

REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: FGF11

Product name(s): Telaron Alpha / Patton Alpha
Azoxystrobin 160 + Prothioconazole 200 g/L SC

Chemical active substance(s):

Azoxystrobin, 160 g/L
Prothioconazole, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(new authorization)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: November 2024, update January 2025

MS Finalisation date: February 2025 (initial Core Assessment)

August 2025 (final Core Assessment)

Version history

When	What
November 2024	dRR Part B – Section 8; Version 1 submitted by applicant
January 2025	v2 - Revised version from Applicant following request from evaluator. All changes are highlighted in green.
February 2025	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through~~ and ~~shaded~~ for transparency. Following the evaluation and before sending the document for commenting, all coloured highlighting was removed, from the parts updated by the Applicant, for better legibility.
August 2025	Final report (Core Assessment updated following the commenting period). No additional information or assessments after the commenting period.

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8 Fate and behaviour in the environment (KCP 9)

This document reviews the environmental fate studies and modelling for the product FGF11 / Azoxystrobin 160 + Prothioconazole 200 g/L SC containing the active substances azoxystrobin and prothioconazole.

Azoxystrobin and prothioconazole were approved in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, following Commission Implementing Regulation (EU) No 1199/2013 amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

Where appropriate this document refers to the conclusions of the EU review of the active substances azoxystrobin (**Azoxystrobin, EFSA Journal 2010; 8(4):1542 and Confirmatory Data, EC, 2014**) and prothioconazole (**EFSA Scientific Report, 2007, 106, 1-98**).

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.

Concentrations of FGF11 / Azoxystrobin 160 + Prothioconazole 200 g/L SC in various environmental compartments are predicted following the proposed use pattern. The predicted environmental concentrations (PEC values) in soil, surface water, sediment, and groundwater are provided. The long-term concentrations are based on results obtained for the active substance contained in the formulation.

A summary of modelled substances (active ingredients and their respective metabolites) at the different compartments is provided in Table 8-1.

Table 8-1: Active substances and their metabolites as considered in the evaluation

Compound name	Compartment(s)
Azoxystrobin	Soil, groundwater, surface water, sediment, air
R401553	Soil, groundwater, surface water, sediment
R402173	Soil, groundwater, surface water, sediment
R234886	Soil, groundwater, surface water, sediment
Prothioconazole	Soil, groundwater, surface water, sediment, air
JAU 6476-S-methyl (M01)	Soil, groundwater, surface water, sediment
JAU 6476-desthio (M04)	Soil, groundwater, surface water, sediment
JAU 6476-thiazocine (M12)	Surface water, sediment
1,2,4-triazole (M13)	Surface water, sediment

8.1 Critical GAP and overall conclusions

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. (e)	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 ^(f)	Conclusions Groundwater
					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			
1	CEU (AT, BE, CZ, DE, HU, IE, NL, PL, RO, SI, SK) FR Maritime	Winter wheat (TRZAW), Spring wheat (TRZAS), Durum wheat (TRSDU), Spelt (TRZSP)	F	Wheat: Septoria leaf blotch (<i>Zymoseptoria tritici</i>), yellow rust (<i>Puccinia striiformis</i>), brown rust (<i>Puccinia recondita</i>)	Foliar spray application	BBCH 30 – 69	a) 1 b) 1	-	a) 1.0 L/ha b) 1.0 L/ha	a) 160 g as/ha (AZY) / 200 g as/ha (PTZ) b) 160 g as/ha (AZY) / 200 g as/ha (PTZ)	100 – 400	35		A
2	CEU (AT, BE, CZ, DE, HU, IE, NL PL, RO, SI, SK) FR Maritime	Winter triticale (TTLWI), Spring triticale (TTLSO)	F	Wheat: Septoria leaf blotch (<i>Zymoseptoria tritici</i>), yellow rust (<i>Puccinia striiformis</i>), brown rust (<i>Puccinia recondita</i>)	Foliar spray application	BBCH 30 – 69	a) 1 b) 1	-	a) 1.0 L/ha b) 1.0 L/ha	a) 160 g as/ha (AZY) / 200 g as/ha (PTZ) b) 160 g as/ha (AZY) / 200 g as/ha (PTZ)	100 – 400	35		A
3	CEU (AT, BE, CZ, DE, HU, IE, NL PL, RO, SI, SK) FR Maritime	Winter barley (HORVW), Spring barley (HORVS)	F	Net blotch (<i>Pyrenophora teres</i>) Ramularia (<i>Ramularia collo-cygni</i>) Leaf blotch (<i>Rhynchosporium secali</i>) Rust (<i>Puccinia hordei</i>)	Foliar spray application	BBCH 30 – 59	a) 1 b) 1	-	a) 1.0 L/ha b) 1.0 L/ha	a) 160 g as/ha (AZY) / 200 g as/ha (PTZ) b) 160 g as/ha (AZY) / 200 g as/ha (PTZ)	100 – 400	35		A
4	CEU (AT, BE, CZ, DE, HU, IE, NL PL, RO, SI, SK) FR Maritime	Winter oilseed rape (BRSNW), Spring oilseed rape (BRSNS)	F	Cottony rot (<i>Sclerotinia sclerotiorum</i>) Black spot (<i>Alternaria brassicae</i>)	Foliar spray application	BBCH 61 – 73	a) 1 b) 1	-	a) 1.0 L/ha b) 1.0 L/ha	a) 160 g as/ha (AZY) / 200 g as/ha (PTZ) b) 160 g as/ha (AZY) / 200 g as/ha (PTZ)	100 – 400	35		A
5	CEU (AT, BE, CZ, DE, HU, IE, NL PL, RO, SI, SK) FR Maritime	Winter rye (SECCW), Spring rye (SECCS)	F	Brown rust (<i>Puccinia recondita</i>)	Foliar spray application	BBCH 30 – 69	a) 1 b) 1	-	a) 1.0 L/ha b) 1.0 L/ha	a) 160 g as/ha (AZY) / 200 g as/ha (PTZ) b) 160 g as/ha (AZY) / 200 g as/ha (PTZ)	100 – 400	35		A
6	CEU (AT, BE, CZ, DE, HU, IE, NL PL, RO, SI, SK) FR Maritime	Winter wheat (TRZAW), Spring wheat (TRZAS), Durum wheat (TRSDU), Spelt (TRZSP)	F	Fusarium (<i>microdochium nivale</i> , <i>Fusarium roseum</i>)	Foliar spray application	BBCH 59 – 69	a) 1 b) 1	-	a) 1.0 L/ha b) 1.0 L/ha	a) 160 g as/ha (AZY) / 200 g as/ha (PTZ) b) 160 g as/ha (AZY) / 200 g as/ha (PTZ)	100 – 400	35		A

* 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

Remarks
table:

- (1)

Numeration necessary to allow references
- (2)

Use official codes/nomenclatures of EU
- (3)

For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (4)

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
- (5)

Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named
- (6)

Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
- (7)

Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- (8)

The maximum number of application possible under practical conditions of use must be provided
- (9)

Minimum interval (in days) between applications of the same product.
- (10)

For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products
- (11)

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

If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
- (13)

PHI - minimum pre-harvest interval
- (14)

Remarks may include: Extent of use/economic importance/restrictions

Table 8.1-2: Assessed (critical) uses during 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	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	EU	Broccoli / Cauliflower / Brussel sprouts / Kale	F	<i>Albugo candida</i> , <i>Alternaria brassicae</i> , <i>Mycosphaerella brassicicola</i> , <i>Peronospora parasitica</i>	Foliar spray	BBCH 35 – BBCH 39	1-2	12		0.250	200-600	14	
2	EU	Barley	F	<i>Pyrenophora teres Puccinia hordei Rhynchosporium secalis Gaeumannomyces graminis var. Tritici</i> Barley spotting	Foliar spray	BBCH 31 – BBCH 59	1-2	14		0.250	200-600	35	*Timing of applications determined primarily by growth stage; 1st no later than BBCH39, 2nd no later than BBCH59.
3	EU	Wheat	F	<i>Septoria tritici Septoria nodorum Puccinia striiformis Puccinia recondita Gaeumannomyces graminis var. tritici</i>	Foliar spray	BBCH 31 – BBCH 69	1-2	14		0.250	200-600	35	**Timing of applications determined primarily by growth stage; 1st application no later than BBCH39, 2nd application no later than BBCH69.

* 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 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 or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	EU	Wheat, Triticale, Rye, Spelt	F		Foliar spray	BBCH 25-69	1-2	14-21	1.25	a) 187.5 b) 375			Product: Aviator
2	EU	Barley, Oat	F		Foliar spray	BBCH 25-61	1-2	14-21	1.0	a) 150 b) 300			Product: Aviator
3	EU	Wheat, Barley, Oat, Spelt, Triticale	F		Seed treatment	BBCH 00	1	-	-	18 - 23			Product: Redigo

* 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 azoxystrobin potentially relevant for exposure assessment

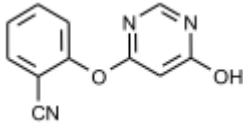
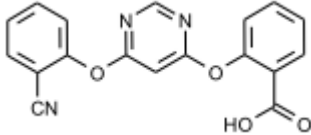
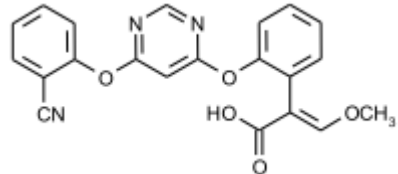
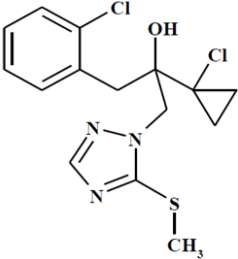
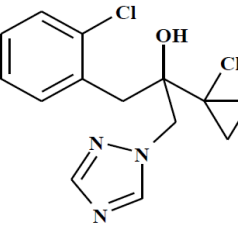
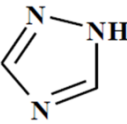
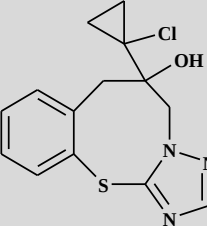
Metabolite	Molar mass (g/mol)	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
R401553	213.2		<u>Soil</u> : 17 % AR (photolysis) <u>Water</u> : 8.9 % AR (photolysis)	PEC _{SOIL} , PEC _{GW} , PEC _{SW/SED}
R402173	333.3		<u>Soil</u> : 17 % AR (photolysis)	PEC _{SOIL} , PEC _{GW} , PEC _{SW/SED}
R234886	389.4		<u>Soil</u> : 28.8 % AR <u>Water</u> : 10.8 % AR <u>Sediment</u> : 15.6 % AR <u>Whole system</u> : 18 % AR	PEC _{SOIL} , PEC _{GW} , PEC _{SW/SED}

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

Metabolite	Molar mass (g/mol)	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
JAU 6476-S-methyl (M01)	358.3		<u>Soil</u> : 14.6 % <u>water/sediment (anaerobic)</u> : 77% (in sediment, not detected in water) <u>water/sediment (aerobic)</u> : 12.7% (whole system); 3.1% (water); 9.6% (sediment)	PEC _{SOIL} , PEC _{GW} , PEC _{SW/SED}
JAU 6476-desthio (M04)	312.2		<u>Soil</u> : 57.1 % <u>Water</u> : 32.3% (water-sediment studies), 55.7 % (aqueous photolysis) <u>Sediment</u> : 26.9 % <u>Whole system</u> : 54.6 %	PEC _{SOIL} , PEC _{GW} , PEC _{SW/SED}
1,2,4-triazole (M13)	69.1		<u>Water</u> : 37.2 % <u>Sediment</u> : 6.1 % <u>Whole system</u> : 41.8 %	PEC _{SW/SED}
JAU 6476-thiazocine (prothioconazole-thiazocine, M12)	307.8		Aqueous photolysis study: 14.1% on day 5	Considered not relevant in EFSA (2007)

zRMS comments:

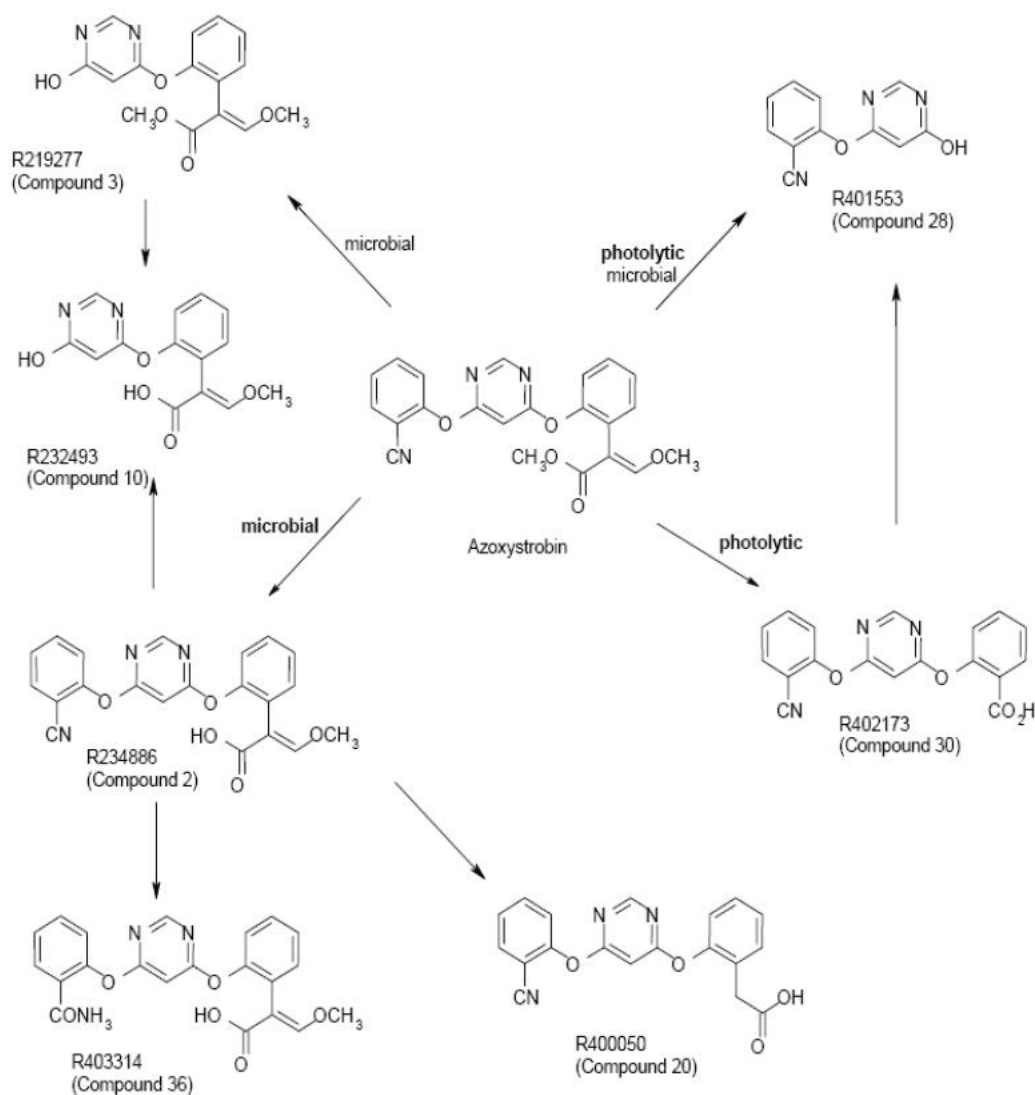
Information regarding azoxystrobin metabolites is in line with EU agreed endpoints reported in EFSA Journal 2010; 8(4):1542. Information regarding prothioconazole metabolites is in general in line with EU agreed endpoints reported in EFSA Scientific Report (2007) 106, with some minor corrections.

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.

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.

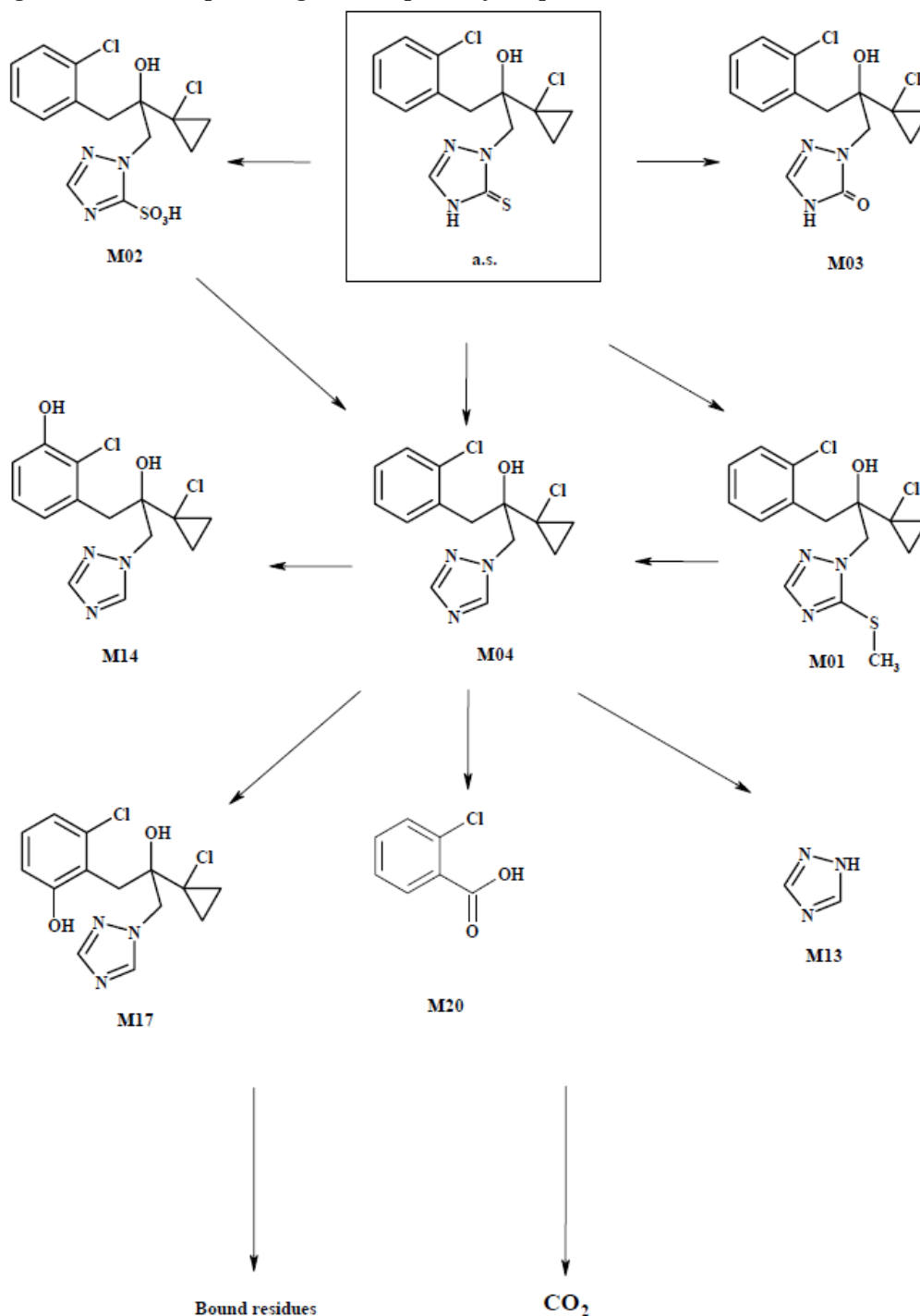
8.3.1.1 Azoxystrobin and its metabolites



8.3.1.2 Prothioconazole and its metabolites

The proposed degradation pathway is shown in the figure below.

Figure 8.3-1: Proposed degradation pathway for prothioconazole in aerobic soil



a.s. = prothioconazole
 M01 = prothioconazole -S-methyl
 M02 = prothioconazole -sulfonic acid
 M03 = prothioconazole -triazolinone
 M04 = prothioconazole -desthio

M13 = 1,2,4-triazole
 M14 = prothioconazole -3-hydroxy-desthio
 M17 = prothioconazole -6-hydroxy-desthio
 M20 = 2-chlorobenzoic acid

8.3.2 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.2.1 Azoxystrobin and its metabolites

Studies on the aerobic degradation rates of azoxystrobin and its metabolites R401553, R402173 and R234886 are data provided in support of the active substance. All relevant detailed experimental information has been submitted for EU review of azoxystrobin (**Azoxystrobin, EFSA Journal 2010; 8(4):1542 and Confirmatory Data, EC, 2014**).

Table 8.3-1: Summary of aerobic degradation rates for azoxystrobin – Laboratory studies

Parent azoxystrobin, laboratory studies, aerobic conditions										
Soil name	Soil type	pH (H ₂ O)	t. °C	MWHC %	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa	Chi ² (%)	Kinetic model	Evaluated on EU level Reference
18 Acres (Tummons, 1995)	sandy clay loam	6.4	20	40 %	56.4	187	35.2	3.70	SFO	Yes / EFSA (2010)
East Anglia	sand	7.9	20	40 %	66.9	222	57.2	5.34	SFO	
Wisborough Green	silty clay loam	5.9	20	40 %	94.1	313	54.1	5.60	SFO	
18 Acres (Warinton, 1996)	sandy clay loam	7	20	75% 1/3 bar	87.0	289	65.2	2.06	SFO	
Hyde Farm	sandy clay loam	7	20	75% 1/3 bar	72.8	242	48.5	7.10	SFO	
Visalia	sandy loam	8.4	20	75% 1/3 bar	141.6	470	79.9	2.97	SFO	
Derbyshire	clay loam	7.5	20	field capacity	118.4	393	118.4	4.84	SFO	
Holland	sandy loam	8.2	20	field capacity	153.4	510	153.4	1.92	SFO	
Lincolnshire	sandy loam	7.4	20	field capacity	248	824	248	7.5	SFO	
Geometric mean (n = 9)					109.4	363.3 ^a	84.5 ^a			
pH-dependency					-	-	No			

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

Table 8.3-2: Summary of aerobic degradation rates for metabolite R234886 – Laboratory studies

Metabolite R234886, laboratory studies, aerobic conditions											
Soil name	Soil type	pH	t. °C	MWHC %	ff (-)	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa	Chi ² (%)	Kinetic model	Evaluated on EU level Reference
Wisborough Green	silty clay loam	5.3	20	pF 2	- ^a	33.2	259	97.6 ^b	3.4	DFOP	Yes / EFSA (2010) and Confirmatory Data (2014)
Frensham	sandy loam	5.4	20	pF 2	- ^a	52.5	309	110 ^b	2.4	DFOP	
Ohio	sandy clay loam	5.8	20	pF 2	- ^a	89.9	299	89.9	5.0	SFO	
Nuptown	loamy sand	6.2	20	pF 2	- ^a	18.3	203	94.9 ^b	6.0	DFOP	
Georgia	sandy loam	7.1	20	pF 2	- ^a	102	339	102	5.7	SFO	
18 Acres	sandy clay loam	7.0	20	75% 1/3 bar	0.7764	23.7	78.8	17.8	5.9	SFO	
Gartenacker	loamy sand	7.3	20	pF 2	- ^a	25.7	85.3	25.7	3.6	SFO	
Pappelacker	-	7.2	20	pF 2	- ^a	47.1	156	47.1	1.4	SFO	
Hyde Farm	sandy clay loam	7.0	20	75% 1/3 bar	0.9716	31.8	105.6	21.2	12.3	SFO	
East Anglia	loamy sand	7.9	20	40	- ^a	56.5	188	43.4	3.3	SFO	
North Dakota	sandy loam	7.8	20	pF 2	- ^a	65.4	217	65.4	4.7	SFO	
Vetroz	-	7.9	20	pF 2	- ^a	69.1	229	69.1	2.8	SFO	
Geometric mean (pH < 7) (n = 5)					-	-	-	98.6			
Geometric mean (pH ≥ 7) (n = 7)					-	-	-	36.7			
Arithmetic mean					0.874	-	-	-			
pH-dependency					Yes						

^a R234886 applied as parent therefore no formation fractions.

^b Slow phase DFOP DT₅₀ was calculated for the Frensham, Wisborough Green and Nuptown soils.

Table 8.3-3: Summary of aerobic degradation rates for metabolite R401553 – Laboratory studies

Metabolite R401553, laboratory studies, aerobic conditions											
Soil name	Soil type	pH	t. °C	MWHC %	ff (-)	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa	Chi ² (%)	Kinetic model	Evaluated on EU level Reference
Frensham	sandy loam	6.6	20	40	- ^a	1.36	4.52	0.9	9.1	SFO	Yes / EFSA (2010)
Wisborough Green	silty clay loam	6.4	20	40	- ^a	1.59	5.29	0.9	10.9	SFO	
East Anglia	loamy sand	7.9	20	40	- ^a	2.01	6.68	1.5	12.3	SFO	
Geometric mean (n = 3)						1.63	5.43	1.07			
pH-dependency						-	-	No			

^a R401553 applied as parent therefore no formation fractions.

Bold values used for modelling.

Table 8.3-4: Summary of aerobic degradation rates for metabolite R402173 – Laboratory studies

Metabolite R402173, laboratory studies, aerobic conditions											
Soil name	Soil type	pH	t. °C	MWHC %	ff (-)	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa	Chi ² (%)	Kinetic model	Evaluated on EU level Reference
Frensham	sandy loam	6.6	20	40	- ^a	8.44	28.0	5.7	8.6	SFO	Yes / EFSA (2010)
Wisborough Green	silty clay loam	6.4	20	40	- ^a	4.24	14.1	2.4	12.3	SFO	
East Anglia	loamy sand	7.9	20	40	- ^a	9.80	32.6	7.5	12.7	SFO	
Geometric mean (n = 3)						7.05	23.43	4.68			
pH-dependency						-	-	No			

^a R402173 applied as parent therefore no formation fractions.

Bold values used for modelling.

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.

8.3.2.2 Prothioconazole and its metabolites

Studies on the aerobic degradation rates of prothioconazole (JAU 6476) and its metabolites JAU 6476-S-methyl and JAU-6476-desthio are data provided in support of the active substance and have been already evaluated during Annex I inclusion (**EFSA Scientific Report, 2007, 106, 1-98**).

Table 8.3-5: Summary of aerobic degradation rates for prothioconazole – Laboratory studies

Parent prothioconazole, laboratory studies, aerobic conditions									
Soil name	Soil type	pH (CaCl ₂)	t.°C	MWHC %	DT ₅₀ (d)	DT ₉₀ (d)	R ² (-)	Kinetic model	Evaluated on EU level Reference
Laacher Hof (DE)	Sandy loam	6.6	20	48	0.07	5.3	1.00	FOMC	Yes / EFSA (2007)
Stanley (US)	Silty clay loam	5.9	20	48	0.7	78.2	0.989	FOMC	
Höfchen (DE)	Silt	6.8	20	75%1/3 bar	0.30	0.99	0.990	SFO	
Byromville (US)	Loamy sand	6.1	20	75%1/3 bar	1.27	4.22	0.981	SFO	
Geometric mean (n = 4)					0.370	6.45			
pH-dependency					No				

Table 8.3-6: Summary of aerobic degradation rates for metabolite JAU 6476-S-methyl – Laboratory studies

Metabolite JAU 6476-S-methyl, laboratory studies, aerobic conditions – Metabolite applied										
Soil name	Soil type	pH (CaCl ₂)	t.° C	MWHC %	f.f.	DT ₅₀ (d)	DT ₉₀ (d)	R ² (-)	Kinetic model	Evaluated on EU level Reference
Höfchen	Loamy silt	6.5	20	40	-	5.9	19.6	0.97	SFO	Yes / EFSA *2007)
Laacher Hof AIII	Loamy silt	6.7	20	40	-	27.2	90.2	0.955	SFO	
Laacher Hof AXXa	Sandy loam	6.3	20	40	-	8.2	27.2	0.959	SFO	
Stanley	Silty clay	5.2	20	40	-	46.0	153	0.965	SFO	
Geometric mean (n = 4)					-	15.7	52.1			
Arithmetic mean (n = 4)					-	-	-			
pH-dependency					-	No				

Table 8.3-7: Summary of aerobic degradation rates for metabolite JAU 6476-desthio – Laboratory studies

Metabolite JAU 6476-desthio, laboratory studies, aerobic conditions										
Soil name	Soil type	pH (CaCl ₂)	t.°C	MWHC %	f.f.	DT ₅₀ (d)	DT ₉₀ (d)	R ² (-)	Kinetic model	Evaluated on EU level Reference
Höfchen	Loamy silt	6.5	20	40	-	34.0	113	0.820	SFO	Y / EFSA (2007)
Laacher Hof AIII	Loamy silt	6.7	20	40	-	29.6	59.2 98.3	0.987	SFO	
Laacher Hof AXXa	Sandy loam	6.3	20	40	-	7.0	23.2	0.985	SFO	
Stanley	Silty clay	5.2	20	40	-	18.6	61.9	0.979	SFO	
Geometric mean (n = 4)					-	19.0	55.67 63.2			
Arithmetic mean (n = 4)					-	-	-			
pH-dependency					-	No				

zRMS comments:

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

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.

8.3.3 Anaerobic degradation in soil (KCP 9.1.1.1)

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

8.3.3.1 Azoxystrobin and its metabolites

Studies on the anaerobic degradation rates of azoxystrobin are data provided in support of the active substance. All relevant detailed experimental information has been submitted for EU review of azoxystrobin (Azoxystrobin, EFSA Journal 2010; 8(4):1542).

Table 8.3-8: Summary of anaerobic degradation rates for azoxystrobin – Laboratory studies

Parent azoxystrobin, Laboratory studies, anaerobic conditions									
Soil type (USDA)	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 / Reference
Sandy clay loam	7.0	20	Flooded	59.8	198	59.8	3.41	SFO	Yes / EFSA (2010)
Sandy loam	7.0	20	Flooded	49.0	163	49.0	6.76	SFO	
Geometric mean (n = 2)				54.1	180	54.1			

zRMS comments:

Anaerobic soil degradation data for azoxystrobin are in line with the EU agreed endpoints reported in EFSA Journal 2010; 8(4):1542.

8.3.3.2 Prothioconazole and its metabolites

Studies on the anaerobic degradation rates of prothioconazole are data provided in support of the active substance. All relevant detailed experimental information has been submitted for EU review of prothioconazole (**Prothioconazole, EFSA Scientific Report, 2007, 106, 1-98**).

Not applicable.

A case was presented that due to the proposed use patterns as a foliar fungicide prothioconazole will not, in general, be exposed to anaerobic conditions. However, since a seed treatment formulation is also being considered, an anaerobic aquatic metabolism study was submitted. The anaerobic study indicated relatively rapid breakdown of parent to prothioconazole-S-methyl (M01), which seems to accumulate. This might indicate that if prothioconazole was applied to an anaerobic soil there would be significant formation of M01. However, the only major period of anaerobic conditions is likely to be in the winter, i.e. following autumn seed treatment. Drilling will only take place in relatively good aerobic conditions under which there will be relatively rapid degradation of the parent compound. Therefore, it is unlikely that there would be significant formation of M01 under field conditions.

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 FGF11 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 Azoxystrobin and its metabolites

Studies on the field dissipation rates of azoxystrobin are data provided in support of the active substance. All relevant detailed experimental information has been submitted for the EU review of azoxystrobin (**Azoxystrobin, EFSA Journal 2010; 8(4):1542 and Confirmatory Data, EC, 2014**).

Table 8.4-1: Summary of aerobic degradation rates for azoxystrobin – Field studies

Parent azoxystrobin, field studies, aerobic conditions, applied to bare soil and incorporated								
Location	Soil type (USDA)	pH	Depth (cm)	DT₅₀ (d)	DT₉₀ (d)	DT₅₀ (d) 20°C pF2/10kPa	Kinetic model	Evaluated on EU level Reference
Spalding, Lincolnshire (UK)	sandy clay loam	7.5 (0-15 cm)	30	261.9	869.9	106.7	SFO	Yes / EFSA (2010)
Nagele (NL)	silty clay loam	7.9 (0-15 cm)	30	186.4	619.3	86.3	SFO	
Shirebrook, Derbyshire (UK)	sandy clay loam (0-20 cm depth)	6.7 (0-20 cm)	30	120.9	401.7	56.1	SFO	
Geometric mean (n = 3)						80.2		
Parent azoxystrobin, field studies, aerobic conditions, applied to bare soil and not incorporated								
Location	Soil type (USDA)	pH	Depth (cm)	DT₅₀ quick phase (d)	DT₅₀ slow phase (d)		Kinetic model	Evaluated on EU level Reference
Volpedo (IT)	clay loam	8.2 (0-20cm)	30	2.62	80.6		DFOP	Yes / EFSA (2010)
Bienenbittel-Varendorf (DE)	sandy loam	6.4 (0-30cm)	30	2.95	61.3		DFOP	
Saxa-Anhalt (DE)	sandy clay loam	6.6 (0-30cm)	30	1.64	93.7		DFOP	
Isle/ Sorgue (FR)	clay loam	8.5 (0-20cm)	30	4.65	121.6		DFOP	
Monteux Vaucluse (FR)	sandy loam	8.5 (0-20cm)	30	4.03	68		DFOP	
St Vigor (FR)	silt loam	6.1 (0-20cm)	30	3.02	34.5		DFOP	
Massalombarda (FR)	silty clay loam	8.3 (0-20cm)	30	1.39	105		DFOP	
Grisolles (FR)	clay loam	7.7 (0-20cm)	30	13.3	66		DFOP	
Cambridgeshire (UK)	clay	8.0 (0-20cm)	30	2.09	93.7		DFOP	
Somerset (UK)	clay	8.1 (0-20cm)	30	0.42	73.7		DFOP	
Geometric mean (n = 10)				2.55	75.9			
Overall geometric mean ^a (n = 13)				78				

^a Calculated from the geometric mean of the soil incorporated field studies (80.2 days) and the slow phase of the non-incorporated studies (75.9 days).

zRMS comments:

Field degradation data presented in table 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.

8.4.1.2 Prothioconazole and its metabolites

Studies on the field dissipation rates of prothioconazole (JAU-6476) and its metabolite JAU-6476-desthio are data provided in support of the active substance and have been already evaluated during Annex I inclusion (EFSA Scientific Report, 2007, 106, 1-98). However, based on these data recalculations have been performed to address current guidance documents to be considered (EFSA, 2014, FOCUS, 2006 and 2014).

Table 8.4-2: Summary of aerobic degradation rates for prothioconazole – Field studies

Parent prothioconazole, Field studies									
Soil type	Location	pH (CaCl ₂)	Depth (cm)	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C, pF2 ^a	R ² (-)	Kinetic model	Evaluated on EU level / Reference
Silt loam (bare)	Germany	6.25	0-50 cm	1.9	6.4	1.2	1.00	SFO	Yes / EFSA (2007)
Sandy clay loam (bare)	United Kingdom	7.56	0-50 cm	1.6	5.5	0.8	0.999	SFO	
Silt (bare)	France (North)	6.42	0-50 cm	1.3	4.4	1.6	0.995	SFO	
Sandy clay loam (cropped)	United Kingdom	7.56	0-50 cm	2.8	9.3	1.4	0.997	SFO	
Silt (cropped)	France (North)	6.42	0-50 cm	1.4	4.5	1.6	0.998	SFO	
Silt loam (cropped)	France (South)	7.61	0-50 cm	1.7	5.6	1.1	1.00	SFO	
Sandy loam (cropped)	Italy	7.56	0-50 cm	1.6	5.4	1.5	0.999	SFO	
Sandy loam (bare)	Germany	6.32	0-50 cm	1.5	5.1	0.6	1.00	SFO	
Geometric mean (n = 8)				1.7	5.8	1.2			
Maximum value				2.8	9.3	-			
pH-dependency				No					

^a Using a Q₁₀ of 2.2.

Table 8.4-3: Summary of aerobic degradation rates for relevant metabolite(s) – Field studies

JAU 6476-desthio, Field studies										
Soil type	Location	pH (CaCl ₂)	Depth (cm)	f.f. (-)	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C, pF2 ^a	R ² (-)	Kinetic model	Evaluated on EU level / Reference
Silt loam (bare)	Germany	6.25	0-50 cm	-	16.3 ^b	54.1 ^b	10.3	0.994	SFO	Yes / EFSA (2007)
Sandy clay loam (bare)	United Kingdom	7.56	0-50 cm	-	54.7	182	27.0	0.978	SFO	
Silt (bare)	France (North)	6.42	0-50 cm	-	47.6	158	27.5	0.859	SFO	
Sandy clay loam (cropped)	United Kingdom	7.56	0-50 cm	-	50.2	167	23.4	0.939	SFO	
Silt (cropped)	France (North)	6.42	0-50 cm	-	36.8	122	20.1	0.859	SFO	
Silt loam (cropped)	France (South)	7.61	0-50 cm	-	72.3	240	61.9	0.969	SFO	
Sandy loam (cropped)	Italy	7.56	0-50 cm	-	30.5	101	20.7	0.951	SFO	
Sandy loam (bare)	Germany	6.32	0-50 cm	-	27.9 ^b	92.6 ^b	15.2	0.996	SFO	
Geometric mean (n = 8)				-	42.0	140	22.7			
Arithmetic mean(n = 8)				- ^c	-	-	-			
Maximum value				-	72.3	240	-			
pH-dependency				No						

^a Using a Q₁₀ of 2.2.

^b Without Day 0 samples, because the maximum concentrations of M04 were at the later sampling dates.

^c The results of the field studies were used to estimate the portion of the active substance degrading to prothioconazole-desthio (57.1%).

zRMS comments:

The triggering endpoints for prothioconazole and metabolite JAU 5479-desthio provided in Tables 8.4-2 and 8.4-3 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.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Based on the field dissipation data, azoxystrobin and prothioconazole are unlikely to significantly accumulate in soil following repeated applications. The potential for accumulation has been assessed by calculation under Annex Point 8.7.

zRMS comments:

No EU agreed data from soil accumulation studies with 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 substance.

8.5.1.1 Azoxystrobin and its metabolites

Studies on the mobility of azoxystrobin and its metabolites R234886, R401553 and R402173 in soil are data provided in support of the active substance. All relevant detailed experimental information has been submitted for EU review of azoxystrobin (**Azoxystrobin, EFSA Journal 2010; 8(4):1542 and Confirmatory Data, EC, 2014**).

Table 8.5-1: Summary of soil adsorption for azoxystrobin

Parent azoxystrobin						
Soil type	OC (%)	pH (-)	K _F (L/kg)	K _{FOC} (L/kg)	1/n (-)	Evaluated on EU level Reference
Sandy clay loam	1.7	7.5	7.9	465	0.84	Yes / EFSA (2010)
Loamy sand A	1.7	7.8	4	235	0.82	
Loamy sand B	3.0	7.9	6.2	207	0.85	
Sand	0.3	5.5	1.5	500	0.84	
Silty clay loam	1.6	4.9	9.5	594	0.90	
Clay loam	2.8	5.5	15	536	0.90	
Arithmetic mean (n = 6)				423	0.86	
pH-dependency				No		

Bold value used for modelling.

As adsorption of metabolites R234886 and R402173 is pH dependent, a worst-case approach for the PEC_{SW} calculations were taken using the lowest K_{FOC} for the surface water PEC calculation and the highest K_{FOC} for sediment PEC calculation (EFSA, 2010). The lowest K_{FOC} was also used for PEC_{GW} calculations.

Table 8.5-2: Summary of soil adsorption for metabolite R401553

Metabolite R401553						
Soil type	OC (%)	pH (-)	K _F (L/kg)	K _{FOC} (L/kg)	1/n (-)	Evaluated on EU level Reference
Sandy clay loam	1.74	7.5	1.9	110	0.81	Yes / EFSA (2010)
Loamy sand	0.29	6.8	0.76	260	0.81	

Metabolite R401553						
Soil type	OC (%)	pH (-)	K _F (L/kg)	K _{FOC} (L/kg)	1/n (-)	Evaluated on EU level Reference
Sandy loam	2.96	8.5	2.4	81	0.84	
Silty clay loam	2.15	6.2	11	500	0.89	
Silty clay loam	2.38	5.6	1.6	66	0.85	
Sandy clay loam	2.61	5.4	2.9	110	0.92	
Arithmetic mean (n = 6)				188	0.85	
pH-dependency				No		

Bold values used for modelling.

Table 8.5-3: Summary of soil adsorption for metabolite R402173

Metabolite R402173						
Soil type	OC (%)	pH (-)	K _F (L/kg)	K _{FOC} (L/kg)	1/n (-)	Evaluated on EU level Reference
Sandy clay loam	1.74	7.5	0.65	37	0.96	Yes / EFSA (2010)
Loamy sand	0.29	6.8	0.27	93	0.95	
Sandy loam	2.96	8.5	0.74	25	0.96	
Silty clay loam	2.15	6.2	4.2	200	0.92	
Silty clay loam	2.38	5.6	2.0	86	0.93	
Clay loam	2.61	5.4	2.9	110	0.96	
Lowest/highest (n = 6)				25 / 200	0.96 / 0.92	
pH-dependency				Yes		

Bold values used for modelling.

Table 8.5-4: Summary of soil adsorption for metabolite R234886

Metabolite R234886							
Soil type	Location	OC (%)	pH (-)	K _F (L/kg)	K _{FOC} (L/kg)	1/n (-)	Evaluated on EU level Reference
Loamy sand	Kenny Hill	2.96	7.5	0.82	28	0.90	Yes / EFSA (2010) and Confirmatory Data (2014)
Clay loam	Picket Piece	2.78	4.8	10	360	0.89	
Loamy sand	East Anglia	1.68	7.3	0.35	21	0.76	
Sand	Lilly Field	0.29	4.6	1.4	490	0.79	
Silty clay loam	Nebo	1.62	4.2	6.8	420	0.90	
Sandy clay loam	Hyde Farm	1.74	6.8	0.85	49	0.85	
Sandy loam	Frensham	1.84	5.0	1.83	100	0.639	
Clay loam	Wisborough Green	2.40	4.8	2.43	101	0.542	
Sandy clay loam	Nuptown	2.47	5.9	1.53	62	0.705	
Loamy sand	Georgia	0.67	6.7	1.22	182	0.832	
Sandy loam	North Dakota	2.78	7.4	1.65	59	0.863	
Loamy sand	Ohio	1.36	5.3	1.52	112	0.663	
Silt loam	Gartenacker	2.67	7.1	0.87	33	0.820	
Loam	Vetroz	2.38	7.9	0.72	30	0.861	
Sandy loam	Pappelacker	1.11	7.2	0.42	37	0.803	
Acidic soils, arithmetic mean (n = 8)				228.4	0.78		
Alkaline soils, arithmetic mean (n = 7)				36.7	0.83		
Lowest / highest (n = 15)				21 / 490	0.72 / 0.79		
pH-dependency				Yes			

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).

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

8.5.1.2 Prothioconazole and its metabolites

Studies on the mobility of prothioconazole and its metabolites JAU 6476-S-methyl and JAU 6476-desthio in soil are data provided in support of the active substance. All relevant detailed experimental information has been submitted for EU review of prothioconazole (**Prothioconazole, EFSA Scientific Report, 2007, 106, 1-98**). These values are presented in the following tables.

Table 8.5-5: Summary of soil adsorption for prothioconazole

Prothioconazole ^a							
	Soil type	OC (%)	pH (-)	K _d (L/kg)	K _d _{oc} (L/kg)	1/n (-)	Evaluated on EU level Reference
Byromville	Loamy sand	0.86	6.7	15.2	1765	0.9 ^b	Yes /
Arithmetic mean (n = 1)					-	-	EFSA (2007)
pH-dependency					No information		

^a Determined on an aged column leaching study.

^b Default value

Table 8.5-6: Summary of soil adsorption for metabolite JAU 6476-S-methyl (M01)

Metabolite JAU 6476-S-methyl							
Soil name	Soil type	OC (%)	pH (-)	K _F (L/kg)	K _{FOC} (L/kg)	1/n (-)	Evaluated on EU level Reference
Laacher Hof AXXa	Sandy loam	2.02	7.2	56.0	2772	0.87	Yes / EFSA (2007)
Höfchen	Silt	2.14	7.1	64.1	2995	0.88	
Stanley	Silty clay loam	1.66	5.9	41.2	2484	0.91	
Byromville	Loamy sand	0.79	6.8	15.6	1974	0.85	
Arithmetic mean (n = 4)					2556.3	0.88	
pH-dependency					No		

[#] Bold values used for modelling.

Table 8.5-7: Summary of soil adsorption for metabolite JAU 6476-desthio (M04)

Metabolite JAU 6476-desthio							
Soil name	Soil type	OC (%)	pH (-)	K _F (L/kg)	K _{FOC} (L/kg)	1/n (-)	Evaluated on EU level Reference
Laacher Hof AXXa	Sandy loam	2.02	7.2	12.46	617	0.79	Yes / EFSA (2007)
Höfchen	Silt	2.14	7.1	13.38	625	0.83	
Stanley	Silty clay loam	1.66	5.9	8.90	536	0.83	
Byromville	Loamy sand	0.79	6.8	4.13	523	0.80	
Arithmetic mean (n = 4)					575.4	0.81	
pH-dependency					No		

[#] bold values used for modelling

Table 8.5-8: Summary of soil adsorption for metabolite 1,2,4-triazole (M13)

Metabolite 1,2,4-triazole (M13)							
Soil name	Soil type	OC (%)	pH (-)	K _F (L/kg)	K _{FOC} (L/kg)	1/n (-)	Evaluated on EU level Reference
	Silty clay	0.70	8.8	0.833	120	0.897	Yes / EFSA conclusion on propiconazole (2017)
	Clay loam	1.74	6.9	0.748	43	0.827	
	Silty clay loam	0.70	7.0	0.722	104	0.922	
	Sandy loam	0.81	6.9	0.719	89	1.016	
Arithmetic mean (n = 4)					89	0.916	
pH-dependency					No		

zRMS comments:

Soil mobility data for prothioconazole and its major soil metabolites presented in Tables 8.5-5 to 8.5-8 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 8.5-8 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 relevant endpoints considered in exposure assessment, please refer to points 8.8 (groundwater) and 8.9 (surface water) of this document.

8.5.2 Column leaching (KCP 9.1.2.1)

Studies on column leaching are data provided in support of the active substance. All relevant detailed experimental information has been submitted for EU review (**Azoxystrobin, EFSA Journal 2010; 8(4):1542** and **Prothioconazole, EFSA Scientific Report, 2007, 106, 1-98**).

8.5.2.1 Prothioconazole and its metabolites

K_d and K_{oc} values of prothioconazole determined in aged column leaching studies due to the instability of the compound in standard batch equilibrium studies.

Column leaching

Guideline: SETAC (1995), BBA Part IV, 6-2 (1986)
Precipitation: 200 mm
Time period: 2 days
Leachate: <1% AR; fractions not investigated

Aged residues leaching

Guideline: US EPA 163-1 (1982)
Aged for: 30 hours
Precipitation: 1000 mL
The total radioactivity in the leachate accounted for only 1.1% of the AR, and no individual leachate fraction resulted in a radioactivity content >0.2% of the AR. Therefore, the leachate fractions were not analysed for parent compound or metabolites.

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 FGF11, 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 of azoxystrobin and their metabolites following application of FGF11 is addressed in groundwater modelling presented in point 8.8 of this document.

8.5.3 Lysimeter studies (KCP 9.1.2.2)

Lysimeter studies with the formulation were not performed since it is possible to extrapolate from data obtained with the active substances.

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 FGF11 is addressed in groundwater modelling presented in point 8.8 of this document.

8.5.4 Field leaching studies (KCP 9.1.2.3)

Lysimeter studies with the formulation were not performed since it is possible to extrapolate from data obtained with the active substances.

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 FGF11 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.

8.6.1.1 Azoxystrobin and its metabolites

The rate of degradation in water/sediment systems of azoxystrobin are data provided in support of the active substance. All relevant detailed experimental information has been submitted for EU review of azoxystrobin (Azoxystrobin, EFSA Journal 2010; 8(4):1542).

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

Parent azoxystrobin Distribution (max. water 91.2 % after 0 days, max. sediment 90.5 % 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 Reference
Old basing	7.5/7.8	234	777	SFO	-	-	-	-	-	Yes / EFSA (2010)
Virgina water	6.4/6.9	180	598	SFO	-	-	-	-	-	
Geometric mean (n = 2)		205	682		-	-		-		

Bold value used for modelling.

Table 8.6-2: Summary of observed metabolites

R234886	Maximum in water 10.8 % after 152 days, maximum in sediment 15.6 % after 152 days, maximum in whole system 18.1 % after 152 days	EFSA (2010)
R401553	Maximum in water/sediment 8.9 % (aqueous photolytic degradation)	
R402173	Maximum in water/sediment 2.4 % (aqueous photolytic degradation)	

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.

8.6.1.2 Prothioconazole and its metabolites

The rate of degradation in water/sediment systems of prothioconazole are data provided in support of the active substance. All relevant detailed experimental information has been submitted for EU review of prothioconazole (**Prothioconazole, EFSA Scientific Report, 2007, 106, 1-98**).

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

Prothioconazole – Distribution (maximum in sediment: 23.4 % AR 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 Reference
Hönniger Weiher	7.84 / 5.8	2.8	76.4	HS	0.8	2.7	SFO			Yes / EFSA (2007)
Angler Weiher	7.45 / 7.4	1.6	23.6	HS	1.0	3.4	SFO			
Geometric mean (n = 2)		n.c.*	-	-		-	-		-	

*Larger value used for modelling.

n.c. = not calculated

Table 8.6-4: Summary of observed metabolites

JAU 6476-desthio (M04)	Maximum in water: 32.3 % AR after 7 days Maximum in sediment: 26.9 % AR after 59 days Maximum in whole system: 54.6 % AR after 7 days	Yes / EFSA (2007)
1,2,4-triazole (M13)	Maximum in water: 37.2 % AR after 121 days Maximum in sediment: 4.6 % AR after 121 days Maximum in whole system: 41.8 % AR after 121 days	

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.

8.7 Predicted Environmental Concentrations in soil (PECs) (KCP 9.1.3)

Unless otherwise stated, EU agreed endpoints refer to those stated in the EU review of azoxystrobin (**Azoxystrobin, EFSA Journal 2010; 8(4):1542** and **Confirmatory Data, EC, 2014**) and prothioconazole (**Prothioconazole, EFSA Scientific Report, 2007, 106, 1-98**).

8.7.1 Justification for new endpoints

EU agreed endpoints were used for PECs calculations of azoxystrobin and prothioconazole, and their respective metabolites.

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

The following PECs calculations for azoxystrobin, R234886, R401553 and R402173 and for prothioconazole, JAU 6476-S-methyl and JAU 6476-desthio have not previously been reviewed.

Table 8.7-1: Input parameters related to application for PECs calculations

Use No.	All
Crop	Cereals (winter & spring) ^a
Application rate (g as/ha)	Azoxystrobin: 160 Prothioconazole: 200
Number of applications/interval (d)	1 / –
Crop interception (%)	80
Depth of soil layer (relevant for PECs,plateau) (cm)	5 / 20 cm (with tillage)
Models used for calculation	Calculation via spreadsheet (CRD PECsoil calculator v2015)

^a PECs calculated for cereals are conservative for the uses on oilseed rape due to the higher application rate and equivalent interception.

Table 8.7-2: Input parameter for active substance(s) and relevant metabolite(s) for PECs calculation

Compound	Molar mass [g/mol]	Max. occurrence [%]	DT ₅₀ [days]	Value in accordance to EU endpoint / Reference
Azoxystrobin	403.4	-	262 (worst-case from field incorporated studies, non-normalised, SFO)	Yes / EFSA (2010)
R401553	213.2	17.0	2.01 (worst-case from laboratory studies, non-normalised, SFO)	Yes / EFSA (2010)
R402173	333.3	17.0	9.8 (worst-case from laboratory studies, non-normalised, SFO)	Yes / EFSA (2010)
R234886	389.4	28.8	102 (worst-case from laboratory studies, non-normalised, SFO)	Yes / EFSA (2010) & Confirmatory Data (2014)
Prothioconazole	344.26	-	2.8 (worst-case from field incorporated studies, non-normalised, SFO)	Yes / EFSA (2007)
JAU 6476-S-methyl	358.3	14.6	46 (worst-case from laboratory studies, non-normalised, SFO)	Yes / EFSA (2007)
JAU 6476-desthio	312.2	57.1	72.3 (worst-case from field studies, non-normalised, SFO)	Yes / EFSA (2007)

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 of 80% in line with FOCUS groundwater guidance (2023) 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 Azoxystrobin and its metabolites

Table 8.7-3: PECs for azoxystrobin on cereals and oilseed rape

PECs (mg/kg)		Cereals and oilseed rape	
		Single application	
		Actual	TWA
PECs _{ini}		0.043	-
Short term	24h	0.043	0.043
	2d	0.042	0.043
	4d	0.042	0.042
Long term	7d	0.042	0.042
	14d	0.041	0.042
	21d	0.040	0.042
	28d	0.040	0.041
	48d	0.038	0.040
	100d	0.033	0.037
PECs _{plateau} (20 cm) with tillage after year 5		0.026	-
PECs _{accumulation} (PECs _{accumulation} = PECs _{ini} + PECs _{plateau})		0.069	-

Table 8.7-4: PECs for metabolite R401553

PECs (mg/kg)		Cereals and oilseed rape	
		Single application	
		Actual	TWA
PECs _{ini}		0.004	-
Short term	24h	0.003	0.003
	2d	0.002	0.003
	4d	0.001	0.002
Long term	7d	< 0.001	0.001
	14d	< 0.001	0.001
	21d	< 0.001	0.001
	28d	< 0.001	< 0.001
	48d	< 0.001	< 0.001
	100d	< 0.001	< 0.001
PECs _{plateau} (20 cm) with tillage		n.r.	-
PECs _{accumulation} (PECs _{accumulation} = PECs _{ini} + PECs _{plateau})		n.r.	-

Table 8.7-5: PECs for metabolite R402173

PEC _s (mg/kg)		Cereals and oilseed rape	
		Single application	
		Actual	TWA
PEC _{s,ini}		0.006	-
Short term	24h	0.006	0.006
	2d	0.005	0.006
	4d	0.005	0.005
Long term	7d	0.004	0.005
	14d	0.002	0.004
	21d	0.001	0.003
	28d	0.001	0.003
	48d	< 0.001	0.002
	100d	< 0.001	0.001
PEC _{s,plateau} (20 cm) with tillage		n.r.	-
PEC _{s,accumulation} (PEC _{s,accumulation} = PEC _{s,ini} + PEC _{s,plateau})		n.r.	-

Table 8.7-6: PECs for metabolite R234886

PEC _s (mg/kg)		Cereals and oilseed rape	
		Single application	
		Actual	TWA
PEC _{s,ini}		0.012	-
Short term	24h	0.012	0.012
	2d	0.012	0.012
	4d	0.012	0.012
Long term	7d	0.011	0.012
	14d	0.011	0.011
	21d	0.010	0.011
	28d	0.010	0.011
	48d	0.009	0.010
	100d	0.006	0.009
PEC _{s,plateau} (20 cm) with tillage after year 2		0.001	-
PEC _{s,accumulation} (PEC _{s,accumulation} = PEC _{s,ini} + PEC _{s,plateau})		0.013	-

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.

The calculated PEC_{SOIL} values for azoxystrobin and its metabolites were similar with these obtained by the Applicant and therefore results reported in Tables 8.7-3 to 8.7-6 above may be used for the soil risk assessment purposes.

8.7.2.2 Prothioconazole and its metabolites

Table 8.7-7: PECs for prothioconazole on cereals and oilseed rape

PECs (mg/kg)		Cereals and oilseed rape	
		Single application	
		Actual	TWA
PEC _{S,ini}		0.053	-
Short term	24h	0.042	0.047
	2d	0.033	0.042
	4d	0.020	0.034
Long term	7d	0.009	0.025
	14d	0.002	0.015
	21d	< 0.001	0.010
	28d	< 0.001	0.008
	48d	< 0.001	0.004
	100d	< 0.001	0.002
PEC _{S,plateau} (20 cm) with tillage		n.r.	-
PEC _{S,accumulation} (PEC _{S,accumulation} = PEC _{S,ini} + PEC _{S,plateau})		n.r.	-

Table 8.7-8: PECs for metabolite JAU 6476-S-methyl

PECs (mg/kg)		Cereals and oilseed rape	
		Single application	
		Actual	TWA
PEC _{S,ini}		0.008	-
Short term	24h	0.008	0.008
	2d	0.008	0.008
	4d	0.008	0.008
Long term	7d	0.007	0.008
	14d	0.007	0.007
	21d	0.006	0.007
	28d	0.005	0.007
	48d	0.004	0.006
	100d	0.002	0.004
PEC _{S,plateau} (20 cm) with tillage		n.r.	-
PEC _{S,accumulation} (PEC _{S,accumulation} = PEC _{S,ini} + PEC _{S,plateau})		n.r.	-

Table 8.7-9a: PECs for metabolite JAU 6476-desthio (M04)

PECs (mg/kg)		Cereals and oilseed rape	
		Single application	
		Actual	TWA
PEC _{S,ini}		0.028	-
Short term	24h	0.027	0.027
	2d	0.027	0.027
	4d	0.027	0.027

PEC _s (mg/kg)		Cereals and oilseed rape	
		Single application	
		Actual	TWA
Long term	7d	0.026	0.027
	14d	0.024	0.026
	21d	0.023	0.025
	28d	0.021	0.024
	48d	0.017	0.022
	100d	0.011	0.018
PEC _{S,plateau} (20 cm) with tillage		n.r.	-
PEC _{S,accumulation} (PEC _{S,accumulation} = PEC _{S,ini} + PEC _{S,plateau})		n.r.	-

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 8.7-7 to 8.7-9a above may be used for the soil risk assessment purposes.

8.7.2.3 PEC_s of FGF11

Table 8.7-10: PEC_s for FGF11 on winter and spring cereals

Active substance/ formulation	Application rate [g/ha] ^a	PEC _{S,ini} [mg/kg] ^b
FGF11	1228	0.327

^a The formulation components are considered to dissipate rapidly after application, therefore only one application is taken into consideration. The rate of formulation was based on a specific density of 1.228 g/mL with a maximum application of 1.0 L/ha assuming 80% crop interception.

^b Calculated as:

$$PEC_{S,ini} [mg/kg] = \frac{A \times (1 - I)}{z \times bd_{SOIL} \times 10}$$

Where:

A = application rate [g product/ha]

PEC_{S,ini} = initial (maximum) concentration in soil [mg product/kg soil]

I = Interception [-]

z = soil mixing depth (5 cm) [m]

bd_{SOIL} = bulk density of the soil (1500 kg/m³) [kg soil/m³]

zRMS comments:

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

8.8 Predicted Environmental Concentrations in groundwater (PECGW) (KCP 9.2.4)

8.8.1 Justification for new endpoints

Unless otherwise stated, EU agreed endpoints refer to those stated in the EU review of azoxystrobin (**Azoxystrobin, EFSA Journal 2010; 8(4):1542** and **Confirmatory Data, EC, 2014**) and prothioconazole (**Prothioconazole, EFSA Scientific Report, 2007**).

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

The following PEC_{GW} modelling for azoxystrobin and its metabolites R234886, R401553 and R402173 and prothioconazole and its metabolites JAU 6476-S-methyl and JAU 6476-desthio has not previously been reviewed and is provided in support of this assessment in the following stand-alone reports.

Report:	KCP 9.2.4.1/01 Worthington, M. (2024a) Azoxystrobin – A leaching assessment for azoxystrobin and its metabolites using the PEARL 5.5.5, PELMO 6.6.4 and MACRO 5.5.4 FOCUS groundwater models following spray application to cereals and oilseed rape in Central Europe. Company report No.: S24-101230-02-002
Guidelines:	FOCUS Groundwater (2023): Generic Guidance for Tier 1 FOCUS Ground Water Assessments v2.4, March 2023.
GLP:	No

Report:	KCP 9.2.4.1/02 Worthington, M. (2024b) Prothioconazole – A leaching assessment for prothioconazole and its metabolites using the PEARL 5.5.5, PELMO 6.6.4 and MACRO 5.5.4 FOCUS groundwater models following spray application to cereals and oilseed rape in Central Europe Company report No.: S24-101230-02-003
Guidelines:	FOCUS Groundwater (2023): Generic Guidance for Tier 1 FOCUS Ground Water Assessments v2.4, March 2023.
GLP:	No

Table 8.8-1: Input parameters related to application for PEC_{GW} calculations

Modelling use No.	1a	1b
GAP use no.	All cereal uses	
FOCUS GW crop [-]	Winter Cereal	
Application rate [g a.s./ha]	Azoxystrobin: 160 / Prothioconazole: 200	
Number of applications / interval [d]	1/-	
Frequency of application [-]	Annual	
Relative application date / BBCH growth stage [-]	- / BBCH 30	- / BBCH 69
Crop interception [%]	80	90
Application method [-]	Ground spray	
Models used for calculation	FOCUS PEARL v5.5.5, PELMO v6.6.4 and MACRO v5.5.4	
Modelling use No.	2a	2b
GAP use no.	All cereal uses	
FOCUS GW crop [-]	Spring Cereal	
Application rate [g a.s./ha]	Azoxystrobin: 160 / Prothioconazole: 200	
Number of applications / interval [d]	1/-	
Frequency of application [-]	Annual	
Relative application date / BBCH growth stage [-]	- / BBCH 30	- / BBCH 69
Crop interception [%]	80	90
Application method [-]	Ground spray	
Models used for calculation	FOCUS PEARL v5.5.5, PELMO v6.6.4 and MACRO v5.5.4	
Modelling use No.	3	4
GAP use no.	-	
FOCUS GW crop [-]	Winter Oilseed Rape	Summer Oilseed Rape
Application rate [g a.s./ha]	Azoxystrobin: 160 / Prothioconazole: 200	Azoxystrobin: 160 / Prothioconazole: 200
Number of applications / interval [d]	1/-	1/-
Frequency of application [-]	Annual	Annual
Relative application date / BBCH growth stage [-]	- / BBCH 61*	- / BBCH 61*
Crop interception [%]	80	80
Application method [-]	Ground spray	Ground spray
Models used for calculation	FOCUS PEARL v5.5.5, PELMO v6.6.4 and MACRO v5.5.4	

* Modelling at this BBCH timing is considered to cover the narrow GAP range.

Table 8.8-2: Application dates used for groundwater risk assessment

Modelling use	Scenario	Application dates
Use No 1a, Winter cereals BBCH 30	Châteaudun	15 April
	Hamburg	4 May
	Jokioinen	14 May
	Kremsmünster	24 April
	Okehampton	21 April
	Piacenza	19 March
	Porto	30 January
	Sevilla	6 January
	Thiva	18 January
Use No 1b, Winter cereals BBCH 69	Châteaudun	14 June
	Hamburg	22 June
	Jokioinen	10 July
	Kremsmünster	25 June
	Okehampton	7 June
	Piacenza	26 May
	Porto	18 May
	Sevilla	28 March
	Thiva	27 April
Use No 2a, Spring cereals BBCH 30	Châteaudun	16 April
	Hamburg	28 April
	Jokioinen	5 June
	Kremsmünster	27 April
	Okehampton	22 April
	Porto	16 April
Use No 2b, Spring cereals BBCH 69	Châteaudun	22 June
	Hamburg	28 June
	Jokioinen	17 July
	Kremsmünster	28 June
	Okehampton	18 June
	Porto	22 June
Use No 3, Winter oilseed rape BBCH 61	Châteaudun	23 April
	Hamburg	8 May
	Kremsmünster	8 May
	Okehampton	3 May
	Piacenza	17 April
	Porto	23 April
Use No 4, Summer oilseed rape BBCH 61	Jokioinen	7 July
	Okehampton	18 May
	Porto	3 June

zRMS comments:

The application pattern assumed in simulations is in line with the critical Central Zone GAP as presented in Table 8.1-1. Assumed crop interception corresponded with BBCH stages at which product FGF11 is intended to be applied. Application dates presented table above were checked by the zRMS using AppDate ver. 3.06 tool and are considered acceptable.

8.8.2.1 Azoxystrobin and its metabolites

In accordance with the AIR-DAR, the different mechanisms of degradation of azoxystrobin were modelled using two separate simulations. The first degradation pathway assumed that azoxystrobin degraded via microbial degradation to R234886 with a formation fraction of 0.874, whilst the second assumed that azoxystrobin degraded due to photolysis to form R401553 and R402173 (subsequently degrading to R401553) with formation fractions of 0.385 to R402173, and 0.392 to R401553.

Table 8.8-3: Input parameters related to active substance azoxystrobin and its metabolites for PEC_{GW} calculations

Parameter	Azoxystrobin	R401553 ^B	R402173 ^B	R234886 ^A	EU endpoint Y/N/ Reference
Molar mass [g/mol]	403.4	213.2	333.3	389.4	Y / EFSA Conclusion (2010) & RAR Addendum (2014)
Water solubility 20°C [mg/L]	6.7	560	61	57	
Saturated vapour pressure at 20 °C [Pa]	1.1×10^{-10}	0 ^E	0 ^E	0 ^E	
DT ₅₀ in soil [days]	78 ^A / 2.55 ^B	1.07	4.7	98.6 ^C / 36.7 ^D	
Transformation rate [d ⁻¹] -	0.008887 ^A / 0.2718 ^B	0.6478	0.1475	0.00703 ^C / 0.01889 ^D	
K _{FOC} [mL/g]	423	188	25	228.4 ^C / 36.7 ^D	
K _{FOM} [mL/g]	245.4	109	14.5	132.5 ^C / 21.3 ^D	
1/n [-]	0.86	0.85	0.96	0.78 ^C / 0.83 ^D	
Formation fraction in soil [-]	--	0.392 ^B / 0.468 ^B	0.385 ^B	0.874 ^A	
Formed from [-]	--	parent ^B / R402173 ^B	parent ^B	Parent ^A	
Plant uptake factor [-]	0	0	0	0	

- ^A Via microbial pathway
^B Via photolytic pathway
^C Acidic soils
^D Alkaline soils
^E Conservative default value

Winter cereals, 1 × 160 g a.s./ha at BBCH 30 to 69

Table 8.8-4: FOCUS PEC_{GW} for azoxystrobin and its metabolites following an application of FGF11 to winter cereals at BBCH 30-69

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]									
		Azoxystrobin (microbial and photolytic)		R401553		R402173		R234886 (acidic)		R234886 (alkaline)	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Use No 1a, Winter cereals 1 × 160 g a.s/ha BBCH 30	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.006	0.004
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.123	0.111
	Jokionen	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.024	0.028
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.072	0.065
	Okehampton	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.099	0.099
	Piacenza	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.035	0.048
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.002	< 0.001	< 0.001	0.035	0.085
	Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.003	0.001
		MACRO		MACRO		MACRO		MACRO		MACRO	
	Châteaudun	< 0.001		< 0.001		< 0.001		< 0.001		0.008	
Use No 1b, Winter cereals 1 × 160 g a.s/ha BBCH 69	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.002	0.001
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.041	0.036
	Jokionen	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.005	0.007
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.020	0.019
	Okehampton	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.034	0.032
	Piacenza	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.012	0.016
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.013	0.036
	Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
		MACRO		MACRO		MACRO		MACRO		MACRO	
	Châteaudun	< 0.001		< 0.001		< 0.001		< 0.001		0.002	

Spring cereals, 1 × 160 g a.s./ha at BBCH 30 to 69

Table 8.8-5: FOCUS PEC_{GW} for azoxystrobin and its metabolites following an application of FGF11 to spring cereals at BBCH 30-69

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]									
		Azoxystrobin (microbial and photolytic)		R401553		R402173		R234886 (acidic)		R234886 (alkaline)	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Use No 2a, Spring cereals 1 × 160 g a.s./ha BBCH 30	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.005	0.003
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.138	0.118
	Jokionen	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.026	0.027
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.073	0.067
	Okehampton	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.092	0.097
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.051	0.070
		MACRO		MACRO		MACRO		MACRO		MACRO	
Use No 2b, Spring cereals 1 × 160 g a.s./ha BBCH 69	Châteaudun	< 0.001		< 0.001		< 0.001		< 0.001		0.008	
	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.001	0.001
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.047	0.041
	Jokionen	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.006	0.006
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.021	0.019
	Okehampton	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.032	0.032
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.021	0.032
		MACRO		MACRO		MACRO		MACRO		MACRO	
	Châteaudun	< 0.001		< 0.001		< 0.001		< 0.001		0.003	

Winter oilseed rape, 1 × 160 g a.s./ha at BBCH 61 to 73

Table 8.8-6: FOCUS PEC_{GW} for azoxystrobin and its metabolites following an application of FGF11 to winter oilseed rape at BBCH 61-73

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]									
		Azoxystrobin (microbial and photolytic)		R401553		R402173		R234886 (acidic)		R234886 (alkaline)	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Use No 3, Winter oilseed rape, 1 × 160 g a.s./ha BBCH 61	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.010	0.005
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.128	0.109
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.074	0.064
	Okehampton	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.096	0.106
	Piacenza	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.028	0.040
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.051	0.106
		MACRO		MACRO		MACRO		MACRO		MACRO	
	Châteaudun	< 0.001		< 0.001		< 0.001		< 0.001		0.009	

Summer oilseed rape, 1 × 160 g a.s./ha at BBCH 61 to 73

Table 8.8-7: FOCUS PEC_{GW} for azoxystrobin and its metabolites following an application of FGF11 to summer oilseed rape at BBCH 61-73

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]									
		Azoxystrobin (microbial and photolytic)		R401553		R402173		R234886 (acidic)		R234886 (alkaline)	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Use No 4, Summer oilseed rape, 1 × 160 g a.s./ha BBCH 61	Jokionen	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.023	0.028
	Okehampton	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.088	0.102
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.054	0.075
		MACRO		MACRO		MACRO		MACRO		MACRO	
	Châteaudun*	-		-		-		-		-	

* Not parameterised for summer oilseed rape.

zRMS comments:

Input parameters for azoxystrobin and its metabolites presented in Table 8.8-3 and used in the modelling are 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).

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 (2023).

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 8.8-4 to 8.8-7. Performed simulations indicate that unacceptable leaching of azoxystrobin and its metabolites R401553 and R402173 is expected following application of FGF11 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 $0.1 \mu\text{g/L}$, with the maximum value of $0.138 \mu\text{g/L}$ in the Hamburg scenario (PEARL model) following application to spring cereals at BBCH 30-69. According to EFSA Journal 2010; 8(4):1542 metabolite R234886 is toxicologically not relevant. Since PEC_{GW} values do not exceed the threshold concentration of $0.75 \mu\text{g/L}$ for non-relevant metabolites, no further assessment is thus necessary.

Overall, no unacceptable leaching of azoxystrobin and its metabolites is expected following application of FGF11 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 Prothioconazole and its metabolites

Table 8.8-8: Input parameters related to active substance prothioconazole and its metabolites for PEC_{GW} calculations

Parameter	Prothioconazole	JAU 6476-S-methyl (M01)	JAU 6476-desthio (M04)	EU endpoint Y/N/ Reference
Molar mass [g/mol]	344.26	358.3	312.2	Y / EFSA Conclusion (2007)
Water solubility 20°C [mg/L]	300	1000 ^a	1000 ^a	
Saturated vapour pressure at 20 °C [Pa]	0 ^b	0 ^a	0 ^a	
DT ₅₀ in soil [d]	1.2	15.7	22.7	
Transformation rate [d ⁻¹]	0.5776	0.0441	0.0305	
K _{FOC} [mL/g]	1765	2556.3	575.4	
K _{FOM} [mL/g]	1023.8	1482.8	333.8	
Formation fraction in soil [-]	--	0.146	0.6 / 1.0	
Formed from [-]	--	parent	Parent / M01	
1/n [-]	0.9	0.88	0.81	
Plant uptake factor [-]	0	0	0	
Q ₁₀ [-]	2.2	2.2	2.2	

^a Conservative default value.

^b Since the soil DT₅₀ comes from a field study, the effects of vapour pressure were already considered.

Winter cereals, 1 × 200 g a.s./ha at BBCH 30 to 69

Table 8.8-9: FOCUS PEC_{GW} for prothioconazole and its metabolites following an application of FGF11 to winter cereals at BBCH 30-69

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]					
		Prothioconazole		JAU 6476-S-methyl (M01)		JAU 6476-desthio (M04)	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Use No 1a, Winter cereals 1 × 200 g a.s/ha BBCH 30	Châteaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Jokionen	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Piacenza	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		<0.001		<0.001	
Use No 1b, Winter cereals 1 × 200 g a.s/ha BBCH 69	Châteaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Jokionen	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Piacenza	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		<0.001		<0.001	

Spring cereals, 1 × 200 g a.s./ha at BBCH 30 to 69

Table 8.8-10: FOCUS PEC_{GW} for prothioconazole and its metabolites following an application of FGF11 to spring cereals at BBCH 30-69

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]					
		Prothioconazole		JAU 6476-S-methyl (M01)		JAU 6476-desthio (M04)	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Use No 2a, Spring cereals 1 × 200 g a.s/ha BBCH 30	Châteaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Jokionen	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		<0.001		<0.001	
Use No 2b, Spring cereals 1 × 200 g a.s/ha BBCH 69	Châteaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Jokionen	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		<0.001		<0.001	

Winter oilseed rape, 1 × 200 g a.s./ha at BBCH 61 to 73

Table 8.8-11: FOCUS PEC_{GW} for prothioconazole and its metabolites following an application of FGF11 to winter oilseed rape at BBCH 61-73

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]					
		Prothioconazole		JAU 6476-S-methyl (M01)		JAU 6476-desthio (M04)	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Use No 3, Winter oilseed rape, 1 × 200 g a.s/ha BBCH 61	Châteaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Piacenza	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
		MACRO		MACRO		MACRO	
	Châteaudun	<0.001		<0.001		<0.001	

Summer oilseed rape, 1 × 200 g a.s./ha at BBCH 61 to 73

Table 8.8-12: FOCUS PEC_{GW} for prothioconazole and its metabolites following an application of FGF11 to summer oilseed rape at BBCH 61-73

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]					
		Prothioconazole		JAU 6476-S-methyl (M01)		JAU 6476-desthio (M04)	
		PEARL	PELMO	PEARL	PELMO	PEARL	PELMO
Use No 4, Summer oilseed rape, 1 × 200 g a.s/ha BBCH 61	Jokionen	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
		MACRO		MACRO		MACRO	
	Châteaudun*	not defined		not defined		not defined	

* Not parameterised for summer oilseed rape.

zRMS comments:

Input parameters for prothioconazole and its metabolites presented in Table 8.8-8 and used in the modelling are in general in line with the EU agreed endpoints reported in EFSA Scientific Report (2007) 106.

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 (2023). 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 8.8-9 to 8.8-12.

Overall, no unacceptable leaching of prothioconazole and its metabolites is expected following application of FGF11 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.

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

8.9.1 Justification for new endpoints

Unless otherwise stated, EU agreed endpoints refer to those stated in the EU review of azoxystrobin (**Azoxystrobin, EFSA Journal 2010; 8(4):1542** and **Confirmatory Data, EC, 2014**) and prothioconazole (**Prothioconazole, EFSA Scientific Report, 2007, 106, 1-98**).

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

The following PEC_{sw} and PEC_{sed} modelling for azoxystrobin and its metabolites R401553, R402173 and R234886, as well as for prothioconazole and its metabolite JAU 6476-S-methyl, JAU 6476-desthio, and 1,2,4-triazole has not previously been reviewed and is provided in support of this assessment in the following stand-alone reports.

Report:	KCP 9.2.5.1/01 Fortin-McCuaig, M. (2024a) Azoxystrobin – A European Environmental Fate Assessment for azoxystrobin and its metabolites using the FOCUS surface water models at Steps 1 to 4 following spray application to cereals and oilseed rape in Central Europe. Company report No.: S24-101230-02-004
Guidelines:	FOCUS Surface Water (2015): Generic Guidance for FOCUS surface water Scenarios. v1.4, FOCUS Working Group on Surface Water Scenarios, May 2015.
GLP:	No

Report:	KCP 9.2.5.1/02 Fortin-McCuaig, M. (2024b) Prothioconazole – A European Environmental Fate Assessment for prothioconazole and its metabolites using the FOCUS surface water models at Steps 1 to 4 following spray application to cereals and oilseed rape in Central Europe. Company Report No.: S24-101230-02-005
Guidelines:	FOCUS Surface Water (2015): Generic Guidance for FOCUS surface water Scenarios. v1.4, FOCUS Working Group on Surface Water Scenarios, May 2015.
GLP:	No

Table 8.9-1: Overview of application and cropping data for Steps 1-2 calculations

FOCUS SW crop [-]	Winter cereals	Spring cereals	Winter oilseed rape	Spring oilseed rape
Application rate [g a.s./ha]	160 ^A / 200 ^P	160 ^A / 200 ^P	160 ^A / 200 ^P	160 ^A / 200 ^P
Number of applications [-] / intervals [days]	1 / –	1 / –	1 / –	1 / –
Application date [-]	BBCH 30-69	BBCH 30-69	BBCH 61-73	BBCH 61-73
Interception [-]	Average (20%)	Average (20%)	Full canopy (75%)	Full canopy (75%)
Region / Season [-]	N-EU: Mar-May, Jun-Sep S-EU: Oct-Feb, Mar-May, Jun-Sep			
Models used for calculation [-]	STEPS 1+2 in FOCUS v3.2			

^A Azoxystrobin
^P Prothioconazole

Table 8.9-2: Overview of application and cropping data for Steps 3-4 calculations

FOCUS SW crop [-]	Winter cereals		Spring cereals	
Application rate [g a.s./ha]	160 ^A / 200 ^P	160 ^A / 200 ^P	160 ^A / 200 ^P	160 ^A / 200 ^P
Number of applications [-] / intervals [days]	1 / –	1 / –	1 / –	1 / –
Application date [-]	> BBCH 30	< BBCH 69*	> BBCH 30	< BBCH 69*
Application method [-]	Ground spray	Ground spray	Ground spray	Ground spray
Chemical Application Method (CAM) [-]	Foliar linear (CAM 2)	Foliar linear (CAM 2)	Foliar linear (CAM 2)	Foliar linear (CAM 2)
Soil depth [cm]	4 (default)	4 (default)	4 (default)	4 (default)
Models used for calculation [-]	FOCUS SWASH v5.3 (MACRO v5.5.4, PRZM v4.3.1, TOXSWA v5.5.3), SWAN v5.0.1			

^A Azoxystrobin
^P Prothioconazole
* As per the GAP table, a PHI of 35 days is considered in the application window dates.

FOCUS SW crop [-]	Winter oilseed rape	Spring oilseed rape
Application rate [g a.s./ha]	160 ^A / 200 ^P	160 ^A / 200 ^P
Number of applications [-] / intervals [days]	1 / –	1 / –
Application date [-]	> BBCH 61*	> BBCH 61*
Application method [-]	Ground spray	Ground spray
Crop interception [%]	Foliar linear (CAM 2)	Foliar linear (CAM 2)
Chemical Application Method (CAM) [-]	4 (default)	4 (default)
Soil depth [cm]	1 / –	1 / –
Models used for calculation [-]	FOCUS SWASH v5.3 (MACRO v5.5.4, PRZM v4.3.1, TOXSWA v5.5.3), SWAN v5.0.1	

^A Azoxystrobin
^P Prothioconazole
* As per the GAP table, a PHI of 35 days is considered in the application window dates.

Table 8.9-3: FOCUS Steps 3 and 4 overview of application timings input parameters

FOCUS Crop	Timing	Scenario	Application window	Julian days	Application date
Winter cereals	> BBCH 30	D1	25-Mar – 24-Apr	84 – 114	29-Mar-82
		D2	04-Apr – 04-May	94 – 124	04-Apr-86
		D3	16-Apr – 16-May	106 – 136	20-Apr-92
		D4	18-Mar – 17-Apr	77 – 107	19-Mar-85
		D5	15-Mar – 14-Apr	74 – 104	08-Apr-78
		D6	16-Feb – 18-Mar	47 – 77	27-Feb-86
		R1	24-Apr – 24-May	114 – 144	26-Apr-84
		R3	19-Mar – 18-Apr	78 – 108	28-Mar-80
		R4	24-Jan – 23-Feb	24 – 54	04-Feb-80
	< BBCH 69*	D1	12-Jun – 12-Jul	163 – 193	17-Jun-82
		D2	03-Jun – 03-Jul	154 – 184	03-Jun-86
		D3	11-Jun – 11-Jul	162 – 192	21-Jun-92
		D4	09-Jun – 09-Jul	160 – 190	04-Jul-85
		D5	03-May – 02-Jun	123 – 153	11-May-78
		D6	28-Mar – 27-Apr	87 – 117	09-Apr-86
		R1	26-May – 25-Jun	146 – 176	13-Jun-84
		R3	26-Apr – 26-May	116 – 146	26-Apr-80
		R4	03-May – 02-Jun	123 – 153	04-May-84
Spring cereals	> BBCH 30	D1	27-May – 26-Jun	147 – 177	17-Jun-82
		D3	28-Apr – 28-May	118 – 148	04-May-92
		D4	18-May – 17-Jun	138 – 168	30-May-85
		D5	09-Apr – 09-May	99 – 129	14-Apr-78
		R4	09-Apr – 09-May	99 – 129	04-May-84
	< BBCH 69*	D1	18-Jun – 18-Jul	169 – 199	24-Jun-82
		D3	29-May – 28-Jun	149 – 179	28-May-92
		D4	09-Jun – 09-Jul	160 – 190	04-Jul-85
		D5	05-May – 04-Jun	125 – 155	11-May-78
		R4	05-May – 04-Jun	125 – 155	05-May-84
Winter oilseed rape	> BBCH 61*	D2	16-Jun – 16-Jul	167 – 197	16-Jun-86
		D3	27-May – 26-Jun	147 – 177	26-May-92
		D4	07-Jun – 07-Jul	158 – 188	04-Jul-85
		D5	12-May – 11-Jun	132 – 162	27-May-78
		R1	27-May – 26-Jun	147 – 177	13-Jun-84
		R3	22-Apr – 22-May	112 – 142	22-Apr-80
Spring oilseed rape	> BBCH 61*	D1	06-Jul – 05-Aug	187 – 217	04-Aug-82
		D3	17-Jun – 17-Jul	168 – 198	23-Jun-92
		D4	20-Jun – 20-Jul	171 – 201	04-Jul-85
		D5	27-May – 26-Jun	147 – 177	27-May-78
		R1	09-Jun – 09-Jul	160 – 190	09-Jun-78

* As per the GAP table, a PHI of 35 days is considered in the application window dates.

zRMS comments:

The application pattern assumed in surface water simulations is in general in line with Central Zone GAP presented in Table 8.1-1.

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

8.9.2.1 Azoxystrobin and its metabolites

Table 8.9-4: Input parameters related to active substance azoxystrobin, R401553, R402173 and R234886 for PEC_{SW/SED} calculations STEP 1 to 4

Parameter	Azoxystrobin (AZY)	R401553	R402173	R234886	EU endpoint Y/N/ Reference
Molar mass [g/mol]	403.4	213.2	333.3	389.4	Y / EFSA Conclusion (2010) & RAR Addendum (2014)
Water solubility at 20°C and pH 7 [mg/L]	6.7	560	61	57	
Saturated vapour pressure at 20°C [Pa]	1.1 × 10 ⁻¹⁰	n.r.	n.r.	n.r.	
DT ₅₀ in soil at 20°C [days]	78	1.07	4.7	98.6 ^D / 36.7 ^E	
K _{FOC} [L/kg]	423	188	200 ^D / 25 ^E	490 ^D / 21 ^E	
K _{FOM} [L/kg]	245.4	n.r.	n.r.	n.r.	
1/n [-]	0.86	n.r.	n.r.	n.r.	
Maximum occurrence in soil [%]	--	17 ^C	17 ^C	28.8	
Steps 1-2					
DT ₅₀ in water at 20°C [days]	205 ^F	1000 ^A	1000 ^A	1000 ^A	
DT ₅₀ in sediment at 20°C [days]	205 ^F	1000 ^A	1000 ^A	1000 ^A	
DT ₅₀ in total system at 20°C [days]	205	1000 ^A	1000 ^A	1000 ^A	
Maximum occurrence in whole system [%]	--	8.9 ^C	2.4 ^C	18.1	
Steps 3-4					
DT ₅₀ in water at 20°C [days]	1000 ^A	n.r.	n.r.	n.r.	
DT ₅₀ in sediment at 20°C [days]	1000 ^A	n.r.	n.r.	n.r.	
Plant uptake factor [-]	0	n.r.	n.r.	n.r.	

n.r.: Not relevant for Steps 1-2

^A FOCUS default value

^B Soil photolysis value

^C Aqueous photolysis value

^D Acidic soils

^E Alkaline soils

^F Whole system value

Winter cereals, 1 × 160 g a.s./ha at BBCH 30 to 69

Table 8.9-5: FOCUS Step 1 and 2 PEC_{SW/SED} for azoxystrobin and its metabolites following an application of FGF11 to winter cereals at BBCH 30-69

Compound	Step	Region	Season	Maximum PEC _{SW} [µg/L]	21-d TWA PEC _{SW} [µg/L]	Maximum PEC _{SED} [µg/kg]
Azoxystrobin	1	-	-	35.6	33.8	148
	2	N-EU	Mar-May	6.32	5.98	26.1
			Jun-Sep	6.32	5.98	26.1
		S-EU	Oct-Feb	11.6	11.1	48.3
			Mar-May	11.6	11.1	48.3
			Jun-Sep	8.95	8.52	37.2
Metabolite R401553	1	-	-	5.91	5.85	11.1
	2	N-EU	Mar-May	0.415	0.408	0.772
			Jun-Sep	0.415	0.408	0.772
		S-EU	Oct-Feb	0.771	0.761	1.44
			Mar-May	0.771	0.761	1.44
			Jun-Sep	0.593	0.585	1.11
Metabolite R402173 (acidic)	1	-	-	6.78	6.72	13.5
	2	N-EU	Mar-May	0.678	0.672	1.35
			Jun-Sep	0.678	0.672	1.35
		S-EU	Oct-Feb	1.33	1.32	2.66
			Mar-May	1.33	1.32	2.66
			Jun-Sep	1.00	0.996	2.01
Metabolite R402173 (alkaline)	1	-	-	8.30	8.24	2.07
	2	N-EU	Mar-May	0.830	0.823	0.207
			Jun-Sep	0.830	0.823	0.207
		S-EU	Oct-Feb	1.63	1.62	0.407
			Mar-May	1.63	1.62	0.407
			Jun-Sep	1.23	1.22	0.307
Metabolite R234886 (acidic)	1	-	-	14.9	14.7	72.3
	2	N-EU	Mar-May	2.44	2.40	11.9
			Jun-Sep	2.44	2.40	11.9
		S-EU	Oct-Feb	4.71	4.65	22.9
			Mar-May	4.71	4.65	22.9
			Jun-Sep	3.58	3.53	17.4
Metabolite R234886 (alkaline)	1	-	-	23.7	23.6	4.98
	2	N-EU	Mar-May	3.79	3.76	0.795
			Jun-Sep	3.79	3.76	0.795
		S-EU	Oct-Feb	7.33	7.28	1.54
			Mar-May	7.33	7.28	1.54
			Jun-Sep	5.56	5.52	1.17

Table 8.9-6: FOCUS Step 3 Global Maximum PEC_{SW} and PEC_{SED} for azoxystrobin following an application of FGF11 to winter cereals

Use: Winter cereals 1 × 160 g a.s./ha	FOCUS scenario	Date of maximum PEC _{SW}	Global maximum		Main Entry Route	PEC _{SW,TWA} [µg/L]		
			PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]		7-d	21-d	28-d
> BBCH 30	D1 Ditch	24-Nov-82	3.04	16.8	Drainage	2.95	2.68	2.55
	D1 Stream	24-Nov-82	1.91	9.76	Drainage	1.84	1.66	1.58
	D2 Ditch	13-Sep-86	3.76	11.0	Drainage	1.80	1.60	1.53
	D2 Stream	13-Sep-86	2.36	6.26	Drainage	1.02	0.931	0.865
	D3 Ditch	20-Apr-92	1.01	0.487	Drift	0.149	0.050	0.038
	D4 Pond	31-Dec-85	0.271	1.99	Drainage	0.270	0.262	0.257
	D4 Stream	19-Mar-85	0.750	0.706	Drift	0.189	0.164	0.157
	D5 Pond	08-Apr-78	0.103	1.11	Drift	0.099	0.097	0.096
	D5 Stream	08-Apr-78	0.812	0.213	Drift	0.082	0.049	0.041
	D6 Ditch	27-Feb-86	1.02	0.470	Drift	0.135	0.086	0.066
	R1 Pond	21-Jun-84	0.114	0.798	Run-off	0.110	0.103	0.100
	R1 Stream	20-May-84	1.00	0.488	Run-off	0.119	0.066	0.054
	R3 Stream	20-Apr-80	1.39	0.980	Run-off	0.193	0.065	0.072
	R4 Stream	19-Mar-80	1.77	0.832	Run-off	0.252	0.084	0.082
< BBCH 69	D1 Ditch	17-Jun-82	1.47	10.7	Drift	1.42	1.35	1.33
	D1 Stream	11-Mar-82	0.915	5.47	Drainage	0.883	0.829	0.823
	D2 Ditch	14-Nov-86	2.17	9.88	Drainage	1.24	0.935	0.905
	D2 Stream	14-Nov-86	1.36	5.80	Drainage	0.906	0.542	0.523
	D3 Ditch	21-Jun-92	1.02	0.571	Drift	0.191	0.065	0.049
	D4 Pond	31-Dec-85	0.212	1.62	Drainage	0.211	0.205	0.202
	D4 Stream	04-Jul-85	0.876	0.559	Drift	0.144	0.124	0.120
	D5 Pond	07-Feb-78	0.113	1.13	Drainage	0.112	0.110	0.109
	D5 Stream	11-May-78	0.946	0.330	Drift	0.094	0.056	0.047
	D6 Ditch	09-Apr-86	1.02	0.906	Drift	0.445	0.174	0.133
	R1 Pond	21-Jun-84	0.139	1.07	Run-off	0.130	0.120	0.117
	R1 Stream	21-Jun-84	1.13	1.42	Run-off	0.133	0.051	0.050
	R3 Stream	13-May-80	1.40	0.597	Run-off	0.185	0.099	0.076
	R4 Stream	18-May-84	1.66	1.51	Run-off	0.481	0.195	0.149

Table 8.9-7: FOCUS Step 4 Global Maximum PEC_{sw} for azoxystrobin following an application of FGF11 to winter cereals

Use:	Azoxystrobin – Step 4 PEC _{sw} [µg/L]					
Winter cereals 1 × 160 g a.s./ha	VFSmod	-	-	-	-	5 m
	Vegetated runoff buffer	0 m	0 m	10 m	20 m	-
	No-spray buffer	0 m	0 m	10 m	20 m	5 m
	Drift-reducing nozzles	0 %	75 %	0 %	0 %	0 %
> BBCH 30	D1 Ditch	3.04	3.04	3.04	3.04	3.04
	D1 Stream	1.91	1.91	1.91	1.91	1.91
	D2 Ditch	3.76	3.76	3.76	3.76	3.76
	D2 Stream	2.36	2.36	2.36	2.36	2.36
	D3 Ditch	1.01	0.253	0.146	0.076	0.275
	D4 Pond	0.271	0.268	0.269	0.268	0.270
	D4 Stream	0.750	0.317	0.317	0.317	0.317
	D5 Pond	0.103	0.099	0.099	0.099	0.099
	D5 Stream	0.812	0.205	0.161	0.161	0.299
	D6 Ditch	1.02	0.264	0.254	0.254	0.285
	R1 Pond	0.114	0.101	0.050	0.027	0.030
	R1 Stream	1.00	1.00	0.455	0.238	0.244
	R3 Stream	1.39	1.39	0.634	0.333	0.594
	R4 Stream	1.77	1.77	0.804	0.421	0.245
< BBCH 69	D1 Ditch	1.47	1.45	1.45	1.45	1.45
	D1 Stream	0.915	0.915	0.915	0.915	0.915
	D2 Ditch	2.17	2.17	2.17	2.17	2.17
	D2 Stream	1.36	1.36	1.36	1.36	1.36
	D3 Ditch	1.02	0.254	0.146	0.076	0.275
	D4 Pond	0.212	0.206	0.209	0.207	0.211
	D4 Stream	0.876	0.265	0.265	0.265	0.320
	D5 Pond	0.113	0.113	0.113	0.113	0.113
	D5 Stream	0.946	0.236	0.183	0.171	0.345
	D6 Ditch	1.02	0.255	0.166	0.166	0.276
	R1 Pond	0.139	0.117	0.063	0.034	0.040
	R1 Stream	1.13	1.13	0.512	0.268	0.245
	R3 Stream	1.40	1.40	0.629	0.328	0.344
	R4 Stream	1.66	1.66	0.754	0.395	0.351

Spring cereals, 1 × 160 g a.s./ha at BBCH 30 to 69

Table 8.9-8: FOCUS Step 1 and 2 PEC_{SW/SED} for azoxystrobin and its metabolites following an application of FGF11 to spring cereals at BBCH 30-69

Compound	Step	Region	Season	Maximum PEC _{SW} [µg/L]	21-d TWA PEC _{SW} [µg/L]	Maximum PEC _{SED} [µg/kg]
Azoxystrobin	1	-	-	35.6	33.8	148
	2	N-EU	Mar-May	6.32	5.98	26.1
			Jun-Sep	6.32	5.98	26.1
		S-EU	Oct-Feb	11.6	11.1	48.3
			Mar-May	11.6	11.1	48.3
			Jun-Sep	8.95	8.52	37.2
Metabolite R401553	1	-	-	5.91	5.85	11.1
	2	N-EU	Mar-May	0.415	0.408	0.772
			Jun-Sep	0.415	0.408	0.772
		S-EU	Oct-Feb	0.771	0.761	1.44
			Mar-May	0.771	0.761	1.44
			Jun-Sep	0.593	0.585	1.11
Metabolite R402173 (acidic)	1	-	-	6.78	6.72	13.5
	2	N-EU	Mar-May	0.678	0.672	1.35
			Jun-Sep	0.678	0.672	1.35
		S-EU	Oct-Feb	1.33	1.32	2.66
			Mar-May	1.33	1.32	2.66
			Jun-Sep	1.00	0.996	2.01
Metabolite R402173 (alkaline)	1	-	-	8.30	8.24	2.07
	2	N-EU	Mar-May	0.830	0.823	0.207
			Jun-Sep	0.830	0.823	0.207
		S-EU	Oct-Feb	1.63	1.62	0.407
			Mar-May	1.63	1.62	0.407
			Jun-Sep	1.23	1.22	0.307
Metabolite R234886 (acidic)	1	-	-	14.9	14.7	72.3
	2	N-EU	Mar-May	2.44	2.40	11.9
			Jun-Sep	2.44	2.40	11.9
		S-EU	Oct-Feb	4.71	4.65	22.9
			Mar-May	4.71	4.65	22.9
			Jun-Sep	3.58	3.53	17.4
Metabolite R234886 (alkaline)	1	-	-	23.7	23.6	4.98
	2	N-EU	Mar-May	3.79	3.76	0.795
			Jun-Sep	3.79	3.76	0.795
		S-EU	Oct-Feb	7.33	7.28	1.54
			Mar-May	7.33	7.28	1.54
			Jun-Sep	5.56	5.52	1.17

Table 8.9-9: FOCUS Step 3 Global Maximum PEC_{SW} and PEC_{SED} for azoxystrobin following an application of FGF11 to spring cereals

Use: Spring cereals 1 × 160 g a.s./ha	FOCUS scenario	Date of maximum PEC _{SW}	Global maximum		Main Entry Route	PEC _{SW,TWA} [µg/L]		
			PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]		7-d	21-d	28-d
> BBCH 30	D1 Ditch	03-Mar-82	2.51	17.0	Drainage	2.41	2.28	2.20
	D1 Stream	03-Mar-82	1.57	9.27	Drainage	1.50	1.42	1.36
	D3 Ditch	04-May-92	1.01	0.525	Drift	0.167	0.056	0.042
	D4 Pond	30-Dec-85	0.300	2.21	Drainage	0.299	0.291	0.286
	D4 Stream	30-May-85	0.830	0.774	Drift	0.213	0.185	0.172
	D5 Pond	07-Feb-78	0.109	1.17	Drainage	0.108	0.106	0.105
	D5 Stream	14-Apr-78	0.853	0.231	Drift	0.090	0.053	0.045
	R4 Stream	15-May-84	1.79	1.57	Run-off	0.516	0.207	0.159
< BBCH 69	D1 Ditch	21-Dec-82	1.65	14.0	Drainage	1.60	1.53	1.49
	D1 Stream	21-Dec-82	1.03	7.61	Drainage	0.996	0.950	0.922
	D3 Ditch	28-May-92	1.02	0.562	Drift	0.187	0.063	0.047
	D4 Pond	31-Dec-85	0.278	2.04	Drainage	0.277	0.270	0.265
	D4 Stream	04-Jul-85	0.874	0.727	Drift	0.194	0.171	0.160
	D5 Pond	07-Feb-78	0.115	1.13	Drainage	0.114	0.112	0.111
	D5 Stream	11-May-78	0.885	0.241	Drift	0.096	0.057	0.048
	R4 Stream	15-May-84	1.83	1.64	Run-off	0.536	0.220	0.165

Table 8.9-10: FOCUS Step 4 Global Maximum PEC_{SW} for azoxystrobin following an application of FGF11 to spring cereals

Use: Spring cereals 1 × 160 g a.s./ha	Azoxystrobin – Step 4 PEC _{SW} [µg/L]					
	VFSmod	-	-	-	-	5 m
	Vegetated runoff buffer	0 m	0 m	10 m	20 m	-
	No-spray buffer	0 m	0 m	10 m	20 m	5 m
	Drift-reducing nozzles	0 %	75 %	0 %	0 %	0 %
> BBCH 30	D1 Ditch	2.51	2.51	2.51	2.51	2.51
	D1 Stream	1.57	1.57	1.57	1.57	1.57
	D3 Ditch	1.01	0.253	0.146	0.076	0.275
	D4 Pond	0.300	0.296	0.298	0.297	0.299
	D4 Stream	0.830	0.355	0.355	0.355	0.355
	D5 Pond	0.109	0.109	0.109	0.109	0.109
	D5 Stream	0.853	0.215	0.172	0.172	0.313
	R4 Stream	1.79	1.79	0.809	0.422	0.361
< BBCH 69	D1 Ditch	1.65	1.65	1.65	1.65	1.65
	D1 Stream	1.03	1.03	1.03	1.03	1.03
	D3 Ditch	1.02	0.254	0.146	0.076	0.275
	D4 Pond	0.278	0.273	0.276	0.274	0.277
	D4 Stream	0.874	0.318	0.318	0.318	0.319
	D5 Pond	0.115	0.115	0.115	0.115	0.115
	D5 Stream	0.885	0.222	0.175	0.175	0.324
	R4 Stream	1.83	1.83	0.827	0.432	1.65

Winter oilseed rape, 1 × 160 g a.s./ha at BBCH 61 to 73

Table 8.9-11: FOCUS Step 1 and 2 PEC_{SW/SED} for azoxystrobin and its metabolites following an application of FGF11 to winter oilseed rape at 61-73

Compound	Step	Region	Season	Maximum PEC _{SW} [µg/L]	21-d TWA PEC _{SW} [µg/L]	Maximum PEC _{SED} [µg/kg]
Azoxystrobin	1	-	-	35.6	33.8	148
	2	N-EU	Mar-May	2.70	2.49	10.8
			Jun-Sep	2.70	2.49	10.8
		S-EU	Oct-Feb	4.35	4.08	17.8
			Mar-May	4.35	4.08	17.8
			Jun-Sep	3.52	3.28	14.3
Metabolite R401553	1	-	-	5.91	5.85	11.1
	2	N-EU	Mar-May	0.170	0.165	0.313
			Jun-Sep	0.170	0.165	0.313
		S-EU	Oct-Feb	0.281	0.276	0.521
			Mar-May	0.281	0.276	0.521
			Jun-Sep	0.226	0.220	0.417
Metabolite R402173 (acidic)	1	-	-	6.78	6.72	13.5
	2	N-EU	Mar-May	0.229	0.226	0.454
			Jun-Sep	0.229	0.226	0.454
		S-EU	Oct-Feb	0.433	0.428	0.862
			Mar-May	0.433	0.428	0.862
			Jun-Sep	0.331	0.327	0.658
Metabolite R402173 (alkaline)	1	-	-	8.30	8.24	2.07
	2	N-EU	Mar-May	0.279	0.277	0.070
			Jun-Sep	0.279	0.277	0.070
		S-EU	Oct-Feb	0.529	0.525	0.132
			Mar-May	0.529	0.525	0.132
			Jun-Sep	0.404	0.401	0.101
Metabolite R234886 (acidic)	1	-	-	14.9	14.7	72.3
	2	N-EU	Mar-May	0.887	0.857	4.23
			Jun-Sep	0.887	0.857	4.23
		S-EU	Oct-Feb	1.59	1.56	7.69
			Mar-May	1.59	1.56	7.69
			Jun-Sep	1.24	1.21	5.96
Metabolite R234886 (alkaline)	1	-	-	23.7	23.6	4.98
	2	N-EU	Mar-May	1.36	1.35	0.285
			Jun-Sep	1.36	1.35	0.285
		S-EU	Oct-Feb	2.46	2.44	0.517
			Mar-May	2.46	2.44	0.517
			Jun-Sep	1.91	1.89	0.401

Table 8.9-12: FOCUS Step 3 Global Maximum PEC_{SW} and PEC_{SED} for azoxystrobin following an application of FGF11 to winter oilseed rape

Use: Winter oilseed rape 1 × 160 g a.s./ha	FOCUS scenario	Date of maximum PEC _{SW}	Global maximum		Main Entry Route	PEC _{SW,TWA} [µg/L]		
			PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]		7-d	21-d	28-d
> BBCH 61	D1 Ditch	16-Jun-86	1.24	6.37	Drift	1.08	0.971	0.932
	D1 Stream	16-Jun-86	1.06	4.39	Drift	0.917	0.803	0.753
	D3 Ditch	26-May-92	1.02	0.620	Drift	0.219	0.074	0.056
	D4 Pond	01-Jan-86	0.188	1.47	Drainage	0.187	0.181	0.178
	D4 Stream	04-Jul-85	0.876	0.508	Drift	0.131	0.111	0.107
	D5 Pond	07-Feb-78	0.110	1.08	Drainage	0.109	0.107	0.106
	D5 Stream	27-May-78	0.946	0.322	Drift	0.093	0.056	0.047
	R1 Pond	21-Jun-84	0.150	1.04	Run-off	0.140	0.129	0.128
	R1 Stream	21-Jun-84	1.13	1.56	Run-off	0.133	0.051	0.053
	R2 Stream	13-May-80	1.10	0.476	Run-off	0.144	0.076	0.057

Table 8.9-13: FOCUS Step 4 Global Maximum PEC_{SW} for azoxystrobin following an application of FGF11 to winter oilseed rape

Use: Winter oilseed rape 1 × 160 g a.s./ha	Azoxystrobin – Step 4 PEC _{SW} [µg/L]					
	VFSmod	-	-	-	-	5 m
> BBCH 61	Vegetated runoff buffer	0 m	0 m	10 m	20 m	-
	No-spray buffer	0 m	0 m	10 m	20 m	5 m
	Drift-reducing nozzles	0 %	75 %	0 %	0 %	0 %
	D2 Ditch	1.24	1.03	1.03	1.03	1.03
	D2 Stream	1.06	0.647	0.647	0.647	0.647
	D3 Ditch	1.02	0.254	0.146	0.038	0.275
	D4 Pond	0.188	0.182	0.185	0.181	0.187
	D4 Stream	0.876	0.248	0.248	0.248	0.320
	D5 Pond	0.110	0.110	0.110	0.110	0.110
	D5 Stream	0.946	0.236	0.183	0.162	0.345
> BBCH 61	R1 Pond	0.150	0.128	0.067	0.037	0.043
	R1 Stream	1.13	1.13	0.515	0.270	0.244
	R3 Stream	1.10	1.10	0.493	0.257	0.344

Spring oilseed rape, 1 × 160 g a.s./ha at BBCH 61 to 73

Table 8.9-14: FOCUS Step 1 and 2 PEC_{SW/SED} for azoxystrobin and its metabolites following an application of FGF11 to spring oilseed rape at 61-73

Compound	Step	Region	Season	Maximum PEC _{SW} [µg/L]	21-d TWA PEC _{SW} [µg/L]	Maximum PEC _{SED} [µg/kg]
Azoxystrobin	1	-	-	35.6	33.8	148
	2	N-EU	Mar-May	2.70	2.49	10.8
			Jun-Sep	2.70	2.49	10.8
		S-EU	Oct-Feb	4.35	4.08	17.8
			Mar-May	4.35	4.08	17.8
			Jun-Sep	3.52	3.28	14.3
Metabolite R401553	1	-	-	5.91	5.85	11.1
	2	N-EU	Mar-May	0.170	0.165	0.313
			Jun-Sep	0.170	0.165	0.313
		S-EU	Oct-Feb	0.281	0.276	0.521
			Mar-May	0.281	0.276	0.521
			Jun-Sep	0.226	0.220	0.417
Metabolite R402173 (acidic)	1	-	-	6.78	6.72	13.5
	2	N-EU	Mar-May	0.229	0.226	0.454
			Jun-Sep	0.229	0.226	0.454
		S-EU	Oct-Feb	0.433	0.428	0.862
			Mar-May	0.433	0.428	0.862
			Jun-Sep	0.331	0.327	0.658
Metabolite R402173 (alkaline)	1	-	-	8.30	8.24	2.07
	2	N-EU	Mar-May	0.279	0.277	0.070
			Jun-Sep	0.279	0.277	0.070
		S-EU	Oct-Feb	0.529	0.525	0.132
			Mar-May	0.529	0.525	0.132
			Jun-Sep	0.404	0.401	0.101
Metabolite R234886 (acidic)	1	-	-	14.9	14.7	72.3
	2	N-EU	Mar-May	0.887	0.857	4.23
			Jun-Sep	0.887	0.857	4.23
		S-EU	Oct-Feb	1.59	1.56	7.69
			Mar-May	1.59	1.56	7.69
			Jun-Sep	1.24	1.21	5.96
Metabolite R234886 (alkaline)	1	-	-	23.7	23.6	4.98
	2	N-EU	Mar-May	1.36	1.35	0.285
			Jun-Sep	1.36	1.35	0.285
		S-EU	Oct-Feb	2.46	2.44	0.517
			Mar-May	2.46	2.44	0.517
			Jun-Sep	1.91	1.89	0.401

Table 8.9-15: FOCUS Step 3 Global Maximum PEC_{SW} and PEC_{SED} for azoxystrobin following an application of FGF11 to spring oilseed rape

Use: Spring oilseed rape 1 × 160 g a.s./ha	FOCUS scenario	Date of maximum PEC _{SW}	Global maximum		Main Entry Route	PEC _{SW,TWA} [µg/L]		
			PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]		7-d	21-d	28-d
> BBCH 61	D1 Ditch	21-Dec-82	2.46	18.5	Drainage	2.37	2.25	2.17
	D1 Stream	21-Dec-82	1.54	10.2	Drainage	1.48	1.38	1.33
	D3 Ditch	23-Jun-92	1.02	0.653	Drift	0.239	0.081	0.061
	D4 Pond	31-Dec-85	0.249	1.85	Drainage	0.248	0.241	0.237
	D4 Stream	04-Jul-85	0.876	0.655	Drift	0.172	0.152	0.144
	D5 Pond	07-Feb-78	0.285	2.12	Drainage	0.283	0.277	0.273
	D5 Stream	27-May-78	0.945	0.570	Drift	0.240	0.144	0.119
	R1 Pond	09-Jul-78	0.243	1.46	Run-off	0.232	0.223	0.217
	R1 Stream	17-Jun-78	1.30	1.58	Run-off	0.154	0.089	0.082

Table 8.9-16: FOCUS Step 4 Global Maximum PEC_{SW} for azoxystrobin following an application of FGF11 to spring oilseed rape

Use: Spring oilseed rape 1 × 160 g a.s./ha	Azoxystrobin – Step 4 PEC _{SW} [µg/L]					
	VFSmod	-	-	-	-	5 m
> BBCH 61	Vegetated runoff buffer	0 m	0 m	10 m	20 m	-
	No-spray buffer	0 m	0 m	10 m	20 m	5 m
	Drift-reducing nozzles	0 %	75 %	0 %	0 %	0 %
	D1 Ditch	2.46	2.46	2.46	2.46	2.46
	D1 Stream	1.54	1.54	1.54	1.54	1.54
	D3 Ditch	1.02	0.254	0.146	0.076	0.276
	D4 Pond	0.249	0.243	0.246	0.245	0.248
	D4 Stream	0.876	0.300	0.300	0.300	0.320
	D5 Pond	0.285	0.285	0.285	0.285	0.285
> BBCH 61	D5 Stream	0.945	0.359	0.359	0.359	0.359
	R1 Pond	0.243	0.226	0.104	0.055	0.062
	R1 Stream	1.30	1.30	0.592	0.310	0.245

zRMS comments:

Input parameters for azoxystrobin presented in Table 8.9-4 are in line with EU agreed data reported in EFSA Journal 2010; 8(4):1542 and in Addendum with confirmatory data for azoxystrobin (September, 2014).

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

Step 4 simulations were performed according to recommendations of the FOCUS work group on landscape and mitigation factors.

The surface water exposure at Step 1-4 was independently validated by the zRMS in additional simulations using the EU agreed input parameters, and only relevant scenarios in the central zone were validated. Therefore results presented for D1, D2 and D6 scenarios were struck through as not relevant.

Results obtained by the zRMS at Step 1-4 for azoxystrobin and its metabolites were in good agreement with values obtained by the Applicant.

Additional Step 4 calculations with consideration of 5 m VFSmod were performed for azoxystrobin mainly for R1 stream, R3 stream and R4 stream scenarios when PEC_{SW} values were above the RAC of 0.954 µg/L. The additional VFSmod refinement demonstrates that winter cereals and winter and spring oilseed rape could be addressed with 5 m mitigation, concerned Member States must decide on its acceptability.

Overall, the surface water exposure for azoxystrobin and its metabolites presented in Tables 8.9-5 to 8.9-16 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 Prothioconazole and its metabolites

Table 8.9-17: Input parameters related to active substance prothioconazole and its metabolite JAU 6476-desthio (M04) for FOCUS PEC_{SW/SED} modelling at Steps 1 to 4

Parameter	Prothioconazole	JAU 6476-desthio (M04)	EU endpoint Y/N/ Reference
Molar mass [g/mol]	344.26	312.2	Y / EFSA Conclusion (2007)
Water solubility at 20°C and pH 8 [mg/L]	300	1000 ^A	
Saturated vapour pressure at 25°C [Pa]	4.0 × 10 ⁻⁷	n.r.	
DT ₅₀ in soil at 20°C [days]	1.2	22.7	
K _{FOC} [L/kg]	1765	575.4	
K _{FOM} [L/kg]	1024	333.8	
1/n [-]	0.9	0.81	
Formation fraction in soil [-]	--	0.6 (parent)	
Maximum occurrence in soil [%]	--	57.1	
Steps 1-2			
DT ₅₀ in water at 20°C [days]	39.5	1000 ^B	
DT ₅₀ in sediment at 20°C [days]	39.5	1000 ^B	
DT ₅₀ in total system at 20°C [days]	39.5	1000 ^B	
Steps 3-4			
DT ₅₀ in water at 20°C [days]	39.5 / 1000 ^B	1000 ^B	
DT ₅₀ in sediment at 20°C [days]	1000 ^B / 39.5	1000 ^B	
Maximum occurrence in whole system [%]	--	54.6	
Plant uptake factor [-]	0	0	

^A Conservative default value

^B FOCUS default value

Table 8.9-18: Input parameters related to active substance prothioconazole and its metabolites JAU 6476-S-methyl (M01), and 1,2,4-triazole (M13) for FOCUS PEC_{SW/SED} modelling at Steps 1 and 2

Parameter	JAU 6476-S-methyl (M01)	1,2,4-triazole (M13)	EU endpoint Y/N/ Reference
Molar mass [g/mol]	358.3	69.065	Y / EFSA Conclusion (2007)
Water solubility at 20°C and pH 8 [mg/L]	1000 ^A	1000 ^A	
Saturated vapour pressure at 25°C [Pa]	n.r.	n.r.	
DT ₅₀ in soil at 20°C [days]	15.7	1000 ^D	
K _{FOC} [L/kg]	2556.3	89 ^F	
K _{FOM} [L/kg]	n.r.	n.r.	
1/n [-]	n.r.	n.r.	
Formation fraction in soil [-]	n.r.	n.r.	
Maximum occurrence in soil [%]	14.6	0	
DT ₅₀ in water at 20°C [days]	1000 ^D	1000 ^D	
DT ₅₀ in sediment at 20°C [days]	1000 ^D	1000 ^D	
DT ₅₀ in total system at 20°C [days]	1000 ^D	1000 ^D	
Maximum occurrence in whole system [%]	n.r. 12.7 (aerobic in whole system) 77 (anaerobic in sediment)	41.8	
Plant uptake factor [-]	n.r.	n.r.	

n.r.: Not relevant

^A Conservative default value

^B Conservative default value used for PEC_{SW} calculations

^C Conservative default value used for PEC_{SED} calculations

^D FOCUS default value

^E Aqueous photolysis value

^F EFSA conclusion on propiconazole (2017)

Winter cereals, 1 × 200 g a.s./ha at BBCH 30 to 69

Table 8.9-19: FOCUS Step 1 and 2 PEC_{SW/SED} for prothioconazole and its metabolites following an application of FGF11 to winter cereals at 30-69

Compound	Step	Region	Season	Maximum PEC _{SW} [µg/L]	21-d TWA PEC _{SW} [µg/L]	Maximum PEC _{SED} [µg/kg]
Prothioconazole	1	-	-	21.7	17.1	354
	2	N-EU	Mar-May	1.84	0.764	14.3
			Jun-Sep	1.84	0.764	14.3
		S-EU	Oct-Feb	1.84	0.993	19.8
			Mar-May	1.84	0.993	19.8
			Jun-Sep	1.84	0.879	17.1
Metabolite JAU 6476-S-methyl (M01)	1	-	-	4.54	4.33	111
	2	N-EU	Mar-May	0.415	0.393	10.1
			Jun-Sep	0.415	0.393	10.1
		S-EU	Oct-Feb	0.755	0.730	18.8
			Mar-May	0.755	0.730	18.8
			Jun-Sep	0.585	0.561	14.4
Metabolite JAU 6476-desthio (M04)	1	-	-	39.1	38.5	223
	2	N-EU	Mar-May	3.66	3.55	20.6
			Jun-Sep	3.66	3.55	20.6
		S-EU	Oct-Feb	6.73	6.59	38.2
			Mar-May	6.73	6.59	38.2
			Jun-Sep	5.20	5.07	29.4
Metabolite 1,2,4-triazole (M13)	1	-	-	5.39	5.34	4.78
			Mar-May	0.260	0.253	0.227
			Jun-Sep	0.260	0.253	0.227
		S-EU	Oct-Feb	0.378	0.370	0.331
			Mar-May	0.378	0.370	0.331
			Jun-Sep	0.319	0.312	0.279

Table 8.9-20: FOCUS Step 3 Global Maximum PEC_{SW} and PEC_{SED} for prothioconazole following an application of FGF11 to winter cereals

Use: Winter cereals 1 × 200 g a.s./ha	FOCUS scenario	Date of maximum PEC _{SW}	Global maximum		Main Entry Route	PEC _{SW,TWA} [µg/L]		
			PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]		7-d	21-d	28-d
> BBCH 30	D1-Ditch	29-Mar-82	1.27	1.15	Drift	0.320	0.111	0.084
	D1-Stream	29-Mar-82	0.986	0.042	Drift	0.008	0.003	0.002
	D2-Ditch	04-Apr-86	1.28	1.60	Drift	0.400	0.138	0.105
	D2-Stream	04-Apr-86	1.08	0.180	Drift	0.035	0.012	0.009
	D3-Ditch	20-Apr-92	1.26	0.775	Drift	0.183	0.062	0.047
	D4-Pond	19-Mar-85	0.044	0.272	Drift	0.039	0.034	0.032
	D4-Stream	19-Mar-85	0.934	0.028	Drift	0.005	0.002	0.001
	D5-Pond	08-Apr-78	0.044	0.275	Drift	0.039	0.035	0.034
	D5-Stream	08-Apr-78	1.01	0.029	Drift	0.005	0.002	0.001
	D6-Ditch	27-Feb-86	1.25	0.382	Drift	0.080	0.027	0.021
	R1-Pond	26-Apr-84	0.044	0.254	Drift	0.039	0.035	0.033
	R1-Stream	26-Apr-84	0.833	0.115	Drift	0.022	0.008	0.007
	R3-Stream	28-Mar-80	1.17	0.236	Drift	0.047	0.016	0.013
	R4-Stream	04-Feb-80	0.836	0.130	Drift	0.025	0.008	0.006
< BBCH 69	D1-Ditch	17-Jun-82	1.28	4.21	Drift	1.00	0.790	0.716
	D1-Stream	17-Jun-82	1.12	0.637	Drift	0.143	0.048	0.036
	D2-Ditch	03-Jun-86	1.28	3.06	Drift	0.994	0.567	0.492
	D2-Stream	03-Jun-86	1.14	2.57	Drift	0.781	0.294	0.238
	D3-Ditch	21-Jun-92	1.27	0.936	Drift	0.234	0.079	0.060
	D4-Pond	04-Jul-85	0.044	0.250	Drift	0.040	0.035	0.034
	D4-Stream	04-Jul-85	1.09	0.228	Drift	0.045	0.015	0.011
	D5-Pond	11-May-78	0.044	0.265	Drift	0.040	0.036	0.034
	D5-Stream	11-May-78	1.18	0.318	Drift	0.065	0.022	0.016
	D6-Ditch	09-Apr-86	1.27	1.60	Drift	0.525	0.210	0.160
	R1-Pond	21-Jun-84	0.048	0.323	Run-off	0.045	0.041	0.040
	R1-Stream	13-Jun-84	0.835	1.21	Drift	0.024	0.014	0.010
	R3-Stream	26-Apr-80	1.18	0.288	Drift	0.058	0.020	0.015
	R4-Stream	04-May-84	0.836	0.977	Drift	0.078	0.036	0.027

Table 8.9-21: FOCUS Step 3 Global Maximum PEC_{SW} and PEC_{SED} for metabolite JAU-6476-desthio (M04) following an application of FGF11 to winter cereals

Use: Winter cereals 1 × 200 g a.s./ha	FOCUS scenario	Date of maximum PEC _{SW}	Global maximum		Main Entry Route	PEC _{SW,TWA} [µg/L]		
			PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]		7-d	21-d	28-d
> BBCH 30	D1 Ditch	30-Mar-82	0.005	0.165	-	0.003	0.002	0.002
	D1 Stream	29-Mar-82	0.019	0.020	-	0.001	0.001	0.001
	D2 Ditch	26-Mar-87	0.027	0.206	-	0.005	0.003	0.003
	D2 Stream	04-Apr-86	0.070	0.040	-	0.003	0.002	0.002
	D3 Ditch	21-Apr-92	0.003	0.079	-	0.001	<0.001	<0.001
	D4 Pond	20-Aug-85	0.007	0.221	-	0.007	0.007	0.007
	D4 Stream	19-Mar-85	0.006	0.005	-	0.001	<0.001	<0.001
	D5 Pond	20-Aug-78	0.010	0.286	-	0.010	0.010	0.010
	D5 Stream	08-Apr-78	0.011	0.003	-	<0.001	<0.001	<0.001
	D6 Ditch	27-Feb-86	0.002	0.041	-	<0.001	<0.001	<0.001
	R1 Pond	21-Jun-84	0.043	0.556	-	0.041	0.039	0.038
	R1 Stream	20-May-84	0.379	0.403	-	0.047	0.026	0.021
	R3 Stream	20-Apr-80	0.464	0.596	-	0.064	0.022	0.023
	R4 Stream	19-Mar-80	0.688	0.460	-	0.101	0.034	0.035
< BBCH 69	D1 Ditch	18-Jul-82	0.091	1.96	-	0.091	0.089	0.088
	D1 Stream	17-Jun-82	0.022	0.077	-	0.003	0.002	0.002
	D2 Ditch	01-Aug-86	0.058	1.38	-	0.058	0.057	0.057
	D2 Stream	09-Jun-86	0.092	0.583	-	0.071	0.029	0.025
	D3 Ditch	22-Jun-92	0.010	0.108	-	0.002	0.001	0.001
	D4 Pond	14-Sep-85	0.010	0.206	-	0.010	0.010	0.010
	D4 Stream	04-Jul-85	0.008	0.024	-	0.001	<0.001	<0.001
	D5 Pond	01-Sep-78	0.011	0.276	-	0.011	0.011	0.011
	D5 Stream	11-May-78	0.014	0.029	-	0.001	<0.001	<0.001
	D6 Ditch	11-Apr-86	0.015	0.308	-	0.010	0.005	0.004
	R1 Pond	09-Sep-84	0.029	0.501	-	0.029	0.028	0.027
	R1 Stream	14-Jul-84	0.245	0.954	-	0.025	0.011	0.011
	R3 Stream	13-May-80	0.452	0.303	-	0.062	0.034	0.025
	R4 Stream	18-May-84	0.504	0.888	-	0.162	0.072	0.054

Table 8.9-22: FOCUS Step 4 Global Maximum PEC_{sw} for metabolite JAU-6476-desthio (M04) following an application of FGF11 to winter cereals

Use:	Metabolite prothioconazole-desthio (M04) – Step 4 PEC _{sw} [µg/L]				
Winter cereals 1×200 g a.s./ha	VFSmod	-	-	-	5 m
	Vegetated runoff buffer	0 m	0 m	10 m	-
	No-spray buffer	0 m	0 m	10 m	5 m
	Drift-reducing nozzles	0 %	50 %	0 %	0 %
> BBCH 30	D1 Ditch	0.005	0.003	0.002	0.002
	D1 Stream	0.019	0.010	0.004	0.007
	D2 Ditch	0.027	0.027	0.027	0.027
	D2 Stream	0.070	0.035	0.017	0.026
	D3 Ditch	0.003	0.002	<0.001	0.001
	D4 Pond	0.007	0.003	0.004	0.006
	D4 Stream	0.006	0.004	0.004	0.004
	D5 Pond	0.010	0.005	0.006	0.009
	D5 Stream	0.011	0.005	0.002	0.004
	D6 Ditch	0.002	0.001	<0.001	<0.001
	R1 Pond	0.043	0.040	0.019	0.008
	R1 Stream	0.379	0.379	0.172	0.024
	R3 Stream	0.464	0.464	0.212	0.195
	R4 Stream	0.688	0.688	0.313	0.085
< BBCH 69	D1 Ditch	0.091	0.044	0.013	0.024
	D1 Stream	0.022	0.011	0.004	0.008
	D2 Ditch	0.058	0.035	0.035	0.035
	D2 Stream	0.092	0.046	0.022	0.033
	D3 Ditch	0.010	0.005	0.001	0.003
	D4 Pond	0.010	0.005	0.006	0.008
	D4 Stream	0.008	0.007	0.007	0.007
	D5 Pond	0.011	0.005	0.007	0.010
	D5 Stream	0.014	0.007	0.003	0.005
	D6 Ditch	0.015	0.007	0.002	0.004
	R1 Pond	0.029	0.025	0.014	0.009
	R1 Stream	0.245	0.245	0.109	0.028
	R3 Stream	0.452	0.452	0.203	0.006
	R4 Stream	0.504	0.504	0.229	0.145

Spring cereals, 1 × 200 g a.s./ha at BBCH 30 to 69

Table 8.9-23: FOCUS Step 1 and 2 PEC_{SW/SED} for prothioconazole and its metabolites following an application of FGF11 to spring cereals at 30-69

Compound	Step	Region	Season	Maximum PEC _{SW} [µg/L]	21-d TWA PEC _{SW} [µg/L]	Maximum PEC _{SED} [µg/kg]
Prothioconazole	1	-	-	21.7	17.1	354
	2	N-EU	Mar-May	1.84	0.764	14.3
			Jun-Sep	1.84	0.764	14.3
		S-EU	Oct-Feb	1.84	0.993	19.8
			Mar-May	1.84	0.993	19.8
			Jun-Sep	1.84	0.879	17.1
Metabolite JAU 6476-S-methyl (M01)	1	-	-	4.54	4.33	111
	2	N-EU	Mar-May	0.415	0.393	10.1
			Jun-Sep	0.415	0.393	10.1
		S-EU	Oct-Feb	0.755	0.730	18.8
			Mar-May	0.755	0.730	18.8
			Jun-Sep	0.585	0.561	14.4
Metabolite JAU 6476-desthio (M04)	1	-	-	39.1	38.5	223
	2	N-EU	Mar-May	3.66	3.55	20.6
			Jun-Sep	3.66	3.55	20.6
		S-EU	Oct-Feb	6.73	6.59	38.2
			Mar-May	6.73	6.59	38.2
			Jun-Sep	5.20	5.07	29.4
Metabolite 1,2,4-triazole (M13)	1	-	-	5.39	5.34	4.78
	2	N-EU	Mar-May	0.260	0.253	0.227
			Jun-Sep	0.260	0.253	0.227
		S-EU	Oct-Feb	0.378	0.370	0.331
			Mar-May	0.378	0.370	0.331
			Jun-Sep	0.319	0.312	0.279

Table 8.9-24: FOCUS Step 3 Global Maximum PEC_{SW} and PEC_{SED} for prothioconazole following an application of FGF11 to spring cereals

Use: Spring cereals 1 × 200 g a.s./ha	FOCUS scenario	Date of maximum PEC _{SW}	Global maximum		Main Entry Route	PEC _{SW,TWA} [µg/L]		
			PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]		7-d	21-d	28-d
> BBCH 30	D1 Ditch	17-Jun-82	1.28	4.21	Drift	1.00	0.790	0.716
	D1 Stream	17-Jun-82	1.12	0.637	Drift	0.143	0.048	0.036
	D3 Ditch	04-May-92	1.27	0.846	Drift	0.205	0.069	0.052
	D4 Pond	30-May-85	0.044	0.251	Drift	0.040	0.035	0.034
	D4 Stream	30-May-85	1.03	0.071	Drift	0.013	0.004	0.003
	D5 Pond	14-Apr-78	0.044	0.270	Drift	0.040	0.035	0.034
	D5 Stream	14-Apr-78	1.06	0.045	Drift	0.008	0.003	0.002
	R4 Stream	04-May-84	0.836	0.898	Drift	0.073	0.034	0.025
< BBCH 69	D1 Ditch	24-Jun-82	1.28	4.14	Drift	1.00	0.787	0.713
	D1 Stream	24-Jun-82	1.12	0.637	Drift	0.143	0.048	0.036
	D3 Ditch	28-May-92	1.27	0.919	Drift	0.228	0.078	0.058
	D4 Pond	04-Jul-85	0.044	0.250	Drift	0.040	0.035	0.034
	D4 Stream	04-Jul-85	1.09	0.209	Drift	0.041	0.014	0.010
	D5 Pond	11-May-78	0.044	0.262	Drift	0.040	0.035	0.034
	D5 Stream	11-May-78	1.10	0.071	Drift	0.013	0.004	0.003
	R4 Stream	05-May-84	0.836	0.982	Drift	0.082	0.037	0.028

Table 8.9-25: FOCUS Step 3 Global Maximum PEC_{SW} and PEC_{SED} for metabolite JAU-6476-desthio (M04) following an application of FGF11 to spring cereals

Use: Spring cereals 1 × 200 g a.s./ha	FOCUS scenario	Date of maximum PEC _{SW}	Global maximum		Main Entry Route	PEC _{SW,TWA} [µg/L]		
			PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]		7-d	21-d	28-d
> BBCH 30	D1 Ditch	18-Jul-82	0.091	1.93	-	0.091	0.089	0.088
	D1 Stream	17-Jun-82	0.022	0.082	-	0.003	0.002	0.002
	D3 Ditch	05-May-92	0.007	0.091	-	0.002	0.001	<0.001
	D4 Pond	23-Aug-85	0.010	0.214	-	0.010	0.010	0.010
	D4 Stream	30-May-85	0.006	0.010	-	0.001	<0.001	<0.001
	D5 Pond	22-Aug-78	0.010	0.282	-	0.010	0.010	0.010
	D5 Stream	14-Apr-78	0.011	0.004	-	<0.001	<0.001	<0.001
	R4 Stream	18-May-84	0.567	0.935	-	0.175	0.080	0.060
< BBCH 69	D1 Ditch	23-Jul-82	0.098	1.87	-	0.098	0.096	0.094
	D1 Stream	24-Jun-82	0.022	0.075	-	0.003	0.002	0.002
	D3 Ditch	29-May-92	0.008	0.104	-	0.002	0.001	0.001
	D4 Pond	01-Sep-85	0.010	0.200	-	0.009	0.009	0.009
	D4 Stream	07-Dec-85	0.009	0.024	-	0.002	0.001	<0.001
	D5 Pond	01-Sep-78	0.011	0.272	-	0.011	0.011	0.011
	D5 Stream	11-May-78	0.012	0.007	-	<0.001	<0.001	<0.001
	R4 Stream	18-May-84	0.584	0.970	-	0.183	0.082	0.062

Table 8.9-26: FOCUS Step 4 Global Maximum PEC_{SW} for metabolite JAU-6476-desthio (M04) following an application of FGF11 to spring cereals

Use: Spring cereals 1×200 g a.s./ha	Metabolite prothioconazole-desthio (M04) – Step 4 PEC _{SW} [µg/L]			
	VFSmod	-	-	5 m
	Vegetated runoff buffer	0 m	0 m	10 m
	No-spray buffer	0 m	0 m	10 m
	Drift-reducing nozzles	0 %	50 %	0 %
> BBCH 30	D1 Ditch	0.091	0.045	0.013
	D1 Stream	0.022	0.011	0.004
	D3 Ditch	0.007	0.004	0.001
	D4 Pond	0.010	0.005	0.006
	D4 Stream	0.006	0.005	0.005
	D5 Pond	0.010	0.005	0.006
	D5 Stream	0.011	0.006	0.002
	R4 Stream	0.567	0.567	0.258
< BBCH 69	D1 Ditch	0.098	0.048	0.013
	D1 Stream	0.022	0.011	0.004
	D3 Ditch	0.008	0.004	0.001
	D4 Pond	0.010	0.005	0.006
	D4 Stream	0.009	0.009	0.009
	D5 Pond	0.011	0.005	0.007
	D5 Stream	0.012	0.006	0.002
	R4 Stream	0.584	0.584	0.266

Winter oilseed rape, 1 × 200 g a.s./ha at BBCH 61 to 73

Table 8.9-27: FOCUS Step 1 and 2 PEC_{SW/SED} for prothioconazole and its metabolites following an application of FGF11 to winter oilseed rape at 61-73

Compound	Step	Region	Season	Maximum PEC _{SW} [µg/L]	21-d TWA PEC _{SW} [µg/L]	Maximum PEC _{SED} [µg/kg]
Prothioconazole	1	-	-	21.7	17.1	354
	2	N-EU	Mar-May	1.84	0.607	10.6
			Jun-Sep	1.84	0.607	10.6
		S-EU	Oct-Feb	1.84	0.679	12.3
			Mar-May	1.84	0.679	12.3
			Jun-Sep	1.84	0.643	11.4
Metabolite Jau 6476-S-methyl (M01)	1	-	-	4.54	4.33	111
	2	N-EU	Mar-May	0.243	0.154	4.12
			Jun-Sep	0.243	0.154	4.12
		S-EU	Oct-Feb	0.287	0.266	6.83
			Mar-May	0.287	0.266	6.83
			Jun-Sep	0.243	0.198	5.47
Metabolite JAU 6476-desthio (M04)	1	-	-	39.1	38.5	223
	2	N-EU	Mar-May	1.56	1.46	8.46
			Jun-Sep	1.56	1.46	8.46
		S-EU	Oct-Feb	2.52	2.41	14.0
			Mar-May	2.52	2.41	14.0
			Jun-Sep	2.04	1.94	11.2
Metabolite 1,2,4-triazole (M13)	1	-	-	5.39	5.34	4.78
	2	N-EU	Mar-May	0.179	0.173	0.155
			Jun-Sep	0.179	0.173	0.155
		S-EU	Oct-Feb	0.216	0.210	0.188
			Mar-May	0.216	0.210	0.188
			Jun-Sep	0.198	0.191	0.171

Table 8.9-28: FOCUS Step 3 Global Maximum PEC_{SW} and PEC_{SED} for prothioconazole following an application of FGF11 to winter oilseed rape

Use: Winter oilseed rape 1 × 200 g a.s./ha	FOCUS scenario	Date of maximum PEC _{SW}	Global maximum		Main Entry Route	PEC _{SW,TWA} [µg/L]		
			PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]		7-d	21-d	28-d
> BBCH 61	D2 Ditch	16-Jun-86	1.28	4.52	Drift	1.00	0.801	0.741
	D2 Stream	16-Jun-86	1.14	3.75	Drift	0.890	0.703	0.639
	D3 Ditch	26-May-92	1.27	1.04	Drift	0.267	0.091	0.069
	D4 Pond	04-Jul-85	0.044	0.250	Drift	0.040	0.035	0.034
	D4 Stream	04-Jul-85	1.09	0.228	Drift	0.045	0.015	0.011
	D5 Pond	27-May-78	0.044	0.257	Drift	0.040	0.036	0.034
	D5 Stream	27-May-78	1.18	0.318	Drift	0.065	0.022	0.016
	R1 Pond	21-Jun-84	0.050	0.336	Run-off	0.047	0.042	0.041
	R1 Stream	13-Jun-84	0.835	1.40	Drift	0.024	0.014	0.010
	R3 Stream	22-Apr-80	1.18	0.277	Drift	0.055	0.019	0.014

Table 8.9-29: FOCUS Step 3 Global Maximum PEC_{SW} and PEC_{SED} for metabolite JAU-6476-desthio (M04) following an application of FGF11 to winter oilseed rape

Use: Winter oilseed rape 1 × 200 g a.s./ha	FOCUS scenario	Date of maximum PEC _{SW}	Global maximum		Main Entry Route	PEC _{SW,TWA} [µg/L]		
			PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]		7-d	21-d	28-d
> BBCH 61	D2 Ditch	03-Aug-86	0.137	1.74	-	0.136	0.129	0.126
	D2 Stream	10-Jul-86	0.118	1.21	-	0.118	0.116	0.114
	D3 Ditch	27-May-92	0.009	0.127	-	0.003	0.001	0.001
	D4 Pond	14-Sep-85	0.010	0.207	-	0.010	0.010	0.010
	D4 Stream	04-Jul-85	0.008	0.023	-	0.001	<0.001	<0.001
	D5 Pond	05-Sep-78	0.011	0.264	-	0.011	0.011	0.011
	D5 Stream	27-May-78	0.014	0.029	-	0.001	<0.001	<0.001
	R1 Pond	31-Jul-84	0.034	0.516	-	0.033	0.032	0.031
	R1 Stream	14-Jul-84	0.280	1.08	-	0.025	0.013	0.012
	R3 Stream	13-May-80	0.350	0.240	-	0.047	0.026	0.019

Table 8.9-30: FOCUS Step 4 Global Maximum PEC_{SW} for metabolite JAU-6476-desthio (M04) following an application of FGF11 to winter oilseed rape

Use:	Metabolite prothioconazole-desthio (M04) – Step 4 PEC _{SW} [µg/L]				
Winter oilseed rape 1 × 200 g a.s./ha	VFSmod	-	-	-	5 m
	Vegetated runoff buffer	0 m	0 m	10 m	-
	No-spray buffer	0 m	0 m	10 m	5 m
	Drift-reducing nozzles	0 %	50 %	0 %	0 %
> BBCH 61	D2 Ditch	0.137	0.066	0.021	0.034
	D2 Stream	0.118	0.057	0.021	0.041
	D3 Ditch	0.009	0.005	0.001	0.003
	D4 Pond	0.010	0.005	0.006	0.008
	D4 Stream	0.008	0.008	0.008	0.008
	D5 Pond	0.011	0.006	0.007	0.010
	D5 Stream	0.014	0.007	0.003	0.005
	R1 Pond	0.034	0.030	0.015	0.009
	R1 Stream	0.280	0.280	0.126	0.032
	R3 Stream	0.350	0.350	0.157	0.006

Spring oilseed rape, 1 × 200 g a.s./ha at BBCH 61 to 73

Table 8.9-31: FOCUS Step 1 and 2 PEC_{SW/SED} for prothioconazole and its metabolites following an application of FGF11 to spring oilseed rape at 61-73

Compound	Step	Region	Season	Maximum PEC _{SW} [µg/L]	21-d TWA PEC _{SW} [µg/L]	Maximum PEC _{SED} [µg/kg]
Prothioconazole	1	-	-	21.7	17.1	354
	2	N-EU	Mar-May	1.84	0.607	10.6
			Jun-Sep	1.84	0.607	10.6
		S-EU	Oct-Feb	1.84	0.679	12.3
			Mar-May	1.84	0.679	12.3
			Jun-Sep	1.84	0.643	11.4
Metabolite JAU 6476-S-methyl (M01)	1	-	-	4.54	4.33	111
	2	N-EU	Mar-May	0.243	0.154	4.12
			Jun-Sep	0.243	0.154	4.12
		S-EU	Oct-Feb	0.287	0.266	6.83
			Mar-May	0.287	0.266	6.83
			Jun-Sep	0.243	0.198	5.47
Metabolite JAU 6476-desthio (M04)	1	-	-	39.1	38.5	223
	2	N-EU	Mar-May	1.56	1.46	8.46
			Jun-Sep	1.56	1.46	8.46
		S-EU	Oct-Feb	2.52	2.41	14.0
			Mar-May	2.52	2.41	14.0
			Jun-Sep	2.04	1.94	11.2
Metabolite 1,2,4-triazole (M13)	1	-	-	5.39	5.34	4.78
	2	N-EU	Mar-May	0.179	0.173	0.155
			Jun-Sep	0.179	0.173	0.155
		S-EU	Oct-Feb	0.216	0.210	0.188
			Mar-May	0.216	0.210	0.188
			Jun-Sep	0.198	0.191	0.171

Table 8.9-32: FOCUS Step 3 Global Maximum PEC_{SW} and PEC_{SED} for prothioconazole following an application of FGF11 to spring oilseed rape

Use: Spring oilseed rape 1 × 200 g a.s./ha	FOCUS scenario	Date of maximum PEC _{SW}	Global maximum		Main Entry Route	PEC _{SW,TWA} [µg/L]		
			PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]		7-d	21-d	28-d
> BBCH 61	D1 Ditch	04-Aug-82	1.28	4.11	Drift	1.00	0.825	0.728
	D1 Stream	04-Aug-82	1.12	0.636	Drift	0.143	0.048	0.036
	D3 Ditch	23-Jun-92	1.27	1.10	Drift	0.291	0.100	0.075
	D4 Pond	04-Jul-85	0.044	0.250	Drift	0.040	0.035	0.034
	D4 Stream	04-Jul-85	1.09	0.228	Drift	0.045	0.015	0.011
	D5 Pond	27-May-78	0.044	0.257	Drift	0.040	0.036	0.034
	D5 Stream	27-May-78	1.18	0.315	Drift	0.064	0.021	0.016
	R1 Pond	17-Jun-78	0.063	0.408	Run-off	0.059	0.053	0.050
	R1 Stream	09-Jun-78	0.836	1.72	Drift	0.029	0.018	0.014

Table 8.9-33: FOCUS Step 3 Global Maximum PEC_{SW} and PEC_{SED} for metabolite JAU-6476-desthio (M04) following an application of FGF11 to spring oilseed rape

Use: Spring oilseed rape 1 × 200 g a.s./ha	FOCUS scenario	Date of maximum PEC _{SW}	Global maximum		Main Entry Route	PEC _{SW,TWA} [µg/L]		
			PEC _{SW} [µg/L]	PEC _{SED} [µg/kg]		7-d	21-d	28-d
> BBCH 61	D1 Ditch	04-Aug-82	0.098	1.41	-	0.090	0.960	0.940
	D1 Stream	04-Aug-82	0.024	0.090	-	0.004	0.003	0.003
	D3 Ditch	24-Jun-92	0.012	0.136	-	0.004	0.001	0.001
	D4 Pond	11-Sep-85	0.010	0.205	-	0.010	0.010	0.010
	D4 Stream	07-Dec-85	0.008	0.024	-	0.002	0.001	<0.001
	D5 Pond	05-Sep-78	0.012	0.268	-	0.012	0.012	0.012
	D5 Stream	27-May-78	0.014	0.029	-	0.001	<0.001	<0.001
	R1 Pond	09-Jul-78	0.080	0.873	-	0.076	0.074	0.072
	R1 Stream	03-Jul-78	0.332	1.22	-	0.062	0.027	0.026

zRMS comments:

Input parameters presented in Table 8.9-17 to 8.9-18 used in the surface water modelling for prothioconazole and its metabolites are in general in line with EU agreed endpoints with following remarks:

- For prothioconazole DT₅₀ in water/sediment of 39.5 days was used instead of 1.0 day agreed in the course of the EU review. Nevertheless, 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 information were added to the Table 8.9-18 and used in the independent zRMS calculations for this metabolite at Step 1-2.

No DT₅₀ values for aquatic systems were available for metabolites, so worst case default of 1000 days was used, which is 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 Applicant's 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

At Step 3 for PUF value of 0 was assumed for prothioconazole and JAU 6476-desthio, 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 1-4 at the national level.

The surface water exposure at Step 1-4 was independently validated by the zRMS in additional modelling using the same parameters as indicated above and only relevant scenarios in the central zone were validated, therefore results presented for D1, D2 and D6 scenarios were struck through as not relevant.

Results obtained by the zRMS of PEC_{sw} and PEC_{sed} for prothioconazole and its metabolites were in good agreement with values calculated by the Applicant.

Results of PEC_{sw} and PEC_{sed} for prothioconazole metabolite JAU 6476-desthio at Step 1-4 obtained by the zRMS in independent modelling were slightly lower when compare with the results obtained by the Applicant.

Additional Step 4 calculations with consideration of 5 m VFS were performed for metabolite JAU 6476-desthio mainly for R1 stream, R3 stream and R4 stream scenarios when PEC_{sw} values were above the RAC of 0.334 µg/L. The additional VFSmod refinement demonstrates that winter and spring cereals and winter oilseed rape could be addressed with 5 m mitigation, concerned Member States must decided on it acceptability.

Overall, surface water exposure presented in Tables 8.9-19 and 8.9-33 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.

8.9.2.3 PEC_{sw} of FGF11

PEC_{sw} for the formulation was calculated for drift only, based on the areic mean percentage drift data from Rautmann (2001) as presented in the SWASH drift calculator. The formulation components are expected to dissipate rapidly after application, therefore only one application and drift entry are taken into consideration.

The initial PEC_{sw} for a single application is calculated as follows:

$$\text{PEC}_{\text{sw}} (\mu\text{g/L}) = \frac{\% \text{ drift} \times \text{application rate (g/ha)}}{\text{water depth (30 cm)} \times 10}$$

Table 8.9-34: Initial PEC_{sw} for FGF11 following a single spray application to cereals or oilseed rape

Application rate [g product/ha] ^A	Crop	Drift buffer [m]	Drift rate [%]	Initial PEC _{sw} [µg product/L]
1122.8	Field crops (cereals and oilseed rape)	1 application (90th percentile drift)		
		1	2.77	10.4
		3	0.95	3.56
		5	0.59	2.21
		10	0.29	1.09

^A The rate of formulation is based on a specific density of of 1.228 g/mL with a maximum application of 1.0 L/ha.

zRMS comments:

Recalculation of the surface water exposure to the formulated product performed by the zRMS using Spray Drift Calculator and application rate of 1228 g/ha resulted with slightly lower PEC_{sw} values. Taking this into account, values obtained by the Applicant represent worst case and may be used in the aquatic risk assessment for the formulation.

Obtained PEC_{sw} results for the formulated product calculated by the zRMS are presented in table below:

Application rate [g product/ha] ^A	Crop	Drift buffer [m]	Drift rate [%]	Initial PEC _{sw} [µg product/L]
1228.0	Field crops (cereals and oilseed rape)	1 application (90th percentile drift)		
		1	2.77	7.89
		3	0.95	3.34
		5	0.59	2.14
		10	0.29	1.13

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

8.10.1.1 Azoxystrobin

The fate and behaviour of azoxystrobin and its metabolites in air are data provided in support of the active substance. All relevant detailed experimental information has been submitted for EU review of azoxystrobin (**Azoxystrobin, EFSA Journal 2010; 8(4):1542 and Confirmatory Data, EC, 2014**).

Table 8.10-1 Summary of atmospheric degradation and behaviour

Compound	Azoxystrobin
Direct photolysis in air	Not studied
Quantum yield of direct phototransformation	Not studied
Photochemical oxidative degradation in air	DT ₅₀ (h): 2.7 derived by the Atkinson model OH (12 hours) concentration assumed = $1.5 \times 10^6 \text{ cm}^{-3}$
Volatilisation	Vapour pressure (Pa): 1.1×10^{-10} (20 °C) Henry's Law Constant (Pa.m ³ /mol): 7.4×10^{-9}
Metabolites	n/a

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.

8.10.1.2 Prothioconazole

The fate and behaviour of prothioconazole and its metabolites in air are data provided in support of the active substance. All relevant detailed information has been submitted for EU review of prothioconazole (**EFSA Scientific Report, 2007, 106, 1-98**).

Table 8.10-2 Summary of atmospheric degradation and behaviour

Compound	Prothioconazole	
Direct photolysis in air	Not studied	
Quantum yield of direct phototransformation	Not studied	
Photochemical oxidative degradation in air	DT ₅₀ (h): 1.1 derived by the Atkinson model OH (12 hours) concentration assumed = $1.5 \times 10^6 \text{ cm}^{-3}$	
Volatilisation	Vapour pressure (Pa):	$< 4 \times 10^{-7}$ 20 °C
	Henry's Law Constant (Pa.m ³ /mol):	3×10^{-5} 20 °C

The vapour pressure at 20 °C of the active substance prothioconazole is $< 10^{-5}$ Pa. Hence the active substance prothioconazole is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance prothioconazole due to volatilization with subsequent deposition should not be considered.

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.

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 azoxystrobin and prothioconazole from the intended uses of FGF11 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
KCP 9.2.4/01	Worthington, M.	2024a	Azoxystrobin – A leaching assessment for azoxystrobin and its metabolites using the PEARL 5.5.5, PELMO 6.6.4 and MACRO 5.5.4 FOCUS groundwater models following spray application to cereals and oilseed rape in Central Europe. Company report No.: S24-101230-02-002 Eurofins Agrosience Services Regulatory GmbH non-GLP Unpublished	N	UPL Europe
KCP 9.2.4/02	Worthington, M.	2024b	Prothioconazole – A leaching assessment for prothioconazole and its metabolites using the PEARL 5.5.5, PELMO 6.6.4 and MACRO 5.5.4 FOCUS groundwater models following spray application to cereals and oilseed rape in Central Europe Company report No.: S24-101230-02-003 Eurofins Agrosience Services Regulatory GmbH non-GLP Unpublished	N	UPL Europe
KCP 9.2.5/01	Fortin-McCuaig, M.	2024a	Azoxystrobin – A European Environmental Fate Assessment for azoxystrobin and its metabolites using the FOCUS surface water models at Steps 1 to 4 following spray application to cereals and oilseed rape in Central Europe Company Report No.: S24-101230-02-004 Eurofins Agrosience Services Regulatory GmbH non-GLP Unpublished	N	UPL Europe
KCP 9.2.5/02	Fortin-McCuaig, M.	2024b	Prothioconazole – A European Environmental Fate Assessment for prothioconazole and its metabolites using the FOCUS surface water models at Steps 1 to 4 following spray application to cereals and oilseed rape in Central Europe. Company Report No.: S24-101230-02-005 Eurofins Agrosience Services Regulatory GmbH non-GLP Unpublished	N	UPL Europe

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
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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
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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
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There were no data relied on and not submitted by the Applicant.

Appendix 2 Detailed evaluation of the new Annex II studies

None.

Appendix 3 Additional information provided by the applicant (e.g. detailed modelling data)

A 3.1 PECs specifications

PEC_S immediately after the first application were calculated using FOCUS guidance¹ with the following equation:

$$\text{PEC (mg/kg)} = \frac{A(\text{g/ha}) \times (1 - F)}{100 \times d \text{ (cm)} \times \rho \text{ (g/cm}^3\text{)}}$$

Where:

A = Application rate

F = Fraction intercepted by crop

d = Depth of field soil layer (5 cm)

ρ = Dry bulk density (1.5 g/cm³)

The PEC at specific times (t) after the application is given by:

$$\text{PEC(mg/kg)} = \text{Initial PEC}_S \text{ after last application} \times e^{-kt}$$

Where:

k = first order degradation/dissipation rate constant (ln(2) / half-life)

The time weighted average (TWA) PEC values are found by calculating a set of TWA PEC over a time window that is moved along the time axis. The average PEC within a day is calculated by:

$$\text{Average PEC over a day (mg/kg)} = \frac{\text{Actual PEC at start of day} \times (1 - e^{-k})}{k}$$

The TWA over the moving window is calculated from the simple numerical average of these daily values.

PEC_{S, accu} specifications

In addition to the seasonal PEC_S calculations, the potential accumulation (PEC_{S,accumulation}) in soil following repeated applications was calculated. Accumulation calculations were based on application every year as a worst case.

For both active substances, the SFO degradation scheme was considered. The maximum plateau concentration (PEC_{S,max. plateau}) was calculated as follows:

$$\text{PEC}_{S,\text{max.plateau}} \text{ [mg/kg]} = \frac{\text{PEC}_{S,\text{ini,d}}}{(1 - e^{(-tk)})}$$

Where:

PEC_{S,ini,d} = PEC_{S,ini} calculated for 20 cm soil depth (incorporation due to ploughing) [mg/kg]

t = time interval between the application schemes [d] (every year = 365d)

¹ FOCUS (1997) Soil persistence models and EU Registration - The Final Report of the Soil Modelling Workgroup of FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use) – 29 February 1997.

The minimum plateau concentration ($PEC_{S,plateau}$), i.e. the minimum concentration in soil before the first annual application, was calculated as:

$$PEC_{S,plateau} [mg/kg] = PEC_{S,max,plateau} \times e^{(-tk)}$$

Where:

t = time interval between the last annual application and the first application in the subsequent season [d]

$PEC_{S,accumulation}$ was calculated as the sum of the $PEC_{S,plateau}$ concentration before the first annual application and the $PEC_{S,ini}$ (calculated for 5 cm soil depth) immediately after the last application:

$$PEC_{S, accumulation} [mg/kg] = PEC_{S, plateau} + PEC_{S,ini}$$