

REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: SAP50SCF

Product name(s): FOLPEC

Chemical active substance:

Folpet, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Selectis Produtos para a Agricultura, S.A.

Submission date: December 2023, update April 2024

MS Finalisation date: May 2024 (initial Core Assessment)

August 2024 (final Core Assessment)

Version history

When	What
December 2023	V0 - Initial version submitted by the Selectis Produtos para a Agricultura, S.A. for submission to Poland in the frame of new PPP registration (According Art. 33 of Regulation EC No 1107/2009)
April 2024	V1 – Revised version submitted by the Selectis Produtos para a Agricultura, S.A. for submission to Poland to address the data gaps received. All changes are highlighted in yellow.
May 2024	<p>Initial zRMS assessment</p> <p>The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency.</p> <p>Following the evaluation and before sending the document for commenting, all coloured highlighting was removed, from the parts updated by the Applicant, for better legibility</p>
August 2024	<p>Final report (Core Assessment updated following the commenting period).</p> <p>No additional information or assessments after the commenting period.</p>

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8 Fate and behaviour in the environment (KCP 9)

This document reviews the environmental fate studies and modelling for the product SAP50SCF, a suspension concentrate formulation containing 500 g/L of folpet, for use on wheat and barley.

Folpet was first included in Annex I by Commission Directive 2007/5/EC of 07 February 2007.

The EFSA conclusions for folpet (EFSA Scientific Report (2009) 297) are considered to provide the relevant review information or a reference to where such information can be found.

SAP50SCF was not a representative formulation in the EU review process. The product has not been previously evaluated in any European member state according to Uniform Principles.

A full risk assessment according to Uniform Principles is provided which demonstrates that the product is safe for the environment.

Addenda may be included containing country specific assessments for some annex points. In those cases, this document should be read in conjunction with the relevant addenda.

8.1 Critical GAP and overall conclusions

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn, G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (da ys)	Remarks: e.g. g saf- ener/ syner- gist per ha	Conclusion
					Method / Kind	Timing / Growth stage of crop & sea- son	Max. number a) per use b) per crop/ season	Min. in- terval be- tween ap- plications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/m ax			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	CEU: DE, RO, PL, HU, CZ, SK, AT, SI, BE, NL, UK	Wheat	F	Septoria	Tractor mounted spray	BBCH 30- 59	a) 2 b) 2	14 days	a) 0.9 – 1.2 L/ha b) 1.8 – 2.4 L/ha	a) 450 - 600 g as/ha b) 900 – 1200 g as/ha	150- 400	42		A
2	CEU: DE, RO, PL, HU, CZ, SK, AT, SI, BE, NL, UK	Barley	F	Helminstorporium	Tractor mounted spray	BBCH 30- 59	a) 2 b) 2	14 days	a) 0.9 – 1.2 L/ha b) 1.8 – 2.4 L/ha	a) 450 - 600 g as/ha b) 900 – 1200 g as/ha	150- 400	42		A

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

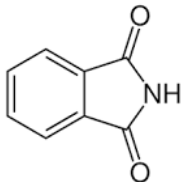
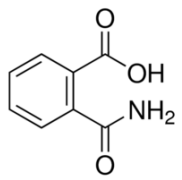
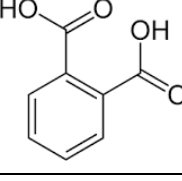
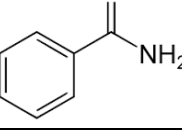
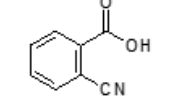
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

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

8.2 Metabolites considered in the assessment

Table 8.2-1: Metabolites of Folpet found in soil, water and sediment

Metabolite	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
Phthalimide		Soil: 64.9 %* Water: 26.0 % Sediment: 5.9 %	PEC _{soil} PEC _{gw} PEC _{sw/sed}
Phthalamic acid		Soil: 16.7 %* Water: 13.3 % Sediment: -	PEC _{soil} PEC _{gw} PEC _{sw/sed}
Phthalic acid		Soil: 16.6 %* Water: 37.5 % Sediment: 3.8 %	PEC _{soil} PEC _{gw} PEC _{sw/sed}
Benzamide		Soil: - Water: 10.2 % Sediment: -	PEC _{sw/sed}
2-cyanobenzoic acid		Soil: - Water: 39.7 % Sediment: -	PEC _{sw/sed}

* Maximum occurrences derived from aerobic soil degradation studies

zRMS comments:

Information regarding metabolites of folpet is in line with EU agreed endpoints reported in EFSA Scientific Report (2009) 297, 1-80.

8.3 Rate of degradation in soil (KCP 9.1.1)

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

Rate of degradation studies of the active substance in soil are discussed in detail in the corresponding documents of the EU review dossier.

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

The proposed pathway of soil degradation of the active substance is shown in Figure 8.3-1. Folpet is rapidly degraded and intensively mineralised to carbon dioxide and bound residues. First degradation step of folpet involves the release of the highly reactive thiophosgene (not labelled and therefore not measured in the study) to form the major soil metabolite phthalimide (max 64.9 % AR after 5 days). Phthalimide is further degraded through phthalamic acid (max. 16.7 % AR at day 1) to phthalic acid (max 16.6 % AR at day 1). None of the degradation product is stable and poses any risk to accumulate in soil. Mineralisation was high (60 % AR as CO₂ after 90 days, 69.8 % AR as CO₂ at the end of the route study after 1 year). Unextractable residues were formed in moderate amounts (max. 31.2 % AR at day 14; 16 % AR after 90 days).

With respect to the thiophosgene moiety further information may be derived from the closely related compound captan¹. Degradation of this compound in soil was investigated with trichloromethyl-¹⁴C labelled compound in three different viable sandy loam soils (25°C and 75-80% of 1/3 bar soil moisture content for 2 of the soils, conditions not reported for the third soil). CO₂ formed reached levels corresponding to 80-91% AR and unextractable residues amounted to 13.3-14.3% AR at the end of the studies at 28-30 days. In captan no thiophosgene was detected but the thiocarbonic acid that may result from its rapid hydrolysis was detected at low levels in the soil extracts between days 7 and 28 (0.6 – 1.1%). The volatiles trap in this study contained only low levels of radioactivity (max. 0.21% AR) that was proposed to be also thiocarbonic acid by the notifier. The experts' meeting considered this was likely but noted it could not be excluded that thiophosgene was present at trace levels in the volatile traps. Therefore, it is not expected that free thiophosgene reach significant levels as a consequence of the degradation of folpet in soil.

Photolysis under natural sunlight does not contribute significantly to the environmental dissipation of folpet.

¹ Molecular formula of captan is C₉H₈Cl₃NO₂S, molecular formula of folpet is C₉H₄Cl₃NO₂S



Table 8.3.1-1: Summary of aerobic degradation rates for Folpet - laboratory studies

^A Normalised data presented in the Addendum of October 2005; ~~Bold values were used in modelling~~

*This value comes from bi-phasic degradation, expressed as SFO. A 1st order value of 4.3 days was also determined based on a different fitting procedure (6.7 days when normalised to 20°C) and used for PECsoil calculations at EU level. The updated normalized value of 6.7 days will be used for risk assessment.

Table 8.3.1-2: Summary of aerobic degradation rates for Folpet Metabolites - laboratory studies

Soil type	pH	%OC	Test system	DT ₅₀ (d)	DT ₅₀ , norm 20°C, pF2, Q ₁₀ =2.2 [d] ^A	DT ₅₀ , norm, 20°C, pF2, Q ₁₀ =2.58 [d]	Kinetic model	Reference
PHTHALIMIDE								
Sandy loam	5.4	1.16	25°C/75 to 80% FC	28.2	26.5	38.75	-	Daly (1991)
Silt loam	6.2	2.6	20°C/40% MWHC	1.7	1.04	1.04	FOMC	Crowe (2001)
Loamy sand	4.8	0.9	20°C/40% MWHC	4.8	3.69	3.69	SFO	Crowe (2001)
Clay loam	7.5	3.9	20°C/40% MWHC	0.5	0.29	0.29	SFO	Crowe (2001)
Geometric mean (n=4)						2.56		
PHTHALAMIC ACID								
Silt loam	6.2	2.6	20°C/40% MWHC	0.4	0.24	0.24	SFO	Crowe (2001)
PHTHALIC ACID								
Silt loam	6.2	1.7	20°C/40% MWHC	1.0	0.61	0.61	SFO	Crowe (2001)
Loamy sand	4.8	4.8	20°C/40% MWHC	4.1	3.15	3.15	SFO	Crowe (2001)
Clay loam	7.5	0.5	20°C/40% MWHC	0.6	0.35	0.35	SFO	Crowe (2001)
Geometric mean (n=3)						0.88		

^A Normalised data presented in the Addendum of October 2005; ~~Bold values were used in modelling~~

zRMS comments:

Soil degradation data for folpet and its metabolites presented in Tables 8.3.1-1 to 8.3.1-2 are in general in line with EU agreed endpoints reported in EFSA Scientific Report (2009) 297, 1-80.

It is noted that in Tables 8.3.1-1 and 8.3.1-2 DT₅₀ values normalised with consideration of Q₁₀ of 2.58 are presented, in line with current FOCUS requirements. Although normalisation using Q₁₀ of 2.58 is currently required, in the exposure assessment endpoints as reported in the LoEP should be used, even if the EU agreed data were normalised using Q₁₀ of 2.2. Taking this into account, the DT₅₀ values recalculated with Q₁₀ of 2.58 were not validated by the zRMS and are struck through in tables above.

For relevant endpoints considered in groundwater and surface water modelling please refer to points 8.8 (groundwater) and 8.9 (surface water) of this document.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Degradation of folpet under dark anaerobic conditions followed the same general route found under aerobic conditions. Both phthalimide (max. 50.6 % AR at the start of the anaerobic phase) and phthalic acid (max. 13.3 % AR after 60 d of the anaerobic phase) were found as major metabolites under anaerobic conditions. These metabolites were already observed at higher occurrence in aerobic degradation studies. Under anaerobic conditions, the degradation of folpet in soil tended to be slower with a maximum DT₅₀ value of 13.5 days; degradation of phthalimide was also slower with a DT₅₀ of 33.6 days.

Folpet is only used in the spring and summer and not in the autumn and winter. In addition, folpet and its major soil metabolites degrade very rapidly in soil. Therefore, it is very unlikely that significant amounts of these substances will be present in soil during times when anaerobic conditions might be experienced (autumn/winter). For these reasons, the anaerobic degradation of folpet was not considered.

zRMS comments:

Anaerobic soil degradation data for folpet are in line with EU agreed endpoints reported in EFSA Scientific Report (2009) 297, 1-80.

8.4 Field studies (KCP 9.1.1.2)

The degradation in soil of folpet under field conditions was evaluated during the Annex I Inclusion and are discussed in detail in the corresponding documents of the EU review dossier. No additional studies have been performed since it is possible to extrapolate from data obtained with the active substance.

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

Three US studies were cited in the European dossier under Point IIA, 7.1.1.2.2. These studies are not considered necessary as the half-lives of folpet and its potentially relevant degradation products in soil under laboratory conditions are significantly below the field study trigger value of 60 days at both, 10°C and 20°C. The three soil dissipation studies confirmed the very quick dissipation of the active substance under more natural conditions and showed that the active substance and its major soil degradation product, phthalimide, do not leach below the top 15 cm of the soil.

Under field conditions folpet half-lives was always below 3 days. It was not possible to determine any field half-life times for the metabolites due to lack of detections, detections at low levels and fast dissipation.

zRMS comments:

Anaerobic soil degradation data for folpet are in line with EU agreed endpoints reported in EFSA Scientific Report (2009) 297, 1-80.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Soil accumulation of the active substances were not investigated during the Annex I Inclusion. No additional studies have been performed since it is not required.

zRMS comments:

According to EFSA Scientific Report (2009) 297, 1-80, soil accumulation testing is not required for folpet.

8.5 Mobility in soil (KCP 9.1.2)

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

The sorption behaviour of folpet was investigated in a batch adsorption / desorption study in four soils. Due to the high instability of folpet in soil-water systems, no adsorption parameter could be derived. However, the KOC was estimated from the octanol / water partition coefficient. Six different methods found in the scientific literature were used and the most conservative value (KOC = 304 mL/g) was selected for PEC calculations in this assessment and in calculation for the European assessment.

The soil adsorption of phthalimide was investigated in a batch equilibrium study in 5 soils. Due to the high instability of this compound under neutral and alkaline conditions all soils investigated were acidic (pH < 6). Phthalimide was found to be medium to high mobile in soil. During the EU peer review, the experts agreed that only the results of three of the five soils should be considered since in two soils there was evidence of a significant deviation from a linear sorption.

Table 8.5-1: Adsorption and desorption constants for Folpet Metabolites in various soils (EFSA Journal (2009) 297)

Soil type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Reference
Phthalimide						
Clay	1.3	5.1	-	385	0.89	Geffke, 2000
Loam	3.45	5.2	-	72	0.88	
Loamy sand	9.25	3.2	-	169	0.84	
Arithmetic mean (n=3)				208.7	0.87	
Geometric mean (n=3)				167.3		

Bold values were used in simulation models

It is proposed to use of the geometric Kfoc value of 167.3 mL/g as a worst-case assumption with the recommended arithmetic mean 1/n value of 0.87 for the purposes of the exposure assessment for the folpet metabolite Phthalimide.

The soil adsorption properties of the metabolites phthalamic acid and phthalic acid were assessed by estimating K_{FOC} values based on structure using the PCKOC model of the US EPA EPIWIN program. Predicted K_{FOC} values were 10 mL/g and 73.06 mL/g for phthalamic acid and phthalic acid, respectively and 1/n value of 1 (default value). The experts' meeting agreed to accept the estimation in this case due to the fast degradation of these metabolites.

zRMS comments:

Soil mobility data for folpet and its metabolite presented above are in line with EU agreed endpoints reported in EFSA Scientific Report (2009) 297, 1-80.

It is noted that the geometric mean Kfoc values were calculated by the Applicant, although in the EFSA conclusion only arithmetic mean values are reported and further used for groundwater and surface water modelling. The geometric mean values calculated by the Applicant were based on the individual Kfoc from the LoEP and are confirmed to be correct.

8.5.1 Column leaching (KCP 9.1.2.1)

The majority of the radioactivity was found in the top 2 cm soil layer as unextractable material. The leachate contained up to 2.6 % AR. Phthalic acid was found as the major component identified in the leachate. Folpet, phthalimide and phthalamic acid were not detected in the leachate.

The results of this study confirm the low mobility of folpet and its metabolites in soil.

zRMS comments:

Information on column leaching studies for folpet and its metabolites described above are in line with these reported in EFSA Scientific Report (2009) 297, 1-80.

8.5.2 Lysimeter studies (KCP 9.1.2.2)

Lysimeter studies are not required for folpet since no leaching is expected.

zRMS comments:

According to EFSA Scientific Report (2009) 297, 1-80, lysimeter studies for folpet were not required.

8.5.3 Field leaching studies (KCP 9.1.2.3)

Field leaching studies are not required for folpet since no leaching is expected.

zRMS comments:

According to EFSA Scientific Report (2009) 297, 1-80, field leaching studies with folpet were not required.

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

Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. Degradation in the water/sediment systems are discussed in detail in the corresponding documents of the EU review dossier.

Hydrolysis of folpet in buffer solutions at environmental relevant pHs (4, 5, 7, 9) and temperature (25 °C) was investigated in three separated studies. Hydrolysis is rapid at acidic and neutral pH ($DT_{50} < 3$ h) and very rapid at alkaline pH ($DT_{50} < 3$ min).

Main hydrolysis metabolites were phthalimide (max. 91 % AR at pH 5 after 24 h) and Phthalic acid (max. 78.4 % AR at pH 9 after 10 min). Two major uncharacterized (unknown 1; max. 36 % AR at pH 9 after 24 h and unknown 2: max. 51.8 % at pH 9 after 1h) metabolites were found in the hydrolysis study performed with the trichloromethyl-14C labelled folpet. No definitive characterization of these metabolites was accomplished but it was postulated that unknown 1 will be the trichloromethylsulfenic acid salt and that unknown 2 will be trichloromethylmercaptan that will degrade to thiophosgene, carbon oxysulfide and ultimately to CO₂.

Hydrolysis of Phthalimide in buffer solutions (pH 4, 7 and 9) was investigated in a separated study at 25, 40 and 100 °C. At 25 °C and pH 4 and 7 Phthalimide was stable. At 25 °C and pH 9 Phthalimide was hydrolysed with a half-life of 2 h. Hydrolysis of Phthalic acid was not investigated further but according to its structure this compound is not prone to suffer hydrolysis and no further investigation was required.

An aqueous photolysis study is available. Contribution of photolysis to the aqueous degradation of folpet was not significant.

Folpet was shown to be readily biodegradable in one of the ready biodegradability studies available (1 mg C/L). At higher concentrations (10 mg C/L) it did not fulfil the criteria to be considered readily biodegradable but could be considered inherently biodegradable. No significant inhibition of the degradation of reference material (sodium benzoate) was observed at the higher concentration and the slower degradation was attributed to the low solubility in water (0.8 mg/L).

A water sediment study investigates the degradation of folpet in the aquatic environment with two different water sediment systems at 20 °C in the dark. Very low recoveries were obtained for some data points and the experiments were repeated with 21 d experiments. This second experiments showed that the most likely reason for the low recoveries on some of the data points of the first experiment was the partly loss of CO₂ during sampling processing. Mineralization at the end of the study (100 d) was relatively high in both systems (51-54 % AR). Folpet degrades very rapidly in both systems and is not found in the sediment phase.

Major metabolites in the water phase were Phthalimide (max. 26.0 % AR at 4 h), Phthalamic acid (max. 13.3 % AR at 1h), Phthalic acid (max. 37.5 % AR at 1d), benzamide (max. 10.2 % AR at 1 d) and 2-cyanobenzoic acid (max. 39.7 % AR at 1d).

No major metabolite was found in the sediment phase. The main metabolites encountered in the sediment were Phthalimide (max. 5.9 %) and Phthalic acid (max. 3.8 %).

Considerable amounts of bound residues were found in the sediment 7 d and 14 d after application. Due to the fact that uses at European level included 10 repeated applications at weekly intervals, the applicant was required to address the potential for accumulation of bounded residues in the sediment (Evaluation meeting, December 2004). Notifier presented the case that sediment was exhaustively extracted and that the remaining non extracted radioactivity was mostly associated to the humin fraction. It was possible to postulate that this residue was covalently bounded to organic matter of the sediment and formed by the Phthalic acid type of moieties that would be further degraded and release as CO₂ and CH₄ (actually not trapped). The rapporteur Member State and experts' meeting agreed that bound residues were not likely to be bioavailable and will not constitute a risk for sediment dwelling organisms.

Table 8.6-1: Summary of degradation in water/sediment of Folpet and its metabolites

Folpet										
Water/sediment system	pH water/sed.	DegT50 whole syst. (d)	DegT90 whole syst. (d)	Ki-netic, Fit	DissT50 water (d)	DissT90 water (d)	Ki-netic, Fit	DissT50 sed. (d)	Ki-netic, Fit	Reference
Silty clay (pond)	8.1/6.8	0.014	-	SFO	0.014	-	SFO	NC	NA	Crowe (1999)
Sandy loam (Lake)	7.1/5.9	0.018	-	SFO	0.017	-	SFO	NC	NA	
Geometric mean (n=2)		0.016	-		0.015	-		-		
Phthalimide: Distribution (max. 26% AR)										
Silty clay (pond)	8.1/6.8	0.583	-	SFO	0.543	-	SFO	NC	NA	Crowe (1999)
Sandy loam (Lake)	7.1/5.9	0.645	-	SFO	0.594	-	SFO	NC	NA	
Geometric mean (n=2)		0.61	-		-	0.57		-		
Phthalamic acid: Distribution (max. water 13.3 % AR)										
Silty clay (pond)	8.1/6.8	3.978	-	SFO	3.546	-	SFO	NC	NA	Crowe (1999)
Sandy loam (Lake)	7.1/5.9	6.087	-	SFO	5.499	-	SFO	NC	NA	
Geometric mean (n=2)		4.90	-		4.42	-		-		
Phthalic acid: Distribution (max. water 37.5% AR)										
Silty clay (pond)	8.1/6.8	1.409	-	SFO	1.381	-	SFO	NC	NA	Crowe (1999)
Sandy loam (Lake)	7.1/5.9	6.453	-	SFO	6.359	-	SFO	NC	NA	
Geometric mean (n=2)		3.01	-		2.96	-				
Benzamide: Distribution (max. water 10.2% AR)										
Silty clay (pond)	8.1/6.8	1.625	-	SFO	1.625	-	SFO	NC	NA	Crowe (1999)
Sandy loam (Lake)	7.1/5.9	-	-	SFO	-	-	SFO	NC	NA	
Geometric mean (n=2)		-	-		-	-				
2-cyannobenzoic acid: Distribution (max. water 39.7% AR)										
Silty clay (pond)	8.1/6.8	0.357	-	SFO	0.334	-	SFO	NC	NA	Crowe (1999)
Sandy loam (Lake)	7.1/5.9	0.716	-	SFO	0.666	-	SFO	NC	NA	
Geometric mean (n=2)		0.51	-		0.47	-				

Bold values were used in simulation models

zRMS comments:

Degradation data for folpet and its metabolites in water/sediment systems described above are in line with EU agreed endpoints reported in EFSA Scientific Report (2009) 297, 1-80 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

No new active substance data have been submitted as part of this application for authorisation/re-registration.

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

Predicted Environmental Concentrations in soil (PEC_{soil}) of Folpet (and its metabolites) are based on excel spreadsheet modelling approach. A soil depth of 5 cm and a bulk density of 1.5 g/cm³ are assumed. Application rates and crop interception (EFSA Journal 2014; 12(5):3662) were selected in concordance with the GAP.

The application rate calculation for each metabolite has been calculated assuming the respective maximum occurrence transformation, multiplying by a conversion factor (metabolite molecular weight ÷ parent molecular weight) to correct the molecular weight.

Although the PEC_{soil} results obtained with the minimum dose advocated for the use of this product are covered by the simulations made with the maximum dose (risk envelope approach), the applicant presents both in this section.

The results obtained with the maximum dose are found below and those obtained with the minimum dose are presented in Appendix 3. At the end, a summary table is presented.

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

Plant protection product	SAP50SCF	
Use No.	1	2
Crop	Winter and Spring Cereals	
Application rate (g as/ha)	folpet: 450 to 600	
Number of applications/interval	2 / 14	
Crop interception (%)	80%	
Depth of soil layer (relevant for plateau concentration) (cm)	5	

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

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
Folpet	296.6	-	22.26 d (SFO, Normalized worst-case value from laboratory studies)	EFSA Scientific Report (2009) 297, 1-80
Phthalimide	147.1	64.9	38.75 (SFO, normalized worst-case value, laboratory studies)	
Phthalamic acid	165.2	16.7	0.4 (SFO, non-normalized worst-case value, laboratory studies)	
Phthalic acid	166.1	16.6	4.1 (SFO, non-normalized worst-case value, laboratory studies)	

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Table 8.7-3: PEC_{soil} for folpet after application of SAP50SCF (maximum dose)

PEC _{soil} (mg/kg)		Cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.160	-	0.263	-
Short term	24h	0.155	0.158	0.255	0.259
	2d	0.150	0.155	0.248	0.255
	4d	0.141	0.150	0.233	0.248
Long term	7d	0.129	0.144	0.212	0.237
	14d	0.103	0.130	0.170	0.214
	21d	0.083	0.117	0.137	0.193
	28d	0.067	0.107	0.110	0.176
	50d	0.034	0.081	0.056	0.134
	100d	0.007	0.049	0.012	0.081

Bold values will be used in risk assessment (see section 9)

PEC_{soil} of metabolites

Table 8.7-4: PEC_{soil} for phthalimide after application of SAP50SCF (maximum dose)

PEC _{soil} (mg/kg)		Cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.051	-	0.092	-
Short term	24h	0.051	0.051	0.090	0.091
	2d	0.050	0.051	0.088	0.090
	4d	0.048	0.050	0.085	0.088
Long term	7d	0.045	0.048	0.081	0.086
	14d	0.040	0.046	0.071	0.081
	21d	0.035	0.043	0.063	0.076
	28d	0.031	0.041	0.056	0.072
	50d	0.021	0.034	0.037	0.061
	100d	0.009	0.024	0.015	0.043

Bold values will be used in risk assessment (see section 9)

Table 8.7-5: PEC_{soil} for phthalamic acid after application of SAP50SCF (maximum dose)

PEC _{soil} (mg/kg)		Cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.015	-	0.015	-
Short term	24h	0.003	0.007	0.003	0.007
	2d	0.000	0.004	0.000	0.004
	4d	0.000	0.002	0.000	0.002
Long term	7d	0.000	0.001	0.000	0.001
	14d	0.000	0.001	0.000	0.001
	21d	0.000	0.000	0.000	0.000
	28d	0.000	0.000	0.000	0.000
	50d	0.000	0.000	0.000	0.000
	100d	0.000	0.000	0.000	0.000

Bold values will be used in risk assessment (see section 9)

Table 8.7-6: PEC_{soil} for phthalic acid after application of SAP50SCF (maximum dose)

PEC _{soil} (mg/kg)		Cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.015	-	0.016	-
Short term	24h	0.013	0.014	0.014	0.015
	2d	0.011	0.013	0.012	0.014
	4d	0.008	0.011	0.008	0.012
Long term	7d	0.005	0.009	0.005	0.010
	14d	0.001	0.006	0.002	0.006
	21d	0.000	0.004	0.000	0.004
	28d	0.000	0.003	0.000	0.003
	50d	0.000	0.002	0.000	0.002
	100d	0.000	0.001	0.000	0.001

Bold values will be used in risk assessment (see section 9)

The predicted environmental concentrations in soil were calculated for the active substance folpet and its metabolites, according to recommendations by the “FOCUS” group (FOCUS report, 29.02.1997). Calculations were based on a simple first tier approach (Excel sheet). In table below, a resume of PEC_{soil} is presented.

Table 8.7-7 Summary of initial PEC_{soil} of folpet and its metabolites

Compound	Use rate [g/ha]	Crop	No. of ap- pln.	Crop intercep- tion [%]	Soil loading [g/ha]	PEC _s initial [mg/kg]
Folpet	600	Cereals	2	80	120	0.263
	450				90	0.198
Phthalimide	193.12				38.62	0.092
	144.84				28.97	0.069
Phthalamic acid	55.78				11.16	0.015
	41.83				8.37	0.011
Phthalic acid	55.78				11.16	0.016
	41.83				8.37	0.012

zRMS comments:

The application pattern presented in Table 8.7-1 and assumed in the soil exposure assessment is in line with the critical Central Zone GAP presented in Table 8.1-1.

Input parameters presented in Table 8.7-2 for folpet and its metabolites are in general in line with EU agreed parameters reported in EFSA Scientific Report (2009) 297, 1-80 with following exceptions:

- for folpet and metabolite phthalimide DT₅₀ used for PEC_{soil} calculation were not stated in EU agreed endpoints (DT₅₀ of 22.26 days and 38.75 days for folpet and metabolite phthalimide, respectively). The Applicant decided to use the highest normalized worst-case value from laboratory studies instead of values from the LoEP (4.3 days for folpet and 28.2 days for metabolite phthalimide). Since the soil DT₅₀ values considered by the Applicant is a worst case it is agreed by the zRMS.

Relevant crop interception of 80% for cereals in line with FOCUS groundwater guidance (2023) has been selected.

The soil exposure for folpet and its metabolite has been independently validated by the zRMS using FOCUS methods and EU agreed endpoints. The calculated PEC_{soil} values were the same and lower from these obtained by the Applicant when considering the DT₅₀ values as reported in EFSA Scientific Report (2009) 297, 1-80. Therefore, results reported in tables above may be used for the soil risk assessment purposes.

8.7.2.1 PEC_{soil} of SAP50SCF

An initial PEC_{soil} value was calculated for the formulation based on the maximum and minimum individual application rate of 1.2 L/ha and 0.9 L/ha, respectively.

The calculation was based on crop interception of 80%, soil depth of 5 cm, bulk density of 1.5 g/cm³ and specific density of 1230 g/L. Time-dependent PEC_{soil} values are not required to be calculated for the formulation since it is considered to be separated in to its individual components by transport and dissipation processes.

Table 8.7-12: PEC_{soil} for SAP50SCF on cereals

Preparation	Application rate (g/ha)	PEC_{act} (mg/kg)
SAP50SCF	1476	0.394
	1107	0.295

zRMS comments:

Soil exposure calculated by the Applicant for the formulated product is agreed by the zRMS and may be used in the risk assessment for soil organisms.

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

8.8.1 Justification for new endpoints

No new active substance data have been submitted as part of this application for authorisation/re-registration.

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

Report:	KCP 9.2.4/01, Fernandes, V., 2022a
Title:	Predicted Environmental Concentrations of Folpet and its metabolites in Groundwater (PEC_{gw}) based on FOCUS PELMO 6.6.4, FOCUS PEARL 5.5.5 and MACRO 5.5.4 for risk assessment of SAP50SCF on Cereals
Document No:	ASC100-2022
Guidelines:	FOCUS (2000): FOCUS groundwater scenarios in the EU review of active substances. Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference Sanco/321/2000, version 2002. FOCUS (2014): Assessing potential for movement of active substances and their metabolites to ground water in the EU. Report of the FOCUS Ground Water Work Group, EC Document Reference Sanco/13144/2010 version 3. FOCUS (2014): Generic guidance for Tier 1 FOCUS ground water assessments, version 2.3. FOCUS groundwater scenarios working group.
GLP	Not applicable, computer modelling study.

This report describes a FOCUS modelling study that examined the potential for folpet (and its metabolites) to reach groundwater following application to winter and spring cereals.

The predicted environmental concentration of the active substance and significant components from the formulated product SAP50SCF in groundwater (PEC_{gw}) is determined using the leaching models FOCUS PELMO 6.6.4, FOCUS PEARL 5.5.5 and MACRO 5.5.4. All runs were performed with annual applications over a total period of 26 years. The first 6 years were run as a warming-up period and the results were extracted from the following 20 years.

Although the PEC_{gw} results obtained with the minimum dose advocated for the use of this product are covered by the simulations made with the maximum dose (risk envelope approach), the applicant presents both in this section.

The results obtained with the maximum dose are found below and those obtained with the minimum dose are presented in Appendix 3. A conclusion for both doses is presented below.

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

Plant protection product	SAP50SCF	
Use No.	1	2
Crop	Winter and Spring Cereals	
Application rate (g as/ha)	folpet: 450 to 600	
Number of applications/interval (d)	2 / 14	
Relative application date	Please see Table 8.8-2	
Crop interception (%)	80	
Frequency of application	annual	
Models used for calculation	FOCUS PEARL v5.5.5, FOCUS PELMO v6.6.4, FOCUS MACRO v5.5.4	

To define the application dates, the AppDate software (M. Klein, 2006. Fraunhofer IME, Germany) was used. AppDate is a software that calculates consistent application dates which can be used in further FOCUS modelling. AppDate uses a database where suitable application dates for major development stages (*e.g.*, BBCH 10, 20, 30) are collected. Between these BBCH stages, the dates are always linearly interpolated. The dates for the major development stages are based on various sources and also dependent on whether they refer to groundwater or surface water scenarios. The 3.06 version of 28 June 2019 was used.

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

Crop	Scenario	Application dates (absolute)	
		Winter cereals	Spring cereals
Cereals BBCH 30	Châteaudun	15/04; 29/04	16/04; 30/04
	Hamburg	04/05; 18/05	28/04; 12/05
	Jokioinen	14/05; 28/05	05/06; 19/06
	Kremsmünster	24/04; 08/05	27/04; 11/05
	Okehampton	21/04; 05/05	22/04; 06/05
	Piacenza	19/03; 02/04	-
	Porto	30/01; 13/02	16/04; 30/04
	Sevilla	06/01; 20/01	-
	Thiva	18/01; 01/02	-

The PEC_{gw} values of Folpet and its metabolites were calculated based on agreed LoEP (EFSA Scientific Report (2009) 297, 1-80).

Folpet is only used in the spring and summer and not in the autumn and winter. In addition, folpet and its major soil metabolites degrade very rapidly in soil. Therefore, it is very unlikely that significant amounts of these substances will be present in soil during times when anaerobic conditions might be experienced (autumn/winter). For these reasons, the anaerobic degradation of folpet was not considered.

Compound	Folpet	Phthalimide	Phthalamic acid	Phthalic acid	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol):	296.6	147.1	165.2	166.1	EFSA Scientific Report (2009) 297, 1-80
Water solubility (g/mol):	0.8 (25°C)	360 (25 °C)	37600 (25 °C)	7010 (25 °C)	
Saturated vapour pressure (Pa):	2.1x10 ⁻⁵ (25°C)	1.38x10 ⁻⁶ (25 °C)	1.53x10 ⁻⁴ (25 °C)	1.01x10 ⁻⁴ (25 °C)	
DT ₅₀ in soil (d)	4.68 (arith. mean; n = 4, lab DT ₅₀ , pF2, 20 °C, Q ₁₀ = 2.2) 1.38 (geomean, n=4)	7.88 (arith. mean; n = 4, lab DT ₅₀ , pF2, 20 °C, Q ₁₀ = 2.2) 2.56 (geomean, n=3)	0.24 (n=1)	3.15 (wost case) 0.88 (geomean, n=3)	
Transformation rate	Parent -> Phthalimide: 0.1481 0.50228	Phthalimide-> Phthalamic acid: 0.08796 0.27076	Phthalamic acid-> Phthalic acid: 2.88811	Phthalic acid-> BR/CO ₂ : 0.2200 0.78767	
K _{foc} (mL/g)/K _{fom}	304 (worst-case assumption)	167.3 (geomean, n=3)	10 (EPWINN)	73.06 (EPWINN)	
1/n	0.9 1 (default value)	0.87 (arith.mean, n=4)	0.9 1 (default value)	0.9 1 (default value)	
Plant uptake factor	0	0	0	0	
Formation fraction	-	1 from parent	1 from phthalimide	1 from phthalamic acid	
Conversion factor*	-	0.496	1.123	1.005	

FINDINGS

[illegible]

After receiving a request from authorities, the applicant adjusted the Q10 value within the model to 2.2. While this modification can be directly implemented in SWASH model calculations, for PEARL calculations, the applicant chose a molar activation energy of 55 kJ/mol due to insufficient detailed information.

As per the Central Zone document, if no Q10 value was agreed upon for Annex I inclusion, the default Q10 value of 2.58 should be pragmatically employed. In cases where an acceptable risk cannot be demonstrated, degradation experiments may need to be re-evaluated by the applicant, adhering to a Q10 value of 2.58 in line with pertinent FOCUS guidance. Moreover, it's worth noting that the most recent versions of the FOCUS model PEARL and PELMO advise utilizing a Q10 value of 2.58. These additional calculations should complement rather than replace those conducted with the Q10 value of 2.58.

The results are presented in the tables below and in appendix 3 of this document. Applicant delivers 2 sets of calculations to demonstrate to authorities that applying the minor different values of DT50 do not affect previous risk assessment conclusion.

[illegible]

Table 8.8-4b: **PEC_{gw} for folpet and metabolites on cereals following application of SAP50SCF (FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5) – additional calculations with DT50 mean values as stated in LoEP, a molar activation energy of 55 kJ/mol and Q10 = 2.2**

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)							
		FOCUS PELMO v.6.6.4				FOCUS PEARL v.5.5.5			
		Parent	Phthalimide	Phthalamic acid	Phthalic acid	Parent	Phthalimide	Phthalamic acid	Phthalic acid
Winter Cereals 2x600 g as/ha	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Spring Cereals 2x600 g as/ha	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

The degradation scheme available in MACRO model does not fit with what is approved for folpet. Nevertheless, the degradation scheme was respected simulating:

- Parent to Phthalamide, with a formation fraction of 0.496
- Phthalamide as a pseudoparent (corrected with molar ratio and formation fraction) to phthalamic acid, with formation fraction of 1.123
- Phthalamic acid as a pseudoparent (corrected with molar ratio and formation fraction) to Phthalic acid, with formation fraction of 1.005

The application rate was also corrected taking into account the formation fraction for each metabolite.

April 2024: Applicant conducted two additional sets of projects in PEARL and PELMO to complement the risk assessment and satisfy authorities' requirements. Upon observing no significant differences in results between both models and set of endpoints, it is anticipated that the outcomes for MACRO 5.5.4 would remain consistent. Consequently, specific calculations for MACRO 5.5.4 were deemed unnecessary.

The output and input files for all additional calculations conducted across the environmental compartments will be included and sent along with this document.

Table 8.8-5: **PEC_{gw} for folpet and its metabolites on cereals following application of SAP50SCF (FOCUS MACRO 5.5.4)**

	PEC _{GW} at 1 m soil depth [µg/L]			
	FOCUS MACRO 5.5.4			
	Parent	Phthalimide	Phthalamic acid	Phthalic acid
Winter Cereals – 2 x 600 g as/ha, Châteaudun scenario	0.000	0.000	0.000	0.000
Spring Cereals – 2 x 600 g as/ha, Châteaudun scenario	0.000	0.000	0.000	0.000

CONCLUSIONS

The risk to groundwater is considered acceptable if the 80th percentile annual leaching concentration at 1 m depth is < 0.1 µg/L.

From the results estimated by two FOCUS recommended models, it can be foreseen that no risk is anticipated for groundwater neither for the active substances or its metabolites when folpet is used according to the proposed GAP (maximum or minimum dose) in winter cereals and spring cereals.

Therefore, no groundwater contamination is expected for parent and its metabolites following the use of the formulation for winter cereals and spring cereals.

zRMS comments:

The application pattern presented in Table 8.8-1 and considered in groundwater exposure assessment for folpet and its metabolites is in line with the critical Central Zone GAP and it is thus agreed by the zRMS. Assumed crop interception corresponded with BBCH stages at product SAP50SC is intended to be applied.

Input parameters for folpet and its metabolites presented in Table 8.8-3 are in general in line with EU agreed parameters reported in EFSA Scientific Report (2009) 297, 1-80 with following exceptions:

- for folpet and its metabolites: phthalimide and phthalic acid the geometric mean soil DT₅₀ values normalised with Q₁₀ of 2.58 were considered although the EU agreed endpoints were normalised with Q₁₀ of 2.2. In line with current FOCUS requirements the Q₁₀ factor of 2.58 should be used in the normalisation procedure, however, the exposure assessment should be based on endpoints as reported in the LoEP, even if the EU agreed data were normalised using Q₁₀ of 2.2. For folpet the EU agreed value of soil DT₅₀ is 4.68 days instead of the value of 1.38 days presented in Table 8.8-3. For metabolites phthalimide and phthalic acid the EU agreed values of soil DT₅₀ are 7.88 days and 3.15 days, respectively. Since consideration of the longer DT₅₀ values represents worst case, thus the respective correction of DT₅₀ and transformation rates were introduced in Table 8.8-3 and further used in independent zRMS calculations.
- for folpet metabolite phthalimide the geometric mean K_{foc} value was considered by the Applicant although in the EFSA conclusion arithmetic mean value is reported. Since the geometric mean value represents worst case in terms of the leaching potential comparing to arithmetic mean and it is accepted by the zRMS.
- for folpet and the metabolites phthalamic acid and phthalic acid 1/n coefficient value of 0.9 is reported in EFSA conclusion, however the Applicant chose a more conservative value of 1. Since in new ground water modelling Applicant use Freundlich exponent of 0.9, respective corrections were introduced in the Table 8.8-3.

The Applicant is kindly reminded, that no new endpoints for active compound and its metabolites should be generated for purposes of the product registration, unless critical for the exposure assessment. In case of folpet, sufficient data were available from the EU review and should have been used for modelling purposes.

In all simulations PUF value of 0 was assumed, in line with recommendations of the most recent version of the FOCUS Groundwater Guidance (2023).

The groundwater modelling was independently validated by the zRMS using FOCUS models PEARL 5.5.5 and PELMO 6.6.4 and the soil DT₅₀ values normalised with Q₁₀ of 2.2 as they are the EU agreed endpoints. Obtained results were in good agreement with these derived by the Applicant and presented in Table 8.8-4b. No unacceptable leaching of folpet and its metabolites is expected following application of SAP50SC according to the intended Central Zone use pattern given in Table 8.8-1.

Since not agreed input values were struck through in Table 8.8-3 and groundwater modelling based entirely on EU agreed parameters has been accepted by the zRMS thus results presented in Tables 8.8-4 and 8.8-4a were struck through and shaded for transparency as not relevant. Nevertheless, no significant differences in results between two sets of endpoints was observed. Thus, no groundwater contamination is expected for parent and its metabolites following application of SAP50SC to winter cereals and spring cereals.

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

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

8.9.1 Justification for new endpoints

No new active substance data have been submitted as part of this application for authorisation/re-registra-tion.

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

Report:	KCP 9.2.5/01, Fernandes, V., 2022b
Title:	Predicted Environmental Concentrations of Folpet and its metabolites in Surface Water and Sediment (PEC _{sw} and PEC _{sed}) based on Tiered FOCUS Approach for risk assessment of SAP50SCF on Cereals
Document No:	ASC101-2022
Guidelines:	FOCUS (2001): FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios. EC Docu-ment Reference SANCO/4802/2001 rev. 2, 245 pp. FOCUS (2015): Generic guidance for FOCUS surface water Scenarios, version 1.4.
GLP	Not applicable, computer modelling study.

This report describes a FOCUS modelling study that examined the potential for folpet (and its metabolites) to reach surface water following application to winter and spring cereals.

The predicted environmental concentration of the active substance and significant components from the formulated product SAP50SCF in surface water (PEC_{sw} and PEC_{sed}) is determined using the standardized recommendations of the FOCUS working group on surface water scenarios (FOCUS 2001⁶ and 2015⁷) using Steps 1-2 and Step 3.

Where necessary and applicable, the calculations were conducted with protective buffer zones for spray drift reduction. Where the contamination of surface water was dominated by run-off events, vegetated buffer zones for the reduction of run-off were introduced as recommended in the FOCUS landscape miti-gation guidance document².

Although the PEC_{sw} results obtained with the minimum dose advocated for the use of this product are covered by the simulations made with the maximum dose (risk envelope approach), the applicant presents both in this section.

The results obtained with the maximum dose are below and those obtained with the minimum dose are presented in Appendix 3. At the end, a summary table is presented.

Single and multiple applications were considered.

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

Plant protection product	SAP50SCF	
Use No.	1	2
Surrogate Crop	Winter and Spring Cereals	
Application rate (kg as/ha)	folpet: 0.450 to 0.600	
Number of applications/interval (d)	2 / 14	
Application window	Step 1-2: Oct-Feb and Mar – May for Winter Cereals Mar – May for Spring Cereals	

² SANCO/10422/2005 version 1.0, May 2005 (p.30) and SANCO/10422/2005 version 2.0, Sept 2007(p. 32)

	Step 3: please see Table 8.9.2
Interception	Step 1-2: Average crop cover; Step 3: including in the model
CAM (Chemical application method)	2
Soil depth (cm)	4
Models used for calculation	STEP 1-2 v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v4.4.3, SWAN 5.0.1

To define the application windows, considered in Step 3 modelling, the AppDate software (M. Klein, 2006. Fraunhofer IME, Germany) was used.

AppDate is a software that calculates consistent application dates which can be used in further FOCUS modelling. AppDate uses a database where suitable application dates for major development stages (e.g., BBCH 10, 20, 30) are collected. Between these BBCH stages, the dates are always linearly interpolated. The dates for the major development stages are based on various sources and also dependent on whether they refer to groundwater or surface water scenarios. The 3.06 version of 28 June 2019 was used.

Table 8.9-2: FOCUS Step 3 Scenario related input parameters for $PEC_{sw/sed}$ calculations for the application of SAP50SCF

Application window used in modelling			
Crop	Scenario	Winter	Spring
Cereals BBCH 30	D1	25/03 – 24/04 (08/05)	27/05 – 26/06 (10/07)
	D2	04/04 – 04/05 (18/05)	-
	D3	16/04 – 16/05 (30/05)	28/04 – 28/05 (11/06)
	D4	18/03 – 17/04 (01/05)	18/05 – 17/06 (01/07)
	D5	15/03 – 14/04 (28/04)	09/04 – 09/05 (23/05)
	D6	16/02 – 18/03 (01/04)	-
	R1	24/04 – 24/05 (07/06)	-
	R3	19/03 – 18/04 (02/05)	-
	R4	24/01 – 23/02 (09/03)	09/04 – 09/05 (23/05)

In brackets, the last day in the application window for multiple application

The PEC_{sw} values of Folpet were calculated at STEP 1-2, STEP 3 and 4. Concerning the metabolites, STEP 1-2 were used to calculate the PEC_{sw} . Further details on aquatic risk assessment can be found in Section 9 of this dRR.

Due to the K_{OC} value for folpet is between 100 and 2000 mL/g, the whole system degradation values should be applied to one compartment (water or sediment) and a default of 1000 days applied to the other compartment. Therefore, 2 sets were performed for the parent folpet.

In Appendix 4, the complete Tables concerning each set performed are presented. The values shown in Table 8.9-6 are the highest among the 2 simulated sets.

Table 8.9-3a: Input parameters related to active substance folpet and metabolite(s) for PEC_{sw/sed} calculations

Compound	Folpet	Phthalimide	Phthalamic acid	Phthalic acid	Value in accordance to EU end-point y/n/ Reference
Molecular weight (g/mol)	296.6	147.1	165.2	166.1	EFSA Scientific Report (2009) 297, 1-80
Water solubility (mg/L)	0.8 (25°C)	360 (25 °C)	37600 (25 °C)	7010 (25 °C)	
Vapour Pressure (Pa)	2.1x10 ⁻⁵ (25°C)	Not necessary for Step 1-2			default
Diffusion coefficient in water (m ² /d)	4.3 x 10 ⁻⁵				
Diffusion coefficient in air (m ² /d)	0.43				FOCUS recommendation
Plant Uptake	0				
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)				default
Freundlich Exponent 1/n	0.9 1 (default value)				EFSA Scientific Report (2009) 297, 1-80
Kfoc (mL/g)	304 (worst-case assumption)	167.3 (geomean, n=3)	10 (estimation) [#]	73.06 (estimation) [#]	
DT50,soil (d)	4.68 (arith. mean; n = 4, lab DT ₅₀ , pF2, 20 °C, Q ₁₀ = 2.2) 1.38 (geomean, n=4)	7.88(arith. mean; n = 4, lab DT ₅₀ , pF2, 20 °C, Q ₁₀ = 2.2) 2.38 (geomean norm., n=3)	0.24 (n=1)	3.15 (worst case) 0.88 (geomean norm., n=3)	
DT50,water (d)	Set 1: 0.018* (higher value) Set 2: 1000 (default value)	0.61 (geomean, n=2)	4.9 (geomean, n=2)	3.01 (geomean, n=2)	
DT50,sed (d)	Set 1: 1000 (default value) Set 2: 0.018* (higher value)	1000 (default value)	1000 (default value)	1000 (default value)	
DT50,whole system (d)	1000 (default value)	0.61 (geomean, n=2)	4.9 (geomean, n=2)	3.01 (geomean, n=2)	
Maximum occurrence observed (% molar basis with respect to the parent)**	-	Soil: 64.9 % Water: 26.0 % Sed.: 5.9 %	Soil: 16.7 % Water: 13.3 % Sediment: -	Soil: 16.6% Water: 37.5 % Sed.: 3.8 %	

* 0.1 day is used on simulations; # based on structure using the PCKOC model

Table 8.9-3b: Input parameters related to active substance folpet and metabolite(s) for PEC_{sw/sed} calculations

Compound	Benzamide	2-cyanobenzoic acid	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	121.1	147.1	EFSA Scientific Report (2009) 297, 1-80
Water solubility (mg/L)	5084	28240	
Vapour Pressure (Pa)	Not necessary for Step 1-2		
Diffusion coefficient in water (m²/d)			
Diffusion coefficient in air (m²/d)			
Plant Uptake			
Wash-Off factor from Crop (1/mm)			
Freundlich Exponent 1/n			
Kfoc (mL/g)			
DT50,soil (d)	1000 (default value)	1000 (default value)	
DT50,water (d)	1000 (default value)	1000 (default value)	
DT50,sed (d)	1000 (default value)	1000 (default value)	
DT50,whole system (d)	1000 (default value)	1000 (default value)	
Maximum occurrence observed (% molar basis with respect to the parent)**	Soil: - Water: 10.2 % Sediment: -	Soil: - Water: 39.7 % Sediment: -	EFSA Scientific Report (2009) 297, 1-80

** used at Step 1-2;

FINDINGS

Folpet

FOCUS Step 1-2

Table 8.9-4: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for Folpet following application of SAP50SCF – set 1 (maximum dose)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	7 d- PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
	Winter cereals				
Step 1	---	<u>295.67</u> 147.83	---	292.0 10.57	888.53 432.64
Step 2					
Northern Europe	Oct-Feb	35.44 (31.48) 7.64 (7.63)	Runoff/Drainage	2.54 (2.25) 0.55 (0.55)	107.90 (95.89) 23.40 (23.40)
Southern Europe		6.11 (6.11)		0.44 (0.44)	18.75 (18.76)
Northern Europe	Mar-May	14.17 (12.59) 4.88 (5.52)	Runoff/Drainage	1.02 (0.90) 0.79 (0.83)	43.26 (38.47) 9.46 (9.47)
Southern Europe		6.11 (6.11)		0.44 (0.44)	18.75 (18.76)
	Spring cereals				
Step 1	---	<u>147.83</u>	---	10.57	432.64
Step 2					
Northern Europe	March-May	14.17 (12.59) 4.88 (5.52)	Runoff/Drainage	1.02 (0.90) 0.79 (0.83)	43.26 (38.47) 9.46 (9.47)
Southern Europe		4.88 (5.52)		0.44 (0.44)	18.75 (18.76)

Bold values are above RAC; values between brackets correspond to single application; *Italic and underline values will be used in aquatic risk assessment (see section 9)*

Table 8.9-5: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for Folpet following application of SAP50SCF set 2 (maximum dose)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	7 d-PEC _{sw,twn} (µg/L)	Max PEC _{sed} (µg/kg)
	Winter cereals				
Step 1	—	<u>147.83</u>	—	10.57	432.64
Step 2					
Northern Europe	Oct-Feb	<u>9.82 (9.98)</u>	Runoff/Drainage	4.74 (4.80)	23.23 (23.21)
Southern Europe		8.29 (8.45)		3.96 (4.02)	18.59 (18.57)
Northern Europe	Mar-May	<u>5.23 (5.52)</u>	Runoff/Drainage	2.40 (4.05)	9.30 (9.29)
Southern Europe		8.29 (8.45)		3.96 (4.02)	18.59 (18.57)
	Spring cereals				
Step 1	—	<u>147.83</u>	—	10.57	432.64
Step 2					
Northern Europe	March-May	<u>5.23 (5.52)</u>	Runoff/Drainage	2.40 (4.05)	9.30 (9.29)
Southern Europe		8.29 (8.45)		3.96 (4.02)	18.59 (18.57)

Bold values are above RAC; values between brackets correspond to single application; *Italic and underline values will be used in aquatic risk assessment (see section 9)*

Due to PEC_{sw} values are greater than RAC for the parent folpet, Step 3 was simulated.

The values shown in table below are the highest among the 2 simulated sets (due to the Koc value, as mentioned above). The complete tables for each set are found in the Appendix 4.

FOCUS Step 3

Table 8.9-6: FOCUS Step 3 PEC_{sw} and PEC_{sed} for folpet following single and multiple applications of SAP50SCF to winter and spring cereals (maximum dose)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d-PEC _{sw, twn} (µg/L)*	Max PEC _{sed} (µg/kg)
<i>Winter Cereals – Multiple applications</i>					
D1 _{set1}	ditch	3.356	drift	0.09338	0.6078
D1 _{set1}	stream	2.834	drift	0.02756	0.2977
D2 _{set1}	ditch	3.364	drift	0.08441	0.5067
D2 _{set1}	stream	2.941	drift	0.04794	0.3567
D3 _{set1}	ditch	3.325	drift	0.08336	0.4012
D4 _{set2}	pond	0.1597	drift	0.1272	0.03732
D4 _{set1}	stream	2.513	drift	0.005374	0.08051
D5 _{set2}	pond	0.1849	drift	0.1471	0.03405
D5 _{set1}	stream	2.899	drift	0.01619	0.1592
D6 _{set2}	ditch	3.34	drift	0.4102	0.4424
R1 _{set2}	pond	0.3032	runoff	0.242	0.04689
R1 _{set2}	stream	4.449	runoff	0.1937	0.4978
R3 _{set2}	stream	5.952	runoff	0.321	1.133
R4 _{set2}	stream	3.386	runoff	0.1669	0.5805
<i>Winter Cereals – Single application</i>					
D1 _{set1}	ditch	3.814	drift	0.1003	0.609

D1 _{set1}	stream	2.964	drift	0.007328	0.1044
D2 _{set1}	ditch	3.838	drift	0.09634	0.5798
D2 _{set1}	stream	3.26	drift	0.02877	0.3063
D3 _{set1}	ditch	3.801	drift	0.06054	0.459
D4 _{set1}	pond	0.1312	drift	0.00417	0.02292
D4 _{set1}	stream	2.807	drift	0.004906	0.07047
D5 _{set1}	pond	0.1312	drift	0.002598	0.01761
D5 _{set1}	stream	3.034	drift	0.005132	0.07358
D6 _{set1}	ditch	3.758	drift	0.04037	0.3769
R1 _{set1}	pond	0.1312	drift	0.00275	0.01794
R1 _{set1}	stream	2.504	drift	0.03728	0.2069
R3 _{set1}	stream	3.518	drift	0.03244	0.3434
R4 _{set1}	stream	2.515	drift	0.01885	0.2172
<i>Spring Cereals – Multiple applications</i>					
D1 _{set2}	ditch	4.488	drift	2.495	0.4683
D1 _{set1}	stream	2.91	drift	0.06172	0.3575
D3 _{set1}	ditch	3.326	drift	0.06112	0.3133
D4 _{set2}	pond	0.1764	drift	0.1362	0.02235
D4 _{set1}	stream	2.777	drift	0.02452	0.1885
D5 _{set2}	pond	0.1643	drift	0.1278	0.02159
D5 _{set1}	stream	2.87	drift	0.009551	0.1333
R4 _{set2}	stream	11.17	runoff	0.9093	1.387
<i>Spring Cereals – Single application</i>					
D1 _{set1}	ditch	3.848	drift	0.05349	0.4155
D1 _{set1}	stream	3.365	drift	0.04304	0.3635
D3 _{set1}	ditch	3.805	drift	0.03493	0.3179
D4 _{set1}	pond	0.1312	drift	0.00213	0.01572
D4 _{set1}	stream	3.111	drift	0.01157	0.1542
D5 _{set1}	pond	0.1312	drift	0.0026	0.01762
D5 _{set1}	stream	3.194	drift	0.007833	0.111
R4 _{set2}	stream	6.215	runoff	0.4145	0.7983

Bold values are above RAC; *two time as required by ecotox

April 2024: After receiving a request from authorities, the applicant adjusted the Q10 value within the models to 2.2. This modification can be directly implemented in SWASH model calculations.

Additionally, the applicant rectified the use of the Freundlich exponent, setting it to the default value of 0.9 as stated in the LoEP and recommended in FOCUS guidance documentation. Furthermore, considering the encouraged use of the geometric mean in the guidance since 2014 and the minor discrepancy between the DT50 values (1.38 days geometric mean vs. 1.6 days arithmetic mean), the applicant opted to retain the geometric mean.

As per the Central Zone document, if no Q10 value was agreed upon for Annex I inclusion, the default Q10 value of 2.58 should be pragmatically employed. In cases where an acceptable risk cannot be demonstrated, degradation experiments may need to be re-evaluated by the applicant, adhering to a Q10 value of 2.58 in line with pertinent FOCUS guidance.

The document EFSA Scientific Report (2009) 297, 44-80 states the following “*Folpet is very low or low persistent in soil (DT50 lab 20 °C = 0.2 -3.8 d; DT50 lab 25 °C = 4.3 d)*”. Moreover, it's worth noting that the most recent versions of the FOCUS SWASH model advise on utilizing a Q10 value of 2.58. Therefore, the additional calculations should complement rather than replace those conducted with the Q10 value of 2.58. The results are presented in the tables below and in appendix 3 and 4 of this document.

Additional calculations with DT50 soil of 1.38 days and Q10=2.2 – Step3

Table 8.9-6a: FOCUS Step 3 PEC_{sw} and PEC_{sed} for *folpet* following single and multiple applications of SAP50SCF to winter and spring cereals (maximum dose) – Set2 with a DT50 of 1000 days applied to the surface water compartment

Scenario FOCUS	Waterbody	Max-PEC _{sw} (µg/L)	Dominant-entry route	21 d-PEC _{sw,twa} (µg/L)*	Max-PEC _{sed} -(µg/kg)
<i>Winter Cereals – Multiple applications</i>					
D1 _{set2}	ditch	3.355	drift	1.039	0.247
D1 _{set2}	stream	2.833	drift	0.034	0.167
D2 _{set2}	ditch	3.364	drift	0.794	0.220
D2 _{set2}	stream	2.941	drift	0.679	0.150
D3 _{set2}	ditch	3.324	drift	0.325	0.160
D4 _{set2}	pond	0.143	drift	0.101	0.011
D4 _{set2}	stream	2.510	drift	0.006	0.061
D5 _{set2}	pond	0.174	drift	0.125	0.010
D5 _{set2}	stream	2.898	drift	0.018	0.097
D6 _{set2}	ditch	3.339	drift	0.394	0.131
R1 _{set2}	pond	0.240	runoff	0.177	0.011
R1 _{set2}	stream	3.572	runoff	0.151	0.147
R3 _{set2}	stream	4.379	runoff	0.248	0.257
R4 _{set2}	stream	2.536	runoff	0.130	0.142
<i>Winter Cereals – Single application</i>					
D1 _{set2}	ditch	3.814	drift	0.303	0.282
D1 _{set2}	stream	2.966	drift	0.008	0.078
D2 _{set2}	ditch	3.838	drift	0.383	0.251
D2 _{set2}	stream	3.260	drift	0.035	0.173
D3 _{set2}	ditch	3.800	drift	0.177	0.182
D4 _{set2}	pond	0.131	drift	0.091	0.011
D4 _{set2}	stream	2.809	drift	0.005	0.062
D5 _{set2}	pond	0.131	drift	0.093	0.007
D5 _{set2}	stream	3.034	drift	0.005	0.059
D6 _{set2}	ditch	3.757	drift	0.078	0.150
R1 _{set2}	pond	0.131	drift	0.092	0.007
R1 _{set2}	stream	2.504	drift	0.042	0.113
R3 _{set2}	stream	3.517	drift	0.046	0.164
R4 _{set2}	stream	2.515	drift	0.025	0.108
<i>Spring Cereals – Multiple applications</i>					
D1 _{set2}	ditch	4.060	drift	2.088	0.130

D1 _{set2}	stream	2.910	drift	0.242	0.112
D3 _{set2}	ditch	3.325	drift	0.351	0.090
D4 _{set2}	pond	0.167	drift	0.118	0.005
D4 _{set2}	stream	2.776	drift	0.032	0.079
D5 _{set2}	pond	0.150	drift	0.107	0.006
D5 _{set2}	stream	2.869	drift	0.011	0.065
R4 _{set2}	stream	8.846	runoff	0.765	0.318
<i>Spring Cereals – Single application</i>					
D1 _{set2}	ditch	3.847	drift	1.570	0.148
D1 _{set2}	stream	3.365	drift	0.140	0.130
D3 _{set2}	ditch	3.804	drift	0.198	0.103
D4 _{set2}	pond	0.131	drift	0.093	0.006
D4 _{set2}	stream	3.110	drift	0.013	0.091
D5 _{set2}	pond	0.131	drift	0.094	0.007
D5 _{set2}	stream	3.194	drift	0.008	0.075
R4 _{set2}	stream	4.639	runoff	0.348	0.167

Bold values are above RAC; *two time as required by ecotox

April 2024: Authorities have highlighted that utilizing normalized values with a Q10 value of 2.2 could impact the risk assessment. Despite the longer non-normalized DT50 values, the geometric mean of these values (equating to 1.77 days for n=4), in accordance with the FOCUS guidance document, still falls within the range specified in the LoEP of 0.2 to 3.8 days.

Nevertheless, the applicant conducted additional calculations to complement the risk assessment, employing a Q10 value of 2.2 and a worst-case DT50 of 4.68 days, corresponding to the arithmetic mean used in groundwater calculations, while still demonstrating safe use. The calculations for Steps 3 and 4 are presented in Appendix 3, titled "Additional Calculations with DT50 Soil of 4.68 Days". The calculation at Step 3 for the maximum dose are presented in Table below.

Table 8.9-6b: FOCUS Step 3 PEC_{sw} and PEC_{sed} for *folpet* following single and multiple applications of SAP50SCF to winter and spring cereals (maximum dose) - Set2 with a DT50 of 1000 days applied to the surface water compartment

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw,twa} (µg/L)*	Max PEC _{sed} (µg/kg)
<i>Winter Cereals - Multiple applications</i>					
D1 _{set2}	ditch	3.363	drift	1.053	0.277
D1 _{set2}	stream	2.838	drift	0.041	0.182
D2 _{set2}	ditch	5.555	drainage	0.926	0.253
D2 _{set2}	stream	3.657	drainage	0.732	0.166
D3 _{set2}	ditch	3.324	drift	0.325	0.191
D4 _{set2}	pond	0.143	drift	0.102	0.013
D4 _{set2}	stream	2.510	drift	0.006	0.062
D5 _{set2}	pond	0.174	drift	0.126	0.012
D5 _{set2}	stream	2.898	drift	0.018	0.107
D6 _{set2}	ditch	3.339	drift	0.395	0.162

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)*	Max PEC _{sed} (µg/kg)
R1 _{set2}	pond	0.597	runoff	0.505	0.032
R1 _{set2}	stream	9.239	runoff	0.485	0.551
R3 _{set2}	stream	10.360	runoff	0.520	0.685
R4 _{set2}	stream	9.376	runoff	0.438	0.609
<i>Winter Cereals - Single application</i>					
D1 _{set2}	ditch	3.819	drift	0.309	0.316
D1 _{set2}	stream	2.970	drift	0.012	0.082
D2 _{set2}	ditch	5.546	drainage	0.384	0.290
D2 _{set2}	stream	3.651	drainage	0.049	0.191
D3 _{set2}	ditch	3.800	drift	0.178	0.218
D4 _{set2}	pond	0.131	drift	0.092	0.013
D4 _{set2}	stream	2.809	drift	0.005	0.063
D5 _{set2}	pond	0.131	drift	0.094	0.009
D5 _{set2}	stream	3.034	drift	0.005	0.062
D6 _{set2}	ditch	3.757	drift	0.079	0.181
R1 _{set2}	pond	0.176	drainage	0.144	0.010
R1 _{set2}	stream	2.504	drift	0.135	0.132
R3 _{set2}	stream	3.517	drift	0.127	0.190
R4 _{set2}	stream	2.515	drift	0.085	0.125
<i>Spring Cereals - Multiple applications</i>					
D1 _{set2}	ditch	4.078	drift	2.110	0.166
D1 _{set2}	stream	2.910	drift	0.242	0.143
D3 _{set2}	ditch	3.325	drift	0.351	0.120
D4 _{set2}	pond	0.167	drift	0.119	0.007
D4 _{set2}	stream	2.776	drift	0.032	0.094
D5 _{set2}	pond	0.151	drift	0.108	0.007
D5 _{set2}	stream	2.869	drift	0.011	0.079
R4 _{set2}	stream	13.350	runoff	1.280	0.620
<i>Spring Cereals - Single application</i>					
D1 _{set2}	ditch	3.851	drift	1.589	0.189
D1 _{set2}	stream	3.365	drift	0.145	0.165
D3 _{set2}	ditch	3.804	drift	0.198	0.137
D4 _{set2}	pond	0.131	drift	0.093	0.008
D4 _{set2}	stream	3.110	drift	0.013	0.104
D5 _{set2}	pond	0.131	drift	0.094	0.009
D5 _{set2}	stream	3.194	drift	0.008	0.079
R4 _{set2}	stream	8.165	runoff	0.671	0.379

Bold values are above RAC; *twa-time as required by ecotox

FOCUS Step 4

Mitigations measures:

The calculations at this Step includes spray drift mitigations as well as runoff mitigations. For spray drift, no spray buffer zones were simulated (from 5 to 20 meters) and for runoff, the reduction came from the vegetated filter strips (10 and 20 meters) was considered. ~~In addition, vegetated filter strip factors for 5 meters and 15 meters were also performed to provide eMS with information on the appropriate mitigation measure for their countries.~~

Table 8.9-7: Reduction efficiencies of surface runoff used for the calculation (according to national requirements)

Buffer width (m)	5 ^a	10 ^b	15 ^c	20 ^b
Reduction in volume of runoff water (%)	40	60	70	80
Reduction in mass of pesticide transported in aqueous phase (%)	40	60	70	80
Reduction in mass of eroded sediment (%)	40	85	90	95
Reduction in mass of pesticide transported in sediment phase (%)	40	85	90	95

^a EXPOSIT 3.0; ^b FOCUS (2007); ^c average of 10 and 20 m

Deposition after volatilization:

Since folpet is a semi-volatile substance and above the trigger for short-range exposure assessment according to FOCUS Air³, deposition on the water surface after volatilization from soil and plants has to be addressed.

The following table provides an overview of the deposition rates considered for each use and included in STEP 4 for PEC_{sw} calculations. Hourly deposition rates were calculated with the Tool EVA 3.0⁴. Deposition after volatilization is assumed to be most relevant within 24 hours.

Table 8.9-8: Hourly deposition rates of folpet due to volatilization after application in arable crops calculated with EVA 3.1

Time [h]	Hourly deposition amounts [mg m ⁻²]						
	Arable crops*						
	Application rate 2x450 g ha ⁻¹			Application rate 2x600 g ha ⁻¹			
	5m	10m	20m	5m	10m	15m	20m
0 - 1	0.0023	0.0018	0.0010	0.0031	0.0024	0.0018	0.0014
1 - 2	0.0023	0.0018	0.0010	0.0031	0.0024	0.0018	0.0014
2 - 3	0.0023	0.0018	0.0010	0.0031	0.0024	0.0018	0.0014
3 - 4	0.0023	0.0018	0.0010	0.0031	0.0024	0.0018	0.0014
4 - 5	0.0012	0.0009	0.0005	0.0016	0.0012	0.0009	0.0007
5 - 6	0.0012	0.0009	0.0005	0.0016	0.0012	0.0009	0.0007
6 - 7	0.0012	0.0009	0.0005	0.0016	0.0012	0.0009	0.0007
7 - 8	0.0012	0.0009	0.0005	0.0016	0.0012	0.0009	0.0007
8 - 9	0.0012	0.0009	0.0005	0.0016	0.0012	0.0009	0.0007
9 - 10	0.0012	0.0009	0.0005	0.0016	0.0012	0.0009	0.0007
10 - 11	0.0012	0.0009	0.0005	0.0016	0.0012	0.0009	0.0007

³ FOCUS (2008): Pesticides in Air: Considerations for Exposure Assessment. Report of the FOCUS Working Group on Pesticides in Air, EC Document Reference Sanco/10553/2002 Rev. 2 June 2008, 327 pp

⁴ HOLDT, G, GROßMANN, D., HÖLLRIGL-ROSTA, A., PICKL, C. (2017): EVA Exposure via air, Assessment of the Short Range Transport and Deposition of Pesticides for Aquatic and Terrestrial Ecosystems (spray drift and volatilization considered). Federal Environment Agency, Germany (UBA)

Time [h]	Hourly deposition amounts [mg m ⁻²]						
	Arable crops*						
	Application rate 2x450 g ha ⁻¹			Application rate 2x600 g ha ⁻¹			
	5m	10m	20m	5m	10m	15m	20m
11 - 12	0.0012	0.0009	0.0005	0.0016	0.0012	0.0009	0.0007
12 - 13	0.0006	0.0004	0.0003	0.0008	0.0006	0.0005	0.0003
13 - 14	0.0006	0.0004	0.0003	0.0008	0.0006	0.0005	0.0003
14 - 15	0.0006	0.0004	0.0003	0.0008	0.0006	0.0005	0.0003
15 - 16	0.0006	0.0004	0.0003	0.0008	0.0006	0.0005	0.0003
16 - 17	0.0006	0.0004	0.0003	0.0008	0.0006	0.0005	0.0003
17 - 18	0.0006	0.0004	0.0003	0.0008	0.0006	0.0005	0.0003
18 - 19	0.0006	0.0004	0.0003	0.0008	0.0006	0.0005	0.0003
19 - 20	0.0006	0.0004	0.0003	0.0008	0.0006	0.0005	0.0003
20 - 21	0.0006	0.0004	0.0003	0.0008	0.0006	0.0005	0.0003
21 - 22	0.0006	0.0004	0.0003	0.0008	0.0006	0.0005	0.0003
22 - 23	0.0006	0.0004	0.0003	0.0008	0.0006	0.0005	0.0003
23 - 24	0.0006	0.0004	0.0003	0.0008	0.0006	0.0005	0.0003

* Considering worst-case crop interception 80% and scenario *arable crops* in EVA.

Table 8.9-9: FOCUS Step 4 PEC_{sw} and PEC_{sed} for folpet following single and multiple applications of SAP50SCF to winter and spring cereals (maximum dose)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d-PEC _{sw,twa} (µg/L)*	Max PEC _{sed} (µg/kg)
<i>Winter Cereals – Multiple applications – 5 meters of vegetated filter strip</i>					
R1 _{set2}	stream	2.750	runoff	0.1187	0.3199
R3 _{set2}	stream	3.892	runoff	0.1982	0.7297
<i>Winter Cereals – Multiple applications – 10 meters of vegetated filter strip</i>					
R1 _{set2}	stream	1.870	runoff	0.08049	0.2009
R3 _{set2}	stream	2.717	runoff	0.1357	0.4563
<i>Spring Cereals – Multiple applications – 15 meters of vegetated filter strip</i>					
D1 _{set2}	ditch	0.4592	drainage	0.2776	0.05204
R4 _{set2}	stream	3.873	runoff	0.3106	0.4707
<i>Spring Cereals – Multiple applications – 20 meters of vegetated filter strip</i>					
D1 _{set2}	ditch	0.3465	drift	0.2088	0.03929
R4 _{set2}	stream	2.640	runoff	0.2119	0.3203
<i>Spring Cereals – Single application – 10 meters of vegetated filter strip</i>					
R4 _{set2}	stream	2.805	runoff	0.1823	0.3546

Bold values are above RAC; *:twa-time as required by ecotox

Additional calculations with DT50 soil of 1.38 days and Q10=2.2 – Step 4

Table 8.9-9a: FOCUS Step 4 PEC_{sw} and PEC_{sed} for folpet following single and multiple applications of SAP50SCF to winter and spring cereals (maximum dose)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d-PEC _{sw,twa} (µg/L)*	Max PEC _{sed} (µg/kg)
----------------	-----------	------------------------------	----------------------	------------------------------------	--------------------------------

<i>Winter Cereals – Multiple applications – 5 meters of vegetated filter strip</i>					
R3_{set2}	stream	2.863	runoff	0.1504	0.1652
<i>Winter Cereals – Multiple applications – 10 meters of vegetated filter strip</i>					
R3 _{set2}	stream	1.999	runoff	0.102	0.099
<i>Spring Cereals - Multiple applications – 15 meters of vegetated filter strip</i>					
D1 _{set2}	ditch	0.407	drift	0.229	0.014
R4 _{set2}	stream	3.067	runoff	0.261	0.109
<i>Spring Cereals - Multiple applications – 20 meters of vegetated filter strip</i>					
D1 _{set2}	ditch	0.307	drift	0.172	0.010
R4 _{set2}	stream	2.090	runoff	0.178	0.074
<i>Spring Cereals - Single application – 5 meters of vegetated filter strip</i>					
R4 _{set2}	stream	3.013	runoff	0.220	0.108
<i>Spring Cereals - Single application – 10 meters of vegetated filter strip</i>					
R4 _{set2}	stream	2.094	runoff	0.152	0.075

Bold values are above RAC; *:two-time as required by ecotox

Additional calculations with DT50 soil of 4.68 days and Q10=2.2 –Step 4 (maximum dose)

Table 8.9-9b: FOCUS Step 4 PEC_{sw} and PEC_{sed} for folpet following single and multiple applications of SAP50SCF to winter and spring cereals (maximum dose)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, two} (µg/L)*	Max PEC _{sed} (µg/kg)
<i>Winter Cereals - Multiple applications – 10 meters of vegetated filter strip</i>					
D2 _{set2}	ditch	5.555	drainage	0.254	0.244
R1 _{set2}	stream	4.197	runoff	0.212	0.233
R3 _{set2}	stream	4.730	runoff	0.227	0.282
R4 _{set2}	stream	4.265	runoff	0.193	0.275
<i>Winter Cereals – Multiple applications – 15 meters of vegetated filter strip</i>					
D2_{set2}	ditch	5.555	drainage	0.215	0.244
R1_{set2}	stream	3.221	runoff	0.162	0.178
R3_{set2}	stream	3.634	runoff	0.174	0.215
R4_{set2}	stream	3.273	runoff	0.148	0.211
<i>Winter Cereals - Multiple applications – 20 meters of vegetated filter strip</i>					
D2 _{set2}	ditch	5.555	drainage	0.193	0.244
R1 _{set2}	stream	2.198	runoff	0.110	0.121
R3 _{set2}	stream	2.482	runoff	0.120	0.145
R4 _{set2}	stream	2.235	runoff	0.101	0.145
<i>Winter Cereals – Single application – 5 meters of vegetated filter strip</i>					
D1_{set2}	ditch	1.040	drift	0.097	0.092
D2_{set2}	ditch	5.546	drainage	0.127	0.243
<i>Winter Cereals - Single application – 10 meters of vegetated filter strip</i>					
D1 _{set2}	ditch	0.554	drift	0.057	0.051
D2 _{set2}	ditch	5.546	drainage	0.127	0.243
<i>Spring Cereals - Multiple applications – 20 meters of vegetated filter strip</i>					

D1 _{set2}	ditch	0.310	drift	0.226	0.025
R4 _{set2}	stream	3.155	runoff	0.300	0.146
<i>Spring Cereals – Single application – 5 meters of vegetated filter strip</i>					
D1_{set2}	ditch	1.072	drift	0.476	0.055
D3_{set2}	ditch	1.031	drift	0.060	0.039
R4_{set2}	stream	5.303	runoff	0.431	0.247
<i>Spring Cereals - Single application – 10 meters of vegetated filter strip</i>					
D1 _{set2}	ditch	0.588	drift	0.263	0.030
D3 _{set2}	ditch	0.547	drift	0.033	0.021
R4 _{set2}	stream	3.684	runoff	0.299	0.170

Bold values are above RAC; *:two-time as required by ecotox

Metabolites of Folpet

Table 8.9-10: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for *Phthalimide* following application of SAP50SCF (maximum dose)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	7 d- PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
	Winter cereals				
Step 1	---	<u>79.29</u>	---	10.67	131.20
Step 2					
Northern Europe	Oct-Feb	<u>24.39 (19.49)</u> 8.08 (7.97)	Runoff/Drainage	<u>3.64 (2.91)</u> 1.24 (1.22)	<u>40.83 (32.63)</u> 13.55 (13.37)
Southern Europe		6.47 (6.38)		0.99 (0.98)	10.85 (10.71)
Northern Europe	Mar-May	<u>9.76 (7.80)</u> 3.24 (3.20)	Runoff/Drainage	<u>1.46 (1.16)</u> 0.50 (0.49)	<u>16.36 (13.08)</u> 5.45 (5.39)
Southern Europe		6.47 (6.38)		0.99 (0.98)	10.85 (10.71)
	Spring cereals				
Step 1	---	<u>79.29</u>	---	10.67	131.20
Step 2					
Northern Europe	March-May	<u>9.76 (7.80)</u> 3.24 (3.20)	Runoff/Drainage	<u>1.46 (1.16)</u> 0.50 (0.49)	<u>16.36 (13.08)</u> 5.45 (5.39)
Southern Europe		6.47 (6.38)		0.99 (0.98)	10.85 (10.71)

Bold values are above RAC; values between brackets correspond to single application; *Italic and underline values will be used in aquatic risk assessment (see section 9)*

Table 8.9-11: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for *Phthalamic acid* following application of SAP50SCF (maximum dose)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	7 d- PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
	Winter cereals				
Step 1	---	66.78	---	42.39	6.60
Step 2					
Northern Europe	Oct-Feb	3.80 (3.40) 1.02 (1.02)	Runoff/Drainage	2.43 (2.17) 0.45 (0.45)	0.38 (0.34) 0.10 (0.010)
Southern Europe		0.86 (0.86)		0.55 (0.55)	0.09 (0.09)
Northern Europe	Mar-May	1.66 (1.50) 0.55 (0.54)	Runoff/Drainage	1.06 (0.96) 0.35 (0.35)	0.17 (0.15) 0.05 (0.05)
Southern Europe		0.86 (0.86)		0.55 (0.55)	0.09 (0.09)
	Spring cereals				
Step 1	---	66.78	---	42.39	6.60
Step 2					
Northern Europe	March-May	1.66 (1.50) 0.55 (0.54)	Runoff/Drainage	1.06 (0.96) 0.35 (0.35)	0.17 (0.15) 0.05 (0.05)
Southern Europe		0.86 (0.86)		0.55 (0.55)	0.09 (0.09)

Bold values are above RAC; values between brackets correspond to single application; *Italic and underline values will be used in aquatic risk assessment (see section 9)*

Table 8.9-12: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for *Phthalic acid* following application of SAP50SCF (maximum dose)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	7 d- PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
	Winter cereals				
Step 1	---	<u>60.37</u>	---	29.97	43.17
Step 2					
Northern Europe	Oct-Feb	12.89 (11.73) <i>3.02 (3.05)</i>	Runoff/Drainage	6.69 (6.08) <i>1.56 (1.58)</i>	9.41 (8.56) <i>2.20 (2.22)</i>
Southern Europe		<i>2.51 (2.54)</i>		<i>1.30 (1.32)</i>	<i>1.82 (1.85)</i>
Northern Europe	Mar-May	5.41 (4.96) <i>1.48 (1.52)</i>	Runoff/Drainage	2.80 (2.57) <i>0.77 (0.79)</i>	3.94 (3.62) <i>1.08 (1.10)</i>
Southern Europe		<i>2.51 (2.54)</i>		<i>1.30 (1.32)</i>	<i>1.82 (1.85)</i>
	Spring cereals				
Step 1	---	<u>60.37</u>	---	29.97	43.17
Step 2					
Northern Europe	March-May	5.41 (4.96) <i>1.48 (1.52)</i>	Runoff/Drainage	2.80 (2.57) <i>0.77 (0.79)</i>	3.94 (3.62) <i>1.08 (1.10)</i>
Southern Europe		<i>2.51 (2.54)</i>		<i>1.30 (1.32)</i>	<i>1.82 (1.85)</i>

Bold values are above RAC; values between brackets correspond to single application; *Italic and underline values will be used in aquatic risk assessment (see section 9)*

Table 8.9-13: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for Benzamide following application of SAP50SCF (maximum dose)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	7 d- PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
	Winter cereals				
Step 1	---	<u>17.12</u>	---	17.08	0.00
Step 2					
Northern Europe	Oct-Feb	2.48 (2.07) <i>0.85 (0.68)</i>	Runoff/Drainage	2.47 (2.07) <i>0.85 (0.67)</i>	0.00 (0.00)
Southern Europe		0.76 (0.59)		0.76 (0.59)	0.00 (0.00)
Northern Europe	Mar-May	1.23 (0.97) <i>0.58 (0.41)</i>	Runoff/Drainage	1.23 (0.96) <i>0.58 (0.41)</i>	0.00 (0.00)
Southern Europe		<i>0.76 (0.59)</i>		<i>0.76 (0.59)</i>	<i>0.00 (0.00)</i>
	Spring cereals				
Step 1	---	<u>17.12</u>	---	17.08	0.00
Step 2					
Northern Europe	March-May	1.23 (0.97) <i>0.58 (0.41)</i>	Runoff/Drainage	1.23 (0.97) <i>0.58 (0.41)</i>	1.23 (0.97) <i>0.58 (0.41)</i>
Southern Europe		<i>0.76 (0.59)</i>		<i>0.76 (0.59)</i>	<i>0.76 (0.59)</i>

Bold values are above RAC; values between brackets correspond to single application; *Italic and underline values will be used in aquatic risk assessment (see section 9)*

Table 8.9-14: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for 2-cyanobenzoic acid following application of SAP50SCF (maximum dose)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	7 d- PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
	Winter cereals				
Step 1	---	<u>80.93</u>	---	80.73	0.00
Step 2					
Northern Europe	Oct-Feb	11.71 (9.79) <i>4.02 (3.20)</i>	Runoff/Drainage	11.68 (9.77) <i>4.01 (3.19)</i>	0.00 (0.00)
Southern Europe		<i>3.60 (2.77)</i>		<i>3.59 (2.77)</i>	0.00 (0.00)
Northern Europe	Mar-May	5.83 (4.57) <i>2.75 (1.93)</i>	Runoff/Drainage	5.81 (4.56) <i>2.74 (1.92)</i>	0.00 (0.00)
Southern Europe		<i>3.60 (2.77)</i>		<i>3.59 (2.77)</i>	0.00 (0.00)
	Spring cereals				
Step 1	---	<u>80.93</u>	---	80.73	0.00
Step 2					
Northern Europe	March-May	5.83 (4.57) <i>2.75 (1.93)</i>	Runoff/Drainage	5.81 (4.56) <i>2.74 (1.92)</i>	0.00 (0.00)
Southern Europe		<i>3.60 (2.77)</i>		<i>3.59 (2.77)</i>	0.00 (0.00)

Bold values are above RAC; values between brackets correspond to single application; *Italic and underline values will be used in aquatic risk assessment (see section 9)*

CONCLUSIONS

Single and multiple applications were considered for simulations that were conducted employing the FOCUS_{sw} tools at Step 1-2 for the active substance and its metabolites. Step 3 and 4 were used to simulated PEC_{sw} for folpet.

Although the PEC_{sw} results obtained with the minimum dose advocated for the use of this product are covered by the simulations made with the maximum dose (risk envelope approach), the applicant presents both in this section (please see Appendix 3 for all results obtained with the minimum dose). A conclusion summary table is presents below.

Therefore, the following mitigation measures should be applied to guarantee a safe assessment for the aquatic systems (please see section 9 of this dRR).

Table 8.9-15: Assessment summary of folpet and its metabolites following application of SAP50SCF

Dose	Application number	Crop	Mitigation measure
Maximum dose	Single	Winter cereals	None
		Spring cereals	R4 scenario: 10 meters of vegetated filter strip
	Multiple	Winter cereals	R1 and R3, R4 scenario: 10 5 meters of vegetated filter strip
		Spring cereals	R4 scenario: 20 15 meters of vegetated filter strip
Minimum dose	Single	Winter cereals	None
		Spring cereals	R4 scenario: 10 5 meters of vegetated filter strip
	Multiple	Winter cereals	R1, R4, R3 scenario: 10 5 meters of vegetated filter strip
		Spring cereals	R4 scenario: 20 10 meters of vegetated filter strip

zRMS comments:

The application pattern considered in the surface water exposure assessment presented in Table 8.9-1 is in general in line with the Central Zone GAP and is protective for intended uses of SAP50SCF in cereals.

Application windows that are presented in modelling reports were checked by the zRMS using AppDate ver. 3.06 tool and are considered acceptable.

The input parameters considered by the Applicant in surface water modelling for folpet and its metabolites presented in Table 8.9-2 are in general in line with EU agreed endpoints reported in EFSA Scientific Report (2009) 297, 1-80 with following exceptions:

- for folpet and its metabolites: phthalimide and phthalic acid the geometric mean soil DT₅₀ values normalised with Q₁₀ of 2.58 were considered although the EU agreed endpoints were normalised with Q₁₀ of 2.2. In line with current FOCUS requirements the Q₁₀ factor of 2.58 should be used in the normalisation procedure, however, the exposure assessment should be based on endpoints as reported in the LoEP, even if the EU agreed data were normalised using Q₁₀ of 2.2. For folpet the EU agreed value of soil DT₅₀ is 4.68 days instead of the value of 1.38 days as presented in Table 8.9-3a. For metabolites phthalimide and phthalic acid the EU agreed values of soil DT₅₀ are 7.88 days and 3.15 days, respectively. Since consideration of the longer DT₅₀ values represents worst case, thus the respective correction were introduced in Table 8.9-3a and used in independent zRMS calculations.
- for folpet metabolite phthalimide the geometric mean K_{foc} value was considered by the Applicant although in the EFSA conclusion arithmetic mean value is reported. Since the geometric mean value represents worst case comparing to arithmetic mean it is accepted by the zRMS.

The Applicant is kindly reminded, that no new endpoints for active compound and its metabolites should be generated for purposes of the product registration, unless critical for the exposure assessment. In case of folpet, sufficient data were available from the EU review and should have been used for modelling purposes.

At Step 3 PUF value of 0 was assumed for folpet, in line with current recommendations.

The surface water exposure was independently validated by the zRMS in additional modelling with modified input parameters of soil DT₅₀ as discussed above, since it represents worst case for surface water exposure.

The information on the dominant entry route at Steps 1-2 was struck through by the zRMS in tables above, since at this stage of the exposure assessment it is not possible to identify the main route of migration.

Results for folpet at Step 1-2 obtained by the zRMS in independent modelling were higher comparing with the results obtained by the Applicant, since the longer soil DT₅₀ value was taken into account. Thus PEC_{sw/sed} values reported in Table 8.9-4 were corrected by the zRMS and may be used for purposes of the aquatic risk assessment.

It is noted that the Applicant performed two sets of simulations ascribing the actual DT₅₀ of the whole system to the water or the sediment phase and using the default value of 1000 days for the other compartment. Since this is relevant only for STEP 3 calculations and was unnecessary for Step 2 calculations, thus results presented in table 8.9-5 were struck through as not relevant.

Step 4 simulations were performed by the Applicant considering vegetated filter strip of 5, 10, 15 and 20 m. However, according to recommendations of the FOCUS work group on landscape and mitigation (SANCO/10422/2005) vegetated filter buffer zones of 10 and 20 m are recommended as reasonable worst-case assumption. Concerned Member States must decide on acceptability if proposed mitigation measures of 5 and 15 m are applicable in their countries. Therefore results performed with assumption of 5 and 15 m vegetated filter strip were not validated by the zRMS and was thus struck through and shaded. Please note that, in Poland refinements using a 5 m and 15 m vegetated filter buffer zones are not considered.

Results for folpet at Step 3-4 obtained by the zRMS in independent modelling with consideration of the longer and the EU agreed value of soil DT₅₀ of 4.68 days were in good agreement with results obtained by the Applicant and presented in Appendix 3.3 in Tables: App 3.3-10 to App 3.3-13 and may be used in the aquatic risk assessment. Since the relevant PEC_{sw} and PEC_{sed} for folpet are presented in Appendix 3.3, the relevant tables with the results of surface water modelling at Step 3 (Table 8.9-6b) and at Step 4 (Table 8.9-9b) for the maximum dose rate: 2 x 600g a.s./ha were copy to the 8.9 section above and may be used in the aquatic risk assessment.

As evaluation should be performed with consideration of the EU agreed endpoints, results obtained at Step 3-4 and presented in Tables: 8.9-5, 8.9-6, 8.9-6a, 8.9-9 and 8.9-9a were not validated by the zRMS and were struck through and shaded for transparency.

The Table 8.9-15 of the assessment summary was amended accordingly by the zRMS.

Results of PEC_{sw} and PEC_{sed} for folpet metabolites at Step 1-2 obtained by the zRMS in independent modelling were higher comparing with those obtained by the Applicant, since higher soil DT₅₀ values were taken into account as they are EU agreed endpoints. Values reported in Tables: 8.9-10- 8.9-14 were thus corrected by the zRMS and may be used for purposes of 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.

8.9.2.1 PEC_{sw/sed} of SAP50SCF

PEC_{sw} of the preparation is calculated with the spray drift calculator included in SWASH v5.3, based on specific density of 1230 g/L and maximum and minimum individual application rate of 1.2 L/ha and 0.9 L/ha, respectively. PEC_{sw} of the preparation via the spray drift route of contamination are presented below.

Table 8.9-16: PEC_{sw} for SAP50SCF on cereals

Application rate (g/ha)	PEC _{swini} (µg/L)		
	FOCUS values	10 m	20 m
1476	9.4828	1.3632	0.7083
1107	7.1121	1.0224	0.5312

zRMS comments:

The surface water exposure to formulation was validated by the zRMS using Spray Drift Calculator. Obtained PEC_{sw} were in agreement with these reported in Table 8.9-16 and may be used in the aquatic risk assessment.

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

The vapour pressure of folpet is 2.1×10^{-5} Pa (at 25 °C) and Henry's law constant is 8×10^{-3} Pa.m³.mol⁻¹ at 25°C. The dry deposition of folpet was taken into account for non-target organisms exposure assessment.

The atmospheric half-life of folpet resulting from photochemical oxidation is estimated from the Atkinson method to 6.16 hours (day length and OH concentration not reported). Therefore, folpet is not expected to have a potential for atmospheric long-range transport (FOCUS AIR, 2008).

Potential release of thiophosgene due to soil degradation of folpet was addressed by the notifier with captan soil degradation studies in EU evaluation. Based on these studies, the experts' meeting concluded that it could not be excluded that thiophosgene might be released to the air as a result of the soil metabolism of folpet, but that if this occurs, it would only be present in trace amounts.

zRMS comments:

Information regarding fate and behaviour of folpet in the air is in line with EU agreed data reported in EFSA Scientific Report (2009) 297, 1-80.

Vapour pressure of folpet is $>10^{-5}$ Pa, so volatilisation from soil and plant surfaces is possible. However, based on the air $DT_{50} < 2$ days, the short- and long-range transport of this compound in the atmosphere is not expected.

Overall, unacceptable contamination of the atmosphere with folpet following application of SAP50SCF is not expected.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2.4/01	Fernandes, V.	2022a	Predicted Environmental Concentrations of Folpet and its metabolites in Groundwater (PEC _{gw}) based on FOCUS PELMO 6.6.4, FOCUS PEARL 5.5.5 and MACRO 5.5.4 for risk assessment of SAP50SCF on Cereals ASC100-2022 non GLP Unpublished	N	Ascenza Agro SA
KCP 9.2.5/01	Fernandes, V.	2022b	Predicted Environmental Concentrations of Folpet and its metabolites in Surface Water and Sediment (PEC _{sw} and PEC _{sed}) based on Tiered FOCUS Approach for risk assessment of SAP50SCF on Cereals ASC101-2022 non GLP Unpublished	N	Ascenza Agro SA

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 studies submitted by the Applicant and not relied on					

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

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

Appendix 2 Detailed evaluation of the new Annex II studies

Nothing is presented under this appendix.

Appendix 3 Additional information provided by the applicant concerning PEC calculations for the minimum dose

zRMS comments:

Detailed comments of the zRMS of the soil exposure, the groundwater and surface water modelling may be found in points 8.7, 8.8 and 8.9 of this document, respectively.

The Predicted Environmental Concentrations results obtained with the minimum dose advocated for the use of this product are covered by the simulations made with the maximum dose (risk envelope approach).

However, the applicant presents, in this appendix, the PEC_{soil} , PEC_{gw} and PEC_{sw} values with the minimum dose for active substance and its metabolites.

All endpoints, dates and assumptions expressed in core section are maintained.

App3.1 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

Table App3.1-1: PEC_{soil} for folpet after application of SAP50SCF (minimum dose)

PEC_{soil} (mg/kg)		Cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.120	-	0.198	-
Short term	24h	0.116	0.118	0.192	0.195
	2d	0.113	0.116	0.186	0.192
	4d	0.106	0.113	0.174	0.186
Long term	7d	0.096	0.108	0.159	0.178
	14d	0.078	0.097	0.128	0.160
	21d	0.062	0.088	0.103	0.145
	28d	0.050	0.080	0.083	0.132
	50d	0.025	0.061	0.042	0.100
	100d	0.005	0.037	0.009	0.061

Bold values will be used in risk assessment (see section 9)

Table App3.1-2: PEC_{soil} for phthalimide after application of SAP50SCF (minimum dose)

PEC_{soil} (mg/kg)		Cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.039	-	0.069	-
Short term	24h	0.038	0.038	0.067	0.068
	2d	0.037	0.038	0.066	0.067
	4d	0.036	0.037	0.064	0.066
Long term	7d	0.034	0.036	0.061	0.065
	14d	0.030	0.034	0.053	0.061
	21d	0.027	0.032	0.047	0.057
	28d	0.023	0.030	0.042	0.054
	50d	0.016	0.026	0.028	0.045
	100d	0.006	0.018	0.011	0.032

Bold values will be used in risk assessment (see section 9)

PEC _{soil} (mg/kg)		Cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.011	-	0.011	-
Short term	24h	0.002	0.005	0.002	0.005
	2d	0.000	0.003	0.000	0.003
	4d	0.000	0.002	0.000	0.002
Long term	7d	0.000	0.001	0.000	0.001
	14d	0.000	0.000	0.000	0.000
	21d	0.000	0.000	0.000	0.000
	28d	0.000	0.000	0.000	0.000
	50d	0.000	0.000	0.000	0.000
	100d	0.000	0.000	0.000	0.000

Table App30-4: PEC_{soil} for phthalic acid after application of SAP50SCF (minimum dose)

PEC _{soil} (mg/kg)		Cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.011	-	0.012	-
Short term	24h	0.009	0.010	0.010	0.011
	2d	0.008	0.009	0.009	0.010
	4d	0.006	0.008	0.006	0.009
Long term	7d	0.003	0.007	0.004	0.007
	14d	0.001	0.004	0.001	0.005
	21d	0.000	0.003	0.000	0.003
	28d	0.000	0.002	0.000	0.003
	50d	0.000	0.001	0.000	0.001
	100d	0.000	0.001	0.000	0.001

App3.2 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4)

[illegible]

[illegible][illegible]

Table App3.2-2: PEC_{GW} for folpet and its metabolites on cereals following application of SAP50SCF (FOCUS MACRO 5.5.4)

	PEC _{GW} at 1 m soil depth [µg/L]			
	FOCUS MACRO 5.5.4			
	Parent	Phthalimide	Phthalamic acid	Phthalic acid
Winter Cereals – 2 x 450 g as/ha, Châteaudun scenario	0.000	0.000	0.000	0.000
Spring Cereals – 2 x 450 g as/ha, Châteaudun scenario	0.000	0.000	0.000	0.000

App3.3 Predicted Environmental Concentrations in surface water (PEC_{sw}) (KCP 9.2.5)

Folpet

FOCUS Step 1-2

Table App3.3-1: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for *Folpet* following application of SAP50SCF – set 1 (minimum dose)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	7 d- PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
	Winter cereals				
Step 1	---	<u>110.87</u>	---	7.93	324.48
Step 2					
Northern Europe	Oct-Feb	5.73 (<u>5.73</u>)	Runoff/Drainage	0.21 (0.21)	17.55 (17.55)
Southern Europe		4.58 (<u>4.58</u>)		0.33 (0.33)	14.06 (14.07)
Northern Europe	Mar-May	3.66 (<u>4.14</u>)	Runoff/Drainage	0.59 (0.62)	7.10 (7.11)
Southern Europe		4.58 (<u>4.58</u>)		0.33 (0.33)	14.06 (14.07)
	Spring cereals				
Step 1	---	<u>110.87</u>	---	7.93	324.48
Step 2					
Northern Europe	March-May	3.66 (<u>4.14</u>)	Runoff/Drainage	0.59 (0.62)	7.10 (7.11)
Southern Europe		4.58 (<u>4.58</u>)		0.33 (0.33)	14.06 (14.07)

Bold values are above RAC; values between brackets correspond to single application; *Italic and underline values will be used in aquatic risk assessment (see section 9)*

Table 0-2: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for *Folpet* following application of SAP50SCF – set 2 (minimum dose)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	7 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
Winter cereals					
Step 1	---	<u>110.87</u>	---	7.93	324.48
Step 2					
Northern Europe	Oct-Feb	7.36 (<u>7.48</u>)	Runoff/Drainage	3.56 (3.60)	17.42 (17.41)
Southern Europe		6.22 (<u>6.34</u>)		2.97 (3.02)	13.94 (13.93)
Northern Europe	Mar-May	3.92 (<u>4.14</u>)	Runoff/Drainage	1.80 (3.04)	6.97 (6.97)
Southern Europe		6.22 (<u>6.34</u>)		2.97 (3.02)	13.94 (13.93)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	7 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
	Spring cereals				
Step 1	---	<u>110.87</u>	---	7.93	324.48
Step 2					
Northern Europe	March-May	3.92 (4.14)	Runoff/Drainage	1.80 (3.04)	6.97 (6.97)
Southern Europe		6.22 (6.34)		2.97 (3.02)	13.94 (13.93)

Bold values are above RAC; values between brackets correspond to single application; *Italic and underline values will be used in aquatic risk assessment (see section 9)*

FOCUS Step 3

Table App3.3-3: FOCUS Step 3 PEC_{sw} and PEC_{sed} for folpet following single and multiple applications of SAP50SCF to winter and spring cereals (minimum dose)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)*	Max PEC _{sed} (µg/kg)
<i>Winter Cereals - Multiple applications</i>					
D1 _{set1}	ditch	2.517	drift	0.07003	0.4558
D1 _{set1}	stream	2.126	drift	0.02067	0.2233
D2 _{set1}	ditch	2.523	drift	0.06331	0.38
D2 _{set1}	stream	2.206	drift	0.03595	0.2675
D3 _{set1}	ditch	2.493	drift	0.06252	0.3009
D4 _{set2}	pond	0.1198	drift	0.09543	0.02799
D4 _{set1}	stream	1.884	drift	0.004031	0.06039
D5 _{set2}	pond	0.1387	drift	0.1103	0.02554
D5 _{set1}	stream	2.174	drift	0.01214	0.1194
D6 _{set1}	ditch	2.505	drift	0.0607	0.2973
R1 _{set2}	pond	0.02274	runoff	0.1815	0.03516
R1 _{set2}	stream	3.337	runoff	0.1453	0.3734
R3 _{set2}	stream	4.464	runoff	0.2408	0.8497
R4 _{set2}	stream	2.54	runoff	0.1252	0.4355
<i>Winter Cereals - Single application</i>					
D1 _{set1}	ditch	2.861	drift	0.07524	0.4567
D1 _{set1}	stream	2.223	drift	0.005496	0.07826
D2 _{set1}	ditch	2.879	drift	0.07226	0.4349
D2 _{set1}	stream	2.445	drift	0.02158	0.2298
D3 _{set1}	ditch	2.851	drift	0.0454	0.3443
D4 _{set1}	pond	0.09837	drift	0.003128	0.01719
D4 _{set1}	stream	2.106	drift	0.00368	0.05285
D5 _{set1}	pond	0.09838	drift	0.001948	0.01321
D5 _{set1}	stream	2.276	drift	0.003849	0.05518
D6 _{set1}	ditch	2.818	drift	0.03028	0.2827
R1 _{set1}	pond	0.09838	drift	0.002062	0.01346
R1 _{set1}	stream	1.878	drift	0.02796	0.1551

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)*	Max PEC _{sed} (µg/kg)
R3 _{set1}	stream	2.638	drift	0.02433	0.2576
R4 _{set1}	stream	1.886	drift	0.01413	0.1629
<i>Spring Cereals - Multiple applications</i>					
D1 _{set2}	ditch	3.366	drift	1.871	0.3512
D1 _{set1}	stream	2.183	drift	0.04629	0.2681
D3 _{set1}	ditch	2.495	drift	0.04584	0.235
D4 _{set2}	pond	0.1323	drift	0.1022	0.01676
D4 _{set1}	stream	2.083	drift	0.01839	0.1414
D5 _{set2}	pond	0.1232	drift	0.09585	0.01619
D5 _{set1}	stream	2.152	drift	0.007163	0.09999
R4 _{set2}	stream	8.38	runoff	0.682	1.041
<i>Spring Cereals - Single application</i>					
D1 _{set1}	ditch	2.886	drift	0.04012	0.3116
D1 _{set1}	stream	2.524	drift	0.03228	0.2726
D3 _{set1}	ditch	2.854	drift	0.0262	0.2385
D4 _{set1}	pond	0.09842	drift	0.001598	0.01179
D4 _{set1}	stream	2.333	drift	0.008681	0.1156
D5 _{set1}	pond	0.09841	drift	0.00195	0.01322
D5 _{set1}	stream	2.396	drift	0.005875	0.08323
R4 _{set2}	stream	4.662	runoff	0.3109	0.5988

Bold values are above RAC; *twa-time as required by ecotox

Additional calculations with DT50 soil of 1.38 days and Q10=2.2 – Minimum dose Step3

Table App3.3-3a: FOCUS Step 3 PEC_{sw} and PEC_{sed} for folpet following single and multiple applications of SAP50SCF to winter and spring cereals (minimum dose) - Set2 with a DT50 of 1000 days applied to the surface water compartment

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)*	Max PEC _{sed} (µg/kg)
<i>Winter Cereals - Multiple applications</i>					
D1 _{set2}	ditch	2.516	drift	0.778	0.186
D1 _{set2}	stream	2.125	drift	0.026	0.126
D2 _{set2}	ditch	2.523	drift	0.595	0.165
D2 _{set2}	stream	2.205	drift	0.509	0.113
D3 _{set2}	ditch	2.493	drift	0.244	0.120
D4 _{set2}	pond	0.107	drift	0.076	0.008
D4 _{set2}	stream	1.882	drift	0.004	0.046
D5 _{set2}	pond	0.130	drift	0.094	0.007
D5 _{set2}	stream	2.173	drift	0.014	0.073
D6 _{set2}	ditch	2.504	drift	0.295	0.098
R1 _{set2}	pond	0.178	runoff	0.132	0.008

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)*	Max PEC _{sed} (µg/kg)
R1 _{set2}	stream	2.615	runoff	0.111	0.108
R3 _{set2}	stream	3.213	runoff	0.183	0.191
R4 _{set2}	stream	1.872	runoff	0.097	0.106
<i>Winter Cereals - Single application</i>					
D1 _{set2}	ditch	2.860	drift	0.227	0.212
D1 _{set2}	stream	2.224	drift	0.006	0.058
D2 _{set2}	ditch	2.878	drift	0.287	0.189
D2 _{set2}	stream	2.445	drift	0.026	0.130
D3 _{set2}	ditch	2.850	drift	0.133	0.137
D4 _{set2}	pond	0.098	drift	0.068	0.008
D4 _{set2}	stream	2.107	drift	0.004	0.046
D5 _{set2}	pond	0.098	drift	0.070	0.005
D5 _{set2}	stream	2.275	drift	0.004	0.044
D6 _{set2}	ditch	2.818	drift	0.059	0.112
R1 _{set2}	pond	0.098	drift	0.069	0.006
R1 _{set2}	stream	1.878	drift	0.031	0.085
R3 _{set2}	stream	2.638	drift	0.035	0.123
R4 _{set2}	stream	1.886	drift	0.019	0.081
<i>Spring Cereals - Multiple applications</i>					
D1 _{set2}	ditch	3.044	drift	1.564	0.097
D1 _{set2}	stream	2.182	drift	0.181	0.084
D3 _{set2}	ditch	2.494	drift	0.263	0.068
D4 _{set2}	pond	0.125	drift	0.089	0.004
D4 _{set2}	stream	2.082	drift	0.024	0.059
D5 _{set2}	pond	0.113	drift	0.080	0.004
D5 _{set2}	stream	2.152	drift	0.009	0.049
R4 _{set2}	stream	6.499	runoff	0.565	0.234
<i>Spring Cereals - Single application</i>					
D1 _{set2}	ditch	2.885	drift	1.177	0.111
D1 _{set2}	stream	2.523	drift	0.105	0.097
D3 _{set2}	ditch	2.853	drift	0.148	0.077
D4 _{set2}	pond	0.098	drift	0.070	0.005
D4 _{set2}	stream	2.332	drift	0.010	0.069
D5 _{set2}	pond	0.098	drift	0.070	0.005
D5 _{set2}	stream	2.395	drift	0.006	0.057
R4 _{set2}	stream	3.410	runoff	0.257	0.123

Bold values are above RAC; *twa-time as required by ecotox

FOCUS Step 4

Table App3.3-4: FOCUS Step 4 PEC_{sw} and PEC_{sed} for *folpet* following single and multiple applications of SAP50SCF to winter and spring cereals (minimum dose)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)*	Max PEC _{sed} (µg/kg)
<i>Winter Cereals - Multiple applications –5 meters of vegetated filter strip</i>					
R3 _{set2}	stream	1.658	runoff	0.07739	0.2831
<i>Winter Cereals - Multiple applications –10 meters of vegetated filter strip</i>					
R3 _{set2}	stream	2.037	runoff	0.1017	0.3422
<i>Spring Cereals - Multiple applications –10 meters of vegetated filter strip</i>					
R4 _{set2}	stream	3.790	runoff	0.3043	0.4611
<i>Spring Cereals - Single application –5 meters of vegetated filter strip</i>					
R4 _{set2}	stream	3.027	runoff	0.1979	0.3877
<i>Spring Cereals - Single application –10 meters of vegetated filter strip</i>					
R4 _{set2}	stream	2.104	runoff	0.1367	0.2660

Bold values are above RAC; *:twa-time as required by ecotox

Additional calculations with DT50 soil of 1.38 days and Q10=2.2 – Minimum dose Step4

Table App3.3-4a: FOCUS Step 4 PEC_{sw} and PEC_{sed} for *folpet* following single and multiple applications of SAP50SCF to winter and spring cereals (minimum dose)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)*	Max PEC _{sed} (µg/kg)
<i>Spring Cereals - Multiple applications –10 meters of vegetated filter strip</i>					
R4 _{set2}	stream	2.937	runoff	0.251	0.105

Bold values are above RAC; *:twa-time as required by ecotox

Metabolites of Folpet

Table App3.3-5: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for *Phthalimide* following application of SAP50SCF (minimum dose)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	7 d- PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
	Winter cereals				
Step 1	---	<u>59.47</u>	---	8.00	98.40
Step 2					
Northern Europe	Oct-Feb	6.06 (5.98)	Runoff/Drainage	0.93 (0.92)	10.16 (10.03)
Southern Europe		4.85 (4.78)		0.74 (0.73)	8.14 (8.03)
Northern Europe	Mar-May	2.43 (2.40)	Runoff/Drainage	0.37 (0.37)	4.09 (4.04)
Southern Europe		4.85 (4.78)		0.74 (0.73)	8.14 (8.03)
	Spring cereals				
Step 1	---	<u>59.47</u>	---	8.00	98.40
Step 2					
Northern Europe	March-May	2.43 (2.40)	Runoff/Drainage	0.37 (0.37)	4.09 (4.04)
Southern Europe		4.85 (4.78)		0.74 (0.73)	8.14 (8.03)

Bold values are above RAC; values between brackets correspond to single application; *Italic and underline values will be used in aquatic risk assessment (see section 9)*

Table App3.3-6: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for Phthalamic acid following application of SAP50SCF (minimum dose)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	7 d- PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
	Winter cereals				
Step 1	---	<u>50.08</u>	---	31.79	4.95
Step 2					
Northern Europe	Oct-Feb	0.76 (0.76)	Runoff/Drainage	0.49 (0.49)	0.08 (0.08)
Southern Europe		0.65 (0.64)		0.41 (0.41)	0.06 (0.06)
Northern Europe	Mar-May	0.41 (0.41)	Runoff/Drainage	0.26 (0.26)	0.04 (0.04)
Southern Europe		0.65 (0.64)		0.41 (0.41)	0.06 (0.06)
	Spring cereals				
Step 1	---	<u>50.08</u>	---	31.79	4.95
Step 2					
Northern Europe	March-May	0.41 (0.41)	Runoff/Drainage	0.26 (0.26)	0.04 (0.04)
Southern Europe		0.65 (0.64)		0.41 (0.41)	0.06 (0.06)

Bold values are above RAC; values between brackets correspond to single application; *Italic and underline values will be used in aquatic risk assessment (see section 9)*

Table App3.3-7: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for Phthalic acid following application of SAP50SCF (minimum dose)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	7 d- PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
	Winter cereals				
Step 1	---	<u>45.28</u>	---	22.47	32.38
Step 2					
Northern Europe	Oct-Feb	2.26 (2.29)	Runoff/Drainage	1.17 (1.18)	1.65 (1.67)
Southern Europe		1.88 (1.91)		0.97 (0.99)	1.37 (1.39)
Northern Europe	Mar-May	1.11 (1.14)	Runoff/Drainage	0.58 (0.59)	0.81 (0.83)
Southern Europe		1.88 (1.91)		0.97 (0.99)	1.37 (1.39)
	Spring cereals				
Step 1	---	<u>45.28</u>	---	22.47	32.38
Step 2					
Northern Europe	March-May	1.11 (1.14)	Runoff/Drainage	0.58 (0.59)	0.81 (0.83)
Southern Europe		1.88 (1.91)		0.97 (0.99)	1.37 (1.39)

Bold values are above RAC; values between brackets correspond to single application; *Italic and underline values will be used in aquatic risk assessment (see section 9)*

Table App3.3-8: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for Benzamide following application of SAP50SCF (minimum dose)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	7 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
	Winter cereals				
Step 1	---	<u>12.84</u>	---	12.81	0.00
Step 2					
Northern Europe	Oct-Feb	0.64 (0.51)	Runoff/Drainage	0.64 (0.51)	0.00 (0.00)
Southern Europe		0.57 (0.44)		0.57 (0.44)	0.00 (0.00)
Northern Europe	Mar-May	0.44 (0.31)	Runoff/Drainage	0.44 (0.31)	0.00 (0.00)
Southern Europe		0.57 (0.44)		0.57 (0.44)	0.00 (0.00)
	Spring cereals				
Step 1	---	<u>12.84</u>	---	12.81	0.00
Step 2					
Northern Europe	March-May	0.44 (0.31)	Runoff/Drainage	0.44 (0.31)	0.00 (0.00)
Southern Europe		0.57 (0.44)		0.57 (0.44)	0.00 (0.00)

Bold values are above RAC; values between brackets correspond to single application; *Italic and underline values will be used in aquatic risk assessment (see section 9)*

Table App3.3-9: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for 2-cyanobenzoic acid following application of SAP50SCF (minimum dose)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	7 d- PEC _{sw,twa} (µg/L)	Max PEC _{sed} (µg/kg)
	Winter cereals				
Step 1	---	<u>60.70</u>	---	60.55	0.00
Step 2					
Northern Europe	Oct-Feb	3.01 (2.40)	Runoff/Drainage	3.01 (2.39)	0.00 (0.00)
Southern Europe		2.70 (2.08)		2.69 (2.08)	0.00 (0.00)
Northern Europe	Mar-May	2.06 (1.45)	Runoff/Drainage	2.06 (1.44)	0.00 (0.00)
Southern Europe		2.70 (2.08)		2.69 (2.08)	0.00 (0.00)
	Spring cereals				
Step 1	---	<u>60.70</u>	---	60.55	0.00
Step 2					
Northern Europe	March-May	2.06 (1.45)	Runoff/Drainage	2.06 (1.44)	0.00 (0.00)
Southern Europe		2.70 (2.08)		2.69 (2.08)	0.00 (0.00)

Bold values are above RAC; values between brackets correspond to single application; *Italic and underline values will be used in aquatic risk assessment (see section 9)*

Additional calculations with DT50 soil of 4.68 days and Q10=2.2

April 2024: As stated previously, the applicant conducted additional calculations to complement the risk assessment, employing a Q10 value of 2.2 and a worst-case DT50 of 4.68 days, corresponding to the arithmetic mean used in groundwater calculations, while still demonstrating safe use. The calculations for Steps 3 and 4 are presented below for both maximum and minimum dose.

Maximum: 2 x 600g a.s./ha

Table App 3.3-10: FOCUS Step 3 PEC_{sw} and PEC_{sed} for folpet following single and multiple applications of SAP50SCF to winter and spring cereals (maximum dose) - Set2 with a DT50 of 1000 days applied to the surface water compartment

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)*	Max PEC _{sed} (µg/kg)
<i>Winter Cereals - Multiple applications</i>					
D1 _{set2}	ditch	3.363	drift	1.053	0.277
D1 _{set2}	stream	2.838	drift	0.041	0.182
D2 _{set2}	ditch	5.555	drainage	0.926	0.253
D2 _{set2}	stream	3.657	drainage	0.732	0.166
D3 _{set2}	ditch	3.324	drift	0.325	0.191
D4 _{set2}	pond	0.143	drift	0.102	0.013
D4 _{set2}	stream	2.510	drift	0.006	0.062
D5 _{set2}	pond	0.174	drift	0.126	0.012
D5 _{set2}	stream	2.898	drift	0.018	0.107
D6 _{set2}	ditch	3.339	drift	0.395	0.162
R1 _{set2}	pond	0.597	runoff	0.505	0.032
R1 _{set2}	stream	9.239	runoff	0.485	0.551

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)*	Max PEC _{sed} (µg/kg)
R3 _{set2}	stream	10.360	runoff	0.520	0.685
R4 _{set2}	stream	9.376	runoff	0.438	0.609
<i>Winter Cereals - Single application</i>					
D1 _{set2}	ditch	3.819	drift	0.309	0.316
D1 _{set2}	stream	2.970	drift	0.012	0.082
D2 _{set2}	ditch	5.546	drainage	0.384	0.290
D2 _{set2}	stream	3.651	drainage	0.049	0.191
D3 _{set2}	ditch	3.800	drift	0.178	0.218
D4 _{set2}	pond	0.131	drift	0.092	0.013
D4 _{set2}	stream	2.809	drift	0.005	0.063
D5 _{set2}	pond	0.131	drift	0.094	0.009
D5 _{set2}	stream	3.034	drift	0.005	0.062
D6 _{set2}	ditch	3.757	drift	0.079	0.181
R1 _{set2}	pond	0.176	drainage	0.144	0.010
R1 _{set2}	stream	2.504	drift	0.135	0.132
R3 _{set2}	stream	3.517	drift	0.127	0.190
R4 _{set2}	stream	2.515	drift	0.085	0.125
<i>Spring Cereals - Multiple applications</i>					
D1 _{set2}	ditch	4.078	drift	2.110	0.166
D1 _{set2}	stream	2.910	drift	0.242	0.143
D3 _{set2}	ditch	3.325	drift	0.351	0.120
D4 _{set2}	pond	0.167	drift	0.119	0.007
D4 _{set2}	stream	2.776	drift	0.032	0.094
D5 _{set2}	pond	0.151	drift	0.108	0.007
D5 _{set2}	stream	2.869	drift	0.011	0.079
R4 _{set2}	stream	13.350	runoff	1.280	0.620
<i>Spring Cereals - Single application</i>					
D1 _{set2}	ditch	3.851	drift	1.589	0.189
D1 _{set2}	stream	3.365	drift	0.145	0.165
D3 _{set2}	ditch	3.804	drift	0.198	0.137
D4 _{set2}	pond	0.131	drift	0.093	0.008
D4 _{set2}	stream	3.110	drift	0.013	0.104
D5 _{set2}	pond	0.131	drift	0.094	0.009
D5 _{set2}	stream	3.194	drift	0.008	0.079
R4 _{set2}	stream	8.165	runoff	0.671	0.379

Bold values are above RAC; *twa-time as required by ecotox

Table App 3.3-11: FOCUS Step 4 PEC_{sw} and PEC_{sed} for folpet following single and multiple applications of SAP50SCF to winter and spring cereals (maximum dose)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)*	Max PEC _{sed} (µg/kg)
<i>Winter Cereals - Multiple applications –10 meters of vegetated filter strip</i>					
D2 _{set2}	ditch	5.555	drainage	0.254	0.244
R1 _{set2}	stream	4.197	runoff	0.212	0.233
R3 _{set2}	stream	4.730	runoff	0.227	0.282
R4 _{set2}	stream	4.265	runoff	0.193	0.275
<i>Winter Cereals – Multiple applications –15 meters of vegetated filter strip</i>					
D2 _{set2}	ditch	5.555	drainage	0.215	0.244
R1 _{set2}	stream	3.221	runoff	0.162	0.178
R3 _{set2}	stream	3.634	runoff	0.174	0.215
R4 _{set2}	stream	3.273	runoff	0.148	0.211
<i>Winter Cereals - Multiple applications –20 meters of vegetated filter strip</i>					
D2 _{set2}	ditch	5.555	drainage	0.193	0.244
R1 _{set2}	stream	2.198	runoff	0.110	0.121
R3 _{set2}	stream	2.482	runoff	0.120	0.145
R4 _{set2}	stream	2.235	runoff	0.101	0.145
<i>Winter Cereals – Single application –5 meters of vegetated filter strip</i>					
D1 _{set2}	ditch	1.040	drift	0.097	0.092
D2 _{set2}	ditch	5.546	drainage	0.127	0.243
<i>Winter Cereals - Single application –10 meters of vegetated filter strip</i>					
D1 _{set2}	ditch	0.554	drift	0.057	0.051
D2 _{set2}	ditch	5.546	drainage	0.127	0.243
<i>Spring Cereals - Multiple applications –20 meters of vegetated filter strip</i>					
D1 _{set2}	ditch	0.310	drift	0.226	0.025
R4 _{set2}	stream	3.155	runoff	0.300	0.146
<i>Spring Cereals – Single application –5 meters of vegetated filter strip</i>					
D1 _{set2}	ditch	1.072	drift	0.476	0.055
D3 _{set2}	ditch	1.031	drift	0.060	0.039
R4 _{set2}	stream	5.303	runoff	0.431	0.247
<i>Spring Cereals - Single application –10 meters of vegetated filter strip</i>					
D1 _{set2}	ditch	0.588	drift	0.263	0.030
D3 _{set2}	ditch	0.547	drift	0.033	0.021
R4 _{set2}	stream	3.684	runoff	0.299	0.170

Bold values are above RAC; *:twa-time as required by ecotox

Minimum dose: 2 x 450g a.s./ha

Table App3.3-12: FOCUS Step 3 PEC_{sw} and PEC_{sed} for *folpet* following single and multiple applications of SAP50SCF to winter and spring cereals (minimum dose) - Set2 with a DT50 of 1000 days applied to the surface water compartment

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)*	Max PEC _{sed} (µg/kg)
<i>Winter Cereals - Multiple applications</i>					
D1 _{set2}	ditch	2.522	drift	0.789	0.208
D1 _{set2}	stream	2.129	drift	0.031	0.137
D2 _{set2}	ditch	3.341	drainage	0.669	0.191
D2 _{set2}	stream	2.212	drainage	0.539	0.124
D3 _{set2}	ditch	2.493	drift	0.244	0.144
D4 _{set2}	pond	0.107	drift	0.076	0.010
D4 _{set2}	stream	1.882	drift	0.004	0.047
D5 _{set2}	pond	0.130	drift	0.094	0.009
D5 _{set2}	stream	2.173	drift	0.014	0.080
D6 _{set2}	ditch	2.504	drift	0.296	0.122
R1 _{set2}	pond	0.443	runoff	0.376	0.024
R1 _{set2}	stream	6.840	runoff	0.361	0.411
R3 _{set2}	stream	7.645	runoff	0.384	0.510
R4 _{set2}	stream	6.974	runoff	0.327	0.455
<i>Winter Cereals - Single application</i>					
D1 _{set2}	ditch	2.864	drift	0.232	0.237
D1 _{set2}	stream	2.227	drift	0.009	0.062
D2 _{set2}	ditch	3.335	drift	0.288	0.218
D2 _{set2}	stream	2.445	drift	0.027	0.144
D3 _{set2}	ditch	2.850	drift	0.133	0.164
D4 _{set2}	pond	0.098	drift	0.069	0.009
D4 _{set2}	stream	2.107	drift	0.004	0.047
D5 _{set2}	pond	0.098	drift	0.070	0.007
D5 _{set2}	stream	2.275	drift	0.004	0.047
D6 _{set2}	ditch	2.818	drift	0.059	0.136
R1 _{set2}	pond	0.131	drift	0.107	0.007
R1 _{set2}	stream	1.878	drift	0.100	0.099
R3 _{set2}	stream	2.638	drift	0.094	0.143
R4 _{set2}	stream	1.886	drift	0.064	0.094
<i>Spring Cereals - Multiple applications</i>					
D1 _{set2}	ditch	3.057	drift	1.581	0.124
D1 _{set2}	stream	2.182	drift	0.181	0.107
D3 _{set2}	ditch	2.494	drift	0.264	0.090
D4 _{set2}	pond	0.125	drift	0.089	0.005
D4 _{set2}	stream	2.082	drift	0.024	0.070

D5 _{set2}	pond	0.113	drift	0.081	0.005
D5 _{set2}	stream	2.152	drift	0.009	0.059
R4 _{set2}	stream	9.871	runoff	0.951	0.460
<i>Spring Cereals - Single application</i>					
D1 _{set2}	ditch	2.888	drift	1.190	0.142
D1 _{set2}	stream	2.523	drift	0.108	0.124
D3 _{set2}	ditch	2.853	drift	0.149	0.103
D4 _{set2}	pond	0.098	drift	0.070	0.006
D4 _{set2}	stream	2.332	drift	0.010	0.078
D5 _{set2}	pond	0.098	drift	0.071	0.007
D5 _{set2}	stream	2.395	drift	0.006	0.059
R4 _{set2}	stream	6.020	runoff	0.501	0.281

Bold values are above RAC; *:two-time as required by ecotox

Table App3.3-13: FOCUS Step 4 PEC_{sw} and PEC_{sed} for folpet following single and multiple applications of SAP50SCF to winter and spring cereals (minimum dose)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)*	Max PEC _{sed} (µg/kg)
<i>Winter Cereals - Multiple applications –10 meters of vegetated filter strip</i>					
R1 _{set2}	stream	3.107	runoff	0.158	0.173
R3 _{set2}	stream	3.489	runoff	0.168	0.209
R4 _{set2}	stream	3.173	runoff	0.144	0.205
<i>Spring Cereals - Multiple applications –10 meters of vegetated filter strip</i>					
R4 _{set2}	stream	4.462	runoff	0.426	0.206
<i>Spring Cereals – Multiple applications –15 meters of vegetated filter strip</i>					
R4_{set2}	stream	3.420	runoff	0.326	0.158
<i>Spring Cereals - Multiple applications –20 meters of vegetated filter strip</i>					
R4 _{set2}	stream	2.332	runoff	0.223	0.108
<i>Spring Cereals - Single application –10 meters of vegetated filter strip</i>					
R4 _{set2}	stream	2.717	runoff	0.223	0.126

Bold values are above RAC; *:two-time as required by ecotox

Appendix 4 Additional information provided by the applicant concerning PEC_{sw} (due to K_{OC} are between 100 and 2000 ml/g)

The Predicted Environmental Concentrations results obtained in each set performed are presents below.

Due to the K_{OC} value for folpet is between 100 and 2000 mL/g, the whole system degradation values should be applied to one compartment (water or sediment) and a default of 1000 days applied to the other compartment. Therefore, 2 sets were performed for the parent folpet.

Table App4.1-1: Sets description

	Compound	DT50, water (d)	DT50, sed (d)
Set 1	Folpet	0.1	1000
Set 2	Folpet	1000	0.1

Table App4.1-2: Set 1 FOCUS Step 3 PEC_{sw} and PEC_{sed} for *folpet* following single and multiple applications of SAP50SCF to winter and spring cereals (maximum dose)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
Winter Cereals - Multiple applications					
D1	ditch	3.356	drift	0.09338	0.6078
D1	stream	2.834	drift	0.02756	0.2977
D2	ditch	3.364	drift	0.08441	0.5067
D2	stream	2.941	drift	0.04794	0.3567
D3	ditch	3.325	drift	0.08336	0.4012
D4	pond	0.1073	drift	0.003411	0.02059
D4	stream	2.513	drift	0.005374	0.08051
D5	pond	0.1074	drift	0.004252	0.01685
D5	stream	2.899	drift	0.01619	0.1592
D6	ditch	3.339	drift	0.08093	0.3964
R1	pond	0.1073	drift	0.004497	0.02717
R1	stream	3.264	runoff	0.155	0.9707
R3	stream	5.832	runoff	0.2775	2.469
R4	stream	3.298	runoff	0.1484	1.013
Winter Cereals - Single application					
D1	ditch	3.814	drift	0.1003	0.609
D1	stream	2.964	drift	0.007328	0.1044
D2	ditch	3.838	drift	0.09634	0.5798
D2	stream	3.26	drift	0.02877	0.3063
D3	ditch	3.801	drift	0.06054	0.459
D4	pond	0.1312	drift	0.00417	0.02292
D4	stream	2.807	drift	0.004906	0.07047
D5	pond	0.1312	drift	0.002598	0.01761
D5	stream	3.034	drift	0.005132	0.07358

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
D6	ditch	3.758	drift	0.04037	0.3769
R1	pond	0.1312	drift	0.00275	0.01794
R1	stream	2.504	drift	0.03728	0.2069
R3	stream	3.518	drift	0.03244	0.3434
R4	stream	2.515	drift	0.01885	0.2172
<i>Spring Cereals - Multiple applications</i>					
D1	ditch	3.362	drift	0.0758	0.3848
D1	stream	2.91	drift	0.06172	0.3575
D3	ditch	3.326	drift	0.06112	0.3133
D4	pond	0.1074	drift	0.002961	0.01286
D4	stream	2.777	drift	0.02452	0.1885
D5	pond	0.1074	drift	0.002127	0.01441
D5	stream	2.87	drift	0.009551	0.1333
R4	stream	10.29	runoff	0.7657	3.356
<i>Spring Cereals - Single application</i>					
D1	ditch	3.848	drift	0.05349	0.4155
D1	stream	3.365	drift	0.04304	0.3635
D3	ditch	3.805	drift	0.03493	0.3179
D4	pond	0.1312	drift	0.00213	0.01572
D4	stream	3.111	drift	0.01157	0.1542
D5	pond	0.1312	drift	0.0026	0.01762
D5	stream	3.194	drift	0.007833	0.111
R4	stream	5.693	runoff	0.359	1.516

April 2024: Additional calculations were requested by the authorities, and the results for the set with a DT50 of 1000 days applied to the sediment compartment is presented in this appendix.

Additional calculations with DT50 soil of 1.38 days and Q10=2.2 – maximum dose

Table App4.1-2a: FOCUS Step 3 PEC_{sw} and PEC_{sed} for *folpet* following single and multiple applications of SAP50SCF to winter and spring cereals (maximum dose) – Set1 with a DT50 of 1000 days applied to the sediment compartment

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)*	Max PEC _{sed} (µg/kg)
<i>Winter Cereals - Multiple applications</i>					
D1 _{set1}	ditch	3.355	drift	0.017	0.242
D1 _{set1}	stream	2.833	drift	0.012	0.179
D2 _{set1}	ditch	3.364	drift	0.015	0.198
D2 _{set1}	stream	2.941	drift	0.011	0.155
D3 _{set1}	ditch	3.324	drift	0.015	0.152
D4 _{set1}	pond	0.107	drift	0.001	0.009
D4 _{set1}	stream	2.510	drift	0.004	0.074
D5 _{set1}	pond	0.107	drift	0.001	0.006

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)*	Max PEC _{sed} (µg/kg)
D5 _{set1}	stream	2.898	drift	0.011	0.114
D6 _{set1}	ditch	3.339	drift	0.016	0.139
R1 _{set1}	pond	0.107	drift	0.001	0.014
R1 _{set1}	stream	2.165	drift	0.063	0.789
R3 _{set1}	stream	3.911	runoff	0.158	2.336
R4 _{set1}	stream	2.194	runoff	0.081	0.858
<i>Winter Cereals - Single application</i>					
D1 _{set1}	ditch	3.814	drift	0.020	0.260
D1 _{set1}	stream	2.966	drift	0.006	0.092
D2 _{set1}	ditch	3.838	drift	0.017	0.227
D2 _{set1}	stream	3.260	drift	0.013	0.179
D3 _{set1}	ditch	3.800	drift	0.012	0.174
D4 _{set1}	pond	0.131	drift	0.001	0.010
D4 _{set1}	stream	2.809	drift	0.004	0.066
D5 _{set1}	pond	0.131	drift	0.000	0.007
D5 _{set1}	stream	3.034	drift	0.004	0.064
D6 _{set1}	ditch	3.757	drift	0.010	0.148
R1 _{set1}	pond	0.131	drift	0.000	0.007
R1 _{set1}	stream	2.504	drift	0.011	0.116
R3 _{set1}	stream	3.517	drift	0.015	0.288
R4 _{set1}	stream	2.515	drift	0.008	0.110
<i>Spring Cereals - Multiple applications</i>					
D1 _{set1}	ditch	3.362	drift	0.012	0.123
D1 _{set1}	stream	2.910	drift	0.010	0.113
D3 _{set1}	ditch	3.325	drift	0.010	0.100
D4 _{set1}	pond	0.107	drift	0.000	0.005
D4 _{set1}	stream	2.776	drift	0.011	0.092
D5 _{set1}	pond	0.107	drift	0.000	0.005
D5 _{set1}	stream	2.869	drift	0.005	0.083
R4 _{set1}	stream	5.648	runoff	0.394	2.469
<i>Spring Cereals - Single application</i>					
D1 _{set1}	ditch	3.847	drift	0.009	0.137
D1 _{set1}	stream	3.365	drift	0.008	0.120
D3 _{set1}	ditch	3.804	drift	0.006	0.100
D4 _{set1}	pond	0.131	drift	0.000	0.006
D4 _{set1}	stream	3.110	drift	0.007	0.101
D5 _{set1}	pond	0.131	drift	0.000	0.007
D5 _{set1}	stream	3.194	drift	0.006	0.088
R4 _{set1}	stream	2.886	runoff	0.205	1.427

Bold values are above RAC; *twa-time as required by ecotox

Table App4.1-3: Set 1 FOCUS Step 3 PEC_{sw} and PEC_{sed} for *folpet* following single and multiple applications of SAP50SCF to winter and spring cereals (minimum dose)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
<i>Winter Cereals - Multiple applications</i>					
D1	ditch	2.517	drift	0.07003	0.4558
D1	stream	2.126	drift	0.02067	0.2233
D2	ditch	2.523	drift	0.06331	0.38
D2	stream	2.206	drift	0.03595	0.2675
D3	ditch	2.493	drift	0.06252	0.3009
D4	pond	0.08047	drift	0.002558	0.01545
D4	stream	1.884	drift	0.004031	0.06039
D5	pond	0.08052	drift	0.003189	0.01264
D5	stream	2.174	drift	0.01214	0.1194
D6	ditch	2.505	drift	0.0607	0.2973
R1	pond	0.08047	drift	0.003373	0.02038
R1	stream	2.448	runoff	0.1162	0.728
R3	stream	4.374	runoff	0.2081	1.851
R4	stream	2.474	runoff	0.1113	0.7602
<i>Winter Cereals - Single application</i>					
D1	ditch	2.861	drift	0.07524	0.4567
D1	stream	2.223	drift	0.005496	0.07826
D2	ditch	2.879	drift	0.07226	0.4349
D2	stream	2.445	drift	0.02158	0.2298
D3	ditch	2.851	drift	0.0454	0.3443
D4	pond	0.09837	drift	0.003128	0.01719
D4	stream	2.106	drift	0.00368	0.05285
D5	pond	0.09838	drift	0.001948	0.01321
D5	stream	2.276	drift	0.003849	0.05518
D6	ditch	2.818	drift	0.03028	0.2827
R1	pond	0.09838	drift	0.002062	0.01346
R1	stream	1.878	drift	0.02796	0.1551
R3	stream	2.638	drift	0.02433	0.2576
R4	stream	1.886	drift	0.01413	0.1629
<i>Spring Cereals - Multiple applications</i>					
D1	ditch	2.522	drift	0.05685	0.2886
D1	stream	2.183	drift	0.04629	0.2681
D3	ditch	2.495	drift	0.04584	0.235
D4	pond	0.08052	drift	0.002221	0.009642
D4	stream	2.083	drift	0.01839	0.1414
D5	pond	0.08052	drift	0.001595	0.01081
D5	stream	2.152	drift	0.007163	0.09999
R4	stream	7.714	runoff	0.5743	2.517

<i>Spring Cereals - Single application</i>					
D1	ditch	2.886	drift	0.04012	0.3116
D1	stream	2.524	drift	0.03228	0.2726
D3	ditch	2.854	drift	0.0262	0.2385
D4	pond	0.09842	drift	0.001598	0.01179
D4	stream	2.333	drift	0.008681	0.1156
D5	pond	0.09841	drift	0.00195	0.01322
D5	stream	2.396	drift	0.005875	0.08323
R4	stream	4.27	runoff	0.2693	1.137

Table App4.1-4: Set 2 FOCUS Step 3 PEC_{sw} and PEC_{sed} for folpet following single and multiple applications of SAP50SCF to winter and spring cereals (maximum dose)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
<i>Winter Cereals - Multiple applications</i>					
D1	ditch	3.356	drift	1.252	0.6988
D1	stream	2.834	drift	0.0347	0.2898
D2	ditch	3.364	drift	0.8839	0.6528
D2	stream	2.941	drift	0.7516	0.4385
D3	ditch	3.325	drift	0.3322	0.4589
D4	pond	0.1597	drift	0.1272	0.03732
D4	stream	2.513	drift	0.00561	0.07408
D5	pond	0.1849	drift	0.1471	0.03405
D5	stream	2.899	drift	0.01805	0.1472
D6	ditch	3.34	drift	0.4102	0.4424
R1	pond	0.3032	runoff	0.242	0.04689
R1	stream	4.449	runoff	0.1937	0.4978
R3	stream	5.952	runoff	0.321	1.133
R4	stream	3.386	runoff	0.1669	0.5805
<i>Winter Cereals - Single application</i>					
D1	ditch	3.814	drift	0.3199	0.7212
D1	stream	2.964	drift	0.007678	0.1013
D2	ditch	3.838	drift	0.4013	0.747
D2	stream	3.26	drift	0.03601	0.301
D3	ditch	3.801	drift	0.1818	0.5251
D4	pond	0.1312	drift	0.1031	0.03188
D4	stream	2.807	drift	0.005066	0.06854
D5	pond	0.1312	drift	0.1037	0.02394
D5	stream	3.034	drift	0.005393	0.07167
D6	ditch	3.758	drift	0.07959	0.3911
R1	pond	0.1312	drift	0.1025	0.02442
R1	stream	2.504	drift	0.05123	0.2017
R3	stream	3.518	drift	0.04654	0.3429

R4	stream	2.515	drift	0.02502	0.2138
<i>Spring Cereals - Multiple applications</i>					
D1	ditch	4.488	drift	2.495	0.4683
D1	stream	2.91	drift	0.2452	0.3729
D3	ditch	3.326	drift	0.3582	0.3255
D4	pond	0.1764	drift	0.1362	0.02235
D4	stream	2.777	drift	0.0319	0.1695
D5	pond	0.1643	drift	0.1278	0.02159
D5	stream	2.87	drift	0.01146	0.1217
R4	stream	11.17	runoff	0.9093	1.387
<i>Spring Cereals - Single application</i>					
D1	ditch	3.848	drift	1.977	0.5347
D1	stream	3.365	drift	0.1424	0.4312
D3	ditch	3.805	drift	0.2019	0.371
D4	pond	0.1312	drift	0.1011	0.02114
D4	stream	3.111	drift	0.01339	0.1441
D5	pond	0.1312	drift	0.1042	0.02399
D5	stream	3.194	drift	0.008444	0.1061
R4	stream	6.215	runoff	0.4145	0.7983

Table App4.1-5: Set 2 FOCUS Step 3 PEC_{sw} and PEC_{sed} for folpet following single and multiple applications of SAP50SCF to winter and spring cereals (minimum dose)

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
<i>Winter Cereals - Multiple applications</i>					
D1	ditch	2.517	drift	0.9389	0.5241
D1	stream	2.126	drift	0.02603	0.2173
D2	ditch	2.523	drift	0.6629	0.4896
D2	stream	2.206	drift	0.5637	0.3289
D3	ditch	2.493	drift	0.2491	0.3442
D4	pond	0.1198	drift	0.09543	0.02799
D4	stream	1.884	drift	0.004208	0.05556
D5	pond	0.1387	drift	0.1103	0.02554
D5	stream	2.174	drift	0.01354	0.1104
D6	ditch	2.505	drift	0.3076	0.3318
R1	pond	0.0274	runoff	0.1815	0.03516
R1	stream	3.337	runoff	0.1453	0.3734
R3	stream	4.464	runoff	0.2408	0.8497
R4	stream	2.54	runoff	0.1252	0.4355
<i>Winter Cereals - Single application</i>					
D1	ditch	2.861	drift	0.2399	0.5409
D1	stream	2.223	drift	0.005759	0.07597
D2	ditch	2.879	drift	0.301	0.5602

D2	stream	2.445	drift	0.02701	0.2258
D3	ditch	2.851	drift	0.1363	0.3938
D4	pond	0.09837	drift	0.07731	0.02391
D4	stream	2.106	drift	0.003799	0.0514
D5	pond	0.09838	drift	0.07774	0.01795
D5	stream	2.276	drift	0.004045	0.05375
D6	ditch	2.818	drift	0.05969	0.2933
R1	pond	0.09838	drift	0.07686	0.01832
R1	stream	1.878	drift	0.03842	0.1513
R3	stream	2.638	drift	0.0349	0.2572
R4	stream	1.886	drift	0.01876	0.1603
<i>Spring Cereals - Multiple applications</i>					
D1	ditch	3.366	drift	1.871	0.3512
D1	stream	2.183	drift	0.1839	0.2797
D3	ditch	2.494	drift	0.2687	0.2441
D4	pond	0.1323	drift	0.1022	0.01676
D4	stream	2.083	drift	0.02392	0.1271
D5	pond	0.1232	drift	0.09585	0.01619
D5	stream	2.152	drift	0.008593	0.09125
R4	stream	8.38	runoff	0.682	1.041
<i>Spring Cereals - Single application</i>					
D1	ditch	2.886	drift	1.483	0.401
D1	stream	2.524	drift	0.1068	0.3234
D3	ditch	2.854	drift	0.1514	0.2783
D4	pond	0.09842	drift	0.07585	0.01586
D4	stream	2.333	drift	0.01004	0.1081
D5	pond	0.09841	drift	0.07816	0.01799
D5	stream	2.396	drift	0.006333	0.07958
R4	stream	4.662	runoff	0.3109	0.5988

Bold values are above RAC; *two-time as required by ecotox

Additional calculations with DT50 soil of 1.38 days and Q10=2.2 – minimum dose

Table App4.1 3b FOCUS Step 3 PEC_{sw} and PEC_{sed} for *folpet* following single and multiple applications of SAP50SCF to winter and spring cereals (minimum dose) – Set1 with a DT50 of 1000 days applied to the sediment compartment

Scenario FOCUS	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)*	Max PEC _{sed} (µg/kg)
<i>Winter Cereals - Multiple applications</i>					
D1 _{set1}	ditch	2.516	drift	0.013	0.182
D1 _{set1}	stream	2.125	drift	0.009	0.135
D2 _{set1}	ditch	2.523	drift	0.011	0.150
D2 _{set1}	stream	2.205	drift	0.008	0.117
D3 _{set1}	ditch	2.493	drift	0.011	0.115
D4 _{set1}	pond	0.080	drift	0.000	0.006

D4 _{set1}	stream	1.882	drift	0.003	0.056
D5 _{set1}	pond	0.080	drainage	0.001	0.005
D5 _{set1}	stream	2.173	drift	0.008	0.086
D6 _{set1}	ditch	2.504	drift	0.012	0.105
R1 _{set1}	pond	0.080	drift	0.000	0.011
R1 _{set1}	stream	1.624	drift	0.046	0.591
R3 _{set1}	stream	2.870	runoff	0.116	1.751
R4 _{set1}	stream	1.631	drift	0.060	0.641
<i>Winter Cereals - Single application</i>					
D1 _{set1}	ditch	2.860	drift	0.015	0.196
D1 _{set1}	stream	2.224	drift	0.004	0.069
D2 _{set1}	ditch	2.878	drift	0.012	0.171
D2 _{set1}	stream	2.445	drift	0.010	0.135
D3 _{set1}	ditch	2.850	drift	0.009	0.131
D4 _{set1}	pond	0.098	drift	0.001	0.007
D4 _{set1}	stream	2.107	drift	0.003	0.050
D5 _{set1}	pond	0.098	drift	0.000	0.005
D5 _{set1}	stream	2.275	drift	0.003	0.048
D6 _{set1}	ditch	2.818	drift	0.007	0.112
R1 _{set1}	pond	0.098	drift	0.000	0.005
R1 _{set1}	stream	1.878	drift	0.008	0.087
R3 _{set1}	stream	2.638	drift	0.011	0.216
R4 _{set1}	stream	1.886	drift	0.006	0.082
<i>Spring Cereals - Multiple applications</i>					
D1 _{set1}	ditch	2.521	drift	0.009	0.091
D1 _{set1}	stream	2.182	drift	0.008	0.082
D3 _{set1}	ditch	2.494	drift	0.007	0.075
D4 _{set1}	pond	0.080	drift	0.000	0.003
D4 _{set1}	stream	2.082	drift	0.008	0.069
D5 _{set1}	pond	0.080	drift	0.000	0.004
D5 _{set1}	stream	2.152	drift	0.004	0.063
R4 _{set1}	stream	4.150	runoff	0.291	1.853
<i>Spring Cereals - Single application</i>					
D1 _{set1}	ditch	2.885	drift	0.006	0.103
D1 _{set1}	stream	2.523	drift	0.006	0.090
D3 _{set1}	ditch	2.853	drift	0.004	0.075
D4 _{set1}	pond	0.098	drift	0.000	0.004
D4 _{set1}	stream	2.332	drift	0.005	0.076
D5 _{set1}	pond	0.098	drift	0.000	0.005
D5 _{set1}	stream	2.395	drift	0.004	0.066
R4 _{set1}	stream	2.121	runoff	0.152	1.080

Bold values are above RAC; *two-time as required by ecotox