REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: SAP2101F

Product name(s): ZELORA START

Chemical active substance(s):

Prothioconazole, 120 g/L
Folpet, 300 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

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

Submission date: December 2023

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 (Acording 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	Initial zRMS assessment 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. 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.
August 2024	Final report (Core Assessment updated following the commenting period) No additional information or assessments after the commenting period.

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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 SAP2101F, a suspension concentrate formulation containing 120 g/L of prothioconazole and 300g/L of folpet, for use on wheat and barley.

Prothioconazole and folpet were first included in Annex I (Commission Directive 2008/44/EC of 4 April 2008 and Commission Directive 2007/5/EC of 07 February 2007, respectively).

The EFSA Scientific report for prothioconazole (EFSA Scientific Report (2007) 107) and 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.

SAP2101F 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: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	~~CEU: DE, RO~~, PL~~, HU, CZ, SK, AT, SI, BE, NL~~	Wheat	F	*Septoria*	Tractor mounted spray	BBCH 32-**61**	a) 2 b) 2	14 days	a) 1.5 L/ha b) 3 L/ha	a) 180 g ai/ha + 450 g ai/ha b) 360 g ai/ha + 900 g ai/ha	150-400	**42**	Range: 1 L/ha - 1,5 L/ha	A
2	~~CEU: DE, RO~~, PL~~, HU, CZ, SK, AT, SI, BE, NL~~	Barley	F	*Helminstorporium*	Tractor mounted spray	BBCH 30-**61**	a) 2 b) 2	14 days	a) 1.5 L/ha b) 3 L/ha	a) 180 g ai/ha + 450 g ai/ha b) 360 g ai/ha + 900 g ai/ha	150-400	**42**	Range: 1 L/ha - 1,5 L/ha	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 Prothioconazole found in soil, water and sediment

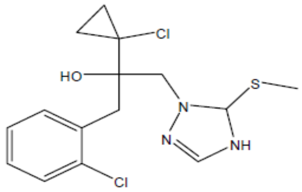
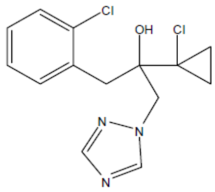
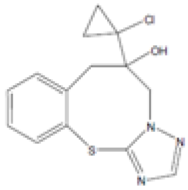
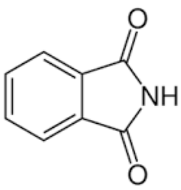
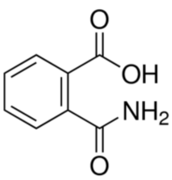
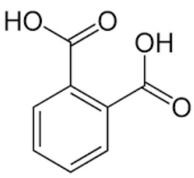
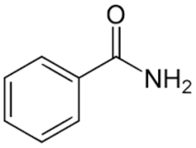
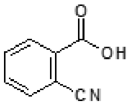
Metabolite	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
M01: JAU 6476-S methyl Prothioconazole-S-Methyl CAS 178928-71-7		Soil: 14.6 % Water: 8.6 % (anaerobic water/sediment study) Sediment: 77 % (anaerobic , in sediment, not detected in water ~~water/sediment study)~~ water/sediment (aerobic): 12.7% (whole system); 3.1% (water); 9.6% (sediment)	PECsoil PECgw PECsw
M04: JAU 6476-desthio Prothioconazole-desthio CAS 120983-64-4		Soil: 49.4% (57.1% conversion (field)) Water: 32.3% (55.7% aqueous photolysis) Sediment: 26.9% whole system: 54.6%	PECsoil PECgw PECsw
M12: Prothioconazole-thiazocine		Soil: - Water: 14.1% (aqueous photolysis) Sediment: -	PECsw
M13: 1,2,4-triazole		Soil: - Water: 37.2 % (11.9% aqueous photolysis) Sediment: 4.6% whole system: 41.8%	PECsw

Table 8.2-2: 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} $PEC_{sw/sed}$

Metabolite	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
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 prothioconazole metabolites is in general line with EU agreed endpoints reported in EFSA Scientific Report (2007) 106, with some minor corrections.
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 substances in soil are discussed in detail in the corresponding documents of the EU review dossiers.

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 Prothioconazole and its metabolites

The aerobic route of degradation of phenyl-UL-14C and 3,5-triazole-14C labelled prothioconazole was investigated in four different soils at 20 ºC and 48-49% maximum water holding capacity (MWHC) under dark conditions. The soils covered a range of pH values (5.9-7.2), clay contents (5.0-39.6%) and organic carbon contents (0.79-2.14%).

Two additional laboratory studies were performed to investigate the aerobic degradation of the major metabolites prothioconazole-S-methyl (M01) and prothioconazole-desthio (M04), under dark conditions at 20 ºC with four soils. By the end of the study (125 and 120 days) the maximum levels of M01 and M04 detected were in the range 2.5%-18.6% AR and 2.3%-20.4% AR, respectively.

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

Prothioconazole, Laboratory studies, aerobic conditions									
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d) 20°C**	**DT90 (d)**	**r^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Laacher Hof	Sandy loam	7.2	20	48	0.07	5.3	1.000	FOMC	Yes Gilges, M. (2000, rev. 2001) – DAR, 2005 (Vol. 3, Annex B.8), Addendum (October 2005)
Stanley	Silty clay loam	5.9	20	48	0.70	78.2	0.989	FOMC	
Höfchen	Silt	7.1	20	49	0.30	0.99	0.99	SFO	Yes Hellpointner, E. (2001b) – DAR, 2005 (Vol. 3, Annex B.8), Addendum (October 2005)
Byromville	Loamy sand	6.8	20	65	1.27	4.22	0.981	SFO	
Geometric mean/Median (n=4)					0.37 / 0.50				
pH-dependency: y/n					No				

Bold values were used in modelling

Table 8.3.1-2: Summary of aerobic degradation rates for Prothioconazole-S-methyl (M01) - laboratory studies

Prothioconazole-S-methyl (M01), Laboratory studies, aerobic conditions									
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d) 20°C**	**DT90 (d)**	**r^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Höfchen	Loamy silt	7.3	20	40	5.9	19.6	0.97	SFO	Yes Gilges, M. (2001a) – DAR, 2005 (Vol. 3, Annex B.8),
Laacher Hof AIII	Loamy Silt	7.9	20	40	27.2	90.2	0.955	SFO	
Laacher Hof	Sandy	7.2	20	40	8.2	27.2	0.959	SFO	

Prothioconazole-S-methyl (M01), Laboratory studies, aerobic conditions									
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d) 20°C**	**DT90 (d)**	**r^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
AXXa	loam								Addendum (October 2005)
Stanley	Silty clay	6.3	20	40	46.0	153	0.965	SFO	
Geometric mean/Median (n=4)					**15.7** / 17.7				
pH-dependency: y/n					No				

Bold values were used in modelling

Table 8.3.1-3: Summary of aerobic degradation rates for Prothioconazole-desthio (M04) - laboratory studies

Prothioconazole-desthio (M04), Laboratory studies, aerobic conditions									
Soil name	**Soil type**	**pH**	**t.oC**	**MWHC %**	**DT50 (d) 20°C**	**DT90 (d)**	**r^2**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Höfchen	Loamy silt	7.3	20	40	34	113	0.820	SFO	Yes Gilges, M. (2001b) – DAR, 2005 (Vol. 3, Annex B.8), Addendum (October 2005)
Laacher Hof AIII	Loamy silt	7.9	20	40	29.6	98.3	0.987	SFO	
Laacher Hof AXXa	Sandy loam	7.2	20	40	7.0	23.2	0.985	SFO	
Stanley	Silty clay	6.3	20	40	18.6	61.9	0.979	SFO	
Geometric mean/Median (n=4)					19.03 / 24.1				
pH-dependency: y/n					No				

Bold values were used in modelling

zRMS comments:

Soil degradation data for prothioconazole and its metabolites are in line with EU agreed endpoints reported in EFSA Scientific Report (2007) 106 and prothioconazole DAR of 2005.

For relevant endpoints considered in exposure assessment, please refer to points 8.7 (soil), 8.8 (groundwater) and 8.9 (surface water) of this document.

8.3.1.2 Folpet and its metabolites

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 CO_2 after 90 days, 69.8 % AR as CO_2 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 captan[1]. Degradation of this compound in soil was investigated with trichloromethyl-^{14}C 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). CO_2 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

[1] Molecular formula of captan is $C_9H_8Cl_3NO_2S$, molecular formula of folpet is $C_9H_4Cl_3NO_2S$

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.

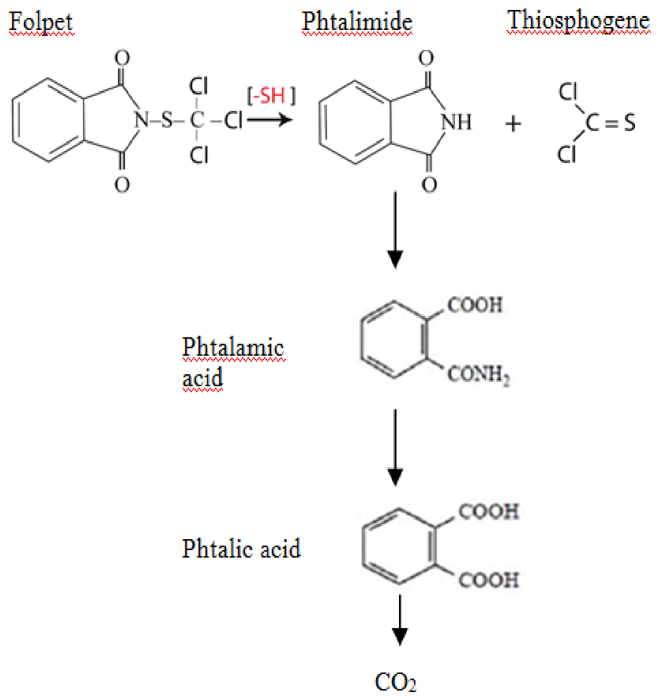


Figure 8.3-1: Proposed degradation pathway for folpet in aerobic soil

The DT_{50} values for folpet and its main metabolites as presented in the EU endpoint list are reported in the following tables. According to current guidelines, normalised values updated using a Q_{10} of 2.58 are also presented.

Table 8.3.1-4: Summary of aerobic degradation rates for Folpet - laboratory studies

Folpet, Laboratory studies, aerobic conditions								
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**
Sandy loam	5.4	1.16	25ºC/75 to 80% FC	16.2 *	15.2	~~22.26~~	-	Daly (1991)
Silt loam	6.2	2.6	20ºC/40%MWHC	0.8	0.49	~~0.49~~	SFO	Crowe (2001)
Loamy sand	4.8	0.9	20ºC/40%MWHC	3.8	2.92	~~2.92~~	SFO	
Clay loam	7.5	3.9	20ºC/40%MWHC	0.2	0.12	~~0.12~~	SFO	
Arithmetic mean (n=4)					4.68			
~~Geometric mean (n=4)~~						~~1.38~~		

[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 8.3.1-5: 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	25ºC/75 to 80% FC	28.2	26.5	~~38.75~~	-	Daly (1991)
Silt loam	6.2	2.6	20ºC/40% MWHC	1.7	1.04	~~1.04~~	FOMC	Crowe (2001)
Loamy sand	4.8	0.9	20ºC/40% MWHC	4.8	3.69	~~3.69~~	SFO	Crowe (2001)
Clay loam	7.5	3.9	20ºC/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	20ºC/40% MWHC	0.4	0.24	~~0.24~~	SFO	Crowe (2001)
PHTHALIC ACID								
Silt loam	6.2	1.7	20ºC/40% MWHC	1.0	0.61	~~0.61~~	SFO	Crowe (2001)
Loamy sand	4.8	4.8	20ºC/40% MWHC	4.1	3.15	~~3.15~~	SFO	Crowe (2001)
Clay loam	7.5	0.5	20ºC/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 and with folpet DAR of 2005.

It is noted that in Tables 8.3.1-4 and 8.3.1-5 the DT_{50} values normalised with consideration of Q_{10} of 2.58 are presented, in line with current FOCUS requirements. Although normalisation using Q_{10} 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 Q_{10} of 2.2. Taking this into account, the DT_{50} values recalculated with Q_{10} 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)

Anaerobic degradation in soil of the active substance prothioconazole was not investigated (DAR-July 2005, addendum (October 2005) and EFSA Scientific Report (2007) 106).

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 DT_{50} value of 13.5 days; degradation of phthalimide was also slower with a DT_{50} 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:
It is noted that in line with information provided in EFSA Scientific Report (2007) 106, prothioconazole might be potentially exposed to anaerobic conditions when applied during the winter, following autumn seed treatment. The application pattern of SAP2101F does not include application as a seed treatment, so anaerobic route of exposure is not considered further, in line with EU conclusions. 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 prothioconazole and folpet under field conditions was evaluated during the Annex I Inclusion and are discussed in detail in the corresponding documents of the EU review dossiers. 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)

8.4.1.1 Prothioconazole and its metabolites

Field dissipation of prothioconazole has been investigated in eight studies at different sites in northern Europe (Germany, Great Britain and France) and southern Europe (France, Italy). Four of the sites were not cropped and the remaining four were sown with spring barley just prior to the application of the test substance directly to the soil surface.

Analyses from each site were conducted on samples from depths up to 50cm. Soil residues were restricted to the top 10cm soil horizon. Neither prothioconazole nor the two metabolites M01 and M04 were detected below this soil layer at any sampling interval in any study.

The maximum levels of prothioconazole detected in the 0-10 cm soil layer were in the range 35.5-70.3 µg/kg and the maximum levels of the metabolite prothioconazole-desthio in the top 10cm horizon were in the range 30.4 – 67.8 µg/kg. The first order half-lives obtained from the field studies were 1.3-2.8 days for prothioconazole, and 16.3-72.3 days for M04.

The metabolite M01 was not detected above the LOQ in any study and was not consider, primally, to be a major metabolite under field conditions. The need for predicted environmental concentration (PEC) in soil for this metabolite was discussed in a meeting of experts (PRAPeR 02). It was agreed that even if the detection limit in the field studies did pick up the metabolite at levels below the LOQ (6 µg/kg), the LOQ (2 µg/kg) was only about 10% relative to the initial concentration of prothioconazole in the field studies. Therefore, it was concluded that the analytical method was not appropriate to measure M01 concentrations in the field studies, and consequently, an exposure assessment for M01 was required.

Table 8.4.1-1: Summary of aerobic degradation rates for prothioconazole - field studies

Prothioconazole, Field studies						
Soil type	**Location**	**pH**	**Depth (cm)**	**DT50 20°C**	**r^2**	**Evaluated on EU level y/n/ Reference**
Silt loam	Höfchen (bare soil)	6.25	50	1.2	1.000	Yes Schramel (2001a) and Schad (2001c) – DAR, 2005 (Vol. 3, Annex B.8), Addendum (October 2005)
Sandy clay loam	Elm Farm (bare soil)	7.56	50	0.8	0.999	
Silt	l'Archeveque (bare soil)	6.42	50	1.6	0.995	
Sandy clay loam	Elm Farm (cropped)	7.56	50	1.4	0.997	
Silt	l'Archeveque (cropped)	6.42	50	1.6	0.998	
Silt loam	St. Etienne du Gres (cropped)	7.61	50	1.1	1.000	
Sandy loam	Di Nogarole Rocca (cropped)	7.56	50	1.5	0.999	
Sandy loam	Laacherhof (bare soil)	6.32	50	0.6	1.000	
Geometric mean (n=8)				**1.2**		
pH-dependency y/n				No		

Bold values were used in modelling

Table 8.4.1-2: Summary of aerobic degradation rates for prothioconazole-desthio (M04) - field studies

Prothioconazole-desthio (M04), Field studies						
Soil type	**Location**	**pH**	**Depth (cm)**	**DT50 20°C**	**r^2**	**Evaluated on EU level y/n/ Reference**
Silt loam	Höfchen (bare soil)	6.25	50	10.3	0.994	Yes Schramel (2001a) and Schad (2001c) – DAR, 2005 (Vol. 3, Annex B.8), Addendum (October 2005)
Sandy clay loam	Elm Farm (bare soil)	7.56	50	27.0	0.978	
Silt	l'Archeveque (bare soil)	6.42	50	27.5	0.859	
Sandy clay loam	Elm Farm (cropped)	7.56	50	23.4	0.939	
Silt	l'Archeveque (cropped)	6.42	50	20.1	0.859	
Silt loam	St. Etienne du Gres (cropped)	7.61	50	61.9	0.969	
Sandy loam	Di Nogarole Rocca (cropped)	7.56	50	20.7	0.951	
Sandy loam	Laacherhof (bare soil)	6.32	50	15.2	0.996	
Geometric mean (n=8)				**22.7**		
pH-dependency y/n				No		

Bold values were used in modelling

zRMS comments:

The triggering endpoints for prothioconazole and metabolite JAU 5479-desthio provided in Tables 8.4-1 and 8.4-2 above are in line with data reported in EFSA Scientific Report (2007) 106 and prothioconazole DAR of 2005.

For relevant endpoints considered in exposure assessment, please refer to points 8.7 (soil), 8.8 (groundwater) and 8.9 (surface water) of this document.

8.4.1.2 Folpet and its metabolites

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:
Soil accumulation testing is not required for prothioconazole, and folpet according to information presented in EFSA Scientific Report (2007) 106 for prothioconazole and in EFSA Scientific Report (2009) 297, 1-80 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.

8.5.1 Prothioconazole and its metabolites

Mobility in soil is discussed in detail in the corresponding documents of the EU review dossiers (DAR-July 2005, addendum (October 2005) and EFSA Scientific Report (2007) 106).

Adsorption coefficient for prothioconazole could not be determined via standard batch equilibrium studies due to the instability of the compound in these systems. Therefore, the distribution of prothioconazole in an aged column leaching study was used to estimate Kd and Koc values.

Adsorption/desorption of prothioconazole -S-methyl (M01) and prothioconazole–desthio (M04) were investigated by batch equilibrium experiments in four soils. The calculated adsorption Koc for M01 was in the range 1973.6 – 2995.0 mL/g, and for M04, the calculated adsorption Koc was in the range 523.0 – 625.3 mL/g (slightly mobile). Based on the agreed (PRAPeR experts'' meeting 12) list of end points for 1,2,4-triazole, the Kfoc values for this minor soil metabolite of prothioconazole are in the range of 43-202 mL/g (n=4).

Table 8.5.1-1: Summary of soil adsorption/desorption for prothioconazole-S-methyl (M01)

Prothioconazole-S-methyl (M01)							
Soil Name	**Soil Type**	**OC (%)**	**pH**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Laacher Hof AXXa	Sandy loam	2.02	7.2	56.0	2772.4	0.87	Yes Hein (1999) – DAR, 2005 (Vol. 3, Annex B.8), Addendum (October 2005)
Höfchen	Silt	2.14	7.1	64.1	2995.0	0.88	
Stanley	Silty clay loam	1.66	5.9	41.2	2484.0	0.91	
Byromville	Loamy sand	0.79	6.8	15.6	1973.6	0.85	
Geometric mean (n=4)					**2525.9**	-	
Arithmetic mean (n=4)					2556.3	**0.88**	
pH-dependency y/n					No		

Bold values were used in modelling

Table 8.5.1-2: Summary of soil adsorption/desorption for prothioconazole-desthio (M04)

Prothioconazole-desthio (M04)							
Soil Name	**Soil Type**	**OC (%)**	**pH**	**Kd (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Laacher Hof AXXa	Sandy loam	2.02	7.2	56.0	616.8	0.79	Yes Fent (1998) – DAR, 2005 (Vol. 3, Annex B.8), Addendum (October 2005)
Höfchen	Silt	2.14	7.1	64.1	625.3	0.83	
Stanley	Silty clay loam	1.66	5.9	41.2	536.4	0.83	
Byromville	Loamy sand	0.79	6.8	15.6	523.0	0.80	
Geometric mean (n=4)					**573.5**	-	
Arithmetic mean (n=4)					575.4	**0.81**	
pH-dependency y/n					No		

Bold values were used in modelling

zRMS comments:

Soil mobility data for prothioconazole and its major soil metabolites are in line with EU agreed endpoints as reported in EFSA Scientific Report (2007) 106 and prothioconazole DAR of 2005.

For metabolites JAU 6476-S-methyl and JAU 6476-desthio 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.

8.5.2 Folpet and its metabolites

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 8.5.2-1: 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				208.7	**0.87**	
Geometric mean				**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 Phththalimide.

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.

8.5.3 Column leaching (KCP 9.1.2.1)

8.5.3.1 Prothioconazole

The distribution of prothioconazole in an aged column leaching study (Reigner, 1999; DAR, 2005 (Vol. 3, Annex B.8), Addendum (October 2005)) was used to estimate Kd and Koc values. Phenyl-UL-14C radiolabelled prothioconazole was applied on a loamy sand soil and incubated at 20ºC under aerobic conditions for 30 hours. The resulting values for prothioconazole were Kd = 15.2 and **Koc = 1765 mL/g** (slightly mobile compound). At the end of the study, the extracted radioactivity was composed of 22.7% unchanged parent compound, the known metabolites from the soil metabolism study M04 (31.8% AR), M01 (8.1% AR) and prothioconazole-sulfonic acid (M02) (1.5%). The total radioactivity in the leachate accounted for only 1.1% of the applied radioactivity, and in the leachate fraction a radioactivity content of < 0.2% of the applied radioactivity was measured.

The leaching behaviour of phenyl-UL-14C radiolabelled prothioconazole was further investigated in a non-aged soil column leaching study (Babczinski, 2001; DAR, 2005 (Vol. 3, Annex B.8), Addendum (October 2005)) on four soils. The level of radioactivity detected in the leachates was < 1% AR in all samples. Therefore, the leachate fractions were not analysed. The majority of the residue of the active substance was detected in the top 6 cm layer (14.6-40.7% AR in 0-6 cm layer, not detected in the 6-12 cm layer), this also being the case for the metabolites prothioconazole-S-methyl (5.5-11.2% AR in the 0-6 cm layer, not detected in the 6-12 cm layer) and prothioconazole-desthio (15.4-28.0% AR in the 0-6 cm layer, not detected in the 6-12 cm layer).

No column leaching studies with metabolites were performed.

zRMS comments:

In EFSA Scientific Report (2007) 106 results of column leaching and aged residues leaching are reported. Their results are, however, not necessary for purposes of evaluation of SAP2101F, as based on results of the groundwater modelling no unacceptable leaching of prothioconazole or its metabolites is expected.

8.5.3.2 Folpet

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. Phtalic acid was found as the major component identified in the leachate. Folpet, phtalimide and phtalamic 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.

8.5.4 Lysimeter studies (KCP 9.1.2.2)

Lysimeter studies are not required neither for prothioconazole neither for folpet since no leaching is expected.

zRMS comments:

According to EFSA Scientific Report (2007) 106 and EFSA Scientific Report (2009) 297, 1-80, lysimeter studies for prothioconazole and folpet were not required.

8.5.5 Field leaching studies (KCP 9.1.2.3)

Field leaching studies are not required neither for prothioconazole neither for folpet since no leaching is expected.

zRMS comments:

According to EFSA Scientific Report (2007) 106 and EFSA Scientific Report (2009) 297, 1-80, field leaching studies for prothioconazole and 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 dossiers.

8.6.1 Prothioconazole and its metabolites

The behaviour of prothioconazole in two different water/sediment systems was investigated under aerobic conditions in the dark at 20ºC. Two radiolabelled compounds, [phenyl-UL-14C] and [3,5- triazole-14C] prothioconazole were used as test substances. A proportion of the active substance partitioned quite rapidly into the sediment, with maximum levels of prothioconazole reaching 22.6% to 23.4% AR in the sediment on day 1 and decreased at the study end (3.3-6.8% AR and 3.4-9.5% AR after 121 days). The amount of the unextracted residues increased significantly during the course of the study. More than 12 metabolites were formed and five of them were identified. Major metabolites in water were prothioconazole-desthio M04 (maximum = 32.3% AR by day 7) and 1,2,4-triazole M13 (maximum = 37.2% AR by day 121). The high levels of metabolite M13 were observed in only one of the systems. In the sediment extracts, M04 was the only major metabolite (maximum = 26.9% AR by day 14).

Table 8.6-1: Summary of degradation in water/sediment of Prothioconazole (laboratory studies)

Water/sediment system	**pH water/sed.**	**DT_{50} water (d)**	**DT_{50} whole system (d)**	**DT_{90} water (d)**	**DT_{90} whole system (d)**	**r^2**	**Method of calculation**	**Evaluated on EU level y/n/ Reference**
Hönniger Weiher (Pond system)	7.84/6.6	0.8	-	2.7	-	0.947	SFO	Yes Brumhard and Oi (2001, amended 2002) – DAR, 2005 (Vol. 3, Annex B.8), Addendum (October 2005)
		-	2.8	-	76.4	0.953	Bi-phasic (‘Hockey Stick’)	
Angler Weiher (Lake System)	7.45/8.5	**1.0**	-	3.4	-	0.999	SFO	
		-	1.6	-	23.6	0.998	Bi-phasic (‘Hockey Stick’)	

Bold values were used in modelling

An aqueous photolysis study was conducted. Continuous exposure was used. The degradation of prothioconazole in the dark control samples demonstrated that photolysis was the main process of degradation.

Prothioconazole-desthio (M04) was identified as the main photolytic degradation product (max. 56% AR). Other two major degradation products were identified as prothioconazole-thiazocine (M12) at 14% AR and 1,2,4-triazole (M13) at 12% AR.

The anaerobic degradation of prothioconazole was investigated in an anaerobic water/sediment system was conducted. The amounts of $^{14}CO_2$ and organic volatile radioactive substances were very low (< 0.1% AR throughout the study). Prothioconazole-S-methyl (M01) was identified as major metabolite in the sediment (maximum 77.0% AR by day 240).

Table 8.6-2: Summary of observed metabolites

		Evaluated on EU level y/n/ Reference
Prothioconazole -desthio (M04) Water/sediment system Photolysis	Max. in water 32.3% AR, 7 d Max. in sediment 26.9% AR, 14 d Max. in total system 54.6% AR, 7 d Max. in water 55.7% AR after 11 d	Yes DAR, 2005 (Vol. 3, Annex B.8) Addendum (October 2005) EFSA , 2007
Prothioconazole-thiazocine (M12) Photolysis	Max. in water, 14.1% after 5 d	
1,2,4-triazole (M13) Water/sediment system Photolysis	Max. in water 37.2%, 121 d in sediment 4.6 % after 121 d in whole system 41.8 % after 121 Max. in water 11.9% after 18 d	
Prothioconazole-S-methyl (M01)	Max. in sediment 77.0% after 240 d	

zRMS comments:
Degradation data for prothioconazole and is metabolites in water/sediment systems provided in tables above are in line with EU agreed endpoints reported in EFSA Scientific Report (2007) 106 and prothioconazole DAR (2005) and are relevant for the surface water exposure assessment. The zRMS completed the Table 8.6-2 with additional information for metabolite 1,2,4-triazole.

8.6.2 Folpet and its metabolites

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 trichlomethylsulfenic acid salt and that unknown 2 will be tricloromethylmercaptan that will degrade to thiophosgene, carbon oxysulfide and ultimately to CO_2.

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 CO_2 and CH_4 (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 8.6-3: 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)**	**Kinetic, Fit**	**DissT50 water (d)**	**DissT90 water (d)**	**Kinetic, Fit**	**DissT50 sed. (d)**	**Kinetic, 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 metaboites in water/sediment systems decribed above are in line with EU agreed endpointes 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 Prothioconazole (and its metabolites) and 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/cm^3 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 in each active substance and its metabolites point and those obtained with the minimum dose are presented in Appendix 3. At the end of each active substance point, a summary table is presented.

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

Plant protection product	SAP2101F	
Use No.	1	2
Crop	Winter and Spring Cereals	
Application rate (g as/ha)	prothioconazole: 120 to 180 folpet: 300 to 450	
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
Prothioconazole	344.3	-	2.8 d (maximum value from field studies)	Y EFSA Scientific Report (2007) 106
Prothioconazole-S-methyl (M01)	358.3	14.6	46.0 d (highest first order, lab studies)	
Prothioconazole-desthio (M04)	312.2	57.1	72.3 (maximum value from field studies)	
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)	

8.7.2.1 Prothioconazole and its metabolites

Table 8.7-3: PEC_{soil} for prothioconazole after application of SAP2101F (maximum dose)

PEC_{soil} (mg/kg)		Cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.048	-	**0.050**	-
Short term	24h	0.037	0.043	0.039	0.044
	2d	0.029	0.038	0.030	0.039
	4d	0.018	0.030	0.018	0.031
Long term	7d	0.008	0.023	0.009	0.024
	14d	0.002	0.013	0.002	0.014
	21d	0.000	0.009	0.000	0.009
	28d	0.000	0.007	0.000	0.007
	50d	0.000	0.004	0.000	0.004
	100d	0.000	0.002	0.000	0.002

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

PEC_{soil} of metabolites

Table 8.7-4: PEC_{soil} for prothioconazole-S-methyl (M01) after application of SAP2101F (maximum dose)

PEC_{soil} (mg/kg)		Cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.007	-	**0.013**	-
Short term	24h	0.007	0.007	0.013	0.013
	2d	0.007	0.007	0.013	0.013
	4d	0.007	0.007	0.012	0.013
Long term	7d	0.007	0.007	0.012	0.013
	14d	0.006	0.007	0.011	0.012
	21d	0.005	0.006	0.010	0.011
	28d	0.005	0.006	0.009	0.011
	50d	0.003	0.005	0.006	0.009
	100d	0.002	0.004	0.003	0.007

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

Table 8.7-5: PEC_{soil} for prothioconazole-desthio (M04) after application of SAP2101F (maximum dose)

PEC_{soil} (mg/kg)		Cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.025	-	**0.047**	-
Short term	24h	0.025	0.025	0.046	0.046
	2d	0.024	0.025	0.046	0.046
	4d	0.024	0.024	0.045	0.046
Long term	7d	0.023	0.024	0.044	0.045
	14d	0.022	0.023	0.041	0.044
	21d	0.020	0.023	0.038	0.042
	28d	0.019	0.022	0.036	0.041
	50d	0.015	0.020	0.029	0.037
	100d	0.010	0.016	0.018	0.030

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

The predicted environmental concentrations in soil were calculated for the active substance prothioconazole 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 8.7-6 Summary of initial PEC_{soil} of prothioconazole and its metabolites

Compound	Crop	Use rate [g/ha]	No. of appln.	Crop inter-ception [%]	Soil loading [g/ha]	$PEC_{s\ initial}$ [mg/kg]
Prothioconazole	Cereals	180	2	80	36	0.050
		120			24	0.033
M01		27.35			5.47	0.013
		18.23			3.65	0.009
M04		93.2			18.64	0.047
		63.13			12.63	0.032

zRMS comments:

The application pattern assumed in soil exposure assessment for prothioconazole is in line with the critical Central Zone GAP and it is thus agreed. Relevant crop interception of 80% in line with FOCUS groundwater guidance (2023) has been selected.

Input parameters presented in Table 8.7-2 are in line with EU agreed parameters reported in EFSA Scientific Report (2007) 106.

The soil exposure for prothioconazole and its metabolites has been independently validated by the zRMS using FOCUS methods and EU agreed endpoints and the pseudo-application rates of metabolites derived with consideration of the parent rate, molar ratio and peak occurrence in soil. The calculated PEC_{SOIL} values were the same as these obtained by the Applicant therefore, results reported in tables above may be used for the soil risk assessment purposes.

8.7.2.2 Folpet and its metabolites

Table 8.7-7: PEC_{soil} for folpet after application of SAP2101F (maximum 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)

PEC_{soil} of metabolites

Table 8.7-8: PEC_{soil} for phthalimide after application of SAP2101F (maximum 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)

Table 8.7-9: PEC_{soil} for phthalamic acid after application of SAP2101F (maximum dose)

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

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

Table 8.7-10: PEC_{soil} for phthalic acid after application of SAP2101F (maximum 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

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 8.7-11 Summary of initial PEC_{soil} of folpet and its metabolites

Compound	Crop	Use rate [g/ha]	No. of appln.	Crop interception [%]	Soil loading [g/ha]	$PEC_{s\ initial}$ [mg/kg]
Folpet	Cereals	450	2	80	90	0.198
		300			60	0.132
Phthalimide		144.84			36.97	0.069
		96.56			19.31	0.045
Phthalamic acid		41.83			8.37	0.011
		27.89			5.58	0.007
Phthalic acid		41.83			8.37	0.012
		27.89			5.58	0.008

zRMS comments:

Input parameters presented in Table 8.7-7 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 DT_{50} used for PEC_{soil} calculation were not stated in EU agreed endpoints (DT_{50} 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 DT_{50} 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 DT_{50} 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.

8.7.2.3 PEC_{soil} of SAP2101F

An initial PEC_{soil} value was calculated for the formulation based on the maximum and minimum individual application rate of 1.5 L/ha and 1.0 L/ha, respectively.

The calculation was based on crop interception of 80%, soil depth of 5 cm, bulk density of 1.5 g/cm^3 and specific density of 1140 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 SAP2101F on cereals

Preparation	Application rate (g/ha)	PEC_{act} (mg/kg)
SAP2101F	1710	0.456
	1140	0.304

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., 2021a
Title:	Predicted Environmental Concentrations of Prothioconazole 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 SAP2101F on Cereals
Document No:	ASC123-2021
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.

Report:	KCP 9.2.4/02, Fernandes, V., 2021b
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 SAP2101F on Cereals
Document No:	ASC124-2021
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.

These reports describe a FOCUS modelling study that examined the potential for prothioconazole (and its metabolites) and folpet (and its metabolites) to reach groundwater following application to winter and spring cereals.

The predicted environmental concentration of the active substances and significant components from the formulated product SAP2101F 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 in each active substance and its metabolites point and those obtained with the minimum dose are presented in Appendix 3. At the end of each active substance point, a conclusion for both doses is presented.

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

Plant protection product	SAP2101F	
Use No.	1	2
Crop	Winter and Spring Cereals	
Application rate (g as/ha)	prothioconazole: 120 to 180 folpet: 300 to 450	
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	-

zRMS comments:
The application pattern presented in Table 8.8-1 and considered in groundwater exposure is in line with the critical Central Zone GAP as presented in Table 8.1-1. Assumed crop interception corresponded with BBCH stages at product SAP2101F is intended to be applied. Application dates presented in Table 8.8-2 were checked by the zRMS using AppDate ver. 3.06 tool and are considered acceptable. It is noticed that according to GAP table application to winter cereals is at BBCH 32-61, which is slightly later. Nevertheless this deviation turned out to have no impact on the PECgw results discussed in the commenting boxes in points 8.8.2.1 and 8.8.2.2.

8.8.2.1 Prothioconazole and its metabolites

The PEC_{gw} values of Prothioconazole and its metabolites were calculated based on agreed LoEP (EFSA Scientific Report (2007) 106, 1-98).

Table 8.8-3: Input parameters related to active substance prothioconazole and metabolites for PEC_{gw} calculations

Compound	Prothioconazole	Prothioconazole -S-methyl (M01)	Prothioconazole-desthio (M04)	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol):	344.3	358.3	312.2	EFSA Scientific Report (2007) 106
Water solubility (g/mol):	22.5 (20ºC, pH 7)	4.6 (20ºC, pH 7)	50.6 (20ºC, pH 7)	
Saturated vapour pressure (Pa):	4 x 10^{-7} Pa (20°C)	8.2 x 10^{-6} Pa (20°C)	1 x 10^{-10} (20ºC)	
DT_{50} in soil (d)	1.2 (field, geomean, n=8)	15.7 (lab., geomean, n=4)	22.7 (field, geomean, n=)	
Transformation rate	Parent -> M01: 0.08433 Parent ->M04: 0.32982 Parent-> BR/CO_2: 0.16347	M01-> BR/CO_2: 0.04415	M04-> BR/CO_2: 0.03054	
K_{foc} (mL/g)/K_{fom}	1765 (Aged soil column leaching study)	2525.9 (geomean, n=4)	573.5 (geomean, n=4)	
1/n	1 (default value)	0.88 (arith.mean, n=4)	0.81 (arith.mean, n=4)	
Plant uptake factor	0	0	0	
Formation fraction	-	0.146 from parent	0.571 from parent	
Conversion factor*	-	0.152	0.518	

* used in Macro model

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Table 8.8-4: PEC_{gw} for prothioconazole and metabolites on cereals following application of SAP2101F (FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)					
		FOCUS PELMO v.6.6.4			FOCUS PEARL v.5.5.5		
		Parent	M01	M04	Parent	M01	M04
Winter Cereals 2x180 g as/ha	Châteaudun	< 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
	Jokioinen	< 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
	Okehampton	< 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
	Porto	< 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
	Thiva	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Spring Cereals 2x180 g as/ha	Châteaudun	< 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
	Jokioinen	< 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
	Okehampton	< 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

Table 8.8-5: PEC_{gw} for prothioconazole and its metabolites on cereals following application of SAP2101F (FOCUS MACRO 5.5.4)

	PEC_{GW} at 1 m soil depth [µg/L]		
	FOCUS MACRO 5.5.4		
	Parent	M01	M04
Winter Cereals – 2 x 180 g as/ha, Châteaudun scenario	0.000	0.000	0.000
Spring Cereals – 2 x 180 g as/ha, Châteaudun scenario	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 prothioconazole 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:

Input parameters presented in Table 8.8-3 and used in the modelling are in general in line with the EU agreed endpoints reported in EFSA Scientific Report (2007) 106 only with one exception:

- for prothioconazole metabolites the geometric mean Kfoc values were considered by the Applicant although in the EFSA conclusion arithmetic mean values are 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.

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

The performed calculations were independently validated by the zRMS in additional modelling using and FOCUS models PEARL 5.5.5 and PELMO 6.6.4 and resulted with the same PEC_{GW} values as these obtained by the Applicant. Overall, no unacceptable leaching of prothioconazole and its metabolites is expected following application of SAP2101F according to the intended use pattern.

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

8.8.2.2 Folpet and its metabolites

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.

Table 8.8-6: Input parameters related to active substance folpet and metabolites for PEC_{gw} calculations

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 (25ºC)	360 (25 ºC)	37600 (25 ºC)	7010 (25 ºC)	
Saturated vapour pressure (Pa):	2.1x10^{-5} (25ºC)	1.38x10^{-6} (25 ºC)	1.53x10^{-4} (25 ºC)	1.01x10^{-4} (25 ºC)	
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	

* used in Macro model

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~~**Table 8.8-7: PEC_{gw} for folpet and metabolites on cereals following application of SAP2101F (FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5)**~~

~~Crop~~	~~Scenario~~	~~80th 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 2x450 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 2x450 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~~

April 2024:

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.

While the Generic Guidance for Tier 1 FOCUS Ground Water Assessments suggests using the geometric mean of laboratory degradation, field degradation, or combined laboratory and field degradation rates after considering available data as outlined in EFSA (2014), the applicant opted for worst-case values of soil DT50 for folpet and metabolites in compliance with authorities' request. Additionally, the applicant rectified the Freundlich exponent, setting it to the default value of 0.9, for Folpet, as stated in the LoEP.

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, applicant delivers 2 sets of calculations to demonstrate to authorities that applying the minor different values of DT50 do not affect previous risk assessment conclusions.

Table 8.8-7a: **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 values as presented in table 8.8-3, a molar activation energy of 55 kJ/mol and Q10 = 2.2**

Crop	Scenario	80th 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 2x450 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 2x450 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

Table 8.8-7b: **PEC_{gw} for folpet and metabolites on cereals following application of SAP2101F ~~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	80th 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 2x450 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 2x450 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 8.8-8: **PECgw for folpet and its metabolites on cereals following application of SAP2101F (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

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:

Input parameters for folpet and its metabolites presented in Table 8.8-6 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 DT_{50} values normalised with Q_{10} of 2.58 were considered although the EU agreed endpoints were normalised with Q_{10} of 2.2. In line with current FOCUS requirements the Q_{10} 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 Q_{10} of 2.2. For folpet the EU agreed value of soil DT_{50} is 4.68 days instead of 1.38 days presented in Table 8.8-6. For metabolites phthalimide and phthalic acid the EU agreed values of soil DT_{50} are 7.88 days and 3.15 days, respectively. Since consideration of the longer soil DT_{50} values represents worst case, thus the respective correction of DT_{50} and consequently transformation rates were introduced in Table 8.8-6 and further used in independent zRMS calculations.
- for folpet metabolite phthalimide the geometric mean Kfoc 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 8.8-6.

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 and FOCUS models PEARL 5.5.5 and PELMO 6.6.4 and the soil DT_{50} 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 8.8-7b. No unacceptable leaching of folpet and its metabolites is expected following application of SAP2101F according to the intended Central Zone use pattern given in Table 8.8-1.

Since not agreed input values were struck through in Table 8.8-6 and groundwater modelling based entirely on EU agreed parameters has been accepted by the zRMS thus results presented in Tables 8.8-7 and 8.8-7a 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 SAP2101F 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-registration.

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

Report:	KCP 9.2.5/01, Fernandes, V., 2021c
Title:	Predicted Environmental Concentrations of Prothioconazole and its metabolites in Surface Water and Sediment (PEC_{sw} and PEC_{sed}) based on Tiered FOCUS Approach for risk assessment of SAP2101F on Cereals
Document No:	ASC111-2021
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 Document 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.

Report:	KCP 9.2.5/02, Fernandes, V., 2021d
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 SAP2101F on Cereals
Document No:	ASC112-2021
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 Document 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.

These reports describe a FOCUS modelling study that examined the potential for prothioconazole (and its metabolites) and folpet (and its metabolites) to reach surface water following application to winter and spring cereals.

The predicted environmental concentration of the active substances and significant components from the formulated product SAP2101F in surface water (PEC_{sw} and PEC_{sed}) is determined using the standardized recommendations of the FOCUS working group on surface water scenarios (FOCUS 2001[6] and 2015[7]) using Steps 1-2 and Step 3.

Where necessary and applicable, mitigations measures will be applied (Step 4). 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) [2] was considered. In addition, vegetated filter strip factors for 5 meters and 15 meters were also performed to provide cMS with information on the appropriate mitigation measure for their countries.

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 found in each active substance and its metabolites point and those obtained with the minimum dose are presented in Appendix 3. At the end of each active substance

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

point, 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	SAP2101F	
Use No.	1	2
Surrogate Crop	Winter and Spring Cereals	
Application rate (kg as/ha)	prothioconazole: 0.120 to 0.180 folpet: 0.300 to 0.450	
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	
	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	

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 SAP2101F

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

zRMS comments:

The application pattern assumed in surface water simulations is in general in line with Central Zone GAP presented in Table 8.1-1.
The application windows presented in Table 8.9-2 were checked by the zRMS using AppDate ver. 3.06 tool and are considered acceptable. It is noticed that according to the GAP table application to winter cereals is at BBCH stage 32-61, which is slightly later than presented in table above. Please note, however, that the zRMS modelling

demonstrated that this difference has no impact on the obtained PECsw results (for more information, see zRMS comment in point 8.9.2.1 and 8.9.2.2).

8.9.2.1 Prothioconazole and its metabolites

The PEC_{sw} values of Prothioconazole were calculated at STEP 1-2 in FOCUS. STEP 3 and 4 were not necessary for the parent assessment.

Concerning the metabolites, STEP 1-2 were used to calculate the PEC_{sw}. For the metabolite prothioconazole-desthio, also STEP 3 was performed. Further details on aquatic risk assessment can be found in Section 9 of this dRR.

Due to the K_{OC} values for both prothioconazole and prothioconazole-desthio are 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 prothioconazole. This approach wasn't taken into account for metabolite prothioconazole-desthio since all simulations were performed considering the worst-case value in all compartments, 1000 days. Otherwise, 4 sets should be simulated.

To calculate PECsw for the metabolite prothioconazole-desthio (Step 3 and Step 4), the EU agreed approach was taken by simulating the metabolite prothioconazole-desthio (M04) as metabolite resulting from the degradation of prothioconazole and with the EU agreed formation fractions (0.571 in soil and 0.323 in water). The SWASH version allows to take into account the metabolite formation in both soil and/or water/sediment compartments.

The values used for the formation fractions of prothioconazole-desthio are in line with the conclusion of the EU review of prothioconazole that for the metabolites the maximum occurrence equals the formation fraction (0.571 and 0.323 in soil and water respectively) due to the rapid conversion of prothioconazole.

In Appendix 4, the complete tables concerning each set performed are presented. The values shown in Table 8.9-9 are the highest among the 2 simulated sets.

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

Compound	Prothioconazole	Prothioconazole-S-methyl (M01)	Prothioconazole-desthio (M04)	1,2,4-triazole (M13)	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	344.26	358.3	312.2	69.065	EFSA Scientific Report (2007) 106
Water solubility (mg/L)	22.5 (20ºC, pH 7)	4.6 (20ºC, pH 7)	50.6 (20ºC, pH 7)	700000 (20ºC, pH 7)	
Vapour Pressure (Pa)	$4x10^{-7}$	Not necessary for Step 1-2	$1x10^{-10}$	Not necessary for Step 1-2	
Diffusion coefficient in water (m²/d)	4.3×10^{-5}		4.3×10^{-5}		default
Diffusion coefficient in air (m²/d)	0.43		0.43		
Plant Uptake	0		0		FOCUS recommendation
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)		0.05 (MACRO) 0.50 (PRZM)		default
Freundlich Exponent 1/n	1 (default value)		0.81 (arith.mean, n=4)		EFSA Scientific Report (2007) 106
Kfoc (mL/g)	1765 (Aged soil column leaching study)	2525.9 (geomean, n=4)	573.5 (geomean, n=4)	83 (geomean, n=4)	

Compound	Prothioconazole	Prothioconazole-S-methyl (M01)	Prothioconazole-desthio (M04)	1,2,4-triazole (M13)	Value in accordance to EU endpoint y/n/ Reference
DT50,soil (d)	1.2 (field, geomean, n=8)	15.7 (lab., geomean, n=4)	22.7 (field, geomean, n=)	1000 (default value)	
DT50,water (d)	Set 1: 1.0 (higher value) Set 2: 1000 (default value)	1000 (default value)	1000 (default value)	1000 (default value)	
DT50,sed (d)	Set 1: 1000 (default value) Set 2: 1.0 (higher value)	1000 (default value)	1000 (default value)	1000 (default value)	
DT50,whole system (d)	1000 (default value)	1000 (default value)	1000 (default value)	1000 (default value)	
Maximum occurrence observed (% molar basis with respect to the parent)*	-	Soil: 14.6% Sediment: 77% (anaerobic) 12.7 (aerobic)	Soil: 57.1 % ~~49.4%~~ Water: 55.7% Sediment: 26.9% whole system: 54.6%	Total water/sediment: 41.8% ~~15.1%~~	

* used at Step 1-2

FINDINGS

Prothioconazole

FOCUS Step 1-2

Table 8.9-4: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for P*rothioconazole* following application of SAP2101F (maximum dose) – set 1

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>19.55</u>***	---	3.92	315.81
Step 2					
Northern Europe	Oct-Feb	1.48 (*<u>1.66</u>*)	~~Runoff/Drainage~~	0.48 (0.50)	16.26 (16.47)
Southern Europe		1.48 (1.66)		0.44 (0.46)	13.75 (13.97)
Northern Europe	Mar-May	1.48 (1.66)	~~Runoff/Drainage~~	0.35 (0.38)	8.74 (8.96)
Southern Europe		1.48 (1.66)		0.44 (0.46)	13.75 (13.97)
	Spring cereals				
Step 1	---	***<u>19.55</u>***	---	3.92	315.81
Step 2					
Northern Europe	March-May	1.48 (*<u>1.66</u>*)	~~Runoff/Drainage~~	0.35 (0.38)	8.74 (8.96)
Southern Europe		1.48 (1.66)		0.44 (0.46)	13.75 (13.97)

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

Table 8.9-5: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for P*rothioconazole* following application of SAP2101F (maximum dose) – set 2

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	---	***19.55***	---	3.92	315.81
Step 2					
Northern Europe	Oct-Feb	1.47 (1.66)	~~Runoff/Drainage~~	0.71 (0.76)	13.78 (13.93)
Southern Europe		1.47 (1.66)		0.65 (0.70)	11.28 (11.42)
Northern Europe	Mar-May	1.47 (1.66)	~~Runoff/Drainage~~	0.53 (0.58)	6.26 (6.41)
Southern Europe		1.47 (1.66)		0.65 (0.70)	11.28 (11.42)
	Spring cereals				
Step 1	---	***19.55***	---	3.92	315.81
Step 2					
Northern Europe	March-May	1.47 (1.66)	~~Runoff/Drainage~~	0.53 (0.58)	6.26 (6.41)
Southern Europe		1.47 (1.66)		0.65 (0.70)	11.28 (11.42)

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)*

Metabolites of Prothioconazole

FOCUS Step 1-2

Table 8.9-6: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for *Prothioconazole-S-methyl (M01)* following application of SAP2101F (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	---	***28.85***	---	26.88	676.46
Step 2					
Northern Europe	Oct-Feb	*2.23* (1.55)	~~Runoff/Drainage~~	2.06 (1.44)	51.66 (36.34)
Southern Europe		1.93 (1.33)		1.75 (0.94)	44.02 (30.60)
Northern Europe	Mar-May	1.53 (1.33)	~~Runoff/Drainage~~	1.05 (0.71)	28.73 (19.12)
Southern Europe		*1.93* (1.33)		1.75 (0.94)	44.02 (30.60)
	Spring cereals				
Step 1	---	***28.85***	---	26.88	676.46
Step 2					
Northern Europe	March-May	*1.53* (1.33)	~~Runoff/Drainage~~	1.05 (0.71)	28.73 (19.12)
Southern Europe		*1.93* (1.33)		1.75 (0.94)	44.02 (30.60)

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 8.9-7: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for *Prothioconazole-desthio (M04)* following application of SAP2101F (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				

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	***66.49***	---	65.65	376.88
Step 2					
Northern Europe	Oct-Feb	***11.92 (7.44)*** ~~*10.56* (6.63)~~	~~Runoff/Drainage~~	11.76 (7.35) ~~10.41 (6.54)~~	67.51 (42.20) ~~59.73 (37.52)~~
Southern Europe		**8.64 (5.41)**		8.49 (5.32)	48.73 (30.56)
Northern Europe	Mar-May	**5.34 (3.30)** ~~4.81 (2.98)~~	~~Runoff/Drainage~~	5.20 (3.22) ~~4.67 (2.90)~~	29.8 (18.47) ~~26.75 (16.63)~~
Southern Europe		***8.64*** **(5.41)**		8.49 (5.32)	48.73 (30.56)
	Spring cereals				
Step 1	---	***66.49***	---	65.65	376.88
Step 2					
Northern Europe	March-May	**5.34 (3.30)** ~~4.81 (2.98)~~	~~Runoff/Drainage~~	5.20 (3.22) ~~4.67 (2.90)~~	29.8 (18.47) ~~26.75 (16.63)~~
Southern Europe		***8.64*** **(5.41)**		8.49 (5.32)	48.73 (30.56)

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 8.9-8: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for *1,2,4-triazole (M13)* following application of SAP2101F (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	---	*3.37*	---	3.36	2.79
Step 2					
Northern Europe	Oct-Feb	0.41 (0.31) ~~0.15 (0.11)~~	~~Runoff/Drainage~~	0.40 (0.30) ~~0.14 (0.11)~~	0.33 (0.25) ~~0.12 (0.09)~~
Southern Europe		0.13 (0.10)		0.13 (0.10)	0.11 (0.08)
Northern Europe	Mar-May	0.30 (0.20) ~~0.11 (0.07)~~	~~Runoff/Drainage~~	0.29 (0.20) ~~0.11 (0.07)~~	0.24 (0.16) ~~0.09 (0.06)~~
Southern Europe		0.13 (0.10)		0.13 (0.10)	0.11 (0.08)
	Spring cereals				
Step 1	---	*3.37*	---	3.36	2.79
Step 2					
Northern Europe	March-May	0.30 (0.20) ~~0.11 (0.07)~~	~~Runoff/Drainage~~	0.29 (0.20) ~~0.11 (0.07)~~	0.24 (0.16) ~~0.09 (0.06)~~
Southern Europe		0.13 (0.10)		0.13 (0.10)	0.11 (0.08)

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)*

PECsw for metabolite Prothioconazole thiazocine (M12) are estimated to be needed as is found under photolysis conditions >10%. Therefore, it is presented a worst-case PECsw determined by multiplying the peak parent PECsw by the maximum observed metabolite level in the photolysis study. First, the maximum observed level must be converted from % Applied Radioactivity (a molar ratio) to % w/w. The conversion factor is the molar mass ratio between the metabolite and the parent.

PEC_{sw} values have only been calculated for the worst-case FOCUS scenario, taken from the parent.

Table 8.9-9 Metabolite formation level in water

Metabolite	Molar mass (g/mol)	Mass ratio (metabolite/parent)	Max % AR	Max % w/w
prothioconazole-thiazocine (M12)	307.8	0.894	14.1	12.6

Table 8.9-10: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for P*rothioconazole-thiazocine (M12)* following application of SAP2101F (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)*
	Cereals				
Step 1	---	***2.464***	---	0.494	-
Step 2					
Southern Europe	Mar-May	0.19 (*0.21*)	~~Runoff/Drainage~~	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)*

Due to PECsw values greater than RAC for the prothioconazole-desthio metabolite, 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 8.9-9: FOCUS Step 3 PEC_{sw} and PEC_{sed} for *prothioconazole-desthio* (M04) following single and multiple applications of SAP2101F to winter and spring cereals (maximum dose)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)		Max PEC_{sed} (µg/kg)	
		Prothioconazole	Prothioconazole-desthio (M04)	Prothioconazole	Prothioconazole-desthio (M04)
Winter Cereals - Multiple applications					
D1 set1	ditch	1.007	0.1446	1.17	0.5667
D1 set1	stream	0.8493	0.04557	0.1481	0.0602
D2 set1	ditch	1.009	0.1753	0.9752	0.5493
D2 set1	stream	0.8814	0.1719	0.7323	0.5061
D3 set1	ditch	0.9966	0.06053	0.5311	0.06566
D4 set1	pond	0.03253	0.01118	0.05697	0.1514
D4 set1	stream	0.7529	0.02906	0.02898	0.006643
D5 set1	pond	0.03339	0.01352	0.04994	0.1798
D5 set1	stream	0.8686	0.04129	0.06461	0.00387
D6 set1	ditch	1.001	0.07893	0.6772	0.1161
R1 set1	pond	0.03288	0.1028	0.04441	0.9955
R1 set1	stream	0.6489	**0.9081**	0.2846	0.9106
R3 set1	stream	0.917	**0.8642**	0.7877	0.9814
R4 set1	stream	0.6527	**1.395**	0.2398	0.923
Winter Cereals - Single application					
D1 set1	ditch	1.143	0.03664	0.7239	0.06951

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)		Max PEC_{sed} (µg/kg)	
		Prothioconazole	Prothioconazole-desthio (M04)	Prothioconazole	Prothioconazole-desthio (M04)
D1 set1	stream	0.8882	0.04348	0.03616	0.01495
D2 set1	ditch	1.15	0.07467	0.9329	0.1048
D2 set1	stream	0.9769	0.05085	0.1475	0.02315
D3 set1	ditch	1.139	0.03627	0.5119	0.03075
D4 set1	pond	0.0393	0.007217	0.04885	0.09008
D4 set1	stream	0.8413	0.03247	0.02421	0.002559
D5 set1	pond	0.03931	0.008345	0.039	0.1112
D5 set1	stream	0.9092	0.04174	0.02572	0.00127
D6 set1	ditch	1.126	0.01962	0.2842	0.008267
R1 set1	pond	0.03931	0.03565	0.03959	0.3898
R1 set1	stream	0.7504	0.3153	0.0955	0.3282
R3 set1	stream	1.054	**0.3948**	0.1893	0.4976
R4 set1	stream	0.7537	**0.5744**	0.107	0.385
Spring Cereals - Multiple applications					
D1 set1	ditch	1.02	**0.3484**	0.9889	1.966
D1 set1	stream	0.8723	0.08887	0.4204	0.2326
D3 set1	ditch	0.9971	0.06289	0.5352	0.08147
D4 set1	pond	0.03227	0.01384	0.03444	0.1636
D4 set1	stream	0.8322	0.03699	0.09628	0.008935
D5 set1	pond	0.03222	0.01331	0.03705	0.1797
D5 set1	stream	0.86	0.0412	0.05643	0.003569
R4 set1	stream	0.8259	**0.9841**	1.01	1.155
Spring Cereals - Single application					
D1 set1	ditch	1.153	0.2055	0.893	1.148
D1 set1	stream	1.008	0.08223	0.4239	0.08375
D3 set1	ditch	1.14	0.07005	0.4823	0.06276
D4 set1	pond	0.03932	0.009042	0.03349	0.1011
D4 set1	stream	0.9321	0.038	0.06119	0.003557
D5 set1	pond	0.03932	0.008413	0.03913	0.1108
D5 set1	stream	0.9573	0.04395	0.03956	0.002004
R4 set1	stream	0.7537	**0.5207**	0.6298	0.8016

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 cMS with information on the appropriate mitigation measure for their countries.

Table 8.9-10: Reduction efficiencies of surface runoff used for the calculation

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~~

Table 8.9-11: FOCUS Step 4 PEC_{sw} for *prothioconazole-desthio* (M04) following application of SAP2101F (maximum dose)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Max PEC_{sed} (µg/kg)
~~*Winter Cereals - Multiple applications – 15 meters of vegetated filter strip*~~			
~~R1 set1~~	~~stream~~	~~0.3164~~	~~0.2369~~
~~R3 set1~~	~~stream~~	~~0.2924~~	~~0.2370~~
Winter Cereals - Multiple applications – 20 meters of vegetated filter strip			
R1 set1	stream	0.2159	0.1579
R3 set1	stream	0.1997	0.1552
R4 set1	stream	0.3323	0.2019
~~*Winter Cereals - Single application – 5 meters of vegetated filter strip*~~			
R3 set1	~~stream~~	~~0.2581~~	~~0.3142~~
Winter Cereals - Single application – 10 meters of vegetated filter strip			
R3 set1	stream	0.1802	0.1556
R4 set1	stream	0.2612	0.1578
Spring Cereals - Multiple applications – 20 meters of vegetated filter strip			
D1 set1	ditch	0.02912	0.4209
R4 set1	stream	0.2311	0.2551
Spring Cereals - Single application – 10 meters of vegetated filter strip			
R4 set1	stream	0.2368	0.3195

Bold values are above RAC

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 for simulated PEC_{sw} for the metabolite prothioconazole-desthio.

Although the PECsw 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 8.9-12: Assessment summary of prothioconazole and its metabolites following application of SAP2101F

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

zRMS comments:

Input parameters used for surface water modelling for prothioconazole and its metabolites and presented in Tables 8.9-3 are in general in line with EU agreed endpoints with following remarks:

For prothioconazole:

- DT_{50} in water of 2.1 days was used instead of 1.0 days agreed in the course of the EU review. Nevertheless, in opinion of the zRMS this deviation is not expected to have significant impact on the obtained results.

For metabolite prothioconazole-S-Methyl

- The Applicant used the maximum occurrence in water/sediment system of 77%, but such formation of prothioconazole-S-Methyl was observed only in sediment in the anaerobic water/sediment study. In the aerobic water/sediment study the maximum occurrence of 12.7% was observed in the whole system. Nevertheless, as assumed 77% represents worst case, it was accepted by the zRMS for Step 1-2 calculations.

For metabolite prothioconazole-desthio:

- Maximum occurrence in soil of 49.4% was used, while 57.1% is the correct value, additionally maximum occurrence in the whole system is 54.6%. Respective changes were introduced in Table 8.9-3 and used in the independent zRMS calculations for this metabolite at Step 1-2.
- With regard to parametrisation of the model at Step 3 and 4, as it is correctly noted that the K_{FOC} of JAU 6476-desthio is between 100 and 2000 mL/g and guidance indicates that in such case 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. The same applies to the parent with EU agreed K_{OC} of 1765 mL/g. Since the risk is driven by exposure via water and not sediment (endpoints for sediment dwellers are expressed in terms of mg/L) the worst case combination was when the shortest DT_{50} value was applied to prothioconazole and the default of 1000 days was applied to prothioconazole-desthio in the water phase (Appendix 4, set 1).Since this combination was used in the Applicant modelling it is agree by the zRMS and other combinations were not considered.

For metabolite 1,2,4-triazole

- For the whole system the Applicant used the maximum occurrence of 15.1%, while the maximum occurrence of 41.8% was observed in the whole system. Respective changes were introduced by the zRMS in Table 8.9-3 and used in the independent zRMS calculations at Step 1-2.

At Step 3 PUF value of 0 was assumed for prothioconazole and metabolite prothioconazole-desthio and it is in line with current recommendations.

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 decided on aceptability 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.

The surface water exposure was independently validated by the zRMS in additional modelling with modified input parameters discussed above. Discussion on obtained results is presented below for each compound.

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.

Prothioconazole:

Results for prothioconazole at Step 1-3 were in good agreement with results obtained by the Applicant. Overall, the surface water exposure reported in Tables 8.9-5 may be used in the aquatic risk assessment.

Metabolite prothioconazole-S-Methyl

Results for metabolite prothioconazole-S-Methyl obtained by the zRMS at Step 1-2 were considerably lower comparing to these obtained by the Applicant due to much higher maximum occurrence assumed in Applicant’s simulations. Overall, values in Tables 8.9-6 may be used further in the aquatic risk assessment.

Metabolite prothioconazole-desthio:

Since higher maximum occurrence in the whole system was considered by the zRMS at Steps 1-2 calculations, obtained results were automatically higher and Tables 8.9-7 were amended accordingly.
$PEC_{SW/SED}$ calculated by the zRMS at Steps 3-4 for were the same or slightly lower comparing to surface water exposure calculated by the Applicant.
As indicated in the commenting box in point 8.9.1 the application windows assumed by the Applicant for Step 3 & 4 simulations for winter cereals was performed for BBCH 30 instead of BBCH 32 as it is presented in the GAP table, nevertheless this slightly earlier application dates cover surface water exposure for later BBCH stage.
Overall, the surface water exposure reported in Tables 8.9-7 (with corrected Step 1-2 results), 8.9-9 (Step 3) and 8.9-11 (Step 4) may be used in the aquatic risk assessment.

Metabolite 1,2,4-triazole

PEC_{SW} and PEC_{SED} calculated by the zRMS at Step 1-2 were higher comparing to these obtained by the Applicant when higher maximum occurrence was taken into account. Values reported in Tables 8.9-8 were thus corrected by the zRMS and may be used for purposes of the aquatic risk assessment.

It is noted that metabolite prothioconazole-thiazocine was found at >10% in aqueous photolysis study. However, it was considered not relevant for the exposure assessment during EU review.

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

8.9.2.2 Folpet and its metabolites

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 8.9-16 are the highest among the 2 simulated sets.

Table 8.9-13a: 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 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 (mg/L)	0.8 (25ºC)	360 (25 ºC)	37600 (25 ºC)	7010 (25 ºC)	
Vapour Pressure (Pa)	2.1x10^{-5} (25ºC)	Not necessary for Step 1-2			
Diffusion coefficient in water (m²/d)	4.3 x 10^{-5}				default
Diffusion coefficient in air (m²/d)	0.43				
Plant Uptake	0				FOCUS recommendation
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; ** used at Step 1-2; # based on structure using the PCKOC model

Table 8.9-13b: 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)	0 (default value)	0 (default value)	FOCUS recommendation
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 8.9-14: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for *Folpet* following application of SAP2101F – 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	---	***110.87***	---	7.93	324.48
Step 2					
Northern Europe	Oct-Feb	**26.58 (23.61)** ~~5.73 (5.73)~~	Runoff/Drainage	1.90 (1.69) ~~0.21 (0.21)~~	80.92 (71.92) ~~17.55 (17.55)~~
Southern Europe		~~4.58 (4.58)~~		~~0.33 (0.33)~~	~~14.06 (14.07)~~
Northern Europe	Mar-May	10.63 (9.44) ~~3.66 (4.14)~~	Runoff/Drainage	0.76 (0.68) ~~0.59 (0.62)~~	32.45 (28.85) ~~7.10 (7.11)~~
Southern Europe		~~4.58 (*4.58*)~~		~~0.33 (0.33)~~	~~14.06 (14.07)~~
	Spring cereals				
Step 1	---	***110.87***	---	7.93	324.48
Step 2					
Northern Europe	March-May	10.63 (9.44) ~~3.66 (4.14)~~	~~Runoff/Drainage~~	0.76 (0.68) ~~0.59 (0.62)~~	32.45 (28.85) ~~7.10 (7.11)~~
Southern Europe		~~4.58 (*4.58*)~~		~~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 8.9-15: FOCUS Step 1,2 PEC$_{sw}$ and PEC$_{sed}$ for *Folpet* following application of SAP2101F – set 2 (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	—	***110.87***	—	7.93	324.48
Step 2					
Northern Europe	Oct-Feb	**7.36 (*7.48*)**	Runoff/Drainage	3.56 (3.60)	17.42 (17.41)
Southern Europe		**6.22 (6.34)**		2.97 (3.02)	13.94 (13.93)
Northern Europe	Mar-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)
	Spring cereals				
Step 1	—	***110.87***	—	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)*~~

Due to PECsw values 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 8.9-16: FOCUS Step 3 PEC$_{sw}$ and PEC$_{sed}$ for *folpet* following single and multiple applications of SAP2101F 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 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	0.2274	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
Winter Cereals - Single application					

~~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~~
~~R3 ^{set1}~~	~~stream~~	~~2.638~~	~~drift~~	~~0.02433~~	~~0.2576~~
~~R4 ^{set1}~~	~~stream~~	~~1.886~~	~~drift~~	~~0.01413~~	~~0.1629~~
~~Spring Cereals - Multiple applications~~					
~~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~~
~~Spring Cereals - Single application~~					
~~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~~

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 8.9-16a: FOCUS Step 3 PEC_{sw} and PEC_{sed} for *folpet* following single and multiple applications of SAP50SCF to winter and spring cereals - 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)~~
~~*Winter Cereals - Multiple applications*~~					
~~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~~
~~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~~
~~*Winter Cereals - Single application*~~					
~~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~~

~~***Spring Cereals - Multiple applications***~~					
~~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~~
~~***Spring Cereals - Single application***~~					
~~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~~

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 calculations at Step 3 for the maximum dose are presented in Table below.

Table 8.9-16b: **FOCUS Step 3 PEC_{sw} and PEC_{sed} for *folpet* following single and multiple applications of SAP2101F ~~SAP50SCF~~ to winter and spring cereals - 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)
Winter Cereals - Multiple applications					
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

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)*	Max PEC_{sed} (µg/kg)
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
Winter Cereals - Single application					
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
Spring Cereals - Multiple applications					
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
Spring Cereals - Single application					
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; *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 cMS with information on the appropriate mitigation measure for their countries.~~

Table 8.9-17: 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 Air[3], 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 3.0[4]. Deposition after volatilization is assumed to be most relevant within 24 hours.

Table 8.9-18: 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 2x300 g ha^{-1}		
	5m	10m	20m	5m	10m	20m
0 - 1	0.0023	0.0018	0.0010	0.0016	0.0012	0.0007
1 - 2	0.0023	0.0018	0.0010	0.0016	0.0012	0.0007
2 - 3	0.0023	0.0018	0.0010	0.0016	0.0012	0.0007
3 - 4	0.0023	0.0018	0.0010	0.0016	0.0012	0.0007
4 - 5	0.0012	0.0009	0.0005	0.0008	0.0006	0.0003
5 - 6	0.0012	0.0009	0.0005	0.0008	0.0006	0.0003
6 - 7	0.0012	0.0009	0.0005	0.0008	0.0006	0.0003
7 - 8	0.0012	0.0009	0.0005	0.0008	0.0006	0.0003
8 - 9	0.0012	0.0009	0.0005	0.0008	0.0006	0.0003
9 - 10	0.0012	0.0009	0.0005	0.0008	0.0006	0.0003
10 - 11	0.0012	0.0009	0.0005	0.0008	0.0006	0.0003

[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 2x300 g ha^{-1}		
	5m	10m	20m	5m	10m	20m
11 - 12	0.0012	0.0009	0.0005	0.0008	0.0006	0.0003
12 - 13	0.0006	0.0004	0.0003	0.0004	0.0003	0.0002
13 - 14	0.0006	0.0004	0.0003	0.0004	0.0003	0.0002
14 - 15	0.0006	0.0004	0.0003	0.0004	0.0003	0.0002
15 - 16	0.0006	0.0004	0.0003	0.0004	0.0003	0.0002
16 - 17	0.0006	0.0004	0.0003	0.0004	0.0003	0.0002
17 - 18	0.0006	0.0004	0.0003	0.0004	0.0003	0.0002
18 - 19	0.0006	0.0004	0.0003	0.0004	0.0003	0.0002
19 - 20	0.0006	0.0004	0.0003	0.0004	0.0003	0.0002
20 - 21	0.0006	0.0004	0.0003	0.0004	0.0003	0.0002
21 - 22	0.0006	0.0004	0.0003	0.0004	0.0003	0.0002
22 - 23	0.0006	0.0004	0.0003	0.0004	0.0003	0.0002
23 - 24	0.0006	0.0004	0.0003	0.0004	0.0003	0.0002

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

~~**Table 8.9-19:** **FOCUS Step 4 PEC$_{sw}$ and PEC$_{sed}$ for *folpet* following single and multiple applications of SAP2101F 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 - 5 meters of vegetated filter strip*~~					
~~R3 ^{set2}~~	~~stream~~	~~1.658~~	~~runoff~~	~~0.07739~~	~~0.2831~~
~~*Winter Cereals - Multiple applications - 10 meters of vegetated filter strip*~~					
~~R3 ^{set2}~~	~~stream~~	~~2.037~~	~~runoff~~	~~0.1017~~	~~0.3422~~
~~*Spring Cereals - Multiple applications - 10 meters of vegetated filter strip*~~					
~~R4 ^{set2}~~	~~stream~~	~~3.790~~	~~runoff~~	~~0.3043~~	~~0.4611~~
~~*Spring Cereals - Single application - 5 meters of vegetated filter strip*~~					
~~R4 ^{set2}~~	~~stream~~	~~3.027~~	~~runoff~~	~~0.1979~~	~~0.3877~~
~~*Spring Cereals - Single application - 10 meters of vegetated filter strip*~~					
~~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**~~

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

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

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

Table 8.9-19a: **FOCUS Step 4 PEC_{sw} and PEC_{sed} for *folpet* following single and multiple applications of SAP2101F ~~SAP50SCF~~ to winter and spring cereals**

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 –10 meters of vegetated filter strip					
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
Spring Cereals - Multiple applications –10 meters of vegetated filter strip					
R4 set2	stream	**4.462**	runoff	0.426	0.206
~~*Spring Cereals - Multiple applications –15 meters of vegetated filter strip*~~					
~~R4 set2~~	~~stream~~	~~3.420~~	~~runoff~~	~~0.326~~	~~0.158~~
Spring Cereals - Multiple applications –20 meters of vegetated filter strip					
R4 set2	stream	2.332	runoff	0.223	0.108
Spring Cereals - Single application –10 meters of vegetated filter strip					
R4 set2	stream	2.717	runoff	0.223	0.126

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

Metabolites of Folpet

Table 8.9-20: **FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for *Phthalimide* following application of SAP2101F (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	---	*59.47*	---	8.00	98.40
Step 2					
Northern Europe	Oct-Feb	19.19 (15.41) ~~6.06 (5.98)~~	~~Runoff/Drainage~~	2.95 (2.37) ~~0.93 (0.92)~~	32.13 (25.81) ~~10.16 (10.03)~~
Southern Europe		4.85 (4.78)		0.74 (0.73)	8.14 (8.03)
Northern Europe	Mar-May	7.68 (6.17) ~~2.43 (2.40)~~	~~Runoff/Drainage~~	1.18 (0.95) ~~0.37 (0.37)~~	12.88 (10.35) ~~4.09 (4.04)~~
Southern Europe		~~4.85 (4.78)~~		~~0.74 (0.73)~~	~~8.14 (8.03)~~
	Spring cereals				
Step 1	---	*59.47*	---	8.00	98.40
Step 2					
Northern Europe	March-May	19.19 (15.41) ~~6.06 (5.98)~~	~~Runoff/Drainage~~	1.18 (0.95) ~~0.37 (0.37)~~	12.88 (10.35) ~~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 8.9-21: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for *Phthalamic acid* following application of SAP2101F (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	---	*50.08*	---	31.79	4.95
Step 2					
Northern Europe	Oct-Feb	2.73 (2.43) ~~0.76 (0.76)~~	~~Runoff/Drainage~~	0.38 (0.34) ~~0.49 (0.49)~~	0.27 (0.24) ~~0.08 (0.08)~~
Southern Europe		~~0.65 (0.64)~~		~~0.41 (0.41~~)	~~0.06 (0.06)~~
Northern Europe	Mar-May	1.10 (0.97) ~~0.41 (0.41)~~	~~Runoff/Drainage~~	0.15 (0.14) ~~0.26 (0.26)~~	0.11 (0.10) 0.04 (0.04)
Southern Europe		~~0.65 (0.64)~~		~~0.41 (0.41)~~	~~0.06 (0.06)~~
	Spring cereals				
Step 1	---	*50.08*	---	31.79	4.95
Step 2					
Northern Europe	March-May	1.10 (0.97) ~~0.41 (0.41)~~	~~Runoff/Drainage~~	0.15 (0.14) ~~0.26 (0.26)~~	0.11 (0.10) 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 8.9-22: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for *Phthalic acid* following application of SAP2101F (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	---	*45.28*	---	22.47	32.38
Step 2					
Northern Europe	Oct-Feb	8.64 (8.08) ~~2.26 (2.29)~~	~~Runoff/Drainage~~	1.21 (1.13) ~~1.17 (1.18)~~	0.86 (0.81) ~~1.65 (1.67)~~
Southern Europe		1.88 (1.91)		0.97 (0.99)	1.37 (1.39)
Northern Europe	Mar-May	3.46 (3.32) ~~1.11 (1.14)~~	~~Runoff/Drainage~~	0.48 (0.45) ~~0.58 (0.59)~~	0.35 (0.32) ~~0.81 (0.83)~~
Southern Europe		~~1.88 (1.91)~~		~~0.97 (0.99)~~	~~1.37 (1.39)~~
	Spring cereals				
Step 1	---	*45.28*	---	22.47	32.38
Step 2					
Northern Europe	March-May	3.46 (3.32) ~~1.11 (1.14)~~	~~Runoff/Drainage~~	0.48 (0.45) ~~0.58 (0.59)~~	0.35 (0.32) ~~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 8.9-23: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for *Benzamide* following application of SAP2101F (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>*12.84*</u>	---	12.81	0.00
Step 2					
Northern Europe	Oct-Feb	1.86 (1.55) ~~0.64 (0.51)~~	~~Runoff/Drainage~~	1.85 (1.55) ~~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	0.92 (0.72) ~~0.44 (0.31)~~	~~Runoff/Drainage~~	0.92 (0.72) ~~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	0.92 (0.72) ~~0.44 (0.31)~~	~~Runoff/Drainage~~	0.92 (0.72) ~~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; <u>*Italic and underline values will be used in aquatic risk assessment (see section 9)*</u>

Table 8.9-24: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for *2-cyanobenzoic acid* following application of SAP2101F (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>*60.70*</u>	---	60.55	0.00
Step 2					
Northern Europe	Oct-Feb	8.78 (7.35) ~~3.01 (2.40)~~	~~Runoff/Drainage~~	8.76 (7.33) ~~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	4.37 (3.43) ~~2.06 (1.45)~~	~~Runoff/Drainage~~	4.36 (3.42) ~~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	4.37 (3.43) ~~2.06 (1.45)~~	~~Runoff/Drainage~~	~~4.36 (3.42)~~ ~~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; <u>*Italic and underline values will be used in aquatic risk assessment (see section 9)*</u>

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 PECsw 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 8.9-25: Assessment summary of folpet and its metabolites following application of SAP2101F

Dose	Application number	Crop	Mitigation measure
Maximum 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
~~Minimum dose~~	~~Single~~	~~Winter and Spring cereals~~	~~None~~
	~~Multiple~~	~~Winter cereals~~	~~None~~
		~~Spring cereals~~	~~R4 scenario: 5 meters of vegetated filter strip~~

zRMS comments:

The input parameters considered by the Applicant in surface water modelling for folpet and its metabolites presented in Table 8.9-13a 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 DT_{50} values normalised with Q_{10} of 2.58 were considered although the EU agreed endpoints were normalised with Q_{10} of 2.2. In line with current FOCUS requirements the Q_{10} 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 Q_{10} of 2.2. For folpet the EU agreed value of soil DT_{50} is 4.68 days instead of the value of 1.38 days as presented in Table 8.9-13a. For metabolites phthalimide and phthalic acid the EU agreed values of soil DT_{50} are 7.88 days and 3.15 days, respectively. Since consideration of the longer DT_{50} values represents worst case, thus the respective correction were introduced in Table 8.9-13a and used in independent zRMS calculations.
- for folpet metabolite phthalimide the geometric mean Kfoc 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 DT_{50} 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 DT_{50} value was taken into account. Thus, PECsw/sed values reported in Table 8.9-14 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 DT_{50} 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 8.9-15 were struck through and shaded 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 decided on aceptability 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. 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 DT_{50} of 4.68 days were in good agreement with results obtained by the Applicnat and presented in Appendix 3.3 in Tables App 3.3-18 (Step 3) and Table App 3.3-19 (Step 4) and may be used in the aquatic risk assessment. Since the relevant PECsw and PECsed for folpet are presented in Appendix 3.3, the relevant tables with the results of surface water modelling at Step 3 (Table 8.9-16b) and Step 4 (Table 8.9-19a) were copy to the 8.9 section above.
As indicated in the commenting box in point 8.9.1 the application windows assumed by the Applicant for Step 3 and 4 simulations for winter cereals were performed for BBCH 30 instead of BBCH 32 as it is presented in the GAP table. Nevertheless this slightly earlier application dates cover surface water exposure for later BBCH stage.

As evaluation should be performed with consideration of the EU agreed endpoints, results obtained at Step 3-4 and presented in Tables 8.9-16, 8.9-16a, and 8.9-19 were not validated by the zRMS and were struck through and shaded for transparency.

The Table 8.9-15 of the assessmnet summary was amanded 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 to these obtained by the Applicant, since higher soil DT_{50} valeus were taken into account as they are EU agreed endpoints. Values reported in Tables: 8.9-20 to 8.9-24 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.

8.9.2.3 $PEC_{sw/sed}$ of SAP2101F

PEC_{sw} of the preparation is calculated with the spray drift calculator included in SWASH v5.3, based on specific density of 1140 g/L and maximum and minimum individual application rate of 1.5 L/ha and 1.0 L/ha, respectively. PEC_{sw} of the preparation via the spray drift route of contamination are presented below.

Table 8.9-26: PECsw for SAP2101F on cereals

Application rate (g/ha)	PEC_{ini} (µg/L)		
	FOCUS values	10 m	20 m
1710	10.9861	1.5793	0.8206
1140	7.3241	1.0529	0.5471

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 8.9-26 and may be used in the aquatic risk assessment.

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

Table 8.10-1 Summary of atmospheric degradation and behaviour

Compound	Prothioconazole
Direct photolysis in air	Not available
Quantum yield of direct phototransformation	Not available
Photochemical oxidative degradation in air	Prothioconazole: DT_{50}: 1.1 hours Chemical lifetime: 1.6 hours (calculated according Atkinson (AOPWIN ver. 1.87, 12 hour day, $1x510^6$ OH radicals/cm^3)) Prothioconazole-desthio (M04): DT_{50}: 14.2 hours Chemical lifetime: 20.5 hours (calculated according Atkinson (AOPWIN ver. 1.87, 12 hour day, $1x510^6$ OH radicals/cm^3))
Volatilisation	Laboratory route and rate soil studies indicated that volatilisation of prothioconazole and prothioconazole-desthio (M04) is unlikely to take place because no volatiles were detected at levels above 0.1% AR.

The vapour pressure at 20°C of the active substance Prothioconazole is < $4x10^{-7}$ Pa. Hence the active substance prothioconazole is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance prothioconazole due to volatilization with subsequent deposition should not be considered.

The vapour pressure of folpet is 2.1 x 10^{-5} Pa (at 25 °C) and Henry's law constant is 8 x 10^{-3} $Pa.m^3.mol^{-1}$ 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 prothioconazole and folpet in the air is in line with EU agreed data reported in in EFSA Scientific Report (2007) 106, 1-98 and EFSA Scientific Report (2009) 297, 1-80, respectively.

Taking into account the low vapour pressure (<10^{-5} Pa) and DT_{50} in air <2 days, prothioconazole and its metabolite are not expected to be subject to volatilisation and the long- or short-range transport.

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 prothioconazole and folpet following application of SAP2101F 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.	2021a	Predicted Environmental Concentrations of Prothioconazole 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 SAP2101F on Cereals ASC123-2021 non GLP Unpublished	N	Ascenza Agro SA
KCP 9.2.4/02	Fernandes, V.	2021b	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 SAP2101F on Cereals ASC124-2021 non GLP Unpublished	N	Ascenza Agro SA
KCP 9.2.5/01	Fernandes, V.	2021c	Predicted Environmental Concentrations of Prothioconazole and its metabolites in Surface Water and Sediment (PEC_{sw} and PEC_{sed}) based on Tiered FOCUS Approach for risk assessment of SAP2101F on Cereals ASC111-2021 non GLP Unpublished	N	Ascenza Agro SA
KCP 9.2.5/02	Fernandes, V.	2021d	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 SAP2101F on Cereals ASC112-2021 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 each 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)

Prothioconazole and its metabolites

Table 01-1: PEC_{soil} for prothioconazole after application of SAP2101F (minimum dose)

PEC_{soil} (mg/kg)		Cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.032	-	**0.033**	-
Short term	24h	0.025	0.028	0.026	0.029
	2d	0.020	0.025	0.020	0.026
	4d	0.012	0.020	0.012	0.021
Long term	7d	0.006	0.015	0.006	0.016
	14d	0.001	0.009	0.001	0.009
	21d	0.000	0.006	0.000	0.006
	28d	0.000	0.005	0.000	0.005
	50d	0.000	0.003	0.000	0.003
	100d	0.000	0.001	0.000	0.001

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

Table App3.1-2: PEC_{soil} for prothioconazole-S-methyl (M01) after application of SAP2101F (minimum dose)

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

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

Table App3.1-3: PEC$_{soil}$ for prothioconazole-desthio (M04) after application of SAP2101F (minimum dose)

PEC$_{soil}$ (mg/kg)		Cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.017	-	**0.032**	-
Short term	24h	0.017	0.017	0.031	0.031
	2d	0.017	0.017	0.031	0.031
	4d	0.016	0.017	0.030	0.031
Long term	7d	0.016	0.016	0.030	0.031
	14d	0.015	0.016	0.028	0.030
	21d	0.014	0.015	0.026	0.029
	28d	0.013	0.015	0.024	0.028
	50d	0.010	0.013	0.020	0.025
	100d	0.006	0.011	0.012	0.020

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

Folpet and its metabolites

Table App3.1-4: PEC$_{soil}$ for folpet after application of SAP2101F (minimum dose)

PEC$_{soil}$ (mg/kg)		Cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.080	-	**0.132**	-
Short term	24h	0.078	0.079	0.128	0.130
	2d	0.075	0.078	0.124	0.128
	4d	0.071	0.075	0.116	0.124
Long term	7d	0.064	0.072	0.106	0.118
	14d	0.052	0.065	0.085	0.107
	21d	0.042	0.059	0.069	0.097
	28d	0.033	0.053	0.055	0.088
	50d	0.017	0.041	0.028	0.067
	100d	0.004	0.025	0.006	0.040

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

Table App3.1-5: PEC$_{soil}$ for phthalimide after application of SAP2101F (minimum dose)

PEC$_{soil}$ (mg/kg)		Cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.025	-	**0.045**	-
Short term	24h	0.025	0.025	0.045	0.045
	2d	0.025	0.025	0.044	0.045
	4d	0.024	0.025	0.042	0.044
Long term	7d	0.022	0.024	0.040	0.043
	14d	0.020	0.023	0.035	0.040
	21d	0.018	0.021	0.031	0.038
	28d	0.015	0.020	0.027	0.036
	50d	0.010	0.017	0.019	0.030
	100d	0.004	0.012	0.008	0.021

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

Table App3.1-6: PEC$_{soil}$ for phthalamic acid after application of SAP2101F (minimum dose)

PEC$_{soil}$ (mg/kg)		Cereals			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.007	-	**0.007**	-
Short term	24h	0.001	0.004	0.001	0.004
	2d	0.000	0.002	0.000	0.002
	4d	0.000	0.001	0.000	0.001
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

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

Table App30-7: PEC$_{soil}$ for phthalic acid after application of SAP2101F (minimum dose)

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

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

App3.2 Predicted Environmental Concentrations in groundwater (PEC$_{gw}$) (KCP 9.2.4)

Prothioconazole and its metabolites

Table App3.2-1: PEC$_{gw}$ for prothioconazole and metabolites on cereals following application of SAP2101F (FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)					
		FOCUS PELMO v.6.6.4			FOCUS PEARL v.5.5.5		
		Parent	M01	M04	Parent	M01	M04
Winter Cereals 2x120 g as/ha	Châteaudun	< 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
	Jokioinen	< 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
	Okehampton	< 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
	Porto	< 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
	Thiva	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

Spring Cereals 2x120 g as/ha	Châteaudun	< 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
	Jokioinen	< 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
	Okehampton	< 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

Table App3.2-2: PECgw for prothioconazole and its metabolites on cereals following application of SAP2101F (FOCUS MACRO 5.5.4)

	PEC$_{GW}$ at 1 m soil depth [µg/L]		
	FOCUS MACRO 5.5.4		
	Parent	M01	M04
Winter Cereals – 2 x 120 g as/ha, Châteaudun scenario	0.000	0.000	0.000
Spring Cereals – 2 x 120 g as/ha, Châteaudun scenario	0.000	0.000	0.000

Folpet and its metabolites

Table App3.2-3: PEC$_{gw}$ for folpet and metabolites on cereals following application of SAP2101F (FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)							
		FOCUS PELMO v.6.6.4				FOCUS PEARL v.5.5.5			
		Parent	Phthalim ide	Phtha-lamic acid	Phthalic acid	Parent	Phthalim ide	Phthalamic acid	Phthalic acid
Winter Cereals 2x300 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 2x300 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

Table App3.2-4: PECgw for folpet and its metabolites on cereals following application of SAP2101F (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 300 g as/ha, Châteaudun scenario	0.000	0.000	0.000	0.000
Spring Cereals – 2 x 300 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)

Prothioconazole and its metabolites

FOCUS Step 1-2

Table App3.3-1: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for P*rothioconazole* following application of SAP2101F (minimum dose) – set 1

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	---	***13.03***	---	2.61	210.54
Step 2					
Northern Europe	Oct-Feb	0.99 (*1.10*)	Runoff/Drainage	0.32 (0.34)	10.84 (10.98)
Southern Europe		0.99 (*1.10*)		0.29 (0.31)	9.17 (9.31)
Northern Europe	Mar-May	0.99 (*1.10*)	Runoff/Drainage	0.23 (0.25)	5.82 (5.97)
Southern Europe		0.99 (*1.10*)		0.29 (0.31)	9.17 (9.31)
	Spring cereals				
Step 1	---	***13.03***	---	2.61	210.54
Step 2					
Northern Europe	March-May	0.99 (*1.10*)	Runoff/Drainage	0.23 (0.25)	5.82 (5.97)
Southern Europe		0.99 (*1.10*)		0.29 (0.31)	9.17 (9.31)

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 App3.3-2: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for P*rothioconazole* following application of SAP2101F (minimum dose) – set 2

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	---	***13.03***	---	2.61	210.54
Step 2					
Northern Europe	Oct-Feb	0.98 (1.10)	Runoff/Drainage	0.47 (0.50)	9.19 (9.29)
Southern Europe		0.98 (1.10)		0.43 (0.47)	7.52 (7.62)
Northern Europe	Mar-May	0.98 (1.10)	Runoff/Drainage	0.35 (0.39)	4.18 (4.27)
Southern Europe		0.98 (1.10)		0.43 (0.47)	7.52 (7.62)
	Spring cereals				
Step 1	---	***13.03***	---	2.61	210.54
Step 2					
Northern Europe	March-May	0.98 (1.10)	Runoff/Drainage	0.35 (0.39)	4.18 (4.27)
Southern Europe		0.98 (1.10)		0.43 (0.47)	7.52 (7.62)

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)*

Metabolites of Prothioconazole

FOCUS Step 1-2

Table App3.3-3: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for *Prothioconazole-S-methyl (M01)* following application of SAP2101F (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>19.23</u>***	---	17.92	450.97
Step 2					
Northern Europe	Oct-Feb	*<u>1.49</u>* (1.03)	Runoff/Drainage	1.37 (0.96)	34.44 (24.22)
Southern Europe	Oct-Feb	1.29 (0.88)	Runoff/Drainage	1.17 (0.62)	29.35 (20.40)
Northern Europe	Mar-May	1.02 (0.88)	Runoff/Drainage	0.70 (0.47)	19.15 (12.75)
Southern Europe	Mar-May	*<u>1.29</u>* (0.88)	Runoff/Drainage	1.17 (0.62)	29.35 (20.40)
	Spring cereals				
Step 1	---	***<u>19.23</u>***	---	17.92	450.97
Step 2					
Northern Europe	March-May	1.02 (0.88)	Runoff/Drainage	0.70 (0.47)	19.15 (12.75)
Southern Europe	March-May	*<u>1.29</u>* (0.88)	Runoff/Drainage	1.17 (0.62)	29.35 (20.40)

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

Table App3.3-4: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for *Prothioconazole-desthio (M04)* following application of SAP2101F (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>44.32</u>***	---	43.77	251.25
Step 2					
Northern Europe	Oct-Feb	***<u>7.04 (4.42)</u>***	Runoff/Drainage	6.94 (4.36)	39.82 (25.01)
Southern Europe	Oct-Feb	5.76 (3.61)	Runoff/Drainage	5.66 (3.55)	32.49 (20.37)
Northern Europe	Mar-May	3.21 (1.99)	Runoff/Drainage	3.11 (1.93)	17.83 (11.09)
Southern Europe	Mar-May	***<u>5.76</u>*** (3.61)	Runoff/Drainage	5.66 (3.55)	32.49 (20.37)
	Spring cereals				
Step 1	---	***<u>44.32</u>***	---	43.77	251.25
Step 2					
Northern Europe	March-May	***<u>3.21</u>*** (1.99)	Runoff/Drainage	3.11 (1.93)	17.83 (11.09)
Southern Europe	March-May	***<u>5.76</u>*** (3.61)	Runoff/Drainage	5.66 (3.55)	32.49 (20.37)

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

Table App3.3-5: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for *1,2,4-triazole (M13)* following application of SAP2101F (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	---	***2.25***	---	2.24	1.86
Step 2					
Northern Europe	Oct-Feb	*0.10* (0.07)	Runoff/Drainage	0.10 (0.07)	0.08 (0.06)
Southern Europe		0.09 (0.07)		0.09 (0.06)	0.07 (0.05)
Northern Europe	Mar-May	0.07 (0.05)	Runoff/Drainage	0.07 (0.05)	0.06 (0.04)
Southern Europe		*0.09* (0.07)		0.09 (0.06)	0.07 (0.05)
	Spring cereals				
Step 1	---	***2.25***	---	2.24	1.86
Step 2					
Northern Europe	March-May	0.07 (0.05)	Runoff/Drainage	0.07 (0.05)	0.06 (0.04)
Southern Europe		*0.09* (0.07)		0.09 (0.06)	0.07 (0.05)

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 P*rothioconazole-thiazocine (M12)* following application of SAP2101F (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)*
	Cereals				
Step 1	---	***1.64***	---	0.38	-
Step 2					
Southern Europe	Mar-May	0.14 (*0.16*)	Runoff/Drainage	0.04 (0.05)	-

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 PECsw values greater than RAC for the prothioconazole-desthio metabolite, 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).

FOCUS Step 3

Table App3.3-7: FOCUS Step 3 PEC_{sw} and PEC_{sed} for *prothioconazole-desthio* (M04) following single and multiple applications of SAP2101F to winter and spring cereals (minimum dose)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)		Max PEC_{sed} (µg/kg)	
		Prothioconazole	Prothioconazole-desthio (M04)	Prothioconazole	Prothioconazole-desthio (M04)
Winter Cereals - Multiple applications					
D1 set1	ditch	0.6711	0.09479	0.7798	0.3761
D1 set1	stream	0.5662	0.03003	0.09872	0.03064
D2 set1	ditch	0.6729	0.1152	0.6501	0.3529

D2 set1	stream	0.5876	0.1134	0.4882	0.3369
D3 set1	ditch	0.6644	0.04034	0.3541	0.04459
D4 set1	pond	0.02169	0.007394	0.03798	0.1028
D4 set1	stream	0.5019	0.01937	0.01932	0.003704
D5 set1	pond	0.02226	0.008947	0.03329	0.1225
D5 set1	stream	0.579	0.02752	0.04307	0.002592
D6 set1	ditch	0.6673	0.05258	0.4515	0.07892
R1 set1	pond	0.02192	0.06485	0.0296	0.6551
R1 set1	stream	0.4326	**0.5627**	0.1897	0.6206
R3 set1	stream	0.6113	**0.5212**	0.5251	0.6585
R4 set1	stream	0.4345	**0.8766**	0.1598	0.6325
Winter Cereals - Single application					
D1 set1	ditch	0.762	0.02416	0.4826	0.04244
D1 set1	stream	0.5922	0.02883	0.0241	0.006897
D2 set1	ditch	0.7668	0.0496	0.622	0.06585
D2 set1	stream	0.6513	0.03385	0.09835	0.009644
D3 set1	ditch	0.7593	0.02417	0.3413	0.02073
D4 set1	pond	0.0262	0.004783	0.03257	0.06156
D4 set1	stream	0.5608	0.02164	0.01614	0.00143
D5 set1	pond	0.02621	0.005534	0.026	0.0758
D5 set1	stream	0.6062	0.02782	0.01715	0.000845
D6 set1	ditch	0.7506	0.01308	0.1895	0.005541
R1 set1	pond	0.02621	0.0225	0.02639	0.257
R1 set1	stream	0.5003	0.1953	0.06367	0.225
R3 set1	stream	0.7027	0.2447	0.1262	0.3348
R4 set1	stream	0.5024	**0.3597**	0.07136	0.2644
Spring Cereals - Multiple applications					
D1 set1	ditch	0.6798	0.2296	0.6593	1.338
D1 set1	stream	0.5815	0.05923	0.2803	0.08426
D3 set1	ditch	0.6647	0.04191	0.3568	0.05553
D4 set1	pond	0.02151	0.009174	0.02296	0.1109
D4 set1	stream	0.5548	0.02466	0.06419	0.005044
D5 set1	pond	0.02148	0.008809	0.0247	0.1225
D5 set1	stream	0.5733	0.02746	0.03762	0.002397
R4 set1	stream	0.5506	**0.6279**	0.6733	0.7727
Spring Cereals - Single application					
D1 set1	ditch	0.7686	0.1356	0.5953	0.7808
D1 set1	stream	0.6723	0.0548	0.2826	0.05477
D3 set1	ditch	0.7601	0.04668	0.3215	0.0424
D4 set1	pond	0.02622	0.006009	0.02233	0.06899
D4 set1	stream	0.6214	0.02532	0.04079	0.001996

D5 set1	pond	0.02621	0.00558	0.02609	0.07547
D5 set1	stream	0.6382	0.02929	0.02637	0.001335
R4 set1	stream	0.5024	0.3274	0.4199	0.5379

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

Table 0: FOCUS Step 4 PEC_{sw} for *prothioconazole-desthio* (M04) following application of SAP2101F (minimum dose)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)		Max PEC_{sed} (µg/kg)	
		Prothioconazole	**Prothioconazole-desthio (M04)**	**Prothioconazole**	**Prothioconazole-desthio (M04)**
Winter Cereals - Multiple applications – 10 meters of vegetated filter strip					
R1 set1	stream	-	0.2555	-	0.2064
R3 set1	stream	-	0.2378	-	0.2052
Winter Cereals - Multiple applications – 15 meters of vegetated filter strip					
R4 set1	stream	-	0.3059	-	0.1980
Winter Cereals - Multiple applications – 20 meters of vegetated filter strip					
R4 set1	stream	-	0.2089	-	0.1352
Winter Cereals - Single application – 5 meters of vegetated filter strip					
R4 set1	stream	-	0.2347	-	0.1722
Winter Cereals - Single application – 10 meters of vegetated filter strip					
R4 set1	stream	-	0.1636	-	0.1060
Spring Cereals - Multiple applications – 10 meters of vegetated filter strip					
R4 set1	stream	-	0.2827	-	0.3175

Bold values are above RAC

Folpet and its metabolites

Folpet

FOCUS Step 1-2

Table App3.3-9: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for *Folpet* following application of SAP2101F – 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	---	***73.92***	---	5.29	216.32
Step 2					
Northern Europe	Oct-Feb	3.82 (3.82)	Runoff/Drainage	0.27 (0.27)	11.70 (11.70)
Southern Europe		3.06 (3.05)		0.22 (0.22)	9.38 (9.38)
Northern Europe	Mar-May	2.44 (2.76)	Runoff/Drainage	0.39 (0.42)	4.73 (4.74)
Southern Europe		3.06 (3.05)		0.22 (0.22)	9.38 (9.38)
	Spring cereals				
Step 1	---	***73.92***	---	5.29	216.32
Step 2					
Northern Europe	March-May	2.44 (2.76)	Runoff/Drainage	0.39 (0.42)	4.73 (4.74)
Southern Europe		3.06 (3.05)		0.22 (0.22)	9.38 (9.38)

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 0-10: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for *Folpet* following application of SAP2101F – 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	---	***73.92***	---	5.29	216.32
Step 2					
Northern Europe	Oct-Feb	**4.91** (***4.99***)	Runoff/Drainage	2.37 (2.40)	11.62 (11.61)
Southern Europe		**4.14** (**4.23**)		1.98 (2.01)	9.29 (9.29)
Northern Europe	Mar-May	2.62 (2.76)	Runoff/Drainage	1.20 (2.03)	4.65 (4.64)
Southern Europe		**4.14** (***4.23***)		1.98 (2.01)	9.29 (9.29)
	Spring cereals				
Step 1	---	***73.92***	---	5.29	216.32
Step 2					
Northern Europe	March-May	2.62 (2.76)	Runoff/Drainage	1.20 (2.03)	4.65 (4.64)
Southern Europe		**4.14** (***4.23***)		1.98 (2.01)	9.29 (9.29)

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 App3.3-11: FOCUS Step 3 PEC_{sw} and PEC_{sed} for *folpet* following single and multiple applications of SAP2101F 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)
Winter Cereals - Multiple applications					
D1 set1	ditch	1.678	drift	0.04669	0.3039
D1 set1	stream	1.417	drift	0.01378	0.1488
D2 set1	ditch	1.682	drift	0.04221	0.2533
D2 set1	stream	1.471	drift	0.02397	0.1784
D3 set1	ditch	1.662	drift	0.04168	0.2006
D4 set2	pond	0.07987	drift	0.06362	0.01866
D4 set1	stream	1.256	drift	0.002687	0.04026
D5 set2	pond	0.09247	drift	0.07355	0.01702
D5 set1	stream	1.449	drift	0.008096	0.07958
D6 set1	ditch	1.67	drift	0.04047	0.1982
R1 set2	pond	0.1516	runoff	0.121	0.02344
R1 set2	stream	2.224	runoff	0.09684	0.2488
R3 set2	stream	2.977	runoff	0.1605	0.5666
R4 set2	stream	1.693	runoff	0.08347	0.2903
Winter Cereals - Single application					
D1 set1	ditch	1.907	drift	0.05016	0.3045
D1 set1	stream	1.482	drift	0.003664	0.05218
D2 set1	ditch	1.919	drift	0.04817	0.2899
D2 set1	stream	1.63	drift	0.01439	0.1532
D3 set1	ditch	1.9	drift	0.03027	0.2295

D4 set1	pond	0.06558	drift	0.002085	0.01146
D4 set1	stream	1.404	drift	0.002453	0.03524
D5 set1	pond	0.06559	drift	0.001299	0.008805
D5 set1	stream	1.517	drift	0.002566	0.03679
D6 set1	ditch	1.879	drift	0.02019	0.1885
R1 set1	pond	0.06559	drift	0.001375	0.00897
R1 set1	stream	1.252	drift	0.01864	0.1034
R3 set1	stream	1.759	drift	0.01622	0.1717
R4 set1	stream	1.258	drift	0.009423	0.1086
Spring Cereals - Multiple applications					
D1 set2	ditch	2.244	drift	1.248	0.2342
D1 set1	stream	1.455	drift	0.03086	0.1787
D3 set1	ditch	1.663	drift	0.03056	0.1567
D4 set2	pond	0.0882	drift	0.06812	0.01117
D4 set1	stream	1.389	drift	0.01226	0.09427
D5 set2	pond	0.08214	drift	0.0639	0.01079
D5 set1	stream	1.435	drift	0.004776	0.06666
R4 set2	stream	**5.585**	runoff	0.4547	0.6935
Spring Cereals - Single application					
D1 set1	ditch	1.924	drift	0.02674	0.2078
D1 set1	stream	1.683	drift	0.02152	0.1817
D3 set1	ditch	1.902	drift	0.01747	0.159
D4 set1	pond	0.06562	drift	0.001065	0.00786
D4 set1	stream	1.555	drift	0.005787	0.0771
D5 set1	pond	0.06561	drift	0.0013	0.008811
D5 set1	stream	1.597	drift	0.003917	0.05549
R4 set2	stream	3.109	runoff	0.2073	0.3993

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

FOCUS Step 4

Table App3.3-12: FOCUS Step 4 PEC_{sw} and PEC_{sed} for *folpet* following single and multiple applications of SAP2101F 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)
Spring Cereals - Multiple applications –5 meters of vegetated filter strip					
R4 set2	stream	3.630	runoff	0.2931	0.4489
Spring Cereals - Multiple applications –10 meters of vegetated filter strip					
R4 set2	stream	2.525	runoff	0.2029	0.3073

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

Metabolites of Folpet

Table App3.3-13: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for *Phthalimide* following application of SAP2101F (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>39.65</u>*	---	5.33	65.60
Step 2					
Northern Europe	Oct-Feb	4.04 (3.98)	Runoff/Drainage	0.62 (0.61)	6.77 (6.68)
Southern Europe		3.23 (3.19)		0.50 (0.49)	5.42 (5.35)
Northern Europe	Mar-May	1.62 (1.60)	Runoff/Drainage	0.25 (0.25)	2.73 (2.69)
Southern Europe		3.23 (3.19)		0.50 (0.49)	5.42 (5.35)
	Spring cereals				
Step 1	---	*<u>39.65</u>*	---	5.33	65.60
Step 2					
Northern Europe	March-May	1.62 (1.60)	Runoff/Drainage	0.25 (0.25)	2.73 (2.69)
Southern Europe		3.23 (3.19)		0.50 (0.49)	5.42 (5.35)

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

Table App3.3-14: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for *Phthalamic acid* following application of SAP2101F (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>33.39</u>*	---	21.20	3.30
Step 2					
Northern Europe	Oct-Feb	0.51 (0.51)	Runoff/Drainage	0.32 (0.32)	0.05 (0.05)
Southern Europe		0.43 (0.43)		0.27 (0.27)	0.04 (0.04)
Northern Europe	Mar-May	0.27 (0.27)	Runoff/Drainage	0.17 (0.17)	0.03 (0.03)
Southern Europe		0.43 (0.43)		0.27 (0.27)	0.04 (0.04)
	Spring cereals				
Step 1	---	*<u>33.39</u>*	---	21.20	3.30
Step 2					
Northern Europe	March-May	0.27 (0.27)	Runoff/Drainage	0.17 (0.17)	0.03 (0.03)
Southern Europe		0.43 (0.43)		0.27 (0.27)	0.04 (0.04)

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

Table App3.3-15: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for *Phthalic acid* following application of SAP2101F (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>30.18</u>*	---	14.98	21.59
Step 2					

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Northern Europe	Oct-Feb	1.51 (1.53)	Runoff/Drainage	0.78 (0.79)	1.10 (1.11)
Southern Europe		1.25 (1.27)		0.65 (0.66)	0.91 (0.92)
Northern Europe	Mar-May	0.74 (0.76)	Runoff/Drainage	0.38 (0.39)	0.54 (0.55)
Southern Europe		1.25 (1.27)		0.65 (0.66)	0.91 (0.92)
	Spring cereals				
Step 1	---	*30.18*	---	14.98	21.59
Step 2					
Northern Europe	March-May	0.74 (0.76)	Runoff/Drainage	0.38 (0.39)	0.54 (0.55)
Southern Europe		1.25 (1.27)		0.65 (0.66)	0.91 (0.92)

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 App3.3-16: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for *Benzamide* following application of SAP2101F (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	---	*8.56*	---	8.54	0.00
Step 2					
Northern Europe	Oct-Feb	0.43 (0.34)	Runoff/Drainage	0.42 (0.34)	0.00 (0.00)
Southern Europe		0.38 (0.29)		0.38 (0.29)	0.00 (0.00)
Northern Europe	Mar-May	0.29 (0.20)	Runoff/Drainage	0.29 (0.20)	0.00 (0.00)
Southern Europe		0.38 (0.29)		0.38 (0.29)	0.00 (0.00)
	Spring cereals				
Step 1	---	*8.56*	---	8.54	0.00
Step 2					
Northern Europe	March-May	0.29 (0.20)	Runoff/Drainage	0.29 (0.20)	0.00 (0.00)
Southern Europe		0.38 (0.29)		0.38 (0.29)	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 App3.3-17: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for *2-cyanobenzoic acid* following application of SAP2101F (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	---	*40.47*	---	40.37	0.00
Step 2					
Northern Europe	Oct-Feb	2.01 (1.60)	Runoff/Drainage	2.01 (1.59)	0.00 (0.00)
Southern Europe		1.80 (1.39)		1.79 (1.38)	0.00 (0.00)
Northern Europe	Mar-May	1.38 (0.96)	Runoff/Drainage	1.37 (0.96)	0.00 (0.00)
Southern Europe		1.80 (1.39)		1.79 (1.38)	0.00 (0.00)
	Spring cereals				
Step 1	---	*40.47*	---	40.37	0.00

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	7 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 2					
Northern Europe	March-May	1.38 (0.96)	Runoff/Drainage	1.37 (0.96)	0.00 (0.00)
Southern Europe		1.80 (1.39)		1.79 (1.38)	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.

Dose: 2 x 450g a.s./ha

Table App3.3-18: FOCUS Step 3 PEC_{sw} and PEC_{sed} for *folpet* following single and multiple applications of SAP2101F ~~SAP50SCF~~ to winter and spring cereals - 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)
Winter Cereals - Multiple applications					
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
Winter Cereals - Single application					
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
Spring Cereals - Multiple applications					
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
Spring Cereals - Single application					
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; *twa-time as required by ecotox

Table App3.3-19: FOCUS Step 4 PEC_{sw} and PEC_{sed} for *folpet* following single and multiple applications of SAP2101F ~~SAP50SCF~~ to winter and spring cereals

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 –10 meters of vegetated filter strip					
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
Spring Cereals - Multiple applications –10 meters of vegetated filter strip					
R4 set2	stream	**4.462**	runoff	0.426	0.206
~~*Spring Cereals - Multiple applications –15 meters of vegetated filter strip*~~					
~~R4 set2~~	~~stream~~	~~3.420~~	~~runoff~~	~~0.326~~	~~0.158~~
Spring Cereals - Multiple applications –20 meters of vegetated filter strip					
R4 set2	stream	2.332	runoff	0.223	0.108
Spring Cereals - Single application –10 meters of vegetated filter strip					
R4 set2	stream	2.717	runoff	0.223	0.126

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

Appendix 4 Additional information provided by the applicant concerning PECsw (due to Koc are between 100 and 2000 ml/g)

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

Prothioconazole and its metabolites

Due to the K_{OC} values for both prothioconazole and prothioconazole-desthio are 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 prothioconazole. This approach wasn't taken into account for metabolite prothioconazole-desthio since all simulations were performed considering the worst-case value in all compartments, 1000 days. Otherwise, 4 sets should be simulated.

Table App4.1-1: Sets description

	Compound	DT50, water (d)	DT50, sed (d)
Set 1	Prothioconazole	1.0	1000
	Prothioconazole-desthio (M04)	1000	1000
Set 2	Prothioconazole	1000	1.0
	Prothioconazole-desthio (M04)	1000	1000

Table App4.1-2: Set 1 FOCUS Step 3 PEC_{sw} and PEC_{sed} for *prothioconazole-desthio* (M04) following single and multiple applications of SAP2101F to winter and spring cereals (maximum dose)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)		Max PEC_{sed} (µg/kg)	
		Prothioconazole	Prothioconazole-desthio (M04)	Prothioconazole	Prothioconazole-desthio (M04)
Winter Cereals - Multiple applications					
D1	ditch	1.007	0.1446	1.17	0.5667
D1	stream	0.8493	0.04557	0.1481	0.0602
D2	ditch	1.009	0.1753	0.9752	0.5493
D2	stream	0.8814	0.1719	0.7323	0.5061
D3	ditch	0.9966	0.06053	0.5311	0.06566
D4	pond	0.03253	0.01118	0.05697	0.1514
D4	stream	0.7529	0.02906	0.02898	0.006643
D5	pond	0.03339	0.01352	0.04994	0.1798
D5	stream	0.8686	0.04129	0.06461	0.00387
D6	ditch	1.001	0.07893	0.6772	0.1161
R1	pond	0.03288	0.1028	0.04441	0.9955
R1	stream	0.6489	0.9081	0.2846	0.9106
R3	stream	0.917	0.8642	0.7877	0.9814
R4	stream	0.6527	1.395	0.2398	0.923
Winter Cereals - Single application					
D1	ditch	1.143	0.03664	0.7239	0.06951

D1	stream	0.8882	0.04348	0.03616	0.01495
D2	ditch	1.15	0.07467	0.9329	0.1048
D2	stream	0.9769	0.05085	0.1475	0.02315
D3	ditch	1.139	0.03627	0.5119	0.03075
D4	pond	0.0393	0.007217	0.04885	0.09008
D4	stream	0.8413	0.03247	0.02421	0.002559
D5	pond	0.03931	0.008345	0.039	0.1112
D5	stream	0.9092	0.04174	0.02572	0.00127
D6	ditch	1.126	0.01962	0.2842	0.008267
R1	pond	0.03931	0.03565	0.03959	0.3898
R1	stream	0.7504	0.3153	0.0955	0.3282
R3	stream	1.054	0.3948	0.1893	0.4976
R4	stream	0.7537	0.5744	0.107	0.385
Spring Cereals - Multiple applications					
D1	ditch	1.02	0.3484	0.9889	1.966
D1	stream	0.8723	0.08887	0.4204	0.2326
D3	ditch	0.9971	0.06289	0.5352	0.08147
D4	pond	0.03227	0.01384	0.03444	0.1636
D4	stream	0.8322	0.03699	0.09628	0.008935
D5	pond	0.03222	0.01331	0.03705	0.1797
D5	stream	0.86	0.0412	0.05643	0.003569
R4	stream	0.8259	0.9841	1.01	1.155
Spring Cereals - Single application					
D1	ditch	1.153	0.2055	0.893	1.148
D1	stream	1.008	0.08223	0.4239	0.08375
D3	ditch	1.14	0.07005	0.4823	0.06276
D4	pond	0.03932	0.009042	0.03349	0.1011
D4	stream	0.9321	0.038	0.06119	0.003557
D5	pond	0.03932	0.008413	0.03913	0.1108
D5	stream	0.9573	0.04395	0.03956	0.002004
R4	stream	0.7537	0.5207	0.6298	0.8016

Table App4.1-3: Set 1 FOCUS Step 3 PEC_{sw} and PEC_{sed} for *prothioconazole-desthio* (M04) following single and multiple applications of SAP2101F to winter and spring cereals (minimum dose)

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)		Max PEC_{sed} (µg/kg)	
		Prothioconazole	Prothioconazole-desthio (M04)	Prothioconazole	Prothioconazole-desthio (M04)
Winter Cereals - Multiple applications					
D1	ditch	0.6711	0.09479	0.7798	0.3761
D1	stream	0.5662	0.03003	0.09872	0.03064
D2	ditch	0.6729	0.1152	0.6501	0.3529

D2	stream	0.5876	0.1134	0.4882	0.3369
D3	ditch	0.6644	0.04034	0.3541	0.04459
D4	pond	0.02169	0.007394	0.03798	0.1028
D4	stream	0.5019	0.01937	0.01932	0.003704
D5	pond	0.02226	0.008947	0.03329	0.1225
D5	stream	0.579	0.02752	0.04307	0.002592
D6	ditch	0.6673	0.05258	0.4515	0.07892
R1	pond	0.02192	0.06485	0.0296	0.6551
R1	stream	0.4326	0.5627	0.1897	0.6206
R3	stream	0.6113	0.5212	0.5251	0.6585
R4	stream	0.4345	0.8766	0.1598	0.6325
Winter Cereals - Single application					
D1	ditch	0.762	0.02416	0.4826	0.04244
D1	stream	0.5922	0.02883	0.0241	0.006897
D2	ditch	0.7668	0.0496	0.622	0.06585
D2	stream	0.6513	0.03385	0.09835	0.009644
D3	ditch	0.7593	0.02417	0.3413	0.02073
D4	pond	0.0262	0.004783	0.03257	0.06156
D4	stream	0.5608	0.02164	0.01614	0.00143
D5	pond	0.02621	0.005534	0.026	0.0758
D5	stream	0.6062	0.02782	0.01715	0.000845
D6	ditch	0.7506	0.01308	0.1895	0.005541
R1	pond	0.02621	0.0225	0.02639	0.257
R1	stream	0.5003	0.1953	0.06367	0.225
R3	stream	0.7027	0.2447	0.1262	0.3348
R4	stream	0.5024	0.3597	0.07136	0.2644
Spring Cereals - Multiple applications					
D1	ditch	0.6798	0.2296	0.6593	1.338
D1	stream	0.5815	0.05923	0.2803	0.08426
D3	ditch	0.6647	0.04191	0.3568	0.05553
D4	pond	0.02151	0.009174	0.02296	0.1109
D4	stream	0.5548	0.02466	0.06419	0.005044
D5	pond	0.02148	0.008809	0.0247	0.1225
D5	stream	0.5733	0.02746	0.03762	0.002397
R4	stream	0.5506	0.6279	0.6733	0.7727
Spring Cereals - Single application					
D1	ditch	0.7686	0.1356	0.5953	0.7808
D1	stream	0.6723	0.0548	0.2826	0.05477
D3	ditch	0.7601	0.04668	0.3215	0.0424
D4	pond	0.02622	0.006009	0.02233	0.06899
D4	stream	0.6214	0.02532	0.04079	0.001996

D5	pond	0.02621	0.00558	0.02609	0.07547
D5	stream	0.6382	0.02929	0.02637	0.001335
R4	stream	0.5024	0.3274	0.4199	0.5379

Table App4.1-4: **Set 2 FOCUS Step 3 PEC_{sw} and PEC_{sed} for *prothioconazole-desthio* (M04) following single and multiple applications of SAP2101F to winter and spring cereals (maximum dose)**

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)		Max PEC_{sed} (µg/kg)	
		Prothioconazole	Prothioconazole-desthio (M04)	Prothioconazole	Prothioconazole-desthio (M04)
Winter Cereals - Multiple applications					
D1	ditch	1.006	0.01068	1.142	0.1045
D1	stream	0.8493	0.006773	0.1419	0.05953
D2	ditch	1.008	0.08811	0.9418	0.2001
D2	stream	0.8814	0.05542	0.8146	0.09219
D3	ditch	0.9962	0.000073	0.4339	0.000103
D4	pond	0.04925	0.001566	0.07876	0.01476
D4	stream	0.7529	0.00745	0.02648	0.006393
D5	pond	0.05619	0.000163	0.07489	0.004694
D5	stream	0.8686	0.000787	0.06017	0.000196
D6	ditch	1.001	0.000294	0.6296	0.000205
R1	pond	0.05542	0.091	0.06818	0.87
R1	stream	0.6489	0.8673	0.2118	0.8969
R3	stream	0.917	0.7154	0.631	0.8981
R4	stream	0.6518	1.326	0.1939	0.9123
Winter Cereals - Single application					
D1	ditch	1.143	0.001231	0.7124	0.02239
D1	stream	0.8882	0.00086	0.03584	0.01409
D2	ditch	1.15	0.02232	0.9477	0.04709
D2	stream	0.9769	0.01401	0.1448	0.02231
D3	ditch	1.139	0.00004	0.4965	0.000039
D4	pond	0.0393	0.000585	0.06097	0.006132
D4	stream	0.8413	0.002925	0.02408	0.002428
D5	pond	0.03931	0.000086	0.04943	0.002721
D5	stream	0.9092	0.000232	0.0255	0.000049
D6	ditch	1.126	0.000095	0.2739	0.000025
R1	pond	0.03931	0.03002	0.04693	0.318
R1	stream	0.7504	0.3101	0.09369	0.3246
R3	stream	1.054	0.381	0.1845	0.4847
R4	stream	0.7537	0.571	0.1049	0.3835
Spring Cereals - Multiple applications					

D1	ditch	1.411	0.02912	1.033	0.3747
D1	stream	0.8721	0.0183	0.3548	0.2247
D3	ditch	0.9967	0.000076	0.4126	0.000142
D4	pond	0.05395	0.001992	0.05222	0.01866
D4	stream	0.8322	0.009338	0.08523	0.007973
D5	pond	0.05078	0.000173	0.05056	0.005188
D5	stream	0.86	0.000836	0.05092	0.000211
R4	stream	0.8327	0.8127	0.4621	0.9813
Spring Cereals - Single application					
D1	ditch	1.153	0.00429	1.023	0.05561
D1	stream	1.008	0.002754	0.4103	0.03524
D3	ditch	1.14	0.000085	0.4642	0.000092
D4	pond	0.03932	0.000789	0.03708	0.008311
D4	stream	0.9321	0.004028	0.06015	0.003163
D5	pond	0.03932	0.00009	0.0498	0.002844
D5	stream	0.9573	0.000306	0.03904	0.000071
R4	stream	0.7537	0.4469	0.3888	0.7093

Table App4.1-5: **Set 2 FOCUS Step 3 PEC_{sw} and PEC_{sed} for *prothioconazole-desthio* (M04) following single and multiple applications of SAP2101F to winter and spring cereals (minimum dose)**

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)		Max PEC_{sed} (µg/kg)	
		Prothioconazole	**Prothioconazole-desthio (M04)**	**Prothioconazole**	**Prothioconazole-desthio (M04)**
Winter Cereals - Multiple applications					
D1	ditch	0.6704	0.002793	0.7612	0.03896
D1	stream	0.5662	0.0018	0.0946	0.02452
D2	ditch	0.6721	0.04544	0.6279	0.09045
D2	stream	0.5876	0.02935	0.5431	0.04273
D3	ditch	0.6642	0.000048	0.2892	0.000069
D4	pond	0.03284	0.000858	0.05251	0.008584
D4	stream	0.5019	0.00431	0.01765	0.00353
D5	pond	0.03746	0.000105	0.04993	0.003279
D5	stream	0.579	0.00045	0.04011	0.000104
D6	ditch	0.6671	0.000164	0.4197	0.000136
R1	pond	0.03694	0.05706	0.04545	0.5687
R1	stream	0.4326	0.5354	0.1411	0.6111
R3	stream	0.6113	0.442	0.4206	0.6018
R4	stream	0.4345	0.8304	0.1293	0.625
Winter Cereals - Single application					
D1	ditch	0.762	0.000478	0.4749	0.01059
D1	stream	0.5922	0.000402	0.02389	0.006205

D2	ditch	0.7668	0.01058	0.6318	0.01697
D2	stream	0.6513	0.006685	0.09652	0.008021
D3	ditch	0.7593	0.000026	0.331	0.000026
D4	pond	0.0262	0.000322	0.04065	0.003609
D4	stream	0.5608	0.001691	0.01605	0.001339
D5	pond	0.02621	0.000056	0.03296	0.001823
D5	stream	0.6062	0.000132	0.017	0.000026
D6	ditch	0.7506	0.000052	0.1826	0.000013
R1	pond	0.02621	0.01879	0.03128	0.2075
R1	stream	0.5003	0.1918	0.06246	0.2225
R3	stream	0.7027	0.2354	0.123	0.3259
R4	stream	0.5024	0.3575	0.06992	0.2634
Spring Cereals - Multiple applications					
D1	ditch	0.9409	0.009598	0.6888	0.09925
D1	stream	0.5814	0.006107	0.2365	0.05688
D3	ditch	0.6644	0.000051	0.2751	0.000096
D4	pond	0.03596	0.001086	0.03482	0.01084
D4	stream	0.5548	0.005367	0.05682	0.004376
D5	pond	0.03385	0.000111	0.03371	0.003428
D5	stream	0.5733	0.000478	0.03395	0.000113
R4	stream	0.5552	0.5136	0.3081	0.6536
Spring Cereals - Single application					
D1	ditch	0.7686	0.001838	0.682	0.03434
D1	stream	0.6723	0.001312	0.2735	0.02168
D3	ditch	0.7601	0.000056	0.3094	0.000062
D4	pond	0.02622	0.000429	0.02472	0.004882
D4	stream	0.6214	0.002299	0.0401	0.001722
D5	pond	0.02621	0.000058	0.0332	0.001897
D5	stream	0.6382	0.000175	0.02602	0.000038
R4	stream	0.5024	0.2782	0.2592	0.4743

Folpet and its metabolites

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 App4.1-6: Sets description

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

Table App4.1-7: Set 1 FOCUS Step 3 PEC_{sw} and PEC_{sed} for *folpet* following single and multiple applications of SAP2101F 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	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
Winter Cereals - Single application					
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
Spring Cereals - Multiple applications					
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
Spring Cereals - Single application					
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

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

Table App4.1-7a: FOCUS Step 3 PEC_{sw} and PEC_{sed} for *folpet* following single and multiple applications of SAP2101F ~~SAP50SCF~~ to winter and spring cereals – 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)
Winter Cereals - Multiple applications					
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
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
Winter Cereals - Single application					
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
Spring Cereals - Multiple applications					
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
Spring Cereals - Single application					
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

Table App4.1-8: Set 1 FOCUS Step 3 PEC_{sw} and PEC_{sed} for *folpet* following single and multiple applications of SAP2101F 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)
Winter Cereals - Multiple applications					
D1	ditch	1.678	drift	0.04669	0.3039
D1	stream	1.417	drift	0.01378	0.1488
D2	ditch	1.682	drift	0.04221	0.2533
D2	stream	1.471	drift	0.02397	0.1784
D3	ditch	1.662	drift	0.04168	0.2006
D4	pond	0.05365	drift	0.001705	0.0103
D4	stream	1.256	drift	0.002687	0.04026

D5	pond	0.05368	drift	0.002126	0.008426
D5	stream	1.449	drift	0.008096	0.07958
D6	ditch	1.67	drift	0.04047	0.1982
R1	pond	0.05365	drift	0.002248	0.01358
R1	stream	1.632	runoff	0.07749	0.4852
R3	stream	2.917	runoff	0.1388	1.234
R4	stream	1.649	runoff	0.07422	0.07422
Winter Cereals - Single application					
D1	ditch	1.907	drift	0.05016	0.3045
D1	stream	1.482	drift	0.003664	0.05218
D2	ditch	1.919	drift	0.04817	0.2899
D2	stream	1.63	drift	0.01439	0.1532
D3	ditch	1.9	drift	0.03027	0.2295
D4	pond	0.06558	drift	0.002085	0.01146
D4	stream	1.404	drift	0.002453	0.03524
D5	pond	0.06559	drift	0.001299	0.008805
D5	stream	1.517	drift	0.002566	0.03679
D6	ditch	1.879	drift	0.02019	0.1885
R1	pond	0.06559	drift	0.001375	0.00897
R1	stream	1.252	drift	0.01864	0.1034
R3	stream	1.759	drift	0.01622	0.1717
R4	stream	1.258	drift	0.009423	0.1086
Spring Cereals - Multiple applications					
D1	ditch	1.681	drift	0.0379	0.1924
D1	stream	1.455	drift	0.03086	0.1787
D3	ditch	1.663	drift	0.03056	0.1567
D4	pond	0.05368	drift	0.001481	0.006428
D4	stream	1.389	drift	0.01226	0.09427
D5	pond	0.05368	drift	0.001063	0.007207
D5	stream	1.435	drift	0.004776	0.06666
R4	stream	5.142	runoff	0.3829	1.678
Spring Cereals - Single application					
D1	ditch	1.924	drift	0.02674	0.2078
D1	stream	1.683	drift	0.02152	0.1817
D3	ditch	1.902	drift	0.01747	0.159
D4	pond	0.06562	drift	0.001065	0.00786
D4	stream	1.555	drift	0.005787	0.0771
D5	pond	0.06561	drift	0.0013	0.008811
D5	stream	1.597	drift	0.003917	0.05549
R4	stream	2.848	runoff	0.1795	0.7581

Table App4.1-9: Set 2 FOCUS Step 3 PEC_{sw} and PEC_{sed} for *folpet* following single and multiple applications of SAP2101F 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	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	0.2274	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
Winter Cereals - Single application					
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
Spring Cereals - Multiple applications					
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
Spring Cereals - Single application					
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

Table App4.1-10: Set 2 FOCUS Step 3 PEC_{sw} and PEC_{sed} for *folpet* following single and multiple applications of SAP2101F 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)
Winter Cereals - Multiple applications					
D1	ditch	1.678	drift	0.626	0.3494
D1	stream	1.417	drift	0.01735	0.1449
D2	ditch	1.682	drift	0.442	0.3264
D2	stream	1.471	drift	0.3758	0.2192
D3	ditch	1.662	drift	0.1661	0.2295
D4	pond	0.07987	drift	0.06362	0.01866
D4	stream	1.256	drift	0.002805	0.03704
D5	pond	0.09247	drift	0.07355	0.01702
D5	stream	1.449	drift	0.009026	0.07362
D6	ditch	1.67	drift	0.2051	0.2212
R1	pond	0.1516	runoff	0.121	0.02344
R1	stream	2.224	runoff	0.09684	0.2488
R3	stream	2.977	runoff	0.1605	0.5666
R4	stream	1.693	runoff	0.08347	0.2903
Winter Cereals - Single application					
D1	ditch	1.907	drift	0.1599	0.3606
D1	stream	1.482	drift	0.003839	0.05065
D2	ditch	1.919	drift	0.2007	0.3735
D2	stream	1.63	drift	0.01801	0.1505
D3	ditch	1.9	drift	0.0909	0.2626
D4	pond	0.06558	drift	0.05154	0.01594
D4	stream	1.404	drift	0.002533	0.03427
D5	pond	0.06559	drift	0.05183	0.01197
D5	stream	1.517	drift	0.002696	0.03583
D6	ditch	1.879	drift	0.03979	0.1955
R1	pond	0.06559	drift	0.05124	0.01221
R1	stream	1.252	drift	0.02562	0.1009

R3	stream	1.759	drift	0.02327	0.1715
R4	stream	1.258	drift	0.01251	0.1069
Spring Cereals - Multiple applications					
D1	ditch	2.244	drift	1.248	0.2342
D1	stream	1.455	drift	0.1226	0.1865
D3	ditch	1.663	drift	0.1791	0.1628
D4	pond	0.0882	drift	0.06812	0.01117
D4	stream	1.389	drift	0.01595	0.08476
D5	pond	0.08214	drift	0.0639	0.01079
D5	stream	1.435	drift	0.005729	0.06083
R4	stream	5.585	runoff	0.4547	0.6935
Spring Cereals - Single application					
D1	ditch	1.924	drift	0.9885	0.2674
D1	stream	1.683	drift	0.07119	0.2156
D3	ditch	1.902	drift	0.1009	0.1855
D4	pond	0.06562	drift	0.05057	0.01057
D4	stream	1.555	drift	0.006696	0.07204
D5	pond	0.06561	drift	0.05211	0.012
D5	stream	1.597	drift	0.004222	0.05305
R4	stream	3.109	runoff	0.2073	0.3993