

REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: ADM.01851.H.1.A

Product name(s): see Part A

Chemical active substances:

Ethofumesate, 500 g/L

Clopyralid, 75 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Country organisation / representative of ADAMA,
as given in Part A

Submission date: July 2024

MS Finalisation date: February 2025 (initial Core Assessment)

June 2025 (final Core Assessment)

Version history

When	What
July 2024	dRR version 1 submitted by applicant
February 2025	Initial assessment by the zRMS The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through~~ and ~~shaded~~ for transparency.
June 2025	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments received from the CMS and the Applicant are highlighted in yellow. Not agreed or not relevant information are ~~struck through~~ and ~~shaded~~ for transparency.

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8 Fate and behaviour in the environment (KCP 9)

8.1 Critical GAP and overall conclusions

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/or situ- ation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Sugar beet BEAVA Fodder beet BEAVC	F	annual dicot weeds and annual grass weeds	foliar spraying, overall	BBCH 10- 19/ March- June	a) 3 b) 3	a) 5 b) 5	a) 0.66 L/ha b) 1.98 L/ha	a) 330 g ethofumesate/ha 49.5 g clopyra- lid/ha b) 990 g ethofumesate/ha 148.5 g clopyralid/ha	100-400	n.a.	Total rate per season 2 L/ha Max. rate of ethofumesate should not exceed 1.0 kg/ha every 2 year ever-3 years Max. rate of clopyralid should not exceed 150 g/ha every 2 years	R Biennial application

* 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

zRMS comments:

It the GAP table above following uncertainty was corrected by the zRMS. For application to sugar beet at BBCH 10-19 at maximum application rate of 1.98 L product/ha per season the zRMS corrected the application frequency. According to groundwater assessment formulation ADM.01851.H.1.A may be applied every second year and not as previously stated every third year, and maximum rate of clopyralid should not exceed 150 g/ha every 2 year, thus, the zRMS added respective information in table above. For more details please refer to the commenting box under the point 8.8.

Table 8.1-2: Assessed (critical) uses during approval of ethofumesate concerning the Section Environmental Fate (Ethofumesate Task Force)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	NEU/SEU	Sugar beet, fodder beet, red beet	F	Annual dicot weeds and annual grasses	Overall spray	Post emergence BBCH 16-18	3	5	0.2-1	200-1000	100-400	n/a	The max. amount of a.s. must not exceed 1.0 kg/ha every 3 years

* 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 ethofumesate concerning the Section Environmental Fate (UPL)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	NEU/CEU/SEU	Sugar beet, fodder beet	F	Annual weeds	Overall spray	Pre-emergence	1	n/a		1000	300-400	n/a	The max. amount of a.s. must not exceed 1.0 kg/ha every 3 years
2	NEU/CEU/SEU	Sugar beet, fodder beet	F	Annual weeds	Overall spray	Post emergence until BBCH 18	6	5		160***	200-300	n/a	The max. amount of a.s. must not exceed 1.0 kg/ha every 3 years

- * 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
- *** Splitting application with a maximum total rate of 1 kg a.s./ha per season. The maximum application rate per treatment is 0.33 kg a.s./ha. The critical GAP therefore is 3 applications of 0.33 kg a.s./ha. More applications (max.6) at a lower application rate are possible, but they do not represent the critical GAP.

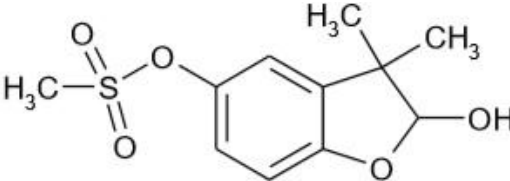
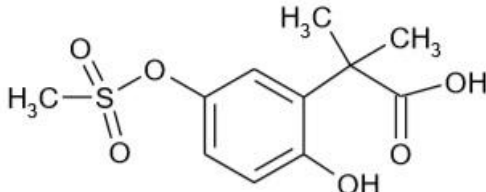
Table 8.1-4: Assessed (critical) uses during approval of clopyralid concerning the Section Environmental Fate

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap- plications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	CEU/SEU	Winter cereals	F	Broad-leaf weeds	Overall broad- cast foliar spray	BBCH 13- 39 (1 st Feb – 30 th Jun)	1	n/a	1	80	80-400	n/a	Treated straw must not be used for compost produc- tion
2	CEU/SEU	Established grassland	F	Broad-leaf weeds	Overall broad- cast foliar spray	1 st Feb – 30 th Sep	1	n/a	1.5	120	100-400	7-14	PHI 7 days for CEU and 14 days for SEU. Do not use treated plant material for composting. Do not use manure from animals fed with treated plants on or before planting of crops.

- * Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
- ** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

8.2 Metabolites considered in the assessment

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

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
NC 8493	258.3		Soil: 24.2%	PEC _{gw} PEC _{soil} PEC _{sw/sea}
NC 20645	274.3		Water/Sediment: 18.8%	PEC _{gw} (potential formation from NC 8493) PEC _{sw/sea}

There are no metabolites of clopyralid relevant for exposure assessment.

zRMS comments:

Information regarding metabolites of ethofumesate is in line with EU agreed endpoints reported in EFSA Journal 2016;14(1):4374.
No relevant metabolites of clopyralid are formed in soil or aquatic systems according to EFSA Journal 2018;16(7):5389.

8.3 Rate of degradation in soil (KCP 9.1.1)

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

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 Ethofumesate and its metabolites

The aerobic degradation of ethofumesate in soil was evaluated during the active substance renewal assessment, EFSA Journal 2016;14(1):4374. The aerobic degradation of metabolites NC8493 and NC20645 were also investigated. Degradation rates for these three substances are summarised in the tables below.

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

Ethofumesate, Laboratory studies, aerobic conditions										
Soil name	Soil type	pH (CaCl ₂)	t.oC	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa ^a	Chi2 (%)	Kinetic model	Evaluated on EU level y Reference
Abington	Sandy loam	7.0	25	75 (of WHC at 33 kPa)	137	454	208	5.8	SFO	EFSA 2016; 14(1):4374
Terling	Loam/ Silt loam	5.8	25	75 (of WHC at 33 kPa)	68.7	228	80.5	3.0	SFO	EFSA 2016; 14(1):4374
AX	Sandy loam	6.1	20.7	55	28.5	94.7	30.4	5.1	SFO	EFSA 2016; 14(1):4374

Ethofumesate, Laboratory studies, aerobic conditions										
Soil name	Soil type	pH (CaCl ₂)	t.oC	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa ^a	Chi2 (%)	Kinetic model	Evaluated on EU level y Reference
HF	Silt loam	6.5	20.7	55	19.4	64.4	20.5	3.3	SFO	EFSA 2016; 14(1):4374
WW	Sandy loam	5.4	20.7	55	19.7	65.6	21.1	5.3	SFO	EFSA 2016; 14(1):4374
DD	Clay loam	7.2	20.7	55	19.1	63.6	20.4	2.0	SFO	EFSA 2016; 14(1):4374
Lufa 2.2	Sand	5.8	20	40	69.9	232	69.9	15.4	SFO	EFSA 2016; 14(1):4374
Fislis	Silt loam	6.82	20	pF 2.5	16.0	53.0	14.1	2.2	SFO	EFSA 2016; 14(1):4374
Horn	Loam	7.23	20	pF 2.5	9.4	31.2	8.5	6.2	SFO	EFSA 2016; 14(1):4374
Montesquieu	Clay	7.37	20	pF 2.5	20.4	67.8	17.9	4.8	SFO	EFSA 2016; 14(1):4374
Sevelen	Sandy loam	7.51	20	pF 2.5	11.7	38.7	9.3	3.4	SFO	EFSA 2016; 14(1):4374
Mussbach	Loam	7.21	20	50	17.72	58.86	15.2	6.0	SFO	EFSA 2016; 14(1):4374
Lufa 5.2	Sandy loam	7.3	20	50	15.36	51.01	14.5	6.9	SFO	EFSA 2016; 14(1):4374
Lufa 2.2	Loamy sand	5.5	20	50	12.78	42.47	12.8	7.9	SFO	EFSA 2016; 14(1):4374
UK1	Clay loam	6.80	20	50	25.52	84.79	25.5	6.5	SFO	EFSA 2016; 14(1):4374
UK2	Sandy loam	6.83	20	50	23.29	77.37	23.3	3.5	SFO	EFSA 2016; 14(1):4374
North France	Loam	7.41	20	50	13.63	45.28	11.4	9.6	SFO	EFSA 2016; 14(1):4374
Austria	Silt loam	7.14	20	50	12.53	41.61	12.5	4.5	SFO	EFSA 2016; 14(1):4374
Spain	Silt loam	7.38	20	50	17.27	57.36	15.5	4.1	SFO	EFSA 2016; 14(1):4374
Geometric mean (n=19)							21.6			
pH-dependency							No			

^a Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

Table 8.3-2: Summary of aerobic degradation rates for NC8493 - laboratory studies

NC8493, Laboratory studies, aerobic conditions										
Soil name	Soil type	pH (CaCl ₂)	t.oC	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa ^a	Chi2 (%)	Kinetic model	Evaluated on EU level y Reference
Fislis	Silt loam	6.82	20	pF 2.5	0.05	0.18	0.04	27.2	SFO	EFSA 2016; 14(1):4374
Horn	Loam	7.23	20	pF 2.5	0.07	0.24	0.06	10.5	SFO	EFSA 2016; 14(1):4374
Sevelen	Sandy loam	7.51	20	pF 2.5	0.05	0.17	0.04	21.1	SFO	EFSA 2016; 14(1):4374
AX	Sandy loam	5.5	20	55	0.02	0.07	0.02	5.1	SFO	EFSA 2016; 14(1):4374
HH	Silt loam	6.1	20	55	0.02	0.07	0.02	1.4	SFO	EFSA 2016; 14(1):4374
DD	Clay loam	7.2	20	55	0.01	0.03	0.01	1.4	SFO	EFSA 2016; 14(1):4374
WW	Sandy	5.0	20	55	0.02	0.06	0.06 ^b	2.2	DFOP	EFSA 2016;

NC8493, Laboratory studies, aerobic conditions										
Soil name	Soil type	pH (CaCl ₂)	t.oC	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa ^a	Chi2 (%)	Kinetic model	Evaluated on EU level y Reference
	loam									14(1):4374
Geometric mean (n=7)							0.03			
pH-dependency							No			

^a Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

^b Calculated from slow-phase degradation constant where k₁ = 76.44, k₂ = 12.59 and g = 0.5346

Table 8.3-3: Summary of aerobic degradation rates for NC20645 - laboratory studies

NC20645, Laboratory studies, aerobic conditions										
Soil name	Soil type	pH (CaCl ₂)	t.oC	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa ^a	Chi2 (%)	Kinetic model	Evaluated on EU level y/n Reference
AX	Sandy loam	5.9	20	55	0.11	0.40	0.11	7.1	SFO	EFSA 2016; 14(1):4374
HH	Silt loam	6.1	20	55	0.08	0.25	0.08	3.0	SFO	
DD	Clay loam	7.0	20	55	0.15	0.52	0.15	5.3	SFO	
WW	Sandy loam	5.2	20	55	0.05	0.30	0.17 ^b	0.0001	DFOP	
Geometric mean (n=4)							0.12			
pH-dependency							No			

^a Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

^b Calculated from slow-phase degradation constant

zRMS comments:

Soil degradation data for ethofumesate and its metabolites presented in Tables 8.3-1 to 8.3-3 are in line with EU agreed endpoints reported in EFSA Journal 2016;14(1):4374.

Additional information of the photodegradation of ethofumesate in soil has been presented in the table below:

Soil name	Soil type	pH (CaCl ₂)	t.(°C)	MWHC (%)	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	St. (χ ²)	Kinetic model	Evaluated on EU level y/n/ Reference
Not provided	Silt loam	6.5	20	50	94.2	313	n/s	9.9	SFO	Y, EFSA, 2016

8.3.1.2 Clopyralid

The aerobic degradation of clopyralid in soil was evaluated during the active substance renewal assessment, EFSA Journal 2018;16(7):5389. Degradation rates are summarised in the table below.

Table 8.3-4: Summary of aerobic degradation rates for clopyralid - laboratory studies

Clopyralid, Laboratory studies, aerobic conditions										
Soil name	Soil type	pH (H ₂ O)	t.oC	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa ^a	Chi2 (%)	Kinetic model	Evaluated on EU level y Reference
Parabraunerde	silt loam	7.7	20	18.63 ^b	44.4	147.3	34.2	6.796	SFO	EFSA 2018; 16(7):5389
Marcham	sandy clay loam	8.3	20	20.19 ^b	34.5	114.7	32.4	5.478	SFO	EFSA 2018; 16(7):5389
Castle Rising	sandy loam	8.0	20	65.13 ^b	26.3	873	26.3	8.284	SFO	EFSA 2018; 16(7):5389

Clopyralid, Laboratory studies, aerobic conditions										
Soil name	Soil type	pH (H ₂ O)	t.oC	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa ^a	Chi2 (%)	Kinetic model	Evaluated on EU level y Reference
Speyer 2.1	sand	6.5	20	12.58 ^b	64.6	214.6	64.6	5.466	SFO	EFSA 2018; 16(7):5389
Speyer 2.2	sand	6.3	200	18.56 ^b	16.2	53.8	16.2	7.78	SFO	EFSA 2018; 16(7):5389
Marshall County	silt loam	6.0	25	23.42 ^c	8.6	28.5	11.6	6.49	SFO	EFSA 2018; 16(7):5389
A	sandy loam	6.2	20	24.28 ^d	16.5	54.8	16.5	4.856	SFO	EFSA 2018; 16(7):5389
B	clay loam	7.6	20	28.05 ^d	23.0	76.4	23.0	.6767	SFO	EFSA 2018; 16(7):5389
C	clay loam	5.6	20	48.17 ^d	4.9	16.2	4.9	12.73	SFO	EFSA 2018; 16(7):5389
D	loam	7.5	20	35.30 ^d	9.8	32.4	9.8	10.17	SFO	EFSA 2018; 16(7):5389
Geometric mean (n=10)							19.1			
pH-dependency							No			

^a Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

^b Reported soil moisture: 40% of maximum WHC

^c Reported soil moisture: 75% of 1/3 bar WHC

^d Reported soil moisture: 45% WHC

zRMS comments:

Soil degradation data for clopyralid presented in Table 8.3-1 are in line with the EU agreed endpoint reported in EFSA Journal 2018;16(7):5389.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

8.3.2.1 Ethofumesate

The anaerobic degradation of ethofumesate in soil was evaluated during the active substance renewal assessment, EFSA Journal 2016;14(1):4374. The degradation rates are summarised in the table below.

Table 8.3-5: Summary of anaerobic degradation rates for ethofumesate - laboratory studies

Ethofumesate, Laboratory studies, anaerobic conditions										
Soil name	Soil type	pH	t.(°C)	MWHC (%)	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa ^a	St. (χ ²)	Kinetic model	Evaluated on EU level y Reference
Not provided	Sandy loam	7.6	25	75 (of WHC at 33 kPa)	1000	1000	1000	n/a	SFO	EFSA 2016; 14(1):4374
Geometric mean (n=1)							1000			

^a Normalised using a Q10 of 2.58

zRMS comments:

Anaerobic soil degradation data for ethofumesate are in line with the EU agreed endpoints reported in EFSA Journal 2016;14(1):4374.

8.3.2.2 Clopyralid

The anaerobic degradation of clopyralid in soil was evaluated during the active substance renewal assessment, EFSA Journal 2018;16(7):5389. Degradation rates are summarised in the table below.

Table 8.3-6: Summary of anaerobic degradation rates for clopyralid - laboratory studies

Clopyralid, Laboratory studies, anaerobic conditions										
Soil name	Soil type	pH (CaCl ₂)	t.(°C)	MWHC (%)	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa ^a	St. (χ ²)	Kinetic model	Evaluated on EU level y Reference
Not provided	Sandy loam	7.4	20	Flooded	>365	>365	>365	n/a	SFO	EFSA 2018; 16(7):5389
Geometric mean (n=1)							>365			

^a Normalised using a Q10 of 2.58

zRMS comments:

Anaerobic soil degradation data for clopyralid according to the EU agreed endpoints as reported in EFSA Journal 2018;16(7):5389 is longer than a year and no major metabolites were detected.

8.4 Field studies (KCP 9.1.1.2)

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

8.4.1.1 Ethofumesate

Field dissipation studies were evaluated during the active substance renewal assessment, EFSA Journal 2016;14(1):4374. The degradation rates are summarised in the table below.

Table 8.4-1: Summary of aerobic degradation rates for Ethofumesate - field studies

Ethofumesate, Field studies									
Soil type	Location	pH ^(a)	Depth (cm)	DT50 (d) actual	DT90 (d) actual	DT50 (d) Norm ^b	St. (χ^2)	Method of calculation	Evaluated on EU level y Reference
Loamy silt (Mainz A)	Germany	7.5	0-30	116	384	69.5	13.3	SFO	EFSA 2016; 14(1):4374
Loamy silt (Mainz B)	Germany	7.5	0-30	114	379	47.4	11.3	SFO	EFSA 2016; 14(1):4374
Loamy silt (Mainz A/B)	Germany	7.5	0-30	-	-	57.4 ^d	-	SFO	EFSA 2016; 14(1):4374
Silty sand (Speyer A)	Germany	6.7	0-30	21 $\alpha=0.004$ $\beta=0.05$	333	- 47.2 ^c	12.5 -	FOMC DFOP	EFSA 2016; 14(1):4374
Silty sand (Speyer B)	Germany	6.7	0-30	13.6 $k_1=0.09528$ $k_2=0.00772$ $g=0.6392$	166	46.5 ^c	3.9	DFOP	EFSA 2016; 14(1):4374
Loamy sand (Isleham)	UK	7.5	0-30	59	196	25.7	12.3	SFO	EFSA 2016; 14(1):4374
Sandy clay loam (Willingham)	UK	7.5	0-30	44	147	18.0	22	SFO	EFSA 2016; 14(1):4374
Sandy loam (Fresno)	California	6.5	0-90	89	295	-	20.7	SFO	EFSA 2016; 14(1):4374
Clay loam (Northwood)	North Dakota	7.3	0-90	1000	-	-	-	SFO	EFSA 2016; 14(1):4374
Sand (Weeze)	Germany	5.8	0-30	157	522	75.7	15.0	SFO	EFSA 2016; 14(1):4374
Sandy loam (Nierswalde)	Germany	3.5	0-30	1000	-	-	-	SFO	EFSA 2016; 14(1):4374
Clay loam (NZ11007/1)	UK	7.13	0-30	21.6	72	15.2	16	SFO	EFSA 2016; 14(1):4374
Silty clay loam (NZ11007/2)	Germany	7.57	0-30	10.2	74	13.5	4.1	SFO	EFSA 2016; 14(1):4374
Silty clay loam (NZ11007/3)	France	7.72	0-30	35.9 $k_1=0.03878$ $k_2=0.003795$ $g=0.5968$	367	110 ^c	6.1	DFOP	EFSA 2016; 14(1):4374
Loam (NZ11007/4)	Spain	7.7	0-30	12.3 $k_1=0.1805$ $k_2=0.00662$ $g=0.0518$	237	60 ^c	12.0	DFOP	EFSA 2016; 14(1):4374
Geometric mean (n=12)							37.8		
pH-dependency							No		

^a Solute in which the pH was measured was not reported

^b Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix

^c Modelling endpoint derived from slow-phase degradation constant

^d Geomean of the paired trials Mainz A and Mainz B to be used for exposure assessment

Modelling endpoints

A combined laboratory and field kinetic soil DT₅₀ for modelling of the active substance ethofumesate is provided in the EFSA conclusion, EFSA 2016;14(1):4374. A geomean value of 26.2 days was calculated with normalisation to 10 kPa or pF₂, 20 °C with Q₁₀ of 2.58 and Walker equation coefficient 0.7.

zRMS comments:

Field degradation data for ethofumesate presented in Table 8.4-1 are in line with the EU agreed endpoints reported in EFSA Journal 2016;14(1):4374.

Please note that in line with EFSA conclusion (EFSA 2016; 14(1):4374) a combined laboratory and field geomean DT₅₀ value of 26.2 days should be used for modelling purposes.

8.4.1.2 Clopyralid

Field dissipation studies were evaluated during the active substance renewal assessment, EFSA Journal 2018;16(7):5389. The degradation rates are summarised in the table below.

Table 8.4-2: Summary of aerobic degradation rates for Clopyralid - field studies: Triggering endpoints

Clopyralid, Field studies									
Soil type	Location	pH ^(a)	Depth (cm)	DT50 (d) actual	DT90 (d) actual	DT50 (d) Norm ^b	St. (χ ²)	Method of calculation	Evaluated on EU level y Reference
Loamy sand (bare)	Bargstedt, Germany	4.3	0-100	21.0	69.6	13.0	23.9	SFO	EFSA 2018; 16(7):5389
Loam (bare)	Wilson, UK	6.2	0-100	16.7	55.6	13.5	22.6	SFO	EFSA 2018; 16(7):5389
Silty clay loam (bare)	Sermaises, France	7.0	0-100	16.3	54.0	7.50	19.3	SFO	EFSA 2018; 16(7):5389
Silty clay loam (bare)	Ansonville, France	8.2	0-20	0.16	12.1	2.07	5.36	DFOP/ SFO Norm	EFSA 2018; 16(7):5389
Clay loam (bare)	Mainbervilliers, France	7.1	0-20	6.04	28.3	2.70	7.22	DFOP/ SFO Norm	EFSA 2018; 16(7):5389
Silty clay loam (bare)	Oederquart, Germany	7.5	0-20	16.2	53.9	5.69	12.0	SFO	EFSA 2018; 16(7):5389
Sandy clay loam (bare)	Middlefart, Denmark	7.5	0-20	23.7	78.7	8.46	13.1	SFO	EFSA 2018; 16(7):5389
Clay loam (bare)	Canals, Spain	8.0	0-100	13.7	45.5	12.3	19.2	SFO	EFSA 2018; 16(7):5389
Silty clay loam (bare)	B. Württemberg, Germany	7.4 ^c	0-100	10.2	33.9	9.34	7.94	SFO	EFSA 2018; 16(7):5389
Silt loam (bare)	B. d'Islemaide, France	7.3 ^c	0-100	9.11	30.3	7.41	17.6	SFO	EFSA 2018; 16(7):5389
Geometric mean (n=10)							7.05		
pH-dependency							No		

^a Measured in water

^b Normalised using a Q₁₀ of 2.58 and Walker equation coefficient of 0.7, values are DegT₅₀matrix

^c 0-30cm

Modelling endpoints

In accordance with EFSA Journal 2018;16(7):5389, laboratory and field kinetic endpoints for modelling are from different populations according to EFSA calculator tool. The field geometric mean value of 7.05 (d) will be used for modelling groundwater concentrations.

zRMS comments:

Field degradation data for clopyralid presented in Table 8.4-2 are in line with EU agreed endpoints reported in EFSA Journal 2018;16(7):5389.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

In the EFSA conclusion, EFSA Journal 2016;14(1):4374, a plateau concentration was calculated of 0.003 mg ethofumesate/kg soil reached after 50 years.

In the EFSA conclusion, EFSA Journal 2018;16(7):5389, it was concluded that soil accumulation and plateau concentration calculation was not relevant for clopyralid since the trigger was not exceeded.

zRMS comments:

Provided above information for ethofumesate is in line with data reported in EFSA Journal 2016;14(1):4374.

According to EFSA Journal 2018;16(7):5389, studies on field degradation of clopyralid is not required.

8.5 Mobility in soil (KCP 9.1.2)

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

8.5.1 Ethofumesate and its metabolites

The adsorption/desorption of ethofumesate in soil was evaluated during the active substance renewal assessment, EFSA Journal 2016;14(1):4374. The soil adsorption/desorption of metabolites NC8493 and NC20645 were also investigated. The results for these three substances are summarised in the tables below.

Table 8.5-1: Summary of soil adsorption/desorption for Ethofumesate

Ethofumesate							
Soil name	Soil type	OC (%)	pH (CaCl ₂)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y Reference
Mueller	Podsol	1.5	6.1	3.7	247	0.96	EFSA 2016; 14(1):4374
Mueller	Parabraunerde	1.1	7.6	1.1	100	0.91	EFSA 2016; 14(1):4374
Mueller	Light sand	1.5	6.7	3.0	200	0.94	EFSA 2016; 14(1):4374
Bruhl	Sandy loam	1.16	6.0	1.13	97	0.84	EFSA 2016; 14(1):4374
Cameron	Sand	1.12	4.6	0.7	63	0.92	EFSA 2016; 14(1):4374
Cameron	Acidic sandy loam	1.45	5.7	0.7	48	0.92	EFSA 2016; 14(1):4374
Cameron	Alkaline sandy loam	1.66	7.3	0.8	48	0.93	EFSA 2016; 14(1):4374
Icklingham	Sand	0.35	6.8	0.73	209	0.87	EFSA 2016; 14(1):4374
Abington	Sandy loam	1.9	7.4	2.3	121	0.93	EFSA 2016; 14(1):4374
Terling	Silt clay loam	3.2	6.6	5.3	166	0.89	EFSA 2016; 14(1):4374
Shelford	Clay	4.9	6.6	6.2	127	0.82	EFSA 2016; 14(1):4374

Ethofumesate							
Soil name	Soil type	OC (%)	pH (CaCl ₂)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y Reference
UPL	Loamy sand	1.41	7.3	2.6	187	0.93	EFSA 2016; 14(1):4374
Geometric mean (n=12)				1.74	118		
Arithmetic mean (n=12)						0.905	
pH-dependency				No			

A study to determine the adsorption/desorption characteristics of NC8493 was presented in the active substance renewal dossier. However, the test substance was not stable in soil/water, therefore no endpoints could be determined. A Kdoc value of 20.82 mL/g for modelling was calculated using EPI WIN and reported in the EFSA Conclusion. This should be used with a worst case 1/n of 1.

Table 8.5-2: Summary of soil adsorption/desorption for NC20645

NC20645							
Soil Name	Soil Type	OC (%)	pH (CaCl ₂)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y Reference
HH	Silt loam	2.9	6.3	0.12	4.3	0.93	EFSA 2016; 14(1):4374
DD	Loam	4.4	7.3	0.16	3.7	0.91	EFSA 2016; 14(1):4374
CA	Sandy loam	0.7	6.7	0.03	4.3	0.87	EFSA 2016; 14(1):4374
NE	Silt loam	1.7	6.6	0.17	10.0	0.99	EFSA 2016; 14(1):4374
Geometric mean (n=4)				0.10	5.1		
Arithmetic mean (n=4)						0.93	
pH-dependency				No			

zRMS comments:

Soil mobility data for ethofumesate and its metabolites presented in Tables 8.5-1 to 8.5-2 are in line with EU agreed endpoints reported in EFSA Journal 2016;14(1):4374.

8.5.2 Clopyralid

The adsorption/desorption of clopyralid in soil was evaluated during the active substance renewal assessment, EFSA Journal 2018;16(7):5389. The results are summarised in the table below.

Table 8.5-3: Summary of soil adsorption/desorption for Clopyralid

Clopyralid							
Soil name	Soil type	OC (%)	pH (CaCl ₂)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y Reference
Merzenhausen	Not provided	1.00	7.19	0.0057	0.57	0.9 ^a	EFSA 2018; 16(7):5389
Kaldenkirchen	Not provided	0.98	5.34	0.0267	2.72	0.9 ^a	EFSA 2018; 16(7):5389
Lanna	Not provided	2.06	6.62	0.0054	0.26	0.9 ^a	EFSA 2018; 16(7):5389
Overhelfeld	Not provided	0.93	6.49	0.0125	1.34	0.9 ^a	EFSA 2018; 16(7):5389

Clopyralid							
Soil name	Soil type	OC (%)	pH (CaCl ₂)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y Reference
Calke	Sandy loam	3.15	5.7	0.01	0.5	0.489	EFSA 2018; 16(7):5389
Longwoods	Sandy loam	3.13	7.4	0.08	2.5	0.9 ^a	EFSA 2018; 16(7):5389
LUFA 2.1	Loamy sand	0.68	4.9	0.03	4.1	0.9 ^a	EFSA 2018; 16(7):5389
Quilen	Loam	4.02	6.9	0.16	3.9	0.804	EFSA 2018; 16(7):5389
DU-L-PF	Clay loam	6.47	6.3	0.14	2.1	0.829	EFSA 2018; 16(7):5389
Geometric mean (n=9)				0.026	1.41		
Arithmetic mean (n=9)						0.836	
pH-dependency				No			

^a For modelling each soil was checked against OECD 106 reliability criterion ($K_d > 0.1$ for direct method and $K_d > 0.3$ for indirect method). Freundlich coefficient of soils not meeting the criteria was set to 0.9.

zRMS comments:

Soil mobility data for clopyralid presented in Table 8.5-1 are in line with the EU agreed endpoints reported in EFSA Journal 2018;16(7):5389.

8.5.3 Column leaching (KCP 9.1.2.1)

Not required as valid adsorption studies are available for both ethofumesate and clopyralid.

zRMS comments:

According to information provided in EFSA Journal 2016;14(1):4374 and EFSA Journal 2018;16(7):5389, no reliable data from column leaching studies were available for ethofumesate and clopyralid, respectively. However, these data are not necessary for purposes of the zonal evaluation of ADM.01851.H.1.A since the leaching potential of ethofumesate and clopyralid and their metabolites has been sufficiently addressed in the groundwater modelling presented in point 8.8.

8.5.4 Lysimeter studies (KCP 9.1.2.2)

Lysimeter studies were submitted as part of the active substance assessment of ethofumesate. Studies were carried out for two years in the UK and Switzerland. All chromatographically resolved substances in the leachate accounted for $< 0.1 \mu\text{g/L}$, with the exception of one study in Bedfordshire, UK where one substance accounted for $0.41 (1^{\text{st}} \text{ year})$ and $0.5 \mu\text{g parent/L} (2^{\text{nd}} \text{ year})$. This substance was identified as a mixture of NC8493-glycoside and NC20645-glycoside.

Lysimeter studies were submitted as part of the active substance assessment of clopyralid. The details provided in EFSA Journal 2018;16(7):5389 are presented below.

1) Germany, spring application of 150 or 200 g clopyralid/ha on oilseed rape + partly a second application of 125 g a.s./ha on winter wheat 1 year later:

A total of 935 mm of precipitation was received in year 1 and 895.5 mm in year 2. 438 – 478 L of leachate was collected in year 1 and 411-437 L in year 2.

In the first year of application the annual average concentration in leachate was $< 0.050 \mu\text{g/L}$ ai equivalent, however occasional exceedances of $0.10 \mu\text{g/L}$ were detected.

In the second year the annual average concentration in leachate was $< 0.055 \mu\text{g/L}$. In the soil cores the majority of radioactivity remained in the top layers of 0 – 40 cm. 11.49 – 12.38 % of AR was found in soil

2 years after the single application.

In the third year the annual average concentration in leachate was 0.001 – 0.019 µg/L. Maximum concentration of ai equivalents in leachate of the third year was 0.043 µg/L in the lysimeter which received two applications. In the soil cores 9.82 – 10.11 % of RA was found 2 years after the second application. The total recovery of RA in the three year monitoring period was 12.81 – 17.53 % of the applied RA, considering the both applications.

2) Germany, winter oilseed rape, 120 or 141 g clopyralid/ha, 847 and 1011 mm rain in years 1 and 204 – 417 mm of leachate was collected in two lysimeters in years 1 and 2. In the lysimeter with higher application rate the annual average concentration of unidentified radioactivity was 0.127 µg/L equivalent in year 1, but taken over the whole study period of two years, the average concentration was 0.064 – 0.078 µg/L equivalent. Occasional exceedances of 0.1 µg/L were detected soon after the application in both lysimeters.

3) Germany, sugar beet, spring application of 118 g clopyralid/ha, 754 and 871 mm rainfall in years 1 and 2:

113 and 196 mm of leachate was collected in years 1 and 2. Annual average concentrations of clopyralid were 0.010 and 0.002 µg/L in years 1 and 2. Unidentified radioactivity was present in the leachate at annual average concentrations of 0.113 and 0.031 µg/L equivalent in years 1 and 2, respectively. Dissolved CO₂ was the major metabolite observed in the leachate. 24.6 % of AR was measured in soil after 111 days, and after 2 years 13.2 % of AR was recovered. (It was considered very unlikely that a single unknown substance would exceed an annual concentration of 0.1 µg/L.)

4) Germany, sugar beet, spring application of 99 or 185 g clopyralid/ha, ca 700 mm rainfall/year:

In year 1 the leachate volume was 180 and 248 mm, and in year 2 70 to 79 mm. Annual average concentrations in the leachate were not calculated, but in individual samples the clopyralid concentrations up to 0.135 µg/L were detected occasionally. 26 months after application 20 % of AR was recovered from the soil, majority of it in tillage layer (0 – 30 cm).

zRMS comments:

Provided above information is in line with data reported in EFSA Journal 2016;14(1):4374 and EFSA Journal 2018;16(7):5389 for ethofumesate and clopyralid, respectively.

8.5.5 Field leaching studies (KCP 9.1.2.3)

No field leaching studies are necessary.

zRMS comments:

Field leaching studies for ethofumesate and clopyralid were not required during the EU review. For details on groundwater modelling please refer to point 8.8 of this document.

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

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

8.6.1 Ethofumesate and its metabolites

The degradation of ethofumesate in water/sediment systems was evaluated during the active substance renewal assessment, EFSA Journal 2016;14(1):4374. The results are summarised in the table below.

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

Ethofumesate Distribution (max. water/sediment 72 % after 104 days)										
Water/ sediment system	pH water/ sed. ^a	DegT50 whole syst. (d)	DegT90 whole syst. (d)	Kinetic Fit	DissT50 water (d)	DissT90 water (d)	Kinetic Fit	DissT50 sed. (d)	Kinetic Fit	Evaluated on EU level y Reference
Rückhaltbecken	8.1/7.2 ¹	250	830	SFO	52	457	DFOP	1000	SFO	EFSA 2016; 14(1):4374
Waldwinkel	7.7/7.1 ¹	294	976	SFO	7.8	101	DFOP	1000	SFO	EFSA 2016; 14(1):4374
Anglersee	8.6/6.8 ²	89	296	SFO	43	187	DFOP	96	SFO	EFSA 2016; 14(1):4374
Hönniger Weiher	7.2/6.3 ²	141	469	SFO	9.9	130	DFOP	1000	SFO	EFSA 2016; 14(1):4374
Rhine River	7.9/6.9 ²	103	342	SFO	13.3	94	DFOP	1000	SFO	EFSA 2016; 14(1):4374
Anwiler Teich	7.9/6.9 ²	164	543	SFO	23	155	DFOP	1000	SFO	EFSA 2016; 14(1):4374
Pond	7.9/7.8 ²	217	722	SFO	37	343	DFOP	258	SFO	EFSA 2016; 14(1):4374
Creek	8.2/7.5 ²	209	693	SFO	141	804	DFOP	273	SFO	EFSA 2016; 14(1):4374
Geometric mean (n=8)		170	564		26.9	215		536		

a) Measured in water (1) or CaCl₂ (2)

Table 8.6-2: Summary of observed metabolites

NC20645 Water/sediment system	Max. in water/sediment 18.8 % after 125 d Kinetic formation fraction (k_t/k_{dp}): Anglersee 0.385 (from parent; whole system) Pond 0.443 (from parent; whole system)	EFSA 2016; 14(1):4374
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The degradation of ethofumesate metabolite NC20645 in water/sediment systems was evaluated during the active substance renewal assessment, EFSA Journal 2016;14(1):4374. The results are summarised in the table below.

Table 8.6-3: Summary of degradation in water/sediment of NC20645

Water/ sediment system	pH water/ sed.	DegT50 whole syst. (d)	DegT90 whole syst. (d)	St. χ^2	Diss T50 water (d)	Diss T90 water (d)	St. χ^2	Diss T50 sed. (d)	Diss T90 sed. (d)	St. χ^2	Kinetic Fit	Evaluated on EU level y Reference
Anglersee	8.6/6.8 ¹	19	62	18.1	1000 ^a	1000 ^a	n/a	36	118	3.2	SFO	EFSA 2016; 14(1):4374
Hönniger Weiher	7.2/6.3 ¹	1000 ^a	1000 ^a	n/a	1000 ^a	1000 ^a	n/a	1000 ^a	1000 ^a	n/a	SFO	EFSA 2016; 14(1):4374

Water/ sediment system	pH water/ sed.	DegT50 whole syst. (d)	DegT90 whole syst. (d)	St. χ^2	Diss T50 water (d)	Diss T90 water (d)	St. χ^2	Diss T50 sed. (d)	Diss T90 sed. (d)	St. χ^2	Kinetic Fit	Evaluated on EU level y Reference
Pond	7.9/ 7.8 ¹	99	329	32.4	1000 ^a	1000 ^a	n/a	1000 ^a	1000 ^a	n/a	SFO	EFSA 2016; 14(1):4374
Creek	8.2/ 7.5 ¹	1000 ^a	1000 ^a	n/a	81	269	11.7	n/d	n/d	n/a	SFO	EFSA 2016; 14(1):4374
Geometric mean (n=4)		208	n/a		533	n/a		330	n/a			

¹ measured in CaCl₂

n/d not detected

^a no reliable DT₅₀ could be calculated

Hydrolysis, phototransformation and ready biodegradability

The hydrolysis, phototransformation in water and ready biodegradability of ethofumesate were evaluated during the active substance renewal assessment, EFSA Journal 2016;14(1):4374. The endpoints are summarised in the table below.

Table 8.6-4. Hydrolysis, Phototransformation and Ready Biodegradability of Ethofumesate

Parameter	Endpoint	Evaluated on EU level y Reference
Hydrolytic degradation of the active substance and metabolites > 10%	pH 5: stable at 20°C	EFSA 2016; 14(1):4374
	pH 7: stable at 20°C	EFSA 2016; 14(1):4374
	pH 9: stable at 20°C	EFSA 2016; 14(1):4374
Photolytic degradation of the active substance and metabolites above 10%	DT ₅₀ : 15.6 d Natural light, 33°N; DT ₅₀ 53.2 days	EFSA 2016; 14(1):4374
Quantum yield of direct phototransformation in water at $\Sigma > 290$ nm	1.92×10^{-4} mol Einstein ⁻¹	EFSA 2016; 14(1):4374
Readily biodegradable (y/n)	No	EFSA 2016; 14(1):4374

zRMS comments:

Provided above degradation data for ethofumesate and its metabolite in water/sediment systems provided in tables above are in line with data reported in EFSA Journal 2016;14(1):4374.

8.6.2 Clopyralid

The degradation of clopyralid in water/sediment systems was evaluated during the active substance renewal assessment, EFSA Journal 2018;16(7):5389. The results are summarised in the table below.

Table 8.6-5: Summary of degradation in water/sediment of clopyralid

Clopyralid										
Distribution: max in water 100.13 % at 0d, max. sediment 19 % at 100 d (Loamy sand)										
Distribution: max in water 99.0 % at 0 d, max sediment 26 % at 100 d (Sandy silt loam)										
Water/ sediment system	pH water/ sed.	DegT50 whole syst. (d)	DegT90 whole syst. (d)	Kinetic Fit	DissT50 water (d)	DissT90 water (d)	Kinetic Fit	DissT50 sed. (d)	Kinetic Fit	Evaluated on EU level y Reference
Loamy sand	6.5/5.5	>500	>500	n/a	128	Not provided	SFO	>500	n/a	EFSA 2018; 16(7):5389
Sandy silt loam	8.16/7.7	>500	>500	n/a	167	Not provided	SFO	>500	n/a	EFSA 2018; 16(7):5389
Geometric mean (n=2)			>500		148			>500		

Hydrolysis, phototransformation and ready biodegradability

The hydrolysis, phototransformation in water and ready biodegradability of clopyralid were evaluated during the active substance renewal assessment, EFSA Journal 2018;16(7):5389. The endpoints are summarised in the table below.

Table 8.6-6. Hydrolysis, Phototransformation and Ready Biodegradability of Clopyralid

Parameter	Endpoint	Evaluated on EU level y Reference
Hydrolytic degradation of the active substance and metabolites > 10%	pH 4: DT ₅₀ > 1 year at 50°C	EFSA 2018; 16(7):5389
	pH 7: DT ₅₀ > 1 year at 50°C	EFSA 2018; 16(7):5389
	pH 9: DT ₅₀ > 1 year at 50°C	EFSA 2018; 16(7):5389
Photolytic degradation of the active substance and metabolites above 10%	Xenon lamp for an equivalent of 41.6 days of summer sunlight at 40 °N, DT ₅₀ ca 38000 days, no photolytic degradation products in aqueous sterile buffer could be observed. Photolysis is not a significant route of degradation of clopyralid in waters	EFSA 2018; 16(7):5389
Quantum yield of direct phototransformation in water at $\sum > 290$ nm	1.01×10^{-6} mol Einstein ⁻¹	EFSA 2018; 16(7):5389
Readily biodegradable (y/n)	No	EFSA 2018; 16(7):5389

zRMS comments:

Information on degradation of clopyralid in water/sediment systems presented in tables above are in line with EU agreed endpoints reported in EFSA Journal 2018;16(7):5389.

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

8.7.1 Justification for new endpoints

No deviation from EU agreed endpoints.

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

PEC_{soil} calculations are calculated below in accordance with FOCUS Guidance (SANCO/10058/2005 v.2.0, 2006).

PEC_{soil} values were calculated using the CTGB “Excel rekensheet PECsoil” dated 05-02-2020. This tool calculates the initial PEC_{soil} value using the following formula:

$$PEC_{S, initial} [mg/kg] = \frac{A[g/ha] \times (1 - F)}{100 \times d [cm] \times \rho [g/cm^3]}$$

Where:

A = Application rate

F = Fraction intercepted by crop

d = Depth of field soil layer (5 cm)

ρ = Dry bulk density (1.5 g/cm³)

PEC_{soil} values after the nth application were calculated assuming SFO degradation kinetics using the following formula:

$$PEC_{S, actual} (n) [mg/kg] = \frac{PEC_{S, initial} \times (1 - e^{-nki})}{(1 - e^{-ki})}$$

Where:

n = number of applications

i = interval in days between applications

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

Time weighted average (TWA) PEC_{soil} values were calculated using the following formulae:

$$\text{Average PEC over a day [mg/kg]} = \frac{PEC_{S, initial} \times (1 - e^{-kt})}{kt}$$

$$PEC_{twa, max} [mg/kg] = \frac{PEC_{S, actual, max} \times (1 - e^{-kt})}{kt}$$

Where:

t = days after application

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

PEC_{plateau} concentrations were calculated using the following formula:

$$PEC_{S,plateau} [mg/kg] = PEC_{S, actual,max} / (1 - e^{(-365 - ((n-1)i)k)})$$

Where:

PEC_{S, actual,max} = PEC_{S, actual,max} calculated for 5 cm soil depth [mg/kg]

n = number of applications (-)

i = interval period between applications (days)

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

Use No.	1
Crop	Sugar beet
Application rate (g as/ha)*	ethofumesate: 335 clopyralid: 50.25
Number of applications/interval	3/5
Crop interception (%)	20
Depth of soil layer (relevant for plateau concentration) (cm)	20 cm (tillage)

* Different values than the ones presented in B0 are used due to rounding of numbers, but as the calculations were done with the higher number, they should be considered acceptable.

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

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU end-point y/n/ Reference
Ethofumesate	286.3	-	157 d (field studies)	EFSA 2016; 14(1):4374
NC8493	258.3	24.2	0.07 d (field studies)	EFSA 2016; 14(1):4374
Clopyralid	191.96	-	23.7 d (field studies)	EFSA 2018; 16(7):5389

zRMS comments:

The application pattern assumed in soil exposure assessment is in line with the critical Central Zone GAP and it is thus agreed. Relevant crop interception of 20% in line with FOCUS groundwater guidance (2023) have been selected.

Input parameters presented in Table 8.7-2 are in line with EU agreed parameters for ethofumesate and clopyralid reported in EFSA Journal 2016;14(1):4374 and EFSA Journal 2018;16(7):5389, respectively.

8.7.2.1 Ethofumesate and its metabolites

Table 8.7-3: PEC_{soil} for ethofumesate on sugar beet (3 x 335 g a.s./ha)

PEC _{soil} (mg/kg)		sugar beet (3 x 335 g a.s./ha)			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.357	-	1.049	-
Short term	24h	0.356	0.357	1.044	1.046
	2d	0.354	0.356	1.040	1.044
	4d	0.351	0.354	1.030	1.040
Long term	7d	0.346	0.352	1.017	1.033
	14d	0.336	0.347	0.986	1.017
	21d	0.326	0.341	0.956	1.002
	28d	0.316	0.336	0.927	0.987
	50d	0.287	0.321	0.841	0.941
	100d	0.230	0.289	0.674	0.848
Plateau concentration (20 cm) after year 5		0.022	-	0.068	-
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		0.380		1.117	

PEC_{soil} of metabolites

Table 8.7-4: PEC_{soil} for NC8493 on sugar beet (3 x 335 g a.s./ha)

PEC _{soil} (mg/kg)		sugar beet (3 x 335 g a.s./ha)			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.078	-	0.078	-
Short term	24h	<0.001	0.001	<0.001	0.001
	2d	<0.001	<0.001	<0.001	<0.001
	4d	<0.001	<0.001	<0.001	<0.001
Long term	7d	<0.001	<0.001	<0.001	<0.001
	14d	<0.001	<0.001	<0.001	<0.001
	21d	<0.001	<0.001	<0.001	<0.001
	28d	<0.001	<0.001	<0.001	<0.001
	50d	<0.001	<0.001	<0.001	<0.001
	100d	<0.001	<0.001	<0.001	<0.001

zRMS comments:

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

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

The zRMS confirms that the application at 3x335 g a.s./ha represents worst case and performed calculations are thus protective for application of 3x300 g a.s./ha presented in the GAP table.

8.7.2.2 Clopyralid

Table 8.7-5: PEC_{soil} for clopyralid on sugar beet (3 x 50.25 g a.s./ha)

PEC _{soil} (mg/kg)		sugar beet (3 x 50.25 g a.s./ha)			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.054	-	0.140	-
Short term	24h	0.052	0.053	0.136	0.138
	2d	0.051	0.052	0.132	0.136
	4d	0.048	0.051	0.124	0.132
Long term	7d	0.044	0.048	0.114	0.127
	14d	0.036	0.044	0.093	0.115
	21d	0.029	0.040	0.076	0.105
	28d	0.024	0.037	0.062	0.096
	50d	0.012	0.028	0.032	0.074
	100d	0.003	0.017	0.008	0.045

zRMS comments:

Input parameters presented in Table 8.7-2 are in line with EU agreed parameters reported in EFSA Journal 2018;16(7):5389.

The soil exposure for clopyralid has been independently validated by the zRMS using FOCUS methods and EU agreed endpoints. The calculated PEC_{soil} values were in good agreement with these obtained by the Applicant. Therefore, results reported in table above may be used for the soil risk assessment purposes.

The zRMS confirms that the application at 3x50.25 g a.s./ha represents worst case and performed calculations are thus protective for application of 3x49.5 g a.s./ha presented in the GAP table.

8.7.2.3 PEC_{soil} of formulation

The initial PEC_{soil} value for the formulation ADM.01851.H.1.A has been calculated using the single application rate of 0.66 L/ha as a worst case and the formulation density of 1.1622 g/mL. The crop interception of 20% was assumed.

Table 8.7-6: PEC_{soil} for formulation on crop

Application rate (g/ha)	Application rate (g/ha)	PEC _{act} (mg/kg)	PEC _{twa21 d} (mg/kg)	Tillage depth (cm)	PEC _{soil,plateau} (mg/kg)	PEC _{accu} = PE- C _{act} + PEC _{soil,plateau} (mg/kg)
ADM.01851.H.1.A	767.1	0.818	-	-	-	-

zRMS comments:

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

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

8.8.1 Justification for new endpoints

For ethofumesate, no new endpoints are proposed, however additional modelling considering a plant uptake factor (PUF) of both 0 and 0.5 is included as part of a tiered approach to the risk assessment. The value of 0.5 is in line with the value used at a European level for surface water modelling (with reference to the EFSA Conclusion for ethofumesate, EFSA Journal 2016; 14(1):4374, Page 76).

For clopyralid, justification of the use of a PUF of 0.5 is provided in Appendix 3.5, however modelling considering both a PUF of 0 and 0.5 is provided as part of a tiered approach to the risk assessment.

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

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

Use No.	1
Crop	Sugar beet
Application rate (g as/ha)*	ethofumesate: 335 clopyralid: 50.25
Number of applications/interval (d)	3/5
Relative application date	See absolute dates
Crop interception (%)	20
Frequency of application	annual, biennial, triennial
Models used for calculation	FOCUS PEARL v5.5.5, FOCUS PELMO v6.6.4, FOCUS MACRO v5.5.4

* Different values than the ones presented in B0 are used due to rounding of numbers, but as the calculations were done with the higher number, they should be considered acceptable.

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

Crop	Scenario	Application dates (absolute) (Julian days)
Sugar beet	Châteaudun	17/04 (107), 22/04 (112), 27/04 (117)
	Hamburg	16/04 (106), 21/04 (111), 26/04 (116)
	Jokioinen	26/05 (146), 31/05 (151), 05/06 (156)
	Kremsmünster	16/04 (106), 21/04 (111), 26/04 (116)
	Okehampton	26/04 (116), 01/05 (121), 06/05 (126)
	Piacenza	21/03 (80), 26/03 (85), 31/03 (90)
	Porto	16/03 (75), 21/03 (80), 26/03 (85)
	Sevilla	11/11 (315), 16/11 (320), 21/11 (325)
	Thiva	02/05 (122), 07/05 (127), 12/05 (132)

zRMS comments:

The application pattern presented in Table 8.8-1 is in general in line with Central Zone GAP presented in Table 8.1-1. The zRMS confirms that the application of 3x335 g ethofumesate per ha and 3x50.25 g clopyralid per ha represents worst case compare to applications rates presented in the GAP Table 8.8-1.

The selected application dates were in line with these suggested by the AppDate v. 3.06. Correct crop interception of 20% is in line with the most recent version of the FOCUS Groundwater Guidance (2023) and is adequate for sugar beet at the BBCH 10-19 stage.

8.8.2.1 Ethofumesate and its metabolites

For further details of the PEC_{GW} calculations for ethofumesate please refer to report KCP 9.4.2-01, Hicks, 2024a, ETF/EFA/14.

Table 8.8-3: Input parameters related to active substance ethofumesate and metabolite(s) for PEC_{gw} calculations

Compound	Ethofumesate	NC8493	NC20645	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	286.3	258.3	274.3	EFSA 2016; 14(1):4374
Water solubility (g/mol):	50 (@ 25°C)	2019 (@ 25°C)	16170 (@ 25°C)	EFSA 2016; 14(1):4374
Saturated vapour pressure (Pa):	6.5×10^{-4} (@ 25°C)	3.73×10^{-6} (@ 25°C)	7.4×10^{-7} (@ 25°C)	EFSA 2016; 14(1):4374
DT ₅₀ in soil (d)	26.2 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7)	0.03*** (geomean, normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7)	0.12 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7)	EFSA 2016; 14(1):4374
Transformation rate	0.0265	23.105	5.776	Calculated from DT ₅₀ in PELMO
K _{foc} (mL/g)	118(geometric mean)	2.082	5.1 (geometric mean)	EFSA 2016; 14(1):4374
K _{fom} (mL/g)	68.45	1.208	2.958	Calculated in PEARL
1/n	0.905 (arithmetic mean)	1 (EPISuite)	0.93 (arithmetic mean)	EFSA 2016; 14(1):4374
Plant uptake factor	0 and 0.5**	0	0	EFSA 2016; 14(1):4374
Formation fraction	-	1 (from Ethofumesate)*	1 (from NC8493)	EFSA 2016; 14(1):4374

* calculated as parent in agreement with EFSA 2016; 14(1):4374;

** A PUF of 0.5 is the agreed EU endpoint, but additional calculations considering a worst case PUF of zero was included in order to provide a tiered approach to the risk assessment (see zRMS comments in the commenting box below)

*** A DT₅₀ value of 0.1 d was used for FOCUS PEARL v. 4.4.4 calculations because 0.03d is not an accepted input value

Tier 1 (TSCF = 0)

Table 8.8-4: PEC_{gw} for ethofumesate and metabolite(s) on sugar beet (3 x 335 g a.s/ha) annual frequency and PUF = 0 (with FOCUS PEARL 5.5.5)

Crop	Scenario	80 th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Ethofumesate	NC8493	NC20645
Sugar beet	Châteaudun	0.1078	<0.001	<0.001
	Hamburg	0.0784	<0.001	<0.001
	Jokioinen	0.0053	<0.001	<0.001
	Kremsmünster	0.0420	<0.001	<0.001
	Okehampton	0.0606	<0.001	<0.001
	Piacenza	0.0414	<0.001	<0.001
	Porto	0.0106	<0.001	<0.001
	Sevilla	0.0012	<0.001	<0.001
	Thiva	0.0017	<0.001	<0.001

Table 8.8-5: PEC_{gw} for ethofumesate and metabolite(s) on sugar beet (3 x 335 g a.s/ha) annual frequency and PUF = 0 (with FOCUS PELMO 6.6.4)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		Ethofumesate	NC8493	NC20645
Sugar beet	Châteaudun	0.032	<0.001	<0.001
	Hamburg	0.067	<0.001	<0.001
	Jokioinen	0.005	<0.001	<0.001
	Kremsmünster	0.051	<0.001	<0.001
	Okehampton	0.090	<0.001	<0.001
	Piacenza	0.057	<0.001	<0.001
	Porto	0.110	<0.001	<0.001
	Sevilla	0.001	<0.001	<0.001
	Thiva	0.001	<0.001	<0.001

Table 8.8-6: PEC_{gw} for ethofumesate and metabolite(s) on sugar beet (3 x 335 g a.s/ha) annual frequency and PUF = 0 (with FOCUS MACRO 5.5.4)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		Ethofumesate	NC8493	NC20645
Sugar beet	Châteaudun	0.0419	<0.001	<0.001

Table 8.8-7: PEC_{gw} for ethofumesate and metabolite(s) on sugar beet (3 x 335 g a.s/ha) biennial frequency and PUF = 0 (with FOCUS PEARL 5.5.5)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		Ethofumesate	NC8493	NC20645
Sugar beet	Châteaudun	0.0488	<0.001	<0.001
	Hamburg	0.0440	<0.001	<0.001
	Jokioinen	0.0015	<0.001	<0.001
	Kremsmünster	0.0164	<0.001	<0.001
	Okehampton	0.0286	<0.001	<0.001
	Piacenza	0.0156	<0.001	<0.001
	Porto	0.0042	<0.001	<0.001
	Sevilla	0.0009	<0.001	<0.001
	Thiva	0.0014	<0.001	<0.001

Table 8.8-8: PEC_{gw} for ethofumesate and metabolite(s) on sugar beet (3 x 335 g a.s/ha) biennial frequency and PUF = 0 (with FOCUS PELMO 6.6.4)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		Ethofumesate	NC8493	NC20645
Sugar beet	Châteaudun	0.014	<0.001	<0.001
	Hamburg	0.038	<0.001	<0.001
	Jokioinen	0.002	<0.001	<0.001
	Kremsmünster	0.020	<0.001	<0.001
	Okehampton	0.037	<0.001	<0.001
	Piacenza	0.020	<0.001	<0.001
	Porto	0.037	<0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001
	Thiva	0.001	<0.001	<0.001

Table 8.8-9: PEC_{gw} for ethofumesate and metabolite(s) on sugar beet (3 x 335 g a.s/ha) biennial frequency and PUF = 0 (with FOCUS MACRO 5.5.4)

Crop	Scenario	80 th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Ethofumesate	NC8493	NC20645
Sugar beet	Châteaudun	0.0179	<0.001	<0.001

Table 8.8-10: PEC_{gw} for ethofumesate and metabolite(s) on sugar beet (3 x 335 g a.s/ha) triennial frequency and PUF = 0 (with FOCUS PEARL 5.5.5)

Crop	Scenario	80 th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Ethofumesate	NC8493	NC20645
Sugar beet	Châteaudun	0.0347	<0.001	<0.001
	Hamburg	0.0155	<0.001	<0.001
	Jokioinen	0.0007	<0.001	<0.001
	Kremsmünster	0.0098	<0.001	<0.001
	Okehampton	0.0162	<0.001	<0.001
	Piacenza	0.0178	<0.001	<0.001
	Porto	0.0021	<0.001	<0.001
	Sevilla	0.0006	<0.001	<0.001
	Thiva	0.0005	<0.001	<0.001

Table 8.8-11: PEC_{gw} for ethofumesate and metabolite(s) on sugar beet (3 x 335 g a.s/ha) triennial frequency and PUF = 0 (with FOCUS PELMO 6.6.4)

Crop	Scenario	80 th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Ethofumesate	NC8493	NC20645
Sugar beet	Châteaudun	0.009	<0.001	<0.001
	Hamburg	0.011	<0.001	<0.001
	Jokioinen	0.001	<0.001	<0.001
	Kremsmünster	0.010	<0.001	<0.001
	Okehampton	0.023	<0.001	<0.001
	Piacenza	0.010	<0.001	<0.001
	Porto	0.036	<0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001

Table 8.8-12: PEC_{gw} for ethofumesate and metabolite(s) on sugar beet (3 x 335 g a.s/ha) triennial frequency and PUF = 0 (with FOCUS MACRO 5.5.4)

Crop	Scenario	80 th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Ethofumesate	NC8493	NC20645
Sugar beet	Châteaudun	0.0152	<0.001	<0.001

Tier 2 (TSCF = 0.5 based on the Briggs equation, to be confirmed by the MS in the course of the mutual recognition process)

Table 8.8-13: PEC_{gw} for ethofumesate and metabolite(s) on sugar beet (3 x 335 g a.s/ha) annual frequency and PUF = 0.5 (with FOCUS PEARL 5.5.5)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		Ethofumesate	NC8493	NC20645
Sugar beet	Châteaudun	0.0818	<0.001	<0.001
	Hamburg	0.0615	<0.001	<0.001
	Jokioinen	0.0043	<0.001	<0.001
	Kremsmünster	0.0350	<0.001	<0.001
	Okehampton	0.0515	<0.001	<0.001
	Piacenza	0.0322	<0.001	<0.001
	Porto	0.0088	<0.001	<0.001
	Sevilla	0.0006	<0.001	<0.001
	Thiva	0.0010	<0.001	<0.001

Table 8.8-14: PEC_{gw} for ethofumesate and metabolite(s) on sugar beet (3 x 335 g a.s/ha) annual frequency and PUF = 0.5 (with FOCUS PELMO 6.6.4)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		Ethofumesate	NC8493	NC20645
Sugar beet	Châteaudun	0.021	<0.001	<0.001
	Hamburg	0.046	<0.001	<0.001
	Jokioinen	0.004	<0.001	<0.001
	Kremsmünster	0.036	<0.001	<0.001
	Okehampton	0.065	<0.001	<0.001
	Piacenza	0.043	<0.001	<0.001
	Porto	0.076	<0.001	<0.001
	Sevilla	0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001

Table 8.8-15: PEC_{gw} for ethofumesate and metabolite(s) on sugar beet (3 x 335 g a.s/ha) annual frequency and PUF = 0.5 (with FOCUS MACRO 5.5.4)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		Ethofumesate	NC8493	NC20645
Sugar beet	Châteaudun	0.0361	<0.001	<0.001

Table 8.8-16: PEC_{gw} for ethofumesate and metabolite(s) on sugar beet (3 x 335 g a.s/ha) biennial frequency and PUF = 0.5 (with FOCUS PEARL 5.5.5)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		Ethofumesate	NC8493	NC20645
Sugar beet	Châteaudun	0.0369	<0.001	<0.001
	Hamburg	0.0341	<0.001	<0.001
	Jokioinen	0.0012	<0.001	<0.001
	Kremsmünster	0.0138	<0.001	<0.001
	Okehampton	0.0241	<0.001	<0.001
	Piacenza	0.0122	<0.001	<0.001
	Porto	0.0034	<0.001	<0.001
	Sevilla	0.0005	<0.001	<0.001
	Thiva	0.0008	<0.001	<0.001

Table 8.8-17: PEC_{gw} for ethofumesate and metabolite(s) on sugar beet (3 x 335 g a.s/ha) biennial frequency and PUF = 0.5 (with FOCUS PELMO 6.6.4)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		Ethofumesate	NC8493	NC20645
Sugar beet	Châteaudun	0.009	<0.001	<0.001
	Hamburg	0.025	<0.001	<0.001
	Jokioinen	0.001	<0.001	<0.001
	Kremsmünster	0.014	<0.001	<0.001
	Okehampton	0.028	<0.001	<0.001
	Piacenza	0.016	<0.001	<0.001
	Porto	0.025	<0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001

Table 8.8-18: PEC_{gw} for ethofumesate and metabolite(s) on sugar beet (3 x 335 g a.s/ha) biennial frequency and PUF = 0.5 (with FOCUS MACRO 5.5.4)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		Ethofumesate	NC8493	NC20645
Sugar beet	Châteaudun	0.0157	<0.001	<0.001

Table 8.8-19: PEC_{gw} for ethofumesate and metabolite(s) on sugar beet (3 x 335 g a.s/ha) triennial frequency and PUF = 0.5 (with FOCUS PEARL 5.5.5)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		Ethofumesate	NC8493	NC20645
Sugar beet	Châteaudun	0.0261	<0.001	<0.001
	Hamburg	0.0121	<0.001	<0.001
	Jokioinen	0.0006	<0.001	<0.001
	Kremsmünster	0.0079	<0.001	<0.001
	Okehampton	0.0138	<0.001	<0.001
	Piacenza	0.0140	<0.001	<0.001
	Porto	0.0017	<0.001	<0.001
	Sevilla	0.0002	<0.001	<0.001
	Thiva	0.0003	<0.001	<0.001

Table 8.8-20: PEC_{gw} for ethofumesate and metabolite(s) on sugar beet (3 x 335 g a.s/ha) triennial frequency and PUF = 0.5 (with FOCUS PELMO 6.6.4)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		Ethofumesate	NC8493	NC20645
Sugar beet	Châteaudun	0.006	<0.001	<0.001
	Hamburg	0.007	<0.001	<0.001
	Jokioinen	0.001	<0.001	<0.001
	Kremsmünster	0.007	<0.001	<0.001
	Okehampton	0.017	<0.001	<0.001
	Piacenza	0.008	<0.001	<0.001
	Porto	0.024	<0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001

Table 8.8-21: **PEC_{gw} for ethofumesate and metabolite(s) on sugar beet (3 x 335 g a.s/ha) triennial frequency and PUF = 0.5 (with FOCUS MACRO 5.5.4)**

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		Ethofumesate	NC8493	NC20645
Sugar beet	Châteaudun	0.0132	<0.001	<0.001

zRMS comments:

The input parameters considered in the groundwater modelling for ethofumesate and presented in Table 8.8-3 are in line with EU agreed endpoints, presented in EFSA Journal 2016;14(1):4374.

It was, however, noted that in simulations the Applicant assumed PUF of 0.5 although according to the most recent version of the FOCUS groundwater guidance, PUF value of 0 should be assumed regardless if the substance is systemic or not.

The plant uptake factor of 0.5 has been based on the outcome of calculation of TSCF using the Briggs equation at the EU level (TSCF of 0.55 has been obtained). The refinement of the uptake of ethofumesate by plants has been discussed during the Pesticides Peer Review TC 121 (October 2015) and it was pointed out that Briggs equation has been developed based on the results of experiments performed on barley and its applicability for sugar beets has been questioned as based on the lipophilicity of ethofumesate the realistic TSCF of ethofumesate in sugar beets is expected to be lower. Furthermore, it was pointed out that the literature data on following crops does not enable to quantitatively assess the actual amount of the active substance taken up by plants since only the total radioactivity has been reported with no identification of particular compounds to distinguish the parent and metabolites. Nevertheless, it was agreed that use of the Briggs equation is a option for refinement of TSCF indicated by the FOCUS groundwater guidance for substance for which a measured log Pow is available. Based on that it was agreed to consider the plant uptake factor of 0.5, being in line with the value of 0.55 calculated with the Briggs equation.

It must be, however, pointed out that consideration of Briggs equation for refinement of the TSCF value is not agreed at the PL national level. Taking this into account, the conditions of authorization of ADM.01851.H.1.A in Poland will be concluded based on results of the Tier 1 groundwater modelling, performed with consideration of TSCF of 0. Nevertheless, the Tier 2 modelling, performed with consideration of TSCF of 0.5 is retained in Tables 8.8-13 to 8.8-21 above for reference of the Member States in the course of the mutual recognition process. Concerned Member States must decide whether they accept the modelling with TSCF refined using the Briggs equation. The results reported in Tables 8.8-13 to 8.8-21 are displayed with grey letters in order to highlight results that may require further national assessments.

Since the PUF of 0 should have been considered in performed modelling, as it is in line with recommendations of the most recent version of the FOCUS Groundwater Guidance, therefore results with PUF value of 0.5 were not considered by the zRMS and results presented in Tables 8.8-13 to 8.8-21 were struck through as not relevant, only simulations performed with the PUF 0 were taken into account in the overall conclusion regarding the groundwater exposure.

The performed calculations were independently validated by the zRMS in additional modelling using PELMO 6.6.4 and PEARL 5.5.5 and MACRO 5.5.4 models and input parameters indicated in Table 8.8-3 and application dates as suggested by AppDate 3.06. Modelling performed with the refined TSCF has been also validated for convenience of the Member States in the course of the mutual recognition process. The results are confirmed to be correct, but the decision on relevance of the TSCF refinement must be taken by each Member State at the national level.

Since Poland is the only cMS indicated in the GAP table, only scenarios required in Poland were considered (Châteaudun, Hamburg and Kremsmünster). Obtained results were in good agreement with these derived by the Applicant for ethofumesate. No unacceptable leaching of ethofumesate in scenarios relevant in Poland is expected following application of ADM.01851.H.1.A to sugar beet at the biennial application rate of 3x335 g/ha at BBCH 10-19. Since the performed modelling at the triennial application was not necessary, thus presented results in Tables 8.8-10 to 8.8-12 were struck through as not relevant.

In case of mutual recognition process additional simulations may be requested by Member States considering other scenarios as representative or not accepting FOCUS modelling at all.

8.8.2.2 Clopyralid

For further details of the PEC_{GW} calculations for clopyralid please refer to report KCP 9.4.2-01, Hicks, 2024b, CLO/EFA/01.

Table 8.8-22: Input parameters related to active substance clopyralid for PEC_{GW} calculations

Compound	Clopyralid	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	191.96	EFSA 2018;16(7):5389
Water solubility (g/mol):	1.43×10^5 at pH 7 and 20°C	EFSA 2018;16(7):5389
Saturated vapour pressure (Pa):	0	EFSA 2018;16(7):5389
DT ₅₀ in soil (d)	7.05 (geomean field, n=10 normalisation to pF2, 20 °C with Q ₁₀ of 2.58)	EFSA 2018;16(7):5389
Transformation rate	-	
K _{foc} (mL/g)/K _{fom}	1.41/ 0.818 (geometric mean)	EFSA 2018;16(7):5389
1/n	0.836 (arithmetic mean)	EFSA 2018;16(7):5389
Plant uptake factor	0 and 0.5**	EFSA 2018;16(7):5389
Formation fraction	-	EFSA 2018;16(7):5389

* calculated as parent in agreement with EFSA 2016; 14(1):4374

** PEC_{GW} values were calculated using both PUFs of 0 and 0.5 as part of a tiered approach to the risk assessment. Please see Appendix 3.5 for justification of the use of 0.5 at Tier 2.

Table 8.8-23: PEC_{GW} for clopyralid on sugar beet (3 x 50.25 g a.s./ha annual, biennial and triennial frequency and PUF = 0 (with FOCUS PEARL 5.5.5))

Crop	Scenario	80 th Percentile PEC_{GW} at 1 m Soil Depth (µg/L)		
		Annual	Biennial	Triennial
Sugar beet	Châteaudun	0.1572	0.0764	0.0592
	Hamburg	0.1187	0.0618	0.0429
	Jokioinen	0.2914	0.1525	0.1194
	Kremsmünster	0.0685	0.0322	0.0226
	Okehampton	0.0715	0.0473	0.0295
	Piacenza	0.0462	0.0344	0.0272
	Porto	0.0490	0.0211	0.0119
	Sevilla	0.3648	0.2006	0.1565
	Thiva	0.0016	0.0008	0.0003

Table 8.8-24: PEC_{GW} for clopyralid on sugar beet (3 x 50.25 g a.s./ha annual, biennial and triennial frequency and PUF = 0 (with FOCUS PELMO 6.6.4))

Crop	Scenario	80 th Percentile PEC_{GW} at 1 m Soil Depth (µg/L)		
		Annual	Biennial	Triennial
Sugar beet	Châteaudun	0.033	0.021	0.018
	Hamburg	0.042	0.022	0.016
	Jokioinen	0.396	0.246	0.142
	Kremsmünster	0.086	0.035	0.026
	Okehampton	0.141	0.083	0.058
	Piacenza	0.382	0.249	0.157
	Porto	0.584	0.181	0.127
	Sevilla	1.332	0.473	0.246
	Thiva	<0.001	<0.001	<0.001

Table 8.8-25: PEC_{gw} for clopyralid on sugar beet (3 x 50.25 g a.s./ha annual, biennial and triennial frequency and PUF = 0 (with FOCUS MACRO 5.5.4))

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		Annual	Biennial	Triennial
Sugar beet	Châteaudun	0.0389	0.0224	0.0181

Table 8.8-26: PEC_{gw} for clopyralid on sugar beet (3 x 50.25 g a.s./ha annual, biennial and triennial frequency and PUF = 0.5 (with FOCUS PEARL 5.5.5))

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		Annual	Biennial	Triennial
Sugar beet	Châteaudun	0.0799	0.0407	0.0311
	Hamburg	0.0464	0.0235	0.0181
	Jokioinen	0.1430	0.0758	0.0591
	Kremsmünster	0.0410	0.0177	0.0122
	Okehampton	0.0487	0.0312	0.0192
	Piacenza	0.0307	0.0268	0.0193
	Porto	0.0271	0.0119	0.0069
	Sevilla	0.3245	0.1739	0.1419
	Thiva	0.0005	0.0002	0.0001

Table 8.8-27: PEC_{gw} for clopyralid on sugar beet (3 x 50.25 g a.s./ha annual, biennial and triennial frequency and PUF = 0.5 (with FOCUS PELMO 6.6.4))

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		Annual	Biennial	Triennial
Sugar beet	Châteaudun	0.013	0.008	0.007
	Hamburg	0.008	0.003	0.002
	Jokioinen	0.136	0.081	0.046
	Kremsmünster	0.039	0.014	0.010
	Okehampton	0.079	0.045	0.028
	Piacenza	0.325	0.211	0.132
	Porto	0.431	0.118	0.095
	Sevilla	1.055	0.424	0.215
	Thiva	<0.001	<0.001	<0.001

Table 8.8-28: PEC_{gw} for clopyralid on sugar beet (3 x 50.25 g a.s./ha annual, biennial and triennial frequency and PUF = 0.5 (with FOCUS MACRO 5.5.4))

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)		
		Annual	Biennial	Triennial
Sugar beet	Châteaudun	0.0279	0.0168	0.0146

zRMS comments:

The input parameters considered in the groundwater modelling for clopyralid and presented in Table 8.8-22 are in line with EU agreed endpoints, presented in EFSA Journal 2018;16(7):5389 with exception of vapour pressure set to 0, which is agreed by the zRMS as representing worst case.

The Applicant for Tier 2 modelling used refined PUF of 0.5, indicating that results of the study by Gourlay (2015) (see Appendix 3.5) confirm that clopyralid is a systemic compound which is taken up by roots of wheat and barley. It should be, however, noted that this study was already evaluated at the EU level and several uncertainties were noted, one of which was that due to the conditions, hydroponic systems promote uptake of the substance by plants

which would be lower if plants were cultivated in soil, since adsorption of the substance to soil particles would reduce its availability. Taking this into account, the PUF value should be refined based on results of experiments performed in plants cultivated in soil and not in the nutrient solutions. Detailed discussion on the study by Gourley (2015) may be found in clopyralid RAR (Vol. 3CP, B.8 of March 2018) and obtained results will not be re-considered given the conclusions taken in the course of the renewal process and agreed by the RMS, MS experts and EFSA. It should be also noted that the uptake of the substance by plants would also depend on other factors, such as the size of soil particles (higher uptake would be expected in sandy soils comparing to clay soils), soil pH, temperature, humidity and the plant itself.

Taking into account all above, the PUF value of 0.5 is not applicable anymore and therefore only PUF of 0 should have been considered in performed modelling, as it is in line with recommendations of the most recent version of the FOCUS Groundwater Guidance. Thus, results with PUF value of 0.5 for clopyralid were not considered by the zRMS and were struck through as not relevant, only simulations performed with the PUF 0 were taken into account in the overall conclusion regarding the groundwater exposure.

The performed calculations were independently validated by the zRMS in additional modelling using PELMO 6.6.4 and PEARL 5.5.5 and MACRO 5.5.4 models and input parameters indicated in Table 8.8-22 and application dates as suggested by AppDate 3.06.

Since Poland is the only cMS indicated in the GAP table, only scenarios required in Poland were considered (Châteaudun, Hamburg and Kremsmünster). Obtained results were in good agreement with these derived by the Applicant for clopyralid. No unacceptable leaching of clopyralid in scenarios relevant in Poland is expected following application of ADM.01851.H.1.A to sugar beet at the biennial application rate of 3x50.25 g/ha at BBCH 10-19.

In case of mutual recognition process additional simulations may be requested by Member States considering other scenarios as representative or not accepting FOCUS modelling at all.

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

8.9.1 Justification for new endpoints

No new endpoints are proposed for ethofumesate, however PEC_{sw} values have been calculated considering plant uptake factors (PUF) of 0 and 0.5 as part of a tiered approach to risk assessment. The value of 0.5 is in line with the value used at a European level for surface water modelling (with reference to the EFSA Conclusion for ethofumesate, EFSA Journal 2016; 14(1):4374, Page 89). PEC_{sw} values for ethofumesate metabolite NC20645 have also been calculated in a tiered approach considering ethofumesate PUFs of 0 and 0.5. The PUF for NC20645 was always 0 as a worst case.

No new endpoints are proposed for clopyralid for surface water modelling.

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

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

Use No.	1
Crop	Sugar beet
Application rate (kg as/ha)*	ethofumesate: 335 clopyralid: 50.25
Number of applications/interval (d)	3/5
Application window	Mar-May (Step 2)
Application method	Ground spray
CAM (Chemical application method)	2 – appln foliar linear (Step 3/4)
Soil depth (cm)	4 (default PRZM input) (Step 3/4)
Models used for calculation	FOCUS Steps 1 and 2 v. 3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3, SWAN v5.01

* Different values than the ones presented in B0 are used due to rounding of numbers, but as the calculations were done with the higher number, they should be considered acceptable.

Table 8.9-2: FOCUS Step 3 Scenario related input parameters for PEC_{sw/sed} calculations for the application of ADM.01851.H.1.A

Crop	Scenario	Application window used in modelling
Sugar beet 3 applications	D3	26/04 – 05/06 (116 - 156)
	D4	05/05 – 14/07 (125 - 165)
	R1	17/04 – 27/05 (107 - 147)
	R3	21/03 – 10/05 (80 - 130)

zRMS comments:

The application pattern assumed in surface water simulations is in general in line with Central Zone GAP presented in Table 8.1-1. The zRMS confirms that the application of 3x335 g ethofumesate per ha and 3x50.25 g clopyralid per ha represents worst case compare to applications rates presented in the GAP 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.

8.9.2.1 Ethofumesate and its metabolites

Table 8.9-3: Input parameters related to active substance ethofumesate and metabolite(s) for PEC_{sw/sed} calculations STEP 1/2 and 3/4

Compound	Ethofumesate	NC8493	NC20645	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	286.3	258.3	274.3	EFSA 2016; 14(1):4374
Saturated vapour pressure (Pa)	6.5×10^{-4} (@ 25°C)	3.73×10^{-6} (@ 25°C)	7.4×10^{-7} (@ 25°C)	EFSA 2016; 14(1):4374
Water solubility (mg/L)	50 (@ 25°C)	2019 (@ 25°C)	16170 (@ 25°C)	EFSA 2016; 14(1):4374
Diffusion coefficient in water (m ² /d)	not required for Step 1+2/ 4.3×10^{-5}	not required for Step 1+2/ 4.3×10^{-5}	not required for Step 1+2/ 4.3×10^{-5}	Default
Diffusion coefficient in air (m ² /d)	not required for Step 1+2/0.43	not required for Step 1+2/0.43	not required for Step 1+2/0.43	Default
K _{foc} (mL/g)	118 (geometric mean)	2.082	5.1 (geometric mean)	EFSA 2016; 14(1):4374
K _{fom} (mL/g)	68.45	1.208	2.958	K _{fom} = K _{foc} /1.724
Freundlich Exponent 1/n	0.905 (arithmetic mean)	1 (EPISuite)	0.93 (arithmetic mean)	EFSA 2016; 14(1):4374
Plant Uptake	0 and 0.5*	0	0	EFSA 2016; 14(1):4374
Wash-Off factor from Crop (1/mm)	not required for Step 1+2/0.05 (MACRO) 0.50 (PRZM)	not required for Step 1+2/0.05 (MACRO)	not required for Step 1+2/0.05 (MACRO)	EFSA 2016; 14(1):4374
DT _{50,soil} (d)	26.2 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7)	0.03 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7)	0.12 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7)	EFSA 2016; 14(1):4374
DT _{50,water} (d)	170	1000	208	EFSA 2016; 14(1):4374
DT _{50,sed} (d)	170 (Step 1/2) 1000 (Step 3/4)	1000	208	EFSA 2016; 14(1):4374
DT _{50,whole system} (d)	170	1000	208	EFSA 2016; 14(1):4374
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 24.2 Water: 0 Sediment: 0 Total system: 0	Soil: 1.82 Water: Sediment: Total system: 18.8	EFSA 2016; 14(1):4374

* A PUF of 0.5 is the agreed EU endpoint, but additional calculations considering a worst case PUF of zero was included in order to provide a tiered approach to the risk assessment.

PEC_{sw/sed}

Table 8.9-4: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for ethofumesate following single/ multiple application(s) of ADM.01851.H.1.A to sugar beet (3 x 335 g a.s./ha)

Scenario	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
FOCUS					
Step 1	---	298.7012	Runoff/drainage	285.0962	349.5566***
Step 2					
Northern Europe	March-May	42.6302	Runoff/drainage	40.6056	49.7838

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Southern Europe	March-May	79.3439	Runoff/drainage	75.7915	92.9297
Step 3 (PUF=0)					
D3	ditch	1.758*	Drift	0.2226	0.5531
D4	pond	0.6032	Drainage	0.5916	2.410
D4	stream	1.454*	Drainage	0.3356	0.9084
R1	pond	0.5146	Runoff	0.4776	1.111
R1	stream	8.639	Runoff	0.2968	1.830
R3	stream	19.99	Runoff	0.9824	5.503
Step 3 (PUF=0.5)					
D3	ditch	1.758*	Drift	0.2225	0.5529
D4	pond	0.5516	Drainage	0.5411	2.246
D4	stream	1.453*	Drainage	0.3042	0.8461
R1	pond	0.4732	Runoff	0.4387	1.027
R1	stream	7.728	Runoff	0.2678	1.648
R3	stream	18.74	Runoff	0.9233	5.183

* single applications should be marked; ** two-time as required by ecotox; *** highest PEC_{sed} on day 1

The Step 3 results indicate that the PUF does not make a significant difference to the PEC_{sw} values.

FOCUS Step 4

Ethofumesate is a volatile substance, therefore redeposition must be considered in the FOCUS Step 4 calculations. Redeposition has been calculated using EVA 3 2h. The results are summarised in the tables below.

Table 8.9-5: Deposition rates of Ethofumesate following application to sugar beet at 3 x 335 g a.s./ha

Time (h)	Deposition rates of ethofumesate [mg m ⁻² h ⁻¹]	
	3x 335 g a.s./ha, BBCH 10-19	
	10 m buffer width	
0–4	0.0041	
4–12	0.0021	
12–24	0.0010	

The reduction factors defined in the FOCUS Landscape and Mitigation Report (SANCO/10422/2005 version 2.0, September 2007) were used to calculate the mitigation following use of a vegetated filter strip at Step 4. These values are summarised in the table below.

Table 8.9-6: Reduction factors for modelling of vegetative buffers using SWAN 5.01

Buffer width (m)	10-12
Reduction in volume of runoff water (%)	60
Reduction in mass of pesticide transported in aqueous phase (%)	60
Reduction in mass of eroded sediment (%)	85
Reduction in mass of pesticide transported in sediment phase (%)	85

Table 8.9-7: Global maximum PEC_{sw} values for ethofumesate following multiple application(s) of ADM.01851.H.1.A to sugar beet (3 x 335 g a.s./ha) according to the central EU zone GAP according to surface water Step 4

PEC _{sw} (µg/L)	Scenario	STEP 4 ethofumesate		
Nozzle reduction	Vegetative strip (m)	None	None	10
	No spray buffer (m)	1/3	10	10
PUF = 0				
None	R1 stream	8.639	8.639	3.917
None	R3 stream	19.99	19.99	9.120
PUF = 0.5				
None	R1 stream	7.728	7.728	3.504
None	R3 stream	18.74	18.74	8.547

Metabolite(s) of Ethofumesate

Table 8.9-8: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for NC8493 following single/multiple application(s) to sugar beet (3 x 335 g a.s./ha)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominat entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	---	72.9389	-	72.4106	1.5186
Step 2					
Northern Europe	March-May	<0.0001	-	<0.0001	<0.0001
Southern Europe	March-May	<0.0001	-	<0.0001	<0.0001

* single applications should be marked; ** two-time as required by ecotox

Table 8.9-9: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for NC20645 following single/multiple application(s) to sugar beet (3 x 335 g a.s./ha)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominat entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	---	67.3995	-	65.8408	3.4254***
Step 2					
Northern Europe	March-May	8.7816	-	8.4789	0.4462
Southern Europe	March-May	16.3832	-	15.8206	0.8326
Step 3 (PUF=0) ****					
D3	ditch	0.000391	-	0.000091	0.000297
D4	pond	0.008967	-	0.008872	0.01111
D4	stream	0.001091	-	0.000616	0.001105
R1	pond	0.01122	-	0.01109	0.01062
R1	stream	0.01221	-	0.000419	0.000973
R3	stream	0.07607	-	0.003627	0.007491
Step 3 (PUF=0.5) *****					
D3	ditch	0.000521*	-	0.000041*	0.000296

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
D4	pond	0.008334	-	0.008281	0.01043
D4	stream	0.000980	-	0.000559	0.001053
R1	pond	0.01032	-	0.01020	0.009796
R1	stream	0.01092	-	0.000378	0.000875
R3	stream	0.07129	-	0.003402	0.007030

* single applications should be marked; ** two-time as required by ecotox; *** highest PEC_{sed} on day 1; **** Calculated with ethofumesate PUF=0 or PUF=0.5, the PUF for metabolite NC20645 was always 0

zRMS comments:

The input parameters used for surface water modelling for ethofumesate presented in Table 8.9-3 are in line with EU agreed endpoints presented in EFSA Journal 2016;14(1):4374.

The zRMS confirms that the application at 3x335 g a.s./ha represents worst case and performed calculations are thus protective for application of 3x300 g a.s./ha presented in the GAP table 8.8-1.

The surface water exposure was independently validated by the zRMS in additional modelling using the EU agreed endpoints and PUF factor of 0. However, at Step 3 modelling for the parent PUF of 0.5 was used by the Applicant although in line with the current FOCUS guidance the PUF value must be set to 0 for all compounds, regardless if systemic or not.

The plant uptake factor of 0.5 has been based on the outcome of calculation of TSCF using the Briggs equation at the EU level (TSCF of 0.55 has been obtained). The refinement of the uptake of ethofumesate by plants has been discussed during the Pesticides Peer Review TC 121 (October 2015) and it was pointed out that Briggs equation has been developed based on the results of experiments performed on barley and its applicability for sugar beets has been questioned as based on the lipophilicity of ethofumesate the realistic TSCF of ethofumesate in sugar beets is expected to be lower. Furthermore, it was pointed out that the literature data on following crops does not enable to quantitatively assess the actual amount of the active substance taken up by plants since only the total radioactivity has been reported with no identification of particular compounds to distinguish the parent and metabolites.

It must be, however, pointed out that consideration of Briggs equation for refinement of the TSCF value is not agreed at the PL national level. Taking this into account, simulations performed with the PUF 0 were taken into account in the overall conclusion regarding the surface water exposure. Nevertheless, modelling, performed with consideration of TSCF of 0.5 is retained in Tables 8.8-4, 8.9-7 and 8.9-9 above for reference of the Member States in the course of the mutual recognition process. Concerned Member States must decide whether they accept the modelling with TSCF refined using the Briggs equation. The results with consideration of TSCF of 0.5 are displayed with grey letters in order to highlight results that may require further national assessments.

Results obtained by the zRMS for ethofumesate and its metabolites at Step 1-3 were the same as these derived by the Applicant and presented in Tables 8.9-4 and 8.9-7 to 8.9-9. Modelling performed with the refined TSCF has been also validated for convenience of the Member States in the course of the mutual recognition process. The results are confirmed to be correct, but the decision on relevance of the TSCF refinement must be taken by each Member State at the national level. The PEC_{sw} values at Step 3 for ethofumesate and metabolite NC20645 calculated with the PUF factor of 0.5, were not considered by the zRMS and were struck through as not relevant, only simulations performed with the PUF 0 were taken into account in the overall conclusion regarding the surface water exposure.

Since the vapour pressure of 6.5×10^{-4} Pa indicate that ethofumesate is a volatile substance the volatilisation of ethofumesate may occur. The degrees of the volatilisation with respective deposition rates of ethofumesate were calculated on an hourly basis using EVA 3 rev.2h considering crop interception of 100% which represents worst case and 10 m buffer width, information presented in Table 8.9-5 are considered acceptable. Simulations at Step 4 were performed according to recommendations of the FOCUS work group on landscape and mitigation factors.

The surface water modelling at Step 4 was independently validated by the zRMS using fully EU agreed input parameters and correct deposition values. Obtained PEC_{sw} and PEC_{sed} values were the same or slightly lower comparing to surface water exposure calculated by the Applicant. Since the crop interception of 100% was assumed for calculations of redeposition values, therefore presented PEC_{sw} values calculated at Step 4 are considered highly conservative and thus represent worst case.

Overall, the surface water exposure for ethofumesate and its metabolites presented in tables above may be used in the aquatic risk assessment.

8.9.2.2 Clopyralid

Table 8.9-10: Input parameters related to active substance clopyralid for PEC_{sw/sed} calculations STEP 1/2 and STEP 3

Compound	Clopyralid	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	191.96	EFSA 2018;16(7):5389
Saturated vapour pressure (Pa)	1.36 x 10 ⁻³ @ 20°C	EFSA 2018;16(7):5389
Water solubility (mg/L)	1.43 x 10 ⁵ @ 20°C	EFSA 2018;16(7):5389
Diffusion coefficient in water (m ² /d)	not required for Step 1+2/ 4.3 x 10 ⁻⁵	Default
Diffusion coefficient in air (m ² /d)	not required for Step 1+2/0.43	Default
K _{foc} (mL/g)	1.41/ 0.818 (geometric mean, n=9)	EFSA 2018;16(7):5389
Freundlich Exponent 1/n	0.836 (arithmetic mean, n=9)	EFSA 2018;16(7):5389
Plant Uptake	0	EFSA 2018;16(7):5389
Wash-Off factor from Crop (1/mm)	not required for Step 1+2/0.05 (MACRO) 0.50 (PRZM)	Default
DT _{50,soil} (d)	7.05 (geomean, field, n=10)	EFSA 2018;16(7):5389
DT _{50,water} (d)	1000	EFSA 2018;16(7):5389
DT _{50,sed} (d)	1000	EFSA 2018;16(7):5389
DT _{50,whole system} (d)	1000	EFSA 2018;16(7):5389

PEC_{sw/sed}

Table 8.9-11: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for clopyralid following single/ multiple application(s) of ADM.01851.H.1.A to sugar beet (3 x 50.25 g a.s./ha)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)*	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)**	Max PEC _{sed} (µg/kg)*
Step 1	---	51.5421	Runoff/drainage	51.1663	0.7262***
Step 2					
Northern Europe	March-May	4.5942	Runoff/drainage	4.5603	0.0647
Southern Europe	March-May	8.1788	Runoff/drainage	8.1190	0.1152
D3	ditch	0.2694*	Drainage	0.04982	0.04206
D4	pond	0.04820	Drainage	0.04764	0.03933
D4	stream	0.2193*	Drainage	0.02703	0.02039
R1	pond	0.02239	Drift	0.02147	0.01288
R1	stream	0.3963	Drift	0.01056	0.02301
R3	stream	1.635	Drift	0.08265	0.1414

* single applications should be marked; ** two-time as required by ecotox; *** highest PEC_{sed} on day 1

zRMS comments:

The input parameters considered by the Applicant in surface water modelling for clopyralid presented in Table 8.9-10 are in line with EU agreed endpoints reported in EFSA Journal 2018;16(7):5389.

The zRMS confirms that the application at 3x50.25 g a.s./ha represents worst case and performed calculations are thus protective for application of 3x49.5 g a.s./ha presented in the GAP table 8.8-1.

The Step 1-2 surface water exposure was independently validated by the zRMS in additional simulations using the same input parameters. Results obtained by the zRMS were in good agreement with values obtained by the Applicant and results reported in Table 8.9-11 may be used in the risk assessment.

Simulations performed at Step 3 were not validated, since acceptable risk to aquatic organisms could be concluded already with Step 2 surface water exposure with all values being below the RAC. Taking this into account, results of Step 3 simulations were struck through and shaded as not relevant.

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

8.9.2.3 PEC_{sw/sed} of formulation

Calculation of PEC_{sw/sed} of the formulation is not required. Aquatic risk assessments are based on individual substance PEC_{sw/sed} values.

zRMS comments:

Calculation of the surface water exposure for the formulated product was deemed not necessary since the risk assessment may be based on more accurate PEC_{SW/SED} values calculated for the active substance with consideration of all relevant routes of entry into surface water bodies.

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

Table 8.10-1 Summary of atmospheric degradation and behaviour - ethofumesate

Compound	Ethofumesate
Direct photolysis in air	No data required
Quantum yield of direct phototransformation	1.92×10^{-4} mol Einstein ⁻¹
Photochemical oxidative degradation in air	DT50 (h): 4.1 derived by the Atkinson model OH (24h) concentration assumed = 5×10^5
Volatilisation	Vapour pressure (Pa): 3.6×10^{-4} (20 °C) 6.5×10^{-4} (25 °C) 4.3×10^{-3} (40 °C) No volatilisation expected
Metabolites	None

The vapour pressure at 20 °C of the active substance ethofumesate is 3.6×10^{-4} Pa. Hence the active substance ethofumesate is regarded as semivolatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance ethofumesate due to volatilization with subsequent deposition should be considered.

Table 8.10-2 Summary of atmospheric degradation and behaviour - clopyralid

Compound	Clopyralid
Direct photolysis in air	No data required
Quantum yield of direct phototransformation	1.01×10^{-6} mol Einstein ⁻¹
Photochemical oxidative degradation in air	DT50 (d): 19.5 derived by the Atkinson model OH (12h) concentration assumed = not provided
Volatilisation	Vapour pressure (Pa): 1.36×10^{-3} Pa at 20°C Henry's Law Constant (Pa.m ³ /mol): 3.28×10^{-10} (20 °C, unbuffered) 2.18×10^{-11} (20 °C, pH 5) 1.80×10^{-11} (20 °C, pH 7) 1.64×10^{-11} (20 °C, pH 9)
Metabolites	None

The vapour pressure at 20 °C of the active substance clopyralid is $> 10^{-4}$ Pa. Hence the active substance clopyralid is regarded as volatile (volatilisation from soil and plant surfaces). Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance clopyralid due to volatilization with subsequent deposition should be considered.

zRMS comments:

Information regarding fate and behaviour of ethofumesate in the air presented in Table 8.10-1 is in line with the EU agreed data reported in EFSA Journal 2016;14(1):4374, where it is stated that ethofumesate is not expected to be subject to volatilisation and the long- or short-range transport despite vapour pressure above the threshold of 10^{-5} Pa.

Information regarding fate and behaviour of clopyralid in the in the air presented in Table 8.10-2 is in line with the EU agreed data reported in EFSA Journal 2018;16(7):5389.

Due to the vapour pressure above trigger of 10^{-5} Pa, clopyralid may be considered as slightly volatile. The volatilisation from soil and plant surfaces was investigated in the course of the renewal process and indicated low volatilisation potential of this compound (<2% and <4% from soil and plant surfaces, respectively).

Taking into account the above data, the contamination of the atmosphere from the intended uses of ADM.01851.H.1.A is considered to be negligible.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2.4	Hicks J.	2024a	PECgroundwater Calculations for Ethofumesate and Metabolites Following Application of ADM.01851.H.1.A For Submission to Central EU Regulatory Zone Company Report No: ETF/EFA/12 000119037 Agrexis A.G., Basel, Switzerland non GLP Unpublished	N	ADAMA
KCP 9.2.4	Hicks J.	2024b	PECgroundwater Calculations for Clopyralid Following Application of ADM.01851.H.1.A For Submission to Central EU Regulatory Zone Company Report No: CLO/EFA/01 000119036 Agrexis A.G., Basel, Switzerland non GLP Unpublished	N	ADAMA
KCP 9.2.5	Hicks J.	2024c	PECsurfacewater and PECsediment Calculations for Ethofumesate and Metabolites Following Application of ADM.01851.H.1.A For Submission to Central EU Regulatory Zone Company Report No. ETF/EFA/13 000119039 Agrexis A.G., Basel, Switzerland non GLP Unpublished	N	ADAMA
KCP 9.2.5	Hicks J.	2024d	PECsurfacewater and PECsediment Calculations for Clopyralid Following Application of ADM.01851.H.1.A For Submission to Central EU Regulatory Zone Company Report No. CLO/EFA/02 000119038 Agrexis A.G., Basel, Switzerland non GLP Unpublished	N	ADAMA

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 all endpoints for the active substances and its metabolites were taken from the EU review of ethofumesate and clopyralid for the list of respective studies please refer to Volume 2 of the RAR for ethofumesate and clopyralid.					

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 Annex II studies

No new data submitted.

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

A 3.1 PEC_{GW} Modelling for Ethofumesate

Comments of zRMS:	The groundwater modelling for ethofumesate has been partly accepted by the zRMS. For evaluation of the input parameters, please refer to points 8.8.
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Reference:	KCP 9.2.4
Report	Hicks J., 2024a, PECgroundwater Calculations for Ethofumesate and Metabolites Following Application of ADM.01851.H.1.A For Submission to Central EU Regulatory Zone, Report No. ETF/EFA/12, Sponsor No. 000119037
Guideline(s):	Yes FOCUS Guidance Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU (SANCO/13144/2010, v. 3, 2014)
Deviations:	No
GLP:	No, GLP not relevant for modelling reports
Acceptability:	Yes

Materials and methods

PEC_{GW} values were calculated using the following models:

- PEARL 5.5.5
- PELMO 6.6.4
- MACRO 5.5.4

The input parameters for ethofumesate and its metabolites NC8493 and NC20465 are listed in section 8.8.2. For ethofumesate plant uptake factors of 0 and 0.5 were considered.

The critical GAP is listed in section 8.1 of this document. The application can be split into 3 or 4 applications which add up to a total annual application rate of 2 L product/ha. The application rates for ethofumesate are 3 x 335 g a.s./ha or 4 x 250 g a.s./ha.

Annual, biennial and triennial applications were considered.

Crop interception was taken into consideration. A crop interception value of 20% was used in accordance with EFSA Journal 2014;12(5):3662.

Absolute application dates were determined using AppDate version 3.06.

Metabolite NC8493 is a photoproduct, therefore PEC_{gw} calculations were carried out with NC8493 as the parent and NC20645 as its metabolite. Pseudo-application rates were calculated using the following equation:

$$\frac{\text{MW metabolite}}{\text{MW parent}} \times \frac{\text{Max. observed}}{100} \times \text{parent app. rate} = \text{pseudo app. rate}$$

The resultant pseudo-application rates are summarised in the table below.

Table A2.1-1: Pseudo-application rates for NC8493

Ethofumesate application rate (g/ha)	NC8493 application rate (g/ha)
335	73.1
250	54.6

Results and discussions

All PEC_{GW} values are summarised in section 8.8.2.1 of this document.

PEC_{GW} values for ethofumesate were <0.1 µg/L with consideration of biennial or triennial applications. All PEC_{GW} values for metabolites NC8493 and NC20645 were <0.001 µg/L.

Conclusion

PEC_{GW} values for ethofumesate were <0.1 µg/L with consideration of biennial or triennial applications. All PEC_{GW} values for metabolites NC8493 and NC20645 were <0.001 µg/L.

A 3.2 PEC_{GW} Modelling for Clopyralid

Comments of zRMS:	The groundwater modelling for clopyralid has been partly accepted by the zRMS. For evaluation of the input parameters, please refer to points 8.8.
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Reference:	KCP 9.2.4
Report	Hicks J., 2024b, PECgroundwater Calculations for Clopyralid Following Application of ADM.01851.H.1.A For Submission to Central EU Regulatory Zone, Report No. CLO/EFA/01, Sponsor No. 000119036
Guideline(s):	Yes FOCUS Guidance Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU (SANCO/13144/2010, v. 3, 2014)
Deviations:	No
GLP:	No, GLP not relevant for modelling reports
Acceptability:	Yes

Materials and methods

PEC_{GW} values were calculated using the following models:

- PEARL 5.5.5
- PELMO 6.6.4
- MACRO 5.5.4

Input values are listed in section 8.8.2 of this document. Plant uptake factors of 0 and 0.5 were considered.

The critical GAP is listed in section 8.1 of this document. The application can be split into 3 or 4 applications which add up to a total annual application rate of 2 L product/ha. The application rates for ethofumesate are 3 x 335 g a.s./ha or 4 x 250 g a.s./ha.

Annual, biennial and triennial applications were considered.

Crop interception was taken into consideration. A crop interception value of 20% was used in accordance with EFSA Journal 2014;12(5):3662.

Absolute application dates were determined using AppDate version 3.06.

Results and discussions

All PEC_{GW} values are summarised in section 8.8.2.2 of this document.

PEC_{GW} values for clopyralid were <0.1 µg/L with consideration of biennial or triennial applications and a plant uptake factor of 0.5 for all scenarios except Sevilla.

Conclusion

PEC_{GW} values for clopyralid were <0.1µg/L with consideration of biennial or triennial applications and a plant uptake factor of 0.5 for all scenarios except Sevilla.

A 3.3 PEC_{SW} Modelling for Ethofumesate

Comments of zRMS:	The surface water modelling for ethofumesate has been partly accepted by the zRMS. For evaluation of the input parameters, please refer to points 8.9.
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Reference:	KCP 9.2.5
Report	Hicks J., 2024c, PEC _{surfacewater} and PEC _{sediment} Calculations for Ethofumesate and Metabolites Following Application of ADM.01851.H.1.A For Submission to Central EU Regulatory Zone, Report No. ETF/EFA/13, Sponsor No. 000119039
Guideline(s):	Yes FOCUS Landscape And Mitigation Factors In Aquatic Ecological Risk Assessment (SANCO/10422/2005 version 2.0, September 2007)
Deviations:	No
GLP:	No, GLP not relevant for modelling reports
Acceptability:	Yes

Materials and methods

PEC_{SW} and PEC_{SED} values were calculated using the following models:

- FOCUS Steps 1 and 2 v. 3.2
- FOCUS SWASH v5.3
- FOCUS PRZM v4.3.1
- FOCUS MACRO v5.5.4
- FOCUS TOXWA v5.5.3
- SWAN v5.01

The input parameters for ethofumesate and its metabolites NC8493 and NC20465 are listed in section 8.9.2. For ethofumesate plant uptake factors of 0 and 0.5 were considered.

The critical GAP is listed in section 8.1 of this document. The application can be split into 3 or 4 applications which add up to a total annual application rate of 2 L product/ha. The application rates for ethofumesate are 3 x 335 g a.s./ha or 4 x 250 g a.s./ha.

Crop interception was taken into consideration at Step 2. A crop interception value of 20% (minimal crop cover) was used.

Absolute application dates were determined using AppDate version 3.06.

Step 4 calculations were required. Volatilisation was taken into account and calculated using EVA 3 rev. 2h. The reduction factors defined in the FOCUS Landscape and Mitigation Report (SANCO/10422/2005 version 2.0, September 2007) were used to calculate the mitigation following use of a vegetated filter strip and are summarised in section 8.9.2 of this document.

Results and discussions

All PEC_{GW} values are summarised in section 8.9.2.1 of this document.

Step 4 PEC_{SW} values with consideration of a 10m vegetative buffer were required for ethofumesate. Step 2 values for metabolite NC8493 were <0.0001µg/L for all scenarios. Step 3 PEC_{SW} values were required for metabolite NC20645.

Conclusion

Step 4 PEC_{SW} values with consideration of a 10m vegetative buffer were required for ethofumesate. Step 2 values for metabolite NC8493 were <0.0001 µg/L for all scenarios. Step 3 PEC_{SW} values were required for metabolite NC20645.

A 3.4 PEC_{SW} Modelling for Clopyralid

Comments of zRMS:	The surface water modelling for clopyralid has been partly accepted by the zRMS. For evaluation of the input parameters, please refer to points 8.9.
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Reference:	KCP 9.2.5
Report	Hicks J., 2024d, PEC _{surfacewater} and PEC _{sediment} Calculations for Clopyralid Following Application of ADM.01851.H.1.A For Submission to Central EU Regulatory Zone, Report No. CLO/EFA/02, Sponsor No. 000119038
Guideline(s):	Yes FOCUS Landscape And Mitigation Factors In Aquatic Ecological Risk Assessment (SANCO/10422/2005 version 2.0, September 2007)
Deviations:	No
GLP:	No, GLP not relevant for modelling reports
Acceptability:	Yes

Materials and methods

PEC_{SW} and PEC_{SED} values were calculated using the following models:

- FOCUS Steps 1 and 2 v. 3.2
- FOCUS SWASH v5.3
- FOCUS PRZM v4.3.1
- FOCUS MACRO v5.5.4
- FOCUS TOXWA v5.5.3

The input parameters for clopyralid are listed in section 8.9.2.

The critical GAP is listed in section 8.1 of this document. The application can be split into 3 or 4 applications which add up to a total annual application rate of 2 L product/ha. The application rates for ethofumesate are 3 x 335 g a.s./ha or 4 x 250 g a.s./ha.

Crop interception was taken into consideration at Step 2. A crop interception value of 20% (minimal crop cover) was used.

Results and discussions

All PEC_{GW} values are summarised in section 8.9.2.2 of this document.

Step 2 values were required for clopyralid solo, but Step 3 values were required for the aquatic risk assessment of the mixture.

Conclusion

Step 2 values were required for clopyralid solo, but Step 3 values were required for the aquatic risk assessment of the mixture.

A 3.5 Justification for Plant Uptake Factor (PUF) refinement

Comments of zRMS:	The information below were used by the Applicant to confirm that clopyralid is taken up by the plant roots and translocated to the upper parts of the plant.
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	However as discussed above in the commenting box under the point 8.8 the performed experiments to refine PUF value are highly uncertain and may lead to overestimation of PUF and in consequence - underestimation of the groundwater exposure. Thus, information below is struck through as being not validated by the zRMS. It must be also emphasised that the study by Gourley (2015) has been evaluated by the RMS (Finland) in the course of the clopyralid renewal process and not agreed for purposes of refinement of the TSCF value (for details, see Vol. 3CP, B.8 for GF-1374 of March 2018). The RMS evaluation and derived conclusions were agreed by the MS experts and EFSA during the peer-review process and the zRMS fully agrees with the derived conclusions and will thus not re-consider the results of the study by Gurley (2015) in the scope of the zonal evaluation of ADM.01851.H.1.A.
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~~Translocation in plants was demonstrated in a dedicated PUF study (Gourlay, 2015¹), and underpinned by comparing the PUF study to the 30 days plant back interval confined rotational study by Hall (2015)² which are available in the RAR for clopyralid.~~

~~The dedicated PUF study by Gourlay (2015) is fully in agreement with the study test design that has been developed by German UBA and the German industry association IVA since October 2018. The study design has been shared for commenting with other Member States by UBA.~~

~~The applicant proposes that Tier 2 calculations with a PUF = 0.5 should be considered as a refinement. The dedicated PUF study Gourlay (2015) is compared to the 30 days plant back interval confined rotational crop study by Hall (2015) which was run with soil. The applicant also wants to draw the attention to previous EFSA conclusion on Succeeding and Rotational Crops (EFSA Scientific Report, 2005 (50), Conclusion on the peer review of clopyralid):~~

~~“Furthermore, metabolism studies indicated that clopyralid is systemically taken into plants and readily translocated in plants. Soil – plant transition factors to estimate the residue situation in rotational crops have been calculated by RMS and presented in the evaluation meeting. The values indicate that there might be good uptake from soil or even accumulation in the plants, and soil residues above 0.001 mg/kg might be present at the time of harvesting rotational crops.”~~

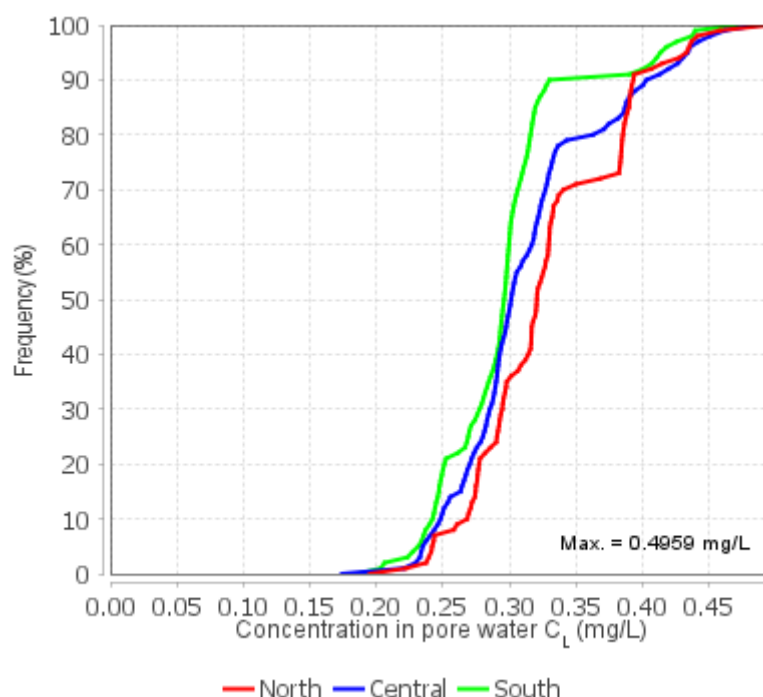
~~The primary intention for conducting the study Gourlay (2015) was not to derive a measured PUF value for use in modelling but to demonstrate under controlled conditions that clopyralid will be taken up by roots and transported to the shoots. The observed PUF values were higher than the default PUF = 0.5 for root systemic substances. The experimentally derived PUF value should represent the potential of a crop to take up a substance. Actual uptake is downregulated in the simulation models. In the groundwater simulation models plant uptake is regulated by a) availability of substance in the pore water, and b) transpiration. This is similar to DegT₅₀, which enters the models determined at (or normalized to) 20°C. Actual degradation rates are adjusted for actual temperature conditions (ignoring soil moisture for the sake of simplicity).~~

~~With regards to a potential overestimation of substance availability in hydroponic systems the applicant would like to add that clopyralid test solution concentration had been selected to mirror what could be expected in soil pore water in the field. The magnitude of concentration had been estimated with EFSA model PERSAM whose mathematical equations are described in the EFSA Scientific Opinion on the assessment of exposure of organisms to substances in soil (EFSA Journal 2012;10(2):2562). Considering the common wheat scenario, a DegT₅₀ = 7.05 days (geometric mean field), K_{OC} = 1.41 L/kg (geometric mean), and an application of 80 g clopyralid/ha (20% crop interception) the Tier 2 CDF of soil pore water concentrations across Europe can be predicted.~~

¹-Gourlay, V.; 2015; Plant uptake of 14C labelled clopyralid in wheat and oilseed rape under greenhouse conditions; RLP Agro-Science GmbH, 67435 Neustadt a.d. Weinstraße, Germany; Lab Study No. AS421; DAS Study No. 150297; 25.06.2015; Unpublished

²-Hall, L. R.; 2015; 14C-Clopyralid: Metabolism in Confined Rotational Crops with a 30-Day Plant-back Interval; ABC Laboratories, Inc., Columbia, Missouri 65202, USA; Lab Study No. 69725; DAS Study No. 130733; 12 January 2015; Unpublished

Below, the $PEC_{\text{pore, water}}$ shown is the 7-day TWA which is considered as more relevant to a study with an exposure duration of similar length. Furthermore, a 20-cm soil depth is considered because the root system will be found predominantly in this layer.



Predicted 7-day pore water concentrations of clopyralid over 20-cm following an application of 80 g clopyralid/ha at BBCH 20-29 to cereals yields a range from 150 to 500 µg/L. The average clopyralid test solution concentration was 70 µg/L in Gourlay (2015). The reason for selecting a lower concentration than predicted was that pre-tests on plant tolerance had shown that higher concentrations would impair plant health in the test system.

Additionally, the applicant would like to point to study Hall (2015), a 30-day plant back interval confined rotational study. One of the primary objectives was to provide an estimate of the total radioactive residues in three rotational crops (wheat, cabbage and radish) following an application of 300 g clopyralid/ha to bare soil 30-days prior to planting. Crops were grown in test plots containing a Missouri sandy loam. Wheat samples were harvested 62 days after treatment (DAT) at BBCH 43, as well as later. The first sampling is closest to the growth stage considered in Gourlay (2015), e.g. BBCH 21-31 at application of test item.

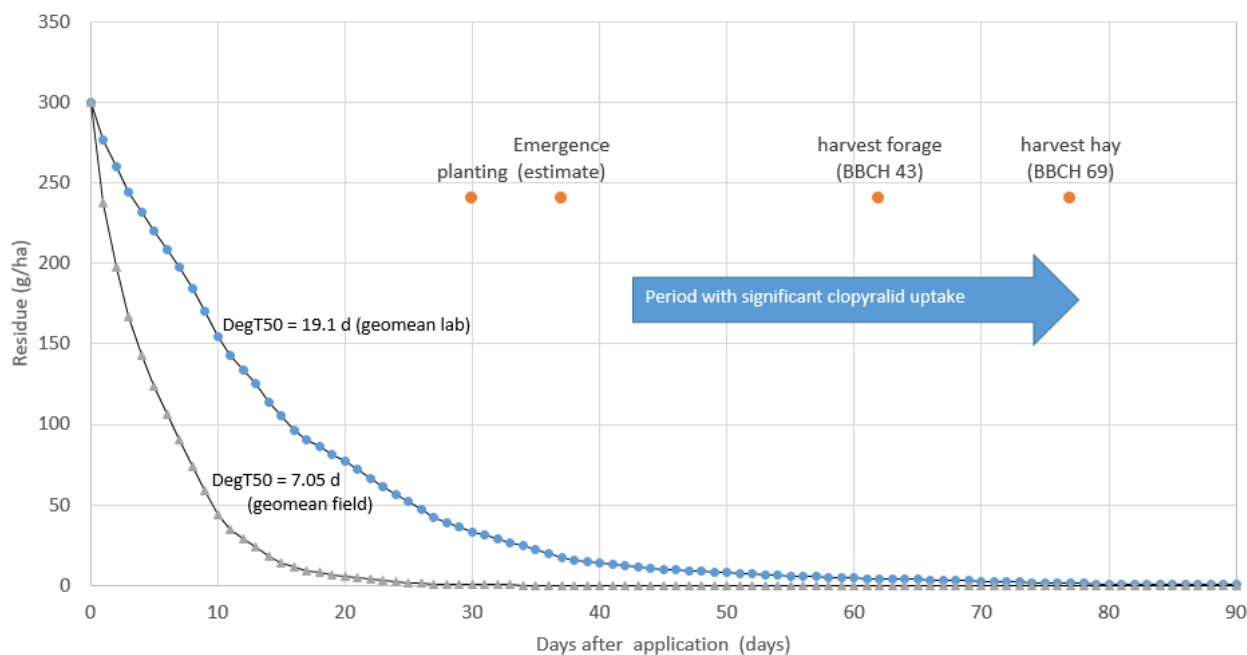
At 62 DAT clopyralid residue in wheat shoots amounted to 0.367 mg/kg. At 78 DAT to 0.729 mg/kg. These values are about one magnitude of order lower than observed by Gourlay (2015):

Replicate	Clopyralid in stem & leaves observed by Gourlay (2015) (mg/kg)
a	8.19
b	7.84
c	6.75
d	6.96
Average	7.43

Dry matter content of clopyralid had not been reported in the study report but is recorded in the raw data.

The lower contents found by Hall (2015) may be explained by a lower exposure to clopyralid in soil. While soil concentrations had not been measured directly, an estimate can be provided. Below clopyralid residue decline is modelled with the geometric mean laboratory $DegT_{50}$ (19.1 d) and the geometric mean field

DegT₅₀ (7.05 d). Considering both DegT₅₀ values should show the range of soil residue that could be expected. The decline has been adjusted for observed daily soil temperature, which was always well above 20°C. Furthermore, the plots had been irrigated often. Soil moisture should not have affected degradation greatly.



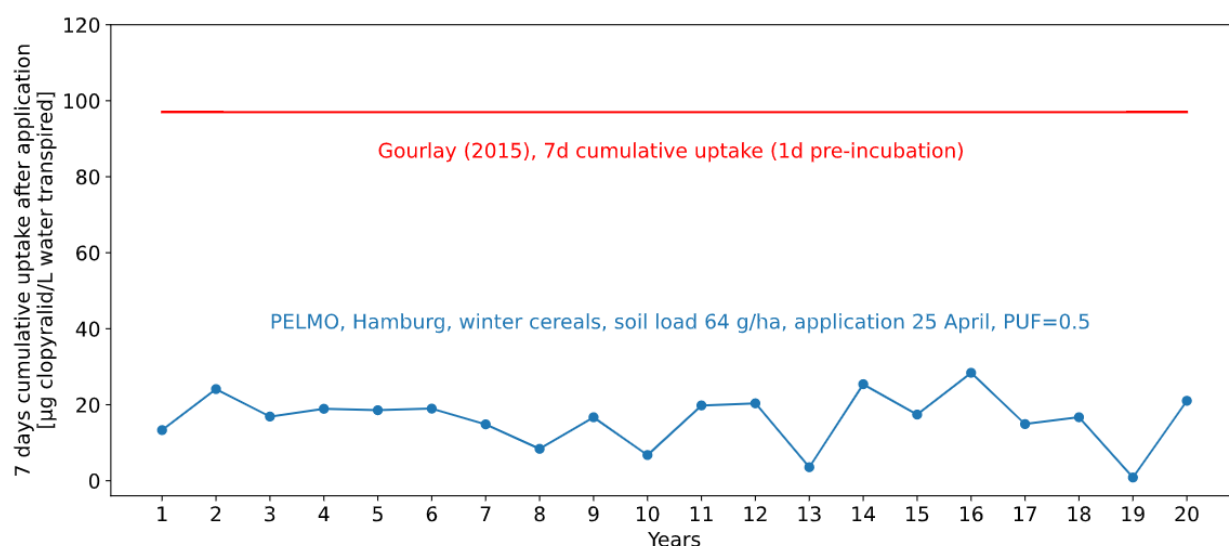
No date is given for emergence of wheat in the trial. However, given the fairly high temperatures one week after planting can be assumed. With regards to clopyralid uptake it can be assumed that seedlings will not take up significant amounts since their canopy is still too small for higher transpiration rates. Taking this crop development into account it can be excluded that plants took up significant amounts of clopyralid before 44 DAT. Looking at the modelled residue decline curves 44 DAT corresponds to 0 to 10 g/ha clopyralid residue, depending on the DegT₅₀. This is a very low level and may explain why wheat dry matter residue contents of clopyralid were lower than in Gourlay (2015), especially when considering that real uptake would not have taken place before BBCH 20. This would correspond to even lower soil residue contents.

Finally, the uptake observed by Gourlay (2015) is put into context with FOCUS PELMO modelling. A comparison is made between the uptake observed and the uptake modelled by FOCUS PELMO for a soil load of 64 g/ha in the Hamburg winter cereals scenario with an application date of 25 April and a refined PUF of 0.5.

FOCUS models do not simulate crop biomass. Therefore, a comparison is made by normalizing substance uptake by water transpired, e.g. for the 7-day period after application the uptake of clopyralid is divided by water transpired in the same period.

FOCUS PELMO output file PLOT.PLM reports variables TETD (water transpired; cm/d) and TUPF (substance taken up by crop; kg/ha.d). For each application year these two variables had been extracted for the 7-day period after application.

Below substance taken up in the 7 days after application is shown for each application year. For comparison the red line shows the uptake in winter wheat observed by Gourlay (2015).



Gourlay (2015) observed a normalized uptake of $97 \mu\text{g/L}^3$ which is well above the amounts simulated by FOCUS PELMO (range 1 to $28 \mu\text{g/L}$). As alluded to above the hydroponic laboratory study can be considered as a best case similar to DegT_{50} soil degradation studies. Actual uptake is scaled down by environmental conditions in the modelling scenarios. Therefore, even with a consideration of a $\text{PUF} = 0.5$ the risk assessment is still conservative.

³ Calculated from data presented in Table A 11 in Gourlay (2015): cumulative uptake with 1 d pre-incubation (mass uptake $26.33 \mu\text{g}$, water uptake 271.8 mL)