REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: GF-3308

Product name(s): Not yet defined

Chemical active substance(s):

Fenpicoxamid (XDE-777), 50 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Corteva Agriscience

Submission date: May 2021

(updated in December 2021 and March 2022)

MS Finalisation date: April 2022 (initial Core Assessment)

October 2022 (final Core Assessment)

Version History

When	What
May 2021	New submission of GF-3308 in the Central Zone.
December 2021	Austria removed from cMS, GAP table updated with 1 use = 1 crop + 1 disease
March 2022	Efate and ecotox updates requested by PL authorities
April 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~~.
October 2022	Final report (Core Assessment updated following the commenting period). Additional information/assessments included by the zRMS in the report in response to comments recieved from the cMS and the Applicant are highlighted in yellow. Information no longer relevant ~~is struck through and shaded~~.

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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-3308, a formulation containing fenpicoxamid (50 g as/L).

8.1 Critical GAP and overall conclusions

Table 8.1-1: Critical use pattern of the formulated product GF-3308 concerning environmental fate

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No.*	Member state(s)	Crop and/or situation (crop destination /purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I**	Pests or goup of pests controlled (additionally: developmental stages of the pest or pest group)	**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)														
1-3, 7-9, 13	PL, AT, CZ, SK, RO	Winter cereals	F	Various diseases	Tractor mounted spray	BBCH 30-69 (spring appn.)	1	-	a) 2 b) 2	a) 100 b) 100	100-300	F		A
4-6, 10-12, 14		Spring cereals	F	Various diseases	Tractor mounted spray	BBCH 30-69 (spring appn.)	1	-	a) 2 b) 2	a) 100 b) 100	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

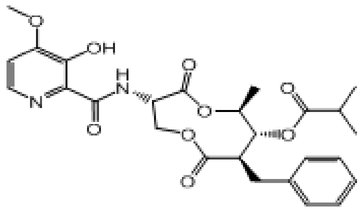
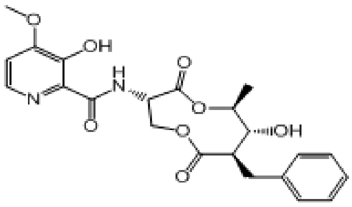
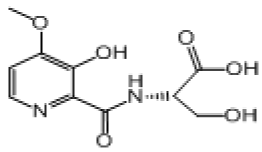
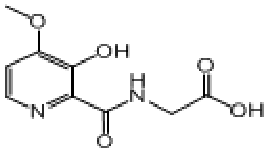
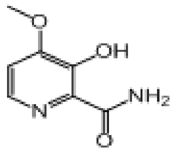
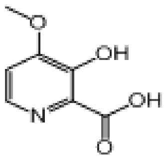
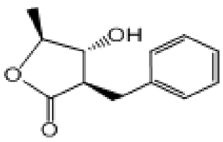
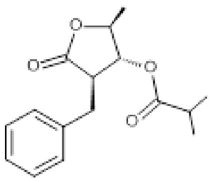
1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No.*	Member state(s)	Crop &/or situation	F, Fn, Fpn G, Gn, Gpn or I**	Pests or group of pests controlled	**Application**				**Application rate**			PHI (d)	Remarks
					Method/ kind	Timing/growth stage of crop & season	Max. number a) per use b) per crop/season	Min. 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.

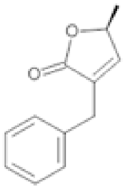
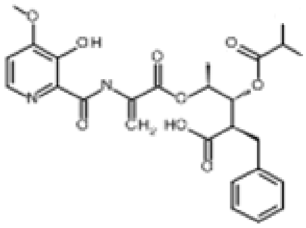
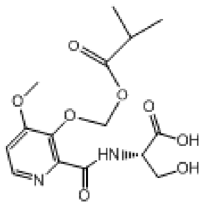
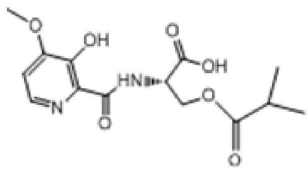
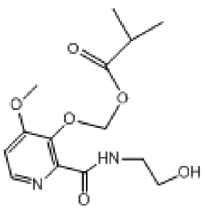
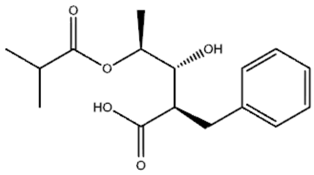
* **Representative uses assessed at EU level are more critical than the ones requested in the current application for GF-3308**

** 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 presented in Table 8.2-1 above is in line with EU agreed data reported in EFSA Journal 2018;16(1):5146.

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)

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) ~~Soil photolysis studies:~~

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

X12314005	~~Soil photolysis~~ 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 – ~~soil photolysis~~ laboratory studies (metabolite applied)

X12019520	~~Soil photolysis~~ 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 – – ~~soil photolysis~~ laboratory studies (metabolite applied)

X12255349	~~Soil photolysis~~ 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	2.6	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**	**Chi² (%)**	**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) ~~Soil photolysis studies:~~

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

X12314005	~~Soil photolysis~~ 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**	**Chi² (%)**	**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 – ~~soil photolysis~~ laboratory studies (metabolite applied)

X12019520	~~Soil photolysis~~ 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**	**Chi² (%)**	**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 – ~~soil photolysis~~ laboratory studies (metabolite applied)

X12255349	~~Soil photolysis~~ 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):5146 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 originate from soil photolysis studies and not studies performed in the dark. Respective information has been added by the zRMS for clarity.

During the commenting period the Applicant pointed out that although significant formation of metabolites X12314005, X12019520 and X12255349 was observed in the parent-dosed soil photolysis study, their degradation in soil was further investigated in the standard OECD 307 study performed in the dark. Information provided by the Applicant was checked in the revised DAR of December 2017 and is confirmed to be correct and it seems that some mistake was done in the EFSA conclusion. Taking this into account, information on the type of the study which the persistence and modelling endpoints were derived from was restored in Tables 8.3-9 to 8.3-11 and 8.3-23 to 8.3-25.
The zRMS would like to emphasize that discrepancies between information in the study reports, DAR and the LoEP should be addressed in the course of the EU review, since validation of information reported in EFSA conclusion is outside the scope of the zonal assessment.

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:

At the EU level 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.

8.4 Field studies (KCP 9.1.1.2)

Field studies (if triggered – see below) were performed either with the formulation relevant to this RR 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 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)**	**Chi² (%)**	**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)**	**Chi² (%)**	**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.

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 soil accumulation testing is not required for fenpicoxamid.

8.5 Mobility in soil (KCP 9.1.2)

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

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

<table>
<tr><th>X12255349</th><th colspan="7">Soil adsorption</th></tr>
<tr><th>Soil</th><th>Soil type (USDA)</th><th>pH ($CaCl_2$)</th><th>OC (%)</th><th>Kf</th><th>Kfoc</th><th>1/n</th><th>Evaluated at EU level</th></tr>
<tr><td>Brierlow</td><td>Silt loam</td><td>5.7</td><td>4.2</td><td>7.1</td><td>168</td><td>1.00</td><td rowspan="8">Yes (EFSA, 2018)</td></tr>
<tr><td>RefSol 03-G</td><td>Silt loam</td><td>6.0</td><td>3.8</td><td>6.9</td><td>182</td><td>0.97</td></tr>
<tr><td>Yolo</td><td>Clay loam</td><td>6.8</td><td>0.5</td><td>98.6</td><td>19725</td><td>1.07</td></tr>
<tr><td>Empingham</td><td>Loam</td><td>7.2</td><td>3.3</td><td>7.0</td><td>211</td><td>1.04</td></tr>
<tr><td>Hareby House</td><td>Clay loam</td><td>7.3</td><td>5.6</td><td>32.6</td><td>581</td><td>1.21</td></tr>
<tr><td colspan="5">Geometric mean (n=5)</td><td>594</td><td></td></tr>
<tr><td colspan="5">Arithmetic mean (n=5)</td><td></td><td>1.06</td></tr>
<tr><td colspan="5">pH dependence</td><td colspan="2">No</td></tr>
</table>

zRMS comments:

Soil mobility data for fenpicoxamid and its metabolites presented on Table 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.

8.5.1 Column leaching (KCP 9.1.2.1)

Column leaching studies have not been carried out.

zRMS comments:

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

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 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.

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 RR.

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 RR.

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) 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.

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 the formulation: GF-3308.

8.7.1 Justification for new endpoints

EFSA endpoints (2018) 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}) = ln2/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}) = ln2/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.	1-14	
Crop	Winter cereals, spring cereals	
Application rate (g as/ha)	100 (Fenpicoxamid)	
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)	
Min. application interval (d)	14	
Frequency of application	Annual	
Depth of soil (cm)	5 (no tillage)	

* Risk envelope GAP of 2 x 100 g as/ha from BBCH 30 is protective of 1 x 100 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	200	614.2	-	14.7 (field, non-normalised)	Yes *(EFSA, 2018)*
X642188	65.9	514.2	39.2% (lab)	67.2 (field, non-normalised)	
X696872	24.8	444.2	17.2% (lab)	18.9 (lab, parent applied)	
X12264475	41.5	256.1	49.4% (lab)	98.1 (field, non-normalised)	
X763024	4.2	226.1	5.7% (lab)	20.8 (lab, metabolite applied)	
X12313581	9.2	168.0	17.1% (field)	92.2 (field, non-normalised)	
X696476	26.3	169.0	46.9% (lab)	5260 (field, non-normalised)	
X11963422	54.6	206.1	80.3% (lab)	5.0 (lab, metabolite applied)	
X12314005	4.9	276.3	5.4% (lab)	0.1 (lab, metabolite applied)	
X12019520	6.1	188.2	9.8% (lab)	6.3 (lab, metabolite applied)	
X12255349	11.6	514.5	6.9% (lab)	4.4 (lab, metabolite applied)	

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 100 g as/ha from BBCH 30 specific to the use of GF-3308 in this RR.

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 100 g as/ha from BBCH 30 with 80% interception (soil loading 20 ~~10~~ 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 8.7-3: PECsoil for fenpicoxamid on cereals*

PECsoil (mg/kg)		Use no. 1-14	
		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 100 g as/ha from BBCH 30

Table 8.7-4: PECsoil for X642188 and X696872 on cereals*

PECsoil (mg/kg)		Use no. 1-14			
		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 100 g as/ha from BBCH 30

Table 8.7-5: PECsoil for X12264475 and X763024 on cereals*

PECsoil (mg/kg)		Use no. 1-14			
		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 100 g as/ha from BBCH 30

Table 8.7-6: PECsoil for X12313581 and X696476 on cereals*

PECsoil (mg/kg)		Use no. 1-14			
		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 100 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).

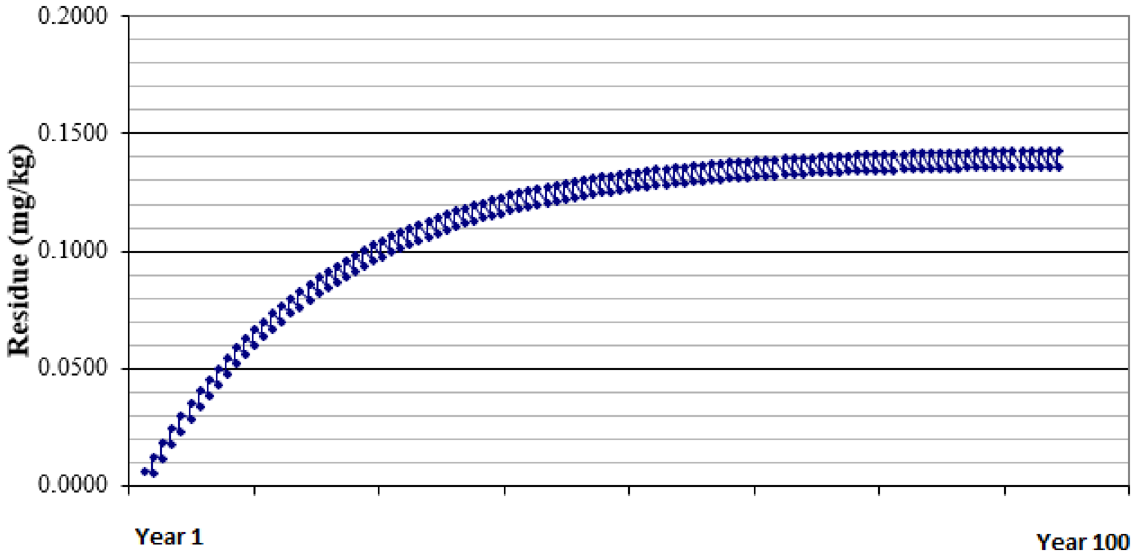


Table 8.7-7: PECsoil for X11963422 and X12314005 on cereals*

PECsoil (mg/kg)		Use no. 1-14			
		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 100 g as/ha from BBCH 30

Table 8.7-8: PECsoil for X12019520 and X12255349 on cereals*

PECsoil (mg/kg)		**Use no. 1-14**			
		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 100 g as/ha from BBCH 30

zRMS comments:

Use pattern

Although multiple applications of GF-3308 are not intended in the Central Zone, they were considered by the Applicant for the soil exposure calculations. 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 earlies BBCH stage of cereals at which GF-3308 will be applied) represents worst case comparing to the effective rate of 20 g a.s./ha, relevant for the intended use pattern of GF-3308. Taking this into account, use pattern assumed by the Applicant is agreed as representing worst case and covering the Central Zone uses of GF-3308.

Input parameters

All input parameters given in Table 8.7-2 above are fully in line with endpoints reported in EFSA Journal 2018;16(1):5146.

The soil exposure for fenpicoxamid and its metabolites has been independently validated by the zRMS using ESCAPE ver. 2. Metabolites were simulated as parent with consideration of the pseudo application rates calculated from the parent rate corrected for molar ratio and maximum occurrence. Obtained results were in good agreement with PEC_{SOIL} values reported in Tables 8.7-3 to 8.7-8 above.

GF-3308

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. Consequently, only an initial formulation PECsoil for a single application was calculated since time-aged values (actual and TWA) are not appropriate. Therefore, the PECsoil was calculated based upon the effective annual soil loading of 406.4 g FP/ha (assuming a formulation density of 1.016 g/mL) from the 2 L FP/ha risk envelope rate (single application only).

Table 8.7-9: PECsoil for GF-3308 on cereals

Formulation	Use no. 1-14			
	Appn. rate (L FP/ha)	**Appn. rate (g FP/ha)**	**Effective appn. rate (g FP/ha)***	**PECsoil (mg/kg)**
GF-3308	2	2032	406.4	0.5419

* Assuming 80% interception

zRMS comments:

PEC_{soil} value for the formulated product GF-3308 presented in Table 8.7-9 above is agreed by the zRMS, and may be used in the risk assessment for soil organisms.

It is noted that it was also calculated for multiple applications at 2.0 L/ha and is thus protective for single application at 2.0 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.

8.8.1 Justification for new endpoints

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

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

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 100 g as/ha from BBCH 30 (80% interception) specific to the use of GF-3308 in this RR.

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-3308 GAP since application (from BBCH 30) at the maximum of 100 g as/ha with 80% interception gives an effective annual soil loading of 20 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.	**1-14**
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 100 g as/ha from BBCH 30

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

FOCUS scenario*	**Use no. 1-14**
	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
** Scenarios 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	
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)	Yes *(EFSA, 2018)*
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	

* Divided 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	

* Divided by 1.724 for Kfom

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

Use no. 1-3, 7-9, 13								
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 100 g as/ha from BBCH 30

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

Use no. 4-6, 10-12, 14								
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 100 g as/ha from BBCH 30

Soil photodegradates

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

Run 1

XDE-777 → X642188 → $\boxed{\text{X12314005} \rightarrow \text{X12019520}}$

Run 2

XDE-777 → X642188 → $\boxed{\text{X12255349}}$

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	

* Divided 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*

Use no. 1-3, 7-9, 13			
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 100 g as/ha from BBCH 30

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

Use no. 4-6, 10-12, 14			
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 100 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-3308. Instead, result of groundwater modelling performed during the EU review of fenpicoxamid were used as being protective for the intended uses of GF-3308 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 single application at 100 g a.s./ha (rate reaching soil: 20 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-3308 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 EU modelling performed, no unacceptable leaching of fenpicoxamid and its metabolites is expected following application of GF-3308 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.

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 values were calculated for the formulation: GF-3308.

8.9.1 Justification for new endpoints

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

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

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 100 g as/ha from BBCH 30 specific to the use of GF-3308 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 single rate of 1 x 100 g 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) (20°C/pF2) (geometric mean)	DT_{50} water, sediment, whole system (d) (20°C) (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. 1-14~~		
			~~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~~

UPDATE – February 2022

The previous Steps 1 and 2 modelling used "full canopy" (70% interception) as deemed relevant for BBCH 30 (e.g. 80% interception is considered for BBCH 30 in the groundwater modelling). However, the zRMS (Poland) requested Steps 1 and 2 be repeated using "intermediate" crop cover, with clarity given to the 1 x 100 g as/ha rate rather than relying upon a risk envelope approach. This updated modelling is described below. **It is not reported separately since the work can be fully described and presented directly in the RR.** The inputs related to application were the same as those shown in Table 8.9-1.

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 the groundwater modelling uses 80%.

Table 8.9-2: Steps 1 and 2 PECsw/sed for fenpicoxamid and metabolites on cereals (1x100 g a.s./ha, BBCH 30-69)

Compound	FOCUS scenario		Use no. 1-52		
			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	0.05	16.14
X642188	Step 1		2.48	0.44	105.37
	Step 2	N Europe	0.30	0.05	13.17
X696872	Step 1		2.19	2.17	14.71
	Step 2	N Europe	0.32	0.32	2.15
X12264475	Step 1		11.48	9.87	35.42
	Step 2	N Europe	1.40	1.20	4.30
X763024	Step 1		0.46	0.46	1.79
	Step 2	N Europe	0.07	0.07	0.26
X12313581	Step 1		1.30	1.28	8.59
	Step 2	N Europe	0.18	0.17	1.16
X696476	Step 1		0.98	0.83	73.43
	Step 2	N Europe	0.17	0.09	8.99
X11963422	Step 1		12.71	12.61	10.91
	Step 2	N Europe	1.64	1.62	1.40
X12314005	Step 1		5.39	0.32	6.19
	Step 2	N Europe	0.33	0.02	0.39
X12019520	Step 1		2.39	2.34	1.60
	Step 2	N Europe	0.19	0.09	0.12
X12255349	Step 1		1.08	1.07	6.39
	Step 2	N Europe	0.08	0.08	0.45
X12335723	Step 1		9.10	1.62	0.09
	Step 2	N Europe	0.73	0.13	0.01
X12386481	Step 1		12.62	12.53	0.13
	Step 2	N Europe	1.23	1.22	0.01
X12446477	Step 1		2.17	2.16	0.02
	Step 2	N Europe	0.21	0.21	<0.01
X12433979	Step 1		5.85	5.80	0.06
	Step 2	N Europe	0.57	0.56	0.01

Steps 3 and 4

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

UPDATE – February 2022

The previous Steps 3 and 4 modelling used a single application date of 1 April for all scenarios. However, the zRMS (Poland) requested Steps 3 and 4 be repeated using application 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 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 in the RR**, with reference to report 8.9.2/01 if needed. The work used the latest versions of the various FOCUS surface water tools.

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

Use no.	**1-52**
Crop	Winter cereals, spring cereals
Application rate (g as/ha)	100 (Fenpicoxamid)
Max. number of applications	1
Frequency of application	Annual
Application window	Date given by AppDate 3.06 (June, 2019) corresponding to 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 8.9-4: Application dates used for PECsw/sed

FOCUS SW scenario	Appn. date (absolute) (BBCH 30)	
	Use no. 1-13, 21-33, 41-49	Use no. 14-20,34-40, 50-52
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 input parameters were used.

Table 8.9-5: 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	
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)	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	
Crop wash-off factor (1/m)	50	50	
Half-life on crop canopy (d)	10	10	
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 40 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 60% and 85% were applied, and for a 20 m VFS the reduction factors used were 80% and 95%. These were taken from the FOCUS Landscape and Mitigation workgroup (2007).

FOCUS Step 3 (1 x 100 g as/ha)

Table 8.9-6: Step 3 PECsw/sed for fenpicoxamid on winter cereals

FOCUS scenario	Use no. 1-3, 7-9, 13 ~~1-13, 21-33, 41-49~~			
	Max. PECsw (µg/L)	Dominant entry route	Max. 21 d TWA PECsw (µg/L)	Max. PECsed (µg/kg)
D3 ditch	0.6228	Drift	0.04349	0.3209
D4 pond	0.02118	Drift	0.01649	0.05195
D4 stream	0.46	Drift	0.001245	0.01346
D5 pond	0.02119	Drift	0.01673	0.03658
D5 stream	0.4969	Drift	0.001322	0.01417
R1 pond	0.02119	Drift	0.01659	0.03478
R1 stream	0.4098	Drift	0.005474	0.1037
R3 stream	0.5763	Drift	0.01134	0.1724
R4 stream	0.4116	Drift	0.006112	0.06055

Table 8.9-7: Step 3 PECsw/sed for X642188 on winter cereals

FOCUS scenario	Use no. 1-3, 7-9, 13 ~~1-13, 21-33, 41-49~~			
	Max. PECsw (µg/L)	Dominant entry route*	Max. 21 d TWA PECsw (µg/L)	Max. PECsed (µg/kg)
D3 ditch	0.001252	Drainflow	0.000813	0.1987
D4 pond	0.002685	Drainflow	0.002649	0.06951
D4 stream	0.000541	Drainflow	0.000024	0.005501
D5 pond	0.002279	Drainflow	0.002262	0.06056
D5 stream	0.00021	Drift	0.000002	0.006333
R1 pond	0.006535	Run-off	0.005492	0.0555
R1 stream	0.03716	Run-off	0.003988	0.273
R3 stream	0.04689	Run-off	0.003718	0.4117
R4 stream	0.08179	Run-off	0.006853	0.4101

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

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

FOCUS scenario	Use no. 4-6, 10-12, 14 ~~14-20, 34-40, 50-52~~			
	Max. PECsw (µg/L)	Dominant entry route	Max. 21 d TWA PECsw (µg/L)	Max. PECsed (µg/kg)
D3 ditch	0.6235	Drift	0.04857	0.2777
D4 pond	0.0212	Drift	0.01678	0.02363
D4 stream	0.5093	Drift	0.003277	0.03385
D5 pond	0.0212	Drift	0.01684	0.03682
D5 stream	0.5232	Drift	0.002069	0.02189
R4 stream	0.4116	Drift	0.008374	1.008

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

FOCUS scenario	Use no. 4-6, 10-12, 14 ~~14-20, 34-40, 50-52~~			
	Max. PECsw (µg/L)	Dominant entry route*	Max. 21 d TWA PECsw (µg/L)	Max. PECsed (µg/kg)
D3 ditch	0.001711	Drainflow	0.000805	0.2369
D4 pond	0.001836	Drainflow	0.001814	0.04592
D4 stream	0.000642	Drainflow	0.00003	0.01648
D5 pond	0.002128	Drainflow	0.002115	0.0612
D5 stream	0.000221	Drift	0.000003	0.009843
R4 stream	0.05631	Run-off	0.01049	1.033

* 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 (1 x 100 g as/ha)

Table 8.9-10: Step 4 PECsw for fenpicoxamid on winter cereals

FOCUS scenario	Use no. 1-3, 7-9, 13 ~~1-13, 21-33, 41-49~~							
	Max. PECsw (µg/L)							
NSZ	40 m	30 m	30 m	10 m	10 m	10 m	5 m	20 m
DRN	None	None	None	50%	75%	90%	90%	90%
VFS	10 m	None	10 m	10 m	10 m	10 m	10 m	20 m
D3 ditch	0.02358	0.03116	0.03116	0.0443	0.02207	0.008781	0.01662	0.004542
D4 pond	0.005388	0.006651	0.006651	0.00654	0.003253	0.001291	0.001802	0.000859
D4 stream	0.02349	0.03103	0.03103	0.04413	0.02199	0.008746	0.01656	0.004524
D5 pond	0.005389	0.006652	0.006652	0.006541	0.003254	0.001292	0.001802	0.000859
D5 stream	0.02538	0.03353	0.03353	0.04767	0.02376	0.00945	0.01789	0.004889
R1 pond	0.005389	0.006652	0.006652	0.006541	0.003254	0.001292	0.001802	0.000859
R1 stream	0.02092	0.02764	0.02764	0.03931	0.01958	0.007789	0.01475	0.004029
R3 stream	0.02944	0.0389	0.0389	0.05531	0.02756	0.01097	0.02075	0.005674
R4 stream	0.02101	0.02776	0.02776	0.03948	0.01967	0.007823	0.01481	0.004047

Table 8.9-11: Step 4 PECsw for X642188 on winter cereals

FOCUS scenario	Use no. 1-3, 7-9, 13 ~~1-13, 21-33, 41-49~~							
	Max. PECsw (µg/L)							
NSZ	40 m	30 m	30 m	10 m	10 m	10 m	5 m	20 m
DRN	None	None	None	50%	75%	90%	90%	90%
VFS	10 m	None	10 m	10 m	10 m	10 m	10 m	20 m
D3 ditch	0.00004	0.000054	0.000054	0.000078	0.000037	0.000014	0.000028	0.000007
D4 pond	0.000656	0.000815	0.000815	0.000801	0.00039	0.00015	0.000212	0.000099
D4 stream	0.000541	0.000541	0.000541	0.000541	0.000541	0.000541	0.000541	0.000541
D5 pond	0.000551	0.000685	0.000685	0.000673	0.000326	0.000125	0.000177	0.000082
D5 stream	0.000105	0.000105	0.000105	0.000105	0.000105	0.000105	0.000105	0.000105
R1 pond	0.002381	0.005405	0.002478	0.002469	0.002218	0.002071	0.002109	0.001051
R1 stream	0.01687	0.03716	0.01687	0.01687	0.01687	0.01687	0.01687	0.008833
R3 stream	0.0214	0.04689	0.0214	0.0214	0.0214	0.0214	0.0214	0.01122
R4 stream	0.03719	0.08179	0.03719	0.03719	0.03719	0.03719	0.03719	0.01949

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

FOCUS scenario	Use no. 4-6, 10-12, 14 ~~14-20, 34-40, 50-52~~							
	Max. PECsw (µg/L)							
NSZ	40 m	30 m	30 m	10 m	10 m	10 m	5 m	20 m
DRN	None	None	None	50%	75%	90%	90%	90%
VFS	10 m	None	10 m	10 m	10 m	10 m	10 m	20 m
D3 ditch	0.02361	0.0312	0.0312	0.04434	0.0221	0.00879	0.01664	0.004547
D4 pond	0.005391	0.006655	0.006655	0.006544	0.003255	0.001292	0.001803	0.000859
D4 stream	0.02602	0.03437	0.03437	0.04887	0.02435	0.009688	0.01834	0.005012
D5 pond	0.00539	0.006654	0.006654	0.006543	0.003255	0.001292	0.001802	0.000859
D5 stream	0.02672	0.03531	0.03531	0.0502	0.02502	0.009953	0.01884	0.005149
R4 stream	0.02101	0.03593	0.02776	0.03948	0.01967	0.01627	0.01627	0.008493

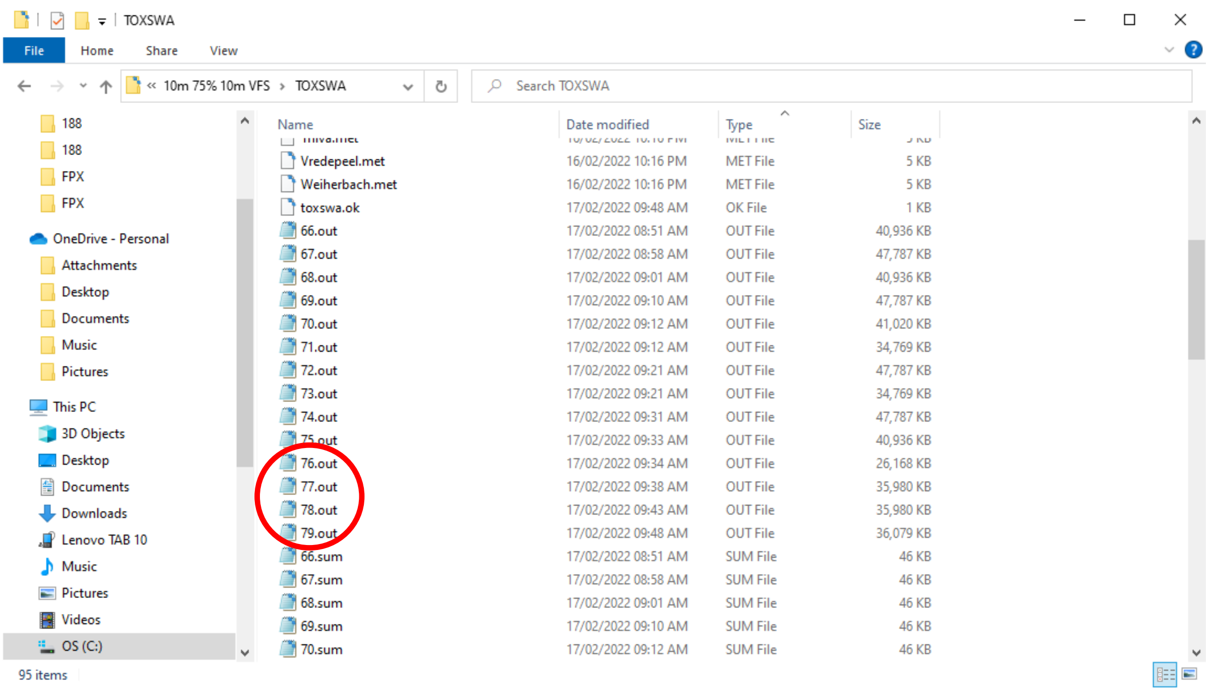
Table 8.9-13: Step 4 PECsw for X642188 on spring cereals

FOCUS scenario	Use no. 4-6, 10-12, 14 ~~14-20, 34-40, 50-52~~							
	Max. PECsw (µg/L)							
NSZ	**40 m**	**30 m**	**30 m**	**10 m**	**10 m**	**10 m**	**5 m**	**20 m**
DRN	**None**	**None**	**None**	**50%**	**75%**	**90%**	**90%**	**90%**
VFS	**10 m**	**None**	**10 m**	**10 m**	**10 m**	**10 m**	**10 m**	**20 m**
D3 ditch	0.000054	0.000072	0.000072	0.000105	0.000050	0.000019	0.000037	0.000009
D4 pond	0.000440	0.000549	0.000549	0.000539	0.000260	0.000099	0.000140	0.000072
D4 stream	0.000642	0.000642	0.000642	0.000642	0.000642	0.000642	0.000642	0.000642
D5 pond	0.000513	0.000638	0.000638	0.000627	0.000303	0.000116	0.000164	0.000076
D5 stream	0.000119	0.000119	0.000119	0.000119	0.000119	0.000119	0.000119	0.000119
R4 stream	0.02546	0.05631	0.02546	0.02546	0.02546	0.02546	0.02546	0.01329

Further Assessment

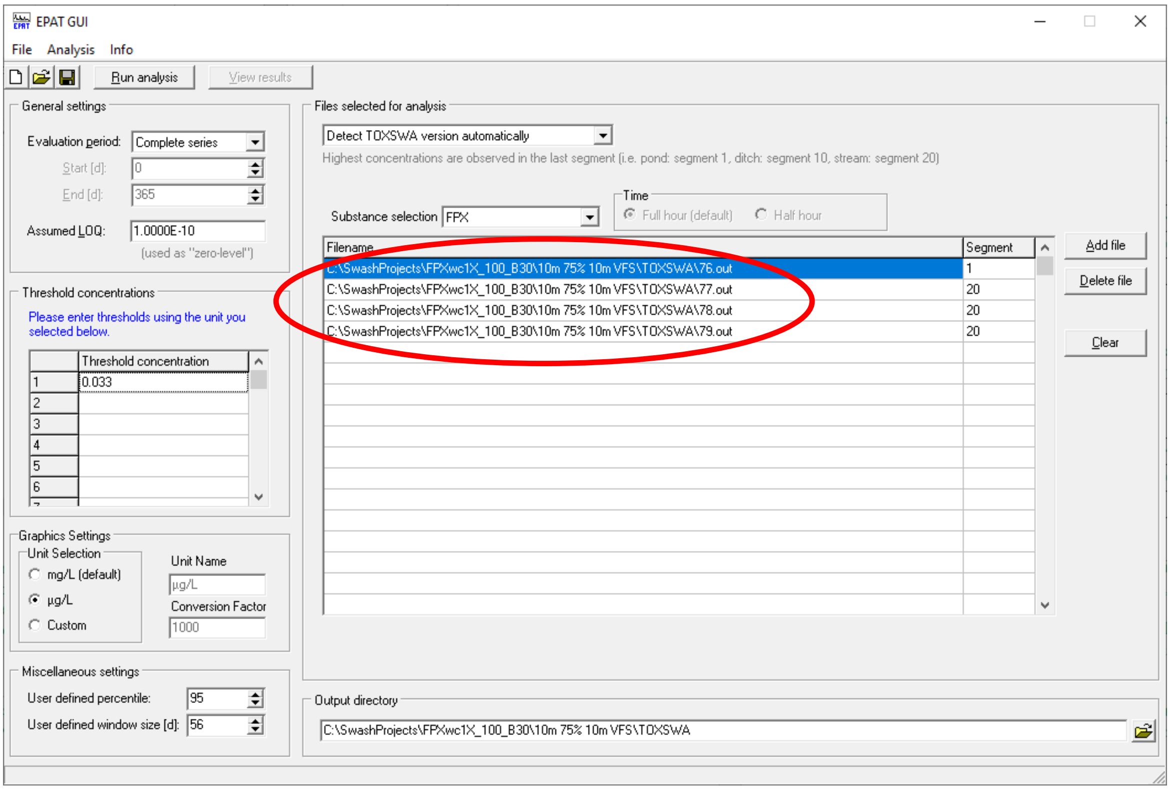
The Step 4 surface water exposure assessment for fenpicoxamid and X642188 described above was further investigated following a “summed” residue approach (fenpicoxamid PECsw plus X642188 PECsw as parent equivalent), where the assumed “summed” RAC is 0.033 µg/L. **It is not reported separately since the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

To facilitate this the SwashProject which produced the Step 4 data shown in Tables 8.9-10 to 8.9-13 were located. The data required for the analysis is contained within the relevant TOXSWA folder in the “.OUT” file (example screen shot below for runs 76-79 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 and 75% DRN with a 10 m VFS, or 5 m NSZ and 90% DRN with a 10 m VFS (example screen shot below for fenpicoxamid and runs 76-79 which correspond in this analysis to R1 pond, R1 stream, R3 stream and R4 stream).



The hourly PECsw values for both fenpicoxamid and X642188 were then copied from the EPAT text file (part extract screen shot example for fenpicoxamid and run 77 (R1 stream) below) into a spreadsheet and the PECsw values for each residue aligned according to hour and day.

77_seg20.con - Notepad
File Edit Format View Help

```
#                              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_100_B30\10m 75% 10m VFS\TOXSWA\77.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
```

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 8.9-25 to 8.9-28 for a 10 m NSZ with 75% DRN and a 10 m VFS or 5 m NSZ and 90% DRN with a 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 the 10 m NSZ, 75% DRN, 10 m VFS analysis (run 77). 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 (10 m NSZ, 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:\SwashProjects\FPXwc1X_100_B30\10m 75% 10m VFS\TOXSWA\77.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*	*0.01958*
# Date/Time	**days**	**Conc**	**Par eq Conc**	**Conc**	X188 MW	514.2		*Max PECsw*	*0.01687*
01-Mar-1984-00h00	0	0	0	0					
01-Mar-1984-01h00	0.042	0	0	0	Max PECsw	**0.02177**	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_100_B30\10m 75% 10m VFS\TOXSWA\77.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 8.9-14: 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	1-13, 21-33, 41-49	0.00335	0.02177	0.02810	0.04655
Spring cereals	14-20, 34-40, 50-52	-*	-*	-*	0.03876

* Scenario not relevant for spring cereals

Table 8.9-15: 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	1-13, 21-33, 41-49	0.00282	0.02177	0.02810	0.04655
Spring cereals	14-20, 34-40, 50-52	-*	-*	-*	0.03876

* 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 RR.

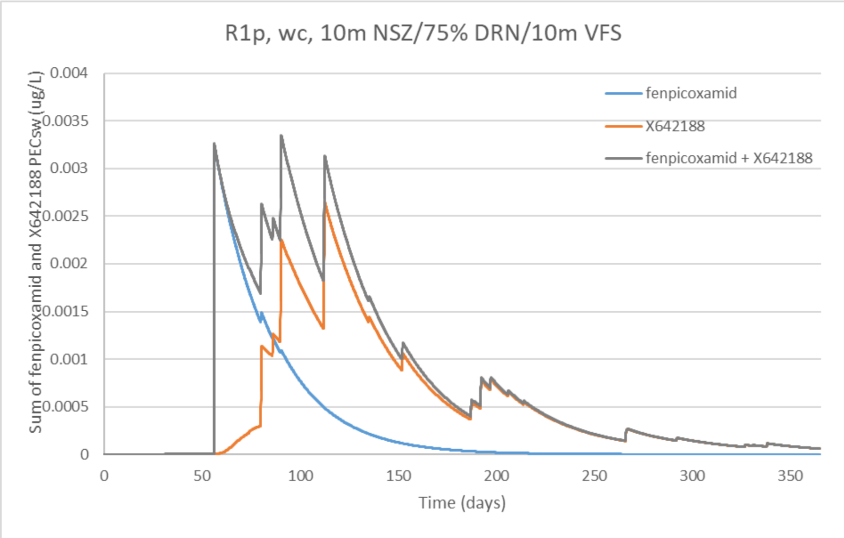
Whilst the “summed” R4 stream scenario PECsw values exceeds the assumed RAC for both winter and spring cereals, this is of no consequence since R4 is only applicable to HU in the Central Zone, and this MS is not supported in the GAP table.

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.

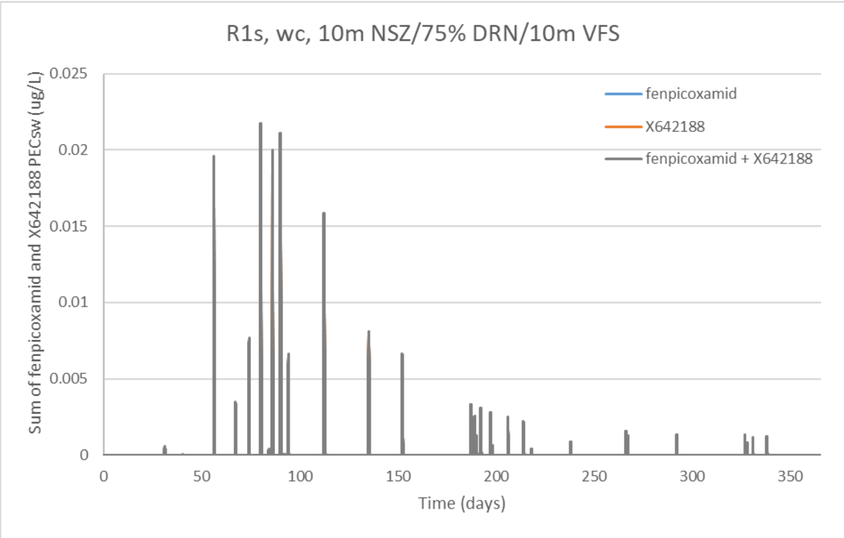
To illustrate the process and derivation of the “summed” PECsw values further, graphs were generated of the fenpicoxamid (blue line) and X642188 (parent equivalent; orange line) concentrations and the “summed” total (grey line) against time (days), and examples for R1 pond and stream are presented as 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 (10 m NSZ, 75% DRN, 10 m VFS)

R1 pond



R1 stream



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

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

~~Use no.~~	~~1-14~~
~~Crop~~	~~Winter cereals, spring cereals~~
~~Application rate (g as/ha)~~	~~100 (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 8.9-4: Application window used for Steps 3 and 4 PECsw/sed**~~

~~FOCUS scenario*~~	~~Use no. 1-14~~
	~~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	-

~~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 8.9-5: 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 100 g as/ha)~~

~~**Table 8.9-6: Step 3 PECsw/sed for fenpicoxamid on winter cereals**~~

~~FOCUS scenario~~	~~Use no. 1-3, 7-9, 13~~			
	~~Max. PECsw (µg/L)~~	~~Dominant entry route~~	~~Max. 21 d TWA PECsw (µg/L)~~	~~Max. PECsed (µg/kg)~~
~~D3 ditch~~	~~0.6223~~	~~Drift~~	~~0.0266~~	~~0.3017~~
~~D4 pond~~	~~0.02118~~	~~Drift~~	~~0.01492~~	~~0.04932~~
~~D4 stream~~	~~0.4753~~	~~Drift~~	~~0.001054~~	~~0.01694~~
~~D5 pond~~	~~0.02118~~	~~Drift~~	~~0.01504~~	~~0.03657~~
~~D5 stream~~	~~0.4968~~	~~Drift~~	~~0.000881~~	~~0.01417~~
~~R1 pond~~	~~0.02118~~	~~Drift~~	~~0.0148~~	~~0.03476~~
~~R1 stream~~	~~0.4098~~	~~Drift~~	~~0.003733~~	~~0.1037~~
~~R3 stream~~	~~0.5797~~	~~Drift~~	~~0.009917~~	~~0.3195~~

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

~~FOCUS scenario~~	~~Use no. 4-6, 10-12, 14~~			
	~~Max. PECsw (µg/L)~~	~~Dominant entry route~~	~~Max. 21 d TWA PECsw (µg/L)~~	~~Max. PECsed (µg/kg)~~
~~D3 ditch~~	~~0.6224~~	~~Drift~~	~~0.02717~~	~~0.3064~~
~~D4 pond~~	~~0.02118~~	~~Drift~~	~~0.0149~~	~~0.0493~~
~~D4 stream~~	~~0.4751~~	~~Drift~~	~~0.001051~~	~~0.01689~~
~~D5 pond~~	~~0.02118~~	~~Drift~~	~~0.01501~~	~~0.03654~~
~~D5 stream~~	~~0.4946~~	~~Drift~~	~~0.000853~~	~~0.01371~~

~~**Table 8.9-8: Step 3 PECsw/sed for X642188 on winter cereals**~~

~~FOCUS scenario~~	~~Use no. 1-3, 7-9, 13~~			
	~~Max. PECsw (µg/L)~~	~~Dominant entry route*~~	~~Max. 21 d TWA PECsw (µg/L)~~	~~Max. PECsed (µg/kg)~~
~~D3 ditch~~	~~0.001027~~	~~Drainflow~~	~~0.000507~~	~~0.1827~~
~~D4 pond~~	~~0.002282~~	~~Drainflow~~	~~0.002243~~	~~0.06541~~
~~D4 stream~~	~~0.000533~~	~~Drainflow~~	~~0.000016~~	~~0.007063~~
~~D5 pond~~	~~0.002278~~	~~Drainflow~~	~~0.002239~~	~~0.06054~~
~~D5 stream~~	~~0.00021~~	~~Drainflow~~	~~0.000001~~	~~0.006333~~
~~R1 pond~~	~~0.006517~~	~~Run-off~~	~~0.005041~~	~~0.05545~~
~~R1 stream~~	~~0.03703~~	~~Run-off~~	~~0.002985~~	~~0.2729~~
~~R3 stream~~	~~0.04042~~	~~Run-off~~	~~0.003297~~	~~0.4512~~

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

~~**Table 8.9-9: Step 3 PECsw/sed for X642188 on spring cereals**~~

~~FOCUS scenario~~	~~Use no. 4-6, 10-12, 14~~			
	~~Max. PECsw (µg/L)~~	~~Dominant entry route*~~	~~Max. 21 d TWA PECsw (µg/L)~~	~~Max. PECsed (µg/kg)~~
~~D3 ditch~~	~~0.001072~~	~~Drainflow~~	~~0.000529~~	~~0.1865~~
~~D4 pond~~	~~0.002252~~	~~Drainflow~~	~~0.002213~~	~~0.06536~~
~~D4 stream~~	~~0.000628~~	~~Drainflow~~	~~0.00002~~	~~0.007042~~
~~D5 pond~~	~~0.002233~~	~~Drainflow~~	~~0.002194~~	~~0.06042~~
~~D5 stream~~	~~0.000209~~	~~Drainflow~~	~~0.000001~~	~~0.006129~~

~~* 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 100 g as/ha)**~~

~~**Table 8.9-10: Step 4 PECsw for fenpicoxamid on winter cereals**~~

~~FOCUS scenario~~	~~Use no. 1-3, 7-9, 13~~							
	~~Max. PECsw (µg/L)~~							
~~NSZ~~	~~40 m~~	~~30 m~~	~~30 m~~	~~10 m~~	~~10 m~~	~~5 m~~	~~10 m~~	~~20 m~~
~~DRN~~	~~None~~	~~None~~	~~None~~	~~50%~~	~~75%~~	~~90%~~	~~90%~~	~~90%~~
~~VFS~~	~~10 m~~	~~None~~	~~10 m~~	~~10 m~~	~~10 m~~	~~10 m~~	~~10 m~~	~~20 m~~
~~D3 ditch~~	~~0.02357~~	~~0.03126~~	~~0.03126~~	~~0.04442~~	~~0.02197~~	~~0.01653~~	~~0.008866~~	~~0.004411~~
~~D4 pond~~	~~0.005368~~	~~0.006624~~	~~0.006624~~	~~0.006528~~	~~0.003247~~	~~0.001806~~	~~0.001327~~	~~0.000849~~
~~D4 stream~~	~~0.02434~~	~~0.03204~~	~~0.03204~~	~~0.04554~~	~~0.02269~~	~~0.01719~~	~~0.00897~~	~~0.004599~~
~~D5 pond~~	~~0.005368~~	~~0.006624~~	~~0.006624~~	~~0.006528~~	~~0.003247~~	~~0.001806~~	~~0.001327~~	~~0.000849~~
~~D5 stream~~	~~0.02545~~	~~0.0335~~	~~0.0335~~	~~0.04761~~	~~0.02372~~	~~0.01798~~	~~0.009378~~	~~0.004809~~
~~R1 pond~~	~~0.005368~~	~~0.006624~~	~~0.006624~~	~~0.006528~~	~~0.003247~~	~~0.001806~~	~~0.001327~~	~~0.000849~~
~~R1 stream~~	~~0.02098~~	~~0.02786~~	~~0.02786~~	~~0.03926~~	~~0.01956~~	~~0.01482~~	~~0.00773~~	~~0.003963~~
~~R3 stream~~	~~0.0297~~	~~0.03943~~	~~0.03943~~	~~0.05557~~	~~0.02769~~	~~0.02098~~	~~0.01095~~	~~0.005614~~

~~**Table 8.9-11: Step 4 PECsw for fenpicoxamid on spring cereals**~~

FOCUS scenario	Use no. 4-6, 10-12, 14							
	Max. PECsw (µg/L)							
NSZ	40 m	30 m	30 m	10 m	10 m	5 m	10 m	20 m
DRN	None	None	None	50%	75%	90%	90%	90%
VFS	10 m	None	10 m	10 m	10 m	10 m	10 m	20 m
D3 ditch	0.02358	0.03127	0.03127	0.04443	0.02197	0.01653	0.008868	0.004412
D4 pond	0.005368	0.006624	0.006624	0.006528	0.003247	0.001806	0.001327	0.000849
D4 stream	0.02433	0.03203	0.03203	0.04552	0.02268	0.01719	0.008966	0.004597
D5 pond	0.005368	0.006624	0.006624	0.006528	0.003247	0.001806	0.001327	0.000849
D5 stream	0.02533	0.03335	0.03335	0.0474	0.02361	0.01789	0.009336	0.004787

~~**Table 8.9-12: Step 4 PECsw for X642188 on winter cereals**~~

FOCUS scenario	Use no. 1-3, 7-9, 13							
	Max. PECsw (µg/L)							
NSZ	40 m	30 m	30 m	10 m	10 m	5 m	10 m	20 m
DRN	None	None	None	50%	75%	90%	90%	90%
VFS	10 m	None	10 m	10 m	10 m	10 m	10 m	20 m
D3 ditch	0.000033	0.000044	0.000044	0.000064	0.000031	0.000023	0.000012	0.000006
D4 pond	0.00055	0.000684	0.000684	0.000674	0.000327	0.000178	0.000129	0.000081
D4 stream	0.000533	0.000533	0.000533	0.000533	0.000533	0.000516	0.000533	0.000533
D5 pond	0.000548	0.000682	0.000682	0.000672	0.000325	0.000177	0.000129	0.000081
D5 stream	0.000129	0.000129	0.000129	0.000129	0.000129	0.000129	0.000129	0.000129
R1 pond	0.002373	0.005386	0.002469	0.002462	0.002211	0.002103	0.002067	0.001047
R1 stream	0.01681	0.03703	0.01681	0.01681	0.01681	0.01682	0.01681	0.008802
R3 stream	0.01844	0.04042	0.01844	0.01844	0.01844	0.01846	0.01844	0.009672

~~**Table 8.9-13: Step 4 PECsw for X642188 on spring cereals**~~

FOCUS scenario	Use no. 4-6, 10-12, 14							
	Max. PECsw (µg/L)							
NSZ	40 m	30 m	30 m	10 m	10 m	5 m	10 m	20 m
DRN	None	None	None	50%	75%	90%	90%	90%
VFS	10 m	None	10 m	10 m	10 m	10 m	10 m	20 m
D3 ditch	0.000034	0.000046	0.000046	0.000067	0.000032	0.000024	0.000012	0.000006
D4 pond	0.000543	0.000675	0.000675	0.000665	0.000322	0.000175	0.000127	0.00008
D4 stream	0.000628	0.000628	0.000628	0.000628	0.000628	0.000627	0.000628	0.000628
D5 pond	0.000538	0.000669	0.000669	0.000659	0.000319	0.000174	0.000126	0.000079
D5 stream	0.000119	0.000119	0.000119	0.000119	0.000119	0.000119	0.000119	0.000119

~~**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; R4 for spring cereals is not relevant for the Central Zone) 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. Note that no new FOCUS surface water modelling was conducted. The procedure is described as follows.~~

~~Firstly, EPAT v1.2.0 was used to generate “seg20.con” text files separately for fenpicoxamid and X642188, focussing on Step 4 with two levels of mitigation, i.e. 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 100 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 8.9-14: 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 100 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 100 g as/ha~~	~~0.0033~~	~~0.0217~~	~~0.0277~~

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

~~Table 8.9-15: 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 100 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 100 g as/ha~~	~~0.0028~~	~~0.0217~~	~~0.0273~~

~~* 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 available, but a small excerpt is shown below from the R1 stream at 1 x 100 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.~~

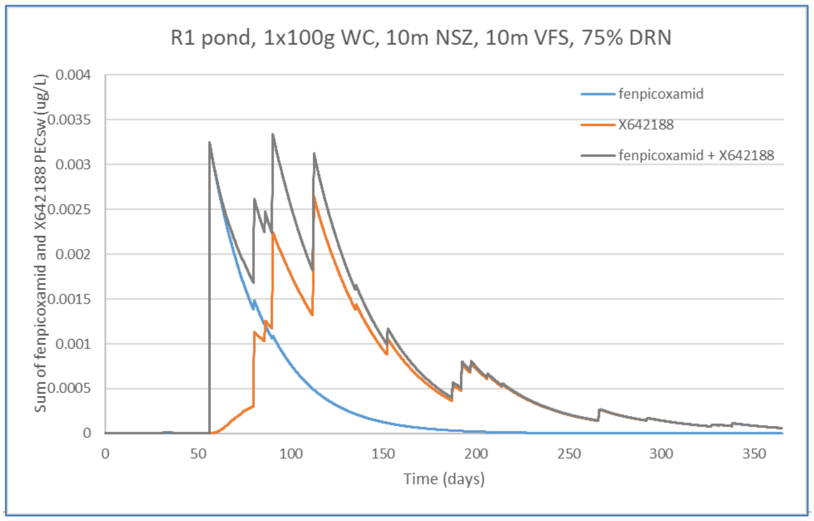
~~Excerpt from R1 stream at 1 x 100 g as/ha extraction example (10 m NSZ, 75% DRN and 10 m VFS)~~

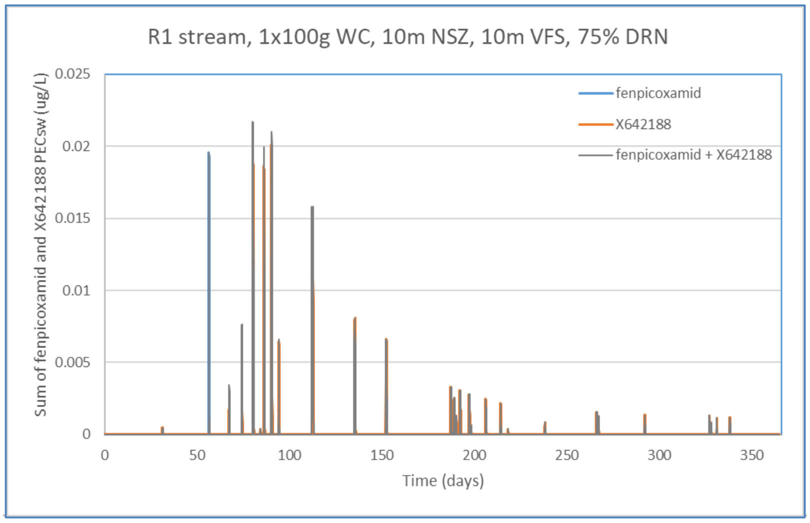
# EPAT CONCENTRATION FILE							
# --							
# EPAT - Exposure Pattern Analysis Tool							
# Version 1.2.0							
# --							
# Sponsored by: Developed by:							
# ECPA RIFCON GmbH							
# European Crop Protection Association							
# 6 Av E. Van Nieuwenhuyse Goldbeckstr. 13							
# 1160 Brussels 691493 Hirschberg							
# Belgium Germany							
# --							
# Analysed source file: C:\SwashProjects\R_10m 75% 10m VBS\TOXSWA\1279.out							
# Selected evaluation period: Complete							
# Selected segment of the water body: 20							
# Selected substance: lt777							
# Selected time: FULL							
# Selected unit: µg/L							
# Selected conversion factor: 1000							
#	**time**	**777**	**X188**	**Sum**	777 MW	614.2	
Date/Time	**days**	**Conc.**	**Par eq Conc.**	**Conc.**	X188 MW	514.2	
01-Mar-1980-00h00	0	0	0	0			
01-Mar-1984-01h00	0.042	0	0	0	Max PECsw	**0.0217**	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			

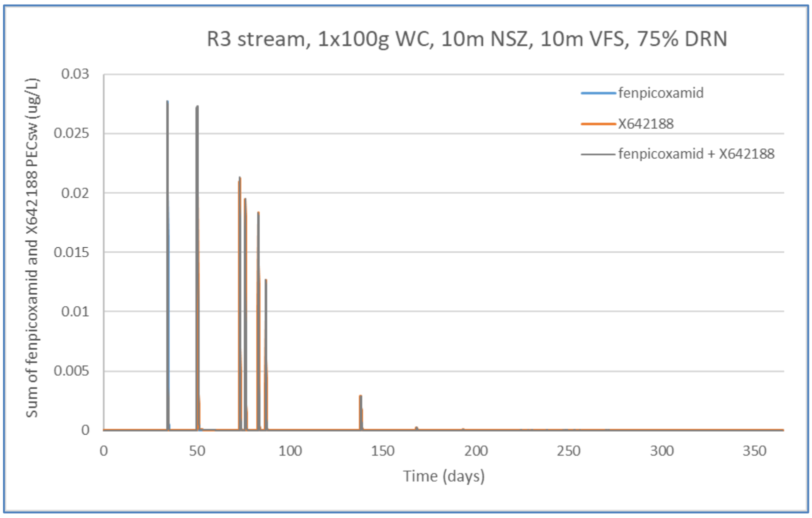
# EPAT CONCENTRATION FILE		
# --		
# EPAT - Exposure Pattern Analysis Tool		
# Version 1.2.0		
# --		
# Sponsored by: Developed by:		
# ECPA RIFCON GmbH		
# European Crop Protection Association		
# 6 Av E. Van Nieuwenhuyse Goldbeckstr. 13		
# 1160 Brussels 691493 Hirschberg		
# Belgium Germany		
# --		
# Analysed source file: C:\SwashProjects\R_10m 75% 10m VBS\TOXSWA\1279.out		
# Selected evaluation period: Complete		
# Selected segment of the water body: 20		
# Selected substance: t188		
# 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 100 g as/ha, winter cereals example (10 m NSZ, 75% DRN and 10 m VFS)**~~







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-3308 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 are the maximum $PEC_{SW/SED}$ derived for single and multiple use or they are 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-3308) "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 8.9-2 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.

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 (1x100 g a.s./ha in winter and spring cereals).
As in case of the groundwater modelling, single date for start of the application window (1st 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-3308 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 1st April - 1st 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 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. 0.509 vs. 0.475 µg/L in D4 and 0.523 vs. 0.495 µg/L in D5). 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 is 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[1].

[1] Working Document of the Central Zone in the Authorisation of Plant Protection Products - Part B section 8 - Environmental fate and behaviour, Version 1 rev. 1, June 2018

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-3308 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.

Taking all this into account, the surface water modelling presented above was not agreed by the zRMS and results reported in tables above were struck through and 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.

Respective modelling based on the assumptions requested by the zRMS has been provided by the Applicant and is presented in Tables 8.9-6 to 8.9-13 with uses numbers corrected by the zRMS in order to reflect the GAP table available in the Core Assessment, Part B, Section 0. Obtained Step 3 & 4 results together with the EPAT analysis were independently validated by the zRMS and are confirmed to be correct. The initial calculations are struck through above as being not relevant for the intended use pattern.

During the commenting period it was pointed out that 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. It was suggested that a simplified approach may be taken with calculation of PEC_{SED} by multiplication of initial PEC_{SED} by 20. On request of the zRMS additional calculation of the accumulated PEC_{SED} for these compounds was performed at Step 3-4 using the EU agreed endpoints and the application pattern according to the GAP presented in Table 8.1-1 (1x100 g a.s./ha in winter and spring cereals). Submitted calculations were independently validated by the zRMS and the same results were obtained. In table below, results of Step 3-4 simulations are given, while below this table PEC_{SED} multiplied by 20 are provided. Since both metabolites are formed exclusively in the sediment, exposure via water column is not reported below.

Step 3 and 4 maximum PEC_{SED} for metabolite X12313581 and X696476 on winter and spring cereals (1 x 100 g as/ha, BBCH 30)

FOCUS scenario	Use no. 1-3, 7-9, 13 (winter cereals) Max. PEC_{SED} (µg/kg)			
	Step 3		Step 4 (10m VFS + 75% DRN)	
	X12313581	X696476	X12313581	X696476
D3 ditch	0.0294	0.0711	-	-
D4 pond	0.1275	0.0518	-	-
D4 stream	0.0365	0.0016	-	-
D5 pond	0.1192	0.0619	-	-
D5 stream	0.0208	0.0021	-	-
R1 pond	0.1021	0.1792	0.063	0.112
R1 stream	0.1234	1.77	0.032	0.275
R3 stream	0.164	4.691	0.047	0.714
R4 stream	0.1338	6.066	0.049	0.925
	Use no. 4-6, 10-12, 14 (spring cereals) Max. PEC_{SED} (µg/kg)			
D3 ditch	0.0441	0.0971	-	-
D4 pond	0.1453	0.0575	-	-
D4 stream	0.0383	0.006	-	-
D5 pond	0.1152	0.0617	-	-
D5 stream	0.0196	0.0033	-	-
R4 stream	0.4413	9.25	0.0918	1.403

Step 1-2 maximum PEC_{SED} for metabolite X12313581 and X696476 multiplied by 20

Metabolite	X12313581	X696476
FOCUS Scenario	Max. PEC_{SED} (µg/kg)	Max. PEC_{SED} (µg/kg)
Step 1	171.80	1468.60
Step 2 - N-Europe	23.20	179.80

Step 3 and 4 maximum PEC$_{SED}$ for metabolite X12313581 and X696476 multiplied by 20

FOCUS scenario	Use no. 1-3, 7-9, 13 (winter cereals) Max. PEC$_{SED}$ (µg/kg)			
	Step 3		Step 4 (10m VFS + 75% DRN)	
	X12313581	X696476	X12313581	X696476
D3 ditch	0.59	1.42	-	-
D4 pond	2.55	1.04	-	-
D4 stream	0.73	0.03	-	-
D5 pond	2.38	1.24	-	-
D5 stream	0.42	0.04	-	-
R1 pond	2.04	3.58	1.26	2.24
R1 stream	2.47	35.40	0.64	5.50
R3 stream	3.28	93.82	0.94	14.28
R4 stream	2.68	121.32	0.98	18.50
	Use no. 1-3, 7-9, 13 (spring cereals) Max. PEC$_{SED}$ (µg/kg)			
D3 ditch	0.88	1.94	-	-
D4 pond	2.91	1.15	-	-
D4 stream	0.77	0.12	-	-
D5 pond	2.30	1.23	-	-
D5 stream	0.39	0.07	-	-
R4 stream	8.83	185.0	1.84	28.06

Provided above sediment exposure to metabolites X12313581 and X696476 may be used in the risk assessment for sediment dwelling organisms.

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-3308

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) are 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 2 L FP/ha is equivalent to 2032 g FP/ha assuming a formulation density of 1.016 g/mL.

Table 8.9-3: PECsw for GF-3308 on winter and spring cereals at 2 L FP/ha

FOCUS water body	Use no. 1-14							
	PECsw (µg FP/L)							
	Default FOCUS distance ~~Step 3~~	Risk mitigation measures ~~Step 4 NSZ~~						
		40 m	30 m	10 m			5 m	20 m
		Std. nozzle	Std. nozzle	50% DRN	75% DRN	90% DRN	90% DRN	90% DRN
Ditch	13.0549	0.5010	0.6611	0.9384	0.4692	0.1877	0.3539	0.0975
Pond	0.4451	0.1142	0.1408	0.1385	0.0692	0.0277	0.0385	0.0185
Stream	9.6883	0.5010	0.6611	0.9384	0.4692	0.1877	0.3539	0.0975

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 Table 8.9-16.

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**
Direct photolysis in air	Not applicable
Quantum yield of direct phototransformation	Not applicable
Photochemical oxidative degradation in air	DT_{50}: 0.261 d (Atkinson)
Vapour pressure	1.2 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.

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.

zRMS comments:

Provided above information is in line with EU agreed data reported in EFSA Journal 2018;16(1):5146.

Taking into account the low vapour pressure (<10^{-5} Pa) and DT_{50} in air <2 days, fenpicoxamid 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.

Overall, based on the EU agreed data, the contamination of the atmosphere with fenpicoxamid and its metabolites from the intended uses of GF-3308 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 9.2.5/01	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/Corteva Agriscience

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/Corteva Agriscience
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/Corteva Agriscience

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 7.1.1.3/01	Cooke L	2013	XDE-777: Soil Photolysis Symbiotic Research, LLC Report No.: 130655 GLP/GEP (Y/N): Y Published (Y/N): N	N	DAS/Corteva Agriscience
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/Corteva Agriscience
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/Corteva Agriscience
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/Corteva Agriscience
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/Corteva Agriscience
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/Corteva Agriscience
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/Corteva Agriscience

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 7.1.2.1.2/09	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/Corteva Agriscience
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/Corteva Agriscience
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/Corteva Agriscience
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/Corteva Agriscience
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/Corteva Agriscience
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/Corteva Agriscience
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/Corteva Agriscience

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 7.1.3.1.2/09	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/Corteva Agriscience
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/Corteva Agriscience
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/Corteva Agriscience
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/Corteva Agriscience
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/Corteva Agriscience
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/Corteva Agriscience
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/Corteva Agriscience

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 7.2.2.3/01	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/Corteva Agriscience
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/Corteva Agriscience
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/Corteva Agriscience
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/Corteva Agriscience
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/Corteva Agriscience
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/Corteva Agriscience

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 9.1.1.2.1/2 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/Corteva Agriscience
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/Corteva Agriscience
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/Corteva Agriscience
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/Corteva Agriscience
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/Corteva Agriscience
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/Corteva Agriscience
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/Corteva Agriscience

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 9.2.5/2	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/Corteva Agriscience

List of data submitted by the applicant and not relied on

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

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
There were no data 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 RR section, and summary information relevant to the risk assessment is provided within the body of this RR. 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.