REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: GF-3307

Product name(s): Not yet defined

Chemical active substance(s):

Fenpicoxamid (XDE-777), 50 g/L

Prothioconazole, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Corteva Agriscience

Submission date: July 2021, updated January 2022, May 2022

MS Finalisation date: October 2022 (initial Core Assessment)

January 2023 (final Core Assessment)

Version History

When	What
July 2021	New submission of GF-3307 in the Central Zone.
December 2021	Austria removed from cMS, GAP table updated with 1 use = 1 crop + 1 disease
May 2022	Efate and ecotox updates as requested for GF-3307 dossier
August 2022	Initial assessment by the zRMS The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through and shaded for transparency~~. Following the evaluation and before sending the document for commenting, all coloured highlighting was removed, from the parts updated by the Applicant, for better legibility.
January 2023	Final report (Core Assessment updated following the commenting period). No additional information or assessments after the commenting period.

Table of Contents

8 Fate and behaviour in the environment (KCP 9)

This document reviews the environmental fate summary and exposure calculations for the plant protection product GF-3307, a formulation containing fenpicoxamid (50 g as/L) and prothioconazole (100 g as/L).

8.1 Critical GAP and overall conclusions

Table 8.1-1: Critical use pattern of the formulated product GF-3307 concerning environmental fate

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No.*	Member state(s)	Crop &/or situation	F, Fn, Fpn G, Gn, Gpn or I**	Pests or goup of pests controlled	**Application**				**Application rate**			PHI ***	Remarks	**Conclusion**
					Method/ kind	Timing/growth stage of crop & season	Max. number a) per use b) per crop/season	Min. interval between appn. (d)	L FP/ha a) max. rate per appn. b) max. total rate per crop/season	g as/ha a) max. rate per appn. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1-68, 69-83	CZ, PL, RO, SK	Winter cereals	F	Various diseases	Tractor mounted spray	BBCH 30-69 (spring appn.)	1	-	1.5	75 + 150 (FPX + PTZ)	100-300	F	-	A
84-117, 118-132		Spring cereals	F	Various diseases	Tractor mounted spray	BBCH 30-69 (spring appn.)	1	-	1.5	75 + 150 (FPX + PTZ)	100-300	F		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

*** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

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 fenpicoxamid (FPX) concerning environmental fate

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No.*	Member state(s)	Crop &/or situation	F, Fn, Fpn G, Gn, Gpn or I**	Pests or group of pests controlled	Application				Application rate			PHI (d)	Remarks
					Method/ kind	Timing/growth stage of crop & season	Max. number a) per use b) per crop/season	Min. interval between appn. (d)	L FP/ha a) max. rate per appn. b) max. total rate per crop/season	g as/ha a) max. rate per appn. b) max. total rate per crop/season	Water L/ha min/max		
-	EU	Winter cereals	F	Septoria tritici	Tractor mounted spray	BBCH 25-69 (spring appn.)	2	14	a) 1 b) 2	a) 130 b) 260	100-300	NA	1 April selected to reflect spring appn.
-	EU	Spring cereals	F	Septoria tritici	Tractor mounted spray	BBCH 25-69 (spring appn.)	2	14	a) 1 b) 2	a) 130 b) 260	100-300	NA	1 April selected to reflect spring appn.

* **Representative uses assessed at EU level are more critical than the ones requested in the current application for GF-3307**

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

Table 8.1-3: Assessed (critical) uses during approval of prothioconazole (PTZ) concerning environmental fate

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No.*	Member state(s)	Crop &/or situation	F, Fn, Fpn G, Gn, Gpn or I**	Pests or group of pests controlled	Application				Application rate			PHI (d)	Remarks
					Method/kind	Timing/ growth stage of crop & season	Max. number a) per use b) per crop/season	Min. interval between appn. (d)	L FP/ha a) max. rate per appn. b) max. total rate per crop/season	g as/ha a) max. rate per appn. b) max. total rate per crop/season	Water L/ha min/max		
-	EU	Wheat, rye, triticale	F	Rusts, eyespot, fusarium spp, powd. mildew, rhynchospor, septoria	Tractor mounted spray	BBCH 26-69	1-3	14-21		200	200-400	35	
-	EU	Barley, oat	F	Rusts, eyespot, pyren. teres, powd. mildew, rhynchospor	Tractor mounted spray	BBCH 30-61	1-2	14-21		200	200-400	35	
-	EU	Rape	F	Sclerotinia, botrytis, alternaria, leptosphaeria	Tractor mounted spray	BBCH 53 onwards	1-2	14-28		175	200-400	56	
-	EU	Wheat, rye,	F	Fusarium spp, bunt,	Seed	Pre-sowing	1	NA		9-18	200-400	NA	

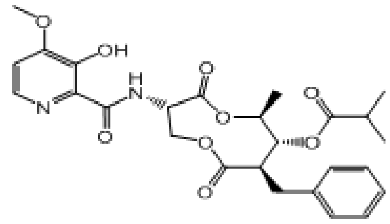
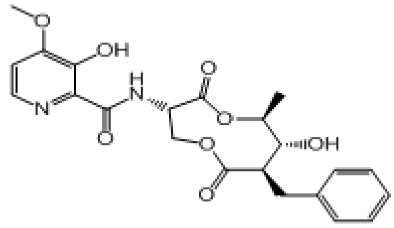
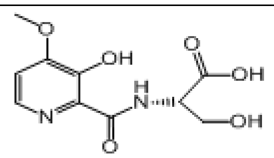
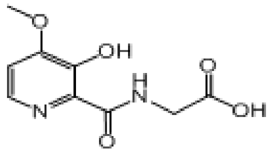
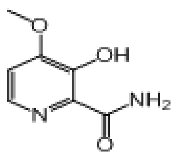
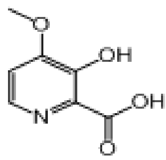
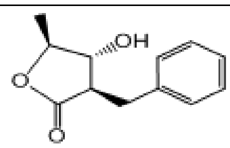
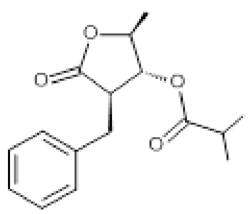
		triticale, oat, barley		smut	treatment					(180 kg seed/ha)			

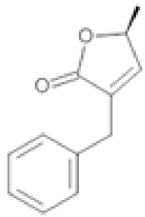
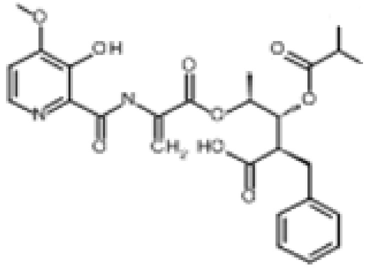
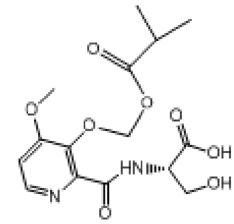
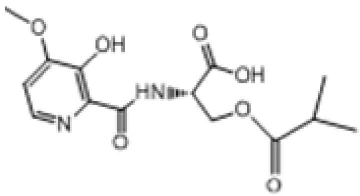
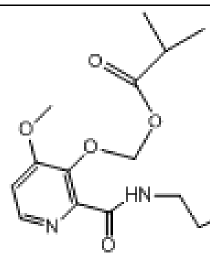
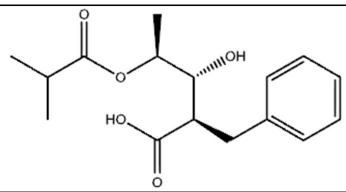
* **Representative uses assessed at EU level are more critical than the ones requested in the current application for GF-3307**

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

8.2 Metabolites considered in the assessment

Table 8.2-1: Major (>5% AR) metabolites of fenpicoxamid (FPX) triggered for exposure assessment

Metabolite	Molar mass (g/mol)	Chemical structure	Maximum observed occurrence (% AR) in compartments*	Exposure assessment
X642188	514.2		Aerobic soil, 39.2% Water/sediment, 19.5%	PECsoil PECgw PECsw PECsed
X696872	444.2		Aerobic soil, 17.2%	PECsoil PECgw PECsw PECsed
X12264475	256.1		Anaerobic soil, 49.4% Water/sediment, 65.3%	PECsoil PECgw PECsw PECsed
X763024	226.1		Aerobic soil, 5.7%	PECsoil PECgw PECsw PECsed
X12313581	168.0		Field soil, 17.1% (10.1% lab) Aerobic mineralisation, 66.1% Water/sediment, 9.3%	PECsoil PECgw PECsw PECsed
X696476	169.0		Anaerobic soil, 46.9% Water/sediment, 67.1%	PECsoil PECgw PECsw PECsed
X11963422	206.1		Anaerobic soil, 80.3% Water/sediment, 45.0%	PECsoil PECgw PECsw PECsed
X12314005	276.3		Soil photolysis (irrad.), 5.4% Aq. photolysis (irrad.), 61.6% Water/sediment, 35.1%	PECsoil PECgw PECsw PECsed

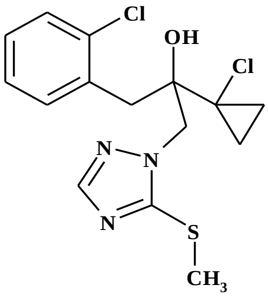
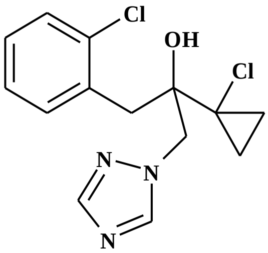
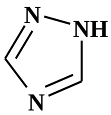
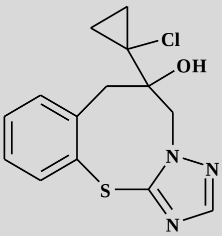
Metabolite	Molar mass (g/mol)	Chemical structure	Maximum observed occurrence (% AR) in compartments*	Exposure assessment
X12019520	188.2		Soil photolysis (irrad.), 9.8% Aerobic mineralisation, 74.0% Water/sediment, 15.3%	PECsoil PECgw PECsw PECsed
X12255349	514.5		Soil photolysis (irrad.), 6.9%	PECsoil PECgw PECsw PECsed
X12335723	356		Aq. photolysis (irrad.), 77.0% Water/sediment, 45.9%	PECsw PECsed
X12386481	326		Aerobic mineralisation, 69.5%	PECsw (water column only)
X12446477	312		Aq. photolysis (irrad.), 12.5%	PECsw (water column only)
X12433979	294		Hydrolysis (pH 9), 35.7%	PECsw (water column only)

* Values relate to **maximum** seen in any individual replicate

zRMS comments:

Information regarding fenpicoxamid metabolites is in line with EU agreed endpoints reported in EFSA Journal 2018;16(1):5145.

Table 8.2-2: Major (>5% AR) metabolites of prothioconazole (PTZ) triggered for exposure assessment

Metabolite	Molar mass (g/mol)	Chemical structure	Maximum observed occurrence (% AR) in compartments	Exposure assessment required due to
JAU 6476-S-methyl (M01)	358.3		Soil, 14.6% Water/sediment, 12.7%	PECsoil PECgw PECsw PECsed
JAU 6476-desthio (M04)	312.2		Soil, 57.1% Water/sediment, 54.4%	PECsoil PECgw PECsw PECsed
1,2,4-triazole (M13)	69.1		Water/sediment, 41.8%	PECsw PECsed
JAU 6476-thiazocine (prothioconazole-thiazocine, M12)	307.8		Aqueous photolysis study: 14.1% on day 5	Considered not relevant in EFSA (2007)

zRMS comments:

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

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

8.3 Rate of degradation in soil (KCP 9.1.1)

Studies on the laboratory degradation rate in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. A summary of the data is given below.

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

Fenpicoxamid

Persistence endpoints

The following tables show persistence endpoints (DT_{50} and DT_{90} given by kinetic model described in the table) derived (where possible) from laboratory studies.

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

Fenpicoxamid	**Dark aerobic conditions, parent applied study**							
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**T(°C)/ MWHC (%)**	**Persistence**				**Evaluated at EU level**
				DT_{50} (d)	**DT_{90} (d)**	**Chi^2 (%)**	**Kinetic model**	
RefSol 03-G	Sandy loam	6.2	20/75.9	1.4	24.9	4.4	DFOP	Yes *(EFSA, 2018)*
Farditch Farm	Silt loam	5.7	20/67.4	1.9	33.1	3.8	DFOP	
Woodside Farm	Clay loam	7.3	20/80.3	0.8	8.6	6.9	DFOP	
Hareby House	Clay	7.6	20/57.6	1.2	8.3	4.7	DFOP	
Geometric mean (n=4)				1.3				
pH dependence				No				

Table 8.3-2: Summary of aerobic degradation rates for X642188 - laboratory studies

X642188	**Dark aerobic conditions, parent applied study**								
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**T(°C)/ MWHC (%)**	**Persistence**					**Evaluated at EU level**
				DT_{50} (d)	**DT_{90} (d)**	**ff**	**Chi^2 (%)**	**Kinetic model**	
Not derived. See field dissipation study.									Yes *(EFSA, 2018)*

Table 8.3-3: Summary of aerobic degradation rates for X696872 - laboratory studies

X696872	**Dark aerobic conditions, parent applied study, top-down fit from peak**								
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**T(°C)/ MWHC (%)**	**Persistence**					**Evaluated at EU level**
				DT_{50} (d)	**DT_{90} (d)**	**ff**	**Chi^2 (%)**	**Kinetic model**	
RefSol 03-G	Sandy loam	6.2	20/75.9	18.9	119	1	5.6	DFOP	Yes *(EFSA, 2018)*
Farditch Farm	Silt loam	5.7	20/67.4	14.0	197	1	8.6	FOMC	
Woodside Farm	Clay loam	7.3	20/80.3	5.5	46.3	1	3.3	DFOP	
Hareby House	Clay	7.6	20/57.6	7.3	24.3	1	10.7	SFO	
Geometric mean (n=4)				10.2					
Arithmetic mean (n=4)						1			
pH dependence				No					

Table 8.3-4: Summary of aerobic degradation rates for X12264475 – laboratory studies (metabolite applied)

X12264475	**Dark aerobic conditions, metabolite applied study**								
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**T(°C)/ MWHC (%)**	**Persistence**					**Evaluated at EU level**
				DT_{50} (d)	**DT_{90} (d)**	**ff**	**Chi^2 (%)**	**Kinetic model**	
RefSol 03-G	Sandy loam	6.2	20/75.9	0.64	5.5	1	1.6	FOMC	Yes *(EFSA, 2018)*
Farditch Farm	Silt loam	5.7	20/67.4	2.0	10.0	1	3.4	DFOP	
Woodside Farm	Clay loam	7.3	20/80.3	0.86	4.4	1	1.7	FOMC	
Hareby House	Clay	7.6	20/57.6	1.8	12.4	1	6.6	DFOP	
Geometric mean (n=4)				1.2					
Arithmetic mean (n=4)						1			
pH dependence				No					

Table 8.3-5: Summary of aerobic degradation rates for X763024 - laboratory studies (metabolite applied)

X763024	**Dark aerobic conditions, metabolite applied study**								
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**T(°C)/ MWHC (%)**	**Persistence**					**Evaluated at EU level**
				DT_{50} (d)	**DT_{90} (d)**	**ff**	**Chi^2 (%)**	**Kinetic model**	
RefSol 03-G	Clay loam	6.2	20/75.9	21.6	71.9	1	12.3	SFO	Yes *(EFSA, 2018)*
Farditch Farm	Loam	5.7	20/67.4	5.6	144	1	8.0	DFOP	
Woodside Farm	Clay loam	7.3	20/80.3	8.3	52.1	1	8.9	DFOP	
Hareby House	Clay	7.6	20/57.6	20.8	69.2	1	14.1	SFO	
Geometric mean (n=4)				12.0					
Arithmetic mean (n=4)						1			
pH dependence				No					

Table 8.3-6: Summary of aerobic degradation rates for X12313581 - laboratory studies (metabolite applied)

X12313581	**Dark aerobic conditions, metabolite ~~parent~~ applied study, top-down fit from peak**								
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**T(°C)/ MWHC (%)**	**Persistence**					**Evaluated at EU level**
				DT_{50} (d)	**DT_{90} (d)**	**ff**	**Chi^2 (%)**	**Kinetic model**	
RefSol 03-G	Sandy loam	6.2	20/75.9	9.0	42.2	1	6.7	DFOP	Yes *(EFSA, 2018)*
Farditch Farm	Silt loam	5.7	20/67.4	8.9	63.6	1	17.0	DFOP	
Woodside Farm	Clay loam	7.3	20/80.3	10.1	68.5	1	14.8	DFOP	
Hareby House	Clay	7.6	20/57.6	23.7	111	1	6.0	FOMC	
Geometric mean (n=4)				11.8					
Arithmetic mean (n=4)						1			
pH dependence				No					

Table 8.3-7: Summary of aerobic degradation rates for X696476 – laboratory studies (parent and metabolite applied)

X696476	Dark aerobic conditions, parent and metabolite applied studies								
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**T(°C)/ MWHC (%)**	**Persistence**					**Evaluated at EU level**
				DT_{50} (d)	**DT_{90} (d)**	**ff**	**Chi^2 (%)**	**Kinetic model**	
No degradation of this metabolite in any soil and so no DT_{50} value derived; conservative value will be selected in the exposure assessment.									Yes *(EFSA, 2018)*

Table 8.3-8: Summary of aerobic degradation rates for X11963422 – laboratory studies (metabolite applied)

X11963422	Dark aerobic conditions, metabolite applied study								
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**T(°C)/ MWHC (%)**	**Persistence**					**Evaluated at EU level**
				DT_{50} (d)	**DT_{90} (d)**	**ff**	**Chi^2 (%)**	**Kinetic model**	
RefSol 03-G	Clay loam	5.9	20/80.3	1.4	4.8	1	5.2	SFO	Yes *(EFSA, 2018)*
Brierlow	Silt loam	5.7	20/67.4	5.0	16.5	1	8.3	SFO	
Woodside Farm	Clay loam	7.4	20/75.9	0.12	4.9	1	5.9	DFOP	
Hareby House	Clay	7.9	20/57.6	0.13	1.5	1	5.3	DFOP	
Geometric mean (n=4)				0.57					
Arithmetic mean (n=4)						1			
pH dependence				No					

Soil photoproducts of fenpicoxamid (detected in soil photolysis study with further investigation of their degradation carried out in standard OECD 307 laboratory study under dark conditions)

Table 8.3-9: Summary of aerobic degradation rates for X12314005 – laboratory studies (metabolite applied)

X12314005	Dark aerobic conditions, metabolite applied study								
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**T(°C)/ MWHC (%)**	**Persistence**					**Evaluated at EU level**
				DT_{50} (d)	**DT_{90} (d)**	**ff**	**Chi^2 (%)**	**Kinetic model**	
RefSol 03-G	Sandy Loam	5.6	20/50	0.02	0.22	1	2.8	FOMC	Yes *(EFSA, 2018)*
Brierlow	Silt loam	5.3	20/50	0.07	0.63	1	3.5	FOMC	
Woodside Farm	Clay Loam	7.2	20/50	0.004	0.07	1	2.2	FOMC	
Hareby House	Clay	7.6	20/50	0.01	0.13	1	2.5	FOMC	
Geometric mean (n=4)				0.02					
Arithmetic mean (n=4)						1			
pH dependence				No					

Table 8.3-10: Summary of aerobic degradation rates for X12019520 – laboratory studies (metabolite applied)

X12019520	**Dark aerobic conditions, metabolite applied study**								
Soil	**Soil type (USDA)**	**pH (CaCl$_2$)**	**T(°C)/ MWHC (%)**	**Persistence**					**Evaluated at EU level**
				DT$_{50}$ (d)	**DT$_{90}$ (d)**	**ff**	**Chi^2 (%)**	**Kinetic model**	
RefSol 03-G	Sandy Loam	5.6	20/50	5.0 ~~4.0~~	13.1	1	8.0	SFO	Yes *(EFSA, 2018)*
Brierlow	Silt loam	5.3	20/50	6.3	21	1	10.9	SFO	
Woodside Farm	Clay Loam	7.2	20/50	1.8	5.9	1	10.6	SFO	
Hareby House	Clay	7.6	20/50	2.0	6.7	1	5.4	SFO	
Geometric mean (n=4)				3.1					
Arithmetic mean (n=4)						1			
pH dependence				No					

Table 8.3-11: Summary of aerobic degradation rates for X12255349 –laboratory studies (metabolite applied)

X12255349	**Dark aerobic conditions, metabolite applied study**								
Soil	**Soil type (USDA)**	**pH (CaCl$_2$)**	**T(°C)/ MWHC (%)**	**Persistence**					**Evaluated at EU level**
				DT$_{50}$ (d)	**DT$_{90}$ (d)**	**ff**	**Chi^2 (%)**	**Kinetic model**	
RefSol 03-G	Sandy Loam	5.6	20/50	2.4	16.9	1	1.7	DFOP	Yes *(EFSA, 2018)*
Brierlow	Silt loam	5.3	20/50	1.3	8.6	1	3.3	DFOP	
Woodside Farm	Clay Loam	7.2	20/50	2.3	7.5	1	5.8	SFO	
Hareby House	Clay	7.6	20/50	4.4	14.4	1	14.3	SFO	
Geometric mean (n=4)				2.4					
Arithmetic mean (n=4)						1			
pH dependence				No					

Modelling endpoints

The following tables show modelling endpoints (DT$_{50}$ from SFO, or "SFO-like" i.e. FOMC DT$_{90}$/3.32 or DFOP k2) derived (where possible) from laboratory studies. The DT$_{90}$ is not shown since this is not a modelling endpoint.

Table 8.3-12: Summary of aerobic degradation rates for fenpicoxamid - laboratory studies

Fenpicoxamid	**Dark aerobic conditions, parent applied study**						
Soil	**Soil type (USDA)**	**pH (CaCl$_2$)**	**T(°C)/ MWHC (%)**	**Modelling (20°C/pF2)**			**Evaluated at EU level**
				DT$_{50}$ (d)	**Chi^2 (%)**	**Kinetic model**	
RefSol 03-G	Sandy loam	5.6	20/75.9	4.6	6.8	FOMC	Yes *(EFSA, 2018)*
Farditch Farm	Silt loam	5.7	20/67.4	6.0	6.0	FOMC	
Woodside Farm	Clay loam	7.2	20/80.3	2.0	5.2	FOMC	
Hareby House	Clay	7.7	20/57.6	2.7	5.6	FOMC	
Geometric mean (n=4)				3.5			
pH dependence				No			

Table 8.3-13: Summary of aerobic degradation rates for X642188 - laboratory studies

X642188	**Dark aerobic conditions, parent applied study, top-down fit from peak**							
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**T(°C)/ MWHC (%)**	**Modelling (20°C/pF2)**				**Evaluated at EU level**
				DT_{50} (d)	**ff***	**Chi^2 (%)**	**Kinetic model**	
RefSol 03-G	Sandy loam	5.6	20/75.9	29.3	0.6	4.1	FOMC	Yes *(EFSA, 2018)*
Farditch Farm	Silt loam	5.7	20/67.4	19.7	0.6	2.9	FOMC	
Woodside Farm	Clay loam	7.2	20/80.3	7.7	0.6	5.9	FOMC	
Hareby House	Clay	7.7	20/57.6	227	0.6	3.6	DFOP	
Geometric mean (n=4)				31.7**				
Arithmetic mean (n=4)					0.6			
pH dependence				No				

* Determined via inverse modelling
** Given as 31.9 d by EFSA, but this is incorrect

Table 8.3-14: Summary of aerobic degradation rates for X696872 - laboratory studies

X696872	**Dark aerobic conditions, parent applied study, top-down fit from peak**							
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**T(°C)/ MWHC (%)**	**Modelling (20°C/pF2)**				**Evaluated at EU level**
				DT_{50} (d)	**ff**	**Chi^2 (%)**	**Kinetic model**	
RefSol 03-G	Sandy loam	5.6	20/75.9	86.1	1	9.6	FOMC	Yes *(EFSA, 2018)*
Farditch Farm	Silt loam	5.7	20/67.4	59.3	1	8.6	FOMC	
Woodside Farm	Clay loam	7.2	20/80.3	17.5	1	3.4	FOMC	
Hareby House	Clay	7.7	20/57.6	10.7	1	9.1	FOMC	
Geometric mean (n=4)				31.3				
Arithmetic mean (n=4)					1			
pH dependence				No				

Table 8.3-15: Summary of aerobic degradation rates for X12264475 - laboratory studies

X12264475	**Dark aerobic conditions, parent applied study, top-down fit from peak**							
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**T(°C)/ MWHC (%)**	**Modelling (20°C/pF2)**				**Evaluated at EU level**
				DT_{50} (d)	**ff**	**Chi^2 (%)**	**Kinetic model**	
RefSol 03-G	Sandy loam	5.6	20/75.9	118	1	2.1	DFOP	Yes *(EFSA, 2018)*
Farditch Farm	Silt loam	5.7	20/67.4	1000*	1	2.4	DFOP	
Woodside Farm	Clay loam	7.2	20/80.3	17.4	1	6.1	FOMC	
Hareby House	Clay	7.7	20/57.6	60.1	1	11.0	DFOP	
Geometric mean (n=4)				105.4				
Arithmetic mean (n=4)					1			
pH dependence				No				

* k2 fixed to 1000 d (conservative default); however, this does not fit the weight of evidence (see below)

The following metabolite applied study for X12264475 results in shorter DT_{50} values compared to the parent applied study above. The data indicate that assigning a default worst case DT_{50} of 1000 days for Farditch Farm does not fit the trend of much shorter DT_{50} values.

Table 8.3-16: Summary of aerobic degradation rates for X12264475 - laboratory studies (metabolite applied)

X12264475	**Dark aerobic conditions, metabolite applied study**							
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**T(°C)/ MWHC (%)**	**Modelling (20°C/pF2)**				**Evaluated at EU level**
				DT_{50} (d)	**ff**	**Chi^2 (%)**	**Kinetic model**	
RefSol 03-G	Sandy ~~Clay~~ loam	6.2	20/75.9	1.7	1	1.6	FOMC	Yes *(EFSA, 2018)*
Farditch Farm	Silt loam	5.7	20/67.4	2.2	1	11.0	SFO	
Woodside Farm	Clay loam	7.3	20/80.3	1.0	1	8.9	SFO	
Hareby House	Clay	7.6	20/57.6	2.1	1	13.0	SFO	
Geometric mean (n=4)				1.7				
Arithmetic mean (n=4)					1			
pH dependence				No				

Table 8.3-17: Summary of aerobic degradation rates for X763024 - laboratory studies (metabolite applied)

X763024	**Dark aerobic conditions, metabolite applied study**							
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**T(°C)/ MWHC (%)**	**Modelling (20°C/pF2)**				**Evaluated at EU level**
				DT_{50} (d)	**ff**	**Chi^2 (%)**	**Kinetic model**	
RefSol 03-G	Sandy ~~Clay~~ loam	6.2	20/75.9	31.6	1	10.8	FOMC	Yes *(EFSA, 2018)*
Farditch Farm	Silt loam	5.7	20/67.4	61.1	1	8.0	DFOP	
Woodside Farm	Clay loam	7.3	20/80.3	23.4	1	16.2	FOMC	
Hareby House	Clay	7.6	20/57.6	25.8	1	14.3	FOMC	
Geometric mean (n=4)				32.8				
Arithmetic mean (n=4)					1			
pH dependence				No				

Table 8.3-18: Summary of aerobic degradation rates for X12313581 - laboratory studies

X12313581	**Dark aerobic conditions, parent applied study, top-down fit from peak**							
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**T(°C)/ MWHC (%)**	**Modelling (20°C/pF2)**				**Evaluated at EU level**
				DT_{50} (d)	**ff**	**Chi^2 (%)**	**Kinetic model**	
RefSol 03-G	Sandy loam	5.6	20/75.9	116	1	5.1	SFO	Yes *(EFSA, 2018)*
Farditch Farm	Silt loam	5.7	20/67.4	284	1	3.3	SFO	
Woodside Farm	Clay loam	7.2	20/80.3	37.2	1	4.9	SFO	
Hareby House	Clay	7.7	20/57.6	136	1	3.3	SFO	
Geometric mean (n=4)				113.6				
Arithmetic mean (n=4)					1			
pH dependence				No				

The following metabolite applied study for X12313581 results in shorter DT_{50} values compared to the parent applied study above.

Table 8.3-19: Summary of aerobic degradation rates for X12313581 - laboratory studies (metabolite applied)

X12313581	**Dark aerobic conditions, metabolite applied study**							
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**T(°C)/ MWHC (%)**	**Modelling (20°C/pF2)**				**Evaluated at EU level**
				DT_{50} (d)	**ff**	**Chi^2 (%)**	**Kinetic model**	
RefSol 03-G	Sandy ~~Clay~~ loam	6.2	20/75.9	10.6	1	11.5	SFO	Yes *(EFSA, 2018)*
Farditch Farm	Silt loam	5.7	20/67.4	19.1	1	17.0	DFOP	
Woodside Farm	Clay loam	7.3	20/80.3	20.6	1	14.8	DFOP	
Hareby House	Clay	7.6	20/57.6	27.0	1	7.2	SFO	
Geometric mean (n=4)				18.3				
Arithmetic mean (n=4)					1			
pH dependence				No				

Table 8.3-20: Summary of aerobic degradation rates for X696476 – laboratory studies (parent and metabolite applied)

X696476	**Dark aerobic conditions, parent and metabolite applied studies**								
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**T(°C)/ MWHC (%)**	**Modelling (20°C/pF2)**					**Evaluated at EU level**
				DT_{50} (d)	**DT_{90} (d)**	**ff**	**Chi^2 (%)**	**Kinetic model**	
No degradation of this metabolite in any soil and so no DT_{50} value derived; conservative value will be selected in the exposure assessment.									Yes *(EFSA, 2018)*

Table 8.3-21: Summary of aerobic degradation rates for X11963422 - laboratory studies

X11963422	**Dark aerobic conditions, parent applied study, top-down fit from peak**							
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**T(°C)/ MWHC (%)**	**Modelling (20°C/pF2)**				**Evaluated at EU level**
				DT_{50} (d)	**ff**	**Chi^2 (%)**	**Kinetic model**	
RefSol 03-G	Sandy loam	5.6	20/75.9	31.9	1	9.4	FOMC	Yes *(EFSA, 2018)*
Farditch Farm	Silt loam	5.7	20/67.4	Not reliable – insufficient data points and low residues.				
Woodside Farm	Clay loam	7.2	20/80.3	Not calculated – metabolite always <5% AR.				
Hareby House	Clay	7.7	20/57.6	Not reliable – insufficient data points.				
Longest value (n=1)				31.9				
Arithmetic mean (n=1)					1			
pH dependence				No				

The following metabolite applied study for X11963422 results in shorter DT_{50} values compared to the parent applied study above.

Table 8.3-22: Summary of aerobic degradation rates for X11963422 - laboratory studies (metabolite applied)

X11963422	Dark aerobic conditions, metabolite applied study							
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**T(°C)/ MWHC (%)**	**Modelling (20°C/pF2)**				**Evaluated at EU level**
				DT_{50} (d)	**ff**	**Chi^2 (%)**	**Kinetic model**	
RefSol 03-G	Clay loam	5.9	20/71.9	1.5	1	5.2	SFO	Yes *(EFSA, 2018)*
Brierlow	Silt loam	5.7	20/84.4	5.0	1	8.3	SFO	
Woodside Farm	Clay loam	7.4	20/77.3	2.3	1	5.9	DFOP	
Hareby House	Clay	7.9	20/55.8	0.35	1	8.7	FOMC	
Geometric mean (n=4)				1.6				
Arithmetic mean (n=4)					1			
pH dependence				No				

Soil photoproducts of fenpicoxamid (detected in soil photolysis study with further investigation of their degradation carried out in standard OECD 307 laboratory study under dark conditions)

Table 8.3-23: Summary of aerobic degradation rates for X12314005 – laboratory studies (metabolite applied)

X12314005	Dark aerobic conditions, metabolite applied study							
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**T(°C)/ MWHC (%)**	**Modelling (20°C/pF2)**				**Evaluated at EU level**
				DT_{50} (d)	**ff**	**Chi^2 (%)**	**Kinetic model**	
RefSol 03-G	Sandy loam	5.6	20/50	0.03	1	18.9	SFO	Yes *(EFSA, 2018)*
Brierlow	Silt loam	5.3	20/50	0.09	1	11.8	SFO	
Woodside Farm	Clay loam	7.2	20/50	0.01	1	13.1 ~~13.3~~	SFO	
Hareby House	Clay	7.6	20/50	0.02	1	16.7	SFO	
Geometric mean (n=4)				0.03				
Arithmetic mean (n=4)					1			
pH dependence				No				

Table 8.3-24: Summary of aerobic degradation rates for X12019520 - laboratory studies (metabolite applied)

X12019520	Dark aerobic conditions, metabolite applied study							
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**T(°C)/ MWHC (%)**	**Modelling (20°C/pF2)**				**Evaluated at EU level**
				DT_{50} (d)	**ff**	**Chi^2 (%)**	**Kinetic model**	
RefSol 03-G	Sandy loam	5.6	20/50	4.0	1	8.0	SFO	Yes *(EFSA, 2018)*
Brierlow	Silt loam	5.3	20/50	6.3	1	10.9	SFO	
Woodside Farm	Clay loam	7.2	20/50	1.8	1	10..6	SFO	
Hareby House	Clay	7.6	20/50	2.0	1	5.4	SFO	
Geometric mean (n=4)				3.1				
Arithmetic mean (n=4)					1			
pH dependence				No				

Table 8.3-25: Summary of aerobic degradation rates for X12255349 - laboratory studies (metabolite applied)

X12255349	Dark aerobic conditions, metabolite applied study							
Soil	Soil type (USDA)	pH ($CaCl_2$)	T(°C)/ MWHC (%)	Modelling (20°C/pF2)				Evaluated at EU level
				DT_{50} (d)	ff	Chi^2 (%)	Kinetic model	
RefSol 03-G	Sandy loam	5.6	20/50	4.6	1	2.8	FOMC	Yes *(EFSA, 2018)*
Brierlow	Silt loam	5.3	20/50	2.5	1	4.1	FOMC	
Woodside Farm	Clay loam	7.2	20/50	2.6	1	5.2	FOMC	
Hareby House	Clay	7.6	20/50	4.4	1	14.3	SFO	
Geometric mean (n=4)				3.4				
Arithmetic mean (n=4)					1			
pH dependence				No				

zRMS comments:

Soil degradation data for fenpicoxamid and its metabolites are in general in line with EU agreed endpoints reported in EFSA Journal 2018;16(1):5145 with some minor corrections introduced by the zRMS.

It is noted that results provided in Tables 8.3-9 to 8.3-11 and 8.3-23 to 8.3-25 describe formation of metabolites X12314005, X12019520 and X12255349 detected in soil photolysis study with further investigation of their degradation carried out in the standard OECD 307 laboratory study under dark conditions, although in EFSA (2018) it is indicated that the degradation of these compounds was investigated in soil photolysis studies, which is a mistake.

Prothioconazole

Persistence endpoints

The following tables show persistence endpoints (DT_{50} and DT_{90} given by kinetic model described in the table) derived (where possible) from laboratory studies.

Table 8.3-26: Summary of aerobic degradation rates for prothioconazole - laboratory studies

Prothioconazole		Dark aerobic conditions						
Soil	Soil type (USDA)	pH ($CaCl_2$)	T(°C)/ MWHC (%)	Persistence (20°C only)				Evaluated at EU level
				DT_{50} (d)	DT_{90} (d)	R^2*	Kinetic model	
Laacher Hof	Sandy loam	6.6	20/48 (pF2)	0.07	5.3	1.000	FOMC	Yes *(EFSA, 2007)*
Stanley	Silty clay loam	5.9	20/48 (pF2)	0.7	78.2	0.989	FOMC	
Hofchen	Silt	6.8	20/50 (pF2)	0.3	0.99	-	SFO	
Byromville	Loamy sand	6.1	20/ 75% 1/3 bar	1.3	4.22	-	SFO	
Median (n=4)				0.5				
pH dependence				No				

* Chi^2 not reported

Table 8.3-27: Summary of aerobic degradation rates for JAU 6476-S-methyl (M01) - laboratory studies

JAU 6476-S-methyl (M01)		Dark aerobic conditions						
Soil	Soil type (USDA)	pH ($CaCl_2$)	T(°C)/ MWHC (%)	Persistence (20°C only)				Evaluated at EU level
				DT_{50} (d)	DT_{90} (d)	R^2*	Kinetic model	
Hofchen	Loamy silt	6.5	20/40 (pF2)	5.9	19.6	0.97	SFO	Yes *(EFSA, 2007)*
Laacher Hof AIII	Loamy silt	6.7	20/40 (pF2)	27.2	90.2	0.955	SFO	
Laacher Hof AXXa	Sandy loam	6.3	20/40 (pF2)	8.2	27.2	0.959	SFO	
Stanley	Silty clay	5.2	20/40 (pF2)	46.0	153	0.965	SFO	
			Median (n=4)	17.7				
			Geometric mean (n=4)	15.7				
			pH dependence	No				

* Chi[2] not reported

Table 8.3-28: Summary of aerobic degradation rates for JAU 6476-desthio (M04) - laboratory studies

JAU 6476-desthio (M04)		Dark aerobic conditions						
Soil	Soil type (USDA)	pH ($CaCl_2$)	T(°C)/ MWHC (%)	Persistence (20°C only)				Evaluated at EU level
				DT_{50} (d)	DT_{90} (d)	R^2*	Kinetic model	
Hofchen	Loamy silt	6.5	20/40 (pF2)	34.0	113	0.820	SFO	Yes *(EFSA, 2007)*
Laacher Hof AIII	Loamy silt	6.7	20/40 (pF2)	29.6	59.2	0.987	SFO	
Laacher Hof AXXa	Sandy loam	6.3	20/40 (pF2)	7.0	23.2	0.985	SFO	
Stanley	Silty clay	5.2	20/40 (pF2)	18.6	61.9	0.979	SFO	
			Median (n=4)	24.1				
			pH dependence	No				

* Chi[2] not reported

Modelling endpoints

The following tables show modelling endpoints (DT_{50} from SFO) derived from laboratory studies. The DT_{90} is not shown since this is not a modelling endpoint.

Data are shown only for JAU 6476-S-methyl (M01) since modelling endpoints for prothioconazole and JAU 6476-desthio (M04) were not given by EFSA, but instead data from the field studies were relied upon.

Table 8.3-29: Summary of aerobic degradation rates for JAU 6476-S-methyl (M01) - laboratory studies

JAU 6476-S-methyl (M01)		Dark aerobic conditions						
Soil	Soil type (USDA)	pH ($CaCl_2$)	T(°C)/ MWHC (%)	Modelling (20°C only)				Evaluated at EU level
				DT_{50} (d)	ff	R^2*	Kinetic model	
Hofchen	Loamy silt	6.5	20/40 (pF2)	5.9	-	0.97	SFO	Yes *(EFSA, 2007)*
Laacher Hof AIII	Loamy silt	6.7	20/40 (pF2)	27.2	-	0.955	SFO	
Laacher Hof AXXa	Sandy loam	6.3	20/40 (pF2)	8.2	-	0.959	SFO	
Stanley	Silty clay	5.2	20/40 (pF2)	46.0	-	0.965	SFO	
Geometric mean (n=4)				15.7 ~~(9.5**)~~				
Arithmetic mean (n=4)					~~0.08***~~			
pH dependence				No				

* Chi² not given
** Geometric mean 9.5 d used for model input when additional normalisation performed for moisture
*** Individual values not given, but 0.08 derived as endpoint for model input

zRMS comments:

Soil degradation data for prothioconazole and its metabolites are in general in line with EU agreed endpoints reported in EFSA Scientific Report (2007) 106 and prothioconazole DAR of 2005.
The only exception concerns new geometric mean DT_{50} of 9.5 d for JAU 6476-S-methyl provided in Table 8.3-29. This value was obtained in the course of additional normalisation procedure performed by the Applicant. However, kinetic re-evaluation or new normalisation generates new active substance data, which should not be used for zonal evaluations, unless critical for the assessment. As this is not the case of JAU 6476-S-methyl, the new value was not validated in is thus struck through.

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)

Degradation rates in anaerobic soil have been calculated, where appropriate. However, these are not required for risk assessment and no further information is provided here.

zRMS comments:

In the course of the EU evaluation of fenpicoxamid the anaerobic soil degradation studies were sufficient to calculate DT_{50} values for the following compounds (data taken from EFSA Journal 2018;16(1):5146):

1. Parent: single soil tested (sandy loam) at 20ºC and 50% MWHC, DT_{50} = 2.2 days.
2. Metabolite X642188: single soil tested (sandy loam) at 20ºC and 50% MWHC, DT_{50} = 7.7 days.

During the anaerobic study following metabolites were observed:

- X696872 at 16% AR, no DT_{50} calculated due to less than 5 data-points in the decline phase,
- X12264475 at 49.4% AR, no DT_{50} calculated due to less than 5 data-points in the decline phase,
- X11963422 (consisting of X11963422 and derivatives) at 80.3% AR, no decline phase.

With regard to prothioconazole, in line with EFSA Scientific Report (2007) 106, prothioconazole might be potentially exposed to anaerobic conditions when applied as a seed treatment in winter cereals. Since application pattern of GF-3307 does not include application as a seed treatment, anaerobic route of exposure is not considered further, in line with EU conclusions.

8.4 Field studies (KCP 9.1.1.2)

Field studies (if triggered – see below) were performed either with the formulation relevant to this dRR or using a comparable formulation to obtain data for the active substance under field conditions. A summary of the data is given below.

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

Fenpicoxamid

Fenpicoxamid readily degrades in laboratory soil and does not trigger field dissipation testing. However, six metabolites triggered persistence testing when considering precautionary worst case assumptions, and the following were included for analysis in a spring applied study; X642188, X696872, X12264475, X763024, X12313581 and X696476. Fenpicoxamid was included to demonstrate that application was correctly made. The seasonal application rate was 260 g as/ha (from 2 x 130 g as/ha) to bare soil.

Maximum levels of each metabolite formed in the field (% parent equivalent) were also monitored. Only X12313581 formed at greater levels in the field (17.1%) compared to the laboratory (10.1%).

Persistence endpoints

Tables here show persistence endpoints (DT_{50} and DT_{90} given by kinetic model using non-normalised data) derived from field studies. Persistence endpoints were not derived for X696872 or X763024 which formed sporadically or were not detected.

Table 8.4-1: Summary of dissipation rates for fenpicoxamid - field studies

Fenpicoxamid	**Field aerobic conditions, parent applied study**							
Location	**Soil type (USDA)**	**pH ($CaCl_2$)**	**Depth (cm)***	**Persistence (non-normalised)**				**Evaluated at EU level**
				DT_{50} (d)	**DT_{90} (d)**	**Chi^2 (%)**	**Kinetic model**	
Germany	Loamy sand	4.9	0-20	5.3	160	10.4	FOMC	Yes *(EFSA, 2018)*
UK	Loam	6.9	0-20	11.6	38.6	4.1	SFO	
N France	Silty clay loam	6.8	0-20	14.7	49	10.4	SFO	
S France	Loam	6.8	0-20	3.1	42.4	24.9	FOMC	
Spain	Silty clay	7.5	0-20	5.4	17.8	20.0	SFO	
Longest value ~~Geometric mean~~ (n=5)				14.7 ~~7.6~~				
pH dependence				No				

* Sampled to 100 cm but residues found only at 0-20 cm depth

Table 8.4-2: Summary of dissipation rates for X642188 - field studies

X642188	Field aerobic conditions, parent applied study (formation fraction 0.6)							
Location	Soil type (USDA)	pH ($CaCl_2$)	Depth (cm)*	Persistence (non-normalised)				Evaluated at EU level
				DT_{50} (d)	DT_{90} (d)	Chi^2 (%)	Kinetic model	
Germany	Loamy sand	4.9	0-20	67.2	223	14.0	SFO	Yes *(EFSA, 2018)*
UK	Loam	6.9	0-20	28.1	93.4	11.8	SFO	
N France	Silty clay loam	6.8	0-20	5.8	19.3	22.4 ~~14.8~~	SFO	
S France	Loam	6.8	0-20	20.2	67.2	3.2	SFO	
Spain	Silty clay	7.5	0-20	Not reliable				
Longest value ~~Geometric mean~~ (n=4)				67.2 ~~21.7~~				
pH dependence				No				

* Sampled to 100 cm but residues found only at 0-20 cm depth

Table 8.4-3: Summary of dissipation rates for X12264475 - field studies

X12264475	Field aerobic conditions, parent applied study (formation fraction 1)							
Location	Soil type (USDA)	pH ($CaCl_2$)	Depth (cm)*	Persistence (non-normalised)				Evaluated at EU level
				DT_{50} (d)	DT_{90} (d)	Chi^2 (%)	Kinetic model	
Germany	Loamy sand	4.9	0-20	Not calculated.				Yes *(EFSA, 2018)*
UK	Loam	6.9	0-20	Not calculated.				
N France	Silty clay loam	6.8	0-20	18	59.7	10.5	SFO	
S France	Loam	6.8	0-20	Not calculated.				
Spain	Silty clay	7.5	0-20	98.1	326	14	SFO	
Longest value (n=2)				98.1				
pH dependence				No				

* Sampled to 100 cm but residues found only at 0-20 cm depth

Table 8.4-4: Summary of dissipation rates for X12313581 - field studies

X12313581	Field aerobic conditions, parent applied study (formation fraction 1)							
Location	Soil type (USDA)	pH ($CaCl_2$)	Depth (cm)*	Persistence (non-normalised)				Evaluated at EU level
				DT_{50} (d)	DT_{90} (d)	Chi^2 (%)	Kinetic model	
Germany	Loamy sand	4.9	0-20	Not calculated; either ND or present at insufficient timepoints.				Yes *(EFSA, 2018)*
UK	Loam	6.9	0-20					
N France	Silty clay loam	6.8	0-20					
S France	Loam	6.8	0-20					
Spain	Silty clay	7.5	0-20	92.2	306	13.0	SFO	
Longest value (n=1)				92.2				
pH dependence				No				

* Sampled to 100 cm but residues found only at 0-20 cm depth

Table 8.4-5: Summary of dissipation rates for X696476 - field studies

X696476	**Field aerobic conditions, parent applied study (formation fraction 1)**							
Location	**Soil type (USDA)**	**pH ($CaCl_2$)**	**Depth (cm)***	**Persistence (non-normalised)**				**Evaluated at EU level**
				DT_{50} (d)	**DT_{90} (d)**	**Chi^2 (%)**	**Kinetic model**	
Germany	Loamy sand	4.9	0-20	Not calculated.				Yes *(EFSA, 2018)*
UK	Loam	6.9	0-20	246	818	8.6	SFO	
N France	Silty clay loam	6.8	0-20	5260	17500	4.8	SFO	
S France	Loam	6.8	0-20	Not calculated.				
Spain	Silty clay	7.5	0-20	Not calculated.				
			Longest value (n=2)	5260				
			pH dependence	No				

* Sampled to 100 cm but residues found only at 0-20 cm depth

Modelling endpoints

In the EFSA conclusion (2018), laboratory DT_{50} values were relied upon for the groundwater and surface water modelling for fenpicoxamid and its metabolites. As such no further information on normalised (20°C/pF2) field DT_{50} values is given since these are not required for the assessment.

zRMS comments:

Field degradation data for fenpicoxamid presented in Table 8.4-1 to 8.4-5 are in general in line with the EU agreed endpoints reported in EFSA Journal 2018;16(1):5146 with some minor corrections introduced by the zRMS.

Since for persistence endpoints the longest value is taken into account, the geometric mean DT_{50} values calculated from actual DT_{50} in Tables 8.4-1 and 8.4-2 were struck through and the longest value has been reported instead.

With regard to the modelling endpoints it is noted that in EFSA Journal 2018;16(1):5146 the normalised DT_{50} values from field dissipation studies are given for the parent (with geomean of 9.83 days) and metabolite X642188 (with geomean of 15.2 days). However, as laboratory data are used for modelling, these values are given here for informative purposes only.

Prothioconazole

Soil dissipation testing was not triggered for prothioconazole or its metabolites. However, bare soil and cropped dissipation studies following spring application (nominal 200 g as/ha) have been carried out.

Persistence endpoints

Tables here show persistence (DT_{50} and DT_{90} given by kinetic model described in the table) endpoints for prothioconazole and JAU-6476-desthio (M04) from field studies. JAU-6476-S-methyl (M01) was <LOQ, and in the majority of cases not detected (<LOD) and so kinetics are not presented.

Table 8.4-6: Summary of dissipation rates for prothioconazole - field studies

Prothioconazole		Field conditions						
Location	Soil type (USDA)	pH ($CaCl_2$)	Depth (cm)*	Persistence (non-normalised)				Evaluated at EU level
				DT_{50} (d)	DT_{90} (d)	R^2 **	Kinetic model	
Germany (bare)	Silt loam	6.25	0-10	1.9	6.4	1.00	SFO	Yes *(EFSA, 2007)*
UK (bare)	Sandy clay loam	7.56	0-10	1.6	5.5	1.00	SFO	
N France (bare)	Silt	6.42	0-10	1.3	4.4	1.00	SFO	
UK (cropped)	Sandy clay loam	7.56	0-10	2.8	9.3	0.99	SFO	
N France (cropped)	Silt	6.42	0-10	1.4	4.5	1.00	SFO	
S France (cropped)	Siltloam	7.61	0-10	1.7	5.6	0.99	SFO	
Italy (cropped)	Sandy loam	7.56	0-10	1.6	5.4	0.99	SFO	
Germany (bare)	Sandy loam	6.32	0-10	1.5	5.1	1.00	SFO	
			Median (n=8)	1.6				
			Worst case (n=8)	2.8				

* Sampled to 50 cm but residues found only at 0-10 cm depth
** Chi^2 not reported

Table 8.4-7: Summary of dissipation rates for JAU 6476-desthio (M04) - field studies

JAU 6476-desthio (M04)		Field conditions						
Location	Soil type (USDA)	pH ($CaCl_2$)	Depth (cm)*	Persistence (non-normalised)				Evaluated at EU level
				DT_{50} (d)	DT_{90} (d)	R^2 **	Kinetic model	
Germany (bare)	Silt loam	6.25	0-10	16.3	54.1	0.98	SFO	Yes *(EFSA, 2007)*
UK (bare)	Sandy clay loam	7.56	0-10	54.7	182	0.96	SFO	
N France (bare)	Silt	6.42	0-10	47.6	158	0.94	SFO	
UK (cropped)	Sandy clay loam	7.56	0-10	50.2	167	0.91	SFO	
N France (cropped)	Silt	6.42	0-10	36.8	122	0.93	SFO	
S France (cropped)	Silt loam	7.61	0-10	72.3	240	0.91	SFO	
Italy (cropped)	Sandy loam	7.56	0-10	30.5	101	0.98	SFO	
Germany (bare)	Sandy loam	6.32	0-10	27.9	92.6	0.98	SFO	
			Median (n=8)	42.2				
			Worst case (n=8)	72.3				

* Sampled to 50 cm but residues found only at 0-10 cm depth
** Chi^2 not reported

Modelling endpoints

Tables here show modelling endpoints (DT_{50} from SFO) derived from field studies using normalised day-lengths for prothioconazole and JAU-6476-desthio (M04). JAU-6476-S-methyl (M01) was <LOQ, and in the majority of cases not detected (<LOD) and so kinetics are not presented.

Table 8.4-8: Summary of dissipation rates for prothioconazole - field studies

Prothioconazole	Field conditions						
Location	Soil type (USDA)	pH ($CaCl_2$)	Depth (cm)*	Modelling (20°C/pF2)			Evaluated at EU level
				DT_{50} (d)	Chi^2 (%)	Kinetic model	
Germany (bare)	Silt loam	6.25	0-10	1.32	-	SFO	Yes (M-429069-01-1)
UK (bare)	Sandy clay loam	7.56	0-10	1.09	-	SFO	
N France (bare)	Silt	6.42	0-10	0.75	-	SFO	
UK (cropped)	Sandy clay loam	7.56	0-10	1.38	-	SFO	
N France (cropped)	Silt	6.42	0-10	0.73	-	SFO	
S France (cropped)	Silt loam	7.61	0-10	0.70	-	SFO	
Italy (cropped)	Sandy loam	7.56	0-10	0.97	-	SFO	
Germany (bare)	Sandy loam	6.32	0-10	0.82	-	SFO	
Geometric mean (n=8)				0.94			

* Sampled to 50 cm but residues found only at 0-10 cm depth

Table 8.4-9: Summary of dissipation rates for JAU 6476-desthio (M04) - field studies

JAU 6476-desthio (M04)		Field conditions						
Location	Soil type (USDA)	pH ($CaCl_2$)	Depth (cm)*	Modelling (20°C/pF2)				Evaluated at EU level
				DT_{50} (d)	ff	Chi^2 (%)	Kinetic model	
Germany (bare)	Silt loam	6.25	0-10	9.0	0.72	-	SFO	Yes (M-429069-01-1)
UK (bare)	Sandy clay loam	7.56	0-10	23.5	0.67	-	SFO	
N France (bare)	Silt	6.42	0-10	29.5	0.42	-	SFO	
UK (cropped)	Sandy clay loam	7.56	0-10	19.8	0.76	-	SFO	
N France (cropped)	Silt	6.42	0-10	24.0	0.39	-	SFO	
S France (cropped)	Silt loam	7.61	0-10	36.4	0.65	-	SFO	
Italy (cropped)	Sandy loam	7.56	0-10	26.7	0.48	-	SFO	
Germany (bare)	Sandy loam	6.32	0-10	17.8	0.74	-	SFO	
Geometric mean (n=8)				21.8				
Arithmetic mean (n=8)					0.60			

* Sampled to 50 cm but residues found only at 0-10 cm

zRMS comments:

The triggering endpoints for prothioconazole and metabolite JAU 5479-desthio provided in Tables 8.4-6 and 8.4-7 above are in line with data reported in EFSA Scientific Report (2007) 106 and prothioconazole DAR of 2005.

The modelling endpoints provided in Tables 8.4-8 and 8.4-9 were obtained in kinetic re-evaluation of the EU agreed studies. However, the kinetic re-evaluation is considered to be a new active substance data (see conclusions of the CZSC of May 2014) and in line with the Working Document of the Central Zone in area of Section 8[1], new active substance data may be considered in the Core Assessments only in exceptional cases:

> *[...] Note that according to the guidance document on the evaluation of new active substance data post approval (SANCO/10328/2004– rev 8, 24.01.2012) new active substance/metabolite data should not be considered unless they are necessary in order to show a safe use, they are needed as additional uses/crops are applied for authorisation, or they are "adverse" data. [...]*

[1] Working Document of the Central Zone in the Authorisation of Plant Protection Products, Section 8, Environmental Fate and Behaviour, Version 1, rev. 1, June 2018

New data for prothioconazole and its metabolites were not necessary to demonstrate safe uses and for this reason their submission is not justified and values as reported in the LoEP should be used for exposure assessment, in line with indications of Working Document of the Central Zone in area of Section 8.

Taking this into account, the new modelling endpoints for prothioconazole and metabolite JAU 6476-desthio obtained in kinetic re-evaluation were not validated by the zRMS and are thus struck through in tables above. 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)

Soil accumulation testing has not been carried out.

zRMS comments:

According to information presented in EFSA Journal 2018;16(1):5146 and in EFSA Scientific Report (2007) 106, soil accumulation testing is not required for fenpicoxamid and prothioconazole, respectively.

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 sorption data obtained with the active substance. A summary of the sorption data is given below.

Fenpicoxamid

Table 8.5-1: Summary of soil adsorption for fenpicoxamid

Fenpicoxamid	**Soil adsorption**						
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**OC (%)**	**Kf**	**Kfoc**	**1/n**	**Evaluated at EU level**
Benton	Silt loam	5.5	1.0	9.36	936	0.630	Yes *(EFSA, 2018)*
Farditch Farm	Silt loam	5.8	3.9	39.5	1012	0.783	
RefSol 03-G	Silt loam	5.8	3.9	2472	63394	1.066	
Fayette	Silt loam	5.9	0.9	20.3	2250	0.608	
Yolo	Clay loam	6.9	0.8	469.8	58719	0.960	
Woodside Farm	Clay loam	7.2	4.4	136.9	3111	0.850	
Hareby House	Clay	7.6	1.7	147.8	8695	0.831	
Geometric mean (n=7)					5776		
Arithmetic mean (n=7)						0.818	
pH dependence					No		

Table 8.5-2: Summary of soil adsorption for X642188

X642188	Soil adsorption						
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**OC (%)**	**Kf**	**Kfoc**	**1/n**	**Evaluated at EU level**
Warsop	Sand	3.9	0.8	22.5	2811	0.823	Yes *(EFSA, 2018)*
Benton	Silt loam	5.5	1.0	21.5	2154	0.855	
Farditch Farm	Silt loam	5.8	3.9	65.1	1669	0.946	
RefSol 03-G	Silt loam	5.8	3.9	63.4	1626	0.875	
Fayette	Silt loam	5.9	0.9	303	33614	1.027	
Yolo	Clay loam	6.9	0.8	220	27506	1.005	
Woodside Farm	Clay loam	7.2	4.4	79.5	1807	0.923	
Longwoods Quarry	Loamy sand	7.4	1.3	52.6	4043	0.986	
Hareby House	Clay	7.6	1.7	120	7069	0.964	
Geometric mean (n=9)					4518		
Arithmetic mean (n=9)						0.934	
pH dependence					No		

Table 8.5-3: Summary of soil adsorption for X696872

X696872	Soil adsorption						
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**OC (%)**	**Kf**	**Kfoc**	**1/n**	**Evaluated at EU level**
Farditch Farm	Silt loam	5.8	3.9	14.7	376	0.96	Yes *(EFSA, 2018)*
RefSol 03-G	Silt loam	5.8	3.9	25.6	657	0.94	
Yolo	Clay loam	6.9	0.8	23.0	2869	1.03	
Woodside Farm	Clay loam	7.2	4.4	11.7	266	0.90	
Hareby House	Clay	7.6	1.7	12.4	731	0.91	
Geometric mean (n=5)					673		
Arithmetic mean (n=5)						0.95	
pH dependence					No		

Table 8.5-4: Summary of soil adsorption for X12264475

X12264475	Soil adsorption						
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**OC (%)**	**Kf**	**Kfoc**	**1/n**	**Evaluated at EU level**
Farditch Farm	Silt loam	5.8	3.9	10.8	277	0.97	Yes *(EFSA, 2018)*
RefSol 03-G	Silt loam	5.8	3.9	11.9	306	0.95	
Yolo	Clay loam	6.9	0.8	5.90	737	0.93	
Woodside Farm	Clay loam	7.2	4.4	6.07	138	0.91	
Hareby House	Clay	7.6	1.7	6.08	358	0.90	
Geometric mean (n=5)					315		
Arithmetic mean (n=5)						0.93	
pH dependence					No		

Table 8.5-5: Summary of soil adsorption for X763024

X763024	Soil adsorption						
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**OC (%)**	**Kf**	**Kfoc**	**1/n**	**Evaluated at EU level**
Farditch Farm	Silt loam	5.8	3.9	20.0	514	0.93	Yes *(EFSA, 2018)*
RefSol 03-G	Silt loam	5.8	3.9	13.0	333	0.94	
Yolo	Clay loam	6.9	0.8	7.08	885	0.90	
Woodside Farm	Clay loam	7.2	4.4	6.99	159	0.94	
Hareby House	Clay	7.6	1.7	6.19	364	0.91	
Geometric mean (n=5)					388		
Arithmetic mean (n=5)						0.92	
pH dependence					No		

Table 8.5-6: Summary of soil adsorption for X12313581

X12313581	Soil adsorption						
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**OC (%)**	**Kf**	**Kfoc**	**1/n**	**Evaluated at EU level**
Farditch Farm	Silt loam	5.8	3.9	30.9	792	0.90	Yes *(EFSA, 2018)*
RefSol 03-G	Silt loam	5.8	3.9	14.0	360	0.89	
Yolo	Clay loam	6.9	0.8	14.2	1775	0.87	
Woodside Farm	Clay loam	7.2	4.4	17.4	396	0.89	
Hareby House	Clay	7.6	1.7	11.4	669	0.84	
Geometric mean (n=5)					669		
Arithmetic mean (n=5)						0.88	
pH dependence					No		

Table 8.5-7: Summary of soil adsorption for X696476

X696476	Soil adsorption						
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**OC (%)**	**Kf**	**Kfoc**	**1/n**	**Evaluated at EU level**
Farditch Farm	Silt loam	5.8	3.9	495.0	12691	0.84	Yes *(EFSA, 2018)*
RefSol 03-G	Silt loam	5.8	3.9	302.0	7752	0.85	
Yolo	Clay loam	6.9	0.8	208.0	26044	0.78	
Woodside Farm	Clay loam	7.2	4.4	171.0	3884	0.80	
Hareby House	Clay	7.6	1.7	93.8	5520	0.77	
Geometric mean (n=5)					8871		
Arithmetic mean (n=5)						0.81	
pH dependence					No		

Table 8.5-8: Summary of soil adsorption for X11963422

X11963422	Soil adsorption						
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**OC (%)**	**Kf**	**Kfoc**	**1/n**	**Evaluated at EU level**
Farditch Farm	Silt loam	5.8	3.9	2.00	51.9 ~~51.3~~	0.93	Yes *(EFSA, 2018)*
RefSol 03-G	Silt loam	5.8	3.9	2.60	66.7	0.89	
Yolo	Clay loam	6.9	0.8	1.72	215	0.88	
Woodside Farm	Clay loam	7.2	4.4	1.29	29.3	0.84	
Hareby House	Clay	7.6	1.7	3.71	218	0.93	
Geometric mean (n=5)					86		
Arithmetic mean (n=5)						0.89	
pH dependence					No		

Table 8.5-9: Summary of soil adsorption for X12314005

X12314005	Soil adsorption						
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**OC (%)**	**Kf**	**Kfoc**	**1/n**	**Evaluated at EU level**
Brierlow	Silt loam	5.7	4.2	2.7	64	0.97	Yes *(EFSA, 2018)*
RefSol 03-G	Silt loam	6.0	3.8	4.7	124	0.99	
Yolo	Clay loam	6.8	0.5	2.3	452	0.96	
Empingham	Loam	7.2	3.3	3.6	110	1.05	
Hareby House	Clay loam	7.3	5.6	3.3	58	1.01	
Geometric mean (n=5)					118		
Arithmetic mean (n=5)						1.00	
pH dependence					No		

Table 8.5-10: Summary of soil adsorption for X12019520

X12019520	Soil adsorption						
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**OC (%)**	**Kf**	**Kfoc**	**1/n**	**Evaluated at EU level**
Brierlow	Silt loam	5.7	4.2	1.8	43	0.90	Yes *(EFSA, 2018)*
RefSol 03-G	Silt loam	6.0	3.8	2.6	68	0.90	
Yolo	Clay loam	6.8	0.5	1.5	301	0.84	
Empingham	Loam	7.2	3.3	1.6	50	0.91	
Hareby House	Clay loam	7.3	5.6	1.8	32	0.92	
Geometric mean (n=5)					68		
Arithmetic mean (n=5)						0.89	
pH dependence					No		

Table 8.5-11: Summary of soil adsorption for X12255349

X12255349	Soil adsorption						
Soil	**Soil type (USDA)**	**pH ($CaCl_2$)**	**OC (%)**	**Kf**	**Kfoc**	**1/n**	**Evaluated at EU level**
Brierlow	Silt loam	5.7	4.2	7.1	168	1.00	Yes *(EFSA, 2018)*
RefSol 03-G	Silt loam	6.0	3.8	6.9	182	0.97	
Yolo	Clay loam	6.8	0.5	98.6	19725	1.07	
Empingham	Loam	7.2	3.3	7.0	211	1.04	
Hareby House	Clay loam	7.3	5.6	32.6	581	1.21	
Geometric mean (n=5)					594		
Arithmetic mean (n=5)						1.06	
pH dependence					No		

zRMS comments:

Soil mobility data for fenpicoxamid and its metabolites presented on Tables 8.5-1 to 8.5-11 are in line with EU agreed endpoints as reported in EFSA Journal 2018;16(1):5146 with some minor corrections introduced by the zRMS.

Prothioconazole

Due to instability of prothioconazole in batch equilibrium studies, sorption data are not available, but Kd (15.2 mL/g) and Koc (1765 mL/g) values were estimated from an aged column leaching study. However, sorption data are available for the soil metabolites.

Table 8.5-12: Summary of soil adsorption for JAU 6476-S-methyl (M01)

JAU 6476-S-methyl (M01)		Soil adsorption					
Soil	**Soil type (USDA)**	**pH (H_2O)**	**OC (%)**	**Kf**	**Kfoc**	**1/n**	**Evaluated at EU level**
Laacher Hof AXXa	Sandy loam	7.2	2.02	56.0	2772.4	0.87	Yes *(EFSA, 2007)*
Hofchen	Silt	7.1	2.14	64.1	2995.0	0.88	
Stanley	Silty clay loam	5.9	1.66	41.2	2484.0	0.91	
Byromville	Loamy sand	6.8	0.79	15.6	1973.6	0.85	
Arithmetic mean (n=4)					2556.3	0.88	
Geometric mean (n=4)					2525.9		
pH-dependency					No		

Table 8.5-13: Summary of soil adsorption for JAU 6476-desthio (M04)

JAU 6476-desthio (M04)		Soil adsorption					
Soil	**Soil type (USDA)**	**pH (H_2O)**	**OC (%)**	**Kf**	**Kfoc**	**1/n**	**Evaluated at EU level**
Laacher Hof AXXa	Sandy loam	7.2	2.02	12.46	616.8	0.79	Yes *(EFSA, 2007)*
Hofchen	Silt	7.1	2.14	13.38	625.3	0.83	
Stanley	Silty clay loam	5.9	1.66	8.90	536.4	0.83	
Byromville	Loamy sand	6.8	0.79	4.13	523.0	0.80	
Arithmetic mean (n=4)					575.4	0.81	
Geometric mean (n=4)					573.5		
pH-dependency					No		

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 Koc 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 Koc 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 Kfoc values were calculated by the Applicant, although in the EFSA conclusion only arithmetic mean values are reported and further used for groundwater and surface water modelling. The geometric mean values calculated by the Applicant were based on the individual Kfoc from the LoEP and are confirmed to be correct. The results of the modelling simulation were validated by the zRMS with consideration of the EU agreed arithmetic mean values.

8.5.1 Column leaching (KCP 9.1.2.1)

Fenpicoxamid

Column leaching studies have not been carried out.

zRMS comments:

Column leaching studies with fenpicoxamid were not performed or required during EU review.

Prothioconazole

Column leaching studies are not relevant since reliable sorption data are available for JAU 6476-S-methyl (M01) and JAU 6476-desthio (M04). However, due to the instability in batch equilibrium studies, sorption parameters were estimated for prothioconazole from an aged column leaching study using a loamy sand soil. Kd and Koc values of 15.2 mL/g and 1765 mL/g, respectively, were derived (EFSA, 2007).

zRMS comments:

In EFSA Scientific Report (2007) 106 results of column leaching and aged residues leaching are reported. However, they are not necessary for purposes of evaluation of GF-3307, as based on results of the groundwater modelling no unacceptable leaching of prothioconazole or its metabolites is expected.

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

8.5.2 Lysimeter studies (KCP 9.1.2.2)

Lysimeter studies have not been carried out.

zRMS comments:

Lysimeter studies with fenpicoxamid and prothioconazole were not performed or required during EU review.

8.5.3 Field leaching studies (KCP 9.1.2.3)

Field leaching studies have not been carried out.

zRMS comments:
Field leaching studies with fenpicoxamid and prothioconazole were not performed or required during EU review.

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

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

Fenpicoxamid

The following tables show modelling endpoints (DT_{50} from SFO, or "SFO-like" i.e. FOMC DT_{90}/3.32 or DFOP k2) derived (where possible) from laboratory studies. The endpoints were also assumed for persistence purposes. The DT_{90} is not shown since this is not a modelling endpoint. Since a one compartment kinetic model was used the tables show the whole system DT_{50} values.

Table 8.6-1: Summary of water/sediment degradation rates for fenpicoxamid – laboratory studies

Fenpicoxamid	**Dark water/sediment, parent applied study**						
Water/ sediment	**Sediment type (USDA)**	**pH ($CaCl_2$) wat/sed**	**T (°C)**	**Whole system (20°C)**			**Evaluated at EU level**
				DT_{50} (d)	**Chi^2 (%)**	**Kinetic model**	
Swiss Lake	Sand	6.7/6.9	20	1.69	8.1	FOMC	Yes *(EFSA, 2018)*
Calwich Abbey Lake	Silt loam	7.9/7.3	20	0.34	4.5	FOMC	
Geometric mean (n=2)				0.76 (see below)			

Based on individual DT_{50} values to two decimal places, the geometric mean is 0.76 days, but when based upon rounded values of 1.7 and 0.3 days, the geometric mean is 0.7 days (all to one decimal place). This latter value of **0.7 days is the DT_{50} relied upon by EFSA in the exposure modelling**, and so this was used in this dRR.

Table 8.6-2: Summary of water/sediment degradation rates for X642188 – laboratory studies

X642188	**Dark water/sediment, parent applied study (formation fraction 1)**						
Water/ sediment	**Sediment type (USDA)**	**pH ($CaCl_2$) wat/sed**	**T (°C)**	**Whole system (20°C)**			**Evaluated at EU level**
				DT_{50} (d)	**Chi^2 (%)**	**Kinetic model**	
Swiss Lake	Sand	6.7/6.9	20	2.37	14.9	SFO	Yes *(EFSA, 2018)*
Calwich Abbey Lake	Silt loam	7.9/7.3	20	Not calculated; insufficient data points.			
Worst case (n=1)				2.37 (see below)			

Only four data points were available for X642188 and residues were very low in Calwich Abbey Lake and so calculating a DT_{50} for this system was not appropriate. However, **as noted by EFSA**, a proposal was made to use a geometric mean of 2.7 days (n=2) using a top-down approach; the RMS derived a slightly different value of 3.5 days based only on Swiss Lake. An additional value of 2.4 days (single value from Swiss Lake) was derived when modelling X642188 as part of the degradation scheme although it was noted that the decline was slightly overestimated when subsequent metabolites were added. All values derived are similar and indicate rapid degradation in the water/sediment system; this slight discrepancy is not expected to have an impact on the exposure modelling, particularly given the high Kfoc for X642188. Therefore the use of a value of **2.7 days is considered acceptable**, and so this was used in this dRR.

Table 8.6-3: Summary of water/sediment degradation rates for X12264475 – laboratory studies

X12264475	Dark water/sediment, parent applied study (formation fraction 1)						
Water/ sediment	Sediment type (USDA)	pH ($CaCl_2$) wat/sed	T (°C)	Whole system (20°C)			Evaluated at EU level
				DT_{50} (d)	Chi^2 (%)	Kinetic model	
Swiss Lake	Sand	6.7/6.9	20	58.9	7.4	SFO	Yes *(EFSA, 2018)*
Calwich Abbey Lake	Silt loam	7.9/7.3	20	40.8	6.8	SFO	
			Geometric mean (n=2)	49.0[1)]			

[1)] According to information available in Vol. 3CA, B.8 (July 2017), geometric mean DT_{50} of 49.0 d was calculated from individual DT_{50} values of 58.9 and 40.8 d for Swiss Lake and Calwich Abbey Lake, respectively, derived using top-down approach, considered as more conservative by the RMS; it seems that DT_{50} values of 53.7 and 38.3 days are reported in EFSA Journal 2018;16(1)5146 by mistake, as they do not give geomean of 49 days and were derived from the pathway fit.

Table 8.6-4: Summary of water/sediment degradation rates for X12313581 – laboratory studies

X12313581	Dark water/sediment, parent applied study (formation fraction 1)						
Water/ sediment	Sediment type (USDA)	pH ($CaCl_2$) wat/sed	T (°C)	Whole system (20°C)			Evaluated at EU level
				DT_{50} (d)	Chi^2 (%)	Kinetic model	
No observed decline in two systems. Assume DT_{50} = 1000 d.							Yes *(EFSA, 2018)*

Table 8.6-5: Summary of water/sediment degradation rates for X696476 – laboratory studies

X696476	Dark water/sediment, parent applied study (formation fraction 1)						
Water/ sediment	Sediment type (USDA)	pH ($CaCl_2$) wat/sed	T (°C)	Whole system (20°C)			Evaluated at EU level
				DT_{50} (d)	Chi^2 (%)	Kinetic model	
No observed decline in two systems. Assume DT_{50} = 1000 d.							Yes *(EFSA, 2018)*

Table 8.6-6: Summary of water/sediment degradation rates for X11963422 – laboratory studies

X11963422	Dark water/sediment, parent applied study (formation fraction 1)						
Water/ sediment	Sediment type (USDA)	pH ($CaCl_2$) wat/sed	T (°C)	Whole system (20°C)			Evaluated at EU level
				DT_{50} (d)	Chi^2 (%)	Kinetic model	
Swiss Lake	Sand	6.7/6.9	20	23.1	34.4	SFO	Yes *(EFSA, 2018)*
Calwich Abbey Lake	Silt loam	7.9/7.3	20	Not reliable (20.2 d).			
			Longest value (n=1)	23.1*			

* Given as 20.2 d by EFSA but indicated as informative due to only 3 data points this is incorrect

Table 8.6-7: Summary of water/sediment degradation rates for X12314005 – laboratory studies

X12314005	Dark water/sediment, parent applied study (formation fraction 1)						
Water/ sediment	Sediment type (USDA)	pH ($CaCl_2$) wat/sed	T (°C)	Whole system (20°C)			Evaluated at EU level
				DT_{50} (d)	Chi^2 (%)	Kinetic model	
Swiss Lake	Sand	6.7/6.9	20	0.89	19	SFO	Yes *(EFSA, 2018)*
Calwich Abbey Lake	Silt loam	7.9/7.3	20	0.58	3.6	SFO	
			Geometric mean (n=2)	0.84			

Table 8.6-8: Summary of water/sediment degradation rates for X12019520 – laboratory studies

X12019520	Dark water/sediment, parent applied study, top-down fit from peak*						
Water/ sediment	**Sediment type (USDA)**	**pH ($CaCl_2$) wat/sed**	**T (°C)**	**Whole system (20°C)**			**Evaluated at EU level**
				DT_{50} (d)	**Chi^2 (%)**	**Kinetic model**	
Swiss Lake	Sand	6.7/6.9	20	Not calculated (not detected).			Yes *(EFSA, 2018)*
Calwich Abbey Lake	Silt loam	7.9/7.3	20	8.8	17.2	SFO*	
Longest value (n=1)				8.8			

Table 8.6-9: Summary of water/sediment degradation rates for X12335723 – laboratory studies

X12335723	Dark water/sediment, parent applied study (formation fraction 1)						
Water/ sediment	**Sediment type (USDA)**	**pH ($CaCl_2$) wat/sed**	**T (°C)**	**Whole system (20°C)**			**Evaluated at EU level**
				DT_{50} (d)	**Chi^2 (%)**	**Kinetic model**	
Swiss Lake	Sand	6.7/6.9	20	3.4	19.5	SFO	Yes *(EFSA, 2018)*
Calwich Abbey Lake	Silt loam	7.9/7.3	20	2.0	11.5	SFO	
Geometric mean (n=2)				2.6[1)]			

[1)] According to information available in Vol. 3CA, B.8 (July 2017), geometric mean DT_{50} of 2.6 d was calculated from individual DT_{50} values of 3.41 and 2.03 d for Swiss Lake and Calwich Abbey Lake, respectively, derived using top-down approach, considered as more conservative by the RMS; it seems that DT_{50} values of 1.2 and 1.4 days are reported in EFSA Journal 2018;16(1)5146 by mistake, as they do not give geomean of 2.6 days and were derived from the pathway fit.

zRMS comments:

Information on degradation of fenpicoxamid and its metabolites in water/sediment systems presented in Tables 8.6-1 to 8.6-9 are in general line with EU agreed endpoints reported in EFSA Journal 2018;16(1):5146. Some additional information has been added by the zRMS for clarity.

Prothioconazole

The following tables show modelling endpoints (DT_{50} from SFO) derived from laboratory studies. The endpoints were also assumed for persistence purposes. The DT_{90} is not shown as this is not a modelling endpoint. Since a one compartment kinetic model was used the tables show the whole system DT_{50} values.

Table 8.6-10: Summary of water/sediment degradation rates for prothioconazole – laboratory studies

Prothioconazole		Dark water/sediment					
Water/ sediment	**Sediment type (USDA)**	**pH ($CaCl_2$) wat/sed**	**T (°C)**	**Whole system (20°C)**			**Evaluated at EU level**
				DT_{50} (d)	**R^2**	**Kinetic model**	
Honniger Weiher	Loam	5.8	20	24.1	>0.9	SFO	Yes *(M298575-01-1)*
Angler Weiher	Loamy sand	7.4	20	1.8	>0.9	SFO	
Longest value (n=2)				24.1			

Table 8.6-11: Summary of water/sediment degradation rates for JAU 6476-desthio (M04) - laboratory studies

JAU 6476-desthio (M04)		Dark water/sediment					
Water/ sediment	Sediment type (USDA)	pH ($CaCl_2$) wat/sed	T (°C)	Whole system (20°C)			Evaluated at EU level
				DT_{50} (d)	R^2	Kinetic model	
Honniger Weiher	Loam	5.8	20	49.9	>0.9	SFO	Yes *(M298575-01-1)*
Angler Weiher	Loamy sand	7.4	20	39.2	>0.9	SFO	
Longest value (n=2)				49.9			

zRMS comments:

Although degradation data for prothioconazole and metabolite JAU 6476-desthio in water/sediment systems provided in tables above are not reported in EFSA Scientific Report (2007) 106, they may be found in the prothioconazole DAR (2005) in point B.8.5 and are thus relevant for the surface water exposure assessment.

In addition to prothioconazole and metabolite JAU 6476-desthio, also DT_{50} values for metabolite JAU 6476-S-methyl are reported there:

- Angler Weiher: 40.2 days,
- Hönniger Weiher: 18.5 days.

8.7 Predicted environmental concentrations in soil (PECsoil) (KCP 9.1.3)

PECsoil values were calculated for fenpicoxamid and major (>5% AR) soil metabolites: X642188, X696872, X12264475, X763024, X12313581, X696476, X11963422, X12314005, X12019520, X12255349.

PECsoil values were calculated for prothioconazole and major (>5% AR) soil metabolites: JAU 6476-S-methyl (M01), JAU 6476-desthio (M04).

PECsoil values were calculated for the formulation: GF-3307.

8.7.1 Justification for new endpoints

Fenpicoxamid

EFSA endpoints (2018) were used for the PECsoil calculations.

Prothioconazole

EFSA endpoints (2007) were used for the PECsoil calculations.

8.7.2 Active substance(s), metabolite(s) and formulation

The initial PECsoil (mg/kg) for active substance and formulation was calculated as follows:

$$\text{Initial PECsoil} = \frac{A}{100 \times d \times \rho}$$

where: A = effective application rate after adjusting for crop interception (g as/ha)
d = depth of soil layer (5 cm)
ρ = soil bulk density (1.5 g/mL)

The actual PECsoil (mg/kg) for active substance and metabolite after application was calculated as follows:

$$\text{Actual PECsoil,t} = \text{Initial PECsoil} \times e^{-kt}$$

where: k = first-order degradation rate constant (d^{-1}) = $\ln 2/DT_{50}$
t = time (d)

The time-weighted average (TWA) PECsoil (mg/kg) for active substance and metabolite after application was calculated as follows:

$$\text{TWA PECsoil,t} = \frac{\text{Initial PECsoil} \times (1 - e^{-kt})}{k \times t}$$

where: k = first-order degradation rate constant (d^{-1}) = $\ln 2/DT_{50}$
t = time (d)

The initial metabolite PECsoil (mg/kg) was calculated from the maximum parent PECsoil with adjustment for the maximum occurrence (% AR) and mw correction as follows:

$$\text{Initial PECsoil}_{,metab} = \text{Initial PECsoil,}_{parent} \times \frac{\text{max \% AR}}{100} \times \frac{\text{mw met}}{\text{mw parent}}$$

Table 8.7-1: Inputs related to application for PECsoil*

Use no.	**1-132**	
Crop	Winter cereals, spring cereals	
Application rate (g as/ha)	100 (Fenpicoxamid) 200 (Prothioconazole)	
Max. number of applications	2	
Crop interception (%)	Appn. 1 Appn. 2	80% (BBCH 30) 80% (BBCH >30)
Effective soil loading (g as/ha)	20 + 20 (Fenpicoxamid) 40 + 40 (Prothioconazole)	
Min. application interval (d)	14	
Frequency of application	Annual	
Depth of soil (cm)	5 (no tillage)	

* Risk envelope GAP of 2 x 100/200 g as/ha from BBCH 30 is protective of 1 x 75/150 g as/ha from BBCH 30

Table 8.7-2: Inputs for fenpicoxamid and metabolites for PECsoil

Compound	**Molar mass (g/mol)**	**Max. occurrence (% AR)**	**Maximum persistence DT_{50} (d)**	**Evaluated at EU level**
Fenpicoxamid	614.2	-	14.7 (field, non-normalised)	Yes *(EFSA, 2018)*
X642188	514.2	39.2% (lab)	67.2 (field, non-normalised)	
X696872	444.2	17.2% (lab)	18.9 (lab, parent applied)	
X12264475	256.1	49.4% (lab)	98.1 (field, non-normalised)	
X763024	226.1	5.7% (lab)	20.8 (lab, metabolite applied)	
X12313581	168.0	17.1% (field)	92.2 (field, non-normalised)	
X696476	169.0	46.9% (lab)	5260 (field, non-normalised)	
X11963422	206.1	80.3% (lab)	5.0 (lab, metabolite applied)	
X12314005	276.3	5.4% (lab)	0.1 (lab, metabolite applied)	
X12019520	188.2	9.8% (lab)	6.3 (lab, metabolite applied)	
X12255349	514.5	6.9% (lab)	4.4 (lab, metabolite applied)	

Table 8.7-3: Input parameters for prothioconazole and metabolites for PECsoil

Compound	**Molar mass (g/mol)**	**Max. occurrence (% AR)**	**Maximum persistence DT_{50} (d)**	**Evaluated at EU level**
Prothioconazole	344.3	-	2.8 (field; non-normalised)	Yes *(EFSA, 2007)*
JAU 6476-S-methyl (M01)	358.3	14.6%	46 (lab)	
JAU 6476-desthio (M04)	312.2	57.1%	72.3 (field; non-normalised)	

zRMS comments:

Although multiple applications of GF-3307 are not intended in the Central Zone, they were considered by the Applicant for the soil exposure calculations.

Fenpicoxamid:

The assumed cumulative effective rate of 40 g a.s./ha (calculated from 2 applications at 100 g a.s./ha and 80% crop interception, relevant for the earliest BBCH stage of cereals at which GF-3307 will be applied) represents worst case comparing to the effective rate of 15 g a.s./ha, relevant for the intended use pattern of GF-3307.

Prothioconazole:

The assumed cumulative effective rate of 80 g a.s./ha (calculated from 2 applications at 200 g a.s./ha and 80% crop interception, relevant for the earlies BBCH stage of cereals at which GF-3307 will be applied) represents worst case comparing to the effective rate of 30 g a.s./ha, relevant for the intended use pattern of GF-3307.

Taking this into account, use pattern assumed by the Applicant is agreed as representing worst case and covering the Central Zone uses of GF-3307.

Input parameters for fenpicoxamid and its metabolites presented in Table 8.7-2 are in line with EU agreed parameters reported in EFSA Journal 2018;16(1):5146.

Input parameters for prothioconazole and its metabolites presented in Table 8-7-3 are in line with EU agreed parameters reported in EFSA Scientific Report (2007) 106.

Fenpicoxamid

Note that the risk envelope GAP of 2 x 100 g as/ha from BBCH 30 used for the PECsoil calculations is protective of the GAP of 1 x 75 g as/ha from BBCH 30 specific to the use of GF-3307 in this dRR.

For the risk envelope GAP, the maximum soil loading for fenpicoxamid results from two applications. In reality, there will be some degradation of fenpicoxamid between applications but as a worst case it was assumed applications were cumulative. Therefore, the PECsoil was calculated based upon the effective risk envelope annual soil loading of 40 g as/ha (from 20 + 20 g as/ha; Table 8.7-1) as a worst case from the 2 x 100 g as/ha rate from BBCH 30 with 80% interception, which is protective of the lower rate of 1 x 75 g as/ha from BBCH 30 with 80% interception (soil loading 15 g as/ha).

Metabolite X696476 has a persistence DT_{90} >1 year, and so a PECsoil from accumulation has only been calculated for this metabolite.

Table 8.7-4: PECsoil for fenpicoxamid on cereals*

PECsoil (mg/kg)		Use no. 1-132	
		Multiple application	
		Actual	TWA
Initial		0.0533	-
Short term	1 d	0.0508	0.0521
	2 d	0.0485	0.0509
	4 d	0.0442	0.0486
Long term	7 d	0.0383	0.0455
	14 d	0.0275	0.0391
	21 d	0.0198	0.0338
	28 d	0.0142	0.0296
	50 d	0.0051	0.0205
	100 d	0.0005	0.0112
Plateau conc. (5 cm) after year x		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

* Risk envelope GAP of 2 x 100 g as/ha from BBCH 30 is protective of 1 x 75 g as/ha from BBCH 30

Table 8.7-5: PECsoil for X642188 and X696872 on cereals*

PECsoil (mg/kg)		Use no. 1-132			
		Multiple application			
		X642188		X696872	
		Actual	TWA	Actual	TWA
Initial		0.0175	-	0.0066	-
Short term	1 d	0.0173	0.0174	0.0064	0.0065
	2 d	0.0171	0.0173	0.0062	0.0064
	4 d	0.0168	0.0171	0.0057	0.0062
Long term	7 d	0.0162	0.0168	0.0052	0.0058
	14 d	0.0151	0.0162	0.0039	0.0052
	21 d	0.0141	0.0157	0.0031	0.0046
	28 d	0.0131	0.0152	0.0024	0.0042
	50 d	0.0105	0.0136	0.0011	0.0030
	100 d	0.0062	0.0109	0.0002	0.0018
Plateau conc. (5 cm) after year x		-	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-	-	-

* Risk envelope GAP of 2 x 100 g as/ha from BBCH 30 is protective of 1 x 75 g as/ha from BBCH 30

Table 8.7-6: PECsoil for X12264475 and X763024 on cereals*

PECsoil (mg/kg)		Use no. 1-132			
		Multiple application			
		X12264475		X763024	
		Actual	TWA	Actual	TWA
Initial		0.0110	-	0.0012	-
Short term	1 d	0.0109	0.0109	0.0012	0.0012
	2 d	0.0108	0.0109	0.0011	0.0012
	4 d	0.0107	0.0108	0.0010	0.0011
Long term	7 d	0.0105	0.0108	0.0009	0.0010
	14 d	0.0100	0.0105	0.0007	0.0009
	21 d	0.0095	0.0102	0.0005	0.0008
	28 d	0.0090	0.0100	0.0005	0.0008
	50 d	0.0077	0.0092	0.0002	0.0005
	100 d	0.0055	0.0079	0.0001	0.0003
Plateau conc. (5 cm) after year x		-	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-	-	-

* Risk envelope GAP of 2 x 100 g as/ha from BBCH 30 is protective of 1 x 75 g as/ha from BBCH 30

Table 8.7-7: PECsoil for X12313581 and X696476 on cereals*

PECsoil (mg/kg)		Use no. 1-132			
		Multiple application			
		X12313581		X696476	
		Actual	TWA	Actual	TWA
Initial		0.0025	-	0.0068	-
Short term	1 d	0.0025	0.0025	0.0068	0.0068
	2 d	0.0025	0.0025	0.0068	0.0068
	4 d	0.0024	0.0025	0.0068	0.0068
Long term	7 d	0.0023	0.0024	0.0068	0.0068
	14 d	0.0022	0.0023	0.0068	0.0068
	21 d	0.0021	0.0023	0.0068	0.0068
	28 d	0.0020	0.0022	0.0068	0.0068
	50 d	0.0017	0.0021	0.0068	0.0068
	100 d	0.0012	0.0017	0.0068	0.0068
Plateau conc. (5 cm) after year 20		-	-	0.137**	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-	0.144**	-

* Risk envelope GAP of 2 x 100 g as/ha from BBCH 30 is protective of 1 x 75 g as/ha from BBCH 30

** See PECsoil(acc) calculation. The exceptionally long extrapolated DT_{50} meant a plateau concentration would not be reached within a meaningful timeframe. However, a period of 100 years was used as an extreme worst case.

A PECsoil(acc) was calculated for X696476 using a DT_{50} of 5260 days based on the initial value of 0.0068 mg/kg and consecutive annual applications (from risk envelope GAP of 2 x 100 g as/ha from BBCH 30). Due to the exceptionally long extrapolated DT_{50}, a plateau concentration would not be reached within a meaningful timeframe. However, a period of 100 years was used as an extreme worst case.

The results showed a concentration in year 100 of *ca* 0.144 mg/kg (*ca* 0.137 mg/kg for residuals).

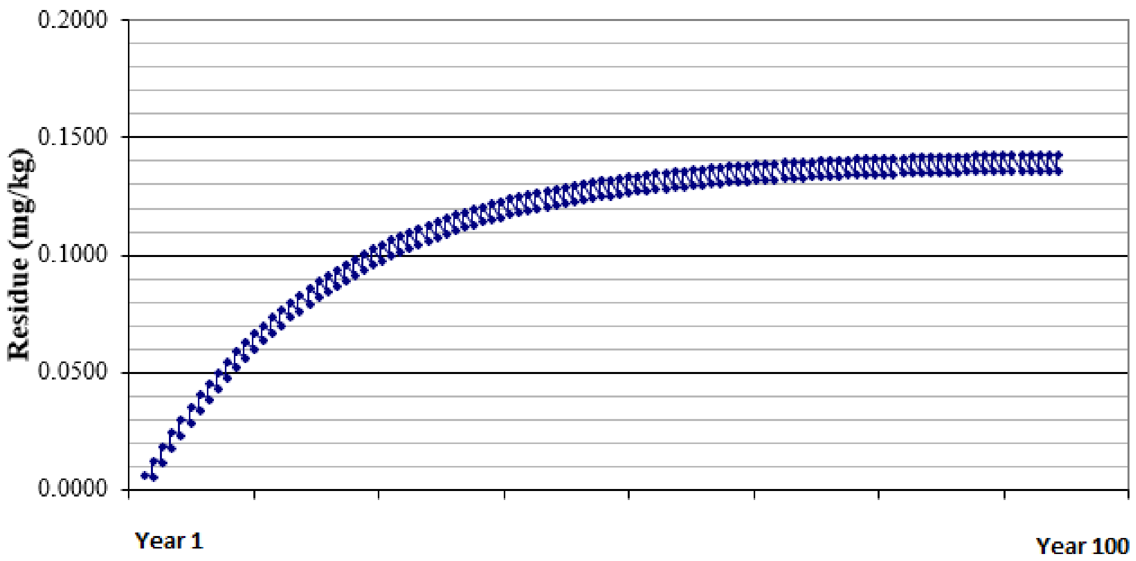


Table 8.7-8: PECsoil for X11963422 and X12314005 on cereals*

PECsoil (mg/kg)		Use no. 1-132			
		Multiple application			
		X11963422		X12314005	
		Actual	TWA	Actual	TWA
Initial		0.0144	-	0.0013	-
Short term	1 d	0.0125	0.0135	0.0000	0.0002
	2 d	0.0109	0.0125	0.0000	0.0001
	4 d	0.0082	0.0111	0.0000	0.0001
Long term	7 d	0.0055	0.0092	0.0000	0.0000
	14 d	0.0021	0.0064	0.0000	0.0000
	21 d	0.0008	0.0047	0.0000	0.0000
	28 d	0.0003	0.0036	0.0000	0.0000
	50 d	0.0000	0.0021	0.0000	0.0000
	100 d	0.0000	0.0010	0.0000	0.0000
Plateau conc. (5 cm) after year x		-	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-	-	-

* Risk envelope GAP of 2 x 100 g as/ha from BBCH 30 is protective of 1 x 75 g as/ha from BBCH 30

Table 8.7-9: PECsoil for X12019520 and X12255349 on cereals*

PECsoil (mg/kg)		Use no. 1-132			
		Multiple application			
		X12019520		X12255349	
		Actual	TWA	Actual	TWA
Initial		0.0016	-	0.0031	-
Short term	1 d	0.0015	0.0015	0.0026	0.0028
	2 d	0.0013	0.0015	0.0022	0.0026
	4 d	0.0011	0.0013	0.0016	0.0023
Long term	7 d	0.0008	0.0012	0.0010	0.0018
	14 d	0.0004	0.0008	0.0003	0.0012
	21 d	0.0002	0.0006	0.0001	0.0009
	28 d	0.0001	0.0005	0.0000	0.0007
	50 d	0.0000	0.0003	0.0000	0.0004
	100 d	0.0000	0.0002	0.0000	0.0002
Plateau conc. (5 cm) after year x		-	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-	-	-

* Risk envelope GAP of 2 x 100 g as/ha from BBCH 30 is protective of 1 x 75 g as/ha from BBCH 30

zRMS comments:

Although multiple applications of GF-3307 are not intended in the Central Zone, they were considered by the Applicant for the soil exposure calculations. However, as indicated in the zRMS comments in point 8.7.2 above, the assumed cumulative effective rate of fenpicoxamid represented worst case comparing to the effective rate resulting from intended single use of GF-3307 and was thus accepted.

The soil exposure for fenpicoxamid and its metabolites has been independently validated by the zRMS using FOCUS methods with consideration of 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 were in good agreement with these obtained by the Applicant. Therefore, results reported in Tables 8.7-4 to 8.7-9 above may be used for the soil risk assessment purposes.

Prothioconazole

Note that the risk envelope GAP of 2 x 200 g as/ha from BBCH 30 used for the PECsoil calculations is protective of the GAP of 1 x 150 g as/ha from BBCH 30 specific to the use of GF-3307 in this dRR.

The max. prothioconazole soil loading comes from two applications for the risk envelope GAP. There will be some degradation between applications but as a worst case applications were assumed additive. The PECsoil was therefore calculated from the risk envelope application rate of 80 g as/ha (from 40 + 40 g as/ha) as a worst case from 2 x 200 g as/ha from BBCH 30 with 80% interception, which is protective of the lower rate of 1 x 150 g as/ha from BBCH 30 with 80% interception (soil loading 30 g as/ha).

Table 8.7-10: PECsoil for prothioconazole on cereals*

PECsoil (mg/kg)		Use no. 1-132	
		Multiple application	
		Actual	TWA
Initial		0.1067	-
Short term	1 d	0.0833	0.0945
	2 d	0.0650	0.0841
	4 d	0.0396	0.0677
Long term	7 d	0.0189	0.0507
	14 d	0.0033	0.0298
	21 d	0.0006	0.0204
	28 d	0.0001	0.0154
	50 d	0.0000	0.0086
	100 d	0.0000	0.0043
Plateau conc. (5 cm) after year x		-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

* Risk envelope GAP of 2 x 200 g as/ha from BBCH 30 is protective of 1 x 150 g as/ha from BBCH 30

Table 8.7-11: PECsoil for JAU 6476-S-methyl (M01) and JAU 6476-desthio (M04) on cereals*

PECsoil (mg/kg)		Use no. 1-132			
		Multiple application			
		JAU 6476-S-methyl (M01)		JAU 6476-desthio (M04)	
		Actual	TWA	Actual	TWA
Initial		0.0162	-	0.0552	-
Short term	1 d	0.0160	0.0161	0.0547	0.0549
	2 d	0.0157	0.0160	0.0542	0.0547
	4 d	0.0153	0.0157	0.0531	0.0542
Long term	7 d	0.0146	0.0154	0.0516	0.0534
	14 d	0.0131	0.0146	0.0483	0.0517
	21 d	0.0118	0.0139	0.0451	0.0500
	28 d	0.0106	0.0132	0.0422	0.0484
	50 d	0.0076	0.0114	0.0342	0.0439
	100 d	0.0036	0.0084	0.0212	0.0355
Plateau conc. (5 cm) after year x		-	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-	-	-

* Risk envelope GAP of 2 x 200 g as/ha from BBCH 30 is protective of 1 x 150 g as/ha from BBCH 30

zRMS comments:

Although multiple applications of GF-3307 are not intended in the Central Zone, they were considered by the Applicant for the soil exposure calculations. However, as indicated in the zRMS comments in point 8.7.2 above, the assumed cumulative effective rate of prothioconazole represented worst case comparing to the effective rate resulting from intended single use of GF-3307 and was thus accepted.

The soil exposure for prothioconazole and its metabolites has been independently validated by the zRMS using FOCUS methods with consideration of 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 were in good agreement with these obtained by the Applicant. Therefore, results reported in Tables 8.7-10 and 8.7-11 above may be used for the soil risk assessment purposes.

GF-3307

The formulation consists of active substance and co-formulants. It will not remain intact in soil after application due to breakdown of its individual components. Therefore, only an initial formulation PECsoil for a single application was calculated since applications would not be cumulative, and time-aged values (actual and TWA) are not appropriate. Therefore, the PECsoil was calculated based upon the effective risk envelope annual soil loading of 417.6 g FP/ha (assuming a formulation density of 1.044 g/mL and 80% interception) as a worst case from the 2 L FP/ha risk envelope rate, which is protective of the lower rate of 1.5 L FP/ha.

Table 8.7-12: PECsoil for GF-3307 on cereals

Formulation	**Use no. 1-**132			
	Appn. rate (L FP/ha)	**Appn. rate (g FP/ha)**	**Effective appn. rate (g FP/ha)****	**PECsoil (mg/kg)**
GF-3307	2	2088**	417.6	0.5568

* Risk envelope rate of 2 L FP/ha from BBCH 30 is protective of 1.5 L FP/ha from BBCH 30
** Assuming 80% interception for first application only

zRMS comments:

PEC_{SOIL} value for the formulated product GF-3307 presented in Table 8.7-12 above is agreed by the zRMS, and may be used in the risk assessment for soil organisms.

It is noted that it was calculated for the higher rate of 2.0 L/ha and is thus protective for lower intended rate of GF-3307 at 1.5 L /ha.

8.8 Predicted environmental concentrations in groundwater (PECgw) (KCP 9.2.4)

PECgw values were calculated for fenpicoxamid and major (>5% AR) soil metabolites: X642188, X696872, X12264475, X763024, X12313581, X696476, X11963422, X12314005, X12019520, X12255349.

PECgw values were calculated for prothioconazole and major (>5% AR) soil metabolites: JAU 6476-S-methyl (M01), JAU 6476-desthio (M04).

8.8.1 Justification for new endpoints

Fenpicoxamid

EFSA endpoints (2018) were used for the PECgw calculations.

Prothioconazole

EFSA endpoints (2007) were used for the PECgw calculations with the following exceptions.

~~Endpoint~~	~~EU agreed endpoint (EFSA, 2007)~~	~~Value used for modelling~~	~~Justification~~
~~Prothioconazole~~			
~~Vapour pressure (Pa)~~	~~<4.0 x 10^{-7}~~	~~1.0 x 10^{-10} (20ºC)~~	~~Worst case~~
~~DT_{50} soil (d), field~~	~~1.6~~	~~0.94 (20ºC/pF2) (geometric mean)~~	~~New evaluation (M-429069-01-1)~~
~~1/n~~	~~0.9~~	~~1~~	~~New default~~
~~JAU 6476-S-methyl (M01)~~			
~~Aqueous solubility (mg/L)~~	~~Not given~~	~~1.5 (25ºC)~~	~~Calculated~~
~~Vapour pressure (Pa)~~	~~Not given~~	~~2.9 x 10^{-8} (25ºC)~~	~~Calculated~~
~~DT_{50} soil (d), lab~~	~~15.7 (20ºC) (geometric mean)~~	~~9.5 (20ºC/pF2) (geometric mean)~~	~~Further normalised to pF2~~
~~Formation fraction (soil; from parent)~~	~~0.14~~	~~0.08~~	~~EU formation fraction based incorrectly on max. % AR~~
~~JAU 6476-desthio (M04)~~			
~~Aqueous solubility (mg/L)~~	~~Not given~~	~~50.6 (20ºC)~~	~~Calculated~~
~~Vapour pressure (Pa)~~	~~Not given~~	~~1.0 x 10^{-10} (20ºC)~~	~~Worst case~~
~~DT_{50} soil (d), field~~	~~42.2 (median)~~	~~21.8 (20ºC/pF2) (geometric mean)~~	~~New evaluation (M-429069-01-1)~~
~~Formation fraction (soil; from parent)~~	~~0.57~~	~~0.60~~	~~New evaluation (M-429069-01-1)~~

zRMS comments:

As not all new data for prothioconazole were agreed by the zRMS the Applicant was requested to performed new groundwater modelling based on endpoints agreed at the EU level.

Detailed discussion regarding endpoints considered in groundwater modelling and their acceptability is presented in the commenting boxes in points 8.8.2 for fenpicoxamid and prothioconazole. New endpoints provided in Table above are thus struck through.

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

Fenpicoxamid

Note that the risk envelope GAP of 2 x 130 g as/ha from BBCH 25 (20% and 80% interception) used for the PECgw calculations is protective of the GAP of 1 x 75 g as/ha from BBCH 30 (80% interception) specific to the use of GF-3307 in this dRR.

To support active approval, groundwater modelling was carried out and is reported in the EFSA conclusions (2018). The GAP modelled for fenpicoxamid in winter and spring cereals was 2 x 130 g as/ha (minimum 14 day interval) at BBCH 25 and 30 from 1 April, assuming interception of 20% and 80%, respectively. This gives effective application rates of 104 and 26 g as/ha (annual soil loading 130 g as/ha).

This risk envelope is protective of the maximum GF-3307 GAP since application (from BBCH 30) at the maximum of 75 g as/ha with 80% interception gives an effective annual soil loading of 15 g as/ha. Therefore, the PECgw values given by EFSA can be relied upon since there are no changes to the endpoints which impact the calculations. The following tables summarise the endpoints used in the groundwater calculations described by EFSA.

Table 8.8-1: Inputs related to application for PECgw for fenpicoxamid*

Use no.	**1-132**
Crop	Winter cereals, spring cereals
Application rate (g as/ha)	130 (Fenpicoxamid)
Max. number of applications	2
Crop interception (%)	20% (BBCH 25) + 80% (BBCH ≥30)
Effective soil loading (g as/ha)	104 + 26 (annual soil loading 130)
Min. application interval (d)	14
Application mode	Soil; effective application rates
Relative application date	Absolute date (Table 8.8-2)
Frequency of application	Annual
Models used	FOCUSPELMO 5.5.3/FOCUSPEARL 4.4.4

* Risk envelope GAP of 2 x 130 g as/ha from BBCH 25 is protective of 1 x 75 g as/ha from BBCH 30

Table 8.8-2: Application date used for PECgw for fenpicoxamid

FOCUS scenario*	**Use no. 1**-132
	First application date (absolute)
CHA, HAM, KRE, OKE, PIA**, POR	1 Apr (reflective of spring appn., BBCH 30)

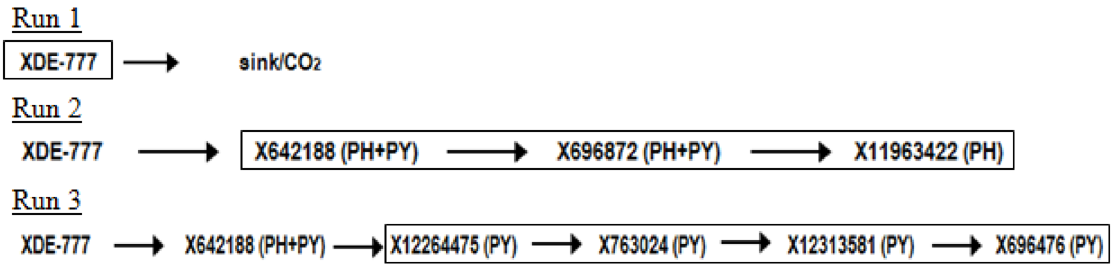
* Only scenarios relevant to countries in this submission
** Scenario not relevant for spring cereals

The AppDate v3.06 tool lists the following calendar dates corresponding to application at BBCH 30 for each groundwater scenario, which supports the selection of the 1 April as a reflective application timing for the Central Zone scenarios relevant to the countries in this submission.

FOCUS scenario	**BBCH 30**	
	w/cereals	**s/cereals**
CHA	15-Apr	16-Apr
HAM	04-May	28-Apr
KRE	24-Apr	27-Apr
OKE	21-Apr	22-Apr
PIA	19-Mar	-
POR	30-Jan	16-Apr

Parent and aerobic/anaerobic soil metabolites

To cover the complexity of the degradation route, three modelling runs were carried out.



A formation fraction of 1 was used for all residues as a worst case~~, although inverse kinetic modelling has shown that 0.6 is appropriate for the formation of X642188 from fenpicoxamid~~.

Table 8.8-3: Inputs for fenpicoxamid and aerobic/anaerobic metabolites for PECgw

Compound	Fenpicoxamid	X642188	X696872	X11963422	Evaluated at EU level
Molar mass (g/mol)	614.2	514.2	444.2	206.1	Yes *(EFSA, 2018)*
Water solubility (mg/L)	1000 (nominal)	1000 (nominal)	1000 (nominal)	1000 (nominal)	
Vapour pressure (Pa)	1.2 x 10^{-7}	Parent as surrogate	Parent as surrogate	Parent as surrogate	
DT_{50} soil (d) (20ºC/pF2) (geometric mean)	3.5	31.7	31.3	31.9 (n=1)	
Formation fraction	-	1**	1	1	
Kfoc* (geometric mean)	5776	4518	673	86	
1/n (arithmetic mean)	0.818	0.934	0.95	0.89	
Plant uptake factor	0	0	0	0	

* Divide by 1.724 for Kfom

~~** Used as a worst case, but otherwise 0.6 is applicable~~

Table 8.8-4: Inputs for fenpicoxamid and aerobic/anaerobic metabolites for PECgw

Compound	X12264475	X763024	X12313581	X696476	Evaluated at EU level
Molar mass (g/mol)	256.1	226.1	168.0	169.0	Yes *(EFSA, 2018)*
Water solubility (mg/L)	1000 (nominal)	1000 (nominal)	1000 (nominal)	1000 (nominal)	
Vapour pressure (Pa)	Parent as surrogate	Parent as surrogate	Parent as surrogate	Parent as surrogate	
DT_{50} soil (d) (20ºC/pF2) (geometric mean)	105.4	32.8	113.6	1000 (nominal)	
Formation fraction	1	1	1	1	
Kfoc* (geometric mean)	315	388	669	8871	
1/n (arithmetic mean)	0.93	0.92	0.88	0.81	
Plant uptake factor	0	0	0	0	

* Divide by 1.724 for Kfom

Table 8.8-5: PECgw for fenpicoxamid and aerobic/anaerobic metabolites on winter cereals*

Uses 1-68, 69-83								
FOCUS scenario	80th Percentile PECgw at 1 m soil depth (µg/L)							
	FPX	X642188	X696872	X11963422	X12264475	X763024	X12313581	X696476
FOCUSPELMO 5.5.3								
CHA	<0.001	<0.001	<0.001	<0.001	0.002	<0.001	0.001	<0.001
HAM	<0.001	<0.001	<0.001	0.025	0.064	0.015	0.019	0.002
KRE	<0.001	<0.001	<0.001	0.010	0.046	0.011	0.013	0.001
OKE	<0.001	<0.001	<0.001	0.023	0.077	0.018	0.026	0.003
PIA	<0.001	<0.001	<0.001	0.010	0.038	0.009	0.012	0.002
POR	<0.001	<0.001	<0.001	0.022	0.039	0.009	0.010	0.002
FOCUSPEARL 4.4.4								
CHA	<0.001	<0.001	<0.001	<0.001	0.004	0.001	0.001	<0.001
HAM	<0.001	<0.001	<0.001	0.021	0.072	0.017	0.024	0.002
KRE	<0.001	<0.001	<0.001	0.009	0.046	0.011	0.014	0.001
OKE	<0.001	<0.001	<0.001	0.021	0.071	0.017	0.025	0.001
PIA	<0.001	<0.001	<0.001	0.007	0.035	0.009	0.012	0.001
POR	<0.001	<0.001	<0.001	0.006	0.024	0.005	0.006	0.001

* Risk envelope GAP of 2 x 130 g as/ha from BBCH 25 is protective of 1 x 75 g as/ha from BBCH 30

Table 8.8-6: PECgw for fenpicoxamid and aerobic/anaerobic metabolites on spring cereals*

Uses 84-117, 118-132								
FOCUS scenario	80th Percentile PECgw at 1 m soil depth (µg/L)							
	FPX	X642188	X696872	X11963422	X12264475	X763024	X12313581	X696476
FOCUSPELMO 5.5.3								
CHA	<0.001	<0.001	<0.001	<0.001	0.001	<0.001	<0.001	<0.001
HAM	<0.001	<0.001	<0.001	0.021	0.054	0.013	0.016	0.001
KRE	<0.001	<0.001	<0.001	0.008	0.037	0.009	0.010	0.001
OKE	<0.001	<0.001	<0.001	0.017	0.058	0.014	0.020	0.002
POR	<0.001	<0.001	<0.001	0.016	0.032	0.007	0.008	0.001
FOCUSPEARL 4.4.4								
CHA	<0.001	<0.001	<0.001	<0.001	0.003	0.001	0.001	<0.001
HAM	<0.001	<0.001	<0.001	0.025	0.083	0.020	0.028	0.002
KRE	<0.001	<0.001	<0.001	0.009	0.047	0.011	0.014	0.001
OKE	<0.001	<0.001	<0.001	0.018	0.064	0.015	0.022	0.001
POR	<0.001	<0.001	<0.001	0.010	0.022	0.005	0.006	<0.001

* Risk envelope GAP of 2 x 130 g as/ha from BBCH 25 is protective of 1 x 75 g as/ha from BBCH 30

Soil photodegradates

To cover the complexity of the degradation route, two modelling runs were carried out.

<u>Run 1</u>

XDE-777 → X642188 → [X12314005 → X12019520]

<u>Run 2</u>

XDE-777 → X642188 → [X12255349]

Endpoints used for fenpicoxamid and X642188 are shown as they are needed to model the photodegradates in sequence. However, their PECgw values were derived from the modelling described for the aerobic/anaerobic metabolites, since the photodegradate modelling gives identical values for these residues.

A formation fraction of 1 was used for all residues as a worst case, ~~although inverse kinetic modelling has shown that 0.6 is appropriate for the formation of X642188 from fenpicoxamid.~~

Table 8.8-7: Inputs for photodegradates for PECgw

Compound	Fenpicoxamid	X642188	X12314005	X12019520	X12255349	Evaluated at EU level
Molar mass (g/mol)	614.2	514.2	276.3	188.2	514.5	Yes *(EFSA, 2018)*
Water solubility (mg/L)	1000 (nominal)	1000 (nominal)	1000 (nominal)	1000 (nominal)	1000 (nominal)	
Vapour pressure (Pa)	1.2×10^{-7}	Parent as surrogate	Parent as surrogate	Parent as surrogate	Parent as surrogate	
DT_{50} soil (d) (20ºC/pF2) (geometric mean)	3.5	31.7	0.03 ~~0.1~~	3.1	2.4 ~~3.4~~	
Formation fraction	-	1~~**~~	1	1	1	
Kfoc* (geometric mean)	5776	4518	118	68	594	
1/n (arithmetic mean)	0.818	0.934	1.00	0.90	1.06	
Plant uptake factor	0	0	0	0	0	

* Divide by 1.724 for Kfom
~~** Used as a worst case, but otherwise 0.6 is applicable~~

Table 8.8-8: PECgw for photodegradates on winter cereals*

Uses 1-68, 69-83			
FOCUS scenario	**80th Percentile PECgw at 1 m soil depth (µg/L)**		
	X12314005	**X12019520**	**X12255349**
FOCUSPELMO 5.5.3			
CHA	<0.001	<0.001	<0.001
HAM	<0.001	<0.001	<0.001
KRE	<0.001	<0.001	<0.001
OKE	<0.001	<0.001	<0.001
PIA	<0.001	<0.001	<0.001
POR	<0.001	<0.001	<0.001
FOCUSPEARL 4.4.4			
CHA	<0.001	<0.001	<0.001
HAM	<0.001	<0.001	<0.001
KRE	<0.001	<0.001	<0.001
OKE	<0.001	<0.001	<0.001
PIA	<0.001	<0.001	<0.001
POR	<0.001	<0.001	<0.001

* Risk envelope GAP of 2 x 130 g as/ha from BBCH 25 is protective of 1 x 75 g as/ha from BBCH 30

Table 8.8-9: PECgw for photodegradates on spring cereals*

Uses 84-117, 118-132			
FOCUS scenario	**80th Percentile PECgw at 1 m soil depth (µg/L)**		
	X12314005	**X12019520**	**X12255349**
FOCUSPELMO 5.5.3			
CHA	<0.001	<0.001	<0.001
HAM	<0.001	<0.001	<0.001
KRE	<0.001	<0.001	<0.001
OKE	<0.001	<0.001	<0.001
POR	<0.001	<0.001	<0.001
FOCUSPEARL 4.4.4			
CHA	<0.001	<0.001	<0.001
HAM	<0.001	<0.001	<0.001
KRE	<0.001	<0.001	<0.001
OKE	<0.001	<0.001	<0.001
POR	<0.001	<0.001	<0.001

* Risk envelope GAP of 2 x 130 g as/ha from BBCH 25 is protective of 1 x 75 g as/ha from BBCH 30

zRMS comments:

No groundwater modelling has been performed by the Applicant in order to specifically address leaching of fenpicoxamid and its metabolites following application of GF-3307. Instead, result of groundwater modelling performed during the EU review of fenpicoxamid were used as being protective for the intended uses of GF-3307 in the Central Zone.

The application and input parameters as well as results presented in tables above were checked and are confirmed to be in line with these reported in EFSA Journal 2016;16(1):5146. The metabolic pathways given in graphs above are in line with these provided in Vol. 3CP, B.8 (October 2017).

The zRMS agrees that EU modelling with two applications at 130 g a.s./ha (rates reaching soil: 104+26 g a.s./ha) clearly represents worst case comparing to the Central Zone GAP with a single application at 75 g a.s./ha (rate reaching soil: 15 g a.s./ha). It is noted that at the EU level 1st April has been assumed as the application date in all scenarios. According to the AppDate the application dates of GF-3307 would be between mid-March till beginning of May with exception of winter cereals in Porto with date of 30th January (see table above). However, the zRMS is of the opinion that uncertainty around application dates is covered by considerably higher application rates assumed in EU modelling.

Overall, based on results of the EU modelling, no unacceptable leaching of fenpicoxamid and its metabolites is expected following application of GF-3307 according to the use pattern intended in the Central Zone.

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

Prothioconazole

Note that the risk envelope GAP of 2 x 187.5 g as/ha from BBCH 25 (50% interception each) used for the PECgw calculations is protective of the GAP of 1 x 150 g as/ha from BBCH 30 (80% interception) specific to the use of GF-3307 in this dRR.

The prothioconazole GAP modelled in winter and spring cereals was 2 x 187.5 g as/ha at BBCH 25 and 30 (14 day interval) (**8.8.2/01 and 8.8.2/02**). The interception used for both was 50%, giving effective application rates of 93.75 g as/ha each (annual soil loading 187.5 g as/ha). This is protective of the maximum GF-3307 GAP since application from BBCH 30 at 150 g as/ha with 80% crop interception gives an annual soil loading of 30 g as/ha.

Table 8.8-10: Inputs related to application for PECgw for prothioconazole*

Use no.	1-132
Crop	Winter cereals, spring cereals
Application rate (g as/ha)	187.5 (Prothioconazole)
Max. number of applications	2
Crop interception (%)	50% (BBCH 25) + 50% (BBCH ≥30)
Effective application rate (g as/ha)	93.75 + 93.75 (annual soil loading 187.5)
Min. application interval (d)	14
Application mode	Soil; effective application rates
Relative application date	Absolute date (Table 8.8-11)
Frequency of application	Annual
Models used	FOCUSPELMO/FOCUSPEARL

* Risk envelope GAP of 2 x 187.5 g as/ha from BBCH 25 is protective of 1 x 150 g as/ha from BBCH 30

Furthermore, the application dates modelled for prothioconazole for winter cereals are more reflective of BBCH 25 which corresponds to an earlier calendar timing than anticipated for BBCH 30. As such the earlier timing is more conservative and hence further protective of the winter cereals GAP for GF-3307.

Table 8.8-11: Application dates used for PECgw for prothioconazole

FOCUS scenario*	Uses 1-68, 69-83	Uses 84-117, 118-132
	First appn. date (absolute)	
CHA	15 Jan	4 Apr
HAM	3 Feb	25 Apr
KRE	31 Jan	28 Apr
OKE	15 Jan	25 Apr

* Only Central Zone scenarios provided as relevant for this dRR

Note that Piacenza and Porto were not modelled in this work which may be relevant for some Central Zone countries. However, based upon the results from the other Central Zone scenarios, this is expected to have no impact, and was not modelled.

The following reports **(8.8.2/01 and 8.8.2/02)** provide the PECgw for prothioconazole, JAU 6476-S-methyl (M01) and JAU 6476-desthio (M04).

Reference:	**8.8.2/01**
Report:	Chapple, A. & Hoerold, C. (2014): Prothioconazole (PTZ) and Metabolites: PECgw FOCUS PEARL, FOCUS PELMO EUR – Use in Winter Cereals in Europe. Bayer CropScience Report No. M-476501-01-1 (EnSa-13-0879).
Guideline(s):	FOCUS (2009): Assessing Potential for Movement of Active substances and their Metabolites to Ground Water in the EU. Report of FOCUS Groundwater Work Group, EC Document Ref. SANCO/13144/2010, Ver. 1, 604 pp.
Deviations:	No
GLP:	No (model calculation)
Acceptability:	Yes

Reference:	**8.8.2/02**
Report:	Chapple, A. & Hoerold, C. (2014): Prothioconazole (PTZ) and Metabolites: PECgw FOCUS PEARL, FOCUS PELMO EUR – Use in Spring Cereals in Europe. Bayer CropScience Report No. M-476508-01-1 (EnSa-13-1015).
Guideline(s):	FOCUS (2009): Assessing Potential for Movement of Active substances and their Metabolites to Ground Water in the EU. Report of FOCUS Groundwater Work Group, EC Document Ref. SANCO/13144/2010, Ver. 1, 604 pp.
Deviations:	No
GLP:	No (model calculation)
Acceptability:	Yes

~~The modelling described in these two reports used arithmetic mean Kfoc values for the two prothioconazole metabolites which was appropriate at the time. However, the modelling has not been repeated using geometric mean Kfoc values since these are very close to the arithmetic means and will have no impact, especially since the resultant PECgw values for all residues are <0.001 µg/L. Furthermore, the Kfoc used for prothioconazole was a single value and so a geometric mean is not appropriate.~~

~~**Table 8.8-12: Inputs for prothioconazole and metabolites for PECgw**~~

~~Compound~~	~~Prothioconazole~~	~~JAU 6476-S-methyl (M01)~~	~~JAU 6476-desthio (M04)~~	~~Evaluated at at EU level~~
~~Molar mass (g/mol)~~	~~344.3~~	~~358.3~~	~~312.2~~	~~Yes *(EFSA, 2007)* [unless specified otherwise under 8.8.1]~~
~~Water solubility (mg/L)~~	~~300~~	~~1.5~~	~~50.6~~	
~~Vapour pressure (Pa)~~	~~1×10^{-10}~~	~~2.9×10^{-8}~~	~~1×10^{-10}~~	
~~DT_{50} soil (d) (20ºC/pF2) (geometric mean)~~	~~0.94 (field)~~	~~9.5 (lab)~~	~~21.8 (field)~~	
~~Formation fraction~~	~~-~~	~~0.08 (parent)~~	~~0.60 (parent)/1 (M01)~~	
~~Kfoc* (arithmetic mean)~~	~~1765**~~	~~2556.3~~	~~575.4~~	
~~1/n (arithmetic mean)~~	~~1 (default)~~	~~0.88~~	~~0.81~~	
~~Plant uptake factor~~	~~0~~	~~0.5~~	~~0~~	

~~* Divide by 1.724 for Kfom~~
~~** Single value estimated from aged leaching study due to instability in batch studies~~

~~**Table 8.8-13: PECgw for prothioconazole and metabolites on winter and spring cereals (FOCUSPELMO/FOCUSPEARL)***~~

~~FOCUS scenario~~	~~Use no. 1-132~~ ~~80th Percentile PECgw at 1 m soil depth (µg/L)~~ ~~Prothioconazole~~	~~JAU 6476-S-methyl (M01)~~	~~JAU 6476-desthio (M04)~~
~~CHA~~	~~<0.001~~	~~<0.001~~	~~<0.001~~
~~HAM~~	~~<0.001~~	~~<0.001~~	~~<0.001~~
~~KRE~~	~~<0.001~~	~~<0.001~~	~~<0.001~~
~~OKE~~	~~<0.001~~	~~<0.001~~	~~<0.001~~

~~* Risk envelope GAP of 2 x 187.5 g as/ha from BBCH 25 is protective of 1 x 150 g as/ha from BBCH 30~~

UPDATE – April 2022

Request from Poland (zRMS):

- *"Kinetic re-evaluation is considered to be the new active substance data, which may be used at the zonal level only in exceptional cases, when e.g. no safe use is identified using the EU agreed endpoints. Furthermore, the Working Document of the Central Zone in area of Section 8 indicates that modelling based on new/refined input parameters should be presented in addition to (and not instead of) simulations based on EU agreed data. Therefore, the degradation data for prothioconazole and its metabolites in soil and aquatic systems considered in the exposure assessment must be in line with EU agreed endpoints presented in EFSA Scientific Report (2007) 106. Taking this into account, the Applicant is kindly requested to provide groundwater and surface water modelling based on endpoints being fully in line with the EU agreed values."*

- *"Since the new groundwater and surface water modelling must be performed anyway, the Applicant is kindly requested to consider application dates (or windows) suggested by AppDate ver. 3.06, in line with Working Document of the Central Zone in area of Section 8, which indicates that the application timing should be selected using the most actual version of the software AppDate."*

- *"In the new groundwater modelling based on EU agreed endpoints, please include Piacenza and Porto scenarios, which are relevant for the Central Zone."*

- *"In groundwater modelling PUF value (TSCF) must be set to 0 for all compounds, in line with most recent recommendations of FOCUS groundwater and surface water guidance documents, as PUF of 0.5 considered at the EU level was not a substance specific parameter, but resulted from indications of previous versions of the guidance documents."*

Response from Applicant:

The zRMS (Poland) requested that groundwater modelling be repeated using dates relevant to BBCH 30 according to AppDate 3.06 (June, 2019), and to include Piacenza and Porto (although these scenarios are not required by any MS relevant to this submission).

The updated modelling at **1 x 150 g as/ha** is described below. It is not reported separately since the work can be fully described and presented directly here in the dRR.

Table 8.8-14: Inputs related to application for PECgw

Use no.	**1-68, 69-83**	**84-117, 118-132**
Crop category	Winter cereals	Spring cereals
Application rate (g as/ha)	150 (Prothioconazole)	
Max. number of applications	1	
Growth stage	From BBCH 30	
Crop interception (%)	80%	
Effective soil loading (g as/ha)	30 (Prothioconazole)	
Application mode	Soil; effective application rates	
Relative application date	Date given by AppDate 3.06 (June, 2019), BBCH 30	
Frequency of application	Annual	
Models used	FOCUSPELMO 6.6.4+, FOCUSPEARL 5.5.5+ (with SPIN 3.3)	

\+ 21 September 2021 versions

The dates modelled for application to winter and spring cereals corresponding to BBCH 30 were selected for each relevant FOCUS groundwater scenario using AppDate 3.06 (June, 2019). All scenarios available for the crop were modelled for completeness, but only those relevant for the Central Zone are described here.

Table 8.8-15: Application dates used for PECgw

FOCUS scenario	**Appn. date (absolute) (BBCH 30)**	
	Use no. 1-68, 69-83	**Use no. 84-117, 118-132**
CHA	15 Apr	16 Apr
HAM	4 May	28 Apr
KRE	24 Apr	27 Apr
OKE	21 Apr	22 Apr
PIA	19 Mar	-*
POR	30 Jan	16 Apr

* Scenarios not relevant for spring cereals

The inputs related to prothioconazole and JAU 6476-desthio (M04) (all from EFSA, 2007; in view of the request from Poland) are given in Table 8.8-16. Any inputs not shown were left as the FOCUS default values in the models.

Table 8.8-16: Inputs related to prothioconazole and metabolite for PECgw

Compound	Prothioconazole	JAU 6476- S-methyl (M01)	JAU 6476- desthio (M04)	Evaluated at at EU level
Molar mass (g/mol)	344.3	358.3	312.2	Yes *(EFSA, 2007)*
Water solubility (20°C) (mg/L)	300*	1.5 (25°C)	50.6	
Vapour pressure (20°C) (Pa)	1 x 10^{-10}*	2.9 x 10^{-8} (25°C)	Parent as surrogate	
DT_{50} soil (d) (20ºC) (geometric mean)	1.2	15.7	22.7	
Formation fraction (arithmetic mean)	-	0.14 (parent)	0.57 (parent)/1 (M01)	
Kfoc (arithmetic mean)	1765 (n=1)	2556.3	575.4	
1/n (arithmetic mean)	0.9	0.88	0.81	
Plant uptake factor	0	0**	0	

* Required for parent in FOCUSPELMO: solubility at T2 (T1 + 10°C) = 2 x solubility at T1 and vapour pressure at T2 (T1 + 10°C) = 4 x vapour pressure at T1

** Worst case compared to 0.5 given by EFSA, 2007

The degradation route modelled was as follows (EFSA, 2007).

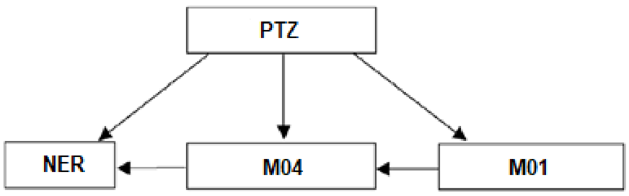


Table 8.8-17: Prothioconazole and metabolites PECgw for winter cereals

FOCUS scenario	Use no. 1-68, 69-83		
	80th Percentile PECgw at 1 m soil depth (µg/L)		
	Prothioconazole	JAU 6476- S-methyl (M01)	JAU 6476- desthio (M04)
FOCUSPELMO 6.6.4			
CHA	<0.001	<0.001	<0.001
HAM	<0.001	<0.001	<0.001
KRE	<0.001	<0.001	<0.001
OKE	<0.001	<0.001	<0.001
PIA	<0.001	<0.001	<0.001
POR	<0.001	<0.001	<0.001
FOCUSPEARL 5.5.5			
CHA	<0.001	<0.001	<0.001
HAM	<0.001	<0.001	<0.001
KRE	<0.001	<0.001	<0.001
OKE	<0.001	<0.001	<0.001
PIA	<0.001	<0.001	<0.001
POR	<0.001	<0.001	<0.001

Table 8.8-18: Prothioconazole and metabolites PECgw for spring cereals

FOCUS scenario	Use no. 84-117, 118-132		
	80th Percentile PECgw at 1 m soil depth (µg/L)		
	Prothioconazole	JAU 6476-S-methyl (M01)	JAU 6476-desthio (M04)
FOCUSPELMO 6.6.4			
CHA	<0.001	<0.001	<0.001
HAM	<0.001	<0.001	<0.001
KRE	<0.001	<0.001	<0.001
OKE	<0.001	<0.001	<0.001
POR	<0.001	<0.001	<0.001
FOCUSPEARL 5.5.5			
CHA	<0.001	<0.001	<0.001
HAM	<0.001	<0.001	<0.001
KRE	<0.001	<0.001	<0.001
OKE	<0.001	<0.001	<0.001
POR	<0.001	<0.001	<0.001

zRMS comments:

As already indicated in points 8.3.1 and 8.4.1 of this document, kinetic re-evaluation is considered to be the new active substance data, which may be used at the zonal level only in exceptional cases, when e.g. no safe use is identified using the EU agreed endpoints. Furthermore, the Working Document of the Central Zone in area of Section 8[2] indicates that modelling based on new/refined input parameters should be presented in addition to (and not instead of) simulations based on EU agreed data. As the DT_{50} values of each compounds presented in Table 8.8-12 were not in line with EU agreed endpoints presented in EFSA Scientific Report (2007) 106, the Applicant was requested to perform new groundwater modelling based on endpoints agreed at the EU level.

Moreover, the modelling should be performed with application dates that are consistent with the most actual version of AppDate (in line with Working Document of the Central Zone in area of Section 8) and with the PUF value of 0 for all compounds.

As on request of the zRMS new modelling has been submitted by the Applicant, the input data and results of the modelling performed by Chapple and Hoerold (2014) were struck through as being replaced by the new simulations.

The zRMS would like to emphasise that even if scenarios Porto and Piacenza are not required by any cMS of the Central Zone, they are required in line with indications of the Working Document of the Central Zone in area of Section 8.

The new modelling was independently validated by the zRMS in additional simulations based on the same EU agreed data and using FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3 and FOCUS MACRO 5.5.4. It is noted that the Applicant used the newest version of FOCUS PELMO 6.6.4, nevertheless PEC_{GW} obtained by the zRMS with older version of the model were the same as these presented in Tables 8.8-17 and 8.8-18.

Overall, all PEC_{GW} were <0.1 µg/L and no unacceptable leaching of prothioconazole and its metabolites is expected following application of GF-3307 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.

[2] Working Document of the Central Zone in the Authorisation of Plant Protection Products, Section 8, Environmental Fate and Behaviour, Version 1, rev. 1, June 2018

8.9 Predicted environmental concentrations in surface water (PECsw/sed) (KCP 9.2.5)

PECsw/sed values were calculated for fenpicoxamid and major (>5% AR) soil/aquatic metabolites: X642188, X696872, X12264475, X763024, X12313581, X696476, X11963422, X12314005, X12019520, X12255349, X12335723, X12386481, X12446477, X12433979.

PECsw/sed values were calculated for prothioconazole and major (>5% AR) soil/aquatic metabolites: JAU 6476-S-methyl (M01), JAU 6476-desthio (M04), 1,2,4-triazole.

PECsw values were calculated for the formulation: GF-3307.

8.9.1 Justification for new endpoints

Fenpicoxamid

EFSA endpoints (2018) were used for the PECsw/sed calculations.

Prothioconazole

EFSA endpoints (2007) were used for the PECsw/sed calculations with the following exceptions.

~~Endpoint~~	~~EU agreed endpoint (EFSA, 2007)~~	~~Value used for modelling~~	~~Justification~~
~~**Prothioconazole**~~			
~~Vapour pressure (Pa)~~	~~$<4.0 \times 10^{-7}$~~	~~1.0×10^{-10} (20ºC)~~	~~Worst case~~
~~DT_{50} soil (d), field~~	~~1.6~~	~~0.94 (20ºC/pF2)~~	~~New evaluation (M-429069-01-1)~~
~~1/n~~	~~0.9~~	~~1~~	~~Current default~~
~~DT_{50} water/sediment (d)~~	~~1.6-2.8~~	~~24.1 (20ºC)~~	~~New evaluation (M298575-01-1)~~
~~DT_{50} water (d)~~	~~0.8-1.0~~	~~24.1 (20ºC)~~	~~New evaluation (M298575-01-1)~~
~~DT_{50} sediment (d)~~	~~Not given~~	~~1000 (20ºC)~~	~~Based on Koc <2000~~
~~**JAU 6476-S-methyl (M01)**~~			
~~Aqueous solubility (mg/L)~~	~~Not given~~	~~1.5 (25ºC)~~	~~Calculated~~
~~DT_{50} water/sediment (d)~~	~~Not given~~	~~40.2 (20ºC)~~	-
~~**JAU 6476-desthio (M04)**~~			
~~Aqueous solubility (mg/L)~~	~~Not given~~	~~50.6 (20ºC)~~	~~Calculated~~
~~Vapour pressure (Pa)~~	~~Not given~~	~~1.0×10^{-10} (20ºC)~~	~~Worst case~~
~~DT_{50} soil (d), field~~	~~42.2~~	~~21.8 (20ºC/pF2)~~	~~New evaluation (M-429069-01-1)~~
~~Formation fraction (soil; from parent)~~	~~0.57~~	~~0.60~~	~~New evaluation (M-429069-01-1)~~
~~DT_{50} water/sediment (d)~~	~~1.6-2.8~~	~~49.9 (20ºC)~~	~~New evaluation (M-429069-01-1)~~
~~DT_{50} water (d)~~	~~Not given~~	~~49.9 (20ºC)~~	~~New evaluation (M-429069-01-1)~~
~~DT_{50} sediment (d)~~	~~Not given~~	~~1000 (20ºC)~~	~~Based on Koc <2000~~
~~Formation fraction (water/sediment; from parent)~~	~~Not given~~	~~1~~	~~Worst case~~

zRMS comments:

As not all new data for prothioconazole were agreed by the zRMS, the Applicant was requested to perform new surface water modelling based on endpoints agreed at the EU level.

Detailed discussion regarding endpoints considered in surface water modelling and their acceptability is presented in the commenting boxes in points 8.9-2 for prothioconazole. Input parameters provided in table above were thus struck through.

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

Fenpicoxamid

Steps 1 and 2

~~**Note that the risk envelope GAP of 2 x 100 g as/ha from BBCH 30 used for the PECsw/sed calculations at Steps 1 and 2 is protective of the GAP of 1 x 75 g as/ha from BBCH 30 specific to the use of GF-3307 in this dRR.**~~

~~The risk envelope GAP modelled for fenpicoxamid in winter and spring cereals was 2 x 100 g as/ha (minimum 14 day interval) at BBCH 30, which is protective of the lower rate of 1 x 75g as/ha. The crop interception was assumed to be "full cover" (i.e. 70%) with the Mar-May application window. The Steps 1 and 2 modelling is not reported separately, but instead is fully described within this dRR.~~

The following endpoints were used to derive the PECsw/sed values. The molar mass values used are not given, but are those presented previously in Table 8.2-1. In addition, the water solubility values used for all residues was a nominal 1000 mg/L.

Table 8.9-1: Inputs related to application for PECsw/sed (Steps 1 and 2)

Compound	Kfoc (geometric mean)	DT_{50} soil (d) (20ºC/pF2) (geometric mean)	DT_{50} water, sediment, whole system (d) (20ºC) (geometric mean)	Max. occurence, soil (% AR)	Max. occurence, water/sed (% AR)	Evaluated at EU level
Fenpicoxamid	5776	3.5	0.7	-	-	Yes *(EFSA, 2018)*
X642188	4518	31.7	2.7	39.2	19.5	
X696872	673	31.3	1000	17.2	-**	
X12264475	315	105.4	49	49.4	65.3	
X763024	388	32.8	1000	5.7	-**	
X12313581	669	113.6	1000	17.1	9.3	
X696476	8871	1000	1000	46.9	67.1	
X11963422	86	31.9 (n=1)	1000	80.3	45.0	
X12314005	118	0.03	0.84	5.4	35.1	
X12019520	68	3.1	8.8	9.8	15.3	
X12255349	594	3.4	1000	6.9	-**	
X12335723	1*	1000	2.6	-**	45.9	
X12386481	1*	1000	1000	-**	69.5^{+}	
X12446477	1*	1000	1000	-**	12.5^{+}	
X12433979	1*	1000	1000	-**	35.7^{++}	

* Nominal default for non-soil metabolite
** Nominal default of 0.001% used to allow model to run
\+ Aqueous photolysis only (not seen in water/sediment)
++ Hydrolysis (pH9, 25°C) (not seen in water/sediment)

~~The results are given as follows.~~

Table 8.9-2: Steps 1 and 2 PECsw/sed for fenpicoxamid and metabolites on cereals*

Compound	FOCUS scenario		Use no. 1-132		
			Max. PECsw (µg/L)	Max. 21 d TWA PECsw (µg/L)	Max. PECsed (µg/kg)
Fenpicoxamid	Step 1		4.75	0.22	221.27
	Step 2	N Europe	0.92	0.04	6.48
		S Europe	0.92	0.05	12.87
X642188	Step 1		1.71	0.29	70.36
	Step 2	N Europe	0.16	0.04	7.01
		S Europe	0.31	0.06	13.72
X696872	Step 1		4.37	4.34	29.42
	Step 2	N Europe	0.21	0.21	1.40
		S Europe	0.42	0.41	2.80
X12264475	Step 1		10.17	8.68	31.13
	Step 2	N Europe	0.84	0.70	2.51
		S Europe	1.38	1.17	4.19
X763024	Step 1		0.92	0.92	3.58
	Step 2	N Europe	0.04	0.04	0.17
		S Europe	0.09	0.09	0.34
X12313581	Step 1		1.69	1.66	11.18
	Step 2	N Europe	0.12	0.11	0.76
		S Europe	0.21	0.21	1.38
X696476	Step 1		1.01	0.70	61.80
	Step 2	N Europe	0.17	0.06	5.60
		S Europe	0.17	0.10	9.14
X11963422	Step 1		16.39	16.25	14.06
	Step 2	N Europe	1.00	0.98	0.85
		S Europe	1.77	1.75	1.51
X12314005	Step 1		0.84	0.05	0.83
	Step 2	N Europe	0.15	0.01	0.04
		S Europe	0.15	0.01	0.04
X12019520	Step 1		1.92	0.94	1.25
	Step 2	N Europe	0.06	0.03	0.04
		S Europe	0.08	0.04	0.05
X12255349	Step 1		2.15	2.13	12.77
	Step 2	N Europe	0.03	0.03	0.18
		S Europe	0.06	0.06	0.36
X12335723	Step 1		0.24	0.04	<0.01
	Step 2	N Europe	0.24	0.04	<0.01
		S Europe	0.24	0.04	<0.01
X12386481	Step 1		0.68	0.67	0.01
	Step 2	N Europe	0.60	0.59	0.01
		S Europe	0.60	0.59	0.01
X12446477	Step 1		0.12	0.12	<0.01
	Step 2	N Europe	0.10	0.10	<0.01
		S Europe	0.10	0.10	<0.01
X12433979	Step 1		0.31	0.31	<0.01
	Step 2	N Europe	0.28	0.27	<0.01
		S Europe	0.28	0.27	<0.01

* Risk envelope GAP of 2 x 100 g as/ha from BBCH 30 is protective of 1 x 75 g as/ha from BBCH 30

UPDATE – April 2022

Request from Poland (zRMS):

- *"The Step 2 surface water modelling for fenpicoxamid and its metabolites should be performed with assumption of "intermediate crop cover", which according to indications of the FOCUS surface water generic guidance (2015) is relevant for applications at BBCH 30 (the earliest intended application of GF-3307). In addition to that, the Step 1/2 modelling was performed with assumption of application at 2 x 100 g as/ha for prothioconazole and its metabolites, but from the information available in the dRR it is not clear, if Step 2 results presented in Table 8.9-2 are the maximum values of single and multiple application, or are relevant for multiple applications only. Please note that in case of rapidly degrading compounds higher PECsw is expected from single application comparing to multiple applications. Taking this into account, the Applicant is kindly requested to provide Step 2 modelling for fenpicoxamid and its metabolites performed for single application at 100 g as/ha (or at 75 g as/ha, in line with the GAP for GF-3307)."*

Response from Applicant:

Previous Steps 1 and 2 modelling used "full canopy" (70% interception) as relevant for BBCH 30 (e.g. 80% interception is used for BBCH 30 in groundwater modelling). However, the zRMS (Poland) requested Steps 1 and 2 be repeated using "intermediate" crop cover, specifically for **1 x 75 g as/ha** rather than using a risk envelope approach from 2 x 100 g as/ha. This updated modelling is described below. It is not reported separately since the work can be fully described and presented directly in the dRR. The inputs specific to fenpicoxamid and X642188 were those already given in Table 8.9-1. Any inputs not shown were left as the FOCUS default values in the models.

Only results for "North Europe" are given as relevant for the Central Zone. It should be noted that STEPS 1-2 in FOCUS 3.2 does not give "intermediate" crop cover, and so "average" crop cover was used (20% interception). This is very conservative given that 80% is appropriate for groundwater modelling.

Table 8.9-3: Steps 1 and 2 PECsw/sed for fenpicoxamid and metabolites on cereals (1x75g a.s./ha, BBCH 30-69)

Compound	FOCUS scenario		Use no. 1-132		
			Max. PECsw (µg/L)	Max. 21 d TWA PECsw (µg/L)	Max. PECsed (µg/kg)
Fenpicoxamid	Step 1		3.56	0.17	165.95
	Step 2	N Europe	0.69	0.04	12.11
X642188	Step 1		1.86	0.33	79.03
	Step 2	N Europe	0.23	0.04	9.88
X696872	Step 1		1.64	1.63	11.03
	Step 2	N Europe	0.24	0.24	1.61
X12264475	Step 1		8.61	7.40	26.57
	Step 2	N Europe	1.05	0.90	3.23
X763024	Step 1		0.35	0.35	1.34
	Step 2	N Europe	0.05	0.05	0.20
X12313581	Step 1		0.98	0.96	6.44
	Step 2	N Europe	0.14	0.13	0.87
X696476	Step 1		0.74	0.62	55.07
	Step 2	N Europe	0.13	0.07	6.74
X11963422	Step 1		9.53	9.46	8.18
	Step 2	N Europe	1.23	1.22	1.05
X12314005	Step 1		4.04	0.24	4.64
	Step 2	N Europe	0.25	0.02	0.29

Compound	FOCUS scenario		Use no. 1-132		
			Max. PECsw (µg/L)	Max. 21 d TWA PECsw (µg/L)	Max. PECsed (µg/kg)
X12019520	Step 1		1.79	1.76	1.20
	Step 2	N Europe	0.14	0.07	0.09
X12255349	Step 1		0.81	0.80	4.79
	Step 2	N Europe	0.06	0.06	0.34
X12335723	Step 1		6.83	1.22	0.07
	Step 2	N Europe	0.55	0.10	0.01
X12386481	Step 1		9.47	9.40	0.10
	Step 2	N Europe	0.92	0.92	0.01
X12446477	Step 1		1.63	1.62	0.02
	Step 2	N Europe	0.16	0.16	<0.01
X12433979	Step 1		4.39	4.35	0.05
	Step 2	N Europe	0.43	0.42	0.01

~~**Steps 3 and 4**~~

~~The following tables summarise the endpoints used at Steps 3 and 4 for fenpicoxamid and X642188.~~

~~**Table 8.9-4: Inputs related to application for PECsw/sed (Steps 3 and 4)**~~

~~Use no.~~	~~1-132~~
~~Crop~~	~~Winter cereals, spring cereals~~
~~Application rate (g as/ha)~~	~~75 (Fenpicoxamid)~~
~~Max. number of applications~~	~~1~~
~~Frequency of application~~	~~Annual~~
~~Application window (Steps 3 and 4)~~	~~Absolute date (Table 8.9-4)~~
~~Application method~~	~~Ground spray~~
~~Chemical application method (CAM)~~	~~2 – appn. foliar linear~~
~~Depth incorporated (cm)~~	~~4~~
~~Models used~~	~~FOCUS SPIN v2.2~~ ~~FOCUS SWASH v5.3~~ ~~FOCUS MACRO v5.5.4~~ ~~FOCUS PRZM v4.3.1~~ ~~FOCUS TOXSWA v4.4.3~~ ~~SWAN v4.0.1 (Step 4)~~

~~**Table 8.9-5: Application window used for Steps 3 and 4 PECsw/sed**~~

~~FOCUS scenario~~	~~Use no. 1-132~~
	~~Application window (absolute)~~
~~D3, D4, D5 R1**, R3**~~	~~1 Apr – 30 Jun (reflective of spring appn, BBCH 30)~~

~~* Only scenarios relevant to countries in this submission~~
~~** Scenarios not relevant for spring cereals~~

~~The AppDate v3.06 tool lists the following calendar dates corresponding to application at BBCH 30 for each surface water scenario, which supports the selection of the 1 April as a reflective application timing for the Central Zone scenarios relevant to the countries in this submission.~~

FOCUS scenario	BBCH 30	
	w/cereals	s/cereals
D3	16-Apr	28-Apr
D4	18-Mar	18-May
D5	15-Mar	09-Apr
R1	24-Apr	-
R3	19-Mar	-

The report below **(8.9.2/01)** provides the FOCUS Steps 3 and 4 PECsw/sed for fenpicoxamid and X642188.

Reference:	**8.9.2/01**
Report:	Reeves, G. (2018): Modelling the Predicted Environmental Concentrations of XDE-777 and its X642188 Metabolite in Surface Water and Sediment (FOCUS Steps 3 and 4) in the EU for Zonal Submission. Dow AgroSciences Report No. 151220. 31 May, 2018.
Guideline(s):	FOCUS (2001): FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC. Report of FOCUS Working Group on Surface Water Scenarios. EC Document Ref. SANCO/4802/2001-Rev.2. 245 pp., and Generic Guidance Document for FOCUS Surface Water Scenarios, Ver. 1.2 (December 2012).
Deviations:	No
GLP:	No (model calculation)
Acceptability:	Yes

~~Fenpicoxamid and the X642188 metabolite were run at Step 3, and at Step 4 to mitigate their aquatic toxicity. The following input parameters were used.~~

~~**Table 8.9-6: Inputs related to fenpicoxamid and metabolite for PECsw/sed - Steps 3 & 4**~~

~~Compound~~	~~Fenpicoxamid~~	~~X642188~~	~~Evaluated at EU level~~
~~Molar mass (g/mol)~~	~~614.2~~	~~514.2~~	~~Yes *(EFSA, 2018)*~~
~~Water solubility (mg/L)~~	~~1000 (nominal)~~	~~1000 (nominal)~~	
~~Vapour pressure (Pa)~~	~~1.2×10^{-7}~~	~~Parent as surrogate~~	
~~Molar enthalpy of vapourisation (kJ/mol)~~	~~95~~	~~95~~	
~~Molar enthalpy of dissolution (kJ/mol)~~	~~27~~	~~27~~	
~~Ref. diffusion co-efficient in water (m^2/d)~~	~~4.3×10^{-5}~~	~~4.3×10^{-5}~~	
~~Ref. diffusion co-efficient in air (m^2/d)~~	~~0.43~~	~~0.43~~	
~~Kfoc (pH independent)* (geometric mean)~~	~~5776~~	~~4518~~	
~~1/n (arithmetic mean)~~	~~0.818~~	~~0.934~~	
~~DT_{50} soil (d) (20ºC/pF2) (geometric mean)~~	~~3.5~~	~~31.7~~	
~~DT_{50} water (d) (20ºC) (geometric mean)~~	~~0.7**~~	~~1000 (nominal)~~	
~~DT_{50} sediment (d) (20ºC) (geometric mean)~~	~~0.7~~	~~2.7~~	
~~Formation fraction, soil~~	~~-~~	~~0.6~~	
~~Formation fraction, water/sediment~~	~~-~~	~~1~~	
~~Crop wash-off factor (1/m)~~	~~50~~	~~50~~	
~~Half-life on crop canopy (d)~~	~~10~~	~~10~~	
~~Plant uptake factor~~	~~0~~	~~0~~	

~~* Divide by 1.724 for Kfom~~
~~** Endpoint given by EFSA (2018) is a total system value (0.7 d); however, 1000 d is the more correct value when a compound is strongly sorbed to sediment according to FOCUS kinetics guidance, and so 1000 d was used for the non-degrading (water) phase, with 0.7 d used for the degrading (sediment) phase.~~

~~**FOCUS Step 3 (1 x 75 g as/ha)**~~

~~**Table 8.9-7: Step 3 PECsw/sed for fenpicoxamid on winter cereals**~~

~~FOCUS scenario~~	~~Uses 1-68, 69-83~~			
	~~Max. PECsw (µg/L)~~	~~Dominant entry route~~	~~Max. 21 d TWA PECsw (µg/L)~~	~~Max. PECsed (µg/kg)~~
~~D3 ditch~~	~~0.4662~~	~~Drift~~	~~0.01992~~	~~0.2262~~
~~D4 pond~~	~~0.01583~~	~~Drift~~	~~0.01115~~	~~0.03694~~
~~D4 stream~~	~~0.3561~~	~~Drift~~	~~0.00079~~	~~0.01269~~
~~D5 pond~~	~~0.01583~~	~~Drift~~	~~0.01124~~	~~0.02737~~
~~D5 stream~~	~~0.3723~~	~~Drift~~	~~0.00066~~	~~0.01061~~
~~R1 pond~~	~~0.01583~~	~~Drift~~	~~0.01106~~	~~0.02601~~
~~R1 stream~~	~~0.307~~	~~Drift~~	~~0.002789~~	~~0.07809~~
~~R3 stream~~	~~0.4344~~	~~Drift~~	~~0.007405~~	~~0.2403~~

Table 8.9-8: Step 3 PECsw/sed for fenpicoxamid on spring cereals

FOCUS scenario	Uses 84-117, 118-132			
	Max. PECsw (µg/L)	Dominant entry route	Max. 21 d TWA PECsw (µg/L)	Max. PECsed (µg/kg)
D3 ditch	0.4663	Drift	0.02036	0.2297
D4 pond	0.01583	Drift	0.01114	0.03693
D4 stream	0.356	Drift	0.000787	0.01265
D5 pond	0.01583	Drift	0.01122	0.02735
D5 stream	0.3706	Drift	0.000639	0.01027

Table 8.9-9: Step 3 PECsw/sed for X642188 on winter cereals

FOCUS scenario	Uses 1-68, 69-83			
	Max. PECsw (µg/L)	Dominant entry route*	Max. 21 d TWA PECsw (µg/L)	Max. PECsed (µg/kg)
D3 ditch	0.000759	Drainflow	0.000377	0.1374
D4 pond	0.001689	Drainflow	0.00166	0.04918
D4 stream	0.000383	Drainflow	0.000011	0.005316
D5 pond	0.001685	Drainflow	0.001656	0.04552
D5 stream	0.000157	Drainflow	0	0.004762
R1 pond	0.004794	Run-off	0.003706	0.04155
R1 stream	0.02725	Run-off	0.002195	0.2066
R3 stream	0.0297	Run-off	0.002425	0.3397

* Drainflow or run-off and/or contribution from degradation of parent drift

Table 8.9-10: Step 3 PECsw/sed for X642188 on spring cereals

FOCUS scenario	Uses 84-117, 118-132			
	Max. PECsw (µg/L)	Dominant entry route*	Max. 21 d TWA PECsw (µg/L)	Max. PECsed (µg/kg)
D3 ditch	0.000792	Drainflow	0.000393	0.1404
D4 pond	0.001666	Drainflow	0.001637	0.04915
D4 stream	0.000451	Drainflow	0.000014	0.005301
D5 pond	0.001652	Drainflow	0.001622	0.04543
D5 stream	0.000157	Drainflow	0	0.004608

* Drainflow or run-off and/or contribution from degradation of parent drift

In the following Step 4 tables, NSZ = no-spray zone, DRN = drift reducing nozzles (both to mitigate drift) and VFS = vegetated filter strip (to mitigate run-off).

Note that separately from report 8.9.2/01, additional Step 4 modelling was carried out and reported in the tables below for a **5 m NSZ with 90% DRN and a 10 m VFS** to provide a further risk assessment option.

FOCUS Step 4 (1 x 75 g as/ha)

Table 8.9-11: Step 4 PECsw for fenpicoxamid on winter cereals

FOCUS scenario	Uses 1-68, 69-83								
	Max. PECsw (µg/L)								
NSZ	**30 m**	**30 m**	**25 m**	**20 m**	**10 m**	**10 m**	**5 m**	**10 m**	**20 m**
DRN	**None**	**None**	**None**	**None**	**50%**	**75%**	**90%**	**90%**	**90%**
VFS	**10 m**	**None**	**None**	**None**	**10 m**	**10 m**	**10 m**	**10 m**	**20 m**
D3 ditch	0.02325	0.02325	0.02774	0.03447	0.03319	0.01653	0.01238	0.006637	0.00346
D4 pond	0.004982	0.004982	0.005658	0.006528	0.004886	0.002478	0.001327	0.000945	0.000659
D4 stream	0.02406	0.02406	0.02874	0.03562	0.03425	0.01692	0.0128	0.006783	0.00351
D5 pond	0.004982	0.004982	0.005658	0.006528	0.004886	0.002478	0.001327	0.000945	0.000659
D5 stream	0.02516	0.02516	0.03005	0.03724	0.0358	0.01769	0.01339	0.007092	0.00367
R1 pond	0.004982	0.004982	0.005658	**0.006528**	**0.004886**	0.002478	0.001327	0.000945	0.000659
R1 stream	0.02074	0.02074	0.02477	**0.03071**	**0.02952**	0.01458	0.01104	0.005845	0.003024
R3 stream	0.02936	0.02936	0.03507	**0.04346**	**0.04178**	0.02065	0.01563	0.008279	0.004285

Table 8.9-12: Step 4 PECsw for fenpicoxamid on spring cereals

FOCUS scenario	Uses 84-117, 118-132 Max. PECsw (µg/L)								
NSZ	30 m	30 m	25 m	20 m	10 m	10 m	5 m	10 m	20 m
DRN	None	None	None	None	50%	75%	90%	90%	90%
VFS	10 m	None	None	None	10 m	10 m	10 m	10 m	20 m
D3 ditch	0.02326	0.02326	0.02774	0.03448	0.03319	0.01653	0.01238	0.006638	0.00346
D4 pond	0.004982	0.004982	0.005658	0.006528	0.004886	0.002478	0.001327	0.000945	0.000659
D4 stream	0.02405	0.02405	0.02873	0.03561	0.03423	0.01691	0.0128	0.00678	0.003508
D5 pond	0.004982	0.004982	0.005658	0.006528	0.004886	0.002478	0.001327	0.000945	0.000659
D5 stream	0.02504	0.02504	0.02991	0.03707	0.03564	0.01761	0.01333	0.007059	0.003653

Table 8.9-13: Step 4 PECsw for X642188 on winter cereals

FOCUS scenario	Uses 1-68, 69-83 Max. PECsw (µg/L)								
NSZ	30 m	30 m	25 m	20 m	10 m	10 m	5 m	10 m	20 m
DRN	None	None	None	None	50%	75%	90%	90%	90%
VFS	10 m	None	None	None	10 m	10 m	10 m	10 m	20 m
D3 ditch	0.000032	0.000032	0.000039	0.000049	0.000047	0.000023	0.000017	0.000009	0.000004
D4 pond	0.000509	0.000509	0.000581	0.000674	0.000499	0.000247	0.000129	0.000091	0.000062
D4 stream	0.000383	0.000383	0.000383	0.000383	0.000383	0.000383	0.000383	0.000383	0.000383
D5 pond	0.000507	0.000507	0.000579	0.000672	0.000497	0.000246	0.000128	0.00009	0.000062
D5 stream	0.000093	0.000093	0.000093	0.000093	0.000093	0.000093	0.000093	0.000093	0.000093
R1 pond	0.001818	0.003961	0.004012	0.004078	0.001811	0.001629	0.001544	0.001516	0.000771
R1 stream	0.01237	0.02725	0.02725	0.02725	0.01237	0.01237	0.01237	0.01237	0.006477
R3 stream	0.01355	0.0297	0.0297	0.0297	0.01355	0.01355	0.01355	0.01355	0.007106

Table 8.9-14: Step 4 PECsw for X642188 on spring cereals

FOCUS scenario	Uses 84-117, 118-132 Max. PECsw (µg/L)								
NSZ	30 m	30 m	25 m	20 m	10 m	10 m	5 m	10 m	20 m
DRN	None	None	None	None	50%	75%	90%	90%	90%
VFS	10 m	None	None	None	10 m	10 m	10 m	10 m	20 m
D3 ditch	0.000034	0.000034	0.000041	0.000051	0.000049	0.000024	0.000017	0.000009	0.000005
D4 pond	0.000502	0.000502	0.000573	0.000665	0.000492	0.000243	0.000127	0.000089	0.000061
D4 stream	0.000451	0.000451	0.000451	0.000451	0.000451	0.000451	0.000451	0.000451	0.000451
D5 pond	0.000498	0.000498	0.000568	0.000659	0.000488	0.000241	0.000126	0.000089	0.000061
D5 stream	0.000086	0.000086	0.000086	0.000086	0.000086	0.000086	0.000085	0.000086	0.000086

Further Assessment

The surface water exposure assessment for fenpicoxamid and X642188 described above was further investigated following a "summed" residue approach (fenpicoxamid plus X642188 as parent equivalent), where the assumed "summed" RAC is 0.033 µg/L. The assessment was carried out for a spring application to winter or spring cereals according to the GAP previously shown in Table 8.1-1.

For this purpose, the FOCUS SwashProjects which produced the Steps 3 and 4 data previously shown above for an application window start date of 1 April were retrieved. The data from the run-off scenarios relevant for the Central Zone (R1 and R3 for winter cereals only; no Central Zone relevant scenarios exist for spring cereals) were then used for an assessment where the hourly PECsw values for fenpicoxamid and X642188 from the full year profile were extracted and "summed", and compared to the assumed "summed" RAC of 0.033 µg/L. The procedure is described as follows.

Firstly, EPAT v1.2.0 was used to generate "seg1.con" for pond or "seg20.con" for stream text files separately for fenpicoxamid and X642188 at Step 4 with a 10 m NSZ and 75% DRN with inherent 10 m VFS, or 5 m NSZ and 90% DRN with inherent 10 m VFS. Files were generated for the 1 x 75 g as/ha application rate. The hourly PECsw values for both residues were then copied from the text file into a spreadsheet and aligned according to hour and day. For the "summed" approach it was necessary to convert the X642188 PECsw to a parent equivalent (x 614.2/514.2) which could be added to the parent PECsw. Once the hourly "summed" PECsw values were obtained, the maximum was located using the MAX function in EXCEL from the >8000 lines of data. As a check that the correct files had been used for each

~~extraction, the max. PECsw values for fenpicoxamid and X642188 were also found from the data, and compared to the Step 4 values for a 10 m NSZ with 75% DRN and inherent 10 m VFS or 5 m NSZ and 90% DRN with inherent 10 m VFS originally presented. In all cases the values matched up to give confirmation that the procedure was working correctly. The "summed" PECsw (fenpicoxamid plus X642188 as parent equivalent) values generated here were then compared to the assumed "summed" RAC of 0.033 µg/L, as presented below. There are no "summed" values which exceed the assumed RAC of 0.033 µg/L.~~

~~Table 8.9-15: Max. "summed" Step 4 (10 m NSZ, 75% DRN, 10 m VFS) PECsw for fenpicoxamid and X642188 (parent equiv.) on winter cereals* at 1 x 75 g as/ha~~

~~Crop~~	~~Appn. rate~~	~~Max "Summed" Step 4 PECsw (µg/L) (fenpicoxamid plus X642188 parent equivalent)~~		
		~~R1 pond~~	~~R1 stream~~	~~R3 stream~~
~~Winter cereals~~	~~1 x 75 g as/ha~~	~~0.0025~~	~~0.0158~~	~~0.0207~~

~~* The only run-off scenario for spring cereals (R4) is not relevant for the Central Zone countries in this submission~~

~~Table 8.9-16: Max. "summed" Step 4 (5 m NSZ, 90% DRN, 10 m VFS) PECsw for fenpicoxamid and X642188 (parent equiv.) on winter cereals* at 1 x 75 g as/ha~~

~~Crop~~	~~Appn. rate~~	~~Max "Summed" Step 4 PECsw (µg/L) (fenpicoxamid plus X642188 parent equivalent)~~		
		~~R1 pond~~	~~R1 stream~~	~~R3 stream~~
~~Winter cereals~~	~~1 x 75 g as/ha~~	~~0.0021~~	~~0.0158~~	~~0.0199~~

~~* The only run-off scenario for spring cereals (R4) is not relevant for the Central Zone countries in this submission~~

~~The spreadsheets from this analysis are provided, but a small excerpt is shown below from the R1 stream at 1 x 75 g as/ha as an example for the 10 m NSZ, 75% DRN, 10 m VFS analysis. The column highlighted in yellow is the X642188 parent equivalent PECsw derived from the X642188 PECsw on the right hand side of the excerpt multiplied by 614.2/514. The "summed" concentration is then given in the light blue column.~~

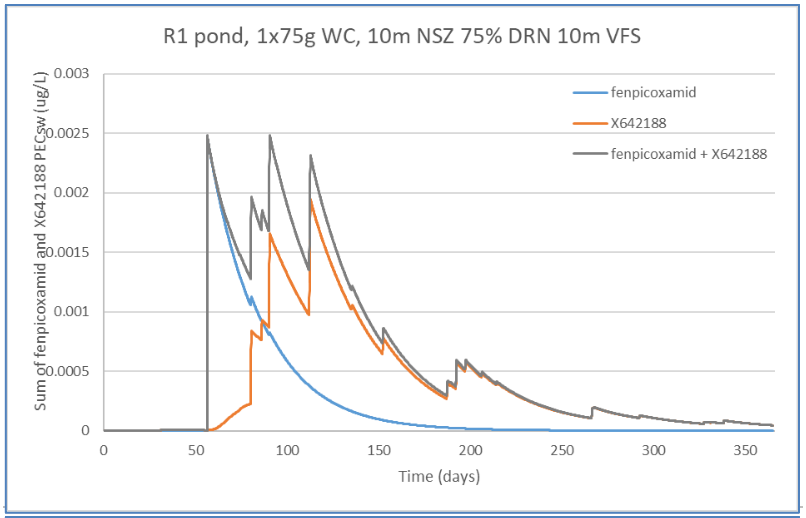
~~Excerpt from R1 stream at 1 x 75 g as/ha extraction example (10 m NDZ, 75% DRN and 10 m VFS)~~

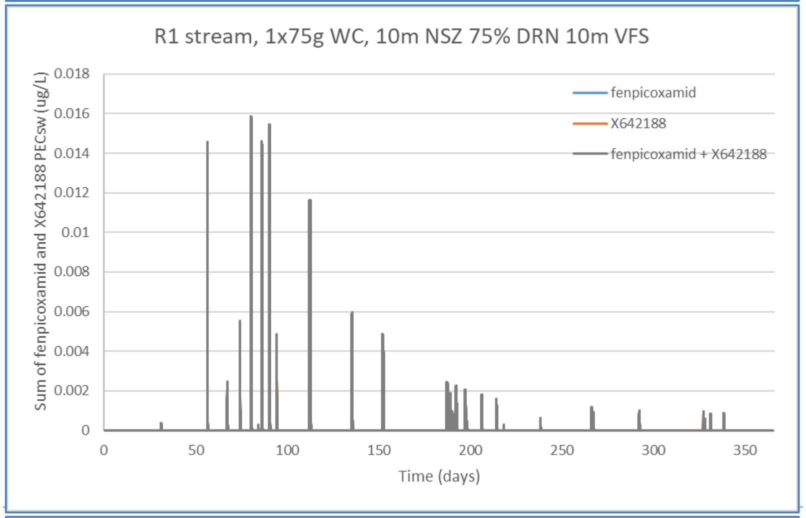
# EPAT CONCENTRATION FILE									
# --									
# EPAT - Exposure Pattern Analysis Tool									
# Version 1.2.0									
# --									
# Sponsored by: Developed by:									
# ECPA RIFCON GmbH									
# European Crop Protection Association									
# 6 Av E. Van Nieuwenhuyse Goldbeckstr. 13									
# 1160 Brussels 691493 Hirschberg									
# Belgium Germany									
# --									
#Analysed source file: C:\Users\graha\777wc1X_75\777wc1X_75\10m 75% + 10m VBS\TOXSWA\441.out									
#Selected evaluation period: Complete									
#Selected segment of the water body: 20									
#Selected substance: 777									
#Selected time: FULL									
#Selected unit: µg/L									
#Selected conversion factor: 1000									
#	**time**	**777**	**X188**	**Sum**	777 MW	614.2		*Max PECsw*	*0.014582*
#Date/Time	**days**	**Conc**	**Par eq Conc**	**Conc**	X188 MW	514.2		*Max PECsw*	*0.012373*
01-Mar-1984-00h00	0	0	0	0					
01-Mar-1984-01h00	0.042	0	0	0	Max PECsw	**0.0158**	ug/L		
01-Mar-1984-02h00	0.083	0	0	0					
01-Mar-1984-03h00	0.125	0	0	0					
01-Mar-1984-04h00	0.167	0	0	0					
01-Mar-1984-05h00	0.208	0	0	0					
01-Mar-1984-06h00	0.25	0	0	0					
01-Mar-1984-07h00	0.292	0	0	0					
01-Mar-1984-08h00	0.333	0	0	0					
01-Mar-1984-09h00	0.375	0	0	0					
01-Mar-1984-10h00	0.417	0	0	0					
01-Mar-1984-11h00	0.458	0	0	0					
01-Mar-1984-12h00	0.5	0	0	0					
01-Mar-1984-13h00	0.542	0	0	0					
01-Mar-1984-14h00	0.583	0	0	0					
01-Mar-1984-15h00	0.625	0	0	0					
01-Mar-1984-16h00	0.667	0	0	0					
01-Mar-1984-17h00	0.708	0	0	0					
01-Mar-1984-18h00	0.75	0	0	0					
01-Mar-1984-19h00	0.792	0	0	0					
01-Mar-1984-20h00	0.833	0	0	0					
01-Mar-1984-21h00	0.875	0	0	0					
01-Mar-1984-22h00	0.917	0	0	0					
01-Mar-1984-23h00	0.958	0	0	0					

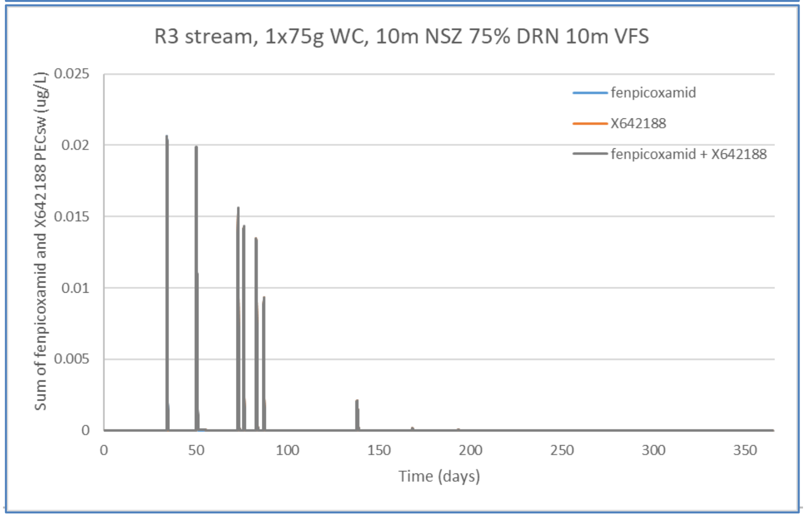
# EPAT CONCENTRATION FILE		
# --		
# EPAT - Exposure Pattern Analysis Tool		
# Version 1.2.0		
# --		
# Sponsored by: Developed by:		
# ECPA RIFCON GmbH		
# European Crop Protection Association		
# 6 Av E. Van Nieuwenhuyse Goldbeckstr. 13		
# 1160 Brussels 691493 Hirschberg		
# Belgium Germany		
# --		
#Analysed source file: C:\Users\graha\777wc1X_75\777wc1X_75\10m 75% + 10m VBS\TOXSWA\441.out		
#Selected evaluation period: Complete		
#Selected segment of the water body: 20		
#Selected substance: 188		
#Selected time: FULL		
#Selected unit: µg/L		
#Selected conversion factor: 1000		
#	**time**	**188**
#Date/Time	**days**	**Conc**
01-Mar-1984-00h00	0	0
01-Mar-1984-01h00	0.042	0
01-Mar-1984-02h00	0.083	0
01-Mar-1984-03h00	0.125	0
01-Mar-1984-04h00	0.167	0
01-Mar-1984-05h00	0.208	0
01-Mar-1984-06h00	0.25	0
01-Mar-1984-07h00	0.292	0
01-Mar-1984-08h00	0.333	0
01-Mar-1984-09h00	0.375	0
01-Mar-1984-10h00	0.417	0
01-Mar-1984-11h00	0.458	0
01-Mar-1984-12h00	0.5	0
01-Mar-1984-13h00	0.542	0
01-Mar-1984-14h00	0.583	0
01-Mar-1984-15h00	0.625	0
01-Mar-1984-16h00	0.667	0
01-Mar-1984-17h00	0.708	0
01-Mar-1984-18h00	0.75	0
01-Mar-1984-19h00	0.792	0
01-Mar-1984-20h00	0.833	0
01-Mar-1984-21h00	0.875	0
01-Mar-1984-22h00	0.917	0
01-Mar-1984-23h00	0.958	0

To illustrate the process and derivation of the "summed" PECsw values further, graphs were generated of the fenpicoxamid (blue line) and X642188 (parent equivalent; orange line) concentrations and the "summed" total (grey line) against time (days), and these are presented as follows. Note that for the stream scenarios, the fenpicoxamid and X642188 exposures cannot easily be seen from the graphs because the peaks co-occur and are very short lived due to stream dilution.

1 x 75 g as/ha, winter cereals example (10 m NSZ, 75% DRN and 10 m VFS)







UPDATE – April 2022

Request from Poland (zRMS):

- *"In the Step 3/4 surface water modelling performed for fenpicoxamid in GF-3307 the same application window has been assumed for both crops and all scenarios (1 Apr-30 Jun). Since differences in PECsw/sed values may have significant impact on the outcome of the aquatic risk assessment and risk mitigation measures necessary to demonstrate acceptable risk, the Applicant is kindly requested to provide new Step 3/4 surface water modelling for fenpicoxamid and metabolite X642188 performed with consideration of the respective application windows suggested by AppDate ver. 3.06, in line with Working Document of the Central Zone in area of Section 8, which indicates that the application timing should be selected using the most actual version of the software AppDate. Please note that assumption of different application windows will require new EPAT analysis, which was considered to derive the cumulative exposure to fenpicoxamid and X642188 used in the aquatic risk assessment."*

- *"In surface water modelling for winter cereals all scenarios relevant for the Central Zone must be included (D3, D4, D5, R1, R3 and R4). For spring cereals all scenarios defined in FOCUS models must be included in calculations (D3, D4, D5 and R4), while scenarios not defined for spring cereals will be considered to be covered by simulations performed for winter cereals."*

Response from Applicant:

Previous Steps 3 and 4 modelling used the same application date (1 April) for all scenarios. However, the zRMS (Poland) requested Steps 3 and 4 be repeated using dates relevant to BBCH 30 according to AppDate 3.06 (June, 2019), and to include R4 (although this scenario is not required by any MS relevant to this submission).

The updated modelling and subsequent EPAT analysis at **1 x 75 g as/ha** used to facilitate the "summed" residue approach is described below. It is not reported separately since the work can be fully described and presented directly here in the dRR.

Table 8.9-17: Inputs related to application for PECsw/sed (Steps 3 & 4)

Use no.	**1-132**
Crop	Winter cereals, spring cereals
Application rate (g as/ha)	75 (Fenpicoxamid)
Max. number of applications	1
Frequency of application	Annual
Application window	Date given by AppDate 3.06 (June, 2019), BBCH 30
Application method	Ground spray
Chemical application method (CAM)	2 – appn. foliar linear
Depth incorporated (cm)	4
Models used	FOCUS SWASH 5.3 FOCUS MACRO 5.5.4 FOCUS PRZM 4.3.1 FOCUS TOXSWA 5.5.3 SWAN v5.0.1 (Step 4)

The dates modelled for application to winter and spring cereals corresponding to BBCH 30 were selected for each relevant FOCUS surface water scenario using AppDate 3.06 (June, 2019). All scenarios available for the crop were modelled for completeness, but only those relevant for the Central Zone are described here. A 30 day window was set in the model as relevant for a single application.

Table 8.9-18: Application dates used for PECsw/sed (Steps 3 & 4)

FOCUS scenario	Appn. date (absolute) (BBCH 30)	
	Use no. 1-68, 69-83	Use no. 84-117, 118-132
D3	16 Apr	28 Apr
D4	18 Mar	18 May
D5	15 Mar	9 Apr
R1	24 Apr	-*
R3	19 Mar	-*
R4	24 Jan	9 Apr

* Scenarios not relevant for spring cereals

Fenpicoxamid and the X642188 metabolite were run at Steps 3 and 4 to mitigate their aquatic toxicity. The following inputs were used. Any inputs not shown were left as the FOCUS default values in the models.

Table 8.9-19: Inputs related to fenpicoxamid and metabolite for PECsw/sed (Steps 3 & 4)

Compound	Fenpicoxamid	X642188	Evaluated at EU level
Molar mass (g/mol)	614.2	514.2	Yes *(EFSA, 2018)*
Water solubility (mg/L)	1000 (nominal)	Parent as surrogate	
Vapour pressure (Pa)	1.2×10^{-7}	Parent as surrogate	
Kfoc (pH independent) (geometric mean)	5776	4518	
1/n (arithmetic mean)	0.818	0.934	
DT_{50} soil (d) (20ºC/pF2) (geometric mean)	3.5	31.7	
DT_{50} water (d) (20ºC) (geometric mean)	1000*	1000	
DT_{50} sediment (d) (20ºC) (geometric mean)	0.7	2.7	
Formation fraction, soil	-	0.6	
Formation fraction, water	-	1	
Formation fraction, sediment	-	1	
Plant uptake factor	0	0	

* Endpoint (0.7 d) given by EFSA, 2018 is for total system, however, 1000 d is more correct when a compound is strongly sorbed to sediment (Koc >2000)

At Step 4, the drift mitigations applied were an increased no-spray zone (NSZ) to 30 m, with or without 50%, 75% or 90% drift reducing nozzles (DRN), and to mitigate run-off a vegetated filter strip (VFS) was used for either a distance of 10 m or 20 m. For a 10 m VFS, reduction factors of 0.6 and 0.85 were applied, and for a 20 m VFS the reduction factors used were 0.8 and 0.95. These were taken from the FOCUS Landsacape and Mitigation workgroup (2007).

FOCUS Step 3

Table 8.9-20: Step 3 PECsw/sed for fenpicoxamid on winter cereals

FOCUS scenario	Use no. 1-68, 69-83			
	Max. PECsw (µg/L)	Dominant entry route	Max. 21 d TWA PECsw (µg/L)	Max. PECsed (µg/kg)
D3 ditch	0.4667	Drift	0.03258	0.2406
D4 pond	0.01586	Drift	0.01234	0.03897
D4 stream	0.3446	Drift	0.000933	0.01008
D5 pond	0.01586	Drift	0.01253	0.02743
D5 stream	0.3723	Drift	0.00099	0.01061
R1 pond	0.01586	Drift	0.01242	0.02606
R1 stream	0.307	Drift	0.004096	0.07809
R3 stream	0.4318	Drift	0.008498	0.1297
R4 stream	0.3084	Drift	0.004579	0.04537

Table 8.9-21: Step 3 PECsw/sed for X642188 on winter cereals

FOCUS scenario	Use no. 1-68, 69-83			
	Max. PECsw (µg/L)	Dominant entry route*	Max. 21 d TWA PECsw (µg/L)	Max. PECsed (µg/kg)
D3 ditch	0.000925	Drainflow	0.000603	0.1495
D4 pond	0.001994	Drainflow	0.001967	0.05239
D4 stream	0.000388	Drainflow	0.000017	0.004141
D5 pond	0.001688	Drainflow	0.001675	0.04561
D5 stream	0.000157	Drift	0.000001	0.004762
R1 pond	0.004809	Run-off	0.00404	0.04163
R1 stream	0.02733	Run-off	0.002932	0.2066
R3 stream	0.03443	Run-off	0.002735	0.3103
R4 stream	0.06013	Run-off	0.005052	0.3131

* Drainflow or run-off and/or contribution from degradation of parent drift

Table 8.9-22: Step 3 PECsw/sed for fenpicoxamid on spring cereals

FOCUS scenario	Use no. 84-117, 118-132			
	Max. PECsw (µg/L)	Dominant entry route	Max. 21 d TWA PECsw (µg/L)	Max. PECsed (µg/kg)
D3 ditch	0.4672	Drift	0.03639	0.2082
D4 pond	0.01587	Drift	0.01257	0.01771
D4 stream	0.3816	Drift	0.002455	0.02536
D5 pond	0.01587	Drift	0.01261	0.02761
D5 stream	0.392	Drift	0.00155	0.0164
R4 stream	0.3084	Drift	0.00617	0.7658

Table 8.9-23: Step 3 PECsw/sed for X642188 on spring cereals

FOCUS scenario	Use no. 84-117, 118-132			
	Max. PECsw (µg/L)	Dominant entry route*	Max. 21 d TWA PECsw (µg/L)	Max. PECsed (µg/kg)
D3 ditch	0.001261	Drainflow	0.000596	0.178
D4 pond	0.001358	Drainflow	0.001342	0.03454
D4 stream	0.000461	Drainflow	0.000021	0.01238
D5 pond	0.001575	Drainflow	0.001566	0.04607
D5 stream	0.000166	Drift	0.000002	0.007401
R4 stream	0.04146	Run-off	0.007719	0.7844

* Drainflow or run-off and/or contribution from degradation of parent drift

In the following Step 4 tables, NSZ = no-spray zone and DRN = drift reducing nozzles (both to mitigate drift) and VFS = vegetated filter strip (to mitigate run-off).

FOCUS Step 4

Table 8.9-24: Step 4 PECsw for fenpicoxamid on winter cereals

FOCUS scenario	Use no. 1-68, 69-83							
	Max. PECsw (µg/L)							
NSZ	30 m	25 m	20 m	10 m	10 m	10 m	5 m	20 m
DRN	None	None	None	50%	75%	90%	90%	90%
VFS	None	None	None	10 m	10 m	10 m	10 m	20 m
D3 ditch	0.02334	0.02783	0.0345	0.03318	0.01653	0.006572	0.01244	0.003399
D4 pond	0.004977	0.00565	0.006551	0.004895	0.002434	0.000966	0.001348	0.000642
D4 stream	0.02325	0.02773	0.03437	0.03306	0.01646	0.006547	0.0124	0.003386
D5 pond	0.004978	0.005651	0.006552	0.004896	0.002434	0.000966	0.001348	0.000642
D5 stream	0.02511	0.02996	0.03713	0.03572	0.01779	0.007075	0.01339	0.003659
R1 pond	0.004978	0.005651	0.006552	0.004896	0.002434	0.000966	0.001348	0.000642
R1 stream	0.0207	0.0247	0.03061	0.02945	0.01466	0.005831	0.01104	0.003015
R3 stream	0.02914	0.03476	0.04307	0.04144	0.02064	0.00821	0.01554	0.004246
R4 stream	0.0208	0.02481	0.03074	0.02958	0.01473	0.005856	0.01109	0.003028

Table 8.9-25: Step 4 PECsw for X642188 on winter cereals

FOCUS scenario	Use no. 1-68, 69-83							
	Max. PECsw (µg/L)							
NSZ	30 m	25 m	20 m	10 m	10 m	10 m	5 m	20 m
DRN	None	None	None	50%	75%	90%	90%	90%
VFS	None	None	None	10 m	10 m	10 m	10 m	20 m
D3 ditch	0.00004	0.000048	0.00006	0.000058	0.000028	0.00001	0.00002	0.000005
D4 pond	0.000605	0.000689	0.000803	0.000595	0.000289	0.000111	0.000157	0.000073
D4 stream	0.000388	0.000388	0.000388	0.000388	0.000388	0.000388	0.000388	0.000388
D5 pond	0.000507	0.000578	0.000674	0.000498	0.000241	0.000092	0.000131	0.00006
D5 stream	0.000076	0.000076	0.000076	0.000076	0.000076	0.000076	0.000076	0.000076
R1 pond	0.003974	0.004025	0.004093	0.001817	0.001631	0.001522	0.00155	0.000773
R1 stream	0.02733	0.02733	0.02733	0.01241	0.01241	0.01241	0.01241	0.006498
R3 stream	0.03443	0.03443	0.03443	0.01571	0.01571	0.01571	0.01571	0.008238
R4 stream	0.06013	0.06013	0.06013	0.02735	0.02735	0.02735	0.02735	0.01433

Table 8.9-26: Step 4 PECsw for fenpicoxamid on spring cereals

FOCUS scenario	Use no. 84-117, 118-132							
	Max. PECsw (µg/L)							
NSZ	30 m	25 m	20 m	10 m	10 m	10 m	5 m	20 m
DRN	None	None	None	50%	75%	90%	90%	90%
VFS	None	None	None	10 m	10 m	10 m	10 m	20 m
D3 ditch	0.02336	0.02786	0.03454	0.03322	0.01654	0.006579	0.01246	0.003403
D4 pond	0.00498	0.005654	0.006555	0.004898	0.002435	0.000966	0.001348	0.000643
D4 stream	0.02575	0.03071	0.03806	0.03662	0.01824	0.007253	0.01373	0.003751
D5 pond	0.00498	0.005653	0.006554	0.004898	0.002435	0.000966	0.001348	0.000642
D5 stream	0.02645	0.03155	0.0391	0.03761	0.01873	0.007451	0.01411	0.003853
R4 stream	0.0253*	0.0253*	0.03074	0.02958	0.01473	0.01145*	0.01145*	0.005977*

* With high levels of drift reduction the dominant exposure route for parent is run-off for R4

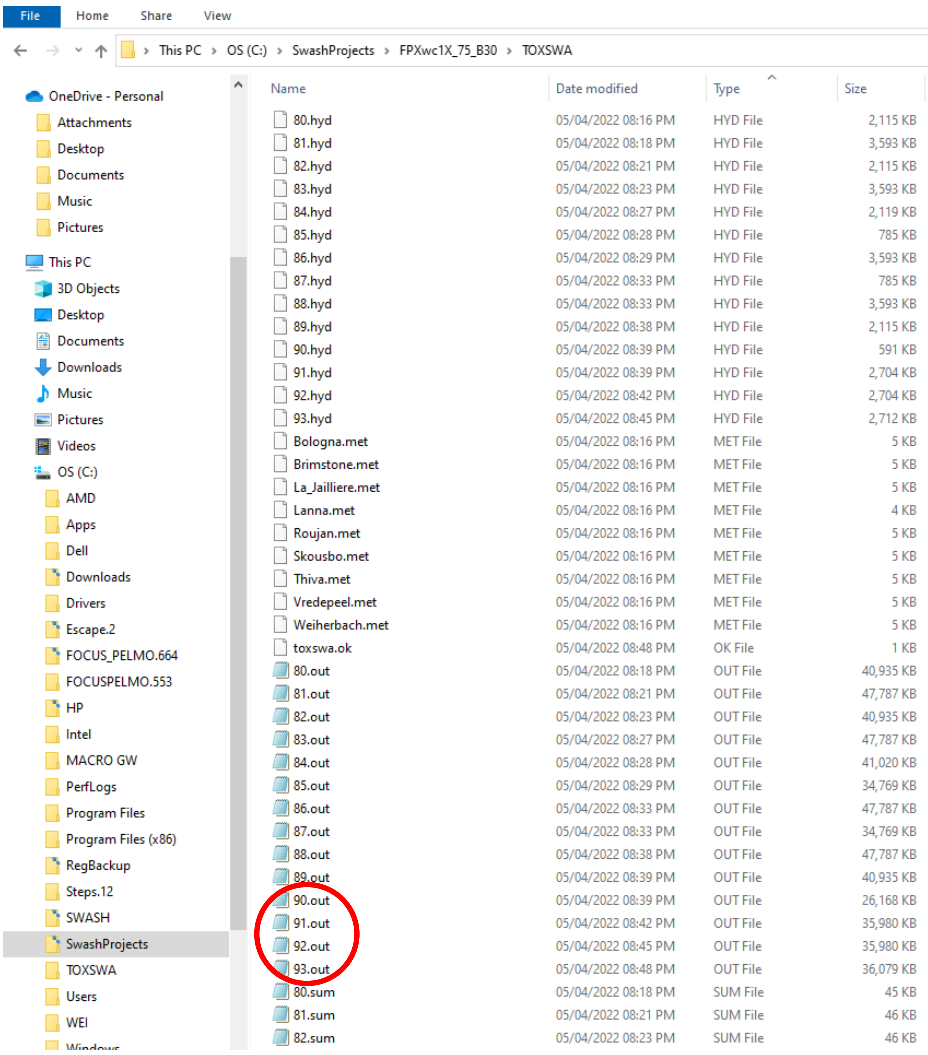
Table 8.9-27: Step 4 PECsw for X642188 on spring cereals

FOCUS scenario	Use no. 84-117, 118-132							
	Max. PECsw (µg/L)							
NSZ	**30 m**	**25 m**	**20 m**	**10 m**	**10 m**	**10 m**	**5 m**	**20 m**
DRN	**None**	**None**	**None**	**50%**	**75%**	**90%**	**90%**	**90%**
VFS	**None**	**None**	**None**	**10 m**	**10 m**	**10 m**	**10 m**	**20 m**
D3 ditch	0.000053	0.000064	0.00008	0.000077	0.000037	0.000014	0.000027	0.000007
D4 pond	0.000406	0.000463	0.00054	0.000399	0.000192	0.000073	0.000104	0.000052
D4 stream	0.000461	0.000461	0.000461	0.000461	0.000461	0.000461	0.000461	0.000461
D5 pond	0.000472	0.000539	0.000628	0.000464	0.000224	0.000086	0.000121	0.000056
D5 stream	0.000086	0.000086	0.000086	0.000086	0.000086	0.000086	0.000086	0.000086
R4 stream	0.04146	0.04146	0.04146	0.01874	0.01874	0.01874	0.01874	0.009788

Further Assessment

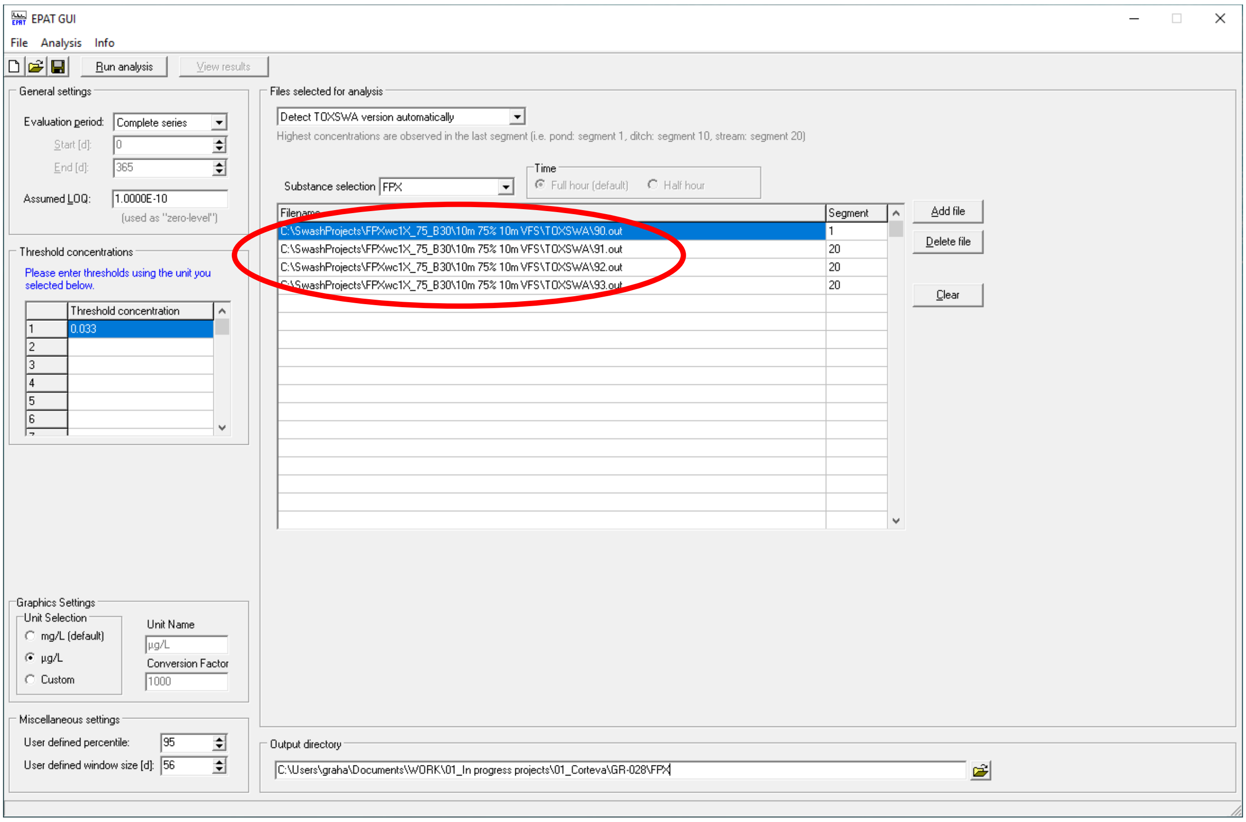
The Step 4 surface water exposure assessment for fenpicoxamid and X642188 described above was further investigated using a "summed" PECsw approach (fenpicoxamid plus X642188 parent equivalent), where the assumed "summed" RAC is 0.033 µg/L. **It is not reported separately since the work can be fully described and presented directly here in the dRR.**

The SwashProjects which produced the Step 4 data shown in Tables 8.9-24 to 8.9-27 were located. The data required is in the relevant TOXSWA folder as the ".OUT" file (example screen shot below for runs #90-93 which correspond in this analysis to R1 pond, R1 stream, R3 stream and R4 stream).



The data from the run-off scenarios relevant for the Central Zone (R1, R3 and R4) were then used for an assessment where the hourly PECsw values from TOXSWA for fenpicoxamid and X642188 from the full exposure profile were extracted and "summed" (i.e. fenpicoxamid PECsw plus X642188 PECsw as parent equivalent), and compared to the assumed "summed" RAC of 0.033 µg/L. The procedure is described in detail as follows.

Firstly, EPAT v1.2.0 was used to generate "seg1.con" or "seg20.con" text files for the pond or stream scenarios, respectively. This was done separately for fenpicoxamid and X642188, focussing on Step 4 with two levels of mitigation, i.e. 10 m NSZ/75% DRN/10 m VFS, or 5 m NSZ/90% DRN/10 m VFS (example screen shot below for fenpicoxamid and runs #90-93 which correspond in this analysis to R1 pond, R1 stream, R3 stream and R4 stream).



The hourly PECsw values for fenpicoxamid and X642188 were then copied from the EPAT "seg1.con" (pond) or "seg20.con" (stream) text file (part extract screen shot example for fenpicoxamid and run #91 (R1 stream) below) into a spreadsheet and the PECsw values aligned according to hour and day.

```
#                              EPAT CONCENTRATION FILE
# ----------------------------------------------------------------------------------
#                        EPAT - Exposure Pattern Analysis Tool
#                                    Version 1.2.0
# ----------------------------------------------------------------------------------
#    Sponsored by:                                          Developed by:
#    ECPA                                                   RIFCON GmbH
#    European Crop Protection Association
#    6 Av E. Van Nieuwenhuyse                               Goldbeckstr. 13
#    1160 Brussels                                          691493 Hirschberg
#    Belgium                                                Germany
# ----------------------------------------------------------------------------------
# Analysed source file:            C:\SwashProjects\FPXwc1X_75_B30\10m 75% 10m VFS\TOXSWA\91.out
# Selected evaluation period:      Complete
# Selected segment of the water body: 20
# Selected substance: FPX
# Selected time:
# Selected unit: µg/L
# Selected conversion factor: 1000
#
# Date/Time                 t               Concentration
01-Mar-1984-00h00       0.000   0
01-Mar-1984-01h00       0.042   0
01-Mar-1984-02h00       0.083   0
01-Mar-1984-03h00       0.125   0
01-Mar-1984-04h00       0.167   0
01-Mar-1984-05h00       0.208   0
01-Mar-1984-06h00       0.250   0
01-Mar-1984-07h00       0.292   0
01-Mar-1984-08h00       0.333   0
01-Mar-1984-09h00       0.375   0
01-Mar-1984-10h00       0.417   0
01-Mar-1984-11h00       0.458   0
01-Mar-1984-12h00       0.500   0
01-Mar-1984-13h00       0.542   0
01-Mar-1984-14h00       0.583   0
01-Mar-1984-15h00       0.625   0
01-Mar-1984-16h00       0.667   0
01-Mar-1984-17h00       0.708   0
01-Mar-1984-18h00       0.750   0
01-Mar-1984-19h00       0.792   0
01-Mar-1984-20h00       0.833   0
01-Mar-1984-21h00       0.875   0
01-Mar-1984-22h00       0.917   0
01-Mar-1984-23h00       0.958   0
02-Mar-1984-00h00       1.000   0
02-Mar-1984-01h00       1.042   0
02-Mar-1984-02h00       1.083   0
02-Mar-1984-03h00       1.125   0
02-Mar-1984-04h00       1.167   0
02-Mar-1984-05h00       1.208   0
02-Mar-1984-06h00       1.250   0
```

For the "summed" approach it was necessary to convert the X642188 PECsw to a parent equivalent based on molecular weight (x 614.2/514.2) which could be added to the fenpicoxamid PECsw in the spreadsheet. Once the hourly "summed" PECsw values were obtained, the maximum was located using the MAX function in EXCEL from the >8000 lines of data. As a check that the correct files had been used for each extraction, the max. PECsw values for fenpicoxamid and X642188 were also found from the >8000 lines of data, and compared to the Step 4 values presented in Tables 8.9-24 to 8.9-27 for 10 m NSZ/75% DRN/10 m VFS or 5 m NSZ/90% DRN/10 m VFS. In all cases the values matched exactly to validate that the procedure constructed in the spreadsheet was working correctly.

The spreadsheets from this analysis are available, but a small excerpt is shown below from the R1 stream as an example for 10 m NSZ/75% DRN/10 m VFS (run #91). The column highlighted in yellow is the X642188 parent equivalent PECsw derived from the X642188 PECsw on the right hand side of the excerpt multiplied by 614.2/514. The "summed" concentration is then given in the pale blue column.

Excerpt from R1 stream extraction example, 1 x 75 g as/ha (Step 4; 10 m NSZ/75% DRN/10 m VFS)

# EPAT CONCENTRATION FILE									
# --									
# EPAT - Exposure Pattern Analysis Tool									
# Version 1.2.0									
# --									
# Sponsored by: Developed by:									
# ECPA RIFCON GmbH									
# European Crop Protection Association									
# 6 Av E. Van Nieuwenhuyse Goldbeckstr. 13									
# 1160 Brussels 691493 Hirschberg									
# Belgium Germany									
# --									
# Analysed source file: C:\SwashProjects\FPXwc1X_75_B30\10m 75% 10m VFS\TOXSWA\91.out									
# Selected evaluation period: Complete									
# Selected segment of the water body: 20									
# Selected substance: FPX									
# Selected time:									
# Selected unit: µg/L									
# Selected conversion factor: 1000									
#	time	FPX	188	Sum	FPX MW	614.2		*Max PECsw*	*0.01466*
# Date/Time	days	Conc	Par eq Conc	Conc	X188 MW	514.2		*Max PECsw*	*0.01241*
01-Mar-1984-00h00	0	0	0	0					
01-Mar-1984-01h00	0.042	0	0	0	Max PECsw	**0.01590**	ug/L		
01-Mar-1984-02h00	0.083	0	0	0					
01-Mar-1984-03h00	0.125	0	0	0					
01-Mar-1984-04h00	0.167	0	0	0					
01-Mar-1984-05h00	0.208	0	0	0					
01-Mar-1984-06h00	0.25	0	0	0					
01-Mar-1984-07h00	0.292	0	0	0					
01-Mar-1984-08h00	0.333	0	0	0					
01-Mar-1984-09h00	0.375	0	0	0					
01-Mar-1984-10h00	0.417	0	0	0					
01-Mar-1984-11h00	0.458	0	0	0					
01-Mar-1984-12h00	0.5	0	0	0					
01-Mar-1984-13h00	0.542	0	0	0					
01-Mar-1984-14h00	0.583	0	0	0					
01-Mar-1984-15h00	0.625	0	0	0					
01-Mar-1984-16h00	0.667	0	0	0					
01-Mar-1984-17h00	0.708	0	0	0					
01-Mar-1984-18h00	0.75	0	0	0					
01-Mar-1984-19h00	0.792	0	0	0					
01-Mar-1984-20h00	0.833	0	0	0					
01-Mar-1984-21h00	0.875	0	0	0					
01-Mar-1984-22h00	0.917	0	0	0					
01-Mar-1984-23h00	0.958	0	0	0					

# EPAT CONCENTRATION FILE		
# --		
# EPAT - Exposure Pattern Analysis Tool		
# Version 1.2.0		
# --		
# Sponsored by: Developed by:		
# ECPA RIFCON GmbH		
# European Crop Protection Association		
# 6 Av E. Van Nieuwenhuyse Goldbeckstr. 13		
# 1160 Brussels 691493 Hirschberg		
# Belgium Germany		
# --		
# Analysed source file: C:\SwashProjects\FPXwc1X_75_B30\10m 75% 10m VFS\TOXSWA\91.out		
# Selected evaluation period: Complete		
# Selected segment of the water body: 20		
# Selected substance: 188		
# Selected time:		
# Selected unit: µg/L		
# Selected conversion factor: 1000		
#	time	188
# Date/Time	days	Conc
01-Mar-1984-00h00	0	0
01-Mar-1984-01h00	0.042	0
01-Mar-1984-02h00	0.083	0
01-Mar-1984-03h00	0.125	0
01-Mar-1984-04h00	0.167	0
01-Mar-1984-05h00	0.208	0
01-Mar-1984-06h00	0.25	0
01-Mar-1984-07h00	0.292	0
01-Mar-1984-08h00	0.333	0
01-Mar-1984-09h00	0.375	0
01-Mar-1984-10h00	0.417	0
01-Mar-1984-11h00	0.458	0
01-Mar-1984-12h00	0.5	0
01-Mar-1984-13h00	0.542	0
01-Mar-1984-14h00	0.583	0
01-Mar-1984-15h00	0.625	0
01-Mar-1984-16h00	0.667	0
01-Mar-1984-17h00	0.708	0
01-Mar-1984-18h00	0.75	0
01-Mar-1984-19h00	0.792	0
01-Mar-1984-20h00	0.833	0
01-Mar-1984-21h00	0.875	0
01-Mar-1984-22h00	0.917	0
01-Mar-1984-23h00	0.958	0

The "summed" PECsw (fenpicoxamid plus X642188 as parent equivalent) values generated were then compared to the assumed "summed" RAC of 0.033 µg/L, as presented below.

Table 8.9-28: Max. "summed" Step 4 (10 m NSZ/75% DRN/10 m VFS) PECsw for fenpicoxamid and X642188 parent equiv.

Crop	Use no.	Max "Summed" Step 4 PECsw (µg/L) (fenpicoxamid plus X642188 parent equiv.)			
		R1 pond	R1 stream	R3 stream	R4 stream
Winter cereals	1-68, 69-83	0.00247	0.01590	0.02056	0.03416
Spring cereals	84-117, 118-132	-*	-*	-*	0.02803

* Scenario not relevant for spring cereals

Table 8.9-29: Max. "summed" Step 4 (5 m NSZ/90% DRN/10 m VFS) PECsw for fenpicoxamid and X642188 parent equiv.

Crop	Use no.	Max "Summed" Step 4 PECsw (µg/L) (fenpicoxamid plus X642188 parent equiv.)			
		R1 pond	R1 stream	R3 stream	R4 stream
Winter cereals	1-68, 69-83	0.00208	0.01590	0.02056	0.03416
Spring cereals	84-117, 118-132	-*	-*	-*	0.02803

* Scenario not relevant for spring cereals

There are no "summed" PECsw values which exceed the assumed RAC of 0.033 µg/L for the R1 and R3 scenarios for the Central Zone MS (PL, CZ, RO and SK) relevant to this dRR.

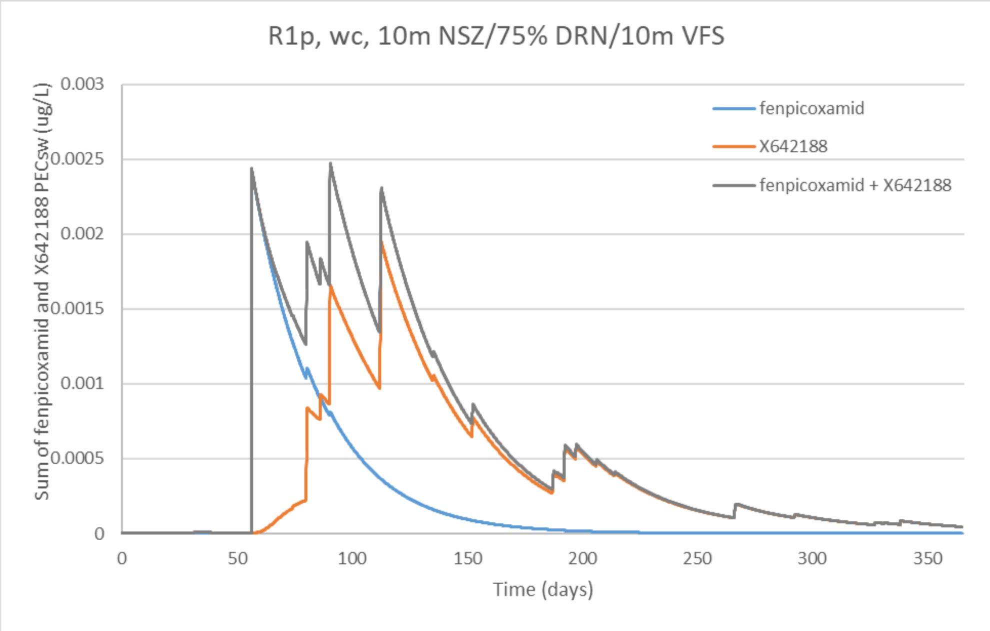
Whilst the "summed" R4 stream scenario PECsw values (0.03416 µg/L) just exceeds the assumed RAC for both winter and spring cereals, this is of no consequence since R4 is only applicable to HU in the Central Zone, and this MS is not supported in the GAP table.

It is noted that the "summed" PECsw values are identical (apart from R1 pond) for the two mitigations (10 m NSZ/75% DRN/10 m VFS and 5 m NSZ/90% DRN/10 m VFS) presented. This is because the dominant exposure route is run-off and the 10 m VFS is common to both mitigation options.

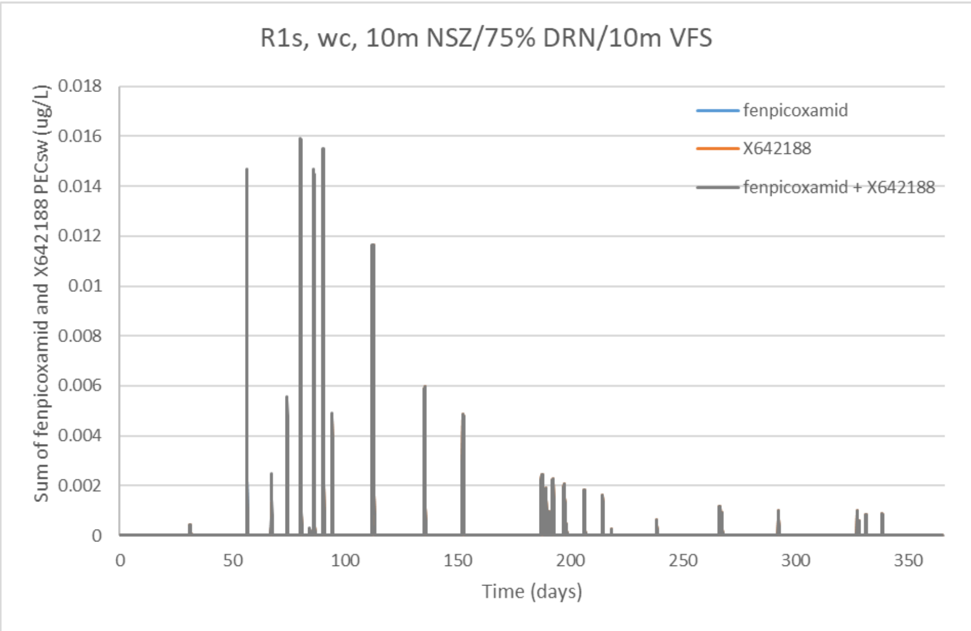
To illustrate the process and derivation of the "summed" PECsw values further, graphs were generated of the fenpicoxamid (blue line) and X642188 (parent equivalent; orange line) concentrations and the "summed" total (grey line) against time (days), and examples for R1 pond (run #90) and stream (run #91) are presented as follows. Note that for the stream scenario, the fenpicoxamid and X642188 exposures cannot easily be seen from the graphs because the peaks co-occur and are very short lived due to stream dilution.

Winter cereals example, 1 x 75 g as/ha (Step 4; 10 m NSZ/75% DRN/10 m VFS)

R1 pond



R1 stream



zRMS comments:

Step 1&2

The input parameters considered in surface water modelling performed by the Applicant at Step 1&2 were in line with the EU agreed endpoints reported in EFSA Journal 2018;16(1):5146.

However, application of GF-3307 at 2x100 g a.s./ha with 14 days interval was assumed by the Applicant, although in the Central Zone only single application of the product is proposed. It was explained by the Applicant that assumption of multiple applications will represent worst case covering single application. The zRMS does not fully agree with the Applicants' approach, since due to specific properties (e.g. short degradation time in aquatic systems, as in case of fenpicoxamid), for some compounds higher $PEC_{SW/SED}$ values may be calculated after single application and in such situation assumption of multiple applications will lead to underestimation of the surface water exposure resulting from the single use. When simulations are performed for multiple applications, results for single application are also reported by the model, but due to lack of detailed modelling report for Step 1&2 it is not possible to confirm if results reported in Table 8.9-2 were the maximum $PEC_{SW/SED}$ derived for single and multiple use or they were relevant for multiple use only.

It is also noted that at Step 1&2 the Applicant assumed interception relevant for "full canopy" while according to the FOCUS surface water generic guidance (2015), for cereals at BBCH 30 (the earliest time for application of GF-3307) "intermediate crop cover" should be assumed. Taking this into account, the Applicant was requested to provide new Step 1&2 calculations performed for uses indicated in GAP and with assumption of intermediate crop cover ("average crop cover" according to the model). Respective calculations were submitted by the Applicant and are presented in Table 8.9-3 above. It was argued that crop interception of 80% (full canopy) assumed in initial modelling was correct, since it is in line with FOCUS groundwater guidance (2014). It should be, however, noted that for surface water modelling FOCUS surface water guidance (2015) is applicable and it clearly states that for cereals at BBCH 30 intermediate crop cover is relevant (see Table 2.4.2-1 of the generic guidance). Newly submitted simulations were independently validated by the zRMS and are confirmed to be correct. Results obtained in initial simulations were struck through as being not agreed by the zRMS. The application pattern assumed in simulations for surface water modelling is in line with the critical Central Zone GAP as presented in Table 8.1-1.

Step 3&4

The input parameters considered in surface water modelling performed by the Applicant at Step 3&4 were in line with the EU agreed endpoints reported in EFSA Journal 2018;16(1):5146. Application pattern was in line with the Central Zone GAP (1x75 g a.s./ha in winter and spring cereals).

As in case of the groundwater modelling, single date for start of the application window (1^{st} of April) was assumed in all scenarios considered in simulations although different dates were suggested by the AppDate. The zRMS would like to emphasise that in case of groundwater modelling for GF-3307 assumption of the single application date in all scenarios could be accepted, since uncertainty related to this issue was covered by much higher application rate and multiple applications assumed in calculations. Furthermore, application to the soil surface is assumed in groundwater modelling with crop interception implemented in the application rates used as input to the model.

In case of surface water modelling, the crop interception is calculated internally by the model and will thus depend on the assumed application windows. In addition to that, it is not possible to judge if application dates selected by the model from application window 1^{st} April – 1^{st} May will represent worst case for drainage and run-off events comparing to application dates selected from the relevant application windows suggested by AppDate.

In order to check possible differences between surface water exposure calculated for the fixed application window for all scenarios and for application windows suggested by the AppDate, additional Step 3 modelling was performed by the zRMS for fenpicoxamid applied in winter and spring cereals. $PEC_{SW/SED}$ values obtained for scenarios D3, D4 (pond) and D5 (pond) were at similar level comparing to these reported by the Applicant. However, $PEC_{SW/SED}$ in scenarios D4 (stream) and D5 (stream) were higher (e.g. 0.382 vs. 0.356 µg/L in D4 and 0.392 vs. 0.371 µg/L in D5). For fenpicoxamid metabolite X642188 applied in winter cereals $PEC_{SW/SED}$ in R3 (stream) scenarios were higher (0.034 vs. 0.030 µg/L). Although observed differences seem to be minor, they may have significant impact on the outcome of the aquatic risk assessment, especially in scenarios in which PEC/RAC ratios are very close to the trigger. In such case even slight difference may decide on acceptability or non-acceptability of the risk. Furthermore, differences in fenpicoxamid $PEC_{SW/SED}$ at Step 3 will have also impact on Step 3 results for metabolite X642188, Step 4 results for the parent and metabolite as well as EPAT analysis, since at all these levels results of Step 3 simulations for the parent are considered by the models.

In addition to that it was noted that scenario R4 was not included in Applicants' simulations for winter cereals, although this scenario is indicated as relevant for the Central Zone in the guidance for evaluation in area of environmental fate and behaviour[3].

Overall, due to uncertainties described above, the zRMS is of the opinion that surface water modelling should be performed with consideration of application windows relevant for each scenario defined for the given crop. Different application windows might be accepted provided that it is clearly demonstrated that they represent worst case for the intended use pattern. This is not the case for GF-3307 and additional simulations performed by the zRMS demonstrated that assumption of the relevant application windows suggested by the AppDate may result with higher surface water exposure, at least in some scenarios.

[3] Working Document of the Central Zone in the Authorisation of Plant Protection Products, Section 8, Environmental Fate and Behaviour, Version 1, rev. 1, June 2018

Taking all this into account, the surface water modelling initially provided by the Applicant was not agreed by the zRMS and its results were struck through. The Applicant was requested to submit new Step 3&4 simulations for fenpicoxamid and metabolite X642188 performed with consideration of application windows indicated by the AppDate and all scenarios required in the Central Zone included. In addition to that also new EPAT analysis based on results of the new Step 3&4 simulations was requested.

Obtained updated Step 3 & 4 results together with the EPAT analysis were independently validated by the zRMS and are confirmed to be correct.

Due to high persistence of two sediment metabolites of fenpicoxamid, X12313581 and X696476, accumulation in sediment over at least 20 consecutive years should be taken into account in exposure calculation. In order to calculated $PEC_{SED,ACCU}$, a simplified approach was taken by the zRMS and maximum annual PEC_{SED} values were multiplied by 20 in order to account for 20 years of application with no degradation. Results relevant for Step 1-2 are presented in the table below. Calculation at Step 3/4 was not required since acceptable risk to sediment dwellers could be concluded with these worst case Step 1/2 values.

Step 1-2 maximum $PEC_{SED,ACCU}$ for metabolites X12313581 and X696476 for application over 20 years

Metabolite	**X12313581**	**X696476**
FOCUS Scenario	**Max. PEC_{SED} (µg/kg)**	**Max. PEC_{SED} (µg/kg)**
Step 1	128.8	1101.4
Step 2 - N-Europe	17.4	134.8

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.

Prothioconazole

~~**Steps 1 and 2**~~

~~**Note that the risk envelope GAP of 2 x 200 g as/ha from BBCH 30 used for the PECsw/sed calculations at Steps 1 and 2 is protective of the GAP of 1 x 150 g as/ha from BBCH 30 specific to the use of GF-3307 in this dRR.**~~

~~The risk envelope GAP modelled for prothioconazole in winter and spring cereals was 2 x 200 g as/ha (minimum 14 day interval) at BBCH 30 from 1 April. To cover the application from BBCH 30, the crop interception was assumed to be "full cover" (i.e. 70%) with the Mar-May application window. The Steps 1 and 2 modelling is not reported separately, but instead is fully described within this dRR.~~

~~The following endpoints were used to derive the PECsw/sed values. The molar mass values used are not given, but are those presented previously in Table 8.2-2.~~

~~**Table 8.9-30: Inputs related to application for PECsw/sed (Steps 1 and 2)**~~

~~Compound~~	~~Water solubility (mg/L) (20ºC)~~	~~Kfoc (geomean)~~	~~DT_{50} soil (d) (20ºC/pF2) (geomean)~~	~~DT_{50} water, sediment, wat/sed (d) (20ºC) (maximum)~~	~~Max. occurence, soil (% AR)~~	~~Max. occurence, wat/sed (% AR)~~	~~Evaluated at EU level~~
~~Prothioconazole~~	~~300 (pH 8)~~	~~1765 (n=1)~~	~~0.94~~	~~24.1~~	-	-	~~Yes (*EFSA, 2007*) [unless specified otherwise under 8.9.1]~~
~~JAU 6476-S-methyl (M01)~~	~~1.5 (25ºC)~~	~~2525.9~~	~~15.7 (20ºC only)~~	~~40.2~~	~~14.2~~	~~12.7~~	
~~JAU 6476-desthio (M04)~~	~~50.6~~	~~573.5~~	~~21.8~~	~~49.9~~	~~57.1~~	~~54.4~~	
~~1,2,4-triazole+~~	~~700000~~	~~83~~	~~1000*~~	~~1000~~	~~0.001**~~	~~41.8~~	

~~* Nominal default for non-soil metabolite~~ ~~** Nominal default of 0.001% used to allow model to run~~
~~+ Aquatic metabolite only~~

~~The results are given as follows for both Northern and Southern Europe.~~

~~**Table 8.9-31: Steps 1 and 2 PECsw/sed for prothioconazole and metabolites on cereals**~~

~~Compound~~	~~FOCUS scenario~~		~~Use no. 1-132*~~		
			~~Max. PECsw (µg/L)~~	~~Max. 21 d TWA PECsw (µg/L)~~	~~Max. PECsed (µg/kg)~~
~~Prothioconazole~~	~~Step 1~~		~~43.44~~	~~30.73~~	~~701.79~~
	~~Step 2~~	~~N Europe~~	~~2.05~~	~~0.74~~	~~13.43~~
		~~S Europe~~	~~2.05~~	~~0.78~~	~~14.50~~
~~JAU 6476-S-methyl (M01)~~	~~Step 1~~		~~9.03~~	~~7.27~~	~~215.85~~
	~~Step 2~~	~~N Europe~~	~~0.29~~	~~0.22~~	~~6.53~~
		~~S Europe~~	~~0.47~~	~~0.37~~	~~11.02~~
~~JAU 6476-desthio (M04)~~	~~Step 1~~		~~78.21~~	~~67.17~~	~~438.11~~
	~~Step 2~~	~~N Europe~~	~~2.67~~	~~2.20~~	~~14.35~~
		~~S Europe~~	~~4.42~~	~~3.73~~	~~24.27~~
~~1,2,4-triazole~~	~~Step 1~~		~~10.38~~	~~10.27~~	~~8.58~~
	~~Step 2~~	~~N Europe~~	~~0.27~~	~~0.26~~	~~0.22~~
		~~S Europe~~	~~0.28~~	~~0.27~~	~~0.23~~

~~* Risk envelope GAP of 2 x 200 g as/ha from BBCH 30 is protective of 1 x 150 g as/ha from BBCH 30~~

UPDATE – April 2022

Request from Poland (zRMS):

- *"Kinetic re-evaluation is considered to be the new active substance data, which may be used at the zonal level only in exceptional cases, when e.g. no safe use is identified using the EU agreed endpoints. Furthermore, the Working Document of the Central Zone in area of Section 8 indicates that modelling based on new/refined input parameters should be presented in addition to (and not instead of) simulations based on EU agreed data. Therefore, the degradation data for prothioconazole and its metabolites in soil and aquatic systems considered in the exposure assessment must be in line with EU agreed endpoints presented in EFSA Scientific Report (2007) 106. Taking this into account, the Applicant is kindly requested to provide groundwater and surface water modelling based on endpoints being fully in line with the EU agreed values."*

- *"The Step 2 surface water modelling should be performed with assumption of "intermediate crop cover", which according to indications of the FOCUS surface water generic guidance (2015) is relevant for applications at BBCH 30 (the earliest intended application of GF-3307). In addition to that, the Step 1/2 modelling was performed with assumption of application at 2 x 200 g as/ha for prothioconazole and its metabolites, but from the information available in the dRR it is not clear, if Step 2 results presented in Table 8.9-17 are the maximum values of single and multiple application, or are relevant for multiple applications only. Please note that in case of rapidly degrading compounds higher PECsw is expected from single application comparing to multiple applications. Taking this into account, the Applicant is kindly requested to provide Step 2 modelling for prothioconazole and its metabolites performed for single application at 200 g as/ha (or at 150 g as/ha, in line with the GAP for GF-3307)."*

Response from Applicant:

Previous Steps 1 and 2 modelling used "full canopy" (70% interception) as relevant for BBCH 30 (e.g. 80% interception is used for BBCH 30 in groundwater modelling). However, the zRMS (Poland) requested Steps 1 and 2 be repeated using "intermediate" crop cover, specifically for **1 x 150 g as/ha** rather than using a risk envelope approach from 2 x 200 g as/ha. This updated modelling is described below. It is not reported separately since the work can be fully described and presented directly in the dRR. The inputs related to prothioconazole and the metabolites (all from EFSA, 2007; in view of the request from Poland) are given in Table 8.9-32. Any inputs not shown were left as the FOCUS default values in the models.

Table 8.9-32: Inputs related to prothioconazole and metabolites for PECsw/sed (Steps 1 & 2)

Compound	Water solubility (mg/L) (20ºC)	Kfoc (arithmetic mean)	DT_{50} soil (d) (20ºC) (geomean)	DT_{50} water, sediment, wat/sed (d) (20ºC) (maximum)	Max. occurence, soil (% AR)	Max. occurence, wat/sed (% AR)	Evaluated at EU level
Prothioconazole	300 (pH 8)	1765 (n=1)	1.2	2.8	-	-	Yes *(EFSA, 2007)*
JAU 6476-S-methyl (M01)	1.5 (25ºC)	2556.3	15.7	1000	14.6	12.7	
JAU 6476-desthio (M04)	50.6	575.4	22.7	1000	57.1	54.4	
1,2,4-triazole+	700000	89	1000*	1000	0.001**	41.8	

* Nominal default for non-soil metabolite
** Nominal default to allow model to run
+ Aquatic metabolite only

Only results for "North Europe" are given as relevant for the Central Zone. It should be noted that STEPS 1-2 in FOCUS 3.2 does not give "intermediate" crop cover, and so "average" crop cover was used (20% interception). This is very conservative given that 80% is appropriate for groundwater modelling.

Table 8.9-33: Steps 1 & 2 PECsw/sed for prothioconazole and metabolites on cereals

Compound	FOCUS scenario		Use no. 1-132		
			Max. PECsw (µg/L)	Max. 21 d TWA PECsw (µg/L)	Max. PECsed (µg/kg)
Prothioconazole	Step 1		16.29	2.95	263.17
	Step 2	N Europe	1.38	0.18	6.52
JAU 6476-S-methyl (M01)	Step 1		3.40	3.24	83.37
	Step 2	N Europe	0.31	0.29	7.56
JAU 6476-desthio (M04)	Step 1		29.29	28.79	166.70
	Step 2	N Europe	2.75	2.66	15.41
1,2,4-triazole	Step 1		3.87	3.83	3.43
	Step 2	N Europe	0.17	0.16	0.14

Steps 3 and 4

The report below **(8.9.2/02)** provides the FOCUS Steps 3 and 4 PECsw/sed values for prothioconazole and the JAU 6476-desthio metabolite (M04).

Reference:	**8.9.2/02**
Report:	Reeves, G. (2018): Modelling the Predicted Environmental Concentrations of Prothioconazole and One Metabolite (JAU 6476-Desthio) in Surface Water and Sediment (FOCUS Steps 3 and 4) in the EU for Zonal Submission. Dow AgroSciences Report No. 151148. 31 May, 2018.
Guideline(s):	FOCUS (2001): FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC. Report of FOCUS Working Group on Surface Water Scenarios. EC Document Ref. SANCO/4802/2001-Rev.2. 245 pp., and Generic Guidance Document for FOCUS Surface Water Scenarios, Ver. 1.2 (December 2012).
Deviations:	No
GLP:	No (model calculation)
Acceptability:	Yes

~~Prothioconazole and JAU 6476-desthio (M04) were run at Steps 3 and 4.~~

~~Table 8.9-34: Inputs related to application for PECsw/sed (Steps 3 and 4)~~

~~Use no.~~	~~1-132~~
~~Crop~~	~~Winter cereals, spring cereals~~
~~Application rate (g as/ha)~~	~~150 (Prothioconazole)~~
~~Max. number of applications~~	~~1~~
~~Frequency of application~~	~~Annual~~
~~Application window (Steps 3 and 4)~~	~~Absolute date (Table 8.9-4)~~
~~Application method~~	~~Ground spray~~
~~Chemical application method (CAM)~~	~~2 – appn. foliar linear~~
~~Depth incorporated (cm)~~	~~4~~
~~Models used~~	~~FOCUS SPIN v2.2 FOCUS SWASH v5.3 FOCUS MACRO v5.5.4 FOCUS PRZM v4.3.1 FOCUS TOXSWA v4.4.3 SWAN v4.0.1 (Step 4)~~

~~Table 8.9-35: Application window used for Steps 3 and 4 PECsw/sed~~

~~FOCUS scenario~~	~~Use no. 1-132~~
	~~Application window (absolute)~~
~~D3, D4, D5 R1**, R3**~~	~~1 Apr – 30 Jun (reflective of spring appn, BBCH 30)~~

~~* Only scenarios relevant to countries in this submission~~
~~** Scenarios not relevant for spring cereals~~

~~The AppDate v3.06 tool lists the following calendar dates corresponding to application at BBCH 30 for each surface water scenario, which supports the selection of the 1 April as a reflective application timing for the Central Zone scenarios relevant to the countries in this submission.~~

FOCUS scenario	BBCH 30	
	w/cereals	s/cereals
D3	16-Apr	28-Apr
D4	18-Mar	18-May
D5	15-Mar	09-Apr
R1	24-Apr	-
R3	19-Mar	-

~~Table 8.9-36: Inputs related to prothioconazole and metabolites for PECsw/sed - Steps 3 and 4~~

~~Compound~~	~~Prothioconazole~~	~~JAU 6476-desthio (M04)~~	~~Evaluated at EU level~~
~~Molar mass (g/mol)~~	~~344.3~~	~~312.2~~	~~Yes *(EFSA, 2007)* [unless specified otherwise under 8.9.1]~~
~~Water solubility (mg/L)~~	~~300 (pH 8)~~	~~50.6~~	
~~Vapour pressure (Pa)~~	~~1.0×10^{-10}~~	~~Parent as surrogate~~	
~~Molar enthalpy of vapourisation (kJ/mol)~~	~~95~~	~~95~~	
~~Molar enthalpy of issolution (kJ/mol)~~	~~27~~	~~27~~	
~~Ref. diffusion co-efficient in water (m^2/d)~~	~~4.3×10^{-5}~~	~~4.3×10^{-5}~~	
~~Ref. diffusion co-efficient in air (m^2/d)~~	~~0.43~~	~~0.43~~	
~~Kfoc (pH independent)* (geometric mean)~~	~~1765 (n=1)~~	~~573.5~~	
~~1/n (arithmetic mean)~~	~~1 (default)~~	~~0.81~~	
~~DT_{50} soil (d) (20ºC/pF2) (geometric mean)~~	~~0.94~~	~~21.8~~	
~~DT_{50} water (d) (20ºC) (maximum)~~	~~24.1~~	~~49.9~~	
~~DT_{50} sediment (d) (20ºC) (maximum)~~	~~1000 (nominal)~~	~~1000 (nominal)~~	
~~Formation fraction, soil~~	~~–~~	~~0.6~~	
~~Formation fraction, wat/sed~~	~~–~~	~~1~~	
~~Crop wash-off factor (1/m)~~	~~50~~	~~50~~	
~~Half-life on crop canopy (d)~~	~~10~~	~~10~~	
~~Plant uptake factor~~	~~0~~	~~0~~	

~~* Divide by 1.724 for Kfom~~
~~** Since Kfoc <2000 mL/g, 1000 d was used for non-degrading (sediment) phase, with whole system DT_{50} used~~

for degrading (water) phase.

FOCUS Step 3 (1 x 150 g as/ha)

Table 8.9-37: Step 3 PECsw/sed for prothioconazole on winter cereals

FOCUS scenario	Uses 1-68, 69-83			
	Max. PECsw (µg/L)	Dominant entry route	Max. 21 d TWA PECsw (µg/L)	Max. PECsed (µg/kg)
D3 ditch	0.948	Drift	0.042525	0.456675
D4 pond	0.032745	Drift	0.025845	0.116175
D4 stream	0.725475	Drift	0.001622	0.02571
D5 pond	0.032745	Drift	0.02553	0.115125
D5 stream	0.7575	Drift	0.001349	0.02154
R1 pond	0.032745	Drift	0.024803	0.1083
R1 stream	0.62535	Drift	0.006719	0.081375
R3 stream	0.8835	Drift	0.019148	0.2004

Table 8.9-38: Step 3 PECsw/sed for prothioconazole on spring cereals

FOCUS scenario	Uses 84-117, 118-132			
	Max. PECsw (µg/L)	Dominant entry route	Max. 21 d TWA PECsw (µg/L)	Max. PECsed (µg/kg)
D3 ditch	0.94875	Drift	0.043493	0.4641
D4 pond	0.032745	Drift	0.025808	0.1152
D4 stream	0.724425	Drift	0.001607	0.025463
D5 pond	0.032745	Drift	0.025485	0.1137
D5 stream	0.7545	Drift	0.001305	0.02085

Table 8.9-39: Step 3 PECsw/sed for JAU 6476-desthio (M04) on winter cereals

FOCUS scenario	Uses 1-68, 69-83			
	Max. PECsw (µg/L)	Dominant entry route*	Max. 21 d TWA PECsw (µg/L)	Max. PECsed (µg/kg)
D3 ditch	0.003899	Drainflow	0.000242	0.004017
D4 pond	0.00656	Drainflow	0.006521	0.112425
D4 stream	0.00678	Drainflow	0.000122	0.001833
D5 pond	0.007598	Drainflow	0.00756	0.126
D5 stream	0.01245	Drainflow	2.25E-05	0.000388
R1 pond	0.02961	Run-off	0.025185	0.27885
R1 stream	0.2796	Run-off	0.019298	0.279225
R3 stream	0.370875	Run-off	0.017453	0.493125

* Drainflow or run-off and/or contribution from degradation of parent drift

Table 8.9-40: Step 3 PECsw/sed for JAU 6476-desthio (M04) on spring cereals

FOCUS scenario	Uses 84-117, 118-132			
	Max. PECsw (µg/L)	Dominant entry route*	Max. 21 d TWA PECsw (µg/L)	Max. PECsed (µg/kg)
D3 ditch	0.003983	Drainflow	0.000252	0.00411
D4 pond	0.006398	Drainflow	0.006361	0.10785
D4 stream	0.00677	Drainflow	0.00014	0.002058
D5 pond	0.007388	Drainflow	0.007356	0.12315
D5 stream	0.012398	Drainflow	2.18E-05	0.000372

* Drainflow or run-off and/or contribution from degradation of parent drift

In the following Step 4 tables, NSZ = no-spray zone, DRN = drift reducing nozzles (both to mitigate drift) and VFS = vegetated filter strip (to mitigate run-off).
Note that separately from report 8.9.2/02, additional Step 4 modelling was carried out and reported in the tables below for a **5 m NSZ with 90% DRN and a 10 m VFS** to provide a further risk assessment option.

FOCUS Step 4 (1 x 150 g as/ha)

Table 8.9-41: Step 4 PECsw for prothioconazole on winter cereals

FOCUS scenario	Uses 1-68, 69-83								
	Max. PECsw (µg/L)								
NSZ	30 m	30 m	25 m	20 m	10 m	10 m	5 m	10 m	20 m
DRN	None	None	None	None	50%	75%	90%	90%	90%
VFS	10 m	None	None	None	10 m	10 m	10 m	10 m	20 m
D3 ditch	0.047985	0.047985	0.0573375	0.0708675	0.06816	0.03408	0.02559	0.013635	0.007087
D4 pond	0.010388	0.010388	0.0117375	0.013605	0.010208	0.005106	0.002841	0.002041	0.001361
D4 stream	0.049463	0.049463	0.05898	0.07314	0.07029	0.035153	0.0264225	0.014055	0.007314
D5 pond	0.010388	0.010388	0.0117375	0.013605	0.010208	0.005106	0.002841	0.002041	0.001361
D5 stream	0.05166	0.05166	0.0615975	0.07635	0.07341	0.036713	0.0276	0.014685	0.007635
R1 pond	0.010388	0.010388	0.0117375	0.013605	0.010208	0.005106	0.002841	0.002041	0.001361
R1 stream	0.042638	0.042638	0.050835	0.063045	0.060585	0.0303	0.0227775	0.01662	0.008393
R3 stream	0.060248	0.0987	0.0987	0.0987	0.085575	0.045053	0.0450525	0.045053	0.02364

Table 8.9-42: Step 4 PECsw for prothioconazole on spring cereals

FOCUS scenario	Uses 84-117, 118-132								
	Max. PECsw (µg/L)								
NSZ	30 m	30 m	25 m	20 m	10 m	10 m	5 m	10 m	20 m
DRN	None	None	None	None	50%	75%	90%	90%	90%
VFS	10 m	None	None	None	10 m	10 m	10 m	10 m	20 m
D3 ditch	0.047993	0.047993	0.057345	0.0708825	0.068175	0.034088	0.0255975	0.013635	0.007088
D4 pond	0.010388	0.010388	0.0117375	0.013605	0.010208	0.005106	0.002841	0.002041	0.001361
D4 stream	0.049395	0.049395	0.05889	0.073035	0.070185	0.0351	0.026385	0.01404	0.007304
D5 pond	0.010388	0.010388	0.0117375	0.013605	0.010208	0.005106	0.002841	0.002041	0.001361
D5 stream	0.051428	0.051428	0.0613125	0.07605	0.073073	0.036548	0.0274725	0.014618	0.007605

Table 8.9-43: Step 4 PECsw for JAU 6476-desthio (M04) on winter cereals

FOCUS scenario	Uses 1-68, 69-83								
	Max. PECsw (µg/L)								
NSZ	30 m	30 m	25 m	20 m	10 m	10 m	5 m	10 m	20 m
DRN	None	None	None	None	50%	75%	90%	90%	90%
VFS	10 m	None	None	None	10 m	10 m	10 m	10 m	20 m
D3 ditch	0.000197	0.000197	0.0002348	0.0002903	0.000279	0.00014	0.000105	0.000056	0.000003
D4 pond	0.002021	0.002021	0.0022905	0.0026655	0.001985	0.000974	0.0005888	0.000533	0.000485
D4 stream	0.00221	0.00221	0.0022095	0.0022095	0.00221	0.00221	0.0022095	0.00221	0.00221
D5 pond	0.002344	0.002344	0.002655	0.0030893	0.0023	0.001132	0.000621	0.000443	0.000293
D5 stream	0.000847	0.000847	0.0010103	0.0012533	0.001204	0.000602	0.0004523	0.000266	0.000266
R1 pond	0.011423	0.026018	0.026235	0.026535	0.011393	0.010575	0.010215	0.010088	0.005086
R1 stream	0.126975	0.2796	0.2796	0.2796	0.126975	0.126975	0.126975	0.126975	0.06648
R3 stream	0.1692	0.370875	0.370875	0.370875	0.1692	0.1692	0.1692	0.1692	0.0888

Table 8.9-44: Step 4 PECsw for JAU 6476-desthio (M04) on spring cereals

FOCUS scenario	Uses 84-117, 118-132								
	Max. PECsw (µg/L)								
NSZ	30 m	30 m	25 m	20 m	10 m	10 m	5 m	10 m	20 m
DRN	None	None	None	None	50%	75%	90%	90%	90%
VFS	10 m	None	None	None	10 m	10 m	10 m	10 m	20 m
D3 ditch	0.000201	0.000201	0.00024	0.000297	0.000285	0.000143	0.0001073	0.000057	0.00003
D4 pond	0.001972	0.001972	0.002235	0.0026003	0.001936	0.00095	0.000618	0.000568	0.000525
D4 stream	0.002345	0.002345	0.0023445	0.0023445	0.002345	0.002345	0.0023445	0.002345	0.002345
D5 pond	0.002279	0.002279	0.0025823	0.0030045	0.002237	0.0011	0.0006038	0.000431	0.000284
D5 stream	0.000843	0.000843	0.0010058	0.0012473	0.001199	0.000599	0.00045	0.000239	0.000218

UPDATE – April 2022

Request from Poland (zRMS):

- *"Kinetic re-evaluation is considered to be the new active substance data, which may be used at the zonal level only in exceptional cases, when e.g. no safe use is identified using the EU agreed endpoints. Furthermore, the Working Document of the Central Zone in area of Section 8 indicates that modelling based on new/refined input parameters should be presented in addition to (and not instead of) simulations based on EU agreed data. Therefore, the degradation data for prothioconazole and its metabolites in soil and aquatic systems considered in the exposure assessment must be in line with EU agreed endpoints presented in EFSA Scientific Report (2007) 106. Taking this into account, the Applicant is kindly requested to provide groundwater and surface water modelling based on endpoints being fully in line with the EU agreed values."*

- *"Since the new groundwater and surface water modelling must be performed anyway, the Applicant is kindly requested to consider application dates (or windows) suggested by AppDate ver. 3.06, in line with Working Document of the Central Zone in area of Section 8, which indicates that the application timing should be selected using the most actual version of the software AppDate."*

- *"In surface water modelling for winter cereals all scenarios relevant for the Central Zone must be included (D3, D4, D5, R1, R3 and R4). For spring cereals all scenarios defined in FOCUS models must be included in calculations (D3, D4, D5 and R4), while scenarios not defined for spring cereals will be considered to be covered by simulations performed for winter cereals."*

Response from Applicant:

Previous Steps 3 and 4 modelling used the same application date (1 April) for all scenarios. However, the zRMS (Poland) requested Steps 3 and 4 be repeated using dates relevant to BBCH 30 according to AppDate 3.06 (June, 2019), and to include R4 (although this scenario is not required by any MS relevant to this submission).

The updated modelling at **1 x 150 g as/ha** is described below. It is not reported separately since the work can be fully described and presented directly here in the dRR.

Table 8.9-45: Inputs related to application for PECsw/sed (Steps 3 & 4)

Use no.	**1-132**
Crop	Winter cereals, spring cereals
Application rate (g as/ha)	150 (Prothioconazole)
Max. number of applications	1
Frequency of application	Annual
Application window	Date given by AppDate 3.06 (June, 2019), BBCH 30
Application method	Ground spray
Chemical application method (CAM)	2 – appn. foliar linear
Depth incorporated (cm)	4
Models used	FOCUS SWASH 5.3 FOCUS MACRO 5.5.4 FOCUS PRZM 4.3.1 FOCUS TOXSWA 5.5.3 SWAN v5.0.1 (Step 4)

The dates modelled for application to winter and spring cereals corresponding to BBCH 30 were selected for each relevant FOCUS surface water scenario using AppDate 3.06 (June, 2019). All scenarios available for the crop were modelled for completeness, but only those relevant for the Central Zone are described here. A 30 day window was set in the model as relevant for a single application.

Table 8.9-46: Application dates used for PECsw/sed (Steps 3 & 4)

FOCUS scenario	Appn. date (absolute) (BBCH 30)	
	Use no. 1-68, 69-83	Use no. 84-117, 118-132
D3	16 Apr	28 Apr
D4	18 Mar	18 May
D5	15 Mar	9 Apr
R1	24 Apr	-*
R3	19 Mar	-*
R4	24 Jan	9 Apr

* Scenarios not relevant for spring cereals

Prothioconazole and the JAU 6476-desthio (M04) metabolite were run at Steps 3 and 4 to mitigate their aquatic toxicity. The inputs related to prothioconazole and JAU 6476-desthio (M04) (all from EFSA, 2007; in view of the request from Poland) are given in Table 8.9-47. Any inputs not shown were left as the FOCUS default values in the models.

Table 8.9-47: Inputs related to prothioconazole and metabolite for PECsw/sed (Steps 3 & 4)

Compound	Prothioconazole	JAU 6476-desthio (M04)	Evaluated at EU level
Molar mass (g/mol)	344.3	312.2	Yes *(EFSA, 2007)*
Water solubility (mg/L)	300 (pH 8)	50.6	
Vapour pressure (Pa)	1 x 10^{-10}	Parent as surrogate	
Kfoc (pH independent)* (arithmetic mean)	1765 (n=1)	575.4	
1/n (arithmetic mean)	0.9 (default)	0.81	
DT_{50} soil (d) (20ºC) (geometric mean)	1.2	22.7	
DT_{50} water (d) (20ºC) (maximum)	2.8	1000 (nominal)**	
DT_{50} sediment (d) (20ºC) (maximum)	1000 (nominal)**	1000 (nominal)**	
Formation fraction, soil	-	0.57	
Formation fraction, water	-	1	
Formation fraction, sediment	-	1	
Plant uptake factor	0	0	

* Divide by 1.724 for Kfom
** Since Kfoc <2000 mL/g, 1000 d was used for non-degrading (sediment) phase, with whole system DT_{50} used for degrading (water) phase.

At Step 4, the drift mitigations applied were an increased no-spray zone (NSZ) to 30 m, with or without 50%, 75% or 90% drift reducing nozzles (DRN), and to mitigate run-off a vegetated filter strip (VFS) was used for either a distance of 10 m or 20 m. For a 10 m VFS, reduction factors of 0.6 and 0.85 were applied, and for a 20 m VFS the reduction factors used were 0.8 and 0.95. These were taken from the FOCUS Landsacape and Mitigation workgroup (2007).

FOCUS Step 3

Table 8.9-48: Step 3 PECsw/sed for prothioconazole on winter cereals

FOCUS scenario	Use no. 1-68, 69-83			
	Max. PECsw (µg/L)	Dominant entry route	Max. 14 d TWA ~~Max. 21 d TWA~~ PECsw (µg/L)	Max. PECsed (µg/kg)
D3 ditch	0.9478	Drift	0.1293	0.557 ~~0.1293~~
D4 pond	0.03267	Drift	0.02472	0.105 ~~0.02472~~
D4 stream	0.7006	Drift	0.003796	0.021 ~~0.003796~~
D5 pond	0.03268	Drift	0.02255	0.088 ~~0.02255~~
D5 stream	0.7566	Drift	0.004027	0.022 ~~0.004027~~
R1 pond	0.03268	Drift	0.02249	0.084 ~~0.02249~~
R1 stream	0.6244	Drift	0.01626	0.085 ~~0.01626~~
R3 stream	0.8772	Drift	0.03439	0.175 ~~0.03439~~
R4 stream	0.6271	Drift	0.01852	0.097 ~~0.01852~~

Table 8.9-49: Step 3 PECsw/sed for JAU 6476-desthio (M04) on winter cereals

FOCUS scenario	Use no. 1-68, 69-83			
	Max. PECsw (µg/L)	Dominant entry route*	Max. 14 d TWA ~~Max. 21 d TWA~~ PECsw (µg/L)	Max. PECsed (µg/kg)
D3 ditch	0.03541	Drainflow	0.03541	0.03053
D4 pond	0.01318	Drainflow	0.01318	0.206
D4 stream	0.04552	Drift	0.04552	0.002121
D5 pond	0.01767	Drainflow	0.01767	0.264
D5 stream	0.0733	Drift	0.0733	0.002178
R1 pond	0.03967	Run-off	0.03967	0.4414
R1 stream	0.2569	Run-off	0.2569	0.2921
R3 stream	0.32	Run-off	0.32	0.4351
R4 stream	0.4677	Run-off	0.4677	0.3327

* Drainflow or run-off and/or contribution from degradation of parent drift

Table 8.9-50: Step 3 PECsw/sed for prothioconazole on spring cereals

FOCUS scenario	Use no. 84-117, 118-132			
	Max. PECsw (µg/L)	Dominant entry route	Max. 14 d TWA ~~Max. 21 d TWA~~ PECsw (µg/L)	Max. PECsed (µg/kg)
D3 ditch	0.9488	Drift	0.06883	0.5761
D4 pond	0.03269	Drift	0.01341	0.07145
D4 stream	0.7755	Drift	0.004987	0.05323
D5 pond	0.03269	Drift	0.01697	0.08834
D5 stream	0.7966	Drift	0.003153	0.03395
R4 stream	0.6271	Drift	0.0278	0.678

Table 8.9-51: Step 3 PECsw/sed for JAU 6476-desthio (M04) on spring cereals

FOCUS scenario	Use no. 84-117, 118-132			
	Max. PECsw (µg/L)	Dominant entry route*	Max. 14 d TWA ~~Max. 21 d TWA~~ PECsw (µg/L)	Max. PECsed (µg/kg)
D3 ditch	0.07275	Drainflow	0.008159	0.06703
D4 pond	0.0192	Drainflow	0.01903	0.2367
D4 stream	0.05171	Drift	0.000351	0.003771
D5 pond	0.01799	Drainflow	0.01784	0.2628
D5 stream	0.07717	Drift	0.000314	0.003417
R4 stream	0.4447	Run-off	0.09253	0.7295

* Drainflow or run-off and/or contribution from degradation of parent drift

In the following Step 4 tables, NSZ = no-spray zone and DRN = drift reducing nozzles (both to mitigate drift) and VFS = vegetated filter strip (to mitigate run-off).

FOCUS Step 4

Table 8.9-52: Step 4 PECsw for prothioconazole on winter cereals

FOCUS scenario	Use no. 1-68, 69-83							
	Max. PECsw (µg/L)							
NSZ	30 m	25 m	20 m	10 m	10 m	10 m	5 m	20 m
DRN	None	None	None	50%	75%	90%	90%	90%
VFS	None	None	None	10 m	10 m	10 m	10 m	20 m
D3 ditch	0.04796	0.05713	0.07074	0.06808	0.03403	0.01361	0.02567	0.007067
D4 pond	0.01032	0.01171	0.01356	0.01015	0.005077	0.002029	0.002823	0.001355
D4 stream	0.04778	0.05692	0.07047	0.06783	0.03391	0.01355	0.02557	0.00704
D5 pond	0.01033	0.01172	0.01357	0.01016	0.005078	0.00203	0.002824	0.001355
D5 stream	0.0516	0.06147	0.0761	0.07325	0.03662	0.01464	0.02761	0.007603
R1 pond	0.01033	0.01172	0.01357	0.01016	0.005078	0.00203	0.002824	0.001355
R1 stream	0.04258	0.05073	0.0628	0.06045	0.03022	0.01208	0.02279	0.006275
R3 stream	0.05982	0.07127	0.08823	0.08493	0.04245	0.01697	0.03201	0.008815
R4 stream	0.04277	0.05095	0.06308	0.06072	0.03035	0.01213	0.02289	0.006302

Table 8.9-53: Step 4 PECsw for JAU 6476-desthio (M04) on winter cereals

FOCUS scenario	Use no. 1-68, 69-83							
	Max. PECsw (µg/L)							
NSZ	30 m	25 m	20 m	10 m	10 m	10 m	5 m	20 m
DRN	None	None	None	50%	75%	90%	90%	90%
VFS	None	None	None	10 m	10 m	10 m	10 m	20 m
D3 ditch	0.001787	0.00213	0.002637	0.002538	0.001268	0.000506	0.000956	0.000263
D4 pond	0.00402	0.004579	0.005324	0.003952	0.001935	0.000752	0.001057	0.000568
D4 stream	0.003101	0.003695	0.004574	0.004403	0.002242	0.002242	0.002242	0.002242
D5 pond	0.005416	0.006167	0.007168	0.005325	0.002613	0.001019	0.00143	0.000674
D5 stream	0.004994	0.00595	0.007367	0.007091	0.003543	0.001416	0.002672	0.000735
R1 pond	0.02934	0.02992	0.03069	0.01438	0.01212	0.01086	0.01118	0.005522
R1 stream	0.2569	0.2569	0.2569	0.1167	0.1167	0.1167	0.1167	0.06108
R3 stream	0.32	0.32	0.32	0.146	0.146	0.146	0.146	0.07661
R4 stream	0.4677	0.4677	0.4677	0.2127	0.2127	0.2127	0.2127	0.1114

Table 8.9-54: Step 4 PECsw for prothioconazole on spring cereals

FOCUS scenario	Use no. 84-117, 118-132							
	Max. PECsw (µg/L)							
NSZ	**30 m**	**25 m**	**20 m**	**10 m**	**10 m**	**10 m**	**5 m**	**20 m**
DRN	**None**	**None**	**None**	**50%**	**75%**	**90%**	**90%**	**90%**
VFS	**None**	**None**	**None**	**10 m**	**10 m**	**10 m**	**10 m**	**20 m**
D3 ditch	0.04801	0.05719	0.07081	0.06815	0.03407	0.01362	0.02569	0.007074
D4 pond	0.01033	0.01172	0.01357	0.01016	0.00508	0.002031	0.002825	0.001356
D4 stream	0.05289	0.06301	0.07801	0.07509	0.03753	0.01501	0.0283	0.007794
D5 pond	0.01033	0.01172	0.01357	0.01016	0.005079	0.00203	0.002824	0.001356
D5 stream	0.05433	0.06472	0.08012	0.07712	0.03855	0.01541	0.02907	0.008005
R4 stream	0.2006*	0.2006*	0.2006*	0.0905*	0.0905*	0.0905*	0.0905*	0.04724*

* With high levels of drift reduction the dominant exposure route for parent is run-off for R4

Table 8.9-55: Step 4 PECsw for JAU 6476-desthio (M04) on spring cereals

FOCUS scenario	Use no. 84-117, 118-132							
	Max. PECsw (µg/L)							
NSZ	**30 m**	**25 m**	**20 m**	**10 m**	**10 m**	**10 m**	**5 m**	**20 m**
DRN	**None**	**None**	**None**	**50%**	**75%**	**90%**	**90%**	**90%**
VFS	**None**	**None**	**None**	**10 m**	**10 m**	**10 m**	**10 m**	**20 m**
D3 ditch	0.04801	0.05719	0.07081	0.06815	0.03407	0.01362	0.02569	0.007074
D4 pond	0.01033	0.01172	0.01357	0.01016	0.00508	0.002031	0.002825	0.001356
D4 stream	0.05289	0.06301	0.07801	0.07509	0.03753	0.01501	0.0283	0.007794
D5 pond	0.01033	0.01172	0.01357	0.01016	0.005079	0.00203	0.002824	0.001356
D5 stream	0.05433	0.06472	0.08012	0.07712	0.03855	0.01541	0.02907	0.008005
R4 stream	0.2006	0.2006	0.2006	0.0905	0.0905	0.0905	0.0905	0.04724

zRMS comments:

In initial version of the dRR the following was noted with regard to the surface water modelling for prothioconazole and its metabolites:

1. The modelling was based on the new input parameters considering the new degradation data for prothioconazole and its metabolites in soil and aquatic systems.
2. The application timing did not corresponded with the most actual version of AppDate (as required by the Working Document of the Central Zone in area of Section 8).
3. Results at Step 2 were based on the assumption of crop interception set to "full crop cover", while according to indications of the FOCUS surface water generic guidance (2015) the “average crop cover” is relevant for applications at BBCH 30.
4. It was not clear if results at Step 1-2 were relevant for single or multiple application and the modelling was performed with assumption of application at 2 x 200 g a.s./ha for prothioconazole and its metabolites. In case of rapidly degrading compounds (such as prothioconazole) surface water exposure form single application exceeds exposure from multiple applications. Therefore it is crucial to know if results reported for double application were the overall maximum of single and multiple application or were relevant for two applications.
5. In the surface water modelling for winter and spring cereals R4 scenario was missing.

Due to listed above deficiencies, the Applicant was requested to provide Step 1-3 surface water modelling for prothioconazole and its metabolites for single application at 200 g a.s./ha (or at 150 g a.s./ha, in line with the GAP for GF-3307) based on EU agreed endpoints and respective application windows determined using AppDate.

Respective calculations were provided by the Applicant and introduced above, while the initial simulations were struck through.

Application dates assumed in updated modelling and presented in Table 8.9-46 were checked by the zRMS using AppDate ver. 3.06 tool and are considered acceptable and relevant for BBCH 30 of winter and spring cereals. The application pattern assumed in simulations was in line with the intended Central Zone GAP.

Input parameters for prothioconazole presented in tables 8.9-32 and 8.9-47 relevant for Step1-2 and Step3-4, respectively, were in general in line with EU agreed endpoints with exception of water DT_{50} for prothioconazole: 2.8 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.

As no DT_{50} values for aquatic systems were available for metabolites, the worst case default of 1000 days was used for water and sediment, which is accepted by the zRMS.

With regard to degradation data for the aquatic systems used in Step 3 and 4 simulations, it is noted that the Kfoc of JAU 6476-desthio is between 100 and 2000 mL/g and the FOCUS surface water guidance (2015) indicates that 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. This approach would result in four combinations for parent and metabolite modelling. It is, however, noted that all these combinations were tested during the recent renewal process of prothioconazole and it turned out that the worst case combination was when the shortest DT_{50} value was applied to prothioconazole and the default of 1000 days was applied to JAU 6476-desthio in the water phase. As this combination was used in simulations provided for GF-3307, there was no need to consider other combinations. It is noted that although the renewal process for prothioconazole was not completed yet, this information may be used, as it has been already agreed during the peer-review and it concerns only combination to be used, but not regards change of the input parameters. The Applicant has access to this information via LoA issued by the owner of the active substance.

At Step 3 PUF value of 0 was assumed for prothioconazole and JAU 6476-desthio and it is in line with current recommendations.

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

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 all compounds are confirmed to be correct.

Obtained PEC_{SW} for prothioconazole and metabolite JAU 6476-desthio at Steps 3-4 were in a good agreement with values calculated by the Applicant. However, obtained PEC_{SED} for prothioconazole following application to winter cereals were considerably higher than these presented by the Applicant.

A typing error in Table 8.9-48 was found, as the 21 days TWA PEC_{SW} were the same as PEC_{SED}. Therefore, results for sediment in Table 8.9-48 were corrected by the zRMS.

Furthermore, according to the zRMS calculations the 21 days TWA PEC_{SW} values in Tables 8.9-48 to 8.9-51 were actually relevant for 14 days TWA PEC_{SW}. Taking this into account, information in the header of Tables 8.9-48 to 8.9-51 was changed in order to avoid not necessary work with presentation of 21-d TWA PEC_{SW}. TWA values calculated at Steps 1 & 2 were correctly reported.

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.

GF-3307

UPDATE – April 2022

A no-spray zone of 20 m was added to the table below to be consistent with the zones used for the active substances.

The formulation consists of active substance(s) and co-formulants. It will not remain intact in aquatic systems after application due to breakdown of its individual components. Therefore, only an initial spray drift PECsw was calculated and time-aged values (actual and TWA) not appropriate. The initial Step 3 PECsw was calculated using the SWASH drift calculator for the ditch, pond and stream, in addition to Step 4 using increased no-spray zones (NSZ) and drift reducing nozzles (DRN) as required for the active substance. The formulation rate of 1.5 L FP/ha is equivalent to 1566 g FP/ha assuming a formulation density of 1.044 g/mL.

Table 8.9-56: PECsw for GF-3307 on winter and spring cereals at 1.5 L FP/ha

FOCUS water body	Use no. 1-132								
	PECsw (µg FP/L)								
	Default FOCUS distance ~~Step 3~~	Risk mitigation measures ~~Step 4 NSZ~~							
		30 m	25 m	20 m	10 m			5 m	20 m
		Std. nozzle	Std. nozzle	Std. nozzle	50% DRN	75% DRN	90% DRN	90% DRN	90% DRN
Ditch	10.0610	0.5095	0.6070	0.7515	0.7232	0.3616	0.1447	0.2727	0.0752
Pond	0.3430	0.1085	0.1231	0.1425	0.1067	0.0533	0.0214	0.0297	0.0143
Stream	7.4665	0.5095	0.6070	0.7515	0.7232	0.3616	0.1447	0.2727	0.0752

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 8.9-29, and may be used in the risk assessment.

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

Table 8.10-1: Summary of atmospheric degradation and behaviour

Compound	Fenpicoxamid	Prothioconazole
Direct photolysis in air	Not applicable	Not applicable
Quantum yield of direct phototransformation	Not applicable	Not applicable
Photochemical oxidative degradation in air	DT_{50}: 0.261 d (Atkinson)	DT_{50}: <1 d (Atkinson)
Vapour pressure	1.2 x 10^{-7} Pa	<4 x 10^{-7} (Pa)
Metabolites	All metabolite DT_{50} values (Atkinson) are <2 d except for X696476 (3.0 d). However, this is a terminal metabolite so there will be little potential for long-range transport. Also, POP criteria only apply to active substances.	Not applicable

Fenpicoxamid

The vapour pressure at 20°C of fenpicoxamid is <10^{-5} Pa. Hence the active substance is regarded as non-volatile from both soil and plant surfaces. Therefore, assessment of exposure of adjacent surface waters and terrestrial ecosystems by fenpicoxamid due to volatilization and subsequent deposition is not required.

Prothioconazole

The vapour pressure at 20°C of prothioconazole is <10^{-5} Pa. Hence the active substance is regarded as non-volatile from both soil and plant surfaces. Therefore, assessment of exposure of adjacent surface waters and terrestrial ecosystems by prothioconazole due to volatilization and subsequent deposition is not required.

zRMS comments:

Provided above information is in line with EU agreed data reported in EFSA Journal 2018;16(1):5145 and EFSA Scientific Report (2007) 106 for fenpicoxamid and prothioconazole, respectively.

Taking into account the low vapour pressure (<10^{-5} Pa) and DT_{50} in air <2 days, fenpicoxamid and prothioconazole is not expected to be subject to volatilisation and the long- or short-range transport.

With regard to metabolite X696476 the following is stated in the EFSA report:

[...] X696476 is the terminal metabolite there will be little potential for the formation of aerosols and therefore long-range transport of this metabolite is not expected.

Taking this into account the contamination of the atmosphere with fenpicoxamid and prothioconazole and its metabolites from the intended uses of GF-3307 is considered to be negligible.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2.4/01	Chapple A Hoerold C	2018 (updated in 2022)	Prothioconazole (PTZ) and Metabolites: PECgw FOCUS PEARL, FOCUS PELMO EUR – Use in Winter Cereals in Europe. Bayer CropScience Report No. M-476501-01-1 (EnSa-13-0879). GLP/GEP (Y/N): N Published (Y/N): N	N	Bayer CropScience*
KCP 9.2.4/02	Chapple A Hoerold C	2018 (updated in 2022)	Prothioconazole (PTZ) and Metabolites: PECgw FOCUS PEARL, FOCUS PELMO EUR – Use in Spring Cereals in Europe. Bayer CropScience Report No. M-476508-01-1 (EnSa-13-1015). GLP/GEP (Y/N): N Published (Y/N): N	N	Bayer CropScience*
KCP 9.2.5/01	Reeves G	2018 (updated in 2022)	Modelling the Predicted Environmental Concentrations of DE-777 and Two Metabolites (X642188 and X12255349) in Surface Water and Sediment (FOCUS Steps 3 and 4) in the EU for Zonal Submission. Dow AgroSciences Report No. 151220 GLP/GEP (Y/N): N Published (Y/N): N	N	DAS
KCP 9.2.5/02	Reeves G	2018 (updated in 2022)	Modelling the Predicted Environmental Concentrations of Prothioconazole and One Metabolite (JAU 6476 Desthio) in Surface Water and Sediment (FOCUS Steps 3 and 4) in the EU for Zonal Submission. Dow AgroSciences Report No. 151148 GLP/GEP (Y/N): N Published (Y/N): N	N	DAS

*Letter of Access is provided in Part A for Bayer CropScience data

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

zRMS comments:

As all endpoints for fenpicoxamid and its relevant metabolites were taken from the EU review, for the list of respective studies please refer to Volume 2 of the RAR for fenpicoxamid. The below list was not validated by the zRMS.

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
KCA 7.1.1.1/01 KCA 7.1.2.1.1/01	Hastings MJ Jackson AU	2013	Degradation of 14C-XDE-777 in Four Soils Under Aerobic Conditions (Revision) Dow AgroSciences LLC Report No.: 110492 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCA 7.1.1.2/01 KCA 7.1.2.1.3	Liu D Balcer J Kish B	2013	Degradation of 14C-XDE-777 in One Soil Under Anaerobic Conditions Dow AgroSciences LLC Report No.: 120539 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCA 7.1.1.3/01	Cooke L	2013	XDE-777: Soil Photolysis Symbiotic Research, LLC Report No.: 130655 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCA 7.1.2.1.2/03	Austin R	2013	X12264475: Rate of Degradation under Aerobic Conditions in Four Soils at 20 °C Battelle UK Ltd Report No.: 121010 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCA 7.1.2.1.2/04	Seck C	2013	X763024: Rate of Degradation under Aerobic Conditions in Four Soils at 20 °C Battelle UK Ltd Report No.: 121012 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS

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
KCA 7.1.2.1.2/05	Oddy A	2013	X12313581: Rate of Degradation under Aerobic Conditions in Four Soils at 20 °C Battelle UK Ltd Report No.: 121011 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCA 7.1.2.1.2/06	Oddy A	2013	X696476: Rate of Degradation under Aerobic Conditions in Four Soils at 20 °C Battelle UK Ltd Report No.: 121009 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCA 7.1.2.1.2/07	Oddy A	2013	X11963422: Rate of Degradation under Aerobic Conditions in Four Soils at 20 °C Battelle UK Ltd Report No.: 121013 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCA 7.1.2.1.2/08	Ma M Li Q	2014	Degradation of X12255349, X12314005, X12019520, and X12442397 in Four Soils under Aerobic Conditions Dow AgroSciences LLC Report No.: 140543 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCA 7.1.2.1.2/09	Liu D Lynn KJ Adusumilli H	2014	Degradation of Multi-Component Region from the XDE-777 Anaerobic Soil Study and the Aerobic Aquatic Study in Two Soils under Aerobic Conditions Dow AgroSciences LLC Report No.: 141023 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCA 7.1.2.2.1/01 KCP 9.1.1.2.1/01	Fischer A	2015	Soil Dissipation Study With One Spring Application of GF-2925 (XDE-777) at Five Sites to Bare Soil in Europe in 2013-2015 DAS Report No.: 130672 Eurofins Agroscience Services GmbH GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCA 7.1.2.2.1/02 KCP 9.1.1.2.1/02	Reeves G	2015a	Field Soil Degradation Kinetics for XDE-777 and its Metabolites DAS Report No.: 150411 Dow AgroSciences GLP/GEP (Y/N): N Published (Y/N): N	N	DAS

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
KCA 7.1.2.2.1/03 KCP 9.1.1.2.1/03	Li Q Slinkard EW	2015	Frozen Storage Stability of XDE-777 and its Metabolites in Soil – 5 Month Interim Report DAS Report No.: 141045 Dow AgroSciences GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCA 7.1.3.1.1/01 KCA 7.1.3.1.2/01	Liu D Brackman R Zhou X	2013	Batch Equilibrium Adsorption/Desorption of XDE-777 and Adsorption of X642188 Dow AgroSciences LLC Report No.: 120540 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCA 7.1.2.1.3/02-07	ZhouX Liu D Brackman R Jonas N	2014	Batch Equilibrium Adsorption of the Aerobic Soil Metabolites of XDE-777 (Revision) Dow AgroSciences LLC Report No.: 121024 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCA 7.1.3.1.2/08	Zhou X	2014	Batch Equilibrium Adsorption of the Soil Photodegradates of XDE-777 Dow AgroSciences LLC Report No.: 140540 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCA 7.1.3.1.2/09	Blakeslee B	2017	Estimation of the Photochemical Oxidation Rates of XDE-777 metabolites X642188, X696872, X12264475, X763024, X12313581, X696476, X11963422, X12314005, X12019520, X12255349, X12335723, X12386481 and X12446477 DAS Report No. 170682 Dow AgroSciences LLC GLP/GEP (Y/N): Yes Published (Y/N): No	N	DAS
KCA 7.2.1.1/01	Yoder RN Jackson AU	2014	Hydrolysis of XDE-777 at pH 4, 7, and 9 (Revision) Dow AgroSciences LLC Report No.: 120538 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCA 7.2.1.1/02	Austin R	2013	Hydrolysis of X642188 at pH 4, 7 and 9 Battelle UK Ltd Report No.: 130663 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS

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
KCA 7.2.1.1/03	Cooke L	2013	Solubility Determination of XDE-777 in 1% Acetonitrile Co-solvent in Water Symbiotic Research, LLC Report No.: 130599 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCA 7.2.1.2/01	Blakeslee BA Jackson AU	2014	Aqueous Photolysis of XDE-777 in pH 7 Buffer under Xenon Light (Revision) Dow AgroSciences LLC Report No.: 110422 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCA 7.2.2.1/01	Tunink A	2012	XDE-777: Determination of Ready Biodegradability Using the CO_2 Evolution Method ABC Laboratories, Inc. Report No.: 120559 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCA 7.2.2.2/01	Adam D	2013	[^{14}C]-XDE-777 – Aerobic Mineralisation in Surface Water – Simulation Biodegradation Test Innovative Environmental Services (IES) Ltd Report No.: 130702 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCA 7.2.2.3/01	Adusumilli H Jackson AU	2014	Aerobic Aquatic Degradation of XDE-777 in Two Sediment and Pond Water Systems (Revision) Dow AgroSciences LLC Report No.: 120839 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
KCA 7.3.1/01	Zhou X	2013	Estimation of the Photochemical Oxidation Rate of XDE-777 Dow AgroSciences LLC Report No.: 131075 GLP/GEP (Y/N): N Published (Y/N): N	N	DAS
CP 9.1.1.1/1	Reeves G	2014a	Laboratory Soil Degradation Kinetics for XDE-777 and its Aerobic Metabolites for Model Input in the EU Derived From the Parent Applied Study DAS Report No.: 140267 Dow AgroSciences GLP/GEP (Y/N): N Published (Y/N): N	N	DAS

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
CP 9.1.1.1/2	Reeves G	2014b	Laboratory Soil Degradation Kinetics for XDE-777 Aerobic Metabolites for Model Input in the EU Derived From the Metabolite Applied Studies DAS Report No.: 140308 Dow AgroSciences GLP/GEP (Y/N): N Published (Y/N): N	N	DAS
CP 9.1.1.1/3	Reeves G	2014c	Laboratory Degradation Kinetics for XDE-777 Soil Photodegradates for Model Input in the EU Derived From the Metabolite Applied Studies DAS Report No.: 140626 Dow AgroSciences GLP/GEP (Y/N): N Published (Y/N): N	N	DAS
CP 9.1.1.2.1/1 Submitted under CA 7.1.2.2.1/1	Fischer A	2015	Soil Dissipation Study With One Spring Application of GF-2925 (XDE-777) at Five Sites to Bare Soil in Europe in 2013-2015 DAS Report No.: 130672 Eurofins Agroscience Services GmbH GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
CP 9.1.1.2.1/2 Submitted under CA 7.1.2.2.1/2	Reeves G	2015a	Field Soil Degradation Kinetics for XDE-777 and its Metabolites DAS Report No.: 150411 Dow AgroSciences GLP/GEP (Y/N): N Published (Y/N): N	N	DAS
CP 9.1.1.2.1/3 Submitted under CA 7.1.2.2.1/3	Li Q Slinkard EW	2015	Frozen Storage Stability of XDE-777 and its Metabolites in Soil – 5 Month Interim Report DAS Report No.: 141045 Dow AgroSciences GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS
CP 9.2.2/1	Reeves G	2014d	Laboratory Water/Sediment Degradation Kinetics for XDE-777 and its Metabolites for Model Input in the EU Derived From the Parent Applied Study DAS Report No.: 140309 Dow AgroSciences GLP/GEP (Y/N): N Published (Y/N): N	N	DAS

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
CP 9.2.4.1/1	Reeves G	2014e	Modelling the Leaching of XDE-777 and its Aerobic Soil Metabolites to Groundwater in the EU DAS Report No.: 140269 Dow AgroSciences GLP/GEP (Y/N): N Published (Y/N): N	N	DAS
CP 9.2.4.1/2	Reeves G	2014f	Modelling the Leaching of Three Soil Photodegradates of XDE-777 to Groundwater in the EU DAS Report No.: 141067 Dow AgroSciences GLP/GEP (Y/N): N Published (Y/N): N	N	DAS
CP 9.2.4.1/3	Reeves G	2015b	Modelling the Leaching of XDE-777 to Groundwater in the EU When Using a Field DT50 DAS Report No.: 150551 Dow AgroSciences GLP/GEP (Y/N): N Published (Y/N): N	N	DAS
CP 9.2.5/1	Reeves G	2015c	Modelling the Predicted Environmental Concentrations of XDE-777 and its Metabolites in Surface Water and Sediment in the EU Using a 10-12 m VBS DAS Report No.: 150623 Dow AgroSciences GLP/GEP (Y/N): N Published (Y/N): N	N	DAS
CP 9.2.5/2	Reeves G	2015d	Modelling the Predicted Environmental Concentrations of XDE-777 and its Metabolites in Surface Water and Sediment in the EU Using a Field DT50 DAS Report No.: 150552 Dow AgroSciences GLP/GEP (Y/N): N Published (Y/N): N	N	DAS

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 9.1.1.2.1/01 9.2.4 9.2.5	Hardy IAJ	2012	Kinetic modelling analysis of prothioconazole from field soil residue studies conducted in Europe normalised to 20ºC and pF2 Battelle UK Ltd., Ongar, Essex, United Kingdom Bayer CropScience, Report No.: VC/11/022F, Edition Number: M-429069-01-1 Date: 2012-04-11 GLP/GEP (Y/N): N Published (Y/N): N	N	Bayer CropScience*	New active substance data, not necessary for purposes of the evaluation, since EU agreed data were sufficuent
KCP 9.2/01 9.2.1 9.2.2 9.2.3	Schad T Zerbe P	2008	Dissipation of prothioconazole and JAU6476-desthio under field conditions in Europe Kinetic evaluation and calculation of non-referenced DT50 Bayer Crop Science, Report No.: M298575-01-1 GLP/GEP (Y/N): N Published (Y/N): N	N	Bayer CropScience*	

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

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

Appendix 2 Detailed evaluation of the new Annex II studies

Not applicable.

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

Detailed modelling data are contained within the PECgw and PECsw/sed reports referenced within this dRR section, and summary information relevant to the risk assessment is provided within the body of this dRR. For this reason, and due to the significant number of tables required to present the full modelling outputs, no further information is provided here in Appendix 3. Instead, the individual modelling reports can be consulted if needed.