REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: AG-E1-500 SC1

Product name(s): see Part A

Chemical active substance:

Ethofumesate, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Sponsor: Adama Agan Ltd.

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

Submission date: March 2021

MS Finalisation date: January 2022 (initial Core Assessment)

June 2022 (final Core Assessment)

Version history

When	What
March 2021	dRR version 1 submitted by applicant
January 2022	Initial assessment by the zRMS The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through and shaded for transparency~~.
June 2022	Final report (Core Assessment updated following the commenting period). Additional information/assessments included by the zRMS in the report in response to comments recieved from the cMS and the Applicant are highlighted in yellow. Information no longer relevant ~~is struck through and shaded~~.

DATA PROTECTION CLAIM

Under Article 59, Regulation 1107/2009/EC, on behalf of the Sponsor Company the applicant claims data protection for these studies. The data protection status and corresponding justification as valid for the respective country will be confirmed in the respective PART A

STATEMENT FOR OWNERSHIP

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8 Fate and behaviour in the environment (KCP 9)

8.1 Critical GAP and overall conclusions

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 situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha 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, 2	HU, SK	Sugar beet BEAVA Fodder beet BEAVC	F	annual dicot weeds and annual grass weeds	foliar spraying, overall	BBCH 10-18/ spring	a) 2 b) 2	a) 5 b) 5	a) 1 L/ha b) 2 L/ha	a) 500 b) 1000	100-400	n.a.	Max. rate of active must not exceed 1.0 kg/ha every 3 years (from all used products with ethofumesate).	R Triennial application Maximum cumulative rate of ethofumesate on the treated field from all used products with this substance is 1000 g a.s. every three years
3	PL	Sugar beet BEAVA Fodder beet BEAVC	F	annual dicot weeds and annual grass weeds	foliar spraying, overall	BBCH 10-18/ spring	a) 3 b) 3	a) 5 b) 5	a) 0.6 L/ha b) 1.8 L/ha	a) 300 b) 900	100-400	n.a	Max. rate of active must not exceed 1.0 kg/ha every 3 years. At each time can be applied in tankmix: AG-E1-50 SC 0.5 L/ha + Goltix Titan 565 SC 1.5 L/ha + Atpolan BIO 80 EC 1.0 L/ha (from all used products with ethofumesate).	R Triennial application Maximum cumulative rate of ethofumesate on the treated field from all used products with this substance is 1000 g a.s. every three 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

Explanation for column 15 "Conclusion"

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

Table 8.1-2: Assessed (critical) uses during EU approval of Ethofumesate 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, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					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	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
Task Force Ethofumesate	North, Central and South EU	Sugar beet, fodder beet, red beet	F	Annual dicot weeds and annual grasses	Overall spray	Post-emergence BBCH 16-18	a) 1-3 b) 1-3	5	a) 2 b) 2	a) 1 b) 1	100-400	n/a	The maximum amount of a.s. must not exceed 1.0 kg/ha every 3 years
United Phosphorus Limited	North, Central and South EU	Sugar beet, fodder beet	F	Annual weeds	Overall spray	Pre-emergence	a) 1 b) 1	n/a	a) 2 b) 2	a) 1 b) 1	300-400	n/a	PHI covered by the vegetation period, max. 1 kg a.s./ha every three years
United Phosphorus Limited	North, Central and South EU	Sugar beet, fodder beet	F	Annual weeds	Overall spray	Post-emergence until BBCH 18	a) 6***	5	a) 0.32***	a) 0.16***	200-300	n.a	PHI covered by the vegetation period, max. 1 kg a.s./ha every three years

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

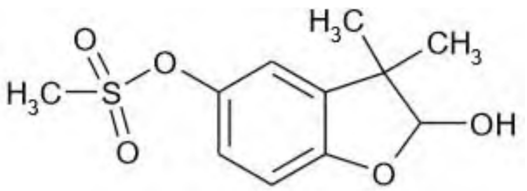
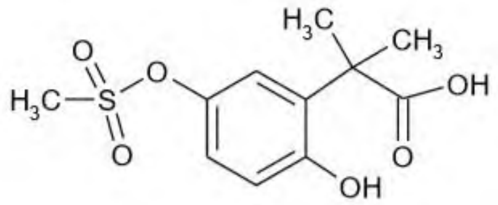
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

*** 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

n/a not applicable

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% (photolysis)	PEC_{gw}: leaching potential to groundwater PEC_{soil}: >10% of a.s. $PEC_{sw/sed}$: run-off/drainage potential to surface water
NC 20645	274.3		Water/Sediment: 18.8%	PEC_{gw}: potential formation from NC 8493 $PEC_{sw/sed}$: >10% of a.s.

zRMS comments:

Information regarding metabolites of ethofumesate provided in Table 9.1-3 above is in line with EU agreed data reported in EFSA Journal 2016:14(1):4374. Additional information has been added by the zRMS for completeness.

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)

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
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
Montesqiuieu	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 loam	5.0	20	55	0.02	0.06	0.06[b]	2.2	DFOP	EFSA 2016; 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.(°C)**	**MWHC (%)**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa[a]**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y 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	EFSA 2016; 14(1):4374
DD	Clay loam	7.0	20	55	0.15	0.52	0.15	5.3	SFO	EFSA 2016; 14(1):4374
WW	Sandy loam	5.2	20	55	0.05	0.30	0.17[b]	0.0001	DFOP	EFSA 2016; 14(1):4374
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 where k1 = 5.1835, k2 = 126.72 and g = 0.28569

Soil Photolysis

The photolysis 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 8.3-4: Summary of photolysis degradation rates for ethofumesate - laboratory studies

Ethofumesate, Laboratory studies, aerobic conditions										
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 Reference**
Not provided	Silt loam	6.5	20	50	94.2	313	n/s	9.9	SFO	EFSA 2016; 14(1):4374

zRMS comments:

Soil degradation data for ethofumesate and its metabolites presented in Tables 8.3-2 to 8.3-4 are in line with EU agreed endpoints reported in EFSA Journal 2016;14(1):4374.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

The aerobic 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.

8.4 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)

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.

Triggering endpoints

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

Ethofumesate, Field studies – Triggering endpoints									
Soil type	**Location**	**pH ([a])**	**Depth (cm)**	**DissT50 (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 α=0.004 β=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 k1=0.09528 k2=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 k1=0.03878 k2=0.003795 g=0.5968	367	110 [c]	6.1 ~~6.7~~	DFOP	EFSA 2016; 14(1):4374
Loam (NZ11007/4)	Spain	7.7	0-30	12.3 k1=0.1805k2=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 DT_{50} 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 Q_{10} of 2.58 and Walker equation coefficient 0.7.

zRMS comments:

Field degradation data for ethofumesate presented in Table 8.4-1 are in general in line with the EU agreed endpoints reported in EFSA Journal 2016;14(1):4374 with correction of the χ^2 reported for silty clay loam soil (NZ11007/3).

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.

zRMS comments:

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

8.5 Mobility in soil (KCP 9.1.2)

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

The 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

Ethofuemsate							
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
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. The metabolite NC8493 has a very short half-life in soil (Geomean DT_{50} = 0.03, though DT_{50} = 0.07 used in PECsoil calculations of EFSA). A Kdoc value of 20.82 mL/g was calculated using EPI WIN.

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 metabolite NC20645 presented in Tables 8.5-1 and 8.5-2 are is in line with EU agreed endpoints reported in EFSA Journal 2016;14(1):4374. For metabolite NC8493 the K_{doc} of 20.82 mL/g with 1/n of 1 is reported in the LoEP with no other information.

8.5.1 Column leaching (KCP 9.1.2.1)

In the active substance assessment of ethofumesate it is stated that no reliable column leaching studies were available, but this was not identified as a data gap because valid batch adsorption studies are available.

zRMS comments:

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

8.5.2 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 µg/L, with the exception of one study in Befordshire, UK where one substance accounted for 0.41 (1st year) and 0.5 µg parent/L (2nd year) ~~in each year~~. This substance was identified as a mixture of NC8493-glycoside and NC20645-glycoside.

zRMS comments:

Provided above information is in line with data reported in EFSA Journal 2016;14(1):4374 with some addional information intrduced by the zRMS for clarity.

8.5.3 Field leaching studies (KCP 9.1.2.3)

No field leaching studies are considered necessary.

zRMS comments:

Field leaching studies with ethofumesate were not performed or required during EU review.

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.

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.**	**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	250	830	SFO	52	457	DFOP	1000	SFO	EFSA 2016; 14(1):4374
Waldwinkel	7.7/7.1	294	976	SFO	7.8	101	DFOP	1000	SFO	EFSA 2016; 14(1):4374
Anglersee	8.6/6.8	89	296	SFO	43	187	DFOP	96	SFO	EFSA 2016; 14(1):4374
Hönniger Weiher	7.2/6.3	141	469	SFO	9.9	130	DFOP	1000	SFO	EFSA 2016; 14(1):4374
Rhine River	7.9/6.9	103	342	SFO	13.3	94	DFOP	1000	SFO	EFSA 2016; 14(1):4374
Anwiler Teich	7.9/6.9	164	543	SFO	23	155	DFOP	1000	SFO	EFSA 2016; 14(1):4374
Pond	7.9/7.8	217	722	SFO	37	343	DFOP	258	SFO	EFSA 2016; 14(1):4374
Creek	8.2/7.5	209	693	SFO	141	804	DFOP	273	SFO	EFSA 2016; 14(1):4374
Geometric mean (n=8)		170	564		26.9	215		536		

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_f/k_{dp}): Anglersee 0.385 (from parent; whole system) Pond 0.443 (from parent; whole system)	EFSA 2016; 14(1):4374

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
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 $CaCl_2$
n/d not detected
[a] no reliable DT_{50} 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 ∑ > 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:

Information on degradation of ethofumesate and its metabolite NC20645 in water/sediment systems presented in Tables 8.6-1 to 8.6-3 and information on hydrolysis and phototransformation in water presented in Table 8.6-4 are in line with EU agreed endpoints reported in EFSA Journal 2016;14(1):4374.

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

8.7.1 Justification for new endpoints

No deviation from the EU agreed endpoints.

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

PECsoil calculations are calculated below in accordance with FOCUS Guidance (SANCO/10058/2005 v.2.0, 2006). Note that EFSA Guidance for predicting environmental concentrations in soil (EFSA Journal 2017;15(10):4982) is not yet noted and the modelling tool PERSAM is not intended for regulatory use in support of 1107/2009, according to the Joint Research Centre, European Soil Data Centre website (https://esdac.jrc.ec.europa.eu/content/european-food-safety-authority-efsa-data-persam-software-tool).

Use 1 in the critical GAP table (please refer to section 8.1 of this document) has been calculated as a worst-case scenario. This assumption is supported by the EFSA conclusion, EFSA 2016;14(1):4374, which demonstrates that calculations for 3 applications of 333 g a.s./ha result in lower PECsoil values than calculations for 2 applications of 500 g a.s./ha.

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

Use No.	1, 2 (covering also use No. 3)
Crop	Sugar beet
Application rate (g as/ha)	Ethofumesate: 500
Number of applications/interval	2/5
Crop interception (%)	20
Depth of soil layer (cm)	5
Depth of mixing layer for annual tillage (cm)	20

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 endpoint y 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

~~**Table 8.7-3: PEC_{soil} for Ethofumesate on sugar beet**~~

~~PEC_{soil} (mg/kg)~~		~~Sugar beet~~			
		~~Single application~~		~~Multiple applications~~	
		~~Actual~~	~~TWA~~	~~Actual~~	~~TWA~~
~~Initial~~		~~0.533~~	-	~~1.055~~	-
~~Short term~~	~~24h~~	~~0.531~~	~~0.532~~	~~1.050~~	~~1.053~~
	~~2d~~	~~0.529~~	~~0.531~~	~~1.046~~	~~1.050~~
	~~4d~~	~~0.524~~	~~0.529~~	~~1.037~~	~~1.046~~
~~Long term~~	~~7d~~	~~0.517~~	~~0.525~~	~~1.023~~	~~1.039~~
	~~14d~~	~~0.501~~	~~0.517~~	~~0.992~~	~~1.023~~
	~~21d~~	~~0.486~~	~~0.509~~	~~0.962~~	~~1.008~~
	~~28d~~	~~0.471~~	~~0.502~~	~~0.932~~	~~0.992~~
	~~50d~~	~~0.428~~	~~0.479~~	~~0.846~~	~~0.947~~
	~~100d~~	~~0.343~~	~~0.431~~	~~0.678~~	~~0.853~~
~~Plateau concentration (20 cm) after year 20~~		-	-	~~0.067~~	-
~~$PEC_{accumulation}$ (20 cm) (PEC_{act} + $PEC_{soil\ plateau}$)~~		-	-	~~1.122~~	-

~~PEC_{soil} of metabolites~~

~~Table 8.7-4: PEC_{soil} for NC8493 on sugar beet~~

~~PEC_{soil} (mg/kg)~~		~~Sugar beet~~			
		~~Single application~~		~~Multiple applications~~	
		~~Actual~~	~~TWA~~	~~Actual~~	~~TWA~~
~~Initial~~		~~0.116~~	~~-~~	~~0.116~~	~~-~~
~~Short term~~	~~24h~~	~~<0.001~~	~~0.012~~	~~<0.001~~	~~0.012~~
	~~2d~~	~~<0.001~~	~~0.006~~	~~<0.001~~	~~0.006~~
	~~4d~~	~~<0.001~~	~~0.003~~	~~<0.001~~	~~0.003~~
~~Long term~~	~~7d~~	~~<0.001~~	~~0.002~~	~~<0.001~~	~~0.002~~
	~~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 application pattern considered in soil exposure assessment and presented in Table 8.7-1 is in line with the critical Central Zone GAP and it is thus agreed by the zRMS.
According to EFSA Journal 2016;14(1):4374 application at 2x500 g a.s./ha with 5 day interval represents worst case comparing to application at 3x333 g a.s./ha (comparable with 3x300 g a.s./ha proposed use No. 3 for AG-E1-500 SC1) and for this reason would be protective for all uses of AG-E1-500 SC1 intended in the Central Zone. It is, however, noted that the soil exposure at the EU level was calculated with assumption of application every third year and impact of this assumption on potential accumulation of the active compound in soil is unclear. Most probably the $PEC_{SOIL,ACCU}$ after triennial application would be still higher after 2 applications at 500 g a.s./ha comparing to 3 applications at 333 g a.s./ha, but no calculations are available for confirmation.
In order to address this concern, additional PEC_{SOIL} values have been calculated by the zRMS, but in order to cover absolutely worst case, application of the cumulative rate of 1000 g a.s./ha was assumed (also in line with approach taken by the Applicant in calculation of PEC_{SOIL} for the formulated product). Results are presented in table below. For consistency also PEC_{SOIL} for metabolite was recalculated for these assumptions. Calculations were performed using ESCAPE ver. 2 with climate assumptions set to "Laboratory conditions", but with metabolite applied as a parent with pseudo-application rate of 218 g/ha calculated using molar ratio and maximum occurrence in soil. When metabolic pattern is not assumed, climate scenarios are switched off and bi-phasic degradation is not considered, ESCAPE serves as a simple calculator since when compounds are modelled as parent, it uses the same equations as these defined in FOCUS methodology. Short- and long-term PEC_{SOIL} values as well as detailed TWA PEC_{SOIL} values are not reported below as being not required for the risk assessment purposes.

Substance	$PEC_{SOIL, INI}$ [mg/kg dws]	$PEC_{SOIL, PLATEAU}$ [mg/kg dws]	$PEC_{SOIL, ACCU}$ [mg/kg dws]	21 d TWA PEC_{SOIL} [mg/kg dws]
Ethofumesate	1.0667	0.0665	1.1332	1.0852
NC 8493	0.2325	not relevant	not relevant	0.0055

Since acceptable risk to soil organisms could be concluded for PEC_{SOIL} values based on the worst case application pattern (i.e. single application at cumulative rate of 1000 g a.s./ha), no further calculations for detailed GAP are deemed necessary.

8.7.2.1 PEC_{soil} of AG-E1-500 SC1

The initial PECsoil value for the formulation AG-E1-500 SC1 has been calculated using the application rate of 1 L/ha and the formulation density of 1.12 g/ml. A worst-case crop interception of 20% was assumed.

Table 8.7-5: PEC_{soil} for AG-E1-500 SC1 on sugar beet

Active substance/ reparation	Application rate (g/ha)	PEC_{act} (mg/kg)	PEC_{twa}21 d (mg/kg)	Tillage depth (cm)	$PEC_{soil,plateau}$ (mg/kg)	$PEC_{accu} = PEC_{act} + PEC_{soil,plateau}$ (mg/kg)
AG-E1-500 SC1	1120	1.195	n/r	n/r	n/r	n/r

n/r not relevant

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. However, since the soil exposure for the formulated product does not account for potential accumulation of ethofumesate in soil, the zRMS recommends to perform the risk assessment with consideration of the soil exposure calculated for the active substance and formulation endpoints expressed in terms of the active substance.

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

8.8.1 Justification for new endpoints

No deviation from the EU agreed endpoints.

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, 2, 3
Crop	Sugar beet
Application rate (g as/ha)	Ethofumesate: 500 or 330 [1)]
Number of applications/interval (d)	2/5 or 3/5
Relative application dates	10 days after emergence, 15 days after emergence, 20 days after emergence
Absolute application dates	26th April (116), 1st May (121), 6th May (126) (for FOCUS MACRO calculations)
Crop interception (%)	20
Frequency of application	triennial
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3, FOCUS MACRO v5.5.4

[1)] Modelling performed for application at 3x330 g a.s./ha, but in line with the GAP the intended rate is 3x300 g a.s./ha

Table 8.8-2: Input parameters related to active substance Ethofumesate and metabolites for PEC_{gw} calculations

Compound	Ethofumesate	NC8493	NC20645	Value in accordance with EU endpoint y Reference*
Molecular weight (g/mol):	286.3	258.3	274.3	EFSA 2016; 14(1):4374
Water solubility (g/mol):	50	2019	16170	EFSA 2016; 14(1):4374
Saturated vapour pressure (Pa):	6.5×10^{-4}	3.73×10^{-6}	7.4×10^{-7}	EFSA 2016; 14(1):4374
DT_{50} in soil (d)	26.2 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58 and Walker equation coefficient 0.7)	0.03 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58 and Walker equation coefficient 0.7)	0.12 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} 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)/K_{fom}	118 / 68 (geometric mean)	2.082 / 1.210	5.1 / 2.964 (geometric mean)	EFSA 2016; 14(1):4374
1/n	0.905 (arithmetic mean)	1 (EPISuite)	0.93 (arithmetic mean)	EFSA 2016; 14(1):4374
Plant uptake factor	0	0	0	EFSA 2016; 14(1):4374
Formation fraction	n/a	1 (from Ethofumesate)	1 (from NC8493)	EFSA 2016; 14(1):4374

Table 8.8-3: PEC$_{gw}$ for Ethofumesate and metabolites following application of 2 x 500 g a.s./ha on sugar beet (with FOCUS PEARL 4.4.4/PELMO 5.5.3/MACRO 5.5.4)

Crop	Scenario	80[th] Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)		
		Ethofumesate	NC8493	NC20645
Sugar beet	Châteaudun	0.042/0.009/0.018	<0.001/<0.001/<0.001	<0.001/<0.001/<0.001
	Hamburg	0.017/0.009	<0.001/<0.001	<0.001/<0.001
	Jokioinen	0.001/0.001	0.004/0.004	0.001/0.004
	Kremsmünster	0.010/0.010	<0.001/<0.001	<0.001/<0.001
	Okehampton	0.018/0.019	<0.001/<0.001	<0.001/<0.001
	Piacenza	0.018/0.035	<0.001/<0.001	<0.001/<0.001
	Porto	0.002/0.009	<0.001/<0.001	<0.001/0.001
	Sevilla	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001
	Thiva	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001

Table 8.8-4: PEC$_{gw}$ for Ethofumesate and metabolites following application of 3 x 330 g a.s./ha on sugar beet (with FOCUS PEARL 4.4.4/PELMO 5.5.3/MACRO 5.5.4) [1)]

Crop	Scenario	80[th] Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)		
		Ethofumesate	NC8493	NC20645
Sugar beet	Châteaudun	0.059/0.009/0.023	<0.001/<0.001/<0.001	0.001/<0.001/<0.001
	Hamburg	0.025/0.009	<0.001/<0.001	<0.001/<0.001
	Jokioinen	0.002/0.001	0.005/0.004	0.002/0.004
	Kremsmünster	0.014/0.009	<0.001/<0.001	<0.001/<0.001
	Okehampton	0.027/0.020	<0.001/<0.001	<0.001/<0.001
	Piacenza	0.025/0.034	<0.001/<0.001	<0.001/<0.001
	Porto	0.003/0.009	<0.001/<0.001	0.001/0.001
	Sevilla	0.001/<0.001	<0.001/<0.001	<0.001/<0.001
	Thiva	0.001/<0.001	<0.001/<0.001	<0.001/<0.001

[1)] Modelling performed for application at 3x330 g a.s./ha, but in line with the GAP the intended rate is 3x300 g a.s./ha

zRMS comments:

The application pattern considered in the groundwater exposure assessment presented in Table 8.8-1 is in line with the critical Central Zone GAP. It is noted that according to the GAP for use No. 3 application at 3x300 g a.s./ha is proposed, while simulations were performed for slightly higher rate of 3x330 g a.s./ha, representing worst case.

Assumed crop interception is in line with the most recent version of the FOCUS Groundwater Guidance (2021) and is adequate for sugar beet at the BBCH 10-18 stage.

Assumed application dates correspond with the intended application timing, with the first application performed 10 days after emergence.

Input parameters presented in Table 8.8-2 used for ground water modelling are in line with EU agreed endpoints reported in EFSA Journal 2016;14(1):4374. Correct PUF of 0 has been assumed for all modelled compounds.

Simulations were performed with assumption of triennial application, in line with indications of the EFSA Journal 2016;14(1):4374.

The performed calculations were independently validated by the zRMS in additional modelling using FOCUS PEARL 4.4.4, PELMO 5.5.3 and FOCUS MACRO 5.5.4 on the basis of the same input parameters. Obtained PEC$_{GW}$ values were in good agreement with these reported by the Applicant in Tables 8.8-3 and 8.8-4 above.

Overall, no unacceptable leaching of ethofumesate and its metabolites is expected following triennial application of AG-E1-500 SC1 according to the intended use pattern. Please note that the maximum cumulative rate of ethofumesate on the treated field from all used products with this substance cannot exceed 1000 g a.s. every three years

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

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

8.9.1 Justification for new endpoints

No deviation from the EU agreed endpoints.

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

Plant protection product	AG-E1-500 SC1
Use No.	1,2,3
Crop	Sugar beet
Application rate (g as/ha)	Ethofumesate: 500 or 330 [1)]
Number of applications/interval (d)	2/5 or 3/5
Application window	Mar-May
Application method	Ground spray
CAM (Chemical application method)	2 – appln foliar linear
Soil depth (cm)	4 (default PRZM input)
Models used for calculation	FOCUS Steps 1-2 v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.6.2, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3, SPIN v3.3, SWAN v5.0.1, EVA3 rev. 2h

[1)] Modelling performed for application at 3x330 g a.s./ha, but in line with the GAP the intended rate is 3x300 g a.s./ha

Table 8.9-2: FOCUS Step 3 Scenario related input parameters for $PEC_{sw/sed}$ calculations for the application of AG-E1-500 SC1

Crop	Scenario	Application window used in modelling Dates (Julian days)*
Sugar beet	D3	11 Apr – 16 May/21 May (101-136/141)
	D4	20 Apr – 25 May/31 May (110-145/151)
	R1	02 Apr – 07 May/27 May (92-127/147)
	R3	06 Mar – 10 Apr/15 Apr (65-100/105)

* Longer application windows are required for 3 applications compared to two applications

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

Compound	**Ethofumesate**	**NC8493**	**NC20645**	**Value in accordance to EU endpoint y Reference**
Molecular weight (g/mol)	286.3	258.3	274.3	EFSA 2016; 14(1):4374
Saturated vapour pressure (Pa)	6.5×10^{-4}	3.73×10^{-6}	7.4×10^{-7}	EFSA 2016; 14(1):4374
Water solubility (mg/L)	50	2019	16170	EFSA 2016; 14(1):4374
Diffusion coefficient in water (m²/d)	4.3×10^{-5}	4.3×10^{-5}	4.3×10^{-5}	default
Diffusion coefficient in air (m²/d)	0.43	0.43	0.43	default
K_{foc} (mL/g)	118 (geometric mean)	2.082	5.1 (geometric mean)	EFSA 2016; 14(1):4374
Freundlich Exponent 1/n	0.905 (arithmetic mean)	1 (EPISuite)	0.93 (arithmetic mean)	EFSA 2016; 14(1):4374
Plant Uptake	0	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)	default
$DT_{50,soil}$ (d)	26.2 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58 and Walker equation coefficient 0.7)	0.03 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58 and Walker equation coefficient 0.7)	0.12 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} 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

$PEC_{sw/sed}$

Table 8.9-4: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for Ethofumesate following 2 x 500 g a.s./ha applications of AG-E1-500 SC1 to sugar beet

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	---	297.22	Runoff/drainage	283.68	347.82
Step 2					
Northern Europe	March-May	46.05	Runoff/drainage	43.83	53.74
Southern Europe	March-May	84.94	Runoff/drainage	81.10	99.44
Step 3					
D3	ditch	2.276	Drift	0.2292	0.7059
D4	pond	0.5254	Drainage	0.5151	2.114
D4	stream	1.912	Drainage	0.2934	0.7717
R1	pond	0.3942	Runoff	0.3633	0.8779
R1	stream	5.612	Runoff	0.2186	1.250
R3	stream	29.30	Runoff	1.218	4.835

* single applications should be marked.
** twa-time as required by ecotox

Table 8.9-5: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for Ethofumesate following 3 x 330 g a.s./ha applications of AG-E1-500 SC1 to sugar beet [1)]

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	---	294.24	Runoff/drainage	280.84	336.46
Step 2					
Northern Europe	March-May	41.99	Runoff/drainage	40.00	49.04
Southern Europe	March-May	78.16	Runoff/drainage	74.66	91.54
Step 3					
D3	ditch	1.259	Drift	0.1382	0.4608
D4	pond	0.5490	Drainage	0.5383	2.214
D4	stream	1.119	Drainage	0.3051	0.8311
R1	pond	0.5140	Runoff	0.4818	1.123
R1	stream	8.677	Runoff	0.2973	1.840
R3	stream	18.96	Runoff	0.7927	3.205

* single applications should be marked.
** twa-time as required by ecotox
[1)] Modelling performed for application at 3x330 g a.s./ha, but in line with the GAP the intended rate is 3x300 g a.s./ha

FOCUS Step 4

FOCUS guidance (Generic Guidance for FOCUS Surface Water Scenarios, version 1.4, 2015) states “When calculating Step 4 PEC where spray drift is mitigated, practitioners are also referred to the FOCUS (2008) Pesticides in Air workgroup report, which identifies that re-deposition of volatilised pesticide to surface water should be accounted for substances that have vapour pressures (at 20ºC) greater than $1x10^{-5}$ Pa (foliar application) or $1x10^{-4}$ Pa (soil application)”. Re-deposition of volatilized ethofumesate has been calculated below using EVA 3 rev. 2h. These deposition values were then included in the Step 4 calculations using SWAN v. 5.

Table 8.9-6. **Deposition rates of ethofumesate following 2 x 500 g a.s./ha applications of AG-E1-500 SC1 to sugar beet**

Time [hours]	Deposition rates of ethofumesate [mg m^{-2} h^{-1}]		
	GAP use no. 1: BBCH 10-18, 20% crop interception		
	5 m buffer width	10 m buffer width	20 m buffer width
0–4	0.0070	0.0053	0.0031
4–12	0.0035	0.0027	0.0015
12–24	0.0017	0.0013	0.0008

Table 8.9-7. **Deposition rates of ethofumesate following 3 x 330 g a.s./ha applications of AG-E1-500 SC1 to sugar beet** [1)]

Time [hours]	Deposition rates of ethofumesate [mg m^{-2} h^{-1}]		
	GAP use no. 3: BBCH 10-18, 20% crop interception		
	5 m buffer width	10 m buffer width	20 m buffer width
0–4	0.0046	0.0035	0.0020
4–12	0.0023	0.0018	0.0010
12–24	0.0012	0.0009	0.0005

[1)] Modelling performed for application at 3x330 g a.s./ha, but in line with the GAP the intended rate is 3x300 g a.s./ha

Table 8.9-8: **Global maximum PEC$_{sw}$ values for Ethofumesate, following 2 x 500 g a.s./ha applications of AG-E1-500-SC to sugar beet according to surface water Step 4**

PEC$_{sw}$ (µg/L)	Scenario	STEP 4 Ethofumesate				
Nozzle reduction	Vegetative strip (m)	None	None	None	10	20
	No spray buffer (m)	1/3	10	20	10	20
None	R3 stream	29.30	29.30	29.30	~~1.367~~	~~0.2716~~
90 %		29.30	n/c	n/c	~~n/c~~	~~n/c~~

n/c not calculated

Table 8.9-9: **Global maximum PEC$_{sw}$ values for Ethofumesate, following 3 x 330 g a.s./ha applications of AG-E1-500-SC to sugar beet according to surface water Step 4** [1)]

PEC$_{sw}$ (µg/L)	Scenario	STEP 4 Ethofumesate				
Nozzle reduction	Vegetative strip (m)	None	None	None	10	20
	No spray buffer (m)	1/3	10	20	10	20
None	R3 stream	18.96	18.96	18.96	~~2.070~~	~~0.1585~~
90 %		18.96	n/c	n/c	~~n/c~~	~~n/c~~

n/c not calculated
[1)] Modelling performed for application at 3x330 g a.s./ha, but in line with the GAP the intended rate is 3x300 g a.s./ha

Metabolites of Ethofumesate

Table 8.9-10: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for NC8493 following 2 x 500 g a.s./ha applications to sugar beet

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	---	72.58	Runoff/drainage	72.05	1.51
Step 2					
Northern Europe	March-May	<0.001	n/a	<0.001	<0.001
Southern Europe	March-May	<0.001	n/a	<0.001	<0.001

* single applications should be marked.
** twa-time as required by ecotox

Table 8.9-11: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for NC8493 following 2 x 330 g a.s./ha applications to sugar beet [1)]

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	---	71.85	Runoff/drainage	71.33	1.49
Step 2					
Northern Europe	March-May	<0.001	n/a	<0.001	<0.001
Southern Europe	March-May	<0.001	n/a	<0.001	<0.001

* single applications should be marked.
** twa-time as required by ecotox
[1)] Modelling performed for application at 3x330 g a.s./ha, but in line with the GAP the intended rate is 3x300 g a.s./ha

Table 8.9-12: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for NC20645 following 2 x 500 g a.s./ha applications to sugar beet

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	---	67.06	Runoff/drainage	64.76	3.41
Step 2					
Northern Europe	March-May	9.48	Runoff/drainage	9.15	0.48
Southern Europe	March-May	17.53	Runoff/drainage	16.93	0.89
Step 3					
D3	ditch	0.000318	Drift	0.000042	0.000043
D4	pond	0.007521	Drainage	0.007470	0.007775
D4	stream	0.000741	Drainage	0.000454	0.000275
R1	pond	0.008503	Runoff	0.008414	0.006853
R1	stream	0.007728	Runoff	0.000305	0.000614
R3	stream	0.1108	Runoff	0.004481	0.006467

* single applications should be marked.
** twa-time as required by ecotox

Table 8.9-13: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for NC20645 following 3 x 330 g a.s./ha applications to sugar beet [1)]

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	---	66.39	Runoff/drainage	64.11	3.37
Step 2					
Northern Europe	March-May	10.52	Runoff/drainage	10.16	0.53
Southern Europe	March-May	19.88	Runoff/drainage	19.20	1.01
Step 3					
D3	ditch	0.000371	Drift	0.000041	0.00005
D4	pond	0.007898	Drainage	0.007768	0.008118
D4	stream	0.000765	Drainage	0.000472	0.000291
R1	pond	0.01119	Runoff	0.01107	0.008936
R1	stream	0.01195	Runoff	0.000407	0.000918
R3	stream	0.07171	Runoff	0.002928	0.004240

* single applications should be marked.
** twa-time as required by ecotox

zRMS comments:

The application pattern considered in the surface water simulation presented in Table 8.9-1 is in line with the critical Central Zone GAP. The uses numbers were corrected in order to comply with information presented in Table 8.1-1.

Application dates presented in Table 8.9-2 were checked by the zRMS using AppDate ver. 3.06 and some deviations were noted, however application dates assumed by the Applicant were in line with EU agreed dates for the same BBCH stages and are thus agreed by the zRMS.

Input parameters presented in Table 8.9-3 used for surface water modelling for ethofumesate and its metabolites are fully in line with EU agreed endpoints reported in EFSA Journal 2016;14(1):4374. Corrects PUF of 0 was assumed at Step 3 for all relevant compounds.

The calculations performed at Steps 1-4 were independently validated by the zRMS in additional modelling using the same input parameters. PEC_{SW} and PEC_{SED} calculated at Step 1-3 for all relevant compounds were in good agreement with values obtained by the Applicant. However, Step 4 PEC_{SW} values calculated by the zRMS in scenario R3 with assumption of 10 and 20 m vegetated filter strip with run-off mitigation in line with indications of FOCUS L&M were considerably higher comparing to these obtained by the Applicant. For confirmation Step 4 PEC_{SW} values for R3 scenario calculated at the EU level for similar application pattern (2x500 and 2x333 g a.s./ha with 5 d interval) with consideration of the dry deposition calculated using EVA 3.1 were consulted and were at level to these obtained by the zRMS (i.e. higher than Applicants' values). Summary of zRMS Step 4 results is given in table below.

Scenario	Application	STEP 4 Ethofumesate PEC_{sw} (µg/L)	
		VFS (run-off reduction in line with FOCUS L&M)	
		10 m	20 m
R3 stream	2 x 500 g a.s./ha	13.25	6.932
	3 x 330 g a.s./ha	8.572	4.486

Since both, zRMS and EU agreed, Step 4 PEC_{SW} are at similar level for comparable application patterns, values reported in table above are recommended for risk assessment purposes, while Applicants' results provided in Tables 8.9-8 and 8.9-9 are struck through as being uncertain. It cannot be excluded that in the Applicants' simulations run-off was mitigated using VFSmod which would explain significantly lower PEC_{SW} values in scenario R3, but this cannot be confirmed since detailed information was not included in the modelling report (Hicks, 2021b, Doc. No. 000107867) and the SWAN logs containing this information were not attached (only SWAN reports with results and input parameters were available in the modelling report, but they do not provide information on method for run-off reduction).

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.

8.9.2.1 $PEC_{sw/sed}$ of AG-E1-500 SC1

The formulated product AG-E1-500 SC1 contains only one active substance, ethofumesate. Therefore, calculation of PECsw/sed for the formulation is not required as this can be extrapolated from the active substance.

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

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 x 10^{5}
Volatilisation	Vapour pressure (Pa): 3.6 x 10^{-4} (20 °C) 6.5 x 10^{-4} (25 °C) 4.3 x 10^{-3} (40 °C) No volatilisation expected
Metabolites	None

The vapour pressure at 20 °C of the active substance ethofumesate is 3.6 x 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.

zRMS comments:

Provided above information regarding fate and behaviour in the air is in line with the EU agreed data reported in EFSA Journal 2016;14(1):4374, where is stated that ethofumesate is not expected to be subject to volatilisation and the long- or short-range transport.

Taking this into account the contamination of the atmosphere from the intended uses of AG-E1-500 SC1 is considered to be negligible.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2.4/01	Hicks J.	2021a	PECgroundwater Calculations for Ethofumesate and Metabolites For Submission to Central and Southern EU Regulatory Zones ETF/EFA/01; Sponsor Reference Number: 000107866 Agrexis AG, Basel, Switzerland non GLP Unpublished	N	Adama
KCP 9.2.5/01	Hicks J.	2021b	PECsurfacewater and PECsediment Calculations for Ethofumesate and Metabolites – FOCUS Steps 1, 2, 3 and 4 For Submission to the Central and Southern EU Regulatory Zones ETF/EFA/02; Sponsor Reference Number: 000107867 Agrexis AG, 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

zRMS comments:

As most of endpoints for ethofumesate and its relevant metabolites was taken from the EU review, for the list of respective studies please refer to Volume 2 of the RAR for ethofumesate.

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

New reports are summaries of environmental fate modelling, please see Appendix 3.

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

Comments of zRMS:	The groundwater modelling performed by the Applicant was agreed by the zRMS. For discussion on input parameters and obtained results, please refer to point 8.8 of this document.

Reference:	**KCP 9.2.4/01**
Report	PECgroundwater Calculations for Ethofumesate and Metabolites For Submission to Central and Southern EU Regulatory Zones, Hicks J., 2021a, ETF/EFA/01
Guideline(s):	Yes: SANCO/13144/2010 v. 3, 10 October 2014
Deviations:	No
GLP:	No, not applicable
Acceptability:	Acceptable

Materials and methods

Predicted environmental concentrations of ethofumesate and its metabolites were calculated in accordance with SANCO/13144/2010 v. 3 using the following modelling software:
- FOCUS PEARL version 4.4.4
- FOCUS PELMO version 5.5.3
- FOCUS MACRO version 5.5.4

There are two metabolites of ethofumesate; NC8493 and NC20645.

Input parameters were taken from EFSA Journal 2016;14(1):4374 and are presented in section 8.8.2 of this document.

The critical GAPs presented in section 8.1 of this document were assessed, with crop interception values in accordance with EFSA Journal 2014;12(5):3662.

The relative application dates were chosen considering the software AppDate for the foreseen GAP use BBCH 10-18 and the dates provided in the PEARL and PELMO models. For MACRO calculations the same absolute date as used in the PEARL and PELMO calculations was chosen.

PECgw calculations of metabolites in MACRO are limited to one metabolite per parent substance. Concentrations of metabolite NC8493 were modelled as a metabolite of ethofumesate. Concentrations of metabolite NC20645 were modelled as a metabolite of NC8493. The pseudo-application rate for NC8493 as a parent substance was 400 g/ha, which assumes that 100% of ethofumesate is metabolised to NC8493 (the application rate of ethofumesate is 500 g a.s./ha with 20% crop interception).

Results and discussions

All PEGgw values are presented in 8.8.2 of this document. There were no PECgw values above 0.1 µg/L for any substance.

Conclusion

All PECgw values for ethofumesate and its metabolites were below the drinking water limit of 0.1 µg/L.

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Comments of zRMS:	The surface water modelling performed by the Applicant was in general agreed by the zRMS with exception of Step 4 results obtained by the Applicant in scenario R3. For discussion on input parameters and obtained results, please refer to point 8.9 of this document.

Reference:	**KCP 9.2.5**
Report	PECsurface water and PECsediment calculations for Ethofumesate and Metabolites – FOCUS Steps 1, 2, 3 and 4 For Submission to Central and Southern Regulatory Zones, Hicks J., 2021b, ETF/EFA/02
Guideline(s):	Yes: Generic guidance for FOCUS surface water Scenarios v. 1.4, May 2015
Deviations:	No
GLP:	No: not applicable
Acceptability:	Acceptable with exception of results obtained by the Applicant at Step 4 in scenario R3

Materials and methods

Predicted environmental concentrations of ethofumesate and its metabolites were calculated in accordance with Generic guidance for FOCUS surface water Scenarios v. 1.4 using the following modelling software:

- FOCUS steps 1 and 2 version 3.2
- FOCUS SWASH version 5.3
- FOCUS MACRO version 5.5.4
- FOCUS PRZM version 4.6.2
- FOCUS TOXSWA version 4.4.3
- EVA 3 rev. 2h
- SWAN version 5.01

There are 2 metabolites of ethofumesate; NC8493 and NC20645.

Input parameters were taken from EFSA Journal 2016;14(1):4374 and are presented in section 8.9.2 of this document.

The critical GAPs presented in section 8.1 of this document were assessed, with crop interception values in accordance with EFSA Journal 2014;12(5):3662.

Step 2 PECsw values were calculated for both north and south scenarios and for March – May.

Step 3 PECsw values were calculated for D3 ditch, D4 pond, D4 stream, R1 pond, R1 stream and R3 stream. Application dates were taken from EFSA Journal 2016;14(1):4374.

Step 4 PECsw values were calculated for R3 stream because this resulted in the worst-case PECsw values at step 3. Deposition rates were calculated using EVA 3 because ethofumesate is considered to be semivolatile. These deposition rates were included in the step 4 calculations.

Results and discussions

All PECsw and PECsed values are presented in 8.8.2 of this document.

Conclusion

ThePECsw and PECsed calculations were considered acceptable and used in the aquatic risk assessment.