

REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: HBZ10

Product name: Wizard

Chemical active substances:

Phenmedipham, 125 g/L

Ethofumesate, 125 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Authorisation - Art. 33 application)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: October 2021, updated August 2022

Finalisation date: December 2022 (initial Core Assessment)

October 2023 (final Core Assessment)

Version history

When	What
October 2021	Part B - Section 8 - Core Assessment - Central Zone, version 1
August 2022	Part B - Section 8 - Core Assessment - Central zone, version 2, PUF update following zRMS request.
December 2022	<p>Initial assessment by the zRMS</p> <p>The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency.</p>
October 2023	<p>Final report (Core Assessment updated following the commenting period)</p> <p>Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Information no longer relevant is struck through and shaded.</p>

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8 Fate and behaviour in the environment (KCP 9)

8.1 Critical GAP and overall conclusions

The product HBZ10 containing Ethofumesate (125 g/L) and Phenmedipham (125 g/L) is intended to be applied as an herbicide on beet crops after emergence (BBCH 10-39) by multiple applications per season. The maximum intended application rate is 2.4 L product/ha per application (equivalent to 0.3 kg Ethofumesate/ha and 0.3 kg Phenmedipham/ha).

Table 8.1-1 Critical use pattern of the formulated product

PPP (product name/code)	Wizard / HBZ10	Formulation type:	EC
Active substance 1	Ethofumesate	Conc. of as 1:	125 g/L
Active substance 2	Phenmedipham	Conc. of as 2:	125 g/L
Safener	None	Conc. of safener:	Not relevant
Synergist	None	Conc. of synergist:	Not relevant
Applicant:	UPL Holdings Coöperatief U.A.	Professional use	<input checked="" type="checkbox"/>
Zone:	central	Non professional use	<input type="checkbox"/>
Verified by MS:	no		

Verified by MS.															
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 saf- ener/ 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)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./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)															
Use group 1: 1, 6, 11, 16, 21	NL	Beet crops (sugar beet, red beet, yellow beet fodder beet, chard)	F	Broadleaf weeds	Spraying	Spring-summer BBCH 10-39	a) 6 b) 6	5	a) 1.2 b) 7.2	a) 150 g/ha Ethofumesate 150 g/ha Phenmedipham b) 900 g/ha Ethofumesate 900 g/ha Phenmedipham	80 – 400	-	Max. 7.2 L/ha per year	R Biennial application (Châteaudun)	
														A (H, J, K, N, P, O, S, T)	
Use group 2: 2, 7, 12, 17, 22	NL	Beet crops (sugar beet, red beet, yellow beet fodder beet, chard)	F	Broadleaf weeds	Spraying	Spring-summer BBCH 10-39	a) 3 b) 3	6	a) 2.4 b) 7.2	a) 300 g/ha Ethofumesate 300 g/ha Phenmedipham b) 900 g/ha Ethofumesate 900 g/ha Phenmedipham	80 – 400	-	Max. 7.2 L/ha per year	C Biennial application (Châteaudun, FOCUS PEARL 4.4.4)	A (Châteaudun, FOCUS PEARL 5.5.5)
														A (H, J, K, N, P, O, S, T, both versions of the models)	

Use group 3: 3, 8, 13, 18, 23	BE CZ PL AT	Beet crops (sugar beet, red beet, yellow beet fodder beet, chard)	F	Broadleaf weeds	Spraying	Spring-summer BBCH 10-39	a) 5 b) 5	7	a) 1.2 b) 6.0	a) 150 g/ha Ethofumesate 150 g/ha Phenmedipham b) 750 g/ha Ethofumesate 750 g/ha Phenmedipham	80 – 400	-	Max. 6.0 L/ha per year	A (all scenarios, both versions of the models)	
Use group 4: 4, 9, 14, 19, 24	NL BE CZ PL AT	Beet crops (sugar beet, red beet, yellow beet fodder beet, chard)	F	Broadleaf weeds	Spraying	Spring-summer BBCH 10-39	a) 3 b) 3	6	a) 1.8 b) 5.4	a) 225 g/ha Ethofumesate 225 g/ha Phenmedipham b) 675 g/ha Ethofumesate 675 g/ha Phenmedipham	80 – 400	-	Max. 5.4 L/ha per year	A (all scenarios, both versions of the models)	
Use group 5: 5, 10, 15, 20, 25	BE CZ PL AT	Beet crops (sugar beet, red beet, yellow beet fodder beet, chard)	F	Broadleaf weeds	Spraying	Spring-summer BBCH 10-39	a) 3 b) 3	9	a) 2.4 b) 7.2	a) 300 g/ha Ethofumesate 300 g/ha Phenmedipham b) 900 g/ha Ethofumesate 900 g/ha Phenmedipham	80 – 400	-	Max. 7.2 L/ha per year	C Biennial application (Châteaudun, FOCUS PEARL 4.4.4)	A (Châteaudun, FOCUS PEARL 5.5.5)
														A (H, J, K, N, P, O, S, T, both versions of the models)	

* 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:

Additional groundwater modelling provided by the Applicant was performed with consideration of old (FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4) and most recent (FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5) versions of the models. The version of the model had no impact on the results obtained in use groups 1, 3 and 4. However, significant differences were observed in Châteaudun scenario in use groups 5 and 2, where leaching of the parent $>0.1 \mu\text{g/L}$ was observed in FOCUS PEARL 4.4.4 (indicating need for mitigation measures), but the threshold concentration in this scenario was not exceeded when simulations were performed using FOCUS PEARL 5.5.5.

Although the zRMS is of the opinion that the modelling should be performed using models in place at the time of dossier submission (in case of HBZ10 this would be FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4), some cMS may prefer to rely on results obtained using the most recent versions of the models. Taking this into account, difference in results obtained for Châteaudun scenario in both versions of FOCUS PEARL were reflected in conclusions presented in GAP table above. Concerned Member States must decide which version of the model they will rely on to authorise the product in order to conclude if the mitigation measures are deemed necessary. In PL the decision on authorisation and respective restrictions will be made based on results obtained with FOCUS PEARL 4.4.4, valid at the time of dossier submission.

Table 8.1-2 Assessed (critical) uses during 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)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
2	Central EU	Sugar beet, fodder beet	F	Annual weeds	Overall spray	Pre- emergence	a) 1 b) 1	-	a) 2.0 b) 2.0	a) 1.0 b) 1.0	300-400	PHI is covered by the normal vegetation period between last application and harvest	United Phosphorus Limited Max. 1 kg a.s./ha every three years
3	Central EU	Sugar beet, fodder beet	F	Annual weeds	Overall spray	Post- emergence until BBCH 18	a) 6*** b) 6***	5	a) 2.0 b) 2.0	a) 0.33 b) 1.0	200-300	PHI is covered by the normal vegetation period between last application and harvest	United Phosphorus Limited 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.

Table 8.1-3 Assessed (critical) uses during approval of Phenmedipham 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	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
-	EU	Sugar & fodder beet	F	Annual dicot weeds	Overall spray	Post- emergence, from cotyledon to 8 leaf stage of beet	a) 1 b) 4	5-14	-	a) 0.160-0.320 b) 0.96	80-400	90	Sequential application
-	EU	Red beet (Beetroot)	F	Annual dicot weeds	Overall spray	Post- emergence, from cotyledon to 8 leaf stage of beet	a) 1 b) 3	5-14	-	a) 0.160-0.320 b) 0.96	150-400	90	Sequential application

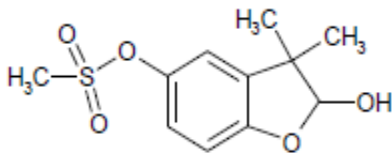
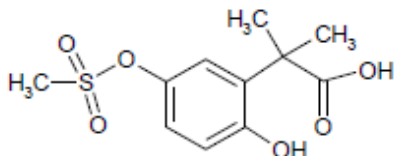
* Use number(s) in accordance with the list of all intended GAPS in Part B, Section 0 should be given in column 1

** 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

8.2 Metabolites considered in the assessment

Please refer to below table for the metabolites of Ethofumesate potentially relevant for exposure assessment.

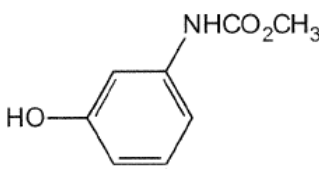
Table 8.2-1 Metabolites of Ethofumesate potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
NC 8493	258.3	 [RS]-2-hydroxy-3,3-dimethyl-2,3-dihydro-1-benzofuran-5-yl methanesulfonate	Soil: 24.2% Water/Sediment: -	PEC _{GW} : yes, leaching potential to groundwater PEC _{Soil} : yes PEC _{SW/SED} : yes
NC 20645	274.3	 2-{2-hydroxy-5-[(methylsulfonyl)methyl]phenyl}-2-methylpropanoic acid	Soil: 4.8%, detected in a soil photolysis study Water/Sediment: 18.8%	PEC _{GW} : yes, leaching potential to groundwater PEC _{SW/SED} : yes

Metabolite CW 35117 determined as major only in the aerobic surface mineralization study, does not need to be considered for exposure assessment. Metabolite NC20645 detected < 5% in soil, does not need to be considered for soil exposure assessment.

Please refer to below table for the metabolites of Phenmedipham potentially relevant for exposure assessment.

Table 8.2-2 Metabolites of Phenmedipham potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
MHPC	167.2		Soil: 54% Water/Sediment: 70%	PEC _{GW} : yes, leaching potential to groundwater PEC _{Soil} : yes PEC _{SW/SED} : yes

zRMS comments:

Information regarding metabolites of ethofumesate and phenmedipham is in line with EU agreed endpoints reported in EFSA Journal 2016;14(1):4374 and Review Report (2004), respectively.

8.3 Rate of degradation in soil (KCP 9.1.1)

As it is possible to extrapolate from data provided for the active substances, no further data are provided on the preparation.

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 Ethofumesate and its metabolites

A summary of the aerobic degradation studies as presented in the EFSA¹ conclusions (2016) for Ethofumesate and its metabolites formed in soil are presented in **Table 8.3.1.1-1** to **Table 8.3.1.1-3**. No further studies were performed since then.

Table 8.3.1.1-1 Summary of aerobic degradation rates for Ethofumesate - laboratory studies

Ethofumesate, Laboratory studies, dark aerobic conditions										
Soil name	Soil type	pH ^{a)}	t.°C	MWHC %	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa ^{b)}	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Abington	Sandy Loam	7.0	25	75% of WHC at 33 kPa	137	454	208	5.8	SFO	Y, EFSA, 2016
Terling	Loam/Silt Loam	5.8	25	75% of WHC at 33 kPa	68.7	228	80.5	3.0	SFO	
AX	Sandy Loam	6.1	20.7	55	28.5	94.7	30.4	5.1	SFO	
HF	Silt Loam	6.5	20.7	55	19.4	64.4	20.5	3.3	SFO	
WW	Sandy Loam	5.4	20.7	55	19.7	65.6	21.1	5.3	SFO	
DD	Clay Loam	7.2	20.7	55	19.1	63.6	20.4	2.0	SFO	
Lufa 2.2	Sand	5.8	20	40% MWHC	69.9	232	69.9	15.4	SFO	
Fislis	Silt Loam	6.82	20	pF 2.5	16.0	53	14.1	2.2	SFO	
Horn	Loam	7.23	20	pF 2.5	9.4	31.2	8.5	6.2	SFO	
Montesquieu	Clay	7.37	20	pF 2.5	20.4	67.8	17.9	4.8	SFO	
Sevelen	Sandy Loam	7.51	20	pF 2.5	11.7	38.7	9.3	3.4	SFO	
Mussbach	Loam	7.21	20	50	17.72	58.86	15.2	6.0	SFO	
Lufa 5.2	Sandy loam	7.3	20	50	15.36	51.01	14.5	6.9	SFO	
Lufa 2.2	Loamy sand	5.5	20	50	12.78	42.47	12.8	7.9	SFO	
UK1	Clay loam	6.8	20	50	25.52	84.79	25.5	6.5	SFO	
UK2	Sandy loam	6.83	20	50	23.29	77.37	23.3	3.5	SFO	
North France	Loam	7.41	20	50	13.63	45.28	11.4	9.6	SFO	
Austria	Silt loam	7.14	20	50	12.53	41.61	12.5	4.5	SFO	
Spain	Silt loam	7.38	20	50	17.27	57.36	15.5	4.1	SFO	
Geometric mean (n=19)							21.6			
pH-dependency:							No			

a) Measured in CaCl₂

b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

¹ EFSA Journal 2016;14(1):4374.

Table 8.3.1.1-2 Summary of aerobic degradation rates for NC 8493 - laboratory studies

NC 8493, Laboratory studies, dark aerobic conditions										
Soil name	Soil type	pH ^{a)}	t.°C	MWHC %	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa ^{b)}	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Fislis	Silt Loam	6.82	20	pF 2.5	0.05	0.18	0.04	27.2	SFO	Y, EFSA, 2016
Horn	Loam	7.23	20	pF 2.5	0.07	0.24	0.06	10.5	SFO	
Sevelen	Sandy loam	7.51	20	pF 2.5	0.05	0.17	0.04	21.1	SFO	
AX	Sandy loam	5.5	20	55	0.02	0.07	0.02	5.1	SFO	
HH	Silt loam	6.1	20	55	0.02	0.07	0.02	1.4	SFO	
DD	Clay loam	7.2	20	55	0.01	0.03	0.01	1.4	SFO	
WW	Sandy loam	5.0	20	55	0.02 ^{c)}	0.06 ^{c)}	0.06 ^{d)}	2.2	DFOP	
Geometric mean (n=7)							0.03			
pH-dependency:							No			

a) Measured in CaCl₂

b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

c) k₁ = 76.44, k₂ = 12.59, g = 0.5346

d) Calculated from slow-phase degradation constant

Table 8.3.1.1-3 Summary of aerobic degradation rates for NC 20645 - laboratory studies

NC 20645, Laboratory studies, dark aerobic conditions										
Soil name	Soil type	pH ^{a)}	t.°C	MWHC %	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa ^{b)}	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	Y, EFSA, 2016
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 ^{c)}	0.30 ^{c)}	0.17 ^{d)}	0.0001	DFOP	
Geometric mean (n=4)							0.12			
pH-dependency:							No			

a) Measured in CaCl₂

b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

c) k₁ = 5.1835, k₂ = 126.72, g = 0.28569

d) Calculated from slow-phase degradation constant

zRMS comments:

Soil degradation data for ethofumesate and its metabolites presented in Tables 8.3.1.1-1 to 8.3.1.1-3 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. (γ2)	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 Phenmedipham and its metabolites

From the Review report (2004), the degradation of ^{14}C -aminophenol-labelled Phenmedipham was studied in two tests. The applied radioactivity (AR) recovered as CO_2 ranged between 13.3 and 16.5% after 120 days. The non-extractable residues amounted to between 63.6 and 64.1% of the AR within 120 days. The major metabolites were methyl-3-hydroxy-phenylcarbamate (= MHPC, maximum 14% at day 14) and m-amino phenyl-N-(3-methylphenyl) (= APMP, max. 4% of AR after 56 days).

The degradation of phenoxy-ring- ^{14}C labelled Phenmedipham was studied in three soils. In this test, between 9.7% and 11.3% of the AR was recovered as CO_2 within 120 days, confirming that the mineralisation rate was acceptable. The non-extractable residues amounted to up to 71.3 - 73.8% of AR. High concentrations of the main metabolite, MHPC, were observed on days 1-5 (54% at day 5).

The estimated DT_{50} values obtained in the laboratory studies of Phenmedipham at 20°C and 40-50% MWHC were 26, 42 and 43 days. (SFO, $r^2 = 0.932-0.953$).

Half-lives reported in the studies have not been normalised either for moisture or for temperature as recommended in SANCO/321/2000 rev. 2². The available summaries indicate that the study was conducted at 40-50% MWHC. For normalization to pF2, and as worst case, the moisture conditions during the study were assumed to be 50% MWHC. Results adjusted to field capacity (pF2) and normalised to 20°C can be found below.

Table 8.3.1.2-1 Summary of aerobic degradation rates for Phenmedipham

Soil	Speyer 2.1	Speyer 2.2	Speyer 2.3
Type	Sandy	Loamy sand	Sandy loam
Moisture conditions during study ^a	50% MWHC ^a		
100% MWHC ^b	24 ^b	24 ^b	27 ^b
DT_{50} at 40-50% MWHC and 20°C [days]	43	42	26
50% MWHC (θ) ^a	12	12	13.5
Field capacity (pF2) from FOCUS (θ _{ref}) ^b	12	14	19
Correction factor (θ/θ _{ref}) ^{0.7}	1	0.898	0.787
DT_{50} adjusted for pF2 and 20°C [days]	43.0	37.7	20.5
Geometric mean of DT_{50} at pF2 and 20°C [days]	29.9		

a Moisture conditions during the study assumed to be 50% WHC as worst case, since the report indicates that the moisture content was 40 -50% of WHC.

b Default values from SANCO/321/2000. FOCUS Groundwater scenarios in the EU review of active substances. Chapter 5.4.2. Original not available

For MHPC, the estimated DT_{50} values obtained in a laboratory study at 20°C and 40-50% MWHC were 0.1, 0.2 and 0.3 days (SFO, geometric mean = 0.18 days, $r^2 = 0.992-0.999$). Half-lives reported in this study have not been normalised for moisture as recommended in SANCO/321/2000 rev. 2. However, the DT_{50} is so short that normalization to pF2 would provide only negligible variations in the resulting DT_{50} . Therefore, those values can be assumed to be normalised to pF2.

zRMS comments:

Soil degradation data for phenmedipham presented above are in line with EU agreed endpoints reported in Review Report (2004) and DAR (2003).

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

The anaerobic degradation in soil for Ethofumesate has been assessed in the EFSA conclusions (2016). Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

A summary of the anaerobic degradation study as presented in the EFSA conclusion (2016) for Ethofumesate is presented in the table below.

² SANCO/321/2000. FOCUS Groundwater scenarios in the EU review of active substances.

Table 8.3.2-1 Summary of the anaerobic degradation of Ethofumesate

Soil name	Soil type	pH	t.°C	MWHC %	DT ₅₀ /DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa ^{a)}	Chi ² (%)	Kinetic model	Evaluated on EU level
-	Sandy loam	7.6	25	75% of WHC at 33 kPa	1000	1000	-	SFO	Y, EFSA, 2016
Geometric mean (n=1)						1000			

a) Normalised using a Q10 of 2.58

An anaerobic degradation study with ¹⁴C-AP-labelled Phenmedipham confirmed the major metabolite to be MHPC with a maximum of 19% of the applied amount (32 days). At the end of the test, 6.6% of the activity had evolved as CO₂, and the non-extractable residues were 74.3% of the AR after 97 days. The estimated rate of degradation found in the laboratory studies was DT₅₀ (20°C, anaerobic) = 15 days (n=1, r² = 0.934).

zRMS comments:

Anaerobic soil degradation data for ethofumesate and phenmedipham are in line with the EU agreed endpoints reported in EFSA Journal 2016;14(1):4374 and Review Report 2004, respectively.

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 and its metabolites

As it is possible to extrapolate from data provided for the active substance, no further data are provided on the preparation.

Several field studies were conducted investigating the route and rate of degradation of Ethofumesate. For details please refer to the RAR (Austria 2015) and EFSA Conclusions (2016). A summary of results for Ethofumesate is presented in **Table 8.4.1.1-1**.

Table 8.4.1.1-1 Summary of aerobic degradation rates for Ethofumesate - field studies triggering endpoints

Ethofumesate, Field studies – Triggering endpoints									
Soil type	Location	pH ^{a)}	Depth (cm)	DissT ₅₀ (d) actual	DT ₉₀ (d) actual	DissT ₅₀ (d) Normalised ^{b)}	St. (x ²)	Method of calculation	Evaluated on EU level y/n/ Reference
Loamy silt, bare soil	Mainz A, Germany	7.5	0-30	116	384	69.5	13.3	SFO	Y, EFSA, 2016
Loamy silt, bare soil	Mainz B, Germany	7.5	0-30	114	379	47.4	11.3	SFO	
Loamy silt, bare soil	Mainz A/B, Germany	7.5	0-30	-	-	57.4 ^{c)}	-	SFO	
Silty sand, bare soil	SpeyerA, Germany	6.7	0-30	21 $\alpha = 0.004$, $\beta = 0.05$	333	47.2 ^{d)}	12.5	FOMC ^{e)} DFOP ^{f)}	
Silty sand, bare soil	SpeyerB, Germany	6.7	0-30	13.6 $k_1 = 0.09528$, $k_2 = 0.00772$, $g = 0.6392$	166	46.5 ^{d)}	3.9	DFOP	
Loamy sand, bare soil	Isleham, UK	7.5	0-30	59	196	25.7	12.3	SFO	
Sandy clay loam, bare soil	Willingham, UK	7.5	0-30	44	147	18.0	22	SFO	

Ethofumesate, Field studies – Triggering endpoints									
Soil type	Location	pH ^{a)}	Depth (cm)	DissT ₅₀ (d) actual	DT ₉₀ (d) actual	DissT ₅₀ (d) Normalised ^{b)}	St. (x ²)	Method of calculation	Evaluated on EU level y/n/ Reference
Sandy loam, cropped with alfalfa and sugar beet	Fresno, California	6.5	0-90	89	295	-	20.7	SFO	
Clay loam, cropped with alfalfa and sugar beet	Northwood, North Dakota	7.3	0-90	1000	-	-	-	SFO	
Sand, bare soil	Weeze, Germany	5.8	0-30	157	522	75.7	15.0	SFO	
Sandy loam, bare soil	Nierswalde, Germany	3.5	0-30	1000	-	-	-	SFO	
Clay loam, bare soil	NZ11007/1, UK	7.13	0-30	21.6	72	15.2	16	SFO	
Silty clay loam, bare soil	NZ11007/2, Germany	7.57	0-30	10.2	74	13.5	4.1	SFO	
Silty clay loam, bare soil	NZ11007/3, France	7.72	0-30	35.9 k1 = 0.03878, k2 = 0.003795, g = 0.5968	367	110 ^{d)}	6.1	DFOP	
Loam, bare soil	NZ11007/4, Spain	7.7	0-30	12.3 k1 = 0.1805, k2 = 0.00662, g = 0.0518	237	60 ^{d)}	12.0	DFOP	
Maximum (n=12)				157	522				
Geometric mean (n=10)						37.8			
pH-dependency y/n						No			

a) Solute in which the pH was measured not reported

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

c) Geomean of the paired trials Mainz A and Mainz B to be used for exposure assessment

d) Modelling endpoint derived from slow-phase degradation constant

e) For DisT₅₀ actual

f) For normalised DT₅₀

zRMS comments:

Field degradation data for ethofumesate presented in Table 8.4.1.1-1 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 Phenmedipham and its metabolites

Studies on field dissipation rates with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. The field dissipation rates of Phenmedipham were evaluated during the Annex I Inclusion. No additional studies have been performed.

The dissipation of Phenmedipham under field conditions was evaluated in four locations in Germany and one site in USA. The obtained half-lives ranged between 5.8 and 39.9 days (bare soil, mean 17.6 days, SFO) in Germany, and was of 13.3 days in California (sandy loam, red beet stage 4-6 leaf, SFO) demonstrating a fast dissipation from soil.

zRMS comments:

Field degradation data for phenmedipham presented above are in line with information reported in Review Report, 2004.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

As it is possible to extrapolate from data provided for the active substance, no further data are provided on the preparation.

For Ethofumesate, the DT₉₀ values in field dissipation studies are above one year (maximum 522 days) for some soils (EFSA, 2016). Therefore, PEC_{accumulation} was calculated assuming a worst case pre-emergence application of Ethofumesate at a rate equivalent to 1.0 kg a.s./ha. A PEC_{Soil} plateau concentration of 0.333 mg a.s./kg dry soil occurring after six years consecutive application (one application every year) is determined and the corresponding PEC_{accumulation} is 1.666 mg. a.s./kg dry soil.

Studies on soil accumulation were not required for the active substance Phenmedipham (Review Report, 2004).

zRMS comments:

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

In line with the Review Report (2004), studies on soil accumulation of phenmedipham were not required.

8.5 Mobility in soil (KCP 9.1.2)

As it is possible to extrapolate from data provided for the active substances, no further data are provided on the preparation.

8.5.1 Ethofumesate and its metabolites

Studies on the mobility in soil for Ethofumesate have been assessed in the EFSA conclusion (2016). A summary of the soil mobility results for Ethofumesate and its relevant metabolites NC 8493 and NC 20645 is presented in **Table 8.5.1-1 to 8.5.1-3**.

Table 8.5.1-1 Summary of soil adsorption/desorption for Ethofumesate

Ethofumesate						
Soil type	OC (%)	pH (-) ^{a)}	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Mueller Podsol	1.5	6.1	3.7	247	0.96	Y, EFSA, 2016
Mueller Parabraunerde	1.1	7.6	1.1	100	0.91	
Mueller light sand	1.5	6.7	3	200	0.94	
Bruhl Sandy loam	1.16	6	1.13	97	0.84	
Cameron Sand	1.12	4.6	0.7	63	0.92	
Cameron Acidic sandy loam	1.45	5.7	0.7	48	0.92	
Cameron Alkaline Sandy loam	1.66	7.3	0.8	48	0.93	
Icklingham, Sand	0.35	6.8	0.73	209	0.87	
Abington, sandy loam	1.9	7.4	2.3	121	0.93	
Terling, silt clay loam	3.2	6.6	5.3	166	0.89	
Shelford clay	4.9	6.6	6.2	127	0.82	
UPL loamy sand	1.41	7.3	2.6	187	0.93	
Geometric mean (n=12)				1.74	118	
Arithmetic mean (n=12)						0.905
pH-dependency y/n				No		

a) measured in CaCl₂

Table 8.5.1-2 Summary of soil adsorption/desorption for NC 8493

NC 8493						
Soil Name & type	OC (%)	pH (-)	Kd (mL/g)	Kdoc ^{a)} (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
-	-	-	-	20.82	1	Y, EFSA, 2016
pH-dependency y/n				No		

a) Compound is unstable, KFoc calculated with EPI WIN

Table 8.5.1-3 Summary of soil adsorption/desorption for NC 20645

NC 20645						
Soil name & type	OC (%)	pH (-) ^{a)}	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
Silt loam HH	2.9	6.3	0.12	4.3	0.93	Y, EFSA 2016
Loam DD	4.4	7.3	0.16	3.7	0.91	
Sandy loam CA	0.7	6.7	0.03	4.3	0.87	
Silt loam NE	1.7	6.6	0.17	10.0	0.99	
Geometric mean (n=4)			0.1	5.1		
Arithmic mean (n=4)					0.93	
pH-dependency y/n			No			

a) Measured in CaCl₂

zRMS comments:

Soil mobility data for ethofumesate and its metabolites presented in Tables 8.5.1-1 to 8.5.1-3 are in line with EU agreed endpoints reported in EFSA Journal 2016;14(1):4374.

8.5.2 Phenmedipham and its metabolites

The mobility in soil of Phenmedipham and MHPC was evaluated during the Annex I Inclusion. No additional studies have been performed.

Table 8.5.2-1 Summary of soil adsorption/desorption for Phenmedipham

Soil Selection	OC (%)	pH	Clay (%)	K _{Foc} (mL/g)	1/n
Sand	0.48	6.0	5.3	934	0.821
Sandy loam	1.2	4.75	17	1072	0.865
Clay	2.79	6.87	41.6	657	0.854
Arithmetic mean				888	0.847

Table 8.5.2-2 Summary of soil adsorption/desorption for MHPC

Soil Selection	OC (%)	pH	Clay (%)	K _{oc} (mL/g)	1/n
Sand	0.48	6.6	3.3	212	0.515
Loamy sand	1.93	5.7	7.3	138	0.699
Sandy loam	0.99	5.0	5.9	58	0.949
Loamy sand	1.03	5.9	12.0	470	0.805
Arithmetic mean				220	0.742

zRMS comments:

Soil mobility data for phenmedipham and its metabolite presented in tables above are in line with EU agreed endpoints reported in Review Report, 2004.

8.5.3 Column leaching (KCP 9.1.2.1)

Of the studies assessed in the EFSA conclusions for Ethofumesate (2016), no reliable studies with a not aged design were available. However, this was not required as valid batch adsorption studies are available for the active substance. In one study with aged Ethofumesate it was observed that over the study period of 30 days, 2.7% of the AR - mainly consisting of Ethofumesate and NC 20645 - were found in the leachate (RAR, Austria, 2015).

For Phenmedipham, it is expected that there is limited potential for the parent compound and its soil metabolite to leach in significant quantities to groundwater as a result of its adsorption and degradation characteristics. Therefore, the existing K_{oc} value is considered as reliable enough for the risk assessment. Further mobility studies are therefore regarded as not necessary.

zRMS comments:

According to information provided in EFSA Journal 2016;14(1):4374, no reliable data from column leaching studies were available for ethofumesate. These data are, however, **not** necessary for purposes of the zonal evaluation of HBZ10 since the leaching potential of ethofumesate, phenmedipham 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)

As it is possible to extrapolate from data provided for the active substance, no further data are provided on the preparation.

Lysimeter studies for Ethofumesate have been assessed in the EFSA conclusions (2016). In lysimeter studies of two years duration carried out in the UK and Switzerland all chromatographically resolved components in leachate accounted for < 0.1 µg/L as annual average concentrations except for one peak which was subsequently identified as being a mixture of NC 8493-glycoside and NC 20645-glycoside.

Furthermore, due to its behaviour in soil, it is not expected that the parent compound or its metabolite reaches the groundwater at levels of concern. This is confirmed by the PEC_{GW} values calculated by means of FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4 models. Following these results, no risk of groundwater contamination was predicted. Therefore, lysimeter studies with this product are not required.

For Phenmedipham, Lysimeter studies are not required. Due to its behaviour in soil, it is not expected that the parent compound or its metabolite reaches the ground water at levels of concern. This is confirmed by the PEC_{GW} values calculated by means of FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4 models. Following these results, no risk of groundwater contamination was predicted. Therefore, lysimeter studies with this product are not required.

This is supported by the results of the lysimeter studies summarised in the DAR for Ethofumesate. The results indicate that after application of 1 kg a.i./ha, during two or three years, no Phenmedipham was found in the leachates and no metabolites could be identified.

zRMS comments:

Provided above information is in line with data reported in EFSA Journal 2016;14(1):4374 and Review Report, 2004 for ethofumesate and phenmedipham, respectively.

8.5.5 Field leaching studies (KCP 9.1.2.3)

As it is possible to extrapolate from data provided for the active substance, no further data are provided on the preparation.

Field leaching studies are not required. Due to their behaviour in soil, it is not expected that any of the active substances or its metabolites reach the groundwater at levels of concern. This is confirmed by the PEC_{GW} values calculated by means of FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4 models. Following these results, no risk of ground water contamination was predicted. Therefore, field leaching studies with this product are not required.

zRMS comments:

Field leaching studies with ethofumesate were not performed or 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)

As it is possible to extrapolate from data provided for the active substance, no further data are provided on the preparation.

8.6.1 Ethofumesate and its metabolites

Studies on the degradation in water/sediment of Ethofumesate have been assessed in the EFSA conclusions (2016). A summary of the degradation in water/sediment is presented in **Table 8.6.1-1 to 8.6.1-2** below.

Table 8.6.1-1 Summary of degradation in water/sediment of Ethofumesate

Ethofumesate Distribution (max. 72.2% AR in sediment after 104 days)											
Water / sediment system	pH water/ sed.	DegT ₅₀ whole syst. (d)	DegT ₉₀ whole syst. (d)	Kinetic, Fit	DissT ₅₀ water (d)	DissT ₉₀ water (d)	Kinetic, Fit	DissT ₅₀ sed. (d)	DissT ₉₀ sed. (d)	Kinetic, Fit	Evaluated on EU level y/n/ Reference
Rückhaltebecken	8.1 / 7.2 ¹	250	830	1.4	52	457 ^{c)}	2.4	1000		-	Y, EFSA, 2016
Waldwinkel	7.7 / 7.1 ¹	294	976	2.3	7.8	101 ^{c)}	2.2	1000		-	
Anglersee	8.6 / 6.8 ²	89	296	4.2	43	187 ^{c)}	2.3	96	320	3.2	
Hönniger Weiher	7.2 / 6.3 ²	141	469	3.4	9.9	130 ^{c)}	4.4	1000		-	
Rhine River	7.9 / 6.9 ²	103	342	1.1	13.3	94 ^{c)}	10.1	1000		-	
Anwiler Teich	7.9 / 6.9 ²	164	543	2.0	23	155 ^{c)}	2.5	1000		-	
Pond	7.9 / 7.8 ²	217	722	5.0	37	343 ^{c)}	5.7	258	857	6.6	
Creek	8.2 / 7.5 ²	209	693	3.6	141	804 ^{c)}	2.4	273	907	1.7	
Geometric mean at 20°C (n=8)		170	564		-	-		536	840		Y, EFSA, 2016

a) Measured in water (1) or CaCl₂ (2)

b) Normalised using a Q10 of 2.58

c) DFOP

Table 8.6.1-2 Summary of observed metabolites

NC 20645 Water/sediment system	Max. in water/sediment 18.8 % after 125 d Kinetic formation fraction (kf/kdp): Anglersee 0.385 (from parent; whole system) Pond 0.443 (from parent; whole system)	Evaluated at EU level EFSA, 2016
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zRMS comments:

Provided above information is in line with data reported in EFSA Journal 2016;14(1):4374 with some additional information of metabolite NC 20645 inserted by the zRMS for consistency with data reported in EFSA Journal 2016;14(1):4374.

The aquatic degradation data for metabolite NC20645 were not provided by the Applicant and are thus presented below for completeness.

Water/ sediment system	pH water/ sed.	DegT ₅₀ whole syst. (d)	DegT ₉₀ whole syst. (d)	St. χ^2	Diss T ₅₀ water (d)	Diss T ₉₀ water (d)	St. χ^2	Diss T ₅₀ sed. (d)	Diss T ₉₀ sed. (d)	St. χ^2	Kinetic Fit
Anglersee	8.6/ 6.8 ¹	19	62	18.1	1000 ^a	1000 ^a	n/a	36	118	3.2	SFO
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
Pond	7.9/ 7.8 ¹	99	329	32.4	1000 ^a	1000 ^a	n/a	1000 ^a	1000 ^a	n/a	SFO
Creek	8.2/ 7.5 ¹	1000 ^a	1000 ^a	n/a	81	269	11.7	n/d	n/d	n/a	SFO
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

8.6.2 Phenmedipham and its metabolites

In water-sediment studies, it was concluded that Phenmedipham rapidly dissipates to sediment where it is degraded by hydrolytic transformation to MHPC. This will be ultimately degraded to minor metabolites (and non-extractable residues) and further on to CO₂. Degradation endpoints for the whole system data of both studies were recalculated with the computer program TopFit 2.0 in the Addendum to the DAR. Resulting whole system half-lives for Phenmedipham were calculated to be 0.11, 0.12 and 0.18 days and for MHPC to be 10.6, 23.9 and 24.9 days. The maximum distribution of MHPC in the whole water-sediment system was found to be 70% on day 2.

For the risk assessment of Phenmedipham, the maximum DT₅₀ system of 0.18 days was used (SFO), while for MHPC the maximum of 24.9 days was considered.

zRMS comments:

Degradation data for phenmedipham and its metabolite in water/sediment systems described above are in line with EU agreed endpoints reported in Review Report (2004) and DAR (2003) and are relevant for the surface water exposure assessment.

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

8.7.1 Justification for new endpoints

For PEC_{soil} calculations the application details and endpoints used for Ethofumesate, Phenmedipham and the relevant metabolites for soil are presented in section 8.7.2. No deviations from EU agreed endpoints are present.

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

No specific studies have been prepared by the applicant for PEC_{soil} calculation (please refer below for further modelling details).

Product HBZ10 containing Ethofumesate (125 g/L) and Phenmedipham (125 g/L) is intended to be used on beet crops after emergence (BBCH 10-39) by up to six applications per season. At a maximum intended application rate of 2.4 L product/ha per application (equivalent to 0.3 kg Ethofumesate/ha and 0.3 kg Phenmedipham/ha).

The 25 intended uses presented in section B0, can be grouped in five main uses as described in Table 8.1-1 of this section, when considering the intended uses on beet crops as a whole (sugar beet, yellow beet, red beet, fodder beet, and chard). Such grouping is used hereafter for a better readability of the calculations results and is described below:

- Use group 1: 6 x 1.2 L prod./ha, 5-days interval (includes uses 1, 6, 11, 16 and 21)
- Use group 2: 3 x 2.4 L prod./ha, 6-days interval (includes uses 2, 7, 12, 17, and 22)
- Use group 3: 5 x 1.2 L prod./ha, 7-days interval (includes uses 3, 8, 13, 18, and 23)
- Use group 4: 3 x 1.8 L prod./ha, 6-days interval (includes uses 4, 9, 14, 19, and 24)
- Use group 5: 3 x 2.4 L prod./ha, 9-days interval (includes uses 5, 10, 15, 20, and 25)

Initial predicted concentrations in soil (PEC_{soil, ini}) were calculated for the proposed use patterns of product HBZ10. No separate report has been prepared for the PEC_{soil} calculations, but the calculation methods and results, as well as an overview of the application data for the calculation of PEC_{soil} values, are described under this point. For a worst-case scenario it is assumed that HBZ10 is applied three times per year at a maximum application rate of 2.4 L product /ha, using 20% interception on beets (use group 2 as critical use pattern). Additionally, PEC_{soil} for use groups 4 and 5 are also presented. Calculated values cover all uses present in GAP table.

The PECs of HBZ10, Ethofumesate, Phenmedipham and their metabolites have been assessed with the FOCUS guidance and approach using the FOCUS groundwater interception values (EFSA, 2014) and the DT₅₀ value established in the EU review.

In order to further refine the risk assessment for non-target organisms (see RR section Part B9), further PEC_{soil} calculations were provided by considering the following:

- For use groups No. 1 and 3, PEC_{soil} calculations have been performed by using Ethofumesate EU agreed DT₅₀ of 26.2 days (according to zRMS comment under point 8.4.1.1), instead of the worst case DT₅₀ of 157 days used in calculations for other uses.
- For use group No. 2, considered as worst-case use and thus covering use groups No. 4 and 5, PEC_{soil} calculations have been refined by splitting the overall BBCH range of application in early application (from BBCH 10 to 39, with consideration of a 20% crop interception in line with FOCUS groundwater interception values (EFSA, 2014)) and late application (from BBCH 20 to 39, with consideration of a 70% crop interception in line with FOCUS groundwater interception values (EFSA, 2014)). New PEC_{soil} calculations for use group No. 2 still considers worst-case DT₅₀ of 157 days for the active substance Ethofumesate.

Parameters representing the application and endpoints for Ethofumesate, Phenmedipham and their relevant metabolites following applications to beets in soil are presented in Table 8.7.2-1 to 8.7.2-2, respectively.

Table 8.7.2-1 Input parameters related to application for PEC_{soil} calculations

Use group No.	1 (considering early application from BBCH 10 to 20)
Crop	Sugar beet
Application rate (g as/ha)	Ethofumesate: 150 Phenmedipham: 150
Number of applications/interval (d)	6/5
Crop interception (%)	20
Depth of soil layer (cm)	5
Tillage depth (relevant for plateau concentration) (cm)	20

Soil bulk density (g/cm ³)	1.5
Use group No.	1 (considering later application from BBCH 20 to 39)
Crop	Sugar beet
Application rate (g as/ha)	Ethofumesate: 150 Phenmedipham: 150
Number of applications/interval (d)	6/5
Crop interception (%)	70
Depth of soil layer (cm)	5
Tillage depth (relevant for plateau concentration) (cm)	20
Soil bulk density (g/cm ³)	1.5
Use group No.	2 (worst-case use considering early application from BBCH 10 to 20)
Crop	Sugar beet
Application rate (g as/ha)	Ethofumesate: 300 Phenmedipham: 300
Number of applications/interval (d)	3/6
Crop interception (%)	20
Depth of soil layer (cm)	5
Tillage depth (relevant for plateau concentration) (cm)	20
Soil bulk density (g/cm ³)	1.5
Use group No.	2 (considering later application from BBCH 20 to 39)
Crop	Sugar beet
Application rate (g as/ha)	Ethofumesate: 300 Phenmedipham: 300
Number of applications/interval (d)	3/6
Crop interception (%)	70
Depth of soil layer (cm)	5
Tillage depth (relevant for plateau concentration) (cm)	20
Soil bulk density (g/cm ³)	1.5
Use group No.	3 (considering early application from BBCH 10 to 20)
Crop	Sugar beet
Application rate (g as/ha)	Ethofumesate: 150 Phenmedipham: 150
Number of applications/interval (d)	5/7
Crop interception (%)	20
Depth of soil layer (cm)	5
Tillage depth (relevant for plateau concentration) (cm)	20
Soil bulk density (g/cm ³)	1.5
Use group No.	4 (considering early application from BBCH 10 to 20)
Crop	Sugar beet
Application rate (g as/ha)	Ethofumesate: 225 Phenmedipham: 225
Number of applications/interval (d)	3/6
Crop interception (%)	20
Depth of soil layer (cm)	5
Tillage depth (relevant for plateau concentration) (cm)	20
Soil bulk density (g/cm ³)	1.5
Use group No.	5 (considering early application from BBCH 10 to 20)
Crop	Sugar beet
Application rate (g as/ha)	Ethofumesate: 300 Phenmedipham: 300
Number of applications/interval (d)	3/9
Crop interception (%)	20
Depth of soil layer (cm)	5
Tillage depth (relevant for plateau concentration) (cm)	20

Soil bulk density (g/cm ³)	1.5
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Table 8.7.2-2 Input parameter for active substance(s) and relevant metabolite(s) for PEC_{Soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT ₅₀ (days)	Value in accordance to EU endpoint y/n/ Reference*
Ethofumesate	286.3	-	157 (SFO, Maximum, representative worst case from field studies, not normalised)	Y, EFSA 2016
NC8493	258.24	24.2 ^{a)}	0.07 (SFO, Maximum, representative worst case from laboratory studies, not normalised)	Y, EFSA 2016
Phenmedipham	300.3	-	43 ^c (Maximum, pF2, SFO, 20°C, n = 3)	Y, RR 2004
MHPC	167.2	54	0.3 (Maximum, pF2, SFO, 20°C, n = 3) ^b	<u>DAR, 2003</u> Y, RR 2004

a) maximum occurrence from soil photolysis study

b) Information from Addendum 3 to the DAR of Phenmedipham (22.10.2003)

c) less than 4 soils (SANCO/10058/2005 vs 2. Guidance document on estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration. 2006)

* EFSA Conclusions regarding peer review of the pesticide risk assessment of the active substance Ethofumesate (2016). doi:10.2903/j.efsa.2016.4374 and review report for Phenmedipham SANCO/4060/2001 - final, 2004.

zRMS comments:

The application pattern assumed in soil exposure assessment presented in Table 8.7.2-1 is in line with the critical Central Zone GAP and it is thus agreed by the zRMS.

It is noted that the application pattern of 3 x 300 g a.s./ha with 6 days interval (use group 2) was considered as a worst case, covering all intended zonal uses. Selected crop interception of 20% is in line with FOCUS groundwater guidance (2014).

During the commenting period the further refinement of the risk assessment for non-target organisms was necessary (see RR section Part B9), therefore additional calculations was performed for:

- use group No. 1 - 6 x 150 g a.s./ha with 5-days interval considering early application (from BBCH 10 to 20) with consideration of 20% crop interception and late application (from BBCH 20 to 39) with consideration of 70% crop interception, which is in line with FOCUS groundwater guidance (2021).
- use group No. 2 - 3 x 300 g a.s./ha with 6-days interval for late application (from BBCH 20 to 39) with consideration of a 70% crop interception. The use group No. 2 is considered as worst-case use and thus covering use groups No. 4 and 5 for late application.
- use group No. 3 5x 150 g a.s./ha with 7-days interval considering early application (from BBCH 10 to 20) with consideration of 20% crop interception which is in line with FOCUS groundwater guidance (2021).

Input parameters presented in Table 8.7.2-2 are in line with EU agreed parameters reported in EFSA Journal 2016;14(1):4374 and Review Report, 2004 for ethofumesate and phenmedipham respectively. In absence of the respective endpoint in the LoEP, the soil DT₅₀ of 0.3 days for the metabolite MHPC was taken from phenmedipham DAR (2003).

8.7.2.1 Ethofumesate and its metabolites

To calculate the initial concentrations of Ethofumesate in soil after use of product HBZ10, an even distribution of the compounds within a soil layer of 5 cm depth and a bulk density of 1.5 g/cm³ is assumed. Following one application, the initial PEC_{Soil} value immediately after application is calculated according to the following formula³ :

3 European Commission, Directorate for Agriculture, VI B II. 1, 09.08.99, Guidance Document on the Calculation of Predicted Environmental Concentration Values (PEC) of Plant Protection Products for Soil, Ground Water, Surface Water and Sediment, 7193/VI/99 rev. 0, DRAFT Working Document

$$PEC_{Soil, ini} = A \cdot \frac{(1 - f_d)}{(100 \cdot depth \cdot bd)}$$

where

$PEC_{Soil, ini}$	initial PEC_{soil} value [mg/kg] immediately following a single application
A	application rate [g/ha]
f_d	fraction of the product intercepted by crop canopy
depth	soil mixing depth [cm]
bd	soil bulk density [g/cm ³]

Following multiple applications, the initial PEC_{Soil} value immediately after the last application (n^{th} application) is obtained by the following formula:

$$PEC_{Soil, ini (n)} = \frac{PEC_{Soil, ini (1)} (1 - e^{-nki})}{(1 - e^{-ki})}$$

where

$PEC_{Soil, ini (n)}$	initial PEC_{soil} value [mg/kg] immediately following the last application
$PEC_{Soil, ini (1)}$	initial PEC_{Soil} value [mg/kg] immediately following first application
n	number of applications
i	application interval [day]
k	degradation rate of the compound [1/day]

the PEC_{Soil} values at specific time (t) after the final application is given by the following formula:

$$TWA \text{ } PEC_{Soil, l (t)} = PEC_{Soil, ini} \cdot \frac{DT_{50}}{t \cdot \ln(2)} \left(1 - e^{(-t \ln(2)/DT_{50})}\right)$$

where

Actual $PEC_{Soil, l(t)}$	actual concentration at time t
TWA $PEC_{Soil, l(t)}$	time-weighted average concentration at time t
$PEC_{Soil, ini}$	initial concentration in soil
t	time period

and the TWA value over the moving window is calculated from the simple numerical average of these daily values.

The calculated initial PEC_{Soil} values for the Ethofumesate and its relevant metabolites are summarised in the following tables.

In addition to the seasonal PEC_{soil} calculations, the potential accumulation of Ethofumesate in soil following repeated annual applications of the product was estimated by the notifier using the ESCAPE tool, version 2.0. A detailed summary of the input and output data of the ESCAPE calculations can be found in **Appendix 3**.

Table 8.7.2.1-1 **PEC_{Soil} for Ethofumesate on sugar beets, use group 2 - 3 × 300 g a.s./ha with 6-days interval considering early application from BBCH 10**

PEC _{Soil} [mg/kg]		Sugar beets			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.320	-	0.935	-
Short term	24 h	0.319	0.319	0.931	0.933
	2 d	0.317	0.319	0.927	0.931
	4 d	0.314	0.317	0.919	0.927
Long term	7 d	0.310	0.315	0.907	0.921
	14 d	0.301	0.310	0.879	0.907
	21 d	0.292	0.306	0.852	0.893
	50 d	0.257	0.287	0.750	0.840
	100 d	0.206	0.259	0.601	0.758
Plateau concentration (20 cm) after year 10		0.0199	-	0.0583	-
PECaccumulation (PECact + PECSoil plateau)		0.3399	-	0.9934	-

Table 8.7.2.1-2 **PEC_{Soil} for Ethofumesate on sugar beets, use group 2 - 3 × 300 g a.s./ha with 6-days interval considering later application from BBCH 20**

PEC _{Soil} [mg/kg]		Sugar beets			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.120	-	0.351	-
Short term	24 h	0.119	0.120	0.349	0.350
	2 d	0.119	0.119	0.348	0.349
	4 d	0.118	0.119	0.345	0.348
Long term	7 d	0.116	0.118	0.340	0.345
	14 d	0.113	0.116	0.330	0.340
	21 d	0.109	0.115	0.320	0.335
	50 d	0.096	0.108	0.281	0.315
	100 d	0.077	0.097	0.226	0.283
Plateau concentration (20 cm) after year 10		0.007	-	0.023	-
PECaccumulation (PECact + PECSoil plateau)		0.127	-	0.374	-

Table 8.7.2.1-3 **PEC_{Soil} for Ethofumesate on sugar beets, use group 4 - 3 × 225 g a.s./ha with 6-days interval considering early application from BBCH 10**

PEC _{Soil} [mg/kg]		Sugar beets			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.240	-	0.701	-
Short term	24 h	0.239	0.240	0.698	0.700
	2 d	0.238	0.239	0.695	0.698
	4 d	0.236	0.238	0.689	0.695
Long term	7 d	0.233	0.236	0.680	0.691
	14 d	0.226	0.233	0.659	0.680
	21 d	0.219	0.229	0.639	0.670
	50 d	0.193	0.215	0.562	0.630
	100 d	0.154	0.194	0.451	0.569
Plateau concentration (20 cm) after year 10		0.015	-	0.044	-
PECaccumulation (PECact + PECSoil plateau)		0.255	-	0.745	-

Table 8.7.2.1-4 3 **PEC_{Soil} for Ethofumesate on sugar beets, use group 5 - 3 × 300 g a.s./ha with 9-days interval considering early application from BBCH 10**

PEC _{Soil} [mg/kg]		Sugar beets			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.320	-	0.923	-
Short term	24 h	0.319	0.319	0.919	0.921
	2 d	0.317	0.319	0.915	0.919
	4 d	0.314	0.317	0.907	0.915
Long term	7 d	0.310	0.315	0.895	0.909
	14 d	0.301	0.310	0.868	0.895
	21 d	0.292	0.306	0.841	0.882
	50 d	0.257	0.287	0.740	0.829
	100 d	0.206	0.259	0.594	0.749
Plateau concentration (20 cm) after year 10		0.020	-	0.058	-
PEC _{accumulation} (PEC _{act} + PEC _{Soil} plateau)		0.340	-	0.981	-

PEC_{Soil} of metabolites

Table 8.7.2.1-5 4 **PEC_{Soil} for NC8493 on sugar beets, use group 2 - 3 × 300 g a.s./ha with 6-days interval considering early application from BBCH 10**

PEC _{Soil} [mg/kg]		Sugar beets			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.07	-	0.07	-
Short term	24 h	< 0.001	0.007	< 0.001	0.007
	2 d	< 0.001	0.004	< 0.001	0.004
	4 d	< 0.001	0.002	< 0.001	0.002
Long term	7 d	< 0.001	0.001	< 0.001	0.001
	14 d	< 0.001	0.001	< 0.001	0.001
	21 d	< 0.001	< 0.001	< 0.001	< 0.001
	50 d	< 0.001	< 0.001	< 0.001	< 0.001
	100 d	< 0.001	< 0.001	< 0.001	< 0.001
Plateau concentration (5/20 cm) after year x		-	-	-	-
PEC _{accumulation} (PEC _{act} + PEC _{Soil} plateau)		-	-	-	-

* Application rate: 65.5 g NC8493/ha assuming NC8493 is formed at a max. of 24.2% of the applied dose and a molecular weight relative to the parent of 0.902

Table 8.7.2.1-6 5 **PEC_{Soil} for NC8493 on sugar beets, use group 4 - 3 × 225 g a.s./ha with 6-days interval considering early application from BBCH 10**

PEC _{Soil} [mg/kg]		Sugar beets			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.052	-	0.052	-
Short term	24 h	< 0.001	0.005	< 0.001	0.005
	2 d	< 0.001	0.003	< 0.001	0.003
	4 d	< 0.001	0.001	< 0.001	0.001
Long term	7 d	< 0.001	0.001	< 0.001	0.001
	14 d	< 0.001	< 0.001	< 0.001	< 0.001
	21 d	< 0.001	< 0.001	< 0.001	< 0.001
	50 d	< 0.001	< 0.001	< 0.001	< 0.001

PEC _{Soil} [mg/kg]		Sugar beets			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
	100 d	< 0.001	< 0.001	< 0.001	< 0.001
Plateau concentration (20 cm) after year x		-	-	-	-
PEC _{accumulation} (PEC _{act} + PEC _{Soil plateau})		-	-	-	-

* Application rate: 49.12 g NC8493/ha assuming NC8493 is formed at a max. of 24.2% of the applied dose and a molecular weight relative to the parent of 0.902

Table 8.7.2.1-7 6 **PEC_{Soil} for NC8493 on sugar beets, use group 5 - 3 × 300 g a.s./ha with 9-days interval considering early application from BBCH 10**

PEC _{Soil} [mg/kg]		Sugar beets			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.070	-	0.070	-
Short term	24 h	< 0.001	0.007	< 0.001	0.007
	2 d	< 0.001	0.004	< 0.001	0.004
	4 d	< 0.001	0.002	< 0.001	0.002
Long term	7 d	< 0.001	0.001	< 0.001	0.001
	14 d	< 0.001	0.001	< 0.001	0.001
	21 d	< 0.001	< 0.001	< 0.001	< 0.001
	50 d	< 0.001	< 0.001	< 0.001	< 0.001
	100 d	< 0.001	< 0.001	< 0.001	< 0.001
Plateau concentration (20 cm) after year x		-	-	-	-
PEC _{accumulation} (PEC _{act} + PEC _{Soil plateau})		-	-	-	-

* Application rate: 65.5 g NC8493/ha assuming NC8493 is formed at a max. of 24.2% of the applied dose and a molecular weight relative to the parent of 0.902

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 3x300 g a.s./ha with 6 days interval represents worst case and performed calculations are thus protective for other crops listed in the Central Zone GAP.

During the commenting period the further refinement of the risk assessment for non-target organisms was necessary (see RR section Part B9), therefore additional calculations was performed by the Applicant for ethofumesate for:

- use group No. 2 - 3 x 300 g a.s./ha with 6-days interval for late application (from BBCH 20) with consideration of a 70% crop interception which is in line with FOCUS groundwater guidance (EFSA, 2021). Since the use group No. 2 is considered as worst-case use it is covering use groups No. 4 and 5 for late application. The PEC_{soil} results presented in Table 8.7.2.1-2 are agree by the zRMS.
- use group No. 1 - 6 x 150 g a.s./ha with 5-days interval considering early application (from BBCH 10), and use group No. 3 - 5 x 150g a.s./ha with 7-days interval considering early application (from BBCH 10). However, Applicant performed PEC_{soil} calculations for use group No. 1 and 3 with consideration of DT₅₀ of 26.2 days (normalised geomean value) instead of the worst-case DT₅₀ of 157 days (maximum not normalised value from field studies). Since the wrong DT₅₀ value was used, the Applicant's results are not reported, instead the zRMS performed additional PEC_{soil} calculations using the EU agreed value of DT₅₀ of 157 days. Obtained results are presented in table below. Short- and long-term PEC_{SOIL} values as well as detailed TWA PEC_{SOIL} values are not reported as being not required for the risk assessment purposes.

PEC _{soil} for Ethofumesate on sugar beets, Use group 1 - 6 x 150 g a.s./ha with 5-days interval considering early application from BBCH 10								
Substance	Single application				Multiple applications			
	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]	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	0.159	0.010	0.169	0.153	0.905	0.057	0.962	0.868

PEC _{soil} for Ethofumesate on sugar beets, Use group 3 - 5 x 150 g a.s./ha with 7-days interval considering early application from BBCH 10								
Substance	Single application				Multiple applications			
	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]	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	0.159	0.010	0.169	0.153	0.749	0.047	0.796	0.719

Since the further refinement was required, the zRMS performed additional calculation for use group No.1 (6 x 150g a.s./ha with 5-days interval) considering late application (from BBCH 20 to 39) with consideration of a 70% crop interception (in line with FOCUS groundwater guidance (EFSA, 2021)). The use group No. 1 is considered as worst-case use and thus covering use group No. 3 (5x 150g a.s./ha with 7-days interval) for late application. The obtained PEC_{soil} results are presented in table below. Short- and long-term PEC_{soil} values as well as detailed TWA PEC_{soil} values are not reported as being not required for the risk assessment purposes.

PEC _{soil} for Ethofumesate on sugar beets, Use group 1 - 6 x 150 g a.s./ha with 5-days interval considering late application from BBCH 20								
Substance	Single application				Multiple applications			
	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]	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	0.049	0.0001	0.049	0.0003	0.339	0.021	0.361	0.311

8.7.2.2 Phenmedipham and its metabolites

Initial predicted concentrations in soil (PEC_{soil, ini}) were calculated for a worst-case use of the proposed use patterns of product HBZ10. No separate report has been prepared for the PEC_{soil} calculations, but the calculation methods and results, as well as an overview of the application data for the calculation of PEC_{soil} values, are described under this point.

To calculate the initial concentrations of Phenmedipham in soil after use of the product, an even distribution of the compounds within a soil layer of 5 cm depth and a bulk density of 1.5 g/cm³ is assumed. Following one application, the initial PEC_{soil} value immediately after application is calculated according to the following formula⁴ :

$$PEC_{soil, ini} = A \cdot \frac{(1 - f_d)}{(100 \cdot \text{depth} \cdot \text{bd})}$$

where

PEC_{soil, ini} initial PEC_{soil} value [mg/kg] immediately following a single application
A application rate [g/ha]
f_d fraction of the product intercepted by crop canopy

4 European Commission, Directorate for Agriculture, VI B II. 1, 09.08.99, Guidance Document on the Calculation of Predicted Environmental Concentration Values (PEC) of Plant Protection Products for Soil, Ground Water, Surface Water and Sediment, 7193/VI/99 rev. 0, DRAFT Working Document

depth soil mixing depth [cm]
bd soil bulk density [g/cm³]

Following multiple applications, the initial PEC_{Soil} value immediately after the last application (nth application) is obtained by the following formula:

$$PEC_{Soil, ini (n)} = \frac{PEC_{Soil, ini (1)}(1 - e^{-nki})}{(1 - e^{-ki})}$$

where

PEC_{Soil, ini (n)} initial PEC_{soil} value [mg/kg] immediately following the last application
PEC_{Soil, ini (1)} initial PEC_{Soil} value [mg/kg] immediately following first application
n number of applications
i application interval [day]
k degradation rate of the compound [1/day]

the PEC_{Soil} values at specific time (t) after the final application is given by the following formula:

$$TWA \text{ } PEC_{Soil, l (t)} = PEC_{Soil, ini} \cdot \frac{DT_{50}}{t \cdot \ln(2)} \left(1 - e^{(-t \ln(2)/DT_{50})}\right)$$

where

Actual PEC_{Soil, l(t)} actual concentration at time t
TWA PEC_{Soil, l(t)} time-weighted average concentration at time t
PEC_{Soil, ini} initial concentration in soil
t time period

and the TWA value over the moving window is calculated from the simple numerical average of these daily values.
The calculated initial PEC_{Soil} values for the Phenmedipham and its relevant metabolites are summarised in the following tables.

Table 8.7.2.2-1 PEC_{Soil} for Phenmedipham on sugar beets, Use group 1 - 6 x 150 g a.s./ha with 5-days interval considering early application from BBCH 10

PEC _{Soil} [mg/kg]		Sugar beets			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.160	-	0.792	-
Short term	24 h	0.157	0.159	0.780	0.786
	2 d	0.155	0.157	0.767	0.780
	4 d	0.150	0.155	0.743	0.767
Long term	7 d	0.143	0.151	0.708	0.749
	14 d	0.128	0.143	0.632	0.709
	21 d	0.114	0.136	0.565	0.672
	50 d	0.071	0.110	0.354	0.544
	100 d	0.032	0.079	0.158	0.393
Plateau concentration (20 cm) after year 20		-	-	-	-
PEC _{accumulation} (PEC _{act} + PEC _{Soil plateau})		-	-	-	-

Table 8.7.2.2-2 ± PEC_{Soil} for Phenmedipham on sugar beets, Use group 2 - 3 x 300 g a.s./ha with 6-days interval considering early application from BBCH 10

PEC _{Soil} [mg/kg]		Sugar beets			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.320	-	0.874	-
Short term	24 h	0.315	0.317	0.860	0.867
	2 d	0.310	0.315	0.846	0.860
	4 d	0.300	0.310	0.820	0.847
Long term	7 d	0.286	0.303	0.781	0.827
	14 d	0.255	0.286	0.698	0.783

PEC _{Soil} [mg/kg]		Sugar beets			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
	21 d	0.228	0.271	0.623	0.742
	50 d	0.143	0.220	0.390	0.600
	100 d	0.064	0.159	0.174	0.434
Plateau concentration (20 cm) after year 20		-	-	-	-
PEC _{accumulation} (PEC _{act} + PEC _{Soil plateau})		-	-	-	-

Table 8.7.2.2-3 PEC_{Soil} for Phenmedipham on sugar beets, Use group 2 - 3 × 300 g a.s./ha with 6-days interval considering late application from BBCH 20

PEC _{Soil} [mg/kg]		Sugar beets			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.120	-	0.328	-
Short term	24 h	0.118	0.119	0.323	0.325
	2 d	0.116	0.118	0.317	0.323
	4 d	0.113	0.116	0.307	0.317
Long term	7 d	0.107	0.113	0.293	0.310
	14 d	0.096	0.107	0.262	0.293
	21 d	0.086	0.102	0.234	0.278
	50 d	0.054	0.082	0.146	0.225
	100 d	0.024	0.060	0.065	0.163
Plateau concentration (20 cm) after year 20		-	-	-	-
PEC _{accumulation} (PEC _{act} + PEC _{Soil plateau})		-	-	-	-

Table 8.7.2.2-4 PEC_{Soil} for Phenmedipham on sugar beets, Use group 3 - 5 × 150 g a.s./ha with 7-days interval considering early application from BBCH 10

PEC _{Soil} [mg/kg]		Sugar beets			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.160	-	0.647	-
Short term	24 h	0.157	0.159	0.636	0.641
	2 d	0.155	0.157	0.626	0.636
	4 d	0.150	0.155	0.606	0.626
Long term	7 d	0.143	0.151	0.578	0.611
	14 d	0.128	0.143	0.516	0.579
	21 d	0.114	0.136	0.461	0.548
	50 d	0.071	0.110	0.289	0.444
	100 d	0.032	0.079	0.129	0.321
Plateau concentration (20 cm) after year 20		-	-	-	-
PEC _{accumulation} (PEC _{act} + PEC _{Soil plateau})		-	-	-	-

Table 8.7.2.2-5 2 **PEC_{Soil} for Phenmedipham on sugar beets, Use group 4 - 3 × 225 a.s./ha with 6-days interval considering early application from BBCH 10**

PEC _{Soil} [mg/kg]		Sugar beets			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.240	-	0.656	-
Short term	24 h	0.236	0.238	0.645	0.650
	2 d	0.232	0.236	0.635	0.645
	4 d	0.225	0.232	0.615	0.635
Long term	7 d	0.214	0.227	0.586	0.620
	14 d	0.192	0.215	0.523	0.587
	21 d	0.171	0.204	0.467	0.556
	50 d	0.107	0.165	0.293	0.450
	100 d	0.048	0.119	0.131	0.326
Plateau concentration (20 cm) after year 20		-	-	-	-
PEC _{accumulation} (PEC _{act} + PEC _{Soil plateau})		-	-	-	-

Table 8.7.2.2-6 3 **PEC_{Soil} for Phenmedipham on sugar beets, Use group 5 - 3 × 300 a.s./ha with 9-days interval considering early application from BBCH 10**

PEC _{Soil} [mg/kg]		Sugar beets			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.320	-	0.836	-
Short term	24 h	0.315	0.317	0.823	0.829
	2 d	0.310	0.315	0.810	0.823
	4 d	0.300	0.310	0.784	0.810
Long term	7 d	0.286	0.303	0.747	0.791
	14 d	0.255	0.286	0.667	0.749
	21 d	0.228	0.271	0.596	0.709
	50 d	0.143	0.220	0.373	0.574
	100 d	0.064	0.159	0.167	0.415
Plateau concentration (20 cm) after year 20		-	-	-	-
PEC _{accumulation} (PEC _{act} + PEC _{Soil plateau})		-	-	-	-

PEC_{Soil} of metabolites

Table 8.7.2.2-7 4 **PEC_{Soil} for MHPC on sugar beets, Use group 2 - 3 × 300 g a.s./ha with 6-days interval considering early application from BBCH 10**

PEC _{Soil} [mg/kg]		Sugar beets			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.096	-	0.096	-
Short term	24 h	0.010	0.038	0.010	0.038
	2 d	0.001	0.021	0.001	0.021
	4 d	< 0.001	0.010	< 0.001	0.010
Long term	7 d	< 0.001	0.006	< 0.001	0.006
	14 d	< 0.001	0.003	< 0.001	0.003
	21 d	< 0.001	0.002	< 0.001	0.002
	50 d	< 0.001	0.001	< 0.001	0.001
	100 d	< 0.001	< 0.001	< 0.001	< 0.001
Plateau concentration (5/20 cm) after year x		-	-	-	-
PEC _{accumulation} (PEC _{act} + PEC _{Soil plateau})		-	-	-	-

* Application rate: 90.2 g MHPC/ha assuming metabolite is formed at a max. of 54% of the applied dose and a molecular weight relative to the parent of 0.557

Table 8.7.2.1-8 5 **PEC_{Soil} for MHPC on sugar beets, Use group 4 - 3 × 225 a.s./ha with 6-days interval considering early application from BBCH 10**

PEC _{Soil} [mg/kg]		Sugar beets			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.072	-	0.072	-
Short term	24 h	0.007	0.028	0.007	0.028
	2 d	0.001	0.015	0.001	0.015
	4 d	< 0.001	0.008	< 0.001	0.008
Long term	7 d	< 0.001	0.004	< 0.001	0.004
	14 d	< 0.001	0.002	< 0.001	0.002
	21 d	< 0.001	0.001	< 0.001	0.001
	50 d	< 0.001	0.001	< 0.001	0.001
	100 d	< 0.001	< 0.001	< 0.001	< 0.001
Plateau concentration (20 cm) after year x		-	-	-	-
PEC _{accumulation} (PEC _{act} + PEC _{Soil plateau})		-	-	-	-

* Application rate: 67.7 g MHPC/ha assuming metabolite is formed at a max. of 54% of the applied dose and a molecular weight relative to the parent of 0.557

Table 8.7.2.1-9 6 **PEC_{Soil} for MHPC on sugar beets, Use group 5 - 3 × 300 a.s./ha with 9-days interval considering early application from BBCH 10**

PEC _{Soil} [mg/kg]		Sugar beets			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.096	-	0.096	-
Short term	24 h	0.010	0.038	0.010	0.038
	2 d	0.001	0.021	0.001	0.021
	4 d	< 0.001	0.010	< 0.001	0.010
Long term	7 d	< 0.001	0.006	< 0.001	0.006
	14 d	< 0.001	0.003	< 0.001	0.003
	21 d	< 0.001	0.002	< 0.001	0.002
	50 d	< 0.001	0.001	< 0.001	0.001
	100 d	< 0.001	< 0.001	< 0.001	< 0.001
Plateau concentration (20 cm) after year x		-	-	-	-
PEC _{accumulation} (PEC _{act} + PEC _{Soil plateau})		-	-	-	-

* Application rate: 90.2 g MHPC/ha assuming metabolite is formed at a max. of 54% of the applied dose and a molecular weight relative to the parent of 0.557

zRMS comments:

The soil exposure for phenmedipham and its metabolite MHPC has been independently validated by the zRMS using FOCUS methods and EU agreed endpoints. The pseudo-application rates of metabolite were 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 3x300 g a.s./ha with 6 days interval represents worst case and performed calculations are thus protective for other crops listed in the Central Zone GAP.

During the commenting period the further refinement of the risk assessment for non-target organisms was necessary (see RR section Part B9), therefore additional calculations were performed by the Applicant for phenmedipham for:

- use groups No. 1 - 6 x 150g a.s./ha with 5-days interval considering early application (from BBCH 10)
- use group No. 2 - 3 x 300 g a.s./ha with 6-days interval for late application (from BBCH 20 to 39) with consideration of a 70% crop interception. The use group No. 2 is considered as worst-case use and thus covering use groups No. 4 and 5 for late application
- use group No. 3 5x 150g a.s./ha with 7-days interval considering early application (from BBCH 10).

The calculations were independently validated by the zRMS in additional modelling using the same input parameters. The PEC_{soil} results were in good agreement with values obtained by the Applicant. Therefore, results reported in Tables: 8.7.2.2-1, 8.7.2.2-3 and 8.7.2.2-4 may be used for the soil risk assessment purposes.

Since the further refinement was required, the zRMS performed additional calculation for use group No. 1 (6 x 150g a.s./ha with 5-days interval) considering late application (from BBCH 20 to 39) with consideration of a 70% crop interception (in line with FOCUS groundwater guidance (EFSA, 2021)). The use group No. 1 is considered as worst-case use and thus covering use group No. 3 (5x 150g a.s./ha with 7-days interval) for late application. The obtained PEC_{soil} results are presented in table below. Short- and long-term PEC_{soil} values as well as detailed TWA PEC_{soil} values are not reported as being not required for the risk assessment purposes.

PEC_{soil} for Phenmedipham on sugar beets, Use group 1 - 6 x 150 g a.s./ha with 5-days interval considering late application from BBCH 20

Substance	Single application				Multiple applications			
	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]	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]
Phenmedipham	0.060	-	-	0.043	0.297	-	-	0.260

8.7.2.3 PEC_{soil} of formulation

For the product HBZ10, the PEC_{soil} was calculated following the same method as for the active substances, for use on beets at 7.2 L HBZ10/ha which results in the highest total loading, considering a 20% crop interception. The respective initial PEC_{soil} value for the formulated product was calculated considering a density of the product of 0.978 kg/dm³.

Table 8.7.2.3-1 PEC_{soil} for HBZ10 following application on sugar beets considering cumulated dose application

Active substance / preparation	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]
HBZ10	7041.6	7.511	7.457 7.511	-	-	-

PEC_{accu} Accumulation concentration

PEC_{act} Actual concentration

The maximum PEC_{soil} cumulative dose calculation presented above is considered as highest worst-case. Therefore, a more realistic approach is provided as refinement, considering the maximum single dose application rate per application of 2.4 L/ha, according to standard practice in risk assessment, since the formulation will break down to component parts after application and will not persist as formulated product. The PEC_{soil} presented below for the risk assessment was calculated with the highest maximum rate of 2.4 L/ha per application on beets, considering a 20% crop interception. The respective initial PEC_{soil} value for the formulated product was calculated considering a density of the product of 0.978 kg/dm³ and result is provided below in Table 8.7.2.3-2.

Table 8.7.2.3-2 PEC_{Soil} for HBZ10 following application on sugar beets considering single dose application

Active substance / preparation	Application rate [g/ha]	PEC _{act} [mg/kg]	PEC _{twā} 21 d [mg/kg]	Tillage depth [cm]	PEC _{Soil plateau} [mg/kg]	PEC _{accu.} = PEC _{act.} + PEC _{Soil plateau} [mg/kg]
HBZ10	2347.2	2.504	2.485	-	-	-

PEC_{accu} Accumulation concentration

PEC_{act} Actual concentration

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. The PEC_{twā} 21 d presented in Table 8.7.2.3-1 was re-calculated and amended for the correct value.

During the commenting period the further refinement of the risk assessment for non-target organisms was necessary (see RR section Part B9), therefore additional calculations was performed by the Applicant considering the maximum single dose application rate of 2.4 L/ha. The PEC_{soil} value calculated by the Applicant for the formulated product presented in Table above is agreed by the zRMS.

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

8.8.1 Justification for new endpoints

The input values for Ethofumesate, Phenmedipham and their metabolites were taken from the EFSA conclusions (2016) and Annex I inclusion (SANCO/4060/2001-Final, 2004), respectively.

For both Ethofumesate and Phenmedipham, no deviation was made from the EU agreed endpoints.

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

A FOCUS GW calculation for the product was performed in order to predict the concentration of residues in groundwater (PEC_{GW}). The product HBZ10 containing Ethofumesate (125 g/L) and Phenmedipham (125 g/L) is intended to be used on beet crops after emergence (BBCH 10-39). At a maximum intended application rate of 2.4 L product/ha per application (equivalent to 0.3 kg Ethofumesate/ha and 0.3 kg Phenmedipham/ha).

The 25 intended uses presented in section B0, can be grouped in five main uses as described in Table 8.1-1 of this section, when considering the intended uses on beet crops as a whole (sugar beet, yellow beet, red beet, fodder beet, and chard). Such grouping is used hereafter for a better readability of the calculations results and is described below:

- Use group 1: 6 x 1.2 L prod./ha, 5-days interval (includes uses 1, 6, 11, 16 and 21)
- Use group 2: 3 x 2.4 L prod./ha, 6-days interval (includes uses 2, 7, 12, 17, and 22)
- Use group 3: 5 x 1.2 L prod./ha, 7-days interval (includes uses 3, 8, 13, 18, and 23)
- Use group 4: 3 x 1.8 L prod./ha, 6-days interval (includes uses 4, 9, 14, 19, and 24)
- Use group 5: 3 x 2.4 L prod./ha, 9-days interval (includes uses 5, 10, 15, 20, and 25)

PEC_{GW} values were calculated assuming the first application to take place 1 day after emergence for early application (BBCH 10, 20% crop interception) and assuming the last application to take place on BBCH 39 for late application (70% crop interception) for the worst case uses (three applications at maximum application rate of 2.4 L product/ha, use group 2; six applications at maximum application rate of 1.2 L product/ha, use group 1. Additionally, uses 3 (3 x 150 g a.s./ha), 4 (3 x 225 g a.s./ha) and 5 (3 x 300 g a.s./ha) were also simulated. The modelled uses cover all intended uses in Part B, Section 0 for CEU.

The latest version of FOCUS GW models (FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3) were used for the calculations of PEC values for the actives and metabolites. In addition, and according to the working document of the central zone, PEC_{GW} values were calculated using FOCUS MACRO 5.5.4 when necessary, since sugar beets are parameterised for scenario Châteaudun. Since new modelling versions were published since the original submission, the new versions (FOCUS PEARL 5.5.5 and FOCUS PELMO 6.6.4) are also considered in the update of the calculations for the plant uptake factor of 0.

Input parameters related to application of the product are presented in **Table 8.8.2-1** and input parameters related to the actives Ethofumesate and Phenmedipham and their metabolites are presented in **Tables 8.8.2.1-1** and **8.8.2.2-1**.

PEC_{GW} values presented below are based on the results obtained from the study by Lindim (2021a). The study is presented in Appendix 1.

Table 8.8.2-1 Input parameters related to application for PEC_{GW} calculations

Use group No. ^a	1 (covers use group 3)	2 (covers use groups 4 and 5)	3	4	5
Crop	Sugar beet	Sugar beet	Sugar beet	Sugar beet	Sugar beet
Application rate [g a.s./ha]	Ethofumesate: 150 Phenmedipham: 150	Ethofumesate: 300 Phenmedipham: 300	Ethofumesate: 150 Phenmedipham: 150	Ethofumesate: 225 Phenmedipham: 225	Ethofumesate: 300 Phenmedipham: 300
Number of applications	6/year	3/year	5/year	3/year	3/year
Interval between applications [d]	5	6	7	6	9
Crop interception [%]	Early application: 20 Late application: 70				
Frequency of application	Annual				
Models used for calculation	FOCUS PEARL v4.4.4 & v.5.5.5 FOCUS PELMO v5.5.3 & v.6.6.4, FOCUS MACRO v5.5.4				

^a please, refer to GAP table in Part B, Section 0

Table 8.8.2-2 FOCUS Scenario related input parameters for PEC_{GW} calculations for the application of product HBZ10

Crop	Scenario	Application window used in modelling			
		Julian days	Dates (early application)	Julian days	Dates (late application)
Sugar beets 6 applications (use group 1)	Châteaudun	107 – 132	17 April – 12 May	167 – 192	16 June – 11 July
	Hamburg	106 – 131	16 April – 11 May	210 – 235	29 July – 23 August
	Jokioinen	146 – 171	26 May – 20 June	193 – 218	12 July – 6 August
	Kremsmünster	106 – 131	16 April – 11 May	210 – 235	29 July – 23 August
	Okehampton	116 – 141	26 April – 21 May	211 – 236	30 July – 24 August
	Piacenza	80 – 105	21 March – 15 April	168 – 193	17 June – 12 July
	Porto	75 – 100	16 March – 10 April	93 – 118	3 April – 28 April
	Sevilla	315 – 340	11 November – 6 December	72 – 97	13 March – 7 April
	Thiva	122 – 147	2 May – 27 May	122 – 178	2 May – 27 June
Sugar beets 3 applications (use group 2) And Sugar beets 3 applications (use group 4)	Châteaudun	107 – 119	17 April – 29 April	180 – 192	29 June – 11 July
	Hamburg	106 – 118	16 April – 28 April	223 – 235	11 August – 23 August
	Jokioinen	146 – 158	26 May – 7 June	206 – 218	25 July – 6 August
	Kremsmünster	106 – 118	16 April – 28 April	223 – 235	11 August – 23 August
	Okehampton	116 – 128	26 April – 8 May	224 – 236	12 August – 24 August
	Piacenza	80 – 92	21 March – 2 April	181 – 193	30 June – 12 July
	Porto	75 – 87	16 March – 28 March	106 – 118	16 April – 28 April
	Sevilla	315 – 327	11 November – 23 November	85 – 97	26 March – 7 April
	Thiva	122 – 134	2 May – 14 May	166 – 178	15 June – 27 June
Sugar beets 5 applications (use group 3)	Châteaudun	107 – 135	17 April – 15 May	164 – 192	13 June – 11 July
	Hamburg	106 – 134	16 April – 14 May	207 – 235	26 July – 23 August
	Jokioinen	146 – 174	26 May – 23 June	190 – 218	9 July – 6 August
	Kremsmünster	106 – 134	16 April – 14 May	207 – 235	26 July – 23 August
	Okehampton	116 – 144	26 April – 24 May	208 – 236	27 July – 24 August
	Piacenza	80 – 108	21 March – 18 April	165 – 193	14 June – 12 July
	Porto	75 – 103	16 March – 13 April	90 – 118	31 March – 28 April
	Sevilla	315 – 350	11 November – 16 December	69 – 97	10 March – 7 April
	Thiva	122 – 150	2 May – 30 May	150 – 178	30 May – 27 June
Sugar beets 3 applications (use group 5)	Châteaudun	107 – 125	17 April – 5 May	174 – 192	23 June – 11 July
	Hamburg	106 – 124	16 April – 4 May	217 – 235	5 August – 23 August
	Jokioinen	146 – 164	26 May – 13 June	200 – 218	19 July – 6 August
	Kremsmünster	106 – 124	16 April – 4 May	217 – 235	5 August – 23 August
	Okehampton	116 – 134	26 April – 14 May	218 – 236	6 August – 24 August
	Piacenza	80 – 98	31 March – 8 April	175 – 193	24 June – 12 July
	Porto	75 – 95	16 March – 3 April	100 – 118	10 April – 28 April
	Sevilla	315 – 333	11 November – 29 November	79 – 97	20 March – 7 April
	Thiva	122 – 140	2 May – 20 May	160 – 178	9 June – 27 June

zRMS comments:

The application pattern considered in the groundwater exposure assessment presented in Table 8.8.2-1 is in line with the critical Central Zone GAP.

Assumed crop interception of 20% and 70% is in line with the most recent version of the FOCUS Groundwater Guidance (2021) and is adequate for sugar beet at the BBCH 10-39 stage.

Application dates presented in Table 8.8.2-2 were checked by the zRMS using AppDate ver. 3.06 tool and are considered acceptable.

It is noted that in updated simulations performed with PUF of 0 the Applicant used the most recent version of the FOCUS modelling programs (PELMO 6.6.4 and PEARL 5.5.5) in addition to older versions of FOCUS models (PELMO 5.5.3 and PEARL 4.4.4).

The zRMS is of the opinion that models in place at the date of submission should be used for calculations. As the dossier for HBZ10 was submitted before 1st of January 2022 (i.e. date of entry into force of the new versions of the models), results of calculations performed using PELMO 5.5.3 and PEARL 4.4.4 were considered by the zRMS as formally binding. Nevertheless, the simulations performed using new versions were retained for convenience of the CMS that prefer results obtained using newer versions of the models.

8.8.2.1 Ethofumesate and its metabolites

Table 8.8.2.1-1 Input parameters related to Ethofumesate and metabolites NC 8493 and NC 20645 for PEC_{GW} calculation

Compound	Ethofumesate	NC 8493	NC 20645	Value in accordance with EU endpoint y/n/ Reference
Molecular weight (g/mol)	286.3	258.3	274.3	Y, EFSA, 2016
Water solubility (mg/L)	@ 20°C: 41.5 @ 25°C: 50 @ 30°C: 59.8	@ 20°C: 1676.7 @ 25°C: 2019 @ 30°C: 2416.3	@ 25°C: 16170	Y ^{a)} , EFSA, 2016
Saturated vapour pressure (Pa)	@ 20°C: 3.38E-04 @ 25°C: 6.5E-04 @ 30°C: 1.22E-03	@ 20°C: 1.94E-06 @ 25°C: 3.73E-06 @ 30°C: 7.02E-06	@ 25°C: 7.40E-07	Y ^{a)} , EFSA, 2016
DT ₅₀ in soil (d)	26.2 (geomean lab and field studies, normalisation to pF2, 20°C with Q ₁₀ of 2.58, n = 29)	0.03 (geometric mean, laboratory studies, n=7) ^{c)}	0.12 (geometric mean, laboratory studies, n=4)	Y, EFSA, 2016
Transformation rate for PELMO (1/d)	n.r.	n.r. ^{b)}	1	Y, EFSA, 2016
K _{foc} (mL/g)	118 (geometric mean, n = 12)	2.082 (estimated, n=1)	5.1 (geometric mean, n = 4)	Y, EFSA, 2016
K _{fom} (mL/g)	68	1.207	2.96	Y, EFSA, 2016
Freundlich exponent of sorption (1/n)	0.905 (arithmetic mean, n = 12)	1	0.93 (arithmetic mean, n=4)	Y, EFSA, 2016
Plant uptake factor (-)	0 (updated calculations)	0	0	Y, EFSA, 2016
Formation fraction (-)	-	n.r. ^{b)}	NC 8493 -> NC 20645: 1	Y, EFSA, 2016

n.r. not relevant, not used in the present risk assessment

a) values at 25°C from EFSA, temperature corrections with EVA 3.0

b) modelled as a parent

c) 0.1 used for PEARL 4.4.4 modelling

The predicted PEC_{GW} values obtained for Ethofumesate and metabolites are presented in the tables below.

Additional runs were calculated considering the plant uptake factor of 0 instead of 0.5. These are presented in the tables (b) in the following.

Table 8.8.2.1-2a **PEC_{GW} for Ethofumesate and metabolites following six applications of product to sugar beets, use group 1 (with FOCUS PEARL 4.4.4/PELMO 5.5.3/ MACRO 5.5.4) – Early application**

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]		
		Ethofumesate	NC 8493*	NC 20645
	FOCUS PEARL 4.4.4			
Sugar beets	Châteaudun	0.087	< 0.001	< 0.001
	Hamburg	0.059	< 0.001	< 0.001
	Jokioinen	0.005	< 0.001	< 0.001
	Kremsmünster	0.030	< 0.001	< 0.001
	Okehampton	0.049	< 0.001	< 0.001
	Piacenza	0.029	< 0.001	< 0.001
	Porto	0.008	< 0.001	< 0.001
	Sevilla	0.001	< 0.001	< 0.001
	Thiva	0.001	< 0.001	< 0.001
FOCUS PELMO 5.5.3				
Sugar beets	Châteaudun	0.014	< 0.001	< 0.001
	Hamburg	0.029	< 0.001	< 0.001
	Jokioinen	0.003	< 0.001	< 0.001
	Kremsmünster	0.025	< 0.001	< 0.001
	Okehampton	0.045	< 0.001	< 0.001
	Piacenza	0.045	< 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
FOCUS MACRO 5.5.4				
Sugar beets	Châteaudun	0.0723	-	-

* Application rate: 26.2 g NC8493/ha assuming NC8493 is formed at a max. of 24.2% of the applied dose and a molecular weight relative to the parent of 0.902 as well as a crop interception of 20%.

Additional runs were calculated considering the plant uptake factor of 0 instead of 0.5. These are presented in the tables (b) in the following. The new calculations are presented with the old and new versions of the groundwater modelling tools.

Table 8.8.2.1-2b **PEC_{GW} for Ethofumesate and metabolites following six applications of product to sugar beets – use group 1 (with FOCUS PEARL 4.4.4 & 5.5.5, PELMO 5.5.3 & 6.6.4/ MACRO 5.5.4) – Early application – PUF = 0**

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]	
Model		FOCUS PEARL 4.4.4	FOCUS PEARL 5.5.5
Sugar beets	Châteaudun, application every year	0.112	0.101
	Châteaudun, application every second year	0.049	0.044
	Hamburg	0.074	0.073
	Jokioinen	0.006	0.005
	Kremsmünster	0.036	0.036
	Okehampton	0.058	0.056
	Piacenza	0.037	0.037
	Porto	0.009	0.009
	Sevilla	0.001	0.001
	Thiva	0.002	0.002
Model		FOCUS PELMO 5.5.3	FOCUS PELMO 6.6.4
Sugar beets	Châteaudun	0.021	0.014
	Hamburg	0.041	0.025

	Jokioinen	0.004	0.001
	Kremsmünster	0.035	0.020
	Okehampton	0.062	0.037
	Piacenza	0.064	0.078
	Porto	0.034	0.029
	Sevilla	<0.001	<0.001
	Thiva	<0.001	0.001
Model	FOCUS MACRO 5.5.4		
Sugar beets	Châteaudun	0.040	

Since the PEC_{GW} values for the scenario Châteaudun was above the trigger value of 0.1 µg/L, an application every second year was modelled as well for the scenario Châteaudun.

Table 8.8.2.1-3a **PEC_{GW} for Ethofumesate and metabolites following three applications of product to sugar beets, use group 2 (with FOCUS PEARL 4.4.4/PELMO 5.5.3/ MACRO 5.5.4) – Early application**

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]		
		Ethofumesate	NC 8493*	NC 20645
		FOCUS PEARL 4.4.4		
Sugar beets	Châteaudun	0.081	< 0.001	< 0.001
	Hamburg	0.056	< 0.001	< 0.001
	Jokioinen	0.005	< 0.001	< 0.001
	Kremsmünster	0.030	< 0.001	< 0.001
	Okehampton	0.047	< 0.001	< 0.001
	Piacenza	0.029	< 0.001	< 0.001
	Porto	0.008	< 0.001	< 0.001
	Sevilla	0.001	< 0.001	< 0.001
	Thiva	0.001	< 0.001	< 0.001
		FOCUS PELMO 5.5.3		
Sugar beets	Châteaudun	0.010	< 0.001	< 0.001
	Hamburg	0.020	< 0.001	< 0.001
	Jokioinen	0.002	< 0.001	< 0.001
	Kremsmünster	0.018	< 0.001	< 0.001
	Okehampton	0.032	< 0.001	< 0.001
	Piacenza	0.034	< 0.001	< 0.001
	Porto	0.020	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001
		FOCUS MACRO 5.5.4		
Sugar beets	Châteaudun	0.0753	-	-

* Application rate: 52.4 g NC8493/ha assuming NC8493 is formed at a max. of 24.2% of the applied dose and a molecular weight relative to the parent of 0.902 as well as a crop interception of 20%.

Table 8.8.2.1-3b PEC_{GW} for Ethofumesate and metabolites following three applications of product to sugar beets, use group 2 (with FOCUS PEARL 4.4.4 & 5.5.5, PELMO 5.5.3 & 6.6.4/ MACRO 5.5.4) – Early application - PUF = 0

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]	
Model		FOCUS PEARL 4.4.4	FOCUS PEARL 5.5.5
Sugar beets	Châteaudun, application every year	0.106	0.095
	Châteaudun, application every second year	0.048	-
	Hamburg	0.070	0.069
	Jokioinen	0.006	0.005
	Kremsmünster	0.036	0.037
	Okehampton	0.055	0.053
	Piacenza	0.038	0.036
	Porto	0.010	0.009
	Sevilla	0.001	0.001
	Thiva	0.002	0.002
Model		FOCUS PELMO 5.5.3	FOCUS PELMO 6.6.4
Sugar beets	Châteaudun	0.018	0.013
	Hamburg	0.046	0.025
	Jokioinen	0.003	0.001
	Kremsmünster	0.035	0.020
	Okehampton	0.064	0.036
	Piacenza	0.054	0.076
	Porto	0.040	0.031
	Sevilla	<0.001	<0.001
	Thiva	<0.001	0.001
Model	FOCUS MACRO 5.5.4		
Sugar beets	Châteaudun	0.041	

Since the PEC_{GW} values for the scenario Châteaudun was above the trigger value of 0.1µg/L, an application every second year was modelled as well for the scenario Châteaudun.

Table 8.8.2.1-4a PEC_{GW} for Ethofumesate and metabolites following five applications of product to sugar beets, use group 3 (with FOCUS PEARL 4.4.4/PELMO 5.5.3/ MACRO 5.5.4) – Early application

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]		
		Ethofumesate	NC 8493*	NC 20645
	FOCUS PEARL 4.4.4			
Sugar beets	Châteaudun	0.065	< 0.001	< 0.001
	Hamburg	0.045	< 0.001	< 0.001
	Jokioinen	0.004	< 0.001	< 0.001
	Kremsmünster	0.022	< 0.001	< 0.001
	Okehampton	0.037	< 0.001	< 0.001
	Piacenza	0.023	< 0.001	< 0.001
	Porto	0.006	< 0.001	< 0.001
	Sevilla	0.001	< 0.001	< 0.001
	Thiva	0.001	< 0.001	< 0.001
	FOCUS PELMO 5.5.3			
Sugar beets	Châteaudun	0.011	< 0.001	< 0.001
	Hamburg	0.022	< 0.001	< 0.001
	Jokioinen	0.002	< 0.001	< 0.001
	Kremsmünster	0.019	< 0.001	< 0.001

	Okehampton	0.034	< 0.001	< 0.001
	Piacenza	0.038	< 0.001	< 0.001
	Porto	0.022	< 0.001	< 0.001
	Sevilla	<0.001	< 0.001	< 0.001
	Thiva	<0.001	< 0.001	< 0.001
	FOCUS MACRO 5.5.4			
Sugar beets	Châteaudun	0.056	-	-

* Application rate: 26.2 NC8493/ha assuming NC8493 is formed at a max. of 24.2% of the applied dose and a molecular weight relative to the parent of 0.902 as well as a crop interception of 20%.

Table 8.8.2.1-4b **PEC_{GW} for Ethofumesate and metabolites following five applications of product to sugar beets use group 3 (with FOCUS PEARL 4.4.4 & 5.5.5, PELMO 5.5.3 & 6.6.4/ MACRO 5.5.4)- Early application - PUF = 0**

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]	
Model		FOCUS PEARL 4.4.4	FOCUS PEARL 5.5.5
Sugar beets	Châteaudun	0.084	0.075
	Hamburg	0.056	0.055
	Jokioinen	0.004	0.003
	Kremsmünster	0.026	0.027
	Okehampton	0.044	0.042
	Piacenza	0.029	0.028
	Porto	0.007	0.006
	Sevilla	0.001	<0.001
	Thiva	0.002	0.001
Model		FOCUS PELMO 5.5.3	FOCUS PELMO 6.6.4
Sugar beets	Châteaudun	0.015	0.010
	Hamburg	0.028	0.018
	Jokioinen	0.003	0.001
	Kremsmünster	0.025	0.014
	Okehampton	0.045	0.027
	Piacenza	0.047	0.055
	Porto	0.027	0.021
	Sevilla	<0.001	<0.001
	Thiva	<0.001	<0.001
Model		FOCUS MACRO 5.5.4	
Sugar beets	Châteaudun	0.027	

Table 8.8.2.1-5a **PEC_{GW} for Ethofumesate and metabolites following three applications of product to sugar beets, use group 4 (with FOCUS PEARL 4.4.4/PELMO 5.5.3/ MACRO 5.5.4) – Early application**

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]		
		Ethofumesate	NC 8493*	NC 20645
		FOCUS PEARL 4.4.4		
Sugar beets	Châteaudun	0.051	< 0.001	< 0.001
	Hamburg	0.035	< 0.001	< 0.001
	Jokioinen	0.003	< 0.001	< 0.001
	Kremsmünster	0.018	< 0.001	< 0.001
	Okehampton	0.029	< 0.001	< 0.001
	Piacenza	0.018	< 0.001	< 0.001
	Porto	0.005	< 0.001	< 0.001
	Sevilla	<0.001	< 0.001	< 0.001
	Thiva	0.001	< 0.001	< 0.001

FOCUS PELMO 5.5.3				
Sugar beets	Châteaudun	0.007	< 0.001	< 0.001
	Hamburg	0.020	< 0.001	< 0.001
	Jokioinen	0.002	< 0.001	< 0.001
	Kremsmünster	0.015	< 0.001	< 0.001
	Okehampton	0.028	< 0.001	< 0.001
	Piacenza	0.024	< 0.001	< 0.001
	Porto	0.019	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001
FOCUS MACRO 5.5.4				
Sugar beets	Châteaudun	0.022	-	-

* Application rate: 39.30 g NC8493/ha assuming NC8493 is formed at a max. of 24.2% of the applied dose and a molecular weight relative to the parent of 0.902 as well as a crop interception of 20%.

Table 8.8.2.1-5b PEC_{GW} for Ethofumesate ~~and metabolites~~ following three applications of product to sugar beets, use group 4 (with FOCUS PEARL 4.4.4 & 5.5.5, PELMO 5.5.3 & 6.6.4/ MACRO 5.5.4)- Early application - PUF = 0

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]	
Model		FOCUS PEARL 4.4.4	FOCUS PEARL 5.5.5
Sugar beets	Châteaudun	0.066	0.059
	Hamburg	0.044	0.044
	Jokioinen	0.003	0.002
	Kremsmünster	0.022	0.022
	Okehampton	0.034	0.033
	Piacenza	0.024	0.023
	Porto	0.006	0.005
	Sevilla	< 0.001	< 0.001
	Thiva	0.001	0.001
Model		FOCUS PELMO 5.5.3	FOCUS PELMO 6.6.4
Sugar beets	Châteaudun	0.011	0.008
	Hamburg	0.029	0.015
	Jokioinen	0.002	0.001
	Kremsmünster	0.021	0.012
	Okehampton	0.040	0.022
	Piacenza	0.035	0.048
	Porto	0.025	0.019
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001
Model		FOCUS MACRO 5.5.4	
Sugar beets	Châteaudun	0.026	

Table 8.8.2.1-6a **PEC_{GW} for Ethofumesate and metabolites following three applications of product to sugar beets, use group 5 (with FOCUS PEARL 4.4.4/PELMO 5.5.3/ MACRO 5.5.4) – Early application**

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]		
		Ethofumesate	NC 8493*	NC 20645
		FOCUS PEARL 4.4.4		
Sugar beets	Châteaudun	0.083	< 0.001	< 0.001
	Hamburg	0.057	< 0.001	< 0.001
	Jokioinen	0.005	< 0.001	< 0.001
	Kremsmünster	0.029	< 0.001	< 0.001
	Okehampton	0.048	< 0.001	< 0.001
	Piacenza	0.029	< 0.001	< 0.001
	Porto	0.008	< 0.001	< 0.001
	Sevilla	0.001	< 0.001	< 0.001
	Thiva	0.001	< 0.001	< 0.001
FOCUS PELMO 5.5.3				
Sugar beets	Châteaudun	0.013	< 0.001	< 0.001
	Hamburg	0.028	< 0.001	< 0.001
	Jokioinen	0.003	< 0.001	< 0.001
	Kremsmünster	0.024	< 0.001	< 0.001
	Okehampton	0.041	< 0.001	< 0.001
	Piacenza	0.047	< 0.001	< 0.001
	Porto	0.027	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001
FOCUS MACRO 5.5.4				
Sugar beets	Châteaudun	0.046	-	-

* Application rate: 52.40 g NC8493/ha assuming NC8493 is formed at a max. of 24.2% of the applied dose and a molecular weight relative to the parent of 0.902 as well as a crop interception of 20%.

Table 8.8.2.1-6b **PEC_{GW} for Ethofumesate and metabolites following three applications of product to sugar beets, use group 5 (with FOCUS PEARL 4.4.4 & 5.5.5, PELMO 5.5.3 & 6.6.4/ MACRO 5.5.4)- Early application- PUF = 0**

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]	
Model		FOCUS PEARL 4.4.4	FOCUS PEARL 5.5.5
Sugar beets	Châteaudun, application every year	0.109	0.098
	Châteaudun, application every second year	0.048	-
	Hamburg	0.072	0.070
	Jokioinen	0.006	0.005
	Kremsmünster	0.035	0.036
	Okehampton	0.056	0.054
	Piacenza	0.037	0.036
	Porto	0.010	0.009
	Sevilla	0.001	0.001
	Thiva	0.002	0.002
Model		FOCUS PELMO 5.5.3	FOCUS PELMO 6.6.4
Sugar beets	Châteaudun	0.020	0.014
	Hamburg	0.040	0.024
	Jokioinen	0.003	0.001
	Kremsmünster	0.033	0.019

	Okehampton	0.058	0.035
	Piacenza	0.068	0.077
	Porto	0.036	0.030
	Sevilla	<0.001	<0.001
	Thiva	0.001	0.001
Model	FOCUS MACRO 5.5.4		
Sugar beets	Châteaudun	0.051	

Since the PEC_{GW} values for the scenario Châteaudun were above the trigger value of 0.1 µg/L for three of the application schemes, an application every second year was modelled for use groups 1, 2 and 5. The application every other year resulted in PEC_{GW} values below the trigger value and lead therefore to safe uses when considering this restriction.

Thus, the restriction to apply the product only in every second year is proposed for the early application scenario for the use groups 1, 2 and 5.

All early applications resulted in higher PEC_{GW} values compared to late application scenarios. For the updated calculations considering a PUF factor of 0, it could be shown that all early application schemes and scenarios end up with values below the trigger value when considering an application every second year. Since these represents the worst-case scenarios, the later application scenarios are not repeated with the update PUF value since these are covered by the updated early calculations with both model versions as presented above.

Table 8.8.2.1-7 **PEC_{GW} for Ethofumesate and metabolites following six applications of product to sugar beets, use group 1 (with FOCUS PEARL 4.4.4/PELMO 5.5.3/ MACRO 5.5.4) – Late application**

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]		
		Ethofumesate	NC 8493*	NC 20645
		FOCUS PEARL 4.4.4		
Sugar beets	Châteaudun	0.017	< 0.001	< 0.001
	Hamburg	0.034	< 0.001	< 0.001
	Jokioinen	0.001	< 0.001	< 0.001
	Kremsmünster	0.011	< 0.001	< 0.001
	Okehampton	0.028	< 0.001	< 0.001
	Piacenza	0.007	< 0.001	< 0.001
	Porto	0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001
		FOCUS PELMO 5.5.3		
Sugar beets	Châteaudun	0.002	< 0.001	< 0.001
	Hamburg	0.018	< 0.001	< 0.001
	Jokioinen	0.001	< 0.001	< 0.001
	Kremsmünster	0.008	< 0.001	< 0.001
	Okehampton	0.017	< 0.001	< 0.001
	Piacenza	0.005	< 0.001	< 0.001
	Porto	0.005	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001
		FOCUS MACRO 5.5.4		
Sugar beets	Châteaudun	0.014	-	-

* Application rate: 9.82 g NC8493/ha assuming NC8493 is formed at a max. of 24.2% of the applied dose and a molecular weight relative to the parent of 0.902 as well as a crop interception of 70%.

Table 8.8.2.1-8 **PEC_{GW} for Ethofumesate and metabolites following three applications of product to sugar beets, use group 2 (with FOCUS PEARL 4.4.4/PELMO 5.5.3/ MACRO 5.5.4) – Late application**

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]		
		Ethofumesate	NC 8493*	NC 20645
	FOCUS PEARL 4.4.4			
Sugar beets	Châteaudun	0.017	< 0.001	< 0.001
	Hamburg	0.037	< 0.001	< 0.001
	Jokioinen	0.001	< 0.001	< 0.001
	Kremsmünster	0.012	< 0.001	< 0.001
	Okehampton	0.031	< 0.001	< 0.001
	Piacenza	0.008	< 0.001	< 0.001
	Porto	0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001
	FOCUS PELMO 5.5.3			
Sugar beets	Châteaudun	0.002	< 0.001	< 0.001
	Hamburg	0.019	< 0.001	< 0.001
	Jokioinen	0.001	< 0.001	< 0.001
	Kremsmünster	0.007	< 0.001	< 0.001
	Okehampton	0.020	< 0.001	< 0.001
	Piacenza	0.004	< 0.001	< 0.001
	Porto	0.005	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001
	FOCUS MACRO 5.5.4			
Sugar beets	Châteaudun	0.015	-	-

* Application rate: 19.6 g NC8493/ha assuming NC8493 is formed at a max. of 24.2% of the applied dose and a molecular weight relative to the parent of 0.902 as well as a crop interception of 70%.

Table 8.8.2.1-9 **PEC_{GW} for Ethofumesate and metabolites following five applications of product to sugar beets, use group 3 (with FOCUS PEARL 4.4.4/PELMO 5.5.3/ MACRO 5.5.4) – Late application**

application				
Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]		
		Ethofumesate	NC 8493*	NC 20645
	FOCUS PEARL 4.4.4			
Sugar beets	Châteaudun	0.014	< 0.001	< 0.001
	Hamburg	0.024	< 0.001	< 0.001
	Jokioinen	0.001	< 0.001	< 0.001
	Kremsmünster	0.008	< 0.001	< 0.001
	Okehampton	0.020	< 0.001	< 0.001
	Piacenza	0.005	< 0.001	< 0.001
	Porto	0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001
FOCUS PELMO 5.5.3				
Sugar beets	Châteaudun	0.001	< 0.001	< 0.001
	Hamburg	0.013	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001	< 0.001
	Kremsmünster	0.006	< 0.001	< 0.001
	Okehampton	0.013	< 0.001	< 0.001
	Piacenza	0.003	< 0.001	< 0.001

	Porto	0.004	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001
	FOCUS MACRO 5.5.4			
Sugar beets	Châteaudun	0.004	-	-

* Application rate: 9.82 NC8493/ha assuming NC8493 is formed at a max. of 24.2% of the applied dose and a molecular weight relative to the parent of 0.902 as well as a crop interception of 70%.

Table 8.8.2.1-10 PEC_{GW} for Ethofumesate and metabolites following three applications of product to sugar beets, use group 4 (with FOCUS PEARL 4.4.4/PELMO 5.5.3/ MACRO 5.5.4) – Late application

Crop	Scenario	80 th Percentile PECGW at 1 m Soil Depth [mg/L]		
		Ethofumesate	NC 8493*	NC 20645
		FOCUS PEARL 4.4.4		
Sugar beets	Châteaudun	0.010	< 0.001	< 0.001
	Hamburg	0.022	< 0.001	< 0.001
	Jokioinen	0.001	< 0.001	< 0.001
	Kremsmünster	0.007	< 0.001	< 0.001
	Okehampton	0.020	< 0.001	< 0.001
	Piacenza	0.005	< 0.001	< 0.001
	Porto	0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001
		FOCUS PELMO 5.5.3		
Sugar beets	Châteaudun	0.001	< 0.001	< 0.001
	Hamburg	0.011	< 0.001	< 0.001
	Jokioinen	0.001	< 0.001	< 0.001
	Kremsmünster	0.005	< 0.001	< 0.001
	Okehampton	0.012	< 0.001	< 0.001
	Piacenza	0.003	< 0.001	< 0.001
	Porto	0.003	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001
		FOCUS MACRO 5.5.4		
Sugar beets	Châteaudun	0.010	-	-

* Application rate: 14.74 g NC8493/ha assuming NC8493 is formed at a max. of 24.2% of the applied dose and a molecular weight relative to the parent of 0.902 as well as a crop interception of 70%.

Table 8.8.2.1-11 PEC_{GW} for Ethofumesate and metabolites following three applications of product to sugar beets, use group 5 (with FOCUS PEARL 4.4.4/PELMO 5.5.3/ MACRO 5.5.4) – Late application

Crop	Scenario	80 th Percentile PECGW at 1 m Soil Depth [mg/L]		
		Ethofumesate	NC 8493*	NC 20645
		FOCUS PEARL 4.4.4		
Sugar beets	Châteaudun	0.018	< 0.001	< 0.001
	Hamburg	0.035	< 0.001	< 0.001
	Jokioinen	0.001	< 0.001	< 0.001
	Kremsmünster	0.011	< 0.001	< 0.001
	Okehampton	0.029	< 0.001	< 0.001
	Piacenza	0.008	< 0.001	< 0.001
	Porto	0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001

	FOCUS PELMO 5.5.3			
Sugar beets	Châteaudun	0.002	< 0.001	< 0.001
	Hamburg	0.018	< 0.001	< 0.001
	Jokioinen	0.001	< 0.001	< 0.001
	Kremsmünster	0.007	< 0.001	< 0.001
	Okehampton	0.019	< 0.001	< 0.001
	Piacenza	0.005	< 0.001	< 0.001
	Porto	0.006	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001
	FOCUS MACRO 5.5.4			
Sugar beets	Châteaudun	0.013	-	-

* Application rate: 19.65 g NC8493/ha assuming NC8493 is formed at a max. of 24.2% of the applied dose and a molecular weight relative to the parent of 0.902 as well as a crop interception of 70%.

The maximum PEC_{GW} value for Ethofumesate following early applications of HBZ10 amounts to 0.112 µg/L (six applications, use group 1) for an application every year and 0.049 when only applied every second year.

The maximum PEC_{GW} value for Ethofumesate following late applications of HBZ10 amounts to 0.037 µg/L (three applications, use group 2).

The calculated PEC_{GW} values for Ethofumesate are therefore < 0.1 µg/L for all modelled scenarios and crops when crop rotation is considered for the early application in three use schemes.

The calculated PEC_{GW} values for the metabolites following application of HBZ10 are < 0.001 µg/L for each substance for all modelled scenarios and use groups.

The results indicate that any contamination of groundwater at concentrations relevant for the environment and for consumer exposure by Ethofumesate as well as its major metabolites must not be expected following GAP use of HBZ10 in beets when considering an application every second year for the early application of the use groups 1, 2 and 5.

zRMS comments:

The input parameters for ethofumesate presented in Table 8.8.2.1-1 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 Applicant was thus requested to submit additional simulations for ethofumesate performed with consideration of PUF value of 0.

As already indicated in zRMS comment in point 8.8.2 above, these new simulations were performed using both, older and most recent versions of the modelling programs. The zRMS is of the opinion that versions in force at the time of the dossier submission should be used (in case of HBZ10 this would be FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4), nevertheless results of simulations performed with PELMO 6.6.4 and PEARL 5.5.5 were retained for convenience of the CMS that prefer results derived using these new versions of the models (shaded and not struck through results in tables above).

The groundwater modelling has been independently validated by the zRMS in additional modelling performed with FOCUS PEARL 4.4.4, PELMO 5.5.3 and FOCUS MACRO 5.5.4 using the same EU agreed input parameters and PUF of 0. Obtained PEC_{GW} values for ethofumesate for the early application schemes were the same as these derived by the Applicant in updated calculation. Thus, results reported in tables above marked with letter (b) are confirmed to be correct. PEC_{GW} values for ethofumesate calculated with the PUF factor of 0.5, presented in tables above marked with letter (a) were struck through in order to easily distinguish agreed from not agreed results.

As early applications resulted in higher PEC_{GW} values compared to late application scenarios, the later application scenarios were not calculated by the Applicant with the updated PUF value of 0 as they are covered by the updated calculations for early applications. However, to confirm this conclusion the zRMS performed the independent

modelling which resulted with all PEC_{GW} below the threshold concentration of 0.1 µg/L for each use groups. Therefore, results presented in Tables 8.8.2.1-7 to 8.8.2.1-11 represent worst case and demonstrate no unacceptable leaching of ethofumesate following later application of HBZ10 in beets.

In case of early applications in the use groups 1, 2 and 5, PEC_{GW} values for ethofumesate were above the threshold concentration in Châteaudun scenario. Thus, the application frequency must be restricted to one every second year for the use groups 1, 2 and 5.

The calculated PEC_{GW} values for the metabolites following application of HBZ10 were all below 0.001 µg/L in all use groups and all modelled scenarios.

Results obtained with the models PELMO 6.6.4 and PEARL 5.5.5 were shaded for transparency as not considered for the ground water assessment. However, concerned Member States must decide on applicability of the new versions of FOCUS models in their countries.

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

8.8.2.2 Phenmedipham and its metabolites

Table 8.8.2.2-1 Input parameters related to Phenmedipham and metabolite MHPC for PEC_{GW} calculation

Compound	Phenmedipham	MHPC	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	300.3	167.2	Y, 2004
Water solubility (mg/L):	1.8 (20°C) 2.59 (30°C) ^a	8620 (20°C) ^b	Y, 2004
Saturated vapour pressure (Pa):	3.64×10^{-10} (20°C) ^a 7×10^{-10} (25°C) 1.32×10^{-09} (30°C) ^a	7×10^{-10} (at 25°C, same as parent)	Y, 2004
DT ₅₀ in soil (d)	43 ^c (Maximum, pF2, 20°C, n = 3)	0.18 (Geomean, SFO, 20 °C, pF2, n = 3) ^d	DAR 2003 Y, 2004
K _{foc} (mL/g)	657 (minimum, n = 3)	220 (Arithmetic mean, n=4)	Y, 2004
K _{fom} (mL/g)	381	127.5	Y, 2004
Freundlich exponent of sorption (1/n)	0.854 (n = 3)	0.742 (Arithmetic mean, n=4)	Y, 2004
Plant uptake factor (-)	0	0	Default
Formation fraction (-)	-	1 Worst case	Y, 2004

* review report for Phenmedipham SANCO/4060/2001 -final, 2004.

a temperature conversion with EVA 3.0 rev.2h

b predicted with WSKOWWIN v1.43 (temperature conversion with EVA 3.0 rev.2h)

c less than 4 soils (SANCO/10058/2005 vs 2. Guidance document on estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration. 2006)

d Information from Addendum 3 to the DAR of Phenmedipham (22.10.2003)

The predicted PEC_{GW} values obtained for Phenmedipham and metabolites following GAP table application on beets are presented in the following tables.

Table 8.8.2.2-2 PEC_{GW} for Phenmedipham and metabolite MHPC following six applications of product to sugar beets, use group 1 (with FOCUS PEARL 4.4.4/PELMO 5.5.3) – Early application

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]	
		Phenmedipham	MHPC
	FOCUS PEARL 4.4.4		
Sugar beets	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001
FOCUS PELMO 5.5.3			
Sugar beets	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001

Table 8.8.2.2-3 PEC_{GW} for Phenmedipham and metabolite MHPC following three applications of product to sugar beets, use group 2 (with FOCUS PEARL 4.4.4/PELMO 5.5.3) – Early application

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]	
		Phenmedipham	MHPC
	FOCUS PEARL 4.4.4		
Sugar beets	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001
FOCUS PELMO 5.5.3			
Sugar beets	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001

Table 8.8.2.2-4 PEC_{GW} for Phenmedipham and metabolite MHPC following five applications of product to sugar beets, use group 3 (with FOCUS PEARL 4.4.4/PELMO 5.5.3) – Early application

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]	
		Phenmedipham	MHPC
		FOCUS PEARL 4.4.4	
Sugar beets	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001
FOCUS PELMO 5.5.3			
Sugar beets	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001

Table 8.8.2.2-5 PEC_{GW} for Phenmedipham and metabolites following three applications of product to sugar beets, use group 4 (with FOCUS PEARL 4.4.4/PELMO 5.5.3/ MACRO 5.5.4) – Early application

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]	
		Phenmedipham	MHPC
		FOCUS PEARL 4.4.4	
Sugar beets	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001
FOCUS PELMO 5.5.3			
Sugar beets	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001

Table 8.8.2.2-6 PEC_{GW} for Phenmedipham and metabolites following three applications of product to sugar beets, use group 5 (with FOCUS PEARL 4.4.4/PELMO 5.5.3/ MACRO 5.5.4) – Early application

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]	
		Phenmedipham	MHPC
	FOCUS PEARL 4.4.4		
Sugar beets	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001
FOCUS PELMO 5.5.3			
Sugar beets	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001

Table 8.8.2.2-7 PEC_{GW} for Phenmedipham and metabolite MHPC following six applications of product to sugar beets, use group 1 (with FOCUS PEARL 4.4.4/PELMO 5.5.3) – Late application

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]	
		Phenmedipham	MHPC
	FOCUS PEARL 4.4.4		
Sugar beets	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001
FOCUS PELMO 5.5.3			
Sugar beets	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001

Table 8.8.2.2-8 PEC_{GW} for Phenmedipham and metabolite MHPC following three applications of product to sugar beets, use group 2 (with FOCUS PEARL 4.4.4/PELMO 5.5.3) – Late application

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]	
		Phenmedipham	MHPC
		FOCUS PEARL 4.4.4	
Sugar beets	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001
FOCUS PELMO 5.5.3			
Sugar beets	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001

Table 8.8.2.1-9 PEC_{GW} for Phenmedipham and metabolite MHPC following five applications of product to sugar beets, use group 3 (with FOCUS PEARL 4.4.4/PELMO 5.5.3) – Late application

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]	
		Phenmedipham	MHPC
		FOCUS PEARL 4.4.4	
Sugar beets	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001
FOCUS PELMO 5.5.3			
Sugar beets	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001

Table 8.8.2.2-10 PEC_{GW} for Phenmedipham and metabolites following three applications of product to sugar beets, use group 4 (with FOCUS PEARL 4.4.4/PELMO 5.5.3/ MACRO 5.5.4) – Late application

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]	
		Phenmedipham	MHPC
		FOCUS PEARL 4.4.4	
Sugar beets	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001
FOCUS PELMO 5.5.3			
Sugar beets	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001

Table 8.8.2.2-11 PEC_{GW} for Phenmedipham and metabolites following three applications of product to sugar beets, use group 5 (with FOCUS PEARL 4.4.4/PELMO 5.5.3/ MACRO 5.5.4) – Late application

Crop	Scenario	80 th Percentile PEC _{GW} at 1 m Soil Depth [µg/L]	
		Phenmedipham	MHPC
		FOCUS PEARL 4.4.4	
Sugar beets	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001
FOCUS PELMO 5.5.3			
Sugar beets	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001

The calculated PEC_{GW} values for Phenmedipham and metabolite MHPC following use every year are $< 0.001 \mu\text{g/L}$ for each substance for all modelled uses, scenarios and crops.

The results indicate that any contamination of groundwater at concentrations relevant for the environment and for consumer exposure by Phenmedipham as well as its major metabolites must not be expected following GAP use of HBZ10 in beets.

zRMS comments:

Input parameters presented in Table 8.8.2.2-1 for phenmedipham and used in the modelling are in line with EU agreed endpoints reported in Review Report (2004) and in Addendum 3 to the phenmedipham DAR (2003).

In simulations PUF value of 0 was assumed for all compounds, which is in line with recommendations of the most recent version of the FOCUS Groundwater Guidance (2014 and 2021).

The performed groundwater modelling was independently validated by the zRMS in additional simulations performed with consideration the same input data. Obtained results were the same as these derived in Applicants' simulations.

Overall, no unacceptable leaching of phenmedipham and its metabolite is expected following application of HBZ10 in beets.

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

The input values for Ethofumesate, Phenmedipham and their metabolites were taken from the EFSA conclusions (2016) and Annex I inclusion (SANCO/4060/2001-Final, 2004) respectively.

For both Ethofumesate and Phenmedipham, no deviations from the agreed endpoints were considered.

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

Input parameters related to the application of HBZ10 and to the active substances and their relevant metabolites used for calculations are presented in **Table 8.9.2-1 to 8.9.2-3**.

The 25 intended uses presented in section B0, can be grouped in five main uses as described in Table 8.1-1 of this section, when considering the intended uses on beet crops as a whole (sugar beet, yellow beet, red beet, fodder beet, and chard). Such grouping is used hereafter for a better readability of the calculations results and is described below:

- Use group 1: 6 x 1.2 L prod./ha, 5-days interval (includes uses 1, 6, 11, 16 and 21)
- Use group 2: 3 x 2.4 L prod./ha, 6-days interval (includes uses 2, 7, 12, 17, and 22)
- Use group 3: 5 x 1.2 L prod./ha, 7-days interval (includes uses 3, 8, 13, 18, and 23)
- Use group 4: 3 x 1.8 L prod./ha, 6-days interval (includes uses 4, 9, 14, 19, and 24)
- Use group 5: 3 x 2.4 L prod./ha, 9-days interval (includes uses 5, 10, 15, 20, and 25)

The application windows were set using Appdate considering the first application on 1 DAE (for early applications) and the last application at BBCH 39 (for late applications). Use group 2 is considered to cover use groups 4 and 5 from the GAP table.

PEC_{SW} values presented below are based on the results obtained from the study by Lindim (2021b). The study is presented in Appendix 1.

Table 8.9.2-1 Input parameters related to application for PEC_{SW/SED} calculations

Plant protection product	HBZ10	HBZ10	HBZ10	HBZ10	HBZ10
Use group No.	1	2	3	4	5
Crop	Sugar beet	Sugar beet	Sugar beet	Sugar beet	Sugar beet
Application rate [kg a.s./ha]	Ethofumesate: 0.150 Phenmedipham: 0.150	Ethofumesate: 0.300 Phenmedipham: 0.300	Ethofumesate: 0.150 Phenmedipham: 0.150	Ethofumesate: 0.225 Phenmedipham: 0.225	Ethofumesate: 0.300 Phenmedipham: 0.300
Number of applications	6/year	3/year	5/year	3/year	3/year
Interval between application [d]	5	6	7	6	9
Application window for Step 1-2	Mar – May Jun - Sep	Mar – May Jun - Sep	Mar – May Jun - Sep	Mar – May Jun - Sep	Mar – May Jun - Sep
Application window	Early: First appl: 1 DAE Late: Last appl: BBCH 39	Early: First appl: 1 DAE Late: Last appl: BBCH 39	Early: First appl: 1 DAE Late: Last appl: BBCH 39	Early: First appl: 1 DAE Late: Last appl: BBCH 39	Early: First appl: 1 DAE Late: Last appl: BBCH 39
Application method	Ground Spray	Ground Spray	Ground Spray	Ground Spray	Ground Spray
CAM (Chemical application method)	2	2	2	2	2
Interception	Step 2: minima	Step 2: minimal	Step 2: minimal	Step 2: minimal	Step 2: minimal
Models used for calculation	FOCUS- STEPs 1-2 v3.2 FOCUS SWASH v5.3 FOCUS PRZM v4.3.1 FOCUS MACRO v5.5.4 FOCUS TOXWA v5.5.3 Swan 5.0.1				

Table 8.9.2-2 FOCUS Step 3 Scenario related input parameters for PEC_{SW/SED} calculations for the application of product HBZ10

Crop	Scenario	Application window used in modelling (Early Application)	
		Julian day	Date
Sugar Beet 3 Applications (use groups 2 and 4)	D3	116 – 158	26 April – 7 June
	D4	125 – 167	5 May – 16 June
	R1	107 – 149	17 April – 29 May
	R3	80 – 122	21 March – 2 May
Sugar Beet 6 Applications (use group 1)	D3	116 – 171	26 April – 20 June
	D4	125 – 180	5 May – 29 June
	R1	107 – 162	17 April – 11 June
	R3	80 – 135	21 March – 15 May
Sugar Beet 5 Applications (use group 3)	D3	116 – 174	26 April – 23 June
	D4	125 – 183	5 May – 2 July
	R1	107 – 165	17 April – 14 June
	R3	80 – 138	21 March – 18 May
Sugar Beet 1 Application (single application covering all use groups)	D3	116 – 146	26 April – 26 May
	D4	125 – 155	5 May – 4 June
	R1	107 – 137	17 April – 17 May
	R3	80 -110	21 March – 20 April
Sugar Beet 3 Applications (use group 5)	D3	116 – 164	26 April – 13 June
	D4	125 – 173	5 May – 22 June
	R1	107 – 155	17 April – 4 June
	R3	80 – 128	21 March – 8 May

Table 8.9.2-3 FOCUS Step 3 Scenario related input parameters for PEC_{SW/SED} calculations for the application of product HBZ10

Crop	Scenario	Application window used in modelling (Late Application)	
		Julian day	Date
Sugar Beet 3 Applications (use groups 2 and 4)	D3	160-202	09 Jun-21 Jul
	D4	163-205	12 Jun-24 Jul
	R1	150-192	30 May-11 Jul
	R3	129-171	09 May-20 Jun
Sugar Beet 6 Applications (use group 1)	D3	147-202	27 May-21 Jul
	D4	150-205	30 May-24 Jul
	R1	137-192	17 May-11 Jul
	R3	116-171	26 Apr-20 Jun
Sugar Beet 5 Applications (use group 3)	D3	144-202	24 May-21 Jul
	D4	147-205	27 May-24 Jul
	R1	134-192	14 May-11 Jul
	R3	113-171	23 Apr-20 Jun
Sugar Beet 1 Application (single application covering all use groups)	D3	172-202	21 Jun -21 Jul
	D4	175-205	24 Jun -24 Jul
	R1	162-192	11 Jun -11 Jul
	R3	141-171	21 May-20 Jun
Sugar Beet 3 Applications (use group 5)	D3	154-202	3 June – 21 July
	D4	157-205	6 June – 24 July
	R1	144-192	24 May – 11 July
	R3	123-171	3 May – 20 June

8.9.2.1 Ethofumesate and its metabolites

All FOCUS SW site scenarios were used without any change. The concentrations presented are the maximum concentrations in the given simulation period. In case of stream and ditch, it was predicted for the last segment in the water body representing worst case conditions.

Predicted environmental concentrations in surface water for all relevant European scenarios were calculated based on the critical use pattern for the product.

The PEC values for the active substance Ethofumesate and metabolites in surface water and sediment have been assessed with the FOCUS SW models and the endpoints presented in **Table 8.9.2.1-1**. Where an endpoint was not available, a worst-case assumption was selected.

In case the predicted PEC_{SW} values for the Ethofumesate and / or its relevant metabolite(s), were above the ecotoxicological RAC value, calculations of PEC_{SW} values at step 3 were performed using FOCUS surface water models and all relevant crop scenarios.

Input parameters for the active substance Ethofumesate and metabolites for calculation of PEC_{SW} and PEC_{SED} are presented in **Tables 8.9.2.1-1** and **8.9.2.1-2**.

Table 8.9.2.1-1 Input parameters related to Ethofumesate and metabolite(s) for $PEC_{SW/SED}$ calculations STEP 1/2 and 3(4)

Compound	Ethofumesate	NC 8493	NC 20645	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	286.3	258.3	274.3	y / EFSA LoE
Saturated vapour pressure (Pa)	@ 25°C: 6.5E-04	n.r.	@ 25°C: 7.4E-07	y / EFSA, 2016
Water solubility (mg/L)	@ 25°C: 50 ^{a)}	@ 25°C: 2019 ^{b)}	@ 25°C: 16170 ^{c)}	y / EFSA, 2016
Diffusion coefficient in water (m ² /d)	Not required for Step 1+2/ 4.3 × 10 ⁻⁵	Not required for Step 1+2	Not required for Step 1+2/ 4.3 × 10 ⁻⁵	Default
Diffusion coefficient in air (m ² /d)	0.43	Not required for Step 1+2	0.43	Default
K _{foc} (mL/g)	118 (geomean, mean, n = 13)	2.082 (n = 1)	5.1 (geometric mean, n=4)	y / EFSA, 2016
K _{fom} (mL/g)	68	n.r.	2.96	y, K _{foc} / 1.724
Freundlich Sorption Exponent 1/n (-)	0.905 (arithmetic mean, n = 13)	1	0.93 (arithmetic mean, n = 4)	y / EFSA, 2016
DT _{50,soil} (d)	26.2 (geomean lab and field, normalisation to pF2, 20°C with Q ₁₀ of 2.58, n = 29)	0.03 (geomean laboratory, normalisation to pF2, 20°C with Q ₁₀ of 2.58, n=7)	0.12 (geomean laboratory, normalisation to pF2, 20°C with Q ₁₀ of 2.58, n=4)	y / EFSA, 2016
DT _{50,water} (d)	170 ^{d)} (geometric mean whole system, (DegT ₅₀) n=8)	1000	208 (geometric mean whole system, n=4)	y / EFSA, 2016
DT _{50,sed} (d)	Step 1&2: 170 Step 3: 1000 ^{d)}	1000	Step 1&2: 208 Step 3: 1000	y / EFSA, 2016
DT _{50,whole system} (d)	170	1000	208	y / EFSA, 2016
Plant Uptake	0 (updated calculations)	Not required for Step 1+2		
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 24.2 Total system: - ^{e)}	Soil: 1.8 Total system: 18.8	y / EFSA, 2016
Kinetic formation fraction of metabolites (Step 3)	-	n.r.	0.414 (arithmetic mean, n = 2, from parent, whole system)	y / Calculated from EFSA, 2016

n.r. not relevant, not used in the present risk assessment

a) 46.68 (20°C) (calculated with EVA)

- b) 1884.8 (20°C) (calculated with EVA)
- c) 15094.8 (20°C) (calculated with EVA)
- d) FOCUS SW Generic guidance v1.4: usual evaluation practice has been to ascribe the whole system DT₅₀ to the water phase for compounds with a K_{oc} < ca. 100 mL/g, since K_{oc} value of Ethofumesate is close to 100 mL/g the whole system value was assigned to water phase. This is in line with EFSA LoE
- e) a value of 0.1 used for Step 1&2

Since Ethofumesate is classified as semi-volatile, atmospheric deposition has to be considered following spray application. Dry deposition needs only be considered in addition to drift for distances greater than 1 m if drift mitigation at FOCUS SW Step 4 is required. The degrees of volatilisation with respective deposition rates were calculated on an hourly basis using EVA 3 (rev2) as presented in the table below.

Table 8.9.2.1-2 Deposition rates for Ethofumesate (EVA 3.0) following ~~three applications~~ 3 x 300 g a.s./ha applications of HBZ10 to sugar beets

		dist. (m)	1	5	10	15	20
time (h)	v/d per h arable crop	v/d in 24 h no dissip.	0.221%	0.178%	0.135%	0.103%	0.079%
0 - 1	9.09%		0.0060	0.0048	0.0037	0.0028	0.0021
1 - 2	9.09%		0.0060	0.0048	0.0037	0.0028	0.0021
2 - 3	9.09%		0.0060	0.0048	0.0037	0.0028	0.0021
3 - 4	9.09%		0.0060	0.0048	0.0037	0.0028	0.0021
4 - 5	4.55%		0.0030	0.0024	0.0018	0.0014	0.0011
5 - 6	4.55%		0.0030	0.0024	0.0018	0.0014	0.0011
6 - 7	4.55%		0.0030	0.0024	0.0018	0.0014	0.0011
7 - 8	4.55%		0.0030	0.0024	0.0018	0.0014	0.0011
8 - 9	4.55%		0.0030	0.0024	0.0018	0.0014	0.0011
9 - 10	4.55%		0.0030	0.0024	0.0018	0.0014	0.0011
10 - 11	4.55%		0.0030	0.0024	0.0018	0.0014	0.0011
11 - 12	4.55%		0.0030	0.0024	0.0018	0.0014	0.0011
12 - 13	2.27%		0.0015	0.0012	0.0009	0.0007	0.0005
13 - 14	2.27%		0.0015	0.0012	0.0009	0.0007	0.0005
14 - 15	2.27%		0.0015	0.0012	0.0009	0.0007	0.0005
15 - 16	2.27%		0.0015	0.0012	0.0009	0.0007	0.0005
16 - 17	2.27%		0.0015	0.0012	0.0009	0.0007	0.0005
17 - 18	2.27%		0.0015	0.0012	0.0009	0.0007	0.0005
18 - 19	2.27%		0.0015	0.0012	0.0009	0.0007	0.0005
19 - 20	2.27%		0.0015	0.0012	0.0009	0.0007	0.0005
20 - 21	2.27%		0.0015	0.0012	0.0009	0.0007	0.0005
21 - 22	2.27%		0.0015	0.0012	0.0009	0.0007	0.0005
22 - 23	2.27%		0.0015	0.0012	0.0009	0.0007	0.0005
23 - 24	2.27%		0.0015	0.0012	0.0009	0.0007	0.0005
0 - 24	100.00%		0.0661	0.0532	0.0405	0.0309	0.0235

PEC_{SW/SED}

All PEC_{SW} values for Ethofumesate were recalculated considering a plant uptake factor of 0. These additional values are presented in the table numbers (b) and are presented below each original table (table numbers (a) referring to calculations based on PUF of 0.5).

Table 8.9.2.1-3a FOCUS Step 1, 2 and 3 PEC_{SW} and PEC_{SED} for Ethofumesate following six applications of product to sugar beets, use group 1– PUF = 0.5

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	---	267.494	-	255.310	313.036
Step 2	Northern Europe March-May	31.636 (7.447)	-	30.144 (7.085)	36.958 (8.686)
	Southern Europe March-May	59.129 (13.665)	-	56.493 (13.044)	69.268 (15.994)
	Northern Europe June-Sept	31.636 (7.447)	-	30.144 (7.085)	36.958 (8.686)
	Southern Europe June-Sept	45.383 (10.556)	-	43.319 (10.065)	53.113 (12.340)
Step 3 Early application					
D3	Ditch	0.465 (0.787)	Drift (drift)	0.111 (0.045)	0.269 (0.215)
D4	Pond	0.596 (0.068)	Drainage (drainage)	0.584 (0.066)	2.275 (0.296)
D4	Stream	0.581 (0.650)	Drainage (drift)	0.338 (0.038)	0.860 (0.104)
R1	Pond	0.956 (0.062)	Runoff (runoff)	0.852 (0.057)	2.008 (0.155)
R1	Stream	7.693 (0.822)	Runoff (runoff)	0.548 (0.032)	2.200 (0.197)
R3	Stream	12.480 (1.552)	Runoff (runoff)	0.618 (0.073)	3.530 (0.467)
Step 3 Late application					
D3	Ditch	0.465 (0.787)	Drift (drift)	0.080 (0.045)	0.265 (0.215)
D4	Pond	0.809 (0.068)	Drainage (drainage)	0.000 (0.066)	2.847 (0.296)
D4	Stream	0.849 (0.650)	Drainage (drift)	0.793 (0.038)	1.054 (0.104)
R1	Pond	0.708 (0.062)	Runoff (runoff)	0.023 (0.057)	1.718 (0.155)
R1	Stream	9.247 (0.822)	Runoff (runoff)	0.474 (0.032)	2.656 (0.197)
R3	Stream	8.383 (1.552)	Runoff (runoff)	0.002 (0.073)	2.546 (0.467)

* Single applications in parenthesis. Values above RAC in bold.

** twa-time as required by ecotox

Table 8.9.2.1-3b FOCUS Step 3 PEC_{SW} and PEC_{SED} for Ethofumesate following six applications of product to sugar beets, use group 1 – PUF = 0

Scenario FOCUS	Waterbody	Max PEC _{SW} [µg/L]*	Dominant entry route	21 d- PEC _{SW} , twa [µg/L]**	Max PEC _{SED} [µg/kg]*
Step 3 Early application					
D3	Ditch	0.465 (0.787)	Drift (drift)	0.111 (0.045)	0.269 (0.215)
D4	Pond	0.648 (0.073)	Drainage (drainage)	0.636 (0.072)	2.440 (0.315)
D4	Stream	0.641 (0.650)	Drainage (drift)	0.370 (0.041)	0.922 (0.111)
R1	Pond	1.003 (0.069)	Runoff (runoff)	0.894 (0.064)	2.089 (0.170)
R1	Stream	8.491 (0.972)	Runoff (runoff)	0.572 (0.037)	2.244 (0.229)
R3	Stream	13.78 (1.729)	Runoff (runoff)	0.679 (0.082)	3.862 (0.515)
Step 3 Late application					
D3	Ditch	0.465 (0.786)	Drift (drift)	0.080 (0.038)	0.265 (0.196)
D4	Pond	0.870 (0.122)	Drainage (drainage)	0.852 (0.119)	3.031 (0.454)
D4	Stream	0.919 (0.610)	Drainage (drift)	0.511 (0.071)	1.125 (0.160)
R1	Pond	0.841 (0.451)	Runoff (runoff)	0.763 (0.398)	2.006 (0.860)
R1	Stream	12.160 (3.442)	Runoff (runoff)	0.499 (0.150)	3.136 (0.992)
R3	Stream	9.325 (2.166)	Runoff (runoff)	0.536 (0.127)	2.728 (0.600)

* Single applications in parenthesis. Values above RAC in bold.

** twa-time as required by ecotox

Table 8.9.2.1-4a FOCUS Step 1, 2 and 3 PEC_{SW} and PEC_{SED} for Ethofumesate following three applications of product to sugar beets, use group 2 – PUF = 0.5

Scenario FOCUS	Waterbody	Max PEC _{SW} [µg/L]*	Dominant entry route*	21 d- PEC _{SW} , tw [µg/L]**	Max PEC _{SED} [µg/kg]*
Step 1	---	267.494	-	255.310	313.036
Step 2	Northern Europe March-May	37.379 (14.893)	-	35.600 (14.170)	43.646 (17.372)
	Southern Europe March-May	69.480 (27.330)	-	66.365 (26.089)	81.372 (31.987)
	Northern Europe June-Sept	37.379 (14.893)	-	35.600 (14.170)	43.646 (17.372)
	Southern Europe June-Sept	53.429 (21.112)	-	50.982 (20.129)	62.509 (24.680)
Step 3 Early application					
D3	Ditch	1.145 (1.574)	Drift (drift)	0.136 (0.091)	0.455 (0.418)
D4	Pond	0.482 (0.141)	Drainage (drainage)	0.472 (0.139)	1.924 (0.603)
D4	Stream	1.020 (1.301)	Drainage (drift)	0.27 (0.079)	0.712 (0.212)
R1	Pond	0.436 (0.119)	Runoff (runoff)	0.408 (0.110)	0.961 (0.289)
R1	Stream	7.189 (1.541)	Runoff (runoff)	0.248 (0.060)	1.540 (0.362)
R3	Stream	16.07 (3.023)	Runoff (runoff)	0.794 (0.143)	4.475 (0.886)
Step 3 Late application					
D3	Ditch	1.144 (1.572)	Drift (drift)	0.177 (0.075)	0.440 (0.381)
D4	Pond	0.773 (0.234)	Drainage (drainage)	0.758 (0.229)	2.799 (0.871)
D4	Stream	0.996 (1.222)	Drift (drift)	0.447 (0.136)	1.017 (0.307)
R1	Pond	1.491 (0.849)	Runoff (runoff)	1.312 (0.751)	2.761 (1.587)
R1	Stream	19.230 (6.452)	Runoff (runoff)	0.858 (0.285)	5.344 (1.954)
R3	Stream	11.980 (3.924)	Runoff (runoff)	0.748 (0.239)	3.567 (1.101)

* Single applications in parenthesis. Values above RAC in bold.

** twa-time as required by ecotox

Table 8.9.2.1-4b FOCUS Step 3 PEC_{SW} and PEC_{SED} for Ethofumesate following three applications of product to sugar beets, use group 2 – PUF = 0

Scenario FOCUS	Waterbody	Max PEC _{SW} [µg/L]*	Dominant entry route	21 d- PEC _{SW} , tw [µg/L]**	Max PEC _{SED} [µg/kg]*
Step 3 Early application					
D3	Ditch	1.145 (1.574)	Drift (drift)	0.136 (0.091)	0.456 (0.418)
D4	Pond	0.528 (0.154)	Drainage (drainage)	0.517 (0.151)	2.070 (0.643)
D4	Stream	1.023 (1.302)	Drift (drift)	0.298 (0.086)	0.767 (0.227)
R1	Pond	0.490 (0.143)	Runoff (runoff)	0.456 (0.132)	1.057 (0.339)
R1	Stream	8.373 (2.057)	Runoff (runoff)	0.286 (0.078)	1.767 (0.472)
R3	Stream	19.580 (3.877)	Runoff (runoff)	0.959 (0.183)	5.370 (1.116)
Step 3 Late application					
D3	Ditch	1.144 (1.572)	Drift (drift)	0.177 (0.075)	0.440 (0.381)
D4	Pond	0.836 (0.252)	Drainage (drainage)	0.819 (0.247)	2.989 (0.926)
D4	Stream	1.000 (1.223)	Drift (drift)	0.485 (0.147)	1.090 (0.329)
R1	Pond	1.880 (0.947)	Runoff (runoff)	1.655 (0.836)	3.443 (1.744)
R1	Stream	24.660 (7.243)	Runoff (runoff)	1.106 (0.314)	6.712 (2.008)
R3	Stream	16.490 (5.702)	Runoff (runoff)	0.983 (0.343)	4.643 (1.502)

* Single applications in parenthesis. Values above RAC in bold.

** twa-time as required by ecotox

Table 8.9.2.1-5a FOCUS Step 1, 2 and 3 PEC_{SW} and PEC_{SED} for Ethofumesate following five applications of product to sugar beets, use group 3– PUF = 0.5

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	---	222.911	-	212.758	260.86
Step 2	Northern Europe March-May	25.986 (7.447)	-	24.745 (7.085)	30.338 (8.686)
	Northern Europe June-Sept	25.986 (7.447)	-	24.745 (7.085)	30.338 (8.686)
	Southern Europe March-May	48.198 (13.665)	-	46.032 (13.044)	56.441 (15.994)
	Southern Europe June-Sept	37.092 (10.556)	-	35.389 (10.065)	43.389 (12.340)
Step 3 Early application					
D3	Ditch	0.508	Drift	0.062	0.232
D4	Pond	0.468	Drainage	0.459	1.803
D4	Stream	0.479	Drift	0.266	0.674
R1	Pond	0.695	Runoff	0.619	1.563
R1	Stream	7.134	Runoff	0.279	1.677
R3	Stream	8.037	Runoff	0.403	2.301
Step 3 Late application					
D3	Ditch	0.508	Drift	0.084	0.250
D4	Pond	0.656	Drainage	0.644	2.345
D4	Stream	0.693	Drainage	0.383	0.868
R1	Pond	0.570	Runoff	0.528	1.438
R1	Stream	5.012	Runoff	0.243	1.607
R3	Stream	5.909	Runoff	0.605	2.267

* Single application values are the same as for 6 applications- vd. Corresponding 6 applications table. Values above RAC in bold.

** twa-time as required by ecotox

Table 8.9.2.1-5b FOCUS Step 3 PEC_{SW} and PEC_{SED} for Ethofumesate following five applications of product to sugar beets, use group 3– PUF = 0

Scenario FOCUS	Waterbody	Max PEC _{SW} [µg/L]*	Dominant entry route	21 d- PEC _{SW} , twa [µg/L]**	Max PEC _{SED} [µg/kg]*
Step 3 Early application					
D3	Ditch	0.508	Drift	0.062	0.232
D4	Pond	0.510	Drainage	0.500	1.934
D4	Stream	0.505	Drainage	0.291	0.724
R1	Pond	0.789	Runoff	0.701	1.737
R1	Stream	7.698	Runoff	0.303	1.986
R3	Stream	8.936	Runoff	0.445	2.534
Step 3 Late application					
D3	Ditch	0.508	Drift	0.084	0.250
D4	Pond	0.705	Drainage	0.691	2.493
D4	Stream	0.750	Drainage	0.413	0.926
R1	Pond	0.657	Runoff	0.605	1.634
R1	Stream	6.682	Runoff	0.303	1.914
R3	Stream	6.815	Runoff	0.657	2.457

* Single application values are the same as for use 3 - vd. Corresponding applications table. Values above RAC in bold

** twa-time as required by ecotox

Table 8.9.2.1-6a FOCUS Step 1, 2 and 3 PEC_{SW} and PEC_{SED} for Ethofumesate following three applications of product to sugar beets, use group 4 – PUF = 0.5

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	---	200.620	--	191.483	234.777
Step 2	Northern Europe March-May	28.034 (11.170)		26.700 (10.627)	32.735 (13.029)
Step 2	Northern Europe June-Sept	28.034 (11.170)		26.700 (10.627)	32.735 (13.029)
Step 2	Southern Europe March-May	52.110 (20.498)	--	49.774 (19.566)	61.029 (23.991)
Step 2	Southern Europe June-Sept	40.072 (15.834)	-	38.237 (15.097)	46.882 (18.510)
Step 3 Early application					
D3	Ditch	0.859 (1.181)	Drift (drift)	0.102 (0.068)	0.346 (0.317)
D4	Pond	0.353 (0.104)	Drainage (drainage)	0.346 (0.102)	1.425 (0.449)
D4	Stream	0.763 (0.975)	Drift (drift)	0.198 (0.058)	0.526 (0.157)
R1	Pond	0.331 (0.091)	Runoff (runoff)	0.311 (0.084)	0.741 (0.223)
R1	Stream	5.485 (1.188)	Runoff (runoff)	0.189 (0.046)	1.186 (0.281)
R3	Stream	12.06 (2.293)	Runoff (runoff)	0.595 (0.108)	3.399 (0.679)
Step 3 Late application					
D3	Ditch	0.858 (1.179)	Drift (drift)	0.133 (0.057)	0.334 (0.289)
D4	Pond	0.569 (0.173)	Drainage (drainage)	0.558 (0.170)	2.073 (0.648)
D4	Stream	0.743 (0.915)	Drift (drift)	0.330 (0.101)	0.752 (0.228)
R1	Pond	1.110 (0.634)	Runoff (runoff)	0.977 (0.561)	2.085 (1.201)
R1	Stream	14.32 (4.815)	Runoff (runoff)	0.639 (0.214)	4.036 (1.481)
R3	Stream	8.936 (2.930)	Runoff (runoff)	0.560 (0.179)	2.699 (0.834)

* Single applications in parenthesis. Values above RAC in bold.

** twa-time as required by ecotox

Table 8.9.2.1-6b FOCUS Step 3 PEC_{SW} and PEC_{SED} for Ethofumesate following three applications of product to sugar beets, use group 4 – PUF = 0

Scenario FOCUS	Waterbody	Max PEC _{SW} [µg/L]*	Dominant entry route	21 d- PEC _{SW, twa} [µg/L]**	Max PEC _{SED} [µg/kg]*
Step 3 Early application					
D3	Ditch	0.859 (1.181)	Drift (drift)	0.102 (0.068)	0.346 (0.317)
D4	Pond	0.386 (0.113)	Drainage (drainage)	0.378 (0.111)	1.531 (0.478)
D4	Stream	0.766 (0.976)	Drift (drift)	0.218 (0.064)	0.567 (0.169)
R1	Pond	0.351 (0.101)	Runoff (runoff)	0.327 (0.093)	0.771 (0.244)
R1	Stream	5.923 (1.408)	Runoff (runoff)	0.203 (0.054)	1.268 (0.328)
R3	Stream	13.420 (2.558)	Runoff (runoff)	0.660 (0.121)	3.746 (0.751)
Step 3 Late application					
D3	Ditch	0.858 (1.179)	Drift (drift)	0.133 (0.057)	0.334 (0.289)
D4	Pond	0.614 (0.186)	Drainage (drainage)	0.602 (0.182)	2.211 (0.688)
D4	Stream	0.746 (0.916)	Drift (drift)	0.358 (0.109)	0.805 (0.244)
R1	Pond	1.299 (0.679)	Runoff (runoff)	1.143 (0.599)	2.410 (1.268)
R1	Stream	16.940 (5.179)	Drift (runoff)	0.765 (0.224)	4.709 (1.462)
R3	Stream	10.280 (3.256)	Runoff (runoff)	0.592 (0.189)	3.004 (0.885)

* Single applications in parenthesis. Values above RAC in bold.

** twa-time as required by ecotox

Table 8.9.2.1-7a FOCUS Step 1, 2 and 3 PEC_{SW} and PEC_{SED} for Ethofumesate following three applications of product to sugar beets, use group 5 – PUF = 0.5

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	---	267.494	--	255.310	313.036
Step 2	Northern Europe March-May	35.177 (14.893)		33.493 (14.170)	41.063 (17.372)
	Northern Europe June-Sept	35.177 (14.893)		33.493 (14.170)	41.063 (17.372)
	Southern Europe March-May	65.140 (27.330)	--	62.209 (26.089)	76.275 (31.987)
	Southern Europe June-Sept	50.159 (21.112)	--	47.851 (20.129)	58.669 (24.680)
Step 3 Early application					
D3	Ditch	1.145 (1.574)	Drift (drift)	0.136 (0.091)	0.455 (0.418)
D4	Pond	0.534 (0.141)	Drainage (drainage)	0.524 (0.139)	2.062 (0.603)
D4	Stream	1.021 (1.301)	Drift (drift)	0.302 (0.079)	0.762 (0.212)
R1	Pond	0.525 (0.119)	Runoff (runoff)	0.469 (0.110)	1.240 (0.289)
R1	Stream	5.762 (1.541)	Runoff (runoff)	0.264 (0.060)	1.200 (0.362)
R3	Stream	11.250 (3.023)	Runoff (runoff)	0.567 (0.143)	3.203 (0.886)
Step 3 Late application					
D3	Ditch	1.144 (1.572)	Drift (drift)	0.178 (0.075)	0.436 (0.381)
D4	Pond	0.765 (0.234)	Drainage (drainage)	0.749 (0.229)	2.682 (0.871)
D4	Stream	0.987 (1.222)	Drift (drift)	0.447 (0.136)	0.981 (0.307)
R1	Pond	0.812 (0.849)	Drift (runoff)	0.737 (0.751)	1.703 (1.587)
R1	Stream	10.090 (6.452)	Runoff (runoff)	0.489 (0.285)	2.890 (1.954)
R3	Stream	11.980 (3.924)	Runoff (runoff)	0.748 (0.239)	3.567 (1.101)

* Single applications in parenthesis. Values above RAC in bold.

** two-time as required by ecotox

Table 8.9.2.1-7b FOCUS Step 3 PEC_{SW} and PEC_{SED} for Ethofumesate following three applications of product to sugar beets, use group 5 – PUF = 0

Scenario FOCUS	Waterbody	Max PEC _{SW} [µg/L]*	Dominant entry route	21 d- PEC _{SW, twa} [µg/L]**	Max PEC _{SED} [µg/kg]*
Step 3 Early application					
D3	Ditch	1.145	Drift	0.136	0.456
D4	Pond	0.584	Drainage	0.573	2.218
D4	Stream	1.025	Drift	0.333	0.821
R1	Pond	0.556	Runoff	0.496	1.306
R1	Stream	7.831	Runoff	0.305	1.314
R3	Stream	12.580	Runoff	0.630	3.545
Step 3 Late application					
D3	Ditch	1.144	Drift	0.178	0.436
D4	Pond	0.826	Drainage	0.809	2.868
D4	Stream	0.991	Drift	0.485	1.053
R1	Pond	0.975	Drift	0.887	2.004
R1	Stream	12.440	Runoff	0.612	3.509
R3	Stream	13.760	Runoff	0.788	3.965

* Single application values are the same as for use 2 - vd. Corresponding applications table. Values above RAC in bold.

** two-time as required by ecotox

PEC_{SW} from the FOCUS-STEPs 1-2 Ethofumesate in surface water do not provide an acceptable risk assessment, as some of these PEC_{SW} values exceed the regulatory acceptable concentrations (RAC) for aquatic organisms in the risk assessment for aquatic organisms. Therefore, a STEP 3 approach was considered necessary.

PEC_{SW} from the FOCUS-STEP 3 for Ethofumesate in surface water does not provide an acceptable risk assessment, as the PEC_{SW} value for the R1 and R3 stream scenarios following the three applications in use group 2 and 4 for late and early application, exceeds the RAC of 15.6 µg/L. A further refinement is required by including risk mitigation measures.

FOCUS Step 4

Table 8.9.2.1-8 Global maximum PEC_{sw} values for Ethofumesate, following multiple application(s) of product HBZ10 to sugar beets according to the central EU zone GAP according to surface water Step 4 – Early Application

	PEC _{sw} [µg/L]	Scenario	STEP 4 Ethofumesate – Early Application						
	Nozzle reduction [%]	Vegetative strip [m]	None	None	None	None	None	10	20
		No spray buffer [m]	1/3	5	10	15	20	10	20
6 Applications at 150 g a.s/ha, use group 1	None	R3 stream						6.285	2.504
	50								
3 Applications at 300 g a.s/ha, use group 2	None	R1 stream						3.797	1.508
	50								
3 Applications at 300 g a.s/ha, use group 2	None	R3 stream						8.934	3.558
	50								
3 Applications at 225 g a.s/ha, use group 4	None	R1 stream						7.704	1.067
	50								
3 Applications at 225 g a.s/ha, use group 4	None	R3 stream						4.685	2.439
	50								
3 Applications at 300 g a.s/ha, use group 5	None	R3 stream						5.737	2.285
	50								

Table 8.9.2.1-9 Global maximum PEC_{sw} values for Ethofumesate, following multiple application(s) of product HBZ10 to sugar beets according to the central EU zone GAP according to surface water Step 4 – Late Application

	PEC _{sw} [µg/L]	Scenario	STEP 4 Ethofumesate – Late Application						
	Nozzle reduction [%]	Vegetative strip [m]	None	None	None	None	None	10	20
		No spray buffer [m]	1/3	5	10	15	20	10	20
6 Applications at 150 g a.s/ha, use group 1	None	R1 stream						5.386	2.114
	50								
	None	R3 stream						4.250	1.693
	50								
3 Applications at 300 g a.s/ha, use group 2	None	R1 stream						11.21	4.460
	50								
	None	R3 stream						7.514	2.992
	50								
3 applications at 225 g a.s/ha, use group 4	None	R1 stream						7.704	3.064
	50								
3 applications at 225 g a.s/ha, use group 4	None	R3 stream						4.685	1.866
	50								
3 Applications at 300 g a.s/ha, use group 5	None	R1 stream						5.657	2.250
	50								
3 Applications at 300 g a.s/ha, use group 5	None	R3 stream						6.273	2.498
	50								

The implementation of a no spray buffer zone and vegetated strip of 10 m is sufficient to reach safe values for Ethofumesate for R1 (late application) and R3 (early and late applications) scenarios in use group 2 and for R1 scenario in use group 4 (late application) in beets, including when considering mixture toxicity.

No mitigation measures are considered as necessary for the other intended uses in beet crops (namely, use groups 1, 3, 4 and 5).

Metabolites of Ethofumesate

Table 8.9.2.1-10 FOCUS Step 1, 2 PEC_{SW} and PEC_{SED} for NC8493 following six applications of product to sugar beets, use group 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	---	65.319	-	64.846	1.359
Step 2	Northern Europe March-May	0.000 (0.000)	-	0.000 (0.000)	0.000 (0.000)
	Southern Europe March-May	0.000 (0.000)	-	0.000 (0.000)	0.000 (0.000)
	Northern Europe June-Sept	0.000 (0.000)	-	0.000 (0.000)	0.000 (0.000)
	Southern Europe June-Sept	0.000 (0.000)	-	0.000 (0.000)	0.000 (0.000)

* Single applications in parenthesis. Values above RAC in bold.

** twa-time as required by ecotox

Table 8.9.2.1-11 FOCUS Step 1, 2 PEC_{SW} and PEC_{SED} for NC8493 following three applications of product to sugar beets, use group 2

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	---	65.319	-	64.846	1.359
Step 2	Northern Europe March-May	0.000 (0.000)	-	0.000 (0.000)	0.000 (0.000)
	Southern Europe March-May	0.000 (0.000)	-	0.000 (0.000)	0.000 (0.000)
	Northern Europe June-Sept	0.000 (0.000)	-	0.000 (0.000)	0.000 (0.000)
	Southern Europe June-Sept	0.000 (0.000)	-	0.000 (0.000)	0.000 (0.000)

* Single applications in parenthesis. Values above RAC in bold.

** twa-time as required by ecotox

Table 8.9.2.1-12 FOCUS Step 1, 2 PEC_{SW} and PEC_{SED} for NC8493 following five applications of product to sugar beets, use group 3

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	---	54.432	-	54.038	1.132
Step 2	Northern Europe March-May	0.000 (0.000)	-	0.000 (0.000)	0.000 (0.000)
	Southern Europe March-May	0.000 (0.000)	-	0.000 (0.000)	0.000 (0.000)
	Northern Europe June-Sept	0.000 (0.000)	-	0.000 (0.000)	0.000 (0.000)
	Southern Europe June-Sept	0.000 (0.000)	-	0.000 (0.000)	0.000 (0.000)

* Single applications in parenthesis. Values above RAC in bold.

** twa-time as required by ecotox

Table 8.9.2.1-13 FOCUS Step 1, 2 PEC_{SW} and PEC_{SED} for NC8493 following three applications of product to sugar beets, use group 4

Scenario FOCUS	Waterbody	Max PEC _{SW} [µg/L]*	Dominant entry route	21 d- PEC _{SW} , two [µg/L]**	Max PEC _{SED} [µg/kg]*
Step 1	---	48.991	--	48.636	1.019
Step 2	Northern Europe March-May	0.000 (0.000)	-	0.000 (0.000)	0.000 (0.000)
	Southern Europe March-May	0.000 (0.000)	-	0.000 (0.000)	0.000 (0.000)
	Northern Europe June-Sept	0.000 (0.000)	-	0.000 (0.000)	0.000 (0.000)
	Southern Europe June-Sept	0.000 (0.000)	-	0.000 (0.000)	0.000 (0.000)

* Single applications in parenthesis. Values above RAC in bold.

** two-time as required by ecotox

Table 8.9.2.1-14 FOCUS Step 1, 2 PEC_{SW} and PEC_{SED} for NC8493 following three applications of product to sugar beets, use group 5

Scenario FOCUS	Waterbody	Max PEC _{SW} [µg/L]*	Dominant entry route	21 d- PEC _{SW} , two [µg/L]**	Max PEC _{SED} [µg/kg]*
Step 1	---	65.321	--	64.848	1.359
Step 2	Northern Europe March-May	0.000 (0.000)	-	0.000 (0.000)	0.000 (0.000)
	Southern Europe March-May	0.000 (0.000)	-	0.000 (0.000)	0.000 (0.000)
	Northern Europe June-Sept	0.000 (0.000)	-	0.000 (0.000)	0.000 (0.000)
	Southern Europe June-Sept	0.000 (0.000)	-	0.000 (0.000)	0.000 (0.000)

* Single applications in parenthesis. Values above RAC in bold.

** two-time as required by ecotox

Table 8.9.2.1-15a FOCUS Step 1, 2 and 3 PEC_{SW} and PEC_{SED} for NC20645 following six applications of product to sugar beets, use group 1

Scenario FOCUS	Waterbody	Max PEC _{SW} [µg/L]*	Dominant entry route*	21 d- PEC _{SW} , two [µg/L]**	Max PEC _{SED} [µg/kg]*
Step 1	---	60.358	-	58.285	3.002
Step 2	Northern Europe March-May	6.523 (1.532)	-	6.299 (1.479)	0.332 (0.078)
	Southern Europe March-May	12.216 (2.819)	-	11.796 (2.722)	0.621 (0.143)
	Northern Europe June-Sept	6.523 (1.532)	-	6.299 (1.479)	0.332 (0.078)
	Southern Europe June-Sept	9.370 (2.175)	-	9.047 (2.101)	0.476 (0.111)
Step 3 Early Application					
D3	Ditch	0.000 (0.001)	Drainage (drainage)	-	0.001 (0.000)
D4	Pond	0.019 (0.002)	Drainage (drainage)	-	0.023 (0.003)
D4	Stream	0.002 (0.000)	Drainage (drift)	-	0.002 (0.000)
R1	Pond	0.048 (0.003)	Runoff (runoff)	-	0.045 (0.003)
R1	Stream	0.023 (0.002)	Runoff (runoff)	-	0.002 (0.000)
R3	Stream	0.104 (0.013)	Runoff (runoff)	-	0.010 (0.001)
Step 3 Late Application					
D3	Ditch	0.000 (0.001)	Drainage (drainage)	-	0.000 (0.000)
D4	Pond	0.023 (0.002)	Drainage (drainage)	-	0.028 (0.003)
D4	Stream	0.003 (0.000)	Drainage (drift)	-	0.002 (0.000)
R1	Pond	0.040 (0.003)	Runoff (runoff)	-	0.038 (0.003)
R1	Stream	0.028 (0.002)	Runoff (runoff)	-	0.003 (0.000)
R3	Stream	0.070 (0.013)	Runoff (runoff)	-	0.008 (0.001)

* Single applications in parenthesis. Values above RAC in bold.

** two-time as required by ecotox

Table 8.9.2.1-15b FOCUS Step 3 PEC_{SW} and PEC_{SED} for NC20645 following six applications of product to sugar beets, use group 1

Scenario FOCUS	Waterbody	Max PEC _{SW} [µg/L]*	Dominant entry route	21 d- PEC _{SW} , two [µg/L]**	Max PEC _{SED} [µg/kg]*
Step 3 Early Application					
D3	Ditch	0.000 (0.001)	Drainage (drainage)	0.000 (0.000)	0.001 (0.000)
D4	Pond	0.020 (0.002)	Drainage (drainage)	0.020 (0.002)	0.0244 (0.003)
D4	Stream	0.002 (0.000)	Drainage (drift)	0.001 (0.000)	0.002 (0.000)
R1	Pond	0.050 (0.00)	Runoff (runoff)	0.049 (0.003)	0.047 (0.004)
R1	Stream	0.026 (0.003)	Runoff (runoff)	0.002 (0.000)	0.003 (0.000)
R3	Stream	0.115 (0.014)	Runoff (runoff)	0.005 (0.001)	0.011 (0.001)
Step 3 Late Application					
D3	Ditch	0.000 (0.000)	Drainage (drainage)	0.000 (0.000)	0.000 (0.000)
D4	Pond	0.024 (0.003)	Drainage (drainage)	0.024 (0.003)	0.029 (0.004)
D4	Stream	0.003 (0.000)	Drainage (drainage)	0.002 (0.000)	0.003 (0.000)
R1	Pond	0.048 (0.018)	Runoff (runoff)	0.047 (0.018)	0.044 (0.017)
R1	Stream	0.038 (0.010)	Runoff (runoff)	0.002 (0.000)	0.004 (0.001)
R3	Stream	0.078 (0.018)	Runoff (runoff)	0.005 (0.001)	0.008 (0.002)

* Single applications in parenthesis. Values above RAC in bold.

** two-time as required by ecotox

Table 8.9.2.1-16a FOCUS Step 1, 2 and 3 PEC_{SW} and PEC_{SED} for NC20645 following three applications of product to sugar beets, use group 2

Scenario FOCUS	Waterbody	Max PEC _{SW} [µg/L]*	Dominant entry route*	21 d- PEC _{SW} , two [µg/L]**	Max PEC _{SED} [µg/kg]*
Step 1	---	60.358	-	58.285	3.002
Step 2	Northern Europe March-May	7.700 (3.063)	-	7.434 (2.957)	0.391 (0.156)
	Southern Europe March-May	14.347 (5.638)	-	13.854 (5.444)	0.729 (0.287)
	Northern Europe June-Sept	7.700 (3.063)	-	7.434 (2.957)	0.391 (0.156)
	Southern Europe June-Sept	11.023 (4.351)	-	10.644 (4.201)	0.560 (0.221)
Step 3 Early Application					
D3	Ditch	0.001 (0.001)	Drainage (drainage)	-	0.001 (0.000)
D4	Pond	0.016 (0.005)	Drainage (drainage)	-	0.020 (0.006)
D4	Stream	0.002 (0.001)	Drainage (drift)	-	0.002 (0.001)
R1	Pond	0.021 (0.006)	Runoff (runoff)	-	0.021 (0.006)
R1	Stream	0.022 (0.005)	Runoff (runoff)	-	0.002 (0.000)
R3	Stream	0.134 (0.025)	Runoff (runoff)	-	0.013 (0.003)
Step 3 Late Application					
D3	Ditch	0.001 (0.001)	Drainage (drainage)	-	0.001 (0.000)
D4	Pond	0.023 (0.007)	Drainage (drainage)	-	0.028 (0.008)
D4	Stream	0.003 (0.001)	Drainage (drainage)	-	0.002 (0.001)
R1	Pond	0.069 (0.035)	Runoff (runoff)	-	0.062 (0.033)
R1	Stream	0.058 (0.020)	Runoff (runoff)	-	0.006 (0.002)
R3	Stream	0.100 (0.033)	Runoff (runoff)	-	0.011 (0.003)

* Single applications in parenthesis. Values above RAC in bold.

** two-time as required by ecotox

Table 8.9.2.1-16b FOCUS Step 3 PEC_{SW} and PEC_{SED} for NC20645 following three applications of product to sugar beets, use group 2

Scenario FOCUS	Waterbody	Max PEC _{SW} [µg/L]*	Dominant entry route	21 d- PEC _{SW} , two [µg/L]**	Max PEC _{SED} [µg/kg]*
Step 3 Early Application					
D3	Ditch	0.001 (0.001)	Drainage (drainage)	0.000 (0.000)	0.001 (0.000)
D4	Pond	0.017 (0.005)	Drainage (drainage)	0.016 (0.005)	0.021 (0.007)
D4	Stream	0.002(0.001)	Drainage (drift)	0.001 (0.000)	0.002 (0.001)
R1	Pond	0.024 (0.007)	Runoff (runoff)	0.023 (0.007)	0.023 (0.007)
R1	Stream	0.025 (0.006)	Runoff (runoff)	0.001 (0.000)	0.002 (0.001)
R3	Stream	0.163 (0.032)	Runoff (runoff)	0.008 (0.002)	0.016 (0.003)
Step 3 Late Application					
D3	Ditch	0.001 (0.001)	Drainage (drainage)	0.000 (0.000)	0.001 (0.000)
D4	Pond	0.025 (0.007)	Drainage (drainage)	0.024 (0.007)	0.029 (0.009)
D4	Stream	0.003 (0.001)	Drainage (drainage)	0.002 (0.000)	0.003 (0.001)
R1	Pond	0.086 (0.038)	Runoff (runoff)	0.085 (0.038)	0.078 (0.036)
R1	Stream	0.075 (0.022)	Runoff (runoff)	0.003 (0.001)	0.007 (0.002)
R3	Stream	0.137 (0.048)	Runoff (runoff)	0.008 (0.003)	0.014 (0.004)

* Single applications in parenthesis. Values above RAC in bold.

** two-time as required by ecotox

Table 8.9.2.1-17a FOCUS Step 1, 2 and 3 PEC_{SW} and PEC_{SED} for NC20645 following five applications of product to sugar beets, use group 3

Scenario FOCUS	Waterbody	Max PEC _{SW} [µg/L]*	Dominant entry route	21 d- PEC _{SW} , two [µg/L]**	Max PEC _{SED} [µg/kg]*
Step 1	---	50.298	-	48.571	2.56
Step 2	Northern Europe March-May	5.357 (1.532)	-	5.172 (1.479)	0.272 (0.078)
	Northern Europe June-Sept	5.357 (1.532)	-	5.172 (1.479)	0.272 (0.078)
	Southern Europe March-May	9.956 (2.819)	-	9.614 (2.722)	0.506 (0.143)
	Southern Europe June-Sept	7.656 (2.175)	-	7.393 (2.101)	0.389 (0.111)
Step 3 Early Application					
D3	Ditch	0.000	Drainage	-	0.000
D4	Pond	0.015	Drainage	-	0.018
D4	Stream	0.002	Drainage	-	0.002
R1	Pond	0.037	Runoff	-	0.035
R1	Stream	0.022	Runoff	-	0.002
R3	Stream	0.067	Runoff	-	0.007
Step 3 Late Application					
D3	Ditch	0.000	Drainage	-	0.000
D4	Pond	0.019	Drainage	-	0.023
D4	Stream	0.002	Drainage	-	0.002
R1	Pond	0.034	Runoff	-	0.032
R1	Stream	0.015	Runoff	-	0.002
R3	Stream	0.049	Runoff	-	0.007

* Single application values are the same as for 6 applications- vd. Corresponding 6 applications table. Values above RAC in bold.

** two-time as required by ecotox

Table 8.9.2.1-17b FOCUS Step 3 PEC_{SW} and PEC_{SED} for NC20645 following five applications of product to sugar beets, use group 3

Scenario FOCUS	Waterbody	Max PEC _{SW} [µg/L]*	Dominant entry route	21 d- PEC _{SW} , twa [µg/L]**	Max PEC _{SED} [µg/kg]*
Step 3 Early Application					
D3	Ditch	0.000	Drainage	0.000	0.000
D4	Pond	0.016	Drainage	0.015	0.019
D4	Stream	0.002	Drainage	0.001	0.002
R1	Pond	0.041	Runoff	0.041	0.039
R1	Stream	0.023	Runoff	0.001	0.003
R3	Stream	0.074	Runoff	0.004	0.007
Step 3 Late Application					
D3	Ditch	0.000	Drainage	0.000	0.000
D4	Pond	0.020	Drainage	0.020	0.024
D4	Stream	0.003	Drainage	0.001	0.002
R1	Pond	0.039	Runoff	0.038	0.036
R1	Stream	0.021	Runoff	0.001	0.003
R3	Stream	0.057	Runoff	0.005	0.007

* Single application values are the same as for use 1 - vd. Corresponding applications table. Values above RAC in bold.

** two-time as required by ecotox

Table 8.9.2.1-18a FOCUS Step 1, 2 and 3 PEC_{SW} and PEC_{SED} for NC20645 following three applications of product to sugar beets, use group 4

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	---	45.268	--	43.714	2.301
Step 2	Northern Europe March-May	5.775 (2.297)	--	5.576 (2.218)	0.293 (0.117)
	Northern Europe June-Sept	5.775 (2.297)	--	5.576 (2.218)	0.293 (0.117)
	Southern Europe March-May	10.760 (4.229)	--	10.390 (4.083)	0.547 (0.215)
	Southern Europe June-Sept	8.267 (3.263)	--	7.983 (3.151)	0.420 (0.166)
Step 3 Early Application					
D3	Ditch	0.001 (0.001)	Drainage (drainage)	-	0.000 (0.000)
D4	Pond	0.011 (0.004)	Drainage (drainage)	-	0.015 (0.005)
D4	Stream	0.001 (0.001)	Drainage (drift)	-	0.001 (0.000)
R1	Pond	0.016 (0.004)	Runoff (runoff)	-	0.016 (0.005)
R1	Stream	0.017 (0.004)	Runoff (runoff)	-	0.001 (0.000)
R3	Stream	0.100 (0.019)	Runoff (runoff)	-	0.010 (0.002)
Step 3 Late Application					
D3	Ditch	0.001 (0.001)	Drainage (drainage)	-	0.000 (0.000)
D4	Pond	0.017 (0.005)	Drainage (drainage)	-	0.020 (0.006)
D4	Stream	0.002 (0.001)	Drainage (drainage)	-	0.002 (0.000)
R1	Pond	0.051 (0.026)	Runoff (runoff)	-	0.047 (0.025)
R1	Stream	0.043 (0.015)	Runoff (runoff)	-	0.004 (0.001)
R3	Stream	0.074 (0.024)	Runoff (runoff)	-	0.008 (0.002)

* Single applications in parenthesis. Values above RAC in bold.

** two-time as required by ecotox

Table 8.9.2.1-18b FOCUS Step 3 PEC_{SW} and PEC_{SED} for NC20645 following three applications of product to sugar beets, use group 4

Scenario FOCUS	Waterbody	Max PEC _{SW} [µg/L]*	Dominant entry route	21 d- PEC _{SW, twa} [µg/L]**	Max PEC _{SED} [µg/kg]*
Step 3 Early Application					
D3	Ditch	0.000 (0.001)	Drainage (drainage)	0.000 (0.000)	0.000 (0.000)
D4	Pond	0.012 (0.004)	Drainage (drainage)	0.012 (0.004)	0.015 (0.005)
D4	Stream	0.001 (0.001)	Drainage (drift)	0.001 (0.000)	0.001 (0.000)
R1	Pond	0.017 (0.005)	Runoff (runoff)	0.017 (0.005)	0.017 (0.005)
R1	Stream	0.018 (0.004)	Runoff (runoff)	0.001 (0.000)	0.001 (0.000)
R3	Stream	0.112 (0.021)	Runoff (runoff)	0.005 (0.001)	0.011 (0.002)
Step 3 Late Application					
D3	Ditch	0.001 (0.001)	Drainage (drainage)	0.000 (0.000)	0.000 (0.000)
D4	Pond	0.018 (0.005)	Drainage (drainage)	0.018 (0.005)	0.023 (0.007)
D4	Stream	0.002 (0.001)	Drainage (drainage)	0.001 (0.000)	0.002 (0.001)
R1	Pond	0.059 (0.027)	Runoff (runoff)	0.059 (0.027)	0.054 (0.026)
R1	Stream	0.051 (0.016)	Runoff (runoff)	0.002 (0.001)	0.005 (0.002)
R3	Stream	0.086 (0.027)	Runoff (runoff)	0.005 (0.002)	0.009 (0.003)

* Single applications in parenthesis. Values above RAC in bold.

** two-time as required by ecotox

Table 8.9.2.1-19a FOCUS Step 1, 2 and 3 PEC_{SW} and PEC_{SED} for NC20645 following three applications of product to sugar beets, use group 5

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	---	60.358	--	58.285	3.068
Step 2	Northern Europe March-May	7.247 (3.063)	--	6.997 (2.957)	0.368 (0.156)
	Northern Europe June-Sept	7.247 (3.063)	--	6.997 (2.957)	0.368 (0.156)
	Southern Europe March-May	13.451 (5.638)	--	12.989 (5.444)	0.684 (0.287)
	Southern Europe June-Sept	10.349 (4.351)	--	9.993 (4.201)	0.526 (0.221)
Step 3 Early Application					
D3	Ditch	0.001 (0.001)	Drainage (drainage)	-	0.001 (0.000)
D4	Pond	0.017 (0.005)	Drainage (drainage)	-	0.021 (0.006)
D4	Stream	0.002 (0.001)	Drainage (drift)	-	0.002 (0.001)
R1	Pond	0.029 (0.006)	Runoff (runoff)	-	0.027 (0.006)
R1	Stream	0.018 (0.005)	Runoff (runoff)	-	0.002 (0.000)
R3	Stream	0.094 (0.025)	Runoff (runoff)	-	0.009 (0.003)
Step 3 Late Application					
D3	Ditch	0.001 (0.001)	Drainage (drainage)	-	0.001 (0.000)
D4	Pond	0.022 (0.007)	Drainage (drainage)	-	0.026 (0.008)
D4	Stream	0.003 (0.001)	Drainage (drainage)	-	0.002 (0.001)
R1	Pond	0.041 (0.035)	Runoff (runoff)	-	0.038 (0.033)
R1	Stream	0.031 (0.020)	Runoff (runoff)	-	0.003 (0.002)
R3	Stream	0.100 (0.033)	Runoff (runoff)	-	0.011 (0.003)

* Single applications in parenthesis. Values above RAC in bold.

** two-time as required by ecotox

Table 8.9.2.1-19b FOCUS Step 3 PEC_{SW} and PEC_{SED} for NC20645 following three applications of product to sugar beets, use group 5

Scenario FOCUS	Waterbody	Max PEC _{SW} [µg/L]*	Dominant entry route	21 d- PEC _{SW} , twa [µg/L]**	Max PEC _{SED} [µg/kg]*
Step 3 Early Application					
D3	Ditch	0.001	Drainage	0.000	0.001
D4	Pond	0.018	Drainage	0.018	0.022
D4	Stream	0.002	Drainage	0.001	0.002
R1	Pond	0.031	Runoff	0.030	0.029
R1	Stream	0.025	Runoff	0.001	0.002
R3	Stream	0.105	Runoff	0.005	0.010
Step 3 Late Application					
D3	Ditch	0.001	Drainage	0.000	0.001
D4	Pond	0.024	Drainage	0.023	0.028
D4	Stream	0.003	Drainage	0.001	0.002
R1	Pond	0.045	Runoff	0.048	0.045
R1	Stream	0.034	Runoff	0.002	0.004
R3	Stream	0.115	Runoff	0.007	0.012

* Single application values are the same as for use 2 - vd. Corresponding applications table. Values above RAC in bold.

** twa-time as required by ecotox

PEC_{SW} from the FOCUS-STEPs 1-2 for the metabolite NC8493 provide an acceptable risk assessment, as all PEC_{SW} values are below the respective RAC. No further refinement is required.

PEC_{SW} from the FOCUS-STEPs 1-2 for NC20645 in surface water do not provide an acceptable risk assessment, as some of these PEC_{SW} values exceed the regulatory acceptable concentrations (RAC) for aquatic organisms in the risk assessment for aquatic organisms. Therefore, a STEP 3 approach was considered necessary.

PEC_{SW} from the FOCUS-STEP 3 for NC20645 in surface water provide an acceptable risk for all use groups. No further refinement is required.

zRMS comments:

The input parameters used for surface water modelling for ethofumesate presented in Table 8.9.2.1-1 are in line with EU agreed endpoints presented in EFSA Journal 2016;14(1):4374.

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. Therefore, the Applicant was requested to provide additional simulations with PUF value of 0, which were inserted in the report (tables marked with letter (b)).

The surface water exposure was independently validated by the zRMS in additional modelling using the EU agreed endpoints and PUF factor of 0. Results obtained by the zRMS for ethofumesate and its metabolites at Step 1-3 for the early and late applications were the same as these derived by the Applicant in updated calculations. Thus, results reported in tables above marked with letter (b) are confirmed to be correct. PEC_{SW} values at Step 3 for ethofumesate and metabolite NC20645 calculated with the PUF factor of 0.5, presented in tables marked with letter (a) were struck through in order to easily distinguish agreed from not agreed results.

Step 4 simulations were performed according to recommendations of the FOCUS work group on landscape and mitigation factors and were performed for the parent for following use groups and scenarios:

- early application: R3 scenario in use group 1, R1 and R3 scenario in use group 2, R1 and R3 scenario in use group 4, and R3 scenario in use group 5
- late applications: R1 and R3 scenario in use group 1, R1 and R3 scenarios in use group 2 and R1 and R3 scenario in use group 4, R1 and R3 scenario in use group 5

The surface water modelling at Step 4 was independently validated by the zRMS using fully EU agreed input parameters. Obtained PEC_{SW} and PEC_{SED} values were the same or slightly lower comparing to surface water exposure calculated by the Applicant.

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

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

8.9.2.2 Phenmedipham and its metabolites

All FOCUS SW site scenarios were used without any change. The concentrations presented are the maximum concentrations in the given simulation period. In case of stream and ditch, it was predicted for the last segment in the water body representing worst case conditions.

Predicted environmental concentrations in surface water for all relevant European scenarios were calculated based on the critical use pattern for product.

The PEC values for the active substance in surface water and sediment have been assessed with the FOCUS SW models and the endpoints presented in **Table 8.9.2.1-1**. Where an endpoint was not available, a worst case assumption was selected.

In case the predicted PEC_{SW} values for the Phenmedipham and / or its relevant metabolite(s), were below the ecotoxicological TER value, calculations of PEC_{SW} values at step 3 were performed using FOCUS surface water models and all relevant crop scenarios.

Input parameters for the active substance and metabolite(s) for calculation of PEC_{SW} and PEC_{SED} are presented in **Table 8.9.2.2-1**, the results in the following tables.

Table 8.9.2.2-1 Input parameters related to Phenmedipham and metabolite(s) for PEC_{SW/SED} calculations STEP 1/2 and 3(4)

Compound	Phenmedipham	MHPC	Value in accordance to EU endpoint y/n/ Reference*
Molecular weight [g/mol]	300.3	167.2	Y, 2004
Saturated vapour pressure [Pa]	7×10^{-10} (25°C)	7×10^{-10} (25°C)	Y, 2004
Water solubility [mg/L]	1.8 (20°C)	8620 (20°C) ^b	Y, 2004
K _{foc} [mL/g]	657 ^c (Minimum, n = 3)	220 (Arithmetic mean, n=4)	Y, 2004
Freundlich Exponent 1/n [-]	0.854 (n = 3)	0.742 (Arithmetic mean, n=4)	Y, 2004
Plant Uptake [-]	0	0	Focus default
Wash-Off factor from Crop [1/mm]	not required for Step 1 + 2/ 0.05 (MACRO) 0.50 (PRZM)		Focus default
DT ₅₀ Soil [d]	43 ^c (Maximum, SFO, pF2, 20°C, n = 3)	0.18 (Geomean, SFO, pF2, 20°C, n = 3)	Y, 2004 DAR, 2003
DT ₅₀ Water [d]	0.18 ^d (Maximum, SFO, 20°C n = 3)	24.9 ^a (Maximum, SFO, 20°C n = 3)	Y, 2004 DAR, 2003
DT ₅₀ Sediment [d]	Step 2: 0.18 ^d (Maximum, SFO, 20°C n = 3) Step 3+4: 1000	Step 2: 24.9 ^a (Maximum, SFO, 20°C n = 3) Step 3+4: 1000	Y, 2004 DAR, 2003
DT ₅₀ Whole system [d]	0.18 (Maximum, SFO, 20°C n = 3)	24.9 ^a (Maximum, SFO, 20°C n = 3)	Y, 2004 DAR, 2003
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 54% Total system: 70%	Y, 2004

* review report for Phenmedipham SANCO/4060/2001 -final, 2004.

a worst case.

b predicted with WSKOWWIN v1.43 (temperature conversion with EVA 3.0 rev.2h).

c less than 4 soils (SANCO/10058/2005 vs 2. Guidance document on estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration. 2006).

d DT₅₀ system used since sediment and water values not available.

PEC_{SW/SED}

Table 8.9.2.2-2 FOCUS Step 1, 2 and 3 PEC_{SW} and PEC_{SED} for Phenmedipham following six applications of product to sugar beets, use group 1

Scenario FOCUS	Waterbody	Max PEC _{SW} [µg/L]*	Dominant entry route*	21 d- PEC _{SW} , two [µg/L]**	Max PEC _{SED} [µg/kg]*
Step 1	---	28.032	-	0.689	175.107
Step 2	Northern Europe March-May	19.797 (3.998)	-	0.492 (0.099)	130.067 (26.268)
	Southern Europe March-May	39.594 (7.996)	-	0.984 (0.199)	260.135 (52.535)
	Northern Europe June-Sept	19.797 (3.998)	-	0.492 (0.099)	130.067 (26.268)
	Southern Europe June-Sept	29.696 (5.997)	-	0.738 (0.149)	195.101 (39.401)
Step 3 Early Application					
D3	Ditch	0.463 (0.786)	Drift (drift)	0.029 (0.012)	0.223 (0.162)
D4	Pond	0.090 (0.032)	Drainage (drift)	0.030 (0.002)	0.161 (0.017)
D4	Stream	0.823 (0.641)	Drainage (drift)	0.247 (0.014)	1.213 (0.092)
R1	Pond	0.275 (0.032)	Runoff (drift)	0.021 (0.003)	0.269 (0.032)
R1	Stream	6.015 (0.880)	Runoff (runoff)	0.414 (0.054)	5.545 (0.582)
R3	Stream	5.916 (1.089)	Runoff (runoff)	0.286 (0.049)	4.757 (0.890)
Step 3 Late Application					
D3	Ditch	0.463 (0.786)	Drift (drift)	0.018 (0.012)	0.191 (0.162)
D4	Pond	0.108 (0.032)	Drainage (drift)	0.032 (0.002)	0.181 (0.017)
D4	Stream	1.022 (0.641)	Drainage (drift)	0.255 (0.014)	1.255 (0.092)
R1	Pond	0.112 (0.032)	Runoff (drift)	0.006 (0.003)	0.119 (0.032)
R1	Stream	3.455 (0.880)	Runoff (runoff)	0.183 (0.054)	3.327 (0.582)
R3	Stream	4.425 (1.089)	Runoff (runoff)	0.360 (0.049)	4.718 (0.890)

* Single applications in parenthesis. Values above RAC in bold.

** two-time as required by ecotox

Table 8.9.2.2-3 FOCUS Step 1, 2 and 3 PEC_{SW} and PEC_{SED} for Phenmedipham following three applications of product to sugar beets, use group 2

Scenario FOCUS	Waterbody	Max PEC _{SW} [µg/L]*	Dominant entry route*	21 d- PEC _{SW} , two [µg/L]**	Max PEC _{SED} [µg/kg]*
Step 1	---	56.064	--	1.377	350.213
Step 2	Northern Europe March-May	21.845 (2.999)	--	0.543 (0.075)	143.523 (19.701)
	Southern Europe March-May	43.690 (5.997)	--	1.085 (0.149)	287.045 (39.401)
	Northern Europe June-Sept	21.845 (2.999)	--	0.543 (0.075)	143.523 (19.701)
	Southern Europe June-Sept	32.768 (4.498)	--	0.814 (0.112)	215.284 (29.551)
Step 3 Early Application					
D3	Ditch	1.143 (1.572)	Drift (drift)	0.035 (0.024)	0.365 (0.319)
D4	Pond	0.080 (0.063)	Drainage (drift)	0.028 (0.006)	0.160 (0.039)
D4	Stream	0.959 (1.282)	Drift (drift)	0.247 (0.045)	1.225 (0.241)
R1	Pond	0.227 (0.063)	Runoff (drift)	0.019 (0.005)	0.194 (0.061)
R1	Stream	7.108 (1.900)	Runoff (runoff)	0.411 (0.114)	3.656 (1.110)
R3	Stream	8.977 (2.363)	Runoff (runoff)	0.427 (0.106)	6.721 (1.786)
Step 3 Late Application					
D3	Ditch	1.142 (1.570)	Drift (drift)	0.044 (0.021)	0.320 (0.284)
D4	Pond	0.108 (0.063)	Drainage (drift)	0.034 (0.005)	0.184 (0.042)
D4	Stream	1.001 (1.198)	Drainage (drift)	0.277 (0.036)	1.350 (0.234)
R1	Pond	0.251 (0.135)	Runoff (runoff)	0.012 (0.007)	0.244 (0.169)
R1	Stream	7.059 (2.246)	Runoff (runoff)	0.290 (0.148)	6.620 (3.880)
R3	Stream	5.442 (1.537)	Runoff (drift)	0.453 (0.126)	5.923 (1.867)

* Single applications in parenthesis. Values above RAC in bold.

** two-time as required by ecotox

Table 8.9.2.2-4 FOCUS Step 1, 2 and 3 PEC_{SW} and PEC_{SED} for Phenmedipham following five applications of product to sugar beets, use group 3

Scenario FOCUS	Waterbody	Max PEC _{SW} [µg/L]*	Dominant entry route*	21 d- PEC _{SW} , two [µg/L]**	Max PEC _{SED} [µg/kg]*
Step 1	---	28.030	-	0.69	175.110
Step 2	Northern Europe March-May	16.156 (3.998)	-	0.401 (0.099)	106.144 (26.268)
	Northern Europe June-Sept	16.156 (3.998)	-	0.401 (0.099)	106.144 (26.268)
	Southern Europe March-May	32.312 (7.996)	-	0.803 (0.19)	212.288 (52.535)
	Southern Europe June-Sept	24.234 (5.997)	-	0.602 (0.149)	159.216 (39.401)
Step 3 Early Application					
D3	Ditch	0.507	Drift	0.016	0.180
D4	Pond	0.071	Drainage	0.023	0.126
D4	Stream	0.650	Drainage	0.186	0.931
R1	Pond	0.122	Runoff	0.011	0.161
R1	Stream	3.654	Runoff	0.230	4.019
R3	Stream	4.127	Runoff	0.202	3.324
Step 3 Late Application					
D3	Ditch	0.507	Drift	0.020	0.181
D4	Pond	0.086	Drainage	0.025	0.145
D4	Stream	0.815	Drainage	0.196	0.964
R1	Pond	0.090	Runoff	0.005	0.115
R1	Stream	2.533	Runoff	0.119	3.003
R3	Stream	3.292	Runoff	0.320	4.676

* Single application values are the same as for 6 applications- vd. Corresponding 6 applications table. Values above RAC in bold.

** two-time as required by ecotox

Table 8.9.2.2-5 FOCUS Step 1, 2 and 3 PEC_{SW} and PEC_{SED} for Phenmedipham following three applications of product to sugar beets, use group 4

Scenario FOCUS	Waterbody	Max PEC _{SW} [µg/L]*	Dominant entry route*	21 d- PEC _{SW} , two [µg/L]**	Max PEC _{SED} [µg/kg]*
Step 1	---	42.048	--	1.033	262.660
Step 2	Northern Europe March-May	16.384 (5.997)	--	0.407 (0.149)	107.642 (39.401)
	Northern Europe June-Sept	16.384 (5.997)	--	0.407 (0.149)	107.642 (39.401)
	Southern Europe March-May	32.768 (11.994)	--	0.814 (0.298)	215.284 (78.803)
	Southern Europe June-Sept	24.576 (8.996)	--	0.611 (0.224)	161.463 (59.102)
Step 3 Early Application					
D3	Ditch	0.857 (1.179)	Drift (drift)	0.027 (0.018)	0.277 (0.241)
D4	Pond	0.057 (0.048)	Drainage (drift)	0.019 (0.004)	0.108 (0.028)
D4	Stream	0.719 (0.962)	Drift (drift)	0.159 (0.028)	0.810 (0.156)
R1	Pond	0.165 (0.048)	Runoff (drift)	0.014 (0.004)	0.147 (0.046)
R1	Stream	5.170 (1.381)	Runoff (runoff)	0.302 (0.083)	2.793 (0.848)
R3	Stream	6.505 (1.715)	Runoff (runoff)	0.310 (0.077)	5.023 (1.337)
Step 3 Late Application					
D3	Ditch	0.857 (1.177)	Drift (drift)	0.033 (0.016)	0.243 (0.214)
D4	Pond	0.075 (0.048)	Drainage (drift)	0.022 (0.004)	0.128 (0.029)
D4	Stream	0.713 (0.899)	Drainage (drift)	0.169 (0.023)	0.839 (0.163)
R1	Pond	0.181 (0.097)	Runoff (runoff)	0.008 (0.005)	0.184 (0.128)
R1	Stream	5.094 (1.620)	Runoff (runoff)	0.210 (0.108)	4.974 (2.966)
R3	Stream	3.939 (1.152)	Runoff (drift)	0.330 (0.092)	4.511 (1.427)

* Single applications in parenthesis. Values above RAC in bold.

** two-time as required by ecotox

Table 8.9.2.2-6 FOCUS Step 1, 2 and 3 PEC_{SW} and PEC_{SED} for Phenmedipham following three applications of product to sugar beets, use group 5

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	---	56.064	--	1.377	350.213
Step 2	Northern Europe March-May	20.895 (7.996)	--	0.519 (0.199)	137.280 (52.535)
	Northern Europe June-Sept	20.895 (7.996)	--	0.519 (0.199)	137.280 (52.535)
	Southern Europe March-May	41.790 (15.992)	--	1.038 (0.397)	274.559 (105.070)
	Southern Europe June-Sept	31.342 (11.994)	--	0.779 (0.298)	205.920 (78.803)
Step 3 Early Application					
D3	Ditch	1.143 (1.572)	Drift (drift)	0.036 (0.024)	0.365 (0.319)
D4	Pond	0.087 (0.063)	Drainage (drift)	0.030 (0.006)	0.165 (0.039)
D4	Stream	0.959 (1.282)	Drift (drift)	0.254 (0.045)	1.254 (0.241)
R1	Pond	0.148 (0.063)	Runoff (drift)	0.014 (0.005)	0.157 (0.061)
R1	Stream	4.613 (1.900)	Runoff (runoff)	0.289 (0.114)	3.771 (1.110)
R3	Stream	5.708 (2.364)	Runoff (runoff)	0.282 (0.106)	4.538 (1.786)
Step 3 Late Application					
D3	Ditch	1.142 (1.570)	Drift (drift)	0.044 (0.021)	0.313(0.284)
D4	Pond	0.103 (0.063)	Drainage (drift)	0.031 (0.005)	0.174 (0.042)
D4	Stream	0.972 (1.198)	Drainage (drift)	0.247 (0.036)	1.201 (0.234)
R1	Pond	0.146 (0.135)	Runoff (runoff)	0.007 (0.007)	0.143 (0.169)
R1	Stream	4.114 (2.246)	Runoff (runoff)	0.173 (0.148)	3.882 (3.880)
R3	Stream	5.442 (1.537)	Runoff (drift)	0.453 (0.126)	5.923 (1.867)

* Single applications in parenthesis. Values above RAC in bold.

** twa-time as required by ecotox

PEC_{SW} from the FOCUS-STEPs 1-2 for Phenmedipham in surface water do not provide an acceptable risk assessment, as some of these PEC_{SW} values exceed the regulatory acceptable concentrations (RAC) for aquatic organisms in the risk assessment for aquatic organisms. Therefore, a STEP 3 approach was considered necessary.

PEC_{SW} from the FOCUS-STEP 3 for Phenmedipham in surface water does not provide an acceptable risk assessment, as the PEC_{SW} value for the R1 and R3 stream scenarios for all the uses (except single application), exceeds the RAC of 2.5 µg/L. Further refinement is required by including risk mitigation measures.

FOCUS Step 4

Table 8.9.2.2-7 Global maximum PEC_{SW} values for Phenmedipham, following multiple application(s) of product HBZ10 to sugar beets according to the central EU zone GAP according to surface water Step 4 – Early Application

	PEC _{SW} [µg/L]	Scenario	STEP 4 Phenmedipham – Early Application						
	Nozzle reduction [%]	Vegetative strip [m]	None	None	None	None	None	10	20
		No spray buffer [m]	1/3	5	10	15	20	10	20
6 Applications at 150 g a.s/ha, use group 1	None	R1 stream	-	-	-	-	-	2.726	1.425
	50		-	-	-	-	-	-	-
	75		-	-	-	-	-	-	-
	90		-	-	-	-	-	-	-
	None	R3 stream	-	-	-	-	-	2.695	1.413

	PEC _{sw} [µg/L]	Scenario	STEP 4 Phenmedipham – Early Application						
6 Applications at 150 g a.s/ha, use	Nozzle reduction [%]	Vegetative strip [m]	None	None	None	None	None	10	20
		No spray buffer [m]	1/3	5	10	15	20	10	20
	50		-	-	-	-	-	-	-
	75		-	-	-	-	-	-	-
	90		-	-	-	-	-	-	-
3 Applications at 300 g a.s/ha, use group 2	None	R1 stream	-	-	-	-	-	3.216	1.682
	50		-	-	-	-	-	-	-
	75		-	-	-	-	-	-	-
	90		-	-	-	-	-	-	-
3 Applications at 300 g a.s/ha, use group 2	None	R3 stream	-	-	-	-	-	4.089	2.144
	50		-	-	-	-	-	-	-
	75		-	-	-	-	-	-	-
	90		-	-	-	-	-	-	-
5 applications at 150 g a.s/ha, use group 3	None	R1 stream	-	-	-	-	-	1.653	-
	50		-	-	-	-	-	-	-
	75		-	-	-	-	-	-	-
	90		-	-	-	-	-	-	-
5 applications at 150 g a.s/ha, use group 3	None	R3 stream	-	-	-	-	-	1.880	-
	50		-	-	-	-	-	-	-
	75		-	-	-	-	-	-	-
	90		-	-	-	-	-	-	-
3 applications at 225 g a.s/ha, use group 4	None	R1 stream	-	-	-	-	-	2.340	-
	50		-	-	-	-	-	-	-
	75		-	-	-	-	-	-	-
	90		-	-	-	-	-	-	-
3 applications at 225 g a.s/ha, use group 4	None	R3 stream						2.963	1.553
	50		-	-	-	-	-	-	-
	75		-	-	-	-	-	-	-
	90		-	-	-	-	-	-	-
3 applications at 300 g a.s/ha, use group 5	None	R1 stream	-	-	-	-	-	2.087	-
	50		-	-	-	-	-	-	-
	75		-	-	-	-	-	-	-
	90		-	-	-	-	-	-	-
3 applications at 300 g a.s/ha, use group 5	None	R3 stream	-	-	-	-	-	2.600	1.363
	50		-	-	-	-	-	-	-
	75		-	-	-	-	-	-	-
	90		-	-	-	-	-	-	-

Table 8.9.2.2-8 Global maximum PEC_{sw} values for Phenmedipham, following multiple application(s) of product HBZ10 to sugar beets according to the central EU zone GAP according to surface water Step 4 – Late Application

	PEC _{sw} [µg/L]	Scenario	STEP 4 Phenmedipham – Late Application						
	Nozzle reduction [%]	Vegetative strip [m]	None	None	None	None	None	10	20
		No spray buffer [m]	1/3	5	10	15	20	10	20
6 Applications at 150 g a.s/ha, use group 1	None	R1 stream	-	-	-	-	-	1.508	-
	50		-	-	-	-	-	-	-
	75		-	-	-	-	-	-	-
	90		-	-	-	-	-	-	-
6 Applications at 150 g a.s/ha, use group 1	None	R3 stream	-	-	-	-	-	2.010	-
	50		-	-	-	-	-	-	-
	75		-	-	-	-	-	-	-
	90		-	-	-	-	-	-	-
3 Applications at 300 g a.s/ha, use group 2	None	R1 stream	-	-	-	-	-	3.200	1.675
	50		-	-	-	-	-	-	-
	75		-	-	-	-	-	-	-
	90		-	-	-	-	-	-	-
3 Applications at 300 g a.s/ha, use group 2	None	R3 stream	-	-	-	-	-	2.472	-
	50		-	-	-	-	-	-	-
	75		-	-	-	-	-	-	-
	90		-	-	-	-	-	-	-
5 applications at 150 g a.s/ha, use group 3	None	R1 stream	-	-	-	-	-	1.148	-
	50		-	-	-	-	-	-	-
	75		-	-	-	-	-	-	-
	90		-	-	-	-	-	-	-
5 applications at 150 g a.s/ha, use group 3	None	R3 stream	-	-	-	-	-	1.496	-
	50		-	-	-	-	-	-	-
	75		-	-	-	-	-	-	-
	90		-	-	-	-	-	-	-
3 applications at 225 g a.s/ha, use group 4	None	R1 stream	-	-	-	-	-	2.308	-
	50		-	-	-	-	-	-	-
	75		-	-	-	-	-	-	-
	90		-	-	-	-	-	-	-
3 applications at 225 g a.s/ha, use group 4	None	R3 stream	-	-	-	-	-	1.789	-
	50		-	-	-	-	-	-	-
	75		-	-	-	-	-	-	-
	90		-	-	-	-	-	-	-
3 applications at 300 g a.s/ha, use group 5	None	R1 stream	-	-	-	-	-	1.864	-
	50		-	-	-	-	-	-	-
	75		-	-	-	-	-	-	-
	90		-	-	-	-	-	-	-
3 applications at 300 g a.s/ha, use group 5	None	R3 stream	-	-	-	-	-	2.472	-
	50		-	-	-	-	-	-	-
	75		-	-	-	-	-	-	-
	90		-	-	-	-	-	-	-

The implementation of a no spray buffer zone and vegetated strip of 10 m is sufficient to reach safe values for Phenmedipham for all scenarios in use groups 3 in beets, including when considering mixture toxicity.

The implementation of a no spray buffer zone and vegetated strip of 20 m is sufficient to reach safe values for Phenmedipham for all scenarios in use groups 1, 2, 4 and 5 in beets, including when considering mixture toxicity.

Metabolite of Phenmedipham

Table 8.9.2.2-9 FOCUS Step 1, 2 and 3 PEC_{SW} and PEC_{SED} for metabolite MHPC following six applications of product to sugar beets, use group 1

Scenario FOCUS	Waterbody	Max PEC _{SW} [µg/L]*	Dominant entry route*	21 d- PEC _{SW} , two [µg/L]**	Max PEC _{SED} [µg/kg]*
Step 1	---	163.371	-	123.173	352.319
Step 2	Northern Europe March-May	12.228 (2.663)	-	9.203 (1.994)	26.142 (5.632)
	Southern Europe March-May	23.420 (4.923)	-	17.678 (3.706)	50.764 (10.535)
	Northern Europe June-Sept	12.228 (2.663)	-	9.203 (1.994)	26.142 (5.632)
	Southern Europe June-Sept	17.824 (3.793)	-	13.440 (2.850)	38.453 (8.050)
Step 3 Early Application					
D3	Ditch	0.116 (0.190)	Drainage (drainage)	-	0.202 (0.143)
D4	Pond	0.136 (0.011)	Drainage (drainage)	-	0.914 (0.113)
D4	Stream	0.299 (0.040)	Drainage (drift)	-	0.448 (0.038)
R1	Pond	0.256 (0.033)	Runoff (runoff)	-	1.030 (0.235)
R1	Stream	2.236 (0.330)	Runoff (runoff)	-	1.273 (0.185)
R3	Stream	2.182 (0.402)	Runoff (runoff)	-	1.303 (0.271)
Step 3 Late Application					
D3	Ditch	0.125 (0.190)	Drift (drainage)	-	0.239 (0.143)
D4	Pond	0.147 (0.011)	Drainage (drainage)	-	1.241 (0.113)
D4	Stream	0.372 (0.040)	Drainage (drift)	-	0.515 (0.038)
R1	Pond	0.097 (0.033)	Runoff (runoff)	-	0.861 (0.235)
R1	Stream	1.780 (0.330)	Runoff (runoff)	-	0.922 (0.185)
R3	Stream	1.711 (0.402)	Runoff (runoff)	-	1.323 (0.271)

* Single applications in parenthesis. Values above RAC in bold.

** two-time as required by ecotox

Table 8.9.2.2-10 FOCUS Step 1, 2 and 3 PEC_{SW} and PEC_{SED} for metabolite MHPC following three applications of product to sugar beets, use group 2

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	---	163.371	-	123.173	352.319
Step 2	Northern Europe March-May	13.862 (5.325)	-	10.414 (3.988)	29.415 (11.264)
	Southern Europe March-May	26.212 (9.846)	-	19.766 (7.411)	56.557 (21.070)
	Northern Europe June-Sept	13.862 (5.325)	-	10.414 (3.988)	29.415 (11.264)
	Southern Europe June-Sept	20.037 (7.585)	-	15.090 (5.700)	42.972 (16.100)
Step 3 Early Application					
D3	Ditch	0.282 (0.380)	Drainage (drainage)	-	0.315 (0.269)
D4	Pond	0.134 (0.025)	Drainage (drainage)	-	0.904 (0.197)
D4	Stream	0.259 (0.080)	Drainage (drift)	-	0.449 (0.097)
R1	Pond	0.243 (0.070)	Runoff (runoff)	-	0.966 (0.333)
R1	Stream	2.664 (0.706)	Runoff (runoff)	-	1.104 (0.348)
R3	Stream	3.312 (0.864)	Runoff (runoff)	-	1.917 (0.555)
Step 3 Late Application					
D3	Ditch	0.303 (0.376)	Drainage (drift)	-	0.311 (0.233)
D4	Pond	0.155 (0.024)	Drainage (drainage)	-	1.031 (0.172)
D4	Stream	0.364 (0.090)	Drainage (drainage)	-	0.494 (0.092)
R1	Pond	0.220 (0.141)	Runoff (runoff)	-	0.670 (0.594)
R1	Stream	2.698 (0.843)	Runoff (runoff)	-	1.456 (0.478)
R3	Stream	2.104 (0.593)	Runoff (runoff)	-	1.357 (0.400)

* Single applications in parenthesis. Values above RAC in bold.

** twa-time as required by ecotox

Table 8.9.2.2-11 FOCUS Step 1, 2 and 3 PEC_{SW} and PEC_{SED} for metabolite MHPC following five applications of product to sugar beets, use group 3

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	---	136.140	-	102.644	293.600
Step 2	Northern Europe March-May	10.053 (2.663)	-	7.562 (1.994)	21.443 (5.632)
	Northern Europe June-Sept	10.053 (2.663)	-	7.562 (1.994)	21.443 (5.632)
	Southern Europe March-May	19.187 (4.923)	-	14.479 (3.706)	41.536 (10.535)
	Southern Europe June-Sept	14.620 (3.793)	-	11.020 (2.850)	31.489 (8.050)
Step 3 Early Application					
D3	Ditch	0.132	Drainage	-	0.165
D4	Pond	0.103	Drainage	-	0.711
D4	Stream	0.237	Drainage	-	0.349
R1	Pond	0.167	Runoff	-	0.721
R1	Stream	1.369	Runoff	-	0.901
R3	Stream	1.522	Runoff	-	0.933
Step 3 Late Application					
D3	Ditch	0.137	Drift	-	0.220
D4	Pond	0.113	Drainage	-	0.973
D4	Stream	0.297	Drainage	-	0.386
R1	Pond	0.101	Runoff	-	0.718
R1	Stream	1.188	Runoff	-	0.690
R3	Stream	1.263	Runoff	-	1.144

* Single application values are the same as for 6 applications- vd. Corresponding 6 applications table. Values above RAC in bold.

** twa-time as required by ecotox

Table 8.9.2.2-12 FOCUS Step 1, 2 and 3 PEC_{SW} and PEC_{SED} for metabolite MHPC following three applications of product to sugar beets, use group 4

Scenario FOCUS	Waterbody	Max PEC _{SW} [µg/L]*	Dominant entry route*	21 d- PEC _{SW} , tw [µg/L]**	Max PEC _{SED} [µg/kg]*
Step 1	---	122.528	--	92.380	264.239
Step 2	Northern Europe March-May	10.397 (3.994)	--	7.810 (2.991)	22.061 (8.448)
	Northern Europe June-Sept	10.397 (3.994)	--	7.810 (2.991)	22.061 (8.448)
	Southern Europe March-May	19.659 (7.384)	--	14.824 (5.558)	42.418 (15.803)
	Southern Europe June-Sept	15.028 (5.689)	--	11.317 (4.275)	32.229 (12.075)
Step 3 Early Application					
D3	Ditch	0.211 (0.285)	Drainage (drainage)	-	0.271 (0.209)
D4	Pond	0.088 (0.016)	Drainage (drainage)	-	0.816 (0.194)
D4	Stream	0.186 (0.060)	Drainage (drift)	-	0.337 (0.067)
R1	Pond	0.179 (0.051)	Runoff (runoff)	-	0.972 (0.343)
R1	Stream	1.938 (0.518)	Runoff (runoff)	-	0.874 (0.276)
R3	Stream	2.400 (0.632)	Runoff (runoff)	-	1.438 (0.416)
Step 3 Late Application					
D3	Ditch	0.227 (0.282)	Drainage (drainage)	-	0.267 (0.181)
D4	Pond	0.098 (0.017)	Drainage (drainage)	-	0.866 (0.172)
D4	Stream	0.259 (0.064)	Drainage (drainage)	-	0.342 (0.066)
R1	Pond	0.160 (0.105)	Runoff (runoff)	-	0.694 (0.596)
R1	Stream	1.947 (0.608)	Runoff (runoff)	-	1.088 (0.406)
R3	Stream	1.523 (0.427)	Runoff (runoff)	-	1.135 (0.327)

* Single applications in parenthesis. Values above RAC in bold.

** twa-time as required by ecotox

Table 8.9.2.2-13 FOCUS Step 1, 2 and 3 PEC_{SW} and PEC_{SED} for metabolite MHPC following three applications of product to sugar beets, use group 5

Scenario FOCUS	Waterbody	Max PEC _{SW} [µg/L]*	Dominant entry route*	21 d- PEC _{SW} , tw [µg/L]**	Max PEC _{SED} [µg/kg]*
Step 1	---	163.371	--	123.173	352.319
Step 2	Northern Europe March-May	13.220 (5.325)	--	9.933 (3.988)	28.058 (11.264)
	Northern Europe June-Sept	13.220 (5.325)	--	9.933 (3.988)	28.058 (11.264)
	Southern Europe March-May	25.032 (9.846)	--	18.878 (7.411)	54.039 (21.070)
	Southern Europe June-Sept	19.126 (7.585)	--	14.406 (5.700)	41.045 (16.100)
Step 3 Early Application					
D3	Ditch	0.281 (0.380)	Drainage (drainage)	-	0.351 (0.273)
D4	Pond	0.141 (0.026)	Drainage (drainage)	-	1.221 (0.287)
D4	Stream	0.285 (0.080)	Drainage (drift)	-	0.513 (0.103)
R1	Pond	0.194 (0.070)	Runoff (runoff)	-	1.107 (0.448)
R1	Stream	1.729 (0.712)	Runoff (runoff)	-	1.104 (0.366)
R3	Stream	2.106 (0.872)	Runoff (runoff)	-	1.274 (0.561)
Step 3 Late Application					
D3	Ditch	0.304 (0.376)	Drainage (drainage)	-	0.345 (0.237)
D4	Pond	0.142 (0.024)	Drainage (drainage)	-	1.206 (0.247)
D4	Stream	0.354 (0.090)	Drainage (drainage)	-	0.485 (0.094)
R1	Pond	0.135 (0.143)	Runoff (runoff)	-	0.805 (0.784)
R1	Stream	1.632 (0.843)	Runoff (runoff)	-	0.900 (0.534)
R3	Stream	2.104 (0.593)	Runoff (runoff)	-	1.515 (0.438)

* Single applications in parenthesis. Values above RAC in bold.

** twa-time as required by ecotox

PEC_{SW} from the FOCUS-STEPs 1-2 for MHPC in surface water do not provide an acceptable risk assessment, as some of these PEC_{SW} values exceed the regulatory acceptable concentrations (RAC) for aquatic organisms in the risk assessment for aquatic organisms. Therefore, a STEP 3 approach was considered necessary.

PEC_{SW} from the FOCUS-STEP 3 for MHPC in surface water provide an acceptable risk assessment, as the PEC_{SW} abide the RAC of 12.8 µg/L.

zRMS comments:

Input parameters presented in Table 8.9.2.2-1 used for surface water modelling for phenmedipham and its metabolite MHPC are in line with EU agreed endpoints reported in Review Report (2004) and DAR (2003).

In Step 3 simulations PUF value of 0 was assumed, in line with current recommendations.

The surface water exposure was independently validated by the zRMS in additional simulations using the same input parameters. Results obtained by the zRMS at Step 1-4 were in good agreement with values obtained by the Applicant. Overall, the surface water exposure of for phenmedipham and its metabolite presented in Tables 8.9.2.2-3 to 8.9.2.2-13 may be used in the aquatic risk assessment.

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

8.9.2.3 PEC_{SW}/SED of formulation HBZ10

The PEC_{SW} values for the product HBZ10 based on drift only were calculated using the FOCUS SWASH Drift calculator. The water body stream was corrected for upstream input with a factor of 1.2. Only PEC_{SW} values were calculated, no transfer into sediment was assumed.

The maximum application rate per treatment is 2.4 L product/ha which corresponds to 2347.2 g product/ha based on a product density of 0.978 g/mL. Calculations were performed for single application of the product in sugar beets. The maximum initial PEC_{SW} from spray drift entry are presented in the table below.

Table 8.9.2.3-1 Initial predicted surface water concentration [µg/L] of product HBZ10 from spray drift entry following single application in sugar beets

Crop	Nozzle mitigation	Distance				
		FOCUS Default	5 m	10 m	14 m	20 m
Sugar beet (single application)	None	11.654	4.905	2.601	1.897	1.352

Additionally, PEC_{SW} values for the product HBZ10, for an application rate per treatment of 1.8 L product/ha was calculated.

Table 8.9.2.3-2 Initial predicted surface water concentration [µg/L] of product HBZ10 from spray drift entry following single application in sugar beets

Crop	Nozzle mitigation	Distance				
		FOCUS Default	5 m	10 m	14 m	20 m
Sugar beet (single application)	None	8.740	3.679	1.951	1.422	1.014

zRMS comments:

The surface water exposure to formulation was validated by the zRMS using Spray Drift Calculator. Obtained results were in agreement with these reported in tables above.

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	Not studied
Quantum yield of direct phototransformation	$1.92 \times 10^{-4} \text{ mol} \times \text{Einstein}^{-1}$
Photochemical oxidative degradation in air	DT ₅₀ (h): 4.1 derived by the Atkinson model OH (24 h) concentration assumed = 5×10^5
Volatilisation	No volatilisation expected Vapour pressure (Pa) at 25°C: 6.5×10^{-4} Vapour pressure (Pa) at 20°C: 3.6×10^{-4} Henry's Law Constant (Pa m ³ /mol): 3.72×10^{-3}
Metabolites	None

Ethofumesate has a vapour pressure of 6.5×10^{-4} Pa (25°C) and Henry's law constant of 3.72×10^{-4} Pa·m³/mol (25°C). Additionally, the photochemical oxidative degradation in air for Ethofumesate was estimated to be 4.1 hours (calculated according to Atkinson) and therefore, long-range transport and accumulation in the stratosphere is deemed unlikely. Considering the relatively short half-life in the air, it is not expected that Ethofumesate can be transported in the gaseous phase over long distances or can accumulate in the air.

Hence the active substance Ethofumesate is regarded as semi volatile (volatilisation only from plant surfaces). Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance Ethofumesate due to volatilisation with subsequent dry deposition should be considered.

Table 8.10-2 Summary of atmospheric degradation and behaviour

Compound	Phenmedipham
Direct photolysis in air	Not studied, no data required
Quantum yield of direct phototransformation	-
Photochemical oxidative degradation in air	DT ₅₀ (h): 6.7 derived by the Atkinson model
Volatilisation	Vapour pressure [Pa]: 7×10^{-10} (25°C) Henry's Law Constant [Pa·m ³ /mol]: 5×10^{-8} (20°C)
Metabolites	No data required

The low vapour pressure (7×10^{-10} Pa (25°C)), low Henry's law constant (5×10^{-8} Pa·m³/mol (20°C) and short DT₅₀ value for hydrolysis of Phenmedipham indicate a low volatility and thus, a negligible environmental concentration in air.

Therefore, exposure of adjacent surface waters and terrestrial ecosystems by Phenmedipham due to volatilization with subsequent deposition should not 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 on vapour pressure was added by the zRMS for completeness.

Information regarding fate and behaviour of phenmedipham in the air presented in Table 8.10-2 is in line with the EU agreed data reported in Review Report, 2004 for phenmedipham. Taking into account the low vapour pressure ($<10^{-5}$ Pa) and DT₅₀ in air <2 days, phenmedipham is not expected to be subject to volatilisation and the long- or short-range transport.

Taking into account the above data, the contamination of the atmosphere from the intended uses of HBZ10 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	Lindim, C.	2021a	CALCULATION OF PREDICTED ENVIRONMENTAL CONCENTRATIONS IN GROUNDWATER (PECGW) FOR THE ACTIVE SUBSTANCES ETHOFUMESATE AND PHENMEDIPHAM INCLUDING MAJOR METABOLITES USING THE MODEL SOFTWARE FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3 AND FOCUS MACRO 5.5.4 - PRODUCT HBZ10 - Report No. 1182122-CP-090204-01-CEU GAB Consulting GmbH, Stade, Germany GLP/GEP: no Published: no	N	UPL
KCP 9.2.5/01	Lindim, C.	2021b	CALCULATION OF PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SURFACE WATER (PECSW) AND SEDIMENT (PECSED) FOR THE ACTIVE SUBSTANCES ETHOFUMESATE AND PHENMEDIPHAM INCLUDING MAJOR METABOLITES USING FOCUS SW MODELLING SOFTWARE AND SCENARIOS - PRODUCT HBZ10 - Report No. 1182122-CP-090205-01-CEU GAB Consulting GmbH, Stade, Germany GLP/GEP: no Published: no	N	UPL

*The sponsor company UPL Europe Ltd is the owner of all studies (abbreviation UPL)

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 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
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All the data for particular active compounds were taken from the EFSA conclusion (ethofumesate) and Review Report (phenmedipham) and were thus evaluated at the EU level. For list of respective studies, please refer to Vol. 2 of the monograph for individual substances.

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
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There were no data not submitted by the Applicant and relied on.

Appendix 2 Detailed evaluation of the new Annex II studies

No new data.

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

Appendix 3.1 Predicted environmental concentrations soil - ESCAPE v. 2.0 for Ethofumesate

3 Applications, use group 2

ESCAPE Estimation of Soil Concentrations After PEsticide Applications

developed by Michael Klein

Program version: 2.0 (26 November 2019)
Date of this simulation: 17/03/2021, 15:14:30
Calculation problem: Programcheck

PROGRAM SETTINGS

Calculation mode: Residues from different applications are considered
separately over one year
Application mode: Single annual application pattern (calculation period 1 year)

SCENARIO DATA USED IN THE CALCULATION

Name of the scenario: Programcheck
Name of the soil: Borstel
Soil density (kg/L): 1.5
Soil depth (cm): 5
Tillage depth (cm)*: 20
Organic carbon content (%): 1.5
Field capacity (Vol%): 29.2
Wilting point (Vol%): 6.4

Climatic conditions: 20 °C constant
(* for calculation of background concentrations)

APPLICATION PATTERN USED IN THE CALCULATION

Crop rotation: every year
Number of Applications : 3
1st Application date: 10 May
Application rate (g/ha): 300
Time between two applications (d): 6
Crop interception (%): 20

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme: Parent compound without metabolites

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

Soil study: soil study 1

Metabolism scheme: Parent compound without metabolites

Kinetics for Programcheck: Single First order (SFO)
DT50 (d): 157
Rate constant (1/d): 0.0044
Q10-factor: 2.58
Walker-exponent: 0.7
Ref. temperature (°C): 20

RESULTS OF THE CALCULATION

Metabolism scheme: Parent compound without metabolites

RESULTS FOR: Programcheck

Calculations over one year

Maximum annual total soil concentration for Programcheck over 5 cm(mg/kg): 0.9351 occurring on day 12

Calculated time dependent total soil concentrations over 5 cm for Programcheck after one year (mg/kg)

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.9310	0.9331	12	13
2	0.9269	0.9310	12	14
4	0.9188	0.9269	12	16
7	0.9067	0.9208	12	19
14	0.8791	0.9068	12	26
21	0.8523	0.8931	12	33
28	0.8264	0.8796	12	40
42	0.7769	0.8535	12	54
50	0.7499	0.8396	11	61
100	0.6014	0.7584	6	106

(* PECact values are related to the time after the maximum concentration)

Calculation of background concentrations after many years

Final Background concentration in total soil for Programcheck over 20 cm(mg/kg):
0.0583**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): 0.0583

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for Programcheck over 5 cm considering accumulation* (mg/kg)
0.9934

(* a tillage depth of 20 cm was considered for calculating the background concentration)

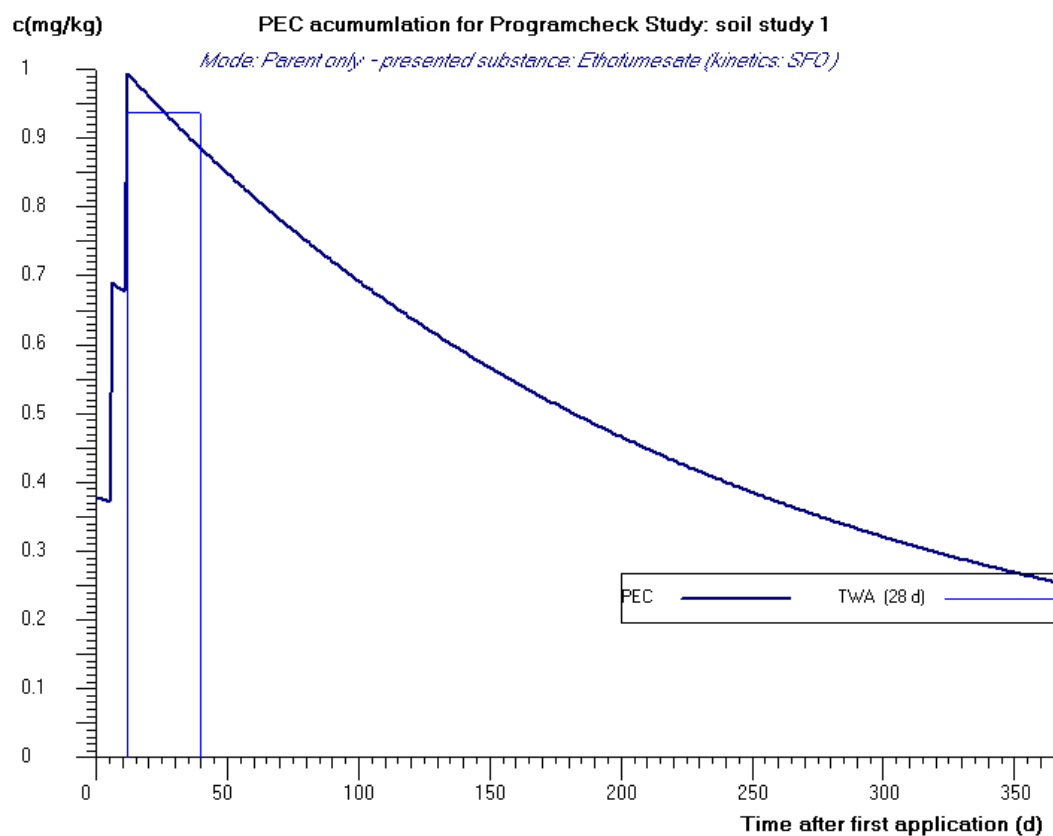
Calculated time dependent total soil concentrations over 5 cm for Programcheck(mg/kg) considering accumulation*

Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.9893	0.9914	12	13
2	0.9852	0.9893	12	14
4	0.9771	0.9852	12	16
7	0.9650	0.9791	12	19
14	0.9374	0.9651	12	26
21	0.9106	0.9514	12	33
28	0.8847	0.9379	12	40
42	0.8351	0.9118	12	54
50	0.8082	0.8979	11	61
100	0.6597	0.8167	6	106

(* a tillage depth of 20 cm was considered for calculating the background concentration)

(** PECact values are related to the time after the maximum concentration)'

GRAPHIC REPRESENTATION OF THE CALCULATION



Single Application

ESCAPE

Estimation of Soil Concentrations After Pesticide Applications

developed by Michael Klein

Program version: 2.0 (26 November 2019)
Date of this simulation: 22/04/2021, 12:44:20
Calculation problem: Programcheck

PROGRAM SETTINGS

Calculation mode: Residues from different applications are considered
separately over one year
Application mode: Single annual application pattern (calculation period 1 year)

SCENARIO DATA USED IN THE CALCULATION

Name of the scenario: Programcheck
Name of the soil: Borstel
Soil density (kg/L): 1.5
Soil depth (cm): 5
Tillage depth (cm)*: 20
Organic carbon content (%): 1.5
Field capacity (Vol%): 29.2
Wilting point (Vol%): 6.4

Climatic conditions: 20 °C constant
(* for calculation of background concentrations)

APPLICATION PATTERN USED IN THE CALCULATION

Crop rotation: every year

Application date: 10 May
Application rate (g/ha): 300
Crop interception (%): 20

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme: Parent compound without metabolites

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

Soil study: soil study 1

Metabolism scheme: Parent compound without metabolites

Kinetics for Programcheck: Single First order (SFO)
DT50 (d): 157
Rate constant (1/d): 0.0044
Q10-factor: 2.58
Walker-exponent: 0.7
Ref. temperature (°C): 20

RESULTS OF THE CALCULATION

Metabolism scheme: Parent compound without metabolites

RESULTS FOR: Programcheck

Calculations over one year

Maximum annual total soil concentration for Programcheck over 5 cm(mg/kg): 0.3200 occurring on day 0

Calculated time dependent total soil concentrations over 5 cm for Programcheck after one year (mg/kg)

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.3186	0.3193	0	1
2	0.3172	0.3186	0	2
4	0.3144	0.3172	0	4
7	0.3103	0.3151	0	7
14	0.3008	0.3103	0	14
21	0.2917	0.3056	0	21
28	0.2828	0.3010	0	28
42	0.2658	0.2921	0	42
50	0.2566	0.2871	0	50
100	0.2058	0.2587	0	100

(* PECact values are related to the time after the first application)

Calculation of background concentrations after many years

Final Background concentration in total soil for Programcheck over 20 cm(mg/kg):
0.0199**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): 0.0199

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for Programcheck over 5 cm considering accumulation* (mg/kg)
0.3399

(* a tillage depth of 20 cm was considered for calculating the background concentration)

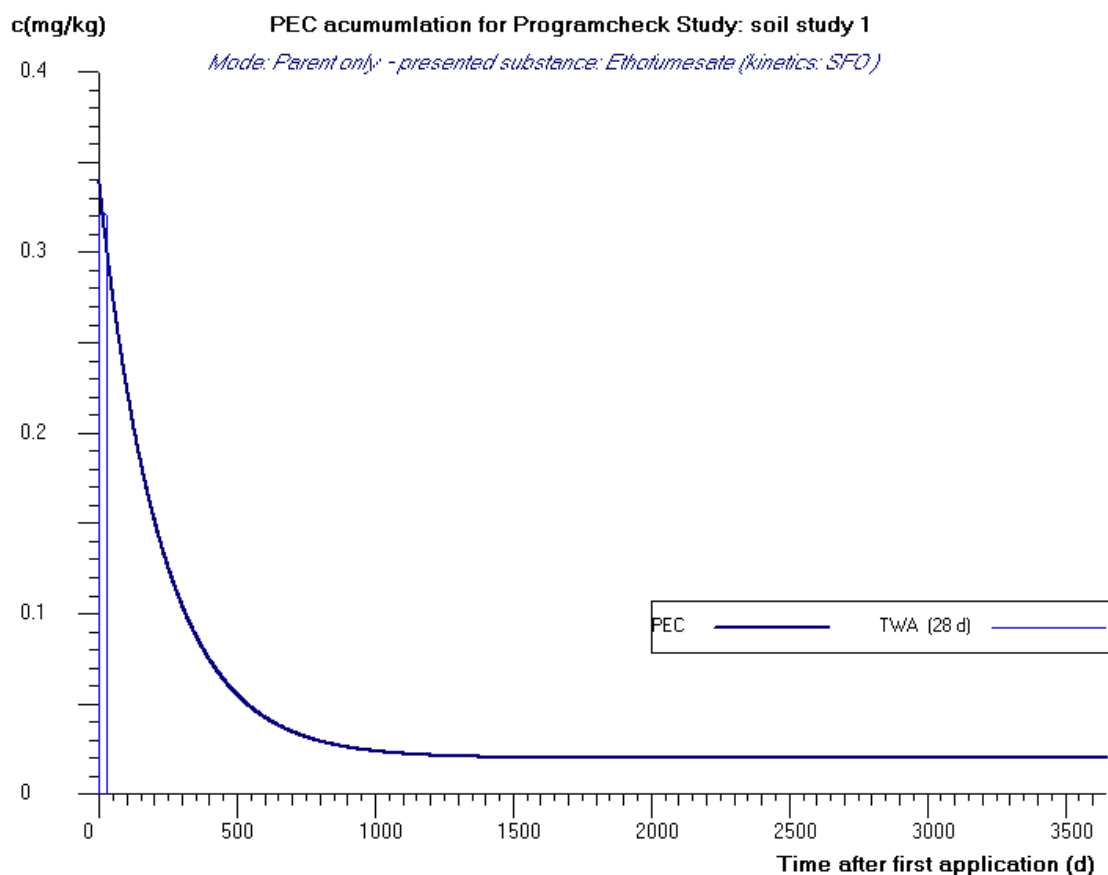
Calculated time dependent total soil concentrations over 5 cm for Programcheck(mg/kg) considering accumulation*

Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.3385	0.3392	0	1
2	0.3371	0.3385	0	2
4	0.3343	0.3371	0	4
7	0.3302	0.3351	0	7
14	0.3208	0.3303	0	14
21	0.3116	0.3256	0	21
28	0.3027	0.3210	0	28
42	0.2858	0.3120	0	42

50	0.2766	0.3071	0	50
100	0.2257	0.2787	0	100

(* a tillage depth of 20 cm was considered for calculating the background concentration)
 (** PECact values are related to the time after the first application)

GRAPHIC REPRESENTATION OF THE CALCULATION



Appendix 3.2 Predicted environmental concentrations soil - ESCAPE v. 2.0 for Ethofumesate

3 Applications, use group 4

ESCAPE

Estimation of Soil Concentrations After Pesticide Applications

developed by Michael Klein

Program version: 2.0 (26 November 2019)
Date of this simulation: 05/07/2021, 17:13:39
Calculation problem: Programcheck

PROGRAM SETTINGS

Calculation mode: Residues from different applications are considered separately over one year
Application mode: Single annual application pattern (calculation period 1 year)

SCENARIO DATA USED IN THE CALCULATION

Name of the scenario: Programcheck
Name of the soil: Borstel
Soil density (kg/L): 1.5
Soil depth (cm): 5
Tillage depth (cm)*: 20
Organic carbon content (%): 1.5
Field capacity (Vol%): 29.2
Wilting point (Vol%): 6.4

Climatic conditions: 20 °C constant
(* for calculation of background concentrations)

APPLICATION PATTERN USED IN THE CALCULATION

Crop rotation: every year
Number of Applications : 3
1st Application date: 17 Apr
Application rate (g/ha): 225
Time between two applications (d): 6
Crop interception (%): 20

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme: Parent compound without metabolites

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

Soil study: soil study 1
Metabolism scheme: Parent compound without metabolites
Kinetics for Programcheck: Single First order (SFO)

DT50 (d): 157
Rate constant (1/d): 0.0044
Q10-factor: 2.58
Walker-exponent: 0.7
Ref. temperature (°C): 20

RESULTS OF THE CALCULATION

Metabolism scheme: Parent compound without metabolites

RESULTS FOR: Programcheck

Calculations over one year

Maximum annual total soil concentration for Programcheck over 5 cm(mg/kg): 0.7013 occurring on day 12

Calculated time dependent total soil concentrations over 5 cm for Programcheck after one year (mg/kg)

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.6983	0.6998	12	13
2	0.6952	0.6983	12	14
4	0.6891	0.6952	12	16
7	0.6800	0.6906	12	19
14	0.6593	0.6801	12	26
21	0.6392	0.6698	12	33
28	0.6198	0.6597	12	40
42	0.5826	0.6402	12	54
50	0.5624	0.6297	11	61
100	0.4510	0.5688	6	106

(* PECact values are related to the time after the maximum concentration)

Calculation of background concentrations after many years

Final Background concentration in total soil for Programcheck over 20 cm(mg/kg):
0.0437**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): 0.0437

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for Programcheck over 5 cm considering accumulation* (mg/kg)
0.7451

(* a tillage depth of 20 cm was considered for calculating the background concentration)

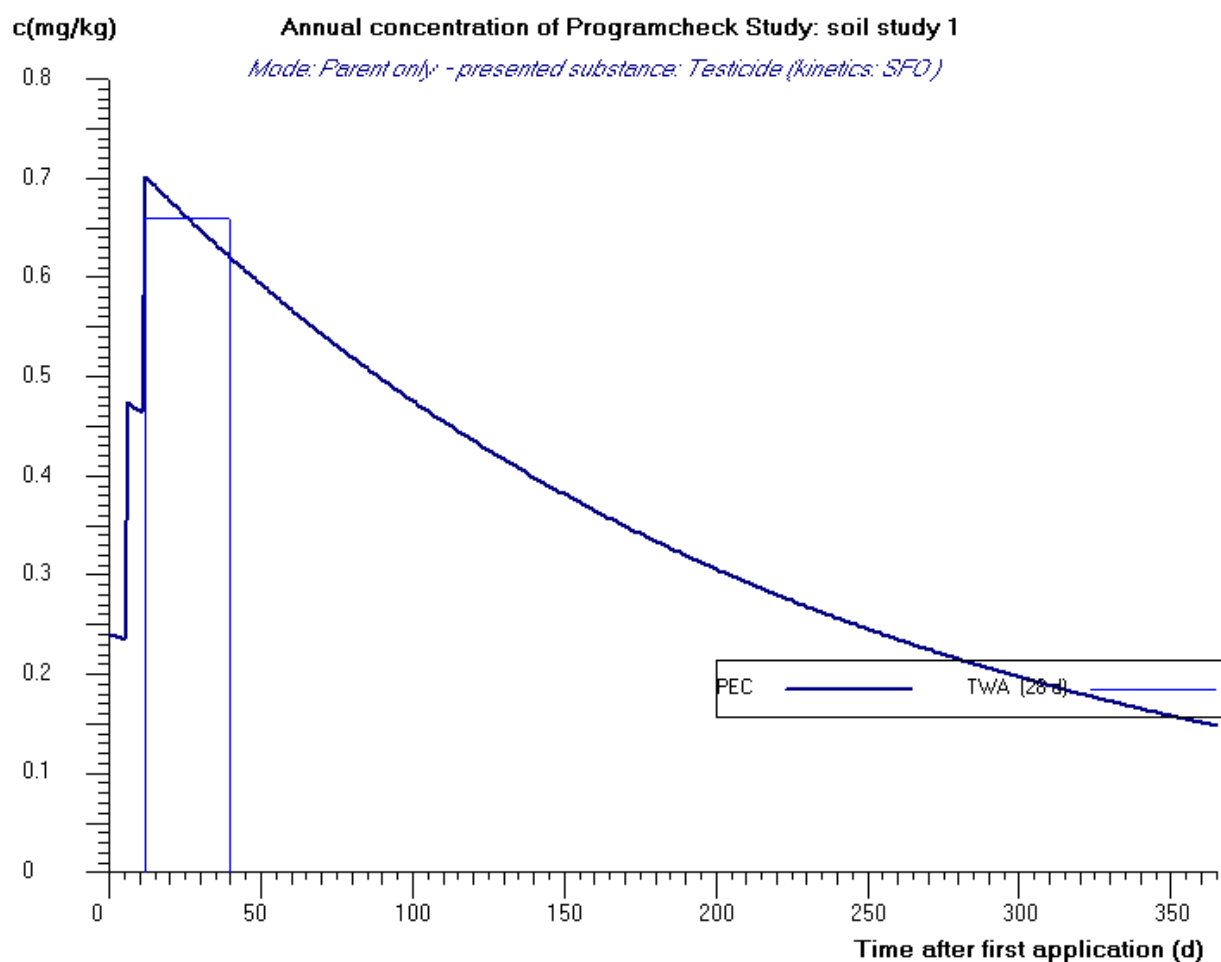
Calculated time dependent total soil concentrations over 5 cm for Programcheck(mg/kg) considering accumulation*

Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.7420	0.7435	12	13

2	0.7389	0.7420	12	14
4	0.7328	0.7389	12	16
7	0.7237	0.7343	12	19
14	0.7030	0.7238	12	26
21	0.6830	0.7135	12	33
28	0.6635	0.7034	12	40
42	0.6264	0.6839	12	54
50	0.6061	0.6734	11	61
100	0.4947	0.6126	6	106

(* a tillage depth of 20 cm was considered for calculating the background concentration)
(** PECact values are related to the time after the maximum concentration)'

GRAPHIC REPRESENTATION OF THE CALCULATION



Single Application

ESCAPE

Estimation of Soil Concentrations After Pesticide Applications

developed by Michael Klein

Program version: 2.0 (26 November 2019)
Date of this simulation: 05/07/2021, 17:14:04
Calculation problem: Programcheck

PROGRAM SETTINGS

Calculation mode: Residues from different applications are considered
separately over one year
Application mode: Single annual application pattern (calculation period 1
year)

SCENARIO DATA USED IN THE CALCULATION

Name of the scenario: Programcheck
Name of the soil: Borstel
Soil density (kg/L): 1.5
Soil depth (cm): 5
Tillage depth (cm)*: 20
Organic carbon content (%): 1.5
Field capacity (Vol%): 29.2
Wilting point (Vol%): 6.4

Climatic conditions: 20 °C constant
(* for calculation of background concentrations)

APPLICATION PATTERN USED IN THE CALCULATION

Crop rotation: every year

Application date: 17 Apr
Application rate (g/ha): 225
Crop interception (%): 20

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme: Parent compound without metabolites

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

Soil study: soil study 1

Metabolism scheme: Parent compound without metabolites

Kinetics for Programcheck: Single First order (SFO)
DT50 (d): 157
Rate constant (1/d): 0.0044
Q10-factor: 2.58

Walker-exponent: 0.7
Ref. temperature (°C): 20

RESULTS OF THE CALCULATION

Metabolism scheme: Parent compound without metabolites

RESULTS FOR: Programcheck

Calculations over one year

Maximum annual total soil concentration for Programcheck over 5 cm(mg/kg): 0.2400 occurring on day 0

Calculated time dependent total soil concentrations over 5 cm for Programcheck after one year (mg/kg)

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.2389	0.2395	0	1
2	0.2379	0.2389	0	2
4	0.2358	0.2379	0	4
7	0.2327	0.2363	0	7
14	0.2256	0.2327	0	14
21	0.2187	0.2292	0	21
28	0.2121	0.2258	0	28
42	0.1994	0.2191	0	42
50	0.1925	0.2154	0	50
100	0.1543	0.1940	0	100

(* PECact values are related to the time after the first application)

Calculation of background concentrations after many years

Final Background concentration in total soil for Programcheck over 20 cm(mg/kg):
0.0150**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): 0.0150

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for Programcheck over 5 cm considering accumulation* (mg/kg)
0.2550

(* a tillage depth of 20 cm was considered for calculating the background concentration)

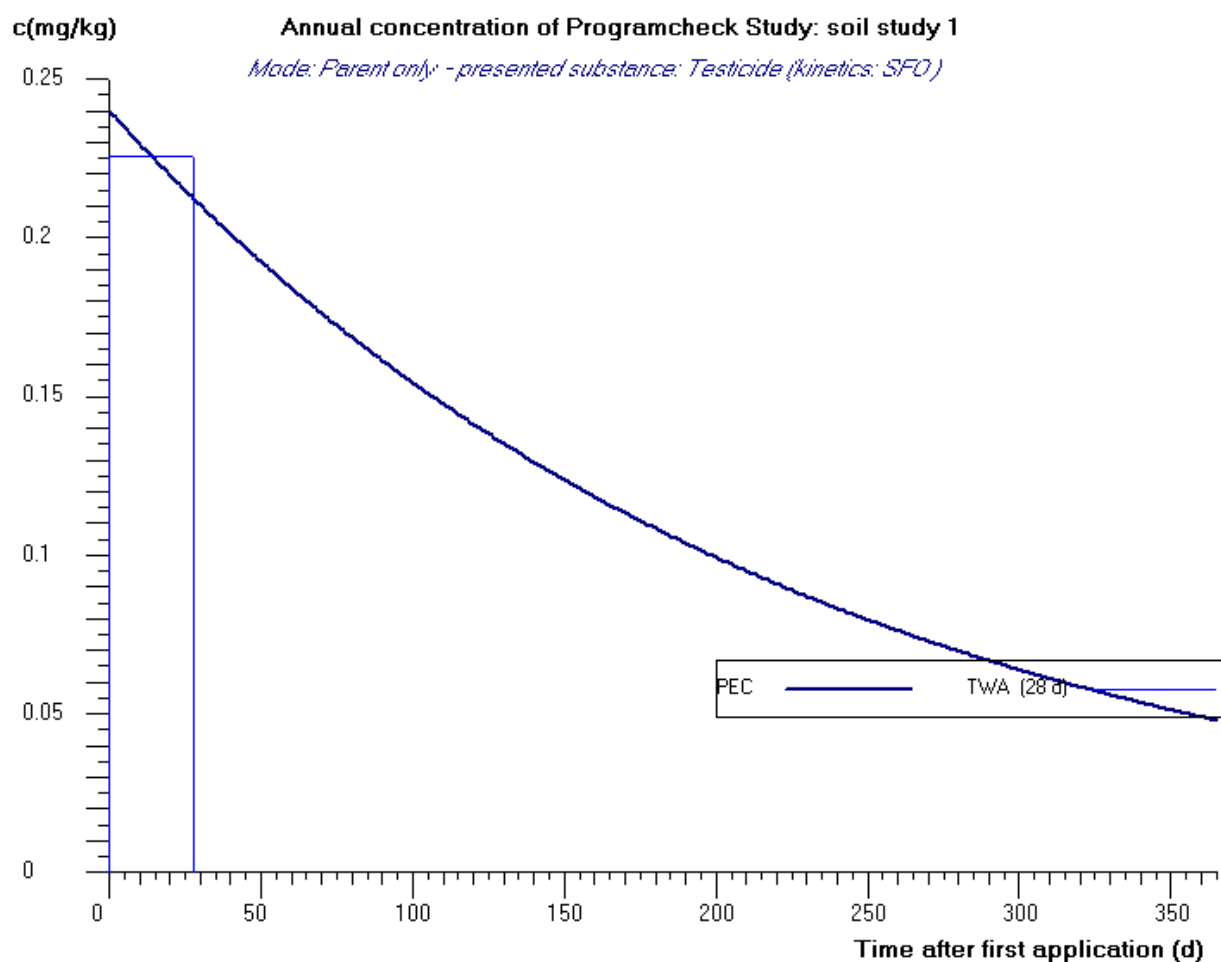
Calculated time dependent total soil concentrations over 5 cm for Programcheck(mg/kg) considering accumulation*

Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.2539	0.2544	0	1
2	0.2529	0.2539	0	2
4	0.2508	0.2529	0	4
7	0.2477	0.2513	0	7
14	0.2406	0.2477	0	14

21	0.2337	0.2442	0	21
28	0.2271	0.2407	0	28
42	0.2143	0.2340	0	42
50	0.2074	0.2303	0	50
100	0.1693	0.2090	0	100

(* a tillage depth of 20 cm was considered for calculating the background concentration)
(** PECact values are related to the time after the first application)

GRAPHIC REPRESENTATION OF THE CALCULATION



Appendix 3.3 Predicted environmental concentrations soil - ESCAPE v. 2.0 for Ethofumesate

3 Applications, use group 5

ESCAPE

Estimation of Soil Concentrations After Pesticide Applications

developed by Michael Klein

Program version: 2.0 (26 November 2019)
Date of this simulation: 05/07/2021, 17:14:33
Calculation problem: Programcheck

PROGRAM SETTINGS

Calculation mode: Residues from different applications are considered
separately over one year
Application mode: Single annual application pattern (calculation period 1
year)

SCENARIO DATA USED IN THE CALCULATION

Name of the scenario: Programcheck
Name of the soil: Borstel
Soil density (kg/L): 1.5
Soil depth (cm): 5
Tillage depth (cm)*: 20
Organic carbon content (%): 1.5
Field capacity (Vol%): 29.2
Wilting point (Vol%): 6.4

Climatic conditions: 20 °C constant
(* for calculation of background concentrations)

APPLICATION PATTERN USED IN THE CALCULATION

Crop rotation: every year
Number of Applications : 3
1st Application date: 17 Apr
Application rate (g/ha): 300
Time between two applications (d): 9
Crop interception (%): 20

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme: Parent compound without metabolites

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

Soil study: soil study 1
Metabolism scheme: Parent compound without metabolites
Kinetics for Programcheck: Single First order (SFO)
DT50 (d): 157

Rate constant (1/d): 0.0044
Q10-factor: 2.58
Walker-exponent: 0.7
Ref. temperature (°C): 20

RESULTS OF THE CALCULATION

Metabolism scheme: Parent compound without metabolites

RESULTS FOR: Programcheck

Calculations over one year

Maximum annual total soil concentration for Programcheck over 5 cm(mg/kg): 0.9231 occurring on day 18

Calculated time dependent total soil concentrations over 5 cm for Programcheck after one year (mg/kg)

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.9190	0.9211	18	19
2	0.9150	0.9190	18	20
4	0.9069	0.9150	18	22
7	0.8950	0.9090	18	25
14	0.8678	0.8951	18	32
21	0.8414	0.8816	18	39
28	0.8157	0.8683	18	46
42	0.7669	0.8426	18	60
50	0.7402	0.8288	17	67
100	0.5936	0.7487	9	109

(* PECact values are related to the time after the maximum concentration)

Calculation of background concentrations after many years

Final Background concentration in total soil for Programcheck over 20 cm(mg/kg):
0.0575**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): 0.0575

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for Programcheck over 5 cm considering accumulation* (mg/kg)
0.9806

(* a tillage depth of 20 cm was considered for calculating the background concentration)

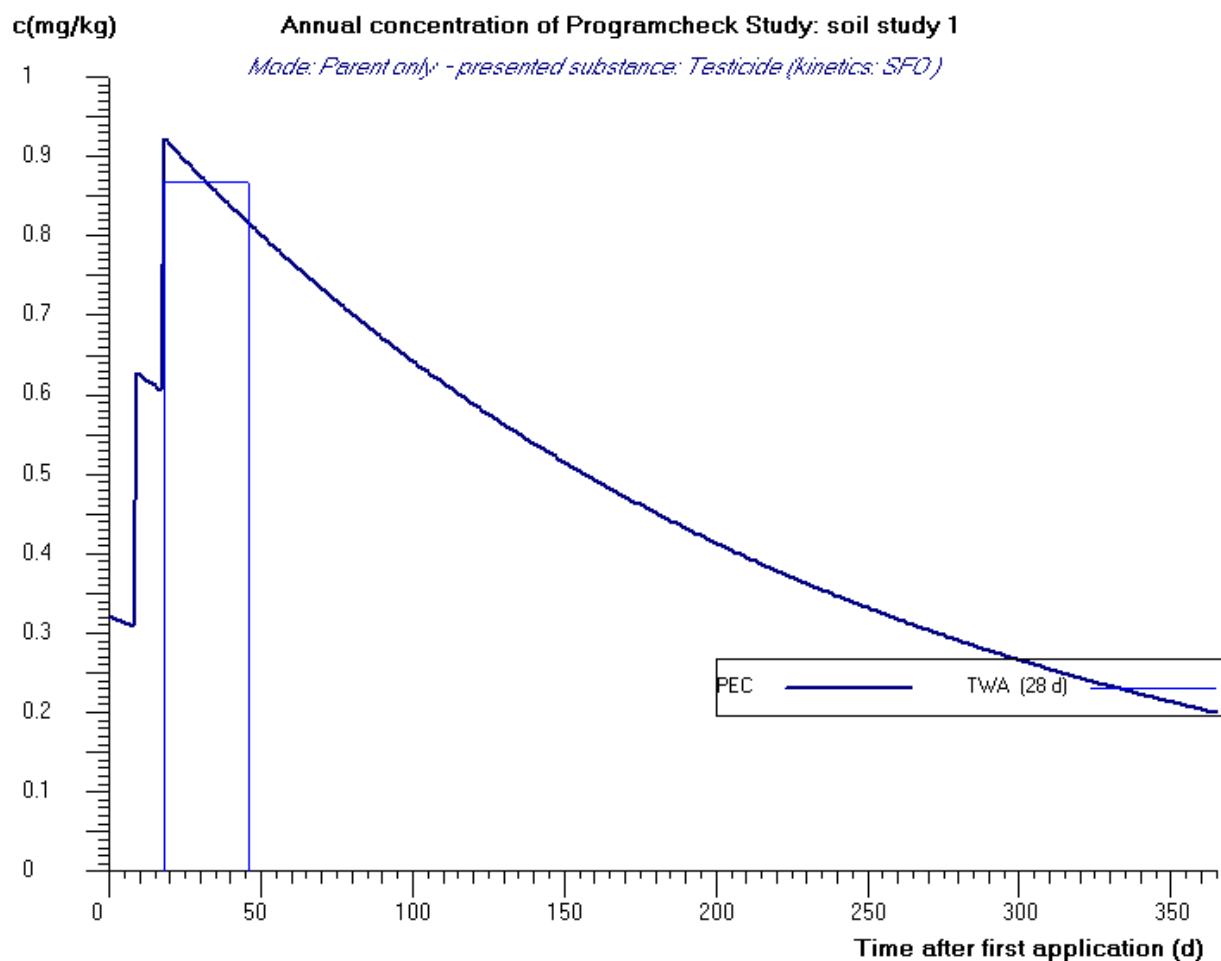
Calculated time dependent total soil concentrations over 5 cm for Programcheck(mg/kg) considering accumulation*

Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.9766	0.9786	18	19
2	0.9725	0.9766	18	20

4	0.9645	0.9725	18	22
7	0.9525	0.9665	18	25
14	0.9253	0.9527	18	32
21	0.8989	0.9391	18	39
28	0.8733	0.9259	18	46
42	0.8244	0.9001	18	60
50	0.7978	0.8863	17	67
100	0.6512	0.8063	9	109

(* a tillage depth of 20 cm was considered for calculating the background concentration)
(** PECact values are related to the time after the maximum concentration)'

GRAPHIC REPRESENTATION OF THE CALCULATION



Single Application

ESCAPE

Estimation of Soil Concentrations After Pesticide Applications

developed by Michael Klein

Program version: 2.0 (26 November 2019)
Date of this simulation: 05/07/2021, 17:15:00
Calculation problem: Programcheck

PROGRAM SETTINGS

Calculation mode: Residues from different applications are considered
separately over one year
Application mode: Single annual application pattern (calculation period 1
year)

SCENARIO DATA USED IN THE CALCULATION

Name of the scenario: Programcheck
Name of the soil: Borstel
Soil density (kg/L): 1.5
Soil depth (cm): 5
Tillage depth (cm)*: 20
Organic carbon content (%): 1.5
Field capacity (Vol%): 29.2
Wilting point (Vol%): 6.4

Climatic conditions: 20 °C constant
(* for calculation of background concentrations)

APPLICATION PATTERN USED IN THE CALCULATION

Crop rotation: every year
Application date: 17 Apr
Application rate (g/ha): 300
Crop interception (%): 20

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme: Parent compound without metabolites

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

Soil study: soil study 1
Metabolism scheme: Parent compound without metabolites
Kinetics for Programcheck: Single First order (SFO)
DT50 (d): 157
Rate constant (1/d): 0.0044
Q10-factor: 2.58
Walker-exponent: 0.7

Ref. temperature (°C): 20

RESULTS OF THE CALCULATION

Metabolism scheme: Parent compound without metabolites

RESULTS FOR: Programcheck

Calculations over one year

Maximum annual total soil concentration for Programcheck over 5 cm(mg/kg): 0.3200 occurring on day 0

Calculated time dependent total soil concentrations over 5 cm for Programcheck after one year (mg/kg)

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.3186	0.3193	0	1
2	0.3172	0.3186	0	2
4	0.3144	0.3172	0	4
7	0.3103	0.3151	0	7
14	0.3008	0.3103	0	14
21	0.2917	0.3056	0	21
28	0.2828	0.3010	0	28
42	0.2658	0.2921	0	42
50	0.2566	0.2871	0	50
100	0.2058	0.2587	0	100

(* PECact values are related to the time after the first application)

Calculation of background concentrations after many years

Final Background concentration in total soil for Programcheck over 20 cm(mg/kg):
0.0199**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): 0.0199

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for Programcheck over 5 cm considering accumulation* (mg/kg)
0.3399

(* a tillage depth of 20 cm was considered for calculating the background concentration)

Calculated time dependent total soil concentrations over 5 cm for Programcheck(mg/kg) considering accumulation*

Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.3385	0.3392	0	1
2	0.3371	0.3385	0	2
4	0.3343	0.3371	0	4
7	0.3302	0.3351	0	7
14	0.3208	0.3303	0	14

21	0.3116	0.3256	0	21
28	0.3027	0.3210	0	28
42	0.2858	0.3120	0	42
50	0.2766	0.3071	0	50
100	0.2257	0.2787	0	100

(* a tillage depth of 20 cm was considered for calculating the background concentration)
(** PECact values are related to the time after the first application)

GRAPHIC REPRESENTATION OF THE CALCULATION

