

REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: GF-4021

Product name: LaDiva

Chemical active substances:

Halauxifen-methyl, 10 g as/L (9.6 g ae/L)

Picloram, 48 g as/L

Aminopyralid, 32 g as/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Dow AgroSciences

Submission date: November 2020

MS Finalisation date: August 2022 (initial Core Assessment)

November 2022 (final Core Assessment)

Version History

When	What
November 2020	New submission of GF-4021 in the Central Zone.
August 2022	<p>Initial zRMS assessment</p> <p>The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency.</p>
November 2022	<p>Final report (Core Assessment updated following the commenting period).</p> <p>Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Information no longer relevant is struck through and shaded.</p>

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8 Fate and behaviour in the environment (KCP 9)

This document presents the environmental fate summary and exposure calculations for the plant protection product GF-4021, a formulation containing halauxifen-methyl (10 g as/L; 9.6 g ae/L), picloram (48 g as/L) and aminopyralid (32 g as/L).

8.1 Critical GAP and overall conclusions

Table 8.1-1: Critical use pattern of the formulated product GF-4021 concerning environmental fate

Table 011-1: Critical use pattern of the formulated product of Ioff concerning environmental rate														
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop &/or situation	F, Fn, Fpn G, Gn, Gpn or I**	Pests or group of pests controlled	Application				Application rate			PHI (d)	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 product/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			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	Czech Republic Germany Hungary Poland Romania, Slovakia, Slovenia, UK	Winter oilseed rape	F	Broadleaf weeds (post-em)	Broadcast foliar spray	BBCH 12-19	1	-	0.25	2.5 (HAL-ME) 12 (PIC) 8 (AMN)	100-300	-	90% of crop has to be at BBCH 12	R Biennial or triennial application, depending on scenario

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

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

Explanation for column 15 “Conclusion”

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

Table 8.1-2: Assessed (critical) uses during approval of halauxifen-methyl (HAL-ME) 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 product/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	Broadleaf weeds	Broadcast foliar spray	BBCH 9-29 BBCH 13-45	2	70	-	7.82 + 6.25 (HAL-ME)	-	-	Autumn (BBCH 9-29) or spring (BBCH 13-45) appn., or both where a 70 d min. interval applies
-	EU	Spring cereals	F	Broadleaf weeds	Broadcast foliar spray	BBCH 13-45	1	-	-	6.25 (HAL-ME)	-	-	Spring only

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

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

Table 8.1-3: Assessed (critical) uses during approval of picloram (PIC) 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 product/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		
1	EU	Winter oilseed rape	F	Broadleaf weeds	Broadcast foliar spray	BBCH 14-31	1 (every 3 years)	-	-	23.45 (PIC)	100-400	-	
-	EU	Spring oilseed rape	F	Broadleaf weeds	Broadcast foliar spray	BBCH 14-31	1 (every 3 years)	-	-	23.45 (PIC)	100-400	-	

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

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

Table 8.1-4: Assessed (critical) uses during approval of aminopyralid (AMN) 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 product/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	Established grassland & rotational pasture	F	Broadleaf weeds	Broadcast foliar spray	Spring/summer	1	-	-	60 (AMN)	200-400	7	
-	EU	Amenity grassland	F	Broadleaf weeds	Broadcast foliar spray	Spring/summer	1	-	-	60 (AMN)	200-600	7	

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

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

8.2 Metabolites considered in the assessment

Table 8.2-1: Major (>5% AR) metabolites of halauxifen-methyl required for exposure assessment

Metabolite	Molar mass (g/mol)	Chemical structure	Maximum occurrence (% AR) in compartment	Exposure assessment required
Halauxifen acid (XDE-729 acid or X11393729)	331		Aerobic soil: 72.7% * Hydrolysis: 13% (pH7), 99% (pH9) Aq. photolysis: 10.7% Water/sediment: water phase 20.0% total system 23.5%	PECsoil PECgw PECsw PECsed
X-757 (X11449757)	317		Aerobic soil: 17.4% ** Water/sediment: water phase 48.3% sediment phase 50.6% total system 76.7%	PECsoil PECgw PECsw PECsed
X-790 (X11406790)	331		Water/sediment: water phase 16.5% sediment phase 10.6% total system 33.4%	PECsw PECsed
Deg 10	326		Aq. photolysis: 12.6%	PECsw
Deg 11	273		Aq. photolysis: 15.7%	PECsw
Deg 14	229		Aq. photolysis: 11.5%	PECsw

* Max. field study molar formation equivalent to 40.1% of applied

** Max. field study molar formation equivalent to 13.8% of applied

Table 8.2-2: Major (>5% AR) metabolites of picloram required for exposure assessment

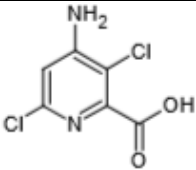
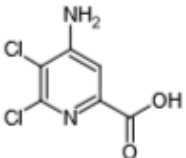
Metabolite	Molar mass (g/mol)	Chemical structure	Maximum occurrence (% AR) in compartment	Exposure assessment required
3,6-dichloro analogue of picloram	207		Water/sediment: water phase 9.0% sediment phase: 5.2% 9.2% total system 11.0%	PEC _{sw} PEC _{sed}
5,6-dichloro analogue of picloram	207		Water/sediment: water phase 1.1% sediment phase: 19.0% 22.1% total system 22.1%	PEC _{sw} PEC _{sed}

Table 8.2-3: Major (>5% AR) metabolites of aminopyralid required for exposure assessment

There are no metabolites of aminopyralid >5% AR.

zRMS comments:

Information regarding metabolites of halauxifen-methyl, picloram and aminopyralid is in general in line with EU agreed endpoints reported in EFSA Journal 2014;12(12):3913, EFSA Journal 2009;7(12):1390, and EFSA Journal 2013;11(9):3352, respectively. Peak occurrence of 3,6-dichloro and 5,6-dichloro analogues of picloram in sediment has been corrected by the zRMS.

8.3 Rate of degradation in soil (KCP 9.1.1)

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

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

Halauxifen-methyl

The rate of degradation of halauxifen-methyl and its metabolites in soil was evaluated for active substance approval. No additional studies have been performed. The aerobic soil degradation data are summarised in the following tables. However, note that field data were relied upon by EFSA for exposure assessment and so no endpoints are highlighted here.

Table 8.3-1: Summary of aerobic degradation data for halauxifen-methyl - lab studies

Soil name	Soil type (USDA)	pH (CaCl ₂)	T (°C)/ MWHC (%)	Persistence				Modelling (20°C/pF2)			Evaluated at EU level
				DT ₅₀ (d)	DT ₉₀ (d)	Chi ² (%)	Kinetic model	DT ₅₀ (d)	Chi ² (%)	Kinetic model	
Yolo	Clay loam	7.1	20/50	1.8	16.3	3.3	FOMC	2.0	18.3	SFO	Yes (EFSA, 2014)
RefSol 03-G	Loam	5.0	20/50	1.1	3.7	8.4	SFO	1.1	8.4	SFO	
Site E	Silt loam	5.9	20/50	1.1	6.1	4.4	FOMC	1.2	10.9 ^D	SFO	
Site I2	Sandy loam	7.5	20/50	0.9	3.8	7.0	SFO	0.9	9.3	SFO	
Geomean(n=4)								1.3*			
Worst case (n=4)				1.8*	16.3*						
pH-dependency				No							

* Not relied upon for exposure assessment (field data used)

^D In EFSA Journal 2014:12(12):3913 Chi² of 110.9% is reported, which is a typing error since Chi² of 10.9 is given in the DAR (see Table B.8.117 in Vol. 3, B.8 of December 2013 and Vol. 3, B.8, Post EU commenting of August 2014)

Table 8.3-2: Summary of aerobic degradation data for halauxifen acid - lab studies

Soil name	Soil type (USDA)	pH (CaCl ₂)	T (°C)/ MWHC (%)	Persistence				Modelling (20°C/pF2)			Evaluated at EU level
				DT ₅₀ (d)	DT ₉₀ (d)	Chi ² (%)	Kinetic model	DT ₅₀ (d)	Chi ² (%)	Kinetic model	
Yolo	Clay loam	7.1	20/50	35.9	119	6.0	SFO-TD	28.7	16.4	SFO	Yes (EFSA, 2014)
RefSol 03-G	Loam	5.0	20/50	2.7	9.0	20.1	SFO-TD	1.6	14.4	SFO	
Site E	Silt loam	5.9	20/50	7.6	25.4	13.1	SFO-TD	4.7	14.4	SFO	
Site I2	Sandy loam	7.5	20/50	13.6	45.2	11.3	SFO-TD	11.7	14.7	SFO	
Geomean (n=4)								7.5*			
Worst case (n=4)				35.9*	119*						
pH-dependency				Yes, increasing DT ₅₀ with increasing pH. Not considered in modelling.							

* Not relied upon for exposure assessment (field data used)

Table 8.3-3: Summary of aerobic degradation data for X-757 - lab studies

Table 6.5-3: Summary of aerobic degradation data for A-757-1a5 studies											
Soil name	Soil type (USDA)	pH (CaCl ₂)	T (°C)/ MWHC (%)	Persistence				Modelling (20°C/pF2)			Evaluated at EU level
				DT ₅₀ (d)	DT ₉₀ (d)	Chi ² (%)	Kinetic model	DT ₅₀ (d)	Chi ² (%)	Kinetic model	
Yolo	Clay loam	7.1	20/50	76.7	255	5.2	SFO-TD	76.7	5.2	SFO-TD	Yes (EFSA, 2014)
RefSol 03-G	Loam	5.0	20/50	20.4	68.4	17.0	SFO-TD	20.4	17.0	SFO-TD	
Site E	Silt loam	5.9	20/50	31.8	106	13.8	SFO-TD	31.8	13.8	SFO-TD	
Site I2	Sandy loam	7.5	20/50	47.7	158	12.3	SFO-TD	47.7	12.3	SFO-TD	
Geomean (n=4)								41.3*			
Worst case (n=4)				76.7*	255*						
pH-dependency				No							

* Not relied upon for exposure assessment (field data used)

zRMS comments:

Soil degradation data for halauxifen-methyl and its metabolites are **in general** in line with EU agreed endpoints reported in EFSA Journal 2014;12(12):3913 **with some minor corrections**.

Picloram

The rate of degradation of picloram in soil was evaluated for active substance approval and in the confirmatory data (2017). No additional studies have been performed. The aerobic soil degradation data are summarised in the following table. However, note that lab data were used for the groundwater assessment at Tier 1.

Table 8.3-4: Summary of aerobic soil degradation data for picloram – lab studies

Soil type (USDA)	pH (water)	T (°C)/ MWHC (%)	Persistence				Modelling (20°C/pF2)			Evaluated at EU level
			DT ₅₀ (d)	DT ₉₀ (d)	R ² (%)	Kinetic model	DT ₅₀ (d)	R ² (%)	Kinetic model	
Sandy clay loam	7.7	20/40	82.8	274.9	0.950	SFO	82.8	0.950	SFO	Yes (EFSA, 2009 & 2017)
Clay loam	6.3	20/40	100.7	334.4	0.899	SFO	96.4	0.899	SFO	
Sand	6.1	20/40	220.6	732.7	0.897	SFO	193.2	0.897	SFO	
Silty loam	8.0	20/40	295.6	982.1	0.855	SFO	292.2	0.855	SFO	
Sandy loam	5.4*	20/75% 1/3 bar	24.5	81.6	0.986	SFO	21.7	0.986	SFO	
Clay loam	6.0*	25/75% 1/3 bar	19.3	64.1	0.993	SFO	26.5	0.993	SFO	
Clay	7.6*	25/75% 1/3 bar	18.3	60.7	0.984	SFO	22.0	0.984	SFO	
Silty clay	6.3*	25/75% 1/3 bar	5.0	16.7	0.970	SFO	5.2	0.970	SFO	
Sandy loam	5.2	20/40	252.6 (slow) 22.0 (fast)	NC	0.999	HS	234**	0.999 (slow) 0.983 (fast)	HS	
Median (n=9)							82.8			
Worst case (n=9)			295.6	982.1						
pH-dependency			Not stated							

* Media for pH measurement not reported

** From slow phase

zRMS comments:

Soil degradation data for picloram are in line with EU agreed endpoints reported in EFSA Journal 2009;7(12):1390. Additional information regarding fast phase degradation in one of the sandy loam soils was added by the zRMS for completeness.

Aminopyralid

The rate of degradation of aminopyralid in soil was evaluated for active substance approval. No additional studies have been performed. The aerobic soil degradation data are summarised in the following tables. However, note that field data were relied upon by EFSA for exposure assessment and so no endpoints are highlighted here.

Table 8.3-5: Summary of aerobic degradation rates for aminopyralid – lab studies

Soil name	Soil type (USDA)	pH (CaCl ₂)	T (°C)/ MWHC (%)	Persistence				Modelling (20°C/pF2)			Evaluated at EU level
				DT ₅₀ (d)	DT ₉₀ (d)	Chi ² (%)	Kinetic model	DT ₅₀ (d)	Chi ² (%)	Kinetic model	
Thessaloniki	Loam	7.7	20/40	26.2	86.9	10.8	SFO	26.2	10.8	SFO	Yes (EFSA, 2013)
Cuckney	Sand	5.6	20/40	144.7	480.8	1.3	SFO	144.7	1.3	SFO	
Charentilly	Loam	5.8	20/40	28.4	94.4	7.2	SFO	28.0 28.4	7.2	SFO	
Parabraun erde	Silt loam	7.7	20/40	84.9	282.0	1.1	SFO	84.9	1.1	SFO	
Geomean (n=4)								54.8 * 54.4*			
Worst case (n=4)				144.7*	480.8*						
pH-dependency				No							

* Not relied upon for exposure assessment (field data used)

zRMS comments:

Soil degradation data for aminopyralid are in general in line with EU agreed endpoints reported in EFSA Journal 2013;11(9):3352 with some minor corrections introduced by the zRMS for Charentilly soil and the geomean.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Studies on rate of anaerobic degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. However, the data are not required for risk assessment and no further information is provided here.

zRMS comments:

Studies on anaerobic degradation of halauxifen-methyl, picloram and aminopyralid were evaluated in the course of the EU review. According to information available in ESA reports, picloram and aminopyralid were stable under anaerobic conditions, while halauxifen-methyl was rapidly degraded with DT₅₀ ranging from 0.9 to 2.8 d forming halauxifen acid and X11449757, which degradation was slower comparing to aerobic conditions. Nevertheless, for purposes of the exposure assessment degradation data derived under aerobic conditions will be considered, in line with conclusions taken at the EU level.

8.4 Field studies (KCP 9.1.1.2)

Field studies were carried out with a comparable formulation from which data for the active substance under field conditions was obtained. A summary of the data is given under the points below.

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

Halauxifen-methyl

Field dissipation studies are not triggered or required. However, the field dissipation of halauxifen-methyl and its metabolites was evaluated for active substance approval. No additional studies have been performed. The dissipation data are summarised in the following tables. Note that the field data were relied upon by EFSA for the exposure assessments.

Table 8.4-1: Summary of degradation rates for halauxifen-methyl - field studies

Location	Soil type (USDA)	pH (CaCl ₂)	Depth (cm)	Persistence				Modelling (20°C/pF2)			Evaluated at EU level
				DissT ₅₀ (d)	DissT ₉₀ (d)	Chi ² (%)	Kinetic model	DT ₅₀ (d)	Chi ² (%)	Kinetic model	
Germany (spring)	Sandy loam	5.73	30	18	60	18.4	SFO	17	24	SFO	Yes (EFSA, 2014)
Germany (autumn)	Sandy loam	6.34	30	5	78	24.4	FOMC	27	24	SFO	
UK (spring)	Silt loam	6.94	30	43	144	19.0	SFO	26	19	SFO	
UK (autumn)	Loam	6.63	30	15	106	8.2	FOMC	8.2	20	SFO	
Spain (spring)	Clay loam	7.71	40	15	51	14.1	SFO	25	32	SFO	
Spain (autumn)	Clay loam	7.61	30	11	86	16.3	FOMC	33	11	SFO	
France (spring)	Loam	5.52	30	15	49	36.6	SFO	17	15	SFO	
France (autumn)	Sandy loam	5.25	30	2.1	51	13.0	DFOP	19	19	SFO	
Geomean (n=8)								20			
Worst case (n=8)				43	144						

Table 8.4-2: Summary of degradation rates for halauxifen-methyl when modelling formation of halauxifen acid - field studies

Location	Soil type (USDA)	pH (CaCl ₂)	Depth (cm)	Modelling (20°C/pF2)						Evaluated at EU level
				Parent DT ₅₀ (d)	Chi ² (%)	Acid DT ₅₀ (d)	Form. fraction	Chi ² (%)	Kinetic model	
Germany (spring)	Sandy loam	5.73	30	0.7*	28	23	0.12	34	SFO-SFO	Yes (EFSA, 2014)
Germany (autumn)	Sandy loam	6.34	30	2.5	32	42	0.44	25	SFO-SFO	
UK (spring)	Silt loam	6.94	30	27	28	35	0.66	33	SFO-SFO	
UK (autumn)	Loam	6.63	30	1.1	40	51	0.36	14	SFO-SFO	
Spain (spring)	Clay loam	7.71	40	6.4	17	34	0.33	49	SFO-SFO	
Spain (autumn)	Clay loam	7.61	30	9.1	20	40	0.34	49	SFO-SFO	
France (spring)	Loam	5.52	30	6.6	40	12.6	-	22	SFO TD**	
France (autumn)	Sandy loam	5.25	30	0.7	27	11	0.34	61	SFO-SFO	
Geomean (n=8)				3.3						
Geomean acidic soil (n=4)						19.1 ⁺				
Geomean alkaline soil (n=2)						36.9 ⁺⁺				
Arithmetic mean acidic soil (n=3)							0.30 ⁺			
Arithmetic mean alkaline soil (n=2)							0.34 ⁺⁺			

* DFOP/SFO model used

** TD = top down

⁺ pH 5.25-6.34

⁺⁺ pH 7.61-7.71

The DT₅₀ data above for halauxifen acid are reproduced again in Table 8.4-4.

Table 8.4-3: Summary of degradation rates for halauxifen-methyl and halauxifen acid when modelling formation of X-757 - field studies

Location	Soil type (USDA)	pH (CaCl ₂)	Depth (cm)	Modelling (20°C/pF2)							Evaluated at EU level
				Parent DT ₅₀ (d)	Acid DT ₅₀ (d)	Acid form. fraction	X-757 DT ₅₀ (d)	X-757 form. fraction	Chi ² (%)	Kinetic model	
Germany (spring)	Sandy loam	5.73	30	NC	NC	NC	NC	NC	NC	SFO-SFO-SFO	Yes (EFSA, 2014)
Germany (autumn)	Sandy loam	6.34	30	1.9	43	0.41	8.9 (76*)	1	16	SFO-SFO-SFO	
UK (spring)	Silt loam	6.94	30	NC	NC	NC	NC (60*)	NC	NC	SFO-SFO-SFO	
UK (autumn)	Loam	6.63	30	1.0	54	0.35	22	0.22	37	SFO-SFO-SFO	
Spain (spring)	Clay loam	7.71	40	NC	NC	NC	NC (84*)	NC	NC	SFO-SFO-SFO	
Spain (autumn)	Clay loam	7.61	30	NC	NC	NC	NC (60*)	NC	NC	SFO-SFO-SFO	
France (spring)	Loam	5.52	30	5.8	1.9	1	73 (107*)	0.18	36	SFO-SFO-SFO	
France (autumn)	Sandy loam	5.25	30	0.7	8.6	0.36	9.5 (37*)	1	30	SFO-SFO-SFO	
Geomean (n=4)				1.7			19 (67*)				
Arithmetic mean (n=4)								0.60			

* Top down SFO (used in surface water modelling)

NC = not calculated

The DT₅₀ data above for X-757 are reproduced again in Table 8.4-5.

Table 8.4-4: Summary of degradation rates for halauxifen acid - field studies

Location	Soil type (USDA)	pH (CaCl ₂)	Depth (cm)	Persistence				Modelling (20°C/pF2)			Evaluated at EU level
				DissT ₅₀ (d)	DissT ₉₀ (d)	Chi ² (%)	Kinetic model	DT ₅₀ (d)	Chi ² (%)	Kinetic model	
Germany (spring)	Sandy loam	5.73*	30	NC	NC	NC	NC	23	34	SFO	Yes (EFSA, 2014)
Germany (autumn)	Sandy loam	6.34*	30	102	338	18.9	SFO-TD	42	25	SFO	
UK (spring)	Silt loam	6.94	30	264	872	7.5	SFO-TD	35	33	SFO	
UK (autumn)	Loam	6.63	30	164	543	12.3	SFO-TD	51	14	SFO	
Spain (spring)	Clay loam	7.71**	40	62	207	14.8	SFO-TD	34	49	SFO	
Spain (autumn)	Clay loam	7.61**	30	108	359	3.2	SFO-TD	40	49	SFO	
France (spring)	Loam	5.52*	30	17	56	14.8	SFO-TD	12.6	22	SFO	
France (autumn)	Sandy loam	5.25*	30	44	145	14.1	SFO-TD	11	61	SFO	
Geomean (n=4* or n=2**)								19.1* 36.9**			
Worst case (n=7)				264	872						

* Acidic soils

** Alkaline soils

NC = not calculated

Table 8.4-5: Summary of degradation rates for X-757 - field studies

Location	Soil type (USDA)	pH (CaCl ₂)	Depth (cm)	Persistence				Modelling (20°C/pF2)			Evaluated at EU level
				DissT ₅₀ (d)	DissT ₉₀ (d)	Chi ² (%)	Kinetic model	DT ₅₀ (d)	Chi ² (%)	Kinetic model	
Germany (spring)	Sandy loam	5.73	30	NC	NC	NC	NC	NC	NC	NC	Yes (EFSA, 2014)
Germany (autumn)	Sandy loam	6.34	30	197	654	9.2	SFO-TD	8.9	16	SFO	
UK (spring)	Silt loam	6.94	30	187	621	16.9	SFO-TD	NC	NC	SFO	
UK (autumn)	Loam	6.63	30	NC	NC	NC	NC	22	37	SFO	
Spain (spring)	Clay loam	7.71	40	113	376	19.8	SFO-TD	NC	NC	NC	
Spain (autumn)	Clay loam	7.61	30	105	348	24.2	SFO-TD	NC	NC	NC	
France (spring)	Loam	5.52	30	146	485	13.8	SFO-TD	73	36	SFO	
France (autumn)	Sandy loam	5.25	30	87.3	290	14.2	SFO-TD	9.5	30	SFO	
Geomean (n=4)								19			
Worst case (n=6)				197	654						

NC = not calculated

zRMS comments:

Field degradation data for halauxifen-methyl and its metabolites are in line with EU agreed endpoints reported in EFSA Journal 2014;12(12):3913.

Picloram

The field dissipation of picloram was evaluated for active substance approval. Since only three DT₅₀ values were validated during the EU review, an additional field study at two sites was carried out. The new field dissipation study and a new kinetics analysis for two sites submitted at EU level, and the two additional sites from the new field study are described in the following two reports (**8.4.1.2/01** and **8.4.1.2/02**; see Appendix 2 for the evaluation of these new studies). Note that the field data were used for the groundwater assessment at Tier 2.

For the 3,6-dichloro analogue metabolite, a normalised field DT₅₀ of **12.1 days** was agreed at EU level by the meeting of experts for the picloram peer review. No data are available for the 5,6-dichloro analogue metabolite, and so the same value was used as a surrogate.

zRMS comments:

The field dissipation study by Kennedy (2008, GHE-P-11837) was agreed by the zRMS (UK) in the course of the Central Zone evaluation of formulation GF-224 SL (Galera, belonging the same Applicant as GF-4021) finalised in 2014. The kinetic assessment by Knowles (2008, GHE-P-11865) included results of the new field dissipation study as well as results of field studies evaluated and agreed in the course of the first EU review of picloram. The zRMS (UK) excluded results obtained for some locations due to poor or unreliable visual fits. After exclusions degradation data were available for four sites. Table below presents DT₅₀ values agreed by the zRMS (UK) for the modelling purposes. Consideration of un-normalised DT₅₀ values for German and Polish soils was agreed by the zRMS (UK) in derivation of the geometric mean DT₅₀.

Study	DT₅₀ (days)	Comment
Germany	39	Annex I submission; not normalised
Poland	49	Annex I submission; not normalised
N. Germany (Dollern)	19.6	New study; normalised
C. Germany (Adenstedt)	6.8	New study; normalised
Geomean	22.5	

In general new active substance data should not be generated at the zonal level. However, Tier 1 groundwater modelling demonstrated leaching of picloram at >0.1 µg/L, so submission of new degradation data to be used in Tier 2 modelling was justified. The zRMS for GF-4021 (LaDiva) is of the opinion that DT₅₀ of 22.5 days derived from field dissipation studies may be used in this report since this value was already agreed and considered in the Central Zone.

The study by Kennedy (2008) and kinetic evaluation by Knowles (2008) were also agreed in the Northern Zone during assessment of formulations belonging to the same Applicant: GF-224 SL (carried out by LT as the zRMS in 2012) and GF-3447 (carried out by DK as the zRMS in 2017). However, in the Northern Zone shorter DT₅₀ values were agreed (13.8 d by LT and 6.71 d by DK), since fits for all soils were included.

The summary of the field dissipation study (Kennedy, 2008) and kinetic evaluation by Knowles (2008) were moved from this point to Appendix 2. The Applicant is kindly reminded that summaries of new active substance studies should be presented in Appendix 2.

Aminopyralid

The field dissipation of aminopyralid was evaluated for active substance approval. No additional studies have been performed. The dissipation data are summarised in the following table. Note that field data were relied upon by EFSA for the exposure assessments.

Table 8.4-11: Summary of degradation rates for aminopyralid - field studies

Location	Soil type (USDA)	pH (H ₂ O)	Depth (cm)	Persistence				Modelling (20°C/pF2)*			Evaluated at EU level
				DissT ₅₀ (d)	DissT ₉₀ (d)	Chi ² (%)	Kinetic model	DT ₅₀ (d)	Chi ² (%)	Kinetic model	
UK	Clay loam	6.6	20	34.9	116.1	11.1	SFO	16.6	4.0	SFO	Yes (EFSA, 2013)
Germany (2008)	Silt loam	6.4	50	22.0	73.0	6.9	SFO	17.2	8.3	SFO	
S France (2008)	Loam	6.2	50	15.4	51.0	16.4	SFO	10.9	18.0	SFO	
N France (2011)	Sandy clay loam	7.8	100	-	-	-	-	12.8	18.7	SFO	
Geomean (n=4)								14.1			
Worst case (n=3)				34.9	116.1						

* After exclusion of data points prior to 10 mm rainfall

zRMS comments:

Field degradation data for aminopyralid are in line with EU agreed endpoints reported in EFSA Journal 2013;11(9):3352.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Soil accumulation studies are not triggered or required.

zRMS comments:

According to conclusions taken at the EU level, soil accumulation testing was not triggered for halauxifen-methyl, picloram and aminopyralid.

8.5 Mobility in soil (KCP 9.1.2)

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

Halauxifen-methyl

The sorption of halauxifen-methyl and its metabolites was evaluated for active substance approval. No additional studies have been performed. The sorption data are summarised in the following tables. Note the EFSA Conclusion gives arithmetic mean K_{foc} and Freundlich exponent (1/n) values, which were used for model inputs during EU review. However, EFSA guidance (2014) recommends using geomean K_{foc} values for model input together with the arithmetic mean 1/n. Therefore, geomean K_{foc} values, which were not included in the EFSA Conclusion, have been derived as shown below.

Table 8.5-1: Summary of sorption data for halauxifen-methyl

Soil type (USDA)	OC (%)	pH (-)	Kf	Kfoc	1/n	Evaluated at EU level
Clay loam	1.3	7.1	24	1812	0.89	Yes (EFSA, 2014)
Loamy sand	1.1	5.2	17	1553	0.88	
Loam	2.5	5	28	1104	0.90	
Silt loam	3.6	5.9	24	660	0.88	
Sandy loam	1.4	7.5	9	652	0.89	
Clay loam	4.4	7.2	8	190	0.76	
Organic*	33.1	4.1	310*	936*	0.98*	
Arithmetic mean (n=6)				995	0.87	
pH-dependency				Very weak, not considered in modelling.		No** (derived from EU data)
Geomean (n=6)				796		

* Results excluded from calculation of mean as soil considered unrepresentative

** Geomean K_{foc} according to current EFSA guidance

Table 8.5-2: Summary of sorption data for halauxifen acid

Table 6a-1: Summary of sorption data for lindaxifen acid						
Soil type (USDA)	OC (%)	pH (-)	Kf	Kfoc	1/n	Evaluated at EU level
Clay loam	1.3	7.1	1.48	113	0.83	Yes (EFSA, 2014)
Loamy sand	1.1	5.2	1.66	151	0.96	
Loam	2.5	5	2.40	96	0.83	
Silt loam	3.6	5.9	2.40	67	0.84	
Sandy loam	1.4	7.5	0.41	29	0.88	
Clay loam	4.4	7.2	1.14	26	0.88	
Organic*	33.1	4.1	113*	341*	0.91*	
Arithmetic mean (n=6)				80.3	0.87	
pH-dependency				No		No** (derived from EU data)
Geomean (n=6)				66.0		

* Results excluded from calculation of mean as soil considered unrepresentative

** Geomean K_{foc} according to current EFSA guidance

Table 8.5-3: Summary of sorption data for X-757

Soil type (USDA)	OC (%)	pH (-)	Kf	Kfoc	1/n	Evaluated at EU level
Clay loam	1.3	7.1	1.84	142	0.87	Yes (EFSA, 2014)
Loamy sand	1.1	5.2	1.86	169	0.86	
Loam	2.5	5	3.28	131	0.83	
Silt loam	3.6	5.9	3.73	104	0.84	
Sandy loam	1.4	7.5	0.26	19	0.90	
Clay loam	4.4	7.2	0.66	15	0.95	
Organic*	33.1	4.1	134*	405*	0.93*	
Arithmetic mean (n=6)				96.7	0.88	
pH-dependency				No		
Geomean (n=6)				67.3		No** (derived from EU data)

* Results excluded from calculation of mean as soil considered unrepresentative

** Geomean Kfoc according to current EFSA guidance

zRMS comments:

Soil mobility data for halauxifen-methyl and its metabolites are in line with EU agreed endpoints reported in EFSA Journal 2014;12(12):3913. Geometric mean K_{FOC} values calculated by the Applicant from EU agreed individual values were checked by the zRMS and are confirm to be correct.

Picloram

The sorption of picloram was evaluated for active substance approval. The sorption data are summarised in the following table, and were derived from a non-Freundlich study. Note the EFSA Conclusion gives arithmetic mean Kfoc values which were used for model input during EU review. However, EFSA guidance (2014) recommends using geomean Kfoc values and so the geomean Kfoc, which was not included in the EFSA Conclusion, has been calculated and is shown below.

Table 8.5-4: Summary of sorption data for picloram (non-Freundlich)

Soil type (-)	OC (%)	pH (-)	Kd	Kdoc	1/n	Evaluated at EU level
Silty clay loam	1.9	7.0	0.76	40	-	Yes (EFSA, 2009)
Clay loam	1.0	5.4	0.33	33	-	
Sandy silt loam	0.8	7.5	0.25	32	-	
Sand	1.3	6.1	0.33	26	-	
Sand	1.8	7.0	0.38	21	-	
Sand	0.6	7.5	0.27	45	-	
Sand	0.6	6.9	0.36	60	-	
Silty loam	0.8	7.2	0.16	20	-	
Arithmetic mean (n=8)				35	-	
pH-dependency				No		
Geomean (n=8)				32.5		No* (derived from EU data)

* Geomean Kfoc calculated according to current EFSA guidance

Since the study evaluated for active substance approval did not report Freundlich isotherms, new Freundlich sorption data have been derived as described in the following report (8.5/01; see Appendix 2 for summary).

Reference:	KCA 7.4.1 (8.5/01)
Report:	Simmonds, M. (2010): [¹⁴ C]-Picloram: Adsorption to and desorption from five soils. Battelle report no. YR/09/010.
Guideline(s):	OECD guideline for the testing of chemicals No. 106
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The Freundlich sorption data for picloram from the new evaluation described in the report above, are summarised in the following table.

Table 8.5-5: Summary of sorption data for picloram (Freundlich)

Soil name	Soil type (USDA)	OC (%)	pH (-)	Kf	Kfoc	1/n	Evaluated at EU level
Warsop	Loamy sand	0.9	4.2	0.50	54	0.896	No (see 8.5/01)
Farditch	Silt loam	2.9	6.0	0.53	18	0.836	
South Witham	Clay loam	3.7	7.3	0.41	11	0.848	
Kenslow	Loam	4.1	5.2	0.85	21	0.764	
Lufa 6S	Clay	1.7	7.1	0.22	13	0.946	
Arithmetic mean (n=5)					23.4	0.858	
pH-dependency					No		
Geomean (n=5)					19.6		

~~This study has already been provided and evaluated for the assessment of another zonal dossier in the southern zone. The study was considered as acceptable by the zRMS (France). The main comments made by the zRMS are summarised in Appendix 2.~~

For the 3,6-dichloro analogue metabolite, a K_{foc} of **4.07** was agreed at EU level by the meeting of experts for the picloram peer review. No data are available for the 5,6-dichloro analogue metabolite, and so the same value was used as a surrogate.

zRMS comments:

Soil mobility data for picloram presented in Table 8.5-4 as well as K_{foc} for 3,6-dichloro and 5,6-dichloro analogue metabolites are in line with EU agreed endpoints reported in EFSA Journal 2009;7(12):1390. The geometric mean K_{doc} calculated by the Applicant from the individual EU agreed values for picloram was checked by the zRMS and is confirmed to be correct.

Since no K_{foc} and 1/n values were derived in the course of the first EU review, new adsorption study was performed by the Applicant (Simmonds, 2010, YR/09/010) and submitted in support of evaluation of GF-4021. The study was already evaluated and agreed by the zRMS (UK) in the course of the Central Zone evaluation of formulation GF-224 SL (Galera, belonging the same Applicant as GF-4021) finalised in 2014. The following was concluded by the zRMS (UK) in the Core Assessment, Part B, Section 5 for Galera (GF-224 SL):

Since the original Annex I studies only measured K_d (not K_f) the UK RMS accepted this new study as being appropriate to replace the Annex I data. This was considered appropriate rather than combining the two data sets (note: combining studies measuring K_d and K_f would be problematic).

In general new active substance data should not be generated at the zonal level. However, in opinion of the zRMS for GF-4021 (LaDiva) geometric mean K_{foc} of 19.6 mL/g derived from the new study by Simmonds (2010) may be used in this report since it was already agreed and considered in the Central Zone. It is also noted that this value represents worst case comparing to the EU agreed arithmetic mean K_{doc} of 35.0 mL/g.

Information on evaluation of the study in the Southern Zone was struck through in the text above, since the Core Assessment prepared by France could not be found on CIRCABC.

Aminopyralid

The sorption of aminopyralid was evaluated for active substance approval. No additional studies have been performed. The sorption data are summarised in the following table. Note the EFSA Conclusion gives both arithmetic mean and median K_{foc} and Freundlich exponent (1/n) values, of which the median values were used for model input during the EU review. Whilst EFSA guidance (2014) recommends using geomean K_{foc} values for model input together with the arithmetic mean 1/n, use of the median values was retained for model input since these are worst case.

Although pH dependence was noted, this is accounted for by excluding data for two very acidic soils in the derivation of the median K_{foc} and Freundlich exponent (1/n) for model input.

Table 8.5-6: Summary of sorption data for aminopyralid

Table 6.5-6: Summary of sorption data for alinopyr and						
Soil name	Soil type (-)	% OC	pH (CaCl ₂)	Kfoc	1/n	Evaluated at EU level
Thessaloniki	Silty clay loam	1.0	7.8	3.91	0.860	Yes (EFSA, 2013)
Faringdon	Clay	3.2	7.5	2.45	0.919	
Ryerson	Silty clay	3.9	7.8	5.94	0.887	
Cuckney	Sand	1.6	6.6	3.92	0.888	
Charentilly	Clay loam	1.0	6.1	4.35	0.824	
Dowling	Clay	1.5	6.9	2.85	0.793	
Barnes*	Clay loam	3.6	4.8	17.36*	0.903*	
Norfolk*	Loamy sand	0.6	4.5	24.46*	0.881*	
Altubheim	Loam	1.7	7.5	11.92	0.95	
Barrow	Sandy loam	4.6	6.3	4.01	0.87	
Hertfordshire	Clay loam	2.2	7.6	8.77	0.96	
Romenberg	Sandy loam	0.7	7.4	14.18	0.92	
Arithmetic mean (n=10)				6.84	0.899	
Median (n=10)				5.14	0.899	
pH-dependency				Yes (stronger in acidic soil)		
Geomean (n=10)				5.27 5.83		No** (derived from EU data)

* Data for very acidic soils were not included in calculation of arithmetic mean/median/geomean

** Geomean K_{foc} calculated according to current EFSA guidance

zRMS comments:

Soil mobility data for aminopyralid are in line with EU agreed endpoints reported in EFSA Journal 2013;11(9):3352. Geometric mean K_{FOC} value calculated by the Applicant from EU agreed individual values was checked by the zRMS and corrected accordingly (in line with EU conclusions soils Barnes and Norfolk were excluded).

8.5.1 Column leaching (KCP 9.1.2.1)

Column leaching studies are not required since reliable sorption data are available.

zRMS comments:

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

8.5.2 Lysimeter studies (KCP 9.1.2.2)

Halauxifen-methyl

Lysimeter studies are not required.

Picloram

A lysimeter study for picloram was evaluated for active substance approval. The annual average concentration of total radioactivity in the lysimeter leachate was <0.1 µg equivalents/L.

Aminopyralid

Lysimeter studies are not required.

zRMS comments:

Lysimeter studies were not performed or required in the course of the EU review of halauxifen-methyl and aminopyralid.

For picloram a lysimeter study was performed and resulted with maximum annual concentration of 0.018 µg/L (as parent equivalents).

8.5.3 Field leaching studies (KCP 9.1.2.3)

Field leaching studies are not required.

zRMS comments:

Field leaching studies 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 water/sediment data obtained with the active substance.

Halauxifen-methyl

Water/sediment studies for halauxifen-methyl and its metabolites were evaluated for active substance approval. No additional studies have been performed. The data are summarised in the following tables.

Table 8.6-1: Summary of water/sediment degradation data for halauxifen-methyl – lab studies

System name	Sed type (USDA)	pH wat/sed	T (°C)	Whole system				Evaluated at EU level
				DT ₅₀ (d)	DT ₉₀ (d)	Chi ² (%)	Kinetic model	
Swiss Lake	Loamy sand	7.0/5.8	20	4	12	9.4	SFO	Yes (EFSA, 2014)
Calwich Abbey Lake	Silt loam	8.3/7.7	20	0.8	2.9	1.3	SFO	
Geomean (n=2)				1.8				

Table 8.6-2: Summary of water/sediment degradation data for halauxifen acid – lab studies

System name	Sed type (USDA)	pH wat/sed	T (°C)	Whole system				Evaluated at EU level
				DT ₅₀ (d)	DT ₉₀ (d)	Chi ² (%)	Kinetic model	
Swiss Lake	Loamy sand	7.0/5.8	20	11	38	20.7	SFO-TD	Yes (EFSA, 2014)
Calwich Abbey Lake	Silt loam	8.3/7.7	20	2	6.7	1.3	SFO-TD	
Geomean (n=2)				4.7				

Table 8.6-3: Summary of water/sediment degradation data for X-757 – lab studies

System name	Sed type (USDA)	pH wat/sed	T (°C)	Whole system				Evaluated at EU level
				DT ₅₀ (d)	DT ₉₀ (d)	Chi ² (%)	Kinetic model	
Swiss Lake	Loamy sand	7.0/5.8	20	38	125	12.1	SFO-TD	Yes (EFSA, 2014)
Calwich Abbey Lake	Silt loam	8.3/7.7	20	87	289	3.1	SFO-TD	
Geomean (n=2)				57.5 57.2				

Table 8.6-4: Summary of water/sediment degradation data for X-790 – lab studies

System name	Sed type (USDA)	pH wat/sed	T (°C)	Whole system				Evaluated at EU level
				DT ₅₀ (d)	DT ₉₀ (d)	Chi ² (%)	Kinetic model	
Swiss Lake	Loamy sand	7.0/5.8	20	7	23	7.4	SFO-TD	Yes (EFSA, 2014)
Calwich Abbey Lake	Silt loam	8.3/7.7	20	1.5	5	2.2	SFO-TD	
Geomean (n=2)				3.2				

zRMS comments:

Information on degradation of halauxifen-methyl and its metabolites in water/sediment systems is in general in line with EU agreed endpoints reported in EFSA Journal 2014;12(12):3913 with some minor corrections.

Picloram

Water/sediment studies for picloram were evaluated for active substance approval. No additional studies have been performed. The data are summarised in the following table.

Table 8.6-5: Summary of water/sediment degradation data for picloram – lab studies

System name	Sed type (USDA)	pH wat/sed	T (°C)	Whole system				Evaluated at EU level
				DT ₅₀ (d)	DT ₉₀ (d)	R ² (%)	Kinetic model	
French	Not stated	5.9/6.1	20	149.9	498	0.962	SFO	Yes (EFSA, 2009)
Italian	Not stated	8.2/7.9	20	256.6	852	0.945	SFO	
Geomean (n=2)				196.1				

zRMS comments:

Information on degradation of picloram in water/sediment systems is in line with EU agreed endpoints reported in EFSA Journal 2009;7(12):1390.

Aminopyralid

Water/sediment studies for aminopyralid were evaluated for active substance approval, where it was concluded that the kinetics assessment was not conducted in line with FOCUS kinetics guidance (2006). Since no additional studies have been performed, the EFSA assigned default DT₅₀ of **1000 days** was used for the surface water modelling for both water and sediment phases.

zRMS comments:

Information on degradation of aminopyralid in water/sediment systems is in line with conclusions derived at the EU level and reported in EFSA Journal 2013;11(9):3352.

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

PECsoil values were calculated for halauxifen-methyl, picloram, aminopyralid and for the formulation GF-4021.

PECsoil values were also calculated for the major soil metabolites of halauxifen-methyl (halauxifen acid, X-757). There are no metabolites of picloram or aminopyralid >5% AR which require PECsoil.

8.7.1 Justification for new endpoints

Halauxifen-methyl

EU endpoints (EFSA, 2014) were used for the PECsoil calculations.

Picloram

A new endpoint (non-normalised field DT₅₀ of 54.3 days) was used for the PECsoil calculations based on the worst case value from the new field dissipation study and additional kinetics analysis described under Point 8.4.1.2. This is more conservative than the EU agreed endpoint of 49 days.

Aminopyralid

EU endpoints (EFSA, 2013) were used for the PECsoil calculations.

zRMS comments:

Although the EU agreed DT₅₀ for picloram was sufficient to perform the soil exposure assessment and the new active substance data were not necessary to finalise the assessment, the zRMS agrees with consideration of DT₅₀ of 54.3 days for picloram as representing slightly worst case. However, no significant impact on the derived PEC_{SOIL} values is expected.

Consideration of the new DT₅₀ of 54.3 days was already agreed by the zRMS (UK) in the course of the Central Zone evaluation of formulation GF-224 SL (Galera, belonging the same Applicant as GF-4021) finalised in 2014.

8.7.2 Active substances and relevant metabolites

Calculations were performed as detailed in Appendix 3.1 of this document using ESCAPE 2.0. Accumulation PECsoil values after repeated annual applications over multiple years (assuming tillage to 20 cm) were calculated only for residues with a persistence field (non-normalised) DT₉₀ >365 days.

Table 8.7-1: Inputs related to application for PECsoil

Use	Winter oilseed rape
Application rate (g as/ha)	Halauxifen-methyl: 2.5 Picloram: 12 Aminopyralid: 8
Max. number of applications	1
Crop interception (%)	40% (BBCH 12-19)
Effective soil loading (g as/ha)	Halauxifen-methyl: 1.5 Picloram: 7.2 Aminopyralid: 4.8
Min. application interval (d)	Not applicable
Frequency of application	Every year (worst case)*
Depth of soil (cm)	5 (no tillage)/20 (tillage; plateau conc.)
Model used for calculation	ESCAPE 2.0

** 1 October used as representative autumn application date but this has no meaningful impact

For the calculations, a crop interception of 40% was used, as relevant for applications from BBCH 12-19.

Table 8.7-2: Inputs for halauxifen-methyl and metabolites for PECsoil

Substance	Molar mass (g/mol)	Max. level (% AR)	Effective appn. rate (g/ha)*	Max. persistence DT ₅₀ (d)**	Max. persistence DT ₉₀ (d)**	Evaluated at EU level
Halauxifen-methyl	345	-	1.5	43	144	Yes (EFSA, 2014)
Halauxifen acid	331	40.1**	0.58	264	872	
X-757	317	13.8**	0.19	197	654	

* Assuming 40% crop interception, and for metabolites based on parent rate x max. % AR x mw correction

** From field studies (DT₅₀/DT₉₀ is maximum non-normalised)

Table 8.7-3: Inputs for picloram for PECsoil

Substance	Molar mass (g/mol)	Max. level (% AR)	Effective appn. rate (g/ha)*	Max. persistence DT ₅₀ (d)**	Max. persistence DT ₉₀ (d)**	Evaluated at EU level
Picloram	241.5	-	7.2	54.3	180	Yes (EFSA, 2009) (with exception of DT ₅₀)

* Assuming 40% crop interception

** From field studies (DT₅₀/DT₉₀ is maximum non-normalised)

Table 8.7-4: Inputs for aminopyralid for PECsoil

Substance	Molar mass (g/mol)	Max. level (% AR)	Effective appn. rate (g/ha)*	Max. persistence DT ₅₀ (d)**	Max. persistence DT ₉₀ (d)**	Evaluated at EU level
Aminopyralid	207	-	4.8	34.9	116.1	Yes (EFSA, 2013)

* Assuming 40% crop interception

** From field studies (DT₅₀/DT₉₀ is maximum non-normalised)

zRMS comments:

The application pattern presented in Table 8.7-1 assumed in soil exposure assessment for halauxifen-methyl, picloram, and aminopyralid is in line with the critical Central Zone GAP and it is thus agreed. Crop interception of 40% is in line with FOCUS groundwater guidance (2014 and 2021).

Input parameters for all substances are in general in line with the EU agreed values with exception of DT₅₀ considered for picloram, which was derived from the new field dissipation study by Kennedy (2008). However, as already indicated in zRMS comments in point 8.7.1 above, the difference between the EU agreed and new DT₅₀ is only slight (49 vs 54.3 days) and is not expected to have significant impact on the obtained PEC_{SOIL} values. For more information and discussion on the new endpoint, please refer to zRMS comments in points 8.7.1 and 8.4.1 above.

Calculations were performed with ESCAPE ver. 2 and the zRMS is aware that use of this modelling program is not harmonised at the Central Zone level. However, when metabolic pattern is not assumed, climate scenarios are switched off and bi-phasic degradation is not considered, ESCAPE serves as a simple calculator since when each compound is modelled as parent, ESCAPE uses the same equations as these defined in FOCUS methodology and results are the same as these obtained using available Excel spreadsheets for PEC_{SOIL} calculations. In case of GF-4021 each substance was calculated separately, metabolites of halauxifen-methyl were modelled as parent with pseudo-application rates calculated with consideration of the molar ratio and maximum occurrence in soil, climatic scenarios were switched off and all DT₅₀ were obtained using SFO kinetics. Taking this into account, consideration of ESCAPE as a simple calculator may be agreed.

Results

The PECsoil values are presented as follows for the active substances and their metabolites.

Halauxifen-methyl

Table 8.7-5: PECsoil for halauxifen-methyl following application to winter oilseed rape at 2.5 g as/ha

Time		PECsoil (mg/kg)	
		Actual	TWA
Initial		0.0020	-
Short term	1 d	0.0020	0.0020
	2 d	0.0019	0.0020
	4 d	0.0019	0.0019
Long term	7 d	0.0018	0.0019
	14 d	0.0016	0.0018
	21 d	0.0014	0.0017
	28 d	0.0013	0.0016
	50 d	0.0009	0.0014
	100 d	0.0004	0.0010
PECsoil plateau (20 cm)		Not calculated; field DT ₉₀ <365 d	
PECaccumulation (PEC _{initial} +PECsoil plateau)			

Table 8.7-6: PECsoil for halauxifen acid following application of halauxifen-methyl to winter oilseed rape at 2.5 g as/ha

Time		PECsoil (mg/kg)	
		Actual	TWA
Initial		0.0008	-
Short term	1 d	0.0008	0.0008
	2 d	0.0008	0.0008
	4 d	0.0008	0.0008
Long term	7 d	0.0008	0.0008
	14 d	0.0008	0.0008
	21 d	0.0008	0.0008
	28 d	0.0008	0.0008
	50 d	0.0007	0.0008
	100 d	0.0006	0.0007
PEC _{soil plateau} (20 cm)		0.0001	-
PEC _{accumulation} (PEC _{initial} +PEC _{soil plateau})		0.0009	-

Table 8.7-7: PECsoil for X-757 following application of halauxifen-methyl to winter oilseed rape at 2.5 g as/ha

Time		PECsoil (mg/kg)	
		Actual	TWA
Initial		0.0003	-
Short term	1 d	0.0003	0.0003
	2 d	0.0003	0.0003
	4 d	0.0002	0.0003
Long term	7 d	0.0002	0.0003
	14 d	0.0002	0.0002
	21 d	0.0002	0.0002
	28 d	0.0002	0.0002
	50 d	0.0002	0.0002
	100 d	0.0002	0.0002
PEC _{soil plateau} (20 cm)		<0.0001	-
PEC _{accumulation} (PEC _{initial} +PEC _{soil plateau})		0.0003	-

Picloram

Table 8.7-8: PECsoil for picloram following application to winter oilseed rape at 12 g as/ha

Time		PECsoil (mg/kg)	
		Actual	TWA
Initial		0.0096	-
Short term	1 d	0.0095	0.0095
	2 d	0.0094	0.0095
	4 d	0.0091	0.0094
Long term	7 d	0.0088	0.0092
	14 d	0.0080	0.0088
	21 d	0.0073	0.0084
	28 d	0.0067	0.0081
	50 d	0.0051	0.0071
	100 d	0.0027	0.0054
PECsoil plateau (20 cm)		Not calculated; field DT ₉₀ <365 d	
PECaccumulation (PEC _{initial} +PECsoil plateau)			

Aminopyralid

Table 8.7-9: PECsoil for aminopyralid following application to winter oilseed rape at 8 g as/ha

Time		PECsoil (mg/kg)	
		Actual	TWA
Initial		0.0064	-
Short term	1 d	0.0063	0.0063
	2 d	0.0062	0.0063
	4 d	0.0059	0.0062
Long term	7 d	0.0056	0.0060
	14 d	0.0048	0.0056
	21 d	0.0042	0.0052
	28 d	0.0037	0.0049
	50 d	0.0024	0.0041
	100 d	0.0009	0.0028
PEC _{soil} plateau (20 cm)		Not calculated; field DT ₉₀ <365 d	
PEC _{accumulation} (PEC _{initial} +PEC _{soil} plateau)			

zRMS comments:

The soil exposure for particular compounds was independently validated by the zRMS using the same methodology and input parameters. Additional calculations were also performed using the Excel spreadsheet for calculation of PEC_{SOIL} values in line with FOCUS equations. The same results were obtained regardless of the method.

Due to high level of non-extractable residues for halauxifen-methyl, the PEC_{SOIL} for NER should be also calculated. According to information available in the DAR, the peak amount of halauxifen-methyl NER was at 82.5% AR. Taking this into account, in line with the approach taken at the EU level (see DAR, Vol. 3, B.8, August 2014), the PEC_{SOIL} for NER would be 0.0017 mg/kg dws.

In addition to that, picloram PEC_{SOIL} values were calculated using the EU agreed DT₅₀ of 49 days. As expected, the differences in short- and long-term as well as TWA PEC_{SOIL} were negligible.

Soil exposure reported in Tables 8.7-5 to 8.7-9 above may be used for purposes of the soil risk assessment. None of the active substances is expected to accumulate in soil, so PEC_{SOIL,INI} are relevant. For halauxifen-methyl metabolites PEC_{SOIL,ACCU} are relevant, however due to very low application rate there is only minor difference between accumulated and initial PEC_{SOIL} values for these compounds.

8.7.3 Formulation

The formulation consists of active substance and co-formulants, and it will not remain intact in soil after application due to breakdown of its individual components. Therefore, only an initial PEC_{soil} was calculated since time-aged or accumulation values are not appropriate. Calculations were performed as detailed in Appendix 3.1 using ESCAPE 2.0.

Table 8.7-10: Inputs related to application for PEC_{soil}

Use	Winter oilseed rape
Application rate (L FP/ha)	0.25
Application rate (g FP/ha)	236.5*
Max. number of applications	1
Crop interception (%)	40% (BBCH 12-19)
Effective soil loading (g FP/ha)	141.9
Min. application interval (d)	Not applicable
Frequency of application	Every year (worst case)**
Depth of soil (cm)	5 (no tillage)
Model used for calculation	ESCAPE 2.0

* Based on formulation density of 0.946 g/mL

** 1 October used as representative autumn application date but this has no meaningful impact

Results

The PEC_{soil} value for the formulation is presented below.

Table 8.7-11: PEC_{soil} for GF-4021 following application to winter oilseed rape at 0.25 L FP/ha

Time	PEC _{soil} (mg/kg)
Initial	0.1892

zRMS comments:

Calculations performed by the zRMS resulted with the same soil exposure to the formulated product and PEC_{SOIL} value reported in Table 8.7-11 is thus confirmed by the zRMS as being relevant for the risk assessment for soil organisms.

8.8 Predicted environmental concentrations in groundwater (PEC_{gw}) (KCP 9.2.4)

PEC_{gw} values were calculated for halauxifen-methyl, picloram and aminopyralid.

PEC_{gw} values were also calculated for the major soil metabolites of halauxifen-methyl (halauxifen acid, X-757). There are no metabolites of picloram or aminopyralid >5% AR which require PEC_{gw}.

8.8.1 Justification for new endpoints

Halauxifen-methyl

EU endpoints (EFSA, 2014) were used for the PEC_{gw} calculations. However, geomean K_{foc}/K_{fom} values were selected instead of arithmetic mean in line with EFSA guidance (2014) (see Point 8.5).

Picloram

EU endpoints (EFSA, 2009) were used for the PEC_{gw} calculations, with the following exceptions. A normalized field DT₅₀ of 22.5 days from the new data (see **8.4.1.2/01** and **8.4.1.2/02**) was used for Tier 2 groundwater modelling, and a K_{foc} of 19.6 and 1/n of 0.858 from the new Freundlich data (see **8.5/01**) were used for both the Tier 1 and Tier 2 groundwater modelling.

Aminopyralid

EU endpoints (EFSA, 2013) were used for the PEC_{gw} calculations. Note that whilst EFSA guidance (2014) recommends using geomean K_{foc} values for model input together with the arithmetic mean 1/n, the use of the median values was retained as these are worst case.

zRMS comments:

For zRMS comments on input parameters considered in groundwater modelling performed for particular active compounds, please refer to respective chapters in point 8.8.2 below.

8.8.2 Active substances and relevant metabolites (KCP 9.2.4.1)

Table 8.8-1: Inputs related to application for PEC_{gw}

Use	Winter oilseed rape
Application rate (g as/ha)	Halauxifen-methyl: 2.5 Picloram: 12 Aminopyralid: 8
Max. number of applications	1
Crop interception (%)	40% (BBCH 12-19)
Effective soil loading (g as/ha)	Halauxifen-methyl: 1.5 Picloram: 7.2 Aminopyralid: 4.8
Application mode	Soil; effective soil loading
Min. application interval (d)	Not applicable
Application date mode	Absolute (see Table 8.8-2)
Frequency of application	Every one, two or three years
Model used for calculation	FOCUSPELMO 5.5.3/FOCUSPEARL 4.4.4

A single application at either BBCH 12 or BBCH 19 was deemed to cover the intended application window and the following dates, as given by AppDate v3.06 (June 2019), were selected for modelling.

Table 8.8-2: Application dates for groundwater assessment (winter oilseed rape)

FOCUS scenario	BBCH 12	BBCH 19
Châteaudun	11 Sep	21 Sep
Hamburg	6 Sep	16 Sep
Kremsmünster	6 Sep	16 Sep
Okehampton	18 Aug	28 Aug
Piacenza	9 Oct	19 Oct
Porto	19 Sep	28 Oct

* Given by AppDate v3.06 (June 2019)

zRMS comments:

The application pattern assumed in groundwater modelling is in line with the Central Zone GAP presented in Table 8.1-1. The absolute application dates presented in Table 8.8-2 were checked by the zRMS using AppDate ver. 3.06 tool and are considered acceptable.

Halauxifen-methyl

The following report (**8.8.2/01**) describes the PEC_{gw} calculations for halauxifen-methyl and its metabolites using FOCUSPELMO 5.5.3 and FOCUSPEARL 4.4.4 following a single annual application for early post-emergence use in winter oilseed rape at 2.5 g as/ha. Application every year represents a worst case since winter oilseed rape is normally rotated with other crops.

Reference:	KCP 9.2.4 (8.8.2/01)
Report:	Reeves, G. (2020): FOCUS groundwater modelling for halauxifen-methyl and its metabolites following early post-emergence use in winter oilseed rape at 2.5 g as/ha. Corteva Agriscience report no. 201596. 31 July 2020.
Guideline(s):	FOCUS (2014): Assessing Potential for Movement of Active substances and their Metabolites to Ground Water in the EU, Report of the FOCUS Groundwater Work Group, EC Document Ref. SANCO/13144/2010, Ver. 3, 613 pp.
Deviations:	No
GLP:	No (model calculation)
Acceptability:	Yes

Model inputs for halauxifen-methyl and its metabolites are summarised in the following tables. It should be noted that since PELMO requires water solubility and vapour pressure values at two temperatures for parent, the following rules were applied to the measured values at 20°C:

- Solubility at 30°C = 2 x solubility at 20°C
- Vapour pressure at 30°C = 4 x vapour pressure at 20°C

Table 8.8-3: PELMO inputs for halauxifen-methyl for PECgw

Parameter	Value	Comment	Evaluated at EU level
Molar mass (g/mol)	345	-	Yes (EFSA, 2014)
<i>Application</i>			
Type	Soil application	Crop processes not implemented	-
Application dates	Absolute	BBCH 12 or 19 (see Table 8.8-2)	-
Frequency	Every year*	26 years (first 6 years equilibration)	-
Plant uptake factor	0	Model default	-
<i>Volatilisation (20°C)</i>			
Henry's constant	Calculated	-	-
Vapour pressure (Pa)	5.9×10^{-9}	Measured (2.36×10^{-8} Pa at 30°C**)	Yes (EFSA, 2014)
Aqueous solubility (mg/L)	1.7	Measured (3.4 mg/L at 30°C**)	Yes (EFSA, 2014)
Diffusion coeff. air (cm ² /s)	0.05	Model default	-
Thickness of boundary layer (cm)	0.1	Model default	-
<i>Sorption (20°C)</i>			
K _{foc}	796	Geomean	No (Point 8.8.1)
Freundlich exponent (1/n)	0.87	Arithmetic mean	Yes (EFSA, 2014)
Limit for Freundlich (µg/L)	0.01	Model default	-
Annual increase (%)	0	Model default	-
Equilibrium constant for DOC (L/kg)	0	Model default	-
Increase for air-dried soil	1	Model default	-
pK _a	20	Default to disable pH dependence	-
Kinetic sorption	0	Default to disable kinetic sorption	-
Depth dependent sorption/trans. data	Standard (Tier 1)	Model default	-
<i>Degradation (20°C/pF2)</i>			
Soil DT ₅₀ (d) (parent alone)	20	Geomean field	Yes (EFSA, 2014)
Rate correction in soil	Recommended	Model default (moisture exp. 0.7)	-
Q ₁₀ value	2.58	Model default	-
Rel. deg at neq sites	0	Model default	-
Soil photolysis (1/d)	0	Default to disable soil photolysis	-

* Application every year represents worst case since winter oilseed rape is normally rotated with other crops

** Extrapolated from 20°C to 30°C (see description in text)

Table 8.8-4: PEARL inputs for halauxifen-methyl for PECgw

Parameter	Value	Comment	Evaluated at EU level
<i>Application</i>			
Type	Soil application	Crop processes not implemented	-
Application dates	Absolute	BBCH 12 or 19 (see Table 8.8-2)	-
Frequency	Every year*	26 years (first 6 years equilibration)	-
<i>General (20°C)</i>			
Molar mass (g/mol)	345	-	Yes (EFSA, 2014)
Vapour pressure (Pa)	5.9×10^{-9}	Measured	Yes (EFSA, 2014)
Aqueous solubility (mg/L)	1.7	Measured	Yes (EFSA, 2014)
Enthalpy of vaporisation (kJ/mol)	95	Model default	-
Enthalpy of dissolution (kJ/mol)	27	Model default	-
<i>Sorption (20°C)</i>			
Option	K _{om}	pH independent	-
K _{fom} (K _{foc} /1.724)	462	Geomean	No (Point 8.8.1)
Freundlich exponent (1/n)	0.87	Arithmetic mean	Yes (EFSA, 2014)
Molar enthalpy of sorption (kJ/mol)	0	Model default	-
Ref. conc. in liq. phase (mg/L)	1	Model default	-

Desorption rate coeff. (1/d)	0	Non-equilibrium sorption not implemented	-
Factor rel. CoffFreNeq and CoffFreEq	0	Non-equilibrium sorption not implemented	-
<i>Degradation (20°C/pF2)</i>			
Soil DT ₅₀ (d) (parent alone)	20	Geomean field	Yes (EFSA, 2014)
Optimum moisture conditions	Yes	Relevant for pF2 or wetter	-
Exponent for effect of liquid	0.7	Model default	-
Molar activation energy (kJ/mol)	65.4	Model default	-
<i>Diffusion</i>			
Ref. temp. for diffusion (°C)	20	Model default	-
Ref. diff. coeff. in water (m ² /d)	4.3 x 10 ⁻⁵	Model default	-
Ref. diff. coeff. in air (m ² /d)	0.43	Model default	-
<i>Crop</i>			
Wash-off factor (1/m)	0.0001	Model default	-
Canopy process option	Lumped	Model default	-
Half-life at crop surface (d)	1000000	Model default	-
Coeff. for uptake by plant	0	Model default	-

* Application every year represents worst case since winter oilseed rape is normally rotated with other crops

As required by each model, input parameters for the halauxifen acid and X-757 metabolites were the same as described for parent with the following exceptions.

Table 8.8-5: PELMO/PEARL inputs for halauxifen acid for PECgw

Parameter	Value	Comment	Evaluated at EU level
<i>General (20°C)</i>			
Molar mass (g/mol)	331	-	Yes (EFSA, 2014)
Vapour pressure (Pa)	2 x 10 ⁻⁵	Measured	Yes (EFSA, 2014)
Aqueous solubility (mg/L)	3070	Measured	Yes (EFSA, 2014)
<i>Sorption(20°C)</i>			
Kfoc (PELMO)	66.0	Geomean	No (Point 8.8.1)
Kfom (<i>Kfoc/1.724</i>) (PEARL)	38.3	Geomean	No (Point 8.8.1)
Freundlich exponent (1/n)	0.87	Arithmetic mean	Yes (EFSA, 2014)
<i>Degradation (20°C/pF2)</i>			
Soil DT ₅₀			
Halauxifen-methyl precursor (d)	3.3	Geomean field sequential fit	Yes (EFSA, 2014)
Halauxifen acid (d)	36.9	Geomean field (high pH soil)	Yes (EFSA, 2014)
Formation fraction for halauxifen acid	0.34	Arithmetic mean field (high pH soil)	Yes (EFSA, 2014)
<i>PELMO transformation rates (1/d)</i>			
	0.2100	Parent total	
	0.0714	Parent → halauxifen acid	Yes (EFSA, 2014)
	0.1386	Parent → CO ₂ /NER	

Table 8.8-6: PELMO/PEARL inputs for X-757 for PECgw

Parameter	Value	Comment	Evaluated at EU level
<i>General (20°C)</i>			
Molar mass (g/mol)	317	-	Yes (EFSA, 2014)
Vapour pressure (Pa)	5 x 10 ⁻⁵	Measured	Yes (EFSA, 2014)
Aqueous solubility (mg/L)	265	Measured	Yes (EFSA, 2014)
<i>Sorption (20°C)</i>			
K _{foc} (PELMO)	67.3	Geomean	No (Point 8.8.1)
K _{fom} (K _{foc} /1.724) (PEARL)	39.0	Geomean	No (Point 8.8.1)
Freundlich exponent (1/n)	0.88	Arithmetic mean	Yes (EFSA, 2014)
<i>Degradation (20°C/pF2)</i>			
Soil DT ₅₀			
Halauixifen-methyl precursor (d)	1.7	Geomean field sequential fit	Yes (EFSA, 2014)
Halauixifen acid precursor (d)	19.1	Geomean field sequential fit (low pH soil)	Yes (EFSA, 2014)
Halauixifen acid formation fraction	0.30	Arithmetic mean field (low pH soil)	Yes (EFSA, 2014)
X-757 (d)	19	Geomean field	Yes (EFSA, 2014)
Formation fraction	0.60	Arithmetic mean	Yes (EFSA, 2014)

Separate model runs were carried out for parent alone using at DT₅₀ of 20 days, and then using a DT₅₀ of either 3.3 days or 1.7 days for the formation of halauixifen acid or X-757, respectively.

Results

The 80th percentile annual average concentrations in groundwater (1 m depth) for the modelled GAP are presented in the following tables to cover the intended use between BBCH 12-19. Application every year represents a worst case since winter oilseed rape is normally rotated with other crops.

Table 8.8-7: PECgw for halauixifen-methyl following application every year to winter oilseed rape at 2.5 g as/ha

FOCUS scenario	80 th Percentile PECgw (µg/L)		
	BBCH 12	BBCH 19	Max.
FOCUS PELMO 5.5.3			
Châteaudun	<0.001	<0.001	<0.001
Hamburg	<0.001	<0.001	<0.001
Kremsmünster	<0.001	<0.001	<0.001
Okehampton	<0.001	<0.001	<0.001
Piacenza	<0.001	<0.001	<0.001
Porto	<0.001	<0.001	<0.001
FOCUS PEARL 4.4.4			
Châteaudun	<0.001	<0.001	<0.001
Hamburg	<0.001	<0.001	<0.001
Kremsmünster	<0.001	<0.001	<0.001
Okehampton	<0.001	<0.001	<0.001
Piacenza	<0.001	<0.001	<0.001
Porto	<0.001	<0.001	<0.001

Table 8.8-8: PECgw for halauxifen acid following application of halauxifen-methyl every year to winter oilseed rape at 2.5 g as/ha

FOCUS scenario	80 th Percentile PECgw (µg/L)		
	BBCH 12	BBCH 19	Max.
FOCUS PELMO 5.5.3			
Châteaudun	<0.001	<0.001	<0.001
Hamburg	<0.001	<0.001	<0.001
Kremsmünster	<0.001	<0.001	<0.001
Okehampton	<0.001	<0.001	<0.001
Piacenza	<0.001	<0.001	<0.001
Porto	<0.001	<0.001	<0.001
FOCUS PEARL 4.4.4			
Châteaudun	<0.001	<0.001	<0.001
Hamburg	<0.001	<0.001	<0.001
Kremsmünster	<0.001	<0.001	<0.001
Okehampton	<0.001	<0.001	<0.001
Piacenza	<0.001	<0.001	<0.001
Porto	<0.001	<0.001	<0.001

Table 8.8-9: PECgw for X-757 following application of halauxifen-methyl every year to winter oilseed rape at 2.5 g as/ha

FOCUS scenario	80 th Percentile PECgw (µg/L)		
	BBCH 12	BBCH 19	Max.
FOCUS PELMO 5.5.3			
Châteaudun	<0.001	<0.001	<0.001
Hamburg	<0.001	<0.001	<0.001
Kremsmünster	<0.001	<0.001	<0.001
Okehampton	<0.001	<0.001	<0.001
Piacenza	<0.001	<0.001	<0.001
Porto	<0.001	<0.001	<0.001
FOCUS PEARL 4.4.4			
Châteaudun	<0.001	<0.001	<0.001
Hamburg	<0.001	<0.001	<0.001
Kremsmünster	<0.001	<0.001	<0.001
Okehampton	<0.001	<0.001	<0.001
Piacenza	<0.001	<0.001	<0.001
Porto	<0.001	<0.001	<0.001

The results showed that the 20-year 80th percentile PECgw values were all <0.001 µg/L for halauxifen-methyl and the halauxifen acid and X-757 metabolites from the worst case modelling of annual applications.

zRMS comments:

The groundwater modelling for halauxifen-methyl and its metabolites was performed by the Applicant using FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4 FOCUS models.

Input parameters presented in Tables 8.8-3 to 8.8-6 are in general in line with EU agreed endpoints reported in EFSA Journal 2014;12(12):3913 with exception of Kfoc values: the Applicant used geometric mean values calculated from the individual EU agreed Kfoc instead of arithmetic mean, agreed at the EU level for modelling purposes. Nevertheless, geometric mean values used by the Applicant are lower comparing to arithmetic means and are thus agreed by the zRMS as representing worst case.

In simulations PUF of 0 was assumed, which is in line with recommendations of the most recent version of the FOCUS groundwater guidance.

Applicants' results were independently validated in simulations performed by the zRMS with consideration of the EU agreed inputs. Obtained PEC_{GW} were all <0.001 µg/L for halauxifen-methyl and its metabolites in all scenarios, confirming results of the modelling performed by the Applicant.

Overall, no unacceptable leaching of halauxifen-methyl and its metabolites is expected following application of GF-4021 according to the intended Central Zone use pattern.

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

Picloram

The following report (8.8.2/02) describes the PEC_{gw} calculations for picloram using FOCUSPELMO 5.5.3 and FOCUSPEARL 4.4.4 following a single application for early post-emergence use in winter oilseed rape at 12 g as/ha. Applications were modelled every one, two or three years at both **Tier 1** using a median **lab DT₅₀** (82.8 days) and at **Tier 2** using a geomean **field DT₅₀** (22.5 days).

Reference:	KCP 9.2.4 (8.8.2/02)
Report:	Reeves, G. (2020): FOCUS groundwater modelling for picloram following early post-emergence use in winter oilseed rape at 12 g as/ha. Corteva Agriscience report no. 201597. 31 July 2020.
Guideline(s):	FOCUS (2014): Assessing Potential for Movement of Active substances and their Metabolites to Ground Water in the EU, Report of the FOCUS Groundwater Work Group, EC Document Ref. SANCO/13144/2010, Ver. 3, 613 pp.
Deviations:	No
GLP:	No (model calculation)
Acceptability:	Yes

Model inputs for picloram are summarised in the following tables. It should be noted that since PELMO requires water solubility and vapour pressure values at two temperatures for parent, the following rules were applied to the measured values at 20°C:

- Solubility at 30°C = 2 x solubility at 20°C
- Vapour pressure at 30°C = 4 x vapour pressure at 20°C

Since the picloram vapour pressure is low, this was assumed to be at 20°C for the extrapolation (despite being measured at 25°C) to align with water solubility value at 20°C.

Table 8.8-10: PELMO inputs for picloram for PEC_{gw}

Parameter	Value	Comment	Evaluated at EU level
Molar mass (g/mol)	241.5	-	Yes (EFSA, 2009)
<i>Application</i>			
Type	Soil application	Crop processes not implemented	-
Application dates	Absolute	BBCH 12 or 19 (see Table 8.8-2)	-
Frequency	Every year	26 years (first six years equilibration)	-
	Every two years	46 years (first six years equilibration)	-
	Every three years	66 years (first six years equilibration)	-
Plant uptake factor	0	Model default	-
<i>Volatilisation (20°C)</i>			
Henry's constant	Calculated	-	-
Vapour pressure (25°C*) (Pa)	8 x 10 ⁻⁸	Measured (3.2 x 10 ⁻⁷ Pa at 30°C**)	Yes (EFSA, 2009)
Aqueous solubility (mg/L)	560	Measured (1120 mg/L at 30°C**)	Yes (EFSA, 2009)
Diffusion coeff. air (cm ² /s)	0.05	Model default	-
Thickness of boundary layer (cm)	0.1	Model default	-

Parameter	Value	Comment	Evaluated at EU level
<u>Sorption</u>			
K _{foc}	19.6	Geomean	No (Point 8.8.1)
Freundlich exponent (1/n)	0.858	Arithmetic mean	No (Point 8.8.1)
Limit for Freundlich (µg/L)	0.01	Model default	-
Annual increase (%)	0	Model default	-
Equilibrium constant for DOC (L/kg)	0	Model default	-
Increase for air-dried soil	1	Model default	-
pK _a	20	Default to disable pH dependence	-
Kinetic sorption	0	Default to disable kinetic sorption	-
Depth dependent sorption/trans. data	Standard (Tier 1)	Model default	-
<u>Degradation (20°C/pF2)</u>			
Soil DT ₅₀ (d)	82.8 (Tier 1) 22.5 (Tier 2)	Median lab Geomean field	Yes (EFSA, 2015) No (Point 8.8.1)
Rate correction in soil	Recommended	Model default (moisture exp. 0.7)	-
Q ₁₀ value	2.58	Model default	-
Rel. deg at neq sites	0	Model default	-
Soil photolysis (1/d)	0	Default to disable soil photolysis	-

* Assumed to be 20°C for the extrapolation but considered to have no impact

** Extrapolated from 20°C to 30°C (see description in text)

Table 8.8-11: PEARL inputs for picloram for PEC_{gw}

Parameter	Value	Comment	Evaluated at EU level
<u>Application</u>			
Type	Soil application	Crop processes not implemented	-
Application dates	Absolute	BBCH 12 or 19 (see Table 8.8-2)	-
Frequency	Every year Every two years Every three years	26 years (first six years equilibration) 46 years (first six years equilibration) 66 years (first six years equilibration)	-
<u>General (20°C)</u>			
Molar mass (g/mol)	359	-	Yes (EFSA, 2009)
Vapour pressure (Pa)	8 x 10 ⁻⁸	Measured (25°C)	Yes (EFSA, 2009)
Aqueous solubility (mg/L)	560	Measured	Yes (EFSA, 2009)
Enthalpy of vaporisation (kJ/mol)	95	Model default	-
Enthalpy of dissolution (kJ/mol)	27	Model default	-
<u>Sorption (20°C)</u>			
Option	K _{om}	pH independent	-
K _{fom} (K _{foc} /1.724)	11.4	Geomean	No (Point 8.8.1)
Freundlich exponent (1/n)	0.858	Arithmetic mean	No (Point 8.8.1)
Molar enthalpy of sorption (kJ/mol)	0	Model default	-
Ref. conc. in liq. phase (mg/L)	1	Model default	-
Desorption rate coeff. (1/d)	0	Non-equilibrium sorption not implemented	-
Factor rel. Coff _{FreNeq} and Coff _{FreEq}	0	Non-equilibrium sorption not implemented	-
<u>Degradation (20°C/pF2)</u>			
Soil DT ₅₀ (d)	82.8 (Tier 1) 22.5 (Tier 2)	Median lab Geomean field	Yes (EFSA, 2009) No (Point 8.8.1)
Optimum moisture conditions	Yes	Relevant for pF2 or wetter	-
Exponent for effect of liquid	0.7	Model default	-
Molar activation energy (kJ/mol)	65.4	Model default	-
<u>Diffusion</u>			
Ref. temp. for diffusion (°C)	20	Model default	-

Ref. diff. coeff. in water (m ² /d)	4.3 x 10 ⁻⁵	Model default	-
Ref. diff. coeff. in air (m ² /d)	0.43	Model default	-
<i>Crop</i>			
Wash-off factor (1/m)	0.0001	Model default	-
Canopy process option	Lumped	Model default	-
Half-life at crop surface (d)	1000000	Model default	-
Coeff. for uptake by plant	0	Model default	-

Results

The 80th percentile annual average concentrations in groundwater (1 m depth) for the modelled GAP are presented in the following tables to cover the intended use between BBCH 12-19. Results are shown for an application every one, two or three years at both **Tier 1** using a median **lab DT₅₀** and at **Tier 2** using a geomean **field DT₅₀**.

Tier 1

Table 8.8-12: Tier 1 PECgw for picloram following application every year to winter oilseed rape at 12 g as/ha

FOCUS scenario	80 th Percentile PECgw (µg/L)		
	BBCH 12	BBCH 19	Max.
FOCUS PELMO 5.5.3			
Châteaudun	0.613	0.638	0.638
Hamburg	0.910	0.925	0.925
Kremsmünster	0.616	0.622	0.622
Okehampton	0.623	0.639	0.639
Piacenza	0.541	0.554	0.554
Porto	0.592	0.556	0.592
FOCUS PEARL 4.4.4			
Châteaudun	0.623	0.651	0.651
Hamburg	0.845	0.861	0.861
Kremsmünster	0.505	0.519	0.519
Okehampton	0.533	0.565	0.565
Piacenza	0.447	0.448	0.448
Porto	0.576	0.528	0.576

Values in **bold** are above the threshold concentration of 0.1 µg/L

Table 8.8-13: Tier 1 PECgw for picloram following application every two years to winter oilseed rape at 12 g as/ha

FOCUS scenario	80 th Percentile PECgw (µg/L)		
	BBCH 12	BBCH 19	Max.
FOCUS PELMO 5.5.3			
Châteaudun	0.307	0.314	0.314
Hamburg	0.450	0.450	0.450
Kremsmünster	0.305	0.313	0.313
Okehampton	0.315	0.328	0.328
Piacenza	0.277	0.272	0.277
Porto	0.302	0.319	0.319
FOCUS PEARL 4.4.4			
Châteaudun	0.292	0.304	0.304
Hamburg	0.421	0.433	0.433
Kremsmünster	0.262	0.266	0.266
Okehampton	0.285	0.296	0.296
Piacenza	0.215	0.219	0.219
Porto	0.273	0.263	0.273

Values in **bold** are above the threshold concentration of 0.1 µg/L

Table 8.8-14: Tier 1 PECgw for picloram following application every three years to winter oilseed rape at 12 g as/ha

FOCUS scenario	80 th Percentile PECgw (µg/L)		
	BBCH 12	BBCH 19	Max.
FOCUS PELMO 5.5.3			
Châteaudun	0.188	0.198	0.198
Hamburg	0.298	0.286	0.298
Kremsmünster	0.212	0.222	0.222
Okehampton	0.198	0.208	0.208
Piacenza	0.191	0.169	0.191
Porto	0.179	0.184	0.184
FOCUS PEARL 4.4.4			
Châteaudun	0.194	0.204	0.204
Hamburg	0.269	0.264	0.269
Kremsmünster	0.172	0.178	0.178
Okehampton	0.177	0.184	0.184
Piacenza	0.166	0.148	0.166
Porto	0.172	0.169	0.172

Values in **bold** are above the threshold concentration of 0.1 µg/L

Tier 2

Table 8.8-15: Tier 2 PECgw for picloram following application every year to winter oilseed rape at 12 g as/ha

FOCUS scenario	80 th Percentile PECgw (µg/L)		
	BBCH 12	BBCH 19	Max.
FOCUS PELMO 5.5.3			
Châteaudun	0.008	0.011	0.011
Hamburg	0.068	0.079	0.079
Kremsmünster	0.034	0.040	0.040
Okehampton	0.055	0.068	0.068
Piacenza	0.075	0.072	0.075
Porto	0.085	0.114	0.114
FOCUS PEARL 4.4.4			
Châteaudun	0.010	0.013	0.013
Hamburg	0.067	0.072	0.072
Kremsmünster	0.032	0.038	0.038
Okehampton	0.044	0.052	0.052
Piacenza	0.050	0.035	0.050
Porto	0.058	0.087	0.087

Values in **bold** are above the threshold concentration of 0.1 µg/L

Table 8.8-16: Tier 2 PECgw for picloram following application every two years to winter oilseed rape at 12 g as/ha

FOCUS scenario	80 th Percentile PECgw (µg/L)		
	BBCH 12	BBCH 19	Max.
FOCUS PELMO 5.5.3			
Châteaudun	0.004	0.005	0.005
Hamburg	0.032	0.038	0.038
Kremsmünster	0.015	0.018	0.018
Okehampton	0.027	0.032	0.032
Piacenza	0.035	0.029	0.035
Porto	0.033	0.056	0.056
FOCUS PEARL 4.4.4			
Châteaudun	0.005	0.006	0.006
Hamburg	0.034	0.038	0.038
Kremsmünster	0.013	0.015	0.015
Okehampton	0.023	0.028	0.028
Piacenza	0.015	0.023	0.023
Porto	0.025	0.041	0.041

Values in **bold** are above the threshold concentration of 0.1 µg/L

Table 8.8-17: Tier 2 PECgw for picloram following application every three years to winter oilseed rape at 12 g as/ha

FOCUS scenario	80 th Percentile PECgw (µg/L)		
	BBCH 12	BBCH 19	Max.
FOCUSPELMO 5.5.3			
Châteaudun	0.002	0.003	0.003
Hamburg	0.022	0.025	0.025
Kremsmünster	0.012	0.015	0.015
Okehampton	0.019	0.023	0.023
Piacenza	0.028	0.017	0.028
Porto	0.024	0.035	0.035
FOCUSPEARL 4.4.4			
Châteaudun	0.003	0.004	0.004
Hamburg	0.022	0.025	0.025
Kremsmünster	0.010	0.011	0.011
Okehampton	0.017	0.020	0.020
Piacenza	0.023	0.012	0.023
Porto	0.018	0.024	0.024

In conclusion at **Tier 1** when using a lab DT₅₀, the results showed that the 20-year 80th percentile PECgw values were all >0.1 µg/L for application every year (up to 0.925 µg/L), every two years (up to 0.450 µg/L) or every three years (up to 0.298 µg/L). However, at **Tier 2** when using a normalised field DT₅₀, the modelling showed that PECgw values were reduced for application every year (up to 0.114 µg/L), every two years (up to 0.056 µg/L) or every three years (up to 0.035 µg/L).

zRMS comments:

The groundwater modelling for picloram was performed by the Applicant using FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4 FOCUS models.

Input parameters presented in Tables 8.8-10 and 8.8-11 are in general in line with EU agreed endpoints reported in EFSA Journal 2009;7(12):1390 with few exceptions, discussed below:

- At Tier 1 and Tier 2 the geomean K_{foc} of 19.6 mL/g with 1/n of 0.858 originating from the new regulatory soil adsorption study was considered instead of the EU agreed K_{doc} of 35 mL/g and default 1/n of 1. Since in the original Annex I study only K_d (not K_f) values were measured and no K_{oc} and 1/n were available, replacement of the EU agreed K_{doc} and default 1/n with reliable K_{foc} and 1/n was agreed at the Central Zone level in the course of the evaluation of formulation GF-224 SL finalised by the UK as the zRMS in 2014. The same conclusion is applicable for GF-4021, especially K_{foc} of 19.6 mL/g with 1/n of 0.858 were already used within the Central Zone. For more details on the UK assessment, please refer to point 8.5 above.
- At Tier 1 for picloram the EU agreed laboratory DT₅₀ of 82.8 days was used. However, at Tier 2 field DT₅₀ of 22.5 days was used. This value was derived based on the results of the EU agreed and new field dissipation studies and was already agreed at the Central Zone level in the course of the evaluation of formulation GF-224 SL finalised by the UK as the zRMS in 2014. The same value may be thus used in evaluation of GF-4021. Consideration of the new active substance data in evaluation performed for GF-4021 was fully justified since unacceptable leaching of picloram was identified in all scenarios when EU agreed parameters were used. For more details on the UK assessment of the field dissipation study, please refer to point 8.4 above

In all simulations PUF value of 0 was assumed, in line with recommendations of the most recent version of the FOCUS Groundwater Guidance.

Results of Applicants' modelling were independently validated by the zRMS in additional simulations based on the same input parameters. The obtained PEC_{GW} values were the same as these presented in Tables 8.8-12 to 8.8-17. At Tier 1 PEC_{GW} values were above the threshold concentration in all scenarios, regardless of the BBCH stage or the application frequency. At Tier 2, no unacceptable leaching was observed in majority of scenarios for annual application and in all scenarios for biennial application.

Overall, no unacceptable leaching of picloram is expected following annual application of GF-4021 in line with the Central Zone GAP in scenarios Châteaudun, Hamburg, Kremsmünster, Okehampton and Piacenza, while for scenario Porto the application frequency must be restricted to one every second year.

Concerned Member States must decide on applicability of the proposed mitigation measures in their countries.

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

Aminopyralid

The following report **(8.8.2/03)** describes the PEC_{gw} calculations for aminopyralid using FOCUSPELMO 5.5.3 and FOCUSPEARL 4.4.4 following a single application for early post-emergence use in winter oilseed rape at 8 g as/ha. Applications were modelled every one, two or three years at both **Tier 1** using a plant uptake factor of 0, or at **Tier 2** using a value of 0.5 for a systemic compound.

Reference:	KCP 9.2.4 (8.8.2/03)
Report:	Reeves, G. (2020): FOCUS groundwater modelling for aminopyralid following early post-emergence use in winter oilseed rape at up to 8 g as/ha. Corteva Agriscience report no. 201598. 31 July 2020.
Guideline(s):	FOCUS (2014): Assessing Potential for Movement of Active substances and their Metabolites to Ground Water in the EU, Report of the FOCUS Groundwater Work Group, EC Document Ref. SANCO/13144/2010, Ver. 3, 613 pp.
Deviations:	No
GLP:	No (model calculation)
Acceptability:	Yes

Model inputs for aminopyralid are summarised in the following tables. It should be noted that since PELMO requires water solubility and vapour pressure values at two temperatures for parent, the following rules were applied to the measured values at 20°C:

- Solubility at 30°C = 2 x solubility at 20°C
- Vapour pressure at 30°C = 4 x vapour pressure at 20°C

Table 8.8-18: PELMO inputs for aminopyralid for PECgw

Parameter	Value	Comment	Evaluated at EU level
Molar mass (g/mol)	207	-	Yes (EFSA, 2013)
<i>Application</i>			
Type	Soil application	Crop processes not implemented	-
Application dates	Absolute	BBCH 12 or 19 (see Table 8.8-2)	-
Frequency	Every year	26 years (first six years equilibration)	-
	Every two years	46 years (first six years equilibration)	-
	Every three years	66 years (first six years equilibration)	-
Plant uptake factor	0 (Tier 1) 0.5 (Tier 2)	Model default Input for systemic compound	-
<i>Volatilisation (20°C)</i>			
Henry's constant	Calculated	-	-
Vapour pressure (Pa)	0	Worst case (20°C and 30°C)	-
Aqueous solubility (mg/L)	205000	Measured (410000 mg/L at 30°C*)	Yes (EFSA, 2013)
Diffusion coeff. air (cm ² /s)	0.05	Model default	-
Thickness of boundary layer (cm)	0.1	Model default	-
<i>Sorption</i>			
K _{foc}	5.14	Median, excl. very acidic soils	Yes (EFSA, 2013)
Freundlich exponent (1/n)	0.899	Median, excl. very acidic soils	Yes (EFSA, 2013)
Limit for Freundlich (µg/L)	0.01	Model default	-
Annual increase (%)	0	Model default	-
Equilibrium constant for DOC (L/kg)	0	Model default	-
Increase for air-dried soil	1	Model default	-
pK _a	20	Default to disable pH dependence	-
Kinetic sorption	0	Default to disable kinetic sorption	-
Depth dependent sorption/trans. data	Standard (Tier 1)	Model default	-
<i>Degradation (20°C/pF2)</i>			
Soil DT ₅₀ (d)	14.1	Geomean field	Yes (EFSA, 2013)
Rate correction in soil	Recommended	Model default (moisture exp. 0.7)	-
Q ₁₀ value	2.58	Model default	-
Rel. deg at neq sites	0	Model default	-
Soil photolysis (1/d)	0	Default to disable soil photolysis	-

* Extrapolated from 20°C to 30°C (see description in text)

Table 8.8-19: PEARL inputs for aminopyralid for PECgw

Parameter	Value	Comment	Evaluated at EU level
<i>Application</i>			
Type	Soil application	Crop processes not implemented	-
Application dates	Absolute	BBCH 12 or 19 (see Table 8.8-2)	-
Frequency	Every year	26 years (first six years equilibration)	-
	Every two years	46 years (first six years equilibration)	-
	Every three years	66 years (first six years equilibration)	-
<i>General (20°C)</i>			
Molar mass (g/mol)	359	-	Yes (EFSA, 2013)
Vapour pressure (Pa)	0	Worst case	-
Aqueous solubility (mg/L)	205000	Measured	Yes (EFSA, 2013)
Enthalpy of vaporisation (kJ/mol)	95	Model default	-
Enthalpy of dissolution (kJ/mol)	27	Model default	-
<i>Sorption (20°C)</i>			
Option	K _{om}	pH independent	-
K _{fom} (K _{foc} /1.724)	2.98	Median, excl. very acidic soils	Yes (EFSA, 2013)
Freundlich exponent (1/n)	0.899	Median, excl. very acidic soils	Yes (EFSA, 2013)

Molar enthalpy of sorption (kJ/mol)	0	Model default	-
Ref. conc. in liq. phase (mg/L)	1	Model default	-
Desorption rate coeff. (1/d)	0	Non-equilibrium sorption not implemented	-
Factor rel. CofFreNeq and CofFreEq	0	Non-equilibrium sorption not implemented	-
<i>Degradation (20°C/pF2)</i>			
Soil DT ₅₀ (d)	14.1	Geomean field	Yes (EFSA, 2013)
Optimum moisture conditions	Yes	Relevant for pF2 or wetter	-
Exponent for effect of liquid	0.7	Model default	-
Molar activation energy (kJ/mol)	65.4	Model default	-
<i>Diffusion</i>			
Ref. temp. for diffusion (°C)	20	Model default	-
Ref. diff. coeff. in water (m ² /d)	4.3 x 10 ⁻⁵	Model default	-
Ref. diff. coeff. in air (m ² /d)	0.43	Model default	-
<i>Crop</i>			
Wash-off factor (1/m)	0.0001	Model default	-
Canopy process option	Lumped	Model default	-
Half-life at crop surface (d)	1000000	Model default	-
Coeff. for uptake by plant	0	Model default	-

Results

The 80th percentile annual average concentrations in groundwater (1 m depth) for the modelled GAP are presented in the following tables to cover the intended use between BBCH 12-19. Results are shown for an application every one, two or three years at both **Tier 1** using a plant uptake factor of 0, and at **Tier 2** using a value of 0.5 for a systemic compound.

Table 8.8-20: PECgw for aminopyralid following application every year to winter oilseed rape at 8 g as/ha

Table 6.6-26: PECgw for aminopyralide following application every year to winter oilseed rape at 0.5 g a.s./ha				
FOCUS scenario	Plant uptake factor	80 th Percentile PECgw (µg/L)		
		BBCH 12	BBCH 19	Max.
FOCUS PELMO 5.5.3				
Châteaudun	0 (Tier 1) 0.5 (Tier 2)	0.041 0.031	0.054 0.039	0.054 0.039
Hamburg	0 (Tier 1) 0.5 (Tier 2)	0.218 0.161	0.247 0.179	0.247 0.179
Kremsmünster	0 (Tier 1) 0.5 (Tier 2)	0.103 0.075	0.125 0.095	0.125 0.095
Okehampton	0 (Tier 1) 0.5 (Tier 2)	0.092 0.060	0.126 0.092	0.126 0.092
Piacenza	0 (Tier 1) 0.5 (Tier 2)	0.242 0.222	0.241 0.212	0.242 0.222
Porto	0 (Tier 1) 0.5 (Tier 2)	0.131 0.099	0.232 0.199	0.232 0.199
FOCUS PEARL 4.4.4				
Châteaudun	0 (Tier 1) 0.5 (Tier 2)	0.038 0.033	0.053 0.046	0.053 0.046
Hamburg	0 (Tier 1) 0.5 (Tier 2)	0.205 0.186	0.218 0.197	0.218 0.197
Kremsmünster	0 (Tier 1) 0.5 (Tier 2)	0.075 0.068	0.091 0.082	0.091 0.082
Okehampton	0 (Tier 1) 0.5 (Tier 2)	0.073 0.071	0.097 0.094	0.097 0.094
Piacenza	0 (Tier 1) 0.5 (Tier 2)	0.143 0.142	0.128 0.127	0.143 0.142
Porto	0 (Tier 1) 0.5 (Tier 2)	0.126 0.112	0.150 0.141	0.150 0.141

Values in **bold** are above the threshold concentration of 0.1 µg/L

Table 8.8-21: PECgw for aminopyralid following application every two years to winter oilseed rape at 8 g as/ha

FOCUS scenario	Plant uptake factor	80 th Percentile PEC _{gw} (µg/L)		
		BBCH 12	BBCH 19	Max.
FOCUS PELMO 5.5.3				
Châteaudun	0 (Tier 1) <i>0.5 (Tier 2)</i>	0.020 <i>0.014</i>	0.024 <i>0.017</i>	0.024 <i>0.017</i>
Hamburg	0 (Tier 1) <i>0.5 (Tier 2)</i>	0.104 <i>0.077</i>	0.125 <i>0.092</i>	0.125 <i>0.092</i>
Kremsmünster	0 (Tier 1) <i>0.5 (Tier 2)</i>	0.046 <i>0.033</i>	0.058 <i>0.042</i>	0.058 <i>0.042</i>
Okehampton	0 (Tier 1) <i>0.5 (Tier 2)</i>	0.052 <i>0.033</i>	0.071 <i>0.051</i>	0.071 <i>0.051</i>
Piacenza	0 (Tier 1) <i>0.5 (Tier 2)</i>	0.125 <i>0.115</i>	0.112 <i>0.096</i>	0.125 <i>0.115</i>
Porto	0 (Tier 1) <i>0.5 (Tier 2)</i>	0.080 <i>0.069</i>	0.112 <i>0.101</i>	0.112 <i>0.101</i>
FOCUS PEARL 4.4.4				
Châteaudun	0 (Tier 1) <i>0.5 (Tier 2)</i>	0.021 <i>0.017</i>	0.027 <i>0.023</i>	0.027 <i>0.023</i>
Hamburg	0 (Tier 1) <i>0.5 (Tier 2)</i>	0.111 <i>0.102</i>	0.114 <i>0.106</i>	0.114 <i>0.106</i>
Kremsmünster	0 (Tier 1) <i>0.5 (Tier 2)</i>	0.034 <i>0.031</i>	0.040 <i>0.036</i>	0.040 <i>0.036</i>
Okehampton	0 (Tier 1) <i>0.5 (Tier 2)</i>	0.042 <i>0.041</i>	0.052 <i>0.051</i>	0.052 <i>0.051</i>
Piacenza	0 (Tier 1) <i>0.5 (Tier 2)</i>	0.073 <i>0.073</i>	0.071 <i>0.070</i>	0.073 <i>0.073</i>
Porto	0 (Tier 1) 0.5 (Tier 2)	0.085 <i>0.077</i>	0.088 <i>0.081</i>	0.088 <i>0.081</i>

Values in **bold** are above the threshold concentration of 0.1 µg/L

Table 8.8-22: PECgw for aminopyralid following application every three years to winter oilseed rape at 8 g as/ha

FOCUS scenario	Plant uptake factor	80 th Percentile PEC _{gw} (µg/L)		
		BBCH 12	BBCH 19	Max.
FOCUS PELMO 5.5.3				
Châteaudun	0 (Tier 1) <i>0.5 (Tier 2)</i>	0.019 <i>0.014</i>	0.018 <i>0.014</i>	0.019 <i>0.014</i>
Hamburg	0 (Tier 1) <i>0.5 (Tier 2)</i>	0.075 <i>0.058</i>	0.083 <i>0.059</i>	0.083 <i>0.059</i>
Kremsmünster	0 (Tier 1) <i>0.5 (Tier 2)</i>	0.034 <i>0.023</i>	0.044 <i>0.030</i>	0.044 <i>0.030</i>
Okehampton	0 (Tier 1) <i>0.5 (Tier 2)</i>	0.039 <i>0.026</i>	0.051 <i>0.040</i>	0.051 <i>0.040</i>
Piacenza	0 (Tier 1) <i>0.5 (Tier 2)</i>	0.078 <i>0.072</i>	0.085 <i>0.073</i>	0.085 <i>0.073</i>
Porto	0 (Tier 1) <i>0.5 (Tier 2)</i>	0.045 <i>0.038</i>	0.072 <i>0.063</i>	0.072 <i>0.063</i>
FOCUS PEARL 4.4.4				
Châteaudun	0 (Tier 1) <i>0.5 (Tier 2)</i>	0.019 <i>0.017</i>	0.020 <i>0.017</i>	0.020 <i>0.017</i>
Hamburg	0 (Tier 1) <i>0.5 (Tier 2)</i>	0.072 <i>0.066</i>	0.078 <i>0.070</i>	0.078 <i>0.070</i>
Kremsmünster	0 (Tier 1) <i>0.5 (Tier 2)</i>	0.024 <i>0.022</i>	0.029 <i>0.026</i>	0.029 <i>0.026</i>
Okehampton	0 (Tier 1) <i>0.5 (Tier 2)</i>	0.031 <i>0.030</i>	0.039 <i>0.038</i>	0.039 <i>0.038</i>
Piacenza	0 (Tier 1) <i>0.5 (Tier 2)</i>	0.044 <i>0.044</i>	0.051 <i>0.050</i>	0.051 <i>0.050</i>
Porto	0 (Tier 1) <i>0.5 (Tier 2)</i>	0.044 <i>0.042</i>	0.059 <i>0.055</i>	0.059 <i>0.055</i>

Values in **bold** are above the threshold concentration of 0.1 µg/L

In conclusion at **Tier 1** (plant uptake factor of 0) the 20-year 80th percentile PEC_{GW} values were all <0.1 µg/L for an application every three years (up to 0.085 µg/L). However, for applications every year or two years the PEC_{GW} values were sometimes >0.1 µg/L ~~even at Tier 2 (plant uptake factor 0.5).~~

zRMS comments:

The groundwater modelling for aminopyralid was performed by the Applicant using FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4 FOCUS models.

Input parameters presented in Tables 8.8-18 and 8.8-19 are in line with EU agreed endpoints reported in EFSA Journal 2013;11(9):3352.

In addition to Tier 1, the Applicant performed also Tier 2 simulations with TSCF set to 0.5, since aminopyralid is systemic. It should be, however, noted, that in line with indications of the current version of the FOCUS groundwater guidance (2014 and 2021), systemicity of the molecule is no longer sufficient justification for consideration of TSCF (PUF) of 0.5 and in absence of respective targeted data TSCF of 0 should be used regardless if the substance is systemic or not. Since no data enabling refinement of TSCF was provided by the Applicant, the Tier 2 modelling is not accepted and its results are struck through in tables above.

Results of Applicants' Tier 1 modelling were independently validated by the zRMS in additional simulations based on the same input parameters. The obtained PEC_{GW} values were the same as these presented in Tables 8.8-20 to 8.8-22. In case of annual application of GF-4021 PEC_{GW} values were above the threshold concentration in majority of scenarios, for biennial application the threshold concentration was exceeded in part of scenarios, while no unacceptable leaching was observed in all scenarios for triennial application.

Overall, no unacceptable leaching of aminopyralid is expected in following scenarios:

- annual application: scenario Châteaudun only,
- biennial application: scenarios Châteaudun, Kremsmünster and Okehampton,
- triennial application: all scenarios defined for winter oilseed rape.

Concerned Member States must decide on applicability of the proposed mitigation measures in their countries.

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

8.9 Predicted environmental concentrations in surface water (PEC_{sw/sed}) (KCP 9.2.5)

PEC_{sw/sed} values were calculated for halauxifen-methyl, picloram, aminopyralid and for the formulation GF-4021.

PEC_{sw/sed} values were also calculated for the major soil/aquatic metabolites of halauxifen-methyl (halauxifen acid, X-757, X-790, Deg 10, Deg 11, Deg 14), and for the major aquatic metabolites of picloram (3,6-dichloro and 5,6-dichloro analogues). There are no metabolites of aminopyralid >5% AR which require PEC_{sw/sed}.

8.9.1 Justification for new endpoints

Halauxifen-methyl

EU endpoints (EFSA, 2014) were used for the PEC_{sw/sed} calculations. However, geomean K_{foc}/K_{fom} values were selected instead of arithmetic mean. This is in line with EFSA guidance (2014) (see Point 8.5).

Picloram

EU endpoints (EFSA, 2009) were used for the PEC_{sw/sed} calculations, except that a K_{foc} of 19.6 and 1/n of 0.858 from the new Freundlich data (see **8.5/01**) were used.

Aminopyralid

EU endpoints (EFSA, 2013) were used for the PEC_{sw/sed} calculations. Note that whilst EFSA guidance (2014) recommends using geomean K_{foc} values for model input together with the arithmetic mean 1/n, the use of the median values was retained as these are worst case, as was the use of a plant uptake factor of 0.

zRMS comments:

For zRMS comments on input parameters considered in surface water modelling performed for particular active compounds, please refer to respective chapters in point 8.9.2 below.

8.9.2 Active substance and relevant metabolites (KCP 9.2.5)

Table 8.9-1: Inputs related to application for PEC_{sw/sed}

Use	Winter oilseed rape
Application rate (g as/ha)	Halauxifen-methyl: 2.5 Picloram: 12 Aminopyralid: 8
Max. number of applications	1
Min. application interval (d)	Not applicable
Application date mode	Absolute
Frequency of application	Every year (worst case)
Appn. window (Steps 1/2)	Oct-Feb (N & S Europe)
Crop cover (Steps 1/2)	Minimal (40% ; worst case for BBCH 12)
Appn. window (Steps 3/4)	See Table 8.9-2
Appn. method (Steps 3/4)	Ground spray
CAM (chemical appn. method)	2 – appn. foliar linear
Depth incorporated (cm)	4
Model used for calculation	STEPS 1-2 v3.2 FOCUS SWASH v5.3 FOCUS MACRO v5.5.4 FOCUS PRZM SW v4.3.1 FOCUS TOXSWA v4.4.3* SWAN v4.0.1 (Step 4)*

* See comment at end of section regarding model version

A single application at either BBCH 12 or BBCH 19 was deemed to cover the intended application window and the following dates, as given by AppDate v3.06 (June 2019), were selected for modelling at Steps 3 and 4 as the start of the 30 day application window. The number in brackets refers to the Julian day.

Table 8.9-2: Application window start dates for surface water assessment (winter oilseed rape)

FOCUS scenario	Application window (30 d) start date	
	BBCH 12	BBCH 19
D2 ditch/stream	19 Sep (262)	29 Sep (272)
D3 ditch	6 Sep (249)	16 Sep (259)
D4 pond/stream	7 Sep (250)	17 Sep (260)
D5 pond/stream	24 Sep (267)	4 Oct (277)
R1 pond/stream	8 Sep (251)	18 Sep (261)
R3 stream	9 Oct (282)	19 Oct (292)

* Given by AppDate v3.06 (June 2019)

zRMS comments:

The application pattern assumed in surface water simulations is in line with the Central Zone GAP presented in Table 8.1-1. The application windows presented in Table 8.9-2 were checked by the zRMS using AppDate ver. 3.06 tool and are considered acceptable.

Halauxifen-methyl

The following report (8.9.2/01) describes the FOCUS Steps 1 to 4 PEC_{sw/sed} calculations for halauxifen-methyl and its metabolites following a single annual application for early post-emergence use in winter oilseed rape at a rate of 2.5 g as/ha. Application every year represents a worst case since winter oilseed rape would be rotated with other crops.

Reference:	KCP 9.2.5 (8.9.2/01)
Report:	Reeves, G. (2020): FOCUS surface water modelling for halauxifen-methyl and its metabolites following early post-emergence use in winter oilseed rape at 2.5 g as/ha. Corteva Agriscience report no. 201599. 31 July 2020.
Guideline(s):	FOCUS (2001): Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev2. FOCUS (2015): Generic Guidance for FOCUS Surface Water Scenarios, Version 1.4, May, 2015.
Deviations:	No
GLP:	No (model calculation)
Acceptability:	Yes

Model inputs for halauxifen-methyl and its metabolites are summarised in the following tables. Other parameters not listed were left as the FOCUS model defaults. The metabolites considered were halauxifen acid and X-757 (soil and water/sediment), X-790 (water/sediment), and three transient aquatic photoproducts, Deg 10, Deg 11 and Deg 14.

Table 8.9-3: Inputs for halauxifen-methyl for PECsw/sed (Steps 1 to 4)

Parameter	Value	Evaluated at EU level
Molar mass (g/mol)	345	Yes (EFSA, 2014)
Vapour pressure (20°C) (Pa)	5.9×10^{-9}	Yes (EFSA, 2014)
Water solubility (20°C) (mg/L)	1.67	Yes (EFSA, 2014)
Soil DT ₅₀ (20°C/pF2) (d)	20 (geomean field) [worst-case when modelling parent alone]	Yes (EFSA, 2014)
Water/sediment DT ₅₀ (20°C) (d)	1.8 (geomean whole system)	Yes (EFSA, 2014)
Water DT ₅₀ (20°C) (d)	1.8 (geomean whole system) or 1000 (default)	Yes (EFSA, 2014)
Sediment DT ₅₀ (20°C) (d)	1000 (default) or 1.8 (geomean whole system)	Yes (EFSA, 2014)
K _{foc}	796 (geomean)	No (Point 8.9.1)
K _{fom} ($K_{foc}/1.724$)	462 (geomean)	No (Point 8.9.1)
Freundlich exponent (1/n)	0.87 (arithmetic mean)	Yes (EFSA, 2014)
Plant uptake factor	0	Yes (EFSA, 2014)

Since the halauxifen-methyl K_{foc} is within the range 100-2000, two sets of Steps 3 and 4 simulations with different water/sediment DT₅₀ inputs are required; one with the whole system DT₅₀ of 1.8 days applied to the water (DT₅₀ of 1000 days for sediment) (= “water degradation”) and one with the whole system DT₅₀ of 1.8 days applied to the sediment (DT₅₀ of 1000 days for water) (= “sediment degradation”).

Table 8.9-4: Inputs for halauxifen acid for PECsw/sed (Steps 1 to 4)

Parameter	Value	Evaluated at EU level
Molar mass (g/mol)	331	Yes (EFSA, 2014)
Vapour pressure (20°C) (Pa)	2.0×10^{-5}	Yes (EFSA, 2014)
Water solubility (20°C) (mg/L)	3070	Yes (EFSA, 2014)
Soil DT ₅₀ halauxifen-methyl (20°C/pF2) (d)	3.3 (geomean field) [worst-case when modelling formation of acid]	Yes (EFSA, 2014)
Soil DT ₅₀ halauxifen acid (20°C/pF2) (d)	36.9 (geomean field, high pH soil)*	Yes (EFSA, 2014)
Water/sediment DT ₅₀ (20°C) (d)	4.7 (geomean whole system)	Yes (EFSA, 2014)
Water DT ₅₀ (20°C) (d)	4.7 (geomean whole system)	Yes (EFSA, 2014)
Sediment DT ₅₀ (20°C) (d)	1000 (default)	Yes (EFSA, 2014)
Formation fraction in soil	0.34 (arithmetic mean field, high pH soil)**	Yes (EFSA, 2014)
Formation fraction water	1 (worst-case)	No (not given)
Formation fraction sediment	1 (worst-case)	No (not given)
Max. water/sediment (% AR)	23.5% (total system)	Yes (EFSA, 2014)
Max. soil (% AR)	40.1% (field)	Yes (EFSA, 2014)
K _{foc}	66.0 (geomean)	No (Point 8.9.1)
K _{fom} ($K_{foc}/1.724$)	38.3 (geomean)	No (Point 8.9.1)
Freundlich exponent (1/n)	0.87 (arithmetic mean)	Yes (EFSA, 2014)
Plant uptake factor	0	Yes (EFSA, 2014)

* Longest DT₅₀ for halauxifen acid from high pH soils together with the highest formation fraction will be worst-case for run-off/drainage so calculations were calculated using the high pH input values

** Value associated with alkaline soil used, but very similar to formation fraction from acidic soil (0.30)

Halauxifen-methyl and halauxifen acid were analysed to Step 3, and then halauxifen-methyl to Step 4 if required for risk assessment. However, when the dominant exposure route for the D scenarios was drainflow, then mitigation at Step 4 was not possible. Where run-off was the dominant exposure route, Step 4 mitigation was possible and so run-off reduction for an inclusive 10 m or 20 m VFS was implemented with reduction factors of 0.6 or 0.8 used for the aqueous phase, and 0.85 or 0.95 for the sediment phase. An inherent 10 m or 20 m no-spray zone (NSZ) was also included since the latter could not exist without the former. The 10 m or 20 m NSZ was also implemented to manage drift in the drainflow scenarios.

However, due to lower toxicity, the X-757 and X-790 metabolites were evaluated at Steps 1 and 2 only. The model inputs are shown in the following table. Both substances were input as a metabolite of halauxifen-methyl, using the parent precursor inputs in Table 8.9-3.

Table 8.9-5: Inputs for X-757 and X-790 for PECsw/sed (Steps 1 and 2)

Parameter	Value		Evaluated at EU level
	X-757	X-790	
Molar mass (g/mol)	317	331	Yes (EFSA, 2014)
Water solubility (20°C) (mg/L)	265	3070*	Yes (EFSA, 2014)
Soil DT ₅₀ halauxifen methyl (20°C/pF2) (d)	3.3 (geomean field) [worst-case when modelling formation of metabolites]		Yes (EFSA, 2014)
Soil DT ₅₀ (20°C/pF2) (d)	67 ⁺ (geomean field)	1000 (default)	Yes (EFSA, 2014)
Water/sediment DT ₅₀ (20°C) (d)	57.5 (geomean whole system)	3.2 (geomean whole system)	Yes (EFSA, 2014)
Water DT ₅₀ (20°C) (d)	57.5 (geomean whole system)	3.2 (geomean whole system)	Yes (EFSA, 2014)
Sediment DT ₅₀ (20°C) (d)	1000 (default)	1000 (default)	Yes (EFSA, 2014)
Max. soil (% AR)	13.8% (field)	1.4%	Yes (EFSA, 2014)
Max. water/sediment (% AR)	76.7%	33.4%	Yes (EFSA, 2014)
Kfoc	67.3 (geomean)	0/1000**	No (Point 8.9.1)

+ Worst-case geomean top down SFO value used

* Value for halauxifen acid used in absence of measured data

** Two sets of analyses performed to maximise water and sediment concentrations, respectively

The three major aquatic photoproducts of halauxifen-methyl, referred to as Deg 10, Deg 11 and Deg 14, are rapidly formed and degraded with DT₅₀ values of 2-3 hours for Deg 10 and Deg 11, and *ca* 1 day for Deg 14. Therefore, they are transient and unlikely to pose an aquatic risk. However, for completeness, Steps 1 and 2 PECsw values for these photoproducts were calculated from the maximum PECsw values for parent, taking into account the % AR formed and the molecular weight difference. The following inputs were used.

Table 8.9-6: Inputs for aquatic photoproducts for PECsw/sed (Steps 1 and 2)

Aquatic photoproduct	mw metab/ mw parent	Max. (% AR)
Deg 10	326/345	12.6%
Deg 11	273/345	15.7%
Deg 14	229/345	11.5%

Results

The halauxifen-methyl and halauxifen acid PECsw/sed values are summarised in the following tables for each of the application timings. At Steps 3 and 4, the concentrations are the maximum obtained from either the “water degradation” or “sediment degradation” analyses. In practice, the two different approaches can be considered equivalent. There were some small differences noted between the PECsed values, however, these have no impact on the risk assessment. Annual applications represent a worst case for winter oilseed rape.

The RAC values assumed for halauxifen-methyl and halauxifen acid were 0.0393 µg/L and 0.158 µg/L, respectively.

Table 8.9-7: PECsw/sed (Steps 1 to 4) for halauxifen-methyl following annual application to winter oilseed rape at 2.5 g as/ha

FOCUS scenario	Max. PECsw (µg/L)	Date of max. PECsw conc.	Appn. date	Dominant entry route	Max. PECsed (µg/kg)
Step 1	0.43	-	-	-	3.22
Step 2 N Europe	0.11	-	-	-	0.88
Step 2 S Europe	0.09	-	-	-	0.71
BBCH 12	Step 3	Step 4*	Step 4**	Step 3	
D2 ditch	0.01595	0.002325	0.001328	9-Oct-86	0.02438
D2 stream	0.01428	0.002654	0.001327	9-Oct-86	0.0219
D3 ditch	0.01581	0.002304	0.001316	26-Sep-92	0.01198
D4 pond	0.000497	0.000298	0.000199	10-Sep-85	0.00102
D4 stream	0.0137	0.002547	0.001273	10-Sep-85	0.00279
D5 pond	0.000497	0.000298	0.000199	24-Sep-78	0.000971
D5 stream	0.01478	0.002748	0.001374	24-Sep-78	0.003791
R1 pond	0.000572	0.0003	0.0002	31-Dec-78	0.001866
R1 stream	0.01047	0.00207	0.001069	17-Sep-78	0.004454
R3 stream	0.01465	0.005384	0.002821	27-Oct-80	0.03017
BBCH 19	Step 3	Step 4*	Step 4**	Step 3	
D2 ditch	0.01595	0.002325	0.001329	9-Oct-86	0.02438
D2 stream	0.01428	0.002655	0.001327	9-Oct-86	0.0219
D3 ditch	0.01581	0.002304	0.001316	26-Sep-92	0.01198
D4 pond	0.000497	0.000298	0.000199	28-Sep-85	0.001167
D4 stream	0.0137	0.002547	0.001273	28-Sep-85	0.00279
D5 pond	0.000497	0.000298	0.000199	4-Oct-78	0.001024
D5 stream	0.01478	0.002748	0.001374	4-Oct-78	0.003849
R1 pond	0.000584	0.0003	0.0002	31-Dec-78	0.001903
R1 stream	0.01047	0.002114	0.001092	18-Sep-78	0.004536
R3 stream	0.01465	0.005384	0.002821	27-Oct-80	0.03017

* 10 m NSZ with 10 m VFS (VFS only for R scenarios)

** 20 m NSZ with 20 m VFS (VFS only for R scenarios)

To assist in the risk assessment, the maximum halauxifen-methyl Steps 3 and 4 PECsw/sed values for the use from BBCH 12-19 is given below.

Table 8.9-8: PECsw/sed summary (Steps 3 and 4) for halauxifen-methyl following annual application to winter oilseed rape at 2.5 g as/ha

FOCUS scenario	Max. PECsw (µg/L)	Max. PECsed (µg/kg)
	Step 3	Step 3
D2 ditch	0.01595	0.02438
D2 stream	0.01428	0.0219
D3 ditch	0.01581	0.01198
D4 pond	0.000497	0.001167
D4 stream	0.0137	0.00279
D5 pond	0.000497	0.001024
D5 stream	0.01478	0.003849
R1 pond	0.000584	0.001903
R1 stream	0.01047	0.004536
R3 stream	0.01465	0.03017

* 10 m NSZ with 10 m VFS (VFS only for R scenarios)

** 20 m NSZ with 20 m VFS (VFS only for R scenarios)

Table 8.9-9: PECsw/sed (Steps 1 to 3) for halauxifen acid following annual application of halauxifen-methyl to winter oilseed rape at 2.5 g as/ha

FOCUS scenario	Max. PECsw (µg/L)	Date of max. PECsw conc.	Appn. date	Dominant entry route	Max. PECsed (µg/kg)
Step 1	0.47	-	-	-	0.31
Step 2 N Europe	0.11	-	-	-	0.07
Step 2 S Europe	0.09	-	-	-	0.06
BBCH 12	Step 3				
D2 ditch	0.07012	9-Nov-86	9-Oct-86	Drainflow	0.07792
D2 stream	0.04527	10-Nov-86	9-Oct-86	Drainflow	0.04963
D3 ditch	0.002608	27-Sep-92	26-Sep-92	Drainflow	0.001345
D4 pond	0.00431	15-Dec-85	10-Sep-85	Drainflow	0.008166
D4 stream	0.007574	7-Dec-85	10-Sep-85	Drainflow	0.006506
D5 pond	0.00298	29-Jan-78	24-Sep-78	Drainflow	0.006354
D5 stream	0.005419	24-Jan-78	24-Sep-78	Drainflow	0.004267
R1 pond	0.000229	23-Sep-78	17-Sep-78	Run-off	0.000387
R1 stream	0.00549	25-Oct-78	17-Sep-78	Run-off	0.001044
R3 stream	0.01237	4-Nov-80	27-Oct-80	Run-off	0.003809
BBCH 19	Step 3				
D2 ditch	0.07019	9-Nov-86	9-Oct-86	Drainflow	0.07932
D2 stream	0.04531	10-Nov-86	9-Oct-86	Drainflow	0.05057
D3 ditch	0.002608	27-Sep-92	26-Sep-92	Drainflow	0.001345
D4 pond	0.005468	15-Dec-85	28-Sep-85	Drainflow	0.01006
D4 stream	0.009679	7-Dec-85	28-Sep-85	Drainflow	0.007961
D5 pond	0.003173	13-Feb-79	4-Oct-78	Drainflow	0.006523
D5 stream	0.00564	24-Jan-78	4-Oct-78	Drainflow	0.004176
R1 pond	0.000229	24-Sep-78	18-Sep-78	Run-off	0.000391
R1 stream	0.005855	25-Oct-78	18-Sep-78	Run-off	0.001109
R3 stream	0.01237	4-Nov-80	27-Oct-80	Run-off	0.003809

To assist in the risk assessment, the maximum halauxifen acid PECsw/sed Step 3 values for the use from BBCH 12-19 is given below.

Table 8.9-10: PECsw/sed summary (Step 3) for halauxifen acid following annual application of halauxifen-methyl to winter oilseed rape at 2.5 g as/ha

FOCUS scenario	Max. PECsw (µg/L)	Max. PECsed (µg/kg)
	Step 3	
D2 ditch	0.07019	0.07932
D2 stream	0.04531	0.05057
D3 ditch	0.002608	0.001345
D4 pond	0.005468	0.01006
D4 stream	0.009679	0.007961
D5 pond	0.003173	0.006523
D5 stream	0.00564	0.004267
R1 pond	0.000229	0.000391
R1 stream	0.005855	0.001109
R3 stream	0.01237	0.003809

The maximum Step 1 and 2 PEC_{sw/sed} values for the X-757 and X-790 metabolites are shown in the following table. Time-aged values are not presented. The maximum values are given below.

Table 8.9-11: PEC_{sw/sed} (Steps 1 and 2) for soil and water/sediment metabolites following annual application of halauxifen-methyl to winter oilseed rape at 2.5 g as/ha

FOCUS scenario	X-757		X-790	
	Max. PEC _{sw} (µg/L)	Max. PEC _{sed} (µg/kg)	Max. PEC _{sw} (µg/L)*	Max. PEC _{sed} (µg/kg)**
Step 1	0.65	0.43	0.29	1.19
Step 2 N Europe	0.11	0.08	0.04	0.18
Step 2 S Europe	0.09	0.06	0.03	0.15

* K_{foc} = 0

** K_{foc} = 1000

The maximum Step 1 and 2 PEC_{sw} values for the Deg 10, Deg 11 and Deg 14 aquatic photoproducts are shown in the following table. Time-aged values were not calculated. The maximum PEC_{sw} values are given below.

Table 8.9-12: PEC_{sw} (Steps 1 and 2) for aquatic photoproducts following annual application of halauxifen-methyl to winter oilseed rape at 2.5 g as/ha

Aquatic photoproduct	Water column PEC _{sw} (µg/L)		
	Step 1	Step 2 N Europe	Step 2 S Europe
Deg 10	0.05	0.01	0.01
Deg 11	0.05	0.01	0.01
Deg 14	0.03	0.01	0.01

zRMS comments:

The surface water exposure for halauxifen-methyl and its metabolites was estimated by the Applicant using respective FOCUS models.

The input parameters presented in Tables 8.9-3 to 8.9-5 are in general in line with EU agreed endpoints with exception of the K_{foc} values: the Applicant used geometric mean values calculated from the individual EU agreed K_{foc} instead of arithmetic mean, agreed at the EU level for modelling purposes. In general, lower K_{foc} assumed in simulations is expected to result with higher PEC_{sw} values and potentially lower PEC_{sed} values. As potential impact on the extent of exposure is not fully certain, the Applicants' results were independently validated by the zRMS using fully EU agreed inputs. Additional simulations performed by the zRMS at Steps 1-3 for halauxifen-methyl and halauxifen-acid resulted with surface water exposure being in good agreement with values obtained by the Applicant. Therefore, surface water exposure presented in Tables 8.9-7 to 8.9-10 may be used in the aquatic risk assessment.

The surface water modelling performed by the zRMS for metabolites X-757 and X-790 based on fully EU agreed endpoints resulted with slightly higher PEC_{sw/sed}. Although observed differences are not expected to have significant impact on the aquatic risk assessment, correct exposure should be used for PEC/RAC calculations. Therefore, Applicants' results in Tables 8.9-11 were struck through and correct values are reported below. It is noted that for metabolite X-790 higher PEC_{sw/sed} were obtained when parent soil DT₅₀ of 20 days was used.

FOCUS scenario	X-757		X-790	
	Max. PEC _{sw} (µg/L)	Max. PEC _{sed} (µg/kg)	Max. PEC _{sw} (µg/L)	Max. PEC _{sed} (µg/kg)
Step 1	0.65	0.60	0.29	1.19
Step 2 N Europe	0.18	0.17	0.08	0.33
Step 2 S Europe	0.14	0.14	0.06	0.27

Simulations performed for halauxifen-methyl at Step 4 were not validated, since acceptable risk to aquatic organisms could be concluded with Step 3 surface water exposure. Taking this into account, results of Step 4 simulations were struck through in Tables 8.9-7 and 8.9-8 above.

Surface water exposure for aquatic photoproducts presented in Table 8.9-12 is confirmed to be correct.

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.

Picloram

The following report (**8.9.2/02**) describes the FOCUS Steps 1 to 4 PEC_{sw}/sed calculations for picloram and its metabolites following a single annual application for early post-emergence use in winter oilseed rape at a rate of 12 g as/ha. Application every year represents a worst case since winter oilseed rape would be rotated with other crops.

Reference:	KCP 9.2.5 (8.9.2/03)
Report:	Reeves, G. (2020): FOCUS surface water modelling for picloram and its metabolites following early post-emergence use in winter oilseed rape at 12 g as/ha. Corteva Agriscience report no. 201600. 31 July 2020.
Guideline(s):	FOCUS (2001): Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev2. FOCUS (2015): Generic Guidance for FOCUS Surface Water Scenarios, Version 1.4, May, 2015.
Deviations:	No
GLP:	No (model calculation)
Acceptability:	Yes

Model inputs for picloram and its metabolites are summarised in the following tables. Other parameters not listed were left as the FOCUS model defaults. The metabolites considered were the 3,6-dichloro and 5,6-dichloro analogues of picloram.

Picloram was analysed to Step 3, and then to Step 4 if required for risk assessment. However, when the dominant exposure route for the D scenarios was drainflow, then mitigation at Step 4 was not possible. Where run-off was the dominant exposure route, Step 4 mitigation was possible and so run-off reduction for an inclusive 10 m or 20 m VFS was implemented with reduction factors of 0.6 or 0.8 used for the aqueous phase, and 0.85 or 0.95 for the sediment phase. An inherent 10 m or 20 m no-spray zone (NSZ) was also included since the latter could not exist without the former. The 10 m or 20 m NSZ was also implemented to manage drift in the drainflow scenarios.

Due to lower toxicity, the two metabolites were evaluated at Steps 1 and 2 only. Both the 3,6-dichloro and 5,6-dichloro analogues were input as a metabolite of picloram, using the parent precursor inputs in Table 8.9-13. Note that no specific inputs were given by EFSA (2009) for the 5,6-dichloro analogue, and so the endpoints given by EFSA (2009) were the same as those used for the 3,6-dichloro analogue.

Table 8.9-13: Inputs for picloram for PEC_{sw}/sed (Steps 1 to 4)

Parameter	Value	Evaluated at EU level
Molar mass (g/mol)	241.5	Yes (EFSA, 2009)
Vapour pressure (25°C) (Pa)	8×10^{-8}	Yes (EFSA, 2009)
Water solubility (20°C) (mg/L)	560	Yes (EFSA, 2009)
Soil DT ₅₀ (20°C/pF2) (d)	82.8 (median lab)	Yes (EFSA, 2009)
Water/sediment DT ₅₀ (20°C) (d)	196.1 (geomean)	Yes (EFSA, 2009)
Water DT ₅₀ (20°C) (d)	196.1 (geomean)	Yes (EFSA, 2009)
Sediment DT ₅₀ (20°C) (d)	1000 (default)	Yes (EFSA, 2009)
K _{foc}	19.6 (geomean)	No (Point 8.9.1)
K _{fom} (K _{foc} /1.724)	11.4 (geomean)	No (Point 8.9.1)
Freundlich exponent (1/n)	0.858 (arithmetic mean)	No (Point 8.9.1)

Parameter	Value	Evaluated at EU level
Plant uptake factor	0 (worst case)	Yes (EFSA, 2009)

Table 8.9-14: Inputs for 3,6-dichloro and 5,6-dichloro analogues for PECsw/sed (Steps 1 and 2)

Parameter	Value		Evaluated at EU level
	3,6-dichloro analogue	5,6-dichloro analogue*	
Molar mass (g/mol)	207.0	207.0	Yes (EFSA, 2009)
Water solubility (20°C) (mg/L)	2480*	2480*	Yes (EFSA, 2009)
Soil DT ₅₀ (20°C/pF2) (d)	12.1 (geomean)	12.1 (geomean)*	Yes (EFSA, 2009)
Water/sediment DT ₅₀ (20°C) (d)	1000 (worst case)	1000 (worst case)*	Yes (EFSA, 2009)
Water DT ₅₀ (20°C) (d)	1000 (worst case)	1000 (worst case)*	Yes (EFSA, 2009)
Sediment DT ₅₀ (20°C) (d)	1000 (worst case)	1000 (worst case)*	Yes (EFSA, 2009)
Max. soil (% AR)	0.0001% **	0.0001% **	Yes (EFSA, 2009)
Max. water/sediment (% AR)	11.0%	22.1%	Yes (EFSA, 2009)
K _{foc}	4.07	4.07*	Yes (EFSA, 2009)

* No data for 5,6- and so values for 3,6- used as surrogate

** Metabolite not observed in soil; therefore low default value used

The picloram PECsw/sed values are summarised in the following table for each of the application timings. Annual applications represent a worst case for winter oilseed rape.

The RAC value assumed for picloram was 55 µg/L.

Table 8.9-15: PECsw/sed (Steps 1 to 4) for picloram following annual application to winter oilseed rape at 12 g as/ha

FOCUS scenario	Max. PECsw (µg/L)			Date of max. PECsw conc.	Appn. date	Dominant entry route	Max. PECsed (µg/kg)
Step 1	4.01			-	-	-	0.78
Step 2 N Europe	1.24			-	-	-	0.24
Step 2 S Europe	1.01			-	-	-	0.20
BBCH 12	Step 3	Step 4*	Step 4**	Step 3			
D2 ditch	1.818	1.818	1.817	19-Oct-86	9-Oct-86	Drainflow	0.8482
D2 stream	1.14	1.14	1.14	19-Oct-86	9-Oct-86	Drainflow	0.521
D3 ditch	0.3123	0.2768	0.2768	26-Sep-92	26-Sep-92	Drift	0.7567
D4 pond	0.5891	0.5889	0.5888	3-Feb-86	10-Sep-85	Drainflow	1.172
D4 stream	0.3176	0.3176	0.3176	9-Dec-85	10-Sep-85	Drainflow	0.4614
D5 pond	0.2959	0.2956	0.2955	17-Feb-79	24-Sep-78	Drainflow	0.6354
D5 stream	0.1702	0.1702	0.1702	30-Dec-78	24-Sep-78	Drainflow	0.1811
R1 pond	0.002595	0.001597	0.001098	17-Sep-78	17-Sep-78	Drift	0.004069
R1 stream	0.05031	0.00977	0.005129	17-Sep-78	17-Sep-78	Drift	0.003895
R3 stream	0.2744	0.1249	0.06546	4-Nov-80	27-Oct-80	Run-off	0.04387
BBCH 19	Step 3	Step 4*	Step 4**	Step 3			
D2 ditch	1.819	1.819	1.819	19-Oct-86	9-Oct-86	Drainflow	0.8478
D2 stream	1.141	1.141	1.141	19-Oct-86	9-Oct-86	Drainflow	0.5197
D3 ditch	0.3163	0.2845	0.2845	26-Sep-92	26-Sep-92	Drift	0.7635
D4 pond	0.5932	0.593	0.5928	3-Feb-86	28-Sep-85	Drainflow	1.172
D4 stream	0.3361	0.3361	0.3361	7-Dec-85	28-Sep-85	Drainflow	0.4582
D5 pond	0.2652	0.2649	0.2648	16-Feb-79	4-Oct-78	Drainflow	0.533
D5 stream	0.1675	0.1675	0.1675	30-Dec-78	4-Oct-78	Drainflow	0.1399
R1 pond	0.002595	0.001597	0.001098	18-Sep-78	18-Sep-78	Drift	0.00407
R1 stream	0.05031	0.00977	0.005129	18-Sep-78	18-Sep-78	Drift	0.003895
R3 stream	0.2744	0.1249	0.06546	4-Nov-80	27-Oct-80	Run-off	0.04387

* 10 m NSZ with 10 m VFS (VFS only for R scenarios)

** 20 m NSZ with 20 m VFS (VFS only for R scenarios)

To assist in the risk assessment, the maximum picloram Steps 3 and 4 PEC_{sw/sed} values for the use from BBCH 12-19 is given below.

Table 8.9-16: PEC_{sw/sed} summary (Steps 3 and 4) for picloram following annual application to winter oilseed rape at 12 g as/ha

FOCUS scenario	Max. PEC _{sw} (µg/L)			Max. PEC _{sed} (µg/kg)
	Step 3	Step 4*	Step 4**	Step 3
D2 ditch	1.819	1.819	1.819	0.8482
D2 stream	1.141	1.141	1.141	0.521
D3 ditch	0.3163	0.2845	0.2845	0.7635
D4 pond	0.5932	0.593	0.5928	1.172
D4 stream	0.3361	0.3361	0.3361	0.4614
D5 pond	0.2959	0.2956	0.2955	0.6354
D5 stream	0.1702	0.1702	0.1702	0.1811
R1 pond	0.002595	0.001597	0.001098	0.00407
R1 stream	0.05031	0.00977	0.005129	0.003895
R3 stream	0.2744	0.1249	0.06546	0.04387

* 10 m NSZ with 10 m VFS (VFS only for R scenarios)

** 20 m NSZ with 20 m VFS (VFS only for R scenarios)

The maximum Step 1 and 2 PEC_{sw/sed} values for the 3,6-dichloro and 5,6-dichloro metabolites are shown in the following table. Time-aged values are not presented.

Table 8.9-17: PEC_{sw/sed} (Steps 1 and 2) for water/sediment metabolites following annual application of picloram to winter oilseed rape at 12 g as/ha

FOCUS scenario	3,6-dichloro analogue		5,6-dichloro analogue	
	Max. PEC _{sw} (µg/L)	Max. PEC _{sed} (µg/kg)	Max. PEC _{sw} (µg/L)	Max. PEC _{sed} (µg/kg)
Step 1	0.39	0.02	0.77	0.03
Step 2 N Europe	0.12	<0.01	0.24	0.01
Step 2 S Europe	0.10	<0.01	0.20	0.01

zRMS comments:

The surface water exposure for picloram and its metabolites was estimated by the Applicant using respective FOCUS models.

The input parameters presented from Tables 8.9-13 and 8.9-14 are in general in line with EU agreed endpoints with exception of the K_{foc} value considered for picloram. For modelling purposes the Applicant used the geomean K_{foc} of 19.6 mL/g with 1/n of 0.858 originating from the new regulatory soil adsorption study instead of the EU agreed K_d of 35 mL/g and default 1/n of 1. Since in the original Annex I study only K_d (not K_f) values were measured and no K_{oc} and 1/n were available, replacement of the EU agreed K_d and default 1/n with reliable K_{foc} and 1/n was agreed at the Central Zone level in the course of the evaluation of formulation GF-224 SL finalised by the UK as the zRMS in 2014. The same conclusion is applicable for GF-4021, especially K_{foc} of 19.6 mL/g with 1/n of 0.858 were already used within the Central Zone. For more details on the UK assessment, please refer to point 8.5 above

The results of the modelling performed by the applicant were independently validated by the zRMS using the same input parameters. Surface water exposure calculated at Steps 1-3 and reported in Tables 8.9-15 to 8.9-17 is confirmed to be correct and may be used for purposes of the aquatic risk assessment.

Simulations performed for picloram at Step 4 were not validated, since acceptable risk to aquatic organisms could be concluded with Step 1 surface water exposure. Taking this into account, results of Step 4 simulations were struck through in Tables 8.9-15 and 8.9-16 above. Results obtained at Step 2 and 3 were retained in case they are necessary for purposes of the combined risk assessment.

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

Aminopyralid

The following report (**8.9.2/03**) describes the FOCUS Steps 1 to 4 PEC_{sw/sed} calculations for aminopyralid following a single annual application for early post-emergence use in winter oilseed rape at a rate of 8 g as/ha. Application every year represents a worst case since winter oilseed rape would be rotated with other crops.

Reference:	KCP 9.2.5 (8.9.2/03)
Report:	Reeves, G. (2020): FOCUS surface water modelling for aminopyralid following early post-emergence use in winter oilseed rape at 8 g as/ha. Corteva Agriscience report no. 201601. 31 July 2020.
Guideline(s):	FOCUS (2001): Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev2. FOCUS (2015): Generic Guidance for FOCUS Surface Water Scenarios, Version 1.4, May, 2015.
Deviations:	No
GLP:	No (model calculation)
Acceptability:	Yes

Model inputs for aminopyralid are summarised in the following table. Median K_{foc} and 1/n values were used as worst case, together with a plant uptake factor of 0. Other parameters not listed were left as the FOCUS model defaults. There are no metabolites >5% AR which require a PEC_{sw/sed} calculation.

Aminopyralid was analysed to Step 3, and then to Step 4 if required for risk assessment. However, when the dominant exposure route for the D scenarios was drainflow, then mitigation at Step 4 was not possible. Where run-off was the dominant exposure route, Step 4 mitigation was possible and so run-off reduction for an inclusive 10 m or 20 m VFS was implemented with reduction factors of 0.6 or 0.8 used for the aqueous phase, and 0.85 or 0.95 for the sediment phase. An inherent 10 m or 20 m no-spray zone (NSZ) was also included since the latter could not exist without the former. The 10 m or 20 m NSZ was also implemented to manage drift in the drainflow scenarios.

Table 8.9-18: Inputs for aminopyralid for PEC_{sw/sed} (Steps 1 to 4)

Parameter	Value	Evaluated at EU level
Molar mass (g/mol)	207.0	Yes (EFSA, 2013)
Vapour pressure (20°C) (Pa)	0 (worst case)	Yes (EFSA, 2013)
Water solubility (20°C) (mg/L)	205000	Yes (EFSA, 2013)
Soil DT ₅₀ (20°C/pF2) (d)	14.1 (geomean field, normalised)	Yes (EFSA, 2013)
Water/sediment DT ₅₀ (20°C) (d)	1000 (default)	Yes (EFSA, 2013)
Water DT ₅₀ (20°C) (d)	1000 (default)	Yes (EFSA, 2013)
Sediment DT ₅₀ (20°C) (d)	1000 (default)	Yes (EFSA, 2013)
K _{foc}	5.14 (median, excl. very acidic soils)	Yes (EFSA, 2013)
K _{fom} (K _{foc} /1.724)	2.98 (median, excl. very acidic soils)	Yes (EFSA, 2013)
Freundlich exponent (1/n)	0.899 (median, excl. very acidic soils)	Yes (EFSA, 2013)
Plant uptake factor	0 (worst case)	Yes (EFSA, 2013)

The aminopyralid PEC_{sw/sed} values are summarised in the following table for each of the application timings. Annual applications represent a worst case for winter oilseed rape.

The RAC value assumed for aminopyralid was 10 µg/L.

Table 8.9-19: PECsw/sed (Steps 1 to 4) for aminopyralid following annual application to winter oilseed rape at 8 g as/ha

FOCUS scenario	Max. PECsw (µg/L)	Date of max. PECsw conc.	Appn. date	Dominant entry route	Max. PECsed (µg/kg)
Step 1	2.72	-	-	-	0.14
Step 2 N Europe	0.73	-	-	-	0.04
Step 2 S Europe	0.60	-	-	-	0.03
BBCH 12	Step 3	Step 4*	Step 4**	Step 3	
D2 ditch	1.049	1.048	1.048	19-Oct-86	0.1761
D2 stream	0.6653	0.6653	0.6653	19-Oct-86	0.1065
D3 ditch	0.1495	0.1059	0.1035	26-Sep-92	0.114
D4 pond	0.1314	0.1312	0.1311	31-Jan-86	0.1227
D4 stream	0.08297	0.08297	0.08297	20-Dec-85	0.04413
D5 pond	0.07135	0.07135	0.07135	8-Mar-78	0.06933
D5 stream	0.04722	0.04001	0.04001	24-Sep-78	0.0235
R1 pond	0.001797	0.001098	0.000699	17-Sep-78	0.00125
R1 stream	0.03346	0.006595	0.00342	17-Sep-78	0.001468
R3 stream	0.1311	0.05969	0.03129	4-Nov-80	0.01229
BBCH 19	Step 3	Step 4*	Step 4**	Step 3	
D2 ditch	1.048	1.048	1.048	19-Oct-86	0.1756
D2 stream	0.6651	0.6651	0.6651	19-Oct-86	0.106
D3 ditch	0.1497	0.1061	0.1036	26-Sep-92	0.1142
D4 pond	0.177	0.1768	0.1767	31-Jan-86	0.1604
D4 stream	0.1202	0.1202	0.1202	7-Dec-85	0.05938
D5 pond	0.07663	0.07642	0.0763	16-Feb-79	0.07355
D5 stream	0.06855	0.06855	0.06855	24-Jan-78	0.01756
R1 pond	0.001797	0.001098	0.000699	18-Sep-78	0.00125
R1 stream	0.03346	0.006595	0.00342	18-Sep-78	0.001468
R3 stream	0.1311	0.05969	0.03129	4-Nov-80	0.01229

* 10 m NSZ with 10 m VFS (VFS only for R scenarios)

** 20 m NSZ with 20 m VFS (VFS only for R scenarios)

To assist in the risk assessment, the maximum aminopyralid Steps 3 and 4 PECsw/sed values for the use from BBCH 12-19 is given below.

Table 8.9-20: PECsw/sed summary (Steps 3 and 4) for aminopyralid following annual application to winter oilseed rape at 8 g as/ha

FOCUS scenario	Max. PECsw (µg/L)			Max. PECsed (µg/kg)
	Step 3	Step 4*	Step 4**	Step 3
D2 ditch	1.049	1.048	1.048	0.1761
D2 stream	0.6653	0.6653	0.6653	0.1065
D3 ditch	0.1497	0.1061	0.1036	0.1142
D4 pond	0.177	0.1768	0.1767	0.1604
D4 stream	0.1202	0.1202	0.1202	0.05938
D5 pond	0.07663	0.07642	0.0763	0.07355
D5 stream	0.06855	0.06855	0.06855	0.0235
R1 pond	0.001797	0.001098	0.000699	0.00125
R1 stream	0.03346	0.006595	0.00342	0.001468
R3 stream	0.1311	0.05969	0.03129	0.01229

* 10 m NSZ with 10 m VFS (VFS only for R scenarios)

** 20 m NSZ with 20 m VFS (VFS only for R scenarios)

zRMS comments:

The surface water exposure for aminopyralid was estimated by the Applicant using respective FOCUS models.

The input parameters considered by the Applicant and presented in Table 8.9-18 are fully in line with EU agreed endpoints.

Results of Applicants' modelling were independently validated by the zRMS in separate simulations based on the same input parameters and application pattern. Obtained values were in good agreement with those obtained by the Applicant and therefore surface water exposure reported in Tables 8.9-19 to 8.9-20 above may be used in the aquatic risk assessment.

Simulations performed for aminopyralid at Step 4 were not validated, since acceptable risk to aquatic organisms could be concluded with Step 1 surface water exposure. Taking this into account, results of Step 4 simulations were struck through in Tables 8.9-19 and 8.9-20 above. Results obtained at Step 2 and 3 were retained in case they are necessary for purposes of the combined risk assessment.

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

Comment regarding versions of TOXSWA and SWAN used

Whilst updated versions of TOXSWA (i.e. 5.5.3) and SWAN (i.e. 5.0.0) are currently available, previous versions of TOXSWA (i.e. 4.4.3) and SWAN (i.e. 4.0.1) were used to generate the PEC_{sw}/sed values presented in this dRR. However, using the previous versions will not have any meaningful impact on the exposure concentrations, particularly for TOXSWA, since the "Differences between FOCUS_TOXSWA 5.5.3 and FOCUS_TOXSWA 4.4.3" document describes changes relating to format improvements and bug fixes. To validate this, additional limited work has been carried out for halauxifen-methyl ("sediment" degradation analysis only as worst case), picloram and aminopyralid for the BBCH 12 timing at Step 3 using TOXSWA 5.5.3, and then using SWAN 5.0.0 at Step 4 for a 10 m no-spray zone with 10 m VFS. The results for global max. PEC_{sw} were then compared to the values already relied upon in this dRR, as shown below.

Table 8.9-21: PEC_{sw}/sed comparison (Step 3 for BBCH 12) following annual application to winter oilseed rape – TOXSWA 4.4.3 vs 5.5.3

FOCUS scenario	Max. Step 3 PEC _{sw} (µg/L)					
	Halauxifen-methyl (sed degn.)		Picloram		Aminopyralid	
	v 4.4.3	v 5.5.3	v 4.4.3	v 5.5.3	v 4.4.3	v 5.5.3
D2 ditch	0.01595	0.01601	1.818	1.818	1.049	1.049
D2 stream	0.01428	0.01424	1.14	1.14	0.6653	0.6653
D3 ditch	0.01581	0.01587	0.3123	0.3123	0.1495	0.1496
D4 pond	0.000497	0.000545	0.5891	0.5891	0.1314	0.1314
D4 stream	0.0137	0.01367	0.3176	0.3176	0.08297	0.08297
D5 pond	0.000497	0.000545	0.2959	0.2959	0.07135	0.07135
D5 stream	0.01478	0.01475	0.1702	0.1702	0.04722	0.04732
R1 pond	0.000572	0.000576	0.002595	0.002624	0.001797	0.00175
R1 stream	0.01047	0.01045	0.05031	0.0503	0.03346	0.03353
R3 stream	0.01465	0.01461	0.2744	0.2744	0.1311	0.1311

At Step 3 for BBCH 12 as an example, there is no meaningful difference between the two TOXSWA model versions (4.4.3 vs 5.5.3). In percentage terms (apart from the D4, D5 and R1 pond scenarios where the concentrations are very low) the difference is only $\pm 0.4\%$.

Table 8.9-22: PEC_{sw}/sed comparison (Step 4 for BBCH 12) following annual application to winter oilseed rape – TOXSWA 4.4.3/SWAN 4.0.1 vs TOXSWA 5.5.3/SWAN 5.0.1

FOCUS scenario	Max. Step 4 PEC _{sw} (µg/L) – 10 m NSZ with 10 VFS					
	Halauxifen-methyl (sed degn.)		Picloram		Aminopyralid	
	v 4.4.3/4.01	v 5.5.3/5.0.1	v 4.4.3/4.01	v 5.5.3/5.0.1	v 4.4.3/4.01	v 5.5.3/5.0.1
D2 ditch	0.002325	0.002301	1.818	1.818	1.048	1.048
D2 stream	0.002654	0.002758	1.14	1.14	0.6653	0.6653
D3 ditch	0.002304	0.00228	0.2768	0.2768	0.106	0.1059
D4 pond	0.000298	0.000339	0.5889	0.5889	0.1312	0.1312
D4 stream	0.002547	0.002647	0.3176	0.3176	0.08297	0.08297
D5 pond	0.000298	0.000339	0.2956	0.2956	0.07135	0.07135
D5 stream	0.002748	0.002855	0.1702	0.1702	0.04001	0.04001
R1 pond	0.0003	0.00034	0.001597	0.001632	0.001088	0.001098
R1 stream	0.00207	0.00207	0.00977	0.009745	0.006497	0.006595
R3 stream	0.005384	0.005384	0.1249	0.1249	0.05969	0.05969

At Step 4 for BBCH 12 as an example (10 m NSZ with 10 m VFS), there is no meaningful difference between the two SWAN model versions (4.0.1 vs 5.5.3) in combination with the appropriate TOXSWA version. In percentage terms (apart from the D4, D5 and R1 pond scenarios where the concentrations are very low) the difference is only $\pm 3.9\%$.

zRMS comments:

The zRMS appreciates the Applicants' effort to compare results of surface water modelling obtained with older and most recent versions of the TOXSWA and SWAN and agrees that the observed differences are negligible and will have no impact on the aquatic risk assessment, which passes with PEC_{sw}/SED calculated at Step 1-3 (depending on the compound) with sufficient margin of safety.

It is also noted that Step 4 simulations using SWAN were deemed not necessary, since acceptable risk could be concluded for all active compounds and the mixture with no need for risk mitigation measures. Nevertheless, comparison of results of modelling performed with SWAN are retained in Table 8.9-22 above for informative purposes.

8.9.3 Formulation

The formulation will not remain intact in aquatic systems after application due to breakdown of its individual components. Therefore, only an initial formulation PEC_{sw} was calculated since time-aged values are not appropriate. ~~The PEC_{sw} was calculated using the Step 3 SWASH drift calculator using default no-spray zones (NSZ) and then at Step 4 using a 10 m or 20 m NSZ.~~

The calculation was based on an application rate to winter oilseed rape of 0.25 L FP/ha, equivalent to a drift loading of 236.5 g FP/ha (from a formulation density of 0.946 g/mL).

Table 8.9-23: PEC_{sw} (Steps 3 and 4) for GF-4021 following annual application to winter oilseed rape at 0.25 L FP/ha (236.5 g FP/ha)

FOCUS scenario	Max. PEC _{sw} (µg/L)		
	Step 3 (default NSZ)	Step 4 (10 m NSZ)	Step 4 (20 m NSZ)
Ditch	1.5194 (1 m)	0.2184	0.1135
Pond	0.0518 (3.5 m)	0.0322	0.0215
Stream	1.1276 (1.5 m)	0.2184	0.1135

zRMS comments:

Recalculation of the surface water exposure to the formulated product performed by the zRMS using Spray Drift Calculator resulted with the same PEC_{sw} values. Therefore values presented in Table 8.9-23 may be used in the aquatic risk assessment for the formulation, although in line with the EFSA aquatic guidance (2013), the risk assessment for the mixture is performed with consideration of PEC_{mix} being the sum of PEC_{sw} for particular active substances. Since acceptable risk could be concluded with no need for risk mitigation measures, PEC_{sw} calculated with assumption of buffer zones were struck through in Table 8.9-23.

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

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

Table 8.10-1: Summary of atmospheric degradation and behaviour

Substance	Halauxifen-methyl	Picloram	Aminopyralid
Vapour pressure	5.9×10^{-9} Pa (20°C)	8×10^{-8} Pa (25°C)	9.5×10^{-9} Pa (20°C)
Direct photolysis in air	No information	No information	No information
Quantum yield of direct phototransformation	5.6	2.98×10^{-3} (pH 5)	No information
Photochemical oxidative degn. in air (DT ₅₀)	2.2 d (Atkinson model)	12.5 h (Atkinson model)	6.4 d (Atkinson model)
Volatilisation	No information	0.3%/3.7% from plant/soil surfaces after 24 h (BBA)	~2.6% from plant/soil surfaces after 24 h (BBA)
Metabolites	Unlikely to be volatile	Unlikely to be volatile	None

Halauxifen-methyl

The vapour pressure of halauxifen-methyl is less than 10^{-5} Pa at 20°C and hence it is regarded as non-volatile from both soil and plant surfaces. PEC_{air} values are therefore not required.

Picloram

The vapour pressure of picloram is 8×10^{-8} Pa at 25°C, and therefore less than 10^{-5} Pa at 20°C and hence it is regarded as non-volatile from both soil and plant surfaces. PEC_{air} values are therefore not required.

Aminopyralid

The vapour pressure of aminopyralid is nominally zero at 20°C, and hence it is regarded as non-volatile from both soil and plant surfaces. PEC_{air} values are therefore not required.

zRMS comments:

Information regarding fate and behaviour in the air presented in Table 8.10-1 is in line with EU agreed data for halauxifen-methyl, picloram and aminopyralid.

As the vapour pressure of all three substances is below the trigger of 10^{-5} Pa, no significant volatilisation from soil and plant surfaces is expected. For this reason none of the substances is expected to be subject of the short- and long-range transport, even if the DT₅₀ in the atmosphere is estimated to be >2 days.

Taking this into account, calculation of the PEC_{AIR} is deemed not necessary, which is in line with the conclusions taken in the course of the EU review of all three active compounds.

Overall, unacceptable contamination of the atmosphere following application of GF-4021 to winter oilseed rape is not expected.

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	zRMS remarks
KCA 7.3.1	Kennedy, S.	2008	Dissipation of picloram in soil following a single application of GF-224 to bare soil, Northern Europe-2007. DAS Report No.: GHE-P-11837. CEMAS GLP (Y/N): Y Published (Y/N): N	N	Corteva Agriscience (Dow AgroSciences)	All these studies were already agreed at the Central Zone level by the UK as the zRMS in the course of evaluation of formulation GF-224 SL (Galera), finalized in 2014. Therefore the studies were relied upon, but not re-evaluated in the course of the zonal assessment of GF-4021 (LaDiva)
KCA 7.3.1	Knowles, S.	2008	Calculation of field kinetics for picloram from two additional field dissipation studies and two accepted studies using FOCUS Kinetics methodology and Q ₁₀ value = 2.5. DAS Report No.: GHE-P-11865. Dow AgroSciences GLP (Y/N): N Published (Y/N): N	N	Corteva Agriscience (Dow AgroSciences)	
KCA 7.4.1	Simmonds, M.	2010	[¹⁴ C]-Picloram: Adsorption to and desorption from five soils. DAS Report No.: 101391. Battelle UK Ltd. GLP (Y/N): Y Published (Y/N): N	N	Corteva Agriscience (Dow AgroSciences)	
KCP 9.2.4	Reeves, G.	2020	FOCUS groundwater modelling for halauxifen-methyl and its metabolites following early post-emergence use in winter oilseed rape at 2.5 g as/ha. DAS Report No.: 201596. Dow AgroSciences GLP (Y/N): N Published (Y/N): N	N	Corteva Agriscience (Dow AgroSciences)	-
KCP 9.2.4	Reeves, G.	2020	FOCUS groundwater modelling for picloram following early post-emergence use in winter oilseed rape at 12 g as/ha. DAS Report no.: 201597. Dow AgroSciences GLP (Y/N): N Published (Y/N): N	N	Corteva Agriscience (Dow AgroSciences)	-
KCP 9.2.4	Reeves, G.	2020	FOCUS groundwater modelling for aminopyralid following early post-emergence use in winter oilseed rape at up to 8 g as/ha. DAS Report No.: 201598. Dow AgroSciences GLP (Y/N): N Published (Y/N): N	N	Corteva Agriscience (Dow AgroSciences)	-

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	zRMS remarks
KCP 9.2.5	Reeves, G.	2020	FOCUS surface water modelling for halauxifen-methyl and its metabolites following early post-emergence use in winter oilseed rape at 2.5 g as/ha. DAS Report No.: 201599. Dow AgroSciences GLP (Y/N): N Published (Y/N): N	N	Corteva Agriscience (Dow AgroSciences)	-
KCP 9.2.5	Reeves, G.	2020	FOCUS surface water modelling for picloram and its metabolites following early post-emergence use in winter oilseed rape at 12 g as/ha. DAS Report No.: 201600. Dow AgroSciences GLP (Y/N): N Published (Y/N): N	N	Corteva Agriscience (Dow AgroSciences)	-
KCP 9.2.5	Reeves, G.	2020	FOCUS surface water modelling for aminopyralid and its metabolites following early post-emergence use in winter oilseed rape at up to 8 g as/ha. DAS Report No.: 201601. Dow AgroSciences GLP (Y/N): N Published (Y/N): N	N	Corteva Agriscience (Dow AgroSciences)	-

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
As most endpoints for halauxifen-methyl, picloram and aminopyralid as well as their relevant metabolites were taken from the EU review, for the list of respective studies please refer to Volume 2 of the RAR for particular substances.					

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the new Active studies

Comments of zRMS:	<p>The summary of the field dissipation study with picloram was moved from point 8.4.1. The Applicant is kindly reminded that summaries of new active substance studies should be presented in Appendix 2.</p> <p>The study was already agreed by the zRMS (UK) in the course of the Central Zone evaluation of formulation GF-224 SL (Galera, belonging the same Applicant as GF-4021) finalised in 2014 and considered relevant to complement the EU agreed dataset.</p> <p>The comments of the zRMS (UK) listing some uncertainties referenced by the Applicant below are confirmed.</p> <p>Since the study was already agreed in the Central Zone, its re-evaluation was deemed not necessary and is expected to be carried out in the course of the picloram EU renewal process. Until endpoints from the renewal are available, results of this study may be used for purposes of the Tier 2 groundwater modelling for picloram.</p> <p>The evaluation by the Southern Zone zRMS (FR) could not be confirmed since the Core Assessment prepared by France could not be localised on CIRCABC platform. Taking this into account, conclusions of FR are struck through in the Applicants' comments below.</p>
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Reference:	KCA 7.3.1 (8.4.1.2/01)
Report:	Kennedy, S. (2008): Dissipation of picloram in soil following a single application of GF-224 to bare soil, Northern Europe-2007. Dow AgroSciences report no. GHE-P-11837.
Guideline(s):	Directive 95/36/EC, amending Council Directive 91/414/EEC concerning the placement of plant protection products on the market
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Applicants' comments:	<p>This study has already been evaluated by UK in the framework of the evaluation of a formulation in the Central Zone and in the framework of the assessment of another zonal dossier in the Southern Zone (evaluated by France). The evaluator considered the study fully reliable and GLP-compliant. No significant deviations occurred that would affect its validity. Some comments on the study follow:</p> <ul style="list-style-type: none"> - Weather data (maximum and minimum soil temperature and soil moisture) from 11 days in the first few weeks after application at the site CEMS3682A (sandy loam soil) was missing; no explanation was provided. - The actual application rate was 24.7 g as/ha. Given that the soil bulk density was measured at 1.4 g/cm³ and that a 0-10 cm layer was sampled then the theoretical concentration in the soil would be 17.6 µg as/kg. For the two sites the measured concentration immediately after application was 11.4 µg as/kg (CEMS3682A) and 9.7 µg as/kg (CEMS3682B). Measured concentrations were greatest at 14.9 µg as/kg on day 1 (CEMS3682A) and 11.8 µg as/kg on day 5 (CEMS3682B). Although below the theoretical application rate, considering the nature of the study, these values were considered reasonable. <p>Comments from France: The France (as zRMS) checked whether results from this study represent true degradation or dissipation, according to the criteria defined in FOCUS Kinetic guidance, and considered that the new study here could be used for deriving appropriate input parameters for FOCUS modelling.</p>

CITATION

Kennedy, S. (2008), Dissipation of Picloram in Soil Following A Single Application of GF-224 to Bare Soil, Northern Europe – 2007. Dow AgroScience Study number GHE-P-11837. Unpublished. 03-September-2008.

COMPLIANCE

Guideline(s):	EC Directive 95/36/EC
Deviations:	None
Dates of work:	31 July 2007 to 3 September 2008
GLP status:	Yes
Number of pages in final report:	111

METHODOLOGY

Field dissipation studies were conducted for picloram on bare ground test plots at Dollern and Adenstedt, Germany, with application in September 2007. The formulated product was applied as a soluble liquid (SL) containing picloram at a nominal concentration of 67 g a.e./L. The actual application rate after calibration was 24.0 g a.e./ha.

The test sites represent a typical oilseed rape growing region in the Germany. Soil characterisation is given in Table 8.4-6. Soil samples were taken at various time intervals up to 365 days following application of picloram at both sites. The test area consisted of plots (60 m × 3 m) which were divided into four subplots of equal size, each transected by an inclined line. The objective of this design was to enable sampling of soil cores along predefined lines incremented by 100 cm at each sampling time without disturbing the unsampled areas. A sample comprising six soil cores was collected for pre-study characterisation from the trial site prior to test item application. The soil cores were collected to a maximum depth of 30 cm (0 – 7 DAT) and 100 cm immediately adjacent to the plot. The cores were capped at each end and all six were placed in a polythene bag and uniquely labelled. Soil samples were collected pre and post-application and at 1, 3, 5, 7, 28, 40, 60, 90, 120 and 240 days following application.

For chemical analysis, the soil cores were cut into 10 cm horizons. The corresponding depth horizons from each core were then combined to form a composite sample. Analytical method GRM 00.18 (determination of clopyralid and picloram residues in soil by gas chromatography with mass selective detection) was used to analyse the samples for picloram. Horizons were analysed to a depth until a non-detect residue was achieved.

Soil characterisation, density and biomass were taken before application.

Table 8.10-6: Characterisation data for soil used to investigate the field dissipation of picloram

Parameter	Dollern, CEMS 3682A	Adenstedt, CEMS 3682B
pH (H ₂ O)	5.9	6.6
pH (1.0M KCl)	5.6	6.3
Organic carbon (%)	2.2	1.0
Organic matter (%)	3.8	1.7
Sand (0.063 – 2 mm) (%)	76	14
Silt (0.002 – 0.063 mm) (%)	17	66
Clay (<0.002 mm) (%)	7	20
Texture	Sandy loam	Silty clay loam
CEC (meq/100 g)	9.0	11.1
Soil bulk density (g/cm ³)	1.4	1.4

FINDINGS

Soil residues are shown in Tables 8.4-7 and 8.4.-8. Dissipation DT₅₀ values for picloram were reported using best-fit kinetics.

No concentration of picloram was observed above the LOQ below 20 cm. Therefore residues were confined to the upper soil layers and appeared to be immobile. The assay for picloram had a LOQ of 0.5 µg/kg and a LOD of 0.1 µg/kg.

Table 8.10-7: Residues per profile segment, Dollern, CEMS 3682A

Sampling point (DAT)	Picloram in horizon 0 - 10 cm (µg/kg)	Picloram in horizon 10 - 20 cm (µg/kg)	Picloram in horizon 20 - 30 cm (µg/kg)	Picloram in horizon 30 - 40 cm (µg/kg)	Picloram in horizon 40 - 50 cm (µg/kg)
Pre-treatment	ND	ND	-	-	-
0 (post-treatment)	11.4	-	-	-	-
6 hours	12.2	-	-	-	-
1 day	14.9	ND	-	-	-
3 days	13.4	ND	-	-	-
5 days	8.6	ND	-	-	-
7 days	14.2	ND	-	-	-
28 days	8.2	0.79	ND	-	-
42 days	6.2	1.0	ND	-	-
60 days	3.4	2.4	0.27	ND	-
90 days	1.6	1.6	0.37	ND	-
120 days	1.3	1.2	0.44	0.14	ND
240 days	0.61	0.23	ND	ND	ND

Residue values reported on a dry weight basis

Limit of quantification (LOQ) = 0.5 µg/kg

Limit of Detection (LOD) = 20% of LOQ = 0.1 µg/kg

ND = Not Detected = Residue values <0.1 µg/kg

Table 8.10-8: Residues per profile segment, Adenstedt, CEMS 3682B

Sampling point (DAT)	Picloram in horizon 0 - 10 cm (µg/kg)	Picloram in horizon 10 - 20 cm (µg/kg)	Picloram in horizon 20 - 30 cm (µg/kg)	Picloram in horizon 30 - 40 cm (µg/kg)	Picloram in horizon 40 - 50 cm (µg/kg)
Pre-treatment	ND	ND	-	-	-
0 (Post-treatment)	9.7	-	-	-	-
6 hours	5.4	-	-	-	-
1 day	10.9	ND	-	-	-
3 days	10.3	0.17	ND	-	-
5 days	11.8	ND	-	-	-
7 days	8.3	ND	-	-	-
28 days	1.2	0.94	0.18	ND	-
42 days	0.53	0.40	ND	-	-
60 days	0.33	0.18	ND	-	-
90 days	0.29	0.12	ND	-	-
120 days	0.20	0.13	ND	-	-

Residue values reported on a dry weight basis

Limit of quantification (LOQ) = 0.5 µg/kg

Limit of Detection (LOD) = 20% of LOQ = 0.1 µg/kg

ND = Not Detected = Residue values <0.1 µg/kg

CONCLUSION

Picloram was degraded moderately rapidly in the soil under Northern European spring field conditions. Soil cores were taken and analysed to a depth at which no soil residues were found.

Comments of zRMS:	<p>The summary of the kinetic evaluation of the results of field dissipation study with picloram was moved from point 8.4.1. The Applicant is kindly reminded that summaries of new active substance studies should be presented in Appendix 2.</p> <p>The kinetic evaluation for some soil was already agreed by the zRMS (UK) in the course of the Central Zone evaluation of formulation GF-224 SL (Galera, belonging the same Applicant as GF-4021) finalised in 2014 and considered relevant to complement the EU agreed dataset.</p> <p>The comments of the zRMS (UK) referenced by the Applicant were amended by the zRMS in line with the original zRMS review presented in the Core Assessment for GF-224 SL, Part B, Section 5 (2014).</p> <p>Since the kinetic evaluation was already agreed in the Central Zone, its re-evaluation was deemed not necessary and is expected to be carried out in the course of the picloram EU renewal process. Until endpoints from the renewal are available, DT₅₀ of 22.5 days agreed by the zRMS for GF-224 SL may be used for purposes of the Tier 2 groundwater modelling for picloram.</p> <p>The evaluation by the Southern Zone zRMS (FR) could not be confirmed since the Core Assessment prepared by France could not be localised on CIRCABC platform. Taking this into account, conclusions of FR are struck through in the Applicants' comments below.</p>
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Reference:	KCA 7.3.1 (8.4.1.2/02)
Report:	Knowles S. (2008): Calculation of field kinetics for picloram from two additional field dissipation studies and two accepted studies using FOCUS Kinetics methodology and Q ₁₀ value = 2.5. Dow AgroSciences report no. GHE-P-11865.
Guideline(s):	SANCO/10058/2005, version 2.0, June 2006
Deviations:	No
GLP:	No (modelling study)
Acceptability:	Yes
Applicants' comments:	<p>This study has already been evaluated by UK in the framework of the evaluation of a formulation in the Central Zone and in the framework of the assessment of another zonal dossier in the Southern Zone (evaluated by France). France agrees with the UK assessment. The main comments from UK are reproduced below:</p> <p>Normalisation procedure</p> <p>For two sites (Dollern and Adenstedt) soil temperature and moisture data were available for each day of the study. The normalisation was carried out according to FOCUS guidance and is considered acceptable by UK. For the sites in the UK and N. France, only temperature and moisture data for the sampling time-points was available. The Applicant states that 'the timepoint value was applied to the days in between the time-points'. This does not strictly follow FOCUS guidance which states that an average soil temperature for the field trial should be used as a reference temperature and that an average moisture or conservative moisture value should be used. It was noted that the Applicant does not specify if the value applied to days in between time-points was from the time-point before or after these days (trial and error calculations by the evaluator appeared to show that the timepoint before was used). It is also noted that actual temperature and moisture data were not provided, only the correction factors. It was possible to extrapolate temperature and moisture values from these factors and there were large differences in soil temperature between the time-points that would bring into question the validity of the approach to normalization.</p> <p>FOCUS kinetics</p> <p>The Applicant only used SFO kinetics and did not exclude outliers, constrain M₀, weight data, or run any biphasic models, despite some chi² values >15%. This was partly justified</p>

by the statement that the degradation of picloram is simple with no soil metabolites. A visual inspection of the data suggested that fitting would not be improved by biphasic modelling and this proved to be the case when the FOMC model was applied by the evaluator. In general it is expected that field data will be more variable due to the inherent practical challenges such studies present and in these studies there was no systematic pattern to the distribution of the residuals (SFO model). For these reasons the use of SFO kinetics was accepted.

The following conclusions were drawn concerning this study:

- The DT₅₀ from the UK site is rejected because of doubts about the normalisation process, the low number of data points used for kinetic fitting, and the fact that the DT₅₀ from this study was rejected during the Annex I review process due to the number of sampling points where residues of picloram were above the LOQ.
- The DT₅₀ from the N. France site is rejected due to the poor visual fitting because of doubts about the normalisation process.
- The normalisation process and kinetic fitting of the data from the two German sites was considered appropriate and the DT₅₀ values suitable endpoints. Accepted values are summarised below:

Location	Field DT ₅₀ (d)	Field DT ₉₀ (d)
N. Germany (Dollern)	19.6	65.1
C. Germany (Adenstedt)	6.8	22.6

Comments from the UK (general)

The results from four field studies were presented as part of the Annex I submission process. There was one site in Germany, France, Poland, and the UK. No DT₅₀ / DT₉₀ endpoint from the UK site was accepted as the number of sampling times where picloram was above the LOQ was low.

The Applicant decided not to normalise the data from the German and Polish trials because of the presence of minor residues in the lowest horizons. The UK site was not included either since not enough samplings are available. It is the opinion of UK that it would have been appropriate to include data from the German and Polish trials in the normalisation process as they were accepted as part of the Annex I review.

Consequently to the Applicant approach, only two normalised DT₅₀ values are available from the study. Moreover, two non-normalised DT₅₀ values are acceptable from German and Polish trials according to EFSA (2009). The UK considered that enough data are available to acknowledge that field degradation of picloram is faster than in laboratory. Therefore, in order to produce a conservative refined risk assessment for groundwater, a geomean of non-normalised and normalised field DT₅₀ values has been calculated.

Study	Field DT ₅₀ (d)	Remark
Germany	39	Annex I review; not normalised
Poland	49	Annex I review; not normalised
N. Germany (Dollern)	19.6	New study; normalised
C. Germany (Adenstedt)	6.8	New study; normalised
Geomean	22.5	

The geomean (22.5 days) was only slightly longer than the longest normalised DT₅₀ value (19.6 days) and would probably have been shorter using normalized data from the German and Polish trails. This value is considered acceptable by the UK in order to refine the groundwater risk assessment.

Comments from France:

France (as zRMS) considers that the approach proposed by the UK is pragmatic and can be considered acceptable. An additional non-normalized DT₅₀ from the French site could

	have been included in the geomean calculation. However, in order to be consistent with the UK approach, the DT ₅₀ geomean value of 22.5 days is considered acceptable for risk assessments.
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CITATION

Knowles, S., (2008). Calculation of Field Kinetics for Picloram From Two Additional Field Dissipation Studies and Two Accepted Studies Using Focus Kinetics Methodology and Q10 Value = 2.58. Dow AgroSciences Study number GHE-P-11865. Unpublished. 27-October-2008.

COMPLIANCE

Guideline(s):	Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration. The final report of Workgroup on Degradation Kinetics of FOCUS, EC Document Reference SANCO/10058/2005, version 2.0, June 2006
Dates of work:	Completed 27-October-2008
GLP status:	No
Number of pages in final report:	40

METHODOLOGY

In this report the results from the four picloram field studies, have been kinetically modelled using KinGUI software (version 1.1) developed by Bayer CropScience. The field data was normalised by daylength correction using daily moisture and temperature.

FINDINGS

Data from four field sites were assessed using methods outlined by the final report of the Work Group on Degradation Kinetics of FOCUS (FORum for the Co-ordination of pesticide fate models and their USE). Time-course data were normalised with an adjusted day length approach and then the decline of picloram were analysed with the KinGUI kinetic analysis tool. For the parent material, a Single First Order (SFO) model was found to represent the decline data, based on statistical and visual measures of goodness-of-fit.

Normalised data were generated from the two field dissipation studies in Adenstedt, Central Germany and Dollern, Northern Germany. The Central German dataset gave a reduction from 15.0 days to 6.82 days using the normalisation procedure. The Northern German dataset gave a reduction from 54.3 days to 19.4 days. Normalised data were generated using the new Q10 value = 2.58. The normalised DT₅₀ values from two previous studies from UK and France were also recalculated using the new Q10 value = 2.58.

Table 8.10-9: Normalised DT₅₀ values for 4 EU soils

Site Location	Field DT ₅₀ (days) Normalised Q10=2.58, SFO	Field DT ₉₀ (days) Normalised Q10=2.58, SFO	Chi2 error (%)
UK	3.56	11.8	14.3
N.France	4.30	14.3	17.3
N Germany(Dollern)	19.4	64.3	15.4
C Germany (Adenstedt)	6.82	22.6	16.6
geo mean	6.71	22.3	-
arith mean	8.52	-	-
CV %	86.7	-	-

CONCLUSION

The geometric mean for the four normalised EU field DT₅₀ for picloram is 6.71 days. This value is recommended for use in higher tier modelling.

Field dissipation data for picloram from the evaluation above are summarised in the following table.

Table 8.10-10: Summary of degradation rates for picloram - field studies

Location	Soil type (USDA)	pH (water)	Depth (cm)	Persistence				Modelling (20°C/pF2)			Evaluated at EU level
				DissT ₅₀ (d)	DissT ₉₀ (d)	Chi ² (%)	Kinetic model	DT ₅₀ (d)	Chi ² (%)	Kinetic model	
UK	Clay	8.0	20	14*	46*	-	SFO	3.56	14.3	SFO	No (see 8.4.1.2/01 and 8.4.1.2/02)
N France	Clay	7.9	20	20*	66*	-	SFO	4.30	17.3	SFO	
N Germany (Dollern)	Sandy loam	5.9	40	54.3	180	15.0	SFO	19.4	15.4	SFO	
C Germany (Adenstedt)	Silty clay loam	6.6	30	15.0	49.9	18.3	SFO	6.82	16.6	SFO	
Geomean (n=4)								6.71**			
Worst case (n=4)				54.3	180						

* From original field dissipation report

** See comments below

Note that these studies have already been evaluated by the UK RMS in the framework of the evaluation of a picloram formulation in the Central Zone and a new geomean DT₅₀ of **22.5 days** was derived by the UK RMS and proposed for use in a groundwater assessment at **Tier 2**.

Comments of zRMS:	<p>In the comments below the Applicant refers to evaluation of the study by the Southern zRMS (FR). However, the Core Assessment prepared by France could not be localised on CIRCABC platform and quoted below conclusions cannot be confirmed, so they were struck through.</p> <p>Nevertheless, the study was already agreed by the zRMS (UK) in the course of the Central Zone evaluation of formulation GF-224 SL (Galera, belonging the same Applicant as GF-4021) finalised in 2014 and considered relevant to replace the EU dataset since only K_{doc} values were derived at the EU level and default 1/n was used in exposure assessment. Conclusions of the zRMS (UK) presented in the Core Assessment, Part B, Section 5 (2014) are reproduced below:</p> <div style="border: 1px solid black; padding: 10px;"> <p><i>The evaluator considered the study fully reliable with regards to the adsorption aspects of the study (GLP-compliant and fully compliant with the OECD test guideline 106).</i></p> <p><i>The K_{FOC} and 1/n values reported in Table 9.3/1-2 were independently checked by the evaluator and agreed.</i></p> <p><i>No significant deviations occurred that would affect the validity of the study but the following comments were made:</i></p> <ul style="list-style-type: none"> <i>The calculation described to give the concentration of the treatment solution for the adsorption phase appears to be incorrect. The data provided suggest that the treatment solution was the correct concentration therefore this part of the study was accepted by the evaluator.</i> <i>There was evidence of increasing adsorption for some soils after 48 h. However it was accepted by the evaluator that 48 h was an appropriate equilibrium time.</i> <i>No details of the centrifugation procedure were given. The conditions should be such that particles larger than 0.2 µm are removed from the supernatant.</i> <p><i>Since the original Annex I studies only measured K_d (not K_f) the UK RMS accepted this new study as being appropriate to replace the Annex I data. This was considered appropriate rather than combining the two data sets (note: combining studies measuring K_d and K_f would be problematic).</i></p> </div>
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	The summary of the study was not included by the Applicant in dRR for GF-4021, however it is considered necessary since the study was not re-evaluated and above conclusions of the zRMS (UK) are applicable also for evaluation of GF-4021.
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Reference:	KCA 7.4.1 (8.5/01)
Report:	Simmonds, M. (2010): [¹⁴ C]-Picloram: Adsorption to and desorption from five soils. Battelle report no. YR/09/010.
Guideline(s):	OECD guideline for the testing of chemicals No. 106
Deviations:	No
GLP:	Yes
Acceptability:	Yes
Applicants' comments:	<p>This study has already been evaluated in the framework of the assessment of another zonal dossier in the Southern Zone (by France). The main comments are reproduced below:</p> <p>The study is acceptable and performed according to relevant guidance. The results can be used in the risk assessment and can supersede the EU agreed endpoints determined at 1 concentration only.</p> <p>K_{foc} (arithmetic mean) = 23.4 mL/g; K_{foc} (geomean) = 19.6 mL/g;</p> <p>1/n (Arithmetic mean) = 0.858</p>

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

A3.1 Predicted environmental concentrations in soil (PEC_{soil}) (KCP 9.1.3)

Comments of zRMS:	<p>The below equations for calculation of soil exposure are in line with recommendations of respective FOCUS methodology.</p> <p>For comments on the calculated PEC_{SOIL} values, please refer to point 8.7 of this report.</p>
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Initial PEC_{soil} values

The initial PEC_{soil} of the active substance is calculated according to Equation 1:

Equation 1
$$PEC_{soil,ini,1} = \frac{(A_1 - (A_1 \times p_1)) \times 10}{d \times bd}$$

Where:

PEC _{soil,ini,1}	= initial concentration in soil after single application (mg/kg)
A	= application rate of the active substance (g/ha)
p ₁	= fraction intercepted by the crop canopy
d	= mixing depth (5 cm)
bd	= soil bulk density (1.5 g/cm ³)

The initial PEC_{soil} of the active substance after n applications is calculated according to Equation 2 considering degradation between the applications:

Equation 2
$$PEC_{soil,ini,n} = PEC_{soil,ini,n-1} \times e^{-k \times (t_n - t_{n-1})} + \frac{(A_n - (A_n \times p_n)) \times 10}{d \times bd}$$

The maximum PEC_{soil} of the metabolite is calculated with the same equation but considering a pseudo-application rate, taking into account the molar mass difference between parent and metabolite and the maximum occurrence of the metabolite in soil.

The actual and time-weighted average concentrations of the compounds are calculated according to Equation 3 and Equation 4, respectively:

Equation 3
$$PEC_{soil,act,t} = PEC_{soil,ini,n} \times e^{-k \times t}$$

Where:

PEC _{soil,act,t}	= actual PEC _{soil} at time t after initial/maximum PEC _{soil} (mg/kg)
PEC _{soil,ini,n}	= initial/maximum PEC _{soil} after n applications (mg/kg)
k	= first order degradation/dissipation rate constant in soil (ln(2)/DT ₅₀) (1/d)
t	= time after initial/maximum PEC _{soil} (d)

Equation 4
$$PEC_{soil,twa,t} = \frac{PEC_{soil,ini,n} \times (1 - e^{-k \times t})}{k \times t}$$

Where:

PEC _{soil,twa,t}	= time-weighted average PEC _{soil} over t days (mg/kg)
PEC _{soil,ini,n}	= initial/maximum PEC _{soil} after n applications (mg/kg)
k	= first order degradation/dissipation rate constant in soil (ln(2)/DT ₅₀) (1/d)
t	= time after initial/maximum PEC _{soil} (d)

Plateau Concentration

In addition to the seasonal PEC_{soil} calculations, the potential accumulation in soil following repeated annual applications of the formulation was calculated. The accumulation potential can be described with the $PEC_{accumulation}$, which is the sum of the $PEC_{soil,ini,n}$ and the plateau concentration directly before the application in the next season ($PEC_{soil\ plateau}$). The calculation of $PEC_{soil\ plateau}$ and $PEC_{accumulation}$ is described in Equation 5 and Equation 6.

Equation 5
$$PEC_{soil\ plateau} = \frac{PEC_{soil,ini,d}}{(1 - e^{-k \times 365})} \times e^{-k \times (365 - (n_a - 1) \times i_a)}$$

Where:

- $PEC_{soil\ plateau}$ = plateau concentration directly before the application in the next season (mg/kg)
- $PEC_{soil,ini,d}$ = $PEC_{soil,ini}$ on last application day with soil parameters for accumulation (20 cm/5 cm soil depth; ploughing considered/not considered between seasons) (mg/kg)
- k = degradation rate (1/d)
- n_a = number of applications
- i_a = interval between applications (d)

Equation 6
$$PEC_{accumulation} = PEC_{soil\ plateau} + PEC_{soil,ini,n}$$

Where:

- $PEC_{accumulation}$ = accumulation PEC_{soil} (mg/kg)
- $PEC_{soil,ini,n}$ = initial PEC_{soil} in one season considering a soil depth of 5 cm (mg/kg)
- $PEC_{soil\ plateau}$ = plateau PEC_{soil} (concentration directly before the first application in the next season) considering a soil depth of 20 cm/5 cm (ploughing considered/not considered between seasons) (mg/kg)