

REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: ADM.03502.F.1.A

(alternative codes: MCW-2091)

Product name(s): see part A

Chemical active substance(s):

Fenpropidin 250 g/L

Prothioconazole 175 g/L

Central zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorisation)

Applicant: Country organisation/representative
as specified in Part A

Submission date: September 2021

MS Finalisation date: December 2022 (initial Core Assessment)

April 2023 (final Core Assessment)

Version history

When	What
September 2021	Version 1 Applicant
December 2022	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 .
April 2023	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow . Information no longer relevant is struck through and shaded .

DATA PROTECTION CLAIM

In order to present a dossier fully compliant with today's requirements (Reg. 284/2013), studies have been performed on ADM.03502.F.1.A . Under Article 59, Regulation 1107/2009/EC. On behalf of the Sponsor Company the applicant claims data protection for the studies conducted with ADM.03502.F.1.A. The data protection status and corresponding justification as valid for the respective country will be confirmed in the respective PART A.

STATEMENT FOR OWNERSHIP

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8 Fate and behaviour in the environment (KCP 9)

8.1 Critical GAP and overall conclusions

The critical GAP uses and application patterns considered in the risk assessments for soil, groundwater and surface water are specified under the respective chapters, i.e. 8.7 (soil), 8.8 (groundwater) and 8.9 (surface water).

For the conclusion in groundwater, the concerned critical GAP uses of ADM.03502.F.1.A are summarised in Table 8.1-1.

Table 8.1-1: Concerned critical GAP uses of ADM.03502.F.1.A for the risk assessment in groundwater

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener / synergist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha Prothioconazole / Fenpropidin a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1, 6, 11, 16, 21, 23, 26, 28, 106	DE, AT, BE, NL, CZ, PL, HU, SK, IR	Winter wheat (TRZAW)	F	Septoria tritici Erysiphe graminis Puccinia striiformis Puccinia recondita	foliar, spraying, overall	-/ BBCH 30- 65 spring	a) 1 b) 1	-	a) 1 L/ha b) 1 L/ha	a) 175 / 250 b) 175 / 250	100 - 400	-		A
1, 6, 11, 16, 21, 23, 26, 28, 106	DE, AT, BE, NL, CZ, PL, HU, SK, IR	Spring wheat (TRZAS)	F	Septoria tritici Erysiphe graminis Puccinia striiformis Puccinia recondita	foliar, spraying, overall	-/ BBCH 30- 65 spring	a) 1 b) 1	-	a) 1 L/ha b) 1 L/ha	a) 175 / 250 b) 175 / 250	100 - 400			A
2, 7, 12, 17, 22, 24, 27, 29, 107	DE, AT, BE, CZ, HU, NL, PL, SK, IR	Winter barley (HORVW)	F	Erysiphe graminis Rhynchosporium secalis Helminthosporium gramineum (Pyrenophora teres) Puccinia hordei	foliar, spraying, overall	-/ BBCH 30- 65 spring	a) 1 b) 1	-	a) 1 L/ha b) 1 L/ha	a) 175 / 250 b) 175 / 250	100 - 400			A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener / synergist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha Prothioconazole / Fenpropidin a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			Groundwater
2, 7, 12, 17, 22, 24, 27, 29, 107	DE, AT, BE, CZ, HU, NL, PL, SK, IR	Spring barley (HORVS)	F	Erysiphe graminis Rhynchosporium secalis Helminthosporium gramineum (Pyrenophora teres) Puccinia hordei	foliar, spraying, overall	-/ BBCH 30- 65 spring	a) 1 b) 1	-	a) 1 L/ha b) 1 L/ha	a) 175 / 250 b) 175 / 250	100 - 400			A
3, 8, 13, 18, 108	DE, AT, BE, NL, IR	Rye (SECCW)	F	Erysiphe graminis Rhynchosporium secalis Puccinia recondita	foliar, spraying, overall	-/ BBCH 30- 65 spring	a) 1 b) 1	-	a) 1 L/ha b) 1 L/ha	a) 175 / 250 b) 175 / 250	100 - 400			A
4, 9, 14, 19, 25, 109	DE, AT, BE, NL, PL, IR	Triticale (TTLSS)	F	Erysiphe graminis Septoria tritici Puccinia recondita Puccinia striiformis	foliar, spraying, overall	-/ BBCH 30- 65 spring	a) 1 b) 1	-	a) 1 L/ha b) 1 L/ha	a) 175 / 250 b) 175 / 250	100 - 400			A
5, 10, 15, 20, 110	DE, AT, BE, NL, IR	Oats (AVESS)	F	Erysiphe graminis Puccinia coronata	foliar, spraying, overall	-/ BBCH 30- 65 spring	a) 1 b) 1	-	a) 1 L/ha b) 1 L/ha	a) 175 / 250 b) 175 / 250	100 - 400			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
n.r.= not relevant, n.a.= not applicable

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

Explanation for column 15 “Conclusion”

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

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

Member state(s)	Crop and/or situation (a)	F, Fn, Fpn G, Gn, Gpn or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate			PHI (days) (l)	Remarks: e.g. g safener / synergist per ha (m)
				Type (d-f)	Conc. of a.s. (i)	Method / Kind (f-h)	Timing / Growth stage of crop & season (j)	Max. number a) per use b) per crop/season (k)	Min. interval between applications (days)	kg or L product/ha min max	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
EU North South	Wheat, rye, triticale	F	Rusts, Eyespot, Fusarium spp., Powd. Mildew, Rhynchospor., Septoria	EC	250 g/L	Overall spray	start 26-29 up to BBCH69	1 – 3 #	14 – 21 #		0.2	200-400	35	# timing, no. of applic. depends on national conditions
EU North South	Barley, oat	F	Rusts, Eyespot, Pyren. teres, Powd. Mildew, Fusarium spp., Rhynchospor.	EC	250 g/L	Overall spray	start 30 up to BBCH 61	1 – 2 #	14 – 21 #		0.2	200-400	35	# timing, no. of applic. depends on national conditions
EU North	Rape	F	Sclerotinia, Botrytis, Alternaria, Leptosphaeria	EC	250 g/L	Overall spray	start BBCH 53	1 – 2 #	14 – 28 #		0.175	200-400	56	# timing , no. of applic. depends on national conditions
EU North South	Wheat, rye, triticale, oat, barley	F	Fusarium spp., Bunt, Smut	FS	250 g/L	Seed Treatment	Pre sowing	1	n.a. (0)		*approx. 9-18 g as/ha (180 kg seed/ha)	200 – 400 ml water /dt	n.a.	*5 – 10 g as/dt seed

Remarks columns: * Uses for which risk assessment could not been concluded due to lack of essential data are marked grey

- (a) 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)
- (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
- (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
- (f) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

- (g) All abbreviations used must be explained
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
- (i) g/kg or g/L
- (j) Growth stage at 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
- (k) The minimum and maximum number of application possible under practical conditions of use must be provided
- (l) PHI - minimum pre-harvest interval
- (m) Remarks may include: Extent of use/economic importance/restrictions

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

Member state(s)	Crop and/or situation (a)	F, Fn, Fpn G, Gn, Gpn or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate			PHI (days) (l)	Remarks: e.g. g safener / synergist per ha (m)
				Type (d-f)	Conc. of a.s. (i)	Method / Kind (f-h)	Timing / Growth stage of crop & season (j)	Max. number a) per use b) per crop/season (k)	Min. interval between applications (days)	L product/ha min max	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
C-EU	Cereals	F	fungi	EC	750 g/L	Spray	BBCH 29-65	1-2	21	1	0.750	100-400	35	[1]
S-EU	Cereals	F	fungi	EC	750 g/L	Spray	BBCH 29-65	1-2	21	0.75	0.562	100-400	28	[1]

[1] The long-term risk to birds is not addressed and needs further refinement. A high risk to aquatic organisms was identified requiring a substantial risk mitigation measures such as a no spray buffer zone of 50 m to achieve TERs above the refined assessment factor. A high first tier high risk to birds and mammals was identified

Remarks * Uses for which risk assessment could not been concluded due to lack of essential data are marked grey

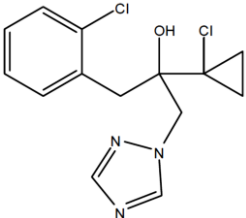
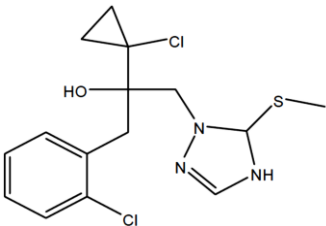
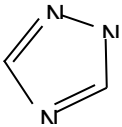
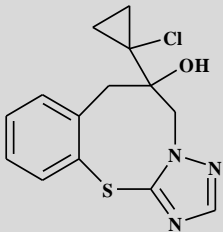
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)

- (c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

- (g) All abbreviations used must be explained
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/L
(j) Growth stage at 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
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

8.2 Metabolites considered in the assessment

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

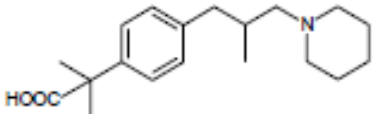
Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
Prothioconazole-desthio (M04) (JAU-desthio)	312.2 g/mol		soil: 57.1 % water: 32.3% sediment: 26.9% whole system: 54.6%	PEC _{SOIL} , PEC _{GW} , PEC _{SW/SED} : current GAP use not considered in the EU assessment (EFSA 2007), and meanwhile FOCUS models are required for PEC _{GW} and PEC _{SW} calculations (soil metabolites now also need to be included in this modelling due to run- off entry)
Prothioconazole-S-methyl (M01) (JAU-S-methyl)	358.3 g/mol		soil: 14.6 % water/sediment: 77 % (anaerob in sediment, not detected in water) water/sediment (aerobic): 12.7% (whole system); 3.1% (water); 9.6% (sediment)	
1,2,4-triazole (M13)	69.065 g/mol		water: 37.2 % sediment: 4.6 % whole system: 41.8%	
JAU 6476-thiazocine (prothioconazole-thiazocine, M12)	307.8		Aqueous photolysis study: 14.1% on day 5	EFSA (2007) Considered not relevant

zRMS comments:

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

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

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

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
CGA 289267 (2-methyl-2-[4-(2-methyl-3-piperidin-1-yl-propyl)-phenyl]-propionic acid)	303.4 g/mol		soil: 10.6 % water: 14.3 % sediment: 2.3% whole system: 16.1%	PEC _{SOIL} , PEC _{GW} , PEC _{SW/SED} : current GAP uses not considered in the EU assessment (EFSA 2007)

zRMS comments:

Information regarding fenpropidin metabolites is in line with EU agreed endpoints reported in EFSA Scientific Report (2007) 124.

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. All relevant detailed experimental information has been submitted for EU review of the active substances prothioconazole and fenpropidin. For details see EFSA (2007)¹ and the DAR (2005)² for prothioconazole and EFSA (2007)³ and DAR (2005)⁴ for fenpropidin, as well as the final addendum to the DAR for fenpropidin (2007)⁵. Additional degradation data were not required as a result of the reviews and not performed.

Prothioconazole

The aerobic route and rate of degradation of phenyl-UL-¹⁴C and 3,5-triazole-¹⁴C labelled prothioconazole under dark conditions was investigated in two laboratory studies. The results of the aerobic soil degradation studies were used to estimate the portion of the active substance degrading to prothioconazole-S-methyl (14.6 % at day 7, triazole label). The portion of active substance converted to prothioconazole-desthio (M04) was calculated to be 57.1%, based on the results of the eight field studies.

No other major metabolites were detected, although six minor metabolites were detected at levels in the range <0.1 to 5.5% AR. 1,2,4-triazole was only detected in relevant amounts in water/sediment studies (37.2 % in the water phase).

¹ EFSA (2007): EFSA Scientific Report (2007) 106, 1–98, Conclusion regarding the peer review of the pesticide risk assessment of the active substance prothioconazole. Issued on 12 July 2007.

² DAR (2005): Draft Assessment Report on Prothioconazole, Volume 3, Annex B, B.8, July 2005.

³ EFSA (2007): EFSA Scientific Report (2007) 124, 1-84, Conclusion on the peer review of fenpropidin, finalised December 2007, revised January 2008.

⁴ DAR (2005): Draft Assessment Report on Fenpropidin, Volume 3, Annex B, B.8, June 2005.

⁵ Final addendum to the DAR (2007): Final addendum to the Draft Assessment Report on Fenpropidin, Volume 3, Annex B, B.8, September 2007.

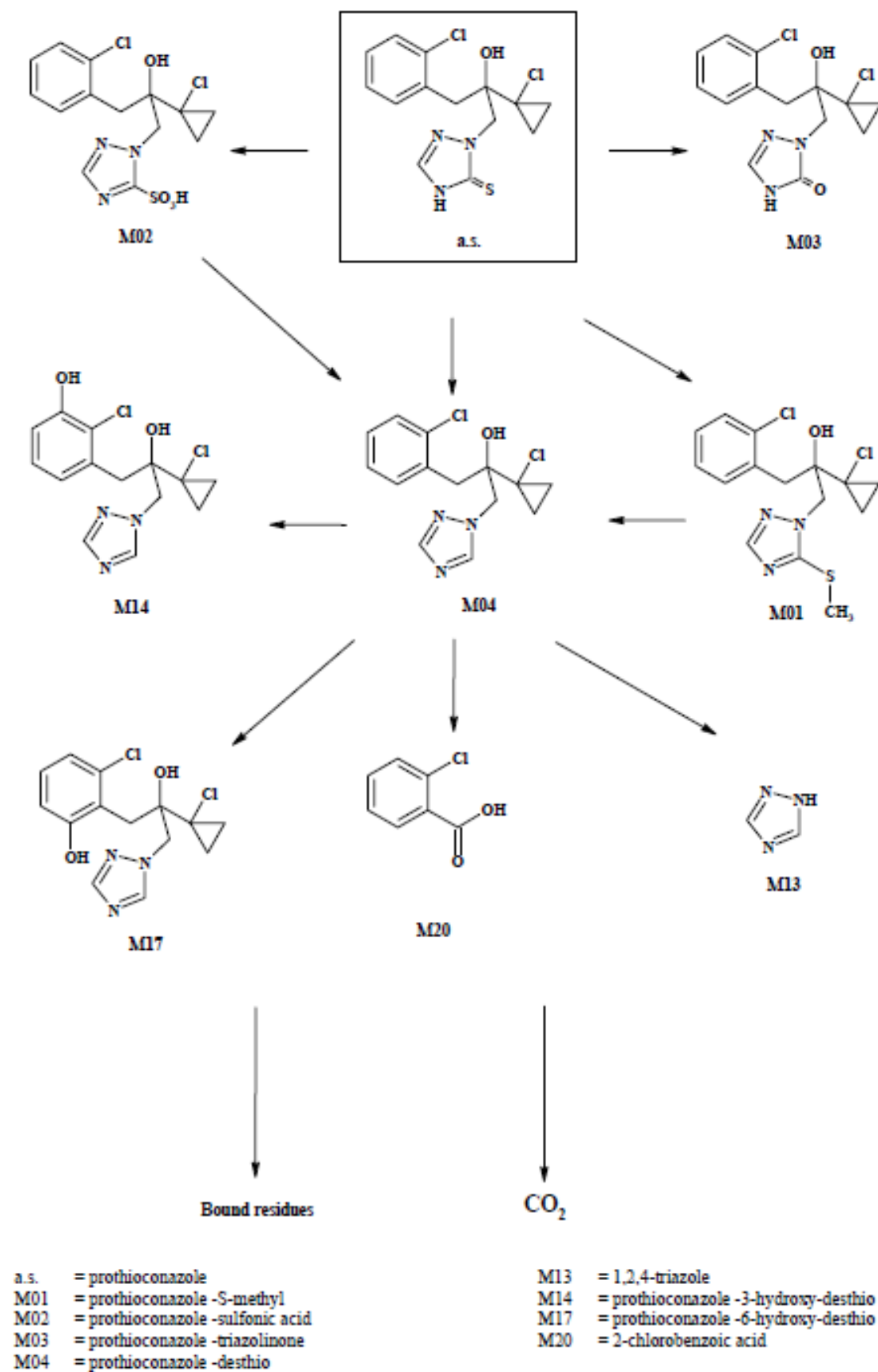


Figure 8.3-1: Degradation scheme of prothioconazole and metabolites

Fenpropidin

The metabolic pathway of fenpropidin is shown in Figure 8.3-1. The metabolite CGA 289267 (2-methyl-2-(4-(2-methyl-3-piperidin-1-yl-propyl)-phenyl)-propionic acid; fenpropidin acid) has a maximum occurrence in soil of 10.6%, in the water sediment system it occurs with 16.1%.

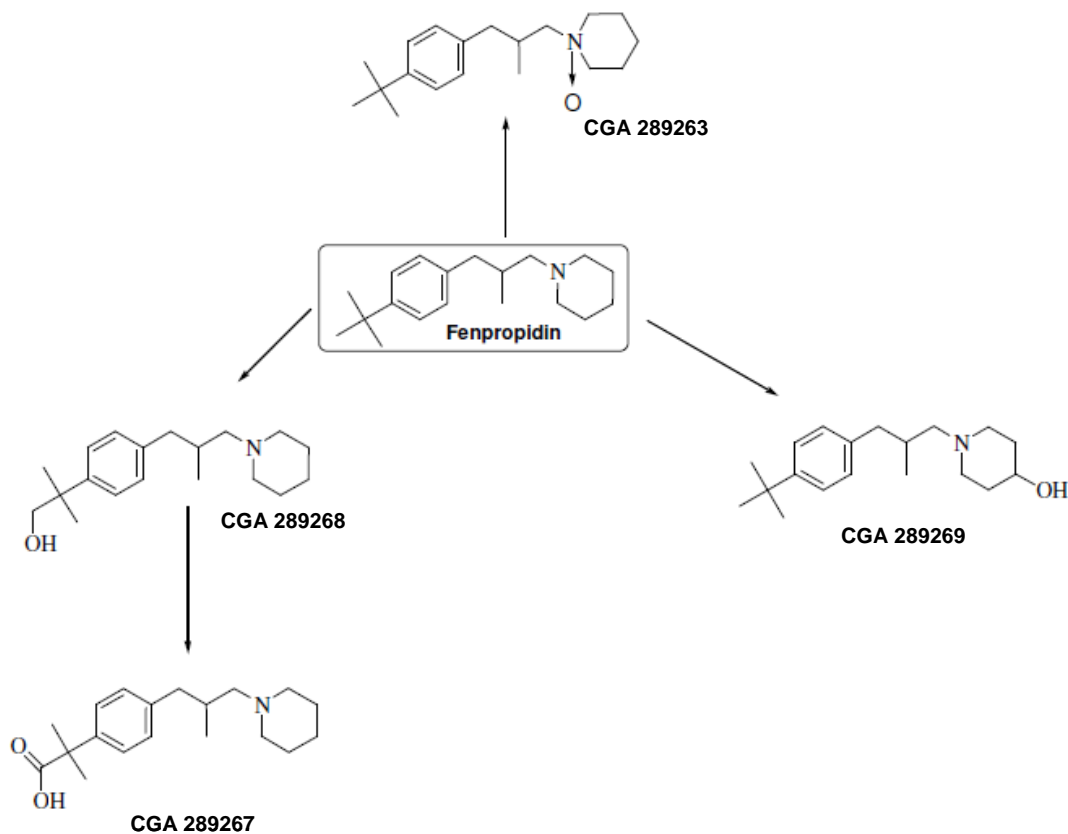


Figure 8.3-2: Degradation scheme of fenpropidin and metabolites

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

Data on the rates of aerobic soil degradation of the active substances prothioconazole and fenpropidin as well as their metabolites are available in the context of the respective EU evaluation processes. For details see EFSA (2007)⁶ and the DAR (2005)⁷ for prothioconazole and EFSA (2007)⁸ and DAR (2005)⁹ for fenpropidin, as well as the final addendum to the DAR for fenpropidin (2007)¹⁰. Additional degradation data were not required as a result of the reviews. Studies on aerobic 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 Prothioconazole and its metabolites

Prothioconazole

A summary of the EU agreed aerobic soil degradation data of prothioconazole is given in Table 8.3-1.

Table 8.3-1: Summary of EU agreed aerobic degradation rates for prothioconazole - laboratory studies (according to DAR 2005)

Prothioconazole, Laboratory studies, aerobic conditions										
Soil name	Soil type (USDA)	pH (CaCl ₂)	t. °C	MWHC %	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa	Chi ² (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Laacher Hof	sandy loam	6.6	20	34.42	0.07	5.3	-	-	FOMC	y/ DAR, 2005; EFSA, 2007
Stanley	silty clay loam	5.9	20	56.25	0.7	78.2	-	-	FOMC	
Höfchen	silt	6.8	20	63.1	0.3	0.99	-	-	SFO	
Byromville	loamy sand	6.1	20	49*	1.27	4.22	-	-	SFO	
Geometric mean/Median (n=4)							0.37/0.5			
pH-dependency: y/n							n			

* % of 1/3 bar moisture

Un-normalised DegT₅₀ and DegT₉₀ values of prothioconazole in aerobic laboratory soils ranged from 0.07 to 1.27 days and 0.99 to 78.2 days, respectively. **For modelling endpoints, please refer to field studies.**

Metabolites

A summary of the EU agreed aerobic soil degradation data of prothioconazole metabolites is given in Table 8.3 2 and Table 8.3 3.

Table 8.3-2: Summary of EU agreed aerobic degradation rates for prothioconazole-S-methyl laboratory studies (according to DAR, 2005)

Prothioconazole-S-methyl, Laboratory studies, aerobic conditions										
Soil name	Soil type (DIN)	pH (CaCl ₂)	t. °C	MWHC %	DT ₅₀ (d)	DT ₉₀ (d)	DegT ₅₀ (d) 20°C pF2/10kPa	Chi ² (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Höfchen	loamy silt	6.5	20	63.1	5.9	19.6	-	-	1 st order SFO	y/ DAR, 2005; EFSA, 2007
Laacher Hof	loamy silt	6.7	20	36.4	27.2	90.2	-	-		
Laacher Hof	sandy loam	6.3	20	34.4	8.2	27.2	-	-		

⁶ EFSA (2007): EFSA Scientific Report (2007) 106, 1–98, Conclusion regarding the peer review of the pesticide risk assessment of the active substance prothioconazole. Issued on 12 July 2007.

⁷ DAR (2005): Draft Assessment Report on Prothioconazole, Volume 3, Annex B, B.8, July 2005.

⁸ EFSA (2007): EFSA Scientific Report (2007) 124, 1-84, Conclusion on the peer review of fenpropidin, finalised December 2007, revised January 2008.

⁹ DAR (2005): Draft Assessment Report on Fenpropidin, Volume 3, Annex B, B.8, June 2005.

¹⁰ Final addendum to the DAR (2007): Final addendum to the Draft Assessment Report on Fenpropidin, Volume 3, Annex B, B.8, September 2007.

Prothioconazole-S-methyl, Laboratory studies, aerobic conditions										
Soil name	Soil type (DIN)	pH (CaCl ₂)	t. °C	MWHC %	DT ₅₀ (d)	DT ₉₀ (d)	DegT ₅₀ (d) 20°C pF2/10kPa	Chi ² (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Stanley	silty clay	5.2	20	43.8	46.0¹⁾	153	-	-		
Geometric mean/Median (n = 4)							15.7²⁾/17.7			
pH-dependency: y/n							n			

bold figure used as EU agreed endpoint for PEC_{soil}¹⁾, PEC_{GW}²⁾ and PEC_{SW/SED}²⁾ calculations

Un-normalised DT₅₀ and DT₉₀ values of prothioconazole-S-methyl ranged from 5.9–46.0 days and 19.6–153 days, respectively. This results in a DT₅₀ geometric mean of 15.7 days which is the EU agreed endpoint (EFSA, 2007) used for PEC_{GW} and PEC_{SW/SED} calculations. **Maximum unnormalized DT₅₀ was used for PEC_{soil} assessment.**

Table 8.3-3: Summary of EU agreed aerobic degradation rates for prothioconazole-desthio laboratory studies (according to DAR, 2005)

Prothioconazole-desthio, Laboratory studies, aerobic conditions										
Soil name	Soil type (DIN)	pH (CaCl ₂)	t. °C	MWHC %	DT ₅₀ (d)	DT ₉₀ (d)	DegT ₅₀ (d) 20°C pF2/10kPa	Chi ² (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Höfchen	loamy silt	6.5	20	36.4	34.0	113.0	-	-	1 st order SFO	y/ DAR, 2005; EFSA, 2007
Laacher Hof	loamy silt	6.7	20	43.8	29.6	59.2 98.3	-	-		
Laacher Hof	sandy loam	6.3	20	43.8	7.0	23.2	-	-		
Stanley	silty clay	5.2	20	43.8	18.6	61.9	-	-		
Geometric mean/Median (n = 4)							19.0/24.1			
pH-dependency: y/n							n			

Un-normalised DT₅₀ and DT₉₀ values of prothioconazole-desthio ranged from 7.0–34.0 days and 23.2–113.0 days, respectively. **For modelling endpoints, please refer to field studies.**

Soil photolysis

Information on soil photolysis of the parent compound prothioconazole is available from the DAR (2005). It is summarised hereafter.

Table 8.3-4 Summary of agreed EU photolysis data of prothioconazole in laboratory soils (according to DAR, 2005)

Prothioconazole, Laboratory studies, soil photolysis										
Soil name	Soil type (USDA)	pH (CaCl ₂)	t. °C	1/3 bar MWHC %	DT ₅₀ (d)	DT ₉₀ (d)	DegT ₅₀ (d) 20°C pF2/10kPa	Chi ² (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Byromville	loamy sand	6.1	20	75	4.1 ^{a)} 14.7 ^{b)} 22.9 ^{c)}	13.7 ^{a)}	-	-	1 st order SFO	y/ DAR, 2005; EFSA, 2007

^{a)} DT₅₀/DT₉₀ experimental

^{b)} predicted environmental half-life under solar summer conditions of Phoenix, AZ, USA in June

^{c)} predicted environmental half-life under solar summer conditions of Athens, Greece in June

A soil photolysis study is available with phenyl-¹⁴C-labelled prothioconazole. Results demonstrated prothioconazole to be degraded rapidly (prothioconazole amounted to 18.6% AR in the irradiated samples after 15 days, end of the study) on soil surface if irradiated by simulated sunlight. However, the fast degradation observed for the dark control (19.0% AR at 15d) revealed phototransformation not to be the

dominant process of degradation. M04 (prothioconazole-desthio) appears at relatively high concentrations in both irradiated and dark control samples (maximum observed at day 7: 38.5% A.R. and 29.4% A.R. respectively), indicating that photolysis will not significantly contribute to the overall degradation of prothioconazole in soil under environmental conditions. The first order DT₅₀ value for the degradation of the active ingredient yielded 4.1 days, equated to 22.9 days under sola summer conditions of Athens (Greece) in June.

Table 8.3-5: Summary of agreed EU photolysis data of prothioconazole in laboratory soils (EFSA, 2007)

Soil photolysis	
Metabolites that may require further consideration for risk assessment	none

zRMS comments:

Soil degradation data for prothioconazole and its metabolites are in line with EU agreed endpoints reported in EFSA Scientific Report (2007) 106 and prothioconazole DAR of 2005. **Minor corrections were introduced by the zRMS so information in table above is fully in line with data reported in the list of endpoints.**

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

8.3.1.2 Fenpropidin and its metabolites

Fenpropidin

EU agreed aerobic soil laboratory degradation data on fenpropidin is available from two studies. The behaviour of fenpropidin in soil under laboratory conditions has been determined in six experiments. Both studies were re-analysed in 2002, considering new guidelines. Resultant normalised to 20 °C and pF 2 DegT_{50lab} values (n = 6) of fenpropidin range between 49–84 days. All analyses were evaluated by EFSA (EFSA Scientific Report (2007) 124, 1-84, Conclusion on the peer review of fenpropidin). Since two test concentrations were used for each soil, the mean value (geometric mean) for each soil was calculated first and then the overall mean. The overall geometric mean DT₅₀ normalised to reference conditions of 66 days was used for fenpropidin for further modelling. An overview on the EU agreed results is given in the following table.

Table 8.3-6: Summary of EU agreed aerobic degradation rates for fenpropidin - laboratory studies (according to EFSA, 2007 and final addendum to the DAR, 2007)

(according to EFSA, 2007 and final addendum to the DAK, 2007)												
Fenpropidin, Laboratory studies, aerobic conditions												
Soil name	Soil type (USDA)	pH (CaCl2)	t. °C	MWHC %	DT50 (d)	DT90 (d)	DT50 norm (d) 20°C pF2/10kPa			r² (-)	Kinetic model	Evaluated on EU level y/n/ Reference
							Single values	Arithm. mean	Geo-mean			
Dielsdorf (low treatm. rate)	Sandy loam	6.9	22	75*	84	278	68	76	76	0.98	SFO	y/ EFSA, 2007
Dielsdorf (high treatm. rate)	Sandy loam	6.9	22	75*	103	342	84 ^(d)			0.99		
Steinmaur (low treatm. rate)	Loam	7.5	22	75*	58	192	49 ^(b)	59	58	0.99		
Steinmaur (high treatm. rate)	Loam	7.5	22	75*	82	271	69			0.998		

Fenpropidin, Laboratory studies, aerobic conditions										
Soil name	Soil type (USDA)	pH (CaCl ₂)	t. °C	MWHC %	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ norm (d) 20°C pF2/10kPa			r ² (-)
							Single values	Arithm. mean	Geo-mean	
Dielsdorf (1 st appl. Series)	Sandy loam	7.4	22	40	98	324 [#]	77	66	64	0.98
Dielsdorf (1 st appl. Series)	Sandy loam	7.4	22	40	68	226	54			0.99
Dielsdorf (1 st appl. Series, low temp.)	Sandy loam	7.4	8	40	217	> 275	-	-	-	0.96
Dielsdorf (1 st appl. Series)	Sandy loam	7.4	22	20	165	> 365	-	-	-	0.95
BBA 2.1	Sand	Results from this study not considered representative because of low biological activity of the soil.								
Arithmetic mean (n=3)							-	67	-	
Geometric mean (n=3)							-	-	66 ^(a,c)	
pH-dependency: y/n							n			y/ EFSA, 2007

bold values used as modelling endpoint for the calculation of ^(a)PEC_{gw} (parent calculation), ^(b)PEC_{gw} (metabolite calculation) in accordance with the final addendum to the DAR (2007) and ^(c)PEC_{sw} (Step 2), ^(d)PEC_{sw} (Step 3–4) acc.to EFSA 2007

[#]Uncertain value based on extrapolation beyond study termination at day 275, hence DT₉₀ previously set to >275 days and previously excluded from calculation of mean.

* 1/3 bar

During the expert meeting a data GAP was observed and two additional degradation studies were requested. Therefore, two new degradation studies (Morlock 2006 a&b) on aerobic degradation in soil were conducted. An overview of the additional DT_{50lab} values based on these studies is given in the table below. A detailed summary is given in Appendix 2. Since the resulting DT₅₀ values are in the range of the EU agreed DT_{50lab} values, the EU agreed DT₅₀ endpoints were considered for further model calculations.

Table 8.3-7: Summary of additional DegT_{50lab} of fenpropidin in laboratory aerobic soils provided by the applicant (Morlock 2006a & b [KCP 9.1.1.1/01 & 02])

Fenpropidin, Laboratory studies, aerobic conditions									
Soil type	pH	t. °C	MWHC %	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa	St. (r ²)	Kinetic model	Evaluated on EU level Reference
Silty sand	7.1	20	45	56.8	188.7	n.a.	0.92	SFO	N/Morlock, 2006a
	7.0	20	45	41.0	136.2	n.a.	0.948	SFO	
	6.5	20	45	106.5	353.7	n.a.	0.96	SFO	N/Morlock, 2006b

Metabolites

During the evaluation by EFSA CGA 289267 was found as the only relevant metabolite. The behaviour of CGA 289267 in soil has been determined in three soils under laboratory conditions and was evaluated by EFSA (EFSA Scientific Report (2007) 124, 1-84, Conclusion on the peer review of fenpropidin). An overview on the EU agreed results is given in the following table.

Table 8.3-8: Summary of EU agreed aerobic degradation rates for CGA 289267 - laboratory studies

CGA 289267, Laboratory studies, aerobic conditions									
Soil type	pH	t. °C	MWHC %	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa	St. (r ²)	Kinetic model	Evaluated on EU level Reference
Sandy loam	7.2	20	40	9.9	33	6.7	0.98	SFO	Y/EFSA 2007
Loam	7.4	20	40	9.5	32	5.8	0.98	SFO	

CGA 289267, Laboratory studies, aerobic conditions									
Soil type	pH	t.°C	MWHC %	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa	St. (r ²)	Kinetic model	Evaluated on EU level Reference
Silt loam	5.7	20	40	63	209	38	0.99	SFO	
Maximum						38			
Geometric Mean (n=3)						11.4			

For metabolite CGA289267 the worst case value of 38 days was selected for modelling as recommended by EFSA (EFSA Scientific Report (2007) 124, 1-84, Conclusion on the peer review of fenpropidin).

As a result of the review a data gap was identified by the experts. The peer review concluded that there was a relatively high variability of the dataset. Therefore, the applicant has conducted an additional laboratory soil degradation study (Flörchinger, 2008) which is not previously evaluated. A detailed summary is given in Appendix 2. A summary of the degradation studies is presented in the following table.

Table 8.3-9: Summary of additional DegT_{50lab} of CGA 289267 laboratory aerobic soils provided by the applicant (Flörchinger, 2008 [KCP 9.1.1.1/03])

CGA 289267, Laboratory studies, aerobic conditions									
Soil type	pH	t.°C	MWHC %	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa	St. (r ²)	Kinetic model	Evaluated on EU level Reference
Loamy sand	5.8	20	40	37	122	35	0.99	SFO	N/Flörchinger, 2008
Sandy loam	7.0	20	40	19	64	17.2	0.98	SFO	
Sandy loam	7.3	20	40	17	56	15.3	0.94	SFO	

Soil photolysis

Information on soil photolysis of the parent compound fenpropidin is available from the DAR (2005) and EFSA (2007). It is summarised hereafter.

A laboratory soil photolysis study indicated that degradation by photolysis would not be expected to be a process that significantly.

Table 8.3-10: Summary of agreed EU photolysis data of fenpropidin in laboratory soils (EFSA, 2007)

Soil photolysis	Insignificant
Metabolites that may require further consideration for risk assessment	None

zRMS comments:

Soil degradation data for fenpropidin and its metabolite reported in Tables 8.3-6 and 8.3-8 are in line with EU agreed endpoints reported in EFSA Scientific Report (2007) 124.

As no arithmetic and geometric mean DT₅₀ for fenpropidin were reported in the LoEP, respective values were calculated by the Applicant on the basis of the EU agreed data. Mean values presented in Table 8.3-6 are confirmed to be correct.

In the course of the EU review it was concluded that the database of laboratory DT₅₀ for fenpropidin was small (available for only 2 soils) and a data gap for studies on 2 additional soils has been identified in order to address the data requirements. The Applicant submitted 2 studies (Morlock 2006a&b), they were, however, not evaluated by the zRMS since during the first EU review the available limited dataset was deemed sufficient by the experts for derivation of the respective modelling endpoints (DT₅₀ of 76 days for parent modelling and 59 days for metabolites modelling). Taking this into account, the new active substance studies should be evaluated in the course of the ongoing renewal process and the new EU agreed endpoints will be used for purposes of re-evaluation of the formulation in line with Art. 43.

The Applicant submitted also new soil degradation study with metabolite CGA289267. However, the study was not evaluated by the zRMS since no data gap in this area has been identified in the course of the first EU review of fenpropidin and endpoints reported in the LoEP were sufficient to finalise the exposure assessment.

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

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

8.3.2.1 Prothioconazole and its metabolites

Soil degradation under anaerobic conditions was not investigated. EFSA (2007) provides the following information on the anaerobic degradation of **prothioconazole**: Due to the fact that a seed treatment formulation was considered in the EU assessment, an anaerobic aquatic metabolism study was submitted. The anaerobic study indicated relatively rapid breakdown of parent to JAU-S-methyl, which seems to accumulate. This might indicate that if prothioconazole was applied to an anaerobic soil there would be significant formation of JAU-S-methyl. However, the only major period of anaerobic conditions is likely to be in winter. According to the underlying GAP table no seed treatment is envisaged and the application of ADM.03502.F.1.A will only take place in spring/summer. Therefore, it is unlikely that there would be significant formation of JAU-S-methyl 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 in the winter, following autumn seed treatment. The application pattern of ADM.03502.F.1.A does not include application as a seed treatment, so anaerobic route of exposure is not considered further, in line with EU conclusions.

8.3.2.2 Fenpropidin and its metabolites

Information on anaerobic degradation in laboratory soil of the parent compound fenpropidin is available from the DAR (2005) and EFSA (2007). It is summarised hereafter.

An anaerobic laboratory soil degradation study indicated that **fenpropidin** is stable under anaerobic laboratory conditions. Thus, no anaerobic half-lives were calculated and no anaerobic major metabolites were observed.

Table 8.3-11: Summary of agreed EU anaerobic soil degradation data of fenpropidin in laboratory soils (EFSA, 2007)

Anaerobic degradation	
Mineralization after 100 days	Stable
Non-extractable residues after 100 days	8.1 % of AR after 59/60 days, 22°C
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	None

zRMS comments:

Anaerobic soil degradation data for fenpropidin presented above are line with EU agreed endpoints reported in EFSA Scientific Report (2007) 124.

8.4 Field studies (KCP 9.1.1.2)

The field dissipation rates of prothioconazole and fenpropidin were evaluated during the EU review. No additional studies have been performed.

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

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

8.4.1.1 Prothioconazole and its metabolites

Dissipation of prothioconazole and prothioconazole-desthio was examined in eight studies under field conditions at four sites in Northern Europe and two sites in Southern Europe. Application of the test substance was directly onto bare soil. Details on soil type and study location are presented in Table 8.4-1 and Table 8.4-2.

Prothioconazole

The DissT_{50field} values of prothioconazole were in the range of 1.3–2.8 days (DT₉₀ = 4.4–9.3 days) (see Table 8.4-1) following 1st order kinetics. The maximum DissT₅₀ of 2.8 days is the EU agreed endpoint (EFSA, 2007) considered for PEC_{SOIL} calculations. Normalised field soil dissipation modelling endpoints of prothioconazole range between 0.6 to 1.6 days. **For PEC_{gw} and PEC_{sw} modelling of prothioconazole the geometric mean of 1.2 days was used.**

Table 8.4-1: Summary of EU agreed aerobic degradation rates for prothioconazole - field studies: Triggering and Modelling endpoints (according to DAR 2005)

Prothioconazole, Field studies – Triggering endpoints (actual) and Modelling endpoints (normalised)									
Soil type DIN 19682 / USDA)	Location	pH	Depth (cm)	DissT ₅₀ (d) actual	DT ₉₀ (d) actual	DT ₅₀ , norm 20°C (d)	St. (r ²)	Method of calculation	Evaluated on EU level y/n/ Reference
Loamy silt / Silt loam	51399 Burscheid, Trial Station Höfchen Germany	6.25	0-10	1.9	6.4	1.2	1.00	1 st order	y/ DAR, 2005; EFSA, 2007
Sandy clay loam / Sandy clay loam	IP31 3SH Thurston, Bury St. Edmunds Elm Farm Development Station Great Britain	7.56	0-10	1.6	5.5	0.8	1.00		
Weak loamy silt / Silt	27700 Fresne l'Archeveque France (North)	6.42	0-10	1.3	4.4	1.6	1.00		
Sandy clay loam / Sandy clay loam	IP31 3SH Thurston, Bury St. Edmunds Elm Farm Development Station Great Britain	7.56	0-10	2.8	9.3	1.4	0.99		
Weak loamy silt / Silt	27700 Fresne l'Archeveque France (North)	6.42	0-10	1.4	4.5	1.6	1.00		
Sandy loamy silt / Silt loam	13103 St. Etienne du Gres France (South)	7.61	0-10	1.7	5.6	1.1	0.99		
Weak loamy sand / Sandy loam	37060 Pradelle Di Nogarole Rocca (VR) Italy	7.56	0-10	1.6	5.4	1.5	0.99		
Loamy sand / Sandy loam	40789 Monheim Trial Station Laacherhof Germany	6.32	0-10	1.5	5.1	0.6	1.00		
Maximum (n=8)				2.8*	9.3	-			
Geomean (n=8)				-	-	1.2[#]			

bold figure represent the EU agreed endpoint considered for *PEC_{SOIL} calculations and [#]PEC_{gw}, PEC_{sw} simulations

Prothioconazole-desthio

The DissT_{50field} of prothioconazole-desthio (see Table 8.4-2) ranged from 16.3 days to 72.3 days (DT₉₀ = 54.1–240 days). The maximum DissT₅₀ of 54.7 days along with a conversion rate of 49.4% was considered as endpoint for PEC_{SOIL} calculations. Normalised field soil dissipation modelling endpoints of prothioconazole-desthio range between 10.3 to 61.9 days. **For PEC_{gw} and PEC_{sw} modelling the geometric mean of 22.7 days along with a conversion rate of 57.1 % for prothioconazole-desthio was used.**

Table 8.4-2: Summary of EU agreed aerobic degradation rates for prothioconazole -desthio field studies: Trigger and Modelling endpoints (according to DAR 2005)

Prothioconazole-desthio, Field studies – Triggering endpoints (actual) & Modelling endpoints (normalised)									
Soil type DIN 19682 / USDA)	Location	pH	Depth (cm)	DissT ₅₀ (d) actual	DT ₉₀ (d) actual	DT _{50, norm} 20°C (d)	St. (r ²)	Method of cal- culation	Evaluated on EU level y/n/ Reference
Loamy silt / Silt loam	51399 Burscheid, Trial Station Höfchen Germany	6.25	0-10	16.3	54.1	10.3	0.98	1 st order	y/ DAR 2005; EFSA, 2007
Sandy clay loam / Sandy clay loam	IP31 3SH Thurston, Bury St. Edmunds Elm Farm Development Station Great Britain	7.56	0-10	54.7	182	27.0	0.96		
Weak loamy silt / Silt	27700 Fresne l'Archeveque France (North)	6.42	0-10	47.6	158	27.5	0.94		
Sandy clay loam / Sandy clay loam	IP31 3SH Thurston, Bury St. Edmunds Elm Farm Development Station Great Britain	7.56	0-10	50.2	167	23.4	0.91		
Weak loamy silt / Silt	27700 Fresne l'Archeveque France (North)	6.42	0-10	36.8	122	20.1	0.93		
Sandy loamy silt / Silt loam	13103 St. Etienne du Gres France (South)	7.61	0-10	72.3 ^{a)}	240	61.9	0.91		
Weak loamy sand / Sandy loam	37060 Pradelle Di Nogarole Rocca (VR) Italy	7.56	0-10	30.5	101	20.7	0.98		
Loamy sand / Sandy loam	40789 Monheim Trial Station Laacherhof Germany	6.32	0-10	27.9 ^{b)}	92.6 ^{b)}	15.2	0.98		
Maximum (n=8)				72.3	240	-			
Maximum (n=7)				54.7³⁵	182	-			
Geomean (n=8)				-	-	22.7[#]			

^{a)} excluded because this soil located in southern France is not considered relevant for application in the central zone

^{b)} without day 0 sample, because maximum concentrations were found at later sampling dates

bold figure represent the EU agreed endpoint considered for *PEC_{SOIL} calculations and [#]PEC_{gw}, PEC_{sw} simulations

zRMS comments:

The triggering endpoints for prothioconazole and metabolite JAU 5479-desthio provided in Tables 8.4-1 and 8.4-2 above are in line with data reported in EFSA Scientific Report (2007) 106 and prothioconazole DAR of 2005.

The Applicant indicated that the maximum field DT₅₀ of 54.7 d is an EU agreed endpoint relevant for PEC_{SOIL} calculations in the Central Zone. It should be, however, noted that the maximum DT₅₀ of 72.3 d was agreed at the EU level for soil exposure assessment and no differentiation was made between soils in particular climatic zones.

Furthermore, the field DT₅₀ values calculated for particular test sites within the EU do not seem to be significantly different and therefore should be merged. Taking this into account, exclusion of the degradation data from trials performed in the Southern Zone is not justified. To support such an exclusion the Applicant would have to provide detailed analysis demonstrating that DT₅₀ from test sites located in the Southern Zone are significantly different comparing to test sites within the Central Zone, which was not done.

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 Fenpropidin and its metabolites

The dissipation behaviour of fenpropidin in soil has been determined in seven soils under field conditions and was evaluated by EFSA (EFSA Scientific Report (2007) 124, 1-84, Conclusion on the peer review of fenpropidin). A summary of the degradation studies is presented in the following table. For the soil risk assessment, the maximum SFO-DT₅₀, field value of 116 days was used, which is considered to be a reliable worst case input parameter for the calculation of PECs.

Table 8.4-3: Summary of EU agreed aerobic degradation rates for fenpropidin field studies: Trigger and Modelling endpoints (according to EFSA, 2007)

Fenpropidin, Field studies – Trigger and Modelling endpoints								
Soil type	Location	pH	Depth (cm)	DissT ₅₀ (d) actual	DT ₉₀ (d) actual	Kinetic parameters	St. (r ²)**	Method of calculation
Sandy clay loam	Switzerland	7.1	0-5	116	384	-	0.93	SFO
Loam	Switzerland	6.4	0-5	47	10712*	α : 0.302, β : 5.263	0.97	FOMC***
Loam	Switzerland	7.8	0-5	24	79	-	0.97	SFO
Silt loam	Switzerland	8.0	0-5	7	22	-	0.997	SFO
Loam	Germany	5.8	0-10	94	312*	-	0.89	SFO
Sandy loam	Switzerland	7.8	0-10	7	217	-	0.97	FOMC****
Maximum (n=6)				116				

Maximum SFO DissT₅₀ used for PECsoil modelling

*These two values are highly uncertain since 30-40% of the day 0 concentrations were measured on the last sampling day

** Non-linear curve fitting, hence r² ≠ coefficient of determination but instead fraction of variation explained by model.

*** α =0.302 and β =5.263.

**** α =0.502 and β =2.214.

zRMS comments:

The triggering endpoints for fenpropidin provided in Table 8.4-3 above are in line with data reported in EFSA Scientific Report (2007) 124. Minor corrections were introduced by the zRMS so information in table above is fully in line with data reported in the list of endpoints.

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)

According to EFSA (2007) no data on soil accumulation was submitted and none is required for **prothioconazole** and **prothioconazole-desthio**. This is substantiated by field soil dissipation studies resulting in DT₉₀ values for prothioconazole and prothioconazole-desthio below the trigger of 1 year in any trial (see Table 8.4-1 and Table 8.4-2, Annex point 8.4.1). For prothioconazole-S-methyl no field studies

are triggered ($DT_{50lab} < 60$ days, see Table 8.3 2.)

Regarding **fenpropidin** in the majority of the performed field trials (see chapter 8.4.1) the DT_{50} value was < 3 months and the DT_{90} value was < 1 year. However, the worst-case $DT_{50 field}$ was 116 days and the $DT_{90 field}$ was > 1 year in 2 of 8 trials. Therefore, the potential for accumulation in soil has to be taken into account.

In order to address the potential for soil accumulation of fenpropidin, PEC_{SOIL} , $ACCU$ calculations were conducted according to SFO kinetics. Results showed that the risk of soil accumulation is low. Details are provided in chapter 8.7.

zRMS comments:

According to information presented in EFSA Scientific Report (2007) 106, soil accumulation testing is not required for prothioconazole.

Potential for accumulation of fenpropidin in soil was considered in soil exposure calculations due to worst case field soil DT_{50} value of 116 days from the field dissipation studies.

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. The mobility in soil of prothioconazole and fenpropidin was evaluated during the EU review. No additional studies have been generated for this submission.

Data on the mobility in soil are available for prothioconazole (DAR 2005; EFSA, 2007) and fenpropidin (EFSA, 2007) are summarised in the following.

8.5.1 Prothioconazole and its metabolites

Prothioconazole

During the EU review adsorption coefficient for prothioconazole could not be determined via standard batch equilibrium studies due to the instability of the compound in these systems. Therefore, K_d and K_{oc} values of prothioconazole were estimated from aged column leaching studies.

Phenyl- $UL-^{14}C$ radiolabelled prothioconazole was applied on a loamy sand soil and incubated at 20 °C under aerobic conditions for 30 hours. The resulting values for prothioconazole were $K_d = 15.2$ and $K_{oc} = 1765$ mL/g (slightly mobile compound). At the end of the study, the extracted radioactivity was composed of 22.7% unchanged parent compound, the known metabolites from the soil metabolism study M04 (31.8% AR), M01 (8.1% AR) and prothioconazole-sulfonic acid (M02) (1.5%). The total radioactivity in the leachate accounted for only 1.1% AR of the applied radioactivity, and in the leachate fraction a radioactivity content of $< 0.2\%$ of the applied radioactivity was measured. The leaching behaviour of phenyl- $UL-^{14}C$ radiolabelled prothioconazole was further investigated in a non-aged soil column leaching study on four soils. The level of radioactivity detected in the leachates was $< 1\%$ AR in all samples. Therefore, the leachate fractions were not analysed. The majority of the residue of the active substance was detected in the top 6 cm layer (14.6-40.7% AR in 0-6 cm layer, not detected in the 6-12 cm layer), this also being the case for the metabolites prothioconazole-S-methyl (5.5-11.2% AR in the 0-6 cm layer, not detected in the 6-12 cm layer) and prothioconazole-desthio (15.4-28.0% AR in the 0-6 cm layer, not detected in the 6-12 cm layer).

The sole K_{oc} value of 1765 mL/g along with a default 1/n (0.9) has been considered for the use in FOCUS PEC groundwater and PEC surface water/sediment modelling.

Metabolites

Adsorption/desorption data from four different soils are available from the EU review for the major metabolite prothioconazole-S-methyl as shown in Table 8.5-1. K_i^{ads} values range from 15.6–64.1 mL/g. The K_{foc}^{ads} values range from 1973.6–2995.0 mL/g resulting in an arithmetic mean of **2556.3** mL/g, which is the EU agreed endpoint (EFSA, 2007) considered for PEC_{GW} and $PEC_{SW/SED}$ calculations. Freundlich

coefficients vary from 0.85–0.91 with an arithmetic mean of **0.88** considered as EU agreed endpoint in PEC_{GW} and PEC_{SW/SED} calculations. No soil pH dependent adsorption was observed.

The second major metabolite prothioconazole-desthio was investigated with the same soils 8during the EU review). Results are presented in Table 8.5-1. K_d^{ads} values range from 4.1–13.4 mL/g. The K_{foc}^{ads} values range from 523.0–625.3 mL/g resulting in an arithmetic mean of **575.4** mL/g, which is the EU agreed endpoint (EFSA, 2007) considered for PEC_{GW} and PEC_{SW/SED} calculations. Freundlich coefficients vary from 0.79–0.83 with an arithmetic mean of **0.81** considered as EU agreed endpoint in PEC_{GW} and PEC_{SW/SED} calculations. No soil pH dependent adsorption was observed.

Table 8.5-1: Summary of EU agreed soil adsorption for prothioconazole-S-methyl (according to DAR, 2005)

Prothioconazole-S-methyl							
Soil Name	Soil Type (USDA)	OC (%)	pH (H ₂ O)	K_d^{ads} (mL/g)	K_{foc}^{ads} (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Laacher Hof AXXa, Rhineland, Germany	sandy loam	2.02	7.2	56.0	2772.4	0.87	y/ DAR 2005; EFSA, 2007
Höfchen, Rhineland, Germany	silt	2.14	7.1	64.1	2995.0	0.88	
Stanley, Kansas, USA	silty clay loam	1.66	5.9	41.2	2484.0	0.91	
Byromville, Georgia, USA	loamy sand	0.79	6.8	15.6	1973.6	0.85	
Arithmetic mean (n = 4)				2556.3	0.88		
Median (n = 4)					2628.2	0.875	
Geometric mean (n=4)					2525.9	0.88	
pH-dependency y/n				n			

bold figures: used as endpoints for PEC_{GW} and PEC_{SW/SED} calculations

Table 8.5-2: Summary of EU agreed soil adsorption for prothioconazole-desthio (according to EFSA, 2007)

Prothioconazole-desthio							
Soil Name	Soil Type (USDA)	OC (%)	pH (H ₂ O)	K_d^{ads} (mL/g)	K_{foc}^{ads} (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Laacher Hof AXXa, Rhineland, Germany	sandy loam	2.02	7.2	12.46	616.8	0.79	y/ DAR, 2005; EFSA, 2007
Höfchen, Rhineland, Germany	silt	2.14	7.1	13.38	625.3	0.83	
Stanley, Kansas, USA	silty clay loam	1.66	5.9	8.90	536.4	0.83	
Byromville, Georgia, USA	loamy sand	0.79	6.8	4.13	523.0	0.80	
Arithmetic mean (n = 4)				575.4	0.81		
Median (n = 4)					576.60	0.82	
Geometric mean (n=4)					573.53	0.81	
pH-dependency y/n				n			

bold figures: used as endpoints for PEC_{GW} and PEC_{SW/SED} calculations

Table 8.5-3 Summary of EU agreed soil adsorption for 1,2,4-triazole (according to EFSA, 2008) of tebuconazole

1,2,4-triazole							
Soil Name	Soil Type (USDA)	OC (%)	pH (H ₂ O)	K _r ^{ads} (mL/g)	K _{foc} ^{ads} (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Alpaugh, USA	Sandy loam	0.70	8.8	0.833	120	0.897	EFSA Scientific Report (2008) 176, 1-109 Conclusion on the peer review of tebuconazole
Hollister, USA	Clay loam	1.74	6.9	0.748	43	0.827	
Lawrenceville, USA	Silty clay loam	0.70	7.0	0.722	104	0.922	
Pachappa, USA	Sandy loam	0.81	6.9	0.720	89 86	1.016	
Arithmetic mean (n = 4)					89	0.916	
Geometric mean (n=4)					83	-	
pH-dependency y/n					n		

bold figures: used as endpoints for PEC_{GW} and PEC_{SW/SED} calculations

zRMS comments:

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

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 review of this active substance. Nevertheless, as the renewal process is still ongoing, the K_{oc} of 1765 mL/g is considered to be an EU agreed endpoint that is relevant for the exposure assessment until new list of endpoints becomes valid.

For metabolites JAU 6476-S-methyl and JAU 6476-desthio the geometric mean K_{foc} values were calculated, although in the EFSA conclusion only arithmetic mean values are reported and further used for groundwater and surface water modelling. The geometric mean values calculated by the Applicant were based on the individual K_{foc} from the LoEP and are confirmed to be correct. However, the results of the modelling were validated by the zRMS with consideration of the EU agreed arithmetic mean values.

Information on soil sorption of the metabolite 1,2,4-triazole presented in Table 8.5-3 is in line with EU agreed endpoints as reported in EFSA Scientific Report (2008) 176 for tebuconazole with some minor amendments. The geometric mean values calculated by the Applicant were based on the individual K_{foc} from the LoEP and are confirmed to be correct. However, the results of the modelling were validated by the zRMS with consideration of the EU agreed arithmetic mean value.

8.5.2 Fenpropidin and its metabolites

Fenpropidin

The adsorption / desorption behaviour of fenpropidin was investigated in 6 soils in satisfactory batch adsorption experiments and have been evaluated by EFSA (EFSA Scientific Report (2007) 124, 1-84, Conclusion on the peer review of fenpropidin). Calculated adsorption K_{foc} values varied from 2105 to 5313 mL/g, (arithmetic mean 3808 mL/g) (1/n 0.56 – 0.8, arithmetic mean 0.71). There was no evidence of a correlation of adsorption with pH. A summary of the results is given in the table below.

Table 8.5-4: Summary of EU agreed soil adsorption for fenpropidin (according to EFSA, 2007)

Soil	pH	Organic carbon [%]	Kf [mL/g]	Kfoc [mL/g]	1/n
Sandy clay loam	7.2	1.9	40.3	2105	0.80
Sandy clay loam	7.3	2.2	117.1	5313	0.72
Loamy sand	7.8	0.46	24.1	5194	0.56
Sand	6.6	0.52	17.4	3333	0.72
Sand	6.9	2.9	64.2	2214	0.74
Sandy loam	5.6	0.93	43.5	4687	0.74
Arithmetic mean				3808	0.71

Bold figures used for PEC modelling

An arithmetic mean K_{foc} of 3808 ml/g and a Freundlich constant of 0.71 have been derived from this study for the use in PEC exposure assessment.

Metabolites

During the EU review CGA289267 was found as the only relevant metabolite. The sorption behaviour of CGA289267 in soil has been determined in five soils under laboratory conditions and was evaluated by EFSA (EFSA Scientific Report (2007) 124, 1-84, Conclusion on the peer review of fenpropidin). A summary of the degradation studies is presented in the following table.

An arithmetic mean K_{foc} of 147 ml/g and a Freundlich constant of 0.93 have been derived from this study for the use in the PEC exposure assessment.

Table 8.5-5: Summary of EU agreed soil adsorption for CGA289267 (according to EFSA, 2007)

Soil	pH	% Organic Carbon	Kd	Koc	K _F	K _{FOC}	1/n
Loamy sand	5.7	2.2	1.7	79	1.5	70	0.92
Loam	7.4	1.3	0.8	59	0.7	54	0.92
Silty clay loam	6.6	1.2	3.7	316	4.2	363	0.91
Sandy loam	7.2	1.2	0.4	36	0.61	51	0.98
Silt loam	5.7	2.1	4.7	224	4.1	196	0.92
Arithmetic mean						147	0.93

Bold figures used for PEC modelling

zRMS comments:

Soil mobility data for fenpropidin and its metabolite are in line with EU agreed endpoints as reported in EFSA Scientific Report (2007) 124.

For fenpropidin and its metabolite the arithmetic mean K_{foc} values are reported and further used for groundwater and surface water modelling, which is in line with the EFSA conclusion.

8.5.3 Column leaching (KCP 9.1.2.1)

Leaching behaviour of **prothioconazole** was investigated under laboratory conditions in four soils and evaluated during the EU review. The study was carried out according to SETAC Guidelines (1995), BBA Guideline Part IV, 4-2 (1986) and in accordance with the principles of GLP. 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.

As outlined above, reliable adsorption coefficients for the active substance **fenpropidin** have been determined for five different soils and evaluated by EFSA. Therefore, the performance of column leaching

studies with the parent compound or with the preparation ADM.03502.F.1.A is not considered to be required. However, during the EU evaluation process two column leaching studies has been performed with fenpropidin in Switzerland. The studies demonstrated a low leaching potential of fresh and aged fenpropidin residues.

zRMS comments:

In EFSA Scientific Report (2007) 106 and in EFSA Scientific Report (2007) 124 results of column leaching and aged residues leaching of prothioconazole and fenpropidin are reported, respectively. Their results are, however, not necessary for purposes of evaluation of ADM.03502.F.1.A, as based on results of the groundwater modelling no unacceptable leaching of prothioconazole, fenpropidin and their metabolites is expected.

During the EU review results of aged residue leaching studies were used for derivation of Koc value for prothioconazole. For comments in this area, please refer to point 8.5 above.

8.5.4 Lysimeter studies (KCP 9.1.2.2)

According to EU evaluation of **prothioconazole** no lysimeter data have been submitted. The results of the PEC_{gw} simulations as given under point 0 indicate a low leaching risk of prothioconazole and metabolites. Therefore, lysimeter studies are not required.

All lysimeter trials on **fenpropidin** have been reviewed by EFSA (EFSA Scientific Report (2007) 124, 1-84, Conclusion on the peer review of fenpropidin) showing that leaching can be excluded.

zRMS comments:

Information on lysimeter studies for prothioconazole and fenpropidin is in line with conclusions derived at the EU level.

8.5.5 Field leaching studies (KCP 9.1.2.3)

According to EU evaluation of **prothioconazole** no field leaching studies have been submitted. Based on the outcome of the PEC_{gw} simulations as provided under point 0, the leaching potential of prothioconazole and metabolites is low, which is why field leaching studies are not required.

All field leaching trials on **fenpropidin** have been reviewed by EFSA (EFSA Scientific Report (2007) 124, 1-84, Conclusion on the peer review of fenpropidin) showing that leaching can be excluded. Thus, no additional studies are necessary.

zRMS comments:

Information on field leaching studies for prothioconazole and fenpropidin is in line with conclusions derived at the EU level.

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

Data on the degradation of the active substance **prothioconazole** and its metabolites in water/sediment systems are available in the context of the respective EU evaluation process. For details see EFSA (2007) and the DAR (2005) for prothioconazole. Data on the degradation of the active substance **fenpropidin** and its metabolites in water/sediment systems are also available in the context of the respective EU evaluation process (EFSA, 2007) and the DAR (2005) & the final addendum (2007) to the DAR for fenpropidin. No additional studies have been generated for this submission.

8.6.1 Prothioconazole and its metabolites

Information on the aerobic degradation of prothioconazole in water sediment systems was available for two aquatic systems (Hönniger Weiher and Angler Weiher). **From the two systems a geometric mean DegT₅₀ of 2.1 days was calculated for the whole system (Table 8.6-1), which is considered as endpoint for PEC_{SW/SED} modelling.** In addition the anaerobic degradation of prothioconazole was investigated in an anaerobic water/sediment system (Fuquay, Montezuma, Georgia, USA). The disappearance of prothioconazole from the total water/sediment system had a DT₅₀ of 72 days, while the DT₅₀ in the supernatant water has calculated to be 2.5 days.

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

DAR 2005: Prothioconazole distribution (max. sediment 23.4% after 1 days)										
Water / sediment system	pH water/ sed. (H₂O)	DegT₅₀ whole syst. (d)	DegT₉₀ whole syst. (d)	Kinetic, Fit	DissT₅₀ water (d)	DissT₉₀ water (d)	Kinetic, Fit	DissT₅₀ sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
Hönniger Weiher	7.84 / 6.6	2.8	76.4	'hockey stick', r ² =0.953	0.8	2.7	1 st order, r ² =0.947	n.c.	-	y/ DAR, 2005; EFSA, 2007
Angler Weiher	7.45 / 8.5	1.6	23.6	'hockey stick', r ² =0.998	1.0	3.4	1 st order, r ² =0.999	n.c.	-	
Geometric mean (n=2)		2.1								FOCUS (2006)¹¹

bold figure used as endpoint for PEC_{SW/SED} calculations; n.c.: not calculated

Table 8.6-2: Summary of observed metabolites

Metabolites in Water/sediment system	Max occurrence [%]	DT₅₀ in sediment/water system [d]	Evaluated on EU level
Prothioconazole-desthio	in water 32.3 % after 7 d in sediment 26.9 % after 14 d in whole system 54.6% (32.3% of day 7 + 22.3% of day 7)	49.9 (whole system value, n=2)	y/ DAR, 2005; EFSA, 2007
Prothioconazole-S-methyl	in sediment 77% after 240 d (anaerob)	40.2 (whole system value, n=2)	
1,2,4-triazole	in water 37.2 % after 121 d in sediment 4.6 % after 121 d in whole system 41.8 % after 121 d	-	

Hydrolysis, phototransformation in water and ready biodegradability

The aqueous **hydrolysis** of prothioconazole was investigated in one study at different pH values at 50 °C. Prothioconazole was found to hydrolyse slowly at pH 7 and 9 (DT₅₀ estimated greater than one year). At pH 4 and 25 °C the DT₅₀ was estimated to be 120 days.

The aqueous **photolysis** of phenyl- and triazole-labelled prothioconazole was studied following SETAC Guidelines (1995), US EPA Guideline 162-1 (1982) in accordance with the principles of GLP. Test solutions made up in sterile aqueous solution at pH 7 with a concentration of approximately 4 mg/l were continuously exposed to simulated sunlight using a xenon light (290 nm UV filter). Exposure period was equated 65.0 solar summer days in June in Arizona (USA) and 100.7 days in Athens (Greece). Prothioconazole was completely photodegraded within the duration of the experiment. Determined mean experimental half-life was 47.7 h (44.3 h, k = 0.0157 h⁻¹, R² = 0.999 for the phenyl-labelled and 51.4 h,

¹¹ FOCUS (2006): Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration; Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005, version 2.0, 434 pp., June 2006

$k = 0.0135 \text{ h}^{-1}$, $R^2 = 0.999$ for the triazole-labelled test substance).

In a second study quantum yields and direct photodegradation of prothioconazole was investigated according to ECETOC method (1981, 1984), Test Guideline ‘Phototransformation of chemicals in water, Part A (Berlin, 1992) and in accordance with the principles of GLP. Mean quantum yields of 0.0638 (pH 4) and 0.0047 (pH 9) were calculated for 50° latitude and a 0 – 5 cm water depth. Resulting assessed environmental direct photolysis half-lives were 50 to < 200 days at pH 4 and 7 to 20 days at pH 9 in the periods of main use.

In another study following the same methods and guidelines quantum yield of prothioconazole-desthio was investigated in pure water. Determined quantum yield was 0.00449. Quantum yield was used for the estimation of the environmental half-life using two different simulation models (GC-SLOAR and Frank & Klöpffer). Results indicated an insignificant contribution of direct photodegradation in water to the overall elimination of prothioconazole-desthio in the environment.

In an aqueous photolysis study prothioconazole-thiazocine was observed in amounts > 10% AR. Data from the study were used to quantify the degradational behaviour by using ‘ACSL Optimize Software’ and first order kinetics. Environmental DT_{50} values assuming summer sunlight conditions in Athens, Greece were 125.3 days for phenyl- and 212.5 days for triazole-labelled prothioconazole.

For a realistic estimation of maximum amounts of prothioconazole-thiazocine in surface water under natural conditions information about the dissipation of prothioconazole from the water phase was combined with data about the photolysis of prothioconazole to its metabolite prothioconazole-thiazocine. It was suggested that due to the fast dissipation of prothioconazole from the water phase (longest $DT_{50} = 1$ day) and the slow photolytic degradation to prothioconazole-thiazocine (longest $DT_{50} = 212.5$ days) an amount of prothioconazole-thiazocine of 1 % of the amount of the active substance reaching surface water will not be exceeded under realistic environmental conditions. Therefore, prothioconazole-thiazocine was not regarded as a major aqueous metabolite by the study author.

In another study the molar extinction coefficient of 1,2,4-triazole was investigated according to Test Guideline ‘Phototransformation of chemicals in water, Part A (Berlin, 1992) and in accordance with principles of GLP. UV-absorption data in the environmentally relevant pH range showed no absorption of light at wavelength above 290 nm by 1,2,4-triazole. Therefore, no contribution of direct photodegradation to the overall elimination of 1,2,4-triazole in the aqueous environment is to be expected.

Table 8.6-3: Summary of agreed EU hydrolysis, photolysis and ready biodegradability data on prothioconazole in water (EFSA, 2007)

Parameter	Endpoints
Hydrolysis of active substance and relevant metabolites	<u>prothioconazole</u> : DT_{50} at 50°C: pH 9 and 7: > 1 year, pH 4: 120 days DT_{50} at 25°C: pH 9, 7 and 4: > 1 year
Photolytic degradation of active substance and relevant metabolites	Aqueous photolysis study (25 °C, pH 7) <u>prothioconazole</u> : phenyl label - $DT_{50} = 44.3$ hrs ($R^2 = 0.999$) triazole label - $DT_{50} = 51.4$ hrs ($R^2 = 0.999$) mean = 47.7 hours (n=2) predicted environmental half-life under solar summer conditions (June) of Phoenix, AZ, USA of 7.1 days and 11 days at Athens mineralisation at study end (18 days) = 3.0% AR (phenyl label), 0.5% AR (triazole label) Dark controls: prothioconazole was stable in the dark control samples, confirming that photolysis was the main process of degradation. %AR at 18 days was 108.7% for the phenyl label and 107.1% for the triazole label. <u>prothioconazole-desthio (M04)</u> : max 55.7% AR 11 d <u>prothioconazole-thiazocine (M12)</u> : max 14.1% AR, 5d <u>1,2,4-triazole (M13)</u> : max 11.9% AR, 18d
Quantum yield	<u>prothioconazole</u> : Quantum yields Φ of 0.0638 (pH 4) and 0.0047 (pH 9) were calculated.

Parameter	Endpoints
	<p>Environmental direct photolysis half-lives were in the range 50 to >200 days at pH 4 and 7 to 20 days at pH 9 for the periods of main use.</p> <p><u>prothioconazole-desthio (M04):</u> A quantum yield of Φ of 0.00449 was calculated. The resulting quantum yield and the UV absorption were used to estimate the environmental half-life of prothioconazole-desthio (M04) concerning direct photodegradation in water by two different simulation models (GC-SOLAR, half-life at 50° latitude and 0-1cm depth in the summer season: 269 days and Frank & Klöpffer, half-life at 50° latitude and 0-1cm depth > 1 year).</p> <p><u>1,2,4-triazole (M13):</u> The UV-absorption data in the environmentally relevant pH range showed that 1,2,4-triazole (M13) dissolved in aqueous solution does not absorb any light at wavelengths above 290 nm.</p>
Ready biodegradable (yes/no)	No data submitted, not required

zRMS comments:

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

8.6.2 Fenpropidin and its metabolites

During the evaluation by EFSA the degradation behaviour of fenpropidin in water and sediment has been determined in two water/sediment systems under laboratory conditions and was evaluated by EFSA (EFSA Scientific Report (2007) 124, 1-84, Conclusion on the peer review of fenpropidin).

In the original study report (DAR, 2005) first order DT₅₀ values for the total systems were calculated by linear regression to 65 days in the river system (excluding day 70 values as outliers) and to 21 days in the pond system. Arithmetic mean SFO DT₅₀ for degradation in the whole system has been calculated to be 43 days. This is the EU agreed endpoint used in the PEC_{sw} modelling during the EU evaluation process.

In accordance with EFSA (2014)¹², the associated geomean DT₅₀ of 37 days is the representative endpoint for the use in the current PEC_{sw} modelling at FOCUS Step 1 (whole system) and Step 2 (water).

Mainly in order to provide DT₉₀ values for degradation, during the EU review the RMS re-calculated the first order whole system degradation DT₅₀ and DT₉₀ values without logarithmic transformation and by using also the data from day 70 from the river system since these are not considered as obvious outliers.

These EU agreed degradation half-lives resulting in a geomean DT₅₀ of 32 days, are presented in the following table and were considered for PEC_{sw} modelling at FOCUS Step 2, 3 and 4 (sediment).

At Step 1-2 the more conservative DT₅₀ values from the original study had to be used in the PEC_{sw} assessment (see above).

Table 8.6-4: Summary of EU agreed degradation data in water/sediment of fenpropidin

EFSA (2007), Fenpropidin Distribution (max. water 81.5-83.9% day 0; Max. in sed 54.6-58.4% after 14 d)										
Water/sediment system	pH water/sed.	DegT ₅₀ whole syst. (d)	DegT ₉₀ whole syst. (d)	St. (r ²)	DissT ₅₀ water (d)	DissT ₉₀ water (d)	St. (r ²)	DissT ₅₀ sed. (d)	St. (r ²)	Evaluated on EU level Reference
River	8.1/8.0	45*	>84	0.89	0.7	64	1.0	-	-	y/ EFSA, 2007 Y/Van Dijk, 1986

¹² EFSA Journal 2014;12(5):3662

EFSA (2007), Fenpropidin Distribution (max. water 81.5-83.9% day 0; Max. in sed 54.6-58.4% after 14 d)										
Water/sediment system	pH water/sed.	DegT ₅₀ whole syst. (d)	DegT ₉₀ whole syst. (d)	St. (r ²)	DissT ₅₀ water (d)	DissT ₉₀ water (d)	St. (r ²)	DissT ₅₀ sed. (d)	St. (r ²)	Evaluated on EU level Reference
Pond	8.6/7.4	23*	77	0.97	3	10	0.996	-	-	y/ EFSA, 2007 Y/Van Dijk, 1986
Geometric mean (n=2)		32*	-		1.4	25		-		

Bold figure used for PEC_{sed} at Step 2 and 3/4, *re-calculated by RMS during the EU review

In contrast conservative DT₅₀ from the original study report (arithmetic mean = 43 days) represents the EU agreed endpoint for PEC_{sw}, the associated **geometric mean 37 d has been used in the current risk assessment at Step 1 (whole system), Step 2 (water)**

Two reliable DegT₅₀ whole system values are derived for fenpropidin resulting in a geometric mean 32 days. The geomean DT₅₀ value is the recommended value for modelling at Step 3 & 4. It was used for the fenpropidin sediment DT₅₀ together with a default worst case DT₅₀ of 1000 days for water.

CGA 289267 was the only major metabolite formed, identified at a maximum of 16.1% in the river system, predominantly in the water column. Based on the EFSA conclusions the degradation rate for the metabolite CGA 289267 is comparable to that of parent fenpropidin whole system. **Thus, the DT₅₀ of the parent compound (geomean 37 d) was used for exposure assessment at Step 1 (whole system), Step 2 and 3 (water and sediment).**

Table 8.6-5: Summary of observed metabolites in water/sediment

Metabolites	Maximum observed value in water/sediment system 16.1 % (river system)	Evaluated on EU level
CGA 289267 Water/sediment system	Distribution: Max. in water 12.9% d 28 in pond system, 14.3% d 70 in river system; Max. in sed 2.3% d 70 in pond system, 1.8% d 70 in river system. DT _{50/90} for metabolite not established due to few sampling points after peak (river system) or variation in concentration after peak (pond system)* No other metabolites identified as >10% of AR.	y/ EFSA, 2007

*parent DT₅₀ value has been used for PEC_{sw}/sed modelling (as EU agreed)

Hydrolysis, phototransformation in water and ready biodegradability

During the EU renewal it has been concluded that fenpropidin is hydrolytically stable under sterile aqueous hydrolysis conditions at 50°C at pH 3, 7 and 9. Measurement of the UV visible absorption spectrum of aqueous solutions of fenpropidin indicated that direct aqueous photolysis of fenpropidin would not be expected due to the absence of any significant absorption over the relevant wavelengths for sunlight (>290 nm). A ready biodegradability test (OECD 301B) indicated that fenpropidin is ‘not readily biodegradable’ using the criteria defined by the test.

Table 8.6-6: Summary of agreed EU hydrolytic degradation of fenpropidin

Hydrolytic degradation of the active substance and metabolites > 10%	Stable under sterile aqueous hydrolysis conditions at 50°C at pH 3, 7 and 9
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Table 8.6-7: Summary of agreed EU aqueous photochemical degradation of fenpropidin

Photolytic degradation of the active substance and metabolites above 5%	Stable
Quantum yield of direct phototransformation in water at $\sum > 290$ nm	No data submitted

zRMS comments:

Degradation data for fenpropidin and its metabolite in water/sediment systems provided in tables above are in line with EU agreed endpoints reported in EFSA Scientific Report (2007) 124.

It is noted that the Applicant refers to the data from the DAR (2005) for DT₅₀ in whole system and considered it in the surface water modelling at Step 1-2 as more conservative.

For relevant endpoints considered in exposure assessment, please refer to the commenting box in section 8.9 (surface water) of this document.

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

According to the residue definition provided in the EFSA conclusion on **prothioconazole** (EFSA, 2007) the following residues are of concern for the exposure and risk assessment in soil:

- *Prothioconazole, prothioconazole-desthio (JAU-desthio), prothioconazole-S-methyl (JAU-S-methyl).*

According to the residue definition provided in the EFSA conclusion on **fenpropidin** (EFSA, 2007) the following residues are of concern for the exposure and risk assessment in soil:

- *Fenpropidin, CGA 289267*

PEC_{SOIL} values were calculated in accordance to FOCUS (1997¹³).

8.7.1 Justification for new endpoints

PEC_{SOIL} calculation for prothioconazole and its metabolites as well as for fenpropidin and its metabolite were performed considering the endpoints agreed in the EU (EFSA conclusion of prothioconazole, 2007 and EFSA conclusion of fenpropidin, 2007). However, sites that are not representative of the central zone were not necessarily considered in the endpoint selection.

zRMS comments:

Detailed discussion regarding endpoints considered in soil exposure assessment and their acceptability is presented in the commenting boxes below.

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

PEC_{SOIL} calculations were performed for a realistic worst case application pattern of ADM.03502.F.1.A covering all intended GAP uses in the Central zone. The overall critical GAP use (refer to Table 8.7-1) was based on the highest intended single application rate of 1 L product/ha, i.e. 175 g prothioconazole/ha and 250 g fenpropidin/ha. The earliest growth stage of the envisaged crop representing minimum crop interception was taken into account. Thus, 80 % crop interception was considered for the treatment at BBCH 30 to cereals. This application pattern represents an overall worst case of the intended GAP uses of ADM.03502.F.1.A in the Central zone, comprising the highest deposit rate (= application rate corrected for crop interception) per year, i.e. 1 x 35 g prothioconazole/ha and 1 x 50 g fenpropidin/ha.

PEC_{soil} were calculated for a standard soil according to the EU guideline FOCUS (1997) considering a dry soil bulk density of 1.5 g/cm³ and a 5 cm soil depth following application to the soil surface. For accumulation, the standard tillage depth of 20 cm for annual field crops was considered.

PEC_{soil} over many years (potential soil accumulation)

As outlined under point 7.1.2.2.2 and 9.1.1.2.2 of Commission Regulations (EU) No 283/2013 and 284/2013, the possibility of accumulation of residues in soil and the level at which a plateau concentration is achieved may be investigated in soil accumulation studies or alternatively by appropriate model calculations.

Soil accumulation testing is required where:

- (a) on basis of soil dissipation studies the DisT_{90field} in one or more soils is greater than one year, and
- (b) repeated application is envisaged, whether in the same growing season or in succeeding years.

¹³ FOCUS (1997): Soil persistence models and EU Registration. The final report of the work of the Soil Modelling Work Group of FOCUS. February 1997.

For the active substance fenpropidin the criteria a) and b) are fulfilled. Therefore, soil accumulation has to be considered based on soil plateau concentrations.

Hence, plateau calculations were performed with the same input parameters as presented above considering continuous application year by year and a ploughing depth of 20 cm. The resulting plateau was added to the PEC_{ini} after multiple applications as calculated above to address the accumulation potential (PEC_{accum}).

For the parent compound prothioconazole and all metabolites soil accumulation testing is not triggered. The results are presented under points 8.7.2.1 and 0.

The input parameters for the risk envelope GAP use of ADM.03502.F.1.A for PEC_{soil} calculations are provided in Table 8.7-1.

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

Use No. ⁽¹⁾	all
Crop	Cereals
Application rate (g a.s./ha)	Prothioconazole: 1 x 175 g Fenpropidin: 1 x 250 g
Number of applications/interval	-
Crop interception (%)	80 (BBCH 30) (FOCUS, 2014)
Frequency of application	Every year
Depth of soil layer (relevant for plateau concentration) (cm)	20

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

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

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT ₅₀ (days)	Value in accordance to EU endpoint y/n/ Reference
Prothioconazole	344.3	-	2.8 (SFO kinetics, maximum from field studies, un-normalised)	y/EFSA, 2007
JAU-S-Methyl	358.3	14.6	46 (SFO kinetics, maximum from lab studies, un-normalised)	y/EFSA, 2007
JAU-desthio	312.2	57.1 49.4*	72.3 (max. field, non-normalised, n= 3) 54.7 (SFO kinetics, maximum from field studies* un-normalised)	y/EFSA, 2007*
Fenpropidin	273.5	-	116 (SFO, max field study, unnormalized)	y/ EFSA, 2007
CGA 289267	303.4	10.6 (8°C)	63 (SFO, lab study, unnormalized)	y/ EFSA, 2007

*one soil located in southern Europe was excluded from calculations because it is not considered relevant for application in the central zone

zRMS comments:

The application pattern assumed in soil exposure assessment presented in Table 8.7-1 is in line with the critical Central Zone GAP and it is thus agreed by the zRMS. Relevant crop interception of 80% in line with FOCUS groundwater guidance (2014) has been selected.

Input parameters presented in Table 8.7-2 are in general in line with the EU agreed parameters reported in EFSA Scientific Report (2007) 106 and EFSA Scientific Report (2007) 124, for prothioconazole and fenpropidin, respectively, with following exceptions:

- for prothioconazole metabolite JAU 6476-desthio the maximum occurrence of 49.4% and DT₅₀ of 54.7 days were taken into account, as one soil located in Southern Europe was excluded from the calculations as considered not relevant by the Applicant for application in the Central Zone. In opinion of the zRMS the max occurrence of 57.1% and DT₅₀ of 72.3 days should be used for PEC_{SOIL} calculation as these values are EU agreed endpoints and exclusion of the degradation data from the Southern France soil should be supported by the respective statistical analysis demonstrating that the results in this soil are significantly different comparing to soils at other locations. For more details, please refer to point 8.4.1.1 above.

Detailed discussion of the results of soil exposure for prothioconazole and its metabolites is presented in the commenting box in point 8.7.2.1 below.

8.7.2.1 Prothioconazole and its metabolites

Table 8.7-3: PEC_{SOIL} for prothioconazole following 1 × 175 g a.s./ha to cereals (BBCH 30)

PEC _{SOIL} (mg/kg)		Cereals (BBCH 30)			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.047	-	-	-
Short term	24h	0.036	0.041	-	-
	2d	0.028	0.037	-	-
	4d	0.017	0.030	-	-
Long term	7d	0.008	0.022	-	-
	14d	0.001	0.013	-	-
	21d	0.000	0.009	-	-
	28d	0.000	0.007	-	-
	50d	0.000	0.004	-	-
	100d	0.000	0.002	-	-
Plateau concentration (20 cm) after year x		not triggered	-	-	-
PEC _{SOIL,accumulation} (PEC _{SOIL,act} + PEC _{SOIL,plateau})		not triggered	-	-	-

PEC_{soil} of metabolites

Table 8.7-4: PEC_{SOIL} for JAU-Desthio and JAU-S-Methyl following 1 × 175 g a.s./ha to cereals

PEC _{SOIL} (mg/kg)		Cereals (BBCH 30)			
		Single applications			
		JAU-Desthio		JAU-S-Methyl	
		Actual	TWA	Actual	TWA
Initial		0.021	-	0.007	-
Short term	24h	0.021	0.021	0.007	0.007
	2d	0.020	0.021	0.007	0.007
	4d	0.020	0.020	0.007	0.007
Long term	7d	0.019	0.020	0.006	0.007
	14d	0.018	0.019	0.006	0.006
	21d	0.016	0.018	0.005	0.006
	28d	0.015	0.018	0.005	0.006
	50d	0.011	0.015	0.003	0.005
	100d	0.006	0.012	0.002	0.004
Plateau concentration (5/20 cm) after year x		not triggered	-	not triggered	-
PEC _{SOIL,accumulation} (PEC _{SOIL,act} + PEC _{SOIL,plateau})		not triggered	-	not triggered	-

zRMS comments:

The soil exposure for prothioconazole and its metabolites has been independently validated by the zRMS using FOCUS methods, 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 metabolite JAU 6476-S-methyl were similar to those obtained by the Applicant, and therefore results for these compounds reported in tables above may be used for the soil risk assessment purposes.

The new calculation and results for metabolite JAU 6476-desthio are presented in the table below, as they were different comparing to Applicants' results. The PEC_{SOIL,ACC} was not required as DT₅₀ of the metabolite is below 90 days. The short- and long-term PEC_{SOIL} values are not reported below as they are not necessary for the risk assessment purposes. Only 21 TWA PEC_{SOIL} is provided as being required for evaluation of the risk of secondary poisoning for birds and mammals.

PEC _{SOIL} JAU-Desthio (mg/kg)	Cereals (BBCH 30)
	Single application
Initial	0.024
21-d TWA	0.022

8.7.2.2 Fenpropidin and its metabolites

Table 8.7-5: PEC_{SOIL} for fenpropidin and its metabolite CGA 289267 following 1 × 250 g a.s./ha to cereals ~~beet~~ (BBCH 30)

PEC _{SOIL} (mg/kg)		Cereals (BBCH 30)			
		Fenpropidin		CGA 289267	
		Single application		Single application	
		Actual	TWA	Actual	TWA
Initial		0.067	-	0.008	-
Short term	24h	0.066	0.066	0.008	0.008
	2d	0.066	0.066	0.008	0.008
	4d	0.065	0.066	0.008	0.008
Long term	7d	0.064	0.065	0.007	0.008
	14d	0.061	0.064	0.007	0.007
	21d	0.059	0.063	0.006	0.007
	28d	0.056	0.061	0.006	0.007
	50d	0.049	0.058	0.005	0.006
	100d	0.037	0.050	0.003	0.005
Plateau concentration (20 cm) after year x		0.002	-	Not triggered	-
PEC _{SOIL,accumulation} (PEC _{SOIL,act} +PEC _{SOIL,plateau})		0.069	-	Not triggered	-

zRMS comments:

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

The calculated PEC_{SOIL} values were in good agreement with these obtained by the Applicant. Therefore, results reported in table above may be used for the soil risk assessment purposes.

8.7.2.3 PEC_{SOIL} of product ADM.03502.F.1.A

Table 8.7-6: PEC_{soil} for ADM.03502.F.1.A

Active substance/ reparation	Application rate (g/ha)	PEC _{act} (mg/kg)	PEC _{twa21 d} (mg/kg)	Tillage depth (cm)	PEC _{soil,plateau} (mg/kg)	PEC _{accu} = PEC _{act} + PEC _{soil,plateau} (mg/kg)
ADM.03502.F.1.A	1040	0.277*	n.r.	20	not calculated [#]	

*based on a relative density of 1.04 g/mL and the worst-case application rate of 1.0 L product/ha, considering interception of 80 %

[#]calculation of accumulation is not possible since no DT₅₀ is available for the formulated product

zRMS comments:

PEC_{soil} value for the formulated product ADM.03502.F.1.A is agreed by the zRMS and may be used in the risk assessment for soil organisms.

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

According to the residue definition provided in the EFSA conclusion on **prothioconazole** (EFSA, 2007) the following residues are of concern for the risk assessment in groundwater:

- Prothioconazole, prothioconazole-desthio, (JAU-desthio), prothioconazole-S-methyl (JAU-S-methyl)

According to the residue definition provided in the EFSA conclusion on **fenpropidin** (EFSA, 2007) the following residues are of concern for the exposure and risk assessment in groundwater:

- Fenpropidin, CGA 289267

8.8.1 Justification for new endpoints

EU agreed endpoints, as defined in the List of Endpoints (LoEP) of the EFSA conclusion for prothioconazole (EFSA, 2007) and fenpropidin (EFSA, 2007), were considered in the groundwater assessment for prothioconazole and its metabolites and fenpropidin and its metabolite, respectively in accordance to the recommendations for the Central zone (2018). However, in addition to the EU agreed endpoints for the plant uptake factor of active substances and its metabolites, a default value of 0.0 is used, which is in accordance with the recommendations of EFSA guidance (2013¹⁴). For vapour pressure and water solubility of prothioconazole metabolites the parent values are used in absence of data in the list of endpoints. In addition, geomean DT₅₀ values have been used for fenpropidin and its metabolite for all compartments in accordance with the current guidance (EFSA, 2014¹⁵; FOCUS, 2014a¹⁶).

Although the DT₅₀ values have been normalized with a Q₁₀ of 2.2 in the underlying studies, for actual PEC calculations the new default Q₁₀ of 2.58 has been used as already implemented in the models (EFSA Panel (2007)¹⁷.

zRMS comments:

Detailed discussion regarding endpoints considered in groundwater modelling and their acceptability is presented in the commenting boxes in points 8.8.2.1 for prothioconazole and 8.8.2.2 for fenpropidin.

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

The following PEC_{GW} modelling for the active substances prothioconazole and fenpropidin and its metabolites (using current model versions FOCUS PELMO 5.5.3 and/or FOCUS PEARL 4.4.4 and/or FOCUS MACRO 5.5.4) has not previously been reviewed and a summary is provided in support of this assessment in Appendix 2 of this document. In accordance with the working document of the central zone the results of one of these models show the PEC_{GW} results to be <0.001 µg/l in all relevant scenarios for all substances triggering groundwater assessment, it is not necessary to perform simulation runs with the other model. Therefore, only FOCUS PEARL results are presented for prothioconazole and its metabolites.

The PEC_{GW} of prothioconazole and its metabolites have been assessed with FOCUS PEARL 4.4.4 following FOCUS (2014b)¹⁸ and the requirements of the Central zone (2018).

In case of the fenpropidin metabolite all three models FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3 and

¹⁴ EFSA (2013): EFSA Journal 2013;11(6):3291: Scientific Opinion on the report of the FOCUS groundwater working group (FOCUS, 2009): assessment of higher tiers.

¹⁵ EFSA (2014): EFSA Journal 2014;12(5):3662: EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT₅₀ values of the active substances of plant protection products and transformation products of these active substances in soil.

¹⁶ FOCUS (2014a): Generic Guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration.

¹⁷ EFSA Journal (2007) 622,1-32: Scientific Opinion of the PPR-Panel.

¹⁸ FOCUS (2014b): Generic Guidance for Tier 1 FOCUS Ground Water Assessments, Version 2.2, May 2014

FOCUS MACRO 5.5.4 are run at tier 1 following FOCUS (2014b) and the requirements of the Central zone (2018).

The exposure assessment in groundwater was based on various application patterns (Table 8.8-1) derived from GAP information.

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

Use No. ⁽¹⁾	1-29, 106-110	1-29, 106-110
Crop / FOCUS _{GW} crop	Cereals, spring	Cereals winter
Application timing (BBCH / month)	30	30
Application rate (g/ha)	Fenpropidin: 250 Prothioconazole: 175	Fenpropidin: 250 Prothioconazole: 175
Number of applications/interval (d)	1/ -	1/ -
Absolute application dates	See Table 8.8.2	
Crop interception (%)	80	
Deposit rates (g a.s./ha) ⁽²⁾	Fenpropidin: 50 Prothioconazole: 35	
Models used for calculation	FOCUS PEARL 4.4.4 (prothioconazole, JAU-Desthio, S-Methyl, fenpropidin, CGA289267) FOCUS PELMO 5.5.3 (fenpropidin, CGA 289267) FOCUS MACRO 5.5.4 (fenpropidin, CGA 289267)	

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

Please note, that the highest resulting deposit rate (application rate corrected for crop interception) results in the maximum PEC_{GW}. That means, the maximum intended rates per treatment were set to the beginning of the intended application timing, where crop interception is lowest. Therefore, the defined application patterns in Table 8.8-1 represent the worst-case of application for the resulting maximum PEC_{GW} of active substances and metabolites for a specific GAP use.

Absolute application dates were determined with Appdate version 3.06 for cereals at BBCH 30 and presented in the table below.

Table 8.8-2: FOCUS Scenario related input parameters for PEC_{GW} calculations for the application of ADM.03502.F.1.A

GAP use	FOCUS Scenario	Absolute application dates (Julian day)	
		Winter crop	Spring crop
Cereals, BBCH 30	Châteaudun	15-April (105)	16-April (106)
	Hamburg	4-May	28-April
	Jokioinen	14-May	5-June
	Kremsmünster	24-April	27-April
	Okehampton	21-April	22-April
	Piacenza	19-March	-
	Porto	30-January	16-April
	Sevilla	6-January	-
	Thiva	18-January	-

zRMS comments:

The application pattern assumed in groundwater modelling is in line with the critical Central Zone GAP as presented in Table 8.1-1.

Application dates presented in Table 8.8-2 were checked by the zRMS using AppDate ver. 3.06 tool and are considered acceptable. Assumed crop interception corresponded with BBCH stages at which ADM.03502.F.1.A is intended to be applied.

8.8.2.1 Prothioconazole and its metabolites

The input parameters of prothioconazole and its metabolites utilised for PEC_{GW} modelling are summarised hereafter.

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

Compound	Prothioconazole	JAU-desthio	JAU-S-methyl	Value in accordance with EU endpoint y/n/ Reference
Molecular weight (g/mol)	344.26	312.2	358.3	y/ EFSA, 2007
Water solubility (mg/L)	300 (20 °C)	300 (20 °C)	300 (20 °C)	Parent y/ EFSA, 2007 Metabolites: parent value
Saturated vapour pressure (Pa)	< 4x10E-07 (20 °C)	< 4x10E-07 (20 °C)	< 4x10E-07 (20 °C)	
DT ₅₀ in soil (d)	1.2 (norm.geomean from field studies), n=8	22.7 (norm.geomean from field studies), n=8	15.7 (geomean from lab studies), n=4	y/ EFSA, 2007
Q ₁₀ (-)	2.58	2.58	2.58	n/ EFSA Panel, 2007 ¹⁹
K _{foc} /K _{fom} (mL/g)	1765/1023.8 (single value)	575.4/333.8 (arithmetic mean, n=4)	2556.3/1482.8 (arithmetic mean, n=4)	y/ EFSA, 2007
1/n	0.9 (default)	0.81 (arithmetic mean, n=4)	0.88 (arithmetic mean, n=4)	y/ EFSA, 2007
Plant uptake factor	0 (default)	0 (default)	0 (default)	n/ EFSA, 2013 ²⁰
Formation fraction	from parent to:	0.571	0.146	y/ EFSA, 2007
		1 (from S-methyl)		

The 80th percentile annual average PEC_{GW} of prothioconazole and metabolites are provided in the following.

Table 8.8-4: Tier 1 PEC_{GW} for prothioconazole and its metabolites JAU-desthio and JAU-S-methyl

Crop / FOCUS _{GW} Crop, Appl. no. & rate (g a.s./ha)	Scenario	PEARL 4.4.4		
		80 th Percentile PEC _{GW} at 1 m Soil Depth (µg/L)		
		Prothioconazole	JAU-Desthio	JAU-S-Methyl
Cereals/ Winter cereals 1 × 175 g prothioconazole.	Châteaudun	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001	< 0.001
	Porto	< 0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001
Cereals/ Spring	Châteaudun	< 0.001	< 0.001	< 0.001

¹⁹ EFSA Journal (2007) 622,1-32: Scientific Opinion of the PPR-Panel.

²⁰ EFSA (2013): EFSA Journal 2013;11(6):3291: Scientific Opinion on the report of the FOCUS groundwater working group (FOCUS, 2009): assessment of higher tiers.

Crop / FOCUS _{GW} Crop, Appl. no. & rate (g a.s./ha)	Scenario	PEARL 4.4.4		
		80 th Percentile PEC _{GW} at 1 m Soil Depth (µg/L)		
		Prothioconazole	JAU-Desthio	JAU-S-Methyl
cereals 1 × 175 g prothioconazole.	Hamburg	< 0.001	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001	< 0.001
	Porto	< 0.001	< 0.001	< 0.001

The results of the Tier 1 FOCUS PEARL show that PEC_{GW} results to be < 0.001 µg/L in all relevant scenarios for all substances (prothioconazole and its metabolites) triggering groundwater assessment, it is not necessary to perform simulation runs with the FOCUS PELMO or FOCUS MACRO model.

Important note: some Member States may request simulations performed with the missing model if the results of that specific model are deemed essential to comply with the national requirements.

Then the corresponding model simulations are presented in the national addenda.

zRMS comments:

Input parameters presented in Table 8.8-3 and used in the modelling are in line with 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 (2014 and 2021).

Since all PEC_{GW} were <0.001 µg/L, simulations performed using single model are deemed sufficient, in line with indications of the Central Zone guidance document in area of efate (2018).

The performed calculations were independently validated by the zRMS in additional modelling using FOCUS PEARL 4.4.4 and with the same input parameters. Obtained PEC_{GW} values were the same as these obtained by the Applicant.

Overall, no unacceptable leaching of prothioconazole and its metabolites is expected following application of ADM.03502.F.1.A 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 Fenpropidin and its metabolites

The input parameters of fenpropidin and its metabolites utilised for PEC_{GW} modelling are summarised hereafter. Two model runs have been performed, once for the active substance fenpropidin considering the geomean DT₅₀ of 66 days and a second run for the metabolite CGA 289267 using the minimum DT₅₀ of parent of 49 days as worst-case assumption for CGA 289267.

Table 8.8-5: Input parameters related to active substance fenpropidin and its metabolite for PEC_{GW} calculations

Compound	Fenpropidin	CGA 289267	Value in accordance with EU endpoint y/n/ Reference
Molecular weight (g/mol)	273.5	303.4	y/ EFSA (2007)
Water solubility (mg/L)	530 (pH 7.0, phosphate buffer, 25°C)	8000 (pH=7, 20°C)	y/ EFSA (2007)
Saturated vapour pressure (Pa)	1.7 x 10 ⁻² (25°C)	8.3 x 10 ⁻⁵ (20°C)	Parent: n/DAR (2005), not stated in EFSA (2007) Metabolite: final addendum to the DAR (2007)
DT ₅₀ in soil (d)	66 days (geometric mean from lab studies, normalised, n = 6) for calculating parent and 49 days minimum value for calculating metabolite (worst case)	38 (max value from lab studies, normalised, worst case metabolite)	Parent: n/FOCUS (2014a) on basis of EFSA (2007) Metabolite: y/ EFSA (2007)
Transformation rate (PELMO)	worst case parent: 0.0029 to CGA 0.0076 to sink worst case metabolite: 0.0040 to CGA 0.0102 to sink	0.0182 to sink	=ln(2)/DT ₅₀
Q ₁₀ (-)	2.58	2.58	n/ EFSA Panel (2007)
K _{foc} /K _{fom} (mL/g)	3808 / 2209 (arithmetic mean, n = 6)	147 / 85.3 (arithmetic mean, n = 5)	y/ EFSA (2007)
1/n	0.71 (arithmetic mean, n = 6)	0.93 (arithmetic mean, n = 5)	y/ EFSA (2007)
Plant uptake factor	0 (default)	0 (default)	n/ EFSA (2013)
Formation fraction	from parent to CGA 289267:	0.28	y/ EFSA (2007)

The Tier 1 80th percentile annual average PEC_{GW} of fenpropidin and metabolites are provided in the following.

Table 8.8-6: Tier 1 PEC_{GW} for fenpropidin and its metabolite CGA 289267

Crop / FOCUS _{Gw} Crop, Appl. no. & rate (g a.s./ha)	Scenario	PEARL 4.4.4		PELMO 5.5.3		MACRO 5.5.4	
		80 th Percentile PEC _{Gw} at 1 m Soil Depth (µg/L)					
		Fen- propidin ¹⁾	CGA 289267 ²⁾	Fen- propidin ¹⁾	CGA 289267 ²⁾	Fen- propidin ¹⁾	CGA 289267 ²⁾
Cereals/ Winter cereals 1× 250 g fenpropidin	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	0.0031	< 0.001	0.003	Not applicable	
	Jokioinen	< 0.001	< 0.001	< 0.001	0.001		
	Kremsmünster	< 0.001	0.0015	< 0.001	0.002		
	Okehampton	< 0.001	0.0033	< 0.001	0.004		
	Piacenza	< 0.001	0.0012	< 0.001	0.001		
	Porto	< 0.001	< 0.001	< 0.001	0.002		
	Sevilla	< 0.001	< 0.001	< 0.001	< 0.001		
Thiva	< 0.001	< 0.001	< 0.001	< 0.001			
Cereals/ Spring cereals	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	0.0036	< 0.001	0.003	Not applicable	
	Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001		

Crop / FOCUS _{GW} Crop, Appl. no. & rate (g a.s./ha)	Scenario	PEARL 4.4.4		PELMO 5.5.3		MACRO 5.5.4	
		80 th Percentile PEC _{GW} at 1 m Soil Depth (µg/L)					
		Fen- propidin ¹⁾	CGA 289267 ²⁾	Fen- propidin ¹⁾	CGA 289267 ²⁾	Fen- propidin ¹⁾	CGA 289267 ²⁾
1× 250 g fenpropidin	Kremsmünster	< 0.001	0.0015	< 0.001	0.001		
	Okehampton	< 0.001	0.0027	< 0.001	0.003		
	Porto	< 0.001	0.0011	< 0.001	0.001		

¹⁾ geomean DT₅₀ of 66 days of parent has been considered for modelling worst case of parent PEC_{GW} values;

²⁾ minimum DT₅₀ of 49 days of parent has been used for modelling worst case of metabolite PEC_{GW} values

The Tier 1 PEC_{GW} of fenpropidin and its metabolite do not exceed the groundwater trigger of 0.1 µg/L.

However, in addition FOCUS MACRO calculation are required since PEC_{GW} of the metabolite CGA 289267 calculated with FOCUS PELMO and PEARL are > 0.001 µg/L.

In conclusion Tier 1 FOCUS PELMO 5.5.3, FOCUS PEARL 4.4.4 and FOCUS MACRO 5.5.4 groundwater modelling performed for worst-case GAP uses of ADM.03502.F.1.A in spring and winter cereals resulted in 80th percentile annual average PEC_{GW} below 0.1 µg/L for prothioconazole and its metabolites JAU-S-methyl and JAU-desthio and as well for fenpropidin and its metabolite CGA 289267 at 1 m depth. Thus, none of these compounds leached to groundwater to any environmentally hazardous extent, and since PEC_{GW} are clearly below the trigger of 0.1 µg/L for drinking water, no toxicological risks are indicated.

zRMS comments:

Input parameters presented in Table 8.8-5 and used in the modelling are in general in line with EU agreed endpoints reported in EFSA Scientific Report (2007) 124, with following exceptions:

- In the parent simulations the Applicant used the geometric mean soil DT₅₀ of 66 days calculated from the EU agreed degradation data. The value itself was calculated correctly, however in line with decision taken during the expert meeting, the longest DT₅₀ of 76 days was considered relevant for the parent simulations. Nevertheless, consideration of slightly shorter DT₅₀ for the parent is not expected to have any impact on the obtained PEC_{GW} since with mean K_{foc} of 3808 mL/g fenpropidin may be considered as not mobile in soil and thus not prone to the leaching behaviour. Deviation from the EU agreed data is thus agreed by the zRMS.
- In simulations performed for the metabolite the shortest DT₅₀ of 49 days was considered for the parent compound instead of 59 days agreed in the course of the expert meeting. Since consideration of the shorter parent DT₅₀ in metabolite simulations represents worst case, the deviation from the EU agreed data is agreed by the zRMS.

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

The performed groundwater modelling was independently validated by the zRMS in additional modelling performed with consideration of the EU agreed endpoints. Obtained results were in good agreement with PEC_{GW} values derived in Applicants' simulations.

Overall, no unacceptable leaching of fenpropidin and its metabolite is expected following application of ADM.03502.F.1.A 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}) (KCP 9.2.5)

According to the residue definition provided in the EFSA conclusion on prothioconazole (EFSA, 2007), the following residues are of concern for the risk assessment in surface water and sediment:

Prothioconazole, JAU-desthio, JAU-S-methyl and 1,2,4-triazole

In contrast to EFSA (2007) PEC_{sw}/sed calculations are also performed for soil metabolite JAU-S-methyl since entry via run-off drainage to surface water could not be excluded considering FOCUS modelling.

According to the residue definition provided in the EFSA conclusion on fenpropidin (EFSA, 2007) the following residues are of concern for the exposure and risk assessment in surface water:

Fenpropidin, CGA 289267 and in sediment: Fenpropidin only.

8.9.1 Justification for new endpoints

Following the requirements for the Central zone (2018), EU agreed endpoints, as defined in the List of Endpoints (LoEP) of the EFSA conclusion for **prothioconazole** (EFSA, 2007), were considered in the assessment for prothioconazole and its metabolites. However, in addition to the EU agreed endpoints for the plant uptake factor of prothioconazole and its metabolites, a default value of 0.0 is used, which is in accordance to the recommendations of EFSA guidance (2013)²¹. For vapour pressure and water solubility of metabolites the parent values are used in absence of data in the list of endpoints. Furthermore, DT₅₀ values for water/sediment (system) are needed for FOCUS modelling and taken from the DAR of prothioconazole (2005) in accordance with FOCUS (2006).

Following the requirements for the Central zone (2018), EU agreed endpoints, as defined in the List of Endpoints (LoEP) of the EFSA conclusion for **fenpropidin** (EFSA, 2007), were considered in the assessment for fenpropidin and its metabolite. However, in addition to the EU agreed endpoints for the plant uptake factor of fenpropidin and its metabolite, a default value of 0.0 is used, which is in accordance to the recommendations of the EFSA guidance.

In case of fenpropidin geomean DT₅₀ values have been used for fenpropidin and its metabolite for all compartments in accordance with the current guidance (EFSA, 2014; FOCUS, 2015²²).

Although the DT₅₀ values have been normalized with a Q₁₀ of 2.2 in the underlying studies, for actual PEC calculations the new default Q₁₀ of 2.58 has been used as already implemented in the models (EFSA Panel (2007)).

zRMS comments:

Detailed discussion regarding endpoints considered in surface water modelling and their acceptability is presented in the commenting boxes in points 8.9.2.1 for prothioconazole and 8.9.2.2 for fenpropidin.

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

The following PEC_{sw}/SED modelling ADM.03502.F.1.A has not previously been reviewed and a summary is provided in support of this assessment in Appendix 2 of this document.

²¹ EFSA (2013): EFSA Journal 2013;11(6):3291: Scientific Opinion on the report of the FOCUS groundwater working group (FOCUS, 2009): assessment of higher tiers.

²² FOCUS (2015): Generic Guidance for FOCUS Surface Water Scenarios, Version 1.4, May 2015
“FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC”. Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2. 245 pp.

A tiered sequence of aquatic exposure model simulations has been performed according to FOCUS requirements for worst case application patterns of the envisaged GAP uses of ADM.03502.F.1.A . Environmental concentrations in surface water (PEC_{sw}) and sediment (PEC_{sed}) were predicted for prothioconazole, fenpropidin and its metabolites of potential concern starting with Steps 1-2 in FOCUS (v3.2). At Step 3 the substances plug in SPIN 2.2 and FOCUS SWASH 5.3, comprising the FOCUS drift calculator, the drainage model FOCUS MACRO 5.5.4, the run-off model FOCUS PRZM SW 4.3.1 and the model FOCUS TOXSWA 5.5.3 were used. Step 4 FOCUS TOXSWA simulations have been performed following application of mitigation measures with the SWAN tool v5.0.0.

Risk envelope GAP uses

The exposure and risk assessment in surface water and sediment was based on the worst-case application patterns derived from GAP information. Modelling was performed considering the representative FOCUS_{sw} crop groups winter and spring cereals. The intended maximum seasonal application rate of 1 x 175 g prothioconazole/ha and 1x 250 g fenpropidin/ha was calculated for cereals from BBCH 30.

PEC_{sw}/SED at Step 1&2 and Step 3&4

The STEP 1 & 2 and STEP 3/4 global maximum PEC_{sw} and PEC_{sed} values of fenpropidin and prothioconazole and its metabolites (if needed) for the worst-case application patterns of the intended GAP uses of ADM.03502.F.1.A are given in the following. For the active substance fenpropidin and the metabolite prothioconazole-desthio as well STEP 4 values are needed and presented. Non spraying buffer zones at 10 and 20 m distances are considered for drift and run-off reduction. The use of drift reducing nozzles (50, 75, 90 %) is also accepted and presented as further mitigation option.

Table 8.9-1: Input parameters related to application for PEC_{sw}/SED calculations

Plant protection product	ADM.03502.F.1.A	
Use No. ⁽¹⁾	6-15, 21-29	6-15, 21-29
Crop / FOCUS _{sw} crop	Spring cereals	Winter cereals
Application rate (g a.s./ha)	1 x 175 g prothioconazole, 1 x 250 g fenpropidin	
No. of applications/interval (d)	1 / -	1 / -
Application timing	post-emergence (BBCH 30–65)	post-emergence (BBCH 30–65)
Application window (relevant for STEP 1 and 2 only)	Mar.–May, June–Sep.	Oct–Feb, Mar.–May, June–Sep.
Application method	Ground spray	Ground spray
CAM (Chemical application method)	2	2
Soil depth (cm)	4	4
Models used for calculation	STEPS 1-2 v3.2, FOCUS SWASH v5.3, FOCUS MACRO v5.5.4, FOCUS PRZM v4.3.1, FOCUS TOXSWA v5.5.3, SWAN v5.0.0	

⁽¹⁾ Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 (Calculations of missing numbers are handled in national addenda)

Start of the application windows were determined with Appdate version 3.06 for cereals at BBCH 30. The considered application windows are presented in the table below.

Table 8.9-2: FOCUS STEP 3 Scenario related input parameters for PEC_{SW/SED} calculations for the application of ADM.03502.F.1.A

Crop	Scenario	Application window used for modelling
		from BBCH 30
Winter cereals	D1	25-Mar - 24-Apr (84-114)
	D2	04-Apr - 04-May (94-124)
	D3	16-Apr - 16-May (106-136)
	D4	18-Mar - 17-Apr (77-107)
	D5	15-Mar - 14-Apr (74-104)
	D6	16-Feb - 18-Mar (47-77)
	R1	04-May - 03-Jun (124-154)
	R3	19-Mar - 18-Apr (78-108)
	R4	24-Jan - 23-Feb (24-54)
Spring cereals	D1	27-May - 26-Jun (147-177)
	D3	28-Apr - 28-May (118-148)
	D4	18-May - 17-Jun (138-168)
	D5	09-Apr - 09-May (99-129)
	R4	09-Apr - 09-May (99-129)

zRMS comments:

The application pattern presented in Table 8.9-1 assumed in simulations is in general line with Central Zone GAP as presented in Table 8.1-1 and covers early uses at BBCH 30 in cereals. The application windows presented in table above are confirmed to be in line with AppDate 3.06. It is noted that the application window for R1 scenario for winter cereals should be between 24th of April and 24th of May (114-144 Julian days). Nevertheless this deviation turned out to have no impact on the PEC_{sw} results discussed in the commenting boxes in points 8.9.2.1 and 8.9.2.2.

It is noted that intended uses of ADM.03502.F.1.A is in spring, therefore the application window assumed at Step 1-2 in Oct-Feb has been removed from Table 8.9-1 as incorrect.

According to application windows assumed for Step 3&4 simulations and presented in Table 8.9-2 it is noted that only early applications of ADM.03502.F.1.A to cereals was considered. However, the product is intended to be used at BBCH 30-65 and later application should be also considered, as it sometimes results with slightly higher surface water exposure, which may have impact on the outcome of the aquatic risk assessment, especially when there are very low endpoints. Therefore, additional modelling was performed by the zRMS with consideration of application of ADM.03502.F.1.A at the latest intended BBCH stages of cereals. The application periods were selected using the AppDate tool version 3.01 because the most recent version of AppDate does not provide possibility for determination of the last possible application date. The application windows are presented in table below.

Application windows assumed in additional zRMS simulations for latest intended BBCH stage

Crop	Scenario	Application window up to BBCH 65
Winter cereals	D1	24-Jun – 24-Jul (175-205)
	D2	25-Jun – 25-Jul (176-206)
	D3	15-Jul – 14-Aug (196-226)
	D4	21-Jun – 21-Jul (172-202)
	D5	15-May - 14-Jun (135-165)
	D6	06-Apr - 06-May (96-126)
	R1	08-Jun – 08-Jul (159-189)
	R3	08-May - 07-Jun (128-158)
	R4	15-May - 14-Jun (135-165)
Spring cereals	D1	30-Jun – 30-Jul (181-211)
	D3	09-Jun – 09-Jul (160-190)
	D4	21-Jun – 21-Jul (172-202)
	D5	16-May - 15-Jun (136-166)
	R4	16-May - 15-Jun (136-166)

8.9.2.1 Prothioconazole and its metabolites

Table 8.9-3: Step 1 in FOCUS input parameters considered for Prothioconazole and its metabolites JAU 6476-desthio, JAU 6476 S-methyl, 1,2,4- triazole for the critical GAP uses in the central zone

Central Zone						
Parameter		Compound	Value	Remark	Value in accordance with EU endpoint y/n/	
Substance specific data						
Water solubility [mg/L]		Prothioconazole	300	Parent value (determined at 20 °C, pH 8)	y/ EFSA (2007)	
		JAU 6476-Desthio	300			
		JAU 6476 S-Methyl	300			
		1,2,4- Triazole	300	assumed as for the other metabolites*		
Koc [L/kg]		Prothioconazole	1765	single value	y/ EFSA (2007)	
		JAU 6476-Desthio	575.4	arithmetic mean, n=4		
		JAU 6476 S-Methyl	2556.3			
		1,2,4-triazole	89	arithmetic mean, n=4*		
DT50 in sediment/water system [d]		Prothioconazole	2.1	geomean (whole system) n=2 from EU agreed studies: DT50 from HS kinetics	y/ EFSA (2007), FOCUS (2006)	
		JAU 6476-Desthio	49.9	max. whole system value (n=2)	DAR (2005)	
		JAU 6476 S-Methyl	40.2			
		1,2,4-triazole	1000	default value	FOCUS (2006)	
Molecular Mass [g/mole]		Prothioconazole	344.3	-	y/ EFSA (2007)	
		JAU 6476-Desthio	312.2			
		JAU 6476 S-Methyl	358.3			
		1,2,4- Triazole	69.1			
Maximum occurrence observed for the metabolite [%]	water/ sediment studies	JAU 6476-Desthio	54.6 32.3	max for whole system -	y/ EFSA (2007)	
		JAU 6476 S-Methyl	12.7 77 (anaerob)			
		1,2,4-triazole	41.8 37.2			
	soil	JAU 6476-Desthio	57.1	-		
		JAU 6476 S-Methyl	14.6			
		1,2,4-triazole	0.0001	No soil metabolite (low value)		
	Application pattern					
Application rate of a.i. [g/ha]		Prothioconazole	175		GAP	
Number of applications per season			1	-		
Time between two applications [d]			-	-		
Crop type			Cereals	Winter and Spring		

* it is known from other documents/substances (e.g. epoxiconazole, tebuconazole, difenoconazole etc.) that the solubility for 1,2,4 -triazole is much higher: 730 000 mg/L (EFSA Journal 2014;12(1):3485 on tebuconazole, p 53). However, this discrepancy will not affect the outcome of the aquatic risk assessment for 1,2,4- triazole

Table 8.9-4: Step 2 in FOCUS input parameters considered for Prothioconazole metabolites JAU 6476-Desthio, JAU 6476 S-Methyl, 1,2,4- Triazole, for the critical GAP uses in the central zone

Step 2				
Parameter		Value	Remark	Value in accordance with EU endpoint y/n/
Substance specific data				
DT ₅₀ in soil [d]	Prothioconazole	1.2	geomean (from field studies), n=8	y/ EFSA (2007)
	JAU 6476-Desthio	22.7		
	JAU 6476 S-Methyl	15.7		
	1,2,4-triazole	1000	default value (no soil metabolite)	FOCUS (2006)
DT ₅₀ in water [d]	Prothioconazole	2.1 (correct value: 1.0 d)	mean (whole system): DT ₅₀ from HS kinetics	y/ EFSA (2007), FOCUS (2006)
	JAU 6476-Desthio	49.9	max. whole system (n=2)	DAR (2005)
	JAU 6476 S-Methyl	40.2		
	1,2,4-triazole	1000	default value	
DT ₅₀ in sediment [d]	Prothioconazole	2.1 (correct value: 1.0 d)	geomean (whole system) n=2 from EU agreed studies: DT ₅₀ from HS kinetics	See above, acc. to FOCUS: System decline DT ₅₀ for both compartments
	JAU 6476-Desthio	49.9	max. whole system (n=2)	
	JAU 6476 S-Methyl	40.2		
	1,2,4-triazole	1000	default value	
Application pattern				
Crop interception	Intermediate Full canopy	BBCH 30 (cereals) from BBCH 40-65 (cereals)		FOCUS (2015) worst case
Region and season of application				
Northern Europe	Mar.–May June–Sep	Cereals (spring+winter)		According to GAP
	Oct–Feb	Cereals (winter)		

Table 8.9-5: Step 3 & 4 FOCUS SWASH input parameters considered for the critical GAP uses

Parameter	Substance	Value	Remark	Value in accordance with EU endpoint y/n/
General				
Molar mass [g/mol]	Prothioconazole	344.3	-	y/ EFSA (2007)
	JAU 6476-desthio	312.2		
Saturated vapour pressure [Pa]	Prothioconazole	4x10E-07	determined at 20 °C	
	JAU 6476-desthio	4x10E-07	parent value	
Molar enthalpy of vaporisation [J/mol]		95000	default value	FOCUS (2001) ²³
Solubility in water [mg/L]	Prothioconazole	300	determined at 20 °C	y/ EFSA (2007)
	JAU 6476-desthio	300	parent value	
Molar enthalpy of dissolution [J/mol]		27000	default value	FOCUS (2001)
Diffusion coefficient in water [m²/d]		4.3E-05	default value	

²³ FOCUS (2001): FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC". Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2. 245 pp.

Parameter	Substance	Value	Remark	Value in accordance with EU endpoint y/n/	
Diffusion coefficient in air [m²/d]		0.43	default value		
Sorption					
General K _{OM} [L/kg]	Prothioconazole	1024	calculated by SWASH based on K _{oc} divided by 1.724		
	JAU 6476-desthio	333.7			
General K _{oc} [L/kg]	Prothioconazole	1765	single value (column leaching study)	y/ EFSA (2007)	
	JAU 6476-desthio	575.4	arithmetic mean, n = 4		
Freundlich exponent [-]	Prothioconazole	0.9	default		
	JAU 6476-desthio	0.81	-		
Ref. concentration in liquid phase [g/m³]		1	default value	-	
Uptake and wash-off					
Factor for the uptake by plant roots in soil	All compounds	0	worst case	EFSA (2013)	
Wash off factor from crop	[1/mm]	0.05	MACRO	FOCUS (2001)	
	[1/cm]	0.5	PRZM		
Transformation					
Conversion factor (parent → metabolite): 0.57 in soil, 0.323 in water, 0.269 in sediment					
Half-life time [d]	water	Prothioconazole	2.1 (value from LoEP: 1.0 d)	geomean (whole system): DT ₅₀ from HS kinetics	y/EFSA (2007), FOCUS (2006)
		JAU 6476-desthio	1000 ¹⁾ 49.9	worst case max. (whole system); n=2	DAR (2005)
	sediment	Prothioconazole	1000	default (worst case)	FOCUS (2006)
		JAU 6476-desthio	49.9 ¹⁾ 1000	worst case	DAR (2005)
	soil	Prothioconazole	1.2	geomean (from field studies, normalised), n=8	y/EFSA (2007)
		JAU 6476-desthio	22.7		
	crop		10.00	default value	FOCUS (2001)
	Activation energy [J/mol]		65400	default value	recommended by the PPR (2007) for EFSA
Exponent [1/K]		0.0948	default value		
Q ₁₀ fac [-]		2.58	default value		
Specifications on transformation in soil					
Exponent for the effect of water content [-]		0	MACRO, PRZM	FOCUS (2001)	
Half life measured at pF		2	MACRO		
Half life measured at moisture content [%]		100.00	PRZM	-	
Relative (% of FC)		yes	-	-	

¹⁾ Combination giving worst case PEC_{sw} at Steps 3&4 (for details, see zRMS comment at the end of this chapter)

ACTIVE SUBSTANCE

Cereals

Table 8.9-6: FOCUS STEP 1-4 PEC_{SW} and PEC_{SED} for prothioconazole following single application of 175 g a.s./ha to spring cereals BBCH 30

Scenario FOCUS	Waterbody	Max PEC _{SW} (µg/L)		Dominant entry route		21 d- PEC _{SW, twa} (µg/L)		Max PEC _{SED} (µg/kg)	
STEP 1	---	19.01		run-off/drainage		2.61		307.03	
STEP 2 (average crop cover)									
Northern Europe	March-May	1.61		spray drift		0.17		6.84	
	June-Sept	1.61		spray drift		0.17		6.84	
STEP 3									
D1	Ditch	1.119		spray drift		0.261		1.685	
D1	Stream	0.979		spray drift		0.039		0.519	
D3	Ditch	1.107		spray drift		0.052		0.648	
D4	Pond	0.038		spray drift		0.009		0.072	
D4	Stream	0.905		spray drift		0.004		0.062	
D5	Pond	0.038		spray drift		0.013		0.089	
D5	Stream	0.929		spray drift		0.003		0.040	
R4	Stream	0.732		spray drift		0.029		0.787	
STEP 4		Max PEC _{SW} (µg/L) considering following mitigation:							
No spray buffer (m)		10	10	10	20	20	20	10	20
Vegetative strip (m)		none	none	none	none	none	none	10	20
Nozzle reduction		none	75%	90%	none	75%	90%	none	none
D1	Ditch	0.161	0.040	0.016	0.084	0.021	0.008	n.r.	n.r.
D1	Stream	0.190	0.047	0.019	0.099	0.025	0.010	n.r.	n.r.
D3	Ditch	0.159	0.040	0.016	0.083	0.021	0.008	n.r.	n.r.
D4	Pond	0.024	0.006	0.002	0.016	0.004	0.002	n.r.	n.r.
D4	Stream	0.175	0.044	0.018	0.091	0.023	0.009	n.r.	n.r.
D5	Pond	0.024	0.006	0.002	0.016	0.004	0.002	n.r.	n.r.
D5	Stream	0.180	0.045	0.018	0.093	0.001	0.009	n.r.	n.r.
R4	Stream	0.238	0.238	0.238	0.238	0.238	0.238	0.142	0.074

n.r.= not relevant

Table 8.9-7: FOCUS STEP 1-4 PEC_{SW} and PEC_{SED} for prothioconazole following single application of 175 g a.s./ha to winter cereals BBCH 30

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)		Dominant entry route		21 d- PEC _{sw, twa} (µg/L)		Max PEC _{sed} (µg/kg)	
STEP 1	---	19.01		run-off/drainage		2.61		307.03	
STEP 2 (average crop cover)									
Northern Europe	March-May	1.61		spray drift		0.17		6.84	
	June-Sept	1.61		spray drift		0.17		6.84	
	Oct-Feb	1.61		spray drift		0.24		14.15	
STEP 3									
D1	Ditch	1.110		spray drift		0.088		0.946	
D1	Stream	0.863		spray drift		0.002		0.036	
D2	Ditch	1.117		spray drift		0.109		1.270	
D2	Stream	0.949		spray drift		0.010		0.156	
D3	Ditch	1.106		spray drift		0.050		0.637	
D4	Pond	0.038		spray drift		0.017		0.109	
D4	Stream	0.817		spray drift		0.001		0.024	
D5	Pond	0.038		spray drift		0.013		0.089	
D5	Stream	0.883		spray drift		0.002		0.025	
D6	Ditch	1.093		spray drift		0.023		0.323	
R1	Pond	0.038		spray drift		0.012		0.083	
R1	Stream	0.726		spray drift		0.010		0.249	
R3	Stream	1.023		spray drift		0.013		0.203	
R4	Stream	0.732		spray drift		0.007		0.112	
STEP 4		Max PEC _{sw} (µg/L) considering following mitigation:							
No spray buffer (m)		10	10	10	20	20	20	10	20
Vegetative strip (m)		none	none	none	none	none	none	10	20
Nozzle reduction		none	75%	90%	none	75%	90%	none	none
D1	Ditch	0.160	0.040	0.016	0.083	0.021	0.008	n.r.	n.r.
D1	Stream	0.167	0.042	0.017	0.087	0.022	0.009	n.r.	n.r.
D2	Ditch	0.161	0.040	0.016	0.083	0.021	0.008	n.r.	n.r.
D2	Stream	0.184	0.046	0.018	0.095	0.024	0.010	n.r.	n.r.
D3	Ditch	0.159	0.040	0.016	0.083	0.021	0.008	n.r.	n.r.
D4	Pond	0.024	0.006	0.002	0.016	0.004	0.002	n.r.	n.r.
D4	Stream	0.158	0.040	0.016	0.082	0.021	0.008	n.r.	n.r.
D5	Pond	0.024	0.006	0.002	0.016	0.004	0.002	n.r.	n.r.
D5	Stream	0.171	0.043	0.017	0.089	0.022	0.009	n.r.	n.r.
D6	Ditch	0.157	0.040	0.016	0.082	0.020	0.008	n.r.	n.r.
R1	Pond	0.023	0.006	0.005	0.016	0.005	0.004	0.024	0.016
R1	Stream	0.141	0.119	0.119	0.119	0.119	0.119	0.141	0.073
R3	Stream	0.198	0.050	0.020	0.103	0.026	0.020	0.198	0.103
R4	Stream	0.142	0.035	0.014	0.074	0.018	0.007	0.142	0.074

n.r.= not relevant

METABOLITES

Prothioconazole-desthio/ Cereals

Table 8.9-8: FOCUS STEP 1-4 PEC_{SW} and PEC_{SED} for prothioconazole-desthio following single application of 175 g a.s./ha to spring cereals BBCH 30

Scenario FOCUS	Waterbody	Max PEC _{Sw} (µg/L)		Dominant entry route		21 d- PEC _{Sw,twa} (µg/L)		Max PEC _{SED} (µg/kg)	
STEP 1	---	34.23 27.23		run-off/drainage		29.40 23.45		192.38 153.99	
STEP 2 (average crop cover)									
Northern Europe	March-May	3.18 2.87		spray-drift		2.70 2.45		17.63 16.04	
	June-Sept	3.18 2.87		spray-drift		2.70 2.45		17.63 16.04	
STEP 3									
D1	Ditch	0.144		-		0.135		0.896	
D1	Stream	0.055		-		0.003		0.065	
D3	Ditch	0.035		-		0.003		0.033	
D4	Pond	0.007		-		0.007		0.068	
D4	Stream	0.024		-		< 0.001		0.003	
D5	Pond	0.007		-		0.006		0.071	
D5	Stream	0.033		-		< 0.001		0.001	
R4	Stream	0.482		-		0.068		0.788	
STEP 4		Max PEC _{Sw} (µg/L) considering following mitigation:							
No spray buffer (m)		10	10	10	20	20	20	10	20
Vegetative strip (m)		none	none	none	none	none	none	10	20
Nozzle reduction		none	75%	90%	none	75%	90%	none	none
D1	Ditch	0.020	0.006	0.004	0.011	0.004	0.004	n.r.	n.r.
D1	Stream	0.011	0.003	0.002	0.006	0.002	0.002	n.r.	n.r.
D3	Ditch	0.005	0.001	0.001	0.003	0.001	<0.001	n.r.	n.r.
D4	Pond	0.004	0.001	0.001	0.003	0.001	0.002	n.r.	n.r.
D4	Stream	0.005	0.002	0.004	0.004	0.004	0.004	n.r.	n.r.
D5	Pond	0.004	<0.001	<0.001	0.003	0.001	<0.001	n.r.	n.r.
D5	Stream	0.006	0.002	<0.001	0.003	0.001	<0.001	n.r.	n.r.
R4	Stream	0.482	0.482	0.482	0.482	0.482	0.482	0.219	0.115

n.r.= not relevant

Table 8.9-9: FOCUS STEP 1-4 PEC_{SW} and PEC_{SED} for prothioconazole-desthio following single application of 175 g a.s./ha to winter cereals BBCH 30

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)		Dominant entry route		21 d- PEC _{sw,twa} (µg/L)		Max PEC _{sed} (µg/kg)	
STEP 1	---	34.23 27.23		run-off/drainage		29.40 23.45		192.38 153.99	
STEP 2 (average crop cover)									
Northern Europe	March-May	3.18 2.87		spray-drift		2.70 2.45		17.63 16.04	
	June-Sept	3.18 2.87		spray-drift		2.70 2.45		17.63 16.04	
	Oct-Feb	6.73		spray-drift		5.80		38.16	
STEP 3									
D1	Ditch	0.018		-		0.003		0.044	
D1	Stream	0.036		-		< 0.001		0.014	
D2	Ditch	0.036		-		0.005		0.060	
D2	Stream	0.042		-		0.001		0.021	
D3	Ditch	0.018		-		0.001		0.015	
D4	Pond	0.005		-		0.005		0.066	
D4	Stream	0.021		-		< 0.001		0.002	
D5	Pond	0.006		-		0.006		0.072	
D5	Stream	0.031		-		< 0.001		< 0.001	
D6	Ditch	0.009		-		< 0.001		0.004	
R1	Pond	0.050		-		0.040		0.412	
R1	Stream	0.431		-		0.032		0.598	
R3	Stream	0.377		-		0.018		0.495	
R4	Stream	0.558		-		0.028		0.382	
STEP 4		Max PEC _{sw} (µg/L) considering following mitigation:							
No spray buffer (m)		10	10	10	20	20	20	10	20
Vegetative strip (m)		none	none	none	none	none	none	10	20
Nozzle reduction		none	75%	90%	none	75%	90%	none	none
D1	Ditch	0.003	0.002	0.001	0.002	0.001	0.001	n.r.	n.r.
D1	Stream	0.008	0.002	0.001	0.004	0.002	0.001	n.r.	n.r.
D2	Ditch	0.021	0.021	0.021	0.021	0.021	0.021	n.r.	n.r.
D2	Stream	0.013	0.013	0.013	0.013	0.013	0.013	n.r.	n.r.
D3	Ditch	0.003	0.001	<0.001	0.001	<0.001	<0.001	n.r.	n.r.
D4	Pond	0.003	0.001	0.001	0.002	0.001	0.001	n.r.	n.r.
D4	Stream	0.004	0.003	0.003	0.003	0.003	0.003	n.r.	n.r.
D5	Pond	0.004	0.001	<0.001	0.003	0.001	<0.001	n.r.	n.r.
D5	Stream	0.006	0.002	0.001	0.003	0.001	<0.001	n.r.	n.r.
D6	Ditch	0.001	0.001	<0.001	0.001	<0.001	<0.001	n.r.	n.r.
R1	Pond	0.048	0.045	0.044	0.046	0.044	0.044	0.021	0.011
R1	Stream	0.431	0.431	0.431	0.431	0.431	0.431	0.196	0.103
R3	Stream	0.377	0.377	0.377	0.377	0.377	0.377	0.172	0.090
R4	Stream	0.558	0.558	0.558	0.558	0.558	0.558	0.254	0.133

n.r.= not relevant

Prothioconazole-S-methyl/ Cereals

Table 8.9-10: FOCUS STEP 1, 2 PEC_{SW} and PEC_{SED} for prothioconazole-S-methyl following 1 × 175 g a.s./ha to spring cereals BBCH 30 (worst case)

Scenario FOCUS	Waterbody	Max PEC _{SW} (µg/L)	Dominant entry route	21 d- PEC _{SW, twa} (µg/L)	Max PEC _{SED} (µg/kg)
STEP 1	---	13.90	run-off/drainage	10.85	324.32
STEP 2 (average crop cover)					
Northern Europe	March-May	1.29	spray-drift	0.62	17.87
	June-Sept	1.29	spray-drift	0.62	17.87

Table 8.9-11: FOCUS STEP 1, 2 PEC_{SW} and PEC_{SED} for prothioconazole-S-methyl following 1 × 175 g a.s./ha to winter cereals BBCH 30 (worst case)

Scenario FOCUS	Waterbody	Max PEC _{SW} (µg/L)	Dominant entry route	21 d- PEC _{SW, twa} (µg/L)	Max PEC _{SED} (µg/kg)
STEP 1	---	13.90	run-off/drainage	10.85	324.32
STEP 2 (average crop cover)					
Northern Europe	March-May	1.29	spray-drift	0.62	17.87
	June-Sept	1.29	spray-drift	0.62	17.87
	Oct-Feb	1.47	spray-drift	1.15	34.37

1,2,4-triazole / Cereals

Table 8.9-12: FOCUS STEP 1, 2 PEC_{SW} and PEC_{SED} for 1,2,4-triazole following 1 × 175 g a.s./ha to spring cereals BBCH 30 (worst case)

Scenario FOCUS	Waterbody	Max PEC _{SW} (µg/L)	Dominant entry route	21 d- PEC _{SW, twa} (µg/L)	Max PEC _{SED} (µg/kg)
STEP 1	---	4.51 4.01	run-off/drainage	4.46 3.97	4.00 3.56
STEP 2 (average crop cover)					
Northern Europe	March-May	0.19 0.17	spray-drift	0.19 0.17	0.17 0.15
	June-Sept	0.19 0.17	spray-drift	0.19 0.17	0.17 0.15

Table 8.9-13: FOCUS STEP 1, 2 PEC_{SW} and PEC_{SED} for 1,2,4-triazole following 1 × 175g a.s./ha to winter cereals BBCH 30 (worst case)

Scenario FOCUS	Waterbody	Max PEC _{SW} (µg/L)	Dominant entry route	21 d- PEC _{SW, twa} (µg/L)	Max PEC _{SED} (µg/kg)
STEP 1	---	4.51 4.01	run-off/drainage	4.46 3.97	4.00 3.56
STEP 2 (average crop cover)					
Northern Europe	March-May	0.19 0.17	spray-drift	0.19 0.17	0.17 0.15
	June-Sept	0.19 0.17	spray-drift	0.19 0.17	0.17 0.15
	Oct-Feb	0.27	spray-drift	0.26	0.23

zRMS comments:

Input parameters used for surface water modelling for prothioconazole and its metabolites and presented in Tables 8.9-3 to 8.9-5 are in general in line with EU agreed endpoints with following remarks:

For prothioconazole:

- DT₅₀ in water of 2.1 days was used instead of 1.0 days agreed in the course of the EU review. Nevertheless, in opinion of the zRMS this deviation is not expected to have significant impact on the obtained results, therefore this deviation from the EU agreed endpoints is agreed.

For metabolite JAU 6476-desthio:

- Maximum occurrence of 32.3% was used for the whole system, however, this is relevant for the maximum observed in the water phase, while for the whole system 54.6% is the correct value. Respective changes were introduced in Table 8.9-3 and used in the independent zRMS calculation for the metabolite at Step 1-2.
- It is noted that at the EU level no separate DT₅₀ values were determined for water and sediment compartments and DT₅₀ of 49.9 days is relevant for the whole system. Nevertheless, in line with indications of the FOCUS Surface Water Generic Guidance (2015), at Steps 1-2 the whole system DT₅₀ may be also attributed to particular compartments.
- 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 the FOCUS surface water 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 the water column and not sediment (endpoints for sediment dwellers are expressed in terms of mg/L) the four combinations indicated in table below were tested by the zRMS in order to check which gives the highest PEC_{SW} values. It turned out that the worst case combination was when the shortest DT₅₀ value was applied to prothioconazole and the default of 1000 days was applied to JAU 6476-desthio in the water phase (combination 2 in table below). This combination was then used in the zRMS modelling performed for purposes of validation of the Applicants' results.

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

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

For the metabolite JAU 6476 S-methyl

- The Applicant used the maximum occurrence in water/sediment system of 77%, but such formation of JAU 6476 S-Methyl was observed only in sediment in the anaerobic water/sediment study. In the aerobic water/sediment study the maximum occurrence of 12.7% was observed in the whole system. Nevertheless, as assumed 77% represents worst case, it was accepted by the zRMS for Step 1-2 calculations.

For the metabolite 1,2,4-triazole

- For the whole system the Applicant used the maximum occurrence of 37.2%, but this is relevant for the water phase, while the maximum occurrence of 41.8% was observed in the whole system. Respective changes were introduced by the zRMS in Table 8.9-3 and were used in the independent calculations at Step 1-2.

Considering all deviations mentioned above, Tables 8.9-3 to 8.9-5 were amended accordingly.

At Step 3 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 at the national level.

The surface water exposure was independently validated by the zRMS in additional modelling with modified input parameters discussed above. Discussion on obtained results is presented below for each compounds.

General

According to the Central Zone GAP presented in Table 8.1-1, ADM.03502.F.1.A is intended to be used in spring, therefore Step 1-2 results for autumn/winter application (Oct-Feb) have been removed from Tables 8.9-9, 8.9-11 and 8.9-13 as being not relevant.

As indicated in the commenting box in point 8.9.2, the application windows assumed by the Applicant for Step 3 & 4 simulations do not cover surface water exposure for the later BBCH stages. Results of the zRMS simulations performed for later stages are reported below.

The information on the dominant entry route at Steps 1-2 was struck through by the zRMS in tables above, since at this stage of the exposure assessment it is not possible to identify the main route of migration.

Prothioconazole

In line with the FOCUS guidance at Step 1-2 for uses in cereals at BBCH >40 the crop interception corresponds to “full canopy” while $PEC_{SW/SED}$ values were calculated by the Applicant only for the “intermediate crop cover” relevant for early BBCH stages. Since the “intermediate crop cover” represents worst case, results obtained by the Applicant may be used in the risk assessment.

Results for prothioconazole at Step 1-3 obtained by the zRMS in independent modelling were in good agreement with results obtained by the Applicant. PEC_{SW} at Step 3-4 were the same, whereas PEC_{SED} values obtained by the zRMS were slightly higher due to the modified combination of DT_{50} values considered in simulations performed for parent+metabolite (JAU 6476-desthio). However, observed differences were negligible and with no impact on the outcome of the risk assessment, which is driven by exposure of aquatic species via the water column.

According to the AppDate ver. 3.06, in R1 scenario for winter cereals application window should be set between 24th of April and 24th of May (114-144 Julian days). Nevertheless, PEC_{SW} obtained by the zRMS for this scenario at Step 3-4 and the correct dates were lower than these obtained by the Applicant, therefore slightly later application assumed in Applicants’ modelling turned out to represent worst case.

As indicated in the commenting box in point 8.9.2, the application windows assumed by the Applicant for Step 3 & 4 modelling for prothioconazole do not cover surface water exposure for the later BBCH stages. Therefore Step 3 and 4 surface water modelling was performed by the zRMS for the last possible dates of application to spring and winter cereals (application windows considered in this modelling are presented in the commenting box in point 8.9.2). The input parameters in additional modelling for prothioconazole were the same as indicated in Table 8.9-5 (after zRMS corrections).

PEC_{SW} values derived for BBCH 65 presented in tables below are mostly the same or slightly higher than surface water exposure calculated for the early BBCH stage. The PEC_{SED} are not presented as being not necessary for the aquatic risk assessment (all endpoints expressed in terms of mg/L).

PEC_{SW} (µg/L) for prothioconazole considering application of 175 g a.s./ha at later BBCH stages

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	Max PEC_{SW} (µg/L)
BBCH up to 65		winter cereals	spring cereals
STEP 3			
D1	Ditch	1.119	1.119
D1	Stream	0.979	0.979
D2	Ditch	1.120	-
D2	Stream	0.997	-
D3	Ditch	1.110	1.109
D4	Pond	0.038	0.038
D4	Stream	0.957	0.954
D5	Pond	0.038	0.038
D5	Stream	1.032	1.031
D6	Ditch	1.111	-
R1	Pond	0.038	-
R1	Stream	0.732	-

R3	Stream	1.025	-
R4	Stream	0.732	0.732

Metabolite JAU 6476-desthio

Since higher maximum occurrence in the whole system was considered by the zRMS at Steps 1-2 calculations, obtained results were automatically higher and Tables 8.9-8 to 8.9-9 were amended accordingly.

The PEC_{SW/SED} calculated by the zRMS at Steps 3-4 for the correct input parameters were the same or lower comparing to these obtained by the Applicant. For the R1 scenario for winter cereals application window should be between 24th of April and 24th of May (114-144 Julian days) according to the AppDate ver. 3.06. Nevertheless, PEC_{SW} obtained by the zRMS for this scenario at Step 3-4 and the correct dates were lower than these obtained by the Applicant, therefore slightly later application assumed in Applicants' modelling turned out to represent worst case.

As indicated in the commenting box in point 8.9.2, the application windows assumed by the Applicant for Step 3 & 4 modelling do not cover surface water exposure for the later BBCH stages. Therefore Step 3 and 4 surface water modelling was performed by the zRMS for the last possible dates of application to spring and winter cereals (application windows considered in this modelling are presented in commenting box in point 8.9.2). The input parameters in additional modelling for metabolite JAU 6476-desthio were the same as indicated in Table 8.9-5 (after zRMS corrections).

PEC_{SW} values derived for BBCH 65 presented in tables below are mostly the same or slightly higher than surface water exposure calculated for the early BBCH stage. The PEC_{SED} are not presented as being not necessary for the aquatic risk assessment (all endpoints expressed in terms of mg/L).

Max PEC_{SW} (µg/L) for metabolite JAU 6476-desthio considering application of 175 g a.s./ha at later BBCH stages

Scenario FOCUS	Waterbody	Max PEC _{SW} (µg/L)	Max PEC _{SW} (µg/L)
BBCH up to 65		winter cereals	spring cereals
STEP 3			
D1	Ditch	0.145	0.158
D1	Stream	0.050	0.058
D2	Ditch	0.155	-
D2	Stream	0.165	-
D3	Ditch	0.049	0.038
D4	Pond	0.007	0.007
D4	Stream	0.026	0.025
D5	Pond	0.007	0.007
D5	Stream	0.038	0.037
D6	Ditch	0.051	-
R1	Pond	0.068	-
R1	Stream	0.262	-
R3	Stream	0.387	-
R4	Stream	0.020	0.020

Maximum PEC_{SW} values highlighted in **bold** exceed the lowest RAC of 0.13 µg a.s./L

Since Step 3 PEC_{SW} for spring cereals are all below the RAC of 0.334 µg/L, further calculation at Step 4 were not necessary for this crop. For winter cereals the calculation at Step 4 was only required for R3 scenario. Run-off in R3 scenario was mitigated in line with indications of FOCUS L&M.

FOCUS STEP 4 Max PEC_{SW} (µg/L) for metabolite JAU 6476-desthio considering application of 175 g a.s./ha

STEP 4		PEC _{SW} (µg/L) winter cereals up to BBCH 65	
Run-off reduction in line with FOCUS L&M		10 m	20 m
R3	Stream	0.171	0.088

Step 3-4 PEC_{SW} values calculated by the zRMS for metabolite JAU 6476-desthio for the later application were slightly higher from these presented in Tables 8.9-8 and 8.9-9 for the early application window (BBCH 30).

Metabolite JAU 6476 S-Methyl

Step 1-2 PEC_{SW} and PEC_{SED} obtained by the zRMS for this compound were considerably lower comparing to these obtained by the Applicant due to much higher maximum occurrence assumed in Applicants' simulations. Overall, values in Tables 8.9-22 to 8.9-27 may be used further in the aquatic risk assessment.

Metabolite 1,2,4-triazole

Step 1-2 PEC_{SW} and PEC_{SED} obtained by the zRMS for this compound were higher comparing to these obtained by the Applicant since higher maximum occurrence was taken into account. Values reported in Tables 8.9-28 to 8.9-33 were thus corrected by the zRMS and may be used for purposes of the aquatic risk assessment.

Please note that not all relevant scenarios are defined for spring cereals therefore results in these scenarios obtained for winter cereals may be used as surrogate.

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 Fenpropidin and its metabolites

Table 8.9-14: Step 1 in FOCUS input parameters considered for Fenpropidin and its metabolite CGA 289267 for the critical GAP uses in the central zone

209267 for the critical GAP uses in the central zone					
Parameter		Compound	Value	Remark	Value in accordance with EU endpoint y/n/
Substance specific data					
Water solubility [mg/L]		Fenpropidin	530	pH 7.0, phosphate buffer, at 25°C	y/EFSA (2007)
		CGA 289267	8000	pH 7	
Koc [L/kg]		Fenpropidin	3808	Arithm. mean, n = 6	y/EFSA (2007)
		CGA 289267	147	Arithm. mean, n = 5	
DT50 in sediment/water system [d]		Fenpropidin	37	Geomean of n=2 DT50 from original study report (25°C in the laboratory, sediment pH 7.4-8.0, water pH 8.1-8.6) for whole system	n/DAR (2005), FOCUS (2015)
			43	In the LoEP for Step 1	
		CGA 289267	37	Parent value from DAR (2005) (whole system)	
			43	In the LoEP for Step 1	
Molecular Mass [g/mole]		Fenpropidin	273.5		y/EFSA (2007)
		CGA 289267	303.4		
Maximum occurrence observed for the metabolite [%]	water/ sediment studies	CGA 289267	16.1	-	y/EFSA (2007)
	soil	CGA 289267	10.6		
Application pattern					
Application rate of a.i. [g/ha]		Fenpropidin	250		According to GAP
Number of applications per season			1		
Time between two applications [d]			-		
Crop type			Cereals	Winter and Spring	

Table 8.9-15: Step 2 in FOCUS input parameters considered for Fenpropidin and its metabolite CGA 289267 for the critical GAP uses in the central zone

Step 2							
Parameter	Compound	Value	Remark	Value in accordance with EU endpoint y/n/			
Substance specific data							
DT ₅₀ in soil [d]	Fenpropidin	66 67	Geomean, n=6 In the LoEP for Step 2	n/ EFSA (2014)			
	CGA 289267	0.01	lowest possible input	y/EFSA (2007)			
	DT ₅₀ in water [d]	Fenpropidin	37 43	Geomean of n=2 DT ₅₀ from original study report (25°C in the laboratory, sediment pH 7.4-8.0, water pH 8.1-8.6) for whole system In the LoEP for Step 2	n/DAR (2005), FOCUS (2015)		
CGA 289267		37 43	parent value (whole system) In the LoEP for Step 2				
		DT ₅₀ in sediment [d]	Fenpropidin	32 28		Geomean of n=2 DT ₅₀ re-calculated by RMS (25°C in the laboratory, sediment pH 7.4-8.0, water pH 8.1-8.6) In the LoEP for Step 2	y/EFSA (2007)
			CGA 289267	37 43		parent value (water) In the LoEP for Step 2	see parent (water)
Application pattern							
Crop interception	Intermediate	BBCH 30 (cereals)		According to GAP, FOCUS (2015)			
Region and season of application							
Northern EU	Mar–May June–Sep	Cereals (spring+winter)		According to GAP			
	Oct–Feb	Cereals (winter)					

Table 8.9-16: Step 3 in FOCUS input parameters considered for Fenpropidin for the critical GAP uses in the central zone

uses in the central zone

Parameter		Value	Remark	Value in accordance with EU endpoint y/n/
General				
Molar mass [g/mol]		273.5		y/EFSA (2007)
Saturated vapour pressure [Pa]		1.7 x 10 ⁻²	25°C	
Molar enthalpy of vaporisation [J/mol]		95000	default value	FOCUS (2001)
Solubility in water [mg/L]		530	pH 7.0, phosphate buffer, at 25°C	y/EFSA (2007)
Molar enthalpy of dissolution [J/mol]		27000	default value	FOCUS (2001)
Diffusion coefficient in water [m²/d]		4.3E-05	default value	
Diffusion coefficient in air [m²/d]		0.43	default value	
Sorption				
General K _{OM} [L/kg]		2209	calculated by SWASH based on K _{oc} divided by 1.724	
General K _{oc} [L/kg]		3808	Arithm. mean n = 6	y/EFSA (2007)
Freundlich exponent [-]		0.71	Arithm. mean n = 6	
Ref. concentration in liquid phase [g/m³]		1	default value	-
Uptake and wash-off				
Factor for the uptake by plant roots in soil		0	worst case	n/EFSA (2014)
Wash off factor from crop	[1/mm]	0.05	MACRO	FOCUS (2001)
	[1/cm]	0.5	PRZM	

Parameter		Value	Remark	Value in accordance with EU endpoint y/n/
Transformation				
Half-life time [d]	water	1000	default	n/ FOCUS (2006)
	sediment	32	Geomean of n=2 DT ₅₀ whole system values re-calculated by RMS during EU review	y/EFSA (2007); DAR (2005), FOCUS (2006)
	soil	84	Max value	y/EFSA (2007)
	crop	10.00	default value	FOCUS default
Activation energy [J/mol]		65400	default value	EFSA Panel (2007)
Exponent [1/K]		0.0948	default value	
Q ₁₀ fac [-]		2.58	default value	
Specifications on transformation in soil				
Exponent for the effect of water content [-]		0	MACRO, PRZM	FOCUS default
Half life measured at pF		2	MACRO	
Half life measured at moisture content [%]		100.00	PRZM	-
Relative (% of FC)		yes	-	-

ACTIVE SUBSTANCE

Cereals

Table 8.9-17: FOCUS STEP 1-4 PEC_{SW} and PEC_{SED} for fenpropidin following single application of 250 g a.s./ha to spring cereals BBCH 30

Scenario FOCUS	Waterbody	Max PEC _{SW} (µg/L)	Dominant entry route	21 d- PEC _{SW,twa} (µg/L)	Max PEC _{SED} (µg/kg)				
STEP 1	---	16.01	Run-off/drainage	11.69	526.61				
STEP 2 (average crop cover)									
Northern Europe	March-May	2.60	Run-off/drainage	1.99	92.27				
	June-Sept	2.60	Run-off/drainage	1.99	92.27				
STEP 3									
D1	Ditch	1.573	spray drift	0.678	7.773				
D1	Stream	1.375	spray drift	0.057	0.904				
D3	Ditch	1.555	spray drift	0.081	1.254				
D4	Pond	0.052	spray drift	0.037	0.586				
D4	Stream	1.270	spray drift	0.005	0.089				
D5	Pond	0.052	spray drift	0.037	0.628				
D5	Stream	1.305	spray drift	0.003	0.056				
R4	Stream	1.026	spray drift	0.039	15.880				
STEP 4		Max PEC _{SED} (µg/kg) considering following mitigation							
No spray buffer zone		10	10	10	10	10	10	10	10
Vegetative buffer zone		1000	1000	1000	1000	1000	1000	10	10
Spray drift reduction		1000	1000	1000	1000	1000	1000	1000	1000
D1	Ditch	0.002	0.002	0.002	0.002	0.002	0.002	10	10
D1	Stream	0.002	0.002	0.002	0.002	0.002	0.002	10	10
D3	Ditch	0.002	0.002	0.002	0.002	0.002	0.002	10	10
D4	Pond	0.002	0.002	0.002	0.002	0.002	0.002	10	10
D4	Stream	0.002	0.002	0.002	0.002	0.002	0.002	10	10
D5	Pond	0.002	0.002	0.002	0.002	0.002	0.002	10	10
D5	Stream	0.002	0.002	0.002	0.002	0.002	0.002	10	10
D6	Stream	0.002	0.002	0.002	0.002	0.002	0.002	10	10
D7	Stream	0.002	0.002	0.002	0.002	0.002	0.002	10	10
D8	Stream	0.002	0.002	0.002	0.002	0.002	0.002	10	10
D9	Stream	0.002	0.002	0.002	0.002	0.002	0.002	10	10
STEP 5 (not relevant)									

Table 8.9-18: FOCUS STEP 1-4 PEC_{SW} and PEC_{SED} for fenpropidin following single application of 250 g a.s./ha to winter cereals BBCH 30

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{SED} (µg/kg)				
STEP 1	---	16.01	Run-off/drainage	11.69	526.61				
STEP 2 (average crop cover)									
Northern Europe	March-May	2.60	Run-off/drainage	1.99	92.27				
	June-Sept	2.60	Run-off/drainage	1.99	92.27				
	Oct-Feb	5.75	Run-off/drainage	4.54	212.44				
STEP 3									
D1	Ditch	1.559	spray drift	0.124	1.887				
D1	Stream	1.211	spray drift	0.003	0.052				
D2	Ditch	1.569	spray drift	0.157	2.465				
D2	Stream	1.332	spray drift	0.014	0.232				
D3	Ditch	1.554	spray drift	0.072	1.142				
D4	Pond	0.052	spray drift	0.036	0.683				
D4	Stream	1.147	spray drift	0.002	0.034				
D5	Pond	0.052	spray drift	0.037	0.636				
D5	Stream	1.239	spray drift	0.002	0.036				
D6	Ditch	1.536	spray drift	0.032	0.517				
R1	Pond	0.052	spray drift	0.040	1.015				
R1	Stream	1.017	spray drift	0.018	7.006				
R3	Stream	1.437	spray drift	0.019	3.345				
R4	Stream	1.026	spray drift	0.013	7.705				
STEP 4		Max PEC _{sw} (µg/L) considering following mitigation							
No spray-drift reduction		16	16	16	16	16	16	16	16
Vegetative strip (m)		1000	1000	1000	1000	1000	1000	1000	1000
Slope reduction		1000	1000	1000	1000	1000	1000	1000	1000
D1	Ditch	0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003
D1	Stream	0.002	0.002	0.002	0.002	0.002	0.002	0.002	0.002
D2	Ditch	0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003
D2	Stream	0.002	0.002	0.002	0.002	0.002	0.002	0.002	0.002
D3	Ditch	0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003
D3	Stream	0.002	0.002	0.002	0.002	0.002	0.002	0.002	0.002
D4	Pond	0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003
D4	Stream	0.002	0.002	0.002	0.002	0.002	0.002	0.002	0.002
D5	Pond	0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003
D5	Stream	0.002	0.002	0.002	0.002	0.002	0.002	0.002	0.002
D6	Ditch	0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003
D6	Stream	0.002	0.002	0.002	0.002	0.002	0.002	0.002	0.002
R1	Pond	0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003
R1	Stream	0.002	0.002	0.002	0.002	0.002	0.002	0.002	0.002
R3	Stream	0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003
R4	Stream	0.003	0.003	0.003	0.003	0.003	0.003	0.003	0.003

PEC_{SW} and PEC_{SED} values are in µg/L and µg/kg respectively

METABOLITE

CGA 289267 /Cereals

Table 8.9-19: FOCUS STEP 1, 2 PEC_{SW} and PEC_{SED} for CGA 289267 following 1 × 250 g a.s./ha to spring cereals BBCH 30 (worst case)

Scenario FOCUS	Waterbody	Max PEC _{SW} (µg/L)	Dominant entry route	21 d- PEC _{SW, twa} (µg/L)	Max PEC _{SED} (µg/kg)
STEP 1	---	21.05	Run-off/drainage	17.53	30.34
STEP 2 (average crop cover)					
Northern Europe	March-May	2.25	Spray drift	1.84	3.21
	June-Sept	2.25	Spray drift	1.84	3.21

Table 8.9-20: FOCUS STEP 1, 2 PEC_{SW} and PEC_{SED} for CGA 289267 following 1 × 250 g a.s./ha to winter cereals BBCH 30 (worst case)

Scenario FOCUS	Waterbody	Max PEC _{SW} (µg/L)	Dominant entry route	21 d- PEC _{SW, twa} (µg/L)	Max PEC _{SED} (µg/kg)
STEP 1	---	21.05	Run-off/drainage	17.53	30.34
STEP 2 (average crop cover)					
Northern Europe	March-May	2.25	Spray drift	1.84	3.21
	June-Sept	2.25	Spray drift	1.84	3.21
	Oct-Feb	5.11	Spray drift	4.21	7.35

zRMS comments:

Input parameters used for surface water modelling for fenpropidin and its metabolite and presented in Tables 8.9-14 to 8.9-16 are in general in line with EU agreed endpoints with following exceptions regarding endpoints for Step 1-2 calculation:

- For fenpropidin geometric mean soil DT₅₀ of 66 days was used instead of EU agreed arithmetic mean of 67 days. This deviation is not expected to have significant impact on the obtained results and is thus agreed by the zRMS.
- For fenpropidin geometric mean water phase DT₅₀ of 37 days was used instead of EU agreed arithmetic mean of 43 days. This deviation is not expected to have significant impact on the obtained results, but validation by the zRMS was performed using EU agreed endpoint.
- For fenpropidin geometric mean sediment DT₅₀ of 37 days was used instead of EU agreed arithmetic mean of 28 days. This deviation is not expected to have significant impact on the obtained results, but validation by the zRMS was performed using EU agreed endpoint.
- For metabolite CGA 289267 geometric mean water and sediment DT₅₀ of 37 days were used instead of EU agreed arithmetic mean of 43 days. This deviation is not expected to have significant impact on the obtained results, but validation by the zRMS was performed using EU agreed endpoints.

As the all deviation mentioned above are expected to have only minor impact on the Step 1-2 results, endpoints used by the Applicant were not struck through, but endpoints in line with EU were added by the zRMS to Tables 8.9-14 and 8.9-15 (values highlighted in grey).

At Step 3 PUF value of 0 was assumed for fenpropidin, in line with current recommendations.

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

The information on the dominant entry route at Steps 1-2 was struck through by the zRMS in tables above, since at this stage of the exposure assessment it is not possible to identify the main route of migration.

According to the Central Zone GAP presented in Table 8.1-1, ADM.03502.F.1.A is intended to be used in spring, therefore Step 1-2 results for autumn/winter application (Oct-Feb) have been removed from Tables 8.9-18 and 8.9-20 and 8.9-13 as being not relevant.

The surface water exposure was independently validated by the zRMS in additional modelling using the EU agreed endpoints.

Results obtained in the updated modelling at Step 1-2 for parent and metabolite were slightly lower comparing to these presented by the Applicant. Steps 3-4 PEC_{SW} and PEC_{SED} obtained by the zRMS were in general in good agreement with values calculated by the Applicant and presented in Tables 8.9-17 and 8.9-18 with exception of R4 scenario at Step 4, for which the zRMS obtained higher results, which were included in Table 8.9-17.

According to the AppDate ver. 3.06, in R1 scenario for winter cereals application window should be set between 24th of April and 24th of May (114-144 Julian days). Nevertheless, PEC_{SW} obtained by the zRMS for this scenario at Step 3-4 and the correct dates were lower than these obtained by the Applicant, therefore slightly later application assumed in Applicants' modelling turned out to represent worst case.

As indicated in the commenting box in point 8.9.2, the application windows assumed by the Applicant for Step 3 & 4 modelling for fenpropidine do not cover surface water exposure for the later BBCH stages. Therefore Step 3 and 4 surface water modelling was performed by the zRMS for the last possible dates of application to spring and winter cereals (application windows considered in this modelling are presented in the commenting box in point 8.9.2). The input parameters in additional modelling for prothioconazole were the same as indicated in Table 8.9-16.

Step 3 PEC_{SW} values derived for BBCH 65 presented in tables below are higher comparing to these calculated for the early BBCH stage. The PEC_{SED} are not presented as being not necessary for the aquatic risk assessment (all endpoints expressed in terms of mg/L).

FOCUS STEP 3- Max PEC_{SW} (µg/L) for fenpropidin considering application of 250 g a.s./ha

Scenario FOCUS	Waterbody	Max PEC _{SW} (µg/L)	Max PEC _{SW} (µg/L)
BBCH up to 65		winter cereals	spring cereals
STEP 3			
D1	Ditch	1,580	1,58
D1	Stream	1,381	1,38
D2	Ditch	1,581	-
D2	Stream	1,406	-
D3	Ditch	1,567	1,555
D4	Pond	0.053	0.052
D4	Stream	1,350	1,366
D5	Pond	0.053	0.052
D5	Stream	1,456	1,455
D6	Ditch	1,539	-
R1	Pond	0.059	-
R1	Stream	1,031	-
R3	Stream	1,446	-
R4	Stream	1,031	1,031

Maximum PEC_{SW} values highlighted in bold exceed the lowest RAC of 0.13 µg a.s./L

In case of spring cereals, Step 4 PEC_{SW} values for late BBCH stages were mostly the same as the results presented in Table 8.9-17. The PEC_{SED} are not presented as being not necessary for the aquatic risk assessment (all endpoints expressed in terms of mg/L).

FOCUS STEP4- Max PEC_{SW} (µg/L) for fenpropidin considering application of 250 g a.s./ha

STEP 4		up to BBCH 65							
No spray buffer (m)		10			20			10	20
Vegetative strip (m)		none	none	none	none	none	none	10	20
Nozzle reduction		none	75%	90%	none	75%	90%	none	none
		winter cereals							
D1	Ditch	0,225	0,056	0,022	0,116	0,029	0,011	n.r.	n.r.

D1	Stream	0.265	0.065	0.026	0.137	0.034	0.013	n.f.	n.f.
D2	Ditch	0.225	0.056	0.022	0.117	0.029	0.011	n.f.	n.f.
D2	Stream	0.270	0.067	0.026	0.140	0.035	0.014	n.f.	n.f.
D3	Ditch	0.223	0.055	0.022	0.116	0.028	0.011	n.f.	n.f.
D4	Pond	0.033	0.008	0.003	0.022	0.005	0.002	n.f.	n.f.
D4	Stream	0.259	0.064	0.025	0.134	0.033	0.013	n.f.	n.f.
D5	Pond	0.033	0.008	0.003	0.022	0.005	0.002	n.f.	n.f.
D5	Stream	0.280	0.069	0.027	0.145	0.036	0.014	n.f.	n.f.
D6	Ditch	0.223	0.055	0.022	0.116	0.028	0.011	n.f.	n.f.
R1	Pond	0.051	0.043	0.041	0.048	0.042	0.041	0.032	0.021
R1	Stream	0.198	0.153	0.153	0.153	0.153	0.153	0.198	0.102
R3	Stream	0.278	0.126	0.126	0.144	0.126	0.126	0.278	0.144
R4	Stream	0.198	0.075	0.075	0.102	0.075	0.075	0.198	0.102
STEP 4		spring cereals							
D1	Ditch	0.225	0.056	0.022	0.115	0.028	0.011	n.f.	n.f.
D1	Stream	0.263	0.065	0.026	0.136	0.033	0.013	n.f.	n.f.
D3	Ditch	0.220	0.054	0.021	0.114	0.028	0.011	n.f.	n.f.
D4	Pond	0.032	0.008	0.003	0.021	0.005	0.002	n.f.	n.f.
D4	Stream	0.259	0.064	0.024	0.134	0.033	0.013	n.f.	n.f.
D5	Pond	0.032	0.008	0.003	0.021	0.005	0.002		
D5	Stream	0.280	0.069	0.027	0.145	0.036	0.014	n.f.	n.f.
R4	Stream	0.198	0.080	0.080	0.102	0.080	0.080	0.102	0.102

Maximum PEC_{sw} values highlighted in **bold** exceed the lowest RAC of 0.13 µg a.s./L

The data below were submitted by Applicants during the commenting process, were reviewed and agreed by the zRMS:

Step 3 PEC_{sw} values at BBCH 65 were calculated by the Applicant and results are presented in tables below. The assumed application windows for the later BBH stages were as presented in the commenting box in point 8.9.2 and input parameters as indicated in Table 8.9-16. Obtained by the zRMS results were similar to this calculated by the Applicant.

FOCUS STEP 3 PEC_{sw} and PEC_{sed} for fenpropidin following 1 × 250 g a.s./ha to spring cereals BBCH 65

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 3					
D1	Ditch	1.573	spray drift	0.673	7.431
D1	Stream	1.375	spray drift	0.057	0.896
D3	Ditch	1.558	spray drift	0.102	1.55
D4	Pond	0.052	spray drift	0.037	0.569
D4	Stream	1.339	spray drift	0.017	0.269
D5	Pond	0.052	spray drift	0.038	0.589
D5	Stream	1.356	spray drift	0.025	0.404
R4	Stream	1.026	spray drift	0.012	21.85

FOCUS STEP 3 PEC_{sw} and PEC_{sed} for fenpropidin following 1 × 250 g a.s./ha to winter cereals BBCH 65

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
STEP 3					
D1	Ditch	1.573	spray drift	0.676	7.538
D1	Stream	1.375	spray drift	0.057	0.904
D2	Ditch	1.575	spray drift	0.684	7.665
D2	Stream	1.400	spray drift	0.601	6.770
D3	Ditch	1.560	spray drift	0.117	1.744

D4	Pond	0.052	spray drift	0.037	0.569
D4	Stream	1.343	spray drift	0.018	0.296
D5	Pond	0.052	spray drift	0.038	0.590
D5	Stream	1.450	spray drift	0.026	0.420
D6	Ditch	1.562	spray drift	0.211	2.861
R1	Pond	0.052	spray drift	0.043	1.228
R1	Stream	1.026	spray drift	0.016	12.840
R3	Stream	1.439	spray drift	0.023	5.882
R4	Stream	1.026	spray drift	0.011	15.760

Since the vapour pressure of 1.7×10^{-2} Pa indicate that fenpropidin is a volatile substance the volatilisation of fenpropidin may occur. Considering a non-spray buffer distance of up to 50 m the degrees of the volatilisation with respective deposition rates of fenpropidin were calculated on an hourly basis using EVA 3 rev.2h as presented in the table below:

Deposition rates of fenpropidin following 1 x 250 g a.s./ha applications of ADM.03502.F.1.A to arable crops

Buffer width (m)	1	10	20	25	30	35	40	50
BBCH	-	30 and 65						
Interception	100	100						
v/d in 24h (%)	1.555	0.953	0.553	0.421	0.321	0.244	0.186	0.108
Time (hours)	Deposition rates (mg m ⁻² h ⁻¹)							
0 – 4	0.0352	0.0216	0.0125	0.0095	0.0073	0.0055	0.0042	0.0024
4-12	0.0176	0.0108	0.0063	0.0048	0.0036	0.0028	0.0021	0.0012
12-24	0.0088	0.0054	0.0031	0.0024	0.0018	0.0014	0.0011	0.0006

These deposition values were then included in the Step 4 calculations using SWAN v. 5. The input parameters used for Step 3- 4 PEC_{sw}/sed modelling were the same as indicated in Table 8.9-16. The results of PEC_{sw} at Step 4 are presented in tables below:

FOCUS STEP 4 PEC_{sw} for fenpropidin following 1 × 250 g a.s./ha to spring cereals at BBCH 30 considering EVA derived deposition rates and a worst-case interception of 100 %

STEP 4		Max PEC _{sw} (µg/L) considering following mitigation:											
No spray buffer (m)		10	10	10	20	20	20	10	20	10	10	20	20
Vegetative strip (m)		none	none	none	none	none	none	10	20	10	10	20	20
Nozzle reduction		none	75%	90%	none	75%	90%	none	none	75%	90%	75%	90%
D3	Ditch	0.678	0.572	0.554	0.382	0.328	0.319	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
D4	Pond	0.142	0.118	0.113	0.084	0.068	0.065	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
D4	Stream	0.384	0.206	0.170	0.207	0.115	0.097	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
D5	Pond	0.142	0.118	0.113	0.084	0.068	0.065	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
D5	Stream	0.348	0.159	0.121	0.185	0.088	0.068	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
R4	Stream	0.416	0.281	0.254	0.229	0.205	0.205	0.416	0.229	0.281	0.254	0.159	0.145
No spray buffer (m)		25	25	25	30	30	30	35	35	35	25	30	35
Vegetative strip (m)		none	none	none	none	none	none	none	none	none	10	10	10
Nozzle reduction		none	75%	90%	none	75%	90%	none	75%	90%	none	none	none
D3	Ditch	0.295	0.251	0.244	0.228	0.190	0.184	0.180	0.147	0.142	n.r.	n.r.	n.r.
D4	Pond	0.066	0.053	0.050	0.052	0.040	0.038	0.042	0.031	0.029	n.r.	n.r.	n.r.
D4	Stream	0.163	0.089	0.074	0.132	0.070	0.057	0.108	0.054	0.044	n.r.	n.r.	n.r.
D5	Pond	0.066	0.053	0.050	0.052	0.040	0.038	0.042	0.031	0.029	n.r.	n.r.	n.r.
D5	Stream	0.147	0.068	0.052	0.120	0.054	0.041	0.100	0.043	0.031	n.r.	n.r.	n.r.
R4	Stream	0.205	0.205	0.205	0.205	0.205	0.205	0.205	0.205	0.205	0.178	0.142	0.113

PEC_{sw} values above the RAC of 0.130 µg/L are shown in **bold**.

STEP 4	Max PEC _{SW} (µg/L) considering following mitigation:
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PEC_{sw} values above the RAC of 0.130 µg/L are shown in **bold**.

Table 21: FOCUS STEP 4 PEC_{sw} for fenpropidin following 1 × 250 g a.s./ha to winter cereals at BBCH 30 considering EVA derived deposition rates and a worst-case interception of 100%

STEP 4		Max PEC _{sw} (µg/L) considering following mitigation:											
No spray buffer (m)		10	10	10	20	20	20	10	20	10	10	20	20
Vegetative strip (m)		none	none	none	none	none	none	10	20	10	10	20	20
Nozzle reduction		none	75%	90%	none	75%	90%	none	none	75%	90%	75%	90%
D3	Ditch	0.656	0.545	0.526	0.370	0.313	0.303	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
D4	Pond	0.141	0.117	0.112	0.084	0.068	0.065	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
D4	Stream	0.281	0.116	0.082	0.149	0.063	0.046	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
D5	Pond	0.141	0.117	0.113	0.084	0.068	0.065	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
D5	Stream	0.303	0.123	0.088	0.160	0.067	0.049	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
R1	Pond	0.142	0.118	0.113	0.084	0.068	0.065	0.141	0.084	0.117	0.113	0.068	0.065
R1	Stream	0.390	0.248	0.220	0.214	0.147	0.147	0.390	0.214	0.248	0.220	0.140	0.126
R3	Stream	0.592	0.421	0.392	0.327	0.240	0.225	0.592	0.327	0.421	0.392	0.240	0.225
R4	Stream	0.416	0.281	0.254	0.229	0.218	0.218	0.416	0.229	0.281	0.254	0.159	0.145
No spray buffer (m)		25	25	25	30	30	30	35	35	35	25	30	35
Vegetative strip (m)		none	none	none	none	none	none	none	none	none	10	10	10
Nozzle reduction		none	75%	90%	none	75%	90%	none	75%	90%	none	none	none
D3	Ditch	0.285	0.239	0.231	0.221	0.182	0.175	0.174	0.140	0.135	n.r.	n.r.	n.r.
D4	Pond	0.066	0.052	0.050	0.052	0.040	0.038	0.042	0.031	0.029	n.r.	n.r.	n.r.
D4	Stream	0.118	0.049	0.035	0.097	0.039	0.028	0.081	0.032	0.022	n.r.	n.r.	n.r.
D5	Pond	0.066	0.053	0.050	0.052	0.040	0.038	0.042	0.031	0.029	n.r.	n.r.	n.r.
D5	Stream	0.127	0.052	0.038	0.104	0.042	0.029	0.088	0.034	0.023	n.r.	n.r.	n.r.
R1	Pond	0.066	0.053	0.050	0.052	0.040	0.038	0.042	0.031	0.030	0.066	0.052	0.042
R1	Stream	0.167	0.147	0.147	0.147	0.147	0.147	0.147	0.147	0.147	0.167	0.133	0.107
R3	Stream	0.254	0.183	0.171	0.202	0.141	0.131	0.161	0.108	0.100	0.254	0.202	0.161
R4	Stream	0.218	0.218	0.218	0.218	0.218	0.218	0.218	0.218	0.218	0.178	0.142	0.113
No spray buffer (m)		40	40	40	50	50	50	-	-	-	-	40	50
Vegetative strip (m)		none	none	none	none	none	none	-	-	-	-	10	10
Nozzle reduction		none	75%	90%	none	75%	90%	-	-	-	-	none	none
D3	Ditch	0.138	0.108	0.103	0.089	0.063	0.059	-	-	-	-	n.r.	n.r.
D4	Pond	0.034	0.024	0.022	0.023	0.014	0.013	-	-	-	-	n.r.	n.r.
D4	Stream	0.070	0.026	0.017	0.053	0.018	0.011	-	-	-	-	n.r.	n.r.
D5	Pond	0.034	0.024	0.022	0.023	0.014	0.013	-	-	-	-	n.r.	n.r.
D5	Stream	0.075	0.028	0.018	0.057	0.019	0.012	-	-	-	-	n.r.	n.r.
R1	Pond	0.034	0.027	0.026	0.027	0.023	0.022	-	-	-	-	0.034	0.023
R1	Stream	0.147	0.147	0.147	0.147	0.147	0.147	-	-	-	-	0.088	0.066
R3	Stream	0.130	0.100	0.100	0.100	0.100	0.100	-	-	-	-	0.130	0.089
R4	Stream	0.218	0.218	0.218	0.218	0.218	0.218	-	-	-	-	0.098	0.098

PEC_{sw} values above the RAC of 0.130 µg/L are shown in bold.

FOCUS STEP 4 PEC_{sw} for fenpropidin following 1 × 250 g a.s./ha to winter cereals at BBCH 65 considering EVA derived deposition rates and a worst-case interception of 100 %

STEP 4		Max PEC _{sw} (µg/L) considering following mitigation:											
No spray buffer (m)		10	10	10	20	20	20	10	20	10	10	20	20
Vegetative strip (m)		none	none	none	none	none	none	10	20	10	10	20	20
Nozzle reduction		none	75%	90%	none	75%	90%	none	none	75%	90%	75%	90%
D3	Ditch	0.768	0.648	0.624	0.433	0.371	0.359	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
D4	Pond	0.142	0.118	0.113	0.084	0.068	0.065	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
D4	Stream	0.522	0.394	0.372	0.290	0.225	0.214	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
D5	Pond	0.142	0.118	0.113	0.084	0.068	0.065	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
D5	Stream	0.596	0.472	0.454	0.333	0.271	0.261	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.
R1	Pond	0.141	0.117	0.113	0.084	0.068	0.065	0.141	0.084	-*	-*	-*	-*
R1	Stream	0.416	0.281	0.254	0.229	0.159	0.146	0.416	0.229	-*	-*	-*	-*
R3	Stream	0.595	0.429	0.398	0.329	0.244	0.229	0.595	0.329	-*	-*	-*	-*
R4	Stream	0.416	0.281	0.254	0.229	0.159	0.145	0.416	0.229	-*	-*	-*	-*
No spray buffer (m)		25	25	25	30	30	30	35	35	35	25	30	35
Vegetative strip (m)		none	none	none	none	none	none	none	none	none	10	10	10
Nozzle reduction		none	75%	90%	none	75%	90%	none	75%	90%	none	none	none
D3	Ditch	0.334	0.284	0.274	0.258	0.216	0.207	0.203	0.167	0.160	n.r.	n.r.	n.r.
D4	Pond	0.066	0.053	0.050	0.052	0.040	0.038	0.042	0.031	0.029	n.r.	n.r.	n.r.
D4	Stream	0.224	0.172	0.162	0.177	0.132	0.124	0.141	0.101	0.094	n.r.	n.r.	n.r.
D5	Pond	0.066	0.053	0.050	0.052	0.040	0.038	0.042	0.031	0.029	n.r.	n.r.	n.r.
D5	Stream	0.257	0.206	0.199	0.202	0.158	0.151	0.160	0.121	0.115	n.r.	n.r.	n.r.
R1	Pond	0.066	0.053	0.051	0.053	0.044	0.043	0.045	0.040	0.040	0.066	0.052	0.042
R1	Stream	0.178	0.122	0.115	0.142	0.115	0.115	0.115	0.115	0.115	0.178	0.142	0.113
R3	Stream	0.255	0.186	0.174	0.203	0.144	0.133	0.162	0.110	0.101	0.255	0.203	0.162
R4	Stream	0.178	0.122	0.110	0.142	0.094	0.085	0.113	0.073	0.065	0.178	0.142	0.113
No spray buffer (m)		40	40	40	50	50	50	-	-	-	-	40	50
Vegetative strip (m)		none	none	none	none	none	none	-	-	-	-	10	10
Nozzle reduction		none	75%	90%	none	75%	90%	-	-	-	-	none	none
D3	Ditch	0.160	0.129	0.122	0.100	0.075	0.070	-	-	-	-	n.r.	n.r.
D4	Pond	0.034	0.024	0.022	0.023	0.014	0.013	-	-	-	-	n.r.	n.r.
D4	Stream	0.114	0.078	0.072	0.078	0.046	0.042	-	-	-	-	n.r.	n.r.
D5	Pond	0.034	0.024	0.022	0.023	0.014	0.013	-	-	-	-	n.r.	n.r.
D5	Stream	0.128	0.093	0.088	0.086	0.055	0.051	-	-	-	-	n.r.	n.r.
R1	Pond	0.041	0.038	0.037	0.037	0.035	0.034	-	-	-	-	0.034	0.023
R1	Stream	0.115	0.115	0.115	0.115	0.115	0.115	-	-	-	-	0.093	0.064
R3	Stream	0.132	0.090	0.090	0.090	0.090	0.090	-	-	-	-	0.132	0.090
R4	Stream	0.092	0.057	0.053	0.064	0.053	0.053	-	-	-	-	0.092	0.063

* not calculated, as PEC_{sw} values are expected to be above the trigger value of 0.130 µg/L (RAC)
PEC_{sw} values above the RAC of 0.130 µg/L are shown in **bold**

The surface water exposure was independently validated by the zRMS in additional simulations using the same input parameters. Results obtained by the zRMS at Step 4 for fenpropidin were in good agreement with values obtained by the Applicant.

Please note, that for active substance fenpropidin exposure assessment due to volatilization and deposition should be considered by Member States in cases spray drift risk mitigation as applied.

Please note that not all relevant scenarios are defined for spring cereals and results in these scenarios obtained for winter cereals may be used as surrogate.

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

8.9.2.3 PEC_{SW/SED} of ADM.03502.F.1.A

The product-based ~~Step 3~~ PEC_{sw} via spray drift were calculated for the standard water body types ditch, pond and stream using the FOCUS drift calculator 1.1 implemented in the FOCUS SWASH 5.3 model. The maximum application rate per treatment (1040 g product/ha) corresponds to 1 L product/ha as worst-case application rate assuming a product density of 1.040 g/mL. Calculations were performed for a single application of the product in cereals. The maximum initial PEC_{sw} from spray drift entry (Step 3) and for standard distances of 10 and 20 m as well as for drift reducing equipment are presented in the table below. The maximum initial PEC_{sw} from spray drift entry (without mitigations) is calculated to be 6.682 µg product/L.

Table 8.9-22: PEC_{sw} of the product ADM.03502.F.1.A from spray drift entry following single application to FOCUS scenarios in arable crops

Application to FOCUS scenarios in arable crops						
Water body	Application rate (g product/ha)	No spray FOCUS buffer distances (m)	Drift entry (%)	PEC _{sw} (µg prod./L) with nozzle reduction		
				0 %	75 %	90 %
Ditch	1040* (single application)	Standard FOCUS buffer <i>Step 3</i>	1.9274	6.6816	1.6704	0.6682
		10	0.2771	0.9605	0.2401	0.0961
		20	0.1440	0.4991	0.1248	0.0499
Pond		Standard FOCUS buffer <i>Step 3</i>	0.2191	0.2278	0.0570	0.0228
		10	0.1363	0.1417	0.0354	0.0142
		20	0.0910	0.0946	0.0237	0.0095
Stream		Standard FOCUS buffer <i>Step 3</i>	1.4304	4.9586	1.2397	0.4959
		10	0.2771	0.9605	0.2401	0.0961
		20	0.1440	0.4991	0.1248	0.0499

* the rate of formulation is based on a specific density of 1.04 g/mL and the worst-case application rate of 1 L product/ha

zRMS comments:

The surface water exposure to formulation was validated by the zRMS using Spray Drift Calculator. Obtained results were in agreement with these reported in Tables 8.9-21.

Please note that no Step 3 PEC_{sw} is calculated for the formulated products, since only spray drift is assumed as the route of entry of the formulation to water and no phys-chem or degradation data are taken into account. For this reason reference to Step 3 calculation has been struck through in the text and table above.

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

Studies on fate and behaviour in air with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substances.

8.10.1 Prothioconazole

The fate and behaviour of prothioconazole in air were evaluated during the EU review and the following information was provided in EFSA Journal 2007; 106; 1-98. No additional studies have been performed.

Table 8.10-1: Summary of atmospheric degradation and behaviour of Prothioconazole

Compound	Prothioconazole
Direct photolysis in air	Not studied – no data requested
Quantum yield of direct phototransformation	Not studied – no data requested
Photochemical oxidative degradation in air	Prothioconazole: Half-life: 1.1 hours Chemical lifetime: 1.6 hours Calculated according to Atkinson (AOPWIN v. 1.87, 12 hour day, 1.5×10^6 OH radicals/cm ³) prothioconazole-desthio (M04): Half-life: 14.2 hours Chemical lifetime: 20.5 hours Calculated according to Atkinson (AOPWIN v. 1.87, 12 hour day, 1.5×10^6 OH radicals/cm ³)
Volatilisation	Laboratory route and rate soil studies indicated that volatilisation of prothioconazole and prothioconazole-desthio (M04) is unlikely to take place because no volatiles were detected at levels above 0.1% AR.
Metabolites	*

*based on the results concerning vapour pressure, Henry Law constant and photo oxidative stability in ambient air, it can be concluded that neither emission of prothioconazole into the air, nor accumulation and contamination by wet or dry deposition are to be expected for the parent compound and its metabolite prothioconazole-desthio (M04).

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

PEC

Maximum concentration	Not calculated
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zRMS comments:

Provided above information is in line with EU agreed data reported in EFSA Scientific Report (2007) 106 for prothioconazole.

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 and contamination of the atmosphere with prothioconazole and its metabolites from the intended uses of ADM.03502.F.1.A is thus considered to be negligible.

8.10.2 Fenpropidin

The fate and behaviour of fenpropidin in air were evaluated during the EU review and the following information was provided in the EFSA Scientific Report (2007) 124, 1-84. No additional studies have been performed.

Table 8.10-2: Summary of atmospheric degradation and behaviour of Fenpropidin

Compound	Fenpropidin
Direct photolysis in air	No study submitted, not required.
Quantum yield of direct phototransformation	No study submitted, not required.
Photochemical oxidative degradation in air	DT ₅₀ about 1 h (estimated; 1.5×10^6 OH-radicals/cm ³ and a 12-hour day length assumed, and the rate constant was calculated to 112.8567×10^{-12} cm ³ /molecule ^{-sec}).
Volatilisation	Volatilization chamber (0.003 and 1.0 m/sec., 20°C): ≤1.9% (24 h) volatilisation from soil at low wind speed; ≤9.0% at high wind speed. Volatilization chamber (1.0-1.1 m/sec., 20-21°C): 25% (24 h) volatilisation from soil; 80% from plants; calculated overall volatilisation 37%. The results above represent indirect measurements of volatilisation as loss from treated material. Only the neutral form of fenpropidin is potentially volatile. pKa is 10.1 and at environmentally relevant pH fenpropidin will predominantly be present in protonated, non-volatile form.
Metabolites	Not study submitted, not required.

There is no current standard method to address potential volatilisation and re-deposition. However, the study of fenpropidin from soil surface under controlled laboratory conditions, evaluated during the EU review, supports the assumption of low volatilisation. After 24 hours, the volatilisation from soil was ≤ 1.9% for low wind speed (276 mL air flow per minute) and ≤ 9% for a higher wind speed of 2040 mL/min. Both values are under the trigger of 20% from the BBA guideline, part IV, 6-1 (July 1990).

PEC

Method of calculation	Not calculated
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The pH of the pure product ADM.03502.F.1.A is not available; the pH in 1% v/v in deionized water is shown to be 7.3 (see dRR part B Section 2).

According to the GAP, the product is used at a maximum of 1 L product/ha dissolved in 100 – 400 L water. This results in a 0.25 - 1.0 % aqueous solution. Since this is a higher dilution than the 1% for which a measured pH (7.3) is available, the pH of the spray solution will also be in the neutral range, i.e. clearly below pH 10. It is thus justified to assume that fenpropidin is predominately protonated under real use conditions and that volatilisation is not relevant.

zRMS comments:

Provided above information is in line with EU agreed data reported in EFSA Scientific Report (2007) 124 for fenpropidin.

Taking into account the low vapour pressure ($<10^{-5}$ Pa) and DT₅₀ in air <2 days fenpropidin is not expected to be subject to volatilisation and the long- or short-range transport and contamination of the atmosphere with fenpropidin and its metabolites from the intended uses of ADM.03502.F.1.A is thus considered to be negligible.

In line with the EU agreed data reported in EFSA Scientific Report (2007) 124, fenpropidin is not expected to be subject to volatilisation and the long range transport despite vapour pressure above the threshold of 10^{-5} Pa (1.7×10^{-2} Pa at 25°C).

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	Penne, C.	2021	Predicted environmental concentrations in groundwater (PEC _{gw}) of prothioconazole, fenpropidin and metabolites using FOCUS PELMO 5.5.3, FOCUS PEARL 4.4.4 and FOCUS MACRO 5.5.4 for critical GAP uses in different crops in the Central zone. Report no.: ADM-210621-01, sponsor no. 000108619 EBRC Consulting GmbH, Hannover, Germany Not GLP Unpublished	N	ADM
KCP 9.2.5/01	Penne, C.	2021	Predicted environmental concentrations in surface water (PEC _{sw}) and sediment (PEC _{sed}) prothioconazole, fenpropidin and metabolites using STEPS 1-2 in FOCUS (v3.2), FOCUS SWASH 5.3 and SWAN v5.0 for critical GAP uses in different crops in the Central zone. Report no.: ADM-210621-02, sponsor no. 000108620 EBRC Consulting GmbH, Hannover, Germany Not GLP Unpublished	N	ADM

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
Not applicable, no such data submitted or referred to.					

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	Reason for rejection
KCP 9.1.1.1/01	Morlock, G.	2006a	Degradation of Fenpropidin in 3 different soils under aerobic conditions at 20° C in the dark Report No 20051244/01-CABJ, sponsor no. 00012949 GLP Unpublished	N	IRVITA*	New active substance data, not necessary for purposes of the evaluation, since sufficient data are available from the EU review
KCP 9.1.1.1/02	Morlock, G.	2006b	Degradation of Fenpropidin in one soil under aerobic conditions at 20° C in the dark Report No 20051244/02-CABJ, sponsor no. 00012950 GLP Unpublished	N	IRVITA*	
KCP 9.1.1.1/03	Flörchinger M.	2008	Degradation of Fenpropidin Acid in 3 Different Soils under Aerobic Conditions at 20°C in the Dark Eurofins-GAB GmbH Report No.S08-01156, sponsor no. 00016350 GLP Unpublished	N	IRVITA*	

* IRVITA, now ADAMA Irvita N.V., ADM is ADAMA Makhteshim Ltd. All ADAMA affiliates are member of ADAMA Agricultural Solutions Ltd.

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 studies

A 2.1 KCP 9.1.1 Rate of degradation in soil

A 2.2 KCP 9.1.1.1 Aerobic degradation in soil

Comments of zRMS:	<p>The study below was not necessary for purposes of the exposure assessment since sufficient data were available from the EU review of fenpropidin.</p> <p>The summary below was thus struck through and shaded.</p> <p>The study should be evaluated in the course of the ongoing EU renewal process.</p>
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Reference:	KCP 9.1.1.1/01
Report	Degradation of Fenpropidin in 3 different soils under aerobic conditions at 20° C in the dark. Morlock, G., 2006a, Report No 20051244/01-CABJ, sponsor no. 00012949
Guideline(s):	Yes, OECD guideline 307
Deviations:	No
GLP:	Yes
Acceptability:	Not evaluated, new active substance data not necessary to finalise the exposure assessment

Materials and methods

A. MATERIALS

1. Test Material:

Fenpropidin

Lot/Batch no.: 0775-10371
Purity: 97.8 %
CAS no.: 67306-00-7
Stability of test compound: June, 2007

Soils:

Three Speyer standard soils (two silty sands and a clay loam) were used. The standard soils were sampled on June 22nd and July 1st, 2005 from agriculturally treated field site, where no pesticide had been applied within the last five years.

Table A 1: Soil physicochemical properties

origin and name	LUFA Speyer standard soil 3A	LUFA Speyer standard soil 5M	LUFA Speyer standard soil 6S
soil texture	Silty sand	silty sand	clay loam
clay1 [%]	3.2	4.1	31.3
silt1 [%]	40.8	20.8	40.7
sand1 [%]	56.1	75.1	27.9
total organic carbon [%]	2.14	1.61	1.80
pH (0.01 M CaCl ₂)	7.1	7.0	7.0
CEC [mval/100g]	20.1	13.3	24.6
MWHC [g/100g dry weight]	38.2	35.8	40.5
Microbial biomass [mg C _{mic} /100 g dry soil]	Day ⁻¹ 43.2	24.4	37.5
	study end 33.6	14.3	25.8

¹: particle size distribution according to DIN 4220

B. STUDY DESIGN

1. Experimental conditions:

The soils were pre-incubated 7–14 days before application of the test substance at 45 % of their maximum water holding capacity and 20°C ± 2°C in the dark. Samples of 50 g soil (related to dry weight), except for biomass control, which contained 100 g soil, were adjusted to 45 % of their MWHC and incubated at 20°C ± 2°C in the dark in 250 mL flasks closed with cotton wool after application of fenpropidin at a concentration of 1.125 mg/kg (equivalent to 1.125 kg/ha). The test item solution was applied dropwise in a

0.1 mL solution (575 mg/L fenpropidin in acetone) to the soil surface and the incorporated by shaking the flasks. The control samples received the same amount of solvent. The soil moisture was adjusted weekly.

2. Sampling:

Duplicate soil samples were taken after 1 hour, 1, 3, 7, 14, 21, 30, 62, 90, 120, 126, 150, 181, 210 and 251 days and analysed for fenpropidin. The microbial biomass was determined in untreated soil samples 15 and 1 days prior to the beginning of the incubation period and 30, 122, 150, 181, 210 (soil 6S) and 251 days (soil 6S) after incubation (Anderson and Domsch, 1978). In treated soils, samples were taken at day 1, 30, 120, 150, 181, 210 (soil 6S) and 251 (soil 6S).

3. Description of analytical procedures:

Soil samples (dry weight) were extracted in a ratio of 1:4 (w/w) with a solution of methanol and a 25 % ammonia solution (ratio of 10:1; v/v) overnight on a flat bed shaker. The extraction was conducted immediately after sampling or after storage for a maximum of 18 days at 4 – 7°C in the dark. After sedimentation an aliquot was filtered through a 0.45 µm single use filter into a HPLC glass vial and diluted 1:10 with methanol/water/acetic acid (50:50:1, v/v/v). Fenpropidin was measured and quantified by HPLC/MS MS.

Validation of the analytical method: The method for determination of fenpropidin in soil was validated at two fortification levels with n = 5 replicates. The mean recovery of the parent compound from the silty sand 3A soil spiked at 0.05 mg/kg and 1.125 mg/kg dry soil was 87 % ± 4 % RSD (relative standard deviation) and 102 % ± 4 % RSD, respectively. Similarly, in the silty sand 5 M soil the mean recovery was found at 91 % ± 3 % RSD (0.05 mg/kg) and 100 % ± 3 % RSD (1.125 mg/kg dry). The recovery from the clay loam 6S soil was 89 % ± 3 % RSD at the low and 96 % ± 4 % RSD at the high concentration.

The limit of quantification (LOQ) was reported to be 2.5 µg/50 g dry soil.

Results and discussions

A. DATA:

Table A 2: Degradation of fenpropidin in soil extracts in % of nominal amount (mean of 2 replicates)

	percentage of initial deposit [%]														
days	0	1	3	7	14	21	30	62	90	120	126	150	181	210	251
3A	101.9	76.1	73.8	67.2	65.1	62.5	53.3	35.4	34.7	11.6	18.5	16.2	15.5	-	-
5M	104.2	81.2	78.8	78.1	58.4	52.0	52.1	31.1	24.4	14.8	-	11.6	4.8	-	-
6S	101.3	82.6	81.8	79.1	76.4	74.9	80.7	77.4	71.2	70.0	-	73.6	64.8	55.1	56.6

-: not measured

Table A 3: Microbial biomass development in three soils (Anderson and Domsch, 1978)

	Biomass, C [mg/100 g dry soil]								
Days	15	1	1	30	122	150	181	210	251
untreated soil									
3A	43.3	43.2	-	36.1	31.6	33.9	33.0	-	-
5M	24.9	24.4	-	21.3	17.6	15.1	15.1	-	-
6S	21.8	37.5	-	37.8	28.7	27.2	30.5	24.2	28.6
treated soil									
3A	-	-	41.7	38.7	29.1	31.4	33.6	-	-
5M	-	-	25.6	21.6	14.6	15.1	14.3	-	-
6S	-	-	44.8	38.1	26.9	29.1	26.6	23.8	25.8

-: not measured

B. MASS BALANCE:

As no volatile compounds were trapped and bound residues as well as metabolites were not analysed, a mass balance was not completed.

C. VOLATILISATION:

Volatile compounds were not analysed.

D. TRANSFORMATION OF PARENT COMPOUND:

The concentration of fenpropidin decreased steadily in the silty sand 5M soil from initial 104.2% of deposit to 52.1% after 30 days and further to 4.8% after termination of the incubation period of 181 days. Similarly, a rapid decline of the test item was observed in the silty sand 3A soil from 101.9% after 1 hour to 53.3 % after 30 days. Concentrations of 15.5 % of initial deposit were reached at test end (day 181). In the 6S clay loam soil a slower degradation occurred. Initial fenpropidin concentrations of 101.3 % decreased to 56.6 % after 251 days.

Results of soil 6S are not considered further for DT₅₀ calculation. This is justified by the fact that the DT₅₀ still was not fully reached at study end of 251 days. Moreover the slow degradation could perhaps have been caused by loss of microbiological activity of the soil over the long time period. Accordingly no appropriate fitting for this soil could be found.

The DT₅₀ and DT₉₀ values of fenpropidin were deduced by single 1st order kinetics, and are based on all samples. The model description provides a good fit to the data sets obtained for the two silty sand soils.

Table A 4: 1st order degradation rates of fenpropidin in two Speyer standard silty sand soils

Soil	DT ₅₀ [days]	DT ₅₀ , 95 % confidence limit [days]	DT ₉₀ [days]	DT ₉₀ , 95 % confidence limit [days]	coefficient of determination (r ²)
3A	56.8	47.5–70.1	188.7	157.7–232.8	0.9222
5M	41.0	34.3–51.0	136.2	114.0–169.3	0.9483

E. DEFICIENCIES:

The study was considered to be reliable without restrictions.

Conclusion

The aerobic degradation of fenpropidin in soil incubated at 45 % of the MWHC and 20°C ± 2°C in the dark was moderate in two silty sand soils and slow in a clay loam soil. SFO DT₅₀ values of 56.8 days (3A) and 41.0 days (5M) were derived, describing the degradation pattern appropriately. No accurate kinetic fit was found for the data basis determined for the clay loam soil. However, it can be estimated that the DT₅₀ was around 250 days with regard to the last sampling results. The biomass examinations lead to the conclusion that the reduction within the study period will not have affected the degradation pattern of fenpropidin.

Comments of zRMS:	<p>The study below was not necessary for purposes of the exposure assessment since sufficient data were available from the EU review of fenpropidin.</p> <p>The summary below was thus struck through and shaded.</p> <p>The study should be evaluated in the course of the ongoing EU renewal process.</p>
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Reference:	KCP 9.1.1.1/02
Report	Degradation of Fenpropidin in one soil under aerobic conditions at 20° C in the dark. Morlock, G., 2006b, Report No 20051244/02-CABJ, sponsor no. 00012950
Guideline(s):	Yes, OECD guideline 307
Deviations:	No
GLP:	Yes
Acceptability:	Not evaluated, new active substance data not necessary to finalise the exposure assessment

Materials and methods

A. MATERIALS

1. Test Material:

Fenpropidin

— Lot/Batch no.:0775-10371

— Purity: 97.8 %

— CAS no.: 67306-00-7
— Stability of test compound: June, 2007

Soils:

A Speyer 2.3 standard soil (silty sand) was used. The standard soil was sampled on October 25th, 2005 from agriculturally treated field site, where no pesticide had been applied within the last five years.

Table A 5: Soil physicochemical properties

origin and name	LUFÄ Speyer standard soil 2.3	
soil texture	silty sand	
clay1 [%]	6.0	
silt1 [%]	33.5	
sand1 [%]	60.4	
total organic carbon [%]	0.93	
pH (0.01 M CaCl ₂)	6.5	
CEC [mval/100g]	10.9	
MWHC [g/100g dry weight]	29.3	
Microbial biomass [mg C _{mic} /100 g dry soil]	Day 1	16.4
	Day 148	11.4

[†]: particle size distribution according to DIN 4220

B. STUDY DESIGN

1. Experimental conditions:

The soil was acclimated for 6 days prior to test item application at 45 % of its MWHC and 20°C ± 2°C in the dark. Samples of 50 g soil (related to dry weight), except for biomass control, which contained 100 g soil, were adjusted to 45 % of their MWHC and incubated at 20°C ± 2°C in the dark in 250 mL flasks closed with cotton wool after application of fenpropidin at a concentration of 1.125 mg/kg (equivalent to 1.125 kg/ha). The solution of fenpropidin was applied dropwise in a 0.1 mL solution (575 mg/L Fenpropidin in acetone) to the soil surface and the incorporated by shaking the flasks. The control samples received the same amount of solvent. The soil moisture was adjusted weekly.

2. Sampling:

Duplicate soil samples were taken after 1 hour, 1, 3, 7, 14, 21, 30, 62, 91, 120 and 148 days and analysed for fenpropidin. The microbial biomass was determined in untreated soil samples 4 and 1 days prior to the start of the study and 30, 120 and 148 days after incubation (Anderson and Domsch, 1978). In the treated assay, soil samples were analysed at day 1, 30, 120 and 148.

3. Description of analytical procedures:

Soil samples (dry weight) were extracted in a ratio of 1:4 (w/w) with a solution of methanol and a 25 % ammonia solution (ratio of 10:1; v/v) overnight on a flat bed shaker. The extraction was conducted immediately after sampling or after storage for a maximum of 20 days at 4–7°C in the dark. After sedimentation an aliquot was filtered through a 0.45 µm single use filter into a HPLC glass vial and diluted 1:10 with methanol/water/acetic acid (50:50:1, v/v/v). Fenpropidin was measured and quantified by HPLC/MS-MS.

Validation of the analytical method: The method for determination of fenpropidin in soil was validated at two fortification levels with n = 5 replicates. The mean recovery of the parent compound from the silty sand soil was 101 % ± 1 % RSD at 0.05 mg/kg and 99 % ± 2 % RSD at 1.125 mg/kg dry soil.

The limit of quantification (LOQ) was reported to be 2.5 µg/50 g dry soil.

Results and discussions

A. DATA:

Table A 6: Degradation of fenpropidin in LUFA Speyer 2.2 soil extracts in % of nominal amount (mean of 2 replicates)

	percentage of initial deposit [%]										
Days	0	1	3	7	14	21	30	62	91	120	148
2.2	97.2	94.0	105.2	91.0	84.9	80.9	78.3	67.5	56.5	42.3	37.3

–: not measured

Table A 7: Microbial biomass development in LUFA Speyer 2.2 soil (Anderson and Domsch, 1978)

	Biomass, C [mg/100 g dry soil]					
Days	4	1	1	30	120	148
untreated soil	13.0	16.4	–	13.1	13.0	11.6
treated soil	–	–	15.5	13.8	12.4	11.4

–: not measured

B. MASS BALANCE:

As no volatile compounds were trapped and bound residues as well as metabolites were not analysed, a mass balance was not completed.

C. VOLATILISATION:

Volatile compounds were not analysed.

D. TRANSFORMATION OF PARENT COMPOUND:

The concentrations of fenpropidin in the silty sand soil declined from initial 97.2 % of deposit to 56.5 % after 91 days and to 37.3 % after 148 days (test end).

The determination of DT₅₀ and DT₉₀ values of fenpropidin was described best by single 1st-order kinetics and based on all samples. The model description provides a good fit to the data set.

Table A 8: 1st-order degradation rates of fenpropidin in the Speyer 2.2 standard silty sand soil

Soil	DT ₅₀ [days]	DT ₅₀ , 95 % confidence limit [days]	DT ₉₀ [days]	DT ₉₀ , 95 % confidence limit [days]	coefficient of determination (r ²)
2.2	106.5	95.1–121.0	353.7	315.9–401.8	0.9580

E. DEFICIENCIES:

The study was considered to be reliable without restrictions.

Conclusion

The determination of an aerobic soil degradation rate for fenpropidin in a silty sand soil, incubated at 45 % of the MWHC and 20°C ± 2°C in the dark, yielded in a moderate and reliable SFO DT₅₀ value of 106.5 days. The biomass examinations lead to the conclusion that the reduction within the study period will not have affected the degradation pattern of fenpropidin.

A 2.3 Flörchinger M. (2008)

Comments of zRMS:	<p>The study below was not necessary for purposes of the exposure assessment since sufficient data were available from the EU review of fenpropidin.</p> <p>The summary below was thus struck through and shaded.</p> <p>The study should be evaluated in the course of the ongoing EU renewal process.</p>
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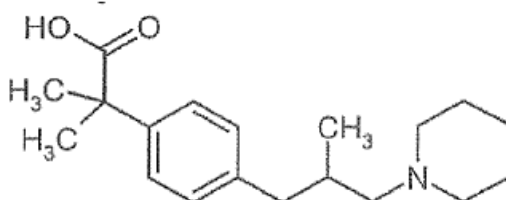
Reference:	KCP 9.1.1.1/03
Report	Degradation of Fenpropidin Acid in 3 Different Soils under Aerobic Conditions at 20°C in the Dark, Flörchinger M., 2008, Report No.S08-01156, sponsor no. 00016350
Guideline(s):	OECD 307
Deviations:	The recovery was slightly below the lower limit of 90 % at one sampling date, i.e. 85.8 % at day 217
GLP:	Yes
Acceptability:	Not evaluated, new active substance data not necessary to finalise the exposure assessment

Materials and methods

A. Materials

1. Test Material:

Non-radiolabelled fenpropidin acid (CGA 289267)



— Lot/Batch #:

FC 2351

— Specific activity:

Not applicable

— Purity:

91.1%

— Stability of test compound:

Determined in study

— Application vehicle:

Acetonitrile

2. Soils:

Three fresh agricultural soils were used for the study.
The soils were chosen to represent a range of soil textures and pH.

Soil physicochemical properties

Name	LUFA 2.2 F2.21308	LUFA 2.3 F221308	LUFA 5M F5M1308
Date of collection	27 March 2008	27 March 2008	27 March 2008
Storage conditions	Overlaid with turf at testing facility on the 11 April 2008	Overlaid with turf at testing facility on the 11 April 2008	Overlaid with turf at testing facility on the 11 April 2008
Particle size (% w/w):			
Clay (<2 µm)	7	9.9	11.7
Silt (50-2 µm)	12.4	31.2	31.1
Sand (2000-50 µm)	80.6	58.9	57.2
Texture (USDA)	Loamy sand	Sandy loam	Sandy loam
pH (0.01M CaCl ₂)	5.80	7.00	7.26
Organic carbon (%)	1.99	1.35	1.35
CEC (mval/100g)	8.88	13.00	24.63
Maximum water holding capacity (%)	42.4	35.0	40.9
Soil density (g/L)	1244	1285	1263
Biomass of untreated samples (mg C/100 g)			
— Initial (start of study)	18.8	15.4	19.6
— Day 29	19.3	14.6	18.6

Final (end of study)	17.9	14.3	14.0
Biomass of treated samples (mg C/100 g)			
Initial (start of study)	20.5	17.4	21.0
Day 29	20.7	15.7	18.6
Final (end of study)	17.9	14.3	15.4

B. Study Design

Experimental design

Parameter		Description
Duration of the test		118 days
Soil condition		Fresh soil
Soil sample weight		50 g (dry weight) per replicate
Test concentration	Actual	0.02 mg a.s. / 50 g soil (0.4 mg/kg)
Control conditions		As for test samples except untreated
Number of replicates		2
Test apparatus		300 mL glass flasks plugged with cotton wool
Traps for CO ₂ & organic volatiles		None
Test material application	Identity of solvent	Water/acetone (80:20 v/v)
	Volume of test solution used/treatment	100 µL
	Application method	Not stated
	Evaporation of application solvent	No, soils mixed thoroughly after treatment
Indication of test material adsorbing to walls of test apparatus		No
Experimental conditions	Temperature (°C)	20±2
	Moisture content	45% of the maximum water holding capacity
	Moisture maintenance method	Vessels weighed weekly and any weight loss relative to Day 0 attributed to water loss. Water added to restore original system.
	Continuous darkness (Yes/No):	Yes

Sampling

Parameter		Description
Sampling intervals	Aerobic, non-sterile	Duplicate samples from each soil type: Zero, 1, 3, 7, 14, 21, 29, 58, 90 and 118 DAT
	Untreated soils for biomass	Zero, 29 and 118 DAT
Soil sampling procedures		Complete treated samples were removed at each sampling time and extracted as detailed below.
Collection of CO ₂ and volatile organics		Not applicable.

Description of analytical procedures

Each soil sample was extracted as follows:

Water (50g) was added to the flask containing the soil sample followed by acetonitrile (50 mL).

Flasks were stoppered and shaken overnight at 150 rpm at 20°C in the dark.

The soil solvent mixture was allowed to precipitate.

An aliquot of each supernatant was diluted 1:10 in matrix and analysed by LC-MS/MS.

At each time point, an untreated sample of each soil was fortified with a defined amount of test item. These samples were extracted and analysed alongside, and in the same manner, as the incubated samples.

Identification of CGA 289267 in the soil extracts was by LC-MS/MS. Three Multiple Reaction Monitoring (MRM) transitions were monitored to confirm the selectivity of the method (172.6 > 173.6, 176.5 > 177.5 and 257.7 > 258.7). For each analytical run, a calibration curve using standards of known concentration was used to quantify the extracts. The LOQ for the method used in this study was 1.0 µg.

Results

Analytical Methodology

The analytical method was validated according to SANCO/3029/99-REV.4 and was shown to be valid in

terms of linearity, accuracy, precision and specificity. The results are presented in the following table.

Table A 9: Validation of the analytical method

CGA 289267 (Fenpropidin Acid)				
Fortification level	No of Fortifications	Recovery (%)	Mean Recovery (%)	RSD (%)
Soil LUFA 2.2				
0.4	5	104, 103, 94, 95, 106	100	6
0.02	5	99, 101, 101, 99, 82	96	8
Soil LUFA 2.3				
0.4	5	94, 96, 93, 92, 98	95	2
0.02	5	88, 78, 85, 96, 84	86	8
Soil LUFA 5M				
0.4	5	100, 87, 95, 72, 85	88	12
0.02	5	89, 92, 100, 91, 102	95	6

The detector response was linear over the concentration range determined with a correlation coefficient of > 0.99 . The absence of interferences was demonstrated by injecting extracts from the untreated control samples prepared from each soil during the method validation. No interference peak at or above 30% of the quantification limit was observed at the retention time of fenpropidin acid in any control sample.

CGA 289267 (Fenpropidin Acid) Concentrations

The concentration of CGA 289267 in the soil extracts dissipated steadily in all three soils. The amount in soil extracts declined from around 20 µg at time zero to approximately 2 µg in the LUFA 2.2 soil by 118 days, similarly the concentration in both the LUFA 2.3 soil and LUFA 5M soil declined from around 20 µg at time zero to $< \text{LOQ}$ (1 µg) by 118 days. The quantities extracted from each soil with time are shown in detail in:

The degradation rate (DegT50) was determined assuming a simple first order model. The dissipation time DT_{50} (50% of the test item is degraded) and DT_{90} (90 % of the test item is degraded) values along with the lower and upper 95% confidence limits were derived from the regression curve. The results are presented in the following tables:

Table A 10: Quantity of CGA 289267 in LUFA 2.2, LUFA 2.3 and LUFA 5M soils with time

Time (days)	LUFA 2.2		LUFA 2.3		LUFA 5M	
	CGA 289267 (µg)	% of applied	CGA 289267 (µg)	% of applied	CGA 289267 (µg)	% of applied
0	21.08	105.4	21.36	106.8	21.89	109.5
0	20.87	104.4	19.62	98.1	18.15	90.8
1 [±]	23.79 [±]	119.0	19.06	95.3	17.77	88.9
1 [±]	22.70 [±]	113.5	17.82	89.1	17.33	86.7
3	21.21	106.1	16.29	81.5	23.94	119.7 [±]
3	20.32	101.6	16.66	83.3	22.08	110.4 [±]
7	16.69	83.5	17.45	87.3 [±]	13.04	65.2
7	17.64	88.2	17.80	89.0 [±]	13.54	67.7
14	16.72	83.6	10.81	54.1	12.48	62.4
14	17.47	87.4	12.28	61.4	11.61	58.1
21	13.87	69.4	9.70	48.5	7.39	37.0
21	15.53	72.7	9.63	48.2	8.26	41.3
29	12.30	61.5	6.69	33.5	2.82	14.1
29	11.74	58.7	6.65	33.3	8.26	41.3
58	6.13	30.7	1.83	9.2	0.58	2.9 [±]
58	8.16	40.8	3.27	16.4	1.01	5.1
90	3.70	18.5	0.50	2.5 [±]	0.66	3.3 [±]
90	4.41	22.1	0.83	4.2 [±]	1.10	5.5
118	1.62	8.1	0.00	0.0 [±]	0.49	2.5 [±]
118	2.39	12.0	0.00	0.0 [±]	0.40	2.0

*Intervals not used for evaluation (outlier or below LOQ ($< 1.0 \mu\text{g}$)).

Table A 11: DT₅₀ and DT₉₀ values for CGA 289267 in 3 European soils

Soil	LUF A 2.2	LUF A 2.3	LUF A 5M
DT ₅₀ [days]	37 (33–41)	19 (17–22)	17 (13–22)
DT ₉₀ [days]	122 (111–136)	64 (57–73)	56 (45–73)
R ²	0.986	0.982	0.942

(Numbers in parentheses are the 95% confidence limits)

CGA 289267 (fenpropidin acid) degraded steadily in all three soils at 20 °C, with a DT₅₀ values of between of 17 and 37 days.

A 2.3 KCP 9.2.4 Predicted Environmental Concentrations in groundwater (PEC_{GW})

Comments of zRMS:	Groundwater modelling performed by the Applicant was agreed by the zRMS. For details, please refer to point 8.8 of this document.
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Reference:	KCP 9.2.4/01
Report	Predicted environmental concentrations in groundwater (PEC _{gw}) of prothioconazole, fenpropidin and its metabolites using FOCUS PELMO 5.5.3, FOCUS PEARL 4.4.4 and FOCUS MACRO 5.5.4 for critical GAP uses in the Central zone. Penne, C. (2021), Report no.: ADM-210621-01, sponsor no. 000108619
Guideline(s):	Generic Guidance for Tier 1 FOCUS Ground Water Assessments, Version 2.2, May 2014 “Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU” Report of the FOCUS Ground Water Work Group, EC Document Reference Sanco/13144/2010 Version 1, June 2009, 604 pp. Working Document of the Central Zone in the Authorisation of Plant Protection Products - Section 8 Environmental Fate and Behaviour, Version 1.1, June 2018
Deviations:	None
GLP:	No (not applicable)
Acceptability:	Acceptable

In this report predicted environmental concentrations in groundwater (PEC_{gw}) of the active substances prothioconazole and fenpropidin and its metabolites JAU-desthio, JAU-S-methyl and CGA 289267 are presented for the critical GAP uses in cereals.

Tier 1 PEC_{gw} were calculated for worst-case application patterns using the models FOCUS PELMO 5.5.3, FOCUS PEARL 4.4.4 and FOCUS MACRO 5.5.4.

PEC_{gw} of all substances in all FOCUS models and all scenarios resulted in 80th percentile annual average PEC_{gw} below the drinking water trigger of 0.1 µg/L at 1 m depth. Thus, none of the compounds leached to groundwater to any environmentally hazardous extent and no toxicological risks are indicated.

A 2.4 KCP 9.2.5 Predicted Environmental Concentrations in surface water (PEC_{sw})

Comments of zRMS:	Surface water modelling performed by the Applicant was in general agreed by the zRMS with some minor amendments. For details, please refer to point 8.9 of this document.
Reference:	KCP 9.2.5/01
Report	Predicted environmental concentrations in surface water (PEC _{sw}) and sediment (PEC _{sed}) of prothioconazole, fenpropidin and metabolites using STEPS 1-2 in FOCUS (v3.2), FOCUS SWASH 5.3 and SWAN v5.0 for critical GAP uses in the Central zone. Penne, C. (2021), Report no.: ADM-210621-02, sponsor no. 000108620
Guideline(s):	Generic Guidance for FOCUS Surface Water Scenarios, Version 1.4, May 2015 “FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC”. Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2. 245 pp Working Document of the Central Zone in the Authorisation of Plant Protection Products - Section 8 Environmental Fate and Behaviour, Version 1.1, June 2018
Deviations:	None
GLP:	No (not applicable)
Acceptability:	Partially acceptable (for details, please refer to point 8.9 of this report)

In this report predicted environmental concentrations in surface water (PEC_{sw}) and sediment (PEC_{sed}) of the active substances prothioconazole and fenpropidin and its metabolites JAU-desthio, JAU-S-methyl, 1,2,4-triazole and CGA 289267 are presented for the critical GAP uses in cereals.

PEC_{sw} and PEC_{swd} were calculated for worst-case application patterns using the models STEPS 1-2 in FOCUS (v3.2), FOCUS SWASH 5.3 and SWAN v5.0. PEC_{sw} and PEC_{sed} for the active substance prothioconazole were calculated up to FOCUS Step 3. Spray drift was the main entry route at Step 3.

For the metabolite JAU-desthio and the active substance fenpropidin PEC_{sw} and PEC_{sed} calculations were calculated up to FOCUS Step 4. Run-off and spray drift were the main entry routes, that can be reduced to an acceptable level with non spraying buffer zones and/or vegetative filter strips of 10m at Step 4.

For the metabolites CGA 289267, JAU-S-methyl and 1,2,4-triazole PEC_{sw} and PEC_{sed} calculations were calculated only up to FOCUS Step 2.

Modelling was sufficient to achieve PEC_{sw} and PEC_{sed} levels acceptable for the eco-toxicological risk assessment.