy was noted on L4.
In the South-East zone, 3 trials were conducted between 2022 and 2023. FGF11 at 1 l/ha achieved sufficient control with the results of 93,4% on L5 and 81,2% on L6. Medium efficacy was observed on L4 (62,8%) in 1 trial. No significant differences between the dose rates of 1 l/ha and 0,75 l/ha were detected. Due to limited number of trials in winter triticale and the opportunities of extrapolation from winter wheat, the claimed dose of 1 l/ha is justified as MED. However, the final decision to accept this use is left to the cMSs.
Taking into account all zones, the dose rate of 1 l/ha can be determined as the minimum effective dose for the control of SEPTTR in winter triticale.

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2 applications
Winter wheat
A total of 51 efficacy trials have been submitted to determine the minimum effective dose for the control of *Zymoseptoria tritici* (SEPTTR) in winter wheat after 2 applications.
In the Maritime EPPO climatic zone, 23 trials were conducted between 2022 and 2023. FGF11 applied at 1 l/ha achieved medium level of control with the result of 73,8% on L1, 77,3% on L2 and 65,4% on L3. Lower doses of 0,75 l/ha and 0,5 l/ha presented significant inferior efficacy.
In the North-East EPPO climatic zone, 14 trials were conducted between 2022 and 2023. FGF11 applied at 1 l/ha achieved good results with the mean effectiveness of 83,5% on L1, 79,5% on L2 and 79,99% on L3. Medium level of control was visible for the lower doses.
In the South-East EPPO climatic zone, 14 trials were conducted between 2022 and 2023. FGF11 applied at 1 l/ha achieved good control of disease pathogens with the results of 91,2% on L1, 84,8% on L2 and 80,5% on L3 after second application. Significant inferior efficacy was observed in case of dose rates of 0,75 l/ha and 0,5l/ha.
Taking into account all zones, the dose rate of 1 l/ha can be determined as the minimum effective dose for the control of SEPTTR in winter wheat.

Durum wheat
A total of 8 efficacy trials have been submitted to determine the minimum effective dose for the control of *Zymoseptoria tritici* (SEPTTR) in durum wheat after 2 applications.
In the Maritime zone, 3 trials were conducted between 2022 and 2023. FGF11 at 1 l/ha achieved good efficacy with the results of 95,8% on L1 and 80,3% on L2. Lower dose of 0,75 l/ha was significant inferior and the dose rate of 0,5 l/ha was insufficient for the control of intended pathogen.
In the South-East zone, 5 trials were carried out between 2022 and 2023. FGF11 at claimed dose presented good control with the results of 100% on L1, 97,2% on L2 and 85,6% on L3. Slight inferior efficacy was visible for lower doses.
No efficacy trials were available in durum wheat in the North-East EPPO zone. Durum wheat is minor crop in Poland and the registration under art. 51 is possible in this case.

Taking into account the Maritime and South-East zone, the dose rate of 1 l/ha can be determined as the minimum effective dose for the control of SEPTTR in durum wheat.

Spring wheat
A total of 9 efficacy trials have been submitted to determine the minimum effective dose for the control of *Zymoseptoria tritici* (SEPTTR) in spring wheat after 2 applications.
In the Maritime zone, 5 trials were carried out between 2022 and 2023. FGF11 at 1 l/ha achieved varied results with the control of 70,7% on L1, 38,7% on L2 and 88,1% on L3. Lower dose rates of 0,75 l/ha and 0,5 l/ha presented inferior results.
In the North-East zone, only 2 trials were conducted between 2022 and 2023. The claimed dose rate of 1 l/ha presented high efficacy in both trials (100% on L2 and 93,84% on L3). Also lower doses achieved sufficient results. The trials submitted from Germany can ~~be~~ support ~~for~~ the Polish registration.
In the South-East zone, only 2 trials were carried out between 2022 and 2023. FGF11 at 1 l/ha achieved good level of control with the results of 87,42% on L1, 85,91% on L2 and 87,95% on L3. Slight differences between the claimed dose and lower dose of 0,75 l/ha was visible. The dose rate of 0,5 l/ha was significant inferior.
Taking into account all zones, the dose rate of 1 l/ha can be determined as the minimum effective dose for the control of SEPTTR in spring wheat.

Spelt
A total of 5 efficacy trials have been submitted to determine the minimum effective dose for the control of *Zymoseptoria tritici* (SEPTTR) in spelt after 2 applications.
In the Maritime zone, 4 trials were conducted between 2022 and 2023. FGF11 applied at 1 l/ha achieved medium level of control in most of trials with the results of 100% on L2 (only 1 trial) and 73,9% on L3. Similar effect was observed for the lower doses. Due to limited number of trials in spelt and the opportunities of extrapolation from winter wheat, the claimed dose of 1 l/ha is justified as MED. However, the final decision to accept this use is left to the cMSs.
In the South-East zone, only 1 trial was carried out in 2023. FGF11 at 1 l/ha achieved medium efficacy with the results of 79,41% on L1 and 71,03% on L3. Significant inferior control was observed for the lower doses. Due to limited number of trials in spelt and the opportunities of extrapolation from winter wheat, the claimed dose of 1 l/ha is justified as MED.
No efficacy trials were available in spelt in the North-East EPPO zone. Spelt is minor crop in Poland and the registration under art. 51 is possible in this case.
Taking into account the Maritime and South-East zone, the dose rate of 1 l/ha can be determined as the minimum effective dose for the control of SEPTTR in spelt.

Winter triticale
A total of 13 efficacy trials have been submitted to determine the minimum effective dose for the control of *Zymoseptoria tritici* (SEPTTR) in winter triticale after 2 applications.
In the Maritime zone, 5 trials were conducted between 2022 and 2023. FGF11 at 1 l/ha achieved high level of control with the results of 100% on L2 and 93,3% on L3. Similar effect was visible for the lower dose of 0,75 l/ha and slight inferior efficacy for the dose rate of 0,5 l/ha. Due to limited number of trials in winter triticale and the opportunities of extrapolation from winter wheat, the claimed dose of 1 l/ha is justified as MED. However, the final decision to accept this use is left to the cMSs.
In the North-East zone, 4 trials were carried out between 2022 and 2023. FGF11 at claimed dose of 1 l/ha presented good control with the results of 95,1% on L1, 92,9% on L2 and 89,4% on L3. Similar effect was observed for the lower dose of 0,75 l/ha and medium efficacy for the dose rate of 0,5 l/ha. Due to limited number of trials in winter triticale and the opportunities of extrapolation from winter wheat, the claimed dose of 1 l/ha is justified as MED. However, the final decision to accept this use is left to the cMSs.
In the South-East zone, 4 trials were conducted between 2022 and 2023. The test product at 1 l/ha achieved sufficient level of control with the results of 76,53% on L1, 78,3% on L2 and 86,3% on L3. Significant inferior efficacy was noted for the lower doses.
Taking into account all zones, the dose rate of 1 l/ha can be determined as the minimum effective dose for the control of SEPTTR in winter triticale.

3.2.2.1.2 Minimum effective dose for control of Yellow rust (*Puccinia striiformis*: PUCCST/PUCCSI)

A total of 34 trials carried out between 2022 and 2023 generated data on the efficacy of FGF11 applied at a range of rates (0.5 L, 0.75 L and 1.0 L product/ha) against PUCCST (21 trials) or PUCCSI (13 trials)

in winter wheat (12 trials), spring wheat (6 trials), durum wheat (1 trial), spelt (2 trials), winter triticale (2 trials) and spring triticale (1 trial).

Of these trials, 15 were carried out in the Maritime EPPO climatic zone (8 in Germany, 2 in Ireland, 3 in the United Kingdom, 2 in France), 9 were carried out in the North-east EPPO climatic zone (all in Poland) and 10 were carried out in the South-east EPPO climatic zone (4 in Bulgaria, 6 in Romania).

Disease developed on all 34 trials and was assessed as percentage severity on the upper leaves (1-3).

Across trials, the efficacy of FGF11 has been evaluated under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in wheat, spelt and triticale crops growing regions across EU Central Registration zone countries.

An overall summary of mean percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCST and PUCCSI in wheat and triticale at 15-22 DA-A1 / 14-45 DA-A2 across trials in each of the EPPO climatic zones is given in Table 3.2-11, with data presented as a Box-Whisker plot in Figure 3.2-4, Figure 3.2-5 and Figure 3.2-6.

Table 3.2-11: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCST and PUCCSI across trials on wheat and triticale in all climatic zones at 15-22 DA-A1 / 14-45 DA-A2

Registration or EPPO climatic zone	No. of trials (no. of data points)	*Untreated*		FGF11						Statistical comparison of 1.0 L/ha to#	
				0.5 L/ha		0.75 L/ha		1.0 L/ha			
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max	0.5 L/ha	0.75 L/ha
CEU	34 (65)	***16.8***	*5.0-75.8*	**77.0**	12.2-100	**85.6**	36.7-100	**89.9**	30.2-100	> (25), = (40)	> (5), = (60)
EPPO MAR	15 (30)	***23.6***	*5.0-75.8*	**76.0**	12.2-100	**83.2**	36.7-100	**87.3**	30.2-100	> (8), = (22)	> (1), = (29)
EPPO NE	9 (17)	***12.9***	*5.3-46.1*	**81.4**	63.6-100	**92.2**	77.1-100	**95.8**	83.9-100	> (8), = (9)	> (3), = (14)
EPPO SE	10 (18)	***9.0***	*5.1-18.0*	**74.4**	58.9-90.4	**83.4**	70.9-96.3	**88.5**	77.8-100	> (9), = (9)	> (1), = (17)

No. of data points where >, = or <, based on statistically significant differences at 95% confidence level

Table 3.2-11a: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCST and PUCCSI across trials on winter wheat in all climatic zones after 1 application

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L2									
Maritime	1 trial	***36,0***	-	**81,11**	-	**89,29**	-	**90,82**	-
L3									
Maritime	3 trials	***16,7***	*4,5-29,0*	**92,9**	85,5-100	**92,9**	82,09-100	**93,2**	82,49-100
North-East (+trials conducted in Germany)	2 trials	***4,95***	*4,5-5,4*	**93,1**	86,2-100	**93,1**	86,2-100	**90,9**	81,7-100
L4									
Maritime	1 trial	***12,23***	-	**93,72**	-	**93,09**	-	**91,58**	-
North-East (+trials conducted in Germany)	1 trial	***5,1***	-	**79,2**	-	**94,9**	-	**100**	-
South-East	2 trials	***5,2***	*4,9-5,5*	**96,1**	92,1-100	**100**	100-100	**100**	100-100

Table 3.2-11b: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCST and PUCCSI across trials on spring wheat in all climatic zones after 1 application

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L1									
Maritime	1 trial	***5,8***	-	**90,85**	-	**100**	-	**100**	-
L2									
Maritime	1 trial	***6,43***	-	**70,87**	-	**88,38**	-	**94,83**	-
L3									
Maritime	1 trial	***14,75***	-	**60,46**	-	**69,52**	-	**91,02**	-

Table 3.2-11c: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCST and PUCCSI across trials on winter triticale in all climatic zones after 1 application

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L2									
North-East (+trials conducted in Germany)	1 trial	***4,17***	-	**70,43**	-	**75,0**	-	**75,0**	-
L3									
North-East (+trials conducted in Germany)	1 trials	***6,63***	-	**97,71**	-	**99,76**	-	**100**	-
South-East	1 trial	***6,7***	-	**88,0**	-	**94,0**	-	**93,8**	-

Table 3.2-11d: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCST and PUCCSI across trials on spring triticale in all climatic zones after 1 application

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L5									
North-East (+trials conducted in Germany)	1 trial	***5,3***	-	**93,3**	-	**95,2**	-	**100**	-

Table 3.2-11e: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCST and PUCCSI across trials on winter wheat in all climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L1									
Maritime	8 trials	***25,2***	*5,0-73,5*	**88,5**	59,19-100	**91,6**	71,2-100	**94,6**	83,61-100
North-East	3 trials	***7,9***	*5,3-11,25*	**73,1**	67,51-78,79	**86,5**	77,13-96,01	**90,6**	83,94-99,22
L2									
Maritime	6 trials	***34,3***	*7,13-75,75*	**85,3**	68,75-100	**87,2**	70,21-100	**90,3**	80,34-99,18
North-East	3 trials	***17,4***	*6,23-34,25*	**79,3**	67,26-90,42	**86,99**	79,6-95,13	**91,6**	84,18-99,59
South-East	5 trials	***8,4***	*6,88-10,3*	**70,9**	65,24-84,45	**82,9**	76,37-96,26	**86,8**	81,73-100
L3									
Maritime	1 trial	***28,75***	-	**51,82**	-	**51,37**	-	**66,64**	-
North-East	1 trial	***46,13***	-	**79,23**	-	**87,0**	-	**88,37**	-
South-East	4 trials	***10,6***	*10,0-11,25*	**75,4**	63,25-88,69	**83,6**	70,88-94,17	**87,8**	77,77-97,04

Table 3.2-11f: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCST and PUCCSI across trials on spring wheat in all climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L1									
Maritime	2 trials	***16,5***	*5,75-27,2*	**45,7**	23,47-67,9	**65,5**	36,71-94,29	**64,8**	30,16-99,38
North-East	2 trials	***8,3***	*6,75-9,75*	**83,5**	78,66-88,39	**97,3**	94,66-100	**100**	100-100
L2									
Maritime	3 trials	***18,2***	*5,75-38,88*	**92,7**	79,01-100	**96,2**	89,61-100	**98,9**	96,56-100
North-East	2 trials	***10,9***	*10,13-11,63*	**83,1**	81,27-84,96	**95,7**	91,42-100	**100**	100-100
L3									
Maritime	2 trials	***22,7***	*15,78-29,63*	**72,2**	49,19-95,23	**80,2**	64,32-96,08	**92,7**	86,79-98,61
North-East	1 trial	***7,0***	-	**100**	-	**100**	-	**100**	-

Table 3.2-11g: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCST and PUCCSI across trials on durum wheat in all climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L1									
Maritime	1trial	***17,73***	-	**18,02**	-	**45,06**	-	**57,31**	-
L2									
Maritime	1 trial	***11,03***	-	**17,92**	-	**43,77**	-	**56,35**	-
L3									
Maritime	1 trial	***17,48***	-	**12,16**	-	**47,7**	-	**66,92**	-
South-East	1 trial	***7,58***	-	**73,05**	-	**79,07**	-	**87,14**	-

Table 3.2-11h: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCST and PUCCSI across trials on spelt in all climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L1									
Maritime	1trial	***17,5***	-	**100**	-	**100**	-	**100**	-
South-East	1 trial	***5,08***	-	**74,98**	-	**77,36**	-	**92,57**	-
L2									
Maritime	2 trials	***15,0***	*5,0-25,0*	**83,3**	66,67-100	**96,9**	93,75-100	**91,3**	82,5-100
South-East	2 trials	***9,7***	*7,18-12,28*	**65,5**	58,89-72,19	**78,8**	78,33-79,28	**86,3**	84,91-87,74
L3									
South-East	2 trials	***11,8***	*5,6-18,0*	**81,1**	71,91-90,37	**87,5**	79,55-95,54	**92,2**	84,41-100

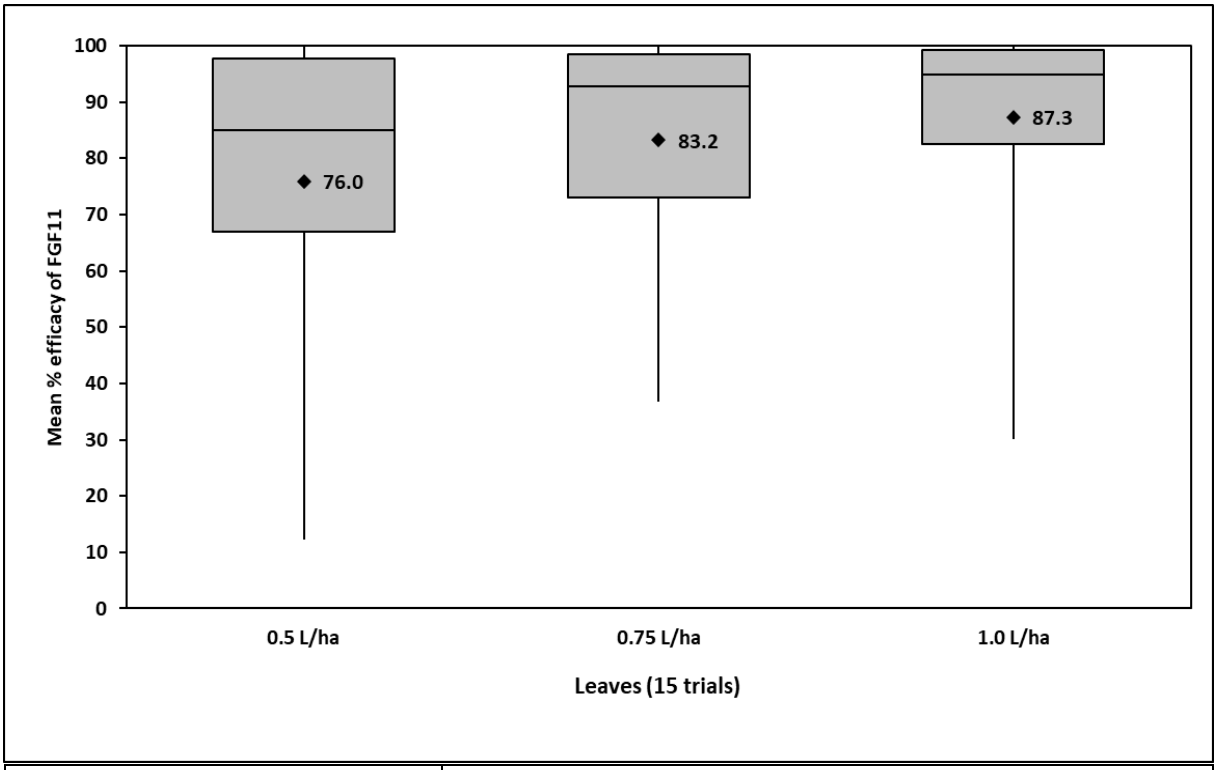
Table 3.2-11i: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCST and PUCCSI across trials on spring triticale in all climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L2									
North-East	1 trial	***10,38***	-	**85,37**	-	**100**	-	**100**	-
L3									
North-East	1 trial	***15,25***	-	**81,01**	-	**94,64**	-	**100**	-

Table 3.2-11j: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCST and PUCCSI across trials on winter triticale in all climatic zones after 2 applications

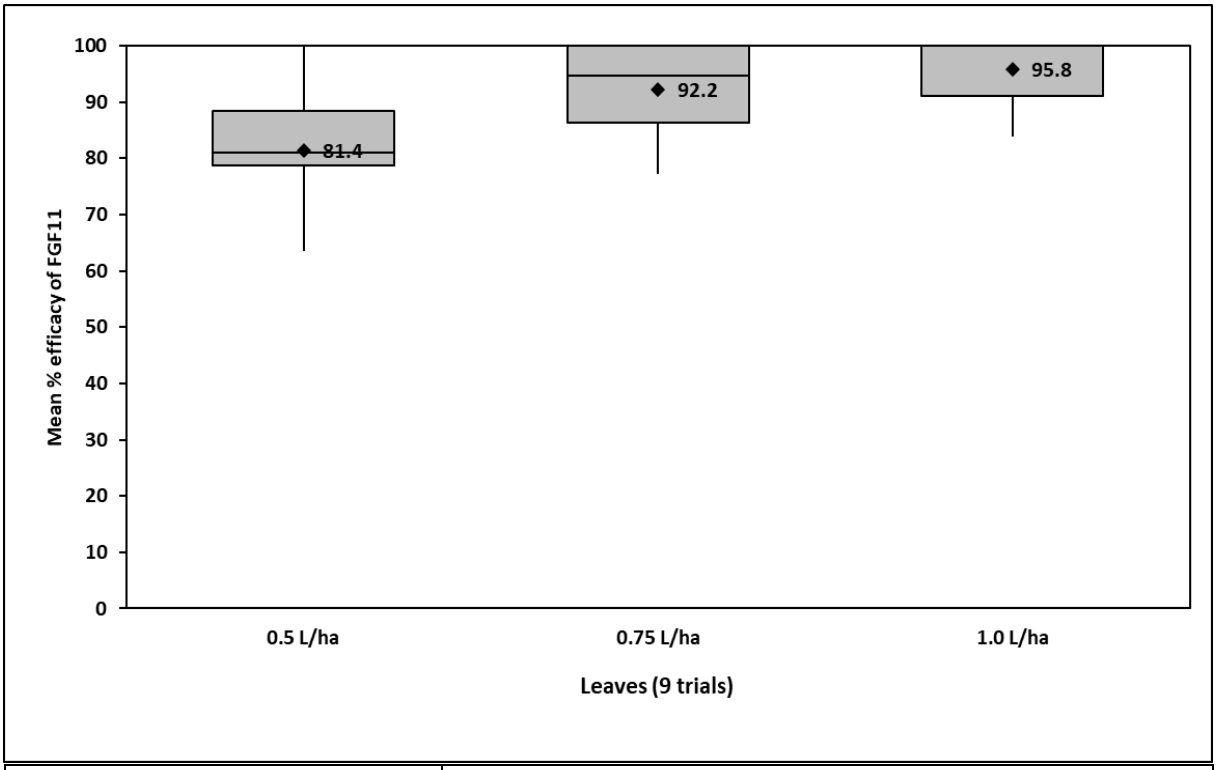
Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L2									
North-East	1 trial	***6,4***	-	**91,34**	-	**93,75**	-	**100**	-
South-East	1 trial	***7,43***	-	**88,9**	-	**92,14**	-	**97,92**	-
L3									
North-East	2 trials	***9,98***	*5,47-14,5*	**78,5**	63,59-93,44	**92,9**	85,82-100	**96,9**	93,7-100
South-East	1 trial	***7,5***	-	**65,32**	-	**76,51**	-	**79,96**	-

Figure 3.2-4: Dose justification; mean efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCST (including PUCCSI) across 15 trials on wheat, Maritime EPPO climatic zone



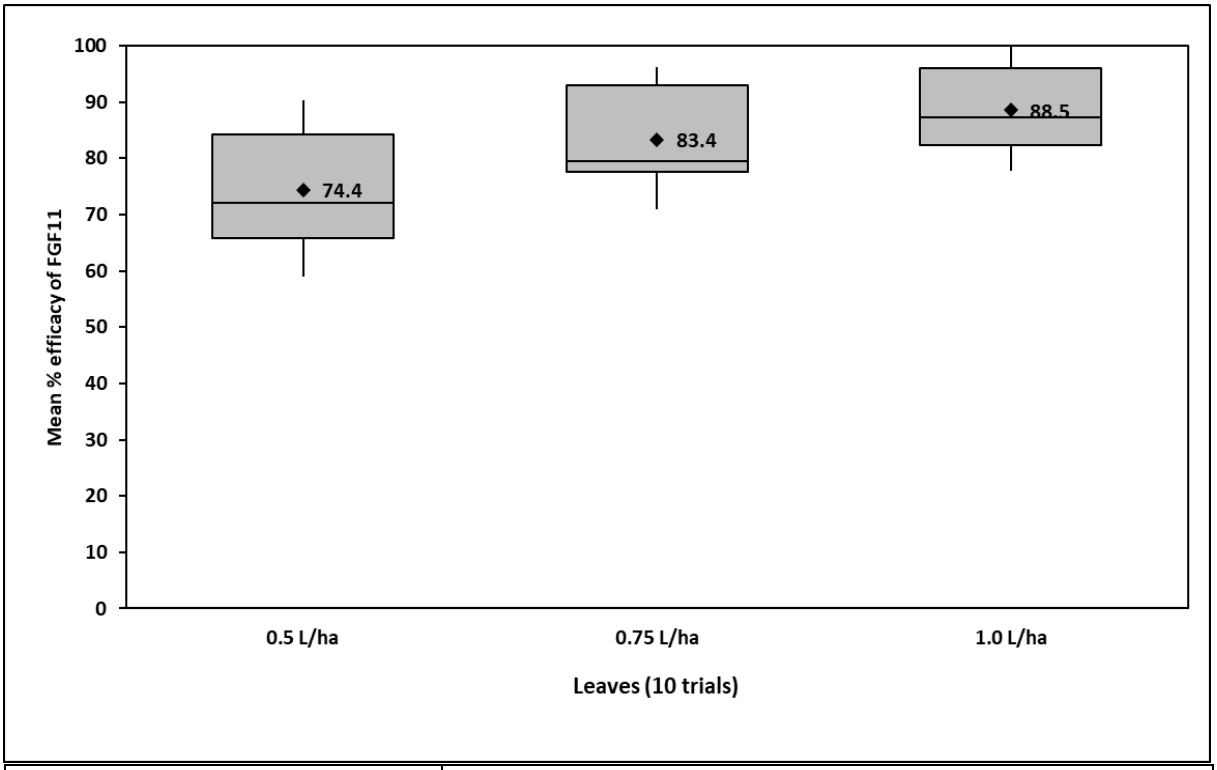
	Mean % efficacy of FGF11		
	0.5 L/ha	**0.75 L/ha**	**1.0 L/ha**
No. of trials (no. of data points)	15 (30)	15 (30)	15 (30)
Mean	**76.0**	**83.2**	**87.3**
S.D.	27.5	20.1	16.8
Q1	67.0	73.1	82.5
Median	84.9	92.8	95.0
Q3	97.7	98.5	99.3

Figure 3.2-5: Dose justification; mean efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCST (including PUCCSI) across 9 trials on wheat and triticale, North-east EPPO climatic zone



	Mean % efficacy of FGF11		
	0.5 L/ha	**0.75 L/ha**	**1.0 L/ha**
No. of trials (no. of data points)	9 (17)	9 (17)	9 (17)
Mean	**81.4**	**92.2**	**95.8**
S.D.	9.8	7.4	6.1
Q1	78.7	86.3	91.1
Median	81.0	94.6	100
Q3	88.4	100	100

Figure 3.2-6: Dose justification; mean efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCST (including PUCCSI) across 10 trials on wheat and triticale, South-east EPPO climatic zone



	Mean % efficacy of FGF11		
	0.5 L/ha	**0.75 L/ha**	**1.0 L/ha**
No. of trials (no. of data points)	10 (18)	10 (18)	10 (18)
Mean	**74.4**	**83.4**	**88.5**
S.D.	10.3	8.3	7.5
Q1	65.8	77.6	82.4
Median	72.1	79.4	87.3
Q3	84.3	92.9	96.1

Data generated in trials carried out in Maritime, North-east and South-east EPPO climatic zones clearly show the efficacy of FGF11 applied at 1.0 L product/ha against PUCCST (including PUCCSI) in wheat and triticale to be higher and more consistent compared to that of lower rates (0.75 L and 0.5 L product/ha).

The morphology, life cycles and infection patterns of different *Puccinia striiformis* rust pathogens affecting cereals, and also the efficacy of fungicides against the different species, are very similar. Therefore, data generated on efficacy against PUCCSI are fully considered to provide justification of the minimum effective dose rate for control of PUCCST.

Whilst no or limited data have been generated in support of justifying the minimum effective dose of FGF11 for control of PUCCST in spring and winter wheat, durum wheat, spelt, winter and/or spring triticale in some of the EPPO climatic zones, the susceptibility of the crops to this fungal pathogen, disease development pressure and development patterns, agronomy of the crops and areas in which the crops are grown in the Central Registration zone and Great Britain can be considered to be sufficiently similar between different cereal crops for the data generated in trials in winter wheat to also provide justification of the same rate with respect to efficacy against PUCCST in spring wheat, durum wheat, spelt, winter and spring triticale.

Furthermore, products containing prothioconazole and azoxystrobin straight and as mixture are already registered against PUCCST and other foliar diseases in the different cereal types mentioned above

throughout Europe. The registered rate is generally the same against SEPTTR, FUSASP and PUCCST in spring, winter and durum wheat, spelt and winter and spring triticale. The minimum effective dose of FGF11 against SEPTTR and FUSASP was extensively proven in winter wheat and was confirmed by trials in other cereal types and by trials targeting PUCCST. It can therefore be considered that the minimum effective dose of FGF11 against SEPTTR, FUSASP and PUCCST in all types of wheat, spelt and triticale is the same.

It is therefore reasonable to conclude that the proposed label rate of 1.0 L product/ha is fully justified as the minimum effective dose for the control of PUCCST in wheat (winter, spring, durum), spelt and triticale (winter and spring) by FGF11.

Comments of zRMS:

1 application

Winter wheat

A total of 6 efficacy trials have been submitted to determine the minimum effective dose for the control of *Puccinia striiformis* (PUCCST) in winter wheat after 1 application.

In the Maritime EPPO climatic zone, 3 trials were conducted between 2022 and 2023. FGF11 applied at the dose rate of 1 l/ha achieved high level of control with the results of 90,82% on L2, 93,2% on L3 and 91,58% on L4. Comparable effect was observed at the lower doses of 0,75 l/ha and 0,5 l/ha. Due to limited number of trials, the cMSs are kindly asked to consider this use at the national level.

In the North-East zone, only 1 trial was carried out in 2023. Also 1 trial from Germany can ~~be~~ support ~~for~~ the Polish registration. The test product at the claimed dose rate presented high efficacy with the results of 90,9% on L3 and 100% on L4. No significant differences between the dose rates of 1 l/ha and 0,75 l/ha. ~~Due to limited number of trials, this use cannot be accepted in Poland.~~

In the South-East zone, only 2 trials were conducted in 2023. FGF11 at 1 l/ha achieved full effectiveness on L4. Also the lower doses 0,75 l/ha and 0,5 l/ha had sufficient results. However, the cMSs are kindly asked to consider this use at the national level because of limited number of trials.

Spring wheat

Only 1 efficacy trial has been submitted to determine the minimum effective dose for the control of *Puccinia striiformis* (PUCCST) in spring wheat after 1 application. This trial was conducted in 2022 in the Maritime EPPO climatic zone. FGF11 at 1 l/ha achieved high level of control with the results of 100% on L1, 94,83% on L2 and 91,02% on L3. Significant inferior efficacy was observed at the lower doses of 0,75 l/ha and 0,5 l/ha on L2 and L3. Due to limited number of trials, the cMSs are kindly asked to consider this use at the national level. No results after 1 application were available in the North-East and South-East EPPO zone. ~~This use cannot be accepted in Poland.~~ The cMSs belonging to the SE zone are kindly asked to consider this use at the national level.

Winter triticale

A total of 2 efficacy trials have been submitted to determine the minimum effective dose for the control of *Puccinia striiformis* (PUCCST) in winter triticale after 1 application.

In the North-East EPPO climatic zone, only 1 trial was conducted in 2023. FGF11 applied at dose rate of 1 l/ha achieved medium level of control on L2 (75%) and higher efficacy on L3 (100%). Similar effect was observed at the lower dose rates of 0,75 l/ha and 0,5 l/ha. ~~This use cannot be accepted in Poland because of very limited number of trials.~~

In the South-East zone, only 1 trial was carried out in 2023. The test product at the claimed dose presented good control with the efficacy of 93,8% on L3. No significant differences between the dose rate of 1 l/ha and 0,75 l/ha were observed. Sligh inferior result was visible at the dose of 0,5 l/ha. Due to limited number of trials, the cMSs are kindly asked to consider this use at the national level.

No results after 1 application were available in the Maritime EPPO zone. The cMSs are kindly asked to consider this use at the national level.

Spring triticale

Only 1 efficacy trial has been submitted to determine the minimum effective dose for the control of *Puccinia striiformis* (PUCCST) in spring triticale after 1 application. This trial was conducted in 2023 in the North-East EPPO climatic zone. FGF11 at 1 l/ha achieved full effectiveness on L5. High level of control was observed also at the lower dose rates of 0,75 l/ha and 0,5 l/ha. ~~Due to limited number of trials, this use cannot be accepted in Poland.~~

No results after 1 application were available in the Maritime and South-East EPPO zone. The cMSs are kindly asked to consider this use at the national level.

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2 applications

Winter wheat

A total of 17 efficacy trials have been submitted to determine the minimum effective dose for the control of *Puccinia striiformis* (PUCCST/PUCCSI) in winter wheat after 2 applications.

In the Maritime EPPO climatic zone, 8 trials were conducted between 2022 and 2023. FGF11 applied at dose rate of 1 l/ha achieved good efficacy in most of trials with the results of 94,6% on L1 on 90,3% on L2. Medium level of control was noted in one trial (66,64% on L3). Slight inferior effect was observed for lower dose rates of 0,75 l/ha and 0,5 l/ha.

In the North-East zone, 4 trials were conducted between 2022 and 2023. The test product at claimed dose was effective on high level with the results of 90,6% on L1, 91,6% on L2 and 88,37% on L3. Lower doses presented slight inferior efficacy. The trials submitted from Germany can ~~be~~ support ~~for~~ the Polish registration.

In the South-East zone, 5 trials were conducted between 2022 and 2023. FGF11 at 1 l/ha achieved good control with the results of 86,8% on L2 and 87,8% on L3. Similar effect was noted at the dose rate of 0,75 l/ha and significant inferior for 0,5 l/ha.

Taking into account all zones, the dose rate of 1 l/ha can be determined as the minimum effective dose for the control of PUCCST in winter wheat.

Spring wheat

A total of 6 efficacy trials have been submitted to determine the minimum effective dose for the control of *Puccinia striiformis* (PUCCST/PUCCSI) in spring wheat after 2 applications.

In the Maritime EPPO climatic zone, 4 trials were conducted between 2022 and 2023. FGF11 at 1 l/ha achieved sufficient level of control in most of trials with the results of 98,9% on L2 and 92,7% on L3. In 2 out of 4 trials, medium efficacy was noted (64,8% on L1). Lower dose of 0,75 l/ha was slight inferior compared to the claimed dose. Significant differences between 1 l/ha and 0,5 l/ha were observed. Due to limited number of trials in spring wheat and the opportunities of extrapolation from winter wheat, the claimed dose of 1 l/ha is justified as MED. However, the final decision to accept this use is left to the cMSs.

In the North-East zone, only 2 trials were carried out in 2023. FGF11 at 1 l/ha presented full control in both trials. Slight differences between the claimed dose and lower doses were observed. Due to limited number of trials in spring wheat and the opportunities of extrapolation from winter wheat, the claimed dose of 1 l/ha is justified as MED.

No trials have been submitted in the South-East zone. The cMSs are kindly asked to consider this use at the national level.

Taking into account the Maritime and North-East zone, the dose rate of 1 l/ha can be determined as the minimum effective dose for the control of PUCCST in spring wheat.

Durum wheat

A total of 2 efficacy trials have been submitted to determine the minimum effective dose for the control of *Puccinia striiformis* (PUCCST/PUCCSI) in durum wheat after 2 applications.

In the Maritime EPPO climatic zone, only 1 trial was conducted in 2023. FGF11 at 1 l/ha achieved medium level of control with the results of 57,31% on L1, 56,35% on L2 and 66,92% on L3. Significant inferior efficacy was noted for the lower doses of 0,75 l/ha and 0,5 l/ha. Due to limited number of trials in durum wheat and the opportunities of extrapolation from winter wheat, the claimed dose of 1 l/ha is justified as MED. However, the final decision to accept this use is left to the cMSs.

In the South-East zone, only 1 trial was conducted in 2022. The test product at 1 l/ha presented good control with the result of 87,14% on L3. Lower doses were effective on medium level. Due to limited number of trials in durum wheat and the opportunities of extrapolation from winter wheat, the claimed dose of 1 l/ha is justified as MED. However, the final decision to accept this use is left to the cMSs.

No trials were available in the North-East EPPO zone. Durum wheat is minor crop in Poland and the registration under art. 51 is possible in this case.

Taking into account the Maritime and South-East zone, the dose rate of 1 l/ha can be determined as the minimum effective dose for the control of PUCCST in durum wheat.

Spelt

A total of 4 efficacy trials have been submitted to determine the minimum effective dose for the control of *Puccinia striiformis* (PUCCST/PUCCSI) in spelt after 2 applications.

In the Maritime EPPO climatic zone, only 2 trials were conducted in 2022. FGF11 at dose rate of 1 l/ha achieved high efficacy with the results of 100% on L1 and 91,3% on L2. Similar effect was observed for the lower doses of 0,75 l/ha and 0,5 l/ha. Due to limited number of trials in durum wheat and the opportunities of extrapolation from winter wheat, the claimed dose of 1 l/ha is justified as MED. However, the final decision to accept this use is left to the cMSs.
In the South-East zone, only 2 trials were carried out in 2023. The test product at claimed dose presented good level of control in both trials with the results of 92,57% on L1, 86,3% on L2 and 92,2% on L3. Medium efficacy was noted for the lower doses on L1 and L2 and slight inferior results compared to the dose rate of 1 l/ha on L3. Due to limited number of trials in durum wheat and the opportunities of extrapolation from winter wheat, the claimed dose of 1 l/ha is justified as MED. However, the final decision to accept this use is left to the cMSs.
No trials were available in the North-East EPPO zone. Spelt is minor crop in Poland and the registration under art. 51 is possible in this case.
Taking into account the Maritime and South-East zone, the dose rate of 1 l/ha can be determined as the minimum effective dose for the control of PUCCST in spelt.

Spring triticale
Only 1 trial has been submitted to determine the minimum effective dose for the control of *Puccinia striiformis* (PUCCST/PUCCSI) in spring triticale after 2 applications. This trial was conducted in the North-East EPPO zone in 2023. FGF11 at 1 l/ha achieved full control on L2 and L3. Sufficient efficacy was observed also for the lower dose rates of 0,75 l/ha and 0,5 l/ha but significant differences were noted between the claimed dose and 0,5 l/ha. Due to limited number of trials in spring triticale and the opportunities of extrapolation from winter wheat, the claimed dose of 1 l/ha is justified as MED. ~~However, the final decision to accept this use is left to the cMSs.~~
No trials were available in the Maritime and South-East zones. The cMs are kindly asked to consider this use at the national level. However, spring triticale is minor crop in Austria, Belgium, Germany, Ireland, Hungary, Netherlands, Romania, Slovenia and Slovakia and the registration under art. 51 is possible in this case, as zRMS supposes.
Taking into account the North-East zone, the dose rate of 1 l/ha can be determined as the minimum effective dose for the control of PUCCST in spring triticale.

Winter triticale
A total of 4 efficacy trials have been submitted to determine the minimum effective dose for the control of *Puccinia striiformis* (PUCCST/PUCCSI) in winter triticale after 2 applications.
In the North-East zone, only 2 trials were conducted between 2022 and 2023. FGF11 at 1 l/ha achieved high level of control in both trials with the results of 100% on L2 and 96,9% on L3. Similar effect was observed for the lower dose of 0,75 l/ha. Due to limited number of trials in winter triticale and the opportunities of extrapolation from winter wheat, the claimed dose of 1 l/ha is justified as MED. ~~However, the final decision to accept this use is left to the cMSs.~~
In the South-East zone, only 2 trials were carried out in 2023. The test product at 1 l/ha presented good control in 1 out 2 trials with the result of 97,92% on L2. Medium efficacy was observed on L3 (79,96%) in other trial. Similar effect was noted for the lower doses of 0,75 l/ha and 0,5 l/ha. Due to limited number of trials in winter triticale and the opportunities of extrapolation from winter wheat, the claimed dose of 1 l/ha is justified as MED. However, the final decision to accept this use is left to the cMSs.
No trials were available in the Maritime EPPO zone. The cMSs are kindly asked to consider this use at the national level. However, winter triticale is minor crop in Belgium, Ireland and Netherlands and the registration under art. 51 is possible in this case, as zRMS supposes.
Taking into account the North-East and South-East zones, the dose rate of 1 l/ha can be determined as the minimum effective dose for the control of PUCCST in winter triticale.

3.2.2.1.3 Minimum effective dose for control of Brown rust (*Puccinia recondita*: PUCCRE/PUCCRT)

A total of 43 trials carried out between 2022 and 2023 generated data on the efficacy of FGF11 applied at a range of rates (0.5 L, 0.75 L and 1.0 L product/ha) against PUCCRE (32 trials) and PUCCRT (11 trials) in winter wheat (24 trials), spring wheat (5 trials), durum wheat (3 trials), spelt (4 trials) and winter triticale (7 trials).

Of these trials, 16 were carried out in the Maritime EPPO climatic zone (10 in Germany, 3 in the United Kingdom, 3 in France), 12 were carried out in the North-east EPPO climatic zone (all in Poland) and 15 were carried out in the South-east EPPO climatic zone (3 in Bulgaria, 7 in Hungary, 5 in Romania).

Disease developed on all 43 trials and was assessed as percentage severity on the upper leaves (1-3).

Across trials, the efficacy of FGF11 has been evaluated under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in wheat, spelt and triticale crops growing regions across EU Central Registration zone countries.

An overall summary of mean percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCRE and PUCCRT in wheat and triticale at 15-47 DA-A2 across trials in each of the EPPO climatic zones is given in Table 3.2-12, with data presented as a Box-Whisker plot in Figure 3.2-7, Figure 3.2-8 and Figure 3.2-9.

Table 3.2-12: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCRE and PUCCRT across trials on wheat and triticale in all EPPO climatic zones at 15-47 DA-A2

Registration or EPPO climatic zone	No. of trials (no. of data points)	*Untreated*		FGF11						Statistical comparison of 1.0 L/ha to#	
				0.5 L/ha		0.75 L/ha		1.0 L/ha			
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max	0.5 L/ha	0.75 L/ha
CEU	43 (84)	***15.7***	*5.0-96.5*	**74.5**	6.8-100	**82.7**	10.6-100	**89.2**	35.1-100	> (42), = (42)	> (16), = (68)
EPPO MAR	16 (34)	***24.9***	*5.2-96.5*	**84.6**	35.7-100	**90.2**	35.6-100	**92.7**	53.2-100	> (6), = (28)	> (2), = (32)
EPPO NE	12 (21)	***8.9***	*5.3-13.3*	**76.9**	49.5-90.3	**89.7**	70.0-100	**94.2**	83.0-100	> (16), = (5)	> (2), = (19)
EPPO SE	15 (29)	***9.9***	*5.0-38.2*	**60.8**	6.8-91.6	**68.9**	10.6-100	**81.6**	35.1-100	> (20), = (9)	> (12), = (17)

No. of data points where >, = or <, based on statistically significant differences at 95% confidence level

Table 3.2-12a: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCRE and PUCCRT across trials on winter wheat in all climatic zones after 1 application

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L3									
Maritime	1 trial	***5,5***	-	**79,4**	-	**93,1**	-	**100**	-
L4									
North-East (+trials conducted in Germany)	1 trial	***5,0***	-	**83,9**	-	**89,8**	-	**93,2**	-
South-East	2 trials	***6,2***	*6,2-6,2*	**65,4**	42,97-87,9	**74,4**	58,05-90,7	**72,3**	49,81-94,8

Table 3.2-12b: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCRE and PUCCRT across trials on winter triticale in all climatic zones after 1 application

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L3									
South-East	1 trial	***4,7***	-	**73,61**	-	**76,47**	-	**89,42**	-

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L4									
North-East (+trials conducted in Germany)	1 trial	***4,8***	-	**79,7**	-	**88,4**	-	**91,0**	-
South-East	1 trial	***7,73***	-	**65,73**	-	**75,47**	-	**85,73**	-
L5									
South-East	2 trials	***4,8***	*4,3-5,2*	**30,6**	12,8-48,4	**46,1**	18,8-73,4	**68,6**	57,3-79,9

Table 3.2-12c: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCRE and PUCCRT across trials on spring wheat in all climatic zones after 1 application

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L3									
South-East	1 trial	***4,1***	-	**53,0**	-	**59,5**	-	**62,9**	-
L4									
South-East	1 trial	***10,5***	-	**22,6**	-	**65,8**	-	**70,2**	-
L5									
South-East	1 trial	***17,2***	-	**20,1**	-	**33,7**	-	**69,3**	-

Table 3.2-12d: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCRE and PUCCRT across trials on winter wheat in all climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L1									
Maritime	10 trials	***34,8***	*9,48-95,0*	**86,9**	56,09-100	**93,2**	67,21-100	**95,6**	77,81-100

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L1									
North-East	5 trials	***7,2***	*5,25-10,63*	**82,9**	72,15-90,34	**93,4**	87,85-100	**96,1**	92,38-100
South-East	4 trials	***6,3***	*5,47-7,63*	**59,9**	46,71-81,29	**72,5**	66,1-84,62	**86,3**	72,45-93,6
L2									
Maritime	9 trials	***23,1***	*9,1-53,0*	**88,1**	69,17-100	**94,4**	80,02-100	**94,9**	87,08-100
North-East	3 trials	***9,2***	*5,91-11,1*	**81,4**	78,85-85,54	**90,8**	87,03-94,78	**95,1**	89,83-98,54
South-East	4 trials	***8,1***	*5,12-12,25*	**66,8**	52,62-80,46	**75,3**	61,02-93,62	**84,2**	69,3-100
L3									
Maritime	4 trials	***7,8***	*5,7-10,28*	**89,3**	82,49-100	**91,3**	76,65-100	**95,8**	88,33-100
North-East	2 trials	***6,97***	*6,2-7,75*	**71,7**	62,46-81,03	**82,4**	75,75-88,98	**89,1**	85,88-92,23
South-East	6 trials	***7,5***	*5,52-10,36*	**53,4**	24,05-91,63	**61,7**	29,89-100	**71,3**	35,06-100

Table 3.2-12e: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCRE and PUCCRT across trials on durum wheat in all climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L1									
Maritime	1 trial	***7,5***	-	**100**	-	**100**	-	**100**	-
L2									
South-East	1 trial	***7,13***	-	**82,96**	-	**92,4**	-	**100**	-
L3									
South-East	1 trial	***6,98***	-	**64,44**	-	**69,71**	-	**77,93**	-

Table 3.2-12f: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCRE and PUCCRT across trials on spelt in all climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L1									
Maritime	4 trials	***28,6***	*5,5-91,25*	**76,6**	51,25-100	**86,2**	69,29-100	**88,5**	77,86-100
L2									
Maritime	3 trials	***39,0***	*8,08-96,5*	**75,0**	51,0-100	**81,0**	52,69-100	**82,99**	53,15-100
L3									
Maritime	2 trials	***8,2***	*6,7-9,75*	**67,8**	35,69-100	**67,8**	35,63-100	**77,1**	54,1-100

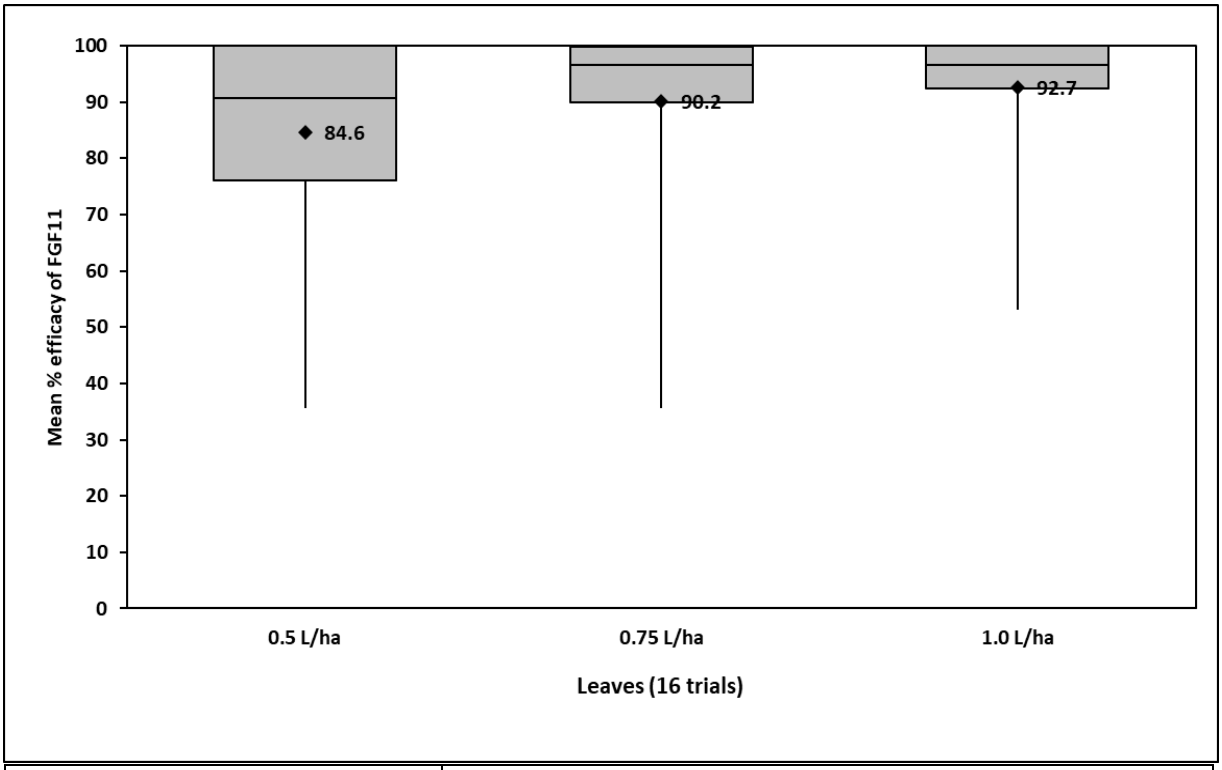
Table 3.2-12g: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCRE and PUCCRT across trials on winter triticale in all climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L1									
North-East	1 trial	***6,38***	-	**80,5**	-	**87,23**	-	**92,29**	-
South-East	2 trials	***7,1***	*5,0-9,15*	**81,1**	80,92-81,21	**86,97**	85,52-88,43	**95,5**	93,15-97,82
L2									
Maritime	1 trial	***5,21***	-	**91,55**	-	**97,03**	-	**99,85**	-
North-East	2 trials	***7,8***	*6,35-9,25*	**74,6**	71,49-77,64	**92,4**	84,89-100	**94,6**	89,13-100
South-East	2 trials	***10,6***	*8,18-13,1*	**80,1**	78,93-81,2	**84,8**	82,99-86,67	**92,8**	89,84-95,67
L3									
North-East	2 trials	***10,9***	*10,38-11,5*	**72,1**	70,62-73,64	**90,9**	81,81-100	**93,8**	87,6-100
South-East	4 trials	***12,5***	*8,68-16,98*	**74,2**	64,88-77,87	**75,9**	67,72-82,64	**87,98**	77,11-93,66

Table 3.2-12h: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCRE and PUCCRT across trials on spring wheat in all climatic zones after 2 applications

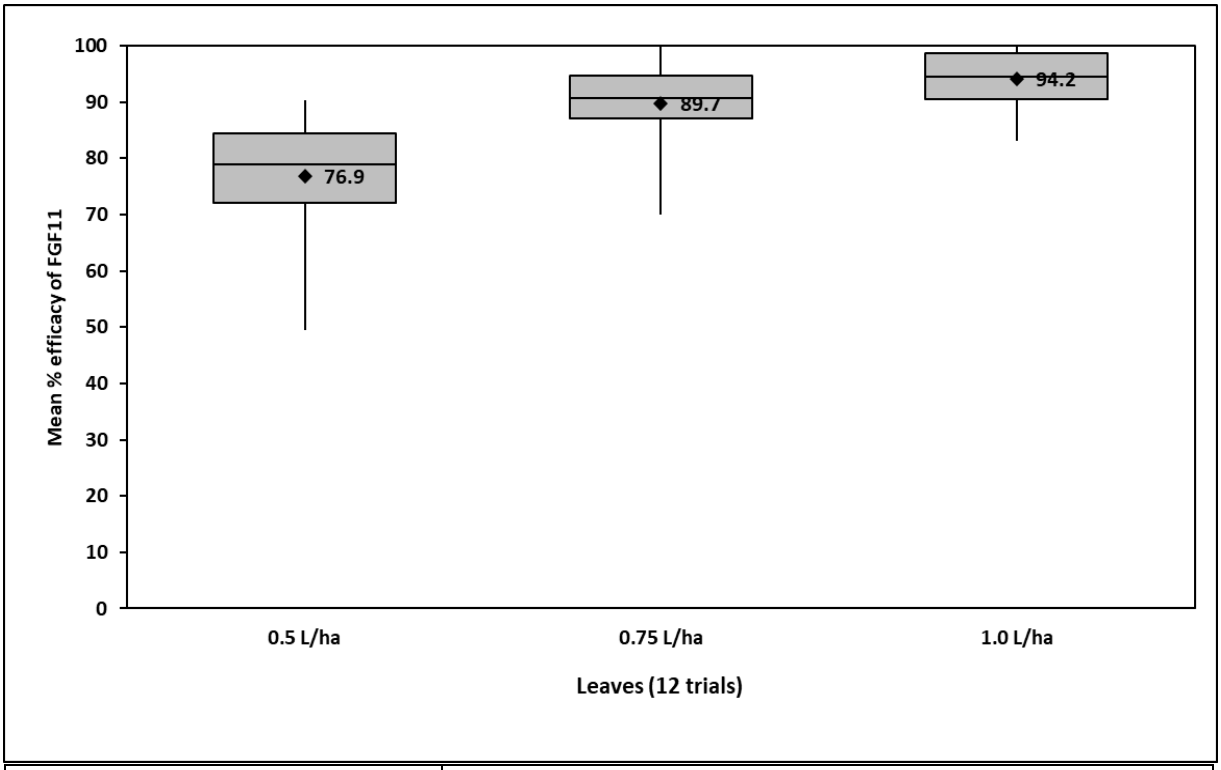
Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L1									
North-East	3 trials	***11,0***	*10,0-12,13*	**79,5**	72,43-87,38	**90,2**	82,72-96,46	**95,0**	90,5-100
South-East	1 trial	***9,06***	-	**24,8**	-	**45,25**	-	**74,24**	-
L2									
North-East	2 trials	***12,7***	*12,13-13,25*	**75,2**	65,95-84,36	**92,3**	90,7-93,95	**97,9**	95,86-100
South-East	2 trials	***13,2***	*6,7-19,64*	**40,3**	14,44-66,09	**51,4**	28,79-73,91	**75,5**	67,36-83,65
L3									
North-East	1 trial	***6,53***	-	**49,45**	-	**70,0**	-	**83,02**	-
South-East	2 trials	***25,0***	*11,88-38,21*	**32,4**	6,79-58,03	**39,1**	10,58-67,63	**62,3**	47,98-76,61

Figure 3.2-7: Dose justification; mean efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCRE and PUCCRT across 16 trials on wheat and triticale, Maritime EPPO climatic zone



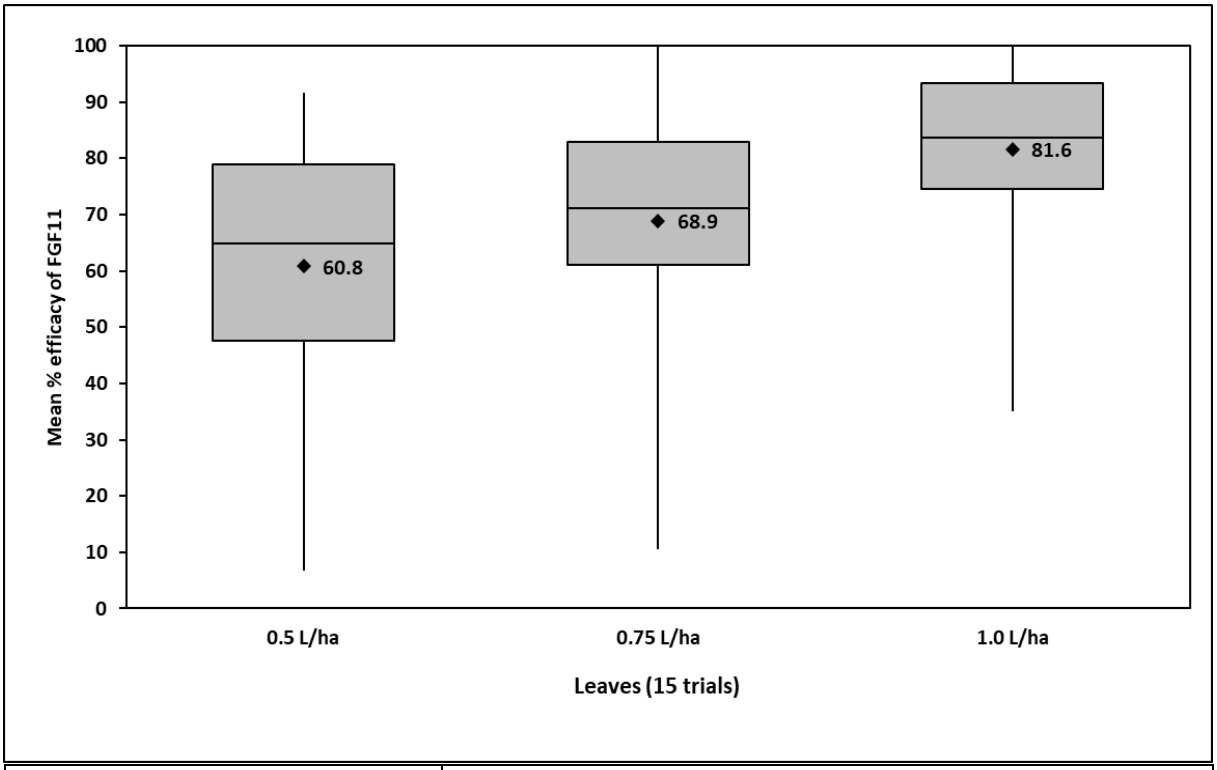
	Mean % efficacy of FGF11		
	0.5 L/ha	**0.75 L/ha**	**1.0 L/ha**
No. of trials (no. of data points)	16 (34)	16 (34)	16 (34)
Mean	**84.6**	**90.2**	**92.7**
S.D.	17.0	14.8	11.8
Q1	76.1	90.0	92.3
Median	90.8	96.6	96.7
Q3	100	99.8	100

Figure 3.2-8: Dose justification; mean efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCRE and PUCCRT across 12 trials on wheat and triticale, North-east EPPO climatic zone



	Mean % efficacy of FGF11		
	0.5 L/ha	**0.75 L/ha**	**1.0 L/ha**
No. of trials (no. of data points)	12 (21)	12 (21)	12 (21)
Mean	**76.9**	**89.7**	**94.2**
S.D.	9.6	7.6	5.1
Q1	72.2	87.0	90.5
Median	78.9	90.7	94.5
Q3	84.4	94.7	98.6

Figure 3.2-9: Dose justification; mean efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCRE and PUCCRT across 15 trials on wheat and triticale, South-east EPPO climatic zone



	Mean % efficacy of FGF11		
	0.5 L/ha	**0.75 L/ha**	**1.0 L/ha**
No. of trials (no. of data points)	15 (29)	15 (29)	15 (29)
Mean	**60.8**	**68.9**	**81.6**
S.D.	22.3	20.6	15.5
Q1	47.5	61.0	74.5
Median	64.9	71.1	83.7
Q3	78.9	83.0	93.4

Data generated in trials carried out in Maritime, North-east and South-east EPPO climatic zones clearly show the efficacy of FGF11 applied at 1.0 L product/ha against PUCCRE and PUCCRT in wheat and triticale to be higher and more consistent compared to that of lower rates (0.75 L and 0.5 L product/ha).

The morphology, life cycles and infection patterns of different *Puccinia* rust pathogens affecting cereals, and also the efficacy of fungicides against the different species, are very similar. Therefore, data generated on efficacy against PUCCRT are fully considered to provide justification of the minimum effective dose rate for control of PUCCRE.

Whilst no or limited data have been generated in support of justifying the minimum effective dose of FGF11 for control of PUCCRE in spring wheat, durum wheat, spelt, winter and/or spring triticale in some of the EPPO climatic zones, the susceptibility of the crops to this fungal pathogen, disease development pressure and development patterns, agronomy of the crops and areas in which the crops are grown in the Central Registration zone and Great Britain can be considered to be sufficiently similar between different cereal crops for the data generated in trials in winter wheat to also provide justification of the same rate with respect to efficacy against PUCCRE in spring wheat, durum wheat, spelt, winter and spring triticale.

Furthermore, products containing prothioconazole and azoxystrobin straight and as mixture are already registered against PUCCRE in the different cereal types mentioned above throughout Europe. The registered rate is generally the same in spring, winter and durum wheat, spelt and winter and spring

triticale. The minimum effective dose of FGF11 against PUCCRE was extensively proven in winter wheat and was confirmed by trials in other cereal types. It can therefore be considered that the minimum effective dose of FGF11 against PUCCRE in all types of wheat, spelt and triticale is the same.

It is therefore reasonable to conclude that the proposed label rate of 1.0 L product/ha is fully justified as the minimum effective dose for the control of PUCCRE in wheat (winter, spring, durum), spelt and triticale (winter and spring) by FGF11.

Comments of zRMS:

1 application

Winter wheat

A total of 4 efficacy trials have been submitted to determine the minimum effective dose for the control of *Puccinia recondita* (PUCCRE/PUCCRT) in winter wheat after 1 application.

In the Maritime EPPO climatic zone, only 1 trial was conducted in 2023. FGF11 applied at dose rate of 1 l/ha achieved full effectiveness on L3. Slight inferior control was observed at lower dose rate of 0,75 l/ha. The cMSs are kindly asked to consider this use at the national level because of very limited number of trials.

In the North-East zone, only 1 trial was carried out in 2023. The test product at the claimed dose rate presented high level of control with the result of 93,2% on L4. Comparable effect was visible at the lowers doses. ~~This use cannot be accepted in Poland because of very limited number of trials.~~

In the South-East zone, 2 trials were conducted in 2023. FGF11 at 1 l/ha achieved medium effectiveness with the result of 72,3% on L4. No significant differences between the claimed and lower dose of 0,75 l/ha were observed. The dose rate of 0,5 l/ha had slight inferior result. The cMSs are kindly asked to consider this use at the national level because of limited number of trials.

Winter triticale

A total of 4 efficacy trials have been submitted to determine the minimum effective dose for the control of *Puccinia recondita* (PUCCRE/PUCCRT) in winter triticale after 1 application.

In the North-East EPPO zone, only 1 trial was conducted in 2023. FGF11 at 1 l/ha achieved good level of control with the result of 91% on L4. Comparable effect was observed at the lower dose of 0,75 l/ha and slight inferior at 0,5 l/ha. ~~This use cannot be accepted in Poland because of very limited number of trials.~~

In the South-East zone, 3 trials were carried out in 2023. The test product at the claimed dose presented sufficient results of 89,42% on L3 and 85,73% on L4. Medium level of control was observed on L5 (68,6%). Significant inferior effectiveness were noted at the lower dose rates of 0,75 l/ha and 0,5 l/ha. The cMSs are kindly asked to consider this use at the national level because of limited number of trials.

No results after 1 application were available in the Maritime EPPO zone. The cMSs are kindly asked to consider this use at the national level.

Spring wheat

Only 2 efficacy trials have been submitted to determine the minimum effective dose for the control of *Puccinia recondita* (PUCCRE/PUCCRT) in spring wheat after 1 application. Both trials were conducted in 2023 in the South-East EPPO climatic zone. FGF11 at 1 l/ha achieved medium level of control with the results of 62,9% on L3, 70,2% on L4 and 69,3% on L5. Significant inferior effectiveness was observed at the lower doses of 0,75 l/ha and 0,5 l/ha. The cMSs are kindly asked to consider this use at the national level because of limited number of trials.

No results after 1 application were available in the Maritime and North-East EPPO zone. ~~This use cannot be accepted in Poland.~~ The cMSs belonging to the MAR zone are kindly asked to consider this use at the national level.

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2 applications

Winter wheat

A total of 24 efficacy trials have been submitted to determine the minimum effective dose for the control of *Puccinia recondita* (PUCCRE/PUCCRT) in winter wheat after 2 applications.

In the Maritime EPPO climatic zone, 10 trials were conducted between 2022 and 2023. FGF11 at dose rate of 1 l/ha achieved high efficacy with the results of 95,6% on L1, 94,9% on L2 and 95,8% on L3. Similar effect was observed for the lower dose of 0,75 l/ha and slight inferior results for the dose of 0,5 l/ha.

In the North-East zone, 7 trials were carried out between 2022 and 2023. The test product at claimed dose presented high control with the results of 96,1% on L1, 95,1% on L2 and 89,1% on L3. The lower dose of 0,75

l/ha had comparable effect. Significant differences was noted for the dose rate of 0,5 l/ha.
In the South-East zone, 7 trials were conducted between 2022 and 2023. FGF11 at 1 l/ha achieved good control with the results of 86,3% on L1 and 84,2% on L2. Medium efficacy was visible on L3 (71,3%). Lower doses had significant inferior results.
Taking into account all zones, the dose rate of 1 l/ha can be determined the minimum effective dose for the control of PUCCRE in winter wheat.

Durum wheat
A total of 3 efficacy trials have been submitted to determine the minimum effective dose for the control of *Puccinia recondita* (PUCCRE/PUCCRT) in durum wheat after 2 applications.
In the Maritime EPPO climatic zone, only 1 trial was conducted in 2022. FGF11 at 1 l/ha achieved full control on L1. Similar effect was visible for other doses. Due to limited number of trials in durum wheat and the opportunities of extrapolation from winter wheat, the claimed dose of 1 l/ha is justified as MED. However, the final decision to accept this use is left to the cMSs.
In the South-East zone, only 2 trials were carried out in 2022. The test product at the claimed dose rate presented full control on L2 and medium efficacy on L3 (77,93%). Significant inferior results were obtained for the lower doses.
No efficacy trials were available in the North-East EPPO zone. Durum wheat is minor crop in Poland and the registration under art. 51 is possible in this case.
Taking into account the Maritime and South-East zone, the dose rate of 1 l/ha can be determined as the minimum effective dose for the control of PUCCRE in durum wheat.

Spelt
4 efficacy trials have been submitted to determine the minimum effective dose for the control of *Puccinia recondita* (PUCCRE/PUCCRT) in spelt after 2 applications. All trials were carried out between 2022 and 2023 in the Maritime EPPO climatic zone. FGF11 at 1 l/ha achieved good control with the results of 88,5% on L1 and 82,99% on L2. Medium efficacy was visible on L3 (77,1%) in 2 out of 4 trials. Lower dose of 0,75 l/ha presented comparable effect with significant differences on L3. Due to limited number of trials in spelt and the opportunities of extrapolation from winter wheat, the claimed dose of 1 l/ha is justified as MED. However, the final decision to accept this use is left to the cMSs.
No efficacy trials were available in the North-East and South-East zones. Spelt is minor crop in Poland and the registration under art. 51 is possible in this case. Similarly, this crop has a minor status in Romania, Slovenia and Slovakia.
Taking into account the Maritime zone, the dose rate of 1 l/ha can be determined as the minimum effective dose for the control PUCCRE in spelt.

Winter triticale
A total of 7 efficacy trials have been submitted to determine the minimum effective dose for the control of *Puccinia recondita* (PUCCRE/PUCCRT) in winter triticale after 2 applications.
In the Maritime EPPO climatic zone, only 1 trial was conducted in 2022. FGF11 at 1 l/ha achieved high control with the result of 99,85% on L2. Comparable effect was visible for the lower dose of 0,75 l/ha and 0,5 l/ha. Due to limited number of trials in winter triticale and the opportunities of extrapolation from winter wheat, the claimed dose of 1 l/ha is justified as MED. However, the final decision to accept this use is left to the cMSs.
In the North-East zone, only 2 trials were carried out in 2023. The test product at the claimed dose presented high efficacy with the results of 92,29% on L1, 94,6% on L2 and 93,8% on L3. No significant differences between the dose rate of 1 l/ha and 0,75 l/ha were observed. Lower dose of 0,5 l/ha had inferior results. Due to limited number of trials in winter triticale and the opportunities of extrapolation from winter wheat, the claimed dose of 1 l/ha is justified as MED.
In the South-East zone, 4 trials were conducted between 2022 and 2023. FGF11 at 1 l/ha achieved sufficient control with the results of 95,5% on L1, 92,8% on L2 and 87,98% on L3. Lower doses had significant inferior efficacy. Due to limited number of trials in winter triticale and the opportunities of extrapolation from winter wheat, the claimed dose of 1 l/ha is justified as MED. However, the final decision to accept this use is left to the cMSs.
Taking into account all zones, the dose rate of 1 l/ha can be determined as the minimum effective dose for the control of PUCCRE in winter triticale.

Spring wheat
A total of 5 efficacy trials have been submitted to determine the minimum effective dose for the control of *Puccinia recondita* (PUCCRE/PUCCRT) in spring wheat after 2 applications.

In the North-East EPPO climatic zone, 3 trials were carried out between 2022 and 2023. FGF11 at dose rate of 1 l/ha achieved high efficacy with the results of 95% on L1, 97,9% on L2 and 83,02% on L3. Comparable effect on L1 and L2 was observed for the dose rate of 0,75 l/ha. Significant inferior result was visible on L3. Due to limited number of trials in spring wheat and the opportunities of extrapolation from winter wheat, the claimed dose of 1 l/ha is justified as MED. However, the final decision to accept this use is left to the cMSs.
In the South-East zone, only 2 trials were carried out in 2023. The test product at claimed dose presented medium level of control with the results of 74,24% on L1, 75,5% on L2 and 62,3% on L3. Significant inferior efficacy was visible for the lower doses of 0,75 l/ha and 0,5 l/ha. Due to limited number of trials in spring wheat and the opportunities of extrapolation from winter wheat, the claimed dose of 1 l/ha is justified as MED. However, the final decision to accept this use is left to the cMSs.
No efficacy trials were available in the Maritime EPPO zone. The cMSs are kindly asked to consider this use at the national level. However, spring wheat is minor crop in Belgium and Ireland and the registration under art. 51 is possible in this case, as zRMS supposes.
Taking into account the North-East and South-East zones, the dose rate of 1 l/ha can be determined as the minimum effective dose for the control of PUCCRE in spring wheat.

3.2.2.2 Minimum effective dose for control of target diseases in winter and spring rye

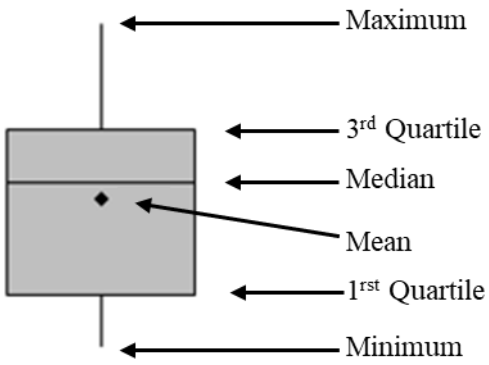
All 14 efficacy trials carried out between 2022 and 2023 generated data on the efficacy of FGF11 applied at a range of rates against PUCCRR in winter rye. The data from these trials are summarised in support of justification of the minimum effective dose rate for control of PUCCRR in rye by FGF11.

The materials and methods used in the efficacy trials from which data are summarized to justify minimum effective dose for control of PUCCRR in rye are given in Section 3.2.3.2.

Data are summarised in this dossier from assessment timings where mean levels of disease in the untreated control reached ≥5% severity at individual leaf levels following application.

Only data with ≥6 data points per EPPO climatic zone are presented as a Box-Whisker plot.

The Box-Whisker plots indicate the following values of the relevant summarised aggregated data:



Efficacy data are summarised across trials from representative assessment timings in this Section.

3.2.2.2.1 Minimum effective dose for control of Brown rust (*Puccinia recondita f. sp. recondita*: PUCCRR)

A total of 14 trials carried out between 2022 and 2023 generated data on the efficacy of FGF11 applied at a range of rates (0.5 L, 0.75 L and 1.0 L product/ha) against PUCCRR in winter rye.

Of these trials, 6 were carried out in the Maritime EPPO climatic zone (2 in Great Britain, 1 in Germany, 1 in Ireland and 2 in France), 3 were carried out in the North-east EPPO climatic zone (all in Poland) and 5 were carried out in the South-east EPPO climatic zone (2 in Hungary, 2 in Romania and 1 in Bulgaria).

Disease developed on all 14 trials and was assessed as percentage severity on the upper leaves (1-3).

Data from 1 of the trials conducted in the Maritime EPPO climatic zone are excluded from overall means as results were highly inconsistent with highest efficacy at lowest dose rate and lowest efficacy at the highest dose rate tested.

Across trials, the efficacy of FGF11 has been evaluated under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in rye crops growing regions across EU Central Registration zone countries.

A summary of mean percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCRR in rye across trials and leaf levels with valid data in each of the EPPO climatic zones is given in Table 3.2-13, with data presented as a Box-Whisker plot in Figure 3.2-10 and Figure 3.2-11.

Table 3.2-13: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCRR across trials on rye in all climatic zones at 14-42 DA-A2

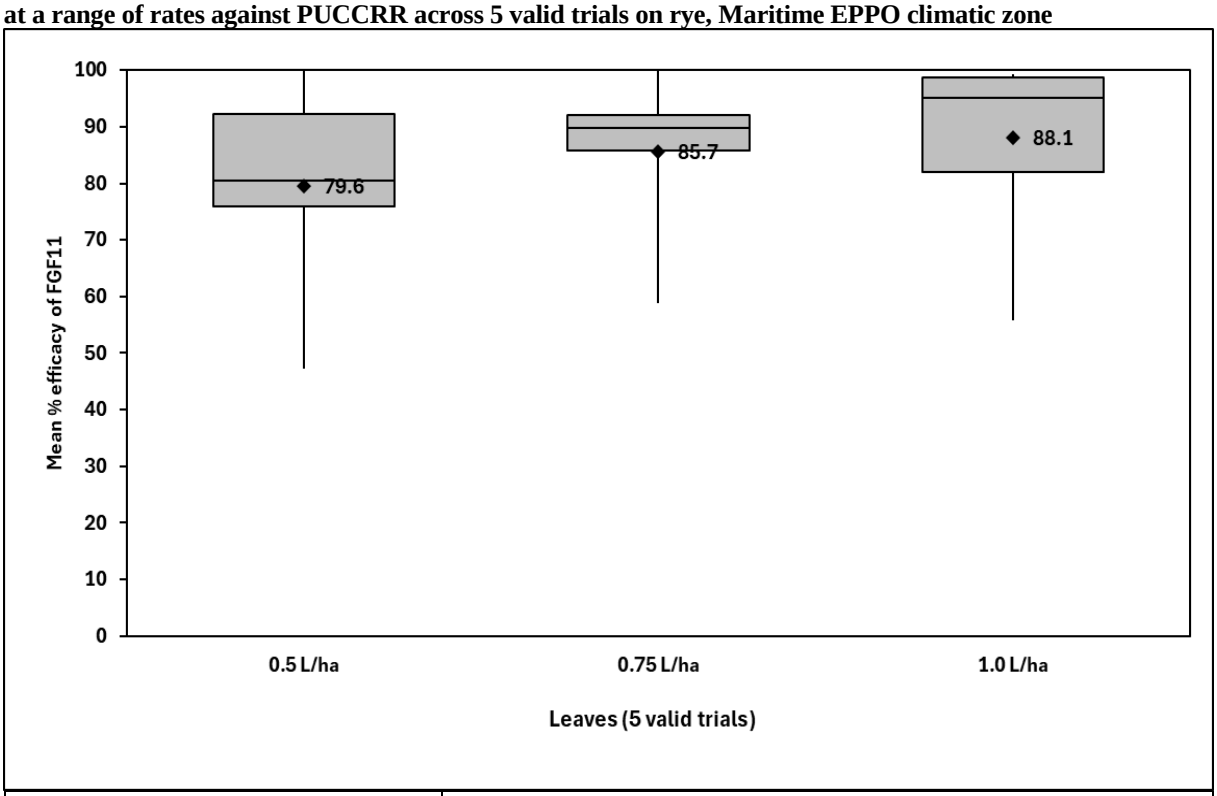
Registration or EPPO climatic zone	No of trials (no of data points)	*Untreated (% severity on leaves)*		FGF11						Statistical comparison of 1.0 L/ha to #	
				0.5 L/ha		0.75 L/ha		1.0 L/ha			
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max	0.5 L/ha	0.75 L/ha
CEU	13 (24)	***22.7***	*5.1 - 92.1*	**76.3**	35 - 100	**85.9**	58.8 - 100	**88.7**	55.8 - 100	> (13), = (11)	> (2), = (22)
EPPO MAR	5 (11)	***19.2***	*5.3 - 64.5*	**79.6**	47.3 - 100	**85.7**	58.8 - 100	**88.1**	55.8 - 99.3	> (3), = (8)	> (1), = (10)
EPPO NE	3 (3)	***10.1***	*6.2 - 12.4*	**81.0**	73.3 - 93.7	**89.5**	83 - 99.6	**92.1**	83.2 - 100	> (2), = (1)	= (3)
EPPO SE	5 (10)	***30.3***	*5.1 - 92.1*	**71.3**	35 - 89.3	**85.0**	65.2 - 99.9	**88.3**	64.9 - 100	> (9), = (1)	> (1), = (9)

No. of data points where >, = or <, based on statistically significant differences at 95% confidence level

Table 3.2-13a: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCRR and PUCCRT across trials on winter rye in all climatic zones after 2 applications

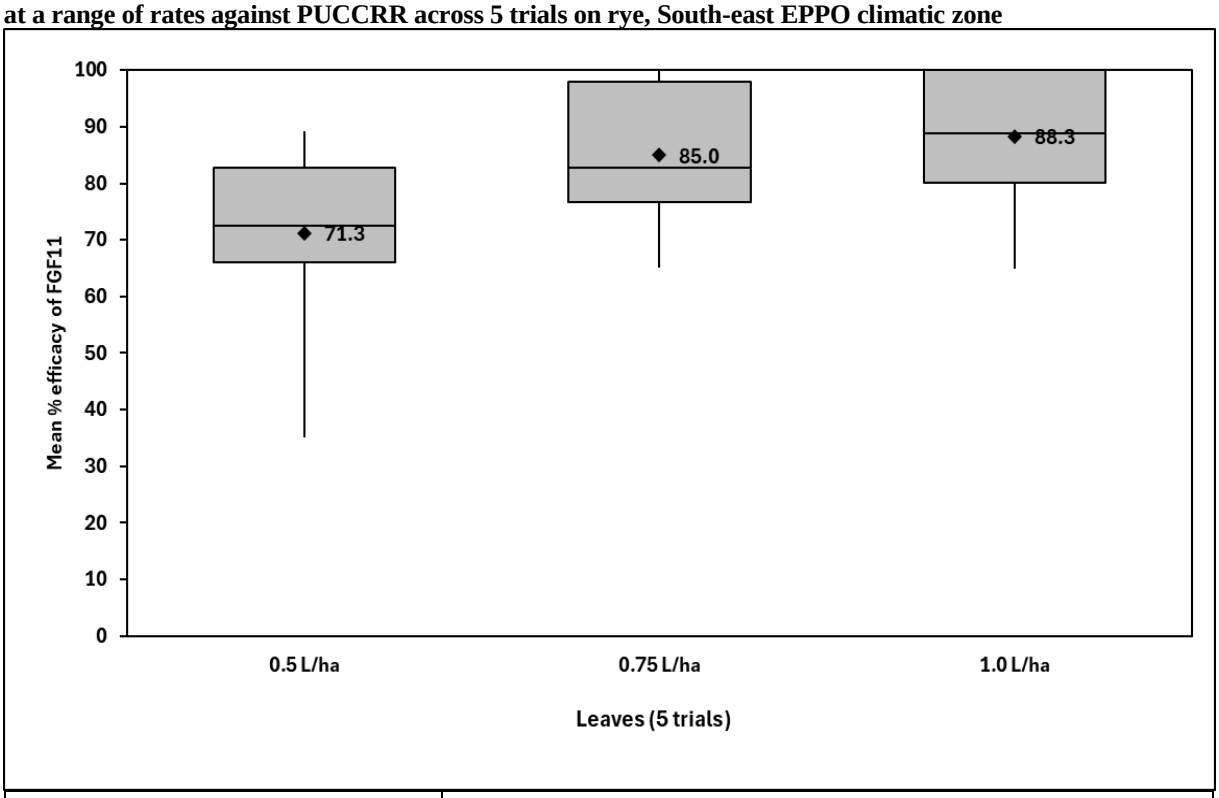
Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L1									
Maritime	2 trials	***14,2***	*13,2-15,28*	**87,0**	78,38-95,68	**91,9**	91,43-92,37	**98,1**	97,01-99,26
North-East	2 trials	***12,1***	*11,75-12,38*	**74,7**	73,29-76,04	**84,4**	82,98-85,88	**88,1**	83,21-92,94
South-East	1 trial	***50,1***	-	**89,31**	-	**99,82**	-	**100**	-
L2									
Maritime	5 trials	***16,0***	*5,25-31,58*	**78,4**	47,32-100	**85,2**	61,59-100	**87,6**	67,35-98,75
North-East	1 trial	***6,23***	-	**93,68**	-	**99,55**	-	**100**	-
South-East	5 trials	***21,7***	*5,08-78,85*	**71,6**	35,04-86,81	**84,6**	65,18-99,76	**88,5**	64,94-100
L3									
Maritime	4 trials	***25,6***	*9,73-64,5*	**77,4**	54,81-91,78	**83,2**	58,77-97,33	**83,8**	55,75-99,01
South-East	4 trials	***36,1***	*8,2-92,12*	**66,4**	63,66-69,54	**81,7**	73,17-99,91	**85,2**	76,21-100

Figure 3.2-10: Dose justification; mean efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCRR across 5 valid trials on rye, Maritime EPPO climatic zone



	Mean % efficacy of FGF11		
	0.5 L/ha	**0.75 L/ha**	**1.0 L/ha**
No. of trials (no. of data points)	5 (11)	5 (11)	5 (11)
Mean	**79.6**	**85.7**	**88.1**
S.D.	16.43	13.35	14.84
Q1	75.84	85.89	82.07
Median	80.58	89.72	95.11
Q3	92.33	92.00	98.70

Figure 3.2-11: Dose justification; mean efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCRR across 5 trials on rye, South-east EPPO climatic zone



	Mean % efficacy of FGF11		
	0.5 L/ha	**0.75 L/ha**	**1.0 L/ha**
No. of trials (no. of data points)	5 (10)	5 (10)	5 (10)
Mean	**71.3**	**85.0**	**88.3**
S.D.	15.71	12.44	12.28
Q1	66.10	76.70	80.18
Median	72.42	82.77	88.78
Q3	82.77	97.99	100.00

Data generated in trials carried out in Maritime, North-east and South-east EPPO climatic zones partially show the efficacy of FGF11 applied at 1.0 L product/ha against PUCCRE in rye to be higher and more consistent compared to that of lower rates (0.75 L and 0.5 L product/ha).

The morphology, life cycles and infection patterns of different *Puccinia recondita* subspecies affecting cereals, and also the efficacy of fungicides against the different species, are very similar. Therefore, data generated on the efficacy against PUCCRE in wheat and triticale (section 3.2.2.1.3) are considered to provide evidence to support minimum effective dose for control of PUCCRR in rye.

Whilst no data have been generated to demonstrate the efficacy of FGF11 against PUCCRR on spring rye in the Maritime, North-east and South-east EPPO climatic zones, the susceptibility of the crops to this fungal pathogen, disease development pressure and development patterns, agronomy of the crops and areas in which the crops are grown in the Central Registration zone can be considered to be sufficiently similar between spring and winter rye to be fully supportive of demonstrating the minimum effective dose for control of PUCCRR in both rye crop types.

Additionally, whilst limited data are presented on the efficacy of FGF11 against PUCCRR on rye from trials carried out in the North-east EPPO climatic zone, data generated on this disease in 1 trial carried out in Germany provide supportive evidence of that in Poland.

Furthermore, products containing prothioconazole and azoxystrobin straight and as mixture are already registered against PUCCRE/PUCCRR in spring and winter rye, spring, winter and durum wheat, spelt

and spring and winter triticale throughout Europe. The registered rate is generally the same in all of the cereal types mentioned above. The minimum effective dose of FGF11 against PUCCRE was extensively proven in winter wheat and was confirmed by trials in other cereal types. It can therefore be considered that the minimum effective dose of FGF11 against PUCCRE/PUCCRR in all types of wheat, spelt, triticale and rye is the same.

It is therefore reasonable to conclude that the proposed label rate of 1.0 L product/ha is fully justified as the minimum effective dose for the control of PUCCRR in spring and winter rye by FGF11.

Comments of zRMS:

1 application
No results after 1 application were available in any EPPO climatic zone. The cMSs belonging to the Maritime and South-East zone are kindly asked to consider the use of FGF11 at 1 l/ha in winter and spring rye against *Puccinia recondita* f.sp. *recondita* (PUCCRR) at the national level. These uses cannot be accepted in Poland (under art. 33). However, spring rye is minor crops in Poland and the registration under art. 51 is possible in this case.

2 applications
Winter rye
A total of 14 efficacy trials have been submitted to determine the minimum effective dose for the control of *Puccinia recondita* f.sp. *recondita* (PUCCRR) in winter rye after 2 applications.
In the Maritime EPPO climatic zone, 6 trials were conducted between 2022 and 2023. FGF11 applied at dose rate of 1 l/ha achieved good control with the results of 98,1% on L1, 87,6% on L2 and 83,8% on L3. Comparable effect was visible for the lower dose rate of 0,75 l/ha. The dose rate of 0,5 l/ha presented medium level of control in most of trials.
In the North-East zone, only 3 trials were carried out between 2022 and 2023. The test product at claimed dose had sufficient efficacy with the results of 88,1% on L1 and 100% on L2. No significant differences between the dose rates of 1l/ha and 0,75 l/ha were observed. Medium level of control was obtained at 0,5 l/ha in 2 out of 3 trials. Due to limited number of trials in winter rye and the opportunities of extrapolation from winter wheat, the claimed dose of 1 l/ha is justified as MED.
In the South-East zone, 5 trials were conducted between 2022 and 2023. FGF11 at 1 l/ha achieved good efficacy with the results of 100% on L1, 88,5% on L2 and 85,2% on L3. No significant differences between the dose rates of 1l/ha and 0,75 l/ha were observed. Medium level of control was obtained at 0,5 l/ha in all trials on L2.
Taking into account all zones, the dose rate of 1 l/ha can be determined as the minimum effective dose for the control of PUCCRR in winter rye.

Spring rye
No efficacy trials have been submitted to determine the minimum effective dose for the control of *Puccinia recondita* f.sp. *recondita* (PUCCRR) in spring rye after 2 applications in any EPPO climatic zone. The cMSs are kindly asked to consider this use at the national level. However, spring rye is minor crops in Poland, Austria, Belgium, Germany, Ireland, Netherlands, Romania, Slovenia and Slovakia and the registration under art. 51 is possible in this case, as zRMS supposes.

3.2.2.3 Minimum effective dose for control of target diseases in winter and spring barley

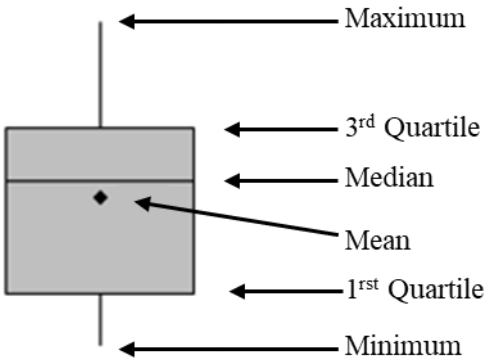
All 33 efficacy trials carried out between 2022 and 2023 generated data on the efficacy of FGF11 applied at a range of rates against target disease in winter and spring barley. The data from these trials are summarised in support of justification of the minimum effective dose rate for control of target diseases in barley by FGF11.

The materials and methods used in the efficacy trials from which data are summarized to justify minimum effective dose for control of target diseases in barley are given in Section 3.2.3.3.

Data are summarised in this dossier from assessment timings where mean levels of disease in the untreated control reached ≥5% severity at individual leaf levels following application.

Only data with ≥6 data points per EPPO climatic zone are presented as a Box-Whisker plot.

The Box-Whisker plots indicate the following values of the relevant summarised aggregated data:



Efficacy data are summarised across trials from representative assessment timings in this Section.

3.2.2.3.1 Minimum effective dose for control of Net blotch (*Pyrenophora teres*: PYRNTE)

A total of 26 trials carried out between 2022 and 2023 generated data on the efficacy of FGF11 applied at a range of rates (0.5 L, 0.75 L and 1.0 L product/ha) against PYRNTE in winter barley (17 trials) and spring barley (9 trials).

Of these trials, 6 were carried out in the Maritime EPPO climatic zone (4 in Great Britain, 1 in Ireland and 1 in France), 8 were carried out in the North-east EPPO climatic zone (5 in Poland, 1 in Lithuania and 2 in Finland) and 12 were carried out in the South-east EPPO climatic zone (4 in Hungary, 4 in Romania and 4 in Bulgaria).

Disease developed on all 26 trials and was assessed as percentage severity on the upper leaves (1-3).

Across trials, the efficacy of FGF11 has been evaluated under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in barley crops growing regions across EU Central Registration zone countries.

A summary of mean percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PYRNTE in barley across trials and leaf levels with valid data in each of the EPPO climatic zones is given in Table 3.2-14, with data presented as a Box-Whisker plot in Figure 3.2-12, Figure 3.2-13 and Figure 3.2-14.

Table 3.2-14: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PYRNTE across trials on barley in all climatic zones at 9-49 DA-A2

Registration or EPPO climatic zone	No of trials (no of data points)	*Untreated (% severity on leaves)*		FGF11						Statistical comparison of 1.0 L/ha to #	
				0.5 L/ha		0.75 L/ha		1.0 L/ha			
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max	0.5 L/ha	0.75 L/ha
CEU	26 (62)	***16.9***	*5.1 - 58.8*	**69.7**	21.7 - 99	**76.7**	38.9 - 99.5	**82.9**	38.6 - 100	> (32), = (30)	> (15), = (47)
EPPO MAR	6 (11)	***4.3***	*5.1 - 40.8*	**75.7**	40.8 - 99	**78.4**	49.3 - 99.5	**83.7**	63.7 - 99.5	= (11)	= (11)
EPPO NE	8 (21)	***24.9***	*5.2 - 58.8*	**73.1**	35.1 - 95.5	**81.3**	51.8 - 96.6	**87.6**	64.2 - 100	> (10), = (11)	> (5), = (16)
EPPO SE	12 (31)	***12.0***	*5.4 - 33.3*	**65.5**	21.7 - 95.4	**73.3**	38.9 - 96.6	**79.7**	38.6 - 100	> (22), = (9)	> (10), = (21)

No. of data points where >, = or <, based on statistically significant differences at 95% confidence level

Table 3.2 14a: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PYRNTE across trials on winter barley in all climatic zones after 1 application

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L4									
North-East (+trials conducted in Germany)	2 trial	***6,4***	*4,2-8,6*	**80,6**	72,1-89,0	**87,2**	83,5-90,8	**90,7**	88,6-92,7
South-East	3 trials	***6,9***	*4,92-8,5*	**78,2**	75,9-80,6	**83,4**	81,1-85,5	**87,1**	85,03-88,8
L5									
North-East (+trials conducted in Germany)	1 trial	***11,5***	-	**68,3**	-	**72,1**	-	**78,3**	-
South-East	1 trial	***5,43***	-	**73,9**	-	**80,7**	-	**91,07**	-
L6									
South-East	1 trial	***6,2***	-	**84,4**	-	**87,9**	-	**86,8**	-

Table 3.2 14b: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PYRNTE across trials on spring barley in all climatic zones after 1 application

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L3									
Maritime	1 trial	***8,53***	-	**35,95**	-	**52,84**	-	**67,66**	-
North-East (+trials conducted in Germany)	1 trial	***4,9***	-	**85,81**	-	**86,86**	-	**79,83**	-
L4									
Maritime	1 trial	***20,48***	-	**39,01**	-	**49,54**	-	**62,35**	-
North-East (+trials conducted in Germany)	2 trials	***10,0***	*9,0-11,08*	**65,2**	37,6-92,79	**65,2**	40,2-90,16	**63,9**	39,4-88,46
South-East	1 trial	***5,8***	-	**91,6**	-	**100**	-	**100**	-
L5									
South-East	1 trial	***5,04***	-	**85,69**	-	**88,89**	-	**96,11**	-

Table 3.2 14c: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PYRNTE across trials on winter barley in all climatic zones after 2 applications

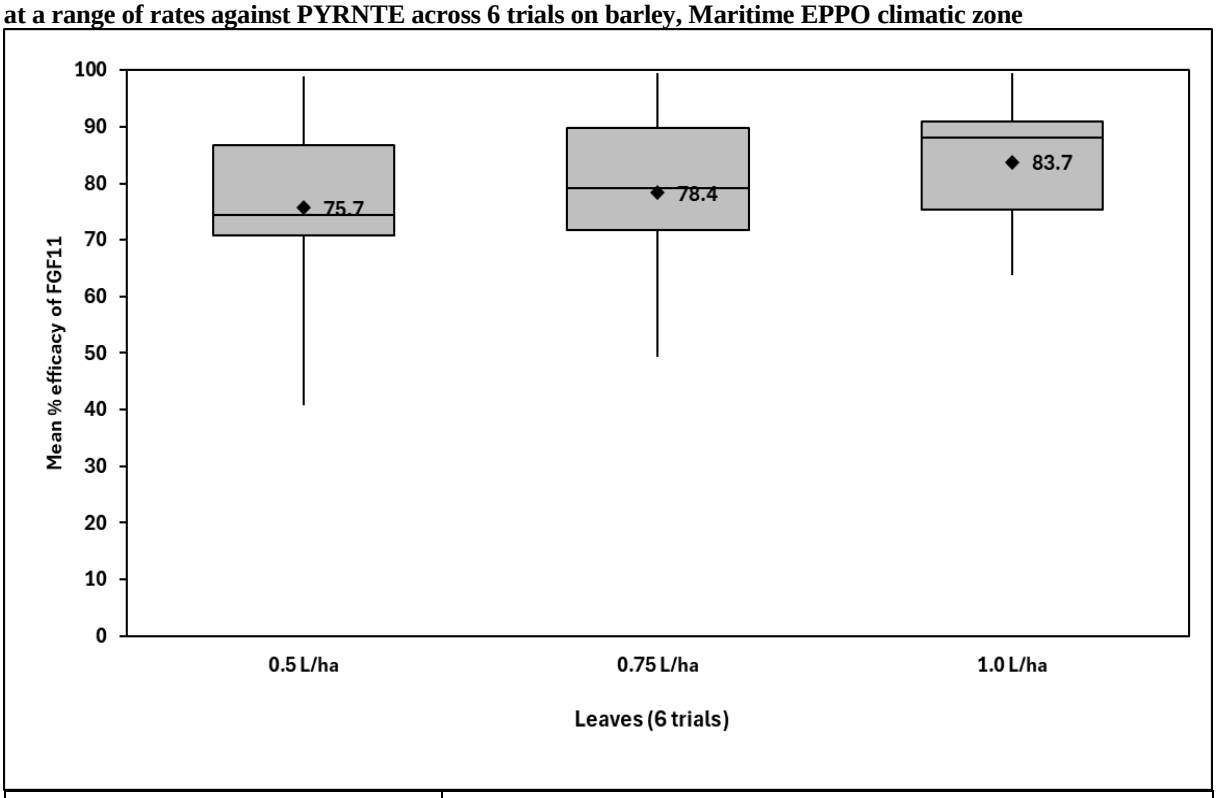
Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L1									
Maritime	1 trial	***5,45***	-	**71,15**	-	**77,94**	-	**75,47**	-
North-East	4 trials	***17,7***	*5,22-43,62*	**61,4**	44,38-78,0	**69,5**	58,25-85,1	**81,4**	72,46-90,4
South-East	6 trials	***7,5***	*5,9-10,34*	**70,6**	50,04-83,69	**76,3**	55,66-92,77	**82,7**	62,95-100
L2									
Maritime	2 trials	***9,3***	*9,1-9,57*	**78,7**	70,43-86,87	**87,6**	82,25-93,03	**90,8**	89,25-92,39

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L1									
North-East	4 trials	***25,5***	*6,25-58,75*	**60,3**	37,86-74,72	**69,7**	51,84-80,38	**79,1**	64,23-86,33
South-East	8 trials	***11,5***	*5,42-21,0*	**65,5**	40,45-80,23	**73,9**	60,94-82,93	**79,6**	64,07-90,95
L3									
Maritime	4 trials	***19,95***	*5,28-40,8*	**89,8**	83,15-99,0	**89,7**	79,22-99,5	**93,4**	87,99-99,5
North-East	3 trials	***21,4***	*9,37-43,87*	**82,3**	74,09-94,36	**89,0**	79,83-94,72	**94,5**	85,56-99,12
South-East	9 trials	***12,6***	*7,02-23,7*	**67,1**	21,7-95,4	**75,1**	53,36-96,6	**79,3**	54,57-100

Table 3.2 14d: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PYRNTE across trials on spring barley in all climatic zones after 2 applications

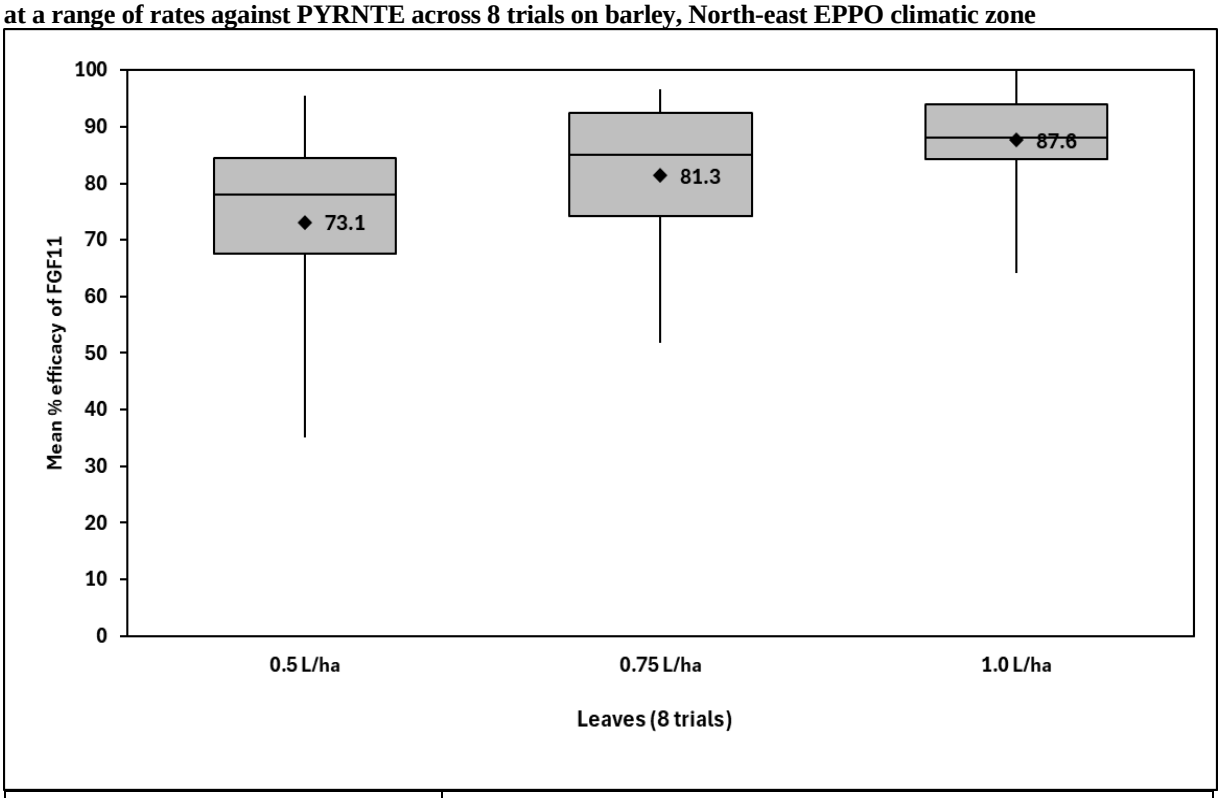
Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L1									
North-East	2 trials	***16,9***	*15,93-17,85*	**88,9**	85,74-92,04	**91,7**	90,18-93,31	**92,7**	91,58-93,76
South-East	2 trials	***19,4***	*5,57-33,25*	**44,7**	22,21-67,15	**55,96**	38,91-73,02	**65,4**	38,63-92,13
L2									
Maritime	2 trials	***17,9***	*7,92-27,87*	**66,1**	57,87-74,36	**67,2**	57,01-77,42	**74,2**	63,75-84,57
North-East	4 trials	***21,1***	*7,1-38,12*	**82,2**	70,83-93,59	**88,3**	84,85-93,35	**92,8**	86,22-100
South-East	3 trials	***10,5***	*8,81-12,25*	**58,9**	45,26-71,65	**65,2**	41,2-79,64	**76,9**	59,15-88,85
L3									
Maritime	2 trials	***8,7***	*5,05-12,25*	**56,3**	40,77-71,83	**57,6**	49,34-65,92	**70,9**	66,65-75,19
North-East	4 trials	***41,9***	*9,62-54,37*	**73,4**	35,07-95,51	**86,9**	72,92-96,59	**89,6**	79,75-97,28
South-East	3 trials	***16,8***	*9,75-20,85*	**71,1**	55,44-81,43	**80,6**	61,48-96,61	**87,4**	70,96-100

Figure 3.2-12: Dose justification; mean efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PYRNTE across 6 trials on barley, Maritime EPPO climatic zone



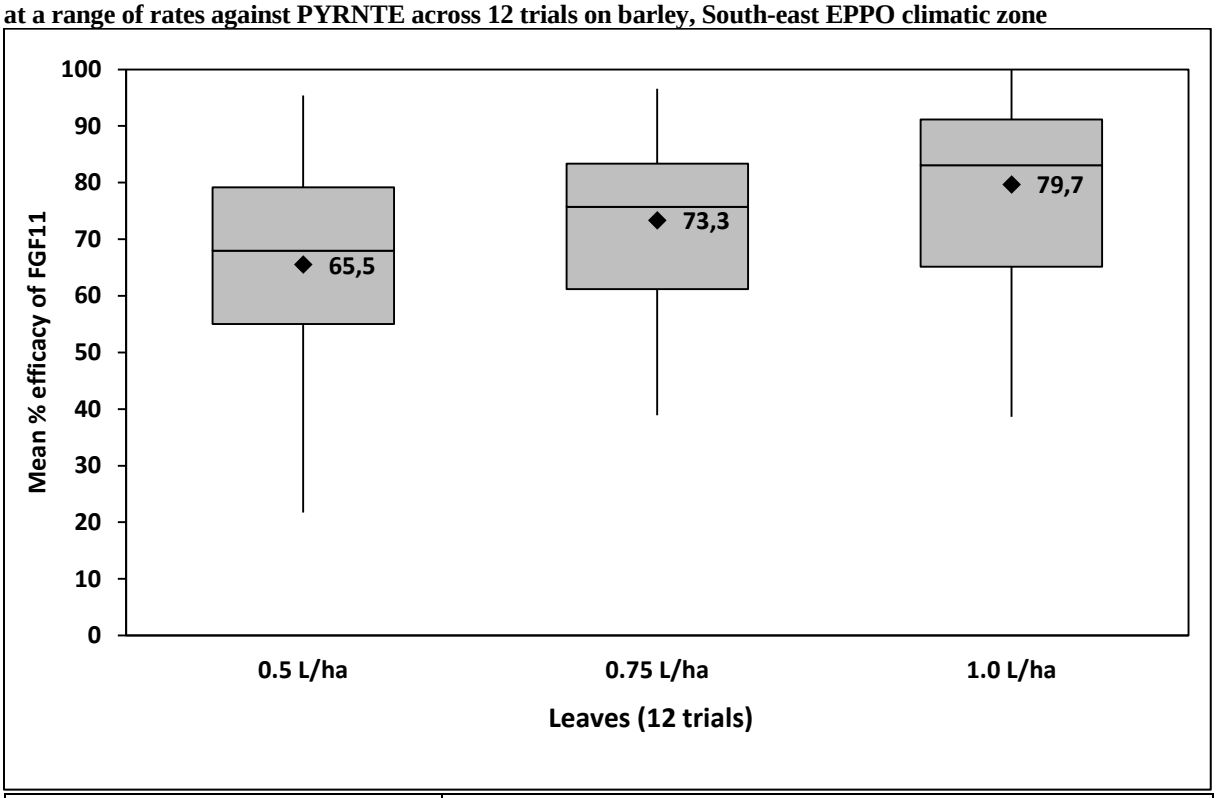
	Mean % efficacy of FGF11		
	0.5 L/ha	**0.75 L/ha**	**1.0 L/ha**
No. of trials (no. of data points)	6 (11)	6 (11)	6 (11)
Mean	**75.7**	**78.4**	**83.7**
S.D.	16.32	15.60	11.86
Q1	70.79	71.67	75.33
Median	74.36	79.22	87.99
Q3	86.66	89.83	90.89

Figure 3.2-13: Dose justification; mean efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PYRNTE across 8 trials on barley, North-east EPPO climatic zone



	Mean % efficacy of FGF11		
	0.5 L/ha	**0.75 L/ha**	**1.0 L/ha**
No. of trials (no. of data points)	8 (20)	8 (20)	8 (20)
Mean	**73.1**	**81.3**	**87.6**
S.D.	17.88	12.77	9.29
Q1	67.58	74.20	84.29
Median	78.00	85.00	88.14
Q3	84.50	92.50	94.00

Figure 3.2-14: Dose justification; mean efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PYRNTE across 12 trials on barley, South-east EPPO climatic zone



	Mean % efficacy of FGF11		
	0.5 L/ha	**0.75 L/ha**	**1.0 L/ha**
No. of trials (no. of data points)	12 (31)	12 (31)	12 (31)
Mean	**65.5**	**73.3**	**79.7**
S.D.	17.86	15.92	15.97
Q1	55.01	61.21	65.13
Median	67.97	75.74	83.10
Q3	79.18	83.34	91.17

Data generated in trials carried out in Maritime, North-east and South-east EPPO climatic zones clearly show the efficacy of FGF11 applied at 1.0 L product/ha against PYRNTE in barley to be higher and more consistent compared to that of lower rates (0.75 L and 0.5 L product/ha).

Whilst only limited data have been generated to demonstrate the minimum effective dose of FGF11 against PYRNTE per barley crop type in most of the EPPO climatic zones, the susceptibility of the crops to this fungal pathogen, disease development pressure and development patterns, agronomy of the crops and areas in which the crops are grown in the Central Registration zone can be considered to be sufficiently similar between spring and winter barley to be fully supportive of demonstrating minimum effective dose against PYRNTE in both barley crop types.

Furthermore, products containing prothioconazole and azoxystrobin straight and as mixture are already registered against PYRNTE and other foliar diseases in spring and winter barley throughout Europe. The registered rate is generally the same against PYRNTE, PUCCHD, RAMUCC and RHYNSE in spring and winter barley and the same can therefore be considered for FGF11. Trials conducted in spring and winter barley against all these targets indicate 1.0 L/ha of FGF11 as the minimum effective dose with all trials together providing a sound dataset.

It is therefore reasonable to conclude that the proposed label rate of 1.0 L product/ha is fully justified as the minimum effective dose for the control of PYRNTE in winter and spring barley by FGF11.

Comments of zRMS:

1 application

Winter barley

A total of 7 efficacy trials have been submitted to determine the minimum effective dose for the control of *Pyrenophora teres* (PYRNTE) in winter barley after 1 application.

In the North-East EPPO climatic zone, 2 trials were conducted in 2023. FGF11 applied at dose rate of 1 l/ha achieved good level of control on L4 with the result of 90,7%. Medium effectiveness was observed on L5 (78,3%) in 1 trial. Comparable effect was noted at the lower dose rate of 0,75 l/ha. ~~However, this use cannot be accepted because of limited number of trials.~~

In the South-East zone, 5 trials were carried out between 2022 and 2023. The test product at the claimed dose presented sufficient effectiveness with the results of 87,1% on L4, 91,07% on L5 and 86,8% on L6. The lower dose of 0,75 l/ha had the control on similar level on L4 and L6.

No results after 1 application were available in the Maritime EPPO zone. The cMSs are kindly asked to consider this use at the national level.

Taking into account the South-East zone, the dose rate of 1 l/ha can be determined as the minimum effective dose for the control of PYRNTE in winter barley.

Spring barley

A total of 5 efficacy trials have been submitted to determine the minimum effective dose for the control of *Pyrenophora teres* (PYRNTE) in spring barley after 1 application.

In the Maritime EPPO climatic zone, only 1 trial was conducted in 2023. FGF11 at 1 l/ha achieved medium level of control with the results of 67,66% on L3 and 62,35% on L4. Significant inferior effectiveness were observed at the lower dose rates of 0,75 l/ha and 0,5 l/ha. Due to limited number of trials, the cMSs are kindly asked to consider this use at the national level.

In the North-East zone, 2 trials were carried out between 2022 and 2023. The test product at the claimed dose presented medium level of control with the results of 79,83% on L3 and 63,9% on L4. The lower dose rates of 0,75 l/ha and 0,5 l/ha obtained comparable effect. ~~Due to limited number of trials and no extrapolation possible, this use cannot be accepted in Poland.~~

In the South-East zone, 2 trials were conducted in 2023. FGF11 at 1 l/ha achieved good effectiveness with the results of 100% on L4 and 96,11% on L5. Similar level of control was observed at the lower doses of 0,75 l/ha and 0,5 l/ha. Due to limited number of trials in spring barley and the opportunities of extrapolation from winter barley, the claimed dose of 1 l/ha is justified as MED. However, the final decision to accept this use is left to the cMSs.

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2 applications

Winter barley

A total of 17 efficacy trials have been submitted to determine the minimum effective dose for the control of *Pyrenophora teres* (PYRNTE) in winter barley after 2 application.

In the Maritime zone, 4 trials were conducted between 2022 and 2023. FGF11 at dose rate of 1 l/ha achieved high level of control with the results of 90,8% on L2 and 93,4% on L3. Medium efficacy was observed on L1 (75,47%) in 1 out of 4 trials. Comparable effect was noted at lower dose rates of 0,75 l/ha and 0,5 l/ha. Due to limited number of trials, the cMSs are kindly asked to consider this use at the national level.

In the North-East zone, 4 trials were carried out in 2023. The test product at claimed dose presented good efficacy with the results of 81,4% on L1 and 94,5% on L3. Medium level of control was visible on L2 (79,1%). Lower doses of 0,75 l/ha and 0,5 l/ha had significant inferior results on L1 and L2. Slight differences were observed on L3. ~~Due to limited number of trials and no extrapolation possible, this use cannot be registration in Poland.~~

In the South-East zone, 9 trials were conducted between 2022 and 2023. FGF11 at 1 l/ha achieved medium level of control with the results of 79,6% on L2 and 79,3% on L3. Slight superior effect was observed on L1 (82,7%) in 6 out of 9 trials. Comparable results were obtained at lower dose rates of 0,75 l/ha and 0,5 l/ha with significant differences between the claimed and lowest dose.

Taking into account the South-East zone, the dose rate of 1 l/ha can be determined as the minimum effective dose for the control of PYRNTE in winter barley.

Spring barley

A total of 9 efficacy trials have been submitted to determine the minimum effective dose for the control of *Pyrenophora teres* (PYRNTE) in spring barley after 2 applications.

In the Maritime EPPO zone, only 2 trials were carried out between 2022 and 2023. FGF11 at 1 l/ha achieved

medium level of control with the results of 74,2% on L2 and 70,9% on L3. Significant inferior efficacy was observed at the lower dose rates of 0,75 l/ha and 0,5 l/ha. Due to limited number of trials in winter barley, the extrapolation is risky in zRMS opinion. However, spring barley is minor crop in Belgium and the registration under art. 51 is possible in this case, as zRMS supposes. The cMSs are kindly asked to consider this use at the national level.
In the North-East zone, 4 trials were conducted between 2022 and 2023. The test product at the claimed dose presented high efficacy with the results of 92,7% on L1, 92,8% on L2 and 89,6% on L3. Comparable effect was visible at the lower dose of 0,75 l/ha. The dose rate of 0,5 l/ha was slight inferior compared to the claimed dose. ~~Due to limited number of trials and no extrapolation possible, this use cannot be registration in Poland.~~
In the South-East zone, 3 trials were conducted in 2023. FGF11 at 1 l/ha achieved medium level of control with the results of 65,4% on L1 and 76,9% on L2. Superior effect was observed on L3 (87,4%). The lower doses of 0,75 l/ha and 0,5 l/ha presented significant inferior results compared to the claimed dose. Due to limited number of trials in spring barley and the opportunities of extrapolation from winter barley, the claimed dose of 1 l/ha is justified as MED.
Taking into account the South-East zone, the dose rate of 1 l/ha can be determined as the minimum effective dose for the control of PYRNTE in spring barley.

3.2.2.3.2 Minimum effective dose for control of Rust (*Puccinia hordeii*: PUCCHD)

A total of 8 trials carried out between 2022 and 2023 generated data on the efficacy of FGF11 applied at a range of rates (0.5 L, 0.75 L and 1.0 L product/ha) against PUCCHD in winter barley (7 trials) and spring barley (1 trial).

Of these trials, 3 were carried out in the Maritime EPPO climatic zone (2 in Germany and 1 in France) and 5 were carried out in the North-east EPPO climatic zone (all in Poland).

Disease developed on all 8 trials and was assessed as percentage severity on the upper leaves (1-3).

Across trials, the efficacy of FGF11 has been evaluated under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in barley crops growing regions across EU Central Registration zone countries.

A summary of mean percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCHD in barley across trials and leaf levels with valid data in each of the EPPO climatic zones is given in Table 3.2-15, with data presented as a Box-Whisker plot in Figure 3.2-15 and Figure 3.2-16.

Table 3.2-15: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCHD across trials on barley in all climatic zones at 14-37 DA-A2

Registration or EPPO climatic zone	No of trials (no of data points)	*Untreated (% severity on leaves)*		FGF11						Statistical comparison of 1.0 L/ha to #	
				0.5 L/ha		0.75 L/ha		1.0 L/ha			
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max	0.5 L/ha	0.75 L/ha
CEU	8 (19)	*14.4*	*5.5 - 46.8*	**89.8**	43.1 - 100	**94.5**	55 - 100	**96.7**	72.9 - 100	> (4), = (15)	> (2), = (17)
EPPO MAR	3 (9)	*8.9*	*5.5 - 15.4*	**99.3**	98 - 100	**99.4**	98.1 - 100	**99.2**	97.2 - 100	= (9)	= (9)
EPONE	5 (10)	*19.4*	*6.5 - 46.8*	**81.3**	43.1 - 100	**90.2**	55 - 100	**94.5**	72.9 - 100	> (4), = (6)	> (2), = (8)

No. of data points where >, = or <, based on statistically significant differences at 95% confidence level

Table 3.2 15a: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCHD across trials on winter barley in all climatic zones after 1 application

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L3									
Maritime	1 trial	***13,55***	-	**98,49**	-	**98,09**	-	**98,88**	-
North-East (+trials conducted in Germany)	1 trial	***13,55***	-	**98,49**	-	**98,09**	-	**98,88**	-
L4									
North-East (+trials conducted in Germany)	1 trial	***5,1***	-	**40,3**	-	**38,6**	-	**59,8**	-
L5									
North-East (+trials conducted in Germany)	1 trial	***7,0***	-	**60,2**	-	**60,4**	-	**66,6**	-

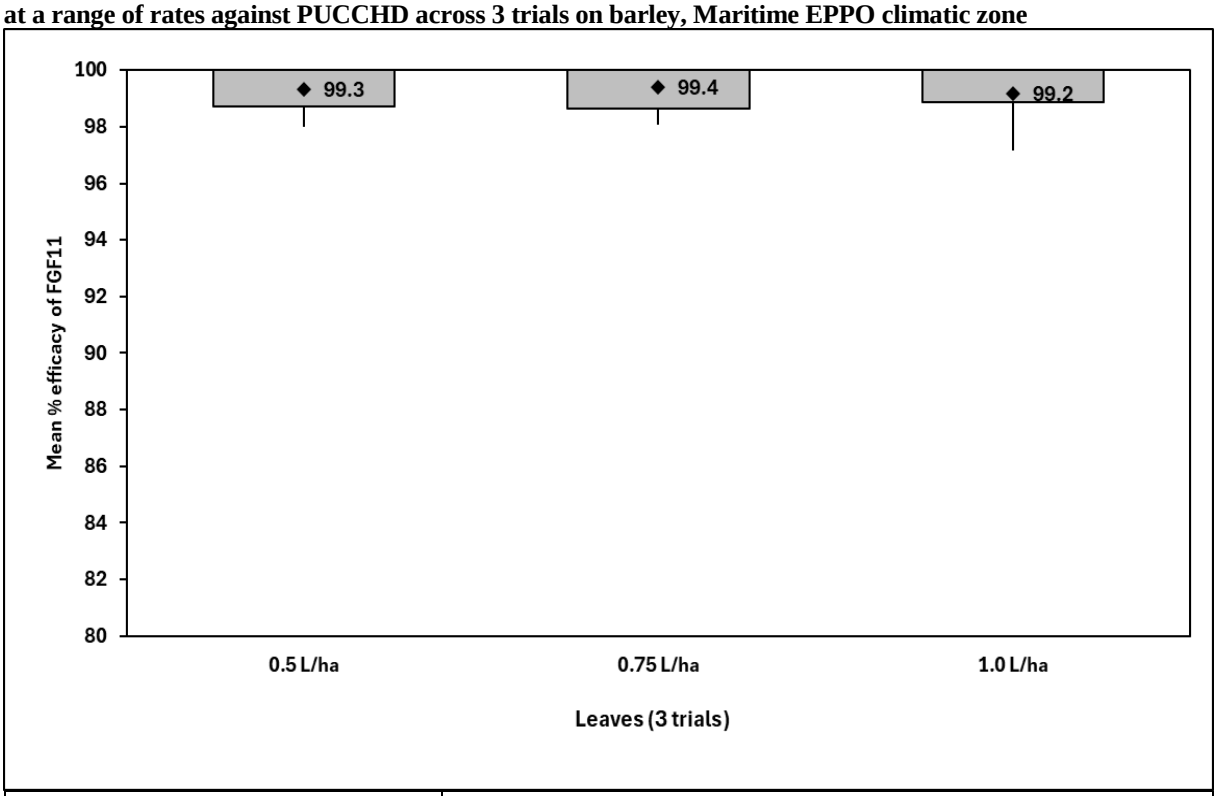
Table 3.2 15b: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCHD across trials on winter barley in all climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L1									
Maritime	3 trials	***9,2***	*6,8-11,47*	**99,3**	98,01-100	**99,7**	99,19-100	**99,8**	99,53-100
North-East	3 trials	***20,0***	*6,47-32,37*	**70,9**	43,13-88,54	**85,5**	61,61-100	**92,1**	79,41-100
L2									
Maritime	3 trials	***8,99***	*5,48-15,35*	**99,6**	98,71-100	**99,6**	98,65-100	**99,1**	97,16-100
North-East	4 trials	***20,5***	*7,4-46,75*	**76,8**	43,78-92,91	**87,7**	55,01-100	**92,6**	72,91-100
L3									
Maritime	1 trial	***13,55***	-	**98,49**	-	**98,09**	-	**98,88**	-
North-East	2 trials	***20,8***	*8,12-33,5*	**96,6**	93,25-100	**97,0**	94,09-100	**99,0**	98,02-100

Table 3.2 15c: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCHD across trials on spring barley in all climatic zones after 2 applications

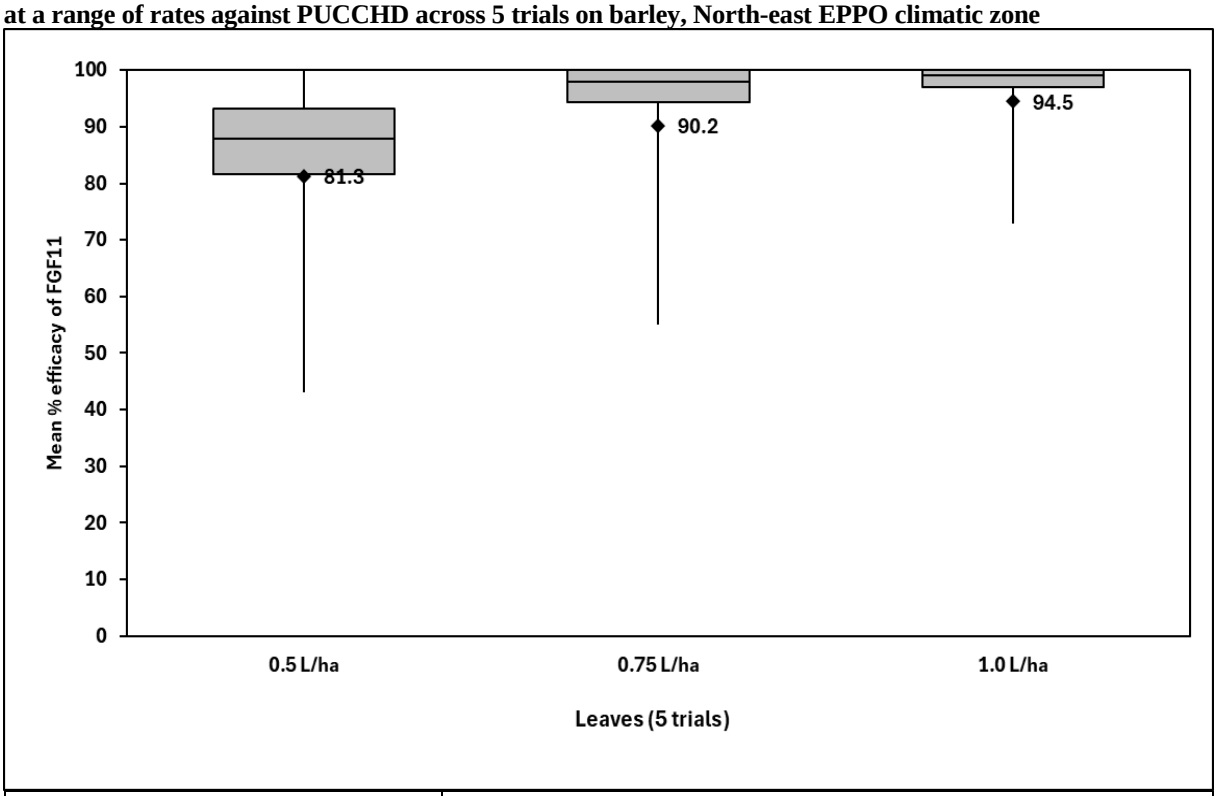
Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L3									
North-East	1 trial	***10,27***	-	**100**	-	**100**	-	**100**	-

Figure 3.2-15: Dose justification; mean efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCHD across 3 trials on barley, Maritime EPPO climatic zone



	Mean % efficacy of FGF11		
	0.5 L/ha	**0.75 L/ha**	**1.0 L/ha**
No. of trials (no. of data points)	3 (9)	3 (9)	3 (9)
Mean	**99.3**	**99.4**	**99.2**
S.D.	0.83	0.76	1.21
Q1	98.71	98.65	98.88
Median	100.00	100.00	100.00
Q3	100.00	100.00	100.00

Figure 3.2-16: Dose justification; mean efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against PUCCHD across 5 trials on barley, North-east EPPO climatic zone



	Mean % efficacy of FGF11		
	0.5 L/ha	**0.75 L/ha**	**1.0 L/ha**
No. of trials (no. of data points)	5 (10)	5 (10)	5 (10)
Mean	**81.3**	**90.2**	**94.5**
S.D.	20.91	17.01	9.84
Q1	81.54	94.30	97.02
Median	87.93	97.95	99.01
Q3	93.16	100.00	100.00

Data generated in trials carried out in Maritime and North-east EPPO climatic zones clearly show the efficacy of FGF11 applied at 1.0 L product/ha against PUCCHD in barley to be higher and more consistent compared to that of lower rates (0.75 L and 0.5 L product/ha).

The data package available in the Maritime and North-east EPPO climatic zone against PUCCHD in barley is limited and no data are presented from the South-east EPPO climatic zone. The morphology, life cycles and infection patterns of *Puccinia sp*. in different cereal crops and also the efficacy of fungicides against this pathogen, including that of azoxystrobin and prothioconazole, are very similar. It is therefore considered that the presented data demonstrating minimum effective dose of FGF11 against PUCCRE and PUCCSI in wheat and triticale (please refer to Section 3.2.2.1.2 and Section 3.2.2.1.3) is also supportive of demonstrating that against PUCCHD in barley. Furthermore, products containing the active substances azoxystrobin and prothioconazole, solo and as mixture, are already registered throughout Europe for control of PUCCHD in barley and efficacy has been demonstrated.

Whilst no or only limited data have been generated to demonstrate the minimum effective dose of FGF11 against PUCCHD on spring barley in the Maritime and North-east EPPO climatic zones, the susceptibility of the crops to this fungal pathogen, disease development pressure and development patterns, agronomy of the crops and areas in which the crops are grown in the Central Registration zone can be considered to be sufficiently similar between spring and winter barley to be fully supportive of demonstrating minimum effective dose against PUCCHD in both barley crop types.

Furthermore, products containing prothioconazole and azoxystrobin straight and as mixture are already registered against PUCCHD and other foliar diseases in spring and winter barley throughout Europe. The registered rate is generally the same against PYRNTE, PUCCHD, RAMUCC and RHYNSE in spring and winter barley and the same can therefore be considered for FGF11. Trials conducted in spring and winter barley against all these targets indicate 1.0 L/ha of FGF11 as the minimum effective dose with all trials together providing a sound dataset.

Whilst limited data are presented on the efficacy of FGF11 against PUCCHD in barley from trials carried out in the North-east EPPO climatic zone, data generated on this disease across trials in the country neighbouring Poland (Germany) provide supportive evidence of that in Poland.

It is therefore reasonable to conclude that the proposed label rate of 1.0 L product/ha is fully justified as the minimum effective dose for the control of PUCCHD in winter and spring barley by FGF11.

Comments of zRMS:

1 application
Winter barley
A total of 2 efficacy trials have been submitted to determine the minimum effective dose for the control of *Puccinia hordeii* (PUCCHD) in winter barley after 1 application.
In the Maritime EPPO climatic zone, only 1 trial was conducted in 2022. FGF11 applied at dose rate of 1 l l/ha achieved high level of control with the result of 98,88% on L3. Comparable effect was visible at the lower doses of 0,75 l/ha and 0,5 l/ha. However, the cMSs are kindly asked to consider this use at the national level because of limited number of trials.
In the North-East zone, 1 trial was carried out in 2023. Also 1 trial from Germany can ~~be~~ support ~~for~~ the Polish registration. The test product at the claimed dose presented medium level of control on L4 (59,8%) and L5 (66,6%). Superior result was observed on L3 (98,88%) in other trial. Significant inferior effectiveness was noted at the lower doses. ~~This use cannot be accepted because of limited number of trials.~~
No results after 1 application were available in the South-East EPPO zone. The cMSs are kindly asked to consider this use at the national level.

Spring barley
No results after 1 application were available in spring barley in any EPPO climatic zones. The cMSs belonging to the MAR and SE zone are kindly asked to consider this use at the national level. ~~This use cannot be accepted in Poland.~~

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2 applications
Winter barley
A total of 4 efficacy trials have been submitted to determine the minimum effective dose for the control of *Puccinia hordeii* (PUCCHD) in winter barley after 2 applications.
In the Maritime EPPO climatic zone, 3 trials were conducted between 2022 and 2023. FGF11 at dose rate of 1 l/ha achieved high level of control with the results of 99,8% on L1, 99,1% on L2 and 98,88% on L3. Similar effect was observed at lower doses of 0,75 l/ha and 0,5 l/ha. Due to limited number of trials, the cMSs are kindly asked to consider this use at the national level.
In the North-East zone, 4 trials were carried out between 2022 and 2023. The test product at claimed dose presented high efficacy with the results of 92,1% on L1, 92,6% on L2 and 99% on L3. Comparable effect was visible for the lower doses on L3. On L2 and L3, the lower doses of 0,75 l/ha and 0,5 l/ha had slight inferior results compared to the dose of 1 l/ha. 2 efficacy trials conducted in Germany can support the registration in Poland.
No efficacy trials were available in the South-East EPPO zone. The cMSs are kindly asked to consider this use at the national level.
Taking into account the North-East zone, the dose rate of 1 l/ha can be determined as the minimum effective dose for the control of PUCCHD in winter barley.

Spring barley
Only 1 efficacy trial has been submitted to determine the minimum effective dose for the control of *Puccinia hordeii* (PUCCHD) in spring barley after 2 applications. This trial was carried out in 2023 in the North-East zone. FGF11 at 1 l/ha achieved full effectiveness on L3. No significant differences between the claimed and

lower doses were observed. Due to limited number of trials in spring barley and the opportunities of extrapolation from winter barley, the claimed dose of 1 l/ha is justified as MED.
No efficacy trials were available in the Maritime and South-East EPPO zone. The cMSs are kindly asked to consider this use at the national level. However, spring barley is minor crop in Belgium and the registration under art. 51 is possible in this case, as zRMS supposes.

3.2.2.3.3 Minimum effective dose for control of Ramularia (*Ramularia collo-cygni*: RAMUCC)

A total of 7 trials carried out between 2022 and 2023 generated data on the efficacy of FGF11 applied at a range of rates (0.5 L, 0.75 L and 1.0 L product/ha) against RAMUCC in winter barley (6 trials) and spring barley (1 trial).

All of the trials were carried out in the Maritime EPPO climatic zone (2 in Germany, 1 in Ireland and 4 in France).

Disease developed on all 7 trials and was assessed as percentage severity on the upper leaves (1-3).

Across trials, the efficacy of FGF11 has been evaluated under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in barley crops growing regions across EU Central Registration zone countries.

A summary of mean percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against RAMUCC in barley across trials and leaf levels with valid data is given in Table 3.2-16, with data presented as a Box-Whisker plot in Figure 3.2-17.

Table 3.2-16: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against RAMUCC across trials on barley at 17-40 DA-A2

Registration or EPPO climatic zone	No of trials (no of data points)	*Untreated (% severity on leaves)*		FGF11						Statistical comparison of 1.0 L/ha to #	
				0.5 L/ha		0.75 L/ha		1.0 L/ha			
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max	0.5 L/ha	0.75 L/ha
CEU/EPPO MAR	7 (9)	*28.3*	*5.3 - 57*	**50.4**	21.4 - 68.6	**69.1**	46.1 - 92.8	**80.6**	57.8 - 92.6	> (4), = (5)	= (9)

No. of data points where >, = or <, based on statistically significant differences at 95% confidence level

Table 3.2 16a: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against RAMUCC across trials on winter barley in all climatic zones after 1 application

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L4									
South-East	1 trial	***5,74***	-	78,05	-	78,34	-	88,91	-

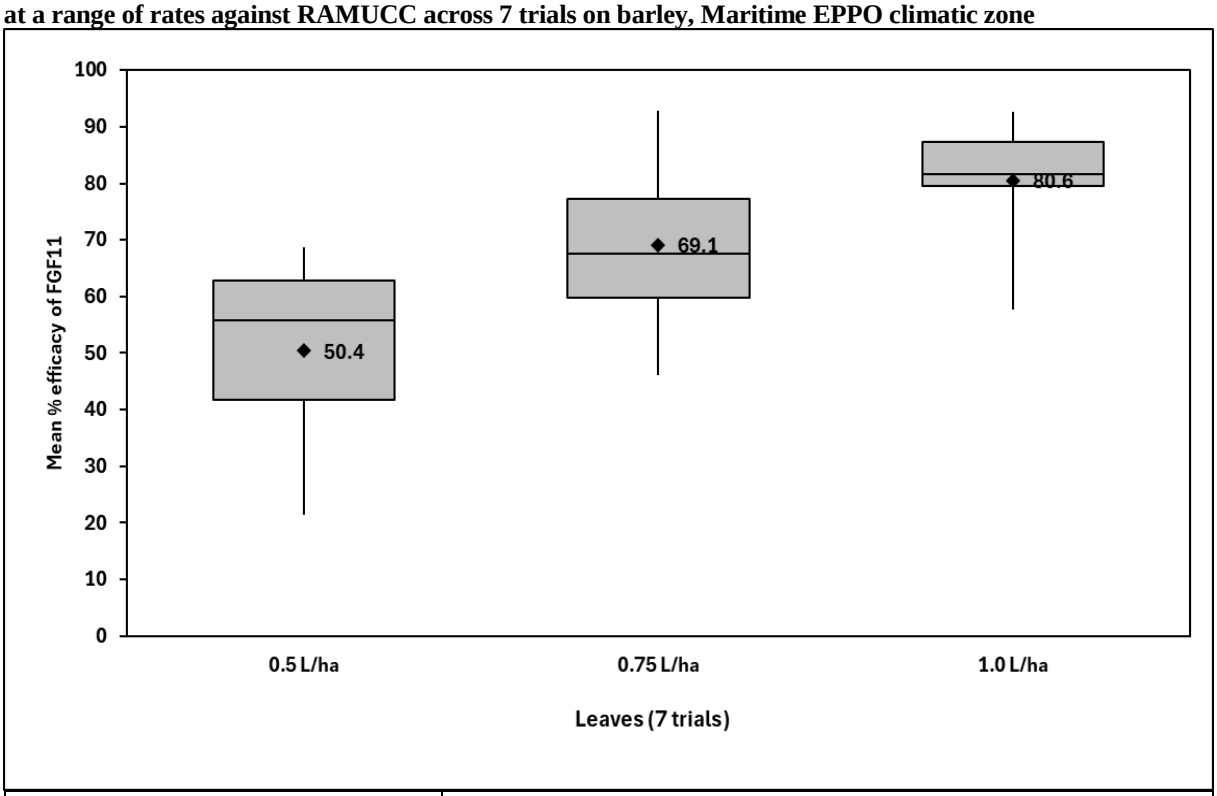
Table 3.2 16b: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against RAMUCC across trials on winter barley in all climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L2									
Maritime	6 trials	***29,7***	*10,3-57,0*	**51,1**	21,36-68,62	**73,5**	46,09-92,81	**81,3**	57,79-92,64
L3									
Maritime	2 trials	***24,2***	*5,25-43,12*	**45,8**	29,04-62,55	**63,6**	59,74-67,5	**83,4**	79,57-87,27

Table 3.2 16c: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against RAMUCC across trials on spring barley in all climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L1									
Maritime	1 trial	***27,57***	-	**55,72**	-	**53,68**	-	**70,59**	-

Figure 3.2-17: Dose justification; mean efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against RAMUCC across 7 trials on barley, Maritime EPPO climatic zone



	Mean % efficacy of FGF11		
	0.5 L/ha	**0.75 L/ha**	**1.0 L/ha**
No. of trials (no. of data points)	7 (9)	7 (9)	7 (9)
Mean	**50.4**	**69.1**	**80.6**
S.D.	16.78	15.01	10.64
Q1	41.68	59.74	79.57
Median	55.72	67.50	81.60
Q3	62.85	77.31	87.27

Data generated in trials carried out in the Maritime EPPO climatic zone clearly show the efficacy of FGF11 applied at 1.0 L product/ha against RAMUCC in barley to be higher and more consistent compared to that of lower rates (0.75 L and 0.5 L product/ha).

Only data from the Maritime EPPO climatic zone are available. Development of the disease is favoured by temperate, humid conditions and conditions in the Maritime EPPO climatic zone therefore represent a worst case scenario. Furthermore, products containing the active substances azoxystrobin and prothioconazole, solo and as mixture, are already registered for control of RAMUCC in barley throughout Europe and efficacy has been demonstrated.

Whilst only limited data have been generated to demonstrate the minimum effective dose of FGF11 against RAMUCC on spring barley, the susceptibility of the crops to this fungal pathogen, disease development pressure and development patterns, agronomy of the crops and areas in which the crops are grown in the Central Registration zone can be considered to be sufficiently similar between spring and winter barley to be fully supportive of demonstrating minimum effective dose against RAMUCC in both barley crop types.

Furthermore, products containing prothioconazole and azoxystrobin straight and as mixture are already registered against RAMUCC and other foliar diseases in spring and winter barley throughout Europe. The registered rate is generally the same against PYRNTE, PUCCHD, RAMUCC and RHYNSE in spring and winter barley and the same can therefore be considered for FGF11. Trials conducted in spring

and winter barley against all these targets indicate 1.0 L/ha of FGF11 as the minimum effective dose with all trials together providing a sound dataset.

It is therefore reasonable to conclude that the proposed label rate of 1.0 L product/ha is fully justified as the minimum effective dose for the control of RAMUCC in winter and spring barley by FGF11.

Comments of zRMS:

1 application
Winter barley
Only 1 trial has been submitted to determine the minimum effective dose for the control of *Ramularia collo-cygni* (RAMUCC) in winter barley after 1 application. This trial was conducted in 2023 in the South-East EPPO climatic zone. FGF11 applied at dose rate of 1 l/ha achieved good effectiveness with the result of 88,91% on L4. Significant inferior level of control was observed at the lower doses of 0,75 l/ha and 0,5 l/ha. The cMSs are kindly asked to consider this use at the national level.
No results after 1 application were available in the Maritime and North-East EPPO zone. The cMSs belonging to the MAR zone are kindly asked to consider this use at the national level. This use cannot be accepted in Poland.

Spring barley
No results after 1 application were available in spring barley in any EPPO climatic zones. The cMSs belonging to the MAR and SE zone are kindly asked to consider this use at the national level. This use cannot be accepted in Poland.

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2 applications
Winter barley
A total of 6 efficacy trials have been submitted to determine the minimum effective dose for the control of *Ramularia collo-cygni* (RAMUCC) in winter barley after 2 applications. All trials were conducted between 2022 and 2023 in the Maritime EPPO climatic zone. FGF11 applied at dose rate of 1 l/ha achieved good control with the results of 81,3% on L2 and 83,4% on L3. Significant inferior effectiveness was observed at the lower doses of 0,75 l/ha and 0,5 l/ha.
No efficacy trials were available in the North-East and South-East EPPO zone. The cMSs belonging to the SE zone are kindly asked to consider this use at the national level. Due to the inability to extrapolate, this use cannot be accepted in Poland.

Spring barley
Only 1 efficacy trial has been submitted to determine the minimum effective dose for the control of *Ramularia collo-cygni* (RAMUCC) in spring barley after 2 applications. This trial was carried out in 2023 in the Maritime EPPO climatic zone. FGF11 at 1 l/ha achieved medium level of control with the result of 70,59% on L1. Significant inferior effectiveness was observed for the lower doses of 0,75 l/ha and 0,5 l/ha. Due to limited number of trials in spring barley and the opportunities of extrapolation from winter barley, the claimed dose of 1 l/ha is justified as MED.
No efficacy trials were available in the North-East and South-East EPPO zone. The cMSs belonging to the SE zone are kindly asked to consider this use at the national level. Due to the inability to extrapolate, this use cannot be accepted in Poland.

3.2.2.3.4 Minimum effective dose for control of Leaf blotch (*Rhynchosporium secalis*: RHYNSE)

A total of 5 trials carried out between 2022 and 2023 generated data on the efficacy of FGF11 applied at a range of rates (0.5 L, 0.75 L and 1.0 L product/ha) against RHYNSE in winter barley.

All of the trials were carried out in the Maritime EPPO climatic zone (2 in Great Britain, 1 in Germany and 2 in France.

Disease developed on all 5 trials and was assessed as percentage severity on the upper leaves (1-3).

Across trials, the efficacy of FGF11 has been evaluated under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in barley crops growing regions across EU Central Registration zone countries.

A summary of mean percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against RHYNSE in barley across trials and leaf levels with valid data is given in Table 3.2-17, with data presented as a Box-Whisker plot in Figure 3.2-19.

Table 3.2-17: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against RHYNSE across trials on barley at 17-40 DA-A2

Registration or EPPO climatic zone	No of trials (no of data points)	*Untreated (% severity on leaves)*		FGF11						Statistical comparison of 1.0 L/ha to #	
				0.5 L/ha		0.75 L/ha		1.0 L/ha			
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max	0.5 L/ha	0.75 L/ha
CEU/EPPO MAR	5 (13)	***24.9***	*5.8 - 57.5*	**52.5**	21.2 - 100	**67.4**	44.4 - 100	**80.9**	53.4 - 100	> (5), = (8)	> (2), = (11)

No. of data points where >, = or <, based on statistically significant differences at 95% confidence level

Table 3.2 17a: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against RHYNSE across trials on winter barley in all climatic zones after 1 application

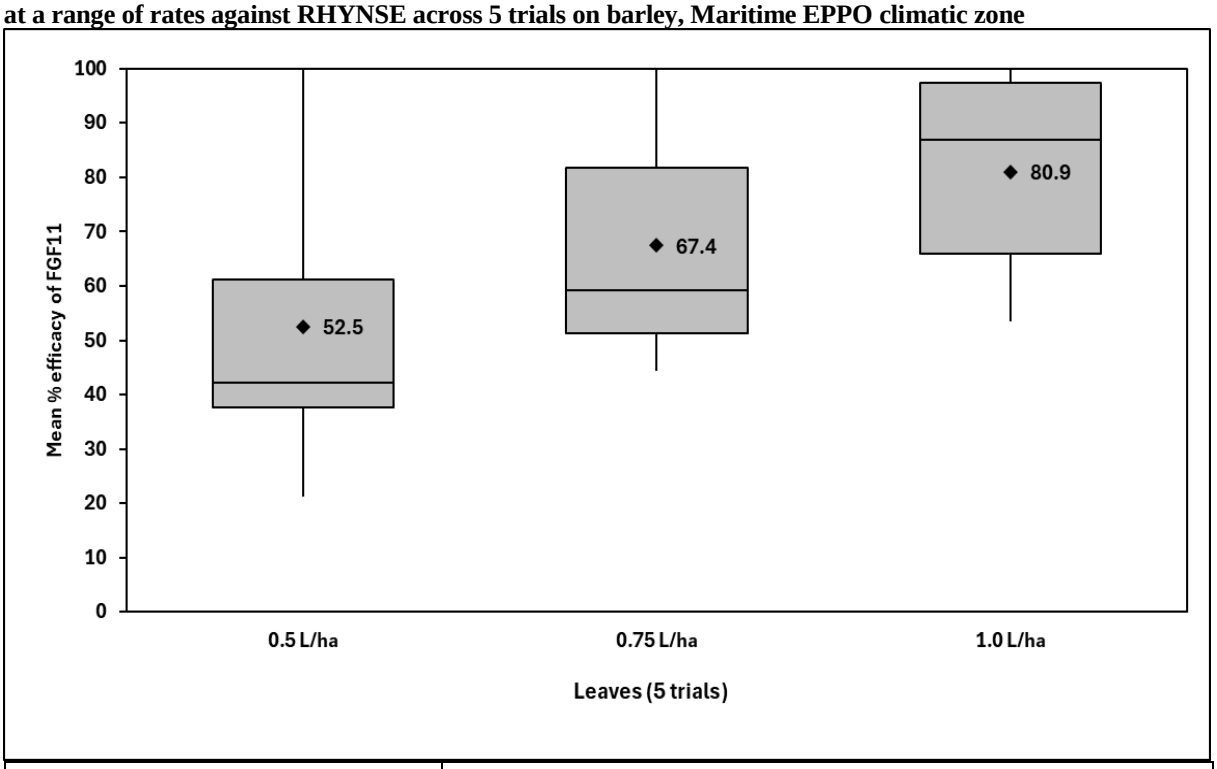
Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L3									
Maritime	2 trials	***5,2***	*4,45-5,98*	**65,2**	40,5-89,86	**70,1**	47,9-92,28	**80,9**	66,9-94,9
North-East (+trials conducted in Germany)	1 trial	***4,45***	-	**40,5**	-	**47,9**	-	**66,9**	-
L4									
Maritime	2 trials	***21,2***	*6,58-35,73*	**53,1**	41,3-64,81	**58,96**	46,3-71,63	**68,8**	67,6-69,96
North-East (+trials conducted in Germany)	1 trial	***6,58***	-	**41,3**	-	**46,3**	-	**67,6**	-

Table 3.2 17b: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against RHYNSE across trials on winter barley in all climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11					
				0.5 L/ha		0.75 L/ha		1.0 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max
L1									
Maritime	5 trials	***22,5***	*5,8-47,62*	**65,0**	23,12-100	**76,9**	45,76-100	**85,8**	65,83-100

Registration or EPPO climatic zone	**No. of trials**	***Untreated***		**FGF11**					
				0.5 L/ha		**0.75 L/ha**		**1.0 L/ha**	
		Mean	***Min-max***	**Mean**	**Min-max**	**Mean**	**Min-max**	**Mean**	**Min-max**
L2									
Maritime	5 trials	***28,9***	*8,32-57,5*	**50,9**	21,24-100	**67,3**	44,43-100	**78,5**	53,38-100
L3									
Maritime	3 trials	***21,99***	*13,32-29,5*	**34,3**	24,91-40,54	**51,9**	47,03-55,84	**76,9**	61,76-87,33

Figure 3.2-18: Dose justification; mean efficacy (based on disease severity on the leaves) of FGF11 applied at a range of rates against RHYNSE across 5 trials on barley, Maritime EPPO climatic zone



	Mean % efficacy of FGF11		
	0.5 L/ha	**0.75 L/ha**	**1.0 L/ha**
No. of trials (no. of data points)	5 (13)	5 (13)	5 (13)
Mean	**52.5**	**67.4**	**80.9**
S.D.	28.89	20.73	16.88
Q1	37.59	51.23	65.83
Median	42.18	59.17	86.97
Q3	61.19	81.84	97.45

Data generated in trials carried out in Maritime EPPO climatic zones clearly show the efficacy of FGF11 applied at 1.0 L product/ha against RHYNSE in barley to be higher and more consistent compared to that of lower rates (0.75 L and 0.5 L product/ha).

Only data from the Maritime EPPO climatic zone are available. Development of the disease is favoured by temperate, humid conditions and conditions in the Maritime EPPO climatic zone therefore represent a worst case scenario. Furthermore, products containing the active substances azoxystrobin and prothioconazole, solo and as mixture, are already registered for control of RHYNSE in barley throughout Europe and efficacy has been demonstrated.

Whilst no data have been generated to demonstrate the minimum effective dose of FGF11 against RHYNSE on spring barley, the susceptibility of the crops to this fungal pathogen, disease development pressure and development patterns, agronomy of the crops and areas in which the crops are grown in the Central Registration zone can be considered to be sufficiently similar between spring and winter barley to be fully supportive of demonstrating minimum effective dose against RHYNSE in both barley crop types.

Furthermore, products containing prothioconazole and azoxystrobin straight and as mixture are already registered against RHYNSE and other foliar diseases in spring and winter barley throughout Europe. The registered rate is generally the same against PYRNTE, PUCCHD, RAMUCC and RHYNSE in spring and winter barley and the same can therefore be considered for FGF11. Trials conducted in spring and winter barley against all these targets indicate 1.0 L/ha of FGF11 as the minimum effective dose with all trials together providing a sound dataset.

It is therefore reasonable to conclude that the proposed label rate of 1.0 L product/ha is fully justified as the minimum effective dose for the control of RHYNSE in winter and spring barley by FGF11.

Comments of zRMS:

1 application
Winter barley
A total of 2 efficacy trials have been submitted to determine the minimum effective dose for the control of *Rhynchosporium secalis* (RHYNSE) in winter barley after 1 application.
In the Maritime EPPO climatic zone, 2 trials were conducted between 2022 and 2023. FGF11 applied at dose rate of 1 l/ha achieved medium efficacy on L4 (68,8%) and superior level of control on L3 (80,9%). The lower doses of 0,75 l/ha and 0,5 l/ha had significant inferior effectiveness. The cMSs are kindly asked to consider this use at the national level because of limited number of trials.
In the North-East zone, no trials were carried out. However, 1 trial from Germany can ~~be~~ support ~~for~~ the Polish registration. FGF11 at 1 l/ha presented medium level of control and it was significant superior effect compared to the lower doses of 0,75 l/ha and 0,5 l/ha.
No results after 1 application were available in the South-East EPPO zone. The cMSs are kindly asked to consider this use at the national level.

Spring barley
No results after 1 application were available in spring barley in any EPPO climatic zones. The cMSs belonging to the MAR and SE zone are kindly asked to consider this use at the national level. This use cannot be accepted in Poland.

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2 applications
Winter barley
5 efficacy trials have been submitted to determine the minimum effective dose for the control of *Rhynchosporium secalis* (RHYNSE) in winter barley after 2 applications. All trials were conducted between 2022 and 2023 in the Maritime EPPO climatic zone. FGF11 applied at dose rate of 1 l/ha achieved medium level of control with the results of 78,5% on L2 and 76,9% on L3. The claimed dose presented superior effect on L1 with the mean efficacy of 85,8%. Significant inferior effectiveness was observed at the lower doses of 0,75 l/ha and 0,5 l/ha. Due to limited number of trials, the cMSs are kindly asked to consider this use at the national level.
No efficacy trials were available in the North-East and South-East EPPO zone. The cMSs belonging to the SE zone are kindly asked to consider this use at the national level. Due to the inability to extrapolate, this use cannot be accepted in Poland.

Spring barley
No efficacy trials were available for spring barley in any EPPO climatic zone. The cMSs belonging to the MAR and SE zone are kindly asked to consider this use at the national level. Due to the inability to extrapolate, this use cannot be accepted in Poland. However, spring barley is minor crop in Belgium and the registration under art. 51 is possible in this case, as zRMS supposes.

3.2.2.4 Minimum effective dose for control of target diseases in winter and spring oilseed rape

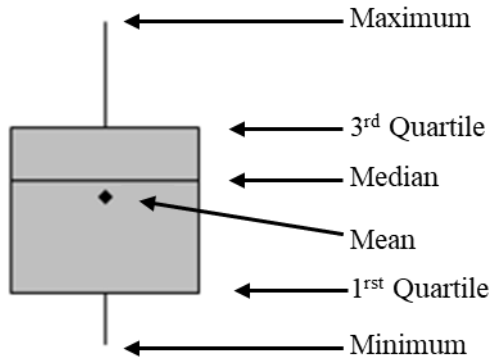
A total of 23 trials carried out between 2022 and 2023 generated data on the efficacy of FGF11 applied at a range of rates against SCLESC in winter oilseed rape. The data from these trials are summarised in support of justification of the minimum effective dose rate for control of target disease in oilseed rape by FGF11.

The materials and methods used in the efficacy trials from which data are summarized to justify minimum effective dose for control of target disease in oilseed rape are given in Section 3.2.3.4.

Data are only summarised in this dossier where mean levels of disease in the untreated control reached ≥5% severity on the part assessed following application.

Only data with ≥6 data points per EPPO climatic zone are presented as a Box-Whisker plot.

The Box-Whisker plots indicate the following values of the relevant summarised aggregated data:



Efficacy data are summarised across trials from representative assessment timings in this Section.

3.2.2.4.1 Minimum effective dose for control of Cottony rot (*Sclerotinia sclerotiorum*: SCLESC)

A total of 23 trials carried out between 2022 and 2023 generated data on the efficacy of FGF11 applied at a range of rates (0.5 L, 0.75 L and 1.0 L product/ha) against SCLESC in winter oilseed rape.

Of these trials, 8 were carried out in the Maritime EPPO climatic zone (3 in Germany, 3 in Great Britain, 2 in France), 5 were carried out within the North-east EPPO climatic zone (1 in Lithuania, 4 in Poland) and 10 were carried out within the South-east EPPO climatic zone (2 in Bulgaria, 5 in Hungary, 3 in Romania). All of these trials were conducted in winter oilseed rape.

Disease developed on all 23 trials and was assessed as percentage severity on the leaves (in 6 trials) and on stems (in all 23 trials).

Across trials, the efficacy of FGF11 has been evaluated under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in oilseed rape crops growing regions across EU Central Registration zone countries.

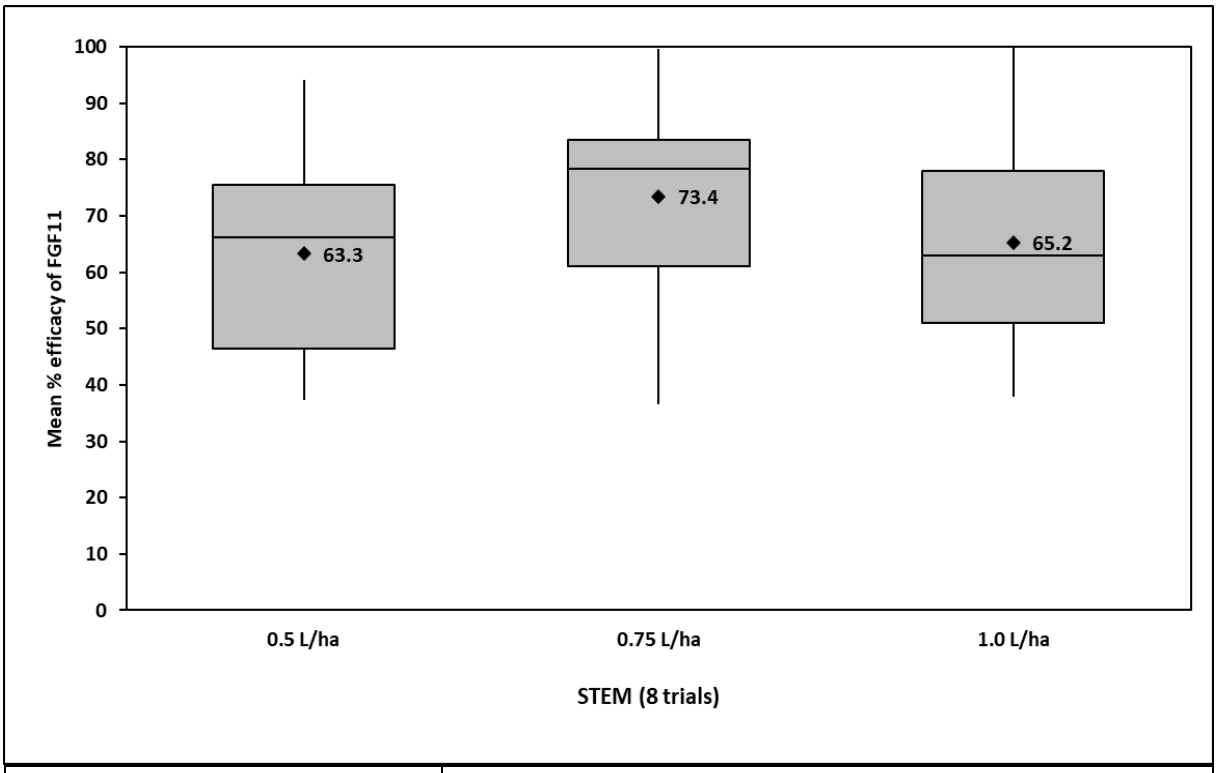
An overall summary of mean percentage efficacy (based on disease severity) of FGF11 applied at a range of rates against SCLESC in winter oilseed rape at 21-65 DA-A across trials in winter oilseed rape in each of the climatic zones is given in Table 3.2-18, with data presented as a Box-Whisker plot in Figure 3.2-18, Figure 3.2-19 and Figure 3.2-20.

Table 3.2-18: Dose justification; mean overall percentage efficacy (based on disease severity on the leaves and stems) of FGF11 applied at a range of rates against SCLESC at 21-65 DA-A across trials in winter oilseed rape

Registration or EPPO climatic zone	No of trials	*Untreated*		FGF11						Statistical comparison of 1.0 L/ha to	
				0.5 L/ha		0.75 L/ha		1.0 L/ha			
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max	0.5 L/ha	0.75 L/ha
Severity on leaves (21-56 DA-A)											
CEU	6	*12.7*	*6.1-16.8*	49.4	10.2-83.5	70.8	58.7-91.5	78.9	67.7-90.4	> (3), = (3)	> (1), = (5)
EPPO MAR	1	*16.8*	-	83.5	-	91.5	-	90.4	-	= (1)	= (1)
EPPO SE	5	*11.9*	*6.1-14.8*	*42.5*	*10.2-65.8*	66.6	58.7-76.8	76.6	67.7-82.4	> (3), = (2)	> (1), = (4)
Severity on stems (42-65 DA-A)											
CEU	23	*22.2*	*5.4-64.8*	61.6	26.9-94.1	72.2	30.2-99.7	74.3	37.3-100	> (11), = (12)	> (3), = (20)
EPPO MAR	8	*17.2*	*5.7-31.1*	63.3	37.4-94.1	73.4	36.6-99.7	65.2	37.9-100	= (8)	= (8)
EPPO NE	5	*18.7*	*9.0-34.8*	77.2	43.9-91.3	83.8	55.1-95.8	84.9	43.6-100	> (4), = (1)	= (5)
EPPO SE	10	*28.1*	*5.4-64.8*	52.4	26.9-79.8	65.4	30.2-90.9	76.2	37.3-92.9	> (7), = (3)	> (3), = (7)

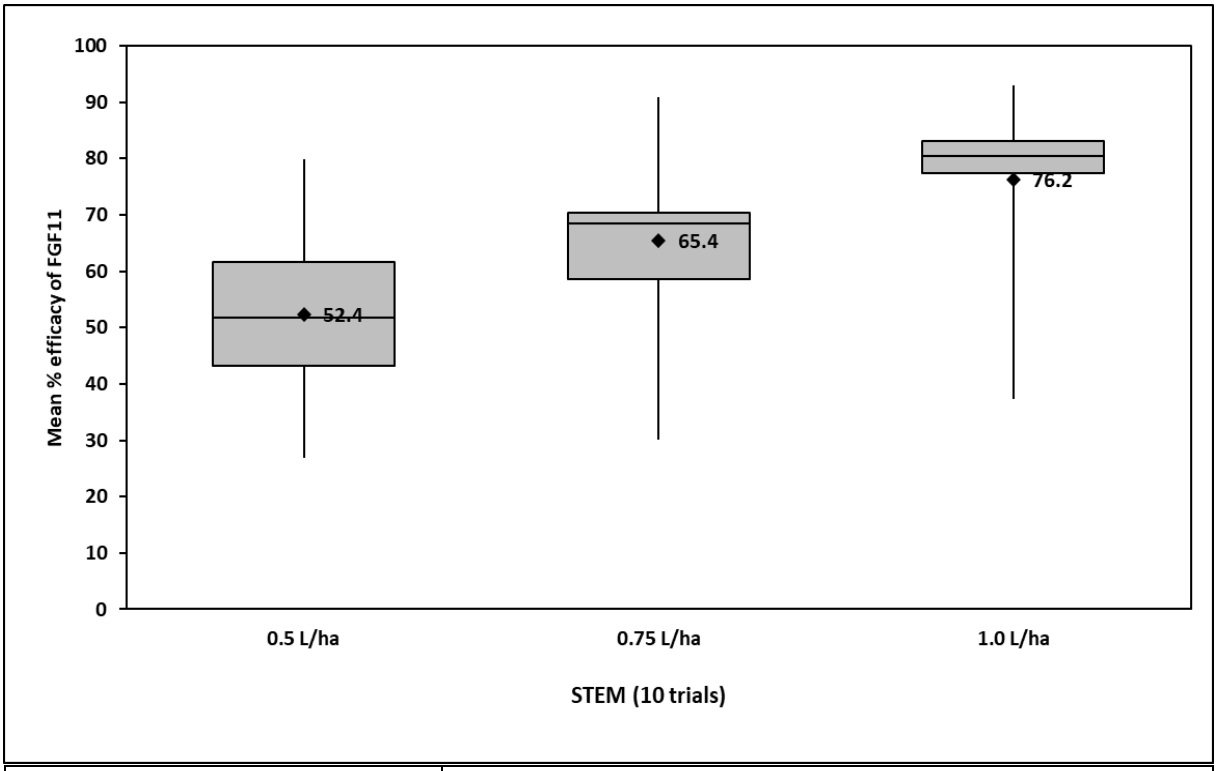
No. of trials where >, < or =, based on statistically significant differences at 95% confidence level

Figure 3.2-19: Dose justification; mean efficacy (based on disease severity on stems) of FGF11 applied at a range of rates against SCLESC across 8 trials on winter oilseed rape, Maritime EPPO climatic zone



	Mean % efficacy of FGF11		
	0.5 L/ha	**0.75 L/ha**	**1.0 L/ha**
No. of trials	8	8	8
Mean	**63.3**	**73.4**	**65.2**
S.D.	19.75	20.06	19.96
Q1	46.43	60.98	51.03
Median	66.26	78.29	62.94
Q3	75.49	83.55	77.99

Figure 3.2-20: Dose justification; mean efficacy (based on disease severity on stems) of FGF11 applied at a range of rates against SCLESC across 10 trials on winter oilseed rape, South-east EPPO climatic zone



	Mean % efficacy of FGF11		
	0.5 L/ha	**0.75 L/ha**	**1.0 L/ha**
No. of trials	10	10	10
Mean	**52.4**	**65.4**	**76.2**
S.D.	17.50	16.42	15.78
Q1	43.23	58.59	77.34
Median	51.84	68.53	80.49
Q3	61.59	70.33	83.11

Whilst only partial dose response was observed in trials carried out across the Maritime and the North-east EPPO climatic zone, data generated in trials carried out in the South-east EPPO climatic zone, where significantly higher disease pressure was noted (representing challenging conditions), clearly show the efficacy of FGF11 applied at 1.0 L product/ha against SCLESC in winter oilseed rape to be higher and more consistent compared to that of lower rates (0.75 L and 0.5 L product/ha).

Whilst no data have been generated in support of justifying the minimum effective dose of FGF11 for control of SCLESC in spring oilseed rape, the susceptibility of the crops to this fungal pathogen, disease development pressure and development patterns, agronomy of the crops and areas in which the crops are grown in the Central Registration zone can be considered to be sufficiently similar between winter and spring oilseed rape for the data generated in trials in winter oilseed rape to also provide justification of the same rate with respect to efficacy against SCLESC in spring oilseed rape.

Whilst limited data are presented on the efficacy of FGF11 against SCLESC in oilseed rape from trials carried out in the North-east EPPO climatic zone, data generated on this disease across trials in the country neighbouring Poland (Germany) provide supportive evidence of that in Poland.

It is therefore reasonable to conclude that the proposed label rate of 1.0 L product/ha is fully justified as the minimum effective dose for the control of SCLESC in winter and spring oilseed rape by FGF11, particularly in higher disease pressure situations.

Comments of zRMS:

1 application
Winter oilseed rape
A total of 23 efficacy trials have been submitted to determine the minimum effective dose for the control of *Sclerotinia sclerotiorum* (SCLESC) in winter oilseed rape.
In the Maritime EPPO climatic zone, 8 trials were conducted between 2022 and 2023. FGF11 applied at dose rate of 1 l/ha achieved medium level of control on stems with the result of 65,2%. The claimed dose presented superior effect on leaves with the effectiveness of 90,4% but in only 1 trial. Similar results were observed for the lower doses of 0,75 l/ha and0,5 l/ha.
In the North-East zone, 5 trials were carried out between 2022 and 2023. The test product at the claimed dose presented good efficacy on stems with the result of 84,9%. No significant differences between dose rates of 1 l/ha and the lower dose of 0,75 l/ha were observed. Slight inferior effect was noted at 0,5 l/ha. The observations on the leaves were not available in the NE zone. 3 efficacy trials conducted in Germany can support the registration in Poland.
In the South-East zone, 10 trials were conducted between 2022 and 2023. FGF11 at 1 l/ha achieved medium effectiveness, either on leaves and stems, with the results of 76,6% and 76,2%, respectively. Significant inferior level of control was visible for the lower doses of 0,75 l/ha and 0,5 l/ha.
Taking into account all EPPO zones, the dose rate of 1 l/ha can be determined the minimum effective dose for the control of SCLESC in winter oilseed rape.

Spring oilseed rape
No efficacy trials were available for spring oilseed rape in any EPPO climatic zone. The cMSs belonging to the MAR and SE zone are kindly asked to consider this use at the national level. Due to the inability to extrapolate, this use cannot be accepted on the registration under art. 33 in Poland. However, spring oilseed rape is minor crop in Poland, Austria, Germany, Ireland, Netherlands, Slovenia and Slovakia and the registration under art. 51 is possible in this case, as zRMS supposes.

3.2.2.5 Minimum effective dose for control of target ear diseases in winter wheat, spring wheat, durum wheat and spelt

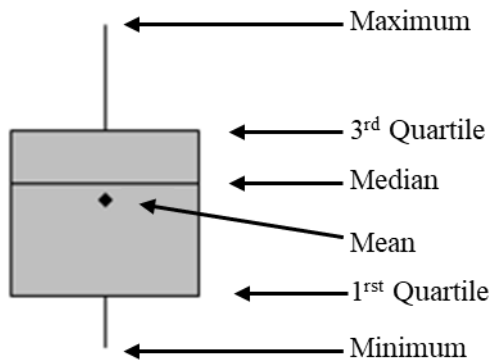
Fourteen (14) of the 40 trials carried out in 2023 generated data on the efficacy of FGF11 applied at a range of rates against target ear disease in wheat (winter, spring, durum) and spelt. The data from these trials are summarised in support of justification of the minimum effective dose rate for control of target ear disease in wheat (winter, spring, durum) and spelt by FGF11.

The materials and methods used in the efficacy trials from which data are summarized to justify minimum effective dose for control of target ear disease in wheat (winter, spring, durum) and spelt are given in Section 3.2.3.5.

Data are summarised in this dossier from assessment timings where mean levels of disease in the untreated control reached ≥5% severity on the ears following application.

Only data with ≥6 data points per EPPO climatic zone are presented as a Box-Whisker plot.

The Box-Whisker plots indicate the following values of the relevant summarised aggregated data:



Efficacy data are summarised across trials from representative single assessment timings in this Section.

3.2.2.5.1 Minimum effective dose for control of Fusarium ear blight (*Fusarium* sp.: FUSASP)

A total of 14 trials carried out in 2023 generated data on the efficacy of FGF11 applied at a range of rates (0.5 L, 0.75 L and 1.0 L product/ha) against FUSASP (10 trials) or GIBBZE (4 trials) in winter wheat.

Of these trials, 3 were carried out in the Maritime EPPO climatic zone (1 in Germany, 1 in Ireland, 1 in the United Kingdom), 6 were carried out in the North-east EPPO climatic zone (all in Poland) and 5 were carried out in the South-east EPPO climatic zone (1 in Bulgaria, 2 in Hungary, 2 in Romania).

Disease developed on all 14 trials and was assessed as percentage severity on the ears.

Across trials, the efficacy of FGF11 has been evaluated under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in wheat and spelt crops growing regions across EU Central Registration zone countries.

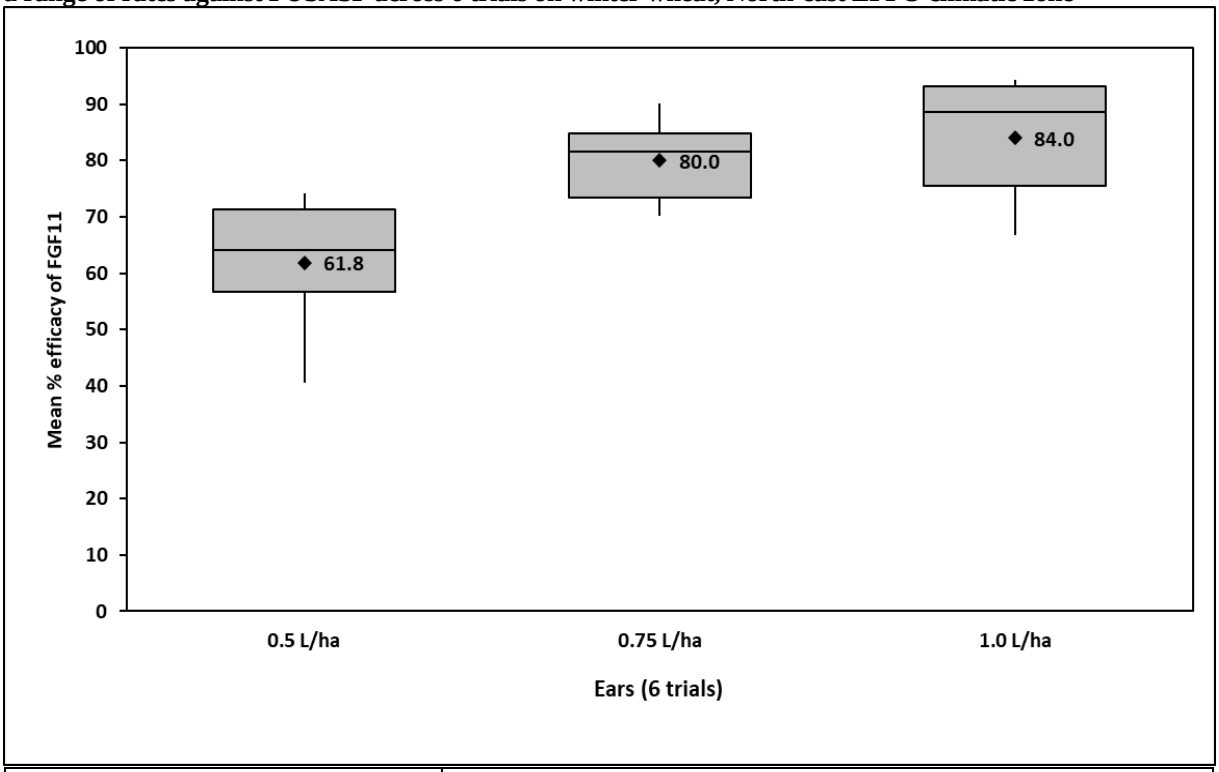
An overall summary of mean percentage efficacy (based on disease severity on the ears) of FGF11 applied at a range of rates against FUSASP in winter wheat at 23-42 DA-A1 across trials in each of the EPPO climatic zones is given in Table 3.2-19, with data presented as a Box-Whisker plot in Figure 3.2-21.

Table 3.2-19: Dose justification; mean overall percentage efficacy (based on disease severity on the ears) of FGF11 applied at a range of rates against FUSASP across trials on winter wheat in all climatic zones at 23-42 DA-A1

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11						Statistical comparison of 1.0 L/ha to#	
				0.5 L/ha		0.75 L/ha		1.0 L/ha			
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max	0.5 L/ha	0.75 L/ha
CEU	14	***22.6***	*5.8-79.8*	**58.4**	22.2-83.4	**69.7**	25.6-90.2	**78.0**	31.1-94.4	> (5), = (9)	> (1), = (13)
EPPO MAR	3	***36.4***	*12.0-79.8*	**34.3**	22.2-43.6	**36.7**	25.6-44.9	**57.8**	31.1-73.1	> (1), = (2)	= (3)
EPPO NE	6	***19.4***	*5.8-36.0*	**61.8**	40.5-74.1	**80.0**	70.1-90.2	**84.0**	66.7-94.4	> (2), = (4)	= (6)
EPPO SE	5	***18.2***	*11.1-31.*	**68.8**	55.4-83.4	**77.1**	60.5-86.1	**83.1**	75.2-89.1	> (2), = (3)	> (1), = (4)

No. of trials where >, = or <, based on statistically significant differences at 95% confidence level

Figure 3.2-21: Dose justification; mean efficacy (based on disease severity on the ears) of FGF11 applied at a range of rates against FUSASP across 6 trials on winter wheat, North-east EPPO climatic zone



	Mean % efficacy of FGF11		
	0.5 L/ha	**0.75 L/ha**	**1.0 L/ha**
No. of trials	6	6	6
Mean	**61.8**	**80.0**	**84.0**
S.D.	12.8	8.0	11.9
Q1	56.7	73.4	75.4
Median	64.1	81.6	88.6
Q3	71.4	84.9	93.2

Data generated in trials carried out in Maritime, North-east and South-east EPPO climatic zones clearly show the efficacy of FGF11 applied at 1.0 L product/ha against FUSASP in winter wheat to be higher and more consistent compared to that of lower rates (0.75 L and 0.5 L product/ha).

Whilst no or limited data have been generated in support of justifying the minimum effective dose of FGF11 for control of FUSASP in spring and winter wheat, durum wheat and spelt, the susceptibility of the crops to this fungal pathogen, disease development pressure and development patterns, agronomy of the crops and areas in which the crops are grown in the Central Registration zone can be considered to be sufficiently similar between different wheat crops for the data generated in trials in winter wheat to also provide justification of the same rate with respect to efficacy against FUSASP in spring wheat, durum wheat and spelt.

Furthermore, products containing prothioconazole and azoxystrobin straight and as mixture are already registered against FUSASP and other foliar diseases in the different cereal types mentioned above throughout Europe. The registered rate is generally the same against FUSASP, SEPTTR and *Puccinia* species in spring, winter and durum wheat and spelt. The minimum effective dose of FGF11 against SEPTTR and *Puccinia* species (PUCCST/PUCCSI/PUCCRE/PUCCRT) was extensively proven in winter wheat and was confirmed by trials in other cereal types and by trials targeting FUSASP. It can therefore be considered that the minimum effective dose of FGF11 against SEPTTR, *Puccinia* species and FUSASP in all types of wheat and spelt is the same.

It is therefore reasonable to conclude that the proposed label rate of 1.0 L product/ha is fully justified as the minimum effective dose for the control of FUSASP in wheat (winter, spring, durum) and spelt by FGF11.

Comments of zRMS:

1 application
Winter wheat
A total of 14 efficacy trials have been submitted to determine the minimum effective dose for the control of *Fusarium* sp. (FUSASP) in winter wheat.
In the Maritime EPPO climatic zone, 3 trials were conducted in 2023. FGF11 applied at dose rate of 1 l/ha achieved insufficient effectiveness on ears with the result of 57,8%. Significant inferior effect was observed for the lower doses of 0,75 l/ha and 0,5 l/ha. Due to limited number of trials and insufficient effectiveness, the cMSs are kindly asked to consider this use at the national level. In the opinion of zRMS, the application of the product to protect winter wheat against FUSASP in the MAR zone is not justified.
In the North-East zone, 6 trials were carried out in 2023. The test product at claimed dose presented good control with the result of 84,0% on ears. No significant differences between the doses 1 l/ha and 0,75 l/ha were observed. The lower dose of 0,5 l/ha had inferior result in 2 out of 6 trials.
In the South-East zone, 5 trials were conducted in 2023. FGF11 at 1 l/ha achieved good effectiveness with the result of 83,1% on ears. Significant inferior effect was visible at the lower doses in part of trials. Due to limited number of trials, the cMSs are kindly asked to consider this use at the national level.
Taking into account the North-East zone, the dose rate of 1 l/ha can be determined as the minimum effective dose for the control of FUSASP in winter wheat.

Spring wheat, durum wheat, spelt
No efficacy trials were available for other wheat crops in any EPPO climatic zone. The cMSs belonging to the MAR and SE zone are kindly asked to consider these uses at the national level. Due to the inability to extrapolate, these uses cannot be accepted on the registration under art. 33 in Poland. However, spring wheat is minor crop in Belgium and Ireland, durum wheat is minor crop in Poland, Belgium, Czech Republic, Ireland, Netherlands and Romania and spelt is minor crop in Poland, Belgium, Czech Republic, Hungary, Ireland, Netherlands, Romania, Slovenia and Slovakia and the registration under art. 51 is possible in these cases, as zRMS supposes.

3.2.3 Efficacy tests (KCP 6.2)

All efficacy trials were carried out by ~~organisations~~ organizations that are officially ~~recognised~~ recognized as competent to carry out efficacy testing in accordance with Regulation (EU) 284/2013 by the authorities in the relevant countries.

Links to copies of the GEP certificates for all trials ~~organisations~~ organizations are included in Section 3.7.

Additional summaries from assessments after the first application (representative of a single application) are presented at the end of each subsection for selected uses. All data is from trials previously presented; the new summaries are of existing data previously presented in Appendix 3 of the Biological Assessment Dossier.

3.2.3.1 Efficacy against target foliar diseases in winter wheat, spring wheat, durum wheat, spelt, winter triticale and spring triticale

A total of 123 trials carried out between 2022 and 2023 have generated data on the efficacy of FGF11 applied the proposed label rate of 1.0 L product/ha against target foliar diseases in wheat (winter, spring, durum), spelt and triticale (winter and spring).

Table 3.2-20: Details on trial methodology (efficacy trials on wheat and triticale)

Maritime EPPO climatic zone		
Guidelines	General guidelines	EPPO PP1/152 (4), EPPO PP1/181 (4), EPPO PP1/135 (4), EPPO PP1/225 (2)
	Specific guidelines	EPPO PP1/26 (4)

Experimental design	Plot design	RCBD (50)
	Plot size	17.5-39 m² (50)
	Number of replications	4 (50)
Crop	Trials per crop	Winter wheat (TRZAW) (27) Spring wheat (TRZAS) (9) Durum wheat (TRZDU) (3) Spelt (TRZSP) (5) Winter triticale (TTLWI) (6)
	Varieties per crop	**TRZAW:** Benchmark (2), Bennington (2), Campesiro (1), Complice (1), Costello (1), Cranium (1), Crusoe (2), Donovan (2), Filon (2), Gleam (1), Insitor (1), JB Diego (1), KWS Donovan (~~1~~ 2), Meister (1), Oregrain (1), RGT Reform (1), Sacramento (2), Siskin (1), Tobak (1), Torp (1) **TRZAS:** Alondra (1), Cochise (1), Helium (1), KWS Jordum (1), KWS Kilburn (1), Mulika (1), Nissaba (1), Quintus (1), Tybalt (1) **TRZDU:** Sambadur (1), Wintergold (2) **TRZSP:** Badenkrone (1), Badensonne (1), Badenstern (1), Hohenloher (1) **TTLWI:** KWS Fido (1), Lombardo (2), Lumaco (1), Securo (2)
	Sowing period	**TRZAW:** September (5), October (21), November (1) **TRZAS:** February (1), March (~~2~~ 3), April (~~5~~ 4), May (1) **TRZDU:** October (3) **TRZSP:** October (~~4~~ 5), ~~n/d (1)~~ **TTLWI:** September (2), October (4)
Targets	Target diseases	SEPTTR (40), PUCCRE (12), PUCRRT (4), PUCCSI (5), PUCCST (10)
Application	Crop stage (BBCH) at application	**TRZAW:** A1: from 31 to 37 (BBCH); A2: from 37-39 to 55-59 (BBCH) **TRZAS:** A1: from 31-32 to 39-51 (BBCH); A2: from 37-40 to 51-61 (BBCH) **TRZDU:** A1: from 31-32 to 32-33 (BBCH); A2: from 41-45 to 49 (BBCH) **TRZSP:** A1: from 32 to 33-37 (BBCH); A2: from 39 to 41-45 (BBCH) **TTLWI:** A1: from 31-32 to 33-37 (BBCH); A2: from 35-39 to 51-55 (BBCH)
	Application period	**TRZAW:** A1: April (19), May (8); A2: April (2), May (25) **TRZAS:** A1: May (2), June (7); A2: May (1), June (~~3~~ 7), July (~~2~~ 1) **TRZDU:** A1: May (3); A2: May (3) **TRZSP:** A1: April (4), May (1); A2: May (5) **TTLWI:** A1: April (2), May (4); A2: May (6)
	Number of applications Interval between applications	2 (50) with intervals of 5-36 days
	Spray volumes	100 L/ha (11), 100-200 L/ha (1), 150 L/ha (1), 180 L/ha (2), 200 L/ha (28), 250 L/ha (2), 300 L/ha (5)
Assessments	Assessment types	% disease severity on leaves, % green leaf area, phytotoxicity, crop yield, hectoliter weight, thousand grain weight
	Assessment dates	between 0 DA-A1 and 22 DA-A1 / 12-57 DA-A2, at harvest
Other relevant information	e.g. Natural / artificial inoculation	Natural (50)

North-east EPPO climatic zone		
Guidelines	General guidelines	EPPO PP1/152 (4), EPPO PP1/181 (4), EPPO PP1/135 (4), EPPO PP1/225 (2)
	Specific guidelines	EPPO PP1/26 (4)
Experimental design	Plot design	RCBD (31)
	Plot size	20-30 m² (31)
	Number of replications	4 (31)
Crop	Trials per crop	Winter wheat (TRZAW) (19) Spring wheat (TRZAS) (4) Winter triticale (TTLWI) (7) Spring triticale (TTLSO) (1)
	Varieties per crop	**TRZAW:** Arkadia (2), Artist (1), Bilanz (1), Euforia (1), Formacja (3), Julius (1), Opoka (1), Patras (2), Produzent (2), RGT Bilanz (~~2~~ 1), Sailor (1), Skagen (2), Venecja (1) **TRZAS:** Arabella (2), Aura (1), Goplana (1) **TTLWI:** Belkanto (1), Meloman (1), Porto (1), Rotondo (2), Tadeus (1), Toledo (1) **TTLSO:** Dublet (1)
	Sowing period	**TRZAW:** September (11), October (6), November (2) **TRZAS:** March (2), April (2) **TTLWI:** September (3), October (4) **TTLSO:** March (1)
Targets	Target diseases	SEPTTR (21), PUCCRE (7), PUCRRT (5), PUCCSI (4), PUCCST (5)
Application	Crop stage (BBCH) at application	**TRZAW:** A1: 61 (BBCH); A1: from 31-32 to 32-33 (BBCH), A2: from 37-39 to 61 (BBCH) **TRZAS:** A1: from 32 to 32-33 (BBCH), A2: from 39 to 45-49 (BBCH) **TTLWI:** A1: from 31-32 to 35 (BBCH), A2: from 39-41 to 43-47 (BBCH) **TTLSO:** A1: 31-32 (BBCH), A2: 41-43 (BBCH)
	Application period	**TRZAW** A1: June (1); A1: April (6), May (12), A2: May (14), June (4) **TRZAS:** A1: May (4), A2: June (4) **TTLWI:** A1: April (4), May (3), A2: May (7) **TTLSO:** A1: April (1), A2: May (1)
	Number of applications Interval between applications	1 (1) 2 (30) with intervals of 14-36 days
	Spray volumes	200 L/ha (19), 250 L/ha (4), ~~200-300 L/ha (1),~~ 300 L/ha (~~6~~ 7), 400 L/ha (1)
Assessments	Assessment types	% disease severity on leaves, % green leaf area, phytotoxicity, crop yield, hectoliter weight, thousand grain weight
	Assessment dates	between 0 DA-A1 and 15 DA-A1 / 14-42 DA-A2, at harvest
Other relevant information	e.g. Natural / artificial inoculation	Natural (31)
South-east EPPO climatic zone		
Guidelines	General guidelines	EPPO PP1/152 (4), EPPO PP1/181 (4), EPPO PP1/135 (4), EPPO PP1/225 (2)
	Specific guidelines	EPPO PP1/26 (4)
Experimental design	Plot design	RCBD (42)
	Plot size	21-30 m² (42)
	Number of replications	4 (42)
Crop	Trials per crop	Winter wheat (TRZAW) (18) Spring wheat (TRZAS) (4) Durum wheat (TRZDU) (7) Spelt (TRZSP) (3) Winter triticale (TTLWI) (10)
	Varieties per crop	**TRZAW:** Bankuti (1), Bernstein (1), Discus (1), Exotic (2), Falado (1), LG Apilko (1), Miranda (2), Murgavets (4), MV Menrot (2), MV Nador (1), PG-102 (1), Taisa (1) **TRZAS:** Granny (1), IS Jariella (1), Liskam (1), Padureni (1) **TRZDU:** Enola (1), Leondur (1), Wintergold (4), Zagorka (1)

		TRZSP: Frankenkorn (1), Oko-10 (1), Zollernspeltz (1) **TTLWI:** GK Rege (1), GK Szemes (1), Haiduc (4), Hungaro (1), Tarzan (2), Trismart (1)
	Sowing period	**TRZAW:** September (1), October (14), November (3) **TRZAS:** February (2), March (1), April (1) **TRZDU:** October (3), November (4) **TRZSP:** October (3) **TTLWI:** October (7), November (3)
Targets	Target diseases	SEPTTR (26), PUCCRE (13), PUCRRT (2), PUCCSI (4), PUCCST (6)
Application	Crop stage (BBCH) at application	**TRZAW:** A1: from 30-32 to 39-41 (BBCH), A2: from 37-39 to 59-61 (BBCH) **TRZAS:** A1: from 31-32 to 32-34 (BBCH), A2: from 37-39 to 41-45 (BBCH) **TRZDU:** A1: from 31-33 to 33-35 (BBCH), A2: from 37-41 to 41-45 (BBCH) **TRZSP:** A1: from 31-33 to 37 (BBCH), A2: from 41-43 to 43-47 (BBCH) **TTLWI:** A1: from 30-33 to 33-35 (BBCH), A2: from 37-39 to 41-47 (BBCH)
	Application period	**TRZAW:** A1: April (11), May (7); A2: April (1), May (~~17~~ 16), June (1) **TRZAS:** A1: May (3), June (1); A2: June (4) **TRZDU:** A1: April (4), May (3); A2: May (6), June (1) **TRZSP:** A1: May (3); A2: May (2), June (1) **TTLWI:** A1: April (6), May (4); A2: May (10)
	Number of applications Interval between applications	2 (54) with intervals of 12-31 days
	Spray volumes	200 L/ha (20), 250 L/ha (4), 300 L/ha (14), 300-400 L/ha (1), 350 L/ha (1), 400 L/ha (2)
Assessments	Assessment types	% disease severity on leaves, % green leaf area, phytotoxicity, crop yield, hectoliter weight, thousand grain weight
	Assessment dates	between 0 DA-A1 and 14-15 DA-A1 / 14-42 DA-A2, at harvest
Other relevant information	e.g. Natural / artificial inoculation	Natural (42)

Applications on all efficacy trials were made using small plot sprayers designed to simulate application using commercial sprayers representative of those used to apply fungicides in cereals.

On all trials, single or multiple applications of the treatments were made on crops growth stage and in water volumes representative of the ones proposed for the application of FGF11.

On 1 of the trials, a single application of the treatments was made. On the other 122 trials, two applications were made. Although only 1 application is claimed for FGF11, trials with 2 applications of FGF11 are considered as fully valid. The 2nd application targeted new infections on the leaves, therefore assessments after the 2nd application is indicative of a single application.

Data are summarised in this dossier from assessment timings where mean levels of disease in the untreated control reached ≥5% severity at individual leaf levels following application.

Efficacy data are summarised across trials for disease on the upper leaves (1-3) from representative assessment timings in this Section.

In the majority of trials, a zonal reference product containing prothioconazole as the active substance was used (generally with the tradename PROLINE). Additionally, local standard reference products were included in some of the trials. These additional local standard reference products are presented in the summaries below only if no reference product containing straight prothioconazole was included in the trial.

3.2.3.1.1 Efficacy against Septoria leaf spot (*Zymoseptoria tritici*: SEPTTR)

A total of 87 trials carried out between 2022 and 2023 generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against SEPTTR in winter wheat (52 trials), spring wheat (9 trials), durum wheat (8 trials), spelt (5 trials) and winter triticale (13 trials).

Of these trials, 40 were carried out in the Maritime EPPO climatic zone (21 in Germany, 1 in Denmark, 4 in Ireland, 7 in the United Kingdom, 7 in France), 21 were carried out in the North-east EPPO climatic zone (4 in Lithuania, 17 in Poland) and 26 were carried out in the South-east EPPO climatic zone (7 in Bulgaria, 7 in Hungary, 12 in Romania).

Disease developed on all 87 trials and was assessed as percentage severity on the upper leaves (1-3).

Across trials, the efficacy of FGF11 has been evaluated under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in wheat, spelt and triticale crops growing regions across EU Central Registration zone countries.

An overall summary of mean percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against SEPTTR in wheat and triticale at 14-15 DA-A1 / 12-57 DA-A2 across trials and leaf levels with valid data in each of the EPPO climatic zones is given in Table 3.2-21.

Table 3.2-21: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against SEPTTR across trials on wheat and triticale in all EPPO climatic zones at 14-15 DA-A1 / 12-57 DA-A2

Registration or EPPO climatic zone	No. of trials (no. of data points)	*Untreated*		FGF11 1.0 L/ha		Proline* 0.8 L/ha*		Prosaro 250 EC 0.8 L/ha		Statistical comparison of FGF11 to SRP#
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max	
CEU	87 (174)	***16.7***	*5.0-100*	**80.4**	12.5-100	-	-	-	-	-
	4 of 87 (170 of 174)	***16.9***	*5.0-100*	**79.9**	12.5-100	**78.4**	30.5-100	-	-	> (16), = (151), < (3)
	2 of 87 (4 of 174)	***6.3***	*5.3-7.3*	**100**	100-100	-	-	**98.1**	94.1-100	= (4)
EPPO MAR	40 (74)	***23.4***	*5.0-100*	**75.2**	12.5-100	**76.3**	30.5-100	-	-	> (1), = (71), < (2)
EPPO NE	21 (43)	***14.1***	*5.1-48.8*	**82.6**	31.1-100	**79.8**	35.0-100	-	-	> (6), = (36), < (1)
EPPO SE	26 (57)	***9.8***	*5.0-25.0*	**85.4**	51.8-100	-	-	-	-	-
	24 of 26 (53 of 57)	***10.1***	*5.0-25.0*	**84.3**	51.8-100	**80.3**	48.1-96.2	-	-	> (9), = (44)
	2 of 26 (4 of 57)	***6.3***	*5.3-7.3*	**100**	100-100	-	-	**98.1**	94.1-100	= (4)

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.2-6
No. of data points where >, = or <, based on statistically significant differences at 95% confidence level

Table 3.2-22a: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against SEPTTR across trials on winter wheat in all EPPO climatic zones after 1 application

EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L2							
North-East (+trials conducted in Germany)	1 trial	***4,1***	-	**90,9**	-	**93,1**	-
South-East	1 trial	***4,13***	-	**88,19**	-	**84,97**	-
L3							
Maritime	1 trial	***7,48***	-	**66,54**	-	**89,08**	-
North-East (+trials conducted in Germany)	1 trial	***5,2***	-	**87,2**	-	**88,2**	-
South-East	4 trials	***6,6***	*5,0-9,23*	**87,8**	81,94-100	**88,8**	80,38-100
L4							
Maritime	3 trials	***21,5***	*5,0-30,75*	**43,0**	29,76-50,0	**54,4**	47,62-65,65
North-East (+trials conducted in Germany)	4 trials	***6,3***	*5,0-7,4*	**69,3**	50,0-85,4	**67,6**	50,0-87,2
South-East	4 trials	***9,4***	*5,08-11,13*	**71,8**	37,63-84,08	**73,2**	38,28-88,7

EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	***Min-max***	**Mean**	**Min-max**	**Mean**	**Min-max**
L2							
North-East (+trials conducted in Germany)	1 trial	***4,1***	-	**90,9**	-	**93,1**	-
South-East	1 trial	***4,13***	-	**88,19**	-	**84,97**	-
L5							
Maritime	4 trials	***32,1***	*4,79-83,75*	**69,5**	49,92-100	**73,1**	60,75-100
North-East (+trials conducted in Germany)	5 trials	***9,2***	*4,79-19,5*	**70,3**	43,6-100	**73,3**	62,4-100
South-East	2 trials	***11,99***	*5,85-18,13*	**90,0**	85,22-94,81	**90,5**	90,23-90,67

Table 3.2-23b: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against SEPTTR across trials on spring wheat in all EPPO climatic zones after 1 application

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	***Min-max***	**Mean**	**Min-max**	**Mean**	**Min-max**
L3							
South-East	1 trial	***5,4***	-	**64,6**	-	**62,1**	-
L4							
Maritime	1 trial	***5,6***	-	**99,46**	-	**88,7**	-
L5							
South-East	1 trial	***5,75***	-	**90,51**	-	**86,16**	-

Table 3.2-24c: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against SEPTTR across trials on durum wheat in all EPPO climatic zones after 1 application

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	***Min-max***	**Mean**	**Min-max**	**Mean**	**Min-max**
L2							
Maritime	1 trial	***5,0***	-	**100**	-	**100**	-
L3							
South-East	1 trial	***4,1***	-	**82,7**	-	**72,67**	-
L4							
Maritime	1 trial	***10,0***	-	**100**	-	**100**	-

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
South-East	1 trial	***5,2***	-	**100**	-	**100**	-

Table 3.2-25d: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against SEPTTR across trials on spelt in all EPPO climatic zones after 1 application

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L4							
Maritime	1 trial	***5,75***	-	**100**	-	**100**	-
L5							
Maritime	2 trials	***9,3***	*6,25-12,25*	**76,1**	61,43-90,83	**87,5**	85,0-90,0

Table 3.2-26e: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against SEPTTR across trials on winter triticale in all EPPO climatic zones after 1 application

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L2							
Maritime	1 trial	***6,9***	-	**100**	-	**100**	-
North-East (+trials conducted in Germany)	1 trial	***6,9***	-	**100**	-	**100**	-
L3							
Maritime	2 trials	***12,7***	*10,4-15,0*	**96,4**	92,7-100	**95,6**	91,1-100
North-East	2 trials	***12,7***	*10,4-15,0*	**96,4**	92,7-100	**95,6**	91,1-100
L4							
Maritime	1 trial	***14,1***	-	**80,9**	-	**76,4**	-
North-East (+trials conducted in Germany)	2 trials	***10,7***	*7,3-14,1*	**83,3**	80,9-85,6	**80,8**	76,4-85,1
South-East	1 trial	***4,4***	-	**62,8**	-	**59,7**	-
L5							
North-East (+trials conducted in Germany)	1 trial	***5,5***	-	**87,7**	-	**89,5**	-

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
South-East	2 trials	***6,8***	*5,15-8,5*	**93,4**	92,81-94,0	**93,4**	90,61-96,1
L6							
South-East	1 trial	***19,8***	-	**81,2**	-	**85,1**	-

Table 3.2-27f: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against SEPTTR across trials on winter wheat in all EPPO climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L1							
Maritime	12 trials	***31,3***	*5,6-100*	**73,8**	46,73-93,75	**72,0**	53,81-95,19
North-East	6 trials	***21,5***	*6,73-48,75*	**83,5**	55,17-99,32	**80,4**	48,78-98,21
South-East	8 trials	***6,9***	*5,12-10,0*	**91,2**	75,19-100	**84,96**	75,01-93,91
L2							
Maritime	20 trials	***24,4***	*5,0-61,25*	**77,3**	52,08-100	**77,3**	42,73-100
North-East	13 trials	***14,4***	*5,08-33,25*	**79,5**	55,44-100	**74,6**	54,22-100
South-East	14 trials	***10,99***	*5,08-22,25*	**84,8**	67,26-90,33	**80,8**	73,34-88,51
L3							
Maritime	19 trials	***24,1***	*5,25-61,25*	**65,4**	32,19-100	**64,9**	30,54-100
North-East	12 trials	***14,8***	*5,28-34,0*	**79,99**	54,36-100	**77,7**	46,33-100
South-East	13 trials	***11,0***	*6,08-20,75*	**80,5**	51,77-100	**76,3**	48,06-93,36

Table 3.2-28g: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against SEPTTR across trials on spring wheat in all EPPO climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L1							
Maritime	2 trials	***7,1***	*6,25-7,98*	**70,7**	42,5-98,83	**88,5**	82,5-94,58
North-East (+trials conducted in Germany)	1 trial	***6,3***	-	**42,5**	-	**82,5**	-
South-East	1 trial	***7,13***	-	**87,42**	-	**83,55**	-
L2							
Maritime	2 trials	***29,9***	*7,5-52,25*	**38,7**	12,5-64,86	**74,8**	64,54-85,0

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
North-East	1 trial	***5,5***	-	**100**	-	**100**	-
North-East (+trials conducted in Germany)	2 trials	***6,5***	*5,5-7,5*	**56,3**	12,5-100	**92,5**	85,0-100
South-East	1 trial	***5,25***	-	**85,91**	-	**83,41**	-
L3							
Maritime	4 trials	***7,5***	*5,5-9,95*	**88,1**	81,06-100	**79,9**	75,0-83,48
North-East	1 trial	***5,9***	-	**93,84**	-	**95,72**	-
North-East (+trials conducted in Germany)	3 trials	***5,9***	*5,5-6,3*	**92,1**	82,5-100	**84,4**	75,0-95,7
South-East	2 trials	***7,8***	*5,3-10,3*	**87,95**	81,6-94,3	**84,4**	79,1-89,62

Table 3.2-29h: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against SEPTTR across trials on durum wheat in all EPPO climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L1							
Maritime	2 trials	***37,2***	*6,88-67,5*	**95,8**	94,66-96,96	**97,2**	94,3-100
South-East	3 trials	***6,8***	*6,25-7,25*	**100**	100-100	**96,2**	94,07-98,44
L2							
Maritime	3 trials	***6,6***	*5,0-9,53*	**80,3**	54,45-100	**81,6**	56,87-100
South-East	3 trials	***6,1***	*5,25-7,38*	**97,2**	91,7-100	**95,6**	86,66-100
L3							
South-East	2 trials	***8,1***	*7,0-9,25*	**85,6**	78,48-92,8	**79,96**	70,47-89,46

Table 3.2-30i: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against SEPTTR across trials on spelt in all EPPO climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L1							
South-East	1 trial	***18,6***	-	**79,41**	-	**68,99**	-
L2							

Registration or EPPO climatic zone	**No. of trials**	***Untreated***		**FGF11**		**Proline/Prosaro 250 EC**	
				1.0 L/ha		**0.8 L/ha**	
		Mean	***Min-max***	**Mean**	**Min-max**	**Mean**	**Min-max**
Maritime	1 trial	***5,25***	-	**100**	-	**100**	-
L3							
Maritime	3 trials	***15,6***	*5,18-35,0*	**73,9**	60,15-83,34	**76,8**	51-58-90,1
South-East	1 trial	***16,3***	-	**71,03**	-	**75,76**	-

Table 3.2-31j: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against SEPTTR across trials on winter triticale in all EPPO climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L1							
North-East	2 trials	***9,6***	*7,63-11,48*	**95,1**	90,18-100	**94,97**	89,95-100
South-East	1 trial	***5,0***	-	**76,53**	-	**72,33**	-
L2							
Maritime	2 trials	***18,99***	*16,13-21,85*	**100**	100-100	**100**	100-100
North-East	4 trials	***9,1***	*5,16-14,63*	**92,9**	85,39-100	**90,4**	81,86-98,75
North-East (+trials conducted in Germany)	6 trials	***12,4***	*5,2-21,9*	**95,3**	85,4-100	**93,6**	81,9-100
South-East	2 trials	***17,6***	*10,13-25,0*	**78,3**	71,32-85,32	**73,9**	63,67-84,07
L3							
Maritime	5 trials	***26,1***	*9,18-37,1*	**93,3**	75,0-100	**97,9**	94,25-100
North-East	3 trials	***13,9***	*6,14-23,5*	**89,4**	85,44-95,91	**88,5**	85,89-91,88
North-East (+trials conducted in Germany)	7 trials	***19,3***	*6,1-37,1*	**90,6**	75-100	**93,6**	85,9-100
South-East	4 trials	***11,0***	*6,3-17,63*	**86,3**	77,56-96,13	**84,1**	74,79-94,02

Data generated across trials carried out in the Maritime, North-east and South-east EPPO climatic zones demonstrate that FGF11 applied at the proposed label rate of 1.0 L product/ha generally gives effective control of SEPTTR in wheat and triticale that is consistently comparable and mostly not statistically significantly different to that given by the standard reference products applied at label rates.

Whilst no or limited data have been generated to demonstrate the efficacy of FGF11 against SEPTTR in spring wheat, durum wheat, spelt, winter and/or spring triticale in some of the EPPO climatic zones, following EPPO guidance PP1/331 (1) principles of efficacy extrapolations for major uses, the susceptibility of the crops to this fungal pathogen, disease development pressure and development patterns, agronomy of the crops and areas in which the crops are grown in the Central Registration zone can be considered to be sufficiently similar between different cereal crops for the data generated on trials in winter wheat to be fully supportive of demonstrating efficacy against SEPTTR in spring wheat, durum wheat, spelt, winter and spring triticale.

Furthermore, products containing prothioconazole and azoxystrobin straight and as mixture are already registered against SEPTTR in the different cereal types mentioned above throughout Europe. The efficacy of FGF11 against SEPTTR was extensively proven in winter wheat and was confirmed by trials in other cereal types. It can therefore be considered that FGF11 effectively controls SEPTTR in all types of wheat, spelt and triticale.

Additionally, whilst limited data are presented on the efficacy of FGF11 against SEPTTR on spring wheat, durum wheat, spelt, winter and spring triticale from trials carried out in the North-east EPPO climatic zone, data generated on this disease across 13 trials (2 in spring wheat, 3 in durum wheat, 4 in spelt, 4 in winter triticale) in country neighbouring Poland (Germany) provide supportive evidence of that in Poland.

To meet the specific requirements for Ireland for wet weather diseases, 4 trials in high disease pressure situations (> 20%) of SEPTTR are required from this country. Although pest severity, as presented in the detailed summary tables was above this threshold in 3 Irish trials only, in total there were 4 Irish trials in this high disease pressure situation based on pest incidence, however conducted only over 1 year. However, products containing the active substances azoxystrobin and prothioconazole, solo or as mixture, are well-known and are already registered for control of SEPTTR in wheat and triticale in Ireland. The available data package is therefore considered as sufficient to demonstrate the efficacy of FGF11 against SEPTTR in high disease pressure situations common in Ireland.

Based on the summarised data, it is therefore considered that claims for control of SEPTTR in wheat (winter, spring, durum), spelt and triticale (winter and spring) by FGF11, applied at the proposed label rate of 1.0 L product/ha and according to other label recommendations, are fully supported.

Comments of zRMS:

1 application
Winter wheat
A total of 16 trials have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Zymoseptoria tritici* (SEPTTR) in winter wheat.
In the Maritime EPPO climatic zone, 6 efficacy trials were carried out in 2022. FGF11 at 1 l/ha achieved medium level of control with the results of 66,54% on L3 and 69,5% on L5. Significant inferior effect was observed on L4 (43%) in 3 out of 6 trials. The reference product had superior results but also on medium level in most trials.
In the North-East zone, 4 trials were conducted in 2023. Also 3 trials from Germany can be support for the Polish registration. The test product at claimed dose presented medium level of control in most of trials with the results of 69,3% on L4 and 70,3% on L5. Superior effect was visible on L2 (90,9%) and L3 (87,2%) but in only 1 trial. The test product at 0,8 l/ha had comparable effectiveness.
Conclusions for 2 applications: 14 trials were conducted between 2022 and 2023. FGF11 applied at 1 l/ha achieved good results with the mean effectiveness of 83,5% on L1, 79,5% on L2 and 79,99% on L3.
In the South-East zone, 6 trials were carried out between 2022 and 2023. FGF11 at 1 l/ha achieved good level of control with the results of 88,19% on L2, 87,8% on L3 and 90% on L5. Slight inferior effectiveness was noted on L4 (71,8%). No significant differences between test and reference product were observed.
Based on all trial results, FGF11 applied once per growing season at dose rate of 1 l/ha can be recommended for

the control of SEPTTR in winter wheat.

Spring wheat
A total of 3 trials have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Zymoseptoria tritici* (SEPTTR) in spring wheat.
In the Maritime EPPO climatic zone, only 1 efficacy trial was conducted in 2022. FGF11 at 1 l/ha achieved high level of control with the result of 99,46% on L4. Sligh inferior effect was observed for the reference product but still on sufficient level. Due to limited number of trials in spring wheat and the opportunities of extrapolation from winter wheat, this use is justified. However, the final decision to accept this use is left to the cMSs.
In the South-East zone, 2 efficacy trials were carried out between 2022 and 2023. The test product at claimed dose presented good efficacy on L5 (90,51%) and medium level of control on L3 (64,6%). Due to limited number of trials in spring wheat and the opportunities of extrapolation from winter wheat, this use is justified. However, the final decision to accept this use is left to the cMSs.
No results after 1 application were available in the North-East EPPO zone. This use cannot be accepted in Poland. ~~However, 2 trials with 2 applications have been submitted and extrapolation from winter wheat is possible for the use in Poland.~~
Conclusions for 2 applications: only 2 trials were conducted between 2022 and 2023. The claimed dose rate of 1 l/ha presented high efficacy in both trials (100% on L2 and 93,84% on L3). The trials submitted from Germany (3 trials) can support the Polish registration.

Durum wheat
A total of 3 trials have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Zymoseptoria tritici* (SEPTTR) in durum wheat.
In the Maritime EPPO climatic zone, only 1 trial was conducted in 2022. FGF11 at dose rate of 1 l/ha achieved full effectiveness on L2 and L4. Similar effect was visible for the reference product. Due to limited number of trials in durum wheat and the opportunities of extrapolation from winter wheat, this use is justified. However, the final decision to accept this use is left to the cMSs.
In the South-East zone, 2 trials were carried out between 2022 and 2023. The test product at the claimed dose rate presented good level of control with the results of 82,7% on L3 and 100% on L4. Significant differences between test and reference product were observed on L3. Due to limited number of trials in durum wheat and the opportunities of extrapolation from winter wheat, this use is justified. However, the final decision to accept this use is left to the cMSs.
No results after 1 application were available in the North-East zone. This use cannot be accepted in Poland. Durum wheat is minor crop in Poland and the registration under art. 51 is possible in this case.
Conclusions after 2 applications in the NE zone: No efficacy trials were available in the North-East EPPO zone for above crop.

Spelt
Only 2 trials have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Zymoseptoria tritici* (SEPTTR) in spelt. Both trials were conducted in 2022 in the Maritime EPPO climatic zone. FGF11 at dose rate of 1 l/ha achieved full control on L4 and medium efficacy on L5 (76,1%). Slight superior effect was observed for the reference product on L5. Due to limited number of trials in spelt and the opportunities of extrapolation from winter wheat, this use is justified. However, the final decision to accept this use is left to the cMSs.
No results after 1 application were available in the North-East and South-East EPPO zone. This use cannot be accepted in Poland. Spelt is minor crop in Poland and the registration under art. 51 is possible in this case. The cMSs belonging to the SE zone are kindly asked to consider this use at the national level.
Conclusions for 2 applications in the NE zone: No efficacy trials were available in the North-East EPPO zone for above crop.

Winter triticale
A total of 8 trials have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Zymoseptoria tritici* (SEPTTR) in winter triticale.
In the Maritime EPPO climatic zone, 3 trials were conducted in 2023. FGF11 applied at dose rate of 1 l/ha achieved good control with the results of 100% on L2, 96,4% on L3 and 80,9% on L4. Similar effect was observed on L2 and L3 and significant inferior efficacy on L4 for the reference product at 0,8 l/ha. Due to limited number of trials in winter triticale and the opportunities of extrapolation from winter wheat, this use is justified. However, the final decision to accept this use is left to the cMSs.
In the North-East zone, 2 trials were carried out in 2023. Also 3 trials from Germany can ~~be~~ support ~~for~~ the

Polish registration. Moreover, the extrapolation from winter wheat is possible. The test product at the claimed dose rate presented good efficacy with the results of 100% on L2, 96,4% on L3, 83,3% on L4 and 87,7% on L5. Comparable effect was visible for the reference product.
Conclusions for 2 applications: 4 trials were carried out between 2022 and 2023. FGF11 at claimed dose of 1 l/ha presented good control with the results of 95,1% on L1, 92,9% on L2 and 89,4% on L3. The trials submitted for Germany (5 trials) can support the Polish registration.
In the South-East zone, 3 trials were conducted between 2022 and 2023. FGF11 at 1 l/ha achieved sufficient control with the results of 93,4% on L5 and 81,2% on L6. Medium efficacy was observed on L4 (62,8%) in 1 trial. The reference product at 0,8 l/ha had similar effectiveness on L5 and L6. Due to limited number of trials in winter triticale and the opportunities of extrapolation from winter wheat, this use is justified. However, the final decision to accept this use is left to the cMSs.

Spring triticale
No results after 1 application were available in any EPPO climatic zone. The cMSs belonging to the Maritime and South-East zone are kindly asked to consider this use at the national level. This use cannot be accepted in Poland.
Conclusions for 2 applications in the NE zone: No efficacy trials were available in the North-East EPPO zone for above crop.

ZRMS conclusion after updated of RR (April 2026)
In summary, the efficacy of FGF11 in controlling *Zymoseptoria tritici* (SEPTTR) has been demonstrated in the North-East EPPO zone in the following trials:

- winter wheat: 7 trials after the first application with PESSEV ≥4% (4 trials from the NE zone and 3 trials from Germany) and 14 trials after the second application with PESSEV ≥5% (conducted in the NE zone)
- winter triticale: 5 trials after the first application with PESSEV ≥4% (2 trials in the NE zone and 3 trials in Germany) and 9 trials after the second application with PESSEV ≥5% (4 trials in the NE zone and 5 trials in Germany)
- spring wheat: no trials after the first application with PESSEV ≥4% and 5 trials after the second application with PESSEV ≥5% (2 trials in the NE zone and 3 trials in Germany)

For spring wheat, no trials were submitted following the first application in the NE zone or in neighboring countries. In this case, the applicant should submit additional trials.

3.2.3.1.2 Efficacy against Yellow rust (*Puccinia striiformis*: PUCCST/PUCCSI)

A total of 34 trials carried out between 2022 and 2023 generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCST (21 trials) or PUCCSI (13 trials) in winter wheat (12 trials), spring wheat (6 trials), durum wheat (1 trial), spelt (2 trials), winter triticale (2 trials) and spring triticale (1 trial).

Of these trials, 15 were carried out in the Maritime EPPO climatic zone (8 in Germany, 2 in Ireland, 3 in the United Kingdom, 2 in France), 9 were carried out in the North-east EPPO climatic zone (all in Poland) and 10 were carried out in the South-east EPPO climatic zone (4 in Bulgaria, 6 in Romania).

Disease developed on all 34 trials and was assessed as percentage severity on the upper leaves (1-3).

Across trials, the efficacy of FGF11 has been evaluated under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in wheat, spelt and triticale crops growing regions across EU Central Registration zone countries.

An overall summary of mean percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCST and PUCCSI in wheat and triticale at 15-22 DA-A1 / 14-45 DA-A2 across trials in each of the EPPO climatic zones is given in Table 3.2-32.

Additionally a summary of mean percentage efficacy (based on disease severity on the leaves) of FGF11 against PUCCST and PUCCSI in wheat and triticale after the first application at 13-36 DA-A1 is given in Table 3.2-43.

Table 3.2-32: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCST and PUCCSI across trials on wheat and triticale in all EPPO climatic zones at 15-22 DA-A1 / 14-45 DA-A2

Registration or EPPO climatic zone	No. of trials (no. of data points)	*Untreated*		FGF11 1.0 L/ha		Proline* 0.8 L/ha*		Statistical comparison of FGF11 to SRP#
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	
CEU	34 (65)	***16.8***	*5.0-75.8*	**89.9**	30.2-100	**86.1**	40.0-100	> (6), = (59)
EPPO MAR	15 (30)	***23.6***	*5.0-75.8*	**87.3**	30.2-100	**83.4**	40.0-100	> (2), = (28)
EPPO NE	9 (17)	***12.9***	*5.3-46.1*	**95.8**	83.9-100	**92.5**	75.1-100	> (2), = (15)
EPPO SE	10 (18)	***9.0***	*5.1-18.0*	**88.5**	77.8-100	**84.6**	69.8-98.1	> (2), = (16)

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.2-6
No. of data points where >, = or <, based on statistically significant differences at 95% confidence level

Table 3.2-33a: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCST and PUCCSI across trials on winter wheat in all EPPO climatic zones after 1 application

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L2							
Maritime	1 trial	***36,0***	-	**90,82**	-	**87,12**	-
L3							
Maritime	3 trials	***16,7***	*4,5-29,0*	**93,2**	82,49-100	**91,8**	83,38-100
North-East (+trials conducted in Germany)	2 trials	***4,95***	*4,5-5,4*	**90,9**	81,7-100	**86,2**	72,3-100
L4							
Maritime	1 trial	***12,23***	-	**91,58**	-	**94,87**	-
North-East (+trials conducted in Germany)	1 trial	***5,1***	-	**100**	-	**86,0**	-
South-East	~~2 trials~~ 4 trials	~~*5,2*~~ ***4,8***	~~*4,9-5,5*~~ *4,0-5,5*	~~**100**~~ **98,7**	~~100-100~~ 96,6-100	~~**100**~~ **96,5**	~~100-100~~ 92,0-100
L5							
South-East	2 trials	***6,7***	*6,3-7,1*	**88,0**	86,4-89,6	**83,1**	82,6-83,6

Table 3.2-34b: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCST and PUCCSI across trials on spring wheat in all EPPO climatic zones after 1 application

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L1							
Maritime	1 trial	***5,8***	-	**100**	-	**100**	-
L2							
Maritime	1 trial	***6,43***	-	**94,83**	-	**75,77**	-
L3							
Maritime	1 trial	***14,75***	-	**91,02**	-	**76,84**	-

Table 3.2-35c: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCST and PUCCSI across trials on spring triticale in all EPPO climatic zones after 1 application

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC* 0.8 L/ha*	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L5							
North-East (+trials conducted in Germany)	1 trial	***5,3***	-	**100**	-	**100**	-

Table 3.2-36d: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCST and PUCCSI across trials on winter triticale in all EPPO climatic zones after 1 application

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L2							
North-East (+trials conducted in Germany)	1 trial	***4,17***	-	**75,0**	-	**74,2**	-
L3							
North-East (+trials conducted in Germany)	1 trial	***6,63***	-	**100**	-	**99,04**	-
South-East	1 trial	***6,7***	-	**93,8**	-	**93,4**	-
L4							
Maritime	1trial	***5,4***	-	**39,7**	-	**39,4**	-

Table 3.2-37e: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCST and PUCCSI across trials on winter wheat in all EPPO climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L1							
Maritime	8 trials	***25,2***	*5,0-73,5*	**94,6**	83,61-100	**88,4**	49,64-100
North-East	3 trials	***7,9***	*5,3-11,25*	**90,6**	83,94-99,22	**88,1**	75,06-100
North-East (+trials conducted in Germany)	7 trials	***11,2***	*5,0-30,5*	**93,5**	83,9-100	**91,2**	75,1-100
L2							
Maritime	6 trials	***34,3***	*7,13-75,75*	**90,3**	80,34-99,18	**85,8**	70,73-99,42
North-East	3 trials	***17,4***	*6,23-34,25*	**91,6**	84,18-99,59	**87,8**	76,61-98,92
North-East (+trials conducted in Germany)	6 trials	***16,8***	*6,2-34,3*	**89,0**	80,3-99,6	**83,9**	70,7-98,9
South-East	5 trials	***8,4***	*6,88-10,3*	**86,8**	81,73-100	**80,6**	69,76-93,38
L3							
Maritime	1 trial	***28,75***	-	**66,64**	-	**48,3**	-
North-East	1 trial	***46,13***	-	**88,37**	-	**86,25**	-
North-East (+trials conducted in Germany)	2 trials	***37,4***	*28,8-46,1*	**77,5**	66,6-88,4	**67,3**	48,3-86,3
South-East	4 trials	***10,6***	*10,0-11,25*	**87,8**	77,77-97,04	**83,2**	74,64-91,63

Table 3.2-38f: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCST and PUCCSI across trials on spring wheat in all EPPO climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L1							
Maritime	2 trials	***16,5***	*5,75-27,2*	**64,8**	30,16-99,38	**72,2**	53,97-90,37
North-East	2 trials	***8,3***	*6,75-9,75*	**100**	100-100	**90,7**	81,36-100
L2							
Maritime	3 trials	***18,2***	*5,75-38,88*	**98,9**	96,56-100	**94,7**	84,1-100
North-East	2 trials	***10,9***	*10,13-11,63*	**100**	100-100	**94,0**	88,02-100
L3							

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
Maritime	2 trials	***22,7***	*15,78-29,63*	**92,7**	86,79-98,61	**79,9**	62,03-97,84
North-East	1 trial	***7,0***	-	**100**	-	**100**	-

Table 3.2-39g: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCST and PUCCSI across trials on durum wheat in all EPPO climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L1							
Maritime	1trial	***17,73***	-	**57,31**	-	**59,37**	-
L2							
Maritime	1 trial	***11,03***	-	**56,35**	-	**59,12**	-
L3							
Maritime	1 trial	***17,48***	-	**66,92**	-	**63,15**	-
South-East	1 trial	***7,58***	-	**87,14**	-	**84,15**	-

Table 3.2-40h: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCST and PUCCSI across trials on spelt in all EPPO climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L1							
Maritime	1trial	***17,5***	-	**100**	-	**100**	-
South-East	1 trial	***5,08***	-	**92,57**	-	**89,67**	-
L2							
Maritime	2 trials	***15,0***	*5,0-25,0*	**91,3**	82,5-100	**97,5**	95,0-100
South-East	2 trials	***9,7***	*7,18-12,28*	**86,3**	84,91-87,74	**80,6**	72,14-88,97
L3							
South-East	2 trials	***11,8***	*5,6-18,0*	**92,2**	84,41-100	**90,4**	85,95-94,83

Table 3.2-41i: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCST and PUCCSI across trials on spring triticale in all EPPO climatic zones after 2 applications

Registration or EPPO climatic zone	**No. of trials**	***Untreated***		**FGF11**		**Proline/Prosaro 250 EC**	
				1.0 L/ha		**0.8 L/ha**	
		Mean	***Min-max***	**Mean**	**Min-max**	**Mean**	**Min-max**
L2							
North-East	1 trial	***10,38***	-	**100**	-	**100**	-
L3							
North-East	1 trial	***15,25***	-	**100**	-	**100**	-

Table 3.2-42j: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCST and PUCCSI across trials on winter triticale in all EPPO climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L2							
North-East	1 trial	***6,4***	-	**100**	-	**96,15**	-
South-East	1 trial	***7,43***	-	**97,92**	-	**98,08**	-
L3							
North-East	2 trials	***9,98***	*5,47-14,5*	**96,9**	93,7-100	**96,8**	95,45-98,08
South-East	1 trial	***7,5***	-	**79,96**	-	**80,24**	-

Table 3.2-43: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 following first application against PUCCST and PUCCSI across trials on wheat and triticale in all EPPO climatic zones at 13-36 DA-A1

Registration or EPPO climatic zone - leaf level	No of trials (No of data points)	*Untreated*		FGF11 (0.5 L/ha)		FGF11 (0.75 L/ha)		FGF11 (1.0 L/ha)		PROLINE* (0.8 L/ha)		Statistical comparison of FGF11 (1.0 L/ha) to SRP#
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max	Mean	Min-max	
EPPO MAR - leaf 1	2 (2)	*3.6*	*1.3 - 5.8*	94.5	90.9 - 98.2	100.0	100-100	100.0	100-100	99.1	98.2 - 100	= (2)
EPPO NE - leaf 1	1 (1)	*1.7*		54.0		64.7		68.9		60.5		= (1)
CEU- leaf 1	**3 (3)**	***2.9***	***1.3 - 5.8***	**81.0**	**54 - 98.2**	**88.2**	**64.7 - 100**	**89.6**	**68.9 - 100**	**86.2**	**60.5 - 100**	**= (3)**
EPPO MAR - leaf 2	5 (5)	*9.1*	*0.8 - 36*	75.4	70.9 - 81.1	84.5	75 - 95	87.1	75 - 100	86.3	75 - 100	= (4), > (1)
EPPO NE - leaf 2	3 (3)	*2.6*	*0.5 - 4.2*	58.8	50 - 70.4	64.0	50 - 75	65.2	50 - 75	61.5	50 - 74.2	= (3)
EPPO NE + neighbouring countries - leaf 2	5 (5)	*2.0*	*0.5 - 4.2*	65.3	50 - 75	68.4	50 - 75	69.1	50 - 75	71.9	50 - 100	= (5)
EPPO SE - leaf 2	6 (6)	*1.3*	*0.6 - 2.8*	92.0	72.5 - 100	94.4	77.5 - 100	97.1	82.5 - 100	96.0	82.5 - 100	= (6)
CEU- leaf 2	**14 (14)**	***4.4***	***0.5 - 36***	**78.9**	**50 - 100**	**84.4**	**50 - 100**	**86.7**	**50 - 100**	**85.2**	**50 - 100**	**= (13), > (1)**
EPPO MAR - leaf 3	9 (9)	*7.7*	*0.5 - 29*	77.1	30 - 100	80.6	50 - 100	84.5	50 - 100	86.8	75 - 100	= (8), > (1)
EPPO NE - leaf 3	3 (3)	*4.2*	*0.7 - 6.6*	94.6	86.2 - 100	95.3	86.2 - 100	93.9	81.7 - 100	90.4	72.3 - 100	= (3)
EPPO NE + neighbouring countries - leaf 3	8 (8)	*2.6*	*0.5 - 6.6*	88.6	50 - 100	88.9	50 - 100	88.3	50 - 100	90.2	72.3 - 100	= (8)
EPPO SE - leaf 3	9 (9)	*2.4*	*0.8 - 6.7*	85.0	55 - 100	89.4	63 - 100	91.8	69.6 - 100	91.8	69.6 - 100	= (9)
CEU- leaf 3	**21 (21)**	***5.0***	***0.5 - 29***	**83.0**	**30 - 100**	**86.4**	**50 - 100**	**89.0**	**50 - 100**	**89.4**	**69.6 - 100**	**= (20), > (1)**
EPPO MAR - leaf 4	6 (6)	*3.5*	*0.5 - 12.2*	64.0	15 - 100	65.2	31.4 - 100	67.7	39.7 - 100	68.2	39.4 - 100	= (6)
EPPO NE - leaf 4	3 (3)	*3.1*	*1.1 - 5.1*	81.4	64.9 - 100	95.3	91 - 100	98.8	96.5 - 100	93.8	86 - 100	= (3)
EPPO NE + neighbouring countries - leaf 4	8 (8)	*2.2*	*0.5 - 5.4*	66.8	15 - 100	73.0	31.4 - 100	76.4	39.7 - 100	74.5	39.4 - 100	= (8)
EPPO SE - leaf 4	6 (6)	*4.1*	*2 - 5.5*	87.8	72.2 - 100	93.5	80 - 100	96.6	84.9 - 100	96.0	90 - 100	= (6)
CEU- leaf 4	**15 (15)**	***3.6***	***0.5 - 12.2***	**77.0**	**15 - 100**	**82.5**	**31.4 - 100**	**85.5**	**39.7 - 100**	**84.4**	**39.4 - 100**	**= (15)**
EPPO MAR - leaf 5	2 (2)	*2.6*	*2.5 - 2.7*	42.4	22.2 - 62.5	46.2	35.7 - 56.7	45.6	30.8 - 60.3	50.3	43.5 - 57.1	= (2)

EPPO NE - leaf 5	1 (1)	*5.3*		93.3		95.2		100.0		100.0		= (1)
EPPO NE + neighbouring countries - leaf 5	3 (3)	*3.5*	*2.5 - 5.3*	59.3	22.2 - 93.3	62.5	35.7 - 95.2	63.7	30.8 - 100	66.9	43.5 - 100	= (3)
EPPO SE - leaf 5	2 (2)	*6.7*	*6.3 - 7.1*	70.8	69.2 - 72.4	79.7	78 - 81.4	88.0	86.4 - 89.6	83.1	82.6 - 83.6	= (2)
CEU- leaf 5	**5 (5)**	***4.8***	***2.5 - 7.1***	**63.9**	**22.2 - 93.3**	**69.4**	**35.7 - 95.2**	**73.4**	**30.8 - 100**	**73.4**	**43.5 - 100**	**= (5)**
EPPO MAR - all leaves	12 (24)	*6.2*	*0.5 - 36*	72.0	15 - 100	76.3	31.4 - 100	78.9	30.8 - 100	80.0	39.4 - 100	= (22), > (2)
EPPO NE - all leaves	6 (11)	*3.3*	*0.5 - 6.6*	77.4	50 - 100	84.0	50 - 100	85.7	50 - 100	81.6	50 - 100	= (11)
EPPO NE + neighbouring countries - all leaves	13 (25)	*2.4*	*0.5 - 6.6*	72.1	15 - 100	75.6	31.4 - 100	76.9	30.8 - 100	77.5	39.4 - 100	= (25)
EPPO SE - all leaves	9 (23)	*2.9*	*0.6 - 7.1*	86.3	55 - 100	90.9	63 - 100	94.1	69.6 - 100	93.2	69.6 - 100	= (23)
CEU- all leaves	**27 (58)**	***4.4***	***0.5 - 36***	**78.7**	**15 - 100**	**83.6**	**31.4 - 100**	**86.2**	**30.8 - 100**	**85.6**	**39.4 - 100**	**= (56), > (2)**

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Appendix 3 and Table 3.2-6
No. of data points where >, = or <, based on statistically significant differences at 95% confidence level

Data generated across trials carried out in the Maritime, North-east and South-east EPPO climatic zones demonstrate that FGF11 applied at the proposed label rate of 1.0 L product/ha generally gives effective control of PUCCST and PUCCSI in wheat and triticale that is consistently comparable and mostly not statistically significantly different to that given by the standard reference product applied at label rate.

Although the intended label claim for FGF11 is a single application, the majority of trials included 2 applications to ensure adequate disease development for a robust efficacy assessment and to reflect prevailing commercial practice, wherein growers typically apply 2 fungicide treatments to maintain season-long control of PUCCST and PUCCSI. The 2nd application specifically targeted newly occurring infections on the leaves; consequently, the assessments conducted after 2 applications are often indicative of the performance of a single application following new infections rather than cumulative sequential effects.

At the assessment after the first application, disease pressure was often too low, symptoms of PUCCST and PUCCSI appeared in only 27 trials and mostly at very low levels, making it difficult to reliably differentiate product performance. By the assessment timing after the second application, all 34 trials had reached sufficiently high disease levels (≥5% on individual leaf levels), creating a robust infection pressure. This allows for a more accurate and statistically meaningful comparison of FGF11's efficacy against the standard reference product. Furthermore, the efficacy of FGF11 and in comparison to the standard reference product at both assessment timings was similar. Therefore, the dataset following the 2nd application is considered more relevant for demonstrating the efficacy of FGF11, even though the intended claim is for a single application.

The morphology, life cycles and infection patterns of different *Puccinia striiformis* rust pathogens affecting cereals, and also the efficacy of fungicides against the different species, are very similar. Therefore, data generated on efficacy against PUCCSI are fully considered to provide evidence to support label claims for control of PUCCST.

Whilst no or limited data are presented to demonstrate the efficacy of FGF11 against PUCCST in spring wheat, durum wheat, spelt, winter and/or spring triticale in some of the EPPO climatic zones, following EPPO guidance PP1/331 (1) principles of efficacy extrapolations for major uses, the susceptibility of the crops to this fungal pathogen, disease development pressure and development patterns, agronomy of the crops and areas in which the crops are grown in the Central Registration zone can be considered to be sufficiently similar between different cereal crops for the data generated on trials in winter wheat to be fully supportive of demonstrating efficacy against PUCCST in spring wheat, durum wheat, spelt, winter and spring triticale.

Furthermore, products containing prothioconazole and azoxystrobin straight and as mixture are already registered against PUCCST in the different cereal types mentioned above throughout Europe. It can therefore be considered that FGF11 effectively controls PUCCST in all types of wheat, spelt and triticale.

Additionally, whilst limited data are presented on the efficacy of FGF11 against PUCCST on winter wheat, spring wheat, durum wheat and spelt from trials carried out in the North-east EPPO climatic zone, data generated on this disease across 8 trials (4 in winter wheat, 1 in spring wheat, 1 in durum wheat, 2 in spelt) in country neighbouring Poland (Germany) provide supportive evidence of that in Poland.

Based on the summarised data, it is therefore considered that claims for control of PUCCST and PUCCSI in wheat (winter, spring, durum), spelt and triticale (winter and spring) by FGF11, applied at the proposed label rate of 1.0 L product/ha and according to other label recommendations, are fully supported.

Comments of zRMS:

1 application

Winter wheat

A total of 6 trials have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Puccinia striiformis* (PUCCST) in winter wheat.

In the Maritime EPPO climatic zone, 3 trials were conducted between 2022 and 2023. FGF11 applied at the dose rate of 1 l/ha achieved high level of control with the results of 90,82% on L2, 93,2% on L3 and 91,58% on L4. Comparable effect was observed for the reference product at 0,8 l/ha. ~~Due to limited number of trials, the cMSs are kindly asked to consider this use at the national level.~~

In the North-East zone, only 1 trial was carried out in 2023. Also 1 trial from Germany can be a support for the Polish registration. The test product at the claimed dose rate presented high efficacy with the results of 90,9% on L3 and 100% on L4. No significant differences between test and reference product were noted. ~~Due to limited number of trials, this use cannot be accepted in Poland.~~

Conclusions for 2 applications: 4 trials were conducted in the NE zone between 2022 and 2023. The test product at claimed dose was effective on high level with the results of 90,6% on L1, 91,6% on L2 and 88,37% on L3. The trials submitted from Germany (4 trials) can support the Polish registration.

In the South-East zone, only 2 trials were conducted in 2023. FGF11 at 1 l/ha achieved full effectiveness on L4. Similar effect was visible for the reference product at 0,8 l/ha. ~~However, the cMSs are kindly asked to consider this use at the national level because of limited number of trials.~~

Spring wheat

Only 1 trial has been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Puccinia striiformis* (PUCCST) in spring wheat. This trial was conducted in 2022 in the Maritime EPPO climatic zone. FGF11 at 1 l/ha achieved high level of control with the results of 100% on L1, 94,83% on L2 and 91,02% on L3. Significant inferior efficacy was observed for the reference product at 0,8 l/ha on L2 and L3. Due to limited number of trials, the cMSs are kindly asked to consider this use at the national level.

No results after 1 application were available in the North-East and South-East EPPO zone. ~~Extrapolation from winter wheat is possible in this case in the NE zone.~~ This use cannot be accepted in Poland. The cMSs belonging to the SE zone are kindly asked to consider this use at the national level.

Conclusions for 2 applications in the NE zone: only 2 trials were carried out in 2023. FGF11 at 1 l/ha presented full control in both trials. 1 trial submitted from Germany can support the Polish registration.

Winter triticale

A total of 2 trials have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Puccinia striiformis* (PUCCST) in winter triticale.

In the North-East EPPO climatic zone, only 1 trial was conducted in 2023. FGF11 applied at dose rate of 1 l/ha achieved medium level of control on L2 (75%) and higher efficacy on L3 (100%). Similar effect was observed for the reference product at 0,8 l/ha. ~~This use cannot be accepted in Poland because of very limited number of trials.~~. Extrapolation from winter wheat is possible in this case in the NE zone.

Conclusions for 2 applications: only 2 trials were conducted between 2022 and 2023. FGF11 at 1 l/ha achieved high level of control in both trials with the results of 100% on L2 and 96,9% on L3.

In the South-East zone, only 1 trial was carried out in 2023. The test product at the claimed dose presented good control with the efficacy of 93,8% on L3. No significant differences between test and reference product were observed. ~~Due to limited number of trials, the cMSs are kindly asked to consider this use at the national level. No results after 1 application were available in the Maritime EPPO zone. The cMSs are kindly asked to consider this use at the national level.~~ In 1 trial conducted in the Maritime zone, the test product presented very limited control (39,7%) comparable to the reference product on L4.

Spring triticale

Only 1 trial has been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Puccinia striiformis* (PUCCST) in spring triticale. This trial was conducted in 2023 in the North-East EPPO climatic zone. FGF11 at 1 l/ha achieved full effectiveness on L5. High level of control was observed also for the reference product at 0,8 l/ha. ~~Due to limited number of trials, this use cannot be accepted in Poland. However, PUCCST on spring triticale is minor use in Poland and the registration under art. 51 is possible.~~ Extrapolation from winter wheat is possible in this case in the NE zone.

Conclusions for 2 applications: Only 1 trial has been submitted in spring triticale after 2 applications. This trial was conducted in the North-East EPPO zone in 2023. FGF11 at 1 l/ha achieved full control on L2 and L3.

No results after 1 application were available in the Maritime and South-East EPPO zone. The cMSs are kindly asked to consider this use at the national level.

Durum wheat and spelt
No results after 1 application were available in any EPPO climatic zone. The cMSs belonging to the Maritime and South-East zone are kindly asked to consider these uses at the national level. These uses cannot be accepted in Poland. However, durum wheat and spelt are minor crops in Poland and the registration under art. 51 is possible in these cases.
Conclusions for 2 applications in the NE zone: No efficacy trials were available in the North-East EPPO zone for above crops.

ZRMS conclusions after updated of RR (February 2026)
The applicant submitted the trial results after the first application following to the previous zRMS conclusions. However, most of the results after one application are based on PESSEV <4% and they cannot be considered valid results but only supportive. Only a small number of results can be taken into account when assessing the effectiveness of the product. Nevertheless, all results show a positive response of FGF11 to PUCCST/PUCCSI control. According to table 3.2-43, FGF11 at a dose rate of 1 L/ha achieved an overall average efficacy percentage on all leaves of 78,9% in the MAR zone, 85,7% in the NE zone and 94,1% in the SE zone on wheat and triticale. Taking into account both the applicant's arguments and the presented results of effectiveness after a single application, zRMS considers it possible to accept this application for winter wheat in each of the zones. In addition, based on EPPO guidance PP 1/331 (1), winter triticale, spring wheat and spring triticale can also be recognized in the MAR and SE zones. In the case of Poland, extrapolation from winter wheat to ~~spring wheat,~~ winter triticale and spring triticale is accepted.

ZRMS conclusion after updated of RR (April 2026)
In summary, the efficacy of FGF11 in controlling *Puccinia striiformis* (PUCCST) has been demonstrated in the North-East EPPO zone in the following trials:

- winter wheat: 2 trials after the first application with PESSEV ≥4% (1 trial from the NE zone and 1 trial from Germany) and 8 trials after the second application with PESSEV ≥5% (4 trials in the NE zone and 4 trials from Germany); in addition, 6 further trials after the first application had PESSEV <2% (PESSEV 0% was observed in 3 out of 6 trials)
- winter triticale: 1 trial after the first application with PESSEV ≥4% (conducted in the NE zone) and 2 trials after the second application with PESSEV ≥5% (conducted in the NE zone); in addition, 2 further trials after the first application had PESSEV <1%
- spring triticale: 1 trial after the first application with PESSEV ≥4% (conducted in the NE zone) and 1 trial after the second application with PESSEV ≥5% (conducted in the NE zone)
- spring wheat: no trials after the first application with PESSEV ≥4% and 3 trials after the second application with PESSEV ≥5% (2 trials in the NE zone and 1 trial in Germany)

For spring wheat, no trials were submitted following the first application in the NE zone or in neighboring countries. In this case, the applicant should submit additional trials.

3.2.3.1.3 Efficacy against Brown rust (*Puccinia recondita*: PUCCRE/PUCCRT)

A total of 43 trials carried out between 2022 and 2023 generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCRE (32 trials) and PUCCRT (11 trials) in winter wheat (24 trials), spring wheat (5 trials), durum wheat (3 trials), spelt (4 trials) and winter triticale (7 trials).

Of these trials, 16 were carried out in the Maritime EPPO climatic zone (10 in Germany, 3 in the United Kingdom, 3 in France), 12 were carried out in the North-east EPPO climatic zone (all in Poland) and 15 were carried out in the South-east EPPO climatic zone (3 in Bulgaria, 7 in Hungary, 5 in Romania).

Disease developed on all 43 trials and was assessed as percentage severity on the upper leaves (1-3).

Across trials, the efficacy of FGF11 has been evaluated under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in wheat, spelt and triticale crops growing regions across EU Central Registration zone countries.

An overall summary of mean percentage efficacy (based on disease severity on the leaves) of FGF11 applied twice at the proposed label rate of 1.0 L product/ha against PUCCRE and PUCCRT in wheat and triticale at 15-47 DA-A2 across trials in each of the EPPO climatic zones is given in Table 3.2-44.

Additionally a summary of mean percentage efficacy (based on disease severity on the leaves) of FGF11 against PUCCRE and PUCCRT in wheat and triticale after first application at 12-46 DA-A1 is given in Table 3.2-53.

Table 3.2-44: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied twice at the proposed label rate of 1.0 L product/ha against PUCCRE and PUCCRT across trials on wheat and triticale in all EPPO climatic zones at 15-47 DA-A2

Registration or EPPO climatic zone	No. of trials (no. of data points)	*Untreated*		FGF11 1.0 L/ha		Proline* 0.8 L/ha*		Prosaro 250 EC 0.8 L/ha		Statistical comparison of FGF11 to SRP#
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max	
CEU	43 (84)	***15.7***	*5.0-96.5*	**89.2**	35.1-100	-	-	-	-	-
	42 of 43 (83 of 84)	***15.8***	*5.0-96.5*	**89.1**	35.1-100	**82.5**	11.9-100	-	-	> (9), = (74)
	1 of 43 (1 of 84)	***7.1***	-	**100**	-	-	-	**96.4**	-	= (1)
EPPO MAR	16 (34)	***24.9***	*5.2-96.5*	**92.7**	53.2-100	**82.2**	11.9-100	-	-	> (2), = (32)
EPPO NE	12 (21)	***8.9***	*5.3-13.3*	**94.2**	83.0-100	**88.6**	46.6-100	-	-	> (3), = (18)
EPPO SE	15 (29)	***9.9***	*5.0-38.2*	**81.6**	35.1-100	-	-	-	-	-
	14 of 15 (28 of 29)	***10.0***	*5.0-38.2*	**80.9**	35.1-100	**78.3**	31.4-95.7	-	-	> (4), = (24)
	1 of 15 (1 of 29)	***7.1***	-	**100**	-	-	-	**96.4**	-	= (1)

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.2-6
No. of data points where >, = or <, based on statistically significant differences at 95% confidence level

Table 3.2-45a: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCRE and PUCCRT across trials on winter wheat in all EPPO climatic zones after 1 application

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L3							
Maritime	1 trial	***5,5***	-	**100**	-	**100**	-
L4							
North-East (+trials conducted in Germany)	1 trial	***5,0***	-	**93,2**	-	**92,8**	-
South-East	2 trials	***6,2***	*6,2-6,2*	**72,3**	49,81-94,8	**67,5**	49,96-85,0
L5							
South-East	1 trial	***5,7***	-	**92,5**	-	**85,9**	-

Table 3.2-46b: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCRE and PUCCRT across trials on spring wheat in all EPPO climatic zones after 1 application

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L3							

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
South-East	1 trial	***4,1***	-	**62,9**	-	**63,5**	-
L4							
South-East	1 trial	***10,5***	-	**70,2**	-	**68,9**	-
L5							
South-East	1 trial	***17,2***	-	**69,3**	-	**64,6**	-

Table 3.2-47c: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCRE and PUCCRT across trials on winter triticale in all EPPO climatic zones after 1 application

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L1							
North-East	1 trial	*6,4*	-	92,3	-	88,2	-
L2							
North-East	1 trial	*9,3*	-	89,1	-	87,3	-
L3							
South-East	1 trial	***4,7***	-	**89,42**	-	**88,79**	-
North-East	1 trial	***10,4***	-	**87,6**	-	**85,6**	-
L4							
North-East (+trials conducted in Germany)	1 trial	***4,8***	-	**91,0**	-	**89,0**	-
South-East	1 trial	***7,73***	-	**85,73**	-	**85,19**	-
L5							
South-East	2 trials	***4,8***	*4,3-5,2*	**68,6**	57,3-79,9	**67,7**	55,5-79,9

Table 3.2-48d: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCRE and PUCCRT across trials on winter wheat in all EPPO climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L1							
Maritime	10 trials	***34,8***	*9,48-95,0*	**95,6**	77,81-100	**84,7**	54,75-100
North-East	5 trials	***7,2***	*5,25-10,63*	**96,1**	92,38-100	**79,4**	46,63-90,09
North-East	9 trials	***24,7***	*5,3-95,0*	**96,6**	92,4-100	**81,9**	46,6-100

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
(+trials conducted in Germany)							
South-East	4 trials	***6,3***	*5,47-7,63*	**86,3**	72,45-93,6	**84,6**	67,86-95,65
L2							
Maritime	9 trials	***23,1***	*9,1-53,0*	**94,9**	87,08-100	**89,4**	62,5-100
North-East	3 trials	***9,2***	*5,91-11,1*	**95,1**	89,83-98,54	**94,1**	87,8-98,01
North-East (+trials conducted in Germany)	7 trials	***14,3***	*5,9-32,1*	**93,9**	87,1-100	**92,9**	83,1-100
South-East	4 trials	***8,1***	*5,12-12,25*	**84,2**	69,3-100	**78,7**	66,33-90,23
L3							
Maritime	4 trials	***7,8***	*5,7-10,28*	**95,8**	88,33-100	**84,4**	42,9-100
North-East	2 trials	***6,97***	*6,2-7,75*	**89,1**	85,88-92,23	**87,8**	84,68-90,94
North-East (+trials conducted in Germany)	4 trials	***6,7***	*5,7-7,8*	**93,2**	85,9-100	**92,6**	84,7-100
South-East	6 trials	***7,5***	*5,52-10,36*	**71,3**	35,06-100	**69,8**	31,38-90,59

Table 3.2-49e: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCRE and PUCCRT across trials on spring wheat in all EPPO climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L1							
North-East	3 trials	***11,0***	*10,0-12,13*	**95,0**	90,5-100	**90,8**	88,36-92,34
South-East	1 trial	***9,06***	-	**74,24**	-	**73,39**	-
L2							
North-East	2 trials	***12,7***	*12,13-13,25*	**97,9**	95,86-100	**95,2**	94,81-95,65
South-East	2 trials	***13,2***	*6,7-19,64*	**75,5**	67,36-83,65	**74,7**	66,6-82,89
L3							
North-East	1 trial	***6,53***	-	**83,02**	-	**81,11**	-
South-East	2 trials	***25,0***	*11,88-38,21*	**62,3**	47,98-76,61	**61,9**	50,02-73,86

Table 3.2-50f: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCRE and PUCCRT across trials on durum wheat in all EPPO climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L1							
Maritime	1 trial	***7,5***	-	**100**	-	**100**	-
L2							
South-East	1 trial	***7,13***	-	**100**	-	**96,41**	-
L3							
South-East	1 trial	***6,98***	-	**77,93**	-	**70,66**	-

Table 3.2-51g: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCRE and PUCCRT across trials on spelt in all EPPO climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L1							
Maritime	4 trials	***28,6***	*5,5-91,25*	**88,5**	77,86-100	**73,2**	34,21-100
L2							
Maritime	3 trials	***39,0***	*8,08-96,5*	**82,99**	53,15-100	**53,6**	11,9-100
L3							
Maritime	2 trials	***8,2***	*6,7-9,75*	**77,1**	54,1-100	**75,5**	51,04-100

Table 3.2-52h: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCRE and PUCCRT across trials on winter triticale in all EPPO climatic zones after 2 applications

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L1							
North-East	1 trial	***6,38***	-	**92,29**	-	**88,21**	-
South-East	2 trials	***7,1***	*5,0-9,15*	**95,5**	93,15-97,82	**91,99**	90,19-93,8
L2							
Maritime	1 trial	***5,21***	-	**99,85**	-	**100**	-
North-East	2 trials	***7,8***	*6,35-9,25*	**94,6**	89,13-100	**93,6**	87,25-100
North-East (+trials conducted in Germany)	3 trials	***6,95***	*5,2-9,3*	**96,3**	89,1-100	**95,8**	87,3-100
South-East	2 trials	***10,6***	*8,18-13,1*	**92,8**	89,84-95,67	**91,4**	88,35-94,38
L3							

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	**Mean**	**Min-max**	**Mean**	**Min-max**
North-East	2 trials	***10,9***	*10,38-11,5*	**93,8**	87,6-100	**92,8**	85,63-100
South-East	4 trials	***12,5***	*8,68-16,98*	**87,98**	77,11-93,66	**84,0**	72,56-90,26

Table 3.2-53: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 following the first application against PUCCRE and PUCCRT across trials on wheat and triticale in all EPPO climatic zones at 12-46 DA-A1

Registration or EPPO climatic zone - leaf level	No of trials (No of data points)	*Untreated*		FGF11 (0.5 L/ha)		FGF11 (0.75 L/ha)		FGF11 (1.0 L/ha)		PROLINE* (0.8 L/ha)		Statistical comparison of FGF11 (1.0 L/ha) to SRP#
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max	Mean	Min-max	
EPPO NE - leaf 1	1 (1)	*6.4*		80.5		87.2		92.3		88.2		= (1)
CEU- leaf 1	**1 (1)**	***6.4***		**80.5**		**87.2**		**92.3**		**88.2**		**= (1)**
EPPO MAR - leaf 2	1 (1)	*2.5*		78.1		100.0		100.0		100.0		= (1)
EPPO NE - leaf 2	3 (3)	*3.7*	*0.8 - 9.3*	88.0	77.6 - 100	95.0	84.9 - 100	96.4	89.1 - 100	95.8	87.3 - 100	= (3)
EPPO NE + neighbouring countries - leaf 2	3 (3)	*3.7*	*0.8 - 9.3*	88.0	77.6 - 100	95.0	84.9 - 100	96.4	89.1 - 100	95.8	87.3 - 100	= (3)
EPPO SE - leaf 2	5 (5)	*1.6*	*0.6 - 3.5*	81.2	63.1 - 100	84.2	64.7 - 100	88.4	69.4 - 100	88.2	67.5 - 100	= (5)
CEU- leaf 2	**9 (9)**	***2.4***	***0.6 - 9.3***	**83.1**	**63.1 - 100**	**89.5**	**64.7 - 100**	**92.3**	**69.4 - 100**	**92.0**	**67.5 - 100**	**= (9)**
EPPO MAR - leaf 3	2 (2)	*3.2*	*0.9 - 5.5*	89.7	79.4 - 100	96.6	93.1 - 100	100.0	100-100	100.0	100-100	= (2)
EPPO NE - leaf 3	3 (3)	*5.2*	*2 - 10.4*	80.6	73.6 - 84.8	89.2	82.8 - 93.5	94.0	87.6 - 100	93.3	85.6 - 100	= (3)
EPPO NE + neighbouring countries - leaf 3	4 (4)	*4.1*	*0.9 - 10.4*	85.5	73.6 - 100	91.9	82.8 - 100	95.5	87.6 - 100	95.0	85.6 - 100	= (4)
EPPO SE - leaf 3	13 (13)	*2.4*	*1.1 - 4.7*	72.1	27 - 100	79.9	55.3 - 100	86.5	62.9 - 100	83.4	63.5 - 100	= (12), > (1)
CEU- leaf 3	**18 (18)**	***2.9***	***0.9 - 10.4***	**75.5**	**27 - 100**	**83.3**	**55.3 - 100**	**89.3**	**62.9 - 100**	**86.9**	**63.5 - 100**	**= (17), > (1)**
EPPO NE - leaf 4	3 (3)	*4.3*	*3.1 - 5*	65.0	31.3 - 83.9	84.1	74 - 89.8	94.0	91 - 97.9	91.6	89 - 93.1	= (3)
EPPO NE + neighbouring countries - leaf 4	3 (3)	*4.3*	*3.1 - 5*	65.0	31.3 - 83.9	84.1	74 - 89.8	94.0	91 - 97.9	91.6	89 - 93.1	= (3)
EPPO SE - leaf 4	7 (7)	*5.7*	*2.7 - 10.5*	50.0	10.5 - 87.9	67.9	25.8 - 93.2	77.5	49.8 - 99.8	74.8	50 - 93.8	= (6), > (1)
CEU- leaf 4	10 (10)	*5.3*	*2.7 - 10.5*	54.5	10.5 - 87.9	72.8	25.8 - 93.2	82.5	49.8 - 99.8	79.8	50 - 93.8	= (9), > (1)
EPPO SE - leaf 5	4 (4)	*8.1*	*4.3 - 17.2*	38.6	12.8 - 73.1	52.2	18.8 - 82.9	74.7	57.3 - 92.5	71.5	55.5 - 85.9	= (3), > (1)
CEU- leaf 5	**4 (4)**	***8.1***	***4.3 - 17.2***	**38.6**	**12.8 - 73.1**	**52.2**	**18.8 - 82.9**	**74.7**	**57.3 - 92.5**	**71.5**	**55.5 - 85.9**	**= (3), > (1)**
EPPO MAR - all leaves	2 (3)	*2.9*	*0.9 - 5.5*	85.8	78.1 - 100	97.7	93.1 - 100	100.0	100-100	100.0	100-100	= (3)
EPPO NE - all leaves	4 (10)	*4.6*	*0.8 - 10.4*	78.1	31.3 - 100	89.2	74 - 100	94.6	87.6 - 100	93.0	85.6 - 100	= (10)
EPPO NE + neighbouring countries - all leaves	5 (11)	*4.3*	*0.8 - 10.4*	80.1	31.3 - 100	90.2	74 - 100	95.1	87.6 - 100	93.7	85.6 - 100	= (11)
EPPO SE - all leaves	14 (29)	*3.8*	*0.6 - 17.2*	63.7	10.5 - 100	73.9	18.8 - 100	83.0	49.8 - 100	80.5	50 - 100	= (26), > (3)
CEU- all leaves	**20 (42)**	***4.0***	***0.6 - 17.2***	**68.7**	**10.5 - 100**	**79.2**	**18.8 - 100**	**87.0**	**49.8 - 100**	**84.9**	**50 - 100**	**= (39), > (3)**

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Appendix 3 and Table 3.2-6
No. of data points where >, = or <, based on statistically significant differences at 95% confidence level

Data generated across trials carried out in the Maritime, North-east and South-east EPPO climatic zones demonstrate that FGF11 applied at the proposed label rate of 1.0 L product/ha generally gives effective control of PUCCRE and PUCCRT in wheat and triticale that is consistently comparable and mostly not statistically significantly different to that given by the standard reference products applied at label rates.

Although the intended label claim for FGF11 is a single application, the majority of trials included 2 applications to ensure adequate disease development for a robust efficacy assessment and to reflect prevailing commercial practice, wherein growers typically apply 2 fungicide treatments to maintain season-long control of PUCCRE and PUCCRT. The 2nd application specifically targeted newly occurring infections on the leaves; consequently, the assessments conducted after 2 applications are often indicative of the performance of a single application following new infections rather than cumulative sequential effects.

At the assessment after the first application, disease pressure was often too low, symptoms of PUCCRE and PUCCRT appeared in only 20 trials and mostly at very low levels, making it difficult to reliably differentiate product performance. The low disease pressure at this timing is not unexpected, as PUCCRE and PUCCRT are typically late-season diseases which appear and have symptoms visible from BBCH 37-39 onwards. By the assessment timing after the second application, all 43 trials had reached sufficiently high disease levels (≥5% on individual leaf levels), creating a robust infection pressure. This allows for a more accurate and statistically meaningful comparison of FGF11's efficacy against the standard reference product. Furthermore, the efficacy of FGF11 in comparison to the standard reference product at both assessment timings was similar. Therefore, the dataset following the 2nd application is considered more relevant for demonstrating the efficacy of FGF11, even though the intended claim is for a single application.

The morphology, life cycles and infection patterns of different *Puccinia* rust pathogens affecting cereals, and also the efficacy of fungicides against the different species, are very similar. Therefore, data generated on efficacy against PUCCRT are fully considered to provide evidence to support label claims for control of PUCCRE.

Whilst no or limited data are presented to demonstrate the efficacy of FGF11 against PUCCRE in spring wheat, durum wheat, spelt, winter and/or spring triticale in some of the EPPO climatic zones, following EPPO guidance PP1/331 (1) principles of efficacy extrapolations for major uses, the susceptibility of the crops to this fungal pathogen, disease development pressure and development patterns, agronomy of the crops and areas in which the crops are grown in the Central Registration zone can be considered to be sufficiently similar between different cereal crops for the data generated on trials in winter wheat to be fully supportive of demonstrating efficacy against PUCCRE in spring wheat, durum wheat, spelt, winter and spring triticale.

Furthermore, products containing prothioconazole and azoxystrobin straight and as mixture are already registered against PUCCRE in the different cereal types mentioned above throughout Europe. The efficacy of FGF11 against PUCCRE was extensively proven in winter wheat and was confirmed by trials in other cereal types. It can therefore be considered that FGF11 effectively controls PUCCRE in all types of wheat, spelt and triticale.

Additionally, whilst limited data are presented on the efficacy of FGF11 against PUCCRE on winter wheat, durum wheat, spelt and winter triticale from trials carried out in the North-east EPPO climatic zone, data generated on this disease across 10 trials (4 in winter wheat, 1 in durum wheat, 4 in spelt, 1 in winter triticale) in country neighbouring Poland (Germany) provide supportive evidence of that in Poland.

Based on the summarised data, it is therefore considered that claims for control of PUCCRE and PUCCRT in wheat (winter, spring, durum), spelt and triticale (winter and spring) by FGF11, applied at the proposed label rate of 1.0 L product/ha and according to other label recommendations, are fully supported.

Comments of zRMS:

1 application

Winter wheat

A total of 4 trials have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Puccinia recondita* (PUCCRE/PUCCRT) in winter wheat.

In the Maritime EPPO climatic zone, only 1 trial was conducted in 2023. FGF11 applied at dose rate of 1 l/ha achieved full effectiveness on L3. Similar result was observed for the reference product at 0,8 l/ha. The cMSs are kindly asked to consider this use at the national level because of very limited number of trials.

In the North-East zone, only 1 trial was carried out in 2023. The test product at the claimed dose rate presented high level of control with the result of 93,2% on L4. Comparable effect was visible for the reference product. ~~This use cannot be accepted in Poland because of very limited number of trials.~~

Conclusions for 2 applications: 7 trials were carried out between 2022 and 2023. The test product at claimed dose presented high control with the results of 96,1% on L1, 95,1% on L2 and 89,1% on L3. The trials submitted for Germany (4 trials) can support the Polish registration.

In the South-East zone, 2 trials were conducted in 2023. FGF11 at 1 l/ha achieved medium effectiveness with the result of 72,3% on L4. The reference product had slight inferior result. The cMSs are kindly asked to consider this use at the national level because of limited number of trials.

Winter triticale

A total of 4 trials have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Puccinia recondita* (PUCCRE/PUCCRT) in winter triticale.

In the North-East EPPO zone, only 1 trial was conducted in 2023. FGF11 at 1 l/ha achieved good level of control with the result of 91% on L4, 92,3% on L1, 89,1% on L2 and 87,6% on L3. Comparable effect was observed for the reference product at 0,8 l/ha. ~~This use cannot be accepted in Poland because of very limited number of trials.~~ Extrapolation from winter wheat is possible in this case in the NE zone.

Conclusions for 2 applications: only 2 trials were carried out in 2023. The test product at the claimed dose presented high efficacy with the results of 92,29% on L1, 94,6% on L2 and 93,8% on L3. 1 trial submitted for Germany can support the Polish registration.

In the South-East zone, 3 trials were carried out in 2023. The test product at the claimed dose presented sufficient results of 89,42% on L3 and 85,73% on L4. Medium level of control was observed on L5 (68,6%). Similar effect was noted for the reference product. The cMSs are kindly asked to consider this use at the national level because of limited number of trials.

No results after 1 application were available in the Maritime EPPO zone. The cMSs are kindly asked to consider this use at the national level.

Spring wheat

Only 2 trials have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Puccinia recondita* (PUCCRE/PUCCRT) in spring wheat. Both trials were conducted in 2023 in the South-East EPPO climatic zone. FGF11 at 1 l/ha achieved medium level of control with the results of 62,9% on L3, 70,2% on L4 and 69,3% on L5. No significant differences between test and reference product were observed. The cMSs are kindly asked to consider this use at the national level because of limited number of trials.

No results after 1 application were available in the Maritime and North-East EPPO zone. ~~Extrapolation from winter wheat is possible in this case in the NE zone~~. This use cannot be accepted in Poland. The cMSs belonging to the MAR zone are kindly asked to consider this use at the national level.

Conclusions for 2 applications in the NE zone: 3 trials were carried out between 2022 and 2023. FGF11 at dose rate of 1 l/ha achieved high efficacy with the results of 95% on L1, 97,9% on L2 and 83,02% on L3.

Spring triticale, durum wheat, spelt

No results after 1 application were available in any EPPO climatic zone. The cMSs belonging to the Maritime and South-East zone are kindly asked to consider these uses at the national level. These uses cannot be accepted in Poland. However, durum wheat and spelt are minor crops in Poland and the registration under art. 51 is possible in these cases.

Conclusions for 2 applications in the NE zone: No efficacy trials were available in the North-East for above crops.

ZRMS conclusions after updated of RR (February 2026)

The applicant submitted the trial results after the first application following to the previous zRMS conclusions.

However, most of the results after one application are based on PESSEV <4% and they cannot be considered valid results but only supportive. Only a small number of results can be taken into account when assessing the effectiveness of the product. Nevertheless, all results show a positive response of FGF11 to PUCCRE/PUCCRT control. According to table 3.2-53, FGF11 at a dose rate of 1 L/ha achieved an overall average efficacy percentage on all leaves of 100% in the MAR zone, 94,6% in the NE zone and 83% in the SE zone on wheat and triticale. Taking into account both the applicant's arguments and the presented results of effectiveness after a single application, zRMS considers it possible to accept this application for winter wheat in each of the zones. In addition, based on EPPO guidance 1/331 (1), spring wheat, winter triticale and spring triticale can also be considered in the MAR and SE zones. In the case of Poland, extrapolation from winter wheat to ~~spring wheat and~~ winter triticale is accepted.

ZRMS conclusion after updated of RR (April 2026)

In summary, the efficacy of FGF11 in controlling *Puccinia recondita* (PUCCRE) has been demonstrated in the North-East EPPO zone in the following trials:

- winter wheat: 1 trial after the first application with PESSEV ≥4% (from the NE zone) and 11 trials after the second application with PESSEV ≥5% (7 trials in the NE zone and 4 trials from Germany); in addition, 5 further trials after the first application had PESSEV <2% (PESSEV 0% was observed in 4 out of 6 trials)
- winter triticale: 1 trial after the first application with PESSEV ≥4% (conducted in the NE zone) and 3 trials after the second application with PESSEV ≥5% (2 trials in the NE zone and 1 trial from Germany); in addition, 1 further trial conducted in Germany after the first application had PESSEV 0%
- spring wheat: no trials after first application with PESSEV ≥4% and 3 trials after second application with PESEV ≥5% (conducted in the NE zone)

For spring wheat, no trials were submitted following the first application in the NE zone or in neighboring countries. In this case, the applicant should submit additional trials.

3.2.3.1.4 Positive effects on green leaf area

Positive effects on green leaf area were assessed on a total of 112 of the trials carried out between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against target foliar diseases in winter wheat (58 trials), spring wheat (16 trials), durum wheat (10 trials), spelt (6 trials), winter triticale (21 trials) and spring triticale (1 trial).

Of these trials, 42 were carried out in the Maritime EPPO climatic zone (1 in Denmark, 22 in Germany, 4 in Ireland, 9 in the United Kingdom, 6 in France), 28 were carried out in the North-east EPPO climatic zone (4 in Lithuania, 24 in Poland) and 42 were carried out in the South-east EPPO climatic zone (10 in Bulgaria, 10 in Hungary, 22 in Romania).

Target foliar diseases that occurred in these trials were PUCCRE on 9 trials, PUCCRT on 5 trials, PUCCSI on 5 trials, PUCCST on 11 trials, SEPTTR on 48 trials, PUCCRE and SEPTTR on 16 trials, PUCCRT and SEPTTR on 3 trials, PUCCRE and PUCCSI on 2 trials, SEPTTR and PUCCSI on 3 trials, SEPTTR and PUCCST on 5 trials, PUCCRE, SEPTTR and PUCCST on 3 trials, PUCCRT, SEPTTR and PUCCSI on 1 trial and PUCCRE, SEPTTR and PUCCSI on 1 trial.

Data are summarised here from representative assessment timings where differences occurred and were assessed on individual upper leaves (1-3) or on a whole plant leaf area basis.

An overall summary of mean percentage green leaf area data following application of FGF11 at the proposed label rate of 1.0 L product/ha, compared to standard reference products applied at the label rates, across these 114 trials in wheat or triticale is given in Table 3.2-54.

Table 3.2-54: Mean overall green leaf area data following an application of FGF11 at the proposed label rate of 1.0 L product/ha across trials in all climatic zones that generated data on efficacy against target foliar disease in wheat and triticale

Registration or EPPO climatic zone	No. of trials (no. of data points)	*Untreated*		FGF11 1.00 L/ha		Proline 0.8 L/ha*		Prosaro 250 EC 0.8 L/ha		Statistical comparison of FGF11 to SRP#
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max	
Leaves 1-3										
CEU	67 (110)	***35.3***	*0.0-95.0*	**58.0**	1.5-100	-	-	-	-	-
	65 of 67 (108 of 110)	***35.3***	*0.0-95.0*	**58.0**	1.5-100	**54.6**	0.0-100	-	-	> (16), = (94)
	2 of 67 (2 of 110)	***33.8***	*32.5-35.0*	**61.3**	60.0-62.5	-	-	**58.8**	57.5-60.0	= (2)
EPPO MAR	28 (55)	***26.8***	*0.0-93.0*	**58.3**	2.5-100	**53.6**	0.0-100	-	-	> (10), = (45)
EPPO NE	16 (23)	***50.9***	*8.8-90.0*	**64.6**	22.5-92.5	**63.3**	20.0-91.3	-	-	> (2), = (23)
EPPO SE	23 (32)	***38.7***	*0.0-95.0*	**52.9**	1.5-100	-	-	-	-	-
	21 of 23 (30 of 32)	***39.1***	*0.0-95.0*	**52.4**	1.5-100	**49.6**	1.0-100	-	-	> (4), = (26)
	2 of 23 (2 of 32)	***33.8***	*32.5-35.0*	**61.3**	60.0-62.5	-	-	**58.8**	57.5-60.0	= (2)
Plant										
CEU	45 (45)	***48.4***	*0.0-90.0*	**70.8**	0.5-100	**69.1**	0.3-100	-	-	> (5), = (40)
EPPO MAR	14 (14)	***35.1***	*0.0-75.0*	**54.5**	0.5-90.0	**55.0**	0.3-90.0	-	-	= (14)
EPPO NE	12 (12)	***49.9***	*20.0-85.0*	**76.4**	36.3-96.5	**73.7**	35.3-95.0	-	-	> (1), = (11)
EPPO SE	19 (19)	***57.2***	*0.0-90.0*	**79.3**	43.8-100	**76.6**	37.5-100	-	-	> (4), = (15)

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.2-6

No. of data points where >, = or <, based on statistically significant differences at 95% confidence level

FGF11 applied at the proposed label rate of 1.0 L product/ha increased green leaf area on the upper leaves in all trials and on a whole plant leaf area basis in great majority of the trials compared to the untreated control. The effects were statistically significant in the majority of cases. These increases produced by FGF11 were generally comparable to those produced by the standard reference products applied at label rates.

These increases in green leaf area were a direct function of the efficacy of FGF11 against the single or multiple target diseases that developed in the trials and the direct effects of disease having prematurely reduced green leaf area in the untreated control.

These increases in green leaf persistence produced by FGF11 applied at the proposed label rate of 1.0 L product/ha therefore provide supplementary evidence in support of label claims for control of target foliar diseases in wheat and triticale.

Comments of zRMS:

Green leaf area was evaluated in wheat and triticale crops in 112 efficacy trials, only after second application. In case of either leaves (1-3) and plant, the increase of mean overall green leaf area was visible after an application of FGF11 at 1 l/ha in all EPPO climatic zone. No statistical differences between test product and Proline/Prosaro 250 EC at 0,8 l/ha were observed in most of trials.

3.2.3.1.5 Positive effects on crop yield and quality in efficacy trials

Evaluations of crop yield were carried out on a total of 61 of the trials carried out between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against target foliar diseases in winter wheat (39 trials), spring wheat (6 trials), durum wheat (5 trials), spelt (4 trials) and winter triticale (7 trials). Of these trials, 31 were carried out in the Maritime EPPO climatic zone (15 in Germany, 5 in Ireland, 5 in the United Kingdom, 6 in France), 14 were carried out in the North-east EPPO climatic zone (4 in Lithuania, 10 in Poland) and 16 were carried out in the South-east EPPO climatic zone (4 in Bulgaria, 6 in Hungary, 6 in Romania).

Evaluations of quality of grain sampled at harvest were also carried out on all 61 trials, with hectolitre weight (HLW) determined on all trials and thousand grain weight (TGW) determined on 45 of the trials.

Target diseases that occurred in these trials were PUCCRE on 4 trials, PUCCRT on 3 trials, PUCCSI on 1 trial, PUCCST on 3 trials, SEPTTR on 23 trials, PUCCRE and SEPTTR on 12 trials, PUCCRT and SEPTTR on 3 trials, SEPTTR and PUCCSI on 1 trial, SEPTTR and PUCCST on 5 trials, PUCCRE and PUCCSI on 1 trial, PUCCRE, SEPTTR and PUCCST on 3 trials, PUCCRT, SEPTTR and PUCCSI on 1 trial and PUCCRE, SEPTTR and PUCCSI on 1 trial.

An overall summary of mean crop yield and grain quality data (expressed as % relative to the untreated control) across trials in each of the climatic zones is given in Table 3.2-55.

Table 3.2-55: Mean overall crop yield and grain quality data (expressed as % relative to the untreated control) following an application of FGF11 at the proposed label rate of 1.0 L product/ha across trials in all climatic zones that generated data on efficacy against target foliar disease in wheat and triticale

Registration or EPPO climatic zone	No. of trials	Untreated	FGF11		Proline		Prosaro 250 EC		Statistical comparison of FGF11 to SRP#
			1.00 L/ha		0.8 L/ha*		0.8 L/ha		
		Mean	Mean	Min-max	Mean	Min-max	Mean	Min-max	
Grain yield									
All trials in wheat and triticale									
CEU	61	**100.0**	**115.0**	96.3-185.4	-	-	-	-	-
	60 of 61	**100.0**	**115.2**	96.3-185.4	**112.4**	94.8-155.7	-	-	> (8), = (52)
	1 of 61	**100.0**	**108.0**	-	-	-	**106.9**	-	= (1)
EPPO MAR	31	**100.0**	**116.9**	96.3-185.4	**114.3**	99.4-155.7	-	-	> (4), = (27)
EPPO NE	14	**100.0**	**112.7**	100.0-151.1	**109.4**	98.4-137.1	-	-	> (1), = (13)
EPPO SE	16	**100.0**	**113.6**	102.0-136.3	-	-	-	-	-
	15 of 16	**100.0**	**113.9**	102.0-136.3	**111.2**	94.8-137.9	-	-	> (3), = (12)
	1 of 16	**100.0**	**108.0**	-	-	-	**106.9**	-	= (1)
Winter wheat									
CEU	39	**100.0**	**117.1**	100.0-185.4	**113.9**	94.8-155.7	-	-	> (6), = (33)
EPPO MAR	21	**100.0**	**121.9**	102.9-185.4	**118.6**	102.8-155.7	-	-	> (4), = (17)
EPPO NE	11	**100.0**	**113.5**	100.0-151.1	**110.4**	98.4-137.1	-	-	> (1), = (10)
EPPO SE	7	**100.0**	**108.0**	102.0-114.1	**105.5**	94.8-113.4	-	-	> (1), = (6)
Spring wheat									
CEU	6	**100.0**	**114.2**	98.9-136.3	**110.8**	99.4-137.9	-	-	= (6)
EPPO MAR	2	**100.0**	**110.0**	98.9-121.1	**104.9**	99.4-110.4	-	-	= (2)
EPPO NE	3	**100.0**	**109.6**	108.7-110.3	**105.8**	102.3-112.1	-	-	= (3)
EPPO SE	1	**100.0**	**136.3**	-	**137.9**	-	-	-	= (1)
Spelt									
CEU	4	**100.0**	**104.7**	101.1-113.4	**106.1**	100.3-118.4	-	-	= (4)
EPPO MAR	3	**100.0**	**101.7**	96.3-114.0	**109.4**	104.3-113.7	-	-	= (3)
EPPO SE	1	**100.0**	**113.4**	-	**118.4**	-	-	-	= (1)

Registration or EPPO climatic zone	No. of trials	Untreated	FGF11		Proline		Prosaro 250 EC		Statistical comparison of FGF11 to SRP#
			1.00 L/ha		0.8 L/ha*		0.8 L/ha		
		Mean	Mean	Min-max	Mean	Min-max	Mean	Min-max	
Durum wheat									
CEU	5	**100.0**	**109.9**	96.3-118.1	-	-	-	-	-
	4 of 5	**100.0**	**110.3**	96.3-118.1	**109.9**	104.3-113.7	-	-	= (4)
	1 of 5	**100.0**	**108.0**	-	-	-	**106.9**	-	= (1)
EPPO MAR	3	**100.0**	**107.7**	96.3-114.0	**109.4**	104.3-113.7	-	-	= (3)
EPPO SE	2	**100.0**	**113.0**	108.0-118.1	-	-	-	-	-
	1 of 2	**100.0**	**118.1**	-	**111.1**	-	-	-	= (1)
	1 of 2	**100.0**		-	-	-	**106.9**	-	= (1)
Winter triticale									
CEU	7	**100.0**	**114.3**	106.0-128.6	**110.3**	103.7-120.5	-	-	> (2), = (5)
EPPO MAR	2	**100.0**	**107.1**	106.5-107.7	**105.3**	103.7-106.9	-	-	= (2)
EPPO SE	5	**100.0**	**117.1**	106.0-128.6	**112.4**	105.5-120.5	-	-	> (2), = (3)
TGW									
All trials in wheat and triticale									
CEU	45	**100.0**	**106.0**	95.9-149.7	-	-	-	-	-
	44 of 45	**100.0**	**106.1**	95.9-149.7	**104.7**	94.5-132.1	-	-	> (2), = (41), < (1)
	1 of 45	**100.0**	**104.2**	-	-	-	**103.7**	-	= (1)
EPPO MAR	22	**100.0**	**108.6**	100.2-149.7	**106.5**	94.5-132.1	-	-	> (1), = (21)
EPPO NE	13	**100.0**	**104.2**	99.2-115.9	**103.8**	99.2-113.2	-	-	= (12), < (1)
EPPO SE	10	**100.0**	**102.8**	95.9-107.8	-	-	-	-	-
	9 of 10	**100.0**	**102.6**	95.9-107.8	**101.6**	97.3-104.9	-	-	> (1), = (8)
	1 of 10	**100.0**	**104.2**	-	-	-	**103.7**	-	= (1)
Winter wheat									
CEU	28	**100.0**	**107.7**	95.9-149.7	**106.1**	97.3-132.1	-	-	> (1), = (26), < (1)
EPPO MAR	13	**100.0**	**111.8**	102.1-149.7	**109.0**	99.8-132.1	-	-	= (13)
EPPO NE	10	**100.0**	**105.2**	99.2-115.9	**104.7**	101.0-113.2	-	-	= (9), < (1)
EPPO SE	5	**100.0**	**102.2**	95.9-107.8	**101.3**	97.3-104.9	-	-	> (1), = (4)
Spring wheat									
CEU	4	**100.0**	**102.1**	100.3-105.5	**101.3**	99.2-104.7	-	-	= (4)
EPPO MAR	1	**100.0**	**105.5**	-	**101.7**	-	-	-	= (1)
EPPO NE	3	**100.0**	**100.9**	100.3-102.2	**101.1**	99.2-104.7	-	-	= (3)

Registration or EPPO climatic zone	No. of trials	Untreated	FGF11		Proline		Prosaro 250 EC		Statistical comparison of FGF11 to SRP#
			1.00 L/ha		0.8 L/ha*		0.8 L/ha		
		Mean	Mean	Min-max	Mean	Min-max	Mean	Min-max	
Spelt									
CEU	4	**100.0**	**102.0**	100.4-103.6	**102.6**	99.8-106.5	-	-	= (4)
EPPO MAR	3	**100.0**	**105.6**	100.2-110.4	**105.5**	94.5-111.9	-	-	= (3)
EPPO SE	1	**100.0**	**103.6**	-	**104.1**	-	-	-	= (1)
Durum wheat									
CEU	4	**100.0**	**105.3**	100.2-110.4	-	-	-	-	-
	3 of 4	**100.0**	**105.6**	100.2-110.4	**105.5**	94.5-111.9	-	-	> (1), = (2)
	1 of 4	**100.0**	**104.2**	-	-	-	**103.7**	-	= (1)
EPPO MAR	3	**100.0**	**105.6**	100.2-110.4	**105.5**	94.5-111.9	-	-	> (1), = (2)
EPPO SE	1	**100.0**	**104.2**	-	-	-	**103.7**	-	= (1)
Winter triticale									
CEU	5	**100.0**	**103.6**	100.6-106.5	**101.3**	100.3-102.3	-	-	= (5)
EPPO MAR	2	**100.0**	**104.6**	102.8-106.4	**101.1**	100.5-101.7	-	-	= (2)
EPPO SE	3	**100.0**	**103.0**	100.6-106.5	**101.4**	100.3-102.3	-	-	= (3)
HLW									
All trials in wheat and triticale									
CEU	61	**100.0**	**102.0**	92.8-118.6	-	-	-	-	-
	60 of 61	**100.0**	**102.0**	92.8-118.6	**102.0**	99.1-114.5	-	-	> (4), = (55), < (1)
	1 of 61	**100.0**	**102.1**	-	-	-	**101.7**	-	= (1)
EPPO MAR	31	**100.0**	**102.6**	92.8-118.6	**102.7**	99.1-114.5	-	-	> (3), = (27), < (1)
EPPO NE	14	**100.0**	**101.0**	99.7-102.6	**100.8**	99.5-102.2	-	-	= (14)
EPPO SE	16	**100.0**	**101.6**	98.8-104.0	-	-	-	-	-
	15 of 16	**100.0**	**101.5**	98.8-104.0	**101.5**	99.1-103.2	-	-	> (1), = (14)
	1 of 16	**100.0**	**102.1**	-	-	-	**101.7**	-	= (1)
Winter wheat									
CEU	39	**100.0**	**102.5**	99.7-118.6	**102.2**	99.1-114.5	-	-	> (3), = (36)
EPPO MAR	21	**100.0**	**103.6**	100.6-118.6	**103.3**	99.1-114.5	-	-	> (3), = (18)
EPPO NE	11	**100.0**	**101.1**	99.7-102.6	**100.9**	99.5-102.2	-	-	= (11)
EPPO SE	7	**100.0**	**101.2**	100.4-101.9	**101.0**	100.0-101.6	-	-	= (7)

Registration or EPPO climatic zone	No. of trials	Untreated	FGF11		Proline		Prosaro 250 EC		Statistical comparison of FGF11 to SRP#
			1.00 L/ha		0.8 L/ha*		0.8 L/ha		
		Mean	Mean	Min-max	Mean	Min-max	Mean	Min-max	
Spring wheat									
CEU	6	**100.0**	**101.1**	99.6-103.1	**100.9**	99.9-103.1	-	-	= (6)
EPPO MAR	2	**100.0**	**100.9**	99.6-102.1	**100.3**	99.9-100.7	-	-	= (2)
EPPO NE	3	**100.0**	**100.6**	99.9-101.0	**100.5**	99.9-100.9	-	-	= (3)
EPPO SE	1	**100.0**	**103.1**	-	**103.1**	-	-	-	= (1)
Spelt									
CEU	4	**100.0**	**99.5**	92.8-105.6	**101.3**	99.1-103.2	-	-	= (3), < (1)
EPPO MAR	3	**100.0**	**99.6**	92.8-105.6	**102.0**	100.5-103.2	-	-	= (2), < (1)
EPPO SE	1	**100.0**	**99.2**	-	**99.1**	-	-	-	= (1)
Durum wheat									
CEU	5	**100.0**	**101.4**	98.2-103.8	-	-	-	-	-
	4	**100.0**	**101.2**	98.2-103.8	**101.9**	100.4-103.1	-	-	= (4)
	1	**100.0**	**102.1**	-	-	-	**101.7**	-	= (1)
EPPO MAR	3	**100.0**	**100.3**	92.8-105.6	**102.0**	100.5-103.2	-	-	= (3)
EPPO SE	2	**100.0**	**103.0**	102.1-103.8	-	-	-	-	-
	1 of 2	**100.0**	**103.8**	-	**103.1**		-	-	= (1)
	1 of 2	**100.0**	**102.1**	-	-	-	**101.7**	-	= (1)
Winter triticale									
CEU	7	**100.0**	**101.6**	98.8-104.0	**101.8**	100.3-103.2	-	-	> (1), = (6)
EPPO MAR	2	**100.0**	**101.3**	101.2-101.3	**101.4**	101.4-101.4	-	-	= (2)
EPPO SE	5	**100.0**	**101.8**	98.8-104.0	**102.0**	100.3-103.2	-	-	> (1), = (4)

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.2-6
No. of trials where >, = or <, based on statistically significant differences at 95% confidence level

In winter wheat, FGF11 applied at the proposed label rate of 1.0 L product/ha increased crop yield compared to the untreated control on 38 of the 39 trials, with the increases being statistically significant on 30 of the trials. Where evaluations of grain quality were carried out on these trials, FGF11 applied at the proposed label rate of 1.0 L product/ha increased TGW compared to the untreated control on 26 of the 28 trials where this quality parameter was assessed, with differences being statistically significant in 15 trials, and HLW in 38 of the 39 trials where this quality parameter was assessed, with differences being statistically significant in 16 trials. These increases produced by FGF11 were generally comparable to those produced by the standard reference product applied at label rate.

In spring wheat, FGF11 applied at the proposed label rate of 1.0 L product/ha increased crop yield compared to the untreated control on 5 of the 6 trials, with the increase being statistically significant on 1 trial. Where evaluations of grain quality were carried out on these trials, FGF11 applied at the proposed label rate of 1.0 L product/ha increased TGW compared to the untreated control on 4 of the 4 trials where this quality parameter was assessed, with differences being statistically not significant, and HLW in 4 of the 6 trials where this quality parameter was assessed, with differences being statistically not significant. These increases produced by FGF11 were generally comparable to those produced by the standard reference product applied at label rate.

In spelt, FGF11 applied at the proposed label rate of 1.0 L product/ha increased crop yield compared to the untreated control on all 4 trials, with the increases being statistically not significant. Where evaluations of grain quality were carried out on these trials, FGF11 applied at the proposed label rate of 1.0 L product/ha increased TGW compared to the untreated control on 1 of the 4 trials where this quality parameter was assessed, with difference being statistically not significant, and HLW in 1 of the 4 trials where this quality parameter was assessed, with differences being statistically not significant. These increases produced by FGF11 were generally comparable to those produced by the standard reference product applied at label rate.

In durum wheat, FGF11 applied at the proposed label rate of 1.0 L product/ha increased crop yield compared to the untreated control on 4 of the 5 trials, with the increases being statistically significant on 4 of the trials. Where evaluations of grain quality were carried out on these trials, FGF11 applied at the proposed label rate of 1.0 L product/ha increased TGW compared to the untreated control on 3 of the 4 trials where this quality parameter was assessed, with differences being statistically significant in 2 trials, and HLW in 4 of the 5 trials where this quality parameter was assessed, with differences being statistically significant in 2 trials. These increases produced by FGF11 were generally comparable to those produced by the standard reference products applied at label rates.

In winter triticale, FGF11 applied at the proposed label rate of 1.0 L product/ha increased crop yield compared to the untreated control on all 7 trials, with the increases being statistically significant on 3 of the trials. Where evaluations of grain quality were carried out on these trials, FGF11 applied at the proposed label rate of 1.0 L product/ha increased TGW compared to the untreated control on all 5 trials where this quality parameter was assessed, with differences being statistically not significant, and HLW in 6 of the 7 trials where this quality parameter was assessed, with differences being statistically significant in 2 trials. These increases produced by FGF11 were generally comparable to those produced by the standard reference product applied at label rate.

The increases in crop yield and grain quality given by both FGF11 and the standard reference products can be considered to be a direct function of control of the target diseases occurring in the trials and their adverse effects on yield in the untreated control.

These increases in crop yield and grain quality produced by FGF11 applied at the proposed label rate of 1.0 L product/ha therefore provide further evidence in support of label claims for control of target foliar diseases in wheat and triticale.

Comments of zRMS:

61 efficacy trials have been submitted to determine the impact of FGF11 on crop yield of wheat and triticale crops. The increase in crop yield was visible in all EPPO climatic zone: 121,9% in the MAR zone, 113,5% in

the NE zone and 108% in the SE zone for winter wheat, 110% in the MAR zone, 109,6% in the NE zone, 136,3% in the SE zone for spring wheat, 101,7% in the MAR zone, 113,4% in the SE zone for spelt, 107,7% in the MAR zone, 113% in the SE zone for durum wheat, 107,1% in the MAR zone and 117,1% in the SE zone for winter triticale. No statistical differences between FGF11 and the reference product Proline at 0,8 l/ha were observed in most of trials. Moreover, the increases have been noted also in case of quality parameter: TGW and HLW. Similar effect was observed either for FGF11 and Proline/Prosaro 250 EC. Taking into account all results, no negative effect of test product on the quantity and quality of wheat and triticale yield was found in any EPPO zone.

3.2.3.2 Efficacy against target diseases in winter and spring rye

A total of 14 trials in winter rye carried out between 2022 and 2023 have generated data on the efficacy of FGF11 applied the proposed label rate of 1.0 L product/ha against PUCCRR in rye.

Table 3.2-56: Details on trial methodology (efficacy trials on rye)

Maritime EPPO climatic zone		
Guidelines	General guidelines	EPPO PP1/152 (4), EPPO PP1/181 (4), EPPO PP1/135 (4), EPPO PP1/223(2), EPPO PP1/225 (2)
	Specific guidelines	EPPO PP1/26 (4)
Experimental design	Plot design	RCBD (6)
	Plot size	17.5-30 m² (6)
	Number of replications	4 (6)
Crop	Trials per crop	winter rye (SECCW) (6)
	Varieties per crop	**SECCW:** Jethro (1), Rubin (1), Mephisto (2), Tayo (2-1), KWS Tayo (1)
	Sowing period	**SECCW:** September (1), October (3), November (2)
Targets	Target diseases	**SECCW :** PUCCRE (6)
Application	Crop stage (BBCH) at application	**SECCW**: A1: from 31-32 to 55 (BBCH), A2: from 39 to 68-71 (BBCH)
	Application period	**SECCW**: A1: April (4), May (2), A2: April (1), May (3), June (2)
	Number of applications Interval between applications	**SECCW:** 2 (6), with interval of 10-23
	Spray volumes	150 L/ha (1), 180 L/ha (1), 200 L/ha (3), 300 L/ha (1)
Assessments	Assessment types	% disease severity on leaf Phytotoxicity, crop vigour, crop yield
	Assessment dates	**SECCW:** between 0 DA-A1 and 32 DA-A2, at harvest
Other relevant information	e.g. Natural / artificial inoculation	Natural (6)
North-east EPPO climatic zone		
Guidelines	General guidelines	EPPO PP1/152 (4), EPPO PP1/181 (4), EPPO PP1/135 (4), EPPO PP1/223(2), EPPO PP1/225 (2)
	Specific guidelines	EPPO PP1/26 (4)
Experimental design	Plot design	RCBD (3)
	Plot size	30 m² (3)
	Number of replications	4 (3)
Crop	Trials per crop	winter rye (SECCW) (3)
	Varieties per crop	**SECCW:** Drive F1 (1-2), KWS Vinetto F1 (1)
	Sowing period	**SECCW:** September (3)
Targets	Target diseases	**SECCW :** PUCCRE (3)
Application	Crop stage (BBCH) at application	**SECCW**: A1: from 32-33 to 33-37 (BBCH), A2: from 39-43 to 45-51 (BBCH)
	Application period	**SECCW**: A1: April (3), A2: May (3)

	Number of applications Interval between applications	**SECCW:** 2 (3), with interval of 14-19
	Spray volumes	150 L/ha (1), 200 L/ha (1), 400 L/ha (1)
Assessments	Assessment types	% disease severity on leaf Phytotoxicity, crop vigour, crop yield
	Assessment dates	**SECCW:** between 0 DA-A1 and 35 DA-A2, at harvest
Other relevant information	e.g. Natural / artificial inoculation	Natural (3)

South-east EPPO climatic zone		
Guidelines	General guidelines	EPPO PP1/152 (4), EPPO PP1/181 (4), EPPO PP1/135 (4), EPPO PP1/223(2), EPPO PP1/225 (2)
	Specific guidelines	EPPO PP1/26 (4)
Experimental design	Plot design	RCBD (5)
	Plot size	21-30 m² (5)
	Number of replications	4 (5)
Crop	Trials per crop	winter rye (SECCW) (5)
	Varieties per crop	**SECCW:** Suceveana (1), Protector (1), Inspector (1), Ryefood (1), DGBato (1)
	Sowing period	**SECCW:** October (4), November (1)
Targets	Target diseases	**SECCW :** PUCCRE (5)
Application	Crop stage (BBCH) at application	**SECCW**: A1: from 30-32 to 35-39 (BBCH), A2: from 37-39 to 39-43 (BBCH)
	Application period	**SECCW**: A1: April (5), A2: May (5)
	Number of applications Interval between applications	**SECCW:** 2 (5), with interval of 12-18
	Spray volumes	250 L/ha (1), 300 L/ha (3), 400 L/ha (1)
Assessments	Assessment types	% disease severity on leaf Phytotoxicity, crop vigour, crop yield
	Assessment dates	**SECCW:** between 0 DA-A1 and 42 DA-A2, at harvest
Other relevant information	e.g. Natural / artificial inoculation	Natural (5)

The pathogen mentioned in the reports is PUCCRE (*Puccinia recondita*), while the pathogen claimed for control by FGF11 is PUCCRR (*Puccinia recondita f. sp. recondita*). As PUCCRR is the subspecies of *Puccinia recondita* that is occurring in rye, it is assumed that the pathogen present in all trials conducted in rye was PUCCRR and trials are therefore fully supportive for the intended label claim.

Applications on all efficacy trials were made using small plot sprayers designed to simulate application using commercial sprayers representative of those used to apply fungicides in rye.

On all trials, 2 applications of the treatments were made on crops growth stage and in water volumes representative of the ones proposed for the application of FGF11.

Although only 1 application is claimed for FGF11, trials with 2 applications of FGF11 are considered as fully valid. The 2nd application targeted new infections on the leaves, therefore assessments after the 2nd application is indicative of a single application.

Data are only summarised in this dossier where mean levels of disease in the untreated control reached ≥5% severity on part assessed following application.

Efficacy data are summarised across trials from representative assessment timings in this Section.

In the majority of trials, a zonal reference product containing prothioconazole as the active substance was used (generally with the tradename PROLINE). Additionally, local standard reference products were included in some of the trials. These additional local standard reference products are presented in the summaries below only if no reference product containing straight prothioconazole was included in the trial.

3.2.3.2.1 Efficacy against Brown rust (*Puccinia recondita f. sp. recondita*: PUCCRR)

A total of 14 trials carried out between 2022 and 2023 generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCRR in winter rye.

Of these trials, 6 were carried out in the Maritime EPPO climatic zone (2 in Great Britain, 1 in Germany, 1 in Ireland and 2 in France), 3 were carried out in the North-east EPPO climatic zone (all in Poland) and 5 were carried out in the South-east EPPO climatic zone (2 in Hungary, 2 in Romania and 1 in Bulgaria).

Disease developed on all 14 trials and was assessed as percentage severity on the upper leaves (1-3).

Data from 1 of the trials conducted in the Maritime EPPO climatic zone are excluded from overall means as results were highly inconsistent with highest efficacy at lowest dose rate and lowest efficacy at the highest dose rate tested.

Across trials, the efficacy of FGF11 has been evaluated under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in rye crops growing regions across EU Central Registration zone countries.

A summary of mean percentage efficacy (based on disease severity on the leaves) of FGF11 applied twice at the proposed label rate of 1.0 L product/ha against PUCCRR in rye across trials and leaf levels with valid data is given in Table 3.2-57.

Additionally a summary of mean percentage efficacy (based on disease severity on the leaves) of FGF11 after first application against PUCCRR in winter rye across trials and leaf levels at 14-19 DA-A1 is given in Table 3.2-60.

Table 3.2-57: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied twice at the proposed label rate of 1.0 L product/ha against PUCCRR across trials on rye at 14-42 DA-A2

Registration or EPPO climatic zone	No of trials (no of data points)	*Untreated (% severity on leaves)*		FGF11 1.0 L/ha		Proline* 0.8 L/ha		Prosaro 0.8 L/ha		Statistical comparison of FGF11 to SRP #
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max	
CEU	13 (24)	***22.7***	*5.1 - 92.1*	**88.7**	55.8 - 100					= (24)
	12 (23)	***23.4***	*5.1 - 92.1*	**75.9**	35 - 100	**87.9**	60.8 - 100	-	-	= (23)
	1 (1)	***6.8***	-	**100.0**	-	**-**	-	**97.9**	-	= (1)
EPPO MAR	5 (11)	***19.2***	*5.3 - 64.5*	**88.1**	55.8 - 99.3	**88.5**	62.5 - 100	**-**	-	= (11)
EPPO NE	3 (3)	***10.1***	*6.2 - 12.4*	**92.1**	83.2 - 100	**94.0**	88.7 - 100	**-**	-	< (1), = (2)
EPPO SE	5 (10)	***30.3***	*5.1 - 92.1*	**88.3**	64.9 - 100	-	-	-	-	= (10)
	4 (9)	***32.9***	*5.1 - 92.1*	**87.0**	64.9 - 100	**85.3**	60.8 - 100	**-**	-	= (9)
	1 (1)	***6.8***	-	**100.0**	-	**-**	-	**97.9**	-	= (1)

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.2-6
No. of data points where >, = or <, based on statistically significant differences at 95% confidence level

Table 3.2-58a: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCRR across trials on winter rye after 2 applications

Registration or EPPO climatic zone	No of trials	*Untreated (% severity on leaves)*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L1							
Maritime	2 trials	***14,2***	*13,2-15,28*	**98,1**	97,01-99,26	**95,4**	92,54-98,31
North-East	2 trials	***12,1***	*11,75-12,38*	**88,1**	83,21-92,94	**90,98**	88,68-93,29
North-East (+trials conducted in Germany)	3 trials	***12,5***	*11,8-13,2*	**91,8**	83,2-99,3	**93,4**	88,7-98,3
South-East	1 trial	***50,1***	-	**100**	-	**100**	-
L2							
Maritime	5 trials	***16,0***	*5,25-31,58*	**87,6**	67,35-98,75	**86,8**	62,53-100
North-East	1 trial	***6,23***	-	**100**	-	**100**	-
North-East (+trials conducted in Germany)	2 trials	***18,9***	*6,2-31,6*	**99,4**	98,8-100	**99,2**	98,4-100
South-East	5 trials	***21,7***	*5,08-78,85*	**88,5**	64,94-100	**86,1**	60,76-100
L3							
Maritime	4 trials	***25,6***	*9,73-64,5*	**83,8**	55,75-99,01	**87,1**	71,44-99,38
North-East	1 trial	***13,1***	-	**99,0**	-	**99,4**	-

(+trials conducted in Germany)							
South-East	4 trials	***36,1***	*8,2-92,12*	**85,2**	76,21-100	**83,7**	71,46-100

Table 3.2-59b: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCRR across trials on winter rye after 1 application

Registration or EPPO climatic zone	No of trials	*Untreated (% severity on leaves)*		FGF11 1.0 L/ha		Proline/Prosaro 250 EC 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L3							
South-East	1 trial	***12,4***	-	**89,2**	-	**88,3**	-

Table 3.2-60: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 following first application against PUCCRR across trials in all EPPO zones on rye at 14-19 DA-A1

Registration or EPPO climatic zone - leaf level	No of trials (No of data points)	*Untreated*		FGF11 (0.5 L/ha)		FGF11 (0.75 L/ha)		FGF11 (1.0 L/ha)		PROLINE* (0.8 L/ha)		Statistical comparison of FGF11 (1.0 L/ha) to SRP#
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max	Mean	Min-max	
EPPO SE - leaf 2	1 (1)	*1.0*		82.9		100.0		100.0		100.0		= (1)
CEU- leaf 2	**1 (1)**	***1.0***		**82.9**		**100.0**		**100.0**		**100.0**		**= (1)**
EPPO MAR - leaf 3	2 (2)	*1.2*	*0.9 - 1.5*	93.6	87.3 - 100	93.9	87.9 - 100	97.0	94 - 100	99.5	98.9 - 100	= (2)
EPPO NE - leaf 3	1 (1)	*1.0*		81.5		86.9		92.1		88.8		= (1)
EPPO NE + neighbouring countries - leaf 3	2 (2)	*0.9*	*0.9 - 1*	84.4	81.5 - 87.3	87.4	86.9 - 87.9	93.0	92.1 - 94	93.8	88.8 - 98.9	= (2)
EPPO SE - leaf 3	2 (2)	*6.7*	*1.1 - 12.4*	76.7	75.4 - 77.9	86.4	84.9 - 88	89.5	89.2 - 89.9	87.2	86.1 - 88.3	= (2)
CEU- leaf 3	**5 (5)**	***3.4***	***0.9 - 12.4***	**84.4**	**75.4 - 100**	**89.5**	**84.9 - 100**	**93.0**	**89.2 - 100**	**92.4**	**86.1 - 100**	**= (5)**
EPPO MAR - leaf 4	1 (1)	*2.3*		71.1		84.3		85.7		93.5		= (1)
EPPO NE + neighbouring countries - leaf 4	1 (1)	*2.3*		71.1		84.3		85.7		93.5		= (1)
EPPO SE - leaf 4	3 (3)	*1.8*	*1.3 - 2.7*	77.7	70.6 - 92.1	84.8	77 - 100	88.1	81.7 - 100	86.7	78.4 - 100	= (3)
CEU- leaf 4	**4 (4)**	***1.9***	***1.3 - 2.7***	**76.1**	**70.6 - 92.1**	**84.7**	**77 - 100**	**87.5**	**81.7 - 100**	**88.4**	**78.4 - 100**	**= (4)**
EPPO SE - leaf 5	1 (1)	*3.2*		92.7		100.0		100.0		100.0		= (1)
CEU- leaf 5	**1 (1)**	***3.2***		**92.7**		**100.0**		**100.0**		**100.0**		**= (1)**
EPPO MAR - all leaves	2 (3)	*1.5*	*0.9 - 2.3*	86.1	71.1 - 100	90.7	84.3 - 100	93.2	85.7 - 100	97.5	93.5 - 100	= (3)
EPPO NE - all leaves	1 (1)	*1.0*		81.5		86.9		92.1		88.8		= (1)
EPPO NE + neighbouring countries - all leaves	2 (3)	*1.4*	*0.9 - 2.3*	80.0	71.1 - 87.3	86.4	84.3 - 87.9	90.6	85.7 - 94	93.7	88.8 - 98.9	= (3)
EPPO SE - all leaves	4 (7)	*3.3*	*1 - 12.4*	80.3	70.6 - 92.7	89.6	77 - 100	91.9	81.7 - 100	90.6	78.4 - 100	= (7)
CEU- all leaves	**7 (11)**	***2.6***	***0.9 - 12.4***	**82.0**	**70.6 - 100**	**89.7**	**77 - 100**	**92.3**	**81.7 - 100**	**92.3**	**78.4 - 100**	**= (11)**

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Appendix 3 and Table 3.2-6

No. of data points where >, = or <, based on statistically significant differences at 95% confidence level

Data generated across trials carried out in the Maritime, North-east and South-east EPPO climatic zones demonstrate that application of FGF11 at the proposed label rate of 1.0 L product/ha generally gives effective control of PUCCRR in rye that is mostly similar and generally not statistically significantly different to that given by the standard reference products applied at label rates.

Although the intended label claim for FGF11 is a single application, the majority of trials included 2 applications to ensure adequate disease development for a robust efficacy assessment and to reflect prevailing commercial practice, wherein growers typically apply 2 fungicide treatments to maintain season-long control of PUCCRR. The 2nd application specifically targeted newly occurring infections on the leaves; consequently, the assessments conducted after 2 applications are often indicative of the performance of a single application following new infections rather than cumulative sequential effects.

At the assessment after the first application, disease pressure was often too low, symptoms of PUCCRR appeared in only 7 trials and mostly at very low levels, making it difficult to reliably differentiate product performance. The low disease pressure at this timing is not unexpected, as PUCCRR is typically a late-season disease which appears and has symptoms visible from BBCH 37-39 onwards. By the assessment timing after the second application, all 13 trials had reached sufficiently high disease levels (≥5% on individual leaf levels), creating a robust infection pressure. This allows for a more accurate and statistically meaningful comparison of FGF11's efficacy against the standard reference product. Furthermore, the efficacy of FGF11 and in comparison to the standard reference product at both assessment timings was similar. Therefore, the dataset following the 2nd application is considered more relevant for demonstrating the efficacy of FGF11, even though the intended claim is for a single application.

The morphology, life cycles and infection patterns of different *Puccinia recondita* subspecies affecting cereals, and also the efficacy of fungicides against the different species, are very similar. Therefore, data generated on the efficacy against PUCCRE in wheat and triticale (Section 3.2.3.1.3) are considered to provide evidence to support label claims for control of PUCCRR in rye.

Whilst no data have been generated to demonstrate the efficacy of FGF11 against PUCCRR on spring rye in the Maritime, North-east and South-east EPPO climatic zones, following EPPO guidance PP1/331 (1) principles of efficacy extrapolations for major uses, the susceptibility of the crops to this fungal pathogen, disease development pressure and development patterns, agronomy of the crops and areas in which the crops are grown in the Central Registration zone can be considered to be sufficiently similar between spring and winter rye to be fully supportive of demonstrating efficacy against PUCCRR in both rye crop types.

Furthermore, products containing prothioconazole and azoxystrobin straight and as mixture are already registered against PUCCRR and PUCCRE in the different cereal types mentioned above throughout Europe. The efficacy of FGF11 against PUCCRE was extensively proven in winter wheat and was confirmed by trials in other cereal types. It can therefore be considered that FGF11 effectively controls PUCCRR in spring and winter rye.

Additionally, whilst limited data are presented on the efficacy of FGF11 against PUCCRR on rye from trials carried out in the North-east EPPO climatic zone, data generated on this disease in 1 trial carried out in Germany provide supportive evidence of that in Poland.

Based on the summarised data, it is therefore considered that claims for control of PUCCRR in rye by FGF11, applied at the proposed label rate of 1.0 L product/ha and according to other label recommendations, are fully supported.

Comments of zRMS:

1 application
In the South-East zone, only 1 trial was recognized for the single application in winter rye. The test product at 1 L/ha achieved the effectiveness of 89,2% on L3. Similar effect was observed on the objects treated with a

reference product. No results after 1 application were available in ~~any~~ the North-East and Maritime EPPO climatic zone. The cMSs belonging to the Maritime ~~and South-East~~ zone are kindly asked to consider the use of FGF11 at 1 l/ha in winter and spring rye against *Puccinia recondita* f.sp. *recondita* (PUCCRR) at the national level. These uses cannot be accepted in Poland (under art. 33). However, spring rye is minor crops in Poland and the registration under art. 51 is possible in this case.

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2 applications

Winter rye

A total of 14 trials have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha twice per growing season for the control of *Puccinia recondita* f.sp. *recondita* (PUCCRR) in winter rye.

In the Maritime EPPO climatic zone, 6 trials were conducted between 2022 and 2023. FGF11 applied at dose rate of 1 l/ha achieved good control with the results of 98,1% on L1, 87,6% on L2 and 83,8% on L3. Comparable effect was visible for the reference product at 0,8 l/ha.

In the North-East zone, only 3 trials were carried out between 2022 and 2023. The test product at claimed dose had sufficient efficacy with the results of 88,1% on L1 and 100% on L2. Comparable effect was visible for the reference product at 0,8 l/ha.

In the South-East zone, 5 trials were conducted between 2022 and 2023. FGF11 at 1 l/ha achieved good efficacy with the results of 100% on L1, 88,5% on L2 and 85,2% on L3. Also the reference product at 0,8 l/ha presented similar level of control.

Spring rye

No efficacy trials have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha twice per growing season for the control of *Puccinia recondita* f.sp. *recondita* (PUCCRR) in spring rye in any EPPO climatic zone. The cMSs are kindly asked to consider this use at the national level. However, spring rye is minor crops in Poland, Austria, Belgium, Germany, Ireland, Netherlands, Romania, Slovenia and Slovakia and the registration under art. 51 is possible in this case, as zRMS supposes.

ZRMS conclusions after updated of RR (February 2026)

The applicant submitted the trial results after the first application following to the previous zRMS conclusions. However, almost all results after one application are based on PESSEV <4% and they cannot be considered valid results but only supportive. Only one result can be taken into account when assessing the effectiveness of the product. Nevertheless, all results show a positive response of FGF11 to PUCCRR control. According to table 3.2-59, FGF11 at a dose rate of 1 L/ha achieved an overall average efficacy percentage on all leaves of 93,2% in the MAR zone, 92,1% in the NE zone and 91,9% in the SE zone on winter rye. Taking into account both the applicant's arguments and the presented results of effectiveness after a single application, zRMS considers it possible to accept this application for winter rye in the SE zone. In addition, based on EPPO guidance PP 1/331 (1), spring rye can also be considered. Due to limited number of trials (in general, 3 trials in the NE zone and 1 trial in Germany in winter rye and lack of trials in spring rye), these uses cannot be accepted in Poland. CMSs belonging to the MAR zone are kindly asked to consider this use at the national level.

ZRMS conclusion after updated of RR (April 2026)

In summary, the efficacy of FGF11 in controlling *Puccinia recondita f. sp. recondita* (PUCCRR) has been demonstrated in the North-East EPPO zone in the following trials:

- winter rye: no trials were submitted after the first application with PESSEV ≥4% and 4 trials after the second application with PESSEV ≥5% (3 trials in the NE zone and 1 trial from Germany); in addition, 4 further trials after the first application had PESSEV <3% (PESSEV 0% was observed in 2 out of 4 trials)

For winter rye, no trials were submitted following the first application in the NE zone or in neighboring countries. In this case, the applicant should submit additional trials.

3.2.3.2.2 Positive effects on green leaf area

Positive effects on green leaf area were assessed on a total of 11 of the trials carried out between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCRR in winter rye.

Of these trials, 3 were carried out in the Maritime EPPO climatic zone (1 in Germany, 1 in Ireland and 1 in France), 3 were carried out in the North-east EPPO climatic zone (all in Poland) and 5 were carried out in the South-east EPPO climatic zone (1 in Bulgaria, 2 in Hungary, 2 in Romania).

A summary of mean green leaf area across trials in each of the climatic zones is given in Table 3.2-61.

Table 3.2-61: Mean overall green leaf area data following application of FGF11 at the proposed label rate of 1.0 L product/ha across trials in all climatic zones that generated data on efficacy against PUCCRR in winter rye

Crop	Registration or EPPO climatic zone	Nº Trials (No of data points)	*Untreated*		FGF11		Proline*		Prosaro		Statical comparison #
					1.0 L/ha		0.8 L/ha		0.8 L/ha		FGF11 to SRP
			Mean	*Min-Max*	Mean	Min-Max	Mean	Min-Max	Mean	Min-Max	
Green leaf area - leaves 1-3											
~~SECCE~~ SECCW	CEU	7 (13)	*48.7*	*3.5-93.8*	**67.1**	18.8-100	-				
		6 (12) of 7 (13)	*49.6*	*3.5-93.8*	**67.3**	18.8-100	**67.4**	15.0-100	-	-	= (12)
		1 (1) of 7 (13)	*37.5*	-	**65.0**	-	-	-	**62.5**	-	= (1)
	EPPO MAR	3 (8)	*34.2*	*3.5-74.8*	**53.8**	18.8-80.0	**53.9**	15.0-80.0	-	-	= (8)
	EPPO NE	2 (2)	*71.3*	*48.8-93.8*	**91.3**	82.5-100	**91.3**	82.5-100	-	-	= (2)
	EPPO SE	2 (3)	*72.5*	*37.5-92.5*	**86.7**	65.0-100	-				
		1 (2) of 2 (3)	*90.0*	*87.5-92.5*	**97.5**	95.0-100	**97.5**	95.0-100	-	-	= (2)
		1 (1) of 2 (3)	*37.5*	-	**65.0**	-	-	-	**62.5**	-	= (1)
Green leaf area - Plants											
~~SECCE~~ SECCW	CEU	4 (4)	*36.3*	*9.5-90.0*	**65.6**	48.8-95.0	**64.7**	48.8-95.0	-	-	= (4)
	EPPO NE	1 (1)	*27.5*	-	**65.0**	-	**62.5**	-	-	-	= (1)
	EPPO SE	3 (3)	*39.3*	*9.5-90.0*	**65.8**	48.8-95.0	**65.4**	48.8-95.0	-	-	= (3)

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.2-6
No. of datapoints where >, = or <, based on statistically significant differences at 95% confidence level

FGF11 applied at the proposed label rate of 1.0 L product/ha significantly increased green leaf area compared to the untreated control in these trials, with the increases being statistically significant on 13 of the 17 datapoints. These increases produced by FGF11 were generally similar to or higher than those produced by the standard reference products applied at label rates with no statistically significant difference in any trial.

The increases in green leaf area given by both FGF11 and the standard reference products can be considered to be a direct function of control of PUCCRR and their adverse effects on green plant tissue in the untreated control.

These increases in green leaf area produced by FGF11 applied at the proposed label rate of 1.0 L product/ha therefore provide further evidence in support of label claims for control of PUCCRR in rye.

Comments of zRMS:

Green leaf area was evaluated in winter rye in 11 efficacy trials, only after second application. In case of either leaves (1-3) and plant, the increase of mean overall green leaf area was visible after an application of FGF11 at 1 l/ha in all EPPO climatic zone. No statistical differences between test product and Proline/Prosaro 250 EC at 0,8 l/ha were observed in most of trials.

3.2.3.2.3 Positive effects on crop yield and quality in efficacy trials

Evaluations of crop yield were carried out on a total of 7 of the trials carried out between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCRR in winter rye.

Of these trials, 2 were carried out in the Maritime EPPO climatic zone (1 in Germany, 1 in Ireland), 2 were carried out in the North-east EPPO climatic zone (both in Poland) and 3 were carried out in the South-east EPPO climatic zone (1 in Bulgaria, 2 in Hungary).

Evaluations of quality of grain sampled at harvest were also carried out on all 7 trials, with hectolitre/specific weight (HLW) determined on all trials and thousand grain weight (TGW) determined on 3 of the trials.

A summary of mean crop yield and grain quality data (expressed as % relative to the untreated control) across trials in each of the climatic zones is given in Table 3.2-62.

Table 3.2-62: Mean overall crop yield and grain quality data (expressed as % relative to the untreated control) following an application of FGF11 at the proposed label rate of 1.0 L product/ha across trials in all climatic zones that generated data on efficacy against PUCCRR in winter rye

Registration or EPPO climatic zone	Nº Trials	*Untreated*	FGF11 1.0 L/ha		Proline* 0.8 L/ha		Prosaro 0.8 L/ha		Statical comparison of FGF11 to SRP#	
		Mean	Mean	Min-Max	Mean	Min-Max	Mean	Min-Max	Proline	Prosaro
Yield										
CEU	7	*100.0*	**116.8**	107.7-134.9	-					
	6 of 7	*100.0*	**118.3**	111.5-134.9	**117.2**	109.0-135.8	-	-	= (6)	-
	1 of 7	*100.0*	**107.7**	-	-	-	**107.2**	-	-	= (1)
EPPO MAR	2	*100.0*	**113.4**	111.5-115.4	**111.6**	109.0-114.2	-	-	= (2)	-
EPPO NE	2	*100.0*	**114.6**	111.8-117.5	**113.0**	110.5-115.5	-	-	= (2)	-
EPPO SE	3	*100.0*	**120.4**	107.7-137.9	-					
	2 of 3	*100.0*	**126.8**	118.7-134.9	**127.1**	118.4-135.8	-	-	= (2)	-
	1 of 3	*100.0*	**107.7**	-	-	-	**107.2**	-	-	= (1)
TGW										
CEU	3	*100.0*	**105.5**	104.0-107.6	-					
	2 of 3	*100.0*	**106.2**	104.8-107.6	**105.8**	105.4-106.1	-	-	= (2)	-
	1 of 3	*100.0*	**104.0**	-	-	-	**103.7**	-	-	= (1)
EPPO MAR	1	*100.0*	**107.6**	-	**106.1**	-	-	-	= (2)	-
EPPO NE	1	*100.0*	**104.8**	-	**105.4**	-	-	-	= (2)	-
EPPO SE	1	*100.0*	**104.0**	-	-	-	**103.7**	-	-	= (1)
HLW										
CEU	7	*100.0*	**101.0**	99.6-102.5	-					
	6 of 7	*100.0*	**101.0**	99.6-102.5	**100.8**	99.9-101.8	-	-	= (6)	-
	1 of 7	*100.0*	**100.5**	-	-	-	**100.3**	-	-	= (1)
EPPO MAR	2	*100.0*	**102.2**	101.8-102.5	**101.5**	101.2-101.8	-	-	= (2)	-
EPPO NE	2	*100.0*	**99.8**	99.6-100.0	**100.0**	99.9-100.0	-	-	= (2)	-
EPPO SE	3	*100.0*	**100.9**	100.5-101.3	-					
	2 of 3	*100.0*	**101.2**	101.0-101.3	**100.9**	100.8-100.9	-	-	= (2)	-
	1 of 3	*100.0*	**100.5**	-	-	-	**100.3**	-	-	= (1)

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.2-6
No. of trials where >, = or <, based on statistically significant differences at 95% confidence level

FGF11 applied at the proposed label rate of 1.0 L product/ha increased crop yield compared to the untreated control on all of the 7 trials, with the increases being statistically significant on 4 of the trials. These increases produced by FGF11 were generally comparable to those produced by the standard reference products applied at label rates without statistically significant differences in any trial.

Where evaluations of grain quality were carried out on these trials, FGF11 applied at the proposed label rate of 1.0 L product/ha increased TGW compared to the untreated control on all 3 trials where this quality parameter was assessed, with differences being statistically significant in 2 trials. HLW was not increased in any of the trials.

The increases in crop yield and grain quality given by both FGF11 and the standard reference products can be considered to be a direct function of control of the target diseases occurring in the trials and their adverse effects on yield in the untreated control.

These increases in crop yield and grain quality produced by FGF11 applied at the proposed label rate of 1.0 L product/ha therefore provide further evidence in support of label claims for control of PUCCRR in rye.

Comments of zRMS:

7 efficacy trials have been submitted to determine the impact of FGF11 on crop yield of winter rye. The increase in crop yield was visible in all EPPO climatic zone: 113,4% in the MAR zone, 114,6% in the NE zone and 120,4% in the SE zone. No statistical differences between FGF11 and the reference product Proline at 0,8 l/ha were observed in all trials. Moreover, the increases have been noted also in case of quality parameter: TGW and HLW. Similar effect was observed either for FGF11 and Proline/Prosaro 250 EC. Taking into account all results, no negative effect of test product on the quantity and quality of winter rye yield was found in any EPPO zone.

3.2.3.3 Efficacy against target diseases in winter and spring barley

A total of 9 trials in spring barley and 24 trials in winter barley carried out between 2022 and 2023 have generated data on the efficacy of FGF11 applied the proposed label rate of 1.0 L product/ha against target diseases in barley.

Table 3.2-63: Details on trial methodology (efficacy trials on barley)

Maritime EPPO climatic zone		
Guidelines	General guidelines	EPPO PP1/152 (4), EPPO PP1/181 (4), EPPO PP1/135 (4), EPPO PP1/223(2), EPPO PP1/225 (2)
	Specific guidelines	EPPO PP1/26 (4)
Experimental design	Plot design	RCBD (12)
	Plot size	20-36 m² (12)
	Number of replications	4 (12)
Crop	Trials per crop	Spring barley (HORVS) (2), winter barley (HORVW) (10)
	Varieties per crop	**HORVS:** KWS Sassy (1), Planet (1) **HORVW:** Quadriga (1), Dementiel (1), Cassia (1), Tower (2), KWS Orbit (1), Etincelle (1), KWS Faro (1), Amandine (1), KWS Orwell (1)
	Sowing period	**HORVS:** March (1), April (1) **HORVW:** September (6), October (4)
Targets	Target diseases	**HORVS:** PYRNTE (2), RAMUCC (1) **HORVW :** PYRNTE (4), RAMUCC (6), PUCCHD (3), RHYNSE (5)
Application	Crop stage (BBCH) at application	**HORVS:** A1: 32 (BBCH), A2: from 45 to 37-49 (BBCH) **HORVW**: A1: from 31-32 to 37-39 (BBCH), A2: from 39 to 54-58 (BBCH)
	Application period	**HORVS:** A1: May (2), A2: June (2) **HORVW**: A1: April (10), A2: April (2), May (8)
	Number of applications Interval between applications	**HORVS:** 2 (2), with interval of 14 days **HORVW:** 2 (10), with interval of ~~14~~ 13-22
	Spray volumes	100 L/ha (3), 200 L/ha (7), 300 L/ha (2)

Assessments	Assessment types	% disease severity on leaf Phytotoxicity, crop vigour, crop yield
	Assessment dates	**HORVS:** between 0 DA-A1 and 29 DA-A2, at harvest **HORVW:** between 0 DA-A1 and 40 DA-A2, at harvest
Other relevant information	e.g. Natural / artificial inoculation	Natural (12)

North-east EPPO climatic zone		
Guidelines	General guidelines	EPPO PP1/152 (4), EPPO PP1/181 (4), EPPO PP1/135 (4), EPPO PP1/223(2), EPPO PP1/225 (2)
	Specific guidelines	EPPO PP1/26 (4)
Experimental design	Plot design	RCBD (9)
	Plot size	20-30 m² (9)
	Number of replications	4 (9)
Crop	Trials per crop	Spring barley (HORVS) (4), winter barley (HORVW) (5)
	Varieties per crop	**HORVS:** Avatar (1), Brienne (1), RGT Planet (1), Atrika (1) **HORVW:** KWS Kosmos (2), Astaire (1), Sandra (1), Lentia (1),
	Sowing period	**HORVS:** April (2), May (2) **HORVW:** September (5)
Targets	Target diseases	**HORVS:** PYRNTE (4), PUCCHD (1) **HORVW :** PYRNTE (4), PUCCHD (4)
Application	Crop stage (BBCH) at application	**HORVS:** A1: from 30-31 to 32-34 (BBCH), A2: from 39-41 to 47-49 (BBCH) **HORVW**: A1: from 32 to 33 (BBCH), A2: from 43-45 to 43-47 (BBCH)
	Application period	**HORVS:** A1: June (4), A2: June (2), July (2) **HORVW**: A1: April (5), A2: May (5)
	Number of applications Interval between applications	**HORVS:** 2 (4), with interval of 14-18 days **HORVW:** 2 (5), with interval of 14-21
	Spray volumes	200 L/ha (5), 250 L/ha (1), 300 L/ha (3)
Assessments	Assessment types	% disease severity on leaf Phytotoxicity, crop vigour, crop yield
	Assessment dates	**HORVS:** between 0 DA-A1 and 35 DA-A2, at harvest **HORVW:** between 0 DA-A1 and 37 DA-A2, at harvest
Other relevant information	e.g. Natural / artificial inoculation	Natural (9)
South-east EPPO climatic zone		
Guidelines	General guidelines	EPPO PP1/152 (4), EPPO PP1/181 (4), EPPO PP1/135 (4), EPPO PP1/223(2), EPPO PP1/225 (2)
	Specific guidelines	EPPO PP1/26 (4)
Experimental design	Plot design	RCBD (12)
	Plot size	21-30 m² (12)
	Number of replications	4 (12)
Crop	Trials per crop	Spring barley (HORVS) (3), winter barley (HORVW) (9)
	Varieties per crop	**HORVS:** Obzor (1), Planet (1), Conchita (1) **HORVW:** GK Judy (2), Jup (1), Kazanova (3), Atlantik (1), Wendy (1), SU Ellen (1)
	Sowing period	**HORVS:** March (2), April (1) **HORVW:** October (9)
Targets	Target diseases	**HORVS:** PYRNTE (3) **HORVW :** PYRNTE (9)
Application	Crop stage (BBCH) at application	**HORVS:** A1: from 31-32 to 37 (BBCH), A2: from 37-39 to 45 (BBCH) **HORVW**: A1: from 21-32 to 35-37 (BBCH), A2: from 37-39 to 43-47 (BBCH)
	Application period	**HORVS:** A1: April (1), May (2), A2: May (2), June (1) **HORVW**: A1: April (9), A2: April (1), May (8)
	Number of applications Interval between applications	**HORVS:** 2 (2), with interval of 13-14 days **HORVW:** 2 (9), with interval of 6-25
	Spray volumes	200 L/ha (5), 250 L/ha (3), 300 L/ha (2), 350 L/ha (1), 300/400 L/ha (1)
Assessments	Assessment types	% disease severity on leaf Phytotoxicity, crop vigour, crop yield

	Assessment dates	**HORVS:** between 0 DA-A1 and 30 DA-A2, at harvest **HORVW:** between 0 DA-A1 and 42 DA-A2, at harvest
Other relevant information	e.g. Natural / artificial inoculation	Natural (12)

Applications on all efficacy trials were made using small plot sprayers designed to simulate application using commercial sprayers representative of those used to apply fungicides in barley.

On all trials, 2 applications of the treatments were made on crops growth stage and in water volumes representative of the ones proposed for the application of FGF11.

Although only 1 application is claimed for FGF11, trials with 2 applications of FGF11 are considered as fully valid. The 2nd application targeted new infections on the leaves, therefore assessments after the 2nd application is indicative of a single application.

Data are only summarised in this dossier where mean levels of disease in the untreated control reached ≥5% severity on part assessed following application.

Efficacy data are summarised across trials from representative assessment timings in this Section.

In the majority of trials, a zonal reference product containing prothioconazole as the active substance was used (generally with the tradename PROLINE). Additionally, local standard reference products were included in some of the trials. These additional local standard reference products are presented in the summaries below only if no reference product containing straight prothioconazole was included in the trial.

3.2.3.3.1 Efficacy against Net blotch (*Pyrenophora teres*: PYRNTE)

A total of 26 trials carried out between 2022 and 2023 generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against PYRNTE in winter barley (17 trials) and spring barley (9 trials).

Of these trials, 6 were carried out in the Maritime EPPO climatic zone (4 in Great Britain, 1 in Ireland and 1 in France), 8 were carried out in the North-east EPPO climatic zone (5 in Poland, 1 in Lithuania and 2 in Finland) and 12 were carried out in the South-east EPPO climatic zone (4 in Hungary, 4 in Romania and 4 in Bulgaria).

Disease developed on all 26 trials and was assessed as percentage severity on the upper leaves (1-3).

Across trials, the efficacy of FGF11 has been evaluated under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in barley crops growing regions across EU Central Registration zone countries.

A summary of mean percentage efficacy (based on disease severity on the leaves) of FGF11 applied twice at the proposed label rate of 1.0 L product/ha against PYRNTE in barley at across trials and leaf levels with valid data in each of the EPPO climatic zones is given in Table 3.2-64.

Additionally a summary of mean percentage efficacy (based on disease severity on the leaves) of FGF11 against PYRNTE in barley after the first application at 13-25 DA-A1 is given in Table 3.2-69

Table 3.2-64: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied twice at the proposed label rate of 1.0 L product/ha against PYRNTE across trials on barley in all EPPO climatic zones at 9-49 DA-A2

Registration or EPPO climatic zone	No of trials (no of data points)	*Untreated (% severity on leaves)*		FGF11 1.0 L/ha		Proline* 0.8 L/ha		Statistical comparison of FGF11 to SRP #
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	
CEU	26 (63)	***16.7***	*5.1 - 58.8*	**83.0**	38.6 - 100	**81.8**	48.7-100	> (3), = (58), < (2)
EPPO MAR	6 (11)	***4.3***	*5.1 - 40.8*	**83.7**	63.7 - 99.5	**83.3**	62.1 - 99.3	= (11)
EPPO NE	8 (21)	***24.9***	*5.2 - 58.8*	**87.6**	64.2 - 100	**85.1**	63.2-100	> (1), = (20)
EPPO SE	12 (31)	***12.0***	*5.4 - 33.3*	**79.7**	38.6 - 100	**79.0**	48.7 - 100	> (2), = (27), < (2)

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.2-6
No. of data points where >, = or <, based on statistically significant differences at 95% confidence level

Table 3.2-65a: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against PYRNTE across trials on winter barley in all EPPO climatic zones after 1 application

Registration or EPPO climatic zone	No of trials	*Untreated (% severity on leaves)*		FGF11 1.0 L/ha		Proline 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L4							
North-East (+trials conducted in Germany)	2 trial	***6,4***	*4,2-8,6*	**90,7**	88,6-92,7	**88,3**	85,6-91,0
South-East	3 trials	***6,9***	*4,92-8,5*	**87,1**	85,03-88,8	**93,0**	86,72-100
L5							
North-East (+trials conducted in Germany)	1 trial	***11,5***	-	**78,3**	-	**77,6**	-
South-East	1 trial	***5,43***	-	**91,07**	-	**84,55**	-
L6							
South-East	1 trial	***6,2***	-	**86,8**	-	**87,2**	-

Table 3.2-66b: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against PYRNTE across trials on spring barley in all EPPO climatic zones after 1 application

Registration or EPPO climatic zone	No of trials	*Untreated (% severity on leaves)*		FGF11 1.0 L/ha		Proline 0.8 L/ha	
		Mean	***Min-max***	**Mean**	**Min-max**	**Mean**	**Min-max**
L3							
Maritime	1 trial	***8,53***	-	**67,66**	-	**70,58**	-
North-East (+trials conducted in Germany)	1 trial	***4,9***	-	**79,83**	-	**80,94**	-
L4							
Maritime	1 trial	***20,48***	-	**62,35**	-	**68,55**	-
North-East (+trials conducted in Germany)	2 trials	***10,0***	*9,0-11,08*	**63,9**	39,4-88,46	**72,4**	51,7-93,01
South-East	1 trial	***5,8***	-	**100**	-	**100**	-
L5							
South-East	1 trial	***5,04***	-	**96,11**	-	**92,91**	-

Table 3.2-67c: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against PYRNTE across trials on winter barley in all EPPO climatic zones after 2 applications

Registration or EPPO climatic zone	No of trials	*Untreated (% severity on leaves)*		FGF11 1.0 L/ha		Proline 0.8 L/ha	
		Mean	***Min-max***	**Mean**	**Min-max**	**Mean**	**Min-max**
L1							
Maritime	1 trial	***5,45***	-	**75,47**	-	**73,89**	-
North-East	4 trials	***17,7***	*5,22-43,62*	**81,4**	72,46-90,4	**80,1**	69,79-93,16
South-East	6 trials	***7,5***	*5,9-10,34*	**82,7**	62,95-100	**83,3**	60,05-95,01
L2							
Maritime	2 trials	***9,3***	*9,1-9,57*	**90,8**	89,25-92,39	**90,8**	88,14-93,51
North-East	4 trials	***25,5***	*6,25-58,75*	**79,1**	64,23-86,33	**80,3**	63,22-88,61
South-East	8 trials	***11,5***	*5,42-21,0*	**79,6**	64,07-90,95	**77,9**	62,72-86,52

L3							
Maritime	4 trials	***19,95***	*5,28-40,8*	**93,4**	87,99-99,5	**93,6**	85,71-99,28
North-East	3 trials	***21,4***	*9,37-43,87*	**94,5**	85,56-99,12	**93,4**	84,35-99,12
South-East	9 trials	***12,6***	*7,02-23,7*	**79,3**	54,57-100	**80,1**	57,57-100

Table 3.2-68d: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against PYRNTE across trials on spring barley in all EPPO climatic zones after 2 applications

Registration or EPPO climatic zone	**No of trials**	***Untreated (% severity on leaves)***		**FGF11**		**Proline**	
				1.0 L/ha		**0.8 L/ha**	
		Mean	***Min-max***	**Mean**	**Min-max**	**Mean**	**Min-max**
L1							
North-East	2 trials	***16,9***	*15,93-17,85*	**92,7**	91,58-93,76	**89,9**	87,69-92,01
South-East	2 trials	***19,4***	*5,57-33,25*	**65,4**	38,63-92,13	**69,2**	48,69-89,72
L2							
Maritime	2 trials	***17,9***	*7,92-27,87*	**74,2**	63,75-84,57	**73,1**	62,12-84,05
North-East	4 trials	***21,1***	*7,1-38,12*	**92,8**	86,22-100	**87,5**	76,67-100
South-East	3 trials	***10,5***	*8,81-12,25*	**76,9**	59,15-88,85	**72,97**	61,01-88,12
L3							
Maritime	2 trials	***8,7***	*5,05-12,25*	**70,9**	66,65-75,19	**70,1**	68,06-72,2
North-East	4 trials	***41,9***	*9,62-54,37*	**89,6**	79,75-97,28	**84,0**	75,16-89,41
South-East	3 trials	***16,8***	*9,75-20,85*	**87,4**	70,96-100	**82,7**	70,42-89,67

Table 3.2-69: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 following first application against PYRNTE across trials on barley in all EPPO climatic zones at 13-25 DA-A1

Registration or EPPO climatic zone - leaf level	No of trials (No of data points)	*Untreated*		FGF11 (0.5 L/ha)		FGF11 (0.75 L/ha)		FGF11 (1.0 L/ha)		PROLINE* (0.8 L/ha)		Statistical comparison of FGF11 (1.0 L/ha) to SRP#
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max	Mean	Min-max	
EPPO MAR - leaf 2	1 (1)	*2.0*		40.2		77.2		83.8		87.2		= (1)
EPPO NE - leaf 2	2 (2)	*1.7*	*1.6 - 1.8*	80.7	61.4 - 100	96.7	93.4 - 100	97.5	94.9 - 100	95.1	90.2 - 100	= (2)
EPPO NE + neighbouring countries - leaf 2	2 (2)	*1.7*	*1.6 - 1.8*	80.7	61.4 - 100	96.7	93.4 - 100	97.5	94.9 - 100	95.1	90.2 - 100	= (2)
EPPO SE - leaf 2	1 (1)	*0.8*		84.4		100.0		100.0		100.0		= (1)
CEU- leaf 2	**4 (4)**	***1.5***	***0.8 - 2***	**71.5**	**40.2 - 100**	**92.6**	**77.2 - 100**	**94.7**	**83.8 - 100**	**94.3**	**87.2 - 100**	**= (4)**
EPPO MAR - leaf 3	1 (1)	*8.5*		36.0		52.8		67.7		70.6		= (1)
EPPO NE - leaf 3	4 (4)	*1.8*	*0.5 - 4.9*	84.1	50.5 - 100	90.2	73.8 - 100	84.1	56.6 - 100	90.7	80.9 - 100	= (4)
EPPO NE + neighbouring countries - leaf 3	4 (4)	*1.8*	*0.5 - 4.9*	84.1	50.5 - 100	90.2	73.8 - 100	84.1	56.6 - 100	90.7	80.9 - 100	= (4)
EPPO SE - leaf 3	7 (7)	*2.3*	*1.3 - 3.5*	80.3	65.8 - 100	84.9	70.6 - 100	95.4	86.7 - 100	93.7	83.6 - 100	= (6), > (1)
CEU- leaf 3	**12 (12)**	***2.6***	***0.5 - 8.5***	**77.8**	**36 - 100**	**84.0**	**52.8 - 100**	**89.3**	**56.6 - 100**	**90.7**	**70.6 - 100**	**= (11), > (1)**
EPPO MAR - leaf 4	1 (1)	*20.5*		39.0		49.5		62.4		68.5		= (1)
EPPO NE - leaf 4	4 (4)	*6.1*	*0.5 - 11.1*	88.5	72.1 - 100	91.1	83.5 - 100	92.5	88.5 - 100	92.4	85.6 - 100	= (4)
EPPO NE + neighbouring countries - leaf 4	4 (4)	*6.1*	*0.5 - 11.1*	88.5	72.1 - 100	91.1	83.5 - 100	92.5	88.5 - 100	92.4	85.6 - 100	= (4)
EPPO SE - leaf 4	6 (6)	*5.3*	*2.4 - 8.5*	78.5	68.5 - 91.6	84.8	74.1 - 100	91.5	85 - 100	92.0	79.8 - 100	= (4), > (1), < (1)
CEU- leaf 4	**11 (11)**	***7.0***	***0.5 - 20.5***	**78.6**	**39 - 100**	**83.9**	**49.5 - 100**	**89.2**	**62.4 - 100**	**90.0**	**68.5 - 100**	**= (9), > (1), < (1)**
EPPO NE - leaf 5	1 (1)	*11.5*		68.3		72.1		78.3		77.6		
EPPO NE + neighbouring countries - leaf 5	1 (1)	*11.5*		68.3		72.1		78.3		77.6		= (1)
EPPO SE - leaf 5	3 (3)	*4.1*	*1.7 - 5.4*	69.1	47.8 - 85.7	79.2	67.9 - 88.9	87.6	75.5 - 96.1	84.5	76 - 92.9	= (3)
CEU- leaf 5	**4 (4)**	***5.9***	***1.7 - 11.5***	**68.9**	**47.8 - 85.7**	**77.4**	**67.9 - 88.9**	**85.2**	**75.5 - 96.1**	**82.8**	**76 - 92.9**	**= (4)**
EPPO SE - leaf 6	1 (1)	*6.2*		84.4		87.9		86.6		87.2		= (1)
CEU- leaf 6	**1 (1)**	***6.2***		**84.4**		**87.9**		**86.6**		**87.2**		**= (1)**
EPPO MAR - all leaves	1 (3)	*10.3*	*2 - 20.5*	38.4	36 - 40.2	59.9	49.5 - 77.2	71.3	62.4 - 83.8	75.4	68.5 - 87.2	= (3)
EPPO NE - all leaves	6 (11)	*4.2*	*0.5 - 11.5*	83.6	50.5 - 100	90.1	72.1 - 100	89.0	56.6 - 100	90.9	77.6 - 100	= (11)
EPPO NE + neighbouring countries - all leaves	6 (11)	*4.2*	*0.5 - 11.5*	83.6	50.5 - 100	90.1	72.1 - 100	89.0	56.6 - 100	90.9	77.6 - 100	= (11)
EPPO SE - all leaves	8 (18)	*3.7*	*0.8 - 8.5*	78.3	47.8 - 100	84.9	67.9 - 100	92.6	75.5 - 100	91.6	76 - 100	= (5), > (2), < (1)
CEU- all leaves	**15 (32)**	***4.5***	***0.5 - 20.5***	**76.4**	**36 - 100**	**84.3**	**49.5 - 100**	**89.4**	**56.6 - 100**	**89.8**	**68.5 - 100**	**= (29), > (2), < (1)**

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Appendix 3 and Table 3.2-6
No. of data points where >, = or <, based on statistically significant differences at 95% confidence level

Data generated across trials carried out in the Maritime, North-east and South-east EPPO climatic zones demonstrate that application of FGF11 at the proposed label rate of 1.0 L product/ha generally gives effective control of PYRNTE in barley that is consistently similar and mostly not statistically significantly different to that given by the standard reference products applied at label rates.

Although the intended label claim for FGF11 is a single application, the majority of trials included 2 applications to ensure adequate disease development for a robust efficacy assessment and to reflect prevailing commercial practice, wherein growers typically apply 2 fungicide treatments to maintain season-long control of PYRNTE. The 2nd application specifically targeted newly occurring infections on the leaves; consequently, the assessments conducted after 2 applications are often indicative of the performance of a single application following new infections rather than cumulative sequential effects.

At the assessment after the first application, disease pressure was often too low, symptoms of PYRNTE appeared in only 15 trials and mostly at very low levels, making it difficult to reliably differentiate product performance. The low disease pressure at this timing is not unexpected, as PYRNTE is typically a late-season disease which appears from BBCH 37-45 onwards, and symptoms are most evident at BBCH 45 onwards. By the assessment timing after the second application, all 26 trials had reached sufficiently high disease levels (≥5% on individual leaf levels), creating a robust infection pressure. This allows for a more accurate and statistically meaningful comparison of FGF11's efficacy against the standard reference product. Furthermore, the efficacy of FGF11 and in comparison to the standard reference product at both assessment timings was similar. Therefore, the dataset following the 2nd application is considered more relevant for demonstrating the efficacy of FGF11, even though the intended claim is for a single application.

Whilst only limited data have been generated to demonstrate the efficacy of FGF11 against PYRNTE per barley crop type in most of the EPPO climatic zones, following EPPO guidance PP1/331 (1) principles of efficacy extrapolations for major uses, the susceptibility of the crops to this fungal pathogen, disease development pressure and development patterns, agronomy of the crops and areas in which the crops are grown in the Central Registration zone can be considered to be sufficiently similar between spring and winter barley to be fully supportive of demonstrating efficacy against PYRNTE in both barley crop types.

Furthermore, products containing prothioconazole and azoxystrobin straight and as mixture are already registered against PYRNTE in spring and winter barley. A reduced dataset is therefore considered to be sufficient to demonstrate that FGF11 effectively controls PYRNTE in spring and winter barley.

To meet the specific requirements for Ireland for wet weather diseases, 4 trials in high disease pressure situations (> 20%) of PYRNTE are required from any country of the Maritime EPPO climatic zone. Although pest severity as presented in the summary tables was above this threshold in 3 trials only, in total there were > 4 trials in this high disease pressure situation based on pest incidence conducted over 2 years and all Irish requirements are therefore met.

Based on the summarised data, it is therefore considered that claims for control of PYRNTE in barley by FGF11, applied at the proposed label rate of 1.0 L product/ha and according to other label recommendations, are fully supported.

Comments of zRMS:

1 application
Winter barley
A total of 7 efficacy trials have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Pyrenophora teres* (PYRNTE) in winter barley.
In the North-East EPPO climatic zone, 2 trials were conducted in 2023. FGF11 applied at dose rate of 1 l/ha achieved good level of control on L4 with the result of 90,7%. Medium effectiveness was observed on L5 (78,3%) in 1 trial. Comparable effect was noted for the reference product Proline at 0,8 l/ha. However, this use cannot be accepted because of limited number of trials.

Conclusions for 2 applications: 4 trials were carried out in 2023. The test product at claimed dose presented good efficacy with the results of 81,4% on L1 and 94,5% on L3. Medium level of control was visible on L2 (79,1%).
In the South-East zone, 5 trials were carried out between 2022 and 2023. The test product at the claimed dose presented sufficient effectiveness with the results of 87,1% on L4, 91,07% on L5 and 86,8% on L6. The reference product Proline at 0,8 l/ha had the control on similar level.
No results after 1 application were available in the Maritime EPPO zone. The cMSs are kindly asked to consider this use at the national level.

Spring barley
A total of 5 efficacy trials have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Pyrenophora teres* (PYRNTE) in spring barley.
In the Maritime EPPO climatic zone, only 1 trial was conducted in 2023. FGF11 at 1 l/ha achieved medium level of control with the results of 67,66% on L3 and 62,35% on L4. No significant differences between test and reference product were observed. Due to limited number of trials, the cMSs are kindly asked to consider this use at the national level.
In the North-East zone, 2 trials were carried out between 2022 and 2023. The test product at the claimed dose presented medium level of control with the results of 79,83% on L3 and 63,9% on L4. The reference product Proline at 0,8 l/ha obtained comparable effect. Due to limited number of trials and no extrapolation possible, this use cannot be accepted in Poland.
Conclusions for 2 applications: 4 trials were conducted between 2022 and 2023. The test product at the claimed dose presented high efficacy with the results of 92,7% on L1, 92,8% on L2 and 89,6% on L3.
In the South-East zone, 2 trials were conducted in 2023. FGF11 at 1 l/ha achieved good effectiveness with the results of 100% on L4 and 96,11% on L5. Similar level of control was observed for the reference product. Due to limited number of trials in spring barley and the opportunities of extrapolation from winter barley, this use is justified. However, the final decision to accept this use is left to the cMSs.

ZRMS conclusions after updated of RR (February 2026)
The applicant submitted the trial results after the first application following to the previous zRMS conclusions. However, most of the results after one application are based on PESSEV <4% and they cannot be considered valid results but only supportive. Only a small number of results can be taken into account when assessing the effectiveness of the product. Nevertheless, all results show a positive response of FGF11 to PYRNTE control. According to table 3.2-68, FGF11 at a dose rate of 1 L/ha achieved an overall average efficacy percentage on all leaves of 71,3% in the MAR zone, 89% in the NE zone and 92,6% in the SE zone on barley. Taking into account both the applicant's arguments and the presented results of effectiveness after a single application, zRMS considers it possible to accept this application for winter barley in ~~each of~~ the MAR and SE zones. In addition, based on EPPO guidance PP 1/331 (1), spring barley can also be considered in the MAR and SE zones. ~~In the case of Poland, extrapolation from winter barley to spring barley is accepted.~~

ZRMS conclusion after updated of RR (April 2026)
In summary, the efficacy of FGF11 in controlling *Pyrenophora teres* (PYRNTE) has been demonstrated in the North-East EPPO zone in the following trials:

- winter barley: 2 trials after the first application with PESSEV ≥4% (from the NE zone) and 4 trials after the second application with PESSEV ≥5% (from the NE zone); in addition, 3 further trials after the first application had PESSEV <2% (PESSEV 0% was observed in 2 out of 3 trials)
- spring barley: 2 trials after the first application with PESSEV ≥4% (conducted in the NE zone) and 4 trials after the second application with PESSEV ≥5% (from the NE zone); in addition, 1 further trial conducted in Finland after the first application had PESSEV 0%

Overall, only 4 efficacy trials in winter barley and 4 trials in spring barley were available for the assessment of this use. In Poland, extrapolation is possible from winter form to spring form or the other way around, but additional trials should be submitted for one of this form.

3.2.3.3.2 Efficacy against Rust (*Puccinia hordeii*: PUCCHD)

A total of 8 trials carried out between 2022 and 2023 generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCHD in winter barley (7 trials) and spring barley (1 trial).

Of these trials, 3 were carried out in the Maritime EPPO climatic zone (2 in Germany and 1 in France) and 5 were carried out in the North-east EPPO climatic zone (all in Poland).

Disease developed on all 8 trials and was assessed as percentage severity on the upper leaves (1-3).

Across trials, the efficacy of FGF11 has been evaluated under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in barley crops growing regions across EU Central Registration zone countries.

A summary of mean percentage efficacy (based on disease severity on the leaves) of FGF11 applied twice at the proposed label rate of 1.0 L product/ha against PUCCHD in barley at across trials and leaf levels with valid data in each of the EPPO climatic zones is given in Table 3.2-70.

Additionally a summary of mean percentage efficacy (based on disease severity on the leaves) of FGF11 against PUCCHD in barley after the first application at 18-19 DA-A1 is given in Table 3.2-74.

Table 3.2-70: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied twice at the proposed label rate of 1.0 L product/ha against PUCCHD across trials on barley in all EPPO climatic zones at 14-37 DA-A2

Registration or EPPO climatic zone	No of trials (no of data points)	*Untreated (% severity on leaves)*		FGF11 1.0 L/ha		Proline* 0.8 L/ha		Statistical comparison of FGF11 to SRP #
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	
CEU	8 (19)	***14.4***	*5.5 - 46.8*	**96.7**	72.9 - 100	**95.4**	70.2 - 100	= (19)
EPPO MAR	3 (9)	***8.9***	*5.5 - 15.4*	**99.2**	97.2 - 100	**98.8**	96.1 - 100	= (9)
EPONE	5 (10)	***19.4***	*6.5 - 46.8*	**94.5**	72.9 - 100	**92.4**	70.2 - 100	= (10)

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.2-6
No. of data points where >, = or <, based on statistically significant differences at 95% confidence level

Table 3.2-71a: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCHD across trials on winter barley in all EPPO climatic zones after 1 application

Registration or EPPO climatic zone	No of trials	*Untreated (% severity on leaves)*		FGF11 1.0 L/ha		Proline 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L3							
Maritime	1 trial	***13,55***	-	**98,88**	-	**98,77**	-
North-East (+trials conducted in Germany)	1 trial	***13,55***	-	**98,88**	-	**98,77**	-
L4							
North-East (+trials conducted in Germany)	1 trial	***5,1***	-	**59,8**	-	**57,8**	-
Maritime	1 trials	***6,2***	-	**88,3**	-	**86,7**	-
L5							
North-East (+trials conducted in Germany)	1 trial	***7,0***	-	**66,6**	-	**73,3**	-

Table 3.2-72b: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCHD across trials on winter barley in all EPPO climatic zones after 2 applications

Registration or EPPO climatic zone	No of trials	*Untreated (% severity on leaves)*	FGF11 1.0 L/ha	Proline 0.8 L/ha

		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L1							
Maritime	3 trials	***9,2***	*6,8-11,47*	**99,8**	99,53-100	**98,7**	96,08-100
North-East	3 trials	***20,0***	*6,47-32,37*	**92,1**	79,41-100	**89,1**	73,17-100
North-East (+trials conducted in Germany)	5 trials	***16,2***	*6,5-32,4*	**95,3**	79,4-100	**93,5**	73,2-100
L2							
Maritime	3 trials	***8,99***	*5,48-15,35*	**99,1**	97,16-100	**99,0**	97,1-100
North-East	4 trials	***20,5***	*7,4-46,75*	**92,6**	72,91-100	**90,2**	70,19-100
North-East (+trials conducted in Germany)	6 trials	***17,3***	*6,2-46,8*	**95,1**	72,9-100	**93,5**	70,2-100
L3							
Maritime	1 trial	***13,55***	-	**98,88**	-	**98,77**	-
North-East	2 trials	***20,8***	*8,12-33,5*	**99,0**	98,02-100	**97,9**	95,84-100
North-East (+trials conducted in Germany)	3 trials	***18,4***	*8,1-33,5*	**98,96**	98-100	**98,2**	95,8-100

Table 3.2-73c: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against PUCCHD across trials on spring barley in all EPPO climatic zones after 2 applications

Registration or EPPO climatic zone	**No of trials**	***Untreated (% severity on leaves)***		**FGF11**		**Proline**	
				1.0 L/ha		**0.8 L/ha**	
		Mean	***Min-max***	**Mean**	**Min-max**	**Mean**	**Min-max**
L3							
North-East	1 trial	***10,27***	-	**100**	-	**100**	-

Table 3.2-74: Mean percentage efficacy of FGF11 (based on disease severity on leaves) after first application against PUCCHD across trials on barley in all EPPO climatic zones at 18-19 DA-A1

Registration or EPPO climatic zone - leaf level	No of trials (No of data points)	*Untreated*		FGF11 (0.5 L/ha)		FGF11 (0.75 L/ha)		FGF11 (1.0 L/ha)		PROLINE* (0.8 L/ha)		Statistical comparison of FGF11 (1.0 L/ha) to SRP#
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max	Mean	Min-max	
EPPO MAR - leaf 3	1 (1)	*3.8*		81.8		75.3		84.6		88.5		= (1)
EPPO NE - leaf 3	1 (1)	*1.8*		63.7		64.6		82.1		93.0		= (1)
EPPO NE + neighboring countries - leaf 3	2 (2)	*2.8*	*1.8 - 3.8*	72.7	63.7 - 81.8	70.0	64.6 - 75.3	83.3	82.1 - 84.6	90.8	88.5 - 93	= (2)
CEU - leaf 3	**2 (2)**	***2.8***	***1.8 - 3.8***	**72.7**	**63.7 - 81.8**	**70.0**	**64.6 - 75.3**	**83.3**	**82.1 - 84.6**	**90.8**	**88.5 - 93**	**= (2)**
EPPO MAR - leaf 4	1 (1)	*6.2*		87.5		83.6		88.3		86.7		= (1)
EPPO NE - leaf 4	1 (1)	*5.1*		40.3		38.6		59.8		57.8		= (1)
EPPO NE + neighboring countries - leaf 4	2 (2)	*5.7*	*5.1 - 6.2*	63.9	40.3 - 87.5	61.1	38.6 - 83.6	74.0	59.8 - 88.3	72.2	57.8 - 86.7	= (2)
CEU - leaf 4	**2 (2)**	***5.7***	***5.1 - 6.2***	**63.9**	**40.3 - 87.5**	**61.1**	**38.6 - 83.6**	**74.0**	**59.8 - 88.3**	**72.2**	**57.8 - 86.7**	**= (2)**
EPPO NE - leaf 5	1 (1)	*7.0*		60.2		60.4		66.6		73.3		= (1)
EPPO NE + neighboring countries - leaf 5	1 (1)	*7.0*		60.2		60.4		66.6		73.3		= (1)
CEU - leaf 5	**1 (1)**	***7.0***		**60.2**		**60.4**		**66.6**		**73.3**		**= (1)**
EPPO MAR - all leaves	1 (2)	*5.0*	*3.8 - 6.2*	84.6	81.8 - 87.5	79.4	75.3 - 83.6	86.4	84.6 - 88.3	87.6	86.7 - 88.5	= (2)
EPPO NE - all leaves	1 (3)	*4.6*	*1.8 - 7*	54.7	40.3 - 63.7	54.5	38.6 - 64.6	69.5	59.8 - 82.1	74.7	57.8 - 93	= (3)
EPPO NE + neighboring countries - all leaves	2 (5)	*4.8*	*1.8 - 7*	66.7	40.3 - 87.5	64.5	38.6 - 83.6	76.3	59.8 - 88.3	79.9	57.8 - 93	= (5)
CEU - all leaves	**2 (5)**	***4.8***	***1.8 - 7***	**66.7**	**40.3 - 87.5**	**64.5**	**38.6 - 83.6**	**76.3**	**59.8 - 88.3**	**79.9**	**57.8 - 93**	**= (5)**

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Appendix 3 and Table 3.2-6
No. of data points where >, = or <, based on statistically significant differences at 95% confidence level

Data generated across trials carried out in the Maritime and North-east EPPO climatic zones demonstrate that application of FGF11 at the proposed label rate of 1.0 L product/ha gives effective control of PUCCHD in barley that is consistently comparable and not statistically significantly different to that given by the standard reference products applied at label rates.

Although the intended label claim for FGF11 is a single application, the majority of trials included 2 applications to ensure adequate disease development for a robust efficacy assessment and to reflect prevailing commercial practice, wherein growers typically apply 2 fungicide treatments to maintain season-long control of PUCCHD. The 2nd application specifically targeted newly occurring infections on the leaves; consequently, the assessments conducted after 2 applications are often indicative of the performance of a single application following new infections rather than cumulative sequential effects.

At the assessment after the first application, disease pressure was often too low, symptoms of PUCCHD appeared in only 2 trials and mostly at very low levels, making it difficult to reliably differentiate product performance. The low disease pressure at this timing is not unexpected, as PUCCHD is typically a late-season diseases which appears from BBCH 37-39 onwards, and symptoms are most evident at BBCH 55-75 onwards. By the assessment timing after the second application, all 8 trials had reached sufficiently high disease levels (≥5% on individual leaf levels), creating a robust infection pressure. This allows for a more accurate and statistically meaningful comparison of FGF11's efficacy against the standard reference product. Furthermore, the efficacy of FGF11 and in comparison to the standard reference product at both assessment timings was similar. Therefore, the dataset following the 2nd application is considered more relevant for demonstrating the efficacy of FGF11, even though the intended claim is for a single application.

The data package available in the Maritime and North-east EPPO climatic zone against PUCCHD in barley is limited and no data are presented from the South-east EPPO climatic zone. The morphology, life cycles and infection patterns of *Puccinia sp*. in different cereal crops and also the efficacy of fungicides against this pathogen, including that of azoxystrobin and prothioconazole, are very similar. Following EPPO guidance PP1/331 (1) principles of efficacy extrapolations for major uses, it is therefore considered that the presented data demonstrating efficacy of FGF11 against PUCCRE and PUCCSI in wheat and triticale (please refer to Sections 3.2.3.1.2 and 3.2.3.1.3) is also supportive of demonstrating that against PUCCHD in barley. Furthermore, products containing the active substances azoxystrobin and prothioconazole, solo and as mixture, are already registered throughout Europe for control of PUCCHD in barley and efficacy has been demonstrated.

Whilst no or only limited data have been generated to demonstrate the efficacy of FGF11 against PUCCHD on spring barley in the Maritime and North-east EPPO climatic zones, the susceptibility of the crops to this fungal pathogen, disease development pressure and development patterns, agronomy of the crops and areas in which the crops are grown in the Central Registration zone can be considered to be sufficiently similar between spring and winter barley to be fully supportive of demonstrating efficacy against PUCCHD in both barley crop types.

Furthermore, products containing prothioconazole and azoxystrobin straight and as mixture are already registered against PUCCHD in spring and winter barley. A reduced dataset is therefore considered to be sufficient to demonstrate that FGF11 effectively controls PUCCHD in spring and winter barley.

Whilst limited data are presented on the efficacy of FGF11 against PUCCHD in barley from trials carried out in the North-east EPPO climatic zone, data generated on this disease across trials in the country neighbouring Poland (Germany) provide supportive evidence of that in Poland

Based on the summarised data, it is therefore considered that claims for control of PUCCHD in barley by FGF11, applied at the proposed label rate of 1.0 L product/ha and according to other label recommendations, are fully supported.

Comments of zRMS:

1 application
Winter barley
A total of 2 efficacy trials have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Puccinia hordeii* (PUCCHD) in winter barley.
In the Maritime EPPO climatic zone, only 1 trial was conducted in 2022. FGF11 applied at dose rate of 1 l l/ha achieved high level of control with the result of 98,88% on L3. Comparable effect was visible for the reference product Proline at 0,8 l/ha. However, the cMSs are kindly asked to consider this use at the national level because of limited number of trials.
In the North-East zone, 1 trial was carried out in 2023. Also 1 trial from Germany can ~~be~~ support ~~for~~ the Polish registration. The test product at the claimed dose presented medium level of control on L4 (59,8%) and L5 (66,6%). Superior result was observed on L3 (98,88%) in other trial. No significant differences between test and reference product were noted. ~~This use cannot be accepted because of limited number of trials.~~
Conclusions for 2 applications: 4 trials were carried out between 2022 and 2023. The test product at claimed dose presented high efficacy with the results of 92,1% on L1, 92,6% on L2 and 99% on L3. 2 efficacy trials conducted in Germany can support the registration in Poland.
No results after 1 application were available in the South-East EPPO zone. The cMSs are kindly asked to consider this use at the national level.

Spring barley
No results after 1 application were available in spring barley in any EPPO climatic zones. The cMSs belonging to the MAR and SE zone are kindly asked to consider this use at the national level. This use cannot be accepted in Poland. Extrapolation from winter barley to spring barley is possible in the case of Poland.
Conclusions for 2 applications in the NE zone: Only 1 efficacy trial was carried out in 2023 in the North-East zone. FGF11 at 1 l/ha achieved full effectiveness on L3.

ZRMS conclusions after updated of RR (February 2026)
The applicant submitted the trial results after the first application following to the previous zRMS conclusions. However, most of the results after one application are based on PESSEV <4% and they cannot be considered valid results but only supportive. Only a small number of results can be taken into account when assessing the effectiveness of the product. Nevertheless, all results show a positive response of FGF11 to PYRNTE control. According to table 3.2-73, FGF11 at a dose rate of 1 L/ha achieved an overall average efficacy percentage on all leaves of 86,4% in the MAR zone and 69,5% in the NE zone on barley. Taking into account both the applicant's arguments and the presented results of effectiveness after a single application, it should be emphasized that the total number of trials submitted for spring and winter barley in the MAR zone was low: 3 trials in HORVW and the lack of trials in HORVS. CMSs belonging to the MAR and SE zones are kindly asked to consider this use at the national level. In the case of Poland, ~~both uses (HORVS and HORVW)~~ only the use of product on HORVW can be accepted ~~(extrapolation from winter barley to spring barley is possible)~~.

ZRMS conclusion after updated of RR (April 2026)
In summary, the efficacy of FGF11 in controlling *Puccinia hordei* (PUCCHD) has been demonstrated in the North-East EPPO zone in the following trials:

- winter barley: 2 trials after the first application with PESSEV ≥4% (1 trial from the NE zone and 1 trial from Germany) and 6 trials after the second application with PESSEV ≥5% (4 trials from the NE zone and 2 trials from Germany); in addition, 1 further trial after the first application had PESSEV <2%
- spring barley: no trials after the first application with PESSEV ≥4% and only 1 trial after the second application with PESSEV ≥5% (from the NE zone)

For spring barley, no trials were submitted following the first application in the NE zone or in neighboring countries. In this case, the applicant should submit additional trials.

3.2.3.3.3 Efficacy against Ramularia (*Ramularia collo-cygni*: RAMUCC)

A total of 7 trials carried out between 2022 and 2023 generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against RAMUCC in winter barley (6 trials) and spring barley (1 trial).

All of the trials were carried out in the Maritime EPPO climatic zone (2 in Germany, 1 in Ireland and 4 in France).

Disease developed on all 7 trials and was assessed as percentage severity on the upper leaves (1-3).

Across trials, the efficacy of FGF11 has been evaluated under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in barley crops growing regions across EU Central Registration zone countries.

A summary of mean percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against RAMUCC in barley at across trials and leaf levels with valid data is given in Table 3.2-75.

Table 3.2-75: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against RAMUCC across trials on barley at 17-40 DA-A2

Registration or EPPO climatic zone	No of trials (no of data points)	*Untreated (% severity on leaves)*		FGF11 1.0 L/ha		Proline* 0.8 L/ha		Statistical comparison of FGF11 to SRP #
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	
CEU/EPPO MAR	7 (9)	***28.3***	*5.3 - 57*	**80.6**	57.8 - 92.6	**81.2**	52.4 - 97.1	= (9)

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.2-6
No. of data points where >, = or <, based on statistically significant differences at 95% confidence level

Table 3.2-76a: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against RAMUCC across trials on winter barley after 1 application

Registration or EPPO climatic zone	No of trials	*Untreated (% severity on leaves)*		FGF11 1.0 L/ha		Proline 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L4							
South-East	1 trial	***5,74***	-	88,91	-	**87,49**	-

Table 3.2-77b: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against RAMUCC across trials on winter barley after 2 applications

Registration or EPPO climatic zone	No of trials	*Untreated (% severity on leaves)*		FGF11 1.0 L/ha		Proline 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L2							
Maritime	6 trials	***29,7***	*10,3-57,0*	**81,3**	57,79-92,64	**83,9**	66,46-97,13
L3							
Maritime	2 trials	***24,2***	*5,25-43,12*	**83,4**	79,57-87,27	**87,8**	87,36-88,28

Table 3.2-78c: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against RAMUCC across trials on spring barley after 2 applications

	No of trials		FGF11	Proline

Registration or EPPO climatic zone		***Untreated (% severity on leaves)***		**1.0 L/ha**		**0.8 L/ha**	
		Mean	***Min-max***	**Mean**	**Min-max**	**Mean**	**Min-max**
L1							
Maritime	1 trial	***27,57***	-	**70,59**	-	**63,61**	-

Data generated across trials carried out in the Maritime EPPO climatic zone demonstrate that application of FGF11 at the proposed label rate of 1.0 L product/ha gives effective control of RAMUCC in barley that is consistently comparable and not statistically significantly different to that given by the standard reference products applied at label rates.

Only data from the Maritime EPPO climatic zone are available. Development of the disease is favoured by temperate, humid conditions and conditions in the Maritime EPPO climatic zone therefore represent a worst case scenario. Furthermore, products containing the active substances azoxystrobin and prothioconazole, solo and as mixture, are already registered for control of RAMUCC in barley throughout Europe and efficacy has been demonstrated.

Whilst only limited data have been generated to demonstrate the efficacy of FGF11 against RAMUCC on spring barley, the susceptibility of the crops to this fungal pathogen, disease development pressure and development patterns, agronomy of the crops and areas in which the crops are grown in the Central Registration zone can be considered to be sufficiently similar between spring and winter barley to be fully supportive of demonstrating efficacy against RAMUCC in both barley crop types.

Furthermore, products containing prothioconazole and azoxystrobin straight and as mixture are already registered against RAMUCC in spring and winter barley. A reduced dataset is therefore considered to be sufficient to demonstrate that FGF11 effectively controls RAMUCC in spring and winter barley.

To meet the specific requirements for Ireland for wet weather diseases, 4 trials in high disease pressure situations (> 20%) of RAMUCC are required (2 trials from any country of the Maritime EPPO climatic zone and 2 trials from Ireland), conducted over 2 years. Only 1 of the trials conducted in Ireland showed sufficient infection with RAMUCC, while all other requirements were met. However, products containing the active substances azoxystrobin and prothioconazole, solo and as mixture, are well-known and are already registered for control of RAMUCC in barley in Ireland. The available data package is therefore considered as sufficient to demonstrate the efficacy of FGF11 against RAMUCC in high disease pressure situations common in Ireland.

Based on the summarised data, it is therefore considered that claims for control of RAMUCC in barley by FGF11, applied at the proposed label rate of 1.0 L product/ha and according to other label recommendations, are fully supported.

Comments of zRMS:

1 application
Winter barley
Only 1 trial has been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Ramularia collo-cygni* (RAMUCC) in winter barley. This trial was conducted in 2023 in the South-East EPPO climatic zone. FGF11 applied at dose rate of 1 l/ha achieved good effectiveness with the result of 88,91% on L4. Comparable effect was observed for the reference product Proline at 0,8 l/ha. The cMSs are kindly asked to consider this use at the national level.
No results after 1 application were available in the Maritime and North-East EPPO zone. The cMSs belonging to the MAR zone are kindly asked to consider this use at the national level. This use cannot be accepted in Poland.
Conclusions for 2 applications in the NE zone: No efficacy trials were available in the North-East.

Spring barley
No results after 1 application were available in spring barley in any EPPO climatic zones. The cMSs belonging to the MAR and SE zone are kindly asked to consider this use at the national level. This use cannot be accepted in Poland.
Conclusions for 2 applications in the NE zone: No efficacy trials were available in the North-East.

3.2.3.3.4 Efficacy against Leaf blotch (*Rhynchosporium secali*: RHYNSE)

A total of 5 trials carried out between 2022 and 2023 generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against RHYNSE in winter barley.

All of the trials were carried out in the Maritime EPPO climatic zone (2 in Great Britain, 1 in Germany and 2 in France.

Disease developed on all 5 trials and was assessed as percentage severity on the upper leaves (1-3).

Across trials, the efficacy of FGF11 has been evaluated under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in barley crops growing regions across EU Central Registration zone countries.

A summary of mean percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against RHYNSE in barley at across trials and leaf levels with valid data is given in Table 3.2-79.

Table 3.2-79: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against RHYNSE across trials on barley at 17-40 DA-A2

Registration or EPPO climatic zone	No of trials (no of data points)	*Untreated (% severity on leaves)*		FGF11 1.0 L/ha		Proline* 0.8 L/ha		Statistical comparison of FGF11 to SRP #
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	
CEU/EPPO MAR	5 (13)	***24.9***	*5.8 - 57.5*	**80.9**	53.4 - 100	**83.9**	61.4 - 100	= (13)

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.2-6
No. of data points where >, = or <, based on statistically significant differences at 95% confidence level

Table 3.2-80a: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against RHYNSE across trials on winter barley after 1 application

Registration or EPPO climatic zone	No of trials	*Untreated (% severity on leaves)*		FGF11 1.0 L/ha		Proline 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L3							
Maritime	2 trials	***5,2***	*4,45-5,98*	**80,9**	66,9-94,9	**75,0**	54,0-96,06
North-East (+trials conducted in Germany)	1 trial	***4,45***	-	**66,9**	-	**54,0**	-
L4							
Maritime	2 trials	***21,2***	*6,58-35,73*	**68,8**	67,6-69,96	**64,4**	50,2-78,63
North-East (+trials conducted in Germany)	1 trial	***6,58***	-	**67,6**	-	**50,2**	-

Table 3.2-81b: Mean overall percentage efficacy (based on disease severity on the leaves) of FGF11 applied at the proposed label rate of 1.0 L product/ha against RHYNSE across trials on winter barley after 2 applications

Registration or EPPO climatic zone	No of trials	*Untreated (% severity on leaves)*		FGF11 1.0 L/ha		Proline 0.8 L/ha	
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max
L1							

Maritime	5 trials	***22,5***	*5,8-47,62*	**85,8**	65,83-100	**84,98**	61,37-100
L2							
Maritime	5 trials	***28,9***	*8,32-57,5*	**78,5**	53,38-100	**85,4**	68,35-100
L3							
Maritime	3 trials	***21,99***	*13,42-29,5*	**76,9**	61,76-87,33	**79,5**	71,15-84,67

Data generated across trials carried out in the Maritime EPPO climatic zone demonstrate that application of FGF11 at the proposed label rate of 1.0 L product/ha gives effective control of RHYNSE in barley that is mostly comparable and never statistically significantly different to that given by the standard reference products applied at label rates.

Only data from the Maritime EPPO climatic zone are available. Development of the disease is favoured by temperate, humid conditions and conditions in the Maritime EPPO climatic zone therefore represent a worst case scenario. Furthermore, products containing the active substances azoxystrobin and prothioconazole, solo and as mixture, are already registered for control of RHYNSE in barley throughout Europe and efficacy has been demonstrated.

Whilst no data have been generated to demonstrate the efficacy of FGF11 against RHYNSE on spring barley, the susceptibility of the crops to this fungal pathogen, disease development pressure and development patterns, agronomy of the crops and areas in which the crops are grown in the Central Registration zone can be considered to be sufficiently similar between spring and winter barley to be fully supportive of demonstrating efficacy against RHYNSE in both barley crop types.

Furthermore, products containing prothioconazole and azoxystrobin straight and as mixture are already registered against RHYNSE in spring and winter barley. A reduced dataset is therefore considered to be sufficient to demonstrate that FGF11 effectively controls RHYNSE in spring and winter barley.

To meet the specific requirements for Ireland for wet weather diseases, 4 trials in high disease pressure situations (> 20%) of RHYNSE are required from trials conducted in Ireland over 2 years. None of the trials were conducted in Ireland but 2 of the trials in high disease pressure situation were conducted in Great Britain with similar favorable conditions for disease development. Furthermore, products containing the active substances azoxystrobin and prothioconazole, solo and as mixture, are well-known and are already registered for control of RHYNSE in barley in Ireland. The available data package is therefore considered as sufficient to demonstrate the efficacy of FGF11 against RHYNSE in high disease pressure situations common in Ireland.

Based on the summarised data, it is therefore considered that claims for control of RHYNSE in barley by FGF11, applied at the proposed label rate of 1.0 L product/ha and according to other label recommendations, are fully supported.

Comments of zRMS:

1 application
Winter barley
A total of 2 efficacy trials have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Rhynchosporium secalis* (RHYNSE) in winter barley.
In the Maritime EPPO climatic zone, 2 trials were conducted between 2022 and 2023. FGF11 applied at dose rate of 1 l/ha achieved medium efficacy on L4 (68,8%) and superior level of control on L3 (80,9%). The reference product Proline at 0,8 l/ha had significant inferior effectiveness on L3 and comparable control on L4. The cMSs are kindly asked to consider this use at the national level because of limited number of trials.
In the North-East zone, no trials were carried out. However, 1 trial from Germany can ~~be~~ support ~~for~~ the Polish registration. FGF11 at 1 l/ha presented medium level of control and it was significant superior effect compared to the reference product Proline at 0,8 l/ha. However, this use cannot be accepted in Poland because of limited number of trials.
Conclusions for 2 applications: No efficacy trials were available in the North-East.
No results after 1 application were available in the South-East EPPO zone. The cMSs are kindly asked to consider this use at the national level.

Spring barley
No results after 1 application were available in spring barley in any EPPO climatic zones. The cMSs belonging to the MAR and SE zone are kindly asked to consider this use at the national level. This use cannot be accepted in Poland.
Conclusions for 2 applications in the NE zone: No efficacy trials were available for spring barley in any EPPO climatic zone.

3.2.3.3.5 Positive effects on green leaf area

Positive effects on green leaf area were assessed on a total of 26 of the trials carried out between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against target foliar diseases in winter barley (20 trials) and spring barley (6 trials).

Of these trials, 7 were carried out in the Maritime EPPO climatic zone (2 in Germany, 1 in Great Britain and 4 in France), 7 were carried out in the North-east EPPO climatic zone (1 in Lithuania, 4 in Poland, 2 in Finland) and 12 were carried out in the South-east EPPO climatic zone (4 in Bulgaria, 4 in Hungary, 4 in Romania).

Target diseases that occurred in these trials were PYRNTE in 17 trials, RAMUCC in 1 trial, PUCCHD in 1 trial, PUCCHD and RAMUCC in 2 trials, PUCCHED and PYRNTE in 2 trials, RAMUCC and RHYNSE in 1 trial, PUCCHD, RAMUCC and RHYNSE in 1 trial and PYRNTE, RAMUCC and RHYNSE in 1 trial.

A summary of mean green leaf area across trials in each of the climatic zones is given in Table 3.2-82.

Table 3.2-82: Mean overall green leaf area data following application of FGF11 at the proposed label rate of 1.0 L product/ha across trials in all climatic zones that generated data on efficacy against target foliar disease in barley

Registration or EPPO climatic zone	Nº Trials (No of data points)	Untreated		FGF11		Proline*		Statistical comparison
				1.0 L/ha		0.8 L/ha		FGF11 to Proline
		Mean	Min-Max	Mean	Min-Max	Mean	Min-Max	
Green leaf area - leaves 1-3								
CEU	12 (19)	***27.4***	*0.0-70.0*	**48.2**	3.0-100	**46.7**	3.3-100	> (3), = (16)
EPPO MAR	2 (2)	***34.1***	*4.5-63.8*	**48.8**	5.0-92.5	**47.3**	3.4-91.3	= (2)
EPPO NE	5 (8)	***45.6***	*4.0-70.0*	**79.2**	11.3-100	**77.6**	15.0-100	> (1), = (7)
EPPO SE	5 (9)	***9.8***	*0.0-30.0*	**20.4**	3.0-60.0	**19.0**	3.3-50.0	> (2), = (7)
Green leaf area - Plants								
CEU	14 (14)	***17.3***	*0.0-50.0*	**42.3**	3.8-97.8	**42.5**	1.0-90.5	> (1), = (13)
EPPO MAR	5 (5)	***5.6***	*0.0-15.0*	**14.1**	3.8-30.0	**13.0**	1.0-30.0	= (5)
EPPO NE	2 (2)	***26.3***	*20.0-32.5*	**83.9**	70.0-97.8	**79.0**	67.5-90.5	> (1), = (1)
EPPO SE	7 (7)	***23.0***	*0.0-50.0*	**50.5**	12.5-76.3	**53.2**	15.0-80.0	= (7)

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.2-6
No. of datapoints where >, = or <, based on statistically significant differences at 95% confidence level

FGF11 applied at the proposed label rate of 1.0 L product/ha significantly increased green leaf area compared to the untreated control in these trials, with the increases being statistically significant on 22 of the 33 datapoints. These increases produced by FGF11 were generally similar to or higher than those produced by the standard reference products applied at label rates with statistically significant differences in 4 of the data points.

The increases in green leaf area given by both FGF11 and the standard reference products can be considered to be a direct function of control of the target diseases occurring in the trials and their adverse effects on green plant tissue in the untreated control.

These increases in green leaf area produced by FGF11 applied at the proposed label rate of 1.0 L product/ha therefore provide further evidence in support of label claims for control of target diseases.

Comments of zRMS:

Green leaf area was evaluated in winter and spring barley in 26 efficacy trials, only after second application. In case of either leaves (1-3) and plant, the increase of mean overall green leaf area was visible after an application of FGF11 at 1 l/ha in all EPPO climatic zone. No statistical differences between test product and Proline at 0,8 l/ha were observed in most of trials.

3.2.3.3.6 Positive effects on crop yield and quality in efficacy trials

Evaluations of crop yield were carried out on a total of 14 of the trials carried out between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against target foliar diseases in winter barley (9 trials) and spring barley (5 trials).

Of these trials, 5 were carried out in the Maritime EPPO climatic zone (2 in Germany, 1 in Ireland and 2 in Great Britain), 6 were carried out in the North-east EPPO climatic zone (1 in Lithuania, 3 in Poland, 2 in Finland) and 3 were carried out in the South-east EPPO climatic zone (1 in Bulgaria, 2 in Hungary).

Evaluations of quality of grain sampled at harvest were also carried out on all 14 trials, with hectolitre/specific weight (HLW) determined on all trials and thousand grain weight (TGW) determined on 9 of the trials.

Target diseases that occurred in these trials were PYRNTE on 6 trials, PYRNTE and PUCCHD on 3 trials, PYRNTE and RAMUCC on 1 trial, PYRNTE, RAMUCC and RHYNSE on 1 trial, PUCCHD and RAMUCC on 1 trial, PUCCHD, RAMUCC and RHYNSE on 1 trial and RHYNSE on 1 trial.

A summary of mean crop yield and grain quality data (expressed as % relative to the untreated control) across trials in each of the climatic zones is given in Table 3.2-83.

Table 3.2-83: Mean overall crop yield and grain quality data (expressed as % relative to the untreated control) following an application of FGF11 at the proposed label rate of 1.0 L product/ha across trials in all climatic zones that generated data on efficacy against target foliar disease in barley

Registration or EPPO climatic zone	Nº Trials	Untreated	FGF11 1.0 L/ha		Proline* 0.8 L/ha		Statical comparison of FGF11 to SRP#
		Mean	Mean	Min-Max	Mean	Min-Max	
Grain yield							
All trials in barley							
CEU	14	*100.0*	**118.5**	110.6-157.6	**112.2**	99.0-138.8	> (1), = (13)
EPPO MAR	5	*100.0*	**116.7**	113.5-121.3	**111.0**	100.5 - 115.6	= (5)
EPPO NE	6	*100.0*	**112.7**	111.4-157.6	**114.4**	99.0-138.8	> (1), = (5)
EPPO SE	3	*100.0*	**113.0**	110.6-116.1	**110.2**	102.7-117.7	= (3)
Winter barley							
CEU	9	*100.0*	**115.8**	111.4-121.3	**111.0**	99.0-117.7	= (9)
EPPO MAR	4	*100.0*	**117.5**	115.4-121.3	**111**	100.5-115.6	= (4)
EPPO NE	3	*100.0*	**114.6**	111.4-116.4	**109.1**	99-116	= (3)
EPPO SE	2	*100.0*	**114.1**	112.1-116.1	**113.9**	110.2-117.7	= (2)
Spring barley							
CEU	5	*100.0*	**123.2**	110.6-157.6	**114.4**	102.7-138.8	> (1), = (4)
EPPO MAR	1	*100.0*	**113.5**	-	**110.7**	-	= (1)
EPPO NE	3	*100.0*	**130.7**	113.6-157.6	**119.6**	109.2-138.8	> (1), = (2)
EPPO SE	1	*100.0*	**110.6**	-	**102.7**	-	= (1)
HLW							
All trials in barley							
CEU	14	*100.0*	**102.6**	98.8-106.5	**101.7**	96.9-106.5	> (1), = (13)
EPPO MAR	5	*100.0*	**101.8**	98.8-103.7	**101.5**	96.9-106.5	= (5)
EPPO NE	6	*100.0*	**103.3**	100.4-106.5	**102.2**	99.7-104.9	> (1), = (5)
EPPO SE	3	*100.0*	**102.6**	100.0-105.1	**101.1**	100.0-102.0	= (3)
Winter barley							
CEU	9	*100.0*	**103.2**	101.0-105.8	**102.3**	100.4-106.5	= (9)
EPPO MAR	4	*100.0*	**102.6**	101-103.7	**102.7**	100.7-106.5	= (4)
EPPO NE	3	*100.0*	**103.5**	101.7-105.8	**102.4**	100.4-103.7	= (3)
EPPO SE	2	*100.0*	**103.9**	102.8-105.1	**101.6**	101.1-102	= (2)
Spring barley							
CEU	5	*100.0*	**101.6**	98.8-106.5	**100.6**	96.9-104.9	> (1), = (4)
EPPO MAR	1	*100.0*	**98.8**	-	**96.9**	-	= (1)
EPPO NE	3	*100.0*	**103.1**	100.4-106.5	**102.1**	99.7-104.9	> (1), = (2)
EPPO SE	1	*100.0*	**100**	-	**100**	-	= (1)

Registration or EPPO climatic zone	Nº Trials	Untreated	FGF11 1.0 L/ha		Proline* 0.8 L/ha		Statical comparison of FGF11 to SRP#
		Mean	Mean	Min-Max	Mean	Min-Max	
TGW							
All trials in barley							
CEU	9	*100.0*	**106.4**	102.5-115.4	**105.0**	99.7-113.4	= (9)
EPPO MAR	2	*100.0*	**105.8**	102.7-108.9	**102.3**	102.2-102.3	= (2)
EPPO NE	5	*100.0*	**107.9**	102.5-115.4	**106.0**	99.7-113.4	= (5)
EPPO SE	2	*100.0*	**105.7**	104.5-106.9	**103.7**	103.2-104.2	= (2)
Winter barley							
CEU	6	*100.0*	**105.5**	102.8-111.6	**104.5**	99.7-109.1	= (6)
EPPO MAR	2	*100.0*	**105.8**	102.7-108.9	**102.3**	102.2-102.3	= (2)
EPPO NE	3	*100.0*	**107.2**	104.7-111.6	**105.1**	99.7-109.1	= (3)
EPPO SE	1	*100.0*	**104.5**	-	**104.2**	-	= (1)
Spring barley							
CEU	3	*100.0*	**109.1**	102.5-115.4	**106.8**	101.5-113.4	= (3)
EPPO NE	2	*100.0*	**109**	102.5-115.4	**107.4**	101.5-113.4	= (2)
EPPO SE	1	*100.0*	**106.9**	-	**103.2**	-	= (1)

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.2-6
No. of trials where >, = or <, based on statistically significant differences at 95% confidence level

In winter barley, FGF11 applied at the proposed label rate of 1.0 L product/ha increased crop yield compared to the untreated control on all of the 9 trials, with the increases being statistically significant on 6 of the trials. These increases produced by FGF11 were generally comparable to or higher than those produced by the standard reference products applied at label rates without any statistically significant differences.

Where evaluations of grain quality were carried out on these trials in winter barley, FGF11 applied at the proposed label rate of 1.0 L product/ha increased TGW compared to the untreated control on 3 of the 6 trials where this quality parameter was assessed, with differences being statistically significant in 2 trials, and HLW in 5 of the 9 trials where this quality parameter was assessed, with differences being statistically significant in 4 of these 6 trials. These increases produced by FGF11 were generally comparable to those produced by the standard reference products applied at label rates.

In spring barley, FGF11 applied at the proposed label rate of 1.0 L product/ha increased crop yield compared to the untreated control on all of the 5 trials, with the increases being statistically significant on 4 of the trials. These increases produced by FGF11 were generally comparable to or higher than those produced by the standard reference products applied at label rates without any statistically significant differences.

Where evaluations of grain quality were carried out on these trials in spring barley, FGF11 applied at the proposed label rate of 1.0 L product/ha increased TGW compared to the untreated control on 3 of the 4 trials where this quality parameter was assessed, with differences being statistically significant in 2 trials, and HLW in 2 of the 5 trials where this quality parameter was assessed, with differences being statistically significant in both trials. These increases produced by FGF11 were generally comparable to those produced by the standard reference products applied at label rates with a slight but statistically significantly higher increase in HLW following application of FGF11 compared to Proline in 1 of the trials.

The increases in crop yield and grain quality given by both FGF11 and the standard reference products can be considered to be a direct function of control of the target diseases occurring in the trials and their adverse effects on yield in the untreated control.

These increases in crop yield and grain quality produced by FGF11 applied at the proposed label rate of 1.0 L product/ha therefore provide further evidence in support of label claims for control of target diseases.

Comments of zRMS:

14 efficacy trials have been submitted to determine the impact of FGF11 on crop yield of winter and spring barley. The increase in crop yield was visible in all EPPO climatic zone: 117,5% in the MAR zone, 114,6% in the NE zone and 114,1% in the SE zone for winter barley and 113,5% in the MAR zone, 130,7% in the NE zone, and 110,6% in the SE zone for spring barley. No statistical differences between FGF11 and the reference product Proline at 0,8 l/ha were observed in most of trials. Moreover, the increases have been noted also in case of quality parameter: TGW and HLW. Similar effect was observed either for FGF11 and Proline/Prosaro 250 EC. Taking into account all results, no negative effect of test product on the quantity and quality of winter and spring barley yield was found in any EPPO zone.

3.2.3.4 Efficacy against target disease in winter and spring oilseed rape

A total of 23 trials carried out between 2022 and 2023 have generated data on the efficacy of FGF11 applied the proposed label rate of 1.0 L product/ha against SCLESC in winter oilseed rape.

Table 3.2-84: Details on trial methodology (efficacy trials on oilseed rape)

Maritime EPPO climatic zone		
Guidelines	General guidelines	EPPO PP1/152 (4), EPPO PP1/181 (4), EPPO PP1/135 (4), EPPO PP1/225 (2)
	Specific guidelines	EPPO PP1/78 (4)

Experimental design	Plot design	RCBD (8)
	Plot size	20-45 m² (8)
	Number of replications	4 (8)
Crop	Trials per crop	Winter oilseed rape (BRSNW) (8)
	Varieties per crop	**BRSNW:** Acacia (1), Avatar (1), Crocodile (1), DK Expansion (1), Feliciano (1), LG Architect (1), LG Aviron (1), Windoz (1)
	Sowing period	**BRSNW:** August (6), September (2)
Targets	Target diseases	**BRSWN:** SCLESC (8)
Application	Crop stage (BBCH) at application	**BRSWN:** from 64-65 to 65-67 (BBCH)
	Application period	13-29 Apr (3), 02-09 May (5)
	Number of applications Interval between applications	1 (8)
	Spray volumes	200 L/ha (2), 300 L/ha (4), 400 L/ha (2)
Assessments	Assessment types	% disease severity on leaf and/or stem Phytotoxicity, crop vigour, crop yield
	Assessment dates	**BRSNW:** between 0-65 DA-A, at harvest
Other relevant information	e.g. Natural / artificial inoculation	Natural (8)
North-east EPPO climatic zone		
Guidelines	General guidelines	EPPO PP1/152 (4), EPPO PP1/181 (4), EPPO PP1/135 (4), EPPO PP1/225 (2)
	Specific guidelines	EPPO PP1/78 (4)
Experimental design	Plot design	RCBD (5)
	Plot size	20-30 m² (5)
	Number of replications	4 (5)
Crop	Trials per crop	Winter oilseed rape (BRSNW) (5)
	Varieties per crop	**BRSNW:** Chopin F1 (1), Floretta B1 Buteo (1), Kepler (1), Oriolus (1), Tom (1)
	Sowing period	**BRSNW:** August (4), September (1)
Targets	Target diseases	**BRSWN:** SCLESC (5)
Application	Crop stage (BBCH) at application	**BRSWN:** from 63-65 to 65 (BBCH)
	Application period	05-20 May (5)
	Number of applications Interval between applications	1 (5)
	Spray volumes	200 L/ha (1), 300 L/ha (4)
Assessments	Assessment types	% disease severity on leaf and/or stem Phytotoxicity, crop vigour, crop yield
	Assessment dates	**BRSNW:** between 0-57 DA-A, at harvest
Other relevant information	e.g. Natural / artificial inoculation	Natural (5)
South-east EPPO climatic zone		
Guidelines	General guidelines	EPPO PP1/152 (4), EPPO PP1/181 (4), EPPO PP1/135 (4), EPPO PP1/225 (2)
	Specific guidelines	EPPO PP1/78 (4)
Experimental design	Plot design	RCBD (10)
	Plot size	21-30 m² (10)

	Number of replications	4 (10)
Crop	Trials per crop	Winter oilseed rape (BRSNW) (10)
	Varieties per crop	**BRSNW:** DK Exception (1), DK Exterrier (1), Imenence (2), KWS Umberto (2), LG Architect (2), LG Condtructor CL (1), PT264 (1)
	Sowing period	**BRSNW:** August (2-1), September (6-9)
Targets	Target diseases	**BRSWN:** SCLESC (10)
Application	Crop stage (BBCH) at application	**BRSWN:** 62-67 (BBCH)
	Application period	26-29 Apr (6), 02-12 May (4)
	Number of applications Interval between applications	1 (10)
	Spray volumes	300 L/ha (5), 400 L/ha (5)
Assessments	Assessment types	% disease severity on leaf and/or stem Phytotoxicity, crop vigour, crop yield
	Assessment dates	**BRSNW:** between 0-57 DA-A, at harvest
Other relevant information	e.g. Natural / artificial inoculation	Natural (10)

Applications on all efficacy trials were made using small plot sprayers designed to simulate application using commercial sprayers representative of those used to apply fungicides in oilseed rape.

On all trials, a single application of the treatments was made on crops growth stage and in water volumes representative of the ones proposed for the application of FGF11.

Data are only summarised in this dossier where mean levels of disease in the untreated control reached ≥5% severity on part assessed following application.

Efficacy data are summarised across trials from representative assessment timings in this Section.

In the majority of trials, a zonal reference product containing prothioconazole as the active substance was used (generally with the tradename PROLINE). Additionally, local standard reference products were included in some of the trials. These additional local standard reference products are presented in the summaries below only if no reference product containing straight prothioconazole was included in the trial. Efficacy against Cottony rot (*Sclerotinia sclerotiorum*: SCLESC)

3.2.3.4.1 Efficacy against Cottony rot (*Sclerotinia sclerotiorum*: SCLESC)

A total of 23 trials carried out between 2022 and 2023 generated data on the efficacy of a single application of FGF11 at the proposed label rate of 1.0 L product/ha against target diseases in oilseed rape.

Of these trials, 8 were carried out in the Maritime EPPO climatic zone (3 in Germany, 3 in Great Britain, 2 in France), 5 were carried out within the North-east EPPO climatic zone (1 in Lithuania, 4 in Poland) and 10 were carried out within the South-east EPPO climatic zone (2 in Bulgaria, 5 in Hungary, 3 in Romania). All of these trials were conducted in winter oilseed rape.

Disease developed on all 23 trials and was assessed as percentage severity on the leaves (in 6 trials) and on stems (in all 23 trials).

Across trials, the efficacy of FGF11 has been evaluated under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in oilseed rape crops growing regions across EU Central Registration zone countries.

An overall summary of mean percentage efficacy (based on disease severity) of FGF11 applied at the proposed label rate of 1.0 L product/ha) against SCLESC in oilseed rape at 21-65 DA-A across trials in each of the climatic zones is given in Table 3.2-85.

Table 3.2-85: Mean overall percentage efficacy (based on disease severity on the leaves and stems) of a single application of FGF11 at the proposed label rate of 1.0 L product/ha against SCLESC across trials on winter oilseed rape in all climatic zones at 21-65 DA-A

Registration or EPPO climatic zone	No of trials	*Untreated*		FGF11 1.0 L/ha		Proline/Praktis 0.7 L/ha		Proline* 0.8 L/ha*		Prosaro 250 EC 0.8 L/ha		Statistical comparison of FGF11 to SRP#
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	Mean	Min-max	Mean	Min-max	
Severity on leaves (21-56 DA-A)												
CEU	6	*12.7*	*6.1-16.8*	78.9	67.7-90.4	-	-	-	-	-	-	-
	5 of 6	*12.3*	*6.1-16.8*	79.0	67.7-90.4	-	-	77.9	64.7-95.3	-	-	= (5)
	1 of 6	*14.6*	-	78.1	-	-	-	-	-	73.9	-	> (1)
EPPO MAR	1	*16.8*	-	90.4	-	-	-	95.3	-	-	-	= (1)
EPPO SE	5	*11.9*	*6.1-14.8*	76.6	67.7-82.4	-	-	-	-	-	-	-
	4 of 5	*11.2*	*6.1-14.8*	76.2	67.7-82.4	-	-	73.6	64.7-84.1	-	-	= (4)
	1 of 5	*14.6*	-	78.1	-	-	-	-	-	73.9	-	> (1)
Severity on stems (42-65 DA-A)												
CEU	23	*22.2*	*5.4-64.8*	74.3	37.3-100	-	-	-	-	-	-	-
	4 of 23	*17.4*	*9.0-31.1*	66.7	37.9-100	77.0	51.7-100	-	-	-	-	= (4)
	18 of 23	*23.6*	*5.4-64.8*	75.7	37.3-100	-	-	72.8	30.6-97.1	-	-	> (1), = (17)
	1 of 23	*17.0*	-	79.4	-	-	-	-	-	74.0	-	> (1)
EPPO MAR	8	*17.2*	*5.7-31.1*	65.2	37.9-100	-	-	-	-	-	-	-
	3 of 8	*20.2*	*11.7-31.1*	55.6	37.9-77.3	69.4	51.7-82.2	-	-	-	-	= (3)
	5 of 8	*15.3*	*5.7-24.4*	71.0	48.9-100	-	-	63.1	30.6-97.1	-	-	= (5)
EPPO NE	5	*18.7*	*9.0-34.8*	84.9	43.6-100	-	-	-	-	-	-	-
	4 of 5	*21.1*	*10.5-34.8*	81.2	43.6-95.2	-	-	85.4	60.8-95.4	-	-	= (4)
	1 of 5	*9.0*	-	100	-	100	-	-	-	-	-	= (1)
EPPO NE + Germany	8	*18,5*	*9,0-34,8*	82,9	43,6-100	-	-	-	-	-	-	-
EPPO SE	10	*28.1*	*5.4-64.8*	76.2	37.3-92.9	-	-	-	-	-	-	-
	9 of 10	*29.3*	*5.4-64.8*	75.9	37.3-92.9	-	-	72.5	59.4-87.2	-	-	> (1), = (8)
	1 of 10	*17.0*	-	79.4	-	-	-	-	-	74.0	-	> (1)

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.2-6
No. of trials where >, = or <, based on statistically significant differences at 95% confidence level

Data generated across trials carried out in the Maritime, North-east and South-east EPPO climatic zones demonstrate that a single application of FGF11 at the proposed label rate of 1.0 L product/ha generally gives effective control of SCLESC in winter oilseed rape that is consistently comparable and not statistically significantly different to that given by the standard reference products applied at label rates.

Whilst no data are presented to demonstrate the efficacy of FGF11 against SCLESC in spring oilseed rape, the susceptibility of the crops to this fungal pathogen, disease development pressure and development patterns, agronomy of the crops and areas in which the crops are grown in the Central Registration zone can be considered to be sufficiently similar between winter and spring oilseed rape for the data generated on trials in winter oilseed rape to be fully supportive of demonstrating efficacy against SCLESC in spring oilseed rape.

Whilst limited data are presented on the efficacy of FGF11 against SCLESC in oilseed rape from trials carried out in the North-east EPPO climatic zone, data generated on this disease across trials in the country neighbouring Poland (Germany) provide supportive evidence of that in Poland.

Based on the summarised data, it is therefore considered that claims for control of SCLESC in winter and spring oilseed rape by FGF11, applied at the proposed label rate of 1.0 L product/ha and according to other label recommendations, are fully supported.

Comments of zRMS:

1 application
Winter oilseed rape
A total of 23 efficacy trials have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Sclerotinia sclerotiorum* (SCLESC) in winter oilseed rape.
In the Maritime EPPO climatic zone, 8 trials were conducted between 2022 and 2023. FGF11 applied at dose rate of 1 l/ha achieved medium level of control on stems with the result of 65,2%. The claimed dose presented superior effect on leaves with the effectiveness of 90,4% but in only 1 trial. The reference product Proline/Praktis at 0,7 l/ha had similar effect on stems with the result of 69,4% in 3 out of 8 trials. The reference product Proline at 0,8 l/ha achieved medium level of control on stems with the result of 63,1% in 5 out 8 trials. Also significant differences between test and reference product were observed on leaves.
In the North-East zone, 5 trials were carried out between 2022 and 2023. The test product at the claimed dose presented good efficacy on stems with the result of 84,9%. No significant differences between test and reference product Proline at 0,8 l/ha were observed in 4 out of 5 trials. The observations on the leaves were not available in the NE zone. 3 efficacy trials conducted in Germany can support the registration in Poland.
In the South-East zone, 10 trials were conducted between 2022 and 2023. FGF11 at 1 l/ha achieved medium effectiveness, either on leaves and stems, with the results of 76,6% and 76,2%, respectively. Similar effect was noted for the reference product Proline at 0,8 l/ha with the results of 73,6% on leaves (in 4 out of 5 trials) and 72,5% on stems (in 9 out of 10 trials).

Spring oilseed rape
No efficacy trials were available for spring oilseed rape in any EPPO climatic zone. The cMSs belonging to the MAR and SE zone are kindly asked to consider this use at the national level. Due to the inability to extrapolate, this use cannot be accepted on the registration under art. 33 in Poland. However, spring oilseed rape is minor crop in Poland, Austria, Germany, Ireland, Netherlands, Slovenia and Slovakia and the registration under art. 51 is possible in this case, as zRMS supposes.

3.2.3.4.2 Positive effects on crop yield and quality in efficacy trials

Evaluations of crop yield were carried out on a total of 14 of the trials carried out between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against target foliar diseases in winter oilseed rape.

Of these trials, 5 were carried out in the Maritime EPPO climatic zone (3 in Germany and 2 in Great Britain), 2 were carried out in the North-east EPPO climatic zone (both in Poland) and 7 were carried out in the South-east EPPO climatic zone (1 in Bulgaria, 3 in Hungary and 3 in Romania).

Evaluations of quality of seed sampled at harvest were also carried out on all 14 trials, with the oil content determined on all trials and thousand grain weight (TGW) determined on 13 of the trials.

Target disease that occurred in these trials was SCLESC in all trials.

An overall summary of mean crop yield and seed quality data (expressed as % relative to the untreated control) across trials in each of the climatic zones is given in Table 3.2-86.

Table 3.2-86: Mean overall crop yield and seed quality data (expressed as % relative to the untreated control) following an application of FGF11 at the proposed label rate of 1.0 L product/ha across trials in all climatic zones that generated data on efficacy against SCLESC in winter oilseed rape

Registration or EPPO climatic zone	No Trials	*Untreated*	FGF11 1.00 L/ha		Proline 0.7 L/ha		Proline 0.8 L/ha*		Prosaro 250 EC 0.8 L/ha		Statistical comparison of FGF11 to SRP#
		Mean	Mean	Min-max	Mean	Min-max	Mean	Min-max	Mean	Min-max	
Yield											
CEU	14	*100*	113.9	100.0-133.7	-	-	-	-	-	-	-
	11 of 14	*100*	112.0	100.4-133.7	-	-	112.4	103.2-130.1	-	-	= (10), < (1)
	2 of 14	*100*	104.5	100-109	98.1	90.6-105.7	-	-	-	-	= (2)
	1 of 14	*100*	105.4	-	-	-	-	-	104.7	-	> (1)
EPPO MAR	5	*100*	103.8	100.0-109.0	-	-	-	-	-	-	-
	2 of 5	*100*	104.5	100.0-109.0	98.1	90.6-105.7	-	-	-	-	= (2)
	3 of 5	*100*	103.3	100.4-106.9	-	-	105.3	103.2-107.2	-	-	= (3)
EPPO NE	2	*100*	127.7	121.7-133.7	-	-	125.2	120.3-130.1	-	-	= (2)
EPPO SE	7	*100*	110.2	101.8-122.5	-	-	-	-	-	-	-
	6 of 7	*100*	111.0	101.8-122.5	-	-	111.6	106.2-119.7	-	-	= (5), < (1)
	1 of 7	*100*	105.4	-	-	-	-	-	104.7	-	> (1)
TGW											
CEU	13	*100*	105.7	99.6-104.2	-	-	-	-	-	-	-
	10 of 13	*100*	108.4	99.6-150.2	-	-	108.6	99-142.5	-	-	= (10)
	2 of 13	*100*	102.8	100.7-104.9	99.5	98.8-100.2	-	-	-	-	= (2)
	1 of 13	*100*	105.6	-	-	-	-	-	104.8	-	= (1)
EPPO MAR	4	*100*	102.4	99.6-104.9	-	-	-	-	-	-	-
	2 of 4	*100*	102.8	100.7-104.9	99.5	98.8-100.2	-	-	-	-	= (2)
	2 of 4	*100*	102.0	99.6-104.5	-	-	101.2	99.0-103.5	-	-	= (2)
EPPO NE	2	*100*	103.2	102.3-104.2	-	-	104.0	101.9-106.2	-	-	= (2)
EPPO SE	7	*100*	111.4	100.7-150.2	-	-	-	-	-	-	-
	6 of 7	*100*	112.3	100.7-150.2	-	-	112.62905	100.6-142.5	-	-	= (6)
	1 of 7	*100*	105.6	-	-	-	-	-	104.8	-	= (1)

Registration or EPPO climatic zone	No Trials	*Untreated*	FGF11		Proline		Proline		Prosaro 250 EC		Statistical comparison of FGF11 to SRP#
			1.00 L/ha		0.7 L/ha		0.8 L/ha*		0.8 L/ha		
		Mean	Mean	Min-max	Mean	Min-max	Mean	Min-max	Mean	Min-max	
Oil content											
CEU	14	*100*	101.4	99.8-107.4	-	-	-	-	-	-	-
	11 of 14	*100*	101.2	99.7-107.4	-	-	101.4	99.6-107	-	-	= (11)
	2 of 14	*100*	100.2	99.5-101	100.7	100.4-100.9	-	-	-	-	= (2)
	1 of 14	*100*	100.5	-	-	-	-	-	100.4	-	> (1)
EPPO MAR	5	*100*	100.3	99.5-101	-	-	-	-	-	-	-
	2 of 5	*100*	100.2	99.5-101	100.7	100.4-100.9	-	-	-	-	= (2)
	3 of 5	*100*	100.4	99.7-100.7	-	-	100.7	99.6-101.2	-	-	= (3)
EPPO NE	2	*100*	100.2	99.8-100.6	-	-	100.2	100-100.4	-	-	= (2)
EPPO SE	7	*100*	101.7	99.8-107.4	-	-	-	-	-	-	-
	6 of 7	*100*	101.9	99.8-107.4	-	-	102.2	99.7-107	-	-	= (6)
	1 of 7	*100*	100.5	-	-	-	-	-	100.4	-	> (1)

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.2-6
No. of trials where >, = or <, based on statistically significant differences at 95% confidence level

FGF11 applied at the proposed label rate of 1.0 L product/ha increased crop yield compared to the untreated control on 9 of the 14 trials, with the increases being statistically significant on 4 of the trials. These increases produced by FGF11 were generally comparable to or slightly higher than those produced by the standard reference products applied at label rates with statistically significant differences in 1 of the trials.

Where evaluations of seed quality were carried out on these trials, FGF11 applied at the proposed label rate of 1.0 L product/ha increased TGW compared to the untreated control on 5 of the 13 trials where this quality parameter was assessed, with differences being statistically significant in 1 trial, and the oil content in 2 of the 14 trials, with differences being statistically significant in both trials. These increases produced by FGF11 were generally comparable to those produced by the standard reference products applied at label rates, with no statistically significant differences in any trial.

The increases in crop yield and seed quality given by both FGF11 and the standard reference products can be considered to be a direct function of control of the target diseases occurring in the trials and their adverse effects on yield in the untreated control.

These increases in crop yield and grain quality produced by FGF11 applied at the proposed label rate of 1.0 L product/ha therefore provide further evidence in support of label claims for control of SCLESC in oilseed rape.

Comments of zRMS:

14 efficacy trials have been submitted to determine the impact of FGF11 on crop yield of winter oilseed rape. The increase in crop yield was visible in all EPPO climatic zone: 103,8% in the MAR zone, 127,7% in the NE zone and 110,2% in the SE zone. No statistical differences between FGF11 and the reference product Proline at 0,8 l/ha were observed in most of trials. Moreover, the increases have been noted also in case of quality parameter: TGW and oil content. Similar effect was observed either for FGF11 and Proline/Prosaro 250 EC. Taking into account all results, no negative effect of test product on the quantity and quality of winter oilseed rape yield was found in any EPPO zone.

3.2.3.5 Efficacy against target ear diseases in winter wheat, spring wheat, durum wheat and spelt

A total of 40 trials carried out in 2023 have generated data on the efficacy of FGF11 applied the proposed label rate of 1.0 L product/ha against target ear diseases in wheat (winter, spring, durum) and spelt.

Table 3.2-87: Details on trial methodology (efficacy trials on wheat)

Maritime EPPO climatic zone		
Guidelines	General guidelines	EPPO PP1/152 (4), EPPO PP1/181 (4), EPPO PP1/135 (4), EPPO PP1/225 (2)
	Specific guidelines	EPPO PP1/26 (4)
Experimental design	Plot design	RCBD (10)
	Plot size	20.6-36.0 m² (10)
	Number of replications	4 (10)
Crop	Trials per crop	Winter wheat (TRZAW) (10)
	Varieties per crop	**TRZAW:** Astronama (1), Chevignon (2), Extase (1), Graham (2), KWS Livius (1), Prestance (1), Torp (1), Zyatt (1)
	Sowing period	**TRZAW:** September (2), October (7), November (1)
Targets	Target diseases	FUSAGR (1), FUSASP (9)
Application	Crop stage (BBCH) at application	**TRZAW:** A1: from 51-63 to 65-69 (BBCH)
	Application period	**TRZAW:** A1: May (2), June (8)
	Number of applications Interval between applications	1 (10)

	Spray volumes	100 L/ha (1), 150 L/ha (2), 200 L/ha (5), 300 L/ha (2)
Assessments	Assessment types	% disease severity on ears, % green leaf area, phytotoxicity, crop yield, hectoliter weight, thousand grain weight, mycotoxin content
	Assessment dates	between 0 DA-A1 and 40 DA-A1, at harvest
Other relevant information	e.g. Natural / artificial inoculation	Artificial (10)

North-east EPPO climatic zone		
Guidelines	General guidelines	EPPO PP1/152 (4), EPPO PP1/181 (4), EPPO PP1/135 (4), EPPO PP1/225 (2)
	Specific guidelines	EPPO PP1/26 (4)
Experimental design	Plot design	RCBD (15)
	Plot size	20.1-30.0 m² (15)
	Number of replications	4 (15)
Crop	Trials per crop	Winter wheat (TRZAW) (15)
	Varieties per crop	**TRZAW:** Askaban (2), Creator (1), Euforia (2), Formacja (1), Hondia (1), Informer (1), LG Keramik (1), Provision (1), Reform (1), Skagen (1), Symetria (1), Venecja (2)
	Sowing period	**TRZAW:** September (9), October (6)
Targets	Target diseases	FUSACU (2), FUSASP (13)
Application	Crop stage (BBCH) at application	**TRZAW:** A1: from 61 to 65 (BBCH)
	Application period	**TRZAW:** A1: June (15)
	Number of applications Interval between applications	1 (15)
	Spray volumes	200 L/ha (12), 250 L/ha (1), 300 L/ha (1), 400 L/ha (1)
Assessments	Assessment types	% disease severity on ears, % green leaf area, phytotoxicity, crop yield, hectoliter weight, thousand grain weight, mycotoxin content
	Assessment dates	between 0 DA-A1 and 35 DA-A1, at harvest
Other relevant information	e.g. Natural / artificial inoculation	Artificial (15)
South-east EPPO climatic zone		
Guidelines	General guidelines	EPPO PP1/152 (4), EPPO PP1/181 (4), EPPO PP1/135 (4), EPPO PP1/225 (2)
	Specific guidelines	EPPO PP1/26 (4)
Experimental design	Plot design	RCBD (15)
	Plot size	20-30 m² (15)
	Number of replications	4 (15)
Crop	Trials per crop	Winter wheat (TRZAW) (15)
	Varieties per crop	**TRZAW:** Avenue (1), Bernstein (2), Boriana (1), Cellule (1), Exotic (1), Glossa (1), Miranda (2), MV Nádor (1), Otilia (2), Teres (1), Ultim (2)
	Sowing period	**TRZAW:** September (1), October (13), November (1)
Targets	Target diseases	GIBBZE (8), FUSASP (7)
Application	Crop stage (BBCH) at application	**TRZAW:** A1: from 57 to 61-69 (BBCH)
	Application period	**TRZAW:** A1: May (11), June (4)
	Number of applications Interval between applications	1 (15)
	Spray volumes	200 L/ha (5), 250 L/ha (1), 300 L/ha (9)
Assessments	Assessment types	% disease severity on ears, % green leaf area, phytotoxicity, crop yield, hectoliter weight, thousand grain weight, mycotoxin content
	Assessment dates	between 0 DA-A1 and 46 DA-A1, at harvest
Other relevant information	e.g. Natural / artificial inoculation	Artificial (15)

Applications on all efficacy trials were made using small plot sprayers designed to simulate application using commercial sprayers representative of those used to apply fungicides in cereals.

On 39 of the 40 trials, a single application of the treatments was made on crops growth stage representative of the ones proposed for the application of FGF11. On the other 1 trial, a single application was done at crop growth stage of 57 and therefore only slightly outside of the GAP crop growth stage. However, it is considered that this slight deviation had no negative impact on the efficacy of the product against target disease and therefore trial is still considered as valid to prove efficacy of FGF11 against FUSASP.

On all trials, a single application of the treatments was made in water volumes representative of the ones proposed for the application of FGF11.

The standard reference products were applied according to the label recommendations.

Data are summarised in this dossier from assessment timings where mean levels of disease in the untreated control reached ≥5% severity on the ears following application.

Efficacy data are summarised across trials from single representative assessment timings in this Section.

In all trials two untreated checks were included (inoculated and non-inoculated with natural infestation). In the reports, calculated % of FUSASP control and % of untreated for yield and quality parameters was not consistent across trials (calculated either based on non-inoculated, inoculated or on mean across both untreated controls). Therefore, in the summary below, manual recalculations were done based on inoculated untreated check for all trials where the non-inoculated untreated check with lower infestation level or mean across both untreated checks were taken for calculations in the reports.

In the majority of trials, a zonal reference product containing prothioconazole as the active substance was used (generally with the tradename PROLINE). Additionally, local standard reference products were included in some of the trials. These additional local standard reference products are presented in the summaries below only if no reference product containing straight prothioconazole was included in the trial. Efficacy against Fusarium ear blight (*Fusarium* sp.: FUSASP)

3.2.3.5.1 Efficacy against Fusarium ear blight (*Fusarium* sp.: FUSASP)

A total of 40 trials carried out in 2023 generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against FUSASP (29), FUSASGR (1 trial), FUSACU (2 trials) and GIBBZE (8 trials) in winter wheat.

Of these trials, 10 were carried out in the Maritime EPPO climatic zone (1 in Denmark, 2 in Germany, 3 in Ireland, 1 in the United Kingdom, 3 in France), 15 were carried out in the North-east EPPO climatic zone (2 in Latvia, 1 in Lithuania, 12 in Poland) and 15 were carried out in the South-east EPPO climatic zone (5 in Bulgaria, 4 in Hungary, 6 in Romania).

Disease developed on all 40 trials and was assessed as percentage severity on the ears.

Across trials, the efficacy of FGF11 has been evaluated under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in wheat crops growing regions across EU Central Registration zone countries.

An overall summary of mean percentage efficacy (based on disease severity on the ears) of FGF11 applied at the proposed label rate of 1.0 L product/ha against FUSASP in wheat at 21-46 DA-A1 across trials in each of the EPPO climatic zones is given in Table 3.2-88.

Table 3.2-88: Mean overall percentage efficacy (based on disease severity on the ears) of FGF11 applied at the proposed label rate of 1.0 L product/ha against FUSASP across trials on winter wheat in all EPPO climatic zones at 21-46 DA-A1

Registration or EPPO climatic zone	No. of trials	*Untreated*		FGF11 1.0 L/ha		Proline* 0.8 L/ha		Statistical comparison of FGF11 to SRP#
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	
CEU	40	***23.7***	*5.8-90.5*	**73.2**	20.5-96.4	**70.7**	24.3-98.2	> (4), = (35), < (1)
EPPO MAR	10	***36.1***	*6.3-90.5*	**49.9**	20.5-83.8	**43.6**	24.3-73.0	> (1), = (8), < (1)
EPPO NE	15	***17.0***	*5.8-50.4*	**78.2**	51.4-96.4	**79.4**	56.2-98.2	= (15)
EPPO SE	15	***22.1***	*6.5-52.1*	**83.7**	61.7-96.4	**80.0**	53.4-95.3	> (3), = (12)

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.2-6
No. of trials where >, = or <, based on statistically significant differences at 95% confidence level

Data generated across trials carried out in the North-east and South-east EPPO climatic zones demonstrate that FGF11 applied at the proposed label rate of 1.0 L product/ha generally gives effective control of FUSASP in wheat that is consistently comparable and mostly not statistically significantly different to that given by the standard reference product applied at label rate. In the Maritime EPPO climatic where FGF11 gave moderate control of FUSASP, the standard reference product also gave lower control of this disease on the ears.

Whilst no data have been generated to demonstrate the efficacy of FGF11 against FUSASP in spring wheat, durum wheat and spelt, the susceptibility of the crops to this fungal pathogen, disease development pressure and development patterns, agronomy of the crops and areas in which the crops are grown in the Central Registration zone can be considered to be sufficiently similar between different wheat crops for the data generated on trials in winter wheat to be fully supportive of demonstrating efficacy against FUSASP in spring wheat, durum wheat and spelt.

Furthermore, products containing prothioconazole and azoxystrobin straight and as mixture are already registered against FUSASP in the different cereal types mentioned above throughout Europe. The efficacy of FGF11 against FUSASP was extensively proven in winter wheat and was confirmed by trials in other cereal types. It can therefore be considered that FGF11 effectively controls FUSASP in all types of wheat and spelt.

Whilst trials that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against FUSASP in wheat were conducted in a single year, data has been generated in relatively high number of trials (40 in total, with 10 in the Maritime, 15 in the North-east and 15 in the South-east EPPO climatic zones) and therefore on a wide range of climatic conditions, agronomic practices and disease development patterns. Additionally, products containing the active substances azoxystrobin and prothioconazole, solo or as mixture, are well-known and are already registered for control of FUSASP in wheat across Central Registration zone and Great Britain. Based on this, it can be considered that presented data are fully sufficient to demonstrate efficacy of FGF11 against FUSASP in wheat crops.

To meet the specific requirements for Ireland for wet weather diseases, 2 trials in high disease pressure situations (> 20%) of FUSASP are required from this country. As presented in the detailed summary tables above this threshold was noted in 3 Irish trials, however conducted only over 1 year. However, products containing the active substances azoxystrobin and prothioconazole, solo or as mixture, are well-known and are already registered for control of FUSASP in wheat in Ireland. The available data package is therefore considered as sufficient to demonstrate the efficacy of FGF11 against FUSASP in high disease pressure situations common in Ireland.

Based on the summarised data, it is therefore considered that claims for control of FUSASP in wheat (winter, spring, durum) and spelt by FGF11, applied at the proposed label rate of 1.0 L product/ha and according to other label recommendations, are fully supported.

Comments of zRMS:

1 application
Winter wheat
A total of 40 efficacy trials have been submitted to evaluate the effectiveness of FGF11 applied at dose rate of 1 l/ha once per growing season for the control of *Fusarium* sp. (FUSASP) in winter wheat.
In the Maritime EPPO climatic zone, 10 trials were conducted in 2023. FGF11 applied at dose rate of 1 l/ha achieved insufficient effectiveness on ears with the result of 49,9%. The reference product Proline at 0,8 l/ha presented comparable effect in 8 out of 10 trials. Due to significant low effectiveness, the cMSs are kindly asked to consider this use at the national level. In the opinion of zRMS, the application of the product to protect winter wheat against FUSASP in the MAR zone is not justified.
In the North-East zone, 15 trials were carried out in 2023. The test product at claimed dose presented medium level of control with the result of 78,2% on ears. No significant differences between test and reference product Proline were observed in all trials.
In the South-East zone, 15 trials were conducted in 2023. FGF11 at 1 l/ha achieved good effectiveness with the result of 83,7% on ears. Similar effect was visible for the reference product Proline at 0,8 l/ha in 12 out of 15 trials.

Spring wheat, durum wheat, spelt
No efficacy trials were available for other wheat crops in any EPPO climatic zone. The cMSs belonging to the MAR and SE zone are kindly asked to consider these uses at the national level. Due to the inability to extrapolate, these uses cannot be accepted on the registration under art. 33 in Poland. However, spring wheat is minor crop in Belgium and Ireland, durum wheat is minor crop in Poland, Belgium, Czech Republic, Ireland, Netherlands and Romania and spelt is minor crop in Poland, Belgium, Czech Republic, Hungary, Ireland, Netherlands, Romania, Slovenia and Slovakia and the registration under art. 51 is possible in these cases, as zRMS supposes.

3.2.3.5.2 Positive effects on green leaf area

Positive effects on green leaf area were assessed on a total of 28 of the trials carried out in 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against FUSASP in winter wheat.

Of these trials, 4 were carried out in the Maritime EPPO climatic zone (1 in Denmark, 1 in Germany, 1 in Ireland, 1 in France), 13 were carried out in the North-east EPPO climatic zone (1 in Latvia, 1 in Lithuania, 11 in Poland) and 11 were carried out in the South-east EPPO climatic zone (3 in Bulgaria, 2 in Hungary, 6 in Romania).

Data are summarised here from representative assessment timings where differences occurred and were assessed on individual upper leaves (1-3) or on a whole plant leaf area basis.

An overall summary of mean percentage green leaf area data following application of FGF11 at the proposed label rate of 1.0 L product/ha, compared to standard reference products applied at the label rates, across these 28 trials in winter wheat is given in Table 3.2-89.

Table 3.2-89: Mean overall green leaf area data following an application of FGF11 at the proposed label rate of 1.0 L product/ha across trials in all climatic zones that generated data on efficacy against FUSASP in winter wheat

Registration or EPPO climatic zone	No. of trials (No. of data points)	*Untreated*		FGF11 1.0 L/ha		Proline* 0.8 L/ha		Statistical comparison of FGF11 to SRP#
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	
Leaves 1-3								
CEU	2 (5)	***59.3***	*22.5-83.8*	**63.0**	30.0-85.0	**63.8**	31.3-85.0	= (2)
EPPO NE	2 (5)	***59.3***	*22.5-83.8*	**63.0**	30.0-85.0	**63.8**	31.3-85.0	= (2)
Plant								
CEU	26 (26)	**35.5**	2.8-96.5	**49.1**	7.0-100	**48.4**	11.3-100	> (1), = (23), < (2)

Registration or EPPO climatic zone	No. of trials (No. of data points)	*Untreated*		FGF11 1.0 L/ha		Proline* 0.8 L/ha		Statistical comparison of FGF11 to SRP#
		Mean	*Min-max*	Mean	Min-max	Mean	Min-max	
EPPO MAR	4 (4)	***32.8***	*2.8-81.3*	**40.3**	7.0-86.3	**38.8**	12.5-85.0	> (1), = (2), < (1)
EPPO NE	11 (11)	***30.7***	*7.5-96.5*	**42.0**	12.5-100	**41.6**	11.3-100	= (11)
EPPO SE	11 (11)	***41.4***	*10.0-91.5*	**59.5**	32.5-91.5	**58.6**	30.0-91.8	= (10), < (1)

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.2-6
No. of trials where >, = or <, based on statistically significant differences at 95% confidence level

FGF11 applied at the proposed label rate of 1.0 L product/ha increased green leaf area on the upper leaves and on a whole plant leaf area basis in great majority of the trials compared to the untreated control. The effects were statistically significant in the majority of cases. These increases produced by FGF11 were generally comparable to those produced by the standard reference products applied at label rates.

These increases in green leaf area were a direct function of the efficacy of FGF11 against the target disease that developed in the trials and the direct effects of disease having prematurely reduced green leaf area in the untreated control.

These increases in green leaf persistence produced by FGF11 applied at the proposed label rate of 1.0 L product/ha therefore provide supplementary evidence in support of label claims for control of FUSASP in winter wheat.

Comments of zRMS:

Green leaf area was evaluated in winter wheat in 28 efficacy trials. In case of either leaves (1-3) and plant, the increase of mean overall green leaf area was visible after an application of FGF11 at 1 l/ha in all EPPO climatic zone. No statistical differences between test product and Proline at 0,8 l/ha were observed in most of trials.

3.2.3.5.3 Positive effects on crop yield and quality in efficacy trials

Evaluations of crop yield were carried out on all 40 trials carried out in 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against FUSASP in winter wheat. Of these trials, 10 were carried out in the Maritime EPPO climatic zone (1 in Denmark, 2 in Germany, 3 in Ireland, 1 in the United Kingdom, 3 in France), 15 were carried out in the North-east EPPO climatic zone (2 in Latvia, 1 in Lithuania, 12 in Poland) and 15 were carried out in the South-east EPPO climatic zone (5 in Bulgaria, 4 in Hungary, 6 in Romania).

Evaluations of quality of grain sampled at harvest were also carried out on all 40 trials, with hectolitre weight (HLW) determined on all trials, thousand grain weight (TGW) determined on 22 of the trials and mycotoxin content determined on 17 of the trials.

An overall summary of mean crop yield and grain quality data (expressed as % relative to the untreated control) across trials in each of the climatic zones is given in Table 3.2-90.

Table 3.2-90: Mean overall crop yield and grain quality data (expressed as % relative to the untreated control) following an application of FGF11 at the proposed label rate of 1.0 L product/ha across trials in all climatic zones that generated data on efficacy against FUSASP in winter wheat

Registration or EPPO climatic zone	No. of trials	*Untreated*	FGF11 1.0 L/ha		Proline* 0.8 L/ha		Statistical comparison of FGF11 to SRP#
		Mean	Mean	Min-max	Mean	Min-max	
Grain yield							
CEU	40	100.0	**107.8**	97.3-141.3	**107.0**	95.0-139.8	> (2), = (38)
EPPO MAR	10	100.0	**107.6**	99.9-141.3	**108.4**	100.0-139.8	= (10)

Registration or EPPO climatic zone	No. of trials	*Untreated*	FGF11		Proline*		Statistical comparison of FGF11 to SRP#
			1.0 L/ha		0.8 L/ha		
		Mean	Mean	Min-max	Mean	Min-max	
EPPO NE	15	100.0	**108.0**	97.3-122.7	**105.2**	95.0-114.1	> (1), = (14)
EPPO SE	15	100.0	**107.8**	100.7-120.7	**107.9**	98.0-123.2	> (1), = (14)
TGW							
CEU	22	100.0	**103.1**	94.0-114.3	**102.9**	95.6-112.7	= (22)
EPPO MAR	3	100.0	**101.2**	96.9-105.0	**100.7**	95.6-104.1	= (3)
EPPO NE	13	100.0	**103.5**	94.0-114.3	**103.2**	97.6-112.7	= (13)
EPPO SE	6	100.0	**103.1**	99.6-107.1	**103.4**	99.9-109.2	= (6)
HLW							
CEU	40	100.0	**102.1**	98.8-121.3	**101.9**	99.1-122.0	> (1), = (39)
EPPO MAR	10	100.0	**104.1**	99.5-121.3	**104.1**	99.7-122.0	= (10)
EPPO NE	15	100.0	**101.7**	99.3-104.9	**101.2**	99.4-104.5	> (1), = (14)
EPPO SE	15	100.0	**101.3**	98.8-103.9	**101.3**	99.1-103.2	= (15)
Mycotoxin content							
CEU	17	100.0	**20.5**	0.0-91.0	**22.0**	0.0-107.0	n/a
EPPO MAR	4	100.0	**23.0**	15.8-35.1	**19.3**	11.5-27.3	n/a
EPPO NE	8	100.0	**7.7**	1.4-19.4	**8.2**	3.1-21.2	n/a
EPPO SE	5	100.0	**39.1**	0.0-91.0	**46.4**	0.0-107.0	n/a

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.2-6
No. of trials where >, = or <, based on statistically significant differences at 95% confidence level. As analysis of mycotoxin was performed on bulked samples, statistic is not available.

FGF11 applied at the proposed label rate of 1.0 L product/ha increased crop yield compared to the untreated control on 34 of the 40 trials, with the increases being statistically significant on 15 of the trials. These increases produced by FGF11 were generally comparable to those produced by the standard reference product applied at label rate.

Where evaluations of grain quality were carried out on these trials, FGF11 applied at the proposed label rate of 1.0 L product/ha increased TGW compared to the untreated control on 17 of the 22 trials where this quality parameter was assessed, with differences being statistically significant in 6 trials, and HLW in 23 of the 40 trials where this quality parameter was assessed, with differences being statistically significant in 10 trials. These increases produced by FGF11 were generally comparable to those produced by the standard reference product applied at label rate.

Where evaluation of mycotoxin content was carried out on 17 of the trials, FGF11 applied at the proposed label rate of 1.0 L product/ha reduced mycotoxin content on all trials where this quality parameter was assessed. These reductions produced by FGF11 were generally comparable to those produced by the standard reference product applied at label rate.

These increases in yield, TGW and HLW and reductions in mycotoxin content given by both FGF11 and the standard reference products can be considered to be a direct function of control of the FUSASP occurring in the trials and their adverse effects on yield in the untreated control.

These increases in yield, TGW and HLW and reductions in mycotoxin content produced by FGF11 applied at the proposed label rate of 1.0 L product/ha therefore provide further evidence in support of label claims for control of FUSASP in wheat.

Comments of zRMS:

40 efficacy trials have been submitted to determine the impact of FGF11 on crop yield of winter wheat. The increase in crop yield was visible in all EPPO climatic zone: 107,6% in the MAR zone, 108% in the NE zone and 107,8% in the SE zone. No statistical differences between FGF11 and the reference product Proline at 0,8 l/ha were observed in most of trials. Moreover, the increases have been noted also in case of quality parameter: TGW and HLW. The evaluation of mycotoxin content was conducted in 17 out of 40 trials. FGF11 at 1 l/ha

reduced mycotoxin content on comparable level to the reference product. Taking into account all results, no negative effect of test product on the quantity and quality of winter wheat yield was found in any EPPO zone.

3.3 Information on the occurrence or possible development of resistance or cross-resistance (KCP 6.3)

FGF11 contains two active ingredients, azoxystrobin and prothioconazole, both of which have fungicidal activity against various diseases in cereals and oilseed rape and different modes of action target sites.

azoxystrobin

Azoxystrobin is a Quinone outside inhibitor (QoI) fungicide belonging to the FRAC Mode of Action group C3 (FRAC code 11). It acts at the Quinone 'outside' (Qo) binding site of the cytochrome bc1 complex. Strobilurins and related compounds inhibit mitochondrial respiration by binding to the ubiquinol oxidation (Qo) site formed by domains of cytochrome b and the iron-sulphur protein within the cytochrome bc1 complex. Because ATP production is compromised, energy-demanding stages of fungal development, such as spore germination, are particularly affected.

The Qo inhibitors (QoIs) have become a key component of disease control strategies on cereals in Europe due to their persistent broad-spectrum disease control and potential extra yield benefits through increased green canopy duration.

prothioconazole

Prothioconazole belongs to DMI (demethylation-inhibiting) fungicide in FRAC Mode of Action group G1 (FRAC code 3), a Mode of Action group within the Sterol Biosynthesis Inhibitors (SBI). The mode of action of prothioconazole and other DMI fungicides is to block sterol biosynthesis by inhibiting the Cytochrome P450-dependent C-14 demethylase reaction leading to a reduction in the normal sterol pathway end products and an accumulation of abnormal sterols. This includes effects on the synthesis of ergosterol, an important structural component of many fungal cell membranes, thereby interfering with synthesis of new membranes needed for cell growth. It is not clear which of the two effects (reduction in sterol production or accumulation of abnormal sterols) is primarily responsible for the impairment of membrane function and limitation of fungal growth.

Prothioconazole is a systemic fungicide with long-lasting preventative, curative and eradicative activity, which is quickly absorbed into plant tissue and then moves up through the plant. A range of commercially available products containing prothioconazole are currently approved and widely used in EU countries for application as foliar applied sprays or as seed treatments for broad spectrum control of fungal pathogens in cereals and oilseed rape.

Evidence of resistance

azoxystrobin

Recorded cases of resistance to QoI fungicides in cereals (MoA group C3, FRAC code 11) are listed in Table 3.3-1 (EPPO Database on Resistance Cases, June 2024, FRAC list of first confirmed cases of plant pathogenic organisms resistant to disease control agents, May 2020) . No resistance in oilseed rape has been reported until now.

Table 3.3-1: Recorded cases of resistance to QoI fungicides (EPPO Database on Resistance Cases, June 2024, FRAC list of first confirmed cases of plant pathogenic organisms resistant to disease control agents, May 2020)

Pathogen	MoA code	Active substance(s)	Crop	Reference	Mechanism of resistance	Occurrence	Year of first detection	Frequency	Resistance factor	Relevance of r. in the field	Comments
Alternaria alternata	C3-11	-	Pistachio	Ma et al. 2003 Avenot & Michallides (2007)							field / laboratory field
		-	Apple	Ishii 2008							field
		-	Citrus	Mondal et al. 200							field
		-	Potato Tomato	FRAC 2011 FRAC 2016							field, G143A, Europe
Alternaria arborescens	C3-11		Pistacho	Ma et al. 2003							Field/laboratory
Alternaria mali	C3-11		Apple	Lu et al. 2003							field
Alternaria solani	C3-11		Potato	Pasche et al.2002, 2004, Pasche et al. 2005 Pasche & Gudmestad 2008							field resistance mechanism fitness of F129L
Alternaria tenuissima	C3-11		Pistacho	Ma et al. 2003							field / laboratory
Ascochyta rabiei	C3-11		Chickpea	Wise et al. 2009							field. Northern Great Plains / Pacific N West
Blumeria graminis, see Erysiphe graminis	C3-11										
Blumeria graminis	C3-11	**Azoxystrobin**, Dimoxystrobin, Famoxadone, Fenamidone, Fluoxastrobin, Kresoxim-methyl, Mandestrobin, Metominostrobin, Orysastrobin, Picoxystrobin, Pyraclostrobin, Trifloxystrobin, Flufenoxystrobin, Fenaminstrobin, Enoxastrobin, Coumoxystrobin, Triclopyricarb, Pyribencarb, Pyraoxystrobin, Pyrametostrobin	Soft wheat	Walker, A.-S., & Leroux, P. (2003)	TSR cytb-G143A	High	2002	Very high	High	Severe impact	
Blumeria graminis	C3-11	**Azoxystrobin**, Dimoxystrobin, Famoxadone, Fenamidone, Fluoxastrobin, Kresoxim-methyl, Mandestrobin, Metominostrobin,	Barley	Walker, A.-S., & Leroux, P. (2003) Walker, A.-S., et al. (2004)	TSR cytb-G143A	High	2002	Very high	High	Severe impact	Test type: Bioassay

Pathogen	MoA code	Active substance(s)	Crop	Reference	Mechanism of resistance	Occurrence	Year of first detection	Frequency	Resistance factor	Relevance of r. in the field	Comments
		Orysastrobin, Picoxystrobin, Pyraclostrobin, Trifloxystrobin, Flufenoxystrobin, Fenaminstrobin, Enoxastrobin, Coumoxystrobin, Triclopyricarb, Pyribencarb, Pyraoxystrobin, Pyrametostrobin		Walker, A.-S., et al. (2006)							

Pathogen	MoA code	Active substance(s)	Crop	Reference	Mechanism of resistance	Occurrence	Year of first detection	Frequency	Resistance factor	Relevance of r. in the field	Comments
Botrytis cinerea	C3-11		Strawberry	Markoglou et al. 2006 FRAC 2007 Ishii 2008 Bardas et al. 2010 FRAC 2015							mutation study Field, G143A, Germany Field, Japan Multiple resistance
			Kiwi fruit								
			Grapes, soft fruit								
Cercospora beticola	C3-11		Sugar beet	Keshav Burla et al. 2012 Bolton et al. 2013							Field G143A Italy Field G143A USA
Cercospora kikuchii	C3-11		Soybeans	Price, P.P III et.al. 2015							Field G143A USA
Cercospora sojina	C3-11		Soybeans	FRAC 2011							Field G143A USA
Colletotrichum graminicola	C3-11		Annual bluegrass / bent grass	Avila-Adame et al. 2003							field
Colletotrichum gloeosporioides	C3-11		Strawberry	Ishii 2008							field
Corynespora cassiicola	C3-11		Cucumber	Ishii 2004 FRAC Brazil G143A 2012							field field
Didymella bryoniae	C3-11		Cucurbits Watermelon	Olaya & Holm 2001 Langston 2002 Stevenson et al. 2002							field field field
Didymella rabiei	C3-11		Chickpea	Gossen & Anderson 2004							field
Erysiphe graminis tritici	C3-11		Wheat	Heaney et al. 2000 Sierotzki et al. 2000a							field resistance mechanism
Erysiphe graminis hordei	C3-11		Barley	Heaney et al. 200							field
Erysiphe necator: see also	C3-11										

Pathogen	MoA code	Active substance(s)	Crop	Reference	Mechanism of resistance	Occurrence	Year of first detection	Frequency	Resistance factor	Relevance of r. in the field	Comments
Uncinula necator											
Fusarium graminearum	C3-11	Trifloxystrobin	Soft wheat (winter)	Dubos, T., et al. (2011)	natural	Moderate	2007	Low	High	Severe impact	
Fusicladium carpophilum	C3-11		Almond	Foerster et al. 2009 Luo et al. 2013							California orchards
Glomerella cingulata (Colletotrichum gloeosporioides)	C3-11		Strawberry	Ishii 2004							
Magnaporthe oryzae	C3-11		Lolium perenne (perennial ryegrass)	Ma & Uddin 2009							Study on 1 field isolate
Microdochium nivale	C3-11	**Azoxystrobin**, Dimoxystrobin, Famoxadone, Fenamidone, Fluoxastrobin, Kresoxim-methyl, Mandestrobin, Metominostrobin, Orysastrobin, Picoxystrobin, Pyraclostrobin, Trifloxystrobin, Flufenoxystrobin, Fenaminstrobin, Enoxastrobin, Coumoxystrobin, Triclopyricarb, Pyribencarb, Pyraoxystrobin, Pyrametostrobin	Soft wheat	Walker, A. S., et al. (2009) Leroux, P., & Walker, A.-S. (2009b)	TSR cytb-G143A	High	2007	High	High	Severe impact	Test type: Bioassay
Microdochium nivale	C3-11		Wheat	FRAC 2011							FRAC Japan report
Microdochium spp.	C3-11		CeStempeals	FRAC 2008							field, France, G143A confirmed
Monilinia laxa M. fructigena M. fructicola	C3-11		Fruit	Meissner & Stammler 2010							Not resistance but evidence of an intron
Mycosphaerella fijiensis	C3-11		Banana	Heaney et al. 2000 Sierotzki et al. 2000b Chin et al. 2001							field resistance mechanism field
Mycosphaerella graminicola See also Septoria tritici	C3-11		Wheat	Armand et al. 2003 Clark 2005 Fraaije et al. 2005 Gisi et al. 2005							field field, review field field

Pathogen	MoA code	Active substance(s)	Crop	Reference	Mechanism of resistance	Occurrence	Year of first detection	Frequency	Resistance factor	Relevance of r. in the field	Comments
Mycovellosiella nattrassii	C3-11		Eggplant / aubergine	Yano & Kawada 2003 Ishii 2004							field / laboratory field
Pestalotiopsis longiseta	C3-11		Tea	Omatsu et al. 2012							field
Phaeosphaeria nodorum	C3-11		Wheat	Blixt et al. 2009							field, molecular data
Phakopsora pachyrhizi	C3-11		Soybean	Klosowski et al. 2015							field
Pseudoperonospora cubensis	C3-11		Cucumber	Heaney et al. 2000							field
Plasmopara viticola	C3-11		Grapevine	Heaney et al. 2000 Gullino et al. 2004 Sierotzki et al. 2005							field review
Podosphaera fusca	C3-11		Cucumber	Ishii et al. 2001 Fernandez-Ortuno et al. 2006 Fernandez-Ortuno et al. 2008							Field Resistance mechanism
Podosphaera xanthii	C3-11		Cucurbits	McGrath & Shishkoff 2003a, b							field trial
Pseudocercospora vitis	C3-11		Grapevines	Kikuhara et al. 2014							Greenhouse /field
Pseudoperonospora cubensis	C3-11		Cucumber	Heaney et al. 2000 Ishii et al. 2001							field
Pyrenophora teres	C3-11		Barley	FRAC Semar et al. 2007							field molecular analysis (F129L)
Pyrenophora teres	C3-11	**Azoxystrobin**, Dimoxystrobin, Famoxadone, Fenamidone, Fluoxastrobin, Kresoxim-methyl, Mandestrobin, Metominostrobin, Orysastrobin, Picoxystrobin, Pyraclostrobin, Trifloxystrobin, Flufenoxystrobin, Fenaminstrobin, Enoxastrobin, Coumoxystrobin, Triclopyricarb, Pyribencarb, Pyraoxystrobin, Pyrametostrobin	Barley	Maumene, C., et al. (2009) Rehfus, A., et al. (2016) ARVALIS, Anses, Inrae. (2022)	TSR cytb-F129L	High	2005	Moderate	Variable	Moderate impact	

Pathogen	MoA code	Active substance(s)	Crop	Reference	Mechanism of resistance	Occurrence	Year of first detection	Frequency	Resistance factor	Relevance of r. in the field	Comments
Pyrenophora tritici-repentis	C3-11	**Azoxystrobin**, Fluoxastrobin, Picoxystrobin, Pyraclostrobin, Trifloxystrobin	Soft wheat	FRAC & Blixt, Eva (2009)	3 specific mutations - Mutation G143A in cyt b	High	2009	High	High	Moderate impact	
Pyrenophora tritici-repentis	C3-11	**Azoxystrobin**, Dimoxystrobin, Famoxadone, Fenamidone, Fluoxastrobin, Kresoxim-methyl, Mandestrobin, Metominostrobin, Orysastrobin, Picoxystrobin, Pyraclostrobin, Trifloxystrobin, Flufenoxystrobin, Fenaminstrobin, Enoxastrobin, Coumoxystrobin, Triclopyricarb, Pyribencarb, Pyraoxystrobin, Pyrametostrobin	Soft wheat	FRAC. (2022) ARVALIS, Anses, Inrae (2022)	TSR cytb-G143A and cytb-F129L	Unknown	2008	Unknown	Variable	No impact	Test type: Bioassay
Pyrenophora tritici-repentis	C3-11		Wheat	Reimann & Deising 2005 FRAC							field field
Pyricularia grisea	C3-11		Perennial ryegrass	Vincelli & Dixon 2002 Kim et al. 2003							Field field / resistance mechanism
Pyricularia oryzae	C3-11		Rice	FRAC Japan							field (G143A)
Pythium aphanidermatum	C3-11		Turf	Gisi et al. 2002 Olaya et al. 2003							laboratory field / resistance mechanism
Ramularia collo-cygni	C3-11		Barley	FRAC 2006							field
Ramularia collo-cygni	C3-11	**Azoxystrobin**, Dimoxystrobin, Famoxadone, Fenamidone, Fluoxastrobin, Kresoxim-methyl, Mandestrobin, Metominostrobin, Orysastrobin, Picoxystrobin, Pyraclostrobin, Trifloxystrobin, Flufenoxystrobin, Fenaminstrobin, Enoxastrobin, Coumoxystrobin, Triclopyricarb, Pyribencarb, Pyraoxystrobin, Pyrametostrobin	Barley	Matusinsky, P., et al. (2010) ARVALIS, Anses, Inrae. (2022)	TSR cytb-G143A	Very high	2007	Very high	High	Severe impact	Test type: Bioassay, High-throuput molecular assay
Rhizoctonia solani			Potato	Djebali et al. 2014							field, F129L

Pathogen	MoA code	Active substance(s)	Crop	Reference	Mechanism of resistance	Occurrence	Year of first detection	Frequency	Resistance factor	Relevance of r. in the field	Comments
Rhizoctonia solani			Rice	FRAC 2011							field, F129L, USA
Rhynchosporium secalis	C3-11	**Azoxystrobin**, Dimoxystrobin, Famoxadone, Fenamidone, Fluoxastrobin, Kresoxim-methyl, Mandestrobin, Metominostrobin, Orysastrobin, Picoxystrobin, Pyraclostrobin, Trifloxystrobin, Flufenoxystrobin, Fenaminstrobin, Enoxastrobin, Coumoxystrobin, Triclopyricarb, Pyribencarb, Pyraoxystrobin, Pyrametostrobin	Barley	Phelan, S. (2017) ARVALIS, Anses, Inrae (2022)	TSR cytb-G143A	Isolated cases	2012	Low	High	No impact	Test type: Bioassay, High-throuput molecular assay
Rhynchosporium secalis	C3-11		Barley	FRAC 2008							field, single isolate, Picardie field, single isolate, Picardie
Saccharomyces cerevisiae	C3-11			Di Rago et al. 1989							resistance mechanism
Septoria nodorum, see Sphaeosphaeria nodorum	C3-11										
Septoria tritici See also Mycosphaerella graminicola and Zymoseptoria tritici	C3-11		Wheat	Fraaije & Lucas 2003							field
Sphaerotheca aphanis var. aphanis	C3-11		Strawberry	Ishii 2008							field
Sphaerotheca fuligenea	C3-11		Cucumber	Heaney et al. 2000 Ishii et al. 2001							field
Stemphylium vesicarium	C3-11		Pears	FRAC 2006 Alberoni et al. 2010a							field
Stemphylium vesicarium	C3-11		Asparagus	FRAC 2006							field
Uncinula necator (see also Erysiphe necator)	C3-11		Grapevine	Wilcox et al. 2003							field

Pathogen	MoA code	Active substance(s)	Crop	Reference	Mechanism of resistance	Occurrence	Year of first detection	Frequency	Resistance factor	Relevance of r. in the field	Comments
Ustilago maydis	C3-11		Maize	Ziogas et al. 2002							laboratory mutants
Venturia inaequalis	C3-11		Apple	Zheng et al. 2000 Farber et al. 2002 Steinfeld et al. 2002 Dux et al. 2005							laboratory mutants field trial field field
Zymoseptoria tritici	C3-11	**Azoxystrobin**, Dimoxystrobin, Famoxadone, Fenamidone, Fluoxastrobin, Kresoxim-methyl, Mandestrobin, Metominostrobin, Orysastrobin, Picoxystrobin, Pyraclostrobin, Trifloxystrobin, Flufenoxystrobin, Fenaminstrobin, Enoxastrobin, Coumoxystrobin, Triclopyricarb, Pyribencarb, Pyraoxystrobin, Pyrametostrobin	Soft wheat	Leroux, P., et al. (2006) Leroux, P., et al. (2006b) Leroux, P., et al. (2007) Leroux, P., & Walker, A.-S. (2009a) Leroux, P., & Walker, A.-S. (2011) Garnault, M., et al. (2019)	TSR cytb-G143A + NTSR efflux (MDR)	Very high	2003	Very high	High	Severe impact	
Zymoseptoria tritici	C3-11		Wheat	Hayes et al. 2013							field

prothioconazole

Recorded cases of resistance to DMI fungicides in cereals (MoA group G1, FRAC code 3) are listed in Table 3.3-2 (EPPO Database on Resistance Cases, June 2024, FRAC list of first confirmed cases of plant pathogenic organisms resistant to disease control agents, May 2020).

Table 3.3-2: Recorded cases of resistance to DMI fungicides (EPPO Database on Resistance Cases, June 2024, FRAC list of first confirmed cases of plant pathogenic organisms resistant to disease control agents, May 2020)

Pathogen	MoA code	Active substance(s)	Crop	Reference	Mechanism of resistance	Occurrence	Year of first detection	Frequency	Resistance factor	Relevance of r. in the field	Comments
Aspergillus nidulans	G1-3		-	De Waard & van Nistelrooy 1979							genetic study
Blumeriella jaapii	G1-3		Cherry	Proffer et al. 2006							field
Blumeria graminis	G1-3	Cyproconazole, Epoxiconazole, Flutriafol, Metconazole, Prochloraz, Propiconazole, **Prothioconazole**, Tebuconazole, Tetraconazole	Soft wheat	Walker, A.-S., & Leroux, P. (2003) Walker, A.-S., et al. (2004) Walker, A.-S., et al. (2006) Delye, C., et al. (1998) Wyand, R. A., & Brown, J. K. M. (2005)	TSR cyp51-Y137F	High	1990	High	Variable	Minimal impact	Test type: Bioassay
Blumeria graminis	G1-3	Tebuconazole	Soft wheat (winter)	FRAG-UK list of known UK resistant pathogens March 2012		Unknown		High	Unknown	Severe impact	
Blumeria graminis f. sp. hordei	G1-3	Cyproconazole, Epoxiconazole, Flutriafol, Metconazole, Prochloraz, Propiconazole, **Prothioconazole,** Tebuconazole, Tetraconazole	Barley	Walker, A.-S., et al. (2004) Walker, A.-S., et al. (2006) Delye, C., et al. (1998) Wyand, R. A., & Brown, J. K. M. (2005)	TSR cyp51-Y137F +/- cyp51-K147Q	High	1990	High	Variable	Minimal impact	Test type: Bioassay
Blumeria graminis f. sp. hordei	G1-3	Tebuconazole	Barley	FRAG-UK list of known UK resistant pathogens March 2012		Unknown		Unknown	Unknown	Severe impact	
Botryosphaeria dothidea	G1-3		-	Fan Kun et al. 2013							Laboratory
Botrytis cinerea	G1-3		Vegetables Various	Elad 1992 Stehmann & De Waard 1996							field laboratory investigation of lack of intrinsic activity
Calonectria pauciramosa	G1-3		Nurseries	Guarnaccia et al. 2014							Field
Calonectria polizzii	G1-3		Nurseries	Guarnaccia et al. 2014							Field

Pathogen	MoA code	Active substance(s)	Crop	Reference	Mechanism of resistance	Occurrence	Year of first detection	Frequency	Resistance factor	Relevance of r. in the field	Comments
Cercospora beticola	G1-3		Sugar beet	Henry & Trivellas 1989 Karaoglanidis et al. 2000 Budakov et al. 2014							Laboratory mutants Field isolates Field
Cladosporium caryigenum	G1-3		Pecan,	Reynolds et al. 1997 cross resistance							laboratory
Colletotrichum gloeosporioides	G1-3		Mango	Gutierrez-Alonso et al. 2003							postharvest / laboratory
Erysiphe graminis f.sp. hordei	G1-3		Barley	Fletcher & Wolfe 1981							field
Erysiphe graminis f.sp. tritici	G1-3		Wheat	De Waard et al. 1986							field
Fusarium asiaticum *Fusarium graminearum*	G1-3		Wheat	Yin et al. 2009							Lab study on isolates from China
Fusarium culmorum	G1-3	Epoxiconazole, Tebuconazole	Soft wheat (winter)	Hellin, P., et al. (2017) Hellin P, et al. (2018)	transporter (FcABC1) upregulation	Isolated cases		Isolated individuals	Medium	Unknown	bioassay and transcriptomic analysis
Fusarium graminearum	G1-3	**Prothioconazole**, Tebuconazole	Soft wheat	ARVALIS, Anses, Inrae (2022)	TSR several mutations on genes encoding Cyp51A and Cyp51 B; evidence of unknown NTSR	High	2020	Unknown	Variable	Moderate impact	Test type: Bioassay, Standard molecular assay
Fusarium graminearum	G1-3		Wheat	Spolti et al. 2014							Field
Fusarium fujikuroi	G1-3		-	Zhao Zhi-hua et al. 2007							Laboratory mutation (prochloraz)
Fusarium monilifore	G1-3		Rice	Yanh HongFu et al. 2013							Field
Fusarium solani. See Nectria haematococca var. cucurbiae	G1-3		Cucurbits	Kalamarakis et al.1991							genetic study

Pathogen	MoA code	Active substance(s)	Crop	Reference	Mechanism of resistance	Occurrence	Year of first detection	Frequency	Resistance factor	Relevance of r. in the field	Comments
Fusarium verticillioides	G1-3		Corn	Fan et al. 2014							Laboratory
Microdochium majus	G1-3	**Prothioconazole**, Tebuconazole	Soft wheat	ARVALIS, Anses, Inrae. (2022). Note Technique commune Maladies des céréales à pailles. https://www.r4p-inra.fr/fr/notes-communes/	TSR several mutations on genes encoding Cyp51A and Cyp51 B; evidence of unknown NTSR	High	2020	Unknown	Variable	Moderate impact	Test type: Bioassay, Standard molecular assay
Microdochium (Fusarium) nivale	G1-3		-	Cristani & Gambogi 1993							Laboratory

Pathogen	MoA code	Active substance(s)	Crop	Reference	Mechanism of resistance	Occurrence	Year of first detection	Frequency	Resistance factor	Relevance of r. in the field	Comments
Microdochium nivale	G1-3	**Prothioconazole**, Tebuconazole	Soft wheat	ARVALIS, Anses, Inrae (2022)	TSR several mutations on genes encoding Cyp51A and Cyp51 B; evidence of unknown NTSR	High	2020	Unknown	Variable	Moderate impact	Test type: Bioassay, Standard molecular assay
Monilinia fructicola	G1-3		Stone fruit	Nuninger-Ney et al. 1989 Elmer et al. 1992 Chen et al. 2013							Laboratory Field Field
Mycosphaerella fijiensis	G1-3		Banana	Anonymous 1992							
Mycosphaerella graminicola	G1-3		Wheat	Metcalfe et al. 2000 Mavroedi & Shaw 2005 HGCA 2005 Cools et al. 2005							field experiments field experiments field laboratory
Mycovellosiella nattrassii	G1-3		Eggplant	Yamaguchi et al. 2000							field
Nectria haematococca var. cucurbiae	G1-3		Cucurbits	Kalamarakis et al. 1991							laboratory genetics
Oculimacula acuformis	G1-3	Epoxiconazole, Prochloraz, Propiconazole, **Prothioconazole**, Tebuconazole, Tetraconazole	Cereal crops	Leroux, P., et al. (2006a) Albertini, C., et al. (2003). Durand, T., et al. (2015) Leroux, P., & Walker, A.-S. (2009a) Leroux, P., et al. (2013)	TSR?	High	1990	High	Variable	Severe impact	Test type: Bioassay
Oculimacula yallundae	G1-3	Epoxiconazole, Prochloraz, Propiconazole, **Prothioconazole**, Tebuconazole, Tetraconazole	Cereal crops	Leroux, P., et al. (2006a) Albertini, C., et al. (2003) Durand, T., et al. (2015) Leroux, P., & Walker, A.-S. (2009a) Leroux, P., et al. (2013)	TSR? + NTSR efflux (MDR)	High	1991	High	Variable	Severe impact	Test type: Bioassay

Pathogen	MoA code	Active substance(s)	Crop	Reference	Mechanism of resistance	Occurrence	Year of first detection	Frequency	Resistance factor	Relevance of r. in the field	Comments
Penicillium digitatum	G1-3		Citrus	Eckert 1987 Wang Jinlong et al. 2014							Laboratory selection Storage
Penicillium italicum	G1-3		-	De Waard et al. 1982							laboratory
Phakopsora pachyrhizi	G1-3		Soybeans	Schmitz et al. 2014							field
Pseudocercosporella herpotrichoides Lente or R type	G1-3		Wheat	Leroux & Marchegay 1991							field
Puccinia horiana	G1-3		Chrysanthemum	Cevat 1992 Cook 2001							field field
Puccinia striiformis	G1-3		Wheat	Bayles et al. 2000 Napier et al. 2000							sensitivity shift laboratory
Puccinia triticina	G1-3	**Prothioconazole**, Tebuconazole	Soft wheat	Stammler, G., et al. (2009)	Cyp51 Y134F substitution detected in 5 isolates. Low impact. Cyp51 overexpression	Unknown	2009	Unknown	Variable	No impact	Test type: Bioassay, Standard molecular assay
Pyrenopeziza brassicae	G1-3		Oilseed Rape	Carter et al.2014							Field
Pyrenophora teres	G1-3		Barley	Sheridan et al. 1985							field
Pyrenophora teres	G1-3	Cyproconazole, Difenoconazole, Epoxiconazole, Metconazole, Prochloraz, Propiconazole, **Prothioconazole**, Tebuconazole	Barley	Mair, W. J., et al. (2016) ARVALIS, Anses, Inrae (2022)	TSR mutations not described	Unknown	1990	Unknown	Variable	Moderate impact	Test type: Bioassay
Pyrenophora tritici-repentis	G1-3		Wheat	Reimann & Deising 2005							field
Rhizoctonia solani	G1-3		Rice	Manish Agrawal et al. 2013							Field
Ramularia collo-cygni	G1-3	Bromuconazole, Cyproconazole, Difenoconazole, Epoxiconazole,	Barley	ARVALIS, Anses, Inrae (2022) Rehfus, A., et al. (2019) Kiiker, R., et al. (2021)	TSR: several combinations of mutations in cyp51	Unknown	2016	Variable	High	Moderate impact	Test type: Bioassay, High-throuput molecular assay

Pathogen	MoA code	Active substance(s)	Crop	Reference	Mechanism of resistance	Occurrence	Year of first detection	Frequency	Resistance factor	Relevance of r. in the field	Comments
		Flutriafol, Metconazole, Prochloraz, Propiconazole, **Prothioconazole,** Tebuconazole, Tetraconazole, mefentrifluconazole			including I32T, I328L, Y403C/N or Y405H						
Ramularia collo-cygni	G1-3	**Prothioconazole**	Barley	FRAC	shifting	Moderate	2016	Moderate	High	Minimal impact	
Ramularia collo-cygni	G1-3	**Prothioconazole**	Barley	Minutes of the 2020 SBI Meeting Recommendations for 2020	shifting	Low		Low	Unknown	Minimal impact	
Ramularia collo-cygni	G1-3	**Prothioconazole**	Barley	FRAC	Shifting	Moderate	2016	Moderate	High	Minimal impact	
Ramularia collo-cygni	G1-3	**Prothioconazole**	Barley	Expert knowledge meetings and FRAC	Shifting	Low	2016	Low	Unknown	Minimal impact	
Rhynchosporium secalis	G1-3		Barley	Hunter et al. 1986 Kendall & Hollomon 1990 Kendall et al. 1993 Cooke et al. 2004							Glasshouse field Field isolates field
Rhynchosporium secalis	G1-3	Cyproconazole, Epoxiconazole, Prochloraz, Propiconazole, **Prothioconazole**, Tebuconazole	Barley	Robbertse, B., et al. (2001) Brunner, P. C., et al. (2016)	TSR	Unknown	1990	Unknown	Medium	No impact	Test type: Bioassay
Rhynchosporium secalis	G1-3	Tebuconazole	Barley	FRAG-UK list of known UK resistant pathogens March 2012		Unknown		Unknown	Unknown	Severe impact	
Sclerotinia homoeocarpa	G1-3		- Turfgrass	Vargas et al. 1992 Ma & Tredway 2013							Laboratory Field
Septoria tritici	G1-3										See *Mycosphaerella graminicola*
Sphaerotheca fuligenea	G1-3		Cucumber	Schepers 1983, 1985a, 1985b							field
Sphaerotheca mors-uvae	G1-3		Blackcurrant	Goszczynski et al. 1988							field

Pathogen	MoA code	Active substance(s)	Crop	Reference	Mechanism of resistance	Occurrence	Year of first detection	Frequency	Resistance factor	Relevance of r. in the field	Comments
Sphaerotheca pannosa	G1-3		Nectarine	Reuveni 2001							field
Trichoderma koningii	G1-3		-	Figueras-Roca et al. 1996							Laboratory
Uncinula necator	G1-3		Grapevine	Steva et al. 1990 Reidi & Steinkellner 1996 Miller & Gubler 2003							field field field
Ustilago avenae	G1-3		Oats	Hippe & Koller 1986							laboratory
Ustilago maydis	G1-3		Maize	Walsh & Sisler 1981							laboratory
Venturia inaequalis	G1-3		Apple	Stanis & Jones 1985; Köller et al. 1991							field laboratory
Venturia nashicola	G1-3		Pear	Tomita & Ishii 1998							field
Zymoseptoria tritici	G1-3	Bromuconazole, Cyproconazole, Difenoconazole, Epoxiconazole, Flutriafol, Metconazole, Prochloraz, Propiconazole, **Prothioconazole**, Tebuconazole, Tetraconazole, mefentrifluconazole	Soft wheat	Leroux, P., et al. (2006b) Leroux, P., et al. (2006) Leroux, P., et al. (2007) Leroux, P., & Walker, A.-S (2009a) Leroux, P., & Walker, A.-S (2011) Omrane, S., et al. (2015) Garnault, M., et al. (2019) ARVALIS, Anses, Inrae (2022)	TSR (combinations of many mutations in cyp51 + overexpression) + NTSR (efflux MDR, at least 3 genotypes)	Very high	1990	Very high	Variable	Moderate impact	Test type: Bioassay, High-throuput molecular assay
Zymoseptoria tritici	G1-3	Epoxiconazole, Metconazole, Prochloraz, Prothioconazole, Tebuconazole	Soft wheat (winter)	Curvers, K., et al. (2014)	combination of mutliple alterations	Very high		Very high	High	Moderate impact	bioassay and DNA sequencing
Zymoseptoria tritici	G1-3	Difenoconazole, Epoxiconazole, Metconazole, Propiconazole, Tebuconazole	Soft wheat	Heick TM, et t al. (2017)	Shifting	High	2014	High	High	Minimal impact	
Zymoseptoria tritici	G1-3	Tebuconazole	Soft wheat (winter)	FRAG-UK list of known UK resistant pathogens March 2012	many CYP51 mutations plus Efflux	Unknown		High	Unknown	Severe impact	

Pathogen	MoA code	Active substance(s)	Crop	Reference	Mechanism of resistance	Occurrence	Year of first detection	Frequency	Resistance factor	Relevance of r. in the field	Comments
Zymoseptoria tritici	G1-3	Epoxiconazole, Propiconazole, Tebuconazole	Soft wheat	Expert knowledge meetings and FRAC	Shifting	High	2004	High	Unknown	Minimal impact	
Zymoseptoria tritici	G1-3	Epoxiconazole, Propiconazole, Tebuconazole	Soft wheat	Expert knowledge, meetings, FRAC		Moderate		High	Unknown	Minimal impact	
Zymoseptoria tritici	G1-3	Difenoconazole, Epoxiconazole, Metconazole, **Prothioconazole**, Tebuconazole	Soft wheat	Heick TM et al. (2017)	Shifting	High	2014	High	High	Minimal impact	

Resistance risk assessment of unrestricted use pattern

The resistance risk analysis is carried out following EPPO Guideline PP 1/213(4).

The actual risk for the evolution of resistance depends on three different parameters: mechanism of resistance against the compound (intrinsic fungicide risk), biology of the fungal pathogen (target risk) and agronomic factors (agronomic risk).

a) Risk inherent to the targets

The risk of resistance development to fungicides is classified from **low to high (1-3)** depending on the pathogen targeted by the present application, as shown in the table below (FRAC Pathogen Risk List, 2019)

Table 3.3-3: Resistance risk to fungicides of the target pathogens

Pathogen (EPPO code)	Crop	Risk class
Ramularia collo-cygni (RAMUCC)	Barley	high
Zymoseptoria tritici (SEPTTR)	Wheat	medium
Pyrenophora teres (PYRNTE)	Barley	medium
Puccinia striiformis (PUCCST/PUCCSI)	Wheat, barley, various	low
Puccinia recondite (PUCCRE)	Wheat, barley, various	low
Puccinia recondita f. sp. recondite (PUCCRR)	Wheat, barley, various	low
Puccinia hordei (PUCCHD)	Wheat, barley, various	low
Rhynchosporium secali (RHYNSE)	Barley	low
Fusarium species (FUSASP)	various	low
Sclerotinia sclerotiorum (SCLESC)	various	low

b) Risk inherent to the active substance

The resistance risk for DMI fungicides, including prothioconazole, is in general estimated as **medium (4)** due to the polygenic basis of resistance, the slow development of the shift and the relatively small resistance factors observed.

QoI fungicides, including azoxystrobin, are single site inhibitors. Resistance is mainly due to target site mutations in the cytb gene. Resistance in field populations has been selected by QoI usage. The intrinsic fungicide risk for azoxystrobin is estimated to be **high (6)**.

However, as FGF11 is co-formulated mixture containing two active ingredients with different modes of action and therefore the overall risk arising from the use of such a co-formulation is considered to be **medium (4)** as they reduce the exposure and hence selection pressure on disease pathogens.

c) Risk inherent to the agronomic practices

A more complex scheme of risk interactions, involving agronomic risk is determined by the geographical area in which the crop is grown, the susceptibility of the cultivar, the expected disease pressure in that area and the disease control practices used, such as number and timings of applications. The risk of infection and spread of all target fungal diseases of cereals and oilseed rape for FGF11 can be reduced using various physical and cultural non-chemical disease management practices. Chemical control of fungal diseases in cereals and oilseed rape typically involves following Good Agricultural Practice and FRAC guidance, with applications of a fungicide made as part of an overall season-long spray program involving other fungicides with different modes of action, as part of a wider disease control strategy. The risk of resistance relating to agronomic practices can therefore be considered as **low (0.25)**.

The calculated overall risk of resistance arising for an ‘unrestricted use pattern’ is therefore **low (1)** with respect to the fungal pathogens *Puccinia sp.*, *Rhynchosporium secali*, and *Fusarium species* in cereals

and *Sclerotinia sclerotiorum* in oilseed rape, **low to medium (2)** with respect to *Zymoseptoria tritici* and *Pyrenophora teres* in cereals, and **moderate (3)** with respect to *Ramularia collo-cygni* in barley (calculated according to the combined resistance risk diagram based on inherent fungicide risk, inherent pathogen risk and agronomic risk presented in the FRAC Pathogen Risk List (September 2019)), Figure 3.3-1.

Fungicide Classes	**Fungicide Risk**	**Combined Risk**			**Agronomic Risk**
QoI Fungicides	High = 6	**1.5**	**3**	**4.5**	Low= 0.25
SBI fungicides	Medium = 4	**1**	**2**	**3**	Low= 0.25
QoI / SBI fungicide mixture	Medium = 4	**1**	**2**	**3**	Low= 0.25
Pathogen risk →		Low = 1	Medium = 2	High = 3	
Pathogen groups*		*Fusarium species* *Puccinia hordei* *Puccinia recondita* *Puccinia recondita f. sp. recondite* *Puccinia striiformis* *Rhynchosporium secali* *Sclerotinia sclerotiorum*	*Pyrenophora teres* *Zymoseptoria tritici*	*Ramularia collo-cygni*	

Figure 3.3-1: Combined resistance risk diagram (according to FRAC Monograph No. 2, by K.J. Brent and D.W., Hollomon, 2007, modified according to Kuck, 2005)

Management strategy

FGF11 combines the complementary activity of two fungicide MoA to give effective preventative, curative and eradicative control of various fungal diseases.

The risk management strategy to reduce the risk of resistance developing to prothioconazole and azoxystrobin from the use of FGF11 is based on Good Agricultural Practice (GAP) and current measures advocated by FRAC.

The risk management strategy to reduce the risk of resistance for QoI fungicides according to FRAC is based on:

General use recommendations (all crops)

- Fungicide programmes must deliver effective disease management. Apply QoI fungicide based products at effective rates and intervals according to manufacturers' recommendations. Effective disease management is a critical component to delay the build-up of resistant pathogen populations.
- The number of applications of QoI fungicide based products within a total disease management program must be limited whether applied solo or in mixtures with other fungicides. This limitation is inclusive to all QoI fungicides. Limitation of QoI fungicides within a spray programme provides time and space when the pathogen population is not influenced by QoI fungicide selection pressure.
- Limitation of the total number of QoI applications is detailed in the specific crop recommendations. In consideration of the cross-resistance profile of subgroups 11 and 11A, the

maximum allowed number of QoI-containing sprays is increased by one, where both QoI fungicides (code 11) and QoI fungicides in subgroup A (code 11A) are included in a spray program in a given cropping season. All crop-specific recommendations will be regularly reviewed based on sensitivity monitoring.

- A consequence of limitation of QoI fungicide based products is the need to use it in a spray program with effective fungicides from different cross-resistance groups (refer to the specific crop recommendations).
- QoI products, containing only the solo QoI fungicide, should be used in single or block applications in alternation with fungicides from a different cross-resistance group. Specific recommendation on the number of consecutive treatments (size of blocks) is given for specific crops.
- Mixture partners for QoI fungicides should be chosen carefully to contribute to effective control of the targeted pathogen(s). The mixture partner must have a different mode of action, and in addition it may increase spectrum of activity or provide needed curative activity. Use of mixtures containing only QoI fungicides (including two-way mixtures of code 11 fungicide and code 11A fungicide) must not be considered as an anti-resistance measure.
- An effective partner for a QoI fungicide is one that provides satisfactory disease control when used alone on the target disease.
- QoI fungicides are very effective at preventing spore germination and should therefore be used at the early stages of disease development (preventive treatment).

Specific recommendations for use of QoIs in cereals

- Apply QoI fungicides always in mixtures with non-cross resistant fungicides to control cereal pathogens. At the rate chosen the respective partner(s) on its/ their own has/ have to provide effective disease control. Refer to manufacturers' recommendations f or rates.
- The maximum number of QoI-containing sprays is 3, but only when QoI fungicides belonging to both QoI Groups (code 11 and 11A) are included in a spray program. QoI fungicides belonging to the individual Codes (11 or 11A) should not be applied more than 2 times either individually or when mixed together.
- Apply QoI fungicides according to manufacturer’s recommendations for the target disease (or complex) at the specific crop growth stage indicated.
- Apply the QoI fungicide preventively or as early as possible in the disease cycle. Do not rely only on the curative potential of QoI fungicides.
- Split / reduced rate programmes, using repeated applications, which provide continuous selection pressure, accelerate the development of resistant populations and therefore must not be used.

FRAC provides the following recommendations for resistance management for SBI fungicides:

General use recommendations for all crops

- 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 use of DMIs in cereals

- The recommendations for the use of DMI and amine fungicides in mixture or alternation programmes with different mode of action fungicides remain unchanged. It needs to be emphasized that it is essential for resistance management purposes to follow strictly the manufacturer's and FRAC recommendations.
- Repeated application of DMI or amine 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.
- Ramularia leaf spot (*Ramularia collo-cygni*) in barley: Given that there already exist populations of *Ramularia collo-cygni* in Europe resistant to all main site-specific modes of actions it is recommended to add precautionary a multi-site to ensure robust disease control and an effective resistance management in barley

This should ensure there is no adverse shift in the sensitivity of the target fungal pathogens to any of the active ingredients included in the product.

Comments of zRMS:

FGF11 (Patton Alpha) contains two active substances of prothioconazole and azoxystrobin. Prothioconazole belongs to the chemical group of triazolinthiones (FRAC Group 3, DMI-fungicides) with medium risk class for resistance. Azoxystrobin belongs to the chemical group of methoxy-acrylates (FRAC Group 11, QoI-fungicides) with high risk class for resistance. Based on the list published on FRAC website (LIST OF FIRST CONFIRMED CASES OF PLANT PATHOGENIC ORGANISMS RESISTANT TO DISEASE CONTROL AGENTS, revised May 2020), there are several cases of plant pathogenic organisms resistant to azoxystrobin in cereals: *Blumeria graminis* (soft wheat, the reference from 2003), *Blumeria graminis* (barley, the reference from 2003 and 2004), *Microdochium nivale* (soft wheat, the reference from 2009), *Pyrenophora teres* (barley, the reference from 2009, 2016 and 2022), *Pyrenophora tritici-repentis* (soft wheat, the reference from 2009 and 2022), *Ramularia collo-cygni* (barley, the reference from 2010 and 2022), *Rhynchosporium secalis* (barley, the reference from 2017 and 2022), *Zymoseptoria tritici* (soft wheat, the reference from 2006, 2007, 2009, 2011 and 2019). No resistance in oilseed rape has been reported until now. Also, 12 pathogenic organisms are resistant to prothioconazole: *Blumeria graminis* (soft wheat, the reference from 1998, 2003, 2004, 2005 and 2006), *Blumeria graminis* f.sp. *hordei* (barley, the reference from 1998, 2004, 2005 and 2006), *Fusarium graminearum* (soft wheat, the reference from 2022), *Microdochium majus* (soft wheat, the reference from 2022), *Microdochium nivale* (soft wheat, the reference from 2022), *Oculimacula acuformis* (cereal crops, the reference from 2003, 2006, 2009, 2013 and 2015), *Oculimacula yallundae* (cereal crops, the reference from 2003, 2006, 2009, 2013 and 2015), *Puccinia triticina* (soft wheat, the reference from 2009), *Pyrenophora teres* (barley, the reference from 2016 and 2022), *Ramularia collo-cygni* (barley, the reference from 2019, 2021 and 2022), *Rhynchosporium secalis* (barley, the reference from 2001 and 2016), *Zymoseptoria tritici* (soft wheat, the reference from 2006, 2007, 2009, 2011, 2015, 2017, 2019 and 2022). The risk of resistance development to fungicides is classified from low to high for the target pathogens intended in the GAP table. High risk was determined for *Ramularia collo-cygni* in barley. FGF11 is co-formulated mixture containing active substances with different intrinsic fungicide risk (medium for prothioconazole and high for azoxystrobin) and the overall is considered to be medium. The risk of resistance relating to agronomic practices can be considered as low. Hence, taking into account
risk inherent to the targets, risk inherent to the active substance and risk inherent to the agronomic practices, it can be concluded that the calculated overall risk of resistance arising for an 'unrestricted use pattern' is low in case of *Puccinia* sp., *Rhynchosporium secali*, *Fusarium* species and *Sclerotinia sclerotiorum*, low to medium in case of *Zymoseptoria tritici* and *Pyrenophora teres* and moderate in case of *Ramularia collo-cygni*. The risk management strategy to reduce the risk of resistance developing to prothioconazole and azoxystrobin available on the FRAC website is recommended limited number of application, preventively use, the use in mixture or alternation programmes with different mode of action and adhere to dosages and spray timings as recommended by manufacturers. In opinion of zRMS, these recommendations are justified and sufficient and should be included in the product label. The below anti-resistance strategy is proposed:

- *do not exceed the maximum recommended number of applications (1 application per growing season for cereals and oilseed rape)*
- *use FGF11 mainly preventively*
- *use FGF11 in rotation with other products containing active substances belonging to other chemical group with a different MoA*
- *use other than chemical methods of protection against diseases, compliant principles of integrated pest management*

3.4 Adverse effects on treated crops (KCP 6.4)

Information on trials submitted (3.4 Crop selectivity data)

Table 3.4-1: Presentation of trials (low disease trials, transformation trials)

Crop*	Country	Type of trial**	Number of trials (no. of valid trials)			Years	GEP, non-GEP, official***	Comments (any other relevant information)
			Mar. zone	N-E zone	S-E zone			
TRZAW	FRA	S + Y + Q	2 (2)	-	-	2023	GEP	Low disease trials
	GBR	S + Y + Q	3 (3)	-	-	2023	GEP	Low disease trials
	NLD	S + Y + Q	1 (1)	-	-	2023	GEP	Low disease trial
	FR	T	2 (2)	-	-	2022	GEP	Processing trials
TOTAL	-	-	**8 (8)**	-	-	**2022-2023**	-	
HORVW	FRA	T	2 (2)	-	-	2022	GEP	Processing trials
TOTAL	-	-	**2 (2)**	-	-	**2022**	-	
HORVS	FRA	T	2 (2)	-	-	2022	GEP	Processing trials
TOTAL	-	-	**2 (2)**	-	-	**2022**	-	
TRZSP	DEU	S + Y + Q	2 (2)	-	-	2023	GEP	Low disease trials
TOTAL	-	-	**2 (2)**	-	-	**2023**	-	
SECCE	GBR	S + Y + Q	1 (1)	-	-	2023	GEP	Low disease trial
TOTAL	-	-	**1 (1)**	-	-	**2023**	-	

* According to the GAP table
** S = low disease trial, Y = trial with yield assessment, Q = trial with quality assessment, T = trial on the basis of the study of impact on transformation process (TP: Physical transformation, TF: transformation involving microbial fermentation), P = trial with assessment of impact on propagation
*** Official: carried out by a national official organisation

Products included in all low disease and processing trials carried out in cereals are listed in Table 3.4-2.

Table 3.4-2: Presentation of reference standards used in trials in cereals (crop selectivity trials, transformation trials)

Crop(s)	Product	Country(ies) where the product is registered[1]	Authorisation number	Active substance(s)	Formulation		Registered appl'n rate[3]	Appl'n rate in trials (per treatment)	Remark[4]
					Type[2]	Concentration of a.s.			
Test product									
All crops	FGF11	-	-	azoxystrobin + prothioconazole	SC	160 + 200 g/L	-	1.0 L/ha	
Standard reference products									
TRZAW	Joao	FRA	2060116	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
	Proline	GBR	12084	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	

Crop(s)	Product	Country(ies) where the product is registered[1]	Authorisation number	Active substance(s)	Formulation		Registered appl'n rate[3]	Appl'n rate in trials (per treatment)	Remark[4]
					Type[2]	Concentration of a.s.			
	Protendo 300 EC	NLD	16355N	prothioconazole	EC	300 g/L	0.65 L/ha	0.65 L/ha	
TRZSP	Proline	DEU	025287-00	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
SECCW	Proline	GBR	12084	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
HORVX	Prosaro	FRA	2100108	prothioconazole + tebuconazole	EC	125 + 125 g/L	1.0 L/ha	1.0 L/ha	

(1) only on use(s) applied for (with the test product)
(2) e.g. WP (wettable powder), EC (emulsifiable concentrate), etc.
(3) dose(s) / dose range authorized on that use in the country
(4) Other relevant information (e.g. uses, number of applications, spray volume, method of application, etc.)

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

Crop safety data are only tabulated and presented in this dossier where FGF11 and/or the standard reference products included in the trial caused phytotoxic symptoms or other adverse effects on the growth and development of the crop. In all cases, for trials and assessment timings where no data are summarised, phytotoxic symptoms or other adverse effects on the crop did not occur.

As no phytotoxicity or other adverse effects on plant occurred on any of the trials, no data are summarised within this section.

3.4.1.1 Phytotoxicity in wheat

Assessments for phytotoxic symptoms and other effects on crop growth and development have been carried out on all 121 trial conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against target diseases in winter wheat (104 trials) and spring wheat (17 trials).

Assessments for phytotoxic symptoms and other adverse effects on crop growth and development have also been carried out at regular intervals following the applications of FGF11 applied at the proposed label rate of 1.0 L product/ha, on a total of 6 trials conducted in 2023, in which no or only low levels of disease developed, and these trials are used in support of demonstrating crop safety only.

Details of the materials and methods used in all efficacy trials summarised in support of demonstrating crop safety in wheat are given in Section 3.2.3.1 and Section 3.2.3.5.

Details of the materials and methods used in all low disease trials in wheat are given here.

Table 3.4-3: Details on trial methodology (low disease trials on wheat)

Maritime EPPO climatic zone		
Guidelines	General guidelines	EPPO PP1/152 (4), EPPO PP1/181 (4), EPPO PP1/135 (4), EPPO PP 1/223 (2), EPPO PP 1/225 (2)
	Specific guidelines	EPPO PP 1/26 (4)
Experimental design	Plot design	RCBD (6)
	Plot size	21-36.25 m² (6)
	Number of replications	4 (6)

Crop	Trials per crop	TRZAW (6)
	Varieties per crop	**TRZAW:** Champion (1), Extase (4), LG Absalon (1)
	Sowing period	**TRZAW:** October (6)
Application	Timing Crop stage (BBCH) at application	Post-emergence **TRZAW:** from 55-59 to 65 (BBCH)
	Number of applications	1 (6)
	Spray volumes	200 L/ha (4), 300 L/ha (2)
Assessments	Assessment types	Phytotoxicity, crop vigour, crop yield
	Assessment dates	**TRZAW:** between 0-67 DA-A1, at harvest

Applications on all crop selectivity trials were made using small plot sprayers designed to simulate application using commercial sprayers representative of those used to apply fungicides in wheat.

On all trials, a single application of the treatments was made on crops growth stage and in water volumes representative of the ones proposed for the application of FGF11.

The standard reference products were applied according to the label recommendations at authorised label rates.

On all trials, 1 or 2 applications of the treatments were made on crops growth stage and in water volumes representative of the ones proposed for the application of FGF11.

Across trials, the crop safety of FGF11 has been evaluated under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in wheat crops growing regions across EU Central Registration zone countries.

Overall summaries of the crop safety of FGF11 across trials carried out in wheat are given in Table 3.4-4 (low disease trials) and Table 3.4-5 (Efficacy trials).

Table 3.4-4: Overall summary of the crop safety of FGF11 across all low disease trials carried out in winter wheat

EPPO climatic zone (no. of trials)	**Timing**	**Levels of phytotoxicity**	**Number of trials**	
			FGF11 (6 trials)	**Proline* (6 trials)**
			1.0 L/ha	**0.8 L/ha**
Maritime (6 trials)	**Maximum and final level of symptoms recorded**	**0%**	6	6
		0.1% to 5%	-	-
		>5% to 10%	-	-
		>10% to 15%	-	-
		>15%	-	-

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.4-2

Table 3.4-5: Overall summary of the crop safety of FGF11 across all efficacy trials carried out in winter and spring wheat

EPPO climatic zone (no. of trials)	**Timing**	**Levels of phytotoxicity**	**Number of trials**	
			FGF11 (121 trial)	**Proline* (121 trial)**
			1.0 L/ha	**0.8 L/ha**
Maritime (46 trials)	**Maximum and final level of symptoms recorded**	**0%**	46	46
		0.1% to 5%	-	-
		>5% to 10%	-	-
		>10% to 15%	-	-

EPPO climatic zone (no. of trials)	Timing	Levels of phytotoxicity	Number of trials	
			FGF11 (121 trial)	Proline* (121 trial)
			1.0 L/ha	0.8 L/ha
		>15%	-	-
North-east (38 trials)	Maximum and final level of symptoms recorded	0%	38	38
		0.1% to 5%	-	-
		>5% to 10%	-	-
		>10% to 15%	-	-
		>15%	-	-
South-east (37 trials)	Maximum and final level of symptoms recorded	0%	37	37
		0.1% to 5%	-	-
		>5% to 10%	-	-
		>10% to 15%	-	-
		>15%	-	-

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.2-6

FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or other adverse effects on crop growth and development on any of the 121 efficacy or 6 low disease trials carried out in winter and spring wheat.

Products containing prothioconazole and/or azoxystrobin are approved and used in wheat for many years in the EU Central registration zone and therefore the safety of both active substances on spring and winter wheat is well established and proven through commercial use when applications are made according to label recommendations.

Therefore, on the basis of the absence of phytotoxic symptoms or other adverse effects on crop growth and development across trials, it is reasonable to conclude that a single application of FGF11 at the proposed label rate of 1.0 L product/ha, and applied according to label recommendations, is crop safe on winter and spring wheat.

Comments of zRMS:

No special selectivity trials have been submitted by the applicant. In general, 6 low disease trials in winter wheat and 121 efficacy trials in winter and spring wheat were conducted in all EPPO climatic zone. FGF11 applied at dose rate of 1 l/ha once per growing season caused no phytotoxicity symptoms in any submitted trials. Based on the trial results it can be concluded that FGF11 is safe for winter and spring wheat if applied according to the recommendations in the product label.

3.4.1.2 Phytotoxicity in spelt

Assessments for phytotoxic symptoms and other effects on crop growth and development have been carried out on all 8 trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against target diseases in spelt.

Assessments for phytotoxic symptoms and other adverse effects on crop growth and development have also been carried out at regular intervals following the applications of FGF11 applied at the proposed label rate of 1.0 L product/ha, on a total of 2 trials conducted in 2023, in which no or only low levels of disease developed, and these trials are used in support of demonstrating crop safety only.

Details of the materials and methods used in all efficacy trials summarised in support of demonstrating crop safety in spelt are given in Section 3.2.3.1.

Details of the materials and methods used in all low disease trials in spelt are given here.

Table 3.4-6: Details on trial methodology (low disease trials on spelt)

Maritime EPPO climatic zone		
Guidelines	General guidelines	EPPO PP1/152 (4), EPPO PP1/181 (4), EPPO PP1/135 (4), EPPO PP 1/223 (2), EPPO PP 1/225 (2)
	Specific guidelines	EPPO PP 1/26 (4)
Experimental design	Plot design	RCBD (2)
	Plot size	24-30 m² (2)
	Number of replications	4 (2)
Crop	Trials per crop	TRZSP (2)
	Varieties per crop	**TRZSP:** Zollernfit (1), Zollernspelz (1)
	Sowing period	**TRZSP:** October (2)
Application	Timing Crop stage (BBCH) at application	Post-emergence **TRZSP:** A1: from 31-33 to 37-39 (BBCH) A2: from 39-42 to 47-49 (BBCH)
	Number of applications	2 (2) with intevals of 14-27 days
	Spray volumes	200 L/ha (2)
Assessments	Assessment types	Phytotoxicity, crop vigour, crop yield
	Assessment dates	**TRZSP:** between 0 DA-A1 -71 DA-A2, at harvest

Applications on all crop selectivity trials were made using small plot sprayers designed to simulate application using commercial sprayers representative of those used to apply fungicides in spelt.

On all trials, two application(s) of the treatments was made on crops growth stage and in water volumes representative of the ones proposed for the application of FGF11.

The standard reference products were applied according to the label recommendations at authorised label rates.

On all trials, 2 applications of the treatments were made on crops growth stage and in water volumes representative of the ones proposed for the application of FGF11.

Across trials, the crop safety of FGF11 has been evaluated under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in spelt crops growing regions across EU Central Registration zone countries.

Overall summaries of the crop safety of FGF11 across trials carried out in spelt are given in Table 3.4-7 (low disease trials) and Table 3.4-8 (Efficacy trials).

Table 3.4-7: Overall summary of the crop safety of FGF11 across all low disease trials carried out in spelt

EPPO climatic zone (no. of trials)	**Timing**	**Levels of phytotoxicity**	**Number of trials**	
			FGF11 (2 trials)	**Proline* (2 trials)**
			1.0 L/ha	**0.8 L/ha**
Maritime (2 trials)	**Maximum and final level of symptoms recorded**	**0%**	2	2
		0.1% to 5%	-	-
		>5% to 10%	-	-
		>10% to 15%	-	-
		>15%	-	-

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.4-2

Table 3.4-8: Overall summary of the crop safety of FGF11 across all efficacy trials carried out in spelt

EPPO climatic zone (no. of trials)	Timing	Levels of phytotoxicity	Number of trials	
			FGF11 (8 trials)	Proline* (8 trials)
			1.0 L/ha	0.8 L/ha
Maritime (5 trials)	Maximum and final level of symptoms recorded	0%	5	5
		0.1% to 5%	-	-
		>5% to 10%	-	-
		>10% to 15%	-	-
		>15%	-	-
South-east (3 trials)	Maximum and final level of symptoms recorded	0%	3	3
		0.1% to 5%	-	-
		>5% to 10%	-	-
		>10% to 15%	-	-
		>15%	-	-

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.2-6

FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or other adverse effects on crop growth and development on any of the 8 efficacy or 2 low disease trials carried out in spelt.

Products containing prothioconazole and/or azoxystrobin are approved and used in spelt for many years in the EU Central registration zone and therefore the safety of both active substances on spelt is well established and proven through commercial use when applications are made according to label recommendations.

Therefore, on the basis of the absence of phytotoxic symptoms or other adverse effects on crop growth and development across trials, it is reasonable to conclude that a single application of FGF11 at the proposed label rate of 1.0 L product/ha, and applied according to label recommendations, is crop safe on spelt.

Comments of zRMS:

No special selectivity trials have been submitted by the applicant. In general, 2 low disease trials and 8 efficacy trials in spelt were conducted in the Maritime and South-East EPPO climatic zone. FGF11 applied at dose rate of 1 l/ha once per growing season caused no phytotoxicity symptoms in any submitted trials. Based on the trial results it can be concluded that FGF11 is safe for spelt if applied according to the recommendations in the product label.

3.4.1.3 Phytotoxicity in durum wheat

Assessments for phytotoxic symptoms and other effects on crop growth and development have been carried out on all 10 trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against target diseases in durum wheat.

Summaries of materials and methods used in these trials are given in Section 3.2.3.1.

On all trials, 2 applications of the treatments was made on crops growth stage and in water volumes representative of the ones proposed for the application of FGF11.

Across trials, the crop safety of FGF11 has been evaluated under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in durum wheat crops growing regions across EU Central Registration zone countries.

An overall summary of the crop safety of FGF11 across trials carried out in durum wheat is given in Table 3.4-9.

Table 3.4-9: Overall summary of the crop safety of FGF11 across all efficacy trials carried out in durum wheat

EPPO climatic zone (no. of trials)	Timing	Levels of phytotoxicity	Number of trials		
			FGF11 (10 trials)	Proline* (7 trials)	Prosaro (3 trials)
			1.0 L/ha	0.8 L/ha	0.8 L/ha
Maritime (3 trials)	Maximum and final levels of symptoms recorded	0%	3	3	-
		0.1% to 5%	-	-	-
		>5% to 10%	-	-	-
		>10% to 15%	-	-	-
		>15%	-	-	-
South-east (7 trials)	Maximum and final levels of symptoms recorded	0%	7	4	3
		0.1% to 5%	-	-	-
		>5% to 10%	-	-	-
		>10% to 15%	-	-	-
		>15%	-	-	-

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.2-6

FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or other adverse effects on crop growth and development on any of these 10 efficacy trials carried out in durum wheat.

Products containing prothioconazole and/or azoxystrobin are approved and used in durum wheat for many years in the EU Central registration zone and therefore the safety of both active substances on durum wheat is well established and proven through commercial use when applications are made according to label recommendations.

Therefore, on the basis of the absence of phytotoxic symptoms or other adverse effects on crop growth and development across trials, it is reasonable to conclude that a single application of FGF11 at the proposed label rate of 1.0 L product/ha, and applied according to label recommendations, is crop safe on durum wheat.

Comments of zRMS:

No special selectivity trials have been submitted by the applicant. In general, 10 efficacy trials in durum wheat were conducted in the Maritime and South-East EPPO climatic zone. FGF11 applied at dose rate of 1 l/ha once per growing season caused no phytotoxicity symptoms in any submitted trials. Based on the trial results it can be concluded that FGF11 is safe for durum wheat if applied according to the recommendations in the product label.

3.4.1.4 Phytotoxicity in triticale

Assessments for phytotoxic symptoms and other effects on crop growth and development have been carried out on all 24 trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against target diseases in winter triticale (23 trials) and spring triticale (1 trial).

Summaries of materials and methods used in these trials are given in Section 3.2.3.1.

On all trials, 2 applications of the treatments was made on crops growth stage and in water volumes representative of the ones proposed for the application of FGF11.

Across trials, the crop safety of FGF11 has been evaluated under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in triticale crops growing regions across EU Central Registration zone countries.

An overall summary of the crop safety of FGF11 across trials carried out in spring and winter triticale is given in Table 3.4-10.

Table 3.4-10: Overall summary of the crop safety of FGF11 across all efficacy trials carried out in spring and winter triticale

EPPO climatic zone (no. of trials)	Timing	Levels of phytotoxicity	Number of trials	
			FGF11 (24 trials)	Proline* (24 trials)
			1.0 L/ha	0.8 L/ha
Maritime (6 trials)	Maximum and final levels of symptoms recorded	0%	6	6
		0.1% to 5%	-	-
		>5% to 10%	-	-
		>10% to 15%	-	-
		>15%	-	-
North-east (8 trials)	Maximum and final levels of symptoms recorded	0%	8	8
		0.1% to 5%	-	-
		>5% to 10%	-	-
		>10% to 15%	-	-
		>15%	-	-
South-east (10 trials)	Maximum and final levels of symptoms recorded	0%	10	10
		0.1% to 5%	-	-
		>5% to 10%	-	-
		>10% to 15%	-	-
		>15%	-	-

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.2-6

FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or other adverse effects on crop growth and development on any of these 24 efficacy trials carried out in winter and spring triticale.

Products containing prothioconazole and/or azoxystrobin are approved and used in triticale for many years in the EU Central registration zone and therefore the safety of both active substances on spring and winter triticale is well established and proven through commercial use when applications are made according to label recommendations.

Therefore, on the basis of the absence of phytotoxic symptoms or other adverse effects on crop growth and development across trials, it is reasonable to conclude that a single application of FGF11 at the proposed label rate of 1.0 L product/ha, and applied according to label recommendations, is crop safe on winter and spring triticale.

Comments of zRMS:

No special selectivity trials have been submitted by the applicant. In general, 24 efficacy trials in winter and spring triticale were conducted in all EPPO climatic zone. FGF11 applied at dose rate of 1 l/ha once per growing season caused no phytotoxicity symptoms in any submitted trials. Based on the trial results it can be concluded that FGF11 is safe for winter and spring triticale if applied according to the recommendations in the product label.

3.4.1.5 Phytotoxicity in rye

Assessments for phytotoxic symptoms and other effects on crop growth and development have been carried out on all 14 trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against target diseases in winter rye.

Assessments for phytotoxic symptoms and other adverse effects on crop growth and development have also been carried out at regular intervals following the applications of FGF11 applied at the proposed label rate of 1.0 L product/ha, on 1 trial conducted in 2023, in which only low levels of disease developed, and this trial is used in support of demonstrating crop safety only.

Details of the materials and methods used in all efficacy trials summarised in support of demonstrating crop safety in rye are given in Section 3.2.3.2.

Details of the materials and methods used in all low disease trials in rye are given here.

Table 3.4-11: Details on trial methodology (low disease trials on rye)

Maritime EPPO climatic zone		
Guidelines	General guidelines	EPPO PP1/152 (4), EPPO PP1/181 (4), EPPO PP1/135 (4), EPPO PP 1/223 (2), EPPO PP 1/225 (2)
	Specific guidelines	EPPO PP 1/26 (4)
Experimental design	Plot design	RCBD (1)
	Plot size	30 m² (1)
	Number of replications	4 (1)
Crop	Trials per crop	SECCW (1)
	Varieties per crop	**SECCW:** Poseidon (1)
	Sowing period	**SECCW:** October (1)
Application	Timing Crop stage (BBCH) at application	Post-emergence **SECCW:** A1: 37 (BBCH) A2: 39-45 (BBCH)
	Number of applications	2 (1) with intevals of 19 days
	Spray volumes	100 L/ha (1)
Assessments	Assessment types	Phytotoxicity, crop vigour, crop yield
	Assessment dates	**TRZSP:** between 0 DA-A1 - 59 DA-A2, at harvest

Applications on all low disease trials were made using small plot sprayers designed to simulate application using commercial sprayers representative of those used to apply fungicides in rye.

On all trials, two application(s) of the treatments was made on crops growth stage and in water volumes representative of the ones proposed for the application of FGF11.

The standard reference products were applied according to the label recommendations at authorised label rates.

Across trials, the crop safety of FGF11 has been evaluated under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in rye crops growing regions across EU Central Registration zone countries.

Overall summaries of the crop safety of FGF11 across trials carried out in rye are given in Table 3.4-12 (low disease trials) and Table 3.4-13 (Efficacy trials).

Table 3.4-12: Overall summary of the crop safety of FGF11 across all low disease trials carried out in winter rye

EPPO climatic zone (no. of trials)	**Timing**	**Levels of phytotoxicity**	**Number of trials**	
			FGF11 (1 trial)	**Proline* (1 trial)**
			1.0 L/ha	**0.8 L/ha**
Maritime (1 trial)	**Maximum and final level of symptoms recorded**	**0%**	1	1
		0.1% to 5%	-	-
		>5% to 10%	-	-
		>10% to 15%	-	-
		>15%	-	-

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.4-2

Table 3.4-13: Overall summary of the crop safety of FGF11 across all efficacy trials carried out in winter rye

EPPO climatic zone (no. of trials)	Timing	Levels of phytotoxicity	Number of trials		
			FGF11 (14 trials)	Proline* (13 trials)	Prosaro (1 trial)
			1.0 L/ha	0.8 L/ha	0.8 L/ha
Maritime (6 trials)	**Maximum and final levels of symptoms recorded**	**0%**	6	6	-
		0.1% to 5%	-	-	-
		>5% to 10%	-	-	-
		>10% to 15%	-	-	-
		>15%	-	-	-
North-east (3 trials)	**Maximum and final levels of symptoms recorded**	**0%**	3	3	-
		0.1% to 5%	-	-	-
		>5% to 10%	-	-	-
		>10% to 15%	-	-	-
		>15%	-	-	-
South-east (5 trials)	**Maximum and final levels of symptoms recorded**	**0%**	5	4	1
		0.1% to 5%	-	-	-
		>5% to 10%	-	-	-
		>10% to 15%	-	-	-
		>15%	-	-	-

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.2-6

FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or other adverse effects on crop growth and development on any of the 14 efficacy or 1 low disease trials carried out in winter rye.

Products containing prothioconazole and/or azoxystrobin are approved and used in rye for many years in the EU Central registration zone and therefore the safety of both active substances on spring and winter rye is well established and proven through commercial use when applications are made according to label recommendations.

Therefore, on the basis of the absence of phytotoxic symptoms or other adverse effects on crop growth and development across trials, it is reasonable to conclude that a single application of FGF11 at the proposed label rate of 1.0 L product/ha, and applied according to label recommendations, is crop safe on winter and spring rye.

Comments of zRMS:

No special selectivity trials have been submitted by the applicant. In general, 1 low disease trial and 14 efficacy trials in winter rye were conducted in all EPPO climatic zone. FGF11 applied at dose rate of 1 l/ha once per growing season caused no phytotoxicity symptoms in any submitted trials. Based on the trial results it can be concluded that FGF11 is safe for winter rye if applied according to the recommendations in the product label.

No phytotoxicity assessment has been provided for spring rye. The cMSs belonging to the MAR and SE zone are kindly asked to consider this use at the national level.

3.4.1.6 Phytotoxicity in barley

Assessments for phytotoxic symptoms and other effects on crop growth and development have been carried out on all 33 trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against target diseases in winter barley (24 trials) and spring barley (9 trials).

Summaries of materials and methods used in these trials are given in Section 3.2.3.3.

On all trials, 2 applications of the treatments were made on crops growth stage and in water volumes representative of the ones proposed for the application of FGF11.

Across trials, the crop safety of FGF11 has been evaluated under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in barley crops growing regions across EU Central Registration zone countries.

An overall summary of the crop safety of FGF11 across trials carried out in spring and winter barley is given in Table 3.4-14.

Table 3.4-14: Overall summary of the crop safety of FGF11 across all efficacy trials carried out in spring and winter barley

EPPO climatic zone (no. of trials)	Timing	Levels of phytotoxicity	Number of trials	
			FGF11 (33 trials)	Proline* (33 trials)
			1.0 L/ha	0.8 L/ha
Maritime (12 trials)	Maximum and final levels of symptoms recorded	0%	12	12
		0.1% to 5%	-	-
		>5% to 10%	-	-
		>10% to 15%	-	-
		>15%	-	-
North-east (9 trials)	Maximum and final levels of symptoms recorded	0%	9	9
		0.1% to 5%	-	-
		>5% to 10%	-	-
		>10% to 15%	-	-
		>15%	-	-
South-east (12 trials)	Maximum and final levels of symptoms recorded	0%	12	12
		0.1% to 5%	-	-
		>5% to 10%	-	-
		>10% to 15%	-	-
		>15%	-	-

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.2-6

FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or other adverse effects on crop growth and development on any of these 33 efficacy trials carried out in winter and spring barley.

Products containing prothioconazole and/or azoxystrobin are approved and used in barley for many years in the EU Central registration zone and therefore the safety of both active substances on spring and winter barley is well established and proven through commercial use when applications are made according to label recommendations.

Therefore, on the basis of the absence of phytotoxic symptoms or other adverse effects on crop growth and development across trials, it is reasonable to conclude that a single application of FGF11 at the proposed label rate of 1.0 L product/ha, and applied according to label recommendations, is crop safe on winter and spring barley.

Comments of zRMS:

No special selectivity trials have been submitted by the applicant. In general, 33 efficacy trials in winter and spring barley were conducted in all EPPO climatic zone. FGF11 applied at dose rate of 1 l/ha once per growing season caused no phytotoxicity symptoms in any submitted trials. Based on the trial results it can be concluded that FGF11 is safe for winter and spring barley if applied according to the recommendations in the product label.

3.4.1.7 Phytotoxicity in oilseed rape

Assessments for phytotoxic symptoms and other effects on crop growth and development have been carried out on all 23 trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1.0 L product/ha against SCLESC in oilseed rape.

Summaries of materials and methods used in these trials are given in Section 3.2.3.4.

On all trials, a single application of the treatments was made on crops growth stage and in water volumes representative of the ones proposed for the application of FGF11.

Across trials, the crop safety of FGF11 has been evaluated under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in oilseed rape crops growing regions across EU Central Registration zone countries.

An overall summary of the crop safety of FGF11 across trials carried out in winter oilseed rape is given in Table 3.4-15.

Table 3.4-15: Overall summary of the crop safety of FGF11 across all crop selectivity trials carried out in winter oilseed rape

EPPO climatic zone (no. of trials)	**Timing**	**Levels of phytotoxicity**	**Number of trials**			
			FGF11 (23 trials)	**Proline/Praktis (4 trials)**	**Proline * (18 trials)**	**Prosaro 250 EC (1 trial)**
			1.0 L/ha	**0.7 L/ha**	**0.8 L/ha***	**0.8 L/ha**
Maritime (8 trials)	**Maximum and final levels of symptoms recorded**	**0%**	8	3	5	-
		0.1% to 5%	-	-	-	-
		>5% to 10%	-	-	-	-
		>10% to 15%	-	-	-	-
		>15%	-	-	-	-
North-east (5 trials)	**Maximum and final levels of symptoms recorded**	**0%**	5	1	4	-
		0.1% to 5%	-	-	-	-
		>5% to 10%	-	-	-	-
		>10% to 15%	-	-	-	-
		>15%	-	-	-	-
South-east (10 trials)	**Maximum and final levels of symptoms recorded**	**0%**	10	-	9	1
		0.1% to 5%	-	-	-	-
		>5% to 10%	-	-	-	-
		>10% to 15%	-	-	-	-
		>15%	-	-	-	-

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.2-6

FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or other adverse effects on crop growth and development on any of these 23 efficacy trials carried out in winter oilseed rape.

Whilst no data have been generated on the crop safety of spring oilseed rape, the susceptibility of this crop to fungicides is considered to be sufficiently similar to that on winter oilseed rape, for data demonstrating crop safety in trials carried out in winter oilseed rape to also demonstrate crop safety in spring oilseed rape.

Furthermore, products containing prothioconazole and/or azoxystrobin are approved and used in oilseed rape for many years in the EU Central registration zone and therefore the safety of both active substances on spring and winter oilseed rape is well established and proven through commercial use when applications are made according to label recommendations.

Therefore, on the basis of the absence of phytotoxic symptoms or other adverse effects on crop growth and development across trials, it is reasonable to conclude that a single application of FGF11 at the proposed label rate of 1.0 L product/ha, and applied according to label recommendations, is crop safe on winter and spring oilseed rape crops.

Comments of zRMS:

No special selectivity trials have been submitted by the applicant. In general, 23 efficacy trials in winter oilseed rape were conducted in all EPPO climatic zone. FGF11 applied at dose rate of 1 l/ha once per growing season caused no phytotoxicity symptoms in any submitted trials. Based on the trial results it can be concluded that FGF11 is safe for winter oilseed rape if applied according to the recommendations in the product label.

No phytotoxicity assessment has been provided for spring oilseed rape. The cMSs belonging to the MAR and SE EPPO zone are kindly asked to consider this use at the national level.

3.4.2 Effects on yield of plants and plant products (KCP 6.4.3)

3.4.2.1 Yield of plants/plant products in wheat (in the absence of disease)

A total of 6 low disease trials carried out in 2023 generated data on crop yield at normal commercial harvest following a single application of FGF11 applied at the proposed label rate of 1.0 L product/ha in the absence of significant disease (<5% pest severity at any assessment) in wheat. All these trials were carried out on winter wheat within the Maritime EPPO climatic zone.

The materials and methods used in all low disease trials are given in Section 3.4.1.1

Evaluations of crop yield have been carried out at normal commercial harvest following the application of FGF11 on a total of 6 low disease trials conducted in 2023 in countries within the Maritime EPPO climatic zone.

Across these trials, a single application of FGF11 at the proposed label rate of 1.0 L product/ha was made on crops growth stage and in water volumes representative of the ones proposed for the application of FGF11.

Across trials, the potential impact of FGF11 on crop yield has been tested under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in wheat crops growing regions across EU Central Registration zone countries.

A single application of FGF11 at the proposed label rate of 1.0 L product/ha caused no significant phytotoxic symptoms or pronounced adverse effects on crop yield on any of these 6 low disease trials carried out in wheat.

Table 3.4-16: Overall mean crop yield (expressed as % relative to the untreated control) in the absence of significant disease following application of FGF11 at the proposed label rate of 1.0 L product/ha in winter wheat

Crop	Registration or EPPO climatic zone	Nº Trials	*Untreated*	FGF11		Proline*		Statical comparison of FGF11 to SRP#
				1.0 L/ha		0.8 L/ha		
			Mean	Mean	Min-Max	Mean	Min-Max	
Yield								
TRZAW	**EPPO MAR**	6	***100.0***	**102.1**	96.0-108.0	**100.8**	94.7-107.0	= (6)

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.4-2
No. of trials where >, = or <, based on statistically significant differences at 95% confidence level.

Also, evaluations of crop yield at normal commercial harvest were carried out on 85 of the efficacy trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1 L product/ha against foliar diseases and fusarium in wheat. Crop yield data in presence of disease from these trials are summarized in Section 3.2.3.1.5 and Section 3.2.3.5.3 .

Whilst FGF11 produced increases in crop yield, compared to the untreated control, as a direct function of control of target disease in the majority of these trials, there was no evidence of 1 or 2 applications of FGF11 at the proposed label rate of 1.0 L product/ha having an adverse impact on crop yield on any of the efficacy trials.

Additionally, applications of FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or adverse effects on crop growth and development on any of the trials carried out on winter and spring wheat. Furthermore, products containing prothioconazole and/or azoxystrobin are approved and used in wheat for many years in the EU Central registration zone and therefore the absence of adverse impact of these active substances on crop yield in both, spring and winter wheat is well established and proven through commercial use when applications are made according to label recommendations.

Furthermore, azoxystrobin is known to prolong green leaf area retention[9] and FGF11 can therefore increase yield even in the absence of disease.

On this basis, it is reasonable to consider that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and applied according to label recommendations, has no adverse impact on crop yield in wheat (winter and spring).

Comments of zRMS:

6 low disease trials have shown that FGF11 applied at dose rate of 1 l/ha is safe for winter wheat. The mean crop yield increased compared to the untreated control (102,1%). No significant differences between FGF11 and the reference product Proline at 0,8 l/ha were observed in all trials.

3.4.2.2 Yield of plants/plant products in spelt (in the absence of disease)

A total of 2 low disease trials carried out in 2023 generated data on crop yield at normal commercial harvest following 2 applications of FGF11 applied at the proposed label rate of 1.0 L product/ha in the absence of significant disease (<5% pest severity at any assessment) in spelt. All these trials were carried out within the Maritime EPPO climatic zone.

The materials and methods used in all low disease trials are given in Section 3.4.1.2.

Evaluations of crop yield have been carried out at normal commercial harvest following the application of FGF11 on a total of 2 low disease trials conducted in 2023 in countries within the Maritime EPPO climatic zone.

Across these trials, two applications of FGF11 at the proposed label rate of 1.0 L product/ha was made on crops growth stage and in water volumes representative of the ones proposed for the application of FGF11.

Across trials, the potential impact of FGF11 on crop yield has been tested under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in spelt crops growing regions across EU Central Registration zone countries.

Two applications of FGF11 at the proposed label rate of 1.0 L product/ha caused no significant phytotoxic symptoms or pronounced adverse effects on crop yield on any of these 2 low disease trials carried out in spelt.

[9]J.R. Bertelsen et al. (2001) Fungicidal effects of azoxystrobin and epoxiconazole on phylllosphere fungi, senescence and yield of winter wheat. Plant Pathology 50 (2), p. 190-205

Table 3.4-17: Overall mean crop yield (expressed as % relative to the untreated control) in the absence of significant disease following application of FGF11 at the proposed label rate of 1.0 L product/ha in spelt

Crop	Registration or EPPO climatic zone	Nº Trials	*Untreated*	FGF11		Proline*		Statical comparison of FGF11 to SRP#
				1.0 L/ha		0.8 L/ha		
			Mean	Mean	Min-Max	Mean	Min-Max	
Yield								
TRZSP	**EPPO MAR**	2	100.0	102.9	100.6-105.2	100.6	95.5-15.8	= (2)

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.4-2
No. of trials where >, = or <, based on statistically significant differences at 95% confidence level.

Also, evaluations of crop yield at normal commercial harvest were carried out on 4 of the efficacy trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1 L product/ha against foliar diseases in spelt. Crop yield data in presence of disease from these trials are summarized in Section 3.2.3.1.5.

Whilst FGF11 produced increases in crop yield, compared to the untreated control, as a direct function of control of target disease in the majority of these trials, there was no evidence of 2 applications of FGF11 at the proposed label rate of 1.0 L product/ha having an adverse impact on crop yield on any of the efficacy trials.

Additionally, applications of FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or adverse effects on crop growth and development on any of the trials carried out on spelt. Furthermore, products containing prothioconazole and/or azoxystrobin are approved and used in spelt for many years in the EU Central registration zone and therefore the absence of adverse impact of these active substances on crop yield in spelt is well established and proven through commercial use when applications are made according to label recommendations.

Furthermore, azoxystrobin is known to prolong green leaf area retention[10] and FGF11 can therefore increase yield even in the absence of disease.

On this basis, it is reasonable to consider that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and applied according to label recommendations, has no adverse impact on crop yield in spelt.

Comments of zRMS:

2 low disease trials have shown that FGF11 applied at dose rate of 1 l/ha is safe for spelt. The mean crop yield increased compared to the untreated control (102,9%). No significant differences between FGF11 and the reference product Proline at 0,8 l/ha were observed in both trials.

3.4.2.3 Yield of plants/plant products in durum wheat

Evaluations of crop yield at normal commercial harvest were carried out on 3 of the efficacy trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1 L product/ha against foliar diseases in durum wheat. Crop yield data from these trials are summarized in Section 3.2.3.1.5. No low disease trials were harvested, therefore no yield data in the absence of significant disease can be presented here.

Whilst FGF11 produced increases in crop yield, compared to the untreated control, as a direct function of control of target disease in these trials, there was no evidence of two applications of FGF11 at the proposed label rate of 1.0 L product/ha having an adverse impact on crop yield on any of the trials.

Additionally, two applications of FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or adverse effects on crop growth and development on any of the trials carried out on durum wheat. Furthermore, products containing prothioconazole and/or azoxystrobin are

[10]J.R. Bertelsen et al. (2001) Fungicidal effects of azoxystrobin and epoxiconazole on phylllosphere fungi, senescence and yield of winter wheat. Plant Pathology 50 (2), p. 190-205

approved and used in durum wheat for many years in the EU Central registration zone and therefore the absence of adverse impact of these active substances on crop yield in durum wheat is well established and proven through commercial use when applications are made according to label recommendations.

Furthermore, azoxystrobin is known to prolong green leaf area retention[11] and FGF11 can therefore increase yield even in the absence of disease.

On this basis, it is reasonable to consider that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and applied according to label recommendations, has no adverse impact on crop yield in durum wheat.

Comments of zRMS:

Accepted.

3.4.2.4 Yield of plants/plant products in triticale

Evaluations of crop yield at normal commercial harvest were carried out on 5 of the efficacy trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1 L product/ha against foliar diseases in triticale. Crop yield data from these trials are summarized in Section 3.2.3.1.5. No low disease trials were harvested, therefore no yield data in the absence of significant disease can be presented here.

Whilst FGF11 produced increases in crop yield, compared to the untreated control, as a direct function of control of target disease in the majority of these trials, there was no evidence of 2 applications of FGF11 at the proposed label rate of 1.0 L product/ha having an adverse impact on crop yield on any of the trials.

Additionally, 2 applications of FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or adverse effects on crop growth and development on any of the trials carried out on triticale. Furthermore, products containing prothioconazole and/or azoxystrobin are approved and used in triticale for many years in the EU Central registration zone and therefore the absence of adverse impact of these active substances on crop yield in both, spring and winter triticale is well established and proven through commercial use when applications are made according to label recommendations.

Furthermore, azoxystrobin is known to prolong green leaf area retention[12] and FGF11 can therefore increase yield even in the absence of disease.

On this basis, it is reasonable to consider that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and applied according to label recommendations, has no adverse impact on crop yield in triticale (winter and spring).

Comments of zRMS:

Accepted.

3.4.2.5 Yield of plants/plant products in rye (in the absence of disease)

A total of 1 low disease trial carried out in 2023 generated data on crop yield at normal commercial harvest following a single application of FGF11 applied at the proposed label rate of 1.0 L product/ha in the absence of significant disease (<5% pest severity at any assessment) in rye. This trial was carried out on winter rye within the Maritime EPPO climatic zone.

[11] J.R. Bertelsen et al. (2001) Fungicidal effects of azoxystrobin and epoxiconazole on phylllosphere fungi, senescence and yield of winter wheat. Plant Pathology 50 (2), p. 190-205

[12] J.R. Bertelsen et al. (2001) Fungicidal effects of azoxystrobin and epoxiconazole on phylllosphere fungi, senescence and yield of winter wheat. Plant Pathology 50 (2), p. 190-205

The materials and methods used in all low disease trials are given in Section 3.4.1.5

Overall conclusions – Crop yield in rye (in the absence of disease)

Evaluations of crop yield have been carried out at normal commercial harvest following the application of FGF11 on 1 low disease trial conducted in 2023 in countries within the Maritime EPPO climatic zone.

On this trial, two applications of FGF11 at the proposed label rate of 1.0 L product/ha were made on crops growth stage and in water volumes representative of the ones proposed for the application of FGF11.

Two applications of FGF11 at the proposed label rate of 1.0 L product/ha caused no significant phytotoxic symptoms or pronounced adverse effects on crop yield on this low disease trial carried out in rye.

Table 3.4-18: Overall mean crop yield (expressed as % relative to the untreated control) in the absence of significant disease following application of FGF11 at the proposed label rate of 1.0 L product/ha in winter rye

Crop	Registration or EPPO climatic zone	Nº Trials	*Untreated*	FGF11		Proline*		Statical comparison of FGF11 to SRP#
				1.0 L/ha		0.8 L/ha		
			Mean	Mean	Min-Max	Mean	Min-Max	
Yield								
SECCW	**EPPO MAR**	1	100.0	101.7	-	102.7	-	= (1)

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.4-2
No. of trials where >, = or <, based on statistically significant differences at 95% confidence level.

Also, evaluations of crop yield at normal commercial harvest were carried out on 7 of the efficacy trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1 L product/ha against foliar diseases in rye. Crop yield data in presence of disease from these trials are summarized in Section 3.2.3.2.3.

Across trials, the potential impact of FGF11 on crop yield has been tested under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in rye crops growing regions across EU Central Registration zone countries.

Whilst FGF11 produced increases in crop yield, compared to the untreated control, as a direct function of control of target disease in the majority of these trials, there was no evidence of 2 applications of FGF11 at the proposed label rate of 1.0 L product/ha having an adverse impact on crop yield on any of the efficacy trials.

Additionally, applications of FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or adverse effects on crop growth and development on any of the trials carried out on winter rye. Furthermore, products containing prothioconazole and/or azoxystrobin are approved and used in rye for many years in the EU Central registration zone and therefore the absence of adverse impact of these active substances on crop yield in both, spring and winter rye is well established and proven through commercial use when applications are made according to label recommendations.

Furthermore, azoxystrobin is known to prolong green leaf area retention[13] and FGF11 can therefore increase yield even in the absence of disease.

On this basis, it is reasonable to consider that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and applied according to label recommendations, has no adverse impact on crop yield in rye (winter and spring).

[13]J.R. Bertelsen et al. (2001) Fungicidal effects of azoxystrobin and epoxiconazole on phylllosphere fungi, senescence and yield of winter wheat. Plant Pathology 50 (2), p. 190-205

Comments of zRMS:

1 low disease trial has shown that FGF11 applied at dose rate of 1 l/ha is safe for winter rye. The mean crop yield increased compared to the untreated control (101,7%). No significant differences between FGF11 and the reference product Proline at 0,8 l/ha were observed in the submitted trial.

3.4.2.6 Yield of plants/plant products in barley

Evaluations of crop yield at normal commercial harvest were carried out on 14 of the efficacy trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1 L product/ha against foliar diseases in barley. Crop yield data from these trials are summarized in Section 3.2.3.3.6. No low disease trials were harvested, therefore no yield data in the absence of significant disease can be presented here.

Whilst FGF11 produced increases in crop yield, compared to the untreated control, as a direct function of control of target disease in the majority of these trials, there was no evidence of 2 applications of FGF11 at the proposed label rate of 1.0 L product/ha having an adverse impact on crop yield on any of the trials.

Additionally, 2 applications of FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or adverse effects on crop growth and development on any of the trials carried out on barley. Furthermore, products containing prothioconazole and/or azoxystrobin are approved and used in barley for many years in the EU Central registration zone and therefore the absence of adverse impact of these active substances on crop yield in both, spring and winter barley is well established and proven through commercial use when applications are made according to label recommendations.

Furthermore, azoxystrobin is known to prolong green leaf area retention[14] and FGF11 can therefore increase yield even in the absence of disease.

On this basis, it is reasonable to consider that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and applied according to label recommendations, has no adverse impact on crop yield in barley (winter and spring).

Comments of zRMS:

Accepted.

3.4.2.7 Yield of plants/plant products in winter and spring oilseed rape

Evaluations of crop yield at normal commercial harvest were carried out on 14 of the efficacy trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1 L product/ha against SCLESC in oilseed rape. Crop yield data from these trials are summarized in Section 3.2.3.4.2. No low disease trials were harvested, therefore no yield data in the absence of significant disease can be presented here.

Whilst FGF11 produced increases in crop yield, compared to the untreated control, as a direct function of control of target disease in the majority of these trials, there was no evidence of a single application of FGF11 at the proposed label rate of 1.0 L product/ha having an adverse impact on crop yield on any of the trials.

Additionally, single applications of FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or adverse effects on crop growth and development on any of the trials carried out on winter oilseed rape. Furthermore, products containing prothioconazole and/or azoxystrobin are approved and used in oilseed rape for many years in the EU Central registration zone and therefore the

[14] J.R. Bertelsen et al. (2001) Fungicidal effects of azoxystrobin and epoxiconazole on phylllosphere fungi, senescence and yield of winter wheat. Plant Pathology 50 (2), p. 190-205

absence of adverse impact of these active substances on crop yield in both, spring and winter oilseed rape is well established and proven through commercial use when applications are made according to label recommendations.

Furthermore, azoxystrobin is known to prolong green leaf area retention[15] and FGF11 can therefore increase yield even in the absence of disease.

On this basis, it is reasonable to consider that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and applied according to label recommendations, has no adverse impact on crop yield in oilseed rape (winter and spring).

Comments of zRMS:

Accepted.

3.4.3 Effects on quality of plants and plant products (KCP 6.4.3)

3.4.3.1 Quality of plants/plant products in wheat (in the absence of disease)

A total of 6 low disease trials carried out in 2023 generated data on quality parameters of the harvested grain following a single application of FGF11 applied at the proposed label rate of 1.0 L product/ha in the absence of significant disease (<5% pest severity at any assessment) in wheat. All these trials were carried out on winter wheat within the Maritime EPPO climatic zone.

The materials and methods used in all low disease trials are given in Section 3.4.1.1.

Evaluations of quality parameters of the harvested grain have been carried out at normal commercial harvest following the application of FGF11 on a total of 6 low disease trials conducted in 2023 in countries within the Maritime EPPO climatic zone.

Across these trials, a single application of FGF11 at the proposed label rate of 1.0 L product/ha was made on crops growth stage and in water volumes representative of the ones proposed for the application of FGF11.

Across trials, the potential impact of FGF11 on quality of the harvested grain has been tested under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in wheat crops growing regions across EU Central Registration zone countries.

A single application of FGF11 at the proposed label rate of 1.0 L product/ha caused no significant phytotoxic symptoms or pronounced adverse effects on quality parameters (HLW, TGW) on any of these 6 low disease trials carried out in wheat.

Table 3.4-19: Overall mean crop quality (expressed as % relative to the untreated control) in the absence of significant disease following application of FGF11 at the proposed label rate of 1.0 L product/ha in winter wheat

Crop	Registration or EPPO climatic zone	Nº Trials	*Untreated*	FGF11		Proline*		Statical comparison of FGF11 to SRP#
				1.0 L/ha		0.8 L/ha		
			Mean	Mean	Min-Max	Mean	Min-Max	
HLW								
TRZAW	**EPPO MAR**	6	***100.0***	**100.4**	99.6-102.7	**99.9**	98.5-100.7	= (6)
TGW								
TRZAW	**EPPO MAR**	2	***100.0***	**101.3**	99.2-103.4	**101.4**	101.0-101.7	= (2)

[15]J.R. Bertelsen et al. (2001) Fungicidal effects of azoxystrobin and epoxiconazole on phylllosphere fungi, senescence and yield of winter wheat. Plant Pathology 50 (2), p. 190-205

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.4-2
No. of trials where >, = or <, based on statistically significant differences at 95% confidence level.

Also evaluations of quality parameters (HLW, TGW) were carried out on 85 of the efficacy trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1 L product/ha against foliar diseases and fusarium in wheat. Data on quality of the harvested grain in presence of disease from these trials are summarized in Section 3.2.3.1.5 and 3.2.3.5.3.

Whilst FGF11 produced increases in quality of the harvested grain, compared to the untreated control, as a direct function of control of target disease in the majority of these trials, there was no evidence of 1 or 2 applications of FGF11 at the proposed label rate of 1.0 L product/ha having an adverse impact on quality of the harvested grain on any of the efficacy trials.

Additionally, applications of FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or adverse effects on crop growth and development on any of the trials carried out on winter and spring wheat. Furthermore, products containing prothioconazole and/or azoxystrobin are approved and used in wheat for many years in the EU Central registration zone and therefore the absence of adverse impact of these active substances on quality of the harvested grain in both, spring and winter wheat is well established and proven through commercial use when applications are made according to label recommendations.

On this basis, it is reasonable to consider that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and applied according to label recommendations, has no adverse impact on quality of the harvested grain in wheat (winter and spring).

Comments of zRMS:

6 low disease trials were conducted in winter wheat in the Maritime EPPO climatic zone. The trial results have shown that FGF11 applied at dose rate of 1 l/ha is safe for quality parameters of the harvested grain. The mean crop quality increased compared to the untreated control: HLW to 100,4% and TGW to 101,3%. No significant differences between FGF11 and the reference product Proline at 0,8 l/ha were observed in the submitted trials.

3.4.3.2 Quality of plants/plant products in spelt (in the absence of disease)

A total of 2 low disease trials carried out in 2023 generated data on quality parameters of the harvested grain following two applications of FGF11 applied at the proposed label rate of 1.0 L product/ha in the absence of significant disease (<5% pest severity at any assessment) in spelt. All these trials were carried out within the Maritime EPPO climatic zone.

The materials and methods used in all low disease trials are given in Section 3.4.1.2.

Evaluations of quality parameters of the harvested grain have been carried out at normal commercial harvest following the application of FGF11 on a total of 2 low disease trials conducted in 2023 in countries within the Maritime EPPO climatic zone.

Across these trials, 2 applications of FGF11 at the proposed label rate of 1.0 L product/ha was made on crops growth stage and in water volumes representative of the ones proposed for the application of FGF11.

Across trials, the potential impact of FGF11 on quality of the harvested grain has been tested under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in spelt crops growing regions across EU Central Registration zone countries.

Two applications of FGF11 at the proposed label rate of 1.0 L product/ha caused no significant phytotoxic symptoms or pronounced adverse effects on quality parameters (HLW, TGW) on any of these 2 low disease trials carried out in spelt.

Table 3.4-20: Overall mean crop quality (expressed as % relative to the untreated control) in the absence of significant disease following application of FGF11 at the proposed label rate of 1.0 L product/ha in spelt

Crop	Registration or EPPO climatic zone	Nº Trials	*Untreated*	FGF11		Proline*		Statical comparison of FGF11 to SRP#
				1.0 L/ha		0.8 L/ha		
			Mean	Mean	Min-Max	Mean	Min-Max	
HLW								
TRZSP	**EPPO MAR**	2	***100.0***	**100.8**	99.8-101.7	**99.9**	97.3-102.5	= (2)
TGW								
TRZSP	**EPPO MAR**	1	***100.0***	**100.3**	-	**99.9**	-	= (1)

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.4-2
No. of trials where >, = or <, based on statistically significant differences at 95% confidence level.

Also, evaluations of quality parameters (HLW, TGW) were carried out on 4 of the efficacy trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1 L product/ha against foliar diseases in spelt. Data on quality of the harvested grain in presence of disease from these trials are summarized in Section 3.2.3.1.5.

Whilst FGF11 produced increases in quality of the harvested grain, compared to the untreated control, as a direct function of control of target disease in the majority of these trials, there was no evidence of 2 applications of FGF11 at the proposed label rate of 1.0 L product/ha having an adverse impact on quality of the harvested grain on any of the efficacy trials.

Additionally, applications of FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or adverse effects on crop growth and development on any of the trials carried out on spelt. Furthermore, products containing prothioconazole and/or azoxystrobin are approved and used in spelt for many years in the EU Central registration zone and therefore the absence of adverse impact of these active substances on quality of the harvested grain in spelt is well established and proven through commercial use when applications are made according to label recommendations.

On this basis, it is reasonable to consider that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and applied according to label recommendations, has no adverse impact on quality of the harvested grain in spelt.

Comments of zRMS:

2 low disease trials were conducted in spelt in the Maritime EPPO climatic zone. The trial results have shown that FGF11 applied at dose rate of 1 l/ha is safe for quality parameters of the harvested grain. The mean crop quality increased compared to the untreated control: HLW to 100,8% and TGW to 100,3%. No significant differences between FGF11 and the reference product Proline at 0,8 l/ha were observed in the submitted trials.

3.4.3.3 Quality of plants/plant products in durum wheat

Evaluations of quality parameters of the harvested grains (TGW and HLW) was carried out on 3 of the efficacy trials conducted in 2022 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1 L product/ha against foliar diseases in durum wheat. Quality parameters data from these trials are summarized in Section 3.2.3.1.5. No low disease trials were harvested, therefore no yield quality data in the absence of significant disease can be presented here.

Whilst FGF11 produced increases in grain quality parameters, compared to the untreated control, as a direct function of control of target disease in these trials, there was no evidence of 2 applications of FGF11 at the proposed label rate of 1.0 L product/ha having an adverse impact on seed quality parameters on these trials.

Additionally, two applications of FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or adverse effects on crop growth and development on any of the trials carried out on durum wheat. Furthermore, products containing prothioconazole and/or azoxystrobin are

approved and used in durum wheat for many years in the EU Central registration zone and therefore the absence of adverse impact of these active substances on grain quality parameter in durum wheat is well established and proven through commercial use when applications are made according to label recommendations.

On this basis, it is reasonable to consider that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and applied according to label recommendations, has no adverse impact on quality of the grains in durum wheat.

Comments of zRMS:

Accepted.

3.4.3.4 Quality of plants/plant products in triticale

Evaluations of quality parameters of the harvested grains (TGW and HLW) was carried out on 5 of the efficacy trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1 L product/ha against foliar diseases in triticale. Quality parameters data from these trials are summarized in Section 3.2.3.1.5. No low disease trials were harvested, therefore no yield quality data in the absence of significant disease can be presented here.

Whilst FGF11 produced increases in grain quality parameters, compared to the untreated control, as a direct function of control of target disease in some of these trials, there was no evidence of a single application of FGF11 at the proposed label rate of 1.0 L product/ha having an adverse impact on grain quality parameters on any of the trials.

Additionally, two applications of FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or adverse effects on crop growth and development on any of the trials carried out on triticale. Furthermore, products containing prothioconazole and/or azoxystrobin are approved and used in triticale for many years in the EU Central registration zone and therefore the absence of adverse impact of these active substances on grain quality parameter in both, spring and winter triticale is well established and proven through commercial use when applications are made according to label recommendations.

On this basis, it is reasonable to consider that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and applied according to label recommendations, has no adverse impact on quality of the seeds in triticale (winter and spring).

Comments of zRMS:

Accepted.

3.4.3.5 Quality of plants/plant products in rye (in the absence of disease)

One (1) low disease trials carried out in 2023 generated data on quality parameters of the harvested grain following a single application of FGF11 applied at the proposed label rate of 1.0 L product/ha in the absence of significant disease (<5% pest severity at any assessment) in rye. This trial was carried out on winter rye within the Maritime EPPO climatic zone.

The materials and methods used in all low disease trials are given in Section 3.4.1.5.

Evaluations of quality parameters of the harvested grain have been carried out at normal commercial harvest following the application of FGF11 on 1 low disease trial conducted in 2023 in countries within the Maritime EPPO climatic zone.

Two applications of FGF11 at the proposed label rate of 1.0 L product/ha were made on crops growth stage and in water volumes representative of the ones proposed for the application of FGF11.

Across trials, the potential impact of FGF11 on quality of the harvested grain has been tested under a wide range of climatic conditions, agronomic practices and disease development patterns and pressures considered to fully represent those in rye crops growing regions across EU Central Registration zone countries.

Two applications of FGF11 at the proposed label rate of 1.0 L product/ha caused no significant phytotoxic symptoms or pronounced adverse effects on quality parameters (HLW) on any of this 1 disease trials carried out in wheat.

Table 3.4-21: Overall mean crop quality (expressed as % relative to the untreated control) in the absence of significant disease following application of FGF11 at the proposed label rate of 1.0 L product/ha in winter rye

Crop	Registration or EPPO climatic zone	Nº Trials	*Untreated*	FGF11		Proline*		Statical comparison of FGF11 to SRP#
				1.0 L/ha		0.8 L/ha		
			Mean	Mean	Min-Max	Mean	Min-Max	
HLW								
SECCW	**EPPO MAR**	1	***100.0***	**101.0**	-	**101.5**	-	= (1)

* Proline at 0.8 L/ha or other reference products at rates delivering 200 g prothioconazole/ha (+/- 5%). For details, please refer to Table 3.4-2
No. of trials where >, = or <, based on statistically significant differences at 95% confidence level.

Also evaluations of quality parameters (HLW, TGW) were carried out on 7 of the efficacy trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1 L product/ha against foliar diseases in rye. Data on quality of the harvested grain in presence of disease from these trials are summarized in Section 3.2.3.2.3.

Whilst FGF11 produced increases in quality of the harvested grain, compared to the untreated control, as a direct function of control of target disease in the majority of these trials, there was no evidence of 2 applications of FGF11 at the proposed label rate of 1.0 L product/ha having an adverse impact on quality of the harvested grain on any of the efficacy trials.

Additionally, applications of FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or adverse effects on crop growth and development on any of the trials carried out on winter rye. Furthermore, products containing prothioconazole and/or azoxystrobin are approved and used in rye for many years in the EU Central registration zone and therefore the absence of adverse impact of these active substances on quality of the harvested grain in both, spring and winter rye is well established and proven through commercial use when applications are made according to label recommendations.

On this basis, it is reasonable to consider that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and applied according to label recommendations, has no adverse impact on quality of the harvested grain in rye (winter and spring).

Comments of zRMS:

1 low disease trial was conducted in winter rye in the Maritime EPPO climatic zone. The trial result has shown that FGF11 applied at dose rate of 1 l/ha is safe for quality parameters of the harvested grain. The mean crop quality increased compared to the untreated control: HLW to 101 %. No significant differences between FGF11 and the reference product Proline at 0,8 l/ha were observed in the submitted trial.

3.4.3.6 Quality of plants/plant products in barley

Evaluations of quality parameters of the harvested grains (TGW and HLW) was carried out on 14 of the efficacy trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1 L product/ha against foliar diseases in triticale. Quality parameters data from these trials are summarized in Section 3.2.3.1.5. No low disease trials were harvested, therefore no yield quality data in the absence of significant disease can be presented here.

Whilst FGF11 produced increases in grain quality parameters, compared to the untreated control, as a direct function of control of target disease in some of these trials, there was no evidence of a single application of FGF11 at the proposed label rate of 1.0 L product/ha having an adverse impact on grain quality parameters on any of the trials.

Additionally, two applications of FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or adverse effects on crop growth and development on any of the trials carried out on barley. Furthermore, products containing prothioconazole and/or azoxystrobin are approved and used in barley for many years in the EU Central registration zone and therefore the absence of adverse impact of these active substances on grain quality parameter in both, spring and winter barley is well established and proven through commercial use when applications are made according to label recommendations.

On this basis, it is reasonable to consider that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and applied according to label recommendations, has no adverse impact on quality of the seeds in barley (winter and spring).

Comments of zRMS:

Accepted.

3.4.3.7 Quality of plants/plant products in winter and spring oilseed rape

Evaluations of quality parameters of the harvested seeds (TGW and/or oil content) were carried out on 14 of the efficacy trials conducted between 2022 and 2023 that generated data on the efficacy of FGF11 applied at the proposed label rate of 1 L product/ha against SCLESC in oilseed rape. Quality parameters data from these trials are summarized in Section 3.2.3.4.2. No low disease trials were harvested, therefore no yield quality data in the absence of significant disease can be presented here.

Whilst FGF11 produced increases in seed quality parameters, compared to the untreated control, as a direct function of control of target disease in some of these trials, there was no evidence of a single application of FGF11 at the proposed label rate of 1.0 L product/ha having an adverse impact on seed quality parameters on any of the trials.

Additionally, single applications of FGF11 applied at the proposed label rate of 1.0 L product/ha caused no phytotoxic symptoms or adverse effects on crop growth and development on any of the trials carried out on winter oilseed rape. Furthermore, products containing prothioconazole and/or azoxystrobin are approved and used in oilseed rape for many years in the EU Central registration zone and therefore the absence of adverse impact of these active substances on seed quality parameter in both, spring and winter oilseed rape is well established and proven through commercial use when applications are made according to label recommendations.

On this basis, it is reasonable to consider that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and applied according to label recommendations, has no adverse impact on quality of the seeds in oilseed rape (winter and spring).

Comments of zRMS:

Accepted.

3.4.4 Effects on transformation processes (KCP 6.4.4)

3.4.4.1 Transformation processes and taints in wheat

Processing (wheat milling, bread baking) has been carried out on grains sampled at commercial harvest following a single applications of FGF11 at the maximum proposed label rate of 1.0 L product/ha on 2 trials carried out in 2022 on winter wheat.

Both trials were carried out in the Maritime EPPO climatic zone.

Table 3.4-22: Details on trial methodology (trials generating samples for processing)

Maritime EPPO climatic zone		
Guidelines	General guidelines	EPPO PP1/152 (4), EPPO PP1/181 (4), EPPO PP1/135 (4), EPPO PP 1/223(2), EPPO 1/225 (2)
	Specific guidelines	EPPO PP1/242 (2), EPPO PP1/243 (2), CEB 218
Experimental design	Plot design	RCBD (2)
	Plot size	26.9-27.0 m² (2)
	Number of replications	3 (2)
Crop	Trials per crop	TRZAW (2)
	Varieties per crop	**TRZAW:** Absalon (1), Complice (1)
	Sowing period	**TRZAW:** October (1)
Application	Timing Crop stage (BBCH) at application	Post-emergence A1: 32-33 (BBCH) A2: from 39-45 to 49-51 (BBCH)
	Number of applications Interval between applications	2 (2) with intervals of 14 days
	Spray volumes	150 L/ha (1), 180 L/ha (1)
Sampling	Application to processing interval (days)	e.g. Taint tests on white bread: 168 (1), 167 (1)
Processing	Procedure – commodity	Wheat milling – flour (2) Bread making – white bread (2)
Assessments	Assessment types	Triangle taint test (2)

Whilst all trials have been carried out in the Maritime EPPO climatic zones, it is reasonable to consider that the potential for a product to impact on processing procedures or to cause taints of the harvested commodity is sufficiently similar under different climatic conditions for the data generated in trials carried out in the Maritime EPPO climatic zones to be fully supportive of demonstrating that FGF11 has no adverse impact on processing and causes no taints under conditions in the Mediterranean, North-east and South-east EPPO climatic zones.

In all trials, FGF11 was applied twice at the proposed label rate of 1.0 L product/ha, with intervals between applications of 14 days. This represents a number higher than the maximum number of applications for FGF11. On all trials, samples of grains from crop treated with FGF11 were compared to that of samples of grains from crop treated with the standard reference product (Joao) applied at the authorised rate and according to label recommendations.

Two applications of FGF11 at the proposed label rate of 1.0 L product/ha, with intervals between applications of 14 days and pre-harvest intervals between the final application and sampling of between 70 and 75 days, had no effects on the processing procedure (wheat milling and bread making) and caused no significant taints of white bread produced from grain sampled from any of these 2 trials.

Based on the absence of effects on processing or taints of the white bread produced from grains on any of these trials, it is therefore reasonable to conclude that a single application of FGF11 at the proposed

label rate of 1.0 L product/ha and when applied according to other label recommendations in winter wheat has no adverse effects on wheat milling and bread making and causes no taints of white bread.

Comments of zRMS:

2 processing tests were carried out in 2022 in France on winter wheat. The field phases were conducted according to the study protocol. Applications were carried out as planned. Harvest of wheat samples was completed on 22 Jul 2022 for trial S22-03055-01 and on 27 Jul 2022 for trial S22-03055-02. FGF11 did not show any negative impact on the crop as well as on its yield parameters. Crop yield was significantly increased by FGF11 and JOAO compared to the untreated (13.91t/ha) for Trial S22-03055-01. No differences were observed for Trial S22-03055-02 compared to the untreated (8.78t/ha). No deviation occurred during the field phases. The quality parameter results of trial S22-03055-01 were within the required quality range. Significant differences were observed between the untreated control and two other treatments on hectolitre weight, thousand grain weight and Protein content parameters with FGF11 and JOAO increasing values. No other significant differences were found between all treatments after applying the statistical tests of comparison Dunett and Newman-Keuls. The quality parameter results of trial S22-03055-02 were within the required quality range. No significant differences were found between all treatments after applying the statistical tests of comparison Dunett and Newman-Keuls, except the homogeneity of variances for Failing number (Hagberg), the conditions were respected for the other parameters. In this regard, the Friedman test has been applied on this parameter which is a non-parametric alternative to the one-way ANOVA with repeated measures. After performing the Friendman's test, no significant differences were found. The taint test occurred as expected and with 24 consumers, minimum required in the guidelines. No specific taste defect was found during the taint tests. For both trials, no significant difference was found between the untreated and reference sample, as well, between the reference and the treated sample. Overall, the phase occurred as expected with no deviations.
Taking into account the above results and the applicant's conclusion, it can be concluded that the application of FGF at dose rate of 1 l/ha once per vegetative season according to the recommendations included in the product label doesn't cause any negative impact on wheat milling and bread making or taints of white bread.

3.4.4.2 Transformation processes and taints in barley

Processing (beer brewing) has been carried out on grains sampled at commercial harvest following two applications of FGF11 at the maximum proposed label rate of 1.0 L product/ha on 4 trials carried out in 2022 on barley. Of these trials 2 were carried out in winter barley and 2 were carried out in spring barley

All these trials were carried out in the Maritime EPPO climatic zone.

Table 3.4-23: Details on trial methodology (trials generating samples for processing)

Maritime EPPO climatic zone		
Guidelines	General guidelines	EPPO PP1/152 (4), EPPO PP1/181 (4/5), EPPO PP1/135 (4)
	Specific guidelines	EPPO PP1/242 (2), EPPO PP1/243 (2), CEB 185
Experimental design	Plot design	RCBD (4)
	Plot size	81.0-120.0 m² (4)
	Number of replications	3 (4)
Crop	Trials per crop	HORVW (2) HORVS (2)
	Varieties per crop	**HORVW:** KWS Faro (2) **HORVS:** RGT Planet (2)
	Sowing period	**HORVW:** October (1), November (1) **HORVS:** February (1), March (1)
Application	Timing Crop stage (BBCH) at application	Post-emergence A1: from 43-49 to 51 (BBCH) A2: from 65-69 to 69 (BBCH)
	Number of applications Interval between applications	2 (4) with intervals of 13-14 days
	Spray volumes	200 L/ha (4)

Sampling	Final application to processing interval (days)	e.g. Taint tests on beer: 398 (1), 399 (1), 412 (1), 417 (1)
Processing	Procedure – commodity	Beer brewing (4)
Assessments	Assessment types	Triangle taint test (4)

Applications on all trials that generated samples for processing and taint tests were made using small plot sprayers designed to simulate application using commercial sprayers representative of those used to apply fungicides in barley.

On all trials, multiple (2) applications of the treatments were made when crops were within the growth stage range of 43-49 to 51 (BBCH) for the first application and within the growth stage range of 65-69 to 69 for the second application and therefore representative of the proposed label range for the application of FGF11. Intervals between applications were 13-14 days. These trials are considered worst case scenario as 2 applications of the product were performed instead of only 1 as described in the GAP. And are therefore considered fully supportive for the application of FGF11.

Whilst all trials have been carried out in the Maritime EPPO climatic zones, it is reasonable to consider that the potential for a product to impact on processing procedures or to cause taints of the harvested commodity is sufficiently similar under different climatic conditions for the data generated in trials carried out in the Maritime EPPO climatic zones to be fully supportive of demonstrating that FGF11 has no adverse impact on processing and causes no taints under conditions in the Mediterranean, North-east and South-east EPPO climatic zones.

In all trials, FGF11 was applied twice at the proposed label rate of 1.0 L product/ha, with intervals between applications of 13-14 days. This represents a number higher than the maximum number of applications for FGF11. On all trials, samples of grains from crop treated with FGF11 were compared to that of samples of grains from crop treated with the standard reference product (Prosaro) applied at the authorised rate and according to label recommendations.

Two applications of FGF11 at the proposed label rate of 1.0 L product/ha, with intervals between applications of 13-14 days and pre-harvest intervals between the final application and sampling of between 46 and 57 days, had no effects on the processing procedure (beer brewing) and caused no significant taints of beer produced from grain sampled from any of these 4 trials.

Based on the absence of effects on processing or taints of the beer produced from grains on any of these trials, it is therefore reasonable to conclude that a single application of FGF11 at the proposed label rate of 1.0 L product/ha and when applied according to other label recommendations in winter and spring barley has no adverse effects on beer brewing and causes no taints of beer.

Comments of zRMS:

4 processing tests were carried out in 2022 in France on winter and spring barley. Not any symptom of phytotoxicity has been observed during all period of trial. All treatments proved to be selective with regard to the winter barley variety KWS FARO (which is a variety on favourite brewar variety list). Also no phytotoxicity symptom was observed for all the treatments on the spring barley variety RGT Planet.
The barley specimen is converted if it conforms to the following brewing criteria:
- Protein content: between 9 and 12% of dry material
- Germination after 3 days > 95%
- Kernel size of barley (>2.5mm) ≥ 60%
- Barley infested by mould < 2%
- Moisture content ≤ 15%

Finaly either for winter and spring barley, the barley specimens conform to the brewing criteria. All the barley samples have a proteins content >12%. No differences between FGF11 and the reference product were observed in the malting studies (the determination of ergosterol, germinative energy and germination index, water sensitivity, enniatins analyses, multi-trichothecens, moisture content, proteins content, quantitative determination of Fusarium sp.). Beer analyses (the evaluation of alcohol and original extract, colour, bitterness, haze, CO2, viscosity, head retention value) showed no negative effect after application of the test and reference

product.
Taking into account the above results and the applicant's conclusion, it can be concluded that the application of FGF at dose rate of 1 l/ha once per vegetative season according to the recommendations included in the product label doesn't cause any negative impact on beer brewing and no taints of beer.

3.4.4.3 Transformation processes and taints in oilseed rape

FGF11 is a fungicide and therefore main impact is expected on processing steps including yeasts or other microorganisms. The only widely used processing step for oilseed rape is oil making which only includes mechanical and chemical steps.

Furthermore, products containing azoxystrobin or prothioconazole, either applied alone or as mixtures, have been approved and widely used as fungicides in oilseed rape in EU countries for many years and are well proven to have no adverse effects on processing and taint.

Therefore, no data are presented, and it is reasonable to conclude that FGF11 applied following label recommendations has no adverse effects on processing and taint and can safely be applied on oilseed rape intended for transformation.

Comments of zRMS:

Accepted.

3.4.4.4 Transformation processes and taints in triticale

FGF11 is a fungicide and therefore main impact is expected on processing steps including yeasts or other microorganisms. Triticale is mainly used for fodder without a processing step.

Therefore, no data are presented, and it is reasonable to conclude that FGF11 applied following label recommendations has no adverse effects on processing and taint and can safely be applied on oilseed rape intended for transformation.

Comments of zRMS:

Accepted.

3.4.5 Impact on treated plants or plant parts to be used for propagation (KCP 6.4.5)

Products containing azoxystrobin or prothioconazole, either applied alone or as mixtures, have been approved and widely used as fungicides in cereals and oilseed rape in EU countries for many years and are well proven to have no adverse effects on the viability of plant parts for propagation.

These products containing azoxystrobin and/or prothioconazole have no label restrictions regarding their use on crops for seed production.

Furthermore, as azoxystrobin and prothioconazole are fungicides with little or no effects on plant growth and development and as no adverse effects on any crop have been observed following application of FGF11 in any trial, they are highly unlikely to affect the viability of progeny seed on cereals and oilseed rape.

Therefore, it is reasonable to conclude that FGF11 applied following label recommendations has no adverse effects on the viability of the progeny seed and can safely be applied on cereals and oilseed rape intended for seed production.

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)

Products containing azoxystrobin or prothioconazole, either applied alone or as mixtures, have been approved and widely used as fungicides in cereals and oilseed rape in EU countries for many years and are well proven to have no adverse effects on succeeding crops.

These products containing azoxystrobin and/or prothioconazole have no label restrictions regarding following/replacement crops.

Furthermore, as azoxystrobin and prothioconazole are fungicides with little or no effects on plant growth and development and as no adverse effects on any crop have been observed following application of FGF11 in any trial, they are highly unlikely to have an effect on succeeding crops.

Nevertheless, one greenhouse pot study carried out in 2023 generated data on the potential impact of FGF11 on a representative range of monocotyledonous and dicotyledonous crop species sown following application to the soil at 1.9 L/ha.

The study was conducted in compliance with the OECD Principles of Good Laboratory Practice by an organisation that is included on the national GLP compliance program.

A copy of the GLP certificate for this ~~organisation~~ organization is included in Section 3.7.

Table 3.5-1: Details on trial methodology (Seedling emergence and seedling growth test)

Guidelines	General guidelines	EPPO PP1/135(4)
	Specific guidelines	OECD Guideline 208 (Seedling Emergence and Seedling Growth Test)
Test conditions	Site details	Growth chamber with controlled climatic conditions
	Air temperature	mean 19.9°C
	Relative humidity	mean 63%
	Exposure to light	16 h light, 8 h dark
	Light intensity	mean 341 µE/m^2
Crop details	Crops / varieties tested	Small radish (RAPSR), cucumber (CUMSA), soybean (GLXMA), lettuce (LACSA), garden onion (ALLCE), perennial ryegrass (LOLPE)
Experimental design	Plot design	n/a
	Number of replications	7-10 pots per treatment group
	Number of seeds	2-3 per pot (dicotyledons), 4 per pot (monocotyledons)
Application	Crop stage (BBCH)* at application	Pre-emergence (1 day after sowing)
	Incorporation situation	Not incorporated
	Number of applications	1
	Spray volumes	100 L/ha
Assessment	Assessment types	Phytotoxicity, seedling emergence, plant mortality, shoot fresh weight

In this study, the most sensitive endpoint was shown to be plant biomass (shoot fresh weight) with the most consistent endpoint being the ER_{10} values. As only 1 dose rate was tested, ER_{10} values could only be calculated as limits.

TER values were not calculated as the ER_{10} values of the most sensitive species could only be calculated as limits (≤1.9 L/ha for RAPSR and GLMAX).

The tested application rate of 1.9 L/ha in this study was almost double of the proposed application rate of FGF11 of 1.0 L/ha. Azoxystrobin and prothioconazole are not persistent in soil with a DT_{50} of 78 and 2.8 days and have no known soil activity. Both active substances as well as mixtures of azoxystrobin and prothioconazole are well-known and on the market for many years already and no adverse effects on succeeding or replacement crops have been reported.

It is therefore assumed that it is safe to sow any crop type after commercial harvest of cereals and oilseed rape on which FGF11 has been applied at the proposed label rate of 1 L product/ha and according to other label recommendations.

In the event of crop failure for any reason following the application of FGF11 at the proposed label rate of 1 L product/ha, it is assumed that any crop type can safely be sown.

The risk of adverse impact on succeeding and replacement crops sown or planted following a single application of FGF11 at the proposed label rate of 1 L product/ha in cereals and oilseed rape is minimal and therefore acceptable, with no restrictions necessary.

Comments of zRMS:

1 greenhouse test was carried out in 2023 in Germany. Based on the results of the non-GLP range finding test, the following rate was tested: 1.90 L test item/ha. Six species were tested, four dicotyledonous (small radish, cucumber, soybean, lettuce) and two monocotyledonous species (garden onion, perennial ryegrass), representing six plant families. Azoxystrobin 160 + Prothioconazole 200 g/L SC was tested for effects on seedling emergence and seedling growth. Based on fresh weight the following effect rates were determined:

Crop species	NOER	LOER	Statistical analysis
	L/ha		
Raphanus sativus	>1.9	≤1.9	1
Cucumis sativus	1.9	>1.9	1
Glycine max	>1.9	≤1.9	1
Lactuca sativa	1.9	>1.9	2
Allium cepa	1.9	>1.9	1
Lolium perenne	1.9	>1.9	1

Student t-test, α = 0.05, one-sided smaller
2 Welch t-test, α = 0.05, one-sided smaller

The analytical recovery rate of the active ingredient Azoxystrobin in the stock solution was 103% of the nominal value and the analytical recovery rate of the active ingredient Prothioconazole in the stock solution was 97% of the nominal value. The emergence rate was not statistically significantly reduced for any species tested. The fresh weight was significantly reduced for *Raphanus sativus* (-9.4%) and *Glycine max* (-11.9%) at 1.90 L test item/ha. Mortality was observed for *Allium cepa* at 1.90 L test item/ha (5%). The mortality counts turned out to be not statistically significant. No phytotoxic effects were observed for any species tested.
Taking into account the above results and the applicant's conclusions, the zRMS accepted that the risk of adverse impact on succeeding and replacement crops sown or planted following a single application of FGF11 at 1 l/ha in cereals and oilseed rape is acceptable. No restrictions on the product label are necessary. Although it is also recommended to consider the final conclusions of the evaluation in the residues section (Part B, Section 7).

3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

Products containing azoxystrobin or prothioconazole, either applied alone or as mixtures, have been approved and widely used as fungicides in cereals and oilseed rape in EU countries for many years and are well proven to have no adverse effects on adjacent crops. These products containing azoxystrobin and/or prothioconazole have no label restrictions regarding adjacent crops.

Furthermore, as azoxystrobin and prothioconazole are fungicides with little or no effects on plant growth and development and as no adverse effects on any crop have been observed following application of FGF11 in any trial, they are highly unlikely to have an effect on adjacent crops.

Nevertheless, 2 greenhouse pot studies and 1 lab study are presented in the following for further evidence.

The two greenhouse pot studies carried out in 2023 generated data on the potential impact of FGF11, applied at a range of rates, either pre-emergence (OECD 208, Seedling emergence and seedling growth test) or early post-emergence (OECD 227, Vegetative vigour test) on a representative range of monocotyledonous and dicotyledonous crop types.

The materials and methods used in the OECD 208 seedling emergence and seedling growth test are given in Section 3.5.1.

Materials and methods used in the OECD 227 vegetative vigour test are given here.

The study was conducted in compliance with the OECD Principles of Good Laboratory Practice by an organisation that is included on the national GLP compliance program.

A copy of the GLP certificate for this organisation is included in Section 3.7.

Table 3.5-2: Details on trial methodology (Vegetative vigour test)

Guidelines	General guidelines	EPPO PP1/135(4)
	Specific guidelines	OECD Guideline 227 (Vegetative Vigour Test)
Test conditions	Site details	Growth chamber with controlled climatic conditions
	Air temperature	mean 19.9°C
	Relative humidity	mean 63%
	Exposure to light	16 h light, 8 h dark
	Light intensity	mean 341 µE/m^2
Crop details	Crops / varieties tested	Small radish (RAPSR), cucumber (CUMSA), soybean (GLXMA), lettuce (LACSA), garden onion (ALLCE), perennial ryegrass (LOLPE)
Experimental design	Plot design	n/a
	Number of replications	7-10 pots per treatment group
	Number of seeds	2-3 per pot (dicotyledons), 4 per pot (monocotyledons)
Application	Crop stage (BBCH)* at application	BBCH 12-14
	Number of applications	1
	Spray volumes	100 L/ha
Assessment	Assessment types	Phytotoxicity, plant mortality, shoot fresh weight, growth stage

In the OECD 227 study, no negative impact on any parameter assessed was observed on any crop. In the OECD 208 study, the most sensitive endpoint was shown to be plant biomass (shoot fresh weight) with the most consistent endpoint being the ER_{50} values. As only 1 dose rate was tested, ER_{50} values could only be calculated as limits.

TER values were not calculated as the ER_{50} values of the most sensitive species could only be calculated as limits (≤1.9 L/ha for RAPSR and GLMAX in the OECD 208 seedling emergence test).

The tested application rate of 1.9 L/ha in this study was almost double of the proposed application rate of FGF11 of 1.0 L/ha and is manyfold above the maximum off-field predicted environmental rate ($PER_{off\text{-}field}$) of 0.0277 L product/ha (4.4+5.5 g a.s./ha) at 1 m from the edge of the area of application. Azoxystrobin and prothioconazole are not persistent in soil with a DT_{50} of 78 and 2.8 days and have no

known soil activity. Both active substances as well as mixtures of azoxystrobin and prothioconazole are well-known and on the market for many years already and no adverse effects on other plants including adjacent crops have been reported.

The risk of adverse impact on other plants including adjacent crops from spray drift when FGF11 is applied at the proposed label rate of 1 L product/ha in cereals and oilseed rape, and according to label recommendations to avoid drift, is therefore considered as minimal and poses no unacceptable risk with no restrictions necessary.

Comments of zRMS:

1 greenhouse test (OECD 227) was carried out in 2023 in Germany. Six plant species from six different plant families were tested: *Raphanus sativus, Cucumis sativus, Glycine max, Lactuca sativa, Allium cepa* and *Lolium perenne*. The spray mixture for the highest rate was prepared by dissolving 10.7 g Azoxystrobin 160 + Prothioconazole 200 g/L SC in 500 mL with deionised water (21.4 g test item/L corresponding to 1.90 L test item/ha in 100 L/ha). The purpose of this study was to determine a possible effect of the test item on the vegetative vigour of six non-target plant species representing six plant families. Parameters measured were plant fresh weight, phytotoxicity and mortality.
The analytical recovery rate of the active ingredient Azoxystrobin in the stock solution was 103% of the nominal value and the analytical recovery rate of the active ingredient Prothioconazole in the stock solution was 97% of the nominal value. No statistically significant reduction of the fresh weight was observed for any species tested. No mortality was observed for any species tested. No definite phytotoxic effects were observed for any species tested.
Taking into account the above results and the applicant's conclusions, the zRMS accepted that the risk of adverse impact on other plants including adjacent crops following a single application of FGF11 at 1 l/ha in cereals and oilseed rape is acceptable. No restrictions on the product label are necessary. Although it is also recommended to consider the final conclusions of the evaluation in the ecotoxicology section (Part B, Section 9).

3.5.2.1 Tank cleaning

Tests have been carried out to determine the effectiveness of the tank cleaning procedure for FGF11 as ~~summarised~~ summarized in in Part B Sections 1, 2 and 4 of the submission for approval of FGF11.

A small scale jar test (UPL/2023/1576) was carried out in 2024. Analysis of residues in tank washings were carried out by a GLP accredited laboratory.

The diluted spray was prepared in the jar by mixing FGF11 with water, at a concentration matching the proposed label rate of 1 L product/ha in the minimum proposed water volume of 100 L/ha. Following emptying of the jar, it was then thoroughly rinsed 3 times with water, and the amount of azoxystrobin and prothioconazole in each of the rinses and in the organic solvent used to remove residues from the jar following the final rinsing was determined. The three sequential rinsings reduced the azoxystrobin and prothioconazole concentrations to an average of 0.18% and 0.31% of the original spray concentrations (mean of 3 samples), after the final rinsing (compared to 18.56% and 23.56% after a single rinse and 3.6% and 6.29% after two rinses).

Azoxystrobin and prothioconazole concentrations of 0.18% and 0.31% of the original spray concentrations equates to 0.0018 and 0.0031 L product/ha respectively. These are well below the NOER of >1.9 L product/ha for all tested species in the OECD 227 Vegetative vigour test (Section 0). Even a single and a double rinse would result in application rates well below the NOER.

On this basis, standard recommended tank cleaning procedures are sufficient to reduce residues of FGF11 in the spray equipment to well below those likely to cause damage to the crop on which the sprayer is next used, following use to apply FGF11 at the proposed label rate of 1 L product/ha.

Comments of zRMS:

1 laboratory test was carried out in 2024 in India. The diluted spray was prepared in the jar by mixing FGF11 with water, at a concentration matching the proposed label rate of 1 L product/ha in the minimum proposed water volume of 100 L/ha. The results of effectiveness of cleaning procedures are presented below:

Parameters				Results
Effectiveness of Cleaning Procedures (Rinsing / % Active Substance Removed from Bottle)	Azoxystrobin (mg/L)	Limit of Detection (LOD)		0.08
		Limit of Quantification (LOQ)		0.20
	Prothioconazole (mg/L)	Limit of Detection (LOD)		0.10
		Limit of Quantification (LOQ)		0.25
	Azoxystrobin (%)	Rinsing	Single	81.44 ± 0.03
			Double	96.40 ± 0.01
			Triple	99.82 ± 0.00
	Prothioconazole (%)	Rinsing	Single	76.44 ± 0.08
			Double	93.71 ± 0.03
			Triple	99.69 ± 0.00
	Accuracy (% Recovery)	Azoxystrobin	Level I	105.50
			Level II	95.06
		Prothioconazole	Level I	93.33
			Level II	92.32

The three sequential rinsings reduced residues of FGF11 in the spray equipment to well below those likely to cause damage to the crop on which the sprayer is next used. Taking into account the test results, zRMS accepted the applicant's conclusion that standard recommended tank cleaning procedure are sufficient.

3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

Neither positive nor adverse effects on other plants including adjacent crops were detected while carrying out the above-mentioned efficacy trials following application of FGF11.

Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in Part B, Section 9 (Ecotoxicology).

Compatibility with current management practices including IPM

FGF11 is intended for use as a fungicide for the control of various diseases in cereals and oilseed rape, for which uses compatibility with current management practices, including IPM practices, is not a relevant consideration.

Comments of zRMS:

Accepted.

3.6 Other/special studies

No additional studies are summarized.

3.7 List of test facilities including the corresponding certificates

Table 3.7-1 gives information of the testing facilities and corresponding certificates valid at the time of the trials were carried out.

All corresponding GEP certificates which are available in the GEP Certificate Database System (Certibase) (http://www.gepcertibase.eu) are provided via the hyperlinks in the table. Remaining certificates are embedded as pdf file.

Table 3.7-1: List of test facilities

Organisation	Country	Trial numbers				GEP certification		
		2022	2023	2024	Total	Valid From	Valid To	Link
Agrartest GmbH	DEU	12	7		19	26/01/2021	26/01/2026	GgA4DE3pvO
Agreco sp. z o.o.	POL		7		7	15/04/2021	-	Agreco Sp. z o.o..pdf
Agrolab A/S	DNK		1		1	01/01/2020	31/12/2025	Waj4vnQ4PB
AgroProspect S.R.L	ROU		3		3	08/01/2018 07/12/2022	08/01/2023 07/12/2027	GEP4O132b0 lngNkwdN3k
CERESTIS	FRA	3			3	12/02/2018 12/02/2023	12/02/2023 11/02/2028	KYn47brNwQ Av7Nm6m43Z
EAS Bulgaria	BGR	8	11		19	20/06/2019 03/12/2020	28/05/2025 28/05/2025	Jvm2yga4V0 k8DNKWENmA
EAS France	FRA	8	11		19	15/03/2022	23/02/2024	Jm74ElONWw
EAS Germany	DEU	5	12		17	26/01/2021	26/01/2026	GgA4DE3pvO
EAS Hungary	HUN	7	18		25	24/10/2019	24/10/2024	GEP4Olapb0
EAS Ireland	IRL	5	6		11	01/01/2022 01/01/2023	31/12/2022 31/12/2023	wzE4z6K4ql jgK2WL5N6v
EAS Poland	POL	12	17		29	10/08/2015	31/12/2100	5Z32oRgpdE
EAS Romania	ROU	10	21		31	24/11/2020	25/11/2025	Pmb2BWANdE
EAS GB	GBR	13	13		26	01/01/2018 01/01/2023	31/12/2022 31/12/2027	GgA4DE1pvO RgW2gRvp5O
EPHYDIA	FRA		2		2	25/02/2021 30/01/2023	29/01/2023 29/01/2028	lngNk9Gp3k jgK2W3L26v
ESSAIS +	FRA	1			1	04/04/2022	16/02/2024	k8DNKx04mA
Eurofins - De Bredelaar	NLD		1		1	22/01/2020	22/01/2026	lqPpwgwpgD
Fertico Sp. z o.o.	POL		4		4	26/04/2011	-	jgK2W9a46v
Field Research Support	POL		12		12	07/06/2013	31/12/2100	jgK2W6Lp6v
Latvian Plant Protection Research Centre	LVA		1		1	05/10/2020	06/10/2026	GgA4Do3NvO
Lithuanian Research Centre for Agriculture and Forestry	LTU	5	1		6	06/12/2021	31/12/2026	10GNJov4d3
Natural Resources Institute Finland (LGBe)	FIN	1	1		2	03/02/2017 01/02/2023	03/02/2023 30/01/2029	Luke (1).pdf Luke (2).pdf
Sagea Agromania	ROU		2		2	24/03/2022	24/03/2027	7XA2nRr2VK
Sagea OOD	BGR		2		2	06/10/2017	06/10/2027	lqPpwYwNgD
SIA AgroLab Baltic	LVA		1		1	15/12/2023	14/12/2028	Y8z4YxPN3R
STAPHYT	FRA		1		1	14/10/2021	13/06/2026	hx7a4REZNjV
Syntech Research Agrico SRL	ROU		1		1	25/04/2023	25/04/2028	KxE49Ax4bZ
Syntech Research Bulgaria EOOD	BGR		1		1	03/05/2023	05/04/2033	walNVLxpPr
UAB Agrolab Baltic	LTU		1		1	22/12/2022	21/12/2027	zKoNajV4Lr
UPL Europe Ltd	GBR			1	1	01/08/2023	31/07/2028	UPL Europe Ltd.pdf
UPL Iberia SA	ESP			1	1	10/11/2022	-	UPL Spain.pdf
VKST Field Trials	DNK		1		1	01/01/2020	31/12/2025	A67Nd6PpGZ

Organisation	Country	Trial numbers				GEP certification		
		2022	2023	2024	Total	Valid From	Valid To	Link
Organisation	**Country**	**Trial numbers**				**GLP certification**		
		2022	**2023**	**2024**	**Total**	**Valid From**	**Valid To**	**Link**
Jai Research Foundation	IND		1		1	04/05/2023	04/08/2025	GLP_tank_cleaning.pdf
Ibacon GmbH	DEU		2		2	20/04/2023	-	GLP_Ibacon.pdf
Total		**90**	**162**	**2**	**254**			

Appendix 1: List of data submitted in support of the evaluation

List of data submitted and relied on

Data points	Author(s)	Year	**Title** **Source (where different from company)** **Company report No.** **GLP or GEP status (Y/N)** **Published or Unpublished**	Data protection claimed Y/N	Owner
KCP 6/01	Eurofins Agroscience Services Regulatory	2024	Biological Assessment Dossier for FGF11 UPL -,- n/a Unpublished This is CONFIDENTIAL INFORMATION	Y	UPL
KCP 6.2/001 KCP 6.4.1/001	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in Europe, 2022. EAS Agrartest, Rosenow F22EU-006-MOA-001 GEP Unpublished	Y	UPL
KCP 6.2/002 KCP 6.4.1/002	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in Europe, 2022. EAS Germany, Detmold F22EU-006-MOA-002 GEP Unpublished	Y	UPL
KCP 6.2/003 KCP 6.4.1/003	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in Europe, 2022. EAS Ireland F22EU-006-MOA-004 GEP Unpublished	Y	UPL
KCP 6.2/004 KCP 6.4.1/004	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in Europe, 2022. EAS Ireland F22EU-006-MOA-005 GEP Unpublished	Y	UPL
KCP 6.2/005 KCP 6.4.1/005	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in Europe, 2022. EAS UK, North West F22EU-006-MOA-006	Y	UPL

Data points	Author(s)	Year	**Title** **Source (where different from company)** **Company report No.** **GLP or GEP status (Y/N)** **Published or Unpublished**	Data protection claimed Y/N	Owner
			GEP Unpublished		
KCP 6.2/006 KCP 6.4.1/006	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in Europe, 2022. Lithuanian Research Centre for Agriculture and Forestry F22EU-006-MOA-008 GEP Unpublished	Y	UPL
KCP 6.2/007 KCP 6.4.1/007	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in Europe, 2022. EUROFINS AGROSCIENCE SERVICES sp z o.o. F22EU-006-MOA-009 GEP Unpublished	Y	UPL
KCP 6.2/008 KCP 6.4.1/008	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in Europe, 2022. EAS Poland, Kazmierz F22EU-006-MOA-010 GEP Unpublished	Y	UPL
KCP 6.2/009 KCP 6.4.1/009	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in Europe, 2022. EAS Hungary, Székesfehérvár F22EU-006-MOA-011 GEP Unpublished	Y	UPL
KCP 6.2/010 KCP 6.4.1/010	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in Europe, 2022. EAS Hungary, Székesfehérvár F22EU-006-MOA-012 GEP Unpublished	Y	UPL
KCP 6.2/011 KCP 6.4.1/011	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in Europe, 2022. EUROFINS AGROSCIENCE SERVICES F22EU-006-MOA-013	Y	UPL

Data points	Author(s)	Year	**Title** **Source (where different from company)** **Company report No.** **GLP or GEP status (Y/N)** **Published or Unpublished**	Data protection claimed Y/N	Owner
			GEP Unpublished		
KCP 6.2/012 KCP 6.4.1/012	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on winter wheat in Europe, 2022. EAS Bulgaria, Letnitsa F22EU-006-MOA-014 GEP Unpublished	Y	UPL
KCP 6.2/013 KCP 6.4.1/013	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on winter wheat in Europe, 2022. Agrartest GmbH F22EU-007-MOA-001 GEP Unpublished	Y	UPL
KCP 6.2/014 KCP 6.4.1/014	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on winter wheat in Europe, 2022. Eurofins PHYLIAE SAS F22EU-007-MOA-002 GEP Unpublished	Y	UPL
KCP 6.2/015 KCP 6.4.1/015	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on winter wheat in Europe, 2022. EUROFINS AGROSCIENCE SERVICES F22EU-007-MOA-003 GEP Unpublished	Y	UPL
KCP 6.2/016 KCP 6.4.1/016	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on winter wheat in Europe, 2022. EAS Ireland F22EU-007-MOA-004 GEP Unpublished	Y	UPL
KCP 6.2/017 KCP 6.4.1/017	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on winter wheat in Europe, 2022. EAS Ireland F22EU-007-MOA-005	Y	UPL

Data points	Author(s)	Year	**Title** **Source (where different from company)** **Company report No.** **GLP or GEP status (Y/N)** **Published or Unpublished**	Data protection claimed Y/N	Owner
			GEP Unpublished		
KCP 6.2/018 KCP 6.4.1/018	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on winter wheat in Europe, 2022. EUROFINS AGROSCIENCE SERVICES F22EU-007-MOA-006 GEP Unpublished	Y	UPL
KCP 6.2/019 KCP 6.4.1/019	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on winter wheat in Europe, 2022. Lithuanian Research Centre for Agriculture and Forestry F22EU-007-MOA-008 GEP Unpublished	Y	UPL
KCP 6.2/020 KCP 6.4.1/020	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on winter wheat in Europe, 2022. EAS Poland, Kazmierz F22EU-007-MOA-009 GEP Unpublished	Y	UPL
KCP 6.2/021 KCP 6.4.1/021	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on winter wheat in Europe, 2022. Eurofins Agroscience services sp. z o.o. F22EU-007-MOA-010 GEP Unpublished	Y	UPL
KCP 6.2/022 KCP 6.4.1/022	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on winter wheat in Europe, 2022. Eurofins Agroscience Services EOOD F22EU-007-MOA-014 GEP Unpublished	Y	UPL
KCP 6.2/023 KCP 6.4.1/023	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter wheat in Europe, 2022. Agrartest GmbH F22EU-008-MOA-001	Y	UPL

Data points	Author(s)	Year	**Title** **Source (where different from company)** **Company report No.** **GLP or GEP status (Y/N)** **Published or Unpublished**	Data protection claimed Y/N	Owner
			GEP Unpublished		
KCP 6.2/024 KCP 6.4.1/024	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter wheat in Europe, 2022. EUROFINS AGROSCIENCE SERVICES F22EU-008-MOA-003 GEP Unpublished	Y	UPL
KCP 6.2/025 KCP 6.4.1/025	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter wheat in Europe, 2022. Agrartest GmbH F22EU-008-MOA-004 GEP Unpublished	Y	UPL
KCP 6.2/026 KCP 6.4.1/026	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter wheat in Europe, 2022. EAS UK, South East F22EU-008-MOA-005 GEP Unpublished	Y	UPL
KCP 6.2/027 KCP 6.4.1/027	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter wheat in Europe, 2022. EAS UK, South East F22EU-008-MOA-006 GEP Unpublished	Y	UPL
KCP 6.2/028 KCP 6.4.1/028	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter wheat in Europe, 2022. Lithuanian Research Centre for Agriculture and Forestry F22EU-008-MOA-008 GEP Unpublished	Y	UPL
KCP 6.2/029 KCP 6.4.1/029	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter wheat in Europe, 2022. EAS Poland, Kazmierz F22EU-008-MOA-009	Y	UPL

Data points	Author(s)	Year	**Title** **Source (where different from company)** **Company report No.** **GLP or GEP status (Y/N)** **Published or Unpublished**	Data protection claimed Y/N	Owner
			GEP Unpublished		
KCP 6.2/030 KCP 6.4.1/030	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter wheat in Europe, 2022. EAS Hungary, Székesfehérvár F22EU-008-MOA-011 GEP Unpublished	Y	UPL
KCP 6.2/031 KCP 6.4.1/031	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter wheat in Europe, 2022. EAS Hungary, Székesfehérvár F22EU-008-MOA-012 GEP Unpublished	Y	UPL
KCP 6.2/032 KCP 6.4.1/032	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter wheat in Europe, 2022. Eurofins Agroscience Services EOOD F22EU-008-MOA-014 GEP Unpublished	Y	UPL
KCP 6.2/033 KCP 6.4.1/033	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on wheat in Europe, 2023 EAS Germany, Detmold F23EU-022-MOA-001 GEP Unpublished	Y	UPL
KCP 6.2/034 KCP 6.4.1/034	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on wheat in Europe, 2023 EAS France, Bretagne F23EU-022-MOA-002 GEP Unpublished	Y	UPL
KCP 6.2/035 KCP 6.4.1/035	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on wheat in Europe, 2023 EUROFINS AGROSCIENCE SERVICES sp z o.o. F23EU-022-MOA-003	Y	UPL

Data points	Author(s)	Year	**Title** **Source (where different from company)** **Company report No.** **GLP or GEP status (Y/N)** **Published or Unpublished**	Data protection claimed Y/N	Owner
			GEP Unpublished		
KCP 6.2/036 KCP 6.4.1/036	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on wheat in Europe, 2023 EAS Poland F23EU-022-MOA-004 GEP Unpublished	Y	UPL
KCP 6.2/037 KCP 6.4.1/037	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on wheat in Europe, 2023 EAS Dobrich F23EU-022-MOA-005 GEP Unpublished	Y	UPL
KCP 6.2/038 KCP 6.4.1/038	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on wheat in Europe, 2023 EUROFINS AGROSCIENCE SERVICES F23EU-022-MOA-006 GEP Unpublished	Y	UPL
KCP 6.2/039 KCP 6.4.1/039	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on winter wheat in Europe, 2023 Agrartest GmbH F23EU-025-MOA-001 GEP Unpublished	Y	UPL
KCP 6.2/040 KCP 6.4.1/040	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on winter wheat in Europe, 2023 EAS France, Centre Beauce F23EU-025-MOA-002 GEP Unpublished	Y	UPL
KCP 6.2/041 KCP 6.4.1/041	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on winter wheat in Europe, 2023 EAS Ireland F23EU-025-MOA-003	Y	UPL

Data points	Author(s)	Year	**Title** **Source (where different from company)** **Company report No.** **GLP or GEP status (Y/N)** **Published or Unpublished**	Data protection claimed Y/N	Owner
			GEP Unpublished		
KCP 6.2/042 KCP 6.4.1/042	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on winter wheat in Europe, 2023 EAS Poland, Jasienica F23EU-025-MOA-004 GEP Unpublished	Y	UPL
KCP 6.2/043 KCP 6.4.1/043	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on winter wheat in Europe, 2023 EAS Dobrich F23EU-025-MOA-005 GEP Unpublished	Y	UPL
KCP 6.2/044 KCP 6.4.1/044	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on winter wheat in Europe, 2023 EUROFINS AGROSCIENCE SERVICES SRL F23EU-025-MOA-006 GEP Unpublished	Y	UPL
KCP 6.2/045 KCP 6.4.1/045	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on winter wheat in Europe, 2023 EAS Romania, Timisoara F23EU-025-MOA-007 GEP Unpublished	Y	UPL
KCP 6.2/046 KCP 6.4.1/046	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on wheat in Europe, 2023 EAS Germany, Detmold F23EU-027-MOA-001 GEP Unpublished	Y	UPL
KCP 6.2/047 KCP 6.4.1/047	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on wheat in Europe, 2023 Agrartest GmbH F23EU-027-MOA-002	Y	UPL

Data points	Author(s)	Year	**Title** **Source (where different from company)** **Company report No.** **GLP or GEP status (Y/N)** **Published or Unpublished**	Data protection claimed Y/N	Owner
			GEP Unpublished		
KCP 6.2/048 KCP 6.4.1/048	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on wheat in Europe, 2023 EAS France, Alsace F23EU-027-MOA-003 GEP Unpublished	Y	UPL
KCP 6.2/049 KCP 6.4.1/049	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on wheat in Europe, 2023 EAS France, Centre Beauce F23EU-027-MOA-004 GEP Unpublished	Y	UPL
KCP 6.2/050 KCP 6.4.1/050	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on wheat in Europe, 2023 EAS UK, South East F23EU-027-MOA-005 GEP Unpublished	Y	UPL
KCP 6.2/051 KCP 6.4.1/051	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on wheat in Europe, 2023 EAS UK, South East F23EU-027-MOA-006 GEP Unpublished	Y	UPL
KCP 6.2/052 KCP 6.4.1/052	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on wheat in Europe, 2023 EAS Poland, Jasienica F23EU-027-MOA-007 GEP Unpublished	Y	UPL
KCP 6.2/053 KCP 6.4.1/053	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on wheat in Europe, 2023 Eurofins Agroscience Services EOOD F23EU-027-MOA-008	Y	UPL

Data points	Author(s)	Year	**Title** **Source (where different from company)** **Company report No.** **GLP or GEP status (Y/N)** **Published or Unpublished**	Data protection claimed Y/N	Owner
			GEP Unpublished		
KCP 6.2/054 KCP 6.4.1/054	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on wheat in Europe, 2023 EUROFINS AGROSCIENCE SERVICES F23EU-027-MOA-009 GEP Unpublished	Y	UPL
KCP 6.2/055 KCP 6.4.1/055	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on wheat in Europe, 2023 EAS Hungary, Székesfehérvár F23EU-027-MOA-010 GEP Unpublished	Y	UPL
KCP 6.2/056 KCP 6.4.1/056	Natalie Birkinshaw	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in Maritime Europe 2023. EAS Germany, Beimerstetten F23EU-033-MOA-003 GEP Unpublished	Y	UPL
KCP 6.4.1/057 KCP 6.4.2/001 KCP 6.4.3/001	Natalie Birkinshaw	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in Maritime Europe 2023. EAS France, Normandie F23EU-033-MOA-004 GEP Unpublished	Y	UPL
KCP 6.4.1/058 KCP 6.4.2/002 KCP 6.4.3/002	Natalie Birkinshaw	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in Maritime Europe 2023. EAS France, Alsace F23EU-033-MOA-006 GEP Unpublished	Y	UPL
KCP 6.2/057 KCP 6.4.1/059	Natalie Birkinshaw	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in Maritime Europe 2023. EAS Ireland F23EU-033-MOA-007	Y	UPL

Data points	Author(s)	Year	**Title** **Source (where different from company)** **Company report No.** **GLP or GEP status (Y/N)** **Published or Unpublished**	Data protection claimed Y/N	Owner
			GEP Unpublished		
KCP 6.2/058 KCP 6.4.1/060	Natalie Birkinshaw	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in Maritime Europe 2023. EUROFINS AGROSCIENCE SERVICES F23EU-033-MOA-008 GEP Unpublished	Y	UPL
KCP 6.4.1/061 KCP 6.4.2/003 KCP 6.4.3/003	Natalie Birkinshaw	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in Maritime Europe 2023. EAS UK F23EU-033-MOA-009 GEP Unpublished	Y	UPL
KCP 6.2/059 KCP 6.4.1/062	Natalie Birkinshaw	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in North-East Europe. EUROFINS AGROSCIENCE SERVICES sp z o.o. F23EU-034-MOA-001 GEP Unpublished	Y	UPL
KCP 6.2/060 KCP 6.4.1/063	Natalie Birkinshaw	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in North-East Europe. EUROFINS AGROSCIENCE SERVICES sp z o.o. F23EU-034-MOA-002 GEP Unpublished	Y	UPL
KCP 6.2/061 KCP 6.4.1/064	Natalie Birkinshaw	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in North-East Europe. EAS Poland F23EU-034-MOA-003 GEP Unpublished	Y	UPL
KCP 6.2/062 KCP 6.4.1/065	Piotr Umiński	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in Poland Europe 2023. Field Research Support F23EU-034-MOA-004	Y	UPL

Data points	Author(s)	Year	**Title** **Source (where different from company)** **Company report No.** **GLP or GEP status (Y/N)** **Published or Unpublished**	Data protection claimed Y/N	Owner
			GEP Unpublished		
KCP 6.2/063 KCP 6.4.1/066	Piotr Umiński	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in Poland Europe 2023. Field Research Support F23EU-034-MOA-005 GEP Unpublished	Y	UPL
KCP 6.2/064 KCP 6.4.1/067	Piotr Umiński	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in Poland Europe 2023. Field Research Support F23EU-034-MOA-006 GEP Unpublished	Y	UPL
KCP 6.2/065 KCP 6.4.1/068	Natalie Birkinshaw	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in South-East Europe. Eurofins Agroscience Services EOOD F23EU-035-MOA-001 GEP Unpublished	Y	UPL
KCP 6.2/066 KCP 6.4.1/069	Natalie Birkinshaw	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in South-East Europe. EUROFINS AGROSCIENCE SERVICES SRL F23EU-035-MOA-003 GEP Unpublished	Y	UPL
KCP 6.2/067 KCP 6.4.1/070	Natalie Birkinshaw	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in South-East Europe. EAS Romania, Timisoara F23EU-035-MOA-004 GEP Unpublished	Y	UPL
KCP 6.2/068 KCP 6.4.1/071	Natalie Birkinshaw	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in South-East Europe. EAS Hungary, Székesfehérvár F23EU-035-MOA-005	Y	UPL

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			GEP Unpublished		
KCP 6.2/069 KCP 6.4.1/072	Natalie Birkinshaw	2024	The efficacy of FGF11 applied in wheat for the control of Fusarium sp. in South-East Europe. EAS Hungary, Székesfehérvár F23EU-035-MOA-006 GEP Unpublished	Y	UPL
KCP 6.2/070 KCP 6.4.1/073	Piotr Umiński	2024	Evaluate the efficacy of FGF11 applied for the control of foliar diseases in cereals in Poland, 2023. Field Research Support F23EU-037-MOA-001 GEP Unpublished	Y	UPL
KCP 6.2/071 KCP 6.4.1/074	Piotr Umiński	2024	Evaluate the efficacy of FGF11 applied for the control of foliar diseases in cereals in Poland, 2023. Field Research Support F23EU-037-MOA-004 GEP Unpublished	Y	UPL
KCP 6.2/072 KCP 6.4.1/075	Krzysztof Rusek	2024	Evaluate the efficacy of FGF11 applied for the control of foliar diseases in cereals in Poland, 2023. Fertico Sp.z o.o. F23EU-037-MOA-005 GEP Unpublished	Y	UPL
KCP 6.2/073 KCP 6.4.1/076	Katarzyna Furman-Fratczak	2024	Evaluate the efficacy of FGF11 applied for the control of foliar diseases in cereals in Poland, 2023. Agreco sp. z o.o. F23EU-037-MOA-007 GEP Unpublished	Y	UPL
KCP 6.2/074 KCP 6.4.1/077	Piotr Umiński	2024	Evaluate the efficacy of FGF11 applied for the control of foliar diseases in cereals in Poland, 2023. Field Research Support F23EU-037-MOA-008	Y	UPL

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			GEP Unpublished		
KCP 6.2/075 KCP 6.4.1/078	Krzysztof Rusek	2024	Evaluate the efficacy of FGF11 applied for the control of foliar diseases in cereals in Poland, 2023. Fertico F23EU-037-MOA-009 GEP Unpublished	Y	UPL
KCP 6.2/076 KCP 6.4.1/079	Gheorghe Botoman	2024	Evaluate the efficacy of FGF11 applied for the control of foliar diseases in cereals in Romania, 2023. AgroProspect S.R.L F23EU-039-MOA-001 GEP Unpublished	Y	UPL
KCP 6.2/077 KCP 6.4.1/080	Gheorghe Botoman	2024	Evaluate the efficacy of FGF11 applied for the control of foliar diseases in cereals in Romania, 2023. AgroProspect S.R.L F23EU-039-MOA-002 GEP Unpublished	Y	UPL
KCP 6.2/078 KCP 6.4.1/081	Andrés SEDANO	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. STAPHYT F23EU-040-AMA-001 GEP Unpublished	Y	UPL
KCP 6.2/079 KCP 6.4.1/082	Gaëtan Wallart	2024	The effecacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. EPHYDIA F23EU-040-AMA-002 GEP Unpublished	Y	UPL
KCP 6.2/080 KCP 6.4.1/083	Gaëtan Wallart	2024	The effecacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. EPHYDIA F23EU-040-AMA-003	Y	UPL

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			GEP Unpublished		
KCP 6.2/081 KCP 6.4.1/084	Natalie Birkinshaw	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. EAS Germany, Stade F23EU-040-AMA-006 GEP Unpublished	Y	UPL
KCP 6.4.1/085 KCP 6.4.2/004 KCP 6.4.3/004	Natalie Birkinshaw	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. Eurofins - De Bredelaar F23EU-040-AMA-007 GEP Unpublished	Y	UPL
KCP 6.2/082 KCP 6.4.1/086	Natalie Birkinshaw	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. EAS Ireland F23EU-040-AMA-008 GEP Unpublished	Y	UPL
KCP 6.2/083 KCP 6.4.1/087	Natalie Birkinshaw	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. EAS Ireland F23EU-040-AMA-009 GEP Unpublished	Y	UPL
KCP 6.4.1/088 KCP 6.4.2/005 KCP 6.4.3/005	Natalie Birkinshaw	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. EAS UK F23EU-040-AMA-010 GEP Unpublished	Y	UPL
KCP 6.4.1/089 KCP 6.4.2/006 KCP 6.4.3/006	Natalie Birkinshaw	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. EAS UK, Wilson Field F23EU-040-AMA-011	Y	UPL

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			GEP Unpublished		
KCP 6.2/084 KCP 6.4.1/090	Evaldas Lelešius	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. Agrolab A/S F23EU-040-AMA-012 GEP Unpublished	Y	UPL
KCP 6.2/085 KCP 6.4.1/091	Piotr Umiński	2024	The effecacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. Field Research Support F23EU-040-AMA-025 GEP Unpublished	Y	UPL
KCP 6.2/086 KCP 6.4.1/092	Piotr Umiński	2024	The effecacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. Field Research Support F23EU-040-AMA-026 GEP Unpublished	Y	UPL
KCP 6.2/087 KCP 6.4.1/093	Piotr Umiński	2024	The effecacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. Field Research Support F23EU-040-AMA-027 GEP Unpublished	Y	UPL
KCP 6.2/088 KCP 6.4.1/094	Piotr Umiński	2024	The effecacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. Field Research Support F23EU-040-AMA-028 GEP Unpublished	Y	UPL
KCP 6.2/089 KCP 6.4.1/095	Krzysztof Rusek	2024	The effecacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. Fertico F23EU-040-AMA-029	Y	UPL

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			GEP Unpublished		
KCP 6.2/090 KCP 6.4.1/096	Krzysztof Rusek	2024	The effecacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. Fertico Sp. z o.o. F23EU-040-AMA-030 GEP Unpublished	Y	UPL
KCP 6.2/091 KCP 6.4.1/097	Natalie Birkinshaw	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. Latvian Plant Protection Research Centre F23EU-040-AMA-031 GEP Unpublished	Y	UPL
KCP 6.2/092 KCP 6.4.1/098	Evaldas Lelešius	2024	The effecacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. SIA AgroLab Baltic F23EU-040-AMA-032 GEP Unpublished	Y	UPL
KCP 6.2/093 KCP 6.4.1/099	Natalie Birkinshaw	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. Institute of Agriculture, LRCAF F23EU-040-AMA-033 GEP Unpublished	Y	UPL
KCP 6.2/094 KCP 6.4.1/100	Evaldas Lelešius	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. UAB Agrolab Baltic F23EU-040-AMA-034 GEP Unpublished	Y	UPL
KCP 6.2/095 KCP 6.4.1/101	Aleksa Dimitrijevic	2024	The efficacy of FGR06 and FGF11 applied in wheat for the control of Fusarium sp. in Southest zone - Romania 2023. Sagea Agromania F23EU-040-AMA-035	Y	UPL

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			GEP Unpublished		
KCP 6.2/096 KCP 6.4.1/102	Aleksa Dimitrijevic	2024	The efficacy of FGR06 and FGF11 applied in wheat for the control of Fusarium sp. in Southeast zone - Romania 2023. Sagea Agromania F23EU-040-AMA-036 GEP Unpublished	Y	UPL
KCP 6.2/097 KCP 6.4.1/103	Aleksa Dimitrijevic	2024	The efficacy of FGR06 and FGF11 applied in wheat for the control of Fusarium sp. in Southeast zone - Bulgaria 2023. Sagea OOD F23EU-040-AMA-037 GEP Unpublished	Y	UPL
KCP 6.2/098 KCP 6.4.1/104	Penyo Penev	2024	The efficacy of FGR06 and FGF11 applied in wheat for the control of Fusarium sp. in Southeast zone - Bulgaria 2023 SAGEA OOD F23EU-040-AMA-038 GEP Unpublished	Y	UPL
KCP 6.2/099 KCP 6.4.1/105	Natalie Birkinshaw	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. EAS Hungary, Székesfehérvár F23EU-040-AMA-039 GEP Unpublished	Y	UPL
KCP 6.2/100 KCP 6.4.1/106	Natalie Birkinshaw	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. EAS Hungary, Székesfehérvár F23EU-040-AMA-040 GEP Unpublished	Y	UPL
KCP 6.2/101 KCP 6.4.1/107	Natalie Birkinshaw	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. EAS Bulgaria, Letnitsa F23EU-040-AMA-041	Y	UPL

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			GEP Unpublished		
KCP 6.2/102 KCP 6.4.1/108	Natalie Birkinshaw	2024	The efficacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. EUROFINS AGROSCIENCE SERVICES F23EU-040-AMA-042 GEP Unpublished	Y	UPL
KCP 6.2/103 KCP 6.4.1/109	Mircea Coman	2024	The effecacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. Syntech Research Agrico SRL F23EU-040-AMA-043 GEP Unpublished	Y	UPL
KCP 6.2/104 KCP 6.4.1/110	Ilia Dimitrov	2024	The effecacy of FGR06 applied in wheat for the control of Fusarium sp. in Europe. Syntech Research Bulgaria EOOD F23EU-040-AMA-044 GEP Unpublished	Y	UPL
KCP 6.2/105 KCP 6.4.1/111	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on spring wheat in Europe, 2022. EAS Germany, Stade F22EU-009-MOA-001 GEP Unpublished	Y	UPL
KCP 6.2/106 KCP 6.4.1/112	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on spring wheat in Europe, 2022. EAS Ireland F22EU-009-MOA-002 GEP Unpublished	Y	UPL
KCP 6.2/107 KCP 6.4.1/113	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on spring wheat in Europe, 2022.	Y	UPL

Data points	Author(s)	Year	**Title** **Source (where different from company)** **Company report No.** **GLP or GEP status (Y/N)** **Published or Unpublished**	Data protection claimed Y/N	Owner
			EAS Poland, Kazmierz F22EU-009-MOA-003 GEP Unpublished		
KCP 6.2/108 KCP 6.4.1/114	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on spring wheat in Europe, 2022. EUROFINS AGROSCIENCE SERVICES F22EU-009-MOA-007 GEP Unpublished	Y	UPL
KCP 6.2/109 KCP 6.4.1/115	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on spring wheat in Europe, 2022. EAS Romania , Timisoara F22EU-009-MOA-009 GEP Unpublished	Y	UPL
KCP 6.2/110 KCP 6.4.1/116	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on spring wheat in Europe, 2022. Agrartest GmbH F22EU-009-MOA-011 GEP Unpublished	Y	UPL
KCP 6.2/111 KCP 6.4.1/117	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on spring wheat in Europe, 2022. EAS UK, Wilson Field F22EU-009-MOA-012 GEP Unpublished	Y	UPL
KCP 6.2/112 KCP 6.4.1/118	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on spring wheat in Europe, 2022. EAS Poland, Kazmierz F22EU-009-MOA-013	Y	UPL

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			GEP Unpublished		
KCP 6.2/113 KCP 6.4.1/119	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on wheat in Europe, 2023 EAS Germany, Stade F23EU-022-MOA-014 GEP Unpublished	Y	UPL
KCP 6.2/114 KCP 6.4.1/120	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on wheat in Europe, 2023 VKST Field Trials F23EU-022-MOA-015 GEP Unpublished	Y	UPL
KCP 6.2/115 KCP 6.4.1/121	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on wheat in Europe, 2023 EAS UK, North West F23EU-022-MOA-016 GEP Unpublished	Y	UPL
KCP 6.2/116 KCP 6.4.1/122	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on wheat in Europe, 2023 EAS Poland F23EU-022-MOA-017 GEP Unpublished	Y	UPL
KCP 6.2/117 KCP 6.4.1/123	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on wheat in Europe, 2023 EAS Romania, Timisoara F23EU-022-MOA-019 GEP Unpublished	Y	UPL
KCP 6.2/118 KCP 6.4.1/124	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on winter wheat in Europe, 2023 EUROFINS AGROSCIENCE SERVICES F23EU-025-MOA-016	Y	UPL

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			GEP Unpublished		
KCP 6.2/119 KCP 6.4.1/125	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on wheat in Europe, 2023 EAS Poland F23EU-027-MOA-016 GEP Unpublished	Y	UPL
KCP 6.2/120 KCP 6.4.1/126	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on wheat in Europe, 2023 EAS Romania, Timisoara F23EU-027-MOA-018 GEP Unpublished	Y	UPL
KCP 6.2/121 KCP 6.4.1/127	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on wheat in Europe, 2023 EAS Hungary, Székesfehérvár F23EU-027-MOA-019 GEP Unpublished	Y	UPL
KCP 6.2/122 KCP 6.4.1/128	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on durum wheat in Europe, 2022. AGRARTEST GmbH F22EU-010-MOA-001 GEP Unpublished	Y	UPL
KCP 6.2/123 KCP 6.4.1/129	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on durum wheat in Europe, 2022. EAS Romania, Timisoara F22EU-010-MOA-005 GEP Unpublished	Y	UPL
KCP 6.2/124 KCP 6.4.1/130	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on durum wheat in Europe, 2022. EAS Bulgaria, Pazardjik F22EU-010-MOA-006	Y	UPL

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			GEP Unpublished		
KCP 6.2/125 KCP 6.4.1/131	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on durum wheat in Europe, 2022. Agrartest GmbH F22EU-011-MOA-001 GEP Unpublished	Y	UPL
KCP 6.2/126 KCP 6.4.1/132	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on durum wheat in Europe, 2022. EAS Romania, Timisoara F22EU-011-MOA-006 GEP Unpublished	Y	UPL
KCP 6.2/127 KCP 6.4.1/133	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on durum wheat in Europe, 2022. EAS Romania, Timisoara F22EU-012-MOA-005 GEP Unpublished	Y	UPL
KCP 6.2/128 KCP 6.4.1/134	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on durum wheat in Europe, 2022. EAS Bulgaria, Pazardjik F22EU-012-MOA-006 GEP Unpublished	Y	UPL
KCP 6.2/129 KCP 6.4.1/135	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on durum wheat in Europe, 2023 EAS Agrartest, Rosenow F23EU-023-MOA-001 GEP Unpublished	Y	UPL
KCP 6.2/130 KCP 6.4.1/136	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on durum wheat in Europe, 2023 Eurofins Agroscience Services EOOD F23EU-023-MOA-008	Y	UPL

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KCP 6.2/131 KCP 6.4.1/137	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on durum wheat in Europe, 2023 EAS Romania, Timisoara F23EU-023-MOA-009 GEP Unpublished	Y	UPL
KCP 6.2/132 KCP 6.4.1/138	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on spelt wheat in Europe, 2022. Agrartest GmbH F22EU-014-MOA-001 GEP Unpublished	Y	UPL
KCP 6.2/133 KCP 6.4.1/139	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on spelt wheat in Europe, 2022. Agrartest GmbH F22EU-014-MOA-003 GEP Unpublished	Y	UPL
KCP 6.2/134 KCP 6.4.1/140	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on spelt wheat in Europe, 2022. Agrartest GmbH F22EU-014-MOA-005 GEP Unpublished	Y	UPL
KCP 6.2/135 KCP 6.4.1/141	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on triticale and spelt wheat in Europe, 2023 EAS Germany, Heidelberg F23EU-024-MOA-008 GEP Unpublished	Y	UPL

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KCP 6.4.1/142 KCP 6.4.2/007 KCP 6.4.3/007	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on triticale and spelt wheat in Europe, 2023 EAS Germany, Beimerstetten F23EU-024-MOA-009 GEP Unpublished	Y	UPL
KCP 6.4.1/143 KCP 6.4.2/008 KCP 6.4.3/008	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on triticale and spelt wheat in Europe, 2023 Agrartest GmbH F23EU-026-MOA-005 GEP Unpublished	Y	UPL
KCP 6.2/136 KCP 6.4.1/144	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on triticale and spelt wheat in Europe, 2023 EAS Germany, Heidelberg F23EU-026-MOA-006 GEP Unpublished	Y	UPL
KCP 6.2/137 KCP 6.4.1/145	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on triticale and spelt wheat in Europe, 2023 EAS Dobrich F23EU-026-MOA-007 GEP Unpublished	Y	UPL
KCP 6.2/138 KCP 6.4.1/146	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on triticale and spelt wheat in Europe, 2023 EAS Romania, Timisoara F23EU-026-MOA-008 GEP Unpublished	Y	UPL
KCP 6.2/139 KCP 6.4.1/147	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on triticale and spelt wheat in Europe, 2023 EAS Hungary, Székesfehérvár F23EU-026-MOA-009 GEP Unpublished	Y	UPL

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KCP 6.2/140 KCP 6.4.1/148	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on triticale in Europe, 2022. Agrartest GmbH F22EU-013-MOA-001 GEP Unpublished	Y	UPL
KCP 6.2/141 KCP 6.4.1/149	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on triticale in Europe, 2022. EAS Poland, Kazmierz F22EU-013-MOA-004 GEP Unpublished	Y	UPL
KCP 6.2/142 KCP 6.4.1/150	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on triticale in Europe, 2022. EAS Romania, Timisoara F22EU-013-MOA-005 GEP Unpublished	Y	UPL
KCP 6.2/143 KCP 6.4.1/151	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on triticale in Europe, 2022. EAS Germany, Stade F22EU-013-MOA-007 GEP Unpublished	Y	UPL
KCP 6.2/144 KCP 6.4.1/152	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on triticale in Europe, 2022. EAS Poland, Kazmierz F22EU-013-MOA-009 GEP Unpublished	Y	UPL
KCP 6.2/145 KCP 6.4.1/153	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis	Y	UPL

Data points	Author(s)	Year	**Title** **Source (where different from company)** **Company report No.** **GLP or GEP status (Y/N)** **Published or Unpublished**	Data protection claimed Y/N	Owner
			(PUCCST) on triticale in Europe, 2022. EAS Romania F22EU-013-MOA-011 GEP Unpublished		
KCP 6.2/146 KCP 6.4.1/154	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR), Puccinia recondita (PUCCRE) and Puccinia striiformis (PUCCST) on triticale in Europe, 2022. EAS Romania, Timisoara F22EU-013-MOA-016 GEP Unpublished	Y	UPL
KCP 6.2/147 KCP 6.4.1/155	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on triticale and spelt wheat in Europe, 2023 EAS Agrartest, Rosenow F23EU-024-MOA-002 GEP Unpublished	Y	UPL
KCP 6.2/148 KCP 6.4.1/156	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on triticale and spelt wheat in Europe, 2023 EAS Agrartest, Rosenow F23EU-024-MOA-003 GEP Unpublished	Y	UPL
KCP 6.2/149 KCP 6.4.1/157	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on triticale and spelt wheat in Europe, 2023 EUROFINS AGROSCIENCE SERVICES sp z o.o. F23EU-024-MOA-004 GEP Unpublished	Y	UPL
KCP 6.2/150 KCP 6.4.1/158	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on triticale and spelt wheat in Europe, 2023 EAS Romania, Timisoara F23EU-024-MOA-005 GEP Unpublished	Y	UPL

Data points	Author(s)	Year	**Title** **Source (where different from company)** **Company report No.** **GLP or GEP status (Y/N)** **Published or Unpublished**	Data protection claimed Y/N	Owner
KCP 6.2/151 KCP 6.4.1/159	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Zymoseptoria tritici (SEPTTR) on triticale and spelt wheat in Europe, 2023 EAS Hungary, Székesfehérvár F23EU-024-MOA-006 GEP Unpublished	Y	UPL
KCP 6.2/152 KCP 6.4.1/160	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on triticale and spelt wheat in Europe, 2023 EAS Germany, Stade F23EU-026-MOA-001 GEP Unpublished	Y	UPL
KCP 6.2/153 KCP 6.4.1/161	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on triticale and spelt wheat in Europe, 2023 EUROFINS AGROSCIENCE SERVICES F23EU-026-MOA-002 GEP Unpublished	Y	UPL
KCP 6.2/154 KCP 6.4.1/162	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on triticale and spelt wheat in Europe, 2023 EAS Poland F23EU-026-MOA-003 GEP Unpublished	Y	UPL
KCP 6.2/155 KCP 6.4.1/163	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia striiformis (PUCCST) on triticale and spelt wheat in Europe, 2023 EAS Romania, Timisoara F23EU-026-MOA-004 GEP Unpublished	Y	UPL
KCP 6.2/156 KCP 6.4.1/164	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on triticale in Europe, 2023 EAS Poland F23EU-028-MOA-003 GEP Unpublished	Y	UPL

Data points	Author(s)	Year	**Title** **Source (where different from company)** **Company report No.** **GLP or GEP status (Y/N)** **Published or Unpublished**	Data protection claimed Y/N	Owner
KCP 6.2/157 KCP 6.4.1/165	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on triticale in Europe, 2023 EUROFINS AGROSCIENCE SERVICES F23EU-028-MOA-004 GEP Unpublished	Y	UPL
KCP 6.2/158 KCP 6.4.1/166	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on triticale in Europe, 2023 EAS Hungary, Székesfehérvár F23EU-028-MOA-005 GEP Unpublished	Y	UPL
KCP 6.2/159 KCP 6.4.1/167	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on triticale in Europe, 2023 EAS Hungary, Székesfehérvár F23EU-028-MOA-006 GEP Unpublished	Y	UPL
KCP 6.2/160 KCP 6.4.1/168	Piotr Umiński	2024	Evaluate the efficacy of FGF11 applied for the control of foliar diseases in cereals in Poland, 2023. Field Research Support F23EU-037-MOA-002 GEP Unpublished	Y	UPL
KCP 6.2/161 KCP 6.4.1/169	Katarzyna Furman-Fratczak	2024	Evaluate the efficacy of FGF11 applied for the control of foliar diseases in cereals in Poland, 2023. Agreco sp. z o.o. F23EU-037-MOA-003 GEP Unpublished	Y	UPL
KCP 6.2/162 KCP 6.4.1/170	Katarzyna Furman-Fratczak	2024	Evaluate the efficacy of FGF11 applied for the control of foliar diseases in cereals in Poland, 2023. Agreco sp. z o.o. F23EU-037-MOA-010 GEP Unpublished	Y	UPL

Data points	Author(s)	Year	**Title** **Source (where different from company)** **Company report No.** **GLP or GEP status (Y/N)** **Published or Unpublished**	Data protection claimed Y/N	Owner
KCP 6.2/163 KCP 6.4.1/171	Gheorghe Botoman	2024	Evaluate the efficacy of FGF11 applied for the control of foliar diseases in cereals in Romania, 2023. AgroProspect S.R.L F23EU-039-MOA-003 GEP Unpublished	Y	UPL
KCP 6.2/164 KCP 6.4.1/172	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2022. EAS France, Val de Loire F22EU-017-MOA-003 GEP Unpublished	Y	UPL
KCP 6.2/165 KCP 6.4.1/173	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2022. EUROFINS AGROSCIENCE SERVICES F22EU-017-MOA-004 GEP Unpublished	Y	UPL
KCP 6.2/166 KCP 6.4.1/174	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2022. EAS UK, South East F22EU-017-MOA-005 GEP Unpublished	Y	UPL
KCP 6.2/167 KCP 6.4.1/175	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2022. EAS UK, South East F22EU-017-MOA-006 GEP Unpublished	Y	UPL
KCP 6.2/168 KCP 6.4.1/176	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2022. EAS Poland, Kazmierz F22EU-017-MOA-009 GEP Unpublished	Y	UPL

Data points	Author(s)	Year	**Title** **Source (where different from company)** **Company report No.** **GLP or GEP status (Y/N)** **Published or Unpublished**	Data protection claimed Y/N	Owner
KCP 6.2/169 KCP 6.4.1/177	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2022. EAS Poland, Kazmierz F22EU-017-MOA-010 GEP Unpublished	Y	UPL
KCP 6.2/170 KCP 6.4.1/178	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2022. EAS Romania, Timisoara F22EU-017-MOA-013 GEP Unpublished	Y	UPL
KCP 6.2/171 KCP 6.4.1/179	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2022. EAS Bulgaria, Pazardjik F22EU-017-MOA-014 GEP Unpublished	Y	UPL
KCP 6.2/172 KCP 6.4.1/180	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2023 EAS Germany, Stade F23EU-029-MOA-002 GEP Unpublished	Y	UPL
KCP 6.2/173 KCP 6.4.1/181	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2023 EAS Ireland F23EU-029-MOA-003 GEP Unpublished	Y	UPL
KCP 6.4.1/182 KCP 6.4.2/009 KCP 6.4.3/009	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2023 EAS UK, South East F23EU-029-MOA-004 GEP Unpublished	Y	UPL

Data points	Author(s)	Year	**Title** **Source (where different from company)** **Company report No.** **GLP or GEP status (Y/N)** **Published or Unpublished**	Data protection claimed Y/N	Owner
KCP 6.2/174 KCP 6.4.1/183	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2023 EAS Poland, Kazmierz F23EU-029-MOA-006 GEP Unpublished	Y	UPL
KCP 6.2/175 KCP 6.4.1/184	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2023 EAS Romania, Timisoara F23EU-029-MOA-007 GEP Unpublished	Y	UPL
KCP 6.2/176 KCP 6.4.1/185	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2023 EAS Hungary, Székesfehérvár F23EU-029-MOA-008 GEP Unpublished	Y	UPL
KCP 6.2/177 KCP 6.4.1/186	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Puccinia recondita (PUCCRE) on winter rye in Europe, 2023 EAS Hungary, Székesfehérvár F23EU-029-MOA-009 GEP Unpublished	Y	UPL
KCP 6.2/178 KCP 6.4.1/187	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2022. EAS Germany, Detmold F22EU-015-MOA-002 GEP Unpublished	Y	UPL
KCP 6.2/179 KCP 6.4.1/188	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2022. EAS France, Normandie F22EU-015-MOA-003 GEP Unpublished	Y	UPL

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KCP 6.2/180 KCP 6.4.1/189	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2022. Eurofins Agroscience Services F22EU-015-MOA-005 GEP Unpublished	Y	UPL
KCP 6.2/181 KCP 6.4.1/190	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2022. EAS UK, Wilson Field F22EU-015-MOA-006 GEP Unpublished	Y	UPL
KCP 6.2/182 KCP 6.4.1/191	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2022. EAS Poland, Kazmierz F22EU-015-MOA-010 GEP Unpublished	Y	UPL
KCP 6.2/183 KCP 6.4.1/192	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2022. EAS Hungary, Székesfehérvár F22EU-015-MOA-011 GEP Unpublished	Y	UPL
KCP 6.2/184 KCP 6.4.1/193	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2022. EAS Romania, Timisoara F22EU-015-MOA-013 GEP Unpublished	Y	UPL
KCP 6.2/185 KCP 6.4.1/194	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2022. Eurofins Agroscience Services EOOD F22EU-015-MOA-014 GEP Unpublished	Y	UPL

Data points	Author(s)	Year	**Title** **Source (where different from company)** **Company report No.** **GLP or GEP status (Y/N)** **Published or Unpublished**	Data protection claimed Y/N	Owner
KCP 6.2/186 KCP 6.4.1/195	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2023 EAS Germany, Detmold F23EU-030-MOA-001 GEP Unpublished	Y	UPL
KCP 6.2/187 KCP 6.4.1/196	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2023 EAS France, Centre Beauce F23EU-030-MOA-003 GEP Unpublished	Y	UPL
KCP 6.2/188 KCP 6.4.1/197	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2023 EAS France, Normandie F23EU-030-MOA-004 GEP Unpublished	Y	UPL
KCP 6.2/189 KCP 6.4.1/198	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2023 EAS France, Bretagne F23EU-030-MOA-005 GEP Unpublished	Y	UPL
KCP 6.2/190 KCP 6.4.1/199	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2023 EAS UK, Wilson Field F23EU-030-MOA-006 GEP Unpublished	Y	UPL
KCP 6.2/191 KCP 6.4.1/200	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2023 EAS UK, Wilson Field F23EU-030-MOA-007 GEP Unpublished	Y	UPL

Data points	Author(s)	Year	**Title** **Source (where different from company)** **Company report No.** **GLP or GEP status (Y/N)** **Published or Unpublished**	Data protection claimed Y/N	Owner
KCP 6.2/192 KCP 6.4.1/201	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2023 EAS Poland, Jasienica F23EU-030-MOA-008 GEP Unpublished	Y	UPL
KCP 6.2/193 KCP 6.4.1/202	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2023 EAS Poland F23EU-030-MOA-009 GEP Unpublished	Y	UPL
KCP 6.2/194 KCP 6.4.1/203	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2023 Eurofins Agroscience Services EOOD F23EU-030-MOA-010 GEP Unpublished	Y	UPL
KCP 6.2/195 KCP 6.4.1/204	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2023 Eurofins Agroscience Services EOOD F23EU-030-MOA-011 GEP Unpublished	Y	UPL
KCP 6.2/196 KCP 6.4.1/205	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2023 EUROFINS AGROSCIENCE SERVICES SRL F23EU-030-MOA-012 GEP Unpublished	Y	UPL
KCP 6.2/197 KCP 6.4.1/206	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2023 EUROFINS AGROSCIENCE SERVICES SRL F23EU-030-MOA-013 GEP Unpublished	Y	UPL

Data points	Author(s)	Year	**Title** **Source (where different from company)** **Company report No.** **GLP or GEP status (Y/N)** **Published or Unpublished**	Data protection claimed Y/N	Owner
KCP 6.2/198 KCP 6.4.1/207	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2023 EAS Hungary, Székesfehérvár F23EU-030-MOA-014 GEP Unpublished	Y	UPL
KCP 6.2/199 KCP 6.4.1/208	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2023 EAS Hungary, Székesfehérvár F23EU-030-MOA-015 GEP Unpublished	Y	UPL
KCP 6.2/200 KCP 6.4.1/209	Katarzyna Furman-Fratczak	2024	Evaluate the efficacy of FGF11 applied for the control of foliar diseases in cereals in Poland, 2023. Agreco sp. z o.o. F23EU-037-MOA-011 GEP Unpublished	Y	UPL
KCP 6.2/201 KCP 6.4.1/210	Piotr Umiński	2024	Evaluate the efficacy of FGF11 applied for the control of foliar diseases in cereals in Poland, 2023. Field Research Support F23EU-037-MOA-012 GEP Unpublished	Y	UPL
KCP 6.2/202 KCP 6.4.1/211	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on spring barley in Europe, 2022. EUROFINS AGROSCIENCE SERVICES F22EU-016-MOA-002 GEP Unpublished	Y	UPL
KCP 6.2/203 KCP 6.4.1/212	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on spring barley in Europe, 2023 EAS Ireland F23EU-031-MOA-003 GEP Unpublished	Y	UPL

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KCP 6.2/204 KCP 6.4.1/213	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on spring barley in Europe, 2023 EUROFINS AGROSCIENCE SERVICES sp z o.o. F23EU-031-MOA-005 GEP Unpublished	Y	UPL
KCP 6.2/205 KCP 6.4.1/214	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on spring barley in Europe, 2023 Natural Resources Institute Finland (Luke) F23EU-031-MOA-006 GEP Unpublished	Y	UPL
KCP 6.2/206 KCP 6.4.1/215	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on spring barley in Europe, 2023 Eurofins Agroscience Services EOOD F23EU-031-MOA-007 GEP Unpublished	Y	UPL
KCP 6.2/207 KCP 6.4.1/216	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on spring barley in Europe, 2023 EAS Romania, Timisoara F23EU-031-MOA-008 GEP Unpublished	Y	UPL
KCP 6.2/208 KCP 6.4.1/217	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on spring barley in Europe, 2023 EAS Hungary, Székesfehérvár F23EU-031-MOA-009 GEP Unpublished	Y	UPL
KCP 6.2/209 KCP 6.4.1/218	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on spring barley in Europe, 2022. Natural Resources Institute Finland (LUKE) F22EU-015-MOA-007 GEP Unpublished	Y	UPL

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KCP 6.2/210 KCP 6.4.1/219	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of Pyrenophora teres (PYRNTE) on winter barley in Europe, 2022. Institute of Agriculture, LRCAF F22EU-015-MOA-008 GEP Unpublished	Y	UPL
KCP 6.2/211 KCP 6.4.1/220	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of sclerotinia sclerotorium on oil seed rape in Europe, 2022. EAS Germany, Stade F22EU-018-MOA-002 GEP Unpublished	Y	UPL
KCP 6.2/212 KCP 6.4.1/221	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of sclerotinia sclerotorium on oil seed rape in Europe, 2022. Agrartest GmbH F22EU-018-MOA-003 GEP Unpublished	Y	UPL
KCP 6.2/213 KCP 6.4.1/222	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of sclerotinia sclerotorium on oil seed rape in Europe, 2022. EAS uk, NorthWest F22EU-018-MOA-005 GEP Unpublished	Y	UPL
KCP 6.2/214 KCP 6.4.1/223	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of sclerotinia sclerotorium on oil seed rape in Europe, 2022. EAS UK, North East F22EU-018-MOA-006 GEP Unpublished	Y	UPL
KCP 6.2/215 KCP 6.4.1/224	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of sclerotinia sclerotorium on oil seed rape in Europe, 2022. Institute of Agriculture, LAMMC F22EU-018-MOA-007 GEP Unpublished	Y	UPL

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KCP 6.2/216 KCP 6.4.1/225	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of sclerotinia sclerotorium on oil seed rape in Europe, 2022. EAS Hungary, Székesfehérvár F22EU-018-MOA-011 GEP Unpublished	Y	UPL
KCP 6.2/217 KCP 6.4.1/226	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of sclerotinia sclerotorium on oil seed rape in Europe, 2022. EAS Hungary, Székesfehérvár F22EU-018-MOA-012 GEP Unpublished	Y	UPL
KCP 6.2/218 KCP 6.4.1/227	Natalie Birkinshaw	2023	The efficacy of FGF11 applied for the control of sclerotinia sclerotorium on oil seed rape in Europe, 2022. EAS Bulgaria, Pazardjik F22EU-018-MOA-013 GEP Unpublished	Y	UPL
KCP 6.2/219 KCP 6.4.1/228	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of sclerotinia sclerotorium on oil seed rape in Europe, 2023 EAS Germany, Beimerstetten F23EU-032-MOA-001 GEP Unpublished	Y	UPL
KCP 6.2/221 KCP 6.4.1/230	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of sclerotinia sclerotorium on oil seed rape in Europe, 2023 EAS France, Bretagne F23EU-032-MOA-003 GEP Unpublished	Y	UPL
KCP 6.2/222 KCP 6.4.1/231	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of sclerotinia sclerotorium on oil seed rape in Europe, 2023 EUROFINS AGROSCIENCE SERVICES F23EU-032-MOA-004 GEP Unpublished	Y	UPL

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KCP 6.2/223 KCP 6.4.1/232	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of sclerotinia sclerotorium on oil seed rape in Europe, 2023 EAS UK, North West F23EU-032-MOA-007 GEP Unpublished	Y	UPL
KCP 6.2/224 KCP 6.4.1/233	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of sclerotinia sclerotorium on oil seed rape in Europe, 2023 EAS Poland F23EU-032-MOA-009 GEP Unpublished	Y	UPL
KCP 6.2/225 KCP 6.4.1/234	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of sclerotinia sclerotorium on oil seed rape in Europe, 2023 Eurofins Agroscience Services EOOD F23EU-032-MOA-010 GEP Unpublished	Y	UPL
KCP 6.2/226 KCP 6.4.1/235	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of sclerotinia sclerotorium on oil seed rape in Europe, 2023 EAS Romania, Timisoara F23EU-032-MOA-011 GEP Unpublished	Y	UPL
KCP 6.2/227 KCP 6.4.1/236	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of sclerotinia sclerotorium on oil seed rape in Europe, 2023 EUROFINS AGROSCIENCE SERVICES SRL F23EU-032-MOA-012 GEP Unpublished	Y	UPL
KCP 6.2/228 KCP 6.4.1/237	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of sclerotinia sclerotorium on oil seed rape in Europe, 2023 EAS Romania , Timisoara F23EU-032-MOA-013 GEP Unpublished	Y	UPL

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KCP 6.2/229 KCP 6.4.1/238	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of sclerotinia sclerotorium on oil seed rape in Europe, 2023 EAS Hungary, Székesfehérvár F23EU-032-MOA-014 GEP Unpublished	Y	UPL
KCP 6.2/230 KCP 6.4.1/239	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of sclerotinia sclerotorium on oil seed rape in Europe, 2023 EAS Hungary, Székesfehérvár F23EU-032-MOA-015 GEP Unpublished	Y	UPL
KCP 6.2/231 KCP 6.4.1/240	Natalie Birkinshaw	2024	The efficacy of FGF11 applied for the control of sclerotinia sclerotorium on oil seed rape in Europe, 2023 EAS Hungary, Székesfehérvár F23EU-032-MOA-016 GEP Unpublished	Y	UPL
KCP 6.2/232 KCP 6.4.1/241	Katarzyna Furman-Fratczak	2024	The efficacy of FGF11 applied for the control of sclerotinia sclerotorium on oil seed rape in Poland, 2022. Agreco sp. z o.o. F23EU-038-MOA-001 GEP Unpublished	Y	UPL
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KCP 6.4.4/01	Natalie Birkinshaw	2024	The evaluation of Non intentional Effects of of FGF11 on quality of Wheat and Bread making, 2022. EUROFINS AGROSCIENCE SERVICES PHYLIAE F22EU-023-MOA-001 GEP Unpublished	Y	UPL
KCP 6.4.4/02	Natalie Birkinshaw	2024	The evaluation of Non intentional Effects of of FGF11 on quality of Wheat and Bread making, 2022. EAS France, Centre Beauce F22EU-023-MOA-002 GEP Unpublished	Y	UPL
KCP 6.4.4/03	Julien Rivet	2023	Unintentional effects of FBQ03, FGR06 and FGF11 on beer and malt making process in barley (field part). ESSAIS + F22EU-038-AMA-001 GEP Unpublished	Y	UPL
KCP 6.4.4/04	Cyprien Tendart	2023	Unintentional effects of FBQ03, FGR06 and FGF11 on beer and malt making process in barley (field part). CERESTIS F22EU-038-AMA-003 GEP Unpublished	Y	UPL
KCP 6.4.4/05	Delphine Thevenet	2023	Unintentional effects of FBQ03, FGR06 and FGF11 on beer and malt making process in barley (field part). CERESTIS F22EU-038-AMA-005 GEP Unpublished	Y	UPL
KCP 6.4.4/06	Cyprien Tendart	2023	Unintentional effects of FBQ03, FGR06 and FGF11 on beer and malt making process in barley (field part). CERESTIS F22EU-038-AMA-006 GEP Unpublished	Y	UPL

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KCP 6.4.4/07	Aude-Emeline Gless	2023	Study of unintentional effects of FBQ03, FGR06 and FGF11 produts applied on winter and spring barley, Harvest 2022, on malt and beer quality and Process IBFM R-A-F-1216 GLP Unpublished	Y	UPL
KCP 6.5/01	Susanne Stürtz, Claudia Horstmann	2024	Azoxystrobin 160 + Prothioconazole 200 g/L SC: Effects on Terrestrial (Non-Target) Plants: Vegetative Vigour Test Ibacon GmbH UPL/2023/2350 GLP Unpublished	Y	UPL
KCP 6.5/02	Susanne Stürtz, Claudia Horstmann	2024	Azoxystrobin 160 + Prothioconazole 200 g/L SC: Effects on Terrestrial (Non-Target) Plants: Seedling Emergence and Seedling Growth Test Ibacon GmbH UPL/2023/2349 GLP Unpublished	Y	UPL
KCP 6.5/03	Bhavana S. Patil	2024	Effectiveness of cleaning procedures of azoxystrobin 160 + prothioconazole 200 g/L SC Jai Research Foundation UPL/2023/1576 GLP Upublished	Y	UPL