

REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: CA3642

Product name(s): Joust Pro

Chemical active substance(s):

Prothioconazole, 150 g/L

Azoxystrobin, 150 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

New Authorisation (Art.33)

Sponsor: Nufarm Crop Products UK Limited

Applicant: Nufarm Polska Sp. z o. o.

Submission date: 01/02/2023, update August 2023

MS Finalisation date: August 2023 (initial Core Assessment)

October 2024, December 2024 (final Core Assessment)

Version history

When	What
February 2023	Original applicant version
August 2023	V 2.0 Addition of PEC values (soil, groundwater and surface water) for Sunflower in response to comments from ZRMS (Poland). Some metabolite PECsoil values were changed due to errors in previous calculations.
August 2023	<p>Initial zRMS assessment</p> <p>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.</p> <p>Following the evaluation and before sending the document for commenting, all colored highlighting was removed, from the parts updated by the Applicant, for better legibility.</p>
October 2024	<p>Final report (Core Assessment updated following the commenting period)</p> <p>Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Information no longer relevant is struck through and shaded for transparency.</p>
December 2024	<p>Final report (Core Assessment updated following the second commenting period)</p> <p>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.</p>

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8 Fate and behaviour in the environment (KCP 9)

This document reviews the environmental fate and behaviour studies for the new product CA3642, an SC formulation containing prothioconazole (150 g/L) and azoxystrobin (150 g/L) in the Central zone (Article 33 application). Prothioconazole was approved at EU level in Commission Directive 2008/44/EC of 4 April 2008, and azoxystrobin was approved in Commission Implementing Regulation (EU) No 703/2011 of 20 July 2011. Prothioconazole and azoxystrobin are currently undergoing renewal at EU level.

CA3642 is a fungicide, intended for use on winter and spring varieties of cereals and oilseed rape. In addition, uses on minor crops (sunflower, flax, linseed, poppy, mustard and gold of pleasure) are included in the proposed GAP. Environmental exposures from these minor crop uses are covered by the proposed major crop uses on oilseed rape.

CA3642 was not the example product for the EU review of the active substances prothioconazole and azoxystrobin, and the uses in the GAP are not completely covered by the evaluations performed in the EU review. New exposure assessments were therefore required.

Where appropriate, this document refers to the conclusions of the EU reviews of prothioconazole and azoxystrobin. This will be where:

- the active substance data is relied upon in the risk assessment of the formulation; or when
- the EU review concluded that additional data/information should be considered at national re-registration.

For the environment this includes consideration of the following as specified in the Commission Directive 2008/44/EC for prothioconazole:

- *The protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied, where appropriate*

For the environment this includes consideration of the following as specified in the Commission Implementing Regulation (EU) No 703/2011 for azoxystrobin:

- *the potential for groundwater contamination, when the active substance is applied in regions with vulnerable soil and/or climatic conditions;*
- *the protection of aquatic organisms.*

These concerns have been addressed within the current submission.

Note: this Part B document only reviews data (active substance or product) and additional information that have not previously been considered within the EU review process, as part of the EU review of prothioconazole and azoxystrobin. However, it is intended that this product registration is evaluated prior to the EU renewal of the active substances; existing EU-agreed endpoints therefore apply, unless further justification has been provided.

For the implementation of the uniform principles of Annex VI, this document follows the conclusions of the review report on prothioconazole (SANCO/3923/07 - final), the EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance prothioconazole (EFSA Scientific Report (2007) 106, 1-98), the EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance azoxystrobin (EFSA Journal 2010; 8(4):1542), EFSA supporting publication 2014:EN-718 on the confirmatory data for azoxystrobin, and the associated DAR documents.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

Appendix 2 of this document details any new studies submitted for this evaluation.

Information on the detailed composition of CA3642 can be found in the confidential dossier of this submission (Registration Report - Part C).

8.1 Critical GAP and overall conclusions

Table 8.1-1: Critical use pattern of the formulated product

Critical use pattern of the formulated product														
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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1.	AT	Wheat (winter & spring) Spelt Einkorn wheat Emmer Wheat Tritordeum	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Yellow Rust <i>Puccinia striiformis</i> (PUC CST) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE) Tan Spot <i>Pyrenophora tritici-repentis</i> (PYRNTR) Head blight of cereals <i>Fusarium</i> spp. (FUSASP) <i>Microdochium</i> spp. (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
2.	BE	Wheat (winter & spring) Spelt Einkorn wheat Emmer Wheat Tritordeum	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Yellow Rust <i>Puccinia striiformis</i> (PUCST) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE) Tan Spot <i>Pyrenophora tritici-repentis</i> (PYRNTR) Head blight of cereals <i>Fusarium</i> spp. (FUSASP) <i>Microdochium</i> spp. (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
3	CZ	Wheat (winter & spring) Spelt Einkorn wheat Emmer Wheat Tritordeum	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Yellow Rust <i>Puccinia striiformis</i> (PUC CST) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE) Tan Spot <i>Pyrenophora tritici-repentis</i> (PYRNTR) Head blight of cereals <i>Fusarium</i> spp. (FUSASP) <i>Microdochium</i> spp. (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A
4	DE	Wheat (winter & spring) (within the group of wheat included: spelt, einkorn wheat, emmer wheat, durum wheat) Tritordeum	F	Septoria leaf spot <i>Zymoseptoria tritici</i> (SEPTTR) Glume blotch <i>Septoria nodorum</i> (LEPTNO) Brown Rust <i>Puccinia recondite f. sp. tritici</i> (PUC CRT) Yellow Rust <i>Puccinia striiformis</i> (PUC CST) Powdery mildew <i>Erysiphe graminis</i> (ERYSGR) Tan Spot <i>Drechslera tritici-repentis</i> (PYRNTR) Head blight of cereals <i>Microdochium</i> spp. (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.4 b) 2.8	a) 420 (210+210) b) 840 (420+420)	150-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
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5.	DE	Wheat (winter & spring) (within the group of wheat included: spelt, einkorn wheat, emmer wheat, durum wheat) Tritordeum	F	Fusarium ear blight <i>Fusarium spp.</i> (FUSASP)	foliar spray	BBCH 61 – 69 (spring)	a) 1 b) 2	N/A	a) 1.4 b) 2.8	a) 420 (210+210) b) 840 (420+420)	150-400	35		A
6.	DE	Wheat (winter & spring) (within the group of wheat included: spelt, einkorn wheat, emmer wheat, durum wheat) Tritordeum	F	<i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE)	foliar spray	BBCH 30 – 32 (spring)	a) 1 b) 2	N/A	a) 1.4 b) 2.8	a) 420 (210+210) b) 840 (420+420)	150-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
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7.	HU	Wheat (winter & spring) Spelt Einkorn wheat Emmer Wheat Tritordeum	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Yellow Rust <i>Puccinia striiformis</i> (PUCST) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE) Tan Spot <i>Pyrenophora tritici-repentis</i> (PYRNTR) Head blight of cereals <i>Fusarium</i> spp. (FUSASP) <i>Microdochium</i> spp. (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A

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Use- No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
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8.	IE	Wheat (winter & spring) Spelt Einkorn wheat Emmer Wheat Tritordeum	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Yellow Rust <i>Puccinia striiformis</i> (PUCST) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE) Tan Spot <i>Pyrenophora tritici-repentis</i> (PYRNTR) Head blight of cereals <i>Fusarium</i> spp. (FUSASP) <i>Microdochium</i> spp. (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A

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					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
9.	LU	Wheat (winter & spring) Spelt Einkorn wheat Emmer Wheat Tritordeum	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Yellow Rust <i>Puccinia striiformis</i> (PUCST) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE) Tan Spot <i>Pyrenophora tritici-repentis</i> (PYRNTR) Head blight of cereals <i>Fusarium</i> spp. (FUSASP) <i>Microdochium</i> spp. (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A

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Use- No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
10.	NL	Wheat (winter & spring) Spelt Einkorn wheat Emmer Wheat Tritordeum	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Yellow Rust <i>Puccinia striiformis</i> (PUCST) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE) Tan Spot <i>Pyrenophora tritici-repentis</i> (PYRNTR) Head blight of cereals <i>Fusarium</i> spp. (FUSASP) <i>Microdochium</i> spp. (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A

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Use- No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
11.	NI	Wheat (winter & spring) Spelt Einkorn wheat Emmer Wheat Tritordeum	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Yellow Rust <i>Puccinia striiformis</i> (PUCST) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE) Tan Spot <i>Pyrenophora tritici-repentis</i> (PYRNTR) Head blight of cereals <i>Fusarium</i> spp. (FUSASP) <i>Microdochium</i> spp. (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A

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Use- No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
12.	PL	Wheat (winter & spring) Spelt Einkorn wheat Emmer Wheat Tritordeum	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Yellow Rust <i>Puccinia striiformis</i> (PUCST) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE) Tan Spot <i>Pyrenophora tritici-repentis</i> (PYRNTR) Head blight of cereals <i>Fusarium</i> spp. (FUSASP) <i>Microdochium</i> spp. (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
13.	RO	Wheat (winter & spring) Spelt Einkorn wheat Emmer Wheat Tritordeum	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Yellow Rust <i>Puccinia striiformis</i> (PUCST) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE) Tan Spot <i>Pyrenophora tritici-repentis</i> (PYRNTR) Head blight of cereals <i>Fusarium</i> spp. (FUSASP) <i>Microdochium</i> spp. (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			
14.	SK	Wheat (winter & spring) Spelt Einkorn wheat Emmer Wheat Tritordeum	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Yellow Rust <i>Puccinia striiformis</i> (PUCST) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE) Tan Spot <i>Pyrenophora tritici-repentis</i> (PYRNTR) Head blight of cereals <i>Fusarium spp.</i> (FUSASP) <i>Microdochium spp.</i> (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A
15.	AT	Durum Wheat	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp.</i> (FUSASP) <i>Microdochium spp.</i> (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
16.	BE	Durum Wheat	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp.</i> (FUSASP) <i>Microdochium spp.</i> (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A
17.	CZ	Durum Wheat	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp.</i> (FUSASP) <i>Microdochium spp.</i> (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A
18.	HU	Durum Wheat	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp.</i> (FUSASP) <i>Microdochium spp.</i> (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
19.	IE	Durum Wheat	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp.</i> (FUSASP) <i>Microdochium spp.</i> (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A
20.	LU	Durum Wheat	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp.</i> (FUSASP) <i>Microdochium spp.</i> (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A
21.	NL	Durum Wheat	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp.</i> (FUSASP) <i>Microdochium spp.</i> (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
22.	NI	Durum Wheat	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp. (FUSASP)</i> <i>Microdochium spp. (MICDSP)</i>	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A
23.	PL	Durum Wheat	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp. (FUSASP)</i> <i>Microdochium spp. (MICDSP)</i>	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A
24.	RO	Durum Wheat	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp. (FUSASP)</i> <i>Microdochium spp. (MICDSP)</i>	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
25.	SK	Durum Wheat	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondita</i> <i>Puccinia tritici</i> (PUCCRT) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp. (FUSASP)</i> <i>Microdochium spp. (MICDSP)</i>	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A
26.	AT	Triticale (winter & spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondite</i> <i>Puccinia tritici</i> (PUCCRT) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Yellow Rust <i>Puccinia striiformis</i> (PUC CST) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp. (FUSASP)</i> <i>Microdochium spp. (MICDSP)</i>	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
27.	BE	Triticale (winter & spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondite</i> <i>Puccinia tritici</i> (PUCCRT) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Yellow Rust <i>Puccinia striiformis</i> (PUCCST) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp.</i> (FUSASP) <i>Microdochium spp.</i> (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
28.	CZ	Triticale (winter & spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondite</i> <i>Puccinia tritici</i> (PUCCRT) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Yellow Rust <i>Puccinia striiformis</i> (PUCCST) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp.</i> (FUSASP) <i>Microdochium spp.</i> (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A
29.	DE	Triticale (winter & spring)	F	Septoria leaf spot <i>Septoria tritici</i> (SEPTTR) Brown Rust <i>Puccinia recondite f. sp. tritici</i> (PUCCRT) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Yellow Rust <i>Puccinia striiformis</i> (PUCCST) Glume blotch <i>Septoria nodorum</i> (LEPTNO) Powdery mildew <i>Erysiphe graminis</i> (ERYSGR) Head blight of cereals	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.4 b) 2.8	a) 420 (210+210) b) 840 (420+420)	150-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
30.	DE	Triticale (winter & spring)	F	<i>Fusarium spp. (FUSASP)</i> <i>Microdochium spp. (MICDSP)</i>	foliar spray	BBCH 61 – 69 (spring)	a) 1 b) 2		a) 1.4 b) 2.8	a) 420 (210+210) b) 840 (420+420)	150-400	35		A
31.	HU	Triticale (winter & spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondite</i> <i>Puccinia tritici (PUCCRT)</i> Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Yellow Rust <i>Puccinia striiformis (PUCCST)</i> Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Powdery mildew <i>Blumeria graminis (ERYSGR)</i> Head blight of cereals <i>Fusarium spp. (FUSASP)</i> <i>Microdochium spp. (MICDSP)</i>	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
32.	IE	Triticale (winter & spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondite</i> <i>Puccinia tritici</i> (PUCCRT) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Yellow Rust <i>Puccinia striiformis</i> (PUCCST) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp.</i> (FUSASP) <i>Microdochium spp.</i> (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
33.	LU	Triticale (winter & spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondite</i> <i>Puccinia tritici</i> (PUCCRT) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Yellow Rust <i>Puccinia striiformis</i> (PUCCST) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp.</i> (FUSASP) <i>Microdochium spp.</i> (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
34.	NL	Triticale (winter & spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondite</i> <i>Puccinia tritici</i> (PUCCRT) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Yellow Rust <i>Puccinia striiformis</i> (PUCCST) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp.</i> (FUSASP) <i>Microdochium spp.</i> (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
35.	NI	Triticale (winter & spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondite</i> <i>Puccinia tritici</i> (PUCCRT) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Yellow Rust <i>Puccinia striiformis</i> (PUCCST) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp.</i> (FUSASP) <i>Microdochium spp.</i> (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
36.	PL	Triticale (winter & spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondite</i> <i>Puccinia tritici</i> (PUCCRT) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Yellow Rust <i>Puccinia striiformis</i> (PUCCST) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp.</i> (FUSASP) <i>Microdochium spp.</i> (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
37.	RO	Triticale (winter & spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondite</i> <i>Puccinia tritici</i> (PUCCRT) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Yellow Rust <i>Puccinia striiformis</i> (PUCCST) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp.</i> (FUSASP) <i>Microdochium spp.</i> (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
38.	SK	Triticale (winter & spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Brown Rust <i>Puccinia recondite</i> <i>Puccinia tritici</i> (PUCCRT) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Yellow Rust <i>Puccinia striiformis</i> (PUCCST) Glume blotch <i>Stagonospora nodorum</i> (LEPTNO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp.</i> (FUSASP) <i>Microdochium spp.</i> (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A
39.	AT	Rye (winter & spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Crown Rust <i>Puccinia recondita f. sp.</i> <i>recondite</i> (PUCCRR) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp.</i> (FUSASP) <i>Microdochium spp.</i> (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
40.	BE	Rye (winter & spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Crown Rust <i>Puccinia recondita f. sp.</i> <i>recondite (PUCCRR)</i> Eyespot <i>Pseudocercospora</i> <i>herpotrichoides (PSDCHE)</i> Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp. (FUSASP)</i> <i>Microdochium spp. (MICDSP)</i>	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A
41.	CZ	Rye (winter & spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Crown Rust <i>Puccinia recondita f. sp.</i> <i>recondite (PUCCRR)</i> Eyespot <i>Pseudocercospora</i> <i>herpotrichoides (PSDCHE)</i> Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp. (FUSASP)</i> <i>Microdochium spp. (MICDSP)</i>	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
42.	DE	Rye (winter & spring)	F	Septoria leaf spot <i>Septoria tritici</i> (SEPTTR) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Crown Rust <i>Puccinia recondita f. sp.</i> <i>recondite</i> (PUCCRR) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.4 b) 2.8	a) 420 (210+210) b) 840 (420+420)	150-400	35		A
43.	DE	Rye (winter & spring)	F	<i>Fusarium spp.</i> (FUSASP) <i>Microdochium spp.</i> (MICDSP)	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.4 b) 2.8	a) 420 (210+210) b) 840 (420+420)	150-400	35		A
44.	DE	Rye (winter & spring)	F	<i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE)	foliar spray	BBCH 30 – 32 (spring)	a) 1 b) 2	N/A	a) 1.4 b) 2.8	a) 420 (210+210) b) 840 (420+420)	150-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
45.	HU	Rye (winter & spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Crown Rust <i>Puccinia recondita f. sp.</i> <i>recondite (PUCCRR)</i> Eyespot <i>Pseudocercospora</i> <i>herpotrichoides (PSDCHE)</i> Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp. (FUSASP)</i> <i>Microdochium spp. (MICDSP)</i>	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A
46.	IE	Rye (winter & spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Crown Rust <i>Puccinia recondita f. sp.</i> <i>recondite (PUCCRR)</i> Eyespot <i>Pseudocercospora</i> <i>herpotrichoides (PSDCHE)</i> Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp. (FUSASP)</i> <i>Microdochium spp. (MICDSP)</i>	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
47.	LU	Rye (winter & spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Crown Rust <i>Puccinia recondita f. sp.</i> <i>recondite (PUCCRR)</i> Eyespot <i>Pseudocercospora</i> <i>herpotrichoides (PSDCHE)</i> Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp. (FUSASP)</i> <i>Microdochium spp. (MICDSP)</i>	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A
48.	NL	Rye (winter & spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Crown Rust <i>Puccinia recondita f. sp.</i> <i>recondite (PUCCRR)</i> Eyespot <i>Pseudocercospora</i> <i>herpotrichoides (PSDCHE)</i> Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp. (FUSASP)</i> <i>Microdochium spp. (MICDSP)</i>	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
49.	NI	Rye (winter & spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Crown Rust <i>Puccinia recondita f. sp.</i> <i>recondite (PUCCRR)</i> Eyespot <i>Pseudocercospora</i> <i>herpotrichoides (PSDCHE)</i> Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp. (FUSASP)</i> <i>Microdochium spp. (MICDSP)</i>	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A
50.	PL	Rye (winter & spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Crown Rust <i>Puccinia recondita f. sp.</i> <i>recondite (PUCCRR)</i> Eyespot <i>Pseudocercospora</i> <i>herpotrichoides (PSDCHE)</i> Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp. (FUSASP)</i> <i>Microdochium spp. (MICDSP)</i>	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
51.	RO	Rye (winter & spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Crown Rust <i>Puccinia recondita f. sp.</i> <i>recondite (PUCCRR)</i> Eyespot <i>Pseudocercospora</i> <i>herpotrichoides (PSDCHE)</i> Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp. (FUSASP)</i> <i>Microdochium spp. (MICDSP)</i>	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A
52.	SK	Rye (winter & spring)	F	Septoria leaf spot <i>Zymoseptoria tritici</i> <i>Mycosphaerella graminicola</i> (SEPTTR) Leaf blotch <i>Rhynchosporium secalis</i> (RHYNSE) Crown Rust <i>Puccinia recondita f. sp.</i> <i>recondite (PUCCRR)</i> Eyespot <i>Pseudocercospora</i> <i>herpotrichoides (PSDCHE)</i> Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Head blight of cereals <i>Fusarium spp. (FUSASP)</i> <i>Microdochium spp. (MICDSP)</i>	foliar spray	BBCH 30 – 69 (spring)	a) 2 b) 2	14-21	a) 1.2-1.4 b) 2.4-2.8	a) 360-420 (180+180 – 210+210) b) 720-840 (360+360 – 420+420)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
53.	AT	Oat (winter & spring)	F	Crown Rust <i>Puccinia coronata</i> (PUCCCO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE)	foliar spray	BBCH 30 – 61 (spring)	a) 2 b) 2	14-21	a) 1.0 b) 2.0	a) 300 (150+150) b) 600 (300+300)	100-400	35		A
54.	BE	Oat (winter & spring)	F	Crown Rust <i>Puccinia coronata</i> (PUCCCO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE)	foliar spray	BBCH 30 – 61 (spring)	a) 2 b) 2	14-21	a) 1.0 b) 2.0	a) 300 (150+150) b) 600 (300+300)	100-400	35		A
55.	CZ	Oat (winter & spring)	F	Crown Rust <i>Puccinia coronata</i> (PUCCCO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHA)	foliar spray	BBCH 30 – 61 (spring)	a) 2 b) 2	14-21	a) 1.0 b) 2.0	a) 300 (150+150) b) 600 (300+300)	100-400	35		A
56.	DE	Oat (winter & spring)	F	Crown Rust <i>Puccinia coronata</i> (PUCCCO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR)	foliar spray	BBCH 30 – 61 (spring)	a) 2 b) 2	14-21	a) 1.0 b) 2.0	a) 300 (150+150) b) 600 (300+300)	150-400	35		A
57.	DE	Oat (winter & spring)	F	Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE)	foliar spray	BBCH 30 – 32 (spring)	a) 1 b) 2		a) 1.0 b) 2.0	a) 300 (150+150) b) 600 (300+300)	150-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
58.	HU	Oat (winter & spring)	F	Crown Rust <i>Puccinia coronata</i> (PUCCCO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE)	foliar spray	BBCH 30 – 61 (spring)	a) 2 b) 2	14-21	a) 1.0 b) 2.0	a) 300 (150+150) b) 600 (300+300)	100-400	35		A
59.	IE	Oat (winter & spring)	F	Crown Rust <i>Puccinia coronata</i> (PUCCCO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE)	foliar spray	BBCH 30 – 61 (spring)	a) 2 b) 2	14-21	a) 1.0 b) 2.0	a) 300 (150+150) b) 600 (300+300)	100-400	35		A
60.	LU	Oat (winter & spring)	F	Crown Rust <i>Puccinia coronata</i> (PUCCCO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE)	foliar spray	BBCH 30 – 61 (spring)	a) 2 b) 2	14-21	a) 1.0 b) 2.0	a) 300 (150+150) b) 600 (300+300)	100-400	35		A
61.	NL	Oat (winter & spring)	F	Crown Rust <i>Puccinia coronata</i> (PUCCCO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE)	foliar spray	BBCH 30 – 61 (spring)	a) 2 b) 2	14-21	a) 1.0 b) 2.0	a) 300 (150+150) b) 600 (300+300)	100-400	35		A
62.	NI	Oat (winter & spring)	F	Crown Rust <i>Puccinia coronata</i> (PUCCCO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE)	foliar spray	BBCH 30 – 61 (spring)	a) 2 b) 2	14-21	a) 1.0 b) 2.0	a) 300 (150+150) b) 600 (300+300)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
63.	PL	Oat (winter & spring)	F	Crown Rust <i>Puccinia coronata</i> (PUCCCO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE)	foliar spray	BBCH 30 – 61 (spring)	a) 2 b) 2	14-21	a) 1.0 b) 2.0	a) 300 (150+150) b) 600 (300+300)	100-400	35		A
64.	RO	Oat (winter & spring)	F	Crown Rust <i>Puccinia coronata</i> (PUCCCO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE)	foliar spray	BBCH 30 – 61 (spring)	a) 2 b) 2	14-21	a) 1.0 b) 2.0	a) 300 (150+150) b) 600 (300+300)	100-400	35		A
65.	SK	Oat (winter & spring)	F	Crown Rust <i>Puccinia coronata</i> (PUCCCO) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE)	foliar spray	BBCH 30 – 61 (spring)	a) 2 b) 2	14-21	a) 1.0 b) 2.0	a) 300 (150+150) b) 600 (300+300)	100-400	35		A
66.	AT	Barley (winter & spring)	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61 (spring)	a) 2 b) 2	14-21	a) 1.0 b) 2.0	a) 300 (150+150) b) 600 (300+300)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
67.	BE	Barley (winter & spring)	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61 (spring)	a) 2 b) 2	14-21	a) 1.0 b) 2.0	a) 300 (150+150) b) 600 (300+300)	100-400	35		A
68.	CZ	Barley (winter & spring)	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61 (spring)	a) 2 b) 2	14-21	a) 1.0 b) 2.0	a) 300 (150+150) b) 600 (300+300)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
69.	DE	Barley (winter & spring)	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61 (spring)	a) 2 b) 2	14-21	a) 1.0 b) 2.0	a) 300 (150+150) b) 600 (300+300)	150-400	35		A
70.	DE	Barley (winter & spring)	F	<i>Pseudocercosporella herpotrichoides</i> (PSDCHE)	foliar spray	BBCH 30 – 32 (spring)	a) 1 b) 2		a) 1.0 b) 2.0	a) 300 (150+150) b) 600 (300+300)	150-400	35		A
71.	HU	Barley (winter & spring)	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Pseudocercosporella herpotrichoides</i> (PSDCHE) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61 (spring)	a) 2 b) 2	14-21	a) 1.0 b) 2.0	a) 300 (150+150) b) 600 (300+300)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
72.	IE	Barley (winter & spring)	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61 (spring)	a) 2 b) 2	14-21	a) 1.0 b) 2.0	a) 300 (150+150) b) 600 (300+300)	100-400	35		A
73.	LU	Barley (winter & spring)	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61 (spring)	a) 2 b) 2	14-21	a) 1.0 b) 2.0	a) 300 (150+150) b) 600 (300+300)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
74.	NL	Barley (winter & spring)	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61 (spring)	a) 2 b) 2	14-21	a) 1.0 b) 2.0	a) 300 (150+150) b) 600 (300+300)	100-400	35		A
75.	NI	Barley (winter & spring)	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61 (spring)	a) 2 b) 2	14-21	a) 1.0 b) 2.0	a) 300 (150+150) b) 600 (300+300)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
76.	PL	Barley (winter & spring)	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61 (spring)	a) 2 b) 2	14-21	a) 1.0 b) 2.0	a) 300 (150+150) b) 600 (300+300)	100-400	35		A
77.	RO	Barley (winter & spring)	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61 (spring)	a) 2 b) 2	14-21	a) 1.0 b) 2.0	a) 300 (150+150) b) 600 (300+300)	100-400	35		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			
78.	SK	Barley (winter & spring)	F	Leaf spot of Barley <i>Ramularia collo-cygni</i> (RAMUCC) Eyespot <i>Pseudocercospora</i> <i>herpotrichoides</i> (PSDCHE) Brown Rust <i>Puccinia hordei</i> (PUCCHD) Powdery mildew <i>Blumeria graminis</i> (ERYSGR) Leaf Blotch <i>Rhynchosporium secalis</i> (RHYNSE) Net Blotch <i>Pyrenophora teres</i> (PYRNTE)	foliar spray	BBCH 30 – 61 (spring)	a) 2 b) 2	14-21	a) 1.0 b) 2.0	a) 300 (150+150) b) 600 (300+300)	100-400	35		A
79.	AT	Winter Oilseed Rape	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR) Brownish-grey mildew <i>Botryotinia fuckeliana</i> (BOTRCI)	foliar spray	BBCH 14 – 18 (Autumn) or BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			
80.	BE	Winter Oilseed Rape	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR) Brownish-grey mildew <i>Botryotinia fuckeliana</i> (BOTRCI)	foliar spray	BBCH 14 – 18 (Autumn) or BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56		A
81.	CZ	Winter Oilseed Rape	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR) Brownish-grey mildew <i>Botryotinia fuckeliana</i> (BOTRCI)	foliar spray	BBCH 14 – 18 (Autumn) or BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
82.	DE	Winter Oilseed Rape	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Light leaf spot <i>Cylindrosporium concentricum</i> (PYRPBR) Brownish-grey mildew <i>Botryotinia fuckeliana</i> (BOTRCI)	foliar spray	BBCH 14 – 18 (Autumn) or BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.2 b) 1.2	a) 360 (180+180) b) 360 (180+180)	150-400	56		A
83.	HU	Winter Oilseed Rape	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR) Brownish-grey mildew <i>Botryotinia fuckeliana</i> (BOTRCI)	foliar spray	BBCH 14 – 18 (Autumn) or BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
84.	IE	Winter Oilseed Rape	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR) Brownish-grey mildew <i>Botryotinia fuckeliana</i> (BOTRCI)	foliar spray	BBCH 14 – 18 (Autumn) or BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56		A
85.	LU	Winter Oilseed Rape	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR) Brownish-grey mildew <i>Botryotinia fuckeliana</i> (BOTRCI)	foliar spray	BBCH 14 – 18 (Autumn) or BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
86.	NL	Winter Oilseed Rape	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR) Brownish-grey mildew <i>Botryotinia fuckeliana</i> (BOTRCI)	foliar spray	BBCH 14 – 18 (Autumn) or BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56		A
87.	NI	Winter Oilseed Rape	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR) Brownish-grey mildew <i>Botryotinia fuckeliana</i> (BOTRCI)	foliar spray	BBCH 14 – 18 (Autumn) or BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
88.	PL	Winter Oilseed Rape	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR) Brownish-grey mildew <i>Botryotinia fuckeliana</i> (BOTRCI)	foliar spray	BBCH 14 – 18 (Autumn) or BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56		A
89.	RO	Winter Oilseed Rape	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR) Brownish-grey mildew <i>Botryotinia fuckeliana</i> (BOTRCI)	foliar spray	BBCH 14 – 18 (Autumn) or BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56		A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
90.	SK	Winter Oilseed Rape	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR) Brownish-grey mildew <i>Botryotinia fuckeliana</i> (BOTRCI)	foliar spray	BBCH 14 – 18 (Autumn) or BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56		A
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														
None														
Minor uses according to Article 51 (zonal uses)														
91.	AT	Spring Oilseed Rape	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR) Brownish-grey mildew <i>Botryotinia fuckeliana</i> (BOTRCI)	foliar spray	BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56	Extrapolation from winter Oilseed Rape (spring use)	A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			
92.	BE	Spring Oilseed Rape	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR) Brownish-grey mildew <i>Botryotinia fuckeliana</i> (BOTRCI)	foliar spray	BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56	Extrapolation from winter Oilseed Rape (spring use)	A
93.	CZ	Spring Oilseed Rape	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR) Brownish-grey mildew <i>Botryotinia fuckeliana</i> (BOTRCI)	foliar spray	BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56	Extrapolation from winter Oilseed Rape (spring use)	A
94.	DE	Spring Oilseed Rape	F	Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Light leaf spot <i>Cylindrosporium concentricum</i> (PYRPBR)	foliar spray	BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.2 b) 1.2	a) 360 (180+180) b) 360 (180+180)	150-400	56	Extrapolation from winter Oilseed Rape (spring use)	A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			
95.	HU	Spring Oilseed Rape	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR) Brownish-grey mildew <i>Botryotinia fuckeliana</i> (BOTRCI)	foliar spray	BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56	Extrapolation from winter Oilseed Rape (spring use)	A
96.	IE	Spring Oilseed Rape	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR) Brownish-grey mildew <i>Botryotinia fuckeliana</i> (BOTRCI)	foliar spray	BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56	Extrapolation from winter Oilseed Rape (spring use)	A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			
97.	LU	Spring Oilseed Rape	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR) Brownish-grey mildew <i>Botryotinia fuckeliana</i> (BOTRCI)	foliar spray	BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56	Extrapolation from winter Oilseed Rape (spring use)	A
98.	NL	Spring Oilseed Rape	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR) Brownish-grey mildew <i>Botryotinia fuckeliana</i> (BOTRCI)	foliar spray	BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56	Extrapolation from winter Oilseed Rape (spring use)	A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			
99.	NI	Spring Oilseed Rape	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR) Brownish-grey mildew <i>Botryotinia fuckeliana</i> (BOTRCI)	foliar spray	BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56	Extrapolation from winter Oilseed Rape (spring use)	A
100.	PL	Spring Oilseed Rape	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR) Brownish-grey mildew <i>Botryotinia fuckeliana</i> (BOTRCI)	foliar spray	BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56	Extrapolation from winter Oilseed Rape (spring use)	A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			
101.	RO	Spring Oilseed Rape	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR) Brownish-grey mildew <i>Botryotinia fuckeliana</i> (BOTRCI)	foliar spray	BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56	Extrapolation from winter Oilseed Rape (spring use)	A
102.	SK	Spring Oilseed Rape	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR) Brownish-grey mildew <i>Botryotinia fuckeliana</i> (BOTRCI)	foliar spray	BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56	Extrapolation from winter Oilseed Rape (spring use)	A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			
103.	PL	Sunflower	F	Sclerotinia Stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Grey mould <i>Botrytis cinerea</i> (BOTCRI) Stalk rot of sunflower <i>Diaporthe helianthi</i> (DIAPHE) Black stem of Sunflower <i>Plenodomus lindquistii</i> (LEPTLI)	foliar spray	BBCH 16– 64 (spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56	Extrapolation from main crops not possible, exposure assessment performed with consideration of maize as a surrogate crop.	A
104.	BE	Flax (for fiber production only)	F	Powdery mildew flax <i>Erysiphe spp</i> (ERYSPP)	Foliar spray	BBCH 33 – 51	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	N/A	Extrapolation from winter Oilseed Rape (spring use)	A
105.	AT	Linseeds, Poppy, Mustard and Gold of pleasure	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 14 – 18 (Autumn) or BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56	Extrapolation from winter Oilseed Rape	A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
106.	BE	Linseeds, Poppy, Mustard and Gold of pleasure	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 14 – 18 (Autumn) or BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56	Extrapolation from winter Oilseed Rape	A
107.	CZ	Linseeds, Poppy, Mustard and Gold of pleasure	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 14 – 18 (Autumn) or BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56	Extrapolation from winter Oilseed Rape	A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
108.	DE	Seed bearing plans: Linseeds, Poppy, Mustard and Gold of pleasure	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Cylindrosporium concentricum</i> (PYRPBR)	foliar spray	BBCH 14 – 18 (Autumn) or BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.2 b) 1.2	a) 360 (180+180) b) 360 (180+180)	150-400	56	Extrapolation from winter Oilseed Rape	A
109.	HU	Linseeds, Poppy, Mustard and Gold of pleasure	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 14 – 18 (Autumn) or BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56	Extrapolation from winter Oilseed Rape	A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
110.	IE	Linseeds, Poppy, Mustard and Gold of pleasure	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 14 – 18 (Autumn) or BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56	Extrapolation from winter Oilseed Rape	A
111.	LU	Linseeds, Poppy, Mustard and Gold of pleasure	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 14 – 18 (Autumn) or BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56	Extrapolation from winter Oilseed Rape	A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			
112.	NL	Linseeds, Poppy, Mustard and Gold of pleasure	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 14 – 18 (Autumn) or BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56	Extrapolation from winter Oilseed Rape	A
113.	NI	Linseeds, Poppy, Mustard and Gold of pleasure	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 14 – 18 (Autumn) or BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56	Extrapolation from winter Oilseed Rape	A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
114.	PL	Linseeds, Poppy, Mustard and Gold of pleasure	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 14 – 18 (Autumn) or BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56	Extrapolation from winter Oilseed Rape	A
115.	RO	Linseeds, Poppy, Mustard and Gold of pleasure	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 14 – 18 (Autumn) or BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56	Extrapolation from winter Oilseed Rape	A

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, Fn, Fpn G, Gn, Gpn 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 saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
116.	SK	Linseeds, Poppy, Mustard and Gold of pleasure	F	Phoma leaf spot/stem canker <i>Leptosphaeria maculans</i> (LEPTMA) Sclerotinia stem rot <i>Sclerotinia sclerotiorum</i> (SCLESC) Powdery mildew <i>Erysiphe cruciferarum</i> (ERYSCR) Alternaria leaf spot <i>Alternaria brassicae</i> (ALTEBA) Light leaf spot <i>Pyrenopeziza brassicae</i> (PYRPBR)	foliar spray	BBCH 14 – 18 (Autumn) or BBCH 20 – 69 (Spring)	a) 1 b) 1	N/A	a) 1.0-1.2 b) 1.0-1.2	a) 300 - 360 (150+150- 180+180) b) 300 - 360 (150+150- 180+180)	100-400	56	Extrapolation from winter Oilseed Rape	A
Minor uses according to Article 51 (interzonal uses)														
None														

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 “Conclusion”

A	Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

Table 8.1-2: Assessed (critical) uses during EU approval of prothioconazole concerning the Section Environmental Fate

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn 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
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
	EU	Wheat, rye, triticale	F	Rusts, Eyespot, Fusarium spp., Powd. Mildew, Rhynchospor., Septoria,	Overall spray	start 26-29 up to BBCH69	a) 3 b) 3	14		200	200-400	35	
	EU	Barley, oat	F	Rusts, Eyespot, Pyren. teres, Powd. Mildew, Fusarium spp., Rhynchospor.	Overall spray	start 30 up to BBCH 61	a) 2 b) 2	14		200	200-400	35	
	EU	Oilseed rape	F	Sclerotinia, Botrytis, Alternaria, Leptosphaeria	Overall spray	start BBCH 53	a) 2 b) 2	14		175	200-400	56	

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Table 8.1-3: Assessed (critical) uses during EU approval of azoxystrobin concerning the Section Environmental Fate

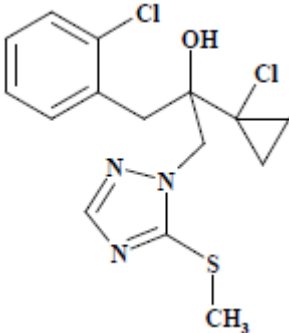
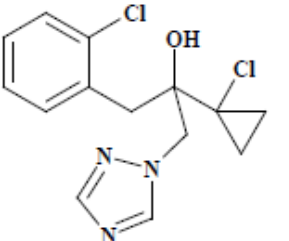
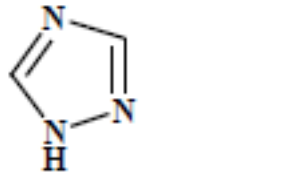
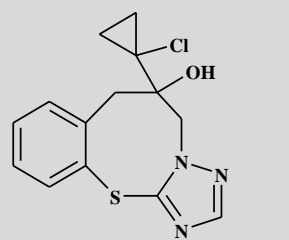
1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
	EU	Broccoli, cauliflower, brussels sprouts, kale	F	<i>Alternaria brassicae</i> , <i>Mycosphaerella brassicicola</i> , <i>Peronospora parasitica</i>	Foliar spray	BBCH 35-39	a) 2 b) 2	12		250	200-600	14	
	EU	Barley	F	<i>Pyrenophora teres</i> <i>Puccinia hordei</i> <i>Rhynchosporium secalis</i> <i>Gaeumannomyces graminis var. Tritici</i> Barley spotting	Foliar spray	BBCH 31-59	a) 2 b) 2	14		250	100-300	35	Timing of applications determined primarily by growth stage; 1st no later than BBCH 39, 2nd no later than BBCH 59.
	EU	Wheat	F	<i>Septoria tritici</i> <i>Septoria nodorum</i> <i>Puccinia striiformis</i> <i>Puccinia recondita</i> <i>Gaeumannomyces graminis var. tritici</i>	Foliar spray	BBCH 31-69	a) 2 b) 2	14		250	100-300	56	Timing of applications determined primarily by growth stage; 1st no later than BBCH 39, 2nd no later than BBCH 69.

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

8.2 Metabolites considered in the assessment

Table 8.2-1: Metabolites of prothioconazole potentially relevant for exposure assessment

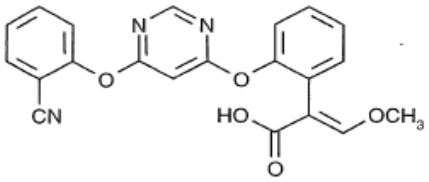
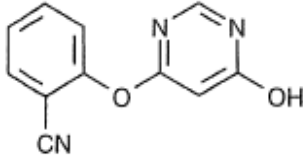
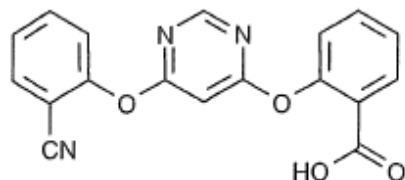
Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
Prothioconazole-S-methyl	358.3		Soil (max. 14.6 % at 7d) water/sediment (anaerobic): 77 % (in sediment, not detected in water) water/sediment (aerobic): 12.7% (whole system); 3.1% (water); 9.6% (sediment)	PEC _{soil} : GAP different to EU assessment PEC _{gw} : Model changes since EU assessment PEC _{sw/sed} : Model changes since EU assessment
Prothioconazole-desthio	312.2		Soil (max. 57.1 % at 7d) Water (max. 32.3 % at 7d) Sediment (max. 26.9 % at 14d) Water/sediment system (54.6% at 7d)	PEC _{soil} : GAP different to EU assessment PEC _{gw} : Model changes since EU assessment PEC _{sw/sed} : Model changes since EU assessment
1,2,4-triazole	69.1		Water (max. 37.2 % at 121d) Sediment (max. 6.1 % at 121d) Water/sediment system (max. 41.8 % at 121d)	PEC _{sw/sed} : Model changes since EU assessment
JAU 6476-thiazocine (prothioconazole-thiazocine, M12)	307.8		Aqueous photolysis study: 14.1% on day 5	Considered not relevant in EFSA (2007)

zRMS comments:

Information regarding prothioconazole metabolites is in general in line with EU agreed endpoints reported in EFSA Scientific Report (2007) 106, with some minor corrections.

Information on metabolite JAU 6476-thiazocine has been added by the zRMS, as this metabolite was found at >10% in aqueous photolysis study. However, it was considered not relevant for the exposure assessment during EU review.

Table 8.2-2: Metabolites of azoxystrobin potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
R234886 (M 02)	389.4		Soil (max. 28.8% at 360 d) Water/sediment system (max. 18.1 % at unspecified time*)	PEC _{soil} : GAP different to EU assessment PEC _{gw} : Model changes since EU assessment PEC _{sw/sed} : Model changes since EU assessment
R401553 (M 28)	213.2		Soil (max. 17% at unspecified time**) Water (photolysis, max. 8.9 % at unspecified time**)	PEC _{soil} : GAP different to EU assessment PEC _{gw} : Model changes since EU assessment PEC _{sw/sed} : Model changes since EU assessment
R402173 (M 30)	333.3		Soil (max. 17% at unspecified time**) Water (photolysis, max. 2.4 % at unspecified time**)	PEC _{soil} : GAP different to EU assessment PEC _{gw} : Model changes since EU assessment PEC _{sw/sed} : Model changes since EU assessment

* According to the EFSA conclusion, the maximum water/sediment concentration for R234886 was agreed to be 18.1% AR (derived by calculating the individual mean for each of 3 label positions from data from 3 TLC solvent systems prior to calculating an overall mean), however no timepoint is specified and no data on metabolite concentrations are provided in study summaries in the 2009 DAR or the 1997 monograph from the previous EU evaluation of azoxystrobin.

* According to the 2009 DAR, the metabolites R401553 and R402173 were found in field studies and aqueous photolysis studies evaluated for the previous approval of azoxystrobin under Dir. 91/414/EEC, but the studies themselves have not been summarised in the DAR. These metabolites are not mentioned in the previous 1998 review report or the 1997 monograph and it was not possible to determine the time at which the peak was reached.

zRMS comments:

Information regarding azoxystrobin metabolites is in line with EU agreed endpoints reported in EFSA Journal 2010; 8(4):1542.

8.3 Rate of degradation in soil (KCP 9.1.1)

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 Prothioconazole and its metabolites

All endpoints are taken from the agreed values in the EFSA 2007 conclusion (EFSA Scientific Report (2007) 106, 1-98) and information taken from the study summaries in the associated DAR. No formulation studies are submitted or required.

Laboratory soil degradation data are available for 4 soils on prothioconazole and the relevant soil metabolites, prothioconazole-S-methyl and prothioconazole-desthio. The endpoints are summarised below in Table 8.3-1 to Table 8.3-3. The agreed endpoints from the 2007 EFSA conclusion are provided, with data from individual studies taken from the DAR.

Table 8.3-1: Summary of aerobic degradation rates for prothioconazole - laboratory studies

Incubation conditions	Soil			Statistical evaluation			Report
	Type	org. C %	pH (H ₂ O)	DT ₅₀ (days)	DT ₉₀ (days)	Kinetics	
Dark, 20°C, 48% max. water holding capacity	Sandy loam (LH)	2.00	7.2	0.07	5.30	FOMC	Gilges, M. (2000) MR-549/99 DAR, 2005; EFSA, 2007
	Silty clay loam (ST)	1.66	5.9	0.70	78.20	FOMC	
Dark, 20°C, 50% max. water holding capacity	Silt (HF)	2.14	7.1	0.30	0.99	SFO	Hellpointner, E. (2001b) MR-104/01 DAR, 2005; EFSA, 2007
	Loamy sand (BV)	0.79	6.8	1.27	4.22	SFO	
Worst-case (persistence, EFSA Conclusion 2007)				1.27*	78.20		
Median (EFSA Conclusion 2007)				0.50*			
Geometric mean				0.37*			

*Note that field data showed longer DT₅₀ values and was selected by EFSA as a worst-case for risk assessment

Table 8.3-2: Summary of aerobic degradation rates for prothioconazole-S-methyl - laboratory studies

Incubation conditions	Soil			Statistical evaluation			Report
	Type	org. C %	pH (H ₂ O)	DT ₅₀ (days)	DT ₉₀ (days)	Kinetics	
Dark, 20°C, 40% max. water holding capacity	Loamy silt (HF)	1.55	7.3	5.9	19.6	SFO	Gilges, M. (2001a) MR 340/00 DAR, 2005; EFSA, 2007
	Loamy Silt (LH)	0.98	7.9	27.2	90.2	SFO	
	Sandy loam (LH)	1.02	7.2	8.2	27.2	SFO	
	Silty clay (ST)	1.46	6.3	46.0	153.0	SFO	
Worst-case (persistence, EFSA Conclusion 2007)				46.0	153.0		
Geometric mean (modelling, EFSA Conclusion 2007)				15.7			

Table 8.3-3: Summary of aerobic degradation rates for prothioconazole-desthio - laboratory studies

Incubation conditions	Soil			Statistical evaluation			Report
	Type	org. C %	pH (H ₂ O)	DT ₅₀ (days)	DT ₉₀ (days)	Kinetics	
Dark, 20°C, 40% max. water holding capacity	Loamy silt (HF)	1.55	7.3	34.0	113.0	SFO	Gilges, M. (2001b) MR 327/00 DAR, 2005; EFSA, 2007
	Loamy Silt (LH)	0.98	7.9	29.6	59.2	SFO	
	Sandy loam (LH)	1.02	7.2	7.0	23.2	SFO	
	Silty clay (ST)	1.46	6.3	18.6	61.9	SFO	
Worst-case (persistence, EFSA Conclusion 2007)				34.0*	113.0*		
Median (EFSA Conclusion 2007)				24.1*			
Geometric mean				20.5*			

*Note that field data showed longer DT₅₀ values and was selected by EFSA as a worst-case for risk assessment

zRMS comments:

Soil degradation data for prothioconazole and its metabolites are in line with EU agreed endpoints reported in EFSA Scientific Report (2007) 106 and prothioconazole DAR of 2005.

For relevant endpoints considered in exposure assessment, please refer to points 8.7 (soil), 8.8 (groundwater) and 8.9 (surface water) of this document.

8.3.1.2 Azoxystrobin and its metabolites

All endpoints are taken from the agreed values in the EFSA 2010 conclusion (EFSA Journal 2010; 8(4):1542), 2014 confirmatory data (EFSA supporting publication 2014:EN-718), and information taken from the study summaries in the associated DAR. No formulation studies are submitted or required.

Laboratory soil degradation data are available for azoxystrobin and the relevant soil metabolites, R234886, R401553 and R402173. The endpoints are summarised below in Table 8.3-4 to Table 8.3-7.

Table 8.3-4: Summary of aerobic degradation rates for azoxystrobin - laboratory studies

Azoxystrobin, laboratory studies, aerobic conditions										
Soil name	Soil type	pH	T.°C	MWHC %	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa	Chi ² (%)	Kinetic model	Evaluated on EU level y/n/ Reference
18 Acres	Sandy clay loam	6.4	20	40	56.4	187	35.2	3.70	SFO	Y, EFSA (2010)
East Anglia	Sand	7.9	20	40	66.9	222	57.2	5.34	SFO	Y, EFSA (2010)
Wisborough Green	Silty clay loam	5.9	20	40	94.1	313	54.1	5.60	SFO	Y, EFSA (2010)
18 Acres	Sandy clay loam	7	20	75% of 1/3 bar	87	289	65.2	2.06	SFO	Y, EFSA (2010)
Hyde Farm	Sandy clay loam	7	20	75% of 1/3 bar	72.8	242	48.5	7.10	SFO	Y, EFSA (2010)
Visalia	Sandy loam	8.4	20	75% of 1/3 bar	141.6	470	79.9	2.97	SFO	Y, EFSA (2010)
Derbyshire	Clay loam	7.5	20	pF2	118.4	393	118.4	4.84	SFO	Y, EFSA (2010)
Holland	Sandy loam	8.2	20	pF2	153.4	510	153.4	1.92	SFO	Y, EFSA (2010)
Lincolnshire	Sandy loam	7.4	20	pF2	248	824	248	7.5	SFO	Y, EFSA (2010)
Geometric mean (n=9 ^a)							84.5			
pH-dependency:							n			

^a true geometric mean (geometric mean of 18 Acres soils taken first)

Table 8.3-5: Summary of aerobic degradation rates for R234886 - laboratory studies

R234886, Laboratory studies, aerobic conditions									
Soil name	Soil type (USDA)	pH (-)	T (°C)	pF	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa	Kinetic model	Evaluated on EU level y/n/ Reference
Wisborough Green	Clay loam	5.3	-	2	97.6	-	97.6	DFOP	Y, EFSA confirmatory data (2014)
Frensham	Sandy loam	5.4	-	2	110	-	110	DFOP	Y, EFSA confirmatory

R234886, Laboratory studies, aerobic conditions									
Soil name	Soil type (USDA)	pH (-)	T (°C)	pF	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa	Kinetic model	Evaluated on EU level y/n/ Reference
									data (2014)
Ohio	Loamy sand	5.8	-	2	89.9	-	89.9	SFO	Y, EFSA confirmatory data (2014)
Nuptown	Sandy clay loam	6.2	-	2	94.9	-	94.9	DFOP	Y, EFSA confirmatory data (2014)
Georgia	Loamy sand	7.1	-	2	102	-	102	SFO	Y, EFSA confirmatory data (2014)
18 Acres	Sandy clay loam	7.0	-	75% of 1/3 bar	23.7	-	17.8	SFO	Y, EFSA (2010)
Gartenacker	Silt loam	7.3	-	2	25.7	-	25.7	SFO	Y, EFSA confirmatory data (2014)
Pappelacker	Sandy loam	7.4	-	2	47.1	-	47.1	SFO	Y, EFSA confirmatory data (2014)
Hyde Farm	Sandy loam	7.5	-	75% of 1/3 bar	31.8	-	21.2	SFO	Y, EFSA (2010)
East Anglia	Loamy sand	7.9	-	40% MWHC	56.5	-	43.4	SFO	Y, EFSA (2010)
North Dakota	Sandy loam	7.8	-	2	65.4	-	65.4	SFO	Y, EFSA confirmatory data (2014)
Vetroz	Loam	7.9	-	2	69.1	-	69.1	SFO	Y, EFSA confirmatory data (2014)
Geometric mean alkaline soils (n=7)							36.7		
Geometric mean acidic soils (n=5)							98.6		
pH-dependency:							y		

Table 8.3-6: Summary of aerobic degradation rates for R401553 - laboratory studies

R401553, Laboratory studies, aerobic conditions										
Soil name	Soil type	pH	T.°C	MWHC %	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa	Chi ² (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Fresham	Sandy loam	6.6	20	40	1.36	4.52	0.9	9.1	SFO	Y, EFSA (2010)
Wisborough Green	Silty clay loam	6.4	20	40	1.59	5.29	0.9	10.9	SFO	Y, EFSA (2010)
East Anglia	Loamy sand	7.9	20	40	2.01	6.68	1.5	12.3	SFO	Y, EFSA (2010)
Geometric mean (n=3)							1.1			
pH-dependency							n			

Table 8.3-7: Summary of aerobic degradation rates for R402173 - laboratory studies

R402173, Laboratory studies, aerobic conditions										
Soil name	Soil type	pH	T.°C	MWHC %	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa	Chi ² (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Fresham	Sandy loam	6.6	20	40	8.44	-	5.7	8.6	SFO	Y, EFSA (2010)

R402173, Laboratory studies, aerobic conditions										
Soil name	Soil type	pH	T.°C	MWHC %	DT₅₀ (d)	DT₉₀ (d)	DT₅₀ (d) 20°C pF2/10kPa	Chi² (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Wisborough Green	Silty clay loam	6.4	20	40	4.24	-	2.4	12.3	SFO	Y, EFSA (2010)
East Anglia	Loamy sand	7.9	20	40	9.8	-	7.5	12.7	SFO	Y, EFSA (2010)
Geometric mean (n=3)							4.7			
pH-dependency							n			

zRMS comments:

Soil degradation data for azoxystrobin and its metabolites are in line with EU agreed endpoints reported in EFSA Journal 2010; 8(4):1542 and in Addendum with confirmatory data for azoxystrobin (September, 2014).

For relevant endpoints considered in exposure assessment, please refer to points 8.7 (soil), 8.8 (groundwater) and 8.9 (surface water) of this document.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

No data were required for active substance approvals. No studies are required for product assessment.

zRMS comments:

It is noted that in line with information provided in EFSA Scientific Report (2007) 106, prothioconazole might be potentially exposed to anaerobic conditions when applied during the winter, following autumn seed treatment. The application pattern of CA3642 does not include application as a seed treatment, so anaerobic route of exposure is not considered further, in line with EU conclusions.

8.4 Field studies (KCP 9.1.1.2)

8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

8.4.1.1 Prothioconazole and its metabolites

All endpoints are taken from the agreed values in the EFSA 2007 conclusion (EFSA Scientific Report (2007) 106, 1-98) and information taken from the study summaries in the associated DAR, though the selection criteria for modelling endpoints has been changed to follow current guidelines (*e.g.* geometric means). No formulation studies are submitted or required.

Field soil degradation data are available for 8 trials on prothioconazole and the relevant soil metabolite, prothioconazole-desthio. The endpoints are summarised below in Table 8.4-1 (as reported in the DAR).

Please note that field data was normalised using the time-step method based on measured daily temperatures and used a Q₁₀ value of 2.2. There is insufficient data in the DAR study summary to perform re-normalisation using a Q₁₀ of 2.58, therefore the values with a Q₁₀ of 2.2 were used in modelling, as they are the current agreed EU endpoint.

Table 8.4-1: Summary of aerobic degradation rates for prothioconazole and prothioconazole-desthio - field studies

		Actual temperatures						Normalised for 20°C			
		Prothioconazole			Desthio-prothioconazole			Prothioconazole		Desthio-prothioconazole	
Trial Location	Cropped or bare	DT ₅₀ (d)	DT ₉₀ (d)	R ²	DT ₅₀ (d)	DT ₉₀ (d)	R ²	DT ₅₀ (d)	R ²	DT ₅₀ (d)	R ²
51399 Höfchen, Germany	Bare	1.9	6.4	1.00	16.3	54.1	0.98	1.2	1.00	10.3	0.99
IP31 3SH, Thurston, Great Britain	Bare	1.6	5.5	1.00	54.7	182	0.96	0.8	1.00	27.0	0.98
27700 Fresne l'Archeveque, France (North)	Bare	1.3	4.4	1.00	47.6	158	0.94	1.6	1.00	27.5	0.86
IP31 3SH Thurston, Great Britain	Cropped	2.8	9.3	0.99	50.2	167	0.91	1.4	1.00	23.4	0.94
27700 Fresne l'Archeveque France (North)	Cropped	1.4	4.5	1.00	36.8	122	0.93	1.6	1.00	20.1	0.86
13103 St. Etienne du Gres, France (South)	Cropped	1.7	5.6	0.99	72.3	240	0.91	1.1	1.000	61.9	0.97
37060 Nogarole Rocca, VR, Italy	Cropped	1.6	5.4	0.99	30.5	101	0.98	1.5	1.00	20.7	0.95
40789 Laacherhof, Germany	Bare	1.5	5.1	1.00	27.9	92.6	0.98	0.6	1.00	15.2	1.00
Worst-case (persistence)		2.8	9.3	-	72.3	240	-				
Geometric mean (modelling, EFSA Conclusion 2007))								1.2	-	22.7	-

zRMS comments:

The triggering endpoints for prothioconazole and metabolite JAU 5479-desthio provided in Tables 8.4-1 above are in line with data reported in EFSA Scientific Report (2007) 106 and prothioconazole DAR of 2005.

For relevant endpoints considered in exposure assessment, please refer to points 8.7 (soil), 8.8 (groundwater) and 8.9 (surface water) of this document.

8.4.1.2 Azoxystrobin and its metabolites

All endpoints are taken from the agreed values in the EFSA 2010 conclusion (EFSA Journal 2010; 8(4):1542), 2014 confirmatory data (EFSA supporting publication 2014:EN-718), and information taken from the study summaries in the associated DAR. No formulation studies are submitted or required.

Field soil dissipation data are available for azoxystrobin. The endpoints for persistence triggers and modelling are summarised below in Table 8.4-2 and Table 8.4-3, respectively.

Table 8.4-2: Summary of aerobic degradation rates for azoxystrobin - field studies: Triggering endpoints

Azoxystrobin, Field studies – Triggering endpoints									
Soil type	Location	pH	Depth (cm)	DissT ₅₀ (d) actual	DT ₉₀ (d) actual	Kinetic parameters	St. (x ²)	Method of calculation	Evaluated on EU level y/n/ Reference
Sandy clay loam	Spalding	7.5	30	261.9	869.9	not available	10.6	SFO	Y, EFSA (2010)
Silty clay loam	Nagele	7.9	30	186.4	619.3	not available	10.2	SFO	Y, EFSA (2010)
Sandy clay loam	Shirebrook	6.7	30	120.9	401.7	not available	17.2	SFO	Y, EFSA (2010)
Maximum (n=3)				261.9	869.9				

Table 8.4-3: Summary of aerobic degradation rates for azoxystrobin - field studies: Modelling endpoints

Azoxystrobin, Field studies – Modelling endpoints								
Soil type	Location	pH	Depth (cm)	DT ₅₀ (d) 20°C, pF2	DT ₅₀ (d) 20°C, pF2 quick	DT ₅₀ (d) 20°C, pF2 slow	Fit	Evaluated on EU level y/n/ Reference
Sandy clay loam	Spalding	7.5	30	106.7	-	-	SFO	Y, EFSA (2010)
Silty clay loam	Nagele	7.9	30	86.3	-	-	SFO	Y, EFSA (2010)
Sandy clay loam	Shirebrook	6.7	30	56.1	-	-	SFO	Y, EFSA (2010)
Clay loam	Volpedo	8.2	30	-	2.62	80.6	DFOP	Y, EFSA (2010)
Sandy loam	Bienenbittel-Varendorf	6.4	30	-	2.95	61.3	DFOP	Y, EFSA (2010)
Sandy clay loam	Saxa-Anhalt	6.6	30	-	1.64	93.7	DFOP	Y, EFSA (2010)
Clay loam	Isle/Sorgue	8.5	30	-	4.65	121.6	DFOP	Y, EFSA (2010)
Sandy loam	Monteux Vaucluse	8.5	30	-	4.03	68	DFOP	Y, EFSA (2010)
Silt loam	St Vigor	6.1	30	-	3.02	34.5	DFOP	Y, EFSA (2010)
Silty clay loam	Massalombarda	8.3	30	-	1.39	105	DFOP	Y, EFSA (2010)
Clay loam	Grisolles	7.7	30	-	13.3	66	DFOP	Y, EFSA (2010)
Clay	Cambridgeshire	8	30	-	2.09	93.7	DFOP	Y, EFSA (2010)
Clay	Somerset	8.1	30	-	0.42	73.7	DFOP	Y, EFSA (2010)
Geometric mean (n=x)				80.2	2.55	75.9		
				78.0^a				
pH-dependency				n				

^a geometric mean (80.2 and 75.9 days)

zRMS comments:

Field degradation data presented in Tables 8.4-2 and 8.4-3 above are in with EU agreed endpoints presented in EFSA Journal 2010; 8(4):1542.

For relevant endpoints considered in exposure assessment, please refer to points 8.7 (soil), 8.8 (groundwater) and 8.9 (surface water) of this document.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

No soil accumulation testing was required.

zRMS comments:

No EU agreed data from soil accumulation studies with and prothioconazole and azoxystrobin are available in EFSA Scientific Report (2007) 106 and EFSA Journal 2010; 8(4):1542, respectively. Potential for soil accumulation is thus addressed in calculation of soil exposure in point 8.7 of this report.

8.5 Mobility in soil (KCP 9.1.2)

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substances.

8.5.1 Prothioconazole and its metabolites

All endpoints are taken from the agreed values in the EFSA 2007 conclusion (EFSA Scientific Report (2007) 106, 1-98) and information taken from the study summaries in the associated DAR, though the selection criteria for modelling endpoints has been changed to follow current guidelines (e.g. geometric means, which in all cases were more conservative if compared with the mean values). No formulation studies are submitted or required.

No batch equilibrium data could be obtained for prothioconazole due to its instability in soil. The K_{oc} was estimated from column leaching studies. Data are available on 4 soils for each of the relevant metabolites in soil and surface water (prothioconazole-S-methyl, prothioconazole-desthio, and 1,2,4-triazole), which are summarised below.

Table 8.5-1: Summary of soil adsorption/desorption for prothioconazole

Prothioconazole							
Soil name	Soil type	OC (%)	pH (H ₂ O)	K _d (mL/g)	K _{oc} (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Byromville, Georgia, USA	loamy sand	0.86	6.7	15.2	1765	N/A*	Y, EFSA (2007)
pH-dependency				No			

* Data were taken from a column leaching study so no Freundlich coefficient is available. A worst-case value of 1 is recommended for use in modelling.

Table 8.5-2: Summary of soil adsorption/desorption for prothioconazole-S-methyl

Prothioconazole-S-methyl							
Soil name	Soil type	OC (%)	pH (H ₂ O)	K _r (mL/g)	K _{foc} (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Laacher Hof	sandy loam	2.02	7.2	56.0	2772.4	0.87	Y, EFSA (2007)
Höfchen,	silt	2.14	7.1	64.1	2995.0	0.88	
Stanley	silty clay loam	1.66	5.9	41.2	2484.0	0.91	
Byromville	loamy sand	0.79	6.8	15.6	1973.6	0.85	
Arithmetic mean (n=4)					2556.3	0.88*	
Geometric mean (n=4)					2525.9*		
pH-dependency				No			

* Used for modelling

Table 8.5-3: Summary of soil adsorption/desorption for prothioconazole-desthio

Prothioconazole-desthio							
Soil Name	Soil Type	OC (%)	pH (H ₂ O)	K _r (mL/g)	K _{foc} (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Laacher Hof	sandy loam	2.02	7.2	12.46	616.8	0.79	Y, EFSA (2007)
Höfchen,	silt	2.14	7.1	13.38	625.3	0.83	
Stanley	silty clay loam	1.66	5.9	8.90	536.4	0.83	
Byromville	loamy sand	0.79	6.8	4.13	523.0	0.80	
Arithmetic mean (n=4)					575.4	0.81*	
Geometric mean (used for modelling) (n=4)					573.5*		
pH-dependency					No		

* Used for modelling

Table 8.5-4: Summary of soil adsorption/desorption for 1,2,4-triazole

1,2,4-triazole							
Soil Name	Soil Type	OC (%)	pH (H ₂ O)	K _r (mL/g)	K _{foc} (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Alpaugh	silty clay	0.70	8.8	0.833	120	0.833	Y, EFSA (2007) Experts' meeting PRAPeR 12 (2007)
Hollister	clay loam	1.74	6.9	0.748	43	0.748	
Lakeland	sand	0.12	4.8	0.234	202 [†]	0.234 [†]	
Lawrenceville	silty clay loam	0.70	7.0	0.722	104	0.722	
Pachappa	sandy loam	0.81	6.9	0.719	89	0.720	
Arithmetic mean (n=4)					89	0.91*	
Geometric mean (used for modelling) (n=4)					83*		
pH-dependency					No		

* Used for modelling

[†] Excluded from mean values as an outlier by EFSA, experts' meeting PRAPeR 12 (2007)

zRMS comments:

Soil mobility data for prothioconazole and its major soil metabolites presented in Tables 8.5-1 to 8.5-3 are in line with EU agreed endpoints as reported in EFSA Scientific Report (2007) 106 and prothioconazole DAR of 2005. Information on soil sorption of the metabolite 1,2,4-triazole presented in Table 8.5-4 is in line with EU agreed endpoints as reported in EFSA Scientific Report (2008) 176 for tebuconazole.

It is noted that at the EU level no respective soil adsorption-desorption studies were performed with prothioconazole and the K_{oc} of 1765 mL/g has been derived from the aged leaching study. The method used for this calculation is questionable and was not agreed during the recent EU renewal of this active substance. Nevertheless, as the renewal process is still ongoing, the K_{oc} of 1765 mL/g is considered to be an EU agreed endpoint that is relevant for the exposure assessment until new list of endpoints becomes valid.

For metabolites JAU 6476-S-methyl and JAU 6476-desthio the geometric mean K_{foc} values were calculated by the Applicant, although in the EFSA conclusion only arithmetic mean values are reported and further used for groundwater and surface water modelling. The geometric mean values calculated by the Applicant were based on the individual K_{foc} from the LoEP and are confirmed to be correct. For relevant endpoints considered in exposure assessment, please refer to points 8.8 (groundwater) and 8.9 (surface water) of this document

8.5.2 Azoxystrobin and its metabolites

All endpoints are taken from the agreed values in the EFSA 2010 conclusion (EFSA Journal 2010; 8(4):1542), 2014 confirmatory data (EFSA supporting publication 2014:EN-718), and information taken from the study summaries in the associated DAR. No formulation studies are submitted or required.

Table 8.5-5: Summary of soil adsorption/desorption for azoxystrobin

Azoxystrobin						
Soil type	OC (%)	pH (-)	K _r (mL/g)	K _{foc} (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Sandy clay loam	1.7	7.5	7.9	465	0.84	Y, EFSA (2010)
Loamy sand A	1.7	7.8	4	235	0.82	Y, EFSA (2010)
Loamy sand B	3	7.9	6.2	207	0.85	Y, EFSA (2010)
Sand	0.3	5.5	1.5	500	0.84	Y, EFSA (2010)
Silty clay loam	1.6	4.9	9.5	594	0.9	Y, EFSA (2010)
Clay loam	2.8	5.5	15	536	0.9	Y, EFSA (2010)
Arithmetic mean (n=6)				423	0.86*	
Geometric mean (n=6)				392*	-	
pH-dependency				No		

* Used for modelling

Table 8.5-6: Summary of soil adsorption/desorption for R234886

R234886							
Soil name	Class*	OC (%)	pH (H ₂ O)	K _r (mL/g)	K _{foc} (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Nebo	acidic	1.62	4.9	6.8	420	0.90	Y, EFSA confirmatory data (2014)
Wisborough Green		2.4	5.3	2.43	101	0.70	Y, EFSA confirmatory data (2014)
Frensham		1.84	5.4	1.83	100	0.70	Y, EFSA confirmatory data (2014)
Lilly Field		0.29	5.5	1.4	490	0.79	Y, EFSA confirmatory data (2014)
Picket Piece		2.78	5.5	10	360	0.89	Y, EFSA confirmatory data (2014)
Ohio		1.36	5.8	1.52	112	0.70	Y, EFSA confirmatory data (2014)
Nuptown		2.47	6.2	1.53	62	0.71	Y, EFSA confirmatory data (2014)
Georgia		0.67	7.1	1.22	182	0.83	Y, EFSA confirmatory data (2014)
Gartenacker	alkaline	2.67	7.3	0.87	33	0.82	Y, EFSA confirmatory data (2014)
Pappelacker		1.11	7.4	0.42	37	0.80	Y, EFSA confirmatory data (2014)
Hyde Farm		1.74	7.5	0.85	49	0.85	Y, EFSA confirmatory data (2014)
East Anglia		1.68	7.8	0.35	21	0.76	Y, EFSA confirmatory data (2014)
North Dakota		2.78	7.8	1.65	59	0.86	Y, EFSA confirmatory data (2014)
Vetroz		2.38	7.9	0.72	30	0.86	Y, EFSA confirmatory data (2014)
Kenny Hill		2.96	7.9	0.82	28	0.90	Y, EFSA (2010)
Arithmetic mean alkaline soils (n=7)					36.7	0.83*	
Geometric mean alkaline soils (n=7)					34.8*	-	
Arithmetic mean acidic soils (n=8)					228.4	0.78*	
Geometric mean acidic soils (n=8)					176.6*	-	
pH-dependency					Yes		

* Used for modelling

Due to the pH-dependency, the EFSA (2014) confirmatory data evaluation agreed to use separate K_{oc} and 1/n endpoints for the modelling of acidic and alkaline conditions. The pH-dependency also applies to soil degradation or R234886, so there is no clear worst-case pH and both sets of parameters must be modelled (acidic soils are the slowest for degradation, but mobility is higher in alkaline soils).

Table 8.5-7: Summary of soil adsorption/desorption for R401553

R401553							
-	Soil Type	OC (%)	pH (H ₂ O)	K _r (mL/g)	K _{foc} (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
	Sandy clay loam	1.74	7.5	1.9	110	0.81	Y, EFSA (2010)
	Loamy sand	0.29	6.8	0.76	260	0.81	Y, EFSA (2010)
	Sandy loam	2.96	8.5	2.4	81	0.84	Y, EFSA (2010)
	Silty clay loam	2.15	6.2	11	500	0.89	Y, EFSA (2010)
	Silty clay loam	2.38	5.6	1.6	66	0.85	Y, EFSA (2010)
	Clay loam	2.61	5.4	2.9	110	0.92	Y, EFSA (2010)
Arithmetic mean (n=6)					188	0.85*	
Geometric mean (n=6)					143*	-	
pH-dependency					No		

* Used for modelling

Table 8.5-8: Summary of soil adsorption/desorption for R402173

R402173							
-	Soil Type	OC (%)	pH (H ₂ O)	K _r (mL/g)	K _{foc} (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
	Sandy clay loam	1.74	7.5	0.65	37	0.96	Y, EFSA (2010)
	Loamy sand	0.29	6.8	0.27	93	0.95	Y, EFSA (2010)
	Sandy loam	2.96	8.5	0.74	25	0.96	Y, EFSA (2010)
	Silty clay loam	2.15	6.2	4.2	200	0.92	Y, EFSA (2010)
	Silty clay loam	2.38	5.6	2	86	0.93	Y, EFSA (2010)
	Clay loam	2.61	5.4	2.9	110	0.96	Y, EFSA (2010)
Arithmetic mean (n=6)					91.8	0.95	
Geometric mean (n=6)					73.9	-	
Worst case					25*	0.96*	
pH-dependency					Yes		

* Used for modelling

Due to the pH-dependent mobility of R402173, the worst-case K_{oc} and 1/n were selected as modelling endpoints in the EFSA (2010) conclusion.

zRMS comments:

Soil mobility data for azoxystrobin and its metabolites are in line with EU agreed endpoints as reported in EFSA Journal 2010; 8(4):1542 and Addendum with confirmatory data for azoxystrobin (September, 2014).

It is noted that for azoxystrobin and its metabolites the geometric mean K_{foc} values were calculated by the Applicant, although in the EFSA conclusion only arithmetic mean values are reported and further used for groundwater and surface water modelling. The geometric mean values calculated by the Applicant were based on the individual K_{foc} from the LoEP and are confirmed to be correct. For relevant endpoints considered in exposure assessment, please refer to points 8.8 (groundwater) and 8.9 (surface water) of this document

8.5.3 Column leaching (KCP 9.1.2.1)

Studies on the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

zRMS comments:

Results of column leaching and aged residues leaching of prothioconazole are reported in EFSA Scientific Report (2007) 106, however are not necessary for purposes of evaluation of CA3642, as based on results of the groundwater modelling no unacceptable leaching of prothioconazole or its metabolites is expected. The column leaching studies were not required during the EU review of azoxystrobin.

The leaching potential azoxystrobin and their metabolites following application of CA3642 is addressed in groundwater modelling presented in point 8.8 of this document.

8.5.4 Lysimeter studies (KCP 9.1.2.2)

Lysimeter studies were not required to support the risk assessment.

zRMS comments:

The lysimeter studies were not required during the EU review of both active substances. The leaching potential of prothioconazole and azoxystrobin and their metabolites following application of CA3642 is addressed in groundwater modelling presented in point 8.8 of this document.

8.5.5 Field leaching studies (KCP 9.1.2.3)

Field leaching studies were not required to support the risk assessment.

zRMS comments:

The field leaching studies were not required during the EU review of both active substances. The leaching potential of prothioconazole and azoxystrobin and their metabolites following application of CA3642 is addressed in groundwater modelling presented in point 8.8 of this document.

8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.6.1 Prothioconazole and its metabolites

All endpoints are taken from the agreed values in the EFSA 2007 conclusion (EFSA Scientific Report (2007) 106, 1-98) and information taken from the study summaries in the associated DAR, though the selection criteria for modelling endpoints has been changed to follow current guidelines (e.g. geometric means). No formulation studies are submitted or required.

Table 8.6-1: Summary of degradation in water/sediment of prothioconazole

Prothioconazole Distribution (max. sediment 23.4 % after 1 day)										
Water/sediment system	pH water/sed.	DegT ₅₀ whole syst. (d)	DegT ₉₀ whole syst. (d)	Kinetic, Fit	DissT ₅₀ water (d)	DissT ₉₀ water (d)	Kinetic, Fit	DissT ₅₀ sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/Reference
Hönniger Weiher	7.84	2.8	76.4	HS	0.8	2.7	SFO	n.d.	n.d.	Y, EFSA

Prothioconazole Distribution (max. sediment 23.4 % after 1 day)										
Water/sediment system	pH water/sed.	DegT ₅₀ whole syst. (d)	DegT ₉₀ whole syst. (d)	Kinetic, Fit	DissT ₅₀ water (d)	DissT ₉₀ water (d)	Kinetic, Fit	DissT ₅₀ sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
Angler Weiher	7.45	1.6	23.6	HS	1.0	3.4	SFO	n.d	n.d	(2007)
Geometric mean (n=2)		2.2	42.5		0.9	3.0		n.d		

n.d. = not determined

Table 8.6-2: Summary of observed metabolites

Prothioconazole-desthio Water/sediment system	Max. in water 32.3 % after 7 d (Angler Weiher, phenyl label) Max. in sediment 26.9 % after 14 d (Angler Weiher, phenyl label) Max. in water/sediment 54.6 % after 7 d (Angler Weiher, phenyl label)	Y, EFSA (2007), DAR Vol.3 B8
1,2,4-Triazole Water/sediment system	Max. in water 37.2 % after 121 d (Angler Weiher, triazole label) Max. in sediment 4.6 % after 121 d (Angler Weiher, triazole label) Max. in water/sediment 41.8 % after 121 d (Angler Weiher, triazole label)	

zRMS comments:

Degradation data for prothioconazole and its metabolites in water/sediment systems provided in tables above are in line with EU agreed endpoints reported in EFSA Scientific Report (2007) 106 and prothioconazole DAR (2005) and are relevant for the surface water exposure assessment.

8.6.2 Azoxystrobin and its metabolites

All endpoints are taken from the agreed values in the EFSA 2010 conclusion (EFSA Journal 2010; 8(4):1542), 2014 confirmatory data (EFSA supporting publication 2014:EN-718), and information taken from the study summaries in the associated DAR. No formulation studies are submitted or required.

Table 8.6-3: Summary of degradation in water/sediment of azoxystrobin

Azoxystrobin Distribution (max. water/sediment 91.2 % after 0 days)										
Water/sediment system	pH water/sed.	DegT ₅₀ whole syst. (d)	DegT ₉₀ whole syst. (d)	Kinetic, Fit	DissT ₅₀ water (d)	DissT ₉₀ water (d)	Kinetic, Fit	DissT ₅₀ sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
Old Basing	7.5	234	777	SFO	-	-	-	-	-	Y, EFSA (2010)
Virgina water	6.4	180	598	SFO	-	-	-	-	-	Y, EFSA (2010)
Geometric mean (n=2)		205	682		-	-		-		

Table 8.6-4: Summary of observed metabolites

R234886 Water/sediment system	Max. in water/sediment 18.1 %	Y, EFSA (2010)
R401553 Water/sediment system	Max. in water/sediment 8.9 %	Y, EFSA (2010)
R402173 Water/sediment system	Max. in water/sediment 2.4 %	Y, EFSA (2010)

zRMS comments:

Degradation data for azoxystrobin and its metabolites in water/sediment systems provided in tables above are in line with EU agreed endpoints reported in EFSA Journal 2010; 8(4):1542 and are relevant for the surface water exposure assessment.

8.7 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

The EU evaluations of soil exposure (EFSA Scientific Report (2007) 106, 1-98 and EFSA Journal 2010; 8(4):1542) did not cover all uses in the product GAP (see Table 8.1-1 and Table 8.1-2). Therefore new calculations have been performed and are summarised below.

8.7.1 Justification for new endpoints

All endpoints are taken from the agreed values in the EFSA 2007 conclusion (EFSA Scientific Report (2007) 106, 1-98) and information taken from the study summaries in the associated DAR.

8.7.2 Active substance(s) and relevant metabolite(s)

PEC_{soil} values have been calculated following the FOCUS guidance in European Commission Document 7617/VI/96. PEC_{soil} values have been calculated for three uses, providing a risk envelope for all uses in the GAP.

Metabolite PEC values were determined by multiplying the parent application rate by the maximum observed level (adjusted for any molecular weight differences) and assuming SFO degradation from this peak (with the slowest DT₅₀ of either parent or metabolite). If the parent accumulates in soil, the application rate for metabolite PEC_{accumulation} was adjusted based on the accumulation factor of the parent substance.

Table 8.7-1: Input parameters related to application for PEC_{soil} calculations

GAP use number	Covering uses 1-78	Covering uses 79-90, 105-116	Covering uses 79-116	Covering use 103
Crop	Cereals	Winter oilseed rape (autumn use)*	Spring or winter oilseed rape (spring use only)**	Sunflower***
Prothioconazole Application rate (g a.s./ha)	210 g a.s./ha	180 g a.s./ha	180 g a.s./ha	180 g a.s./ha
Azoxystrobin Application rate (g a.s./ha)	210 g a.s./ha	180 g a.s./ha	180 g a.s./ha	180 g a.s./ha
Number of applications/interval	2 / 14d	1	1	1
Crop interception (%)	80% (BBCH 30)	40% (BBCH 14)	80% (BBCH 20)	20% (BBCH 16)
Depth of soil layer (relevant for plateau concentration) (cm)	5 cm (20 cm tillage for plateau)			

*Proxy crop covering minor uses in autumn on ~~linseeds~~, poppy, mustard and gold of pleasure

**Proxy crop covering minor uses in spring on flax, ~~sunflower~~, ~~linseeds~~, poppy, mustard and gold of pleasure

*** Proxy crop covering minor uses on linseeds (the worse cae interception for linseed at BBCH 14-18 is 30%)

Table 8.7-2: Input parameter for active substance(s) and relevant metabolite(s) for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT ₅₀ (days)	Value in accordance with EU endpoint y/n/ Reference
Prothioconazole	344.26	-	2.8 d (SFO, worst-case, field)	Y, EFSA Scientific Report (2007) 106, 1-98
Prothioconazole-S-methyl	358.3	14.6 %	46 d (SFO, worst-case, lab)	
Prothioconazole-desthio	312.2	57.1 %	72.3 d (SFO, worst-case, field)	
Azoxystrobin	403.4	-	262 (SFO, worst-case, field)	Y, EFSA J. 2010; 8(4):1542
R234886	389.4	28.8 %	110 (DFOP, worst-case slow phase)*	Y, EFSA 2014:EN-718
R401553	213.2	17.0 %	1.5 (SFO, worst-case lab)	Y, EFSA J. 2010; 8(4):1542
R402173	333.3	17.0 %	7.5 (SFO, worst-case lab)	

* Degradation was calculated using SFO kinetics with the slow phase DFOP DT₅₀ as a conservative first-tier approach

zRMS comments:

The application pattern assumed in soil exposure assessment is in line with the critical Central Zone GAP and it is thus agreed. Relevant crop interception in line with FOCUS groundwater guidance (2021) have been selected.

Input parameters presented in Table 8.7-2 are in line with EU agreed parameters for prothioconazole and azoxystrobin reported in EFSA Scientific Report (2007) 106 and EFSA Journal 2010; 8(4):1542, respectively.

8.7.2.1 Prothioconazole and its metabolites

PEC_{soil} values are provided in the tables below. The worst-case values occur following autumn treatment of winter oilseed rape.

Table 8.7-3: PEC_{soil} for prothioconazole on cereals

PEC _{soil} (mg/kg)		Cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0560	-	0.0578	-
Short term	24h	0.0437	0.0496	0.0451	0.0512
	2d	0.0341	0.0442	0.0352	0.0455
	4d	0.0208	0.0355	0.0215	0.0367
Long term	7d	0.0099	0.0266	0.0102	0.0274
	14d	0.0018	0.0157	0.0018	0.0161
	21d	0.0003	0.0107	0.0003	0.0110
	28d	0.0001	0.0081	0.0001	0.0083
	50d	<0.0001	0.0045	<0.0001	0.0047
	100d	<0.0001	0.0023	<0.0001	0.0023
Plateau concentration (20 cm)		Not relevant. DT ₉₀ < 1 year, does not accumulate			
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})					

Table 8.7-4: PEC_{soil} for prothioconazole on oilseed rape (autumn or spring use)

PEC _{soil} (mg/kg)		Oilseed rape			
		Autumn application		Spring application	
		Actual	TWA	Actual	TWA
Initial		0.1440	-	0.0480	-
Short term	24h	0.1124	0.1276	0.0375	0.0425
	2d	0.0878	0.1136	0.0293	0.0379
	4d	0.0535	0.0914	0.0178	0.0305
Long term	7d	0.0255	0.0684	0.0085	0.0228
	14d	0.0045	0.0403	0.0015	0.0134
	21d	0.0008	0.0275	0.0003	0.0092
	28d	0.0001	0.0208	<0.0001	0.0069
	50d	<0.0001	0.0116	<0.0001	0.0039
	100d	<0.0001	0.0058	<0.0001	0.0019
Plateau concentration (20 cm)		Not relevant. DT ₉₀ < 1 year, does not accumulate			
PEC _{accumulation} (PEC _{act} +PEC _{soil plateau})					

Table 8.7-5: PEC_{soil} for prothioconazole on sunflower

PEC _{soil} (mg/kg)		Sunflower	
		Actual	TWA
Initial		0.1920	-
Short term	24h	0.1499	0.1701
	2d	0.1170	0.1514
	4d	0.0713	0.1219
Long term	7d	0.0339	0.0912
	14d	0.0060	0.0537
	21d	0.0011	0.0367
	28d	0.0002	0.0277
	50d	0.0000	0.0155
	100d	0.0000	0.0078
Plateau concentration (20 cm)		Not relevant. DT ₉₀ < 1 year, does not accumulate	
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})			

Table 8.7-6: PEC_{soil} for prothioconazole-S-methyl on cereals

PEC _{soil} (mg/kg)		Cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0085	-	0.0154	-
Short term	24h	0.0084	0.0084	0.0152	0.0153
	2d	0.0083	0.0084	0.0149	0.0152
	4d	0.0080	0.0083	0.0145	0.0149
Long term	7d	0.0077	0.0081	0.0139	0.0146
	14d	0.0069	0.0077	0.0125	0.0139
	21d	0.0062	0.0073	0.0112	0.0132
	28d	0.0056	0.0069	0.0101	0.0126
	50d	0.0040	0.0060	0.0072	0.0108
	100d	0.0019	0.0044	0.0034	0.0080
Plateau concentration (20 cm)		Not relevant. DT90 < 1 year, does not accumulate			
PEC _{accumulation} (PEC _{act} +PEC _{soil plateau})					

Table 8.7-7: PEC_{soil} for prothioconazole-S-methyl on oilseed rape (autumn or spring use)

PEC _{soil} (mg/kg)		Oilseed rape			
		Autumn application		Spring application	
		Actual	TWA	Actual	TWA
Initial		0.0219	-	0.0073	-
Short term	24h	0.0216	0.0217	0.0072	0.0072
	2d	0.0212	0.0216	0.0071	0.0072
	4d	0.0206	0.0212	0.0069	0.0071
Long term	7d	0.0197	0.0208	0.0066	0.0069
	14d	0.0177	0.0197	0.0059	0.0066
	21d	0.0159	0.0188	0.0053	0.0063
	28d	0.0143	0.0179	0.0048	0.0060
	50d	0.0103	0.0154	0.0034	0.0051
	100d	0.0048	0.0113	0.0016	0.0038
Plateau concentration (20 cm)		Not relevant. DT90 < 1 year, does not accumulate			
PEC _{accumulation} (PEC _{act} +PEC _{soil plateau})					

Table 8.7-8: PEC_{soil} for prothioconazole-S-methyl on sunflower

PEC _{soil} (mg/kg)		Sunflower	
		Actual	TWA
Initial		0.0292	-
Short term	24h	0.0287	0.0290
	2d	0.0283	0.0287
	4d	0.0275	0.0283
Long term	7d	0.0263	0.0277
	14d	0.0236	0.0263
	21d	0.0213	0.0250
	28d	0.0191	0.0238
	50d	0.0137	0.0205
	100d	0.0065	0.0151
Plateau concentration (20 cm)		Not relevant. DT ₉₀ < 1 year, does not accumulate	
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})			

Table 8.7-9: PEC_{soil} for prothioconazole-desthio on cereals

PEC _{soil} (mg/kg)		Cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0290	-	0.0544	-
Short term	24h	0.0286	0.0288	0.0538	0.0541
	2d	0.0281	0.0286	0.0533	0.0538
	4d	0.0273	0.0281	0.0523	0.0533
Long term	7d	0.0261	0.0275	0.0508	0.0526
	14d	0.0235	0.0261	0.0475	0.0509
	21d	0.0211	0.0249	0.0444	0.0492
	28d	0.0190	0.0237	0.0416	0.0477
	50d	0.0137	0.0204	0.0337	0.0432
	100d	0.0064	0.0150	0.0208	0.0350
Plateau concentration (20 cm)		Not relevant. DT90 < 1 year, does not accumulate			
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})					

Table 8.7-10: PEC_{soil} for prothioconazole-desthio on oilseed rape (autumn or spring use)

PEC _{soil} (mg/kg)		Oilseed rape			
		Autumn application		Spring application	
		Actual	TWA	Actual	TWA
Initial		0.0746	–	0.0249	–
Short term	24h	0.0735	0.0740	0.0245	0.0247
	2d	0.0724	0.0735	0.0241	0.0245
	4d	0.0702	0.0724	0.0234	0.0241
Long term	7d	0.0671	0.0708	0.0224	0.0236
	14d	0.0604	0.0672	0.0201	0.0224
	21d	0.0543	0.0639	0.0181	0.0213
	28d	0.0489	0.0608	0.0163	0.0203
	50d	0.0351	0.0524	0.0117	0.0175
	100d	0.0165	0.0385	0.0055	0.0128
Plateau concentration (20 cm)		Not relevant. DT90 < 1 year, does not accumulate			
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})					

Table 8.7-11: PEC_{soil} for prothioconazole-desthio on sunflower

PEC _{soil} (mg/kg)		Sunflower	
		Actual	TWA
Initial		0.0994	-
Short term	24h	0.0985	0.0989
	2d	0.0975	0.0985
	4d	0.0957	0.0975
Long term	7d	0.0930	0.0962
	14d	0.0869	0.0930
	21d	0.0813	0.0901
	28d	0.0760	0.0872
	50d	0.0616	0.0790
	100d	0.0381	0.0639
Plateau concentration (20 cm)		Not relevant. DT ₉₀ < 1 year, does not accumulate	
PEC _{accumulation} (PEC _{act} +PEC _{soil plateau})			

zRMS comments:

The soil exposure for prothioconazole and its metabolites has been independently validated by the zRMS using FOCUS methods using EU agreed endpoints and the pseudo-application rates of metabolites derived with consideration of the parent rate, molar ratio and peak occurrence in soil.

The calculated PEC_{SOIL} values for prothioconazole and its metabolites were similar to those obtained by the Applicant and therefore results reported in Tables 8.7-3 to 8.7-11 above may be used for the soil risk assessment purposes, only with exception for use on oilseed rape. PEC_{SOIL} values for metabolite prothioconazole-desthio have been incorrectly calculated with DT_{50} value of 46 days relevant for prothioconazole-S-methyl, instead of DT_{50} for prothioconazole-desthio of 72.3 days. Therefore results reported in Table 8.7-10 have been struck through as incorrect..

The zRMS performed additional modelling for metabolite prothioconazole-desthio with consideration correct DT_{50} value, the calculated PEC_{SOIL} are presented in table below. The $PEC_{SOIL, ACCU}$ was not required as DT_{50} of the metabolite is below 100 days. The short- and long-term PEC_{SOIL} values are not reported below as they are not necessary for the risk assessment purposes. Only 21 TWA PEC_{SOIL} is provided as being required for evaluation of the risk of secondary poisoning for birds and mammals.

$PEC_{SOIL\ JAU-Desthio}$ (mg/kg)	Oilseed rape	
	Autumn application	Spring application
Initial	0.0746	0.0249
21-d TWA	0.068	0.023

8.7.2.2 Azoxystrobin and its metabolites

PEC_{soil} values are provided in the tables below. The worst-case values occur following autumn treatment of winter oilseed rape. Calculations for azoxystrobin were made using ESCAPE (v2.0) to determine the accumulation over multiple years. Although the metabolites do not themselves accumulate, the PEC_{accumulation} was calculated based on the accumulated parent PEC value.

Table 8.7-12: PEC_{soil} for azoxystrobin on cereals

PEC _{soil} (mg/kg)		Cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0560	-	0.1100	-
Short term	24h	0.0559	0.0559	0.1097	0.1098
	2d	0.0557	0.0559	0.1094	0.1097
	4d	0.0554	0.0557	0.1088	0.1094
Long term	7d	0.0550	0.0555	0.1079	0.1090
	14d	0.0540	0.0550	0.1060	0.1080
	21d	0.0530	0.0545	0.1040	0.1070
	28d	0.0520	0.0540	0.1021	0.1060
	50d	0.0491	0.0525	0.0963	0.1030
	100d	0.0430	0.0492	0.0844	0.0966
Plateau concentration (20 cm)		0.0086		0.0169	
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		0.0646		0.1269	

Table 8.7-13: PEC_{soil} for azoxystrobin on oilseed rape (autumn or spring use)

PEC _{soil} (mg/kg)		Oilseed rape			
		Autumn application		Spring application	
		Actual	TWA	Actual	TWA
Initial		0.1440	-	0.0480	-
Short term	24h	0.1436	0.1438	0.0479	0.0479
	2d	0.1432	0.1436	0.0477	0.0479
	4d	0.1425	0.1432	0.0475	0.0477
Long term	7d	0.1414	0.1427	0.0471	0.0476
	14d	0.1388	0.1414	0.0463	0.0471
	21d	0.1362	0.1401	0.0454	0.0467
	28d	0.1337	0.1388	0.0446	0.0463
	50d	0.1262	0.1349	0.0421	0.0450
	100d	0.1105	0.1265	0.0368	0.0422
Plateau concentration (20 cm)		0.0221		0.0074	
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		0.1661		0.0554	

Table 8.7-14: PEC_{soil} for azoxystrobin on sunflower

PEC _{soil} (mg/kg)		Sunflower	
		Actual	TWA
Initial		0.1920	-
Short term	24h	0.1915	0.1917
	2d	0.1910	0.1915
	4d	0.1900	0.1910
Long term	7d	0.1885	0.1902
	14d	0.1850	0.1885
	21d	0.1816	0.1868
	28d	0.1783	0.1851
	50d	0.1682	0.1798
	100d	0.1474	0.1687
Plateau concentration (20 cm)		0.0295	
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		0.2215	

Table 8.7-15: PEC_{soil} for R234886 on cereals

PEC _{soil} (mg/kg)		Cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0156	-	0.0306	-
Short term	24h	0.0155	0.0155	0.0305	0.0305
	2d	0.0155	0.0155	0.0304	0.0305
	4d	0.0154	0.0155	0.0303	0.0304
Long term	7d	0.0153	0.0154	0.0300	0.0303
	14d	0.0150	0.0153	0.0295	0.0300
	21d	0.0147	0.0151	0.0289	0.0297
	28d	0.0145	0.0150	0.0284	0.0295
	50d	0.0136	0.0146	0.0268	0.0286
	100d	0.0119	0.0137	0.0235	0.0269
Plateau concentration (20 cm)		Metabolite does not accumulate		Metabolite does not accumulate	
PEC _{accumulation} (from parent PEC _{accumulation})		0.0180		0.0353	

Table 8.7-16: PEC_{soil} for R234886 on oilseed rape (autumn or spring use)

PEC _{soil} (mg/kg)		Oilseed rape			
		Autumn application		Spring application	
		Actual	TWA	Actual	TWA
Initial		0.0400	-	0.0133	-
Short term	24h	0.0399	0.0400	0.0133	0.0133
	2d	0.0398	0.0399	0.0133	0.0133
	4d	0.0396	0.0398	0.0132	0.0133
Long term	7d	0.0393	0.0397	0.0131	0.0132
	14d	0.0386	0.0393	0.0129	0.0131
	21d	0.0379	0.0389	0.0126	0.0130
	28d	0.0372	0.0386	0.0124	0.0129
	50d	0.0351	0.0375	0.0117	0.0125
	100d	0.0307	0.0352	0.0102	0.0117
Plateau concentration (20 cm)		Metabolite does not accumulate		Metabolite does not accumulate	
PEC _{accumulation} (from parent PEC _{accumulation})		0.0462		0.0154	

Table 8.7-17: PEC_{soil} for R234886 on sunflower

PEC _{soil} (mg/kg)		Sunflower	
		Actual	TWA
Initial		0.0534	-
Short term	24h	0.0532	0.0533
	2d	0.0531	0.0532
	4d	0.0528	0.0531
Long term	7d	0.0524	0.0529
	14d	0.0514	0.0524
	21d	0.0505	0.0519
	28d	0.0496	0.0515
	50d	0.0468	0.0500
	100d	0.0410	0.0469
Plateau concentration (20 cm)		Metabolite does not accumulate	
PEC _{accumulation} (from parent PEC _{accumulation})		0.0616	

Table 8.7-18: PEC_{soil} for R401553 on cereals

PEC _{soil} (mg/kg)		Cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0050	-	0.0099	-
Short term	24h	0.0050	0.0050	0.0099	0.0099
	2d	0.0050	0.0050	0.0098	0.0099
	4d	0.0050	0.0050	0.0098	0.0098
Long term	7d	0.0049	0.0050	0.0097	0.0098
	14d	0.0048	0.0049	0.0095	0.0097
	21d	0.0048	0.0049	0.0093	0.0096
	28d	0.0047	0.0048	0.0092	0.0095
	50d	0.0044	0.0047	0.0087	0.0093
	100d	0.0039	0.0044	0.0076	0.0087
Plateau concentration (20 cm)		Metabolite does not accumulate		Metabolite does not accumulate	
PEC _{accumulation} (from parent PEC _{accumulation})		0.0058		0.0114	

Table 8.7-19: PEC_{soil} for R401553 on oilseed rape (autumn or spring use)

PEC _{soil} (mg/kg)		Oilseed rape			
		Autumn application		Spring application	
		Actual	TWA	Actual	TWA
Initial		0.0129	-	0.0043	-
Short term	24h	0.0129	0.0129	0.0043	0.0043
	2d	0.0129	0.0129	0.0043	0.0043
	4d	0.0128	0.0129	0.0043	0.0043
Long term	7d	0.0127	0.0128	0.0042	0.0043
	14d	0.0125	0.0127	0.0042	0.0042
	21d	0.0122	0.0126	0.0041	0.0042
	28d	0.0120	0.0125	0.0040	0.0042
	50d	0.0113	0.0121	0.0038	0.0040
	100d	0.0099	0.0114	0.0033	0.0038
Plateau concentration (20 cm)		Metabolite does not accumulate		Metabolite does not accumulate	
PEC _{accumulation} (from parent PEC _{accumulation})		0.0149		0.0050	

Table 8.7-20: PEC_{soil} for R401553 on sunflower

PEC _{soil} (mg/kg)		Sunflower	
		Actual	TWA
Initial		0.0173	-
Short term	24h	0.0172	0.0172
	2d	0.0172	0.0172
	4d	0.0171	0.0172
Long term	7d	0.0169	0.0171
	14d	0.0166	0.0169
	21d	0.0163	0.0168
	28d	0.0160	0.0166
	50d	0.0151	0.0162
	100d	0.0132	0.0152
Plateau concentration (20 cm)		Metabolite does not accumulate	
PEC _{accumulation} (from parent PEC _{accumulation})		0.0199	

Table 8.7-21: PEC_{soil} for R402173 on cereals

PEC _{soil} (mg/kg)		Cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.0079	-	0.0155	-
Short term	24h	0.0078	0.0079	0.0154	0.0154
	2d	0.0078	0.0078	0.0154	0.0154
	4d	0.0078	0.0078	0.0153	0.0154
Long term	7d	0.0077	0.0078	0.0152	0.0153
	14d	0.0076	0.0077	0.0149	0.0152
	21d	0.0074	0.0077	0.0146	0.0150
	28d	0.0073	0.0076	0.0143	0.0149
	50d	0.0069	0.0074	0.0135	0.0145
	100d	0.0060	0.0069	0.0119	0.0136
Plateau concentration (20 cm)		Metabolite does not accumulate		Metabolite does not accumulate	
PEC _{accumulation} (from parent PEC _{accumulation})		0.0091		0.0178	

Table 8.7-22: PEC_{soil} for R402173 on oilseed rape (autumn or spring use)

PEC _{soil} (mg/kg)		Oilseed rape			
		Autumn application		Spring application	
		Actual	TWA	Actual	TWA
Initial		0.0202	-	0.0067	-
Short term	24h	0.0202	0.0202	0.0067	0.0067
	2d	0.0201	0.0202	0.0067	0.0067
	4d	0.0200	0.0201	0.0067	0.0067
Long term	7d	0.0199	0.0200	0.0066	0.0067
	14d	0.0195	0.0199	0.0065	0.0066
	21d	0.0191	0.0197	0.0064	0.0066
	28d	0.0188	0.0195	0.0063	0.0065
	50d	0.0177	0.0189	0.0059	0.0063
	100d	0.0155	0.0178	0.0052	0.0059
Plateau concentration (20 cm)		Metabolite does not accumulate		Metabolite does not accumulate	
PEC _{accumulation} (from parent PEC _{accumulation})		0.0233		0.0078	

Table 8.7-23: PEC_{soil} for R402173 on sunflower

PEC _{soil} (mg/kg)		Sunflower	
		Actual	TWA
Initial		0.0270	-
Short term	24h	0.0269	0.0269
	2d	0.0268	0.0269
	4d	0.0267	0.0268
Long term	7d	0.0265	0.0267
	14d	0.0260	0.0265
	21d	0.0255	0.0262
	28d	0.0250	0.0260
	50d	0.0236	0.0253
	100d	0.0207	0.0237
Plateau concentration (20 cm)		Metabolite does not accumulate	
PEC _{accumulation} (from parent PEC _{accumulation})		0.0311	

zRMS comments:

The soil exposure for azoxystrobin and its metabolites has been independently validated by the zRMS using FOCUS methods using EU agreed endpoints and the pseudo-application rates of metabolites derived with consideration of the parent rate, molar ratio and peak occurrence in soil.

It is noted that for metabolites R234886, R401553 and R402173 the maximum DT₅₀ value of 262 days of azoxystrobin was used for soil exposure calculation, this is accepted by the zRMS as it represents worst case.

The calculated PEC_{soil} values for azoxystrobin and its metabolites were similar and lower to those obtained by the Applicant and therefore results reported in Tables 8.7-12 to 8.7-23 above may be used for the soil risk assessment purposes.

8.7.2.3 PEC_{soil} of formulation

Please note that only the instantaneous PEC_{soil} following a single application is relevant, since the formulation will immediately separate into its components, which then degrade at different rates. The calculation of winter oilseed rape at its earliest stage provides a risk envelope for all other uses.

Table 8.7-24: PEC_{soil} for formulation

Preparation	Use/Crop	Application rate (L/ha)	Product density (kg/L)*	Application rate (g/ha)	Crop interception	PEC _{act} (mg/kg)
CA3642	W/S Cereals	1.4 2.8**	1.1004	1541 3082**	80%	0.411 0.822**
	Winter oilseed rape (autumn use)	1.2	1.1004	1320	40%	1.056
	Winter or spring oilseed rape (spring use)	1.2	1.1004	1320	80%	0.352
	Sunflower	1.2	1.1004	1320	20%	1.4085

* Taken from KCP 2.6.1 (Wang, Q. 2022)

** double application to cereals considered as highest worst-case assumption by some CMS.

zRMS comments:

Soil exposure for the formulated product was recalculated by the zRMS and the same PEC_{soil} were obtained. For this reason PEC_{soil} as reported in table above is considered relevant for the soil risk assessment.

During the commenting period some of Member States required calculations with the sum of application rate, considering cumulated dose as a worst-case approach.

Nevertheless, the zRMS is of the opinion that the risk assessment for the formulated product should be based on soil exposure resulting from multiple applications of particular active compounds and formulation endpoints expressed in terms of the active substance.

8.8 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4)

The EU evaluation of groundwater exposure (EFSA Scientific Report (2007) 106, 1-98 and EFSA Journal 2010; 8(4):1542) did not cover all uses in the product GAP (see Table 8.1-1 and Table 8.1-2) and did not include modelling according to current FOCUS and EFSA guidelines. Therefore, new modelling has been performed and is summarised below.

8.8.1 Justification for new endpoints

All endpoints are taken from the data in the prothioconazole EFSA 2007 conclusion (EFSA Scientific Report (2007) 106, 1-98) and azoxystrobin EFSA 2010 conclusion (2010; 8(4):1542) plus the confirmatory data evaluated at EU level for the metabolite R234886 (EFSA supporting publication 2014:EN-718 and the 2014 DAR addendum). The geometric mean K_{foc} was used instead of the arithmetic mean listed in EFSA 2007 for several substances in order to comply with the requirements of current EFSA guidance (EFSA Journal 2014;12(5):3662). The geometric mean provides a slightly more conservative endpoint (higher soil mobility) than the arithmetic mean, resulting in a worst-case risk envelope that covers older assessments with arithmetic means. The differences are summarised below in Table 8.8-1. Note that no changes were made to the K_{foc} endpoint for prothioconazole or R402173, as mean values were not used.

Table 8.8-1: Justification of new K_{foc} endpoints used in modelling

Substance	Endpoint	Agreed EU modelling endpoint	New modelling endpoint	Justification
Prothioconazole	K _{foc}	1765 (single value)		No change required.
Prothioconazole-S-methyl	K _{foc}	2556.3 (arithmetic mean)	2525.9 (geometric mean)	Geometric means follow current guidelines (EFSA Journal 2014;12(5):3662) and result in a more conservative risk assessment and are required in several member states where approval is requested. The individual endpoints used for calculation of the mean are unchanged from the agreed EU values.
Prothioconazole-desthio	K _{foc}	575.4 (arithmetic mean)	573.5 (geometric mean)	
Azoxystrobin	K _{foc}	423 (arithmetic mean)	392 (geometric mean)	
R234886	K _{foc}	Acidic soils: 228.4 Alkaline soils: 36.7 (arithmetic mean)	Acidic soils: 176.6 Alkaline soils: 34.8 (geometric mean)	
R401553	K _{foc}	188 (arithmetic mean)	143 (geometric mean)	
R402173	K _{foc}	25 (worst-case due to pH dependence, n = 6)		No change required.

zRMS comments:

For prothioconazole metabolites: JAU 6476-S-methyl and JAU 6476-desthio and for azoxystrobin and its metabolites: R234886 and R401553 the geometric mean K_{foc} values were calculated by the Applicant, although in the EFSA conclusion only arithmetic mean values are reported and further used for groundwater modelling. The calculated by the Applicant geometric mean values were based on the individual K_{foc} from the LoEP and are confirmed to be correct. This deviations is agreed by the zRMS since the geometric mean K_{foc} values are lower than arithmetic mean K_{foc} values and is thus more conservative in regards of leaching of the substances to the groundwater. Moreover consideration of geometric mean K_{foc} values is in line with current EFSA recommendations.

8.8.2 Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1)

PEC_{gw} values have been calculated for uses on winter and spring varieties of both oilseed rape and cereals, providing a risk envelope for all uses in the GAP. The application scenarios are summarised in Table 8.8-2 and the modelling was provided in the reports summarised below. As the reports used the same substance endpoints with different crops, they are summarised together.

Table 8.8-2: Input parameters related to application for PEC_{gw} calculations

GAP use number	Covering uses 79-90, 105-116 (autumn applications to winter varieties)	Covering uses 79-90, 105-116 (spring applications to winter varieties)	Covering uses 91-116 (spring applications to spring varieties)
Crop	Winter OSR (autumn)	Winter OSR (spring)	Spring OSR (spring)
Application rate (g as/ha)	180 g/ha prothioconazole 180 g/ha azoxystrobin	180 g/ha prothioconazole 180 g/ha azoxystrobin	180 g/ha prothioconazole 180 g/ha azoxystrobin
Number of applications/interval (d)	1	1	1
Relative application date	AppDate (v3.06): BBCH 14	AppDate (v3.06): BBCH 21*	AppDate (v3.06): BBCH 20
Crop interception (%)	40	80	80
Application to soil (g as/ha)	108	36	36
Frequency of application	Annual		
Models used for calculation	FOCUS PEARL v5.5.5, FOCUS PELMO v6.6.4, FOCUS MACRO v5.5.4		

* Note that AppDate assumes that BBCH 20 is reached in autumn, so BBCH 21 was used to determine the re-start of growth after the winter dormancy period, when the product would be applied. In some southern EU winter OSR scenarios (Piacenza, Porto), BBCH 21 is reached before spring, which would result in applications during winter. The product GAP requires applications to be made in spring, therefore 1st March is used as a conservative worst-case timing.

GAP use number	Covering uses 1-78 (winter varieties)	Covering uses 1-78 (spring varieties)	Covering use 103
Crop	Winter cereals	Spring cereals	Sunflower (maize as surrogate)**
Application rate (g as/ha)	210 g/ha prothioconazole 210 g/ha azoxystrobin	210 g/ha prothioconazole 210 g/ha azoxystrobin	180 g/ha prothioconazole 180 g/ha azoxystrobin
Number of applications/interval (d)	2 / 14	2 / 14	1
Relative application date	AppDate (v3.06): BBCH 30*	AppDate (v3.06): BBCH 30	AppDate (v3.06): BBCH 16
Crop interception (%)	80	80	20
Application to soil (g as/ha)	42	42	144
Frequency of application	Annual		
Models used for calculation	FOCUS PEARL v5.5.5, FOCUS PELMO v6.6.4, FOCUS MACRO v5.5.4		

* In some southern EU winter cereals scenarios (Porto, Sevilla, Thiva), BBCH 30 is reached before spring, which would result in applications during winter. The product GAP requires applications to be made in spring, therefore the 1st March is used as a conservative worst-case timing. ** maize used as surrogate crop for sunflower.

Data point:	K-CP 9.2.4/01
Report author	M. Hale
Report year	2022
Report title	CA3642: Predicted Environmental Concentrations in Groundwater Following Application to Cereals and Oilseed Rape, Using FOCUS-PEARL, FOCUS-PELMO and FOCUS-MACRO
Report No	22/125
Document No	Not applicable
Guidelines followed in study	FOCUS
Deviations from current test guideline	None

Previous evaluation None
GLP/Officially recognised testing facilities NA
Acceptability/Reliability: Yes

Data point: K-CP 9.2.4/02
Report author M. Hale
Report year 2023
Report title CA3642: Predicted Environmental Concentrations in Groundwater Following Application to Sunflower in Poland, Using FOCUS PEARL, FOCUS-PELMO and FOCUS-MACRO
Report No 23/94
Document No Not applicable
Guidelines followed in study FOCUS
Deviations from current test guideline None
Previous evaluation None
GLP/Officially recognised testing facilities NA
Acceptability/Reliability: Yes

The risk to groundwater was assessed through simulations using the environmental fate models FOCUS-PEARL (v5.5.5), FOCUS-PELMO (v6.6.4) and FOCUS-MACRO (v5.5.4). For uses that span a large range of growth stages, the earliest growth stage was used as a worst-case to determine the crop interception. Application dates were set using AppDate (v3.06) to provide the date at which the target BBCH stage is reached in each FOCUS scenario, while remaining within the seasonal timings specified in the GAP. The absolute application timings are given in Table 8.8-3. Please note that the Hale (2022) report contains all FOCUS scenarios, but this summary does not include data for Jokioinen, Sevilla or Thiva because they are not relevant for any countries within the central zone according to the Working Document of the Central Zone in the Authorisation of PPPs (v1r1 June 2018). The Hale (2023) report contains data for the relevant scenarios in Poland only, as Sunflower use is not requested in other countries.

Table 8.8-3: Application dates used for groundwater risk assessment

Application dates (absolute)			
Scenario	Winter OSR (autumn)	Winter OSR (spring)	Spring OSR (spring)
Châteaudun	14/09	02/03	-
Hamburg	09/09	09/04	-
Kremsmünster	09/09	06/04	-
Okehampton	21/08 11/04**	31/03	11/04
Piacenza	12/10	01/03	-
Porto	30/09	01/03	09/04

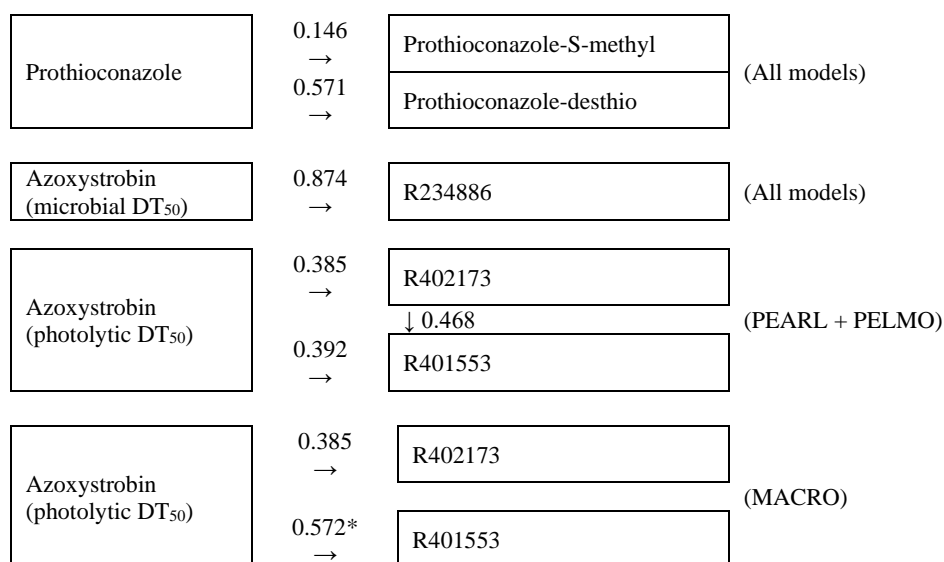
Application dates (absolute)			
Scenario	Winter cereals	Spring cereals	Sunflower*
Châteaudun	15/04, 29/04	16/04, 30/04	23/05
Hamburg	04/05, 18/05	28/04, 12/05	23/05
Kremsmünster	24/04, 08/05	27/04, 11/05	23/05
Okehampton	21/04, 05/05	22/04, 06/05	-
Piacenza	19/03, 02/04	-	-
Porto	01/03, 15/03	02/04, 16/04	-

* Maize used as a surrogate crop

** minor uses on linseeds at BBCH 14-18 only defined for Okehampton scenario

Input parameters for prothioconazole, azoxystrobin and their relevant metabolites were taken from the EU agreed endpoints in the EFSA conclusions and the associated data in the DAR and any confirmatory data. A summary of the environmental fate parameters is given in Table 8.8-4 to Table 8.8-10. Note that two degradation pathways were modelled, to simulate microbial degradation to R234886, and to simulate photolytic degradation to R401553 and R402173. These simulations were performed separately, so R234886 is simulated with the worst-case assumption that there is no competing photolytic degradation, while the photolytic metabolites were simulated by assuming there was no competing microbial degradation. This follows the methods agreed in the EFSA review of confirmatory data (EFSA supporting publication 2014:EN-718). Any parameters not mentioned below were left at the default recommendation of the models. The degradation pathways are shown in

Figure 8.8-1.



* Worst-case single step formation was calculated from the sum of both routes as 0.392+(0.468*0.385)

Scientific guidance on soil phototransformation products in groundwater – consideration, parameterisation and simulation in the exposure assessment of plant protection products (EFSA 2022) was not followed for the calculation of phototransformation products of azoxystrobin because the application was made prior to the enforcement date of 1st January 2024.

Figure 8.8-1: Degradation pathways for prothioconazole and azoxystrobin

Table 8.8-4: Input parameters related to prothioconazole for PEC_{gw} calculations

Parameter	Prothioconazole	Value in accordance with EU endpoint y/n/ Reference
Molecular weight (g/mol)	344.26	Y, EFSA (2007)
Saturated vapour pressure (Pa)	0 (20°C)	Y, EFSA (2007)* (default worst-case)
Water solubility (mg/L)	2000 (20°C, pH 9, worst-case)	Y, EFSA (2007)
DT _{50,soil} (d)	1.2 (geomean, field, normalisation to 20°C with Q ₁₀ of 2.2, n =8)	Y, EFSA (2007), RAR (2005)**
K _{foc} / K _{fom} (mL/g)	1765/1024 (n=1)	Y, EFSA (2007)
Freundlich Exponent 1/n	1	Y, EFSA (2007) (default worst-case)
Plant Uptake	0	Default

* EFSA (2007) gives a vapour pressure of “<< 4× 10⁻⁷ Pa”, below the minimum detectable is testing. A value of 0 was used as a worst-case to prevent volatile losses from soil and water.

** Field DT₅₀ is significantly greater than lab value and is a worst-case even with Q₁₀ of 2.2. The RAR does not contain sufficient data to renormalise the field DT₅₀ using a Q₁₀ of 2.58.

Table 8.8-5: Input parameters related to prothioconazole-S-methyl for PEC_{gw} calculations

Parameter	Prothioconazole-S-methyl	Value in accordance with EU endpoint y/n/ Reference
Molecular weight (g/mol)	358.3	Y, EFSA (2007)
Saturated vapour pressure (Pa)	0 (20°C)	Worst-case default
Water solubility (mg/L)	1×10 ⁶ (20°C)	Worst-case default
DT _{50,soil} (d)	15.7 (geometric mean, n=4)	Y, EFSA (2007), RAR (2005)
K _{foc} / K _{fom} (mL/g)	2525.9 / 1465.1 (geometric mean, n = 4)	N, EFSA (2007), RAR (2005)*
Freundlich Exponent, 1/n	0.88 (arithmetic mean, n = 4)	Y, EFSA (2007), RAR (2005)
Plant Uptake	0	Default
Formation fraction in soil:	0.146 (from prothioconazole)	Y, EFSA (2007)

* value changed to geometric mean in accordance with current EFSA guidance (EFSA 2007 used an arithmetic mean K_{foc} of 2556.3 mL/g).

Table 8.8-6: Input parameters related to prothioconazole-desthio for PEC_{gw} calculations

Parameter	Prothioconazole-desthio	Value in accordance with EU endpoint y/n/ Reference
Molecular weight (g/mol)	312.2	Y, EFSA (2007), RAR (2005)
Saturated vapour pressure (Pa)	0 (20°C)	Worst-case default
Water solubility (mg/L)	1×10 ⁶ (20°C)	Worst-case default
DT _{50,soil} (d)	22.7 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q ₁₀ of 2.2, n =8)**	Y, EFSA (2007), RAR (2005)
K _{foc} / K _{fom} (mL/g)	573.5 / 332.7 (geometric mean, n = 4)	N, EFSA (2007), RAR (2005)*
Freundlich Exponent 1/n	0.81 (arithmetic mean, n = 4)	Y, EFSA (2007), RAR (2005)
Plant Uptake	0	Worst-case default
Formation fraction in soil:	0.571 (from prothioconazole)	Y, EFSA (2007)

* value changed to geometric mean in accordance with current EFSA guidance (EFSA 2007 used an arithmetic mean K_{foc} of 575.4 mL/g).

** Field DT₅₀ is significantly greater than lab value and is a worst-case even with Q₁₀ of 2.2. The RAR does not contain sufficient data to renormalise the field DT₅₀ using a Q₁₀ of 2.58.

Table 8.8-7: Input parameters related to azoxystrobin for PEC_{gw} calculations

Parameter	Azoxystrobin	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	403.4	Y, EFSA (2010)
Saturated vapour pressure (Pa)	1.1 × 10 ⁻¹⁰ (25°C)	Y, EFSA (2010)
Water solubility (mg/L)	6.7 (20°C)	Y, EFSA (2010)
DT _{50,soil} microbial (d)	78.0 (geometric mean of field studies (slow phase), normalisation to 10 kPa or pF2, 20 °C with Q ₁₀ of 2.58, n = 13)	Y, EFSA (2010)
DT _{50,soil} photolysis (d)	2.55 (geometric mean of field studies (fast phase), normalisation to 10 kPa or pF2, 20 °C with Q ₁₀ of 2.58, n = 10)	Y, EFSA (2010)
K _{foc} / K _{fom} (mL/g)	392 / 227.4 (geometric mean, n = 6)	N, EFSA (2010)*
Freundlich Exponent, 1/n	0.86 (arithmetic mean, n = 6)	Y, EFSA (2010)
Plant Uptake	0	Default

* value changed to geometric mean in accordance with current EFSA guidance (EFSA 2010 used an arithmetic mean K_{foc} of 423)

Table 8.8-8: Input parameters related to R234886 for PEC_{gw} calculations

Parameter	R234886	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	389.4	Y, EFSA (2014)
Saturated vapour pressure (Pa)	0	Worst-case
Water solubility (mg/L)	57 (20°C)	Y, EFSA (2014)
DT _{50,soil} (d)	acidic soil: 98.6 neutral/alkaline soils: 36.7	Y, EFSA (2014)
K _{foc} / K _{fom} (mL/g)	acidic soil: 176.6 / 102.4 (geometric mean, n=8) alkaline soils: 34.8 / 20.2 (geometric mean, n=7)	N, EFSA (2014)*
Freundlich Exponent, 1/n	acidic soil: 0.78 neutral/alkaline soils: 0.83	Y, EFSA (2014)
Plant Uptake	0	Default
Formation fraction in soil:	0.874 from azoxystrobin (microbial route)	Y, EFSA (2014)

* values changed to geometric mean in accordance with current EFSA guidance (EFSA 2014 used arithmetic mean K_{foc} of 228.4 and 36.7 for acid and alkaline soils, respectively).

Table 8.8-9: Input parameters related to R401553 for PEC_{gw} calculations

Parameter	R401553	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	213.2	Y, EFSA (2010)
Saturated vapour pressure (Pa)	0	Worst-case
Water solubility (mg/L)	560 (20°C)	Y, EFSA (2010)
DT _{50,soil} (d)	1.1 (geometric mean, n=3)	Y, EFSA (2010)
K _{foc} / K _{fom} (mL/g)	143 / 82.9 (geometric mean, n = 6)	N, EFSA (2010)*
Freundlich Exponent 1/n	0.85 (arithmetic mean, n = 6)	Y, EFSA (2010)
Plant Uptake	0	Default
DT _{50,soil} (d)	1.1 (geometric mean, n=3)	Y, EFSA (2010)
Formation fraction in soil (PEARL/PELMO):	0.392 from azoxystrobin (photolytic route) 0.468 from R402173	Y, EFSA (2010)
Formation fraction in soil (MACRO):	Sum of fractions from both routes: 0.392+(0.468*0.385) = 0.572	Y, EFSA (2010)

* value changed to geometric mean in accordance with current EFSA guidance (EFSA 2010 used an arithmetic mean K_{foc} of 188)

Table 8.8-10: Input parameters related to R402173 for PEC_{gw} calculations

Parameter	R402173	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	333.3	Y, EFSA (2010)
Saturated vapour pressure (Pa)	0	Worst-case
Water solubility (mg/L)	61 (20°C)	Y, EFSA (2010)
DT _{50,soil} (d)	4.7 (geometric mean, n=3)	Y, EFSA (2010)
K _{foc} / K _{fom} (mL/g)	25 / 14.5 (worst-case due to pH dependence, n = 6)	Y, EFSA (2010)
Freundlich Exponent 1/n	0.96 (worst-case due to pH dependence, n = 6)	Y, EFSA (2010)
Plant Uptake	0	Default
Formation fraction in soil:	0.385 from azoxystrobin (photolytic route)	Y, EFSA (2010)

zRMS comments:

The application pattern assumed in simulations is in line with the critical Central Zone GAP as presented in Table 8.1-1. It is noted that the Central Zone GAP includes several minor crops. The following surrogate crops were considered by the Applicant in simulations:

1. Spring and winter oilseed rape (major crop) for flax and linseeds, poppy, mustard and gold of pleasure. The zRMS agrees that winter OSR is most suitable surrogate crop.
2. Maize was used as surrogate crop for sunflower and zRMS agrees with that.

Application dates presented in Table 8.8-3 were checked by the zRMS using AppDate ver. 3.06 tool and are considered acceptable. In case of use in winter OSR for scenarios Piacenza and Porto the application dates at BBCH 21 reflect a winter application, however according to the Central Zone GAP the application should occur in spring thus 1st of March was used as a conservative worst-case timing for application in spring.

The only available FOCUS groundwater scenario for linseed is the Okehampton scenario, therefore respective information of application date was added to the Table 8.8-3.

Input parameters for prothioconazole and its metabolites presented in Table 8.8-4 to 8.8-6 and used in the modelling are in general in line with the EU agreed endpoints reported in EFSA Scientific Report (2007) 106.

Input parameters for azoxystrobin and its metabolites presented in Table 8.8-7 to 8.8-10 and used in the modelling are in general in line with EU agreed endpoints as reported in EFSA Journal 2010; 8(4):1542 and in Addendum with confirmatory data for azoxystrobin (September, 2014).

The only exception is consideration of the geometric mean instead of arithmetic mean K_{foc} values for prothioconazole metabolites and azoxystrobin and its metabolites. This deviation is, however, agreed by the zRMS as the geometric mean K_{foc} values are lower than arithmetic mean values and represent thus worst case in terms of the potential leaching. Moreover, consideration of geometric mean K_{foc} values is in line with current EFSA recommendations.

In simulations PUF value of 0 was assumed for all compounds, which is in line with recommendations of the most recent version of the FOCUS Groundwater Guidance (2014 and 2021).

8.8.2.1 Prothioconazole and its metabolites

The PEC_{gw} results from FOCUS-PEARL, FOCUS-PELMO and FOCUS-MACRO are summarised in Table 8.8-11, Table 8.8-12, and Table 8.8-13 for prothioconazole, prothioconazole-S-methyl, and prothioconazole-desthio, respectively.

Table 8.8-11: PEC_{gw} for prothioconazole

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		PEARL (5.5.5)	PELMO (6.6.4)	MACRO (5.5.4)
Winter OSR (autumn application)	Châteaudun	<0.000001	<0.001	<0.000001
	Hamburg	<0.000001	<0.001	-
	Kremsmünster	<0.000001	<0.001	-
	Okehampton	<0.000001	<0.001	-
	Piacenza	<0.000001	<0.001	-
	Porto	<0.000001	<0.001	-
Winter OSR (spring application)	Châteaudun	<0.000001	<0.001	<0.000001
	Hamburg	<0.000001	<0.001	-
	Kremsmünster	<0.000001	<0.001	-
	Okehampton	<0.000001	<0.001	-
	Piacenza	<0.000001	<0.001	-
	Porto	<0.000001	<0.001	-
Spring OSR	Okehampton	<0.000001	<0.001	-
	Porto	<0.000001	<0.001	-
Winter cereals	Châteaudun	<0.000001	<0.001	<0.000001

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		PEARL (5.5.5)	PELMO (6.6.4)	MACRO (5.5.4)
	Hamburg	<0.000001	<0.001	-
	Kremsmünster	<0.000001	<0.001	-
	Okehampton	<0.000001	<0.001	-
	Piacenza	<0.000001	<0.001	-
	Porto	<0.000001	<0.001	-
Spring cereals	Châteaudun	<0.000001	<0.001	<0.000001
	Hamburg	<0.000001	<0.001	-
	Kremsmünster	<0.000001	<0.001	-
	Okehampton	<0.000001	<0.001	-
	Porto	<0.000001	<0.001	-
Sunflower (maize as surrogate)	Châteaudun	<0.000001	<0.001	<0.000001
	Hamburg	<0.000001	<0.001	-
	Kremsmünster	<0.000001	<0.001	-

Table 8.8-12: PEC_{gw} for prothioconazole-S-methyl

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		PEARL (5.5.5)	PELMO (6.6.4)	MACRO (5.5.4)
Winter OSR (autumn application)	Châteaudun	<0.000001	<0.001	<0.000001
	Hamburg	<0.000001	<0.001	-
	Kremsmünster	<0.000001	<0.001	-
	Okehampton	<0.000001	<0.001	-
	Piacenza	<0.000001	<0.001	-
	Porto	<0.000001	<0.001	-
Winter OSR (spring application)	Châteaudun	<0.000001	<0.001	<0.000001
	Hamburg	<0.000001	<0.001	-
	Kremsmünster	<0.000001	<0.001	-
	Okehampton	<0.000001	<0.001	-
	Piacenza	<0.000001	<0.001	-
	Porto	<0.000001	<0.001	-
Spring OSR	Okehampton	<0.000001	<0.001	-
	Porto	<0.000001	<0.001	-
Winter cereals	Châteaudun	<0.000001	<0.001	<0.000001
	Hamburg	<0.000001	<0.001	-
	Kremsmünster	<0.000001	<0.001	-
	Okehampton	<0.000001	<0.001	-
	Piacenza	<0.000001	<0.001	-
	Porto	<0.000001	<0.001	-
Spring cereals	Châteaudun	<0.000001	<0.001	<0.000001
	Hamburg	<0.000001	<0.001	-
	Kremsmünster	<0.000001	<0.001	-
	Okehampton	<0.000001	<0.001	-
	Porto	<0.000001	<0.001	-
Sunflower (maize as surrogate)	Châteaudun	<0.000001	<0.001	<0.000001
	Hamburg	<0.000001	<0.001	-
	Kremsmünster	<0.000001	<0.001	-

Table 8.8-13: PEC_{gw} for prothioconazole-desthio

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		PEARL (5.5.5)	PELMO (6.6.4)	MACRO (5.5.4)
Winter OSR (autumn application)	Châteaudun	<0.000001	<0.001	<0.000001
	Hamburg	<0.000001	<0.001	-
	Kremsmünster	<0.000001	<0.001	-
	Okehampton	<0.000001	<0.001	-
	Piacenza	<0.000001	<0.001	-
	Porto	<0.000001	<0.001	-
Winter OSR (spring application)	Châteaudun	<0.000001	<0.001	<0.000001
	Hamburg	<0.000001	<0.001	-
	Kremsmünster	<0.000001	<0.001	-
	Okehampton	<0.000001	<0.001	-
	Piacenza	<0.000001	<0.001	-
	Porto	<0.000001	<0.001	-
Spring OSR	Okehampton	<0.000001	<0.001	-
	Porto	<0.000001	<0.001	-
Winter cereals	Châteaudun	<0.000001	<0.001	<0.000001
	Hamburg	<0.000001	<0.001	-
	Kremsmünster	<0.000001	<0.001	-
	Okehampton	<0.000001	<0.001	-
	Piacenza	<0.000001	<0.001	-
	Porto	<0.000001	<0.001	-
Spring cereals	Châteaudun	<0.000001	<0.001	<0.000001
	Hamburg	<0.000001	<0.001	-
	Kremsmünster	<0.000001	<0.001	-
	Okehampton	<0.000001	<0.001	-
	Porto	<0.000001	<0.001	-
Sunflower (maize as surrogate)	Châteaudun	<0.000001	<0.001	<0.000001
	Hamburg	<0.000001	<0.001	-
	Kremsmünster	<0.000001	<0.001	-

PEC_{gw} values were <0.001 µg/L in all models, for prothioconazole and its metabolites in all scenarios and crops. The risk to groundwater was determined to be acceptable for all simulated uses of prothioconazole and its metabolites.

zRMS comments:

The groundwater modelling was independently validated by the zRMS in additional modelling with FOCUS PEARL 5.5.5 and FOCUS PELMO 6.6.4 using the EU agreed input parameters and application dates as suggested by AppDate 3.06.

Obtained results were in good agreement with these derived by the Applicant for prothioconazole and its metabolites presented in Table 8.8-11 to 8.8-13. Overall, no unacceptable leaching of prothioconazole and its metabolites is expected following application of CA3642 according to the intended use pattern.

Please note that additional groundwater modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

8.8.2.2 Azoxystrobin and its metabolites

The PEC_{gw} results from FOCUS-PEARL, FOCUS-PELMO and FOCUS-MACRO are summarised in Table 8.8-14 to Table 8.8-18 for azoxystrobin and its relevant metabolites.

Table 8.8-14: PEC_{gw} for azoxystrobin

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		PEARL (5.5.5)	PELMO (6.6.4)	MACRO (5.5.4)
Winter OSR (autumn application)	Châteaudun	<0.000001	<0.001	<0.000001
	Hamburg	0.000001	<0.001	-
	Kremsmünster	<0.000001	<0.001	-
	Okehampton	<0.000001	<0.001	-
	Piacenza	<0.000001	<0.001	-
	Porto	<0.000001	<0.001	-
Winter OSR (spring application)	Châteaudun	<0.000001	<0.001	<0.000001
	Hamburg	<0.000001	<0.001	-
	Kremsmünster	<0.000001	<0.001	-
	Okehampton	<0.000001	<0.001	-
Spring OSR	Okehampton	<0.000001	<0.001	-
	Porto	<0.000001	<0.001	-
Winter cereals	Châteaudun	<0.000001	<0.001	<0.000001
	Hamburg	<0.000001	<0.001	-
	Kremsmünster	<0.000001	<0.001	-
	Okehampton	<0.000001	<0.001	-
	Piacenza	<0.000001	<0.001	-
	Porto	<0.000001	<0.001	-
Spring cereals	Châteaudun	<0.000001	<0.001	<0.000001
	Hamburg	<0.000001	<0.001	-
	Kremsmünster	<0.000001	<0.001	-
	Okehampton	<0.000001	<0.001	-
	Porto	<0.000001	<0.001	-
Sunflower (maize as surrogate)	Châteaudun	<0.000001	<0.001	<0.000001
	Hamburg	<0.000001	<0.001	-
	Kremsmünster	<0.000001	<0.001	-

Table 8.8-15: PEC_{gw} for R234886 (acidic soils)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		PEARL (5.5.5)	PELMO (6.6.4)	MACRO (5.5.4)
Winter OSR (autumn application)	Châteaudun	<0.000001	<0.001	<0.000001
	Hamburg	0.006886	0.002	-
	Kremsmünster	0.000606	<0.001	-
	Okehampton	0.004780	0.006	-
	Piacenza	0.000696	<0.001	-
	Porto	0.000186	0.002	-
Winter OSR (spring application)	Châteaudun	<0.000001	<0.001	<0.000001
	Hamburg	0.000008	<0.001	-
	Kremsmünster	<0.000001	<0.001	-
	Okehampton	0.000001	<0.001	-

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		PEARL (5.5.5)	PELMO (6.6.4)	MACRO (5.5.4)
	Piacenza	<0.000001	<0.001	-
	Porto	<0.000001	<0.001	-
Spring OSR	Okehampton	<0.000001	<0.001	-
	Porto	<0.000001	<0.001	-
Winter cereals	Châteaudun	<0.000001	<0.001	<0.000001
	Hamburg	0.001203	<0.001	-
	Kremsmünster	0.000047	<0.001	-
	Okehampton	0.001179	0.001	-
	Piacenza	0.000135	<0.001	-
	Porto	0.000002	<0.001	-
Spring cereals	Châteaudun	<0.000001	<0.001	<0.000001
	Hamburg	0.001754	<0.001	-
	Kremsmünster	0.000041	<0.001	-
	Okehampton	0.000792	0.001	-
	Porto	0.000003	<0.001	-
Sunflower (maize as surrogate)	Châteaudun	0.000056	<0.001	0.000002
	Hamburg	0.013153	<0.001	-
	Kremsmünster	0.002087	<0.001	-

Table 8.8-16: PEC_{gw} for R234886 (alkaline soils)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		PEARL (5.5.5)	PELMO (6.6.4)	MACRO (5.5.4)
Winter OSR (autumn application)	Châteaudun	0.227738	0.139	0.203
	Hamburg	1.105915	1.011	-
	Kremsmünster	0.643946	0.601	-
	Okehampton	0.918616	0.987	-
	Piacenza	0.318677	0.438	-
	Porto	0.591242	1.030	-
Winter OSR (spring application)	Châteaudun	0.017268	0.009	0.0144
	Hamburg	0.183911	0.155	-
	Kremsmünster	0.110272	0.098	-
	Okehampton	0.139433	0.154	-
	Piacenza	0.042505	0.060	-
	Porto	0.062124	0.128	-
Spring OSR	Okehampton	0.123711	0.148	-
	Porto	0.058197	0.094	-
Winter cereals	Châteaudun	0.065759	0.043	0.0719
	Hamburg	0.649416	0.573	-
	Kremsmünster	0.405883	0.386	-
	Okehampton	0.547637	0.577	-
	Piacenza	0.209408	0.299	-
	Porto	0.209489	0.391	-
Spring cereals	Châteaudun	0.053627	0.032	0.0683
	Hamburg	0.710675	0.628	-
	Kremsmünster	0.425253	0.408	-

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		PEARL (5.5.5)	PELMO (6.6.4)	MACRO (5.5.4)
	Okehampton	0.518509	0.562	-
	Porto	0.282962	0.382	-
Sunflower (maize as surrogate)	Châteaudun	0.613719	0.323	0.347
	Hamburg	<i>1.523535</i>	<i>1.139</i>	-
	Kremsmünster	<i>0.916919</i>	<i>0.831</i>	-

Bold values >0.1 µg/L, *Italic* values >0.75 µg/L

The PEC_{gw} values for R234886 in alkaline soils were >0.1 µg/L in several scenarios, with a worst-case of 1.524 µg/L in the Hamburg scenario for the PEARL model following application to sunflower. R234886 was determined to be a non-relevant metabolite in the EFSA conclusion on azoxystrobin with acceptable risk to consumers at levels up to 22 µg/L.

Table 8.8-17: PEC_{gw} for R401553

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		PEARL (5.5.5)	PELMO (6.6.4)	MACRO (5.5.4)
Winter OSR (autumn application)	Châteaudun	0.000003	<0.001	<0.000001
	Hamburg	0.000383	<0.001	-
	Kremsmünster	0.000005	<0.001	-
	Okehampton	0.000019	<0.001	-
	Piacenza	0.000495	0.001	-
	Porto	0.000074	<0.001	-
Winter OSR (spring application)	Châteaudun	<0.000001	<0.001	<0.000001
	Hamburg	0.000002	<0.001	-
	Kremsmünster	<0.000001	<0.001	-
	Okehampton	<0.000001	<0.001	-
	Piacenza	0.000001	<0.001	-
	Porto	<0.000001	<0.001	-
Spring OSR	Okehampton	<0.000001	<0.001	-
	Porto	<0.000001	<0.001	-
Winter cereals	Châteaudun	<0.000001	<0.001	<0.000001
	Hamburg	0.000007	<0.001	-
	Kremsmünster	<0.000001	<0.001	-
	Okehampton	0.000001	<0.001	-
	Piacenza	0.000004	<0.001	-
	Porto	<0.000001	<0.001	-
Spring cereals	Châteaudun	<0.000001	<0.001	<0.000001
	Hamburg	0.000009	<0.001	-
	Kremsmünster	<0.000001	<0.001	-
	Okehampton	0.000001	<0.001	-
	Porto	<0.000001	<0.001	-
Sunflower (maize as surrogate)	Châteaudun	<0.000001	<0.001	<0.000001
	Hamburg	0.0000015	<0.001	-
	Kremsmünster	<0.000001	<0.001	-

Table 8.8-18: PEC_{gw} for R402173

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		PEARL (5.5.5)	PELMO (6.6.4)	MACRO (5.5.4)
Winter OSR (autumn application)	Châteaudun	0.000214	0.001	0.00136
	Hamburg	0.007881	0.015	-
	Kremsmünster	0.002212	0.005	-
	Okehampton	0.002499	0.005	-
	Piacenza	0.012196	0.048	-
	Porto	0.017830	0.023	-
Winter OSR (spring application)	Châteaudun	0.000001	<0.001	<0.000001
	Hamburg	0.000033	<0.001	-
	Kremsmünster	0.000047	<0.001	-
	Okehampton	0.000061	<0.001	-
	Piacenza	0.000018	<0.001	-
	Porto	0.000003	<0.001	-
Spring OSR	Okehampton	0.000021	<0.001	-
	Porto	0.000001	<0.001	-
Winter cereals	Châteaudun	0.000001	<0.001	<0.000001
	Hamburg	0.000138	<0.001	-
	Kremsmünster	0.000055	<0.001	-
	Okehampton	0.000092	<0.001	-
	Piacenza	0.000192	<0.001	-
	Porto	0.000097	<0.001	-
Spring cereals	Châteaudun	0.000001	<0.001	<0.000001
	Hamburg	0.000172	<0.001	-
	Kremsmünster	0.000097	<0.001	-
	Okehampton	0.000098	<0.001	-
	Porto	0.000001	<0.001	-
Sunflower (maize as surrogate)	Châteaudun	0.000014	<0.001	<0.000006
	Hamburg	0.000277	<0.001	-
	Kremsmünster	0.000090	<0.001	-

The PEC_{gw} values for azoxystrobin and R401553 were <0.001 µg/L in all models, for all scenarios, and crops. The PEC_{gw} values for R402173 were <0.1 µg/L in all models, for all scenarios, and crops, with a worst-case of 0.048 µg/L in Piacenza for the PELMO model following autumn application to winter oilseed rape. The risk to groundwater was determined to be acceptable for all simulated uses of these compounds.

The PEC_{gw} values for R234886 in acidic soils were a maximum of 0.013 µg/L in the Hamburg scenario for sunflowers in the PEARL model. R234886 in alkaline soils were >0.1 µg/L in several scenarios. The worst-case PEC_{gw} was 1.524 µg/L in the Hamburg scenario for sunflowers in the PEARL model. R234886 was determined to be a non-relevant metabolite in the EFSA conclusion on azoxystrobin with acceptable risk to consumers at levels up to 22 µg/L. R234886 is below the critical limit of 10 µg/L (SANCO/221/2000) for non-relevant metabolites and below levels of toxicological concern for consumers.

The risk to groundwater was determined to be acceptable for all simulated uses of CA3642.

zRMS comments:

The groundwater modelling was independently validated by the zRMS in additional modelling with FOCUS PEARL 5.5.5 and FOCUS PELMO 6.6.4 using the EU agreed input parameters and application dates as suggested by AppDate 3.06.

In line with information presented in Addendum with confirmatory data for azoxystrobin (September, 2014) the degradation of azoxystrobin was modelled using two separate simulations. The first simulations assumed that azoxystrobin degraded via microbial degradation to R234886, whilst the second assumed that azoxystrobin degraded due to photolysis to form metabolites: R401553 and R402173 (subsequently degrading to R401553).

Obtained results from zRMS modelling were in good agreement with these derived by the Applicant for azoxystrobin and its metabolites presented in Table 8.8-14 to 8.8-18. Performed simulations indicate that unacceptable leaching of azoxystrobin and its metabolites R401553 and R402173 is expected following application of CA3642 according to the intended use pattern.

The PEC_{gw} values for metabolite R234886 in acidic soils were $<0.1 \mu\text{g/L}$ in all scenarios and crops. The PEC_{gw} values for metabolite R234886 in alkaline soils were above $0.1 \mu\text{g/L}$ in almost all scenarios with the maximum value of $1.52 \mu\text{g/L}$ in the Hamburg scenario (PEARL model) following application to sunflower. According to EFSA Journal 2010; 8(4):1542 metabolite R234886 is toxicologically not relevant. Since the PEC_{GW} values exceeded the threshold of $0.75 \mu\text{g/L}$ for non-relevant metabolites the consumer risk assessment was required. Details of the evaluation of the toxicological relevance and consumer risk assessment may be found the Core Assessment, Part B, Section 10.

During the commenting period it was correctly noted that for the minor crop linseeds the crop interception at BBCH 14-18 and 20-69 is 30% and 60%, respectively, which is lower than for oilseed rape (40% and 80%) used as a surrogate crop. Since the only available FOCUS groundwater scenario for linseed is the Okehampton scenario, therefore oilseed rape remains as a relevant surrogate crop for other relevant in Central Zone scenarios but with crop interception relevant for the linseed.

To reduce the workload, the additional groundwater modelling was performed by the zRMS only for the autumn application as it is the worst case considering the rate reaching soil. Additional simulations was based on the same input parameters and application dates as presented in Table 8.8-3, with exception for the Okehampton scenario.

Since all scenarios give PEC_{gw} values were lower than $0.001 \mu\text{g/L}$ for both active substances, with the exception of the non-relevant azoxystrobin metabolite R234886 in alkaline soils, thus results only for this metabolite are further discussed. The obtained PEC_{GW} values were above $0.1 \mu\text{g/L}$ in all scenarios, with the maximum value of $1.379 \mu\text{g/L}$ (for Hamburg scenario). Nevertheless as the results were still lower from the maximum PEC_{gw} value of $1.52 \mu\text{g/L}$ following application to sunflower, no impact on the performed consumer risk assessment is expected. Overall, the use on linseed result in no unacceptable PEC_{gw} values, despite the lower crop interception.

Obtained PEC_{gw} result for the azoxystrobin metabolite R234886 in alkaline soils following autumn application to minor crop linseeds are presented in table below:

PEC_{gw} for R234886 (alkaline soils)

Crop	Scenario	80 th Percentile PEC_{gw} at 1 m Soil Depth ($\mu\text{g/L}$)	
		PEARL (5.5.5)	PELMO (6.6.4)
Minor crop Linseeds (BBCH 14-18) 1 x 180 g/ha, 30% int.	Châteaudun	0.302	0.185
	Hamburg	1.379	1.252
	Kremsmünster	0.804	0.752
	Okehampton	0.886	1.025
	Piacenza	0.401	0.561
	Porto	0.743	1.276

Please note that additional groundwater modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

8.9 Predicted Environmental Concentrations in surface water (PEC_{sw}) (KCP 9.2.5)

The EU evaluation of surface water exposure (EFSA Scientific Report (2007) 106, 1-98 and EFSA Journal 2010; 8(4):1542) did not cover all uses in the product GAP (see Table 8.1-1 and Table 8.1-2) and did not include modelling according to current FOCUS and EFSA guidelines. Therefore, new modelling has been performed and is summarised below.

8.9.1 Justification for new endpoints

All endpoints are taken from the data in the prothioconazole EFSA 2007 conclusion (EFSA Scientific Report (2007) 106, 1-98) and azoxystrobin EFSA 2010 conclusion (2010; 8(4):1542) plus the confirmatory data evaluated at EU level for the metabolite R234886 (EFSA supporting publication 2014:EN-718 and the 2014 DAR addendum). The geometric mean K_{foc} was used instead of the arithmetic mean listed in EFSA 2007 for several substances in order to comply with the requirements of current EFSA guidance (EFSA Journal 2014;12(5):3662). The geometric mean provides a slightly more conservative endpoint (higher soil mobility) than the arithmetic mean, resulting in a worst-case risk envelope that covers older assessments with arithmetic means. The differences are summarised below in Table 8.9-1. Note that no changes were made to the K_{foc} endpoint for prothioconazole or R402173, as mean values were not used.

Table 8.9-1: Justification of new K_{foc} endpoints used in modelling

Substance	Endpoint	Agreed EU modelling endpoint	New modelling endpoint	Justification
Prothioconazole	K _{foc}	1765 (single value)		No change required.
Prothioconazole-S-methyl	K _{foc}	2556.3 (arithmetic mean)	2525.9 (geometric mean)	Geometric means follow current guidelines (EFSA Journal 2014;12(5):3662) and result in a more conservative risk assessment and are required in several member states where approval is requested. The individual endpoints used for calculation of the mean are unchanged from the agreed EU values.
Prothioconazole-desthio	K _{foc}	575.4 (arithmetic mean)	573.5 (geometric mean)	
1,2,4-Triazole	K _{foc}	89 (arithmetic mean)	83 (geometric mean)	
Azoxystrobin	K _{foc}	423 (arithmetic mean)	392 (geometric mean)	
R234886	K _{foc}	Acidic soils: 228.4 Alkaline soils: 36.7 (arithmetic mean)	Acidic soils: 176.6 Alkaline soils: 34.8 (geometric mean)	
R401553	K _{foc}	188 (arithmetic mean)	143 (geometric mean)	
R402173	K _{foc}	25 (worst-case due to pH dependence, n = 6)		No change required.

zRMS comments:

For prothioconazole metabolites: JAU 6476-S-methyl, JAU 6476-desthio and 1,2,4-Triazole and for azoxystrobin and its metabolites: R234886 and R401553 the geometric mean K_{foc} values were calculated by the Applicant, although in the EFSA conclusion only arithmetic mean values are reported and further used for surface water modelling. This deviation is agreed by the zRMS since the geometric mean K_{foc} values are lower than arithmetic mean K_{foc} values and represent thus worst case in terms of the water column exposure (relevant for aquatic organisms). Moreover consideration of geometric mean K_{foc} values is in line with current EFSA recommendations. The calculated by the Applicant geometric mean values were based on the individual K_{foc} from the LoEP and are confirmed to be correct.

8.9.2 Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5)

PEC_{sw} values for prothioconazole, azoxystrobin and all relevant metabolites were determined at FOCUS STEPS 1-2. FOCUS STEP 3 and 4 models were required for azoxystrobin, prothioconazole and the metabolite prothioconazole-desthio, a metabolite with relatively high ecotoxicity, persistence and mobility compared to the active substance (please refer to Part B9 for further information on ecotoxicity). PEC_{sw} values were calculated for single and multiple applications for uses on spring and winter cereals, and single applications on spring oilseed rape and winter oilseed rape, which provide a risk envelope for all uses in the GAP. The modelling was provided in the reports below. As the reports used the same substance endpoints with different crops, they are summarised together.

Data point:	K-CP 9.2.5/01
Report author	M. Hale
Report year	2022
Report title	CA3642: Predicted Environmental Concentrations in Surface Water Following Application to Cereals and Oilseed Rape, Using FOCUS STEPS 1-4
Report No	22/126
Document No	Not applicable
Guidelines followed in study	FOCUS
Deviations from current test guideline	None
Previous evaluation	None
GLP/Officially recognised testing facilities	NA
Acceptability/Reliability:	Yes

Data point:	K-CP 9.2.5/02
Report author	M. Hale
Report year	2023
Report title	CA3642: Predicted Environmental Concentrations in Surface Water Following Application to Sunflower in Poland, Using FOCUS STEPS 1-4
Report No	23/95
Document No	Not applicable
Guidelines followed in study	FOCUS
Deviations from current test guideline	None
Previous evaluation	None
GLP/Officially recognised testing facilities	NA
Acceptability/Reliability:	Yes

For simulations at STEPS 1 to 4, modelling was performed for all available FOCUS scenarios that are defined for the relevant crop type, with the exception of sunflower, which is only used in Poland and therefore only modelled for D3, D4 and R1. Application windows were set by using AppDate (v3.06) program to provide dates for the BBCH recommendations in the GAP. The exact application timings were automatically selected by the model, based on the application window and method of application. Full details are given in Table 8.9-2.

Table 8.9-2: Input parameters related to application for PEC_{sw/sed} calculations

GAP use number	Covering uses 79-90, 105-116 (autumn applications to winter varieties)	Covering uses 79-90, 105-116 (spring applications to winter varieties)	Covering uses 91-116 (spring applications to spring varieties)
Crop	Winter OSR (autumn use)	Winter OSR (spring use)	Spring OSR (spring use)
FOCUS-STEPS Crop Group	Winter OSR	Winter OSR	Spring OSR
FOCUS STEPS 1-2 parameters	Oct-Feb Minimal crop cover	Mar-May, Jun-Sep Average crop cover	Mar-May, Jun-Sep Average crop cover
FOCUS STEP 3 Locations	All available*	All available*	All available*
Application window	BBCH 14 (autumn) D3: 252-282 D4: 253-283 D5: 270-300 R1: 254-284 R3: 285-315	BBCH 20 (spring) (Appdate BBCH 21)** D3: 43-73 D4: 51-81 D5: 51-81 R1: 96-126 R3: 57-87	BBCH 20 (spring) D3: 117-147 D4 : 134-164 D5 : 93-123 R1 : 115-145
Application method	Foliar spray	Foliar spray	Foliar spray
Application rate (g as/ha)	180 g/ha prothioconazole 180 g/ha azoxystrobin	180 g/ha prothioconazole 180 g/ha azoxystrobin	180 g/ha prothioconazole 180 g/ha azoxystrobin
Number of applications/interval (d)	1	1	1
CAM (Chemical application method)	2	2	2
Soil depth (cm)	4	4	4
Models used for calculation	FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3		

GAP use number	Covering uses 1-78 (winter varieties)	Covering uses 1-78 (spring varieties)	Covering use 103
Crop	Winter cereals	Spring cereals	Sunflower
FOCUS-STEPS Crop Group	Winter cereals	Spring cereals	Sunflower (R1) Maize (surrogate for D3, D4)
FOCUS STEPS 1-2 parameters	Mar-May, Jun-Sep Average crop cover	Mar-May, Jun-Sep Average crop cover	Mar-May, Jun-Sep Minimal crop cover
FOCUS Locations	All available*	All available*	D3, D4, R1
Application window	BBCH 30 2 Applications: D3: 106-150 D4: 77-121 D5: 74-118 R1: 114-158 R3: 78-122 R4: 60-104† 1 Application: D3: 106-136 D4: 77-107 D5: 74-104 R1: 114-144 R3: 78-108 R4: 60-90†	BBCH 30 2 Applications: D3: 118-162 D4: 138-182 D5: 99-143 R4: 99-143 1 Application: D3: 118-148 D4: 138-168 D5: 99-129 R4: 99-129	BBCH 16 D3: 145-175 D4: 151-181 R1: 135-165
Application method	Foliar spray	Foliar spray	Foliar spray
Application rate (g as/ha)	210 g/ha prothioconazole 210 g/ha azoxystrobin	210 g/ha prothioconazole 210 g/ha azoxystrobin	180 g/ha prothioconazole 180 g/ha azoxystrobin
Number of applications/interval (d)	2 / 14 d ††	2 / 14 d ††	1
CAM (Chemical application method)	2	2	2
Soil depth (cm)	4	4	4
Models used for calculation	FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3		

* Note that the Hale (2022) report contains all FOCUS scenarios, but this summary does not include data for D1, D2, D6 or R2 because they are not relevant for any countries within the central zone according to the Working Document of the Central Zone in the Authorisation of PPPs (v1r1 June 2018).

** Note that AppDate assumes that BBCH 20 is reached in autumn, so BBCH 21 was used. In many scenarios, applications are predicted to occur slightly before spring (e.g. in late February), but this was considered a protective worst-case, given the difficulty of modelling applications in spring after the winter dormancy period in the FOCUS model

† BBCH 30 is reached very early in these scenarios (e.g. R4 = 24th Jan), which is not compatible with the GAP requirement of spring application. Therefore, 1st March was used as a realistic worst-case earliest date for spring application

†† An additional set of modelling was performed using 1 application, since this can result in higher PEC values as TOXSWA uses a lower spray-drift percentage for multiple applications.

The application timings chosen by the model are given below in Table 8.9-3.

Table 8.9-3: FOCUS STEP 3 application timings

Crop	Scenario	Application window used in modelling (Day numbers)	Actual dates selected by the model
Winter oilseed rape (autumn)	D3	252-282	26 Sept
	D4	253-283	10 Sep
	D5	270-300	26 Oct
	R1	254-284	17 Sep
	R3	285-315	27 Oct
Winter oilseed rape (spring)	D3	43-73	29 Feb
	D4	51-81	24 Feb
	D5	51-81	21 Feb
	R1	96-126	7 Apr
	R3	57-87	26 Feb
Spring oilseed rape	D3	117-147	4 May
	D4	134-164	30 May
	D5	93-123	8 Apr
	R1	115-145	26 Apr
Winter cereals*	D3	106-150	20 Apr, 4 May
	D4	77-121	19 Mar, 18 Apr
	D5	74-118	8 Apr, 22 Apr
	R1	114-158	26 Apr, 10 May
	R3	78-122	28 Mar, 11 Apr
	R4	60-104	5 Mar, 21 Mar
Spring cereals*	D3	118-162	4 May, 18 May
	D4	138-182	30 May, 16 Jun
	D5	99-143	14 Apr, 11 May
	R4	99-143	4 May, 20 May
Sunflower	R1	135-165	13 Jun
Maize (surrogate for sunflower)	D3	145-175	26 May
	D4	151-181	31 May

* Single application models used a 30d window starting at the earliest day number, and application was made on the first of the listed dates.

At STEP 4, the SWAN tool was used to modify the drift and runoff input factors used by TOXSWA, based on vegetated buffer strips of 10 and 20 meters. Runoff mitigation factors were taken from the guidance document SANCO/10422/2005 and are summarised below in Table 8.9-4.

Table 8.9-4: Runoff mitigation factors

	10m vegetated filter strip	20m vegetated filter strip
Reduction in runoff volume	60%	80%
Reduction in runoff volume	60%	80%
Reduction in erosion mass	85%	95%
Reduction in erosion flux	85%	95%

Input parameters for prothioconazole, azoxystrobin and their relevant metabolites were taken from the EU agreed endpoints in the EFSA conclusions and the associated data in the DAR and any confirmatory data. A summary of the environmental fate parameters is given in Table 8.9-5 to Table 8.9-12. Any parameters not mentioned below were left at the default recommendation of the models.

Table 8.9-5: Input parameters related to prothioconazole for $PEC_{sw/sed}$ calculations

Parameter	Prothioconazole	Value in accordance with EU endpoint y/n/ Reference
Molecular weight (g/mol)	344.26	Y, EFSA (2007)
Saturated vapour pressure (Pa)	0 (20°C)	Y, EFSA (2007)* (default worst-case)
Water solubility (mg/L)	2000 (20°C, pH 9, worst-case)	Y, EFSA (2007)
Diffusion coefficient in water (m ² /d)	not required for Step 1+2/ 4.3 x 10 ⁻⁵	default
Diffusion coefficient in air (m ² /d)	not required for Step 1+2/0.43	default
K _{foc} / K _{fom} (mL/g)	1765/1024 (n=1)	Y, EFSA (2007)
Freundlich Exponent 1/n	1	Y, EFSA (2007) (default worst-case)
Plant Uptake	0	Default
Wash-Off factor from Crop (1/mm)	not required for Step 1+2/ 0.05 (MACRO) 0.50 (PRZM)	
DT _{50,soil} (d)	1.2 (geomean, field, normalisation to 20°C with Q ₁₀ of 2.2, n =8)	Y, EFSA (2007), RAR (2005)**
DT _{50,water} (d)	2.2 (geomean whole system, n=2) (correct value from LoEP: 1.0 d)	Y, EFSA (2007)
DT _{50,sed} (d)	2.2 (geomean whole system, n=2) (correct value from LoEP: 1.0 d)	Y, EFSA (2007)
DT _{50,whole system} (d)	STEPS 1-2: 2.2 (geomean whole system, n=2) (correct value: 1.0 d) STEPS 3-4: Not used	Y, EFSA (2007)

* EFSA (2007) gives a vapour pressure of “<< 4 × 10⁻⁷ Pa”, below the minimum detectable is testing. A value of 0 was used as a worst-case to prevent volatile losses from soil and water.

** Field DT₅₀ is significantly greater than lab value and is a worst-case even with Q₁₀ of 2.2. The RAR does not contain sufficient data to renormalise the field DT₅₀ using a Q₁₀ of 2.58.

Table 8.9-6: Input parameters related to prothioconazole-S-methyl for PEC_{sw/sed} calculations

Parameter	Prothioconazole-S-methyl	Value in accordance with EU endpoint y/n/ Reference
Molecular weight (g/mol)	358.3	Y, EFSA (2007)
Saturated vapour pressure (Pa)	0 (20°C)	Worst-case default
Water solubility (mg/L)	1×10 ⁶ (20°C)	Worst-case default
Diffusion coefficient in water (m ² /d)	not required for Step 1+2	-
Diffusion coefficient in air (m ² /d)	not required for Step 1+2	-
K _{foc} / K _{fom} (mL/g)	2525.9 / 1465.1 (geometric mean, n = 4)	N, EFSA (2007), RAR (2005)*
Freundlich Exponent 1/n	0.88 (arithmetic mean, n = 4)	Y, EFSA (2007), RAR (2005)
Plant Uptake	0	Default
Wash-Off factor from Crop (1/mm)	not required for Step 1+2	-
DT _{50,soil} (d)	15.7 (geometric mean, n=4)	Y, EFSA (2007), RAR (2005)
DT _{50,water} (d)	1000	Worst-case default
DT _{50,sed} (d)	1000	Worst-case default
DT _{50,whole system} (d)	1000	Worst-case default
Maximum occurrence observed (% molar basis with respect to the parent)	Soil: 14.6 Water/sediment: Not relevant in water 12.7 (aerobic in whole system) 77 (anaerobic in sediment)	Y, EFSA (2007)
Formation fraction in soil:	not required for Step 1+2	-
Formation fraction in water/sediment:	not required for Step 1+2	-

* value changed to geometric mean (EFSA 2007 used an arithmetic mean). Geomean value more conservative than original EU K_{foc} value in EFSA (2007) which was 2556.3 mL/g.

Table 8.9-7: Input parameters related to prothioconazole-desthio for PEC_{sw/sed} calculations

Parameter	Prothioconazole-desthio	Value in accordance with EU endpoint y/n/ Reference
Molecular weight (g/mol)	312.2	Y, EFSA (2007), RAR (2005)
Saturated vapour pressure (Pa)	0 (20°C)	Worst-case default
Water solubility (mg/L)	1×10 ⁶ (20°C)	Worst-case default
Diffusion coefficient in water (m ² /d)	not required for Step 1+2/ 4.3 x 10 ⁻⁵	Default
Diffusion coefficient in air (m ² /d)	not required for Step 1+2/0.43	Default
K _{foc} / K _{fom} (mL/g)	573.5 / 332.7 (geometric mean, n = 4)	N, EFSA (2007), RAR (2005)*
Freundlich Exponent 1/n	0.81 (arithmetic mean, n = 4)	Y, EFSA (2007), RAR (2005)
Plant Uptake	0	Worst-case default
Wash-Off factor from Crop (1/mm)	not required for Step 1+2/ 0.05 (MACRO) 0.50 (PRZM)	Default
DT _{50,soil} (d)	22.7 (geomean, normalisation to 10 kPa or pF ₂ , 20 °C with Q ₁₀ of 2.2, n =8)**	Y, EFSA (2007), RAR (2005)
DT _{50,water} (d)	1000	Worst-case default
DT _{50,sed} (d)	1000	Worst-case default
DT _{50,whole system} (d)	1000	Worst-case default
Maximum occurrence observed (% molar basis with respect to the parent)	Soil: 57.1% Water/sediment (total system): 54.6%	Y, EFSA (2007), RAR (2005)
Formation fraction in soil:	0.571 (from prothioconazole)	Y, EFSA (2007)
Formation fraction in water/sediment:	1 (from prothioconazole)	Worst-case default

* value changed to geometric mean (EFSA 2007 used an arithmetic mean). Geomean value more conservative than original EU K_{foc} value in EFSA (2007) which was 575.4 mL/g.

** Field DT₅₀ is significantly greater than lab value and is a worst-case even with Q₁₀ of 2.2. The RAR does not contain sufficient data to renormalise the field DT₅₀ using a Q₁₀ of 2.58.

Table 8.9-8: Input parameters related to 1,2,4-triazole for PEC_{sw/sed} calculations

Parameter	1,2,4-Triazole	Value in accordance with EU endpoint y/n/ Reference
Molecular weight (g/mol)	69.1	Y, EFSA (2007), RAR (2005)
Saturated vapour pressure (Pa)	0 (20°C)	Worst-case default
Water solubility (mg/L)	1×10 ⁶ (20°C)	Worst-case default
Diffusion coefficient in water (m ² /d)	not required for Step 1+2	-
Diffusion coefficient in air (m ² /d)	not required for Step 1+2	-
K _{foc} / K _{fom} (mL/g)	83 / 48 (geometric mean, n = 4)	N, EFSA (2007), PRAPeR 12 (Jan 2007)*
Freundlich Exponent 1/n	0.916 (arithmetic mean, n = 4)	Y, EFSA (2007)
Plant Uptake	0	Worst-case default
Wash-Off factor from Crop (1/mm)	not required for Step 1+2	-
DT _{50,soil} (d)	1000	Worst-case default
DT _{50,water} (d)	1000	Worst-case default
DT _{50,sed} (d)	1000	Worst-case default
DT _{50,whole system} (d)	1000	Worst-case default
Maximum occurrence observed (% molar basis with respect to the parent)	Soil: Not formed in soil Water/sediment: 41.8 %	Y, EFSA (2007), RAR (2005)
Formation fraction in soil:	not required for Step 1+2	-
Formation fraction in water/sediment:	not required for Step 1+2	-

* value changed to geometric mean (EFSA 2007 used an arithmetic mean) . Geomean value more conservative than original EU K_{foc} value in EFSA (2007) which was 89 mL/g.

Table 8.9-9: Input parameters related to azoxystrobin for PEC_{sw/sed} calculations

Parameter	Azoxystrobin	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	403.4	Y, EFSA (2010)
Saturated vapour pressure (Pa)	1.1 × 10 ⁻¹⁰ (25°C)	Y, EFSA (2010)
Water solubility (mg/L)	6.7 (20°C)	Y, EFSA (2010)
Diffusion coefficient in water (m ² /d)	not required for Step 1+2/ 4.3 × 10 ⁻⁵	default
Diffusion coefficient in air (m ² /d)	not required for Step 1+2/0.43	default
K _{foc} / K _{fom} (mL/g)	392 / 227.4 (geometric mean, n = 6)	N, EFSA (2010)*
Freundlich Exponent, 1/n	0.86 (arithmetic mean, n = 6)	Y, EFSA (2010)
Plant Uptake	0	Default
Wash-Off factor from Crop (1/mm)	not required for Step 1+2/ 0.05 (MACRO) 0.50 (PRZM)	Default
DT _{50,soil} (d)	78.0 (geometric mean of field studies (slow phase), normalisation to 10 kPa or pF2, 20 °C with Q ₁₀ of 2.58, n = 13)	Y, EFSA (2010)
DT _{50,water} (d)	205 (STEPS 1-2) 1000 (default, STEPS 3-4)	Y, EFSA (2010)
DT _{50,sed} (d)	205 (geomean whole system, n=2)	Y, EFSA (2010)
DT _{50,whole system} (d)	STEPS 1-2: 205 (geomean whole system, n=2) STEPS 3-4: Not used	Y, EFSA (2010)

* value changed to geometric mean (EFSA 2010 used an arithmetic mean). Geomean value more conservative than original EU K_{foc} value in EFSA (2010) which was 423 mL/g.

Table 8.9-10: Input parameters related to R234886 for PEC_{sw/sed} calculations

Parameter	R234886	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	389.4	Y, EFSA (2014)
Saturated vapour pressure (Pa)	not required for Step 1+2	-
Water solubility (mg/L)	57 (20°C)	Y, EFSA (2014)
Diffusion coefficient in water (m ² /d)	not required for Step 1+2	-
Diffusion coefficient in air (m ² /d)	not required for Step 1+2	-
K _{foc} / K _{fom} (mL/g)	acidic soil: 176.6 / 102.4 (geometric mean, n=8) alkaline soils: 34.8 / 20.2 (geometric mean, n=7)	N, EFSA (2014)*
Freundlich Exponent, 1/n	not required for Step 1+2	-
Plant Uptake	not required for Step 1+2	-
Wash-Off factor from Crop (1/mm)	not required for Step 1+2	-
DT _{50,soil} (d)	acidic soil: 98.6 alkaline soils: 36.7	Y, EFSA (2014)
DT _{50,water} (d)	1000	Y, EFSA (2014)
DT _{50,sed} (d)	1000	Y, EFSA (2014)
DT _{50,whole system} (d)	1000	Y, EFSA (2014)
Maximum occurrence observed (% molar basis with respect to the parent)	Soil: 28.8% Water/sediment (total system): 18.1%	Y, EFSA (2014)
Formation fraction in soil:	not required for Step 1+2	-
Formation fraction in water/sediment:	not required for Step 1+2	-

* values changed to geometric means (EFSA 2014 used an arithmetic mean). Geomean value more conservative than original EU K_{foc} values in EFSA (2014) which were 228.4 and 36.7 mL/g.

Table 8.9-11: Input parameters related to R401553 for PEC_{sw/sed} calculations

Parameter	R401553	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	213.2	Y, EFSA (2010)
Saturated vapour pressure (Pa)	not required for Step 1+2	-
Water solubility (mg/L)	560 (20°C)	Y, EFSA (2010)
Diffusion coefficient in water (m ² /d)	not required for Step 1+2	-
Diffusion coefficient in air (m ² /d)	not required for Step 1+2	-
K _{foc} / K _{fom} (mL/g)	143 / 82.9 (geometric mean, n = 6)	N, EFSA (2010)*
Freundlich Exponent 1/n	not required for Step 1+2	-
Plant Uptake	not required for Step 1+2	-
Wash-Off factor from Crop (1/mm)	not required for Step 1+2	-
DT _{50,soil} (d)	1.1 (geometric mean, n=3)	Y, EFSA (2010)
DT _{50,water} (d)	1000	Y, EFSA (2010)
DT _{50,sed} (d)	1000	Y, EFSA (2010)
DT _{50,whole system} (d)	1000	Y, EFSA (2010)
Maximum occurrence observed (% molar basis with respect to the parent)	Soil: 17.0% Water/sediment (total system): 8.9%	Y, EFSA (2010)
Formation fraction in soil:	not required for Step 1+2	-
Formation fraction in water/sediment:	not required for Step 1+2	-

* value changed to geometric mean (EFSA 2010 used an arithmetic mean). Geomean value more conservative than original EU K_{foc} value in EFSA (2010) which was 188 mL/g.

Table 8.9-12: Input parameters related to R402173 for PEC_{sw/sed} calculations

Parameter	R402173	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	333.3	Y, EFSA (2010)
Saturated vapour pressure (Pa)	not required for Step 1+2	-
Water solubility (mg/L)	61 (20°C)	Y, EFSA (2010)
Diffusion coefficient in water (m ² /d)	not required for Step 1+2	-
Diffusion coefficient in air (m ² /d)	not required for Step 1+2	-
K _{foc} / K _{fom} (mL/g)	25 / 14.5 (worst-case due to pH dependence, n = 6)	Y, EFSA (2010)
Freundlich Exponent 1/n	not required for Step 1+2	-
Plant Uptake	not required for Step 1+2	-
Wash-Off factor from Crop (1/mm)	not required for Step 1+2	-
DT _{50,soil} (d)	4.7 (geometric mean, n=3)	Y, EFSA (2010)
DT _{50,water} (d)	1000	Y, EFSA (2010)
DT _{50,sed} (d)	1000	Y, EFSA (2010)
DT _{50,whole system} (d)	1000	Y, EFSA (2010)
Maximum occurrence observed (% molar basis with respect to the parent)	Soil: 17.0% Water/sediment (total system): 2.4%	Y, EFSA (2010)
Formation fraction in soil:	not required for Step 1+2	-
Formation fraction in water/sediment:	not required for Step 1+2	-

zRMS comments:

The application pattern assumed in simulations is in line with central Zone GAP as presented in Table 8.1-1. It is noted that the Central Zone GAP includes several minor crops. The following surrogate crops were considered by the Applicant in simulations:

1. Spring and winter oilseed rape (major crop) for flax, linseeds, poppy, mustard and gold of pleasure. The zRMS agrees that winter OSR is most suitable surrogate crop.
2. Maize was used as surrogate crop for sunflower for missing D3 and D4 scenarios, and zRMS agrees with that.

Application dates presented in Table 8.9-3 were checked by the zRMS using AppDate ver. 3.06 tool and are considered acceptable.

Input parameters used for surface water modelling for prothioconazole and its metabolites and presented in Tables 8.9-5 to 8.9-8 are in general in line with EU agreed endpoints with following remarks:

- for prothioconazole DT₅₀ in water/sediment of 2.2 days was used instead of 1.0 days agreed in the course of the EU review. Nevertheless, in opinion of the zRMS this deviation is not expected to have significant impact on the obtained results.
- for the metabolite JAU 6476 S-Methyl in the aerobic water/sediment study the maximum occurrence of 12.7% in the whole system is observed, while in the anaerobic study 77% only in sediment. Thus, respective changes were introduced in Table 8.9-6 and used in the independent zRMS calculations for this metabolite at Step 1-2.
- for metabolites JAU 6476 S-methyl and JAU 6476-desthio and 1,2,4-Triazole the geometric instead of arithmetic mean K_{foc} values were used. This deviation is agreed by the zRMS, as the geometric mean K_{foc} values are lower than arithmetic mean values and represent thus worst case in terms of the potential leaching. Moreover, consideration of geometric mean K_{foc} values is in line with current EFSA recommendations.
- for metabolite JAU 6476-desthio it is noted that at the EU level no separate DT₅₀ values were determined for water and sediment compartments and DT₅₀ of 49.9 days is relevant for the whole system. Nevertheless, assumed 1000 days represents worst case and it was accepted by the zRMS.
- With regard to parametrisation of the model at Step 3 and 4, it is noted that the K_{FOC} of JAU 6476-desthio is between 100 and 2000 mL/g and guidance indicates that in such case the whole system degradation values should be applied to one compartment (water or sediment) and a default of 1000 days applied to the other compartment. The same applies to the parent with EU agreed K_{OC} of 1765 mL/g. This approach gives

four combinations for parent and metabolite modelling. Since the risk is driven by exposure via water and not sediment (endpoints for sediment dwellers are expressed in terms of mg/L) the four combinations indicated in table below were tested by the zRMS in order to check which gives the highest PEC_{sw} values. It turned out that the worst case combination was when the shortest DT₅₀ value was applied to prothioconazole and the default of 1000 days was applied to JAU 6476-desthio in the water phase (combination 2 in table below). This combination was then used in the zRMS modelling performed for purposes of validation of the Applicants' results.

Potential combinations of water and sediment DT₅₀ values for use in Step 3 modelling.

Component	Endpoint	Combination run in FOCUS Step 3 modelling			
		1	2	3	4
Prothioconazole	DT ₅₀ (water phase)	2.1	2.1	1000	1000
	DT ₅₀ (sediment)	1000	1000	2.1	2.1
JAU 6476-desthio	DT ₅₀ (water phase)	49.9	1000	49.9	1000
	DT ₅₀ (sediment)	1000	49.9	1000	49.9

Considering all deviation mentioned above respective changes were introduced in Tables 8.9-5 and to 8.9-6.

Input parameters for azoxystrobin presented in Table 8.9-9 to 8.9-12 and used in the modelling are in general in line with EU agreed endpoints as reported in EFSA Journal 2010; 8(4):1542 and in Addendum with confirmatory data for azoxystrobin (September, 2014) with following remark:

- for azoxystrobin and its metabolites: R234886 and R401553 the geometric instead of arithmetic mean K_{foc} values were used. This deviation is, however agreed by the zRMS, as the geometric mean K_{foc} values are lower than arithmetic mean values and represent thus worst case in terms of the potential leaching. Moreover, consideration of geometric mean K_{foc} values is in line with current EFSA recommendations. However, it should be emphasized that new active substance data should not be generated at the zonal level

At Step 3 PUF value of 0 was assumed for all compounds and it is in line with current recommendations.

Step 4 simulations were performed according to recommendations of the FOCUS work group on landscape and mitigation factors and were validated by the zRMS for convenience of the concerned Member States that consider FOCUS simulations as Step 4 at the national level.

8.9.2.1 Prothioconazole and its metabolites

Prothioconazole STEPS 1-4 PEC_{sw/sed}

Results from the FOCUS STEPS 1-3 surface water modelling for prothioconazole are presented in Table 8.9-13 to Table 8.9-18.

Table 8.9-13: FOCUS STEP 1, 2 and 3 PEC_{sw} and PEC_{sed} for Prothioconazole following application to Winter OSR (autumn applications)

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	-	19.55	315.81
STEP 2				
Northern Europe	Oct-Feb	-	1.66	11.54
STEP 3				
D3	ditch	Drift	1.144	0.5917
D4	pond	Drift	0.03934	0.03467
D4	stream	Drift	0.9854	0.1780
D5	pond	Drift	0.03934	0.02852
D5	stream	Drift	1.063	0.2321
R1	pond	Drift	0.03931	0.03207
R1	stream	Drift	0.7534	0.1033
R3	stream	Drift	1.053	0.2888

Table 8.9-14: FOCUS STEP 1, 2 and 3 PEC_{sw} and PEC_{sed} for Prothioconazole following application to Winter OSR (spring application)

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	-	19.55	315.81
STEP 2				
Northern Europe	March-May	-	1.66	4.24
	June-Sept	-	1.66	4.24
STEP 3				
D3	ditch	Drift	1.136	0.4543
D4	pond	Drift	0.03931	0.05417
D4	stream	Drift	0.8851	0.03506
D5	pond	Drift	0.03925	0.04587
D5	stream	Drift	0.7382	0.00921
R1	pond	Drift	0.03931	0.04324
R1	stream	Drift	0.7492	0.0909
R3	stream	Drift	1.062	0.2408

Table 8.9-15: FOCUS STEP 1, 2 and 3 PEC_{sw} and PEC_{sed} for Prothioconazole following application to Spring OSR

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	-	19.55	315.81
STEP 2				
Northern Europe	March-May	-	1.66	4.24
	June-Sept	-	1.66	4.24
STEP 3				
D3	ditch	Drift	1.141	0.4909
D4	pond	Drift	0.03932	0.03444
D4	stream	Drift	0.9331	0.06181
D5	pond	Drift	0.03931	0.04269
D5	stream	Drift	0.9045	0.02469
R1	pond	Drift	0.03931	0.04325
R1	stream	Drift	0.7504	0.09504

Table 8.9-16: FOCUS STEP 1, 2 and 3 PEC_{sw} and PEC_{sed} for Prothioconazole following application to Winter Cereals

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)		Max PEC _{sed} (µg/kg)	
			1 app	2 apps	1 app	2 apps
STEP 1	-	-	N/A	22.81	N/A	368.44
STEP 2						
Northern Europe	March-May	-	1.93	1.71	8.35	8.09
	June-Sept	-	1.93	1.71	8.35	8.09
STEP 3						
D3	ditch	Drift	1.329	1.162	0.5935	0.5187
D4	pond	Drift	0.04585	0.04049	0.06272	0.06138
D4	stream	Drift	0.9815	0.8784	0.02818	0.03129

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)		Max PEC _{sed} (µg/kg)	
			1 app	2 apps	1 app	2 apps
D5	pond	Drift	0.04586	0.04439	0.04983	0.05877
D5	stream	Drift	1.061	1.013	0.02990	0.07159
R1	pond	Drift	0.04586	0.04255	0.05045	0.04736
R1	stream	Drift	0.8755	0.7571	0.1107	0.2478
R3	stream	Drift	1.230	1.070	0.2190	0.7710
R4	stream	Drift	0.8756	0.7572	0.1112	0.09945

Bold = worst case from 1 or 2 applications

Table 8.9-17: FOCUS STEP 1, 2 and 3 PEC_{sw} and PEC_{sed} for Prothioconazole following application to Spring Cereals

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)		Max PEC _{sed} (µg/kg)	
			1 app	2 apps	1 app	2 apps
STEP 1	-	-	N/A	22.81	N/A	368.44
STEP 2						
Northern	March-May	-	1.93	1.71	8.35	8.09
Europe	June-Sept	-	1.93	1.71	8.35	8.09
STEP 3						
D3	ditch	Drift	1.330	1.163	0.5582	0.5025
D4	pond	Drift	0.04588	0.03895	0.04018	0.03360
D4	stream	Drift	1.087	0.9709	0.07093	0.1018
D5	pond	Drift	0.04587	0.0383	0.05004	0.04093
D5	stream	Drift	1.117	1.003	0.04591	0.06047
R4	stream	Drift	0.8793	0.9307	0.5257	0.6997

Bold = worst case from 1 or 2 applications

Table 8.9-18: FOCUS STEP 1, 2 and 3 PEC_{sw} and PEC_{sed} for Prothioconazole following application to Sunflower

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	-	19.55	315.81
STEP 2				
Northern	Mar-May	-	1.66	12.91
Europe	Jun-Sep	-	1.66	12.91
STEP 3				
D3*	ditch	Drift	0.9438	0.4120
D4*	pond	Drift	0.03809	0.03157
D4*	stream	Drift	0.8092	0.05315
R1	pond	Drift	0.03807	0.02869
R1	stream	Drift	0.6532	0.1122

* maize used as surrogate crop

FOCUS Step 4

While prothioconazole is not expected to drive the risk assessment of CA3642, STEP 4 models were performed to determine the PEC_{sw} for the metabolite prothioconazole-desthio, which required the modelling of the parent prothioconazole. These PEC_{sw} values may also be used to support combined risk assessments with the other active substance azoxystrobin. STEP 4 models were performed using no spray buffer zones and vegetated filter strips (VFS). Mitigation measures were applied using SWAN (v5.0.0) to modify the SWASH input files.

Maximum PEC_{sw} values from the FOCUS-STEP 4 models are presented in Table 8.9-19 to Table 8.9-22. It should be noted that where drift is the dominant entry route, the single application models will often result in a higher PEC_{sw} . In such cases, the single application PEC_{sw} should be used when assessing the risk from multiple applications.

Table 8.9-19: FOCUS STEP 4 global maximum PEC_{sw} values for prothioconazole, following application to Winter Oilseed Rape

Scenario	Winter OSR (autumn application)				Winter OSR (spring application)			
	None	None	10	20	None	None	10	20
Vegetated strip (m)								
No spray buffer (m)	STEP 3	5	10	20	STEP 3	5	10	20
D3 ditch	1.144	0.3102	0.1645	0.0849	1.136	0.3081	0.1634	0.08547
D4 pond	0.03934	0.03403	0.02447	0.01633	0.03931	0.03401	0.02445	0.01634
D4 stream	0.9854	0.3599	0.1909	0.08911	0.8851	0.3232	0.1715	0.09922
D5 pond	0.03934	0.03404	0.02447	0.0163	0.03925	0.03396	0.02442	0.01634
D5 stream	1.063	0.3882	0.2060	0.07433	0.7382	0.2696	0.1430	0.1070
R1 pond	0.03931	0.03401	0.02445	0.01633	0.03931	0.03401	0.02445	0.01633
R1 stream	0.7534	0.2751	0.1460	0.07543	0.7492	0.2736	0.1452	0.07586
R3 stream	1.053	0.3847	0.2041	0.1072	1.062	0.4690	0.2071	0.1061

Table 8.9-20: FOCUS STEP 4 global maximum PEC_{sw} values for prothioconazole, following application to Spring Oilseed Rape

Scenario	Spring OSR			
	None	None	10	20
Vegetated strip (m)				
No spray buffer (m)	STEP 3	5	10	20
D3 ditch	1.141	0.3092	0.1640	0.08520
D4 pond	0.03932	0.03402	0.02446	0.01633
D4 stream	0.9331	0.3408	0.1808	0.09395
D5 pond	0.03931	0.03401	0.02445	0.01633
D5 stream	0.9045	0.3303	0.1753	0.09107
R1 pond	0.03931	0.03401	0.02445	0.01633
R1 stream	0.7504	0.2741	0.1454	0.07556

Table 8.9-21: FOCUS STEP 4 global maximum PEC_{sw} values for prothioconazole, following application to Winter Cereals

Scenario	Winter Cereals (single application)				Winter Cereals (two applications)			
	None	None	10	20	None	None	10	20
Vegetated strip (m)	None	None	10	20	None	None	10	20
No spray buffer (m)	STEP 3	5	10	20	STEP 3	5	10	20
D3 ditch	1.329	0.3602	0.1911	0.09926	1.162	0.3016	0.1567	0.07964
D4 pond	0.04585	0.03967	0.02852	0.01904	0.04049	0.03482	0.02471	0.01625
D4 stream	0.9815	0.3587	0.1902	0.09881	0.8784	0.3103	0.1612	0.08196
D5 pond	0.04586	0.03968	0.02853	0.01905	0.04439	0.03817	0.02708	0.01781
D5 stream	1.061	0.3877	0.2055	0.1068	1.013	0.358	0.1860	0.09456
R1 pond	0.04586	0.03968	0.02853	0.01905	0.04255	0.0366	0.02594	0.01705
R1 stream	0.8755	0.3200	0.1696	0.08814	0.7571	0.2948	0.1389	0.07065
R3 stream	1.230	0.4494	0.2383	0.1238	1.070	0.4904	0.2238	0.1174
R4 stream	0.8756	0.3200	0.1696	0.08815	0.7572	0.2675	0.1390	0.07066

Bold = worst-case from one or two applications

Table 8.9-22: FOCUS STEP 4 global maximum PEC_{sw} values for prothioconazole, following application to Spring Cereals

Scenario	Spring Cereals (single application)				Spring Cereals (two applications)			
	None	None	10	20	None	None	10	20
Vegetated strip (m)	None	None	10	20	None	None	10	20
No spray buffer (m)	STEP 3	5	10	20	STEP 3	5	10	20
D3 ditch	1.330	0.3606	0.1913	0.09937	1.163	0.3017	0.1567	0.07967
D4 pond	0.04588	0.0397	0.02854	0.01906	0.03895	0.03349	0.02376	0.01563
D4 stream	1.087	0.3974	0.2107	0.1095	0.9709	0.3430	0.1782	0.09060
D5 pond	0.04587	0.03969	0.02853	0.01905	0.0383	0.03293	0.02337	0.01537
D5 stream	1.117	0.4082	0.2164	0.1124	1.003	0.3545	0.1841	0.09362
R4 stream	0.8793	0.5565	0.2511	0.1311	0.9307	0.9307	0.4207	0.2198

Bold = worst-case from one or two applications

Table 8.9-23: FOCUS STEP 4 global maximum PEC_{sw} values for prothioconazole, following application to Sunflower

Scenario	Sunflower			
	None	None	10	20
Vegetated strip (m)	None	None	10	20
No spray buffer (m)	STEP 3	5	10	20
D3 ditch*	0.9438	0.3093	0.1640	0.08523
D4 pond*	0.03809	0.03402	0.02446	0.01633
D4 stream*	0.8092	0.3406	0.1807	0.09390
R1 pond	0.03807	0.03401	0.02445	0.01633
R1 stream	0.6532	0.2749	0.1459	0.07579

* maize used as surrogate crop

Prothioconazole-S-methyl STEPS 1-2 PEC_{sw}/sed

Results from the FOCUS STEPS 1-2 surface water modelling for Prothioconazole-S-methyl are presented in Table 8.9-24 to Table 8.9-26. STEP 3 modelling was not performed as the risks to aquatic organisms were expected to be acceptable at STEP 2. Note that at STEPS 1 and 2, the PEC values are not affected by the winter/spring crop variety, only by the season of application.

Table 8.9-24: FOCUS STEP 1 and 2 PEC_{sw} and PEC_{sed} for Prothioconazole-S-methyl following application to Winter OSR (autumn application)

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	-	4.12 2.09	99.77 52.72
STEP 2				
Northern Europe	Oct-Feb	-	0.65 0.52	15.87 13.26

Table 8.9-25: FOCUS STEP 1 and 2 PEC_{sw} and PEC_{sed} for Prothioconazole-S-methyl following application to Winter or Spring OSR (spring application)

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	-	4.12 2.09	99.77 52.72
STEP 2				
Northern	March-May	-	0.22 0.10	4.18 2.65
Europe	June-Sept	-	0.22 0.10	4.18 2.65

Table 8.9-26: FOCUS STEP 1 and 2 PEC_{sw} and PEC_{sed} for Prothioconazole-S-methyl following application to Winter or Spring Cereals

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)		Max PEC _{sed} (µg/kg)	
			1 app	2 apps	1 app	2 apps
STEP 1	-	-	N/A	8.24 4.87	N/A	199.54 123.02
STEP 2						
Northern	March-May	-	0.38 0.33	0.58 0.50	9.05 8.25	13.82 12.69
Europe	June-Sept	-	0.38 0.33	0.58 0.50	9.05 8.25	13.82 12.69

Bold = worst case from 1 or 2 applications

Table 8.9-27: FOCUS STEP 1 and 2 PEC_{sw} and PEC_{sed} for Prothioconazole-S-methyl following application to Sunflower

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	-	4.12 2.09	99.77 52.72
STEP 2				
Northern	Mar-May	-	0.38 0.28	9.05 7.07
Europe	Jun-Sep	-	0.38 0.28	9.05 7.07

1,2,4-Triazole STEPS 1-2 PEC_{sw}/sed

Results from the FOCUS STEPS 1-2 surface water modelling for 1,2,4-Triazole are presented in Table 8.9-28 to Table 8.9-30. STEP 3 modelling was not performed as the risks to aquatic organisms were expected to be acceptable at STEP 2. Note that at STEPS 1 and 2, the PEC values are not affected by the winter/spring crop variety, only by the season of application.

Table 8.9-28: FOCUS STEP 1 and 2 PEC_{sw} and PEC_{sed} for 1,2,4-Triazole following application to Winter OSR (autumn application)

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	-	2.99	16.80
STEP 2				
Northern Europe	Oct-Feb	-	0.18	0.94

Table 8.9-29: FOCUS STEP 1 and 2 PEC_{sw} and PEC_{sed} for 1,2,4-Triazole following application to Winter or Spring OSR (spring application)

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	-	2.99	16.80
STEP 2				
Northern Europe	March-May	-	0.14	0.55
	June-Sept	-	0.14	0.55

Table 8.9-30: FOCUS STEP 1 and 2 PEC_{sw} and PEC_{sed} for 1,2,4-Triazole following application to Winter or Spring Cereals

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)		Max PEC _{sed} (µg/kg)	
			1 app	2 apps	1 app	2 apps
STEP 1	-	-	N/A	6.98	N/A	39.20
STEP 2						
Northern Europe	March-May	-	0.16	0.24	0.83	1.23
	June-Sept	-	0.16	0.24	0.83	1.23

Bold = worst case from 1 or 2 applications

Table 8.9-31: FOCUS STEP 1 and 2 PEC_{sw} and PEC_{sed} for 1,2,4-Triazole following application to Sunflower

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	-	2.99	16.8
STEP 2				
Northern Europe	Mar-May	-	0.14	0.71
	Jun-Sep	-	0.14	0.71

Prothioconazole-desthio STEPS 1-4 PEC_{sw/sed}

Results from the FOCUS STEPS 1-3 surface water modelling for prothioconazole-desthio are presented in Table 8.9-32 to Table 8.9-41. Note that an entry route of “drift” refers to the metabolite forming in surface water from the drift entry of the active substance. Relatively little active substance enters via drainflow and runoff. Entry routes via “drainflow” and “runoff” involve the formation of the metabolite in soil, which is then transferred to surface water.

Table 8.9-32: FOCUS STEP 1, 2 and 3 PEC_{sw} and PEC_{sed} for Prothioconazole-desthio following application to Winter OSR (autumn application)

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	-	35.26	200.05
STEP 2				
Northern Europe	Oct-Feb	-	5.72	32.32
STEP 3				
D3	ditch	Drift	0.1575	0.4459
D4	pond	Drift	0.02497	0.3194
D4	stream	Drift	0.09069	0.05838
D5	pond	Drift	0.02609	0.3256
D5	stream	Drift	0.1452	0.1034
R1	pond	Runoff	0.03418	0.4622
R1	stream	Runoff	0.2791	0.1691
R3	stream	Runoff	0.7631	1.038

Table 8.9-33: FOCUS STEP 1, 2 and 3 PEC_{sw} and PEC_{sed} for Prothioconazole-desthio following application to Winter OSR (spring application)

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	-	35.26	200.05
STEP 2				
Northern Europe	March-May	-	1.58	8.59
	June-Sept	-	1.58	8.59
STEP 3				
D3	ditch	Drift	0.03366	0.1202
D4	pond	Drift	0.01915	0.2726
D4	stream	Drift	0.06826	0.006747
D5	pond	Drift	0.021	0.2918
D5	stream	Drift	0.08112	0.002345
R1	pond	Runoff	0.04732	0.531
R1	stream	Runoff	0.2881	0.3478
R3	stream	Runoff	0.4957	0.2428

Table 8.9-34: FOCUS STEP 1, 2 and 3 PEC_{sw} and PEC_{sed} for Prothioconazole-desthio following application to Spring OSR

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	-	35.26	200.05
STEP 2				
Northern	March-May	-	1.58	8.59
Europe	June-Sept	-	1.58	8.59
STEP 3				
D3	ditch	Drift	0.1147	0.2886
D4	pond	Drift	0.02520	0.3039
D4	stream	Drift	0.07435	0.01886
D5	pond	Drift	0.02290	0.3220
D5	stream	Drift	0.09940	0.006535
R1	pond	Runoff	0.05388	0.5814
R1	stream	Runoff	0.4218	0.3689

Table 8.9-35: FOCUS STEP 1, 2 and 3 PEC_{sw} and PEC_{sed} for Prothioconazole-desthio following application to Winter Cereals

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)		Max PEC _{sed} (µg/kg)	
			1 app	2 apps	1 app	2 apps
STEP 1	-	-	N/A	82.28	N/A	466.78
STEP 2						
Northern	March-May	-	3.85	6.23	21.55	34.78
Europe	June-Sept	-	3.85	6.23	21.55	34.78
STEP 3						
D3	ditch	Drift	0.06281	0.1108	0.1984	0.4342
D4	pond	Drift	0.02159	0.03718	0.3120	0.5161
D4	stream	Drift	0.07570	0.06775	0.005425	0.01040
D5	pond	Drift	0.02706	0.04599	0.3798	0.6118
D5	stream	Drift	0.1166	0.1125	0.007829	0.02431
R1	pond	Runoff	0.05745	0.1475	0.6227	1.452
R1	stream	Runoff	0.3729	1.121	0.4080	1.222
R3	stream	Runoff	0.4835	1.200	0.6354	1.431
R4	stream	Runoff	0.2592	0.7536	0.3113	0.7974

Bold = worst case from 1 or 2 applications

Table 8.9-36: FOCUS STEP 1, 2 and 3 PEC_{sw} and PEC_{sed} for Prothioconazole-desthio following application to Spring Cereals (single application)

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)		Max PEC _{sed} (µg/kg)	
			1 app	2 apps	1 app	2 apps
STEP 1	-	-	N/A	82.28	N/A	466.78
STEP 2						
Northern Europe	March-May	-	3.85	6.23	21.55	34.78
	June-Sept	-	3.85	6.23	21.55	34.78
STEP 3						
D3	ditch	Drift	0.1279	0.1158	0.3155	0.4864
D4	pond	Drift	0.02946	0.0468	0.3423	0.5413
D4	stream	Drift	0.08644	0.08120	0.02146	0.04848
D5	pond	Drift	0.02774	0.04524	0.3778	0.6095
D5	stream	Drift	0.1227	0.1107	0.01195	0.02857
R4	stream	Runoff	0.7175	1.386	1.268	1.991

Bold = worst case from 1 or 2 applications

Table 8.9-37: FOCUS STEP 1, 2 and 3 PEC_{sw} and PEC_{sed} for Prothioconazole-desthio following application to Sunflower

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	-	35.26	200.05
STEP 2				
Northern Europe	Mar-May	-	3.3	18.47
	Jun-Sep	-	3.3	18.47
STEP 3				
D3*	ditch	Drift	0.9443	0.2499
D4*	pond	Drift	0.4766	0.2825
D4*	stream	Drift	0.8109	0.01689
R1	pond	Runoff	1.4681	0.7551
R1	stream	Runoff	2.0891	1.044

* maize used as surrogate crop

FOCUS Step 4

Surface water exposure at STEP 3 indicated potential risks for aquatic organisms due to the metabolite, prothioconazole-desthio. The worst-case PEC values occurred due to runoff. Therefore, STEP 4 models were performed using vegetated filter strips (VFS) to mitigate the exposures. Mitigation measures were applied using SWAN (v5.0.0) to modify the SWASH input files.

Global maximum PEC_{sw} values from the FOCUS-STEP 4 models are presented in Table 8.9-38 to Table 8.9-41. It should be noted that where drift is the dominant entry route, the single application models will often result in a higher PEC_{sw}. In such cases, the single application PEC_{sw} should be used when assessing the risk from multiple applications.

Table 8.9-38: FOCUS STEP 4 global maximum PEC_{sw} values for prothioconazole-desthio, following application to Winter Oilseed Rape

Scenario	Winter OSR (autumn application)				Winter OSR (spring application)			
	None	None	10	20	None	None	10	20
Vegetated strip (m)								
No spray buffer (m)	STEP 3	5	10	20	STEP 3	5	10	20
D3 ditch	0.1575	0.04255	0.02253	0.01169	0.03366	0.009113	0.004829	0.002507
D4 pond	0.02497	0.02154	0.01642	0.01354	0.01915	0.01651	0.01178	0.007791
D4 stream	0.09069	0.05218	0.05218	0.05218	0.06826	0.02491	0.01321	0.006863
D5 pond	0.02609	0.02256	0.01621	0.01085	0.02100	0.01811	0.01293	0.008556
D5 stream	0.1452	0.05299	0.0281	0.02397	0.08112	0.02961	0.01570	0.008156
R1 pond	0.03418	0.0327	0.01614	0.01006	0.04732	0.04453	0.02345	0.01377
R1 stream	0.2791	0.2791	0.1224	0.06315	0.2881	0.2881	0.1306	0.06842
R3 stream	0.7631	0.7631	0.3473	0.1820	0.4957	0.4957	0.2191	0.1135

Table 8.9-39: FOCUS STEP 4 global maximum PEC_{sw} values for prothioconazole-desthio, following application to Spring Oilseed Rape

Scenario	Spring OSR			
	None	None	10	20
Vegetated strip (m)				
No spray buffer (m)	STEP 3	5	10	20
D3 ditch	0.1147	0.03105	0.01645	0.008539
D4 pond	0.02520	0.02175	0.01555	0.01031
D4 stream	0.07435	0.02714	0.01439	0.007475
D5 pond	0.02290	0.01975	0.01410	0.009328
D5 stream	0.09940	0.03628	0.01924	0.009994
R1 pond	0.05388	0.05106	0.02610	0.0151
R1 stream	0.4218	0.4218	0.1915	0.1002

Table 8.9-40: FOCUS STEP 4 global maximum PEC_{sw} values for prothioconazole-desthio, following application to Winter Cereals

Scenario	Winter Cereals (single application)				Winter Cereals (two applications)			
	None	None	10	20	None	None	10	20
Vegetated strip (m)								
No spray buffer (m)	STEP 3	5	10	20	STEP 3	5	10	20
D3 ditch	0.06281	0.01700	0.009012	0.004678	0.1108	0.02868	0.01488	0.007559
D4 pond	0.02159	0.01862	0.01328	0.008787	0.03718	0.03186	0.02242	0.01460
D4 stream	0.07570	0.02765	0.01465	0.00761	0.06775	0.02392	0.01242	0.006312
D5 pond	0.02706	0.02334	0.01665	0.01102	0.04599	0.03942	0.02777	0.01811
D5 stream	0.1166	0.04259	0.02257	0.01172	0.1125	0.03974	0.02063	0.01049
R1 pond	0.05745	0.05416	0.02831	0.01655	0.1475	0.1421	0.06794	0.03787
R1 stream	0.3729	0.3729	0.1694	0.08866	1.121	1.121	0.5091	0.2665
R3 stream	0.4835	0.4835	0.2206	0.1157	1.200	1.200	0.5477	0.2873
R4 stream	0.2592	0.2592	0.1170	0.06104	0.7536	0.7536	0.3400	0.1775

Bold = worst-case from one or two applications

Table 8.9-41: FOCUS STEP 4 global maximum PEC_{sw} values for prothioconazole-desthio, following application to Spring Cereals

Scenario	Spring Cereals (single application)				Spring Cereals (two applications)			
	None	None	10	20	None	None	10	20
Vegetated strip (m)								
No spray buffer (m)	STEP 3	5	10	20	STEP 3	5	10	20
D3 ditch	0.1279	0.03462	0.01835	0.009523	0.1158	0.02999	0.01557	0.007906
D4 pond	0.02946	0.02542	0.01818	0.01205	0.0468	0.04013	0.02828	0.01844
D4 stream	0.08644	0.03157	0.01673	0.00869	0.0812	0.02867	0.01489	0.008024
D5 pond	0.02774	0.02393	0.01709	0.01131	0.04524	0.03878	0.02732	0.01781
D5 stream	0.1227	0.04484	0.02376	0.01234	0.1107	0.03908	0.02029	0.01031
R4 stream	0.7175	0.7175	0.3263	0.1709	1.386	1.386	0.6237	0.3254

Bold = worst-case from one or two applications

Table 8.9-42: FOCUS STEP 4 global maximum PEC_{sw} values for prothioconazole-desthio, following application to Sunflower

Scenario	Sunflower			
	None	None	10	20
Vegetated strip (m)				
No spray buffer (m)	STEP 3	5	10	20
D3 ditch*	0.09735	0.03185	0.01688	0.00876
D4 pond*	0.02443	0.02178	0.01557	0.01033
D4 stream*	0.06438	0.02708	0.01436	0.00746
R1 pond	0.07567	0.07323	0.03593	0.02043
R1 stream	0.6933	0.6933	0.3153	0.1652

* maize used as surrogate crop

zRMS comments:

The surface water exposure was independently validated by the zRMS in additional modelling with modified input parameters discussed above.

Results for prothioconazole at Step 1-4 were in general in good agreement with results obtained by the Applicant. PEC_{sw} at Step 3-4 were the same, whereas PEC_{SED} values obtained by the zRMS were slightly higher due to modified combination of DT₅₀ values considered in simulations performed for parent+metabolite (JAU 6476-desthio). However, observed differences were slight and with no impact on the outcome of the risk assessment, which was driven by exposure of aquatic species via the water column. Overall, the surface water exposure reported in Tables 8.9-13 to 8.9-23 may be used in the aquatic risk assessment.

Results obtained by the zRMS for metabolite JAU 6476 S-Methyl at Step 1-2 were considerably higher comparing to these obtained by the Applicant since higher maximum occurrence in the whole system (12.7%) was considered by the zRMS at Steps 1-2 calculations. Thus, values reported in Tables 8.9-24 to 8.9-27 were corrected by the zRMS and may be used for purposes of the aquatic risk assessment.

Results for metabolite 1,2,4-triazole calculated by the zRMS at Steps 1-2 were the same comparing to these obtained by the Applicant. Overall, values in Tables 8.9-28 and 8.9-31 may be used further in the aquatic risk assessment.

Results for metabolite JAU 6476-desthio at Step 1-4 were in general in good agreement with results obtained by the Applicant. The PEC_{sw/SED} calculated by the zRMS at Steps 1-4 for the correct input parameters were the same or lower comparing to these obtained by the Applicant. Overall, the surface water exposure reported in Tables 8.9-32 to 8.9-42 may be used in the aquatic risk assessment.

Please note that additional surface water modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

8.9.2.2 Azoxystrobin and its metabolites

Azoxystrobin STEPS 1-4 PEC_{sw}/sed

Results from the FOCUS STEPS 1-3 surface water modelling for Azoxystrobin are presented in Table 8.9-43 to Table 8.9-47.

Table 8.9-43: FOCUS STEP 1, 2 and 3 PEC_{sw} and PEC_{sed} for Azoxystrobin following application to Winter OSR (autumn applications)

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	-	41.06	158.19
STEP 2				
Northern Europe	Oct-Feb	-	12.62	48.76
STEP 3				
D3	ditch	Drift	1.145	0.7576
D4	pond	Drainflow	1.111	6.314
D4	stream	Drift	1.263	2.549
D5	pond	Drainflow	0.4981	3.732
D5	stream	Drift	1.064	0.8585
R1	pond	Runoff	0.06035	0.4428
R1	stream	Runoff	1.104	0.3422
R3	stream	Runoff	2.760	1.699

Table 8.9-44: FOCUS STEP 1, 2 and 3 PEC_{sw} and PEC_{sed} for Azoxystrobin following application to Winter OSR (spring application)

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	-	41.06	158.19
STEP 2				
Northern Europe	March-May	-	3.49	13.10
	June-Sept	-	3.49	13.10
STEP 3				
D3	ditch	Drift	1.137	0.4603
D4	pond	Drainflow	0.3373	2.171
D4	stream	Drift	0.8855	0.8426
D5	pond	Drift	0.1255	0.8791
D5	stream	Drift	0.7567	0.1898
R1	pond	Runoff	0.1272	0.7614
R1	stream	Runoff	1.104	0.5398
R3	stream	Runoff	1.860	0.6308

Table 8.9-45: FOCUS STEP 1, 2 and 3 PEC_{sw} and PEC_{sed} for Azoxystrobin following application to Spring OSR

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	-	41.06	158.19
STEP 2				
Northern	March-May	-	3.49	13.10
Europe	June-Sept	-	3.49	13.10
STEP 3				
D3	ditch	Drift	1.141	0.5911
D4	pond	Drainflow	0.3901	2.504
D4	stream	Drift	0.9346	0.9445
D5	pond	Drainflow	0.1387	1.173
D5	stream	Drift	0.9102	0.2789
R1	pond	Runoff	0.1448	0.8488
R1	stream	Runoff	1.566	0.6024

Table 8.9-46: FOCUS STEP 1, 2 and 3 PEC_{sw} and PEC_{sed} for Azoxystrobin following application to Winter Cereals

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)		Max PEC _{sed} (µg/kg)	
			1 app	2 apps	1 app	2 apps
STEP 1	-	-	N/A	95.81	N/A	369.11
STEP 2						
Northern	March-May	-	8.51	15.81	32.62	60.66
Europe	June-Sept	-	8.51	15.81	32.62	60.66
STEP 3						
D3	ditch	Drift	1.330	1.164	0.6163	0.7197
D4	pond	Drainflow	0.4256	0.9800	2.689	5.707
D4	stream	Drift	0.9848	0.9963	1.022	2.175
D5	pond	Drift/Drainflow*	0.1370	0.2858	1.220	2.642
D5	stream	Drift	1.068	1.023	0.2630	0.5531
R1	pond	Runoff	0.1501	0.4057	0.8853	2.188
R1	stream	Runoff	1.399	4.140	0.6441	1.851
R3	stream	Runoff	1.965	4.528	1.274	3.051
R4	stream	Runoff	1.015	2.833	0.5224	1.322

*Dominant entry route for single/multiple applications, respectively

Bold = worst case from 1 or 2 applications

Table 8.9-47: FOCUS STEP 1, 2 and 3 PEC_{sw} and PEC_{sed} for Azoxystrobin following application to Spring Cereals

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)		Max PEC _{sed} (µg/kg)	
			1 app	2 apps	1 app	2 apps
STEP 1	-	-	N/A	95.81	N/A	369.11
STEP 2						
Northern Europe	March-May	-	8.51	15.81	32.62	60.66
	June-Sept	-	8.51	15.81	32.62	60.66
STEP 3						
D3	ditch	Drift	1.331	1.164	0.6625	0.7528
D4	pond	Drainflow	0.467	0.8872	2.969	5.333
D4	stream	Drift	1.089	0.9725	1.118	2.011
D5	pond	Drainflow	0.1391	0.2767	1.298	2.484
D5	stream	Drift	1.122	1.010	0.2797	0.5308
R4	stream	Runoff	2.569	4.321	1.985	3.304

Bold = worst case from 1 or 2 applications

Table 8.9-48: FOCUS STEP 1, 2 and 3 PEC_{sw} and PEC_{sed} for Azoxystrobin following application to Sunflower

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	-	41.06	158.19
STEP 2				
Northern Europe	Mar-May	-	7.3	27.96
	Jun-Sep	-	7.3	27.96
STEP 3				
D3*	ditch	Drift	0.9443	0.5029
D4*	pond	Drainflow	0.4766	3.012
D4*	stream	Drift	0.8109	1.147
R1	pond	Runoff	1.4681	1.332
R1	stream	Runoff	2.0891	1.527

* maize used as surrogate crop

FOCUS Step 4

Surface water exposure at STEP 3 indicated potential risks for aquatic organisms due to azoxystrobin. The worst-case PEC values occurred due to runoff. Therefore, STEP 4 models were performed using vegetated filter strips (VFS) to mitigate the exposures. Mitigation measures were applied using SWAN (v5.0.0) to modify the SWASH input files.

Global maximum PEC_{sw} values from the FOCUS-STEP 4 models are presented in Table 8.9-49 to Table 8.9-52. It should be noted that where drift is the dominant entry route, the single application models will often result in a higher PEC_{sw}. In such cases, the single application PEC_{sw} should be used when assessing the risk from multiple applications

Table 8.9-49: FOCUS STEP 4 global maximum PEC_{sw} values for azoxystrobin, following application to Winter Oilseed Rape

Scenario	Winter OSR (autumn application)				Winter OSR (spring application)			
	None	None	10	20	None	None	10	20
Vegetated strip (m)								
No spray buffer (m)	STEP 3	5	10	20	STEP 3	5	10	20
D3 ditch	1.145	0.3103	0.1646	0.08549	1.137	0.3083	0.1635	0.08492
D4 pond	1.111	1.110	1.107	1.104	0.3373	0.3367	0.3357	0.3348
D4 stream	1.263	1.263	1.263	1.263	0.8855	0.3661	0.3661	0.3661
D5 pond	0.4981	0.4968	0.4943	0.4923	0.1255	0.1202	0.1106	0.1025
D5 stream	1.064	0.9225	0.9225	0.9225	0.7567	0.2878	0.1612	0.1521
R1 pond	0.06035	0.05851	0.02745	0.01636	0.1272	0.1244	0.05608	0.03022
R1 stream	1.104	1.104	0.4842	0.2501	1.104	1.104	0.5009	0.2623
R3 stream	2.760	2.760	1.257	0.6584	1.860	1.860	0.8215	0.4256

Table 8.9-50: FOCUS STEP 4 global maximum PEC_{sw} values for azoxystrobin, following application to Spring Oilseed Rape

Scenario	Spring OSR			
	None	None	10	20
Vegetated strip (m)				
No spray buffer (m)	STEP 3	5	10	20
D3 ditch	1.141	0.3094	0.1640	0.08522
D4 pond	0.3901	0.3891	0.3873	0.3858
D4 stream	0.9346	0.4336	0.4336	0.4336
D5 pond	0.1387	0.1387	0.1387	0.1387
D5 stream	0.9102	0.3356	0.2114	0.2114
R1 pond	0.1448	0.1420	0.06308	0.03371
R1 stream	1.566	1.566	0.7110	0.3723

Table 8.9-51: FOCUS STEP 4 global maximum PEC_{sw} values for azoxystrobin, following application to Winter Cereals

Scenario	Winter Cereals (single application)				Winter Cereals (two applications)			
	None	None	10	20	None	None	10	20
Vegetated strip (m)								
No spray buffer (m)	STEP 3	5	10	20	STEP 3	5	10	20
D3 ditch	1.330	0.3604	0.1911	0.09929	1.164	0.3019	0.1568	0.0797
D4 pond	0.4256	0.4249	0.4235	0.4223	0.9800	0.9785	0.9759	0.9737
D4 stream	0.9848	0.4515	0.4515	0.4515	0.9963	0.9963	0.9963	0.9963
D5 pond	0.1370	0.1308	0.1298	0.1298	0.2858	0.2858	0.2858	0.2858
D5 stream	1.068	0.3947	0.2124	0.2070	1.023	0.4336	0.4336	0.4336
R1 pond	0.1501	0.1468	0.06612	0.03575	0.4057	0.3998	0.1731	0.09073
R1 stream	1.399	1.399	0.6355	0.3328	4.140	4.140	1.881	0.9849
R3 stream	1.965	1.965	0.8966	0.4705	4.528	4.528	2.067	1.084
R4 stream	1.015	1.015	0.4583	0.2392	2.833	2.833	1.279	0.6675

Bold = worst-case from one or two applications

Table 8.9-52: FOCUS STEP 4 global maximum PEC_{sw} values for azoxystrobin, following application to Spring Cereals

Scenario	Spring Cereals (single application)				Spring Cereals (two applications)			
	None	None	10	20	None	None	10	20
Vegetated strip (m)	None	None	10	20	None	None	10	20
No spray buffer (m)	STEP 3	5	10	20	STEP 3	5	10	20
D3 ditch	1.331	0.3607	0.1913	0.09939	1.164	0.302	0.1569	0.07975
D4 pond	0.4670	0.4659	0.4640	0.4623	0.8872	0.8853	0.8818	0.8789
D4 stream	1.089	0.5017	0.5017	0.5017	0.9725	0.9051	0.9051	0.9051
D5 pond	0.1391	0.1391	0.1391	0.1391	0.2767	0.2767	0.2767	0.2767
D5 stream	1.122	0.4129	0.2211	0.2186	1.010	0.4208	0.4208	0.4208
R4 stream	2.569	2.569	1.159	0.6052	4.321	4.321	1.942	1.013

Bold = worst-case from one or two applications

Table 8.9-53: FOCUS STEP 4 global maximum PEC_{sw} values for azoxystrobin, following application to Sunflower

Scenario	Sunflower			
Vegetated strip (m)	None	None	10	20
No spray buffer (m)	STEP 3	5	10	20
D3 ditch*	0.9443	0.3095	0.1641	0.08525
D4 pond*	0.4766	0.4759	0.4743	0.4729
D4 stream*	0.8109	0.5271	0.5271	0.5271
R1 pond	1.4681	0.1771	0.08011	0.04358
R1 stream	2.0891	1.885	0.8572	0.4491

* maize used as surrogate crop

R234886 STEPS 1-2 PEC_{sw}/sed

Results from the FOCUS STEPS 1-2 surface water modelling for R234886 are presented in Table 8.9-54 to Table 8.9-56. STEP 3 modelling was not performed as the risks to aquatic organisms were expected to be acceptable at STEP 2. Note that at STEPS 1 and 2, the PEC values are not affected by the winter/spring crop variety, only by the season of application.

Table 8.9-54: FOCUS STEP 1 and 2 PEC_{sw} and PEC_{sed} for R234886 following application to Winter OSR (autumn application)

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
Acidic soils				
STEP 1	-	-	22.28	39.21
STEP 2				
Northern Europe	Oct-Feb	-	6.64	11.70
Alkaline soils				
STEP 1	-	-	26.19	9.60
STEP 2				
Northern Europe	Oct-Feb	-	7.60	2.78

Table 8.9-55: FOCUS STEP 1 and 2 PEC_{sw} and PEC_{sed} for R234886 following application to Winter or Spring OSR (spring application)

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
Acidic soils				
STEP 1	-	-	22.28	39.21
STEP 2				
Northern Europe	Mar-May	-	1.53	2.67
Northern Europe	Jun-Sep	-	1.53	2.67
Alkaline soils				
STEP 1	-	-	26.25	9.12
STEP 2				
Northern Europe	Mar-May	-	1.75	0.61
Northern Europe	Jun-Sep	-	1.75	0.61

Table 8.9-56: FOCUS STEP 1 and 2 PEC_{sw} and PEC_{sed} for R234886 following application to Winter or Spring Cereals

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)		Max PEC _{sed} (µg/kg)	
			1 app	2 apps	1 app	2 apps
Acidic soils						
STEP 1	-	-	N/A	51.98	N/A	91.50
STEP 2						
Northern Europe	March-May	-	4.27	8.06	7.50	14.17
	June-Sept	-	4.27	8.06	7.50	14.17
Alkaline soils						
STEP 1	-	-	N/A	61.25	N/A	21.08
STEP 2						
Northern	March-May	-	4.89	8.85	1.70	3.07
Europe	June-Sept	-	4.89	8.85	1.70	3.07

Bold = worst case from 1 or 2 applications and acid/alkaline soil

Table 8.9-57: FOCUS STEP 1 and 2 PEC_{sw} and PEC_{sed} for R234886 following application to Sunflower

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
Acidic soils				
STEP 1	-	-	22.28	39.21
STEP 2				
Northern Europe	Mar-May	-	3.66	6.43
Europe	Jun-Sep	-	3.66	6.43
Alkaline soils				
STEP 1	-	-	26.25	9.12
STEP 2				
Northern Europe	Mar-May	-	4.19	1.46
Europe	Jun-Sep	-	4.19	1.46

R401553 STEPS 1-2 PEC_{sw/sed}

Results from the FOCUS STEPS 1-2 surface water modelling for R401553 are presented in Table 8.9-58 to Table 8.9-60. STEP 3 modelling was not performed as the risks to aquatic organisms were expected to be acceptable at STEP 2. Note that at STEPS 1 and 2, the PEC values are not affected by the winter/spring crop variety, only by the season of application.

Table 8.9-58: FOCUS STEP 1 and 2 PEC_{sw} and PEC_{sed} for R401553 following application to Winter OSR (autumn application)

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	-	6.98	9.95
STEP 2				
Northern Europe	Oct-Feb	-	0.86	1.23

Table 8.9-59: FOCUS STEP 1 and 2 PEC_{sw} and PEC_{sed} for R401553 following application to Winter or Spring OSR (spring application)

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	-	6.98	9.95
STEP 2				
Northern Europe	March-May	-	0.23	0.32
	June-Sept	-	0.23	0.32

Table 8.9-60: FOCUS STEP 1 and 2 PEC_{sw} and PEC_{sed} for R401553 following application to Winter or Spring Cereals

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)		Max PEC _{sed} (µg/kg)	
			1 app	2 apps	1 app	2 apps
STEP 1	-	-	N/A	16.28	N/A	23.22
STEP 2						
Northern Europe	March-May	-	0.58	1.01	0.82	1.44
Europe	June-Sept	-	0.58	1.01	0.82	1.44

Bold = worst case from 1 or 2 applications

Table 8.9-61: FOCUS STEP 1 and 2 PEC_{sw} and PEC_{sed} for R401553 following application to Sunflower

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	-	6.98	9.95
STEP 2				
Northern Europe	Mar-May	-	0.49	0.70
Europe	Jun-Sep	-	0.49	0.70

R402173 STEPS 1-2 PEC_{sw/sed}

Results from the FOCUS STEPS 1-2 surface water modelling for R402173 are presented in Table 8.9-62 to Table 8.9-64. STEP 3 modelling was not performed as the risks to aquatic organisms were expected to be acceptable at STEP 2. Note that at STEPS 1 and 2, the PEC values are not affected by the winter/spring crop variety, only by the season of application.

Table 8.9-62: FOCUS STEP 1 and 2 PEC_{sw} and PEC_{sed} for R402173 following application to Winter OSR (autumn application)

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	-	9.34	2.33
STEP 2				
Northern Europe	Oct-Feb	-	1.72	0.43

Table 8.9-63: FOCUS STEP 1 and 2 PEC_{sw} and PEC_{sed} for R402173 following application to Winter or Spring OSR (spring application)

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	-	9.34	2.33
STEP 2				
Northern Europe	March-May	-	0.37	0.09
	June-Sept	-	0.37	0.09

Table 8.9-64: FOCUS STEP 1 and 2 PEC_{sw} and PEC_{sed} for R402173 following application to Winter or Spring Cereals

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)		Max PEC _{sed} (µg/kg)	
			1 app	2 apps	1 app	2 apps
STEP 1	-	-	N/A	21.79	N/A	5.44
STEP 2						
Northern Europe	March-May	-	1.09	1.41	0.27	0.35
	June-Sept	-	1.09	1.41	0.27	0.35

Bold = worst case from 1 or 2 applications

Table 8.9-65: FOCUS STEP 1 and 2 PEC_{sw} and PEC_{sed} for R402173 following application to Sunflower

FOCUS STEP and Scenario	Waterbody or Season	Dominant entry route	Max PEC _{sw} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 1	-	-	9.34	2.33
STEP 2				
Northern Europe	Mar-May	-	0.93	0.23
	Jun-Sep	-	0.93	0.23

zRMS comments:

The surface water exposure was independently validated by the zRMS in additional modelling using the same parameters indicated above. Obtained PEC_{sw} and PEC_{sed} were in good agreement with values calculated by the Applicant. Thus, surface water exposure reported in Tables 8.9-43 to 8.9-65 is relevant for the aquatic risk assessment.

Please note that additional surface water modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

8.9.2.3 PEC_{sw/sed} of formulated product

The risk assessment can generally be extrapolated from the PEC_{sw} and PEC_{sed} values of the active substance and its metabolites. For completeness, the PEC_{sw} values for the formulated product were calculated using the FOCUS 90th percentile drift curves for distances of 1m, 5m, 10m and 20m, with dispersion into a focus STEP 1-2 water body of 0.3m depth with a 10:1 field: water surface area ratio (equivalent to 30,000 L/ha). Multiple applications, drainflow, runoff and sediment concentrations are not relevant for the formulation, as it dissociates into its component substances on contact with soil or water. The maximum individual application rates were used, with the product density of 1100.4 g/L (see KCP 2.6.1) to give an application rate in g product/ha. The PEC_{sw} calculations are summarised in Table 8.9-66 and Table 8.9-67.

Table 8.9-66: Formulated product application rates

Preparation	Use/Crop	Application rate (L/ha)	Product density (g/L)*	Application rate (g/ha)
CA3642	Winter/spring oilseed rape and sunflower	1.2	1.1004	1320
	Winter/spring cereals	1.4	1.1004	1541

* Taken from KCP 2.6.1 (Wang, Q. 2022)

Table 8.9-67: Formulated product PEC_{sw} values

Use/Crop	Application rate (g/ha)	PEC _{sw} (µg/L)			
		1m (2.759 % drift)	5m (0.5719 % drift)	10m (0.2904% drift)	20m (0.1475% drift)
Winter/spring oilseed rape and sunflower	1320	12.144	2.517	1.278	0.649
Winter/spring cereals	1541	14.168	2.937	1.491	0.757

zRMS comments:

The surface water exposure to formulation was validated by the zRMS using Spray Drift Calculator. Obtained results were in agreement with these reported in above and may be used in the aquatic risk assessment.

8.9.2.4 Relevant scenarios for PEC_{sw} assessment

To assist with national evaluations, the relevant worst-case FOCUS scenarios have been assessed for each country. For all substances except the metabolite prothioconazole-desthio and the active substance azoxystrobin, all FOCUS scenarios will result in acceptable risks without mitigation measures (please refer to Part B.9 for the full assessment). The assessment of prothioconazole-desthio and azoxystrobin requires consideration of appropriate exposure scenarios and mitigation measures.

Relevant PEC_{sw} for assessment in Poland and Belgium

For approval in Poland and Belgium, the D4, R1 and R3 scenarios are relevant for risk assessment. The following PEC_{sw} values show the worst-cases for each crop.

Table 8.9-68: Worst-case scenarios for Prothioconazole-desthio in Poland and Belgium

Crop	# Apps	STEP 3		STEP 4					
		Scenario	PEC _{sw}	5m drift buffer		10m VFS		20m VFS	
				Scenario	PEC _{sw}	Scenario	PEC _{sw}	Scenario	PEC _{sw}
Winter	1(Aut)	R1s	0.2791	R1s	0.2791	R1s	0.1224	R1s	0.06315
OSR	1(Spr)	R1s	0.2881	R1s	0.2881	R1s	0.1306	R1s	0.06842
Spring OSR	1	R1s	0.4218	R1s	0.4218	R1s	0.1915	R1s	0.1002
Winter cereals	1	R1s	0.3729	R1s	0.3729	R1s	0.1694	R1s	0.08866
	2	R1s	1.1210	R1s	1.1210	R1s	0.5091	R1s	0.2665
Spring cereals	1	D3d	0.1279	D3d	0.03462	D3d	0.01835	D4p	0.01205
	2	D3d	0.1158	D4p	0.04013	D4p	0.02828	D4p	0.01844
Sunflower*	1	R1s	0.6933	R1s	0.6933	R1s	0.3153	R1s	0.1652

*Poland only

Table 8.9-69: Worst-case scenarios for Azoxystrobin in Poland and Belgium

Crop	# Apps	STEP 3		STEP 4					
		Scenario	PEC _{sw}	5m drift buffer		10m VFS		20m VFS	
				Scenario	PEC _{sw}	Scenario	PEC _{sw}	Scenario	PEC _{sw}
Winter	1(Aut)	D4s	1.263	D4s	1.263	D4s	1.263	D4s	1.263
OSR	1(Spr)	D3d	1.137	R1s	1.104	R1s	0.5009	D3d	0.3661
Spring OSR	1	R1s	1.566	R1s	1.566	R1s	0.7110	D4s	0.4336
Winter cereals	1	R1s	1.399	R1s	1.399	R1s	0.6355	D4s	0.4515
	2	R1s	4.140	R1s	4.140	R1s	1.883	D4s	0.9963
Spring cereals	1	D3d	1.331	D4s	0.5017	D4s	0.5017	D4s	0.5017
	2	D3d	1.164	D4s	0.9051	D4s	0.9051	D4s	0.9051
Sunflower*	1	R1s	2.0891	R1s	1.885	R1s	0.8572	R1s	0.5271

*Poland only

Relevant PEC_{sw} for assessment in Austria and Czechia

For approval in Austria and Czechia, the D4, R1 and R3 scenarios are relevant for risk assessment. The following PEC_{sw} values show the worst-cases for each crop.

Table 8.9-70: Worst-case scenarios for Prothioconazole-desthio in Austria and Czech Republic

Crop	# Apps	STEP 3		STEP 4					
		Scenario	PEC _{sw}	5m drift buffer		10m VFS		20m VFS	
				Scenario	PEC _{sw}	Scenario	PEC _{sw}	Scenario	PEC _{sw}
Winter	1(Aut)	R3s	0.7631	R3s	0.7631	R3s	0.3473	R3s	0.1820
OSR	1(Spr)	R3s	0.4957	R3s	0.4957	R3s	0.2191	R3s	0.1135
Spring OSR	1	R1s	0.4218	R1s	0.4218	R1s	0.1915	R1s	0.1002
Winter cereals	1	R3s	0.4835	R3s	0.4835	R3s	0.2206	R3s	0.1157
	2	R3s	1.200	R3s	1.200	R3s	0.5477	R3s	0.2873
Spring cereals	1	D4s	0.08644	D4s	0.03157	D4p	0.01818	D4p	0.01205
	2	D4s	0.08120	D4p	0.04013	D4p	0.02828	D4p	0.01844

Table 8.9-71: Worst-case scenarios for Azoxystrobin in Austria and Czech Republic

Crop	# Apps	STEP 3		STEP 4					
		Scenar io	PEC _{sw}	5m drift buffer		10m VFS		20m VFS	
				Scena rio	PEC _{sw}	Scena rio	PEC _{sw}	Scena rio	PEC _{sw}
Winter OSR	1(Aut)	R3s	2.760	R3s	2.760	D4s	1.263	D4s	1.263
	1(Spr)	R3s	1.860	R3s	1.860	R3s	0.8215	R3s	0.4256
Spring OSR	1	R1s	1.566	R1s	1.566	R1s	0.7110	D4s	0.4336
Winter cereals	1	R3s	1.965	R3s	1.965	R3s	0.8966	R3s	0.4705
	2	R3s	4.528	R3s	4.528	R3s	2.067	R3s	1.084
Spring cereals	1	D4s	1.089	D4s	0.5017	D4s	0.5017	D4s	0.5017
	2	D4s	0.9725	D4s	0.9051	D4s	0.9051	D4s	0.9051

Relevant PEC_{sw} for assessment in Hungary

For approval in Hungary, the D3, D5, R1, R3 and R4 scenarios are considered relevant for risk assessment. The following PEC_{sw} values show the worst-cases for each crop.

Table 8.9-72: Worst-case scenarios for Prothioconazole-dethio in Hungary

Crop	# Apps	STEP 3		STEP 4					
		Scenar io	PEC _{sw}	5m drift buffer		10m VFS		20m VFS	
				Scena rio	PEC _{sw}	Scena rio	PEC _{sw}	Scena rio	PEC _{sw}
Winter OSR	1(Aut)	R3s	0.7631	R3s	0.7631	R3s	0.3473	R3s	0.1820
	1(Spr)	R3s	0.4957	R3s	0.4957	R3s	0.2191	R3s	0.1135
Spring OSR	1	R1s	0.4218	R1s	0.4218	R1s	0.1915	R1s	0.1002
Winter cereals	1	R3s	0.4835	R3s	0.4835	R3s	0.2206	R3s	0.1157
	2	R3s	1.200	R3s	1.200	R3s	0.5477	R3s	0.2873
Spring cereals	1	R4s	0.7175	R4s	0.7175	R4s	0.3263	R4s	0.1709
	2	R4s	1.386	R4s	1.386	R4s	0.6237	R4s	0.3254

Table 8.9-73: Worst-case scenarios for Azoxystrobin in Hungary

Crop	# Apps	STEP 3		STEP 4					
		Scenar io	PEC _{sw}	5m drift buffer		10m VFS		20m VFS	
				Scena rio	PEC _{sw}	Scena rio	PEC _{sw}	Scena rio	PEC _{sw}
Winter OSR	1(Aut)	R3s	2.760	R3s	2.760	R3s	1.257	D5s	0.9225
	1(Spr)	R3s	1.860	R3s	1.860	R3s	0.8215	R3s	0.4256
Spring OSR	1	R1s	1.566	R1s	1.566	R1s	0.7110	R1s	0.3723
Winter cereals	1	R3s	1.965	R3s	1.965	R3s	0.8966	R3s	0.4705
	2	R3s	4.528	R3s	4.528	R3s	2.067	R3s	1.084
Spring cereals	1	R4s	2.569	R4s	2.569	R4s	1.159	R4s	0.6052
	2	R4s	4.321	R4s	4.321	R4s	1.942	R4s	1.013

Relevant PEC_{sw} for assessment in Ireland

For approval in Ireland, the D4 scenario and at least one of the R scenarios must pass the risk assessment. The following PEC_{sw} values show the critical PEC_{sw} for each crop (the highest value from either D4 or the best-case R scenario).

Table 8.9-74: Worst-case scenarios for Prothioconazole-desthio in Ireland

Crop	# Apps	STEP 3		STEP 4					
		Scenar io	PEC _{sw}	5m drift buffer		10m VFS		20m VFS	
				Scena rio	PEC _{sw}	Scena rio	PEC _{sw}	Scena rio	PEC _{sw}
Winter OSR	1(Aut)	R1s	0.2791	R1s	0.2791	R1s	0.1224	R1s	0.06315
	1(Spr)	R1s	0.2881	R1s	0.2881	R1s	0.1306	R1s	0.06842
Spring OSR	1	R1s	0.4218	R1s	0.4218	R1s	0.1915	R1s	0.1002
Winter cereals	1	R4s	0.2592	R4s	0.2592	R4s	0.1170	R4s	0.06104
	2	R4s	0.7536	R4s	0.7536	R4s	0.3400	R4s	0.1775
Spring cereals	1	R4s	0.7175	R4s	0.7175	R4s	0.3263	R4s	0.1709
	2	R4s	1.386	R4s	1.386	R4s	0.6237	R4s	0.3254

Table 8.9-75: Worst-case scenarios for Azoxystrobin in Ireland

Crop	# Apps	STEP 3		STEP 4					
		Scenar io	PEC _{sw}	5m drift buffer		10m VFS		20m VFS	
				Scena rio	PEC _{sw}	Scena rio	PEC _{sw}	Scena rio	PEC _{sw}
Winter OSR	1(Aut)	D4s	1.263	D4s	1.263	D4s	1.263	D4s	1.263
	1(Spr)	R1s	1.104	R1s	1.104	R1s	0.5009	D4s	0.3661
Spring OSR	1	R1s	1.566	R1s	1.566	R1s	0.7110	D4s	0.4336
Winter cereals	1	R4s	1.015	R4s	1.015	R4s	0.4583	D4s	0.4515
	2	R4s	2.833	R4s	2.833	R4s	1.279	D4s	0.9963
Spring cereals	1	R4s	2.569	R4s	2.569	R4s	1.159	R4s	0.6052
	2	R4s	4.321	R4s	4.321	R4s	1.942	R4s	1.013

Relevant PEC_{sw} for assessment in Romania

For approval in Romania, the D4, D5, R1, R3 and R4 scenarios are considered relevant for risk assessment. The following PEC_{sw} values show the worst-cases for each crop.

Table 8.9-76: Worst-case scenarios for Prothioconazole-desthio in Romania

Crop	# Apps	STEP 3		STEP 4					
		Scenar io	PEC _{sw}	5m drift buffer		10m VFS		20m VFS	
				Scena rio	PEC _{sw}	Scena rio	PEC _{sw}	Scena rio	PEC _{sw}
Winter OSR	1(Aut)	R3s	0.7631	R3s	0.7631	R3s	0.3473	R3s	0.1820
	1(Spr)	R3s	0.4957	R3s	0.4957	R3s	0.2191	R3s	0.1135
Spring OSR	1	R1s	0.4218	R1s	0.4218	R1s	0.1915	R1s	0.1002
Winter cereals	1	R3s	0.4835	R3s	0.4835	R3s	0.2206	R3s	0.1157
	2	R3s	1.200	R3s	1.200	R3s	0.5477	R3s	0.2873
Spring cereals	1	R4s	0.7175	R4s	0.7175	R4s	0.3263	R4s	0.1709
	2	R4s	1.386	R4s	1.386	R4s	0.6237	R4s	0.3254

Table 8.9-77: Worst-case scenarios for Azoxystrobin in Romania

Crop	# Apps	STEP 3		STEP 4					
		Scenar io	PEC _{sw}	5m drift buffer		10m VFS		20m VFS	
				Scena rio	PEC _{sw}	Scena rio	PEC _{sw}	Scena rio	PEC _{sw}
Winter OSR	1(Aut)	R3s	2.760	R3s	2.760	D4s	1.263	D4s	1.263
	1(Spr)	R3s	1.860	R3s	1.860	R3s	0.8215	R3s	0.4256
Spring OSR	1	R1s	1.566	R1s	1.566	R1s	0.7110	D4s	0.4336
Winter cereals	1	R3s	1.965	R3s	1.965	R3s	0.8966	R3s	0.4705
	2	R3s	4.528	R3s	4.528	R3s	2.067	R3s	1.084
Spring cereals	1	R4s	2.569	R4s	2.569	R4s	1.159	R4s	0.6052
	2	R4s	4.321	R4s	4.321	R4s	1.942	R4s	1.013

Relevant PEC_{sw} for assessment in Slovakia

For approval in Romania, the D4, D5 and R1 scenarios are considered relevant for risk assessment. The following PEC_{sw} values show the worst-cases for each crop.

Table 8.9-78: Worst-case scenarios for Prothioconazole-dethio in Slovakia

Crop	# Apps	STEP 3		STEP 4					
		Scenario	PEC _{sw}	5m drift buffer		10m VFS		20m VFS	
				Scenario	PEC _{sw}	Scenario	PEC _{sw}	Scenario	PEC _{sw}
Winter	1(Aut)	R1s	0.2791	R1s	0.2791	R1s	0.1224	R1s	0.06315
OSR	1(Spr)	R1s	0.2881	R1s	0.2881	R1s	0.1306	R1s	0.06842
Spring	1	R1s	0.4218	R1s	0.4218	R1s	0.1915	R1s	0.1002
OSR									
Winter	1	R1s	0.3729	R1s	0.3729	R1s	0.1694	R1s	0.08866
cereals	2	R1s	1.121	R1s	1.121	R1s	0.5091	R1s	0.2665
Spring	1	D5s	0.1227	D5s	0.04484	D5s	0.02376	D5s	0.01234
cereals	2	D5s	0.1107	D5s	0.04013	D4p	0.02828	D4p	0.01844

Table 8.9-79: Worst-case scenarios for Azoxystrobin in Slovakia

Crop	# Apps	STEP 3		STEP 4					
		Scenario	PEC _{sw}	5m drift buffer		10m VFS		20m VFS	
				Scenario	PEC _{sw}	Scenario	PEC _{sw}	Scenario	PEC _{sw}
Winter	1(Aut)	D4s	1.263	D4s	1.263	D4s	1.263	D4s	1.263
OSR	1(Spr)	R1s	1.104	R1s	1.104	R1s	0.5009	D4s	0.3661
Spring	1	R1s	1.566	R1s	1.566	R1s	0.7110	D4s	0.4336
OSR									
Winter	1	R3s	1.965	R3s	1.965	R3s	0.8966	R3s	0.4705
cereals	2	R3s	4.528	R3s	4.528	R3s	2.067	R3s	1.084
Spring	1	D5s	1.122	D4s	0.5017	D4s	0.5017	D4s	0.5017
cereals	2	D5s	1.010	D4s	0.9051	D4s	0.9051	D4s	0.9051

Relevant PEC_{sw} for assessment in Germany and the Netherlands

These member states do not use FOCUS STEPS for risk assessment and specific national models are required. Please refer to the national addenda.

8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

8.10.1 Prothioconazole and its metabolites

The endpoints for prothioconazole in the EFSA 2007 conclusion are sufficient to assess the risk from the product and are summarised below.

Table 8.10-1 Summary of atmospheric degradation and behaviour

Compound	Prothioconazole
Direct photolysis in air	Not studied – no data requested
Quantum yield of direct phototransformation	Not studied – no data requested
Photochemical oxidative degradation in air	Prothioconazole: Half-life: 1.1 hours Chemical lifetime: 1.6 hours Calculated according to Atkinson (AOPWIN v. 1.87, 12 hour day, 1.5×10^6 OH radicals/cm ³) prothioconazole-desthio (M04): Half-life: 14.2 hours Chemical lifetime: 20.5 hours Calculated according to Atkinson (AOPWIN v. 1.87, 12 hour day, 1.5×10^6 OH radicals/cm ³)
Volatilisation	Vapour pressure: $<4 \times 10^{-7}$ Pa Henry's law constant : 3×10^{-5} Pa.m ³ .mol ⁻¹ Laboratory route and rate soil studies indicated that volatilisation of prothioconazole and prothioconazole-desthio (M04) is unlikely to take place because no volatiles were detected at levels above 0.1% AR.
Metabolites	Not studied – no data requested

The vapour pressure at 20 °C of the active substance was $<4 \times 10^{-7}$ Pa, below the minimum detectable level in the study. Hence the active substance is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance will be negligible. Any trace amounts reaching the air will quickly degrade in the atmosphere via reaction with OH radicals and there is no risk of long-range transport or atmospheric accumulation.

zRMS comments:

Provided above information is in line with EU agreed data reported in EFSA Scientific Report (2007) 106, 1-98. Taking into account the low vapour pressure ($<10^{-5}$ Pa) and DT₅₀ in air <2 days, prothioconazole is not expected to be subject to volatilisation and the long- or short-range transport. Taking this into account the contamination of the atmosphere with prothioconazole from the intended uses of CA3642 is considered to be negligible.

8.10.2 Azoxystrobin and its metabolites

The endpoints for azoxystrobin in the EFSA 2010 conclusion are sufficient to assess the risk from the product and are summarised below.

Table 8.10-2: Summary of atmospheric degradation and behaviour

Compound	Azoxystrobin
Direct photolysis in air	Not studied – no data requested
Quantum yield of direct phototransformation	Not studied – no data requested
Photochemical oxidative degradation in air	DT ₅₀ of 2.7 hours derived by the Atkinson model (AOPWIN version 1.8). OH (12h) concentration assumed = 1.5×10^6 cm ⁻³
Volatilisation	Vapour pressure (Pa): 1.1×10^{-10} Henry's Law Constant (Pa.m ³ /mol): 7.4×10^{-9}

	No significant tendency for volatilisation was observed from soil and bean leaf surfaces up to 24 hours after the application of radiolabelled azoxystrobin (dose rates: 264 or 291 g as/ha).
Metabolites	None

The vapour pressure at 20 °C of the active substance azoxystrobin is $< 10^{-5}$ Pa. Hence the active substance azoxystrobin is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance azoxystrobin due to volatilization with subsequent deposition should not be considered. Any trace amounts reaching the air will quickly degrade in the atmosphere via reaction with OH radicals and there is no risk of long-range transport or atmospheric accumulation.

zRMS comments:

Provided above information is in line with EU agreed data reported in EFSA Journal 2010; 8(4):1542. Taking into account the low vapour pressure ($<10^{-5}$ Pa) and DT₅₀ in air <2 days, azoxystrobin is not expected to be subject to volatilisation and the long- or short-range transport. Taking this into account the contamination of the atmosphere with azoxystrobin from the intended uses of CA3642 is considered to be negligible.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
K-CP 9.2.4/01	Hale, M.	2022	CA3642: Predicted Environmental Concentrations in Groundwater Following Application to Cereals and Oilseed Rape, Using FOCUS-PEARL, FOCUS-PELMO and FOCUS-MACRO Staphyt Regulatory, Report No 22/125 Non-GLP Unpublished	N	Nufarm Crop Products UK
K-CP 9.2.4/02	Hale, M	2023	CA3642: Predicted Environmental Concentrations in Groundwater Following Application to Sunflower in Poland, Using FOCUS PEARL, FOCUS-PELMO and FOCUS-MACRO Report No 23/94 Non-GLP Unpublished	N	Nufarm Crop Products UK
K-CP 9.2.5/01	Hale, M.	2022	CA3642: Predicted Environmental Concentrations in Surface Water Following Application to Cereals and Oilseed Rape, Using FOCUS STEPS 1-4 Staphyt Regulatory, Report No 22/126 Non-GLP Unpublished	N	Nufarm Crop Products UK
K-CP 9.2.5/02	Hale, M	2023	CA3642: Predicted Environmental Concentrations in Surface Water Following Application to Sunflower in Poland, Using FOCUS STEPS 1-4 Report No 23/95 Non-GLP Unpublished	N	Nufarm Crop Products UK

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
As all endpoints for the active substances and its metabolites were taken from the EU review of prothioconazole and azoxystrobin, for the list of respective studies please refer to Volume 2 of the RAR.					

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
There were no data submitted by the Applicant and not relied on.					

List of data relied on not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
There were no data relied on and not submitted by the Applicant.					