REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: FHO04

Product name(s): Prothioconazole/Sulphur (50+625) SC, / Patton Supra

Chemical active substance(s): Prothioconazole 50 g/L, Sulphur 625 g/L

Central Zone

Zonal Rapporteur Member State: Poland

Core Assessment

(authorization)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: 31/05/2024

MS Finalisation date: October 2024 (initial Core Assessment)

January 2025 (final Core Assessment)

Version history

When	What
31 May 2024	Applicant version.
October 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 colored highlighting was removed, from the parts updated by the Applicant, for better legibility.
January 2025	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)

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	PL	Winter wheat (TRZAW), Spring wheat (TRZAS), Durum wheat† (TRZDU), Spelt† (TRZSP), Winter triticale (TTLWI), Spring triticale (TTLSO)	F	Septoria (*Zymoseptoria tritici*) SEPTTR Yellow rust (*Puccinia striiformis*) PUCCST Brown rust (*Puccinia triticina*) PUCCRT	Foliar spray	27 - 69	a) 1 b) 2	14	a) 4 L/ha b) 8 L/ha	a) 0.2 –+2.5 kg/ha b) 0.4 –+5.0 kg/ha	100 / 400	35	-	A

† Minor crop according to Article 51
* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 "Conclusion"

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

Table 8.1-2: Assessed (critical) uses during approval of prothioconazole concerning the Section Environmental Fate

1	2		3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	Member state(s)	Product name	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 per treatment			PHI (days)	Remarks: e.g. g safener/ synergist per ha
						Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha	kg as/ha	Water L/ha min/max		
	EU North South	Proline	Wheat, rye, triticale	F	Rusts, Eyespot, Fusarium spp., Powdery Mildew, Rhynchospor., Septoria.	Overall spray	Post-emergence BBCH 26-69	1-3	14-21		0.2	200-400	35	
	EU North South	Proline	Barley, oat	F	Rusts, Eyespot, Pyren. teres, Powdery mildew, Fusarium spp., Rhynchospor.	Overall spray	Post-emergence BBCH 30-61	1-2	14-21		0.2	200-400	35	
	EU North	Proline	Oilseed rape	F	Sclerotinia, Botrytis, Alternaria, Leptosphaeria.	Overall spray	Post emergence BBCH 53	1-2	14-21		0.175	200-400	56	

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

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

Table 8.1-3: Assessed (critical) uses during approval of sulphur concerning the Section Environmental Fate

1	2		3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	Member state(s)	Product Name	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 per treatment			PHI (days)	Remarks: e.g. g safener/ synergist per ha
						Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg a.s./hL min max	kg as/ha min max	Water L/ha min/max		
	DE	KUMULUS WG (80%, w/w)	Cereals – Barley, rye, wheat	F	*Eryrsiphe graminis*	Foliar spray	BBCH 25 - 77	a) 1 b) 2	14	1.2 – 3.2	4.8 – 6.4	200 - 400	35	
	DE	NETZSCHWEFEL STULLN (80% w/w)	Cereals – Barley, rye, wheat	F	*Eryrsiphe graminis*	Foliar spray	BBCH 25 - 77	a) 1 b) 2	14	1.2 – 3.2	4.8 – 6.4	200 - 400	35	

	DE	THIOVIT JET 80 WG (80% w/w)	Cereal group	F	*Eryrsiphe graminis*	Foliar spray	BBCH 25 - 77	a) 1 b) 2	14	1.2 – 3.2	4.8 – 6.4	200 - 400	35	
	DE	MICROTHIOL DISPERSS (80% w/w)	Cereal group	F	*Oidium*	Foliar spray	BBCH 25 - 77	a) 1 b) 2	14	1.2 – 3.2 L	4.8 – 6.4	200 - 600	35	
	DE	KUMULUS WG NETZSCHWEFEL STULLN (80% w/w)	Grapes	F	*Uncinula necator*	Foliar spray	To beginning of ripening	a) 1 b) 8	7	0.16 – 0.64	2.56	400 - 1600	28	
	FR	THIOVIT JET 80 WG (80% w/w)	Grape group	F	*Uncinula necator*	Foliar spray	To beginning of ripening	a) 1 b) 8	7	1.28 – 2.56	2.56	200 - 1000	28	
	FR	THIOVIT JET 80 WG (80% w/w)	Grape group	F	*Uncinula necator*	Foliar spray	To beginning of ripening	a) 1 b) 8	7	0.8 – 4.0	8	200 - 1000	28	
	FR	MICROTHIOL DISPERSS (80% w/w)	Grape group	F	Acrios and Erinose	Foliar spray	To beginning of ripening	a) 1 b) 8	7	0.256 – 1.28	2.56	200 - 1000	28	
	FR	MICROTHIOL DISPERSS (80% w/w)	Grape group	F	Acrios and Erinose	Foliar spray	To beginning of ripening	a) 1 b) 8	7	0.8 – 4.0	8	200 - 1000	28	
	NEU, SEU	Sulfur 80 WG	Grapes	F	Powdery mildew	Spray	To beginning of ripening	5	7 – 10	2.7 – 4.0	2.56	200 - 300	28	
	NEU, SEU	Sulfur dust	Grapes	F	Powdery mildew	Dust	To beginning of ripening	5	7 – 10	NA	19.7 – 29.55	NA	5	
	NEU, SEU	Sulfur 80 WG	Grapes	F	Powdery mildew	Spray	To beginning of ripening	5	7 – 10	2.7 – 4.0	8	200 - 300	28	

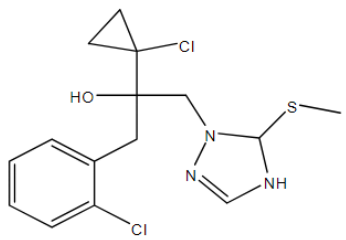
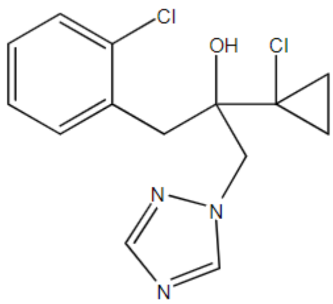
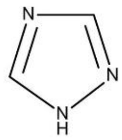
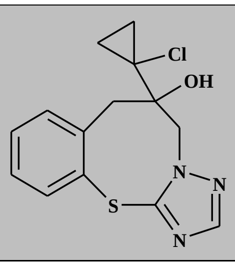
* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

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

8.2 Metabolites considered in the assessment

Prothioconazole degrades extensively in soil to two major metabolites prothioconazole-S-methyl (M01) and prothioconazole-desthio (M04). Major metabolites in water are M04 and the common metabolite 1,2,4-triazole (M13). Further information on the degradation behaviour of prothioconazole can be found in the EFSA conclusion (EFSA Scientific Report (2007) 106, 1-98, Conclusion on the peer review of prothioconazole).

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

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
M01: JAU 6476-S-methyl	358.3	2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(4,5-dihydro-5-methylthio-1,2,4-triazolyl-1)-propan-2-ol 	Soil: 14.6 % AR (lab) ~~Water/Sediment: Not observed~~ water/sediment (anaerobic): 77 % (in sediment, not detected in water) water/sediment (aerobic): 12.7% (whole system); 3.1% (water); 9.6% (sediment)	PEC_{gw}: leaching potential to groundwater PEC_{soil}: formed in soil $PEC_{sw/sed}$: potential to enter surface water
M04: JAU 6476-desthio	312.2	2-(1-chlorocycloproyl)1-(2-chlorophenyl)-3-(1,2,4-triazol-1-yl)-propan-2-ol 	Soil: 57.1 % AR (field) Water: 32.3 % AR Sediment: 26.9 % AR	PEC_{gw}: leaching potential to groundwater PEC_{soil}: formed in soil $PEC_{sw/sed}$: potential to enter surface water
1,2,4-triazole	69.065 g/mol ~~67.07~~		Soil: <2 % AR (lab) Water~~/Sediment~~: 37.2 % AR ~~(water only)~~ Sediment (max. 6.1 % at 121d) Water/sediment system (max. 41.8 % at 121d)	PECgw: not required PECsoil: not required $PEC_{sw/sed}$: formed in water
JAU 6476-thiazocine (prothioconazole-thiazocine, M12)	307.8		Aqueous photolysis study: 14.1% on day 5	Considered not relevant in EFSA (2007)

Sulphur transformation in soil is governed by oxidation, the main transformation products are sulphates, which are part of the sulphur cycle.

Table 8.2-2: Transformation products of sulphur potentially relevant for exposure assessment

Transformation product	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
None	-	-	Soil/Water/Sediment: Not applicable to an active substance that is a mineral	PEC_{gw}: NA PEC_{soil}: NA $PEC_{sw/sed}$:NA

zRMS comments:

Information regarding prothioconazole metabolites is in general in line with EU agreed endpoints reported in EFSA Scientific Report (2007) 106, with some minor corrections.

Information on metabolite JAU 6476-thiazocine has been added by the zRMS, as this metabolite was found at >10% in aqueous photolysis study. However, it was considered not relevant for the exposure assessment during EU review.

According to the sulphur cycle sulphate is a oxidation product of inorganic sulphur.

8.3 Rate of degradation in soil (KCP 9.1.1)

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

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 Prothioconazole and its metabolites

Studies on the aerobic degradation of prothioconazole and its metabolites are available in EFSA (2007). Prothioconazole degrades extensively in soil under laboratory conditions to the metabolite prothioconazole-desthio (M04) forming maximum 49.4 % AR and to another major metabolite, prothioconazole-S-methyl (M01), detected at maximum 14.6 % AR. No other major metabolites were detected, however a total of eight minor degradation products were detected at levels <5.5 % AR. The common metabolite 1,2,4-triazole did not exceed 2 % AR in soil.

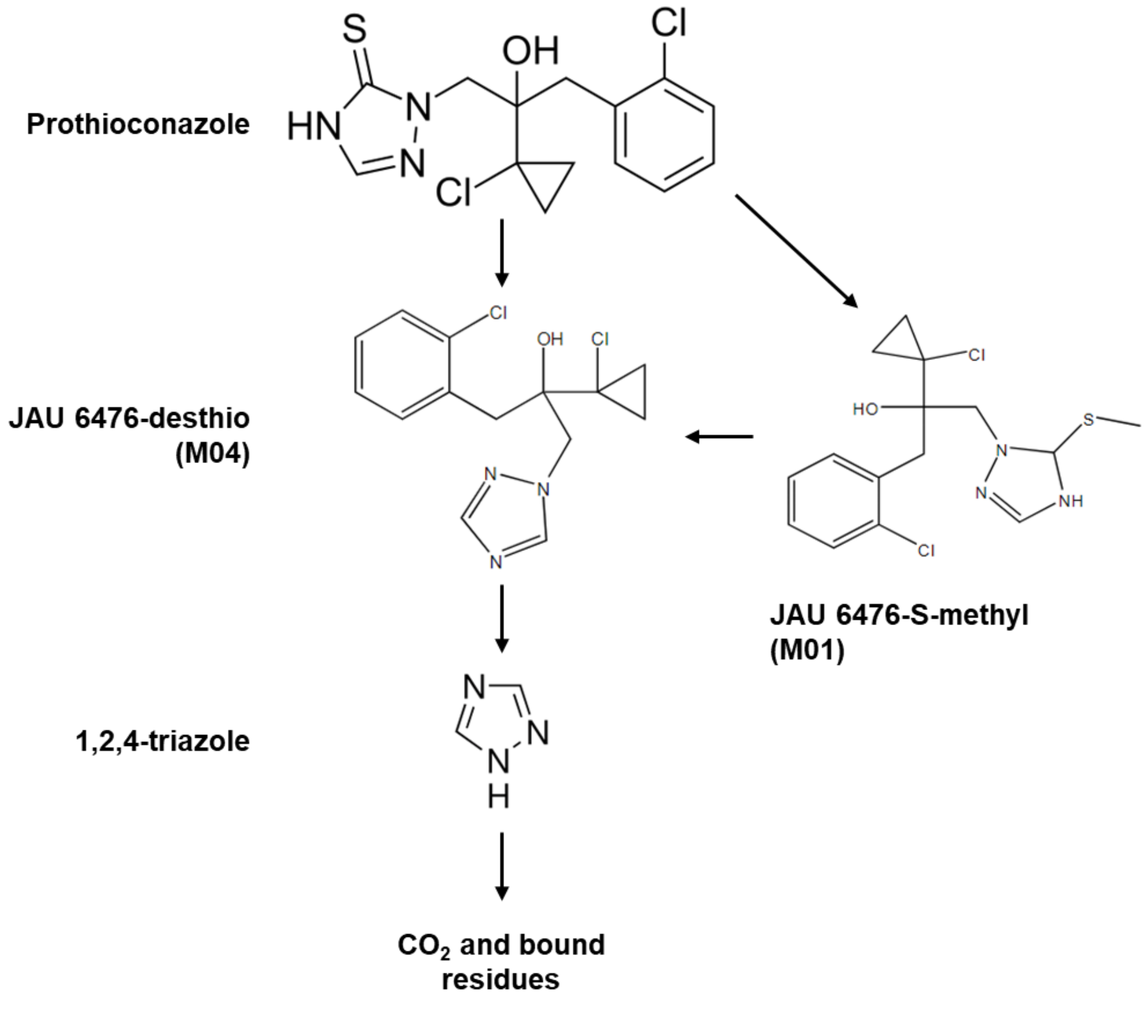


Figure 8.3-1: Simplified degradation pathway of prothioconazole in soil under aerobic conditions (after DAR, 2005)

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

Prothioconazole, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20 °C pF2/10kPa**	**R^2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Laacher Hof	Sandy loam	6.6	20	34.42	0.07	5.3	-	1.00	FOMC	Y, EFSA (2007)
Stanley	Silty clay loam	5.9	20	56.25	0.7	78.2	-	0.989	FOMC	Y, EFSA (2007)
Höfchen	Silt	6.8	20	63.1	0.30	0.99	-	0.990	SFO	Y, EFSA (2007)
Byromville	Loamy sand	6.1	20	Not determined	1.27	4.22	-	0.987	SFO	Y, EFSA (2007)
Median (n=4)							0.5			
pH-dependency: y/n							N			

Table 8.3-2: Summary of aerobic degradation rates for M01 (S-methyl) - laboratory studies

M01 (JAU 6476-S-methyl), Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20 °C pF2/10kPa**	**R^2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Höfchen	Loamy silt	6.5	20	63.1	5.9	19.6	-	0.97	SFO	Y, EFSA (2007)
Laacher Hof AIII	Loamy silt	6.7	20	36.4	27.2	90.2	-	0.955	SFO	Y, EFSA (2007)
Laacher Hof AXXa	Sandy loam	6.3	20	34.4	8.2	27.2	-	0.959	SFO	Y, EFSA (2007)
Stanley	Silty clay	5.2	20	43.8	46.0	153	-	0.965	SFO	Y, EFSA (2007)
Median (n=4)							17.7			
pH-dependency: y/n							N			

Table 8.3-3: Summary of aerobic degradation rates for M04 (desthio) - laboratory studies

M04 (JAU 6476-desthio), Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20 °C pF2/10kPa**	**R^2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Höfchen	Loamy silt	6.5	20	63.1	34.0	113.0	-	0.820	SFO	Y, EFSA (2007)
Laacher Hof AIII	Loamy silt	6.7	20	36.4	29.6	59.2	-	0.987	SFO	Y, EFSA (2007)
Laacher Hof AXXa	Sandy loam	6.3	20	34.4	7.0	23.2	-	0.985	SFO	Y, EFSA (2007)
Stanley	Silty clay	5.2	20	43.8	18.6	61.9	-	0.979	SFO	Y, EFSA (2007)
Median (n=4)							24.1			
pH-dependency: y/n							N			

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 Sulphur and its metabolites

EFSA (2008) concluded that because the sulphur cycle is well known and documented, the route of degradation of sulphur in soil can be satisfactorily addressed by literature data and no further study is necessary.

The available information only enables a qualitative assessment on the oxidation rates of elemental sulphur.

zRMS comments:

Sulphur degradation in soil is governed by oxidation. The natural cycle of oxidation and reduction reactions, transform elemental sulphur into both organic and inorganic products.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

8.3.2.1 Prothioconazole and its metabolites

Soil degradation under anaerobic conditions was not investigated, however it is considered that under the representative uses proposed, prothioconazole will not be exposed to anaerobic conditions.

8.3.2.2 Sulphur and sulphate

No studies on anaerobic degradation in soil were submitted.

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 FHO04 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 for sulphur is not applicable as the active substance is a mineral.

8.4 Field studies (KCP 9.1.1.2)

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

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

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

Prothioconazole, field studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20 °C pF2/10kPa**	**R^2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Höfchen	Loamy silt	6.25	-	-	1.9	6.4	1.2	1.000	SFO	Y, EFSA (2007)

Prothioconazole, field studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20 °C pF2/10kPa**	**R^2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Thurston	Sandy clay loam	7.56	-	-	1.6	5.5	0.8	0.999	SFO	Y, EFSA (2007)
Fresne	Loamy silt	6.42	-	-	1.3	4.4	1.6	0.995	SFO	Y, EFSA (2007)
Thurston	Sandy clay loam	7.56	-	-	2.8	9.3	1.4	0.997	SFO	Y, EFSA (2007)
Fresne	Loamy silt	6.42	-	-	1.4	4.5	1.6	0.998	SFO	Y, EFSA (2007)
St Etienne	Sandy loam silt	7.61	-	-	1.7	5.6	1.1	1.000	SFO	Y, EFSA (2007)
Pradelle	Loamy sand	7.56	-	-	1.6	5.4	1.5	0.999	SFO	Y, EFSA (2007)
Monheim	Loamy sand	6.32	-	-	1.5	5.1	0.6	1.000	SFO	Y, EFSA (2007)
Geometric mean (n=8)							1.2			
pH-dependency:							none			

Table 8.4-2: Summary of aerobic degradation rates for M04 (desthio) – field studies

M04 (JAU 6476-desthio), field studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.oC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20 °C pF2/10kPa**	**R^2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Höfchen	Loamy silt	6.25	-	-	16.3 [a)]	54.1 [a)]	10.3	0.994	SFO	Y, EFSA (2007)
Thurston	Sandy clay loam	7.56	-	-	54.7	182	27.0	0.978	SFO	Y, EFSA (2007)
Fresne	Loamy silt	6.42	-	-	47.6	158	27.5	0.859	SFO	Y, EFSA (2007)
Thurston	Sandy clay loam	7.56	-	-	50.2	167	23.4	0.939	SFO	Y, EFSA (2007)
Fresne	Loamy silt	6.42	-	-	36.8	122	20.1	0.859	SFO	Y, EFSA (2007)
St Etienne	Sandy loam silt	7.61	-	-	72.3	240	61.9	0.969	SFO	Y, EFSA (2007)
Pradelle	Loamy sand	7.56	-	-	30.5	101	20.7	0.951	SFO	Y, EFSA (2007)
Monheim	Loamy sand	6.32	-	-	27.9 [a)]	92.6 [a)]	15.2	0.996	SFO	Y, EFSA (2007)
Geometric mean (n=8)							22.7			
pH-dependency:							none			

a) without day 0 samples, because the maximum concentrations of M04 were at the later sampling dates

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 Sulphur and sulphate

No valid studies on the field dissipation of sulphur or sulphate were included in the EFSA (2008) conclusion.

Triggering endpoints

None proposed.

Modelling endpoints

None proposed.

zRMS comments:
No studies submitted on the field dissipation of sulphur according to EFSA Scientific Report (2008) 221, 46-70.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Not required for either active substance.

zRMS comments:
According to information presented in EFSA Scientific Report (2007) 106 and EFSA Scientific Report (2008) 221, 46-70, soil accumulation testing is not required for prothioconazole and sulphur, respectively.

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

Studies on the mobility in soil of prothioconazole and its metabolites are available in EFSA (2007). The K_d and K_{oc} values of prothioconazole were determined in aged column leaching studies due to the instability of the compound in standard batch equilibrium studies. The resulting values for prothioconazole were K_d = 15.2 and K_{oc} = 1765 mL/g (slightly mobile compound). Adsorption/desorption of prothioconazole-S-methyl (M01) and prothioconazole–desthio (M04) were investigated by batch equilibrium experiments. The calculated adsorption K_{oc} for M01 was in the range 1973.6 – 2995.0 mL/g and for M04 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 K_{foc} values for this minor soil metabolite of prothioconazole are in the range of 43-202 mL/g (n=4).

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

Prothioconazole							
Soil name	**Soil type**	**OC (%)**	**pH (H2O)**	**Kd (mL/g)**	**Kdoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Byromville	Loamy sand	0.86	6.7	15.2	1765	0.9	EFSA, 2007
Arithmetic mean (n=1)							
pH-dependency y/n					No information		

Table 8.5-2: Summary of soil adsorption/desorption for JAU 6476-S-methyl (prothioconazole-S-methyl)

JAU 6476-S-methyl (prothioconazole-S-methyl, M01)							
Soil Name	**Soil Type**	**OC (%)**	**pH (H_2O)**	**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	EFSA, 2007
Höfchen	Silt	2.14	7.1	64.1	2995.0	0.88	EFSA, 2007
Stanley	Silty clay loam	1.66	5.9	41.2	2484.0	0.91	EFSA, 2007
Byromville	Loamy sand	0.79	6.8	15.6	1973.6	0.85	EFSA, 2007
Geometric mean (n=4)					2525.9		
Arithmetic mean (n=4)					2556.3	0.88	
pH-dependency y/n					N		

Table 8.5-3: Summary of soil adsorption/desorption for JAU 6476-desthio (prothioconazole-desthio)

JAU 6476-desthio (prothioconazole-desthio, M04))							
Soil Name	**Soil Type**	**OC (%)**	**pH (H_2O)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Laacher Hof AXXa	Sandy loam	2.02	7..2	12.46	616.8	0.79	EFSA, 2007
Höfchen	Silt	2.14	7.1	13.38	625.3	0.83	EFSA, 2007
Stanley	Silty clay loam	1.66	5.9	8.90	536.4	0.83	EFSA, 2007
Byromville	Loamy sand	0.79	6.8	4.13	523.0	0.80	EFSA, 2007
Geometric mean (n=4)					573.5	-	
Arithmetic mean (n=4)					575.4	0.81	
pH-dependency y/n					N		

Table 8.5-4: Summary of soil adsorption/desorption for 1,2,4-triazole

1,2,4-triazole (M13)							
Soil Name	**Soil Type**	**OC (%)**	**pH**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
	Silty clay	0.70	8.8	0.833	120	0.897	EFSA, 2007
	Clay loam	1.74	6.9	0.748	43	0.827	EFSA, 2007
	Silty clay loam	0.70	7.0	0.722	104	0.922	EFSA, 2007
	Sandy loam	0.81	6.9	0.719	89	1.016	EFSA, 2007
Geometric mean (n=4)					83	-	
Arithmetic mean (n=4)					89	0.916	
pH-dependency y/n					N		

zRMS comments:

Soil mobility data for prothioconazole and its major soil metabolites presented in Tables 8.5-1 to 8.5-3 are in line with EU agreed endpoints as reported in EFSA Scientific Report (2007) 106 and prothioconazole DAR of 2005.
Information on soil sorption of the metabolite 1,2,4-triazole presented in Table 8.5-4 is in line with EU agreed endpoints as reported in EFSA Scientific Report (2008) 176 for tebuconazole.

It is noted that at the EU level no respective soil adsorption-desorption studies were performed with prothioconazole and the Koc of 1765 mL/g has been derived from the aged leaching study. The method used for this calculation is questionable and was not agreed during the recent EU renewal of this active substance. Nevertheless, as the renewal process is still ongoing, the Koc of 1765 mL/g is considered to be an EU agreed endpoint that is relevant for the exposure assessment until new list of endpoints becomes valid.

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

8.5.2 Sulphur and sulphate

Based on a water solubility value of 63 µg/L a calculated Koc value of 1950 mL/g and a Freundlich coefficient of 1.0 were proposed (EFSA, 2008).

zRMS comments:

According to EFSA Scientific Report (2008) 221, 46-70 sulphur exhibits low mobility in soil. A conservative estimation of the Koc value for sulphur was derived from the water solubility value.

8.5.3 Column leaching (KCP 9.1.2.1)

8.5.3.1 Prothioconazole and its metabolites

One study was included in the EFSA (2007) conclusion for prothioconazole:

Guideline: SETAC (1995), BBA Part IV, 6-2 (1986) Precipitation: 200mm Time period: 2days Leachate: <1% AR; fractions not investigated

One study on the leaching of aged residues was included in the EFSA (2007) conclusion for prothioconazole:

Guideline: US EPA 163-1 (1982) Aged for: 30 hours Precipitation: 1000 mL The total radioactivity in the leachate accounted for only 1.1% of the AR, and no individual leachate fraction resulted in a radioactivity content >0.2% of the AR. Therefore the leachate fractions were not analysed for parent compound or metabolites.

zRMS comments:

Results of column leaching and aged residues leaching of prothioconazole are reported in EFSA Scientific Report (2007) 106, however are not necessary for purposes of evaluation of FHO04, as based on results of the groundwater modelling no unacceptable leaching of prothioconazole or its metabolites is expected.

8.5.3.2 Sulphur and sulphate

No valid column leaching studies for sulphur or sulphate were included in the EFSA (2008) conclusion.
No aged residues leaching studies for sulphur or sulphate were submitted.

zRMS comments:

The leaching potential of sulphur and sulphate following application of FHO04 is addressed in groundwater modelling presented in point 8.8 of this document.

8.5.4 Lysimeter studies (KCP 9.1.2.2)

8.5.4.1 Prothioconazole and its metabolites

Studies on the fate behaviour of prothioconazole in lysimeters are not required and none were assessed in EFSA (2007).

8.5.4.2 Sulphur and sulphate

Studies on the fate behaviour of sulphur in lysimeters are available in EFSA (2008).

Table 8.5-5: Summary of lysimeter study for sulphur

Summary	**Evaluated on EU level y/n/ Reference**
Location: England Study type (e.g.lysimeter, field): lysimeter Soil properties: texture, pH = 6.6, OC = 12.7 g/kg Dates of application : Sept 1996 to Sept 1999 Crop : /Interception estimated: Number of applications: 1 application the first year Duration. 3 years Application rate: 50 kg/ha/year + 22 kg atmospheric deposition Average annual rainfall (mm): 615.3 Average annual leachate volume (mm): 214 Leaching rate of organic forms over the three years: equivalent to 68 kg/ha of sulphur as SO_4^{2-} + 4.8 kg/ha as DOS (dissolved organic sulphur) = 72.8 kg/ha, when 72 kg/ha input. No elemental sulphur leached.	Y, EFSA (2008)

zRMS comments:

The lysimeter studies with prothioconazole were not required during the EU review.

Provided above information on the lysimeter study for sulphur is in line with data reported in EFSA Scientific Report (2008) 221, 46-70.

The leaching potential of prothioconazole and its metabolites, sulphur and sulphate following application of FHO04 is addressed in groundwater modelling presented in point 8.8 of this document.

8.5.5 Field leaching studies (KCP 9.1.2.3)

Studies on the fate behaviour of prothioconazole in field leaching studies are not required and none were assessed in EFSA (2007).

No valid studies on the field dissipation of sulphur or sulphate were included in the EFSA (2008) conclusion.

zRMS comments:

The field leaching studies were not required during the EU review of both active substances. The leaching potential of prothioconazole and its metabolies, sulphur and sulphate following application of FHO04 is addressed in groundwater modelling presented in point 8.8 of this document.

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

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

8.6.1 Prothioconazole and its metabolites

Studies on the degradation in water/sediment systems of prothioconazole and its metabolites are available in EFSA (2007). A proportion of the active substance partitioned 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). Major metabolites in water were prothioconazole-desthio (M04) with maximum 32.3 % AR and 1,2,4-triazole (M13) with maximum 37.2 % AR.

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

Prothioconazole distribution (max. sediment 23.4 % after 1 day)										
Water/sediment system	**pH water/ sed.**	**DegT50 whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic, Fit**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic, Fit**	**$DissT_{50}$ sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Hönniger Weiher	6.6	2.8	76.4	H-S	0.8	2.7	SFO	-	-	Y, EFSA, 2007
Angler Weiher	8.5	1.6	23.6	H-S	**1.0***	3.4	SFO	-	-	Y, EFSA, 2007
Geometric mean (n= 2)		NC	NC		-	-		-		

*Larger value used for modelling; NC = not calculated

Table 8.6-2: Summary of observed metabolites

Prothioconazole-desthio (M04) Water/sediment system	Max. in water 32.3 % after 7 d (Angler Weiher, phenyl-label) Max. in sediment 26.9 % after 14 d (Angler Weiher, phenyl label) Max. in water/sediment 54.6 % after 7 d (Angler Weiher, phenyl label)	Evaluated on EU level: EFSA, 2007
1,2,4-triazole Water/sediment system	Max. in water 37.2 % after 121 d (Angler Weiher, triazole) Max. in sediment 4.6 % after 121 d (Angler Weiher, triazole label) Max. in water/sediment 41.8 % after 121 d (Angler Weiher, triazole label)	Evaluated on EU level: EFSA, 2007

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 Table 8.6-2 with additional information for metabolites JAU 6476-desthio (M04) and 1,2,4-triazole.

8.6.2 Sulphur and sulphate

No degradation in water / sediment studies for sulphur or sulphate were submitted. Studies not required for inorganic substances.

zRMS comments:

Degradation data for sulphur are not required and not relevant for inorganic compounds, such as sulphur.
The leaching potential of sulphate following application of FHO04 is addressed in groundwater modelling presented in point 8.8 of this document.

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

Full details of the assessments for prothioconazole and sulphur can be found in the following reports:

KCP 9.1.3/01, Smith (2024): E2023-51 - Predicted environmental concentrations of prothioconazole following applications on spring and winter cereals in the Central Zone.

KCP 9.1.3/02, Tilston (2024): E2023-33 - Predicted environmental concentrations of sulphur and sulphate following applications on spring and winter cereals in the Central and Southern Zones.

The predicted environmental concentrations in soil (PEC_{soil}) of prothioconazole and M04 were calculated using the longest non-normalised field DT_{50} values. The laboratory DT_{50} was used for M01 in accordance with EFSA (2007). Soil accumulation was not considered as the DT_{90} values for all compounds are less than 1 year. Equivalent application rates were calculated for the metabolites based on the total parent rate (i.e., 400 g a.s./ha) adjusted for the molar correction factor and the maximum formation in soil.

8.7.1 Justification for new endpoints

All endpoints were taken from the peer review conclusion for prothioconazole (EFSA, 2007), and the peer review conclusion for sulphur (EFSA, 2008).

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

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

Use No.	1	1
Crop	Cereals – early (BBCH 27)	Cereals – late (BBCH 69)
Application rate (g as/ha)	Prothioconazole: 200 (single), 400 (annual) Sulphur: 2500 (single), 5000 (annual)	Prothioconazole: 200 (single), 400 (annual) Sulphur: 2500 (single), 5000 (annual)
Number of applications/interval	2 applications, 14 d interval	2 applications, 14 d interval
Crop interception (%)	20	90
Depth of soil layer (relevant for plateau concentration) (cm)	5 cm (no tillage)	5 cm (no tillage)
Model	HSE PECsoil calculator v1.0 (2015)	HSE PECsoil calculator v1.0 (2015)

Table 8.7-2: Input parameter for active substances and relevant metabolites for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT_{50} (days)	Value in accordance to EU endpoint y/n/ Reference
Prothioconazole	344.3	-	2.8 (SFO, field)	Y, EFSA (2007)
Prothioconazole- S-methyl (M01)	358.3	14.6	46 (SFO, lab)	Y, EFSA (2007)
Prothioconazole-desthio (M04)	312.2	57.1	72.3 (SFO, field)	Y, EFSA (2007)
Sulphur	32.064	-	-*	Y, EFSA (2008)
Sulphate**	96.1	-	-	Y, EFSA (2008)

* Sulphur is not expected to be persistent, and therefore no accumulation of sulphur is anticipated
** No transformation products are considered to be relevant for exposure and risk assessment in soil

zRMS comments:

The application pattern assumed in soil exposure assessment is in line with the critical Central Zone GAP and it is thus agreed. Relevant crop interception in line with FOCUS groundwater guidance (2021) have been selected.

Input parameters presented in Table above are in line with EU agreed parameters for reported in EFSA Scientific Report (2007) 106.

8.7.2.1 Prothioconazole and its metabolites

Table 8.7-3: PEC_{soil} for prothioconazole on cereals (BBCH 27)

PEC_{soil} (mg/kg)		Cereals- early (20 % interception)			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.213	-	0.220	-
Short term	24h	0.167	0.189	0.172	0.195
	2d	0.130	0.168	0.134	0.174
	4d	0.079	0.135	0.082	0.140
Long term	7d	0.038	0.101	0.039	0.105
	14d	0.007	0.060	0.007	0.061
	21d	0.001	0.041	0.001	0.042
	28d	<0.001	0.031	<0.001	0.032
	50d	<0.001	0.018	<0.001	0.019
	100d	<0.001	0.009	<0.001	0.009

Table 8.7-4: PEC_{soil} for prothioconazole on cereals (BBCH 69)

PEC_{soil} (mg/kg)		Cereals- late (90 % interception)			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.027	-	0.028	-
Short term	24h	0.021	0.024	0.021	0.024
	2d	0.016	0.021	0.017	0.022
	4d	0.010	0.017	0.010	0.017
Long term	7d	0.005	0.013	0.005	0.013
	14d	0.001	0.007	0.001	0.008
	21d	<0.001	0.005	<0.001	0.005
	28d	<0.001	0.004	<0.001	0.004
	50d	<0.001	0.002	<0.001	0.002
	100d	<0.001	0.001	<0.001	0.001

PEC_{soil} of metabolites

Table 8.7-5: PEC_{soil} for prothioconazole-S-methyl (M01) on cereals (BBCH 27)

PEC_{soil} (mg/kg)		Cereals- early (20 % interception)			
		Single application		Multiple applications*	
		Actual	TWA	Actual	TWA
Initial		-	-	0.065	-
Short term	24h	-	-	0.064	0.064
	2d	-	-	0.063	0.064
	4d	-	-	0.061	0.063
Long term	7d	-	-	0.058	0.062
	14d	-	-	0.052	0.058
	21d	-	-	0.047	0.056
	28d	-	-	0.043	0.053
	50d	-	-	0.031	0.046
	100d	-	-	0.014	0.033

* Metabolites assessed as total dose

Table 8.7-6: PEC$_{soil}$ for prothioconazole-S-methyl (M01) on cereals (BBCH 69)

PEC$_{soil}$ (mg/kg)		Cereals- late (90 % interception)			
		Single application		Multiple applications*	
		Actual	TWA	Actual	TWA
Initial		-	-	0.008	-
Short term	24h	-	-	0.008	0.008
	2d	-	-	0.008	0.008
	4d	-	-	0.008	0.008
Long term	7d	-	-	0.007	0.008
	14d	-	-	0.007	0.007
	21d	-	-	0.006	0.007
	28d	-	-	0.005	0.007
	50d	-	-	0.004	0.006
	100d	-	-	0.002	0.004

* Metabolites assessed as total dose

Table 8.7-7: PEC$_{soil}$ for prothioconazole-desthio (M04) on cereals (BBCH 27)

PEC$_{soil}$ (mg/kg)		Cereals- early (20 % interception)			
		Single application		Multiple applications*	
		Actual	TWA	Actual	TWA
Initial		-	-	0.221	-
Short term	24h	-	-	0.219	0.220
	2d	-	-	0.217	0.219
	4d	-	-	0.213	0.217
Long term	7d	-	-	0.207	0.214
	14d	-	-	0.193	0.207
	21d	-	-	0.181	0.200
	28d	-	-	0.169	0.194
	50d	-	-	0.139	0.177
	100d	-	-	0.085	0.142

* Metabolites assessed as total dose

Table 8.7-8: PEC$_{soil}$ for prothioconazole-desthio (M04) on cereals (BBCH 69)

PEC$_{soil}$ (mg/kg)		Cereals- late (90 % interception)			
		Single application		Multiple applications*	
		Actual	TWA	Actual	TWA
Initial		-	-	0.028	-
Short term	24h	-	-	0.027	0.027
	2d	-	-	0.027	0.027
	4d	-	-	0.027	0.027
Long term	7d	-	-	0.026	0.027
	14d	-	-	0.024	0.026
	21d	-	-	0.023	0.025
	28d	-	-	0.021	0.024
	50d	-	-	0.017	0.022
	100d	-	-	0.011	0.018

* Metabolites assessed as total dose

zRMS comments:

The soil exposure for prothioconazole and its metabolites has been independently validated by the zRMS using FOCUS methods using 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 for prothioconazole and its metabolites were similar and slightly lower to those obtained by the Applicant and therefore results reported in Tables 8.7-3 to 8.7-8 above may be used for the soil risk assessment purposes.

8.7.2.2 Sulphur

Table 8.7-9: PEC_{soil} for sulphur on cereals – no interception (see B9, section 9.10 – Non-target plants)

PEC_{soil} (mg/kg)	Cereals (0 % interception)			
	Single application		Multiple applications	
	Actual	TWA	Actual	TWA
Initial	3.333	-	6.667	-

Table 8.7-10: PEC_{soil} for sulphur on cereals – early applications

PEC_{soil} (mg/kg)	Cereals – early applications (20 % interception)			
	Single application		Multiple applications	
	Actual	TWA	Actual	TWA
Initial	2.667	-	5.333	-

Table 8.7-11: PEC_{soil} for sulphur on cereals – late applications

PEC_{soil} (mg/kg)	Cereals – late applications (90 % interception)			
	Single application		Multiple applications	
	Actual	TWA	Actual	TWA
Initial	0.333	-	0.667	-

zRMS comments:

The soil exposure for sulphur has been independently validated by the zRMS using FOCUS methods and using EU agreed endpoints. The calculated PEC_{soil} values were similar to those obtained by the Applicant, therefore results reported in Tables 8.7-9 to 8.7-11 above may be used for the soil risk assessment purposes.

8.7.2.3 PEC_{soil} of formulation

Initial PEC_{soil} of the formulation was calculated based on the total amount of formulation that could be applied (4.0 L/ha). The density of the formulation is 1.36 kg/L, giving an applied dose of 5440 g/ha.

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

Active substance/ reparation	Application rate (g/ha)	$PEC_{initial}$ (mg/kg)	PEC_{twa}21 d (mg/kg)	Tillage depth (cm)	$PEC_{soil,plateau}$ (mg/kg)	PEC_{accu} = PEC_{act} + $PEC_{soil,plateau}$ (mg/kg)
Formulation	5440	5.803	-	5	-	-

zRMS comments:

Soil exposure for the formulated product was recalculated by the zRMS and the same PEC_{soil} were obtained. For this reason PEC_{soil} as reported in table above is considered relevant for the soil risk assessment.

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

Full details of the assessments for prothioconazole and sulphur can be found in the following reports:

KCP 9.2.4/01, Smith (2024): E2023-51 - Predicted environmental concentrations of prothioconazole following applications on spring and winter cereals in the Central Zone.

KCP 9.2.4/02, Tilston (2024): E2023-33 - Predicted environmental concentrations of sulphur and sulphate following applications on spring and winter cereals in the Central and Southern Zones.

Groundwater modelling was performed for prothioconazole and its two major soil metabolites, prothioconazole-S-methyl (M01) and prothioconazole-desthio (M04) using the FOCUS models PEARL v5.5.5 and PELMO v6.6.4.

Predicted environmental concentrations in groundwater (PEC_{gw}) of sulphur and sulphate, following application of sulphur were calculated using total percolate as obtained from the FOCUS models PEARL v5.5.5 and PELMO v6.6.4 for the assessed crops or their surrogates, according to the approach used for active substance approval reported by EFSA (2008).

8.8.1 Justification for new endpoints

All endpoints were taken from the peer review conclusion for prothioconazole (EFSA, 2007), and the peer review conclusion for sulphur (EFSA, 2008).

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

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

Use No.	1	1
Crop	Cereals – early (BBCH 27)	Cereals – late (BBCH 69)
Application rate (g as/ha)	Prothioconazole: 200 (single), 400 (annual) Sulphur: 2500 (single), 5000 (annual)	Prothioconazole: 200 (single), 400 (annual) Sulphur: 2500 (single), 5000 (annual)
Number of applications/interval (d)	2 applications, 14 d interval	2 applications, 14 d interval
Crop interception (%)*	20	90
Frequency of application	annual	annual
Models used for calculation	FOCUS PEARL v5.5.5 FOCUS PELMO v6.6.4	FOCUS PEARL v5.5.5 FOCUS PELMO v6.6.4

*EFSA (2014)

Absolute application dates were obtained from AppDate v3.06.

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

Crop	Scenario	Application dates (absolute)	
		BBCH 27 (early)	BBCH 69 (late)
Spring cereals	Châteaudun	11-Apr (101), 25-Apr (115)	22-Jun (173), 06-Jul (187)
	Hamburg	24-Apr (114), 08-May (128)	28-Jun (179), 12-Jul (193)
	Jokioinen	02-Jun (153), 16-Jun (167)	17-Jul (198), 31-Jul (212)
	Kremsmünster	24-Apr (114), 08-May (128)	28-Jun (179), 12-Jul (193)
	Okehampton	19-Apr (109), 03-May (123)	18-Jun (169), 02-Jul (183)
	Porto	11-Apr (101), 25-Apr (115)	22-Jun (173), 06-Jul (187)
Winter cereals	Châteaudun	12-Apr (102), 26-Apr (116)	14-Jun (165), 28-Jun (179)
	Hamburg	01-May (121), 15-May (135)	22-Jun (173), 06-Jul (187)
	Jokioinen	11-May (131), 25-May (145)	10-Jul (191), 24-Jul (205)
	Kremsmünster	21-Apr (111), 05-May (125)	25 Jun (176), 09-Jul (190)
	Okehampton	18-Apr (108), 02-May (122)	07-Jun (158), 21-Jun (172)
	Piacenza	16-Mar (75), 30-Mar (89)	26-May(146), 09-Jun (152)
	Porto	21-Jan (21), 04-Feb (35)	18-May (138), 01-Jun (152)
	Sevilla	31-Dec (365), 14-Jan (14)	28-Mar (87), 11-Apr (101)
	Thiva	10-Jan (10), 24-Jan (24)	27-Apr (117), 11-May (131)

Julian days in parentheses

zRMS comments:

The application pattern assumed in simulations 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 FHO04 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.

8.8.2.1 Prothioconazole and its metabolites

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	Y, EFSA (2007)
Water solubility (g/mol):	22.5 (20 °C)	4.6 (20 °C)	50.6 (20 °C)	Y, EFSA (2007)
Saturated vapour pressure (Pa):	4 E-7 (20 °C)	8.2 E-6	1 E-10	Y, EFSA (2007)
DT_{50} in soil (d)	1.2 (geomean, field)	15.7 (geomean, lab)	22.7 (geomean, field)	Y, EFSA (2007)
K_{foc} (mL/g)	1765 (column leaching)	2556.3 (arithmetic mean, n=4)	575.4 (arithmetic mean, n=4)	Y, EFSA (2007)
K_{fom} (mL/g)	1023.8	1482.8	333.8	K_{oc}/1.724
1/n	0.9 (default)	0.88	0.81	Y, EFSA (2007)
Plant uptake factor	0 (FOCUS default)	0 (FOCUS default)	0 (FOCUS default)	Y, EFSA (2007)
Formation fraction	-	0.146 (lab)	0.571 (field)	DAR (2005), used for PELMO results reported in EFSA (2007)

*EFSA scientific report (2007; 106, 1-98)

The maximum 80[th] percentile PEC_{gw} values are <0.001 µg/L across all scenarios for both PEARL and PELMO models. PEC_{gw} values of prothioconazole are only presented for the most conservative application timing of BBCH 27. As all PEC_{gw} values for the parent compound and both metabolites are considerably less than the threshold value of 0.1 µg/L, it is not necessary to assess BBCH 69 which would generate lower values. Further investigations using the MACRO model were not considered necessary.

Table 8.8-4: PEC_{gw} for prothioconazole and metabolites on spring cereals, BBCH 27 (with FOCUS PEARL v5.5.5)

Crop	Scenario	80[th] Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Prothioconazole	Prothioconazole-S-methyl (M01)	Prothioconazole-desthio (M04)
Spring cereals BBCH 27	Châteaudun	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001
	Jokioinen	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001

Table 8.8-5: PEC_{gw} for prothioconazole and metabolites on spring cereals, BBCH 27 (with FOCUS PELMO v6.6.4)

Crop	Scenario	80[th] Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Prothioconazole	Prothioconazole-S-methyl (M01)	Prothioconazole-desthio (M04)
Spring cereals BBCH 27	Châteaudun	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001
	Jokioinen	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001

Table 8.8-6: PEC_{gw} for prothioconazole and metabolites on winter cereals, BBCH 27 (FOCUS PEARL v5.5.5)

Crop	Scenario	80[th] Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Prothioconazole	Prothioconazole-S-methyl (M01)	Prothioconazole-desthio (M04)
Winter cereals BBCH 27	Châteaudun	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001
	Jokioinen	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001
	Piacenza	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001

Table 8.8-7: PEC_{gw} for prothioconazole and metabolites on winter cereals, BBCH 27 (FOCUS PELMO v6.6.4)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Prothioconazole	Prothioconazole-S-methyl (M01)	Prothioconazole-desthio (M04)
Winter cereals BBCH 27	Châteaudun	<0.001	<0.001	<0.001
	Hamburg	<0.001	<0.001	<0.001
	Jokioinen	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001
	Piacenza	<0.001	<0.001	<0.001
	Porto	<0.001	<0.001	<0.001
	Sevilla	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001

zRMS comments:

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

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).

Since all PEC_{GW} were <0.001 µg/L, further simulations using the MACRO model were not necessary, in line with indications of the Central Zone guidance document in area of efate (2018).

The groundwater modelling was independently validated by the zRMS in additional modelling 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 FHO04 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 Sulphur and sulphate

Predicted environmental concentrations in groundwater (PEC_{gw}) of sulphur and sulphate, following application of sulphur were calculated using total percolate as obtained from the FOCUS models PEARL v5.5.5 and PELMO v6.6.4 for the assessed crops or their surrogates, according to the approach used for active substance approval reported by EFSA (2008). In brief, PEC_{gw} was calculated for sulphates and assumed a worst-case scenario whereby 100 % of sulphur is oxidised to sulphate and 100 % of sulphur leaches, *i.e.* no sorption or degradation occurs in soil or groundwater.

The total amount of sulphur entering soil after application was calculated as summarised in the tables below.

Table 8.8-8: Application regimes and effective annual application rates to soil for sulphur

Crop	Application timing	Application (g/ha)	Application number	Interception (%)*	Fraction entering soil	Total amount entering soil (g/ha/yr)
Cereals	Early, BBCH 27	2500	2	20	0.8	4000
Cereals	Late, BBCH 65	2500	2	90	0.1	500

*EFSA (2014)

PELMO and MACRO report annual total of percolate at 1 m soil depth (L/m^2) for 26 years by default, PEARL only reports annual totals for 20 years, so to enable comparability with PELMO totals for the last six years were added to the start of the series. Similarly, for consistency with PELMO, negative percolate values in PEARL were treated as 0 percolate.

Table 8.8-9: Total water volume percolated at 1 m during 26 years – spring cereals

Crop	Scenario	Total water volume percolated at 1 m, during 26 years (L/m²)		
		PELMO v6.6.4	**PEARL v5.5.5**	**MACRO v5.5.4**
Spring cereals	Châteaudun	3621.15	4187.401	4884.502
	Hamburg	5427.53	5923.981	-
	Kremsmünster	5880.49	7214.421	-
	Okehampton	8870.90	10798.270	-
	Porto	11707.4	12519.96	-

Table 8.8-10: Total water volume percolated at 1 m during 26 years – winter cereals

Crop	Scenario	Total water volume percolated at 1 m, during 26 years (L/m²)		
		PELMO v6.6.4	**PEARL v5.5.5**	**MACRO v5.5.4**
Winter cereals	Châteaudun	2806.66	3557.814	3671.998
	Hamburg	5437.67	6954.788	-
	Kremsmünster	6104.18	7975.608	-
	Okehampton	8742.00	11392.070	-
	Piacenza	6487.59	8476.433	-
	Porto	10787.4	12014.09	-

Predicted concentrations for sulphur in groundwater were calculated as the 26-year total amount of sulphur entering soil after application referenced to the total water volume percolated at 1 m. PEC_{gw} values for sulphur were converted to sulphate assuming 100 % conversion and taking into account of the fact that eight sulphate ions (molecular mass = 8 × 96.1 = 768.8 g/mol) are formed from the S_8 allotrope (molecular mass = 8 × 32.064 = 256.56 g/mol). A worked example for the winter cereals and Châteaudun scenario combination in PELMO is provided below:

- Total amount of sulphur entering soil:
  2 applications of 2500 g/ha sulphur a year for 26 years, with 20 % crop interception
  = (26 × (2 × 2500)) × ((100 – 20) ÷ 100)
  = 104,000 g/ha sulphur

- Convert to g/m² based on 10,000 m² = 1 ha:
  = 104,000 g/ha ÷ 10,000 m²
  = 10.4 g/m² sulphur

- Reference to total water volume percolated at 1 m to give PEC_{gw} for sulphur:
  Total water volume percolated at 1 m, during 26 years = 2806.66 L/m²
  = 10.4 g/m² ÷ 2806.66 L/m²
  = 0.003705 g/L
  ≡ 3.705 mg/L sulphur

- Calculate concentration of sulphate based on PEC_{gw} for sulphur assuming the formation of 8 sulphate ions from the S8 allotrope and 100 % conversion:
  = 3.705 mg/L × (8 × (96.06 ÷ 256.6))
  = 11.097 mg/L sulphate

Table 8.8-11: PEC$_{gw}$ for sulphur and sulphate on spring cereals (with FOCUS PELMO v6.6.4)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (mg/L)	
		Sulphur	Sulphate
Spring cereals, BBCH 27	Châteaudun	2.872	8.601
	Hamburg	1.916	5.739
	Kremsmünster	1.769	5.297
	Okehampton	1.172	3.511
	Porto	0.888	2.660
Spring cereals, BBCH 69	Châteaudun	0.359	1.075
	Hamburg	0.240	0.717
	Kremsmünster	0.221	0.662
	Okehampton	0.147	0.439
	Porto	0.111	0.333

Table 8.8-12: PEC$_{gw}$ for sulphur and sulphate on spring cereals (with FOCUS PEARL v5.5.5)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (mg/L)	
		Sulphur	Sulphate
Spring cereals, BBCH 27	Châteaudun	2.484	7.441
	Hamburg	1.756	5.260
	Kremsmünster	1.442	4.319
	Okehampton	0.963	2.886
	Porto	0.831	2.489
Spring cereals, BBCH 69	Châteaudun	0.310	0.930
	Hamburg	0.219	0.657
	Kremsmünster	0.180	0.540
	Okehampton	0.120	0.361
	Porto	0.104	0.311

Table 8.8-13: PEC$_{gw}$ for sulphur and sulphate on spring cereals (with FOCUS MACRO v5.5.4)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (mg/L)	
		Sulphur	Sulphate
Spring cereals, BBCH 27	Châteaudun	2.129	6.379
Spring cereals, BBCH 69	Châteaudun	0.266	0.797

Table 8.8-14: PEC$_{gw}$ for sulphur and sulphate on winter cereals (with FOCUS PELMO v6.6.4)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (mg/L)	
		Sulphur	Sulphate
Winter cereals, BBCH 27	Châteaudun	3.705	11.097
	Hamburg	1.913	5.728
	Kremsmünster	1.704	5.102
	Okehampton	1.190	3.563
	Piacenza	1.603	4.801
	Porto	0.964	2.887
Winter cereals, BBCH 69	Châteaudun	0.463	1.387
	Hamburg	0.239	0.716
	Kremsmünster	0.213	0.638
	Okehampton	0.149	0.445
	Piacenza	0.200	0.600
	Porto	0.121	0.361

Table 8.8-15: PEC$_{gw}$ for sulphur and sulphate on winter cereals (with FOCUS PEARL v5.5.5)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (mg/L)	
		Sulphur	Sulphate
Winter cereals, BBCH 27	Châteaudun	2.923	8.758
	Hamburg	1.495	4.480
	Kremsmünster	1.304	3.907
	Okehampton	0.913	2.735
	Piacenza	1.227	3.676
	Porto	0.866	2.594
Winter cereals, BBCH 69	Châteaudun	0.365	1.095
	Hamburg	0.187	0.560
	Kremsmünster	0.163	0.488
	Okehampton	0.114	0.342
	Piacenza	0.153	0.460
	Porto	0.108	0.324

Table 8.8-16: PEC$_{gw}$ for sulphur and sulphate on winter cereals (with FOCUS MACRO v5.5.4)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (mg/L)	
		Sulphur	Sulphate
Winter cereals, BBCH 27	Châteaudun	2.832	8.482
Winter cereals, BBCH 69	Châteaudun	0.354	1.060

Groundwater concentrations of sulphate for the intended uses were not predicted to exceed the indicative parameter of 250 mg/L for sulphate in both the applicable Drinking Water Directives†, therefore applications of sulphur can be considered not to pose a risk to groundwater.

†Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. OJ L 330, 5.12.1988, pp. 32–54; and Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption. OJ L 435, 23.12.2020, pp. 1–62.

zRMS comments:
Assumed crop interceptions presented in Table 8.8-8 correspond with BBCH stages at product FHO04 is intended to be applied and is in line with indication of the FOCUS groundwater guidance (2023). It is noted that, the worst case

application pattern of 1 x 2500 g a.s./ha at BBCH 27 was considered, covering all intended uses presented in the Central Zone GAP (Table 8.1-1).

Since the sulphur is not of concern for the contamination of groundwater, but that the potential for groundwater contamination for sulphates needed to be addressed, as they are highly mobile in soil. The zRMS agrees with the worst case assumption that 100 % of sulphur applied to soil is oxidised to sulphates and 100 % of sulphates will leach to groundwater as it is in line with information presented in EFSA Scientific Report (2008) 221, 46-70.
The PECgw of sulphur and sulphate was independently validated by the zRMS in additional calculation and resulted with the same PEC_{GW} values as these obtained by the Applicant and presented in Tables 8.8-11 to 8.8-16. The correct values of water volume percolated at 1 m depth determined in each FOCUS scenario for winter and spring cereals were considered from the FOCUS models PEARL v5.5.5 and PELMO v6.6.4. The total amount of sulphur applied to soil, and the equivalence in SO_4^{2-} (1 S_8 giving 8 SO_4^{2-}) were determined for a period of 26 years, based on an application rate of 2500 kg S/ha (sulphur applied to cereals twice a year, with 20 % crop interception).

The maximum PECgw value for sulphate was obtained for the Châteaudun scenario (value of 11.097 mg/L) following application to winter cereals, indicated that the potential for groundwater contamination from sulphates is below the drinking water limit of 250 mg/L set in the Drinking Water Directive 98/83/CE.

Overall, no unacceptable leaching of sulphate is expected following application of FHO04 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.

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

Full details of the assessments for prothioconazole and sulphur can be found in the following report:

KCP 9.2.4/01, Smith (2024): E2023-51 - Predicted environmental concentrations of prothioconazole following applications on spring and winter cereals in the Central Zone.

KCP 9.2.4/02, Tilston (2024): E2023-33 - Predicted environmental concentrations of sulphur and sulphate following applications on spring and winter cereals in the Central and Southern Zones.

Multiple applications of prothioconazole to spring and winter cereals were considered for the surface water exposure assessment. The parent compound and metabolites M01, M04 and 1,2,4-triazole were assessed at Step 1-2 in accordance with the approach taken in the EFSA conclusion (2007). Only prothioconazole and M04 were included at Step 3 and Step 4.

The parent compound passed at Step 3. Step 4 mitigation was required for the metabolite M04. No-spray buffer zones and vegetated filter strips (VFS) were simulated for 5, 10, 15 and 20 m. This standard mitigation was sufficient to obtain a pass for the metabolite. However, additional modelling was performed using VFSmod to demonstrate that the width of the combined no-spray buffer and VFS could be reduced. VFSmod values are presented only for the metabolite.

No PEC_{sw} values were calculated for sulphur, as the risk assessment to aquatic organisms was based on an absence of effects on organisms at the greatest water solubility limit of sulphur (maximum determined water solubility: 63 µg/L). PEC_{sed} was calculated according to the conservative approach provided in the Sulphur Addendum to the DAR Volume 3 B5, B6 and B9 for Confirmatory Data (April 2012). See section 8.9.1.2 for further information.

8.9.1 Justification for new endpoints

All endpoints were taken from the peer review conclusion for prothioconazole (EFSA, 2007).
Substance endpoints are not required for PEC_{sed} calculations for sulphur (Confirmatory Data, 2012).

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

Use No.	1	1
Crop	Cereals – early (BBCH 27)	Cereals – late (BBCH 69)
Application rate (kg a.s./ha)	Prothioconazole: 0.2 Sulphur: 2.5	Prothioconazole: 0.2 Sulphur: 2.5
Number of applications/interval (d)	2 applications, 14 d interval	2 applications, 14 d interval
Steps 1-2		
Application timing- Northern Europe	October- February March- May June- September	Spring cereals: June-September Winter cereals: March- May June-September
Application timing- Southern Europe	October- February March- May June- September	Spring cereals: June-September Winter cereals: March- May June-September
Crop interception (Steps 1-2)	Minimal crop cover Intermediate crop cover	Full canopy
Models used for calculation	STEPS 1-2 in FOCUS v3.2	
Step 3-4		
Application method	Overall spray	Overall spray
CAM (Chemical application method)	2 (foliar spray)	2 (foliar spray)
Soil depth (cm)	4 (default)	4 (default)
Models used for calculation	STEP 3: FOCUS SWASH v5.3, FOCUS PRZM v4.6.2 FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3 STEP 4: SWAN v5.0	

The user defined application window was based on dates selected from AppDate v3.06. Step 3 modelling of prothioconazole was performed for both early application timings (BBCH 27) and late application timings (BBCH 69) to spring and winter cereals.

Table 8.9-2: FOCUS Step 3 Scenario related input parameters for $PEC_{sw/sed}$ calculations for applications to spring cereals

Crop	Scenario	Application window used in modelling	
		Early applications (BBCH 27)	**Late applications (BBCH 69)**
Spring cereals	D1	24-May- 07-Jul (144-188)	18-Jul- 31-Aug (199- 243)
	D2	Not parameterised	Not parameterised
	D3	24-Apr- 07-Jun (114-158)	28-Jun- 11-Aug (179- 223)
	D4	15-May- 28-Jun (135- 179)	09-Jul- 22-Aug (190- 234)
	D5	05-Apr- 19-May (95- 139)	04-Jun- 18-Jul (155- 199)
	D6	Not parameterised	Not parameterised
	R1	Not parameterised	Not parameterised
	R2	Not parameterised	Not parameterised
	R3	Not parameterised	Not parameterised
	R4	05-Apr- 19-May (95- 139)	04-Jun- 18-Jul (155- 199)

Julian days in parentheses
Application window 30 days + 14 day interval

Table 8.9-3: FOCUS Step 3 Scenario related input parameters for $PEC_{sw/sed}$ calculations for the applications to winter cereals

Crop	Scenario	Application window used in modelling	
		Early applications (BBCH 27)	**Late applications (BBCH 69)**
Winter cereals	D1	22-Mar- 05-May (81-125)	12-Jul- 25-Aug (193- 237)
	D2	01-Apr- 15May (91-135)	11-Jul- 24-Aug (192- 236)
	D3	13-Apr- 27-May (103- 147)	31-Jul- 13-Sep (212- 256)
	D4	15-Mar- 28-Apr (74- 118)	09-Jul- 22-Aug (190- 234)
	D5	12-Mar- 25-Apr (71- 115)	02-Jun- 16-Jul (153- 197)
	D6	28-Jan- 13-Mar (28-72)	27-Apr- 10-Jun (117- 161)
	R1	21-Apr- 04-Jun (111- 155)	25-Jun- 08-Aug (176- 220)
	R2	Not parameterised	Not parameterised
	R3	16-Mar- 29-Apr (75- 119)	26-May- 09-Jul (146- 190)
	R4	13-Jan- 26-Feb (13-57)	02-Jun- 16-Jul (153-197)

Julian days in parentheses
Application window 30 days + 14 day interval

zRMS comments:

The application pattern assumed in surface water simulations is in line with Central Zone GAP presented in Table 8.1-1. It is noted that minimal crop cover was assumed for simulations, however in line the FOCUS guidance the average crop cover is relevant for cereals at BBCH 20-39. Since crop interception used by the Applicant for surface water simulations represents worst case it is accepted by the zRMS,.
The application windows presented in Table 8.9-2 and 8.9-3 were checked by the zRMS using AppDate ver. 3.06 tool and are considered acceptable.

8.9.1.1 Prothioconazole and its metabolites

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

Compound	Prothioconazole	M01 (S-methyl)	M04 (desthio)	1,2,4-triazole	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	344.3	358.3	312.2	69.1	Y/ EFSA (2007)
Water solubility (mg/L)	22.5	4.6	50.6	700000	Y/ EFSA (2007)
K_{foc} (mL/g)	1765 (column leaching)	2556.3 (arithmetic mean, n=4)	575.4 (arithmetic mean, n=4)	89 (arithmetic mean, n=4)*	Y/ EFSA (2007)
$DT_{50,soil}$ (d)	1.2 (geomean, field)	15.7 (geomean, lab)	22.7 (geomean, field)	1000 (default)	Y/ EFSA (2007)
$DT_{50,water}$ (d)	39.5 (whole system) (correct value from LoEP: 1.0 d)	1000 (default)	1000 (default)	1000 (default)	Y/ EFSA (2007)
$DT_{50,sed}$ (d)	39.5 (whole system) (correct value from LoEP: 1.0 d)	1000 (default)	1000 (default)	1000 (default)	Y/ EFSA (2007)
$DT_{50,whole\ system}$ (d)	39.5 (whole system) (correct value from LoEP: 1.0 d)	1000 (default)	1000 (default)	1000 (default)	Y/ EFSA (2007)
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil:14.6 ~~Water/ Sediment: N/O~~ 12.7 (aerobic in whole system) 77 (anaerobic in sediment)	Soil:57.1 Water/ Sediment:~~59.2~~ 54.6	Soil: 2 Water/ Sediment:37.2	Y/ EFSA (2007)

* Value agreed following the discussion on triazole derivate metabolites during the experts' meeting PRAPeR 12 on fate and behaviour in January 2007.
N/O= not observed

FOCUS surface water guidance (2015, v1.4) recommends that substances with a K_{OC} value <100 mL/g are modelled with the whole system DT_{50} assigned to the water compartment and the default DT_{50} of 1000 days assigned to the sediment compartment. It also recommends that for substances with a K_{OC} >2000 mL/g the whole system DT_{50} is assigned to the sediment compartment and the default DT_{50} assigned to the water compartment. The recommended 'rule of thumb' for substances with a K_{OC} >100 mL/g but <2000 mL/g is that simulations are run both ways and the most conservative results are selected for the risk assessment.

The K_{OC} of prothioconazole is 1765 mL/g and so simulations were run both ways in preliminary investigations, assigning the whole system DT_{50} and the default 1000 day DT_{50} to each compartment in turn. The simulations ran using the default DT_{50} assigned to the water compartment generated marginally higher PEC_{sw} results. The full risk assessment was undertaken using DT_{50} 1000 days for the water compartment.

Table 8.9-5: Input parameters related to active substance prothioconazole and metabolite M04 (prothioconazole-desthio) for $PEC_{sw/sed}$ calculations STEP 3/4

Compound	Prothioconazole	M04 (desthio)	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	344.3	312.2	Y/ EFSA (2007)
Saturated vapour pressure (Pa)	4×10^{-7} (20 °C)	1×10^{-10} (20 °C)	Y/ EFSA (2007)
Water solubility (mg/L)	22.5 (20 °C)	50.6 (20 °C)	Y/ EFSA (2007)
Molar enthalpy of vaporisation (kJ mol-1)	95	95	FOCUS default
Molar enthalpy of dissolution (kJ mol-1)	27	27	FOCUS default
Diffusion coefficient in water (m²/d)	4.3×10^{-5}	4.3×10^{-5}	FOCUS default
Diffusion coefficient in air (m²/d)	0.43	0.43	FOCUS default
K_{foc} (mL/g)	1765 (column leaching)	575.4 (arithmetic mean, n=4)	Y/ EFSA (2007)
K_{fom} (mL/g)	1023.8	333.8	K_{foc}/1.724
Freundlich Exponent 1/n	0.9 (default)	0.81 (arithmetic mean)	Y/ EFSA (2007)
Plant Uptake	0	0	FOCUS default
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	0.05 (MACRO) 0.50 (PRZM)	FOCUS default
$DT_{50,soil}$ (d)	1.2 (geomean, field)	22.7 (geomean, field)	Y/ EFSA (2007)
$DT_{50,water}$ (d) *	~~1000 *~~ (value from LoEP: 1.0 d)	1000 (default)	Y/ EFSA (2007)
$DT_{50,sed}$ (d) *	1000* ~~39.5 *~~	49.9* ~~1000 (default)~~	Y/ EFSA (2007)
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 57.1 Water: 32.2 Sediment: 26.9	Y/ EFSA (2007)

* K_{OC}>100 mL/g and <2000 mL/g so each compartment was run using the whole system DT_{50} and the default DT_{50} 1000 days. The results giving the highest concetrations are presented. See FOCUS Surface Water Generic Guidance 'rule of thumb' (2015, v1.4).

FOCUS Step 1-2 $PEC_{sw/sed}$ prothioconazole and its metabolites

Early applications

Table 8.9-6: FOCUS Step 1-2 PEC_{sw} for prothioconazole and its metabolites following multiple applications to spring cereals (BBCH 27)

FOCUS PEC_{sw} (µg/L)	Spring cereals scenario	Prothioconazole	M01 (S-methyl)	M04 (desthio)	1,2,4-triazole
Step 1		43.44	9.16 ~~4.60~~	81.54	10.38 ~~9.65~~
Step 2					
NEU	Oct- Feb	2.12	1.48	16.43	0.68
	Mar-May	2.12	0.64 ~~0.59~~	7.26	0.41
	June-Sept	2.12	0.64 ~~0.59~~	7.26	0.41
SEU	Oct-Feb	2.12	1.19	13.37	0.59
	Mar-May	2.12	1.19	13.37	0.59
	June-Sept	2.12	0.89	10.32	0.50

Table 8.9-7: FOCUS Step 1-2 PEC_{sed} for prothioconazole and its metabolites following multiple applications to spring cereals (BBCH 27)

FOCUS PEC_{sed} (µg/kg)	Spring cereals scenario	Prothioconazole	M01 (S-methyl)	M04 (desthio)	1,2,4-triazole
Step 1		708.61	221.72 ~~117.47~~	463.93	8.85 ~~8.56~~
Step 2					
NEU	Oct- Feb	31.07	37.88	93.52	0.60
	Mar-May	20.81	15.35 ~~15.15~~	40.79	0.35
	June-Sept	20.81	15.35 ~~15.15~~	40.79	0.35
SEU	Oct-Feb	27.65	30.30	75.95	0.52
	Mar-May	27.65	30.30	75.95	0.52
	June-Sept	24.23	22.73	58.37	0.44

Table 8.9-8: FOCUS Step 1-2 PEC_{sw} for prothioconazole and its metabolites following multiple applications to winter cereals (BBCH 27)

FOCUS PEC_{sw} (µg/L)	Winter cereals scenario	Prothioconazole	M01 (S-methyl)	M04 (desthio)	1,2,4-triazole
Step 1		43.44	9.16 ~~4.60~~	81.54	10.38 ~~9.65~~
Step 2					
NEU	Oct- Feb	2.12	1.48	16.43	0.68
	Mar-May	2.12	0.64 ~~0.59~~	7.26	0.41
	June-Sept	2.12	0.64 ~~0.59~~	7.26	0.41
SEU	Oct-Feb	2.12	1.19	13.37	0.59
	Mar-May	2.12	1.19	13.37	0.59
	June-Sept	2.12	0.89	10.32	0.50

Table 8.9-9: FOCUS Step 1-2 PEC_{sed} for prothioconazole and its metabolites following multiple applications to winter cereals (BBCH 27)

FOCUS PEC_{sed} (µg/kg)	Winter cereals scenario	Prothioconazole	M01 (S-methyl)	M04 (desthio)	1,2,4-triazole
Step 1		708.61	221.72 ~~117.47~~	463.93	8.85 ~~8.56~~
Step 2					
NEU	Oct- Feb	31.07	37.88	93.52	0.60
	Mar-May	20.81	15.35 ~~15.15~~	40.79	0.35
	June-Sept	20.81	15.35 ~~15.15~~	40.79	0.35
SEU	Oct-Feb	27.65	30.30	75.95	0.52
	Mar-May	27.65	30.30	75.95	0.52
	June-Sept	24.23	22.73	58.37	0.44

Late applications

Table 8.9-10: FOCUS Step 1-2 PEC_{sw} for prothioconazole and its metabolites following multiple applications to spring cereals- late (BBCH 69)

FOCUS PEC_{sw} (µg/L)	Spring cereals scenario	Prothioconazole	M01 (S-methyl)	M04 (desthio)	1,2,4-triazole
Step 1		43.44	9.16 ~~4.60~~	81.54	10.38 ~~9.65~~
Step 2	NEU June-Sept	2.12	0.32 ~~0.18~~	2.98	0.28
	SEU June-Sept	2.12	0.42 ~~0.27~~	3.90	0.31

Table 8.9-11: FOCUS Step 1-2 PEC_{sed} for prothioconazole and its metabolites following multiple applications to spring cereals- late (BBCH 69)

FOCUS PEC_{sed} (µg/kg)	Spring cereals scenario	Prothioconazole	M01 (S-methyl)	M04 (desthio)	1,2,4-triazole
Step 1		708.61	221.72 ~~117.47~~	463.93	8.85 ~~8.56~~
Step 2	NEU June-Sept	16.02	7.30 ~~4.55~~	16.18	0.24
	SEU June-Sept	17.05	9.71 ~~6.82~~	21.45	0.26

Table 8.9-12: FOCUS Step 1-2 PEC_{sw} for prothioconazole and its metabolites following multiple applications to winter cereals- late (BBCH 69)

FOCUS PEC_{sw} (µg/L)	Winter cereals scenario	Prothioconazole	M01 (S-methyl)	M04 (desthio)	1,2,4-triazole
Step 1		43.44	9.16 ~~4.60~~	81.54	10.38 ~~9.65~~
Step 2	NEU Mar-May	2.12	0.32 ~~0.18~~	2.98	0.28
	NEU June-Sept	2.12	0.32 ~~0.18~~	2.98	0.28
	SEU Mar-May	2.12	0.51 ~~0.36~~	4.81	0.33
	SEU June-Sept	2.12	0.42 ~~0.27~~	3.90	0.31

Table 8.9-13: FOCUS Step 1-2 PEC_{sed} for prothioconazole and its metabolites following multiple applications to winter cereals- late (BBCH 69)

FOCUS PEC_{sed} (µg/kg)	Winter cereals scenario	Prothioconazole	M01 (S-methyl)	M04 (desthio)	1,2,4-triazole
Step 1		708.61	221.72 ~~117.47~~	463.93	10.38 ~~9.65~~
Step 2	NEU Mar-May	16.02	7.30 ~~4.55~~	16.18	0.24
	NEU June-Sept	16.02	7.30 ~~4.55~~	16.18	0.24
	SEU Mar-May	18.07	12.13 ~~9.09~~	26.73	0.29
	SEU June-Sept	17.05	9.71 ~~6.82~~	21.45	0.26

FOCUS Step 3 $PEC_{sw/sed}$ prothioconazole- early applications

Table 8.9-14: FOCUS Step 3 PEC_{sw} and PEC_{sed} for prothioconazole following multiple applications of 2x 200 g a.s./ha to spring cereals (BBCH 27)

Scenario FOCUS	Waterbody	Application date chosen by model	Date of max PEC_{sw}	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
~~D1~~	~~ditch~~	~~17-Jun/ 02-Jul~~	~~02-Jul~~	~~1.693~~	~~Drift~~	~~6.676~~
~~D1~~	~~stream~~	~~17-Jun/ 02-Jul~~	~~02-Jul~~	~~0.968~~	~~Drift~~	~~0.716~~
D3	ditch	23-Apr/ 14-May	14-May	1.268* 1.106	Drift	0.916
D4	pond	30-May/ 16-Jun	16-Jun	0.061	Drift	0.398
D4	stream	30-May/ 16-Jun	16-Jun	1.037* 0.923	Drift	0.123
D5	pond	08-Apr/ 22-Apr	22-Apr	0.062	Drift	0.424
D5	stream	08-Apr/ 22-Apr	22-Apr	1.007* 0.951	Drift	0.066
R4	stream	04-May/ 19-May	04-May	0.838* 0.723	Drift	1.159

* value correspond to single application

Table 8.9-15: FOCUS Step 3 PEC_{sw} and PEC_{sed} for prothioconazole following multiple applications of 2x 200 g a.s./ha to winter cereals (BBCH 27)

Scenario FOCUS	Waterbody	Application date chosen by model	Date of max PEC_{sw}	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
~~D1~~	~~Ditch~~	~~29-Mar/ 25-Apr~~	~~25-Apr~~	~~1.119~~	~~Drift~~	~~3.271~~
~~D1~~	~~Stream~~	~~29-Mar/ 25-Apr~~	~~25-Apr~~	~~0.942~~	~~Drift~~	~~0.183~~
~~D2~~	~~Ditch~~	~~01-Apr/ 07-May~~	~~07-May~~	~~1.126~~	~~Drift~~	~~3.156~~
~~D2~~	~~Stream~~	~~01-Apr/ 07-May~~	~~07-May~~	~~0.978~~	~~Drift~~	~~2.340~~
D3	Ditch	20-Apr/ 04-May	04-May	1.267* 1.107	Drift	0.952
D4	Pond	19-Mar/ 18-Apr	18-Apr	0.056	Drift	0.421
D4	Stream	19-Mar/ 18-Apr	18-Apr	0.936* 0.835	Drift	0.035
D5	Pond	08-Apr/ 22-Apr	22-Apr	0.062	Drift	0.431
D5	Stream	08-Apr/ 22-Apr	22-Apr	1.011* 0.964	Drift	0.080
D6	Ditch	27-Feb/ 13-Mar	13-Mar	1.111	Drift	1.342
R1	Pond	26-Apr/ 10-May	10-May	0.062	Drift	0.430
R1	Stream	26-Apr/ 10-May	26-Apr	0.835* 0.720	Drift	0.360
R3	Stream	28-Mar/ 11-Apr	11-Apr	1.173* 1.018	Drift	0.990

Scenario FOCUS	Waterbody	Application date chosen by model	Date of max PEC_{sw}	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
R4	Stream	21-Jan/ 04-Feb	04-Feb	0.827* 0.723	Drift	0.138

* value correspond to single application

FOCUS Step 4 prothioconazole- early applications

Step 4 mitigation was applied using SWAN v5.0. Appropriate mitigation measures for the Central Zone were applied: 5, 10, 15 and 20 m no-spray buffer zones and for relevant R scenarios, 5, 10, 15 and 20 m vegetative filter strips (VFS) were applied to address exposure via runoff.

Table 8.9-16: Global maximum Step 4 PEC_{sw} values for prothioconazole, following multiple applications of 2x 200 g a.s./ha to spring cereals (BBCH 27)

STEP 4	Scenario	Max PEC_{sw} (µg/L) prothioconazole								
Nozzle reduction	Vegetative filter strip (m)	None	None	None	None	None	~~5~~	10	~~15~~	20
	No spray buffer (m)	None	5	10	15	20	~~5~~	10	~~15~~	20
~~None~~	~~D1 Ditch~~	~~1.693~~	~~0.434~~	~~0.224~~	~~0.151~~	~~0.113~~	-	-	-	-
~~None~~	~~D1 Stream~~	~~0.968~~	~~0.342~~	~~0.178~~	~~0.120~~	~~0.090~~	-	-	-	-
None	D3 Ditch	1.106	0.287	0.149	0.101	0.076	-	-	-	-
None	D4 Pond	0.061	0.053	0.037	0.029	0.025	-	-	-	-
None	D4 Stream	0.923	0.326	0.169	0.114	0.086	-	-	-	-
None	D5 Pond	0.062	0.054	0.038	0.030	0.025	-	-	-	-
None	D5 Stream	0.951	0.336	0.174	0.118	0.089	-	-	-	-
None	R4 Stream	0.723	0.492	0.492	0.492	0.492	~~0.318~~	0.221	~~0.169~~	0.115

Table 8.9-17: Global maximum Step 4 PEC_{sw} values for prothioconazole, following multiple applications of 2x 200 g a.s./ha to winter cereals (BBCH 27)

STEP 4	Scenario	Max PEC_{sw} (µg/L) prothioconazole								
Nozzle reduction	Vegetative filter strip (m)	None	None	None	None	None	~~5~~	10	~~15~~	20
	No spray buffer (m)	None	5	10	15	20	~~5~~	10	~~15~~	20
~~None~~	~~D1 Ditch~~	~~1.119~~	~~0.290~~	~~0.151~~	~~0.102~~	~~0.077~~	-	-	-	-
~~None~~	~~D1 Stream~~	~~0.942~~	~~0.333~~	~~0.173~~	~~0.117~~	~~0.088~~	-	-	-	-
~~None~~	~~D2 Ditch~~	~~1.126~~	~~0.292~~	~~0.152~~	~~0.102~~	~~0.077~~	-	-	-	-
~~None~~	~~D2 Stream~~	~~0.978~~	~~0.346~~	~~0.179~~	~~0.121~~	~~0.091~~	-	-	-	-
None	D3 Ditch	1.107	0.287	0.149	0.101	0.076	-	-	-	-
None	D4 Pond	0.056	0.048	0.034	0.027	0.022	-	-	-	-
None	D4 Stream	0.835	0.295	0.153	0.103	0.078	-	-	-	-
None	D5 Pond	0.062	0.054	0.038	0.030	0.025	-	-	-	-
None	D5 Stream	0.964	0.341	0.177	0.119	0.090	-	-	-	-
~~None~~	~~D6 Ditch~~	~~1.111~~	~~0.288~~	~~0.150~~	~~0.101~~	~~0.076~~	-	-	-	-
None	R1 Pond	0.062	0.053	0.038	0.031	0.027	~~0.053~~	0.038	~~0.030~~	0.025
None	R1 Stream	0.720	0.254	0.194	0.194	0.194	~~0.254~~	0.132	~~0.089~~	0.067
None	R3 Stream	1.018	0.360	0.240	0.240	0.240	~~0.360~~	0.187	~~0.126~~	0.095
None	R4 Stream	0.723	0.256	0.133	0.089	0.067	~~0.256~~	0.133	~~0.089~~	0.067

Metabolite(s) of prothioconazole- early applications

FOCUS Step 3 metabolite- prothioconazole-desthio (M04)

Table 8.9-18: FOCUS Step 3 PEC_{sw} and PEC_{sed} for M04 (prothioconazole-desthio) following multiple applications of 2x 200 g a.s./ha to spring cereals (BBCH 27)

Scenario FOCUS	Waterbody	Application date chosen by model	Date of max PEC_{sw}	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
~~D1~~	~~ditch~~	~~17-Jun/ 02-Jul~~	~~20-Dec~~	~~0.033~~	~~Drainage~~	~~1.012~~
~~D1~~	~~stream~~	~~17-Jun/ 02-Jul~~	~~20-Dec~~	~~0.021~~	~~Drainage~~	~~0.279~~
D3	ditch	23-Apr/ 14-May	15-May	0.069 ~~<0.001~~	Drainage	0.073 ~~0.043~~
D4	pond	30-May/ 16-Jun	09-Dec	0.015 ~~0.004~~	Drainage	0.125 ~~0.110~~
D4	stream	30-May/ 16-Jun	07-Dec	0.041 ~~0.011~~	Drainage	0.013
D5	pond	08-Apr/ 22-Apr	19-Nov	0.015 0.002	Drainage	0.130
D5	stream	08-Apr/ 22-Apr	24-Jan	0.044 ~~0.001~~	Drainage	0.002
R4	stream	04-May/ 19-May	25-May	**1.061** ~~0.943~~	Runoff/ erosion	1.249 ~~1.182~~

Values in bold exceed the aquatic RAC of 0.334 µg/L (*Oncorhynchus mykiss*, fish prolonged)

Table 8.9-19: FOCUS Step 3 PEC_{sw} and PEC_{sed} for M04 (prothioconazole-desthio) following multiple applications of 2x 200 g a.s./ha to winter cereals (BBCH 27)

Scenario FOCUS	Waterbody	Application date chosen by model	Date of max PEC_{sw}	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
~~D1~~	~~Ditch~~	~~29-Mar/ 25-Apr~~	~~20-Dec~~	~~0.014~~	~~Drainage~~	~~0.310~~
~~D1~~	~~Stream~~	~~29-Mar/ 25-Apr~~	~~20-Dec~~	~~0.009~~	~~Drainage~~	~~0.087~~
~~D2~~	~~Ditch~~	~~01-Apr/ 07-May~~	~~01-Jan~~	~~0.102~~	~~Drainage~~	~~0.358~~
~~D2~~	~~Stream~~	~~01-Apr/ 07-May~~	~~01-Jan~~	~~0.064~~	~~Drainage~~	~~0.168~~
D3	Ditch	20-Apr/ 04-May	05-May	0.068 ~~<0.001~~	Drainage	0.072 ~~0.041~~
D4	Pond	19-Mar/ 18-Apr	09-Dec	0.012 ~~0.003~~	Drainage	0.124 ~~0.112~~
D4	Stream	19-Mar/ 18-Apr	07-Dec	0.032 ~~0.008~~	Drainage	0.008
D5	Pond	08-Apr/ 22-Apr	19-Nov	0.015 ~~0.002~~	Drainage	0.132
D5	Stream	08-Apr/ 22-Apr	24-Jan	0.046 ~~0.001~~	Drainage	0.003
D6	Ditch	27-Feb/ 13-Mar	19-Jan	<0.001	Drainage	0.057
R1	Pond	26-Apr/ 10-May	21-Jun	0.115 ~~0.105~~	Runoff/ erosion	1.066
R1	Stream	26-Apr/ 10-May	20-May	**1.023** ~~0.997~~	Runoff/ erosion	1.055
R3	Stream	28-Mar/ 11-Apr	20-Apr	**0.883** ~~0.818~~	Runoff/ erosion	1.075 ~~1.034~~
R4	Stream	21-Jan/ 04-Feb	19-Mar	**1.341**	Runoff/ erosion	0.757

Values in bold exceed the aquatic RAC of 0.334 µg/L (*Oncorhynchus mykiss*, fish prolonged)

FOCUS Step 4 metabolites- early applications

VFSmod was additionally performed to demonstrate that the width of the buffer and VFS could be reduced. This refinement is relevant for the R scenarios as it addresses the runoff route of exposure. VFSmod results are presented for the metabolite only as the parent compound did not require mitigation to pass.

Table 8.9-20: Global maximum Step 4 PEC$_{sw}$ values for M04 (prothioconazole-desthio), following multiple applications of 2x 200 g a.s./ha to spring cereals (BBCH 27)

STEP 4	Scenario	Max PEC$_{sw}$ (µg/L) prothioconazole-desthio								
Nozzle reduction	Vegetative filter strip (m)	None	None	None	None	None	~~5~~	10	~~15~~	20
	No spray buffer (m)	None	5	10	15	20	~~5~~	10	~~15~~	20
~~None~~	~~D1 Ditch~~	~~0.033~~	~~0.033~~	~~0.033~~	~~0.033~~	~~0.033~~	-	-	-	-
~~None~~	~~D1 Stream~~	~~0.021~~	~~0.021~~	~~0.021~~	~~0.021~~	~~0.021~~	-	-	-	-
~~None~~	~~D3 Ditch~~	~~<0.001~~	~~<0.001~~	~~<0.001~~	~~<0.001~~	~~<0001~~	-	-	-	-
~~None~~	~~D4 Pond~~	~~0.004~~	~~0.003~~	~~0.003~~	~~0.003~~	~~0.003~~	-	-	-	-
~~None~~	~~D4 Stream~~	~~0.011~~	~~0.011~~	~~0.011~~	~~0.011~~	~~0.011~~	-	-	-	-
~~None~~	~~D5 Pond~~	~~0.002~~	~~0.002~~	~~0.001~~	~~0.001~~	~~0.001~~	-	-	-	-
~~None~~	~~D5 Stream~~	~~0.001~~	~~0.001~~	~~0.001~~	~~0.001~~	~~0.001~~	-	-	-	-
None	R4 Stream	**1.063** ~~**0.943**~~	**1.063** ~~**0.943**~~	**1.063** ~~**0.943**~~	**1.063** ~~**0.943**~~	**1.063** ~~**0.943**~~	~~**0.610**~~	**0.477** ~~**0.423**~~	~~0.324~~	0.188 ~~0.221~~
VFSmod refinement										
Nozzle reduction	VFSmod (m)	-	-	-	-	-	5	10	~~15~~	~~20~~
	No spray buffer (m)	-	-	-	-	-	5	10	~~15~~	~~20~~
None	R4 Stream	-	-	-	-	-	0.162 ~~0.146~~	0.059 ~~0.053~~	~~0.008~~	~~0.005~~

Values in bold exceed the aquatic RAC of 0.334 µg/L (*Oncorhynchus mykiss*, fish prolonged)

Table 8.9-21: Global maximum Step 4 PEC$_{sw}$ values for M04 (prothioconazole-desthio), following multiple applications of 2x 200 g a.s./ha to winter cereals (BBCH 27)

STEP 4	Scenario	Max PEC$_{sw}$ (µg/L) prothioconazole-desthio								
Nozzle reduction	Vegetative filter strip (m)	None	None	None	None	None	~~5~~	10	~~15~~	20
	No spray buffer (m)	None	5	10	15	20	~~5~~	10	~~15~~	20
~~None~~	~~D1 Ditch~~	~~0.014~~	~~0.014~~	~~0.014~~	~~0.014~~	~~0.014~~	-	-	-	-
~~None~~	~~D1 Stream~~	~~0.009~~	~~0.009~~	~~0.009~~	~~0.009~~	~~0.009~~	-	-	-	-
~~None~~	~~D2 Ditch~~	~~0.102~~	~~0.102~~	~~0.102~~	~~0.102~~	~~0.102~~	-	-	-	-
~~None~~	~~D2 Stream~~	~~0.064~~	~~0.064~~	~~0.064~~	~~0.064~~	~~0.064~~	-	-	-	-
~~None~~	~~D3 Ditch~~	~~<0.001~~	~~<0.001~~	~~<0.001~~	~~<0.001~~	~~<0.001~~	-	-	-	-
~~None~~	~~D4 Pond~~	~~0.003~~	~~0.003~~	~~0.003~~	~~0.002~~	~~0.002~~	-	-	-	-
~~None~~	~~D4 Stream~~	~~0.008~~	~~0.008~~	~~0.008~~	~~0.008~~	~~0.008~~	-	-	-	-
~~None~~	~~D5 Pond~~	~~0.002~~	~~0.002~~	~~0.001~~	~~0.001~~	~~0.001~~	-	-	-	-
~~None~~	~~D5 Stream~~	~~0.001~~	~~0.001~~	~~0.001~~	~~0.001~~	~~0.001~~	-	-	-	-
~~None~~	~~D6 Ditch~~	~~<0.001~~	~~<0.001~~	~~<0.001~~	~~<0.001~~	~~<0.001~~	-	-	-	-
None	R1 Pond	0.115 ~~0.105~~	0.115 ~~0.105~~	0.115 ~~0.105~~	0.115 ~~0.105~~	0.115 ~~0.105~~	~~0.063~~	0.048 ~~0.042~~	~~0.032~~	~~0.021~~
None	R1 Stream	**1.023** ~~**0.997**~~	**1.023** ~~**0.997**~~	**1.023** ~~**0.997**~~	**1.023** ~~**0.997**~~	**1.023** ~~**0.997**~~	~~**0.650**~~	**0.464** **0.453**	~~**0.347**~~	0.244 ~~0.237~~
None	R3 Stream	**0.883** ~~**0.818**~~	**0.883** ~~**0.818**~~	**0.883** ~~**0.818**~~	**0.883** ~~**0.818**~~	**0.883** ~~**0.818**~~	~~**0.535**~~	**0.403** ~~**0.373**~~	~~0.287~~	0.212 ~~0.196~~
None	R4 Stream	**1.341**	**1.341**	**1.341**	**1.341**	**1.341**	~~**0.875**~~	**0.610**	~~**0.468**~~	0.320
VFSmod refinement										
Nozzle reduction	VFSmod (m)	-	-	-	-	-	5	10	~~15~~	~~20~~
	No spray buffer (m)	-	-	-	-	-	5	10	~~15~~	~~20~~
~~None~~	~~R1 Pond~~	-	-	-	-	-	~~0.008~~	~~0.001~~	~~0.001~~	~~0.001~~

None	R1 Stream	-	-	-	-	-	0.072	<0.001	~~<0.001~~	~~<0.001~~
None	R3 Stream	-	-	-	-	-	**0.368** ~~0.343~~	0.231 ~~0.216~~	~~0.149~~	~~<0.001~~
None	R4 Stream	-	-	-	-	-	0.151	0.052	~~<0.001~~	~~<0.001~~

Values in bold exceed the aquatic RAC of 0.334 µg/L (*Oncorhynchus mykiss*, fish prolonged)

The risk to the surface water environment was adequately addressed for the parent compound at Step 3. However, prothioconazole-desthio (M04) failed several scenarios at Step 3, including one for spring cereals (R4 stream) and three for winter cereals (R1 stream, R3 stream and R4 stream). PEC_{sw} exceeded the aquatic RAC of 0.334 µg/L (*Oncorhynchus mykiss*, fish prolonged). Therefore, appropriate mitigation measures were simulated to assess if the risk could be reduced.

The M04 metabolite failed a single scenario at step 3 for **spring cereals** (R4 stream) for applications at 2x 200 g a.s./ha, BBCH 27. The maximum step 3 PEC_{sw} values was 1.063 ~~0.943~~ µg/L, with entry to the water body predominantly through runoff and erosion. This was adequately addressed at Step 4 with the application of a 20m ~~15 m~~ combined buffer zone and VFS.

M04 failed three scenarios for **winter cereals**, BBCH 27: R1 stream, R3 stream and R4 stream with maximum PEC_{sw} values of 1.023, 0.883, ~~0.997, 0.818~~ and 1.341 µg/L respectively. Exposure was driven by runoff and erosion and therefore VFS mitigation was applied. A 20m ~~15 m~~ combined buffer zone and VFS was necessary for R3 stream, ~~and a 20 m VFS~~ for R1 stream and R4 stream.

The **VFSmod refinement** demonstrates that 5 m mitigation is adequate for the spring cereals R4 stream scenario. Furthermore, mitigation for winter cereals can be reduced from 20 m to 10 m overall. Using VFSmod, the R1 and R4 scenarios can be addressed with 5 m mitigation. The R3 scenario requires 10 m.

The following step 3-4 values are presented for prothioconazole and its metabolite for late applications to BBCH 69.

FOCUS Step 3 $PEC_{sw/sed}$ prothioconazole-late applications

Table 8.9-22: FOCUS Step 3 PEC_{sw} and PEC_{sed} for prothioconazole following multiple applications of 2x 200 g a.s./ha to spring cereals (BBCH 69)

Scenario FOCUS	Waterbody	Application date chosen by model	Date of max PEC_{sw}	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
~~D1~~	~~ditch~~	~~04-Aug/ 28-Aug~~	~~28-Aug~~	~~1.551~~	~~Drift~~	~~6.722~~
~~D1~~	~~stream~~	~~04-Aug/ 28-Aug~~	~~28-Aug~~	~~0.968~~	~~Drift~~	~~0.663~~
D3	ditch	28-Jun/ 24-Jul	24-Jul	1.271 1.110	Drift	1.181
D4	pond	11-Jul/ 25-Jul	25-Jul	0.063	Drift	0.408
D4	stream	11-Jul/ 25-Jul	25-Jul	1.096 0.946	Drift	0.254
D5	pond	09-Jun/ 25-Jun	25-Jul	0.062	Drift	0.404
D5	stream	09-Jun/ 25-Jun	25-Jun	1.183 1.020	Drift	0.348
R4	stream	04-Jun/ 18-Jun	18-Jun	0.838 0.723	Drift	0.144

* value correspond to single application

Table 8.9-23: FOCUS Step 3 PEC$_{sw}$ and PEC$_{sed}$ for prothioconazole following multiple applications of 2x 200 g a.s./ha to winter cereals (BBCH 69)

Scenario FOCUS	Waterbody	Application date chosen by model	Date of max PEC$_{sw}$	Max PEC$_{sw}$ (µg/L)	Dominant entry route	Max PEC$_{sed}$ (µg/kg)
~~D1~~	~~Ditch~~	~~04-Aug/ 18-Aug~~	~~18-Aug~~	~~1.704~~	~~Drift~~	~~6.861~~
~~D1~~	~~Stream~~	~~04-Aug/ 18-Aug~~	~~18-Aug~~	~~0.968~~	~~Drift~~	~~0.717~~
~~D2~~	~~Ditch~~	~~20-Jul/ 06-Aug~~	~~06-Aug~~	~~1.683~~	~~Drift~~	~~7.333~~
~~D2~~	~~Stream~~	~~20-Jul/ 06-Aug~~	~~06-Aug~~	~~1.463~~	~~Drift~~	~~6.131~~
D3	Ditch	04-Aug/ 18-Aug	18-Aug	1.273* 1.114	Drift	1.477
D4	Pond	11-Jul/ 25-Jul	25-Jul	0.063	Drift	0.415
D4	Stream	11-Jul/ 25-Jul	25-Jul	1.096* 0.946	Drift	0.254
D5	Pond	09-Jun/ 25-Jun	25-Jun	0.062	Drift	0.404
D5	Stream	09-Jun/ 25-Jun	25-Jun	1.183* 1.020	Drift	0.348
~~D6~~	~~Ditch~~	~~27-Apr/ 12-May~~	~~12-May~~	~~1.202~~	~~Drift~~	~~3.575~~
R1	Pond	29-Jun/ 13-Jul	18-Jul	0.082	Runoff/ erosion	0.560
R1	Stream	29-Jun/ 13-Jul	29-Jun	0.839* 0.723	Runoff/ erosion	1.619
R3	Stream	01-Jun/ 16-Jun	16-Jun	1.182* 1.020	Drift	0.338
R4	Stream	03-Jun/ 17-Jun	17-Jun	0.838* 0.723	Drift	0.144

* value correspond to single application

FOCUS Step 4 prothioconazole- late applications

Step 4 mitigation was applied using SWAN v5.0. Appropriate mitigation measures for the Central Zone were applied: 5, 10, 15 and 20 m no-spray buffer zones and for relevant R scenarios, 5, 10, 15 and 20 m vegetative filter strips (VFS) were applied to address exposure via runoff.

Table 8.9-24: Global maximum Step 4 PEC$_{sw}$ values for prothioconazole, following multiple applications of 2x 200 g a.s./ha to spring cereals (BBCH 69)

STEP 4	Scenario	Max PEC$_{sw}$ (µg/L) prothioconazole								
Nozzle reduction	Vegetative filter strip (m)	None	None	None	None	None	5	10	15	20
	No spray buffer (m)	None	5	10	15	20	5	10	15	20
None	D1 Ditch	1.551	0.398	0.205	0.138	0.104	-	-	-	-
None	D1 Stream	0.968	0.342	0.178	0.120	0.090	-	-	-	-
None	D3 Ditch	1.110	0.288	0.150	0.101	0.076	-	-	-	-
None	D4 Pond	0.063	0.054	0.038	0.030	0.025	-	-	-	-
None	D4 Stream	0.946	0.334	0.173	0.117	0.088	-	-	-	-
None	D5 Pond	0.062	0.054	0.038	0.030	0.025	-	-	-	-
None	D5 Stream	1.020	0.361	0.187	0.126	0.095	-	-	-	-
None	R4 Stream	0.723	0.256	0.133	0.089	0.067	0.256	0.133	0.089	0.067

Table 8.9-25: Global maximum Step 4 PEC_{sw} values for prothioconazole, following multiple applications of 2x 200 g a.s./ha to winter cereals (BBCH 69)

STEP 4	Scenario	Max PEC_{sw} (µg/L) prothioconazole								
Nozzle reduction	Vegetative filter strip (m)	None	None	None	None	None	5	10	15	20
	No spray buffer (m)	None	5	10	15	20	5	10	15	20
None	D1 Ditch	1.704	0.437	0.226	0.152	0.114	-	-	-	-
None	D1 Stream	0.968	0.342	0.178	0.120	0.090	-	-	-	-
None	D2 Ditch	1.683	0.431	0.223	0.149	0.112	-	-	-	-
None	D2 Stream	1.463	0.512	0.264	0.178	0.134	-	-	-	-
None	D3 Ditch	1.114	0.289	0.150	0.101	0.076	-	-	-	-
None	D4 Pond	0.063	0.054	0.038	0.030	0.025	-	-	-	-
None	D4 Stream	0.946	0.334	0.173	0.117	0.088	-	-	-	-
None	D5 Pond	0.062	0.054	0.038	0.030	0.025	-	-	-	-
None	D5 Stream	1.020	0.361	0.187	0.126	0.095	-	-	-	-
None	D6 Ditch	1.202	0.312	0.162	0.109	0.082	-	-	-	-
None	R1 Pond	0.082	0.075	0.062	0.055	0.050	0.065	0.046	0.036	0.029
None	R1 Stream	0.723	0.256	0.221	0.221	0.221	0.256	0.133	0.089	0.067
None	R3 Stream	1.020	0.360	0.187	0.126	0.095	0.360	0.187	0.126	0.095
None	R4 Stream	0.723	0.256	0.133	0.089	0.067	0.256	0.133	0.089	0.067

Metabolite(s) of prothioconazole- late applications

FOCUS Step 3 metabolite- prothioconazole-desthio (M04)

Table 8.9-26: FOCUS Step 3 PEC_{sw} and PEC_{sed} for M04 (prothioconazole-desthio) following multiple applications of 2x 200 g a.s./ha to spring cereals (BBCH 69)

Scenario FOCUS	Waterbody	Application date chosen by model	Date of max PEC_{sw}	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
~~D1~~	~~ditch~~	~~04-Aug/ 28-Aug~~	~~22-Sep~~	~~0.017~~	~~Drainage~~	~~0.516~~
~~D1~~	~~stream~~	~~04-Aug/ 28-Aug~~	~~28-Aug~~	~~<0.001~~	~~Drift~~	~~0.022~~
D3	ditch	28-Jun/ 24-Jul	25-Jul	0.116 ~~<0.001~~	Drainage	0.160 ~~0.062~~
D4	pond	11-Jul/ 25-Jul	10-Dec	0.013	Drainage	0.166
D4	stream	11-Jul/ 25-Jul	07-Dec	0.053 ~~0.050~~	Drainage	0.056
D5	pond	09-Jun/ 25-Jun	25-Dec	0.016 ~~0.002~~	Drainage	0.129 ~~0.118~~
D5	stream	09-Jun/ 25-Jun	24-Jan	0.067 ~~0.002~~	Drainage	0.028 ~~0.014~~
R4	stream	04-Jun/ 18-Jun	05-Aug	**0.640** ~~0.202~~	Runoff/ erosion	0.373 ~~0.150~~

Values in bold exceed the aquatic RAC of 0.334 µg/L (*Oncorhynchus mykiss*, fish prolonged)

Table 8.9-27: FOCUS Step 3 PEC_{sw} and PEC_{sed} for M04 (prothioconazole-desthio) following multiple applications of 2x 200 g a.s./ha to winter cereals (BBCH 69)

Scenario FOCUS	Waterbody	Application date chosen by model	Date of max PEC_{sw}	Max PEC_{sw} (µg/L)	Dominant entry route	Max PEC_{sed} (µg/kg)
~~D1~~	~~Ditch~~	~~04-Aug/ 18-Aug~~	~~20-Dec~~	~~0.022~~	~~Drainage~~	~~0.772~~
~~D1~~	~~Stream~~	~~04-Aug/ 18-Aug~~	~~20-Dec~~	~~0.014~~	~~Drainage~~	~~0.155~~
~~D2~~	~~Ditch~~	~~20-Jul/ 06-Aug~~	~~09-Jan~~	~~**0.463**~~	~~Drainage~~	~~1.239~~
~~D2~~	~~Stream~~	~~20-Jul/ 06-Aug~~	~~09-Jan~~	~~0.299~~	~~Drainage~~	~~0.697~~
D3	Ditch	04-Aug/ 18-Aug	25-Aug	0.128 ~~<0.001~~	Drainage	0.220 ~~0.066~~
D4	Pond	11-Jul/ 25-Jul	10-Dec	0.016 ~~0.011~~	Drainage	0.168 ~~0.154~~
D4	Stream	11-Jul/ 25-Jul	07-Dec	0.053 ~~0.043~~	Drainage	0.047
D5	Pond	09-Jun/ 25-Jun	30-Dec	0.016 ~~0.002~~	Drainage	0.129 ~~0.119~~
D5	Stream	09-Jun/ 25-Jun	24-Jan	0.067 ~~0.002~~	Drainage	0.028 ~~0.014~~
~~D6~~	~~Ditch~~	~~27-Apr/ 12-May~~	~~24-May~~	~~0.004~~	~~Drainage~~	~~0.310~~
R1	Pond	29-Jun/ 13-Jul	18-Jul	0.130 ~~0.108~~	Runoff/ erosion	0.978
R1	Stream	29-Jun/ 13-Jul	18-Jul	**0.818** ~~**0.771**~~	Runoff/ erosion	1.577
R3	Stream	01-Jun/ 16-Jun	17-Jul	0.198	Runoff/ erosion	0.246
R4	Stream	03-Jun/ 17-Jun	05-Aug	0.165	Runoff/ erosion	0.124

Values in bold exceed the aquatic RAC of 0.334 µg/L (*Oncorhynchus mykiss*, fish prolonged)

FOCUS Step 4 metabolites- late applications

Table 8.9-28: Global maximum Step 4 PEC_{sw} values for M04 (prothioconazole-desthio), following multiple applications of 2x 200 g a.s./ha to spring cereals (BBCH 69)

STEP 4	**Scenario**	**Max PEC_{sw} (µg/L) prothioconazole-desthio**								
Nozzle reduction	**Vegetative filter strip (m)**	**None**	**None**	**None**	**None**	**None**	~~5~~	**10**	~~15~~	**20**
	No spray buffer (m)	**None**	**5**	**10**	**15**	**20**	~~5~~	**10**	~~15~~	**20**
~~None~~	~~D1 Ditch~~	~~0.017~~	~~0.004~~	~~0.002~~	~~0.001~~	~~0.001~~	-	-	-	-
~~None~~	~~D1 Stream~~	~~<0.001~~	~~<0.001~~	~~<0.001~~	~~<0.001~~	~~<0.001~~	-	-	-	-
~~None~~	~~D3 Ditch~~	~~<0.001~~	~~<0.001~~	~~<0.001~~	~~<0.001~~	~~<0.001~~	-	-	-	-
~~None~~	~~D4 Pond~~	~~0.013~~	~~0.013~~	~~0.013~~	~~0.013~~	~~0.013~~	-	-	-	-
~~None~~	~~D4 Stream~~	~~0.050~~	~~0.050~~	~~0.050~~	~~0.050~~	~~0.050~~	-	-	-	-
~~None~~	~~D5 Pond~~	~~0.002~~	~~0.002~~	~~0.001~~	~~0.001~~	~~0.001~~	-	-	-	-
~~None~~	~~D5 Stream~~	~~0.002~~	~~0.002~~	~~0.002~~	~~0.002~~	~~0.002~~	-	-	-	-
None	R4 Stream	**0.640** ~~0.202~~	**0.640** ~~0.202~~	**0.640** ~~0.202~~	**0.640** ~~0.202~~	**0.640** ~~0.202~~	~~0.132~~	0.291 ~~0.092~~	~~0.070~~	~~0.048~~
VFSmod refinement										
Nozzle reduction	**VFSmod (m)**	-	-	-	-	-	**5**	~~10~~	~~15~~	~~20~~
	No spray buffer (m)	-	-	-	-	-	**5**	~~10~~	~~15~~	~~20~~
None	R4 Stream	-	-	-	-	-	0.041 ~~0.014~~	~~0.002~~	~~0.001~~	~~<0.001~~

Values in bold exceed the aquatic RAC of 0.334 µg/L (*Oncorhynchus mykiss*, fish prolonged)

Table 8.9-29: Global maximum Step 4 PEC$_{sw}$ values for M04 (prothioconazole-desthio), following multiple applications of 2x 200 g a.s./ha to winter cereals (BBCH 69)

STEP 4	**Scenario**	**Max PEC$_{sw}$ (µg/L) prothioconazole-desthio**								
Nozzle reduction	**Vegetative filter strip (m)**	**None**	**None**	**None**	**None**	**None**	**5**	**10**	**15**	**20**
	No spray buffer (m)	**None**	**5**	**10**	**15**	**20**	**5**	**10**	**15**	**20**
None	D1 Ditch	0.022	0.022	0.022	0.022	0.022	-	-	-	-
None	D1 Stream	0.014	0.014	0.014	0.014	0.014	-	-	-	-
None	D2 Ditch	**0.463**	**0.463**	**0.463**	**0.463**	**0.463**	-	-	-	-
None	D2 Stream	0.299	0.299	0.299	0.299	0.299	-	-	-	-
None	D3 Ditch	<0.001	<0.001	<0.001	<0.001	<0.001	-	-	-	-
None	D4 Pond	0.011	0.011	0.011	0.010	0.010	-	-	-	-
None	D4 Stream	0.043	0.043	0.043	0.043	0.043	-	-	-	-
None	D5 Pond	0.002	0.002	0.001	0.001	0.001	-	-	-	-
None	D5 Stream	0.002	0.002	0.002	0.002	0.002	-	-	-	-
None	D6 Ditch	0.004	0.001	<0.001	<0.001	<0.001	-	-	-	-
None	R1 Pond	0.108	0.108	0.108	0.108	0.108	0.065	0.043	0.033	0.022
None	R1 Stream	**0.818** **0.771**	**0.818** **0.771**	**0.818** **0.771**	**0.818** **0.771**	**0.818** **0.771**	**0.502**	**0.372** **0.350**	0.268	0.194 0.183
None	R3 Stream	0.198	0.198	0.198	0.198	0.198	0.129	0.090	0.069	0.047
None	R4 Stream	0.165	0.165	0.165	0.165	0.165	0.108	0.075	0.058	0.039
VFSmod refinement										
Nozzle reduction	**VFSmod (m)**	**-**	**-**	**-**	**-**	**-**	**5**	**10**	**15**	**20**
	No spray buffer (m)	**-**	**-**	**-**	**-**	**-**	**5**	**10**	**15**	**20**
None	R1 Pond	-	-	-	-	-	0.021	0.010	0.003	<0.001
None	R1 Stream	-	-	-	-	-	0.124 0.119	0.059	0.016	<0.001
None	R3 Stream	-	-	-	-	-	0.027	<0.001	<0.001	<0.001
None	R4 Stream	-	-	-	-	-	0.011	0.001	0.001	<0.001

Values in bold exceed the aquatic RAC of 0.334 µg/L (*Oncorhynchus mykiss*, fish prolonged)

For later applications to BBCH 69, the M04 metabolite exceeded the aquatic RAC of 0.334 µg/L (*Oncorhynchus mykiss*, fish prolonged) for two scenarios for **winter cereals**. The maximum PEC$_{sw}$ values of 0.463 and 0.771 µg/L were for the D2 and R1 scenarios respectively.

The D2 scenario could not be effectively mitigated at step 4 due to the risk being driven by drainflow. However, this is not a relevant scenario for the Central Zone. The R1 stream PEC$_{sw}$ value was successfully reduced with a 15 m combined buffer zone and VFS. Therefore, no additional mitigation is required for the environmental risk at later growth stages.

The environmental risk to the aquatic environment from applications of prothioconazole to cereals can be adequately addressed through mitigation using standard methods of no-spray buffer zones and vegetated filter strips.

zRMS comments:

Input parameters presented in Table 8.9-4 to 8.9-5 used in the surface water modelling for prothioconazole and its metabolites are in general in line with EU agreed endpoints with following remarks:

General:
For cereals from BBCH 27 the minimal crop cover was considered by the Applicant. However, according to FOCUS Surface Water Generic Guidance (2015), for cereals at BBCH 20-39 crop cover is defined as intermediate. Therefore, respective corrections were introduced in Table 8.9-1. Nevertheless, as the minimal crop interception represents worst case, it is accepted by the zRMS for Step 1-2 calculations for early application. For late application correct crop interception of full canopy was assumed, however results PEC_{sw} and PEC_{sed} for early application represents worst case.

For prothioconazole DT_{50} in water/sediment of 39.5 days was used instead of 1.0 day agreed in the course of the EU review. Thus, respective information were introduced in Table 8.9-4 and used in the independent zRMS calculations at Step 1-2. Nevertheless, this deviation is not expected to have significant impact on the obtained results. Moreover, for early application in cereals the zRMS considered crop interception corresponding with “intermediate crop cover” and thus obtained $PEC_{SW/SED}$ were lower comparing to Applicant’s values, as these were derived with consideration of the “minimal crop cover”. Thus, results obtained by the Applicant may be used in the risk assessment as representing worst case.

For the metabolite JAU 6476 S-Methyl in the aerobic water/sediment study the maximum occurrence of 12.7% in the whole system is observed, while in the anaerobic study 77% only in sediment. Thus, respective changes were introduced in Table 8.9-4 and used in the independent zRMS calculations for this metabolite at Step 1-2. Results obtained by the zRMS at Step 1-2 were mainly higher comparing to these obtained by the Applicant, therefore respective changes were introduced to the Tables 8.9-6 to 8.9-13 for early and late application only in case zRMS values were higher comparing to Applicant’s results.

For metabolite JAU 6476-desthio in water/sediment study the maximum occurrence of 54.6% in the whole system is observed, whereas the Applicant used the value of 59.2%. Thus, respective changes were introduced in Table 8.9-4 and used in the independent zRMS calculations for this metabolite at Step 1-2. Results obtained by the zRMS at Step 1-2 were slightly lower comparing to these obtained by the Applicant, due to higher maximum occurrence assumed in Applicant’s simulations. The results obtained by the Applicant may be used in the risk assessment as representing worst case.

For metabolite 1,2,4-Triazole for the whole system the Applicant used the maximum occurrence of 37.2%, but this is relevant for the water phase, while the maximum occurrence of 41.8% was observed in the whole system. Respective changes were introduced by the zRMS in Table 8.9-4 and were used in the independent calculations at Step 1-2. Since results obtained by the zRMS at Step 1 were higher comparing to these obtained by the Applicant, respective changes were introduced to the Tables 8.9-6 to 8.9-13 for early and late application. Moreover, for early application in cereals the zRMS considered crop interception corresponding with “intermediate crop cover” and thus obtained $PEC_{SW/SED}$ were lower comparing to Applicant’s values, as these were derived with consideration of the “minimal crop cover”. For late application the difference in obtained $PEC_{SW/SED}$ results were insignificant. The results obtained by the Applicant at Step 2 may be used in the risk assessment as representing worst case.

At Step 1-2 for early application to cereals no impact on the outcome of the risk assessment is observed despite differences observed in input parameters. Since the zRMS in the independent calculation, in line the FOCUS guidance at Step 2 for uses in cereals, considered crop interception corresponding with “intermediate crop cover”. Therefore obtained results of $PEC_{SW/SED}$ were lower comparing to Applicant’s values, that were derived with consideration of the “minimal crop cover” for BBCH 27. Despite differences observed in the maximum occurrence in the whole system, the results obtained by the Applicant may be used in the risk assessment as representing worse case.

No DT_{50} values for aquatic systems were available for metabolites, so worst case default of 1000 days was used, which is accepted by the zRMS.

With regard to parametrisation of the model at Step 3 and 4, it is 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. This approach gives four combinations for parent and metabolite modelling. Since the risk is driven by exposure via water and not sediment (endpoints for sediment dwellers are expressed in terms of mg/L) the four combinations indicated in table below were tested by the zRMS in order to check which gives the highest PEC_{SW} values. It turned out that the worst case combination was when the shortest DT_{50} value was applied to prothioconazole and the default of 1000 days was applied to JAU 6476-desthio in the water phase (combination 2 in table below). This combination was then used in the zRMS modelling performed for purposes of validation of the Applicant's results.

Potential combinations of water and sediment DT_{50} values for use in Step 3 modelling.

Component	Endpoint	Combination run in FOCUS Step 3 modelling			
		1	**2**	**3**	**4**
Prothioconazole	DT_{50} (water phase)	2.1	**2.1**	1000	1000
	DT_{50} (sediment)	1000	**1000**	2.1	2.1
JAU 6476-desthio	DT_{50} (water phase)	49.9	**1000**	49.9	1000
	DT_{50} (sediment)	1000	**49.9**	1000	49.9

At Step 3 for PUF value of 0 was assumed for prothioconazole and JAU 6476-desthio, in line with current recommendations.

Step 4 simulations were performed according to recommendations of the FOCUS work group on landscape and mitigation factors. However, only the EU agreed reduction measures for runoff water and eroded sediment at 10 and 20 m, as described in FOCUS Landscape and Mitigation factors in aquatic ecological risk assessment (SANCO/10422/2005) were validated by the zRMS. Concerned Member States must decided on aceptability if proposed mitigation measures of 5 and 15 m of vegetated filter strip are applicable in their countries. Results performed with assumption of 5 and 15 m vegetated filter strip were not validated by the zRMS and were thus struck through. Please note that, in Poland refinements using a 5 m and 15 m vegetated filter buffer zones are not considered.

The surface water exposure at Step 3-4 was independently validated by the zRMS in additional modelling using the same parameters indicated above and only relevant scenarios in the central zone were validated, therefore results presented for D1, D2 and D6 scenarios were struck through as not relevant.

Results of PEC_{sw} and PEC_{sed} **for prothioconazole** at Step 3 for multiple application to cereals were in general in good agreement with values calculated by the Applicant. It is noted that the Applicant performed simulations only for the multiple application, however calculation performed at Step 3 for single application indicated higher PECsw values for the prothioconazole from these presented for multiple application of FHO04 to cereals for both early and late application. Therefore results that correspond to single application were added to the Tables 8.9-14 and 8.9-15 for early application and to the Tables 8.9-22 and 8.9-23 for late application. Since the acceptable risk to aquatic organisms for prothioconazole could be concluded already at Step 3, results for prothioconazole at Step 4 were not validated by the zRMS and results presented in Tables 8.9-16, 8.9-17, 8.9-24 and 8.9-25 were for shaded for transparency.

Results of PEC_{sw} and PEC_{sed} for prothioconazole **metabolite JAU 6476-desthio** at Step 3-4 obtained by the zRMS in independent modelling were higher comparing with the results obtained by the Applicant. Thus, PECsw/sed values reported in Tables 8.9-18 to 8.9-21 for early application and in Tables 8.9-26 to 8.9-29 for late application were corrected by the zRMS and may be used for purposes of the aquatic risk assessment. The scenarios which pass the risk assessment at Step 3 were not further validated at Step 4, thus results reported for Step 4 mainly for D scenarios were struck through as not relevant. Additional Step 4 calculations with consideration of 10 and 20 m VFS were performed for metabolite JAU 6476-desthio mainly for R1 stream, R3 stream and R4 stream scenarios when PEC_{sw} values were above the RAC of 0.334 µg/L. The additional VFSmod refinement demonstrates that spring cereals could be addressed with 5 m mitigation and winter cereals with 10 m mitigation, concerned Member States must decided on it aceptability.

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.

8.9.1.2 Sulphur and sulphates

Specific data on the behaviour of sulphur in natural aerobic water/sediment systems were neither submitted, nor assessed, as part of active substance approval (EFSA, 2008). Justifications for not providing water/sediment studies were presented and considered acceptable by the peer reviewers. The view of the Member State experts was that the cycle of sulphur in the environment is well understood and when entering an aquatic system, sulphur is expected to adsorb preferentially onto sediment and then be oxidised.

The peer reviewers considered the available solubility information sufficient to complete an aquatic exposure assessment at EU level for the applied for intended uses. No PEC_{sw} values were calculated, as the risk assessment to aquatic organisms was based on an absence of effects on organisms at the greatest water solubility limit of sulphur (maximum determined water solubility: 63 µg/L).

New calculations for PEC_{sed} were provided by the rapporteur Member State after the PRAPeR meeting; however, as the new calculations were based on inappropriate input parameters, a data gap for the exposure assessment for the sediment compartment was identified. Additionally, effects data for sediment dwellers were neither submitted, nor assessed, as part of active substance approval (EFSA, 2008).

That data gap for PEC_{sed} was addressed with a conservative approach proposed in the Sulphur Addendum to the DAR Volume 3 B5, B6 and B9 for Confirmatory Data (April 2012). The approach is based on the simplified scenario from SANCO (2001, Report of the FOCUS Working Group on Surface Water Scenarios “FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC”, EC Document Reference SANCO/4802/2001-rev.2, 245 pp) consisting of a static 1000 m^2 (3×10^5 L) water body adjacent to a 1 ha field and represented in FOCUS Step 1 and 2 (Table 8.9-30), BBA (2000, Bekanntmachung über die Abtrifteckwerte, die bei der Prüfung und Zulassung von Pflanzenschutzmitteln herangezogen werden. (8. Mai 2000) in: Bundesanzeiger No.100, amtlicher Teil, vom 25. Mai 2000, S. 9879) spray-drift values (Table 8.9-31) and estimates of the potential loading of sulphur to surface water via run-off, erosion and drainage from FOCUS Step 1 and 2 from FOCUS (2015, Generic guidance for FOCUS surface water scenarios, Version 1.4, May 2015, 367 pp) (see Table 8.9-32).

Table 8.9-30: Step 1 and 2 - standard assumptions for water/sediment body

Parameter	Value
Water depth (cm)	30
Sediment depth (d_{sed}) (cm)	5.0
Sediment bulk density (ρ_{sed}) (g/cm³)	0.8
Ratio of field: water body ($R_{field: water}$)	10

Table 8.9-31 Drift deposition values for one and two applications to cereals

Crop	Distance to water body at edge of field (m)	Drift value (f_{drift})	
		Step 1 (one application)	Step 2 (two applications)
Spring and winter cereals	1	0.02759	0.02438

Table 8.9-32: Step 1 and 2 run-off/erosion and drainage entry fractions for the adjacent water/sediment body

Step	Region and season of application	Run-off/erosion/drainage entry (f_{runoff})
1	Not relevant	0.10
2	North Europe, Oct.–Feb.	0.05
	North Europe, Mar.-May or Jun.–Sep.	0.02
	South Europe, Oct.–Feb. or Mar.-May	0.04
	South Europe, Jun.–Sep.	0.03

The calculations assume that 100 % of sulphur entering water from spray drift (includes deposition after volatilisation) and run-off/drainage are deposited immediately in the sediment. Other biogeochemical processes such as oxidation and reduction are not considered because sulphur is not expected to persist in an elemental form, and therefore no accumulation of elemental sulphur is anticipated (EFSA, 2008).
Step 1 and Step 2 maximum initial PEC_{sed} for sulphur were calculated according to the following equations, substance specific endpoints are not required:

Step 1 and 2: PEC_{sed} from spray drift (mg/kg) = $(A \times f_{drift}) / (100 \times d_{sed} \times \rho_{sed})$

Step 1: PEC_{sed} from run-off (mg/kg) = $(A \times (f_{runoff} \times R_{field,water})) / (100 \times d_{sed} \times \rho_{sed})$

Step 2: PEC_{sed} from run-off (mg/kg) = $((A \times (1 - f_{int})) \times (f_{runoff} \times R_{field,water})) / (100 \times d_{sed} \times \rho_{sed})$

PEC_{sed} (mg/kg) = PEC_{sed} from spray drift + PEC_{sed} from run-off

Where:
A = Annual total application rate (g/ha) (Table 8.9-1)
f_{drift} = fraction from spray drift (Table 8.9-31)
f_{int} = fraction intercepted by crop (Table 8.9-1)
f_{runoff} = fraction from run-off, erosion and drainage (Table 8.9-32)
$R_{field,water}$ = ratio of field: waterbody (Table 8.9-30)
d_{sed} = depth of sediment (cm) (Table 8.9-30)
ρ_{sed} = bulk density of sediment (g/cm^3) (Table 8.9-30)

Table 8.9-33: Step 1 maximum PEC_{sed} for sulphur following applications on cereals

Crop and application rate	PEC_{sed} (mg/kg d.w.)		
	Spray drift (+volatilisation)	Run-off + drainage	Sum
Spring and winter cereals (2 x 2500 g/ha) ~~1 ×~~ 5000 g/ha (Annual total)	0.345	12.500	12.845

Table 8.9-34: Step 2 maximum PEC_{sed} for sulphur following applications on cereals

Spring and winter cereals 1 × 5000 g/ha (Annual total)					
Region	Canopy cover and crop interception	Timing	PEC_{sed} (mg/kg d.w.)		
			Spray drift (+volatilisation)	Run-off + drainage	Sum
North	Minimum (0 %)	Oct - Feb	0.305	6.250	6.555
		Mar - May	0.305	2.500	2.805
	Average (20 %)	Oct - Feb	0.305	5.000	5.305
		Mar - May	0.305	2.000	2.305
	Full (70 %)	Mar – May	0.305	0.750	1.055
		Jun – Sep	0.305	0.750	1.055
South	Minimum (0 %)	Oct - Feb	0.305	5.000	5.305
		Mar - May	0.305	5.000	5.305
	Average (20 %)	Oct - Feb	0.305	4.000	4.305
		Mar - May	0.305	4.000	4.305
	Full (70 %)	Mar – May	0.305	1.500	1.805
		Jun – Sep	0.305	1.125	1.430

zRMS comments:

Information presented in Tables 8.9-30 to 8.9-32 and used for calculation the loading of sulphur to surface water via run-off, erosion and drainage are in line with Generic guidance for FOCUS surface water scenarios, Version 1.4, May 2015.

PECsw simulations were not performed, and the water solubility was considered as the maximum value for PEC_{sw}, meaning 63 µg/L and is agreed by the zRMS since it is in line with EFSA Scientific Report (2008) 221, 47-70.

The PEC_{sed} calculations have been performed based on simplified STEPS 1-2 in FOCUS static water body scenario assumptions representing an unrealistic worst-case. The performed calculations were independently validated by the zRMS and it is confirmed to be correct.

Overall, results obtained by the Applicant and presented in Tables 8.9-33 and 8.9-34 may be used in the 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.

8.9.1.3 PEC_{sw} of formulation

The PEC_{SW} of the formulation due to drift was calculated based on the total amount of formulation that could be applied (4.0 L/ha). The density of the formulation is 1.36 kg/L, giving an applied dose of 5440 g/ha. The formulation contains two active substances, so calculation of PEC_{SW} of formulation was performed using the CRD calculator 'PECsw spray drift (multiple buffer zone) calculator version 1' available at:
https://www.hse.gov.uk/pesticides/pesticides-registration/data-requirements-handbook/fate/environmental-fate-models.htm [Accessed 15 May 2023] to which Ganzelmeier drift values (Ganzelmeier, H; Rautmann, D. 2000. Drift, drift reducing sprayers and sprayer testing. Aspects of Applied Biology 57, 1-10) had been added.

Table 8.9-35: PEC_{SW} due to drift at multiple buffer zone distances for the formulation when applied at 4.0 L/ha to cereals

Distance (m)	PECsw ini (µg/L)
1	61.653
3	21.035
5	12.693
7.5	8.523
10	6.528
15	4.352
20	3.264
30	2.176
50	1.269
75	0.907
100	0.725

zRMS comments:

The surface water exposure to formulation was validated by the zRMS using Spray Drift Calculator. Obtained PEC_{SW} results were lower than these reported in table above, consequently values presented above 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	Sulphur
Direct photolysis in air	Not studied – no data requested	Not relevant, inorganic substance
Quantum yield of direct phototransformation	Not meaured- no data requested	Not relevant, inorganic substance
Photochemical oxidative degradation in air	Parent: DT_{50} (h): 1.1 derived by the Atkinson model (AOPWIN v1.87) OH (12h) concentration assumed =1.5 x10^6 OH radicals/cm^3 M04: DT_{50} (h): 14.2 derived by the Atkinson model (AOPWIN v1.87) OH (12h) concentration assumed =1.5 x10^6 OH radicals/cm^3	-
Volatilisation Vapour pressure (Pa): Henry's Law Constant (Pa.m^3/mol):	Vapour pressure (Pa): <4 x10^{-7} (at 20°C) Henry's Law Constant (Pa.m3/mol): 3 x10^{-5} 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.	 9.8 × 10^{-5} Pa (20 °C) 0.2 Pa m^3 mol^{-1} (20 °C)
Metabolites	M04	None

The fate and behaviour of prothioconazole in air was considered in the EFSA conclusion (2007). The vapour pressure at 20 °C of the prothioconazole is < 10^{-5} Pa and so it 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. Based on expert judgement on the vapour pressure, Henry's Law Constant and the experimental information on volatilisation, it was considered that calculation of PEC_{air} is not necessary. Therefore, it is not considered necessary to further investigate the atmospheric behaviour of prothioconazole within this dossier.

The vapour pressure at 20 °C of the active substance sulphur is between 10^{-5} and 10^{-4} Pa. Hence the active substance sulphur is regarded as semi-volatile (volatilisation only from plant surfaces). Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance sulphur due to volatilization with subsequent deposition should be considered. However, in EFSA (2008) conclusion it is stated that sulphur it not volatile and consequently calculation of PEC_{air} is not necessary.

zRMS comments:

Provided above information is in line with EU agreed data reported in EFSA Scientific Report (2007) 106, 1-98. Taking into account the low vapour pressure (<10^{-5} Pa) and DT_{50} in air <2 days, prothioconazole is not expected to be subject to volatilisation and the long- or short-range transport.

The vapour pressure of sulphur was determined as 9.8 x 10^{-5} Pa at 20ºC. It is therefore non volatile, even if its Henry's law constant was determined at 0.05 Pa m^3 /mol, which is due to its very low water solubility. Sulphur is therefore not expected to transfer to the air compartment.

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 9.1.3/01	Smith, H.	2024	Predicted environmental concentrations of prothioconazole following applications on spring and winter cereals in the Central Zone E2023-51 Enviresearch Ltd Not GLP (modelling study) Unpublished	N	UPL
KCP 9.1.3/02	Tilston, E.L.	2024	Predicted environmental concentrations of sulphur and sulphate following applications on spring and winter cereals in the Central and Southern Zones. E2023-33 Enviresearch Ltd Not GLP (modelling study) Unpublished	N	UPL
KCP 9.2.4/01 (filed in KCP 9.1.3/01)	Smith, H.	2024	Predicted environmental concentrations of prothioconazole following applications on spring and winter cereals in the Central Zone E2023-51Enviresearch Ltd Not GLP (modelling study) Unpublished	N	UPL
KCP 9.2.4/02 (filed in KCP 9.1.3/02)	Tilston, E.L.	2024	Predicted environmental concentrations of sulphur and sulphate following applications on spring and winter cereals in the Central and Southern Zones. E2023-33 Enviresearch Ltd Not GLP (modelling study) Unpublished	N	UPL
KCP 9.2.5/01 (filed in KCP 9.1.3/01)	Smith, H.	2024	Predicted environmental concentrations of prothioconazole following applications on spring and winter cereals in the Central Zone E2023-51 Enviresearch Ltd Not GLP (modelling study) Unpublished	N	UPL
KCP 9.2.5/02 (filed in KCP 9.1.3/02)	Tilston, E.L.	2024	Predicted environmental concentrations of sulphur and sulphate following applications on spring and winter cereals in the Central and Southern Zones. E2023-33 Enviresearch Ltd Not GLP (modelling study) Unpublished	N	UPL

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
As all endpoints for the active substances and its metabolites were taken from the EU review of prothioconazole and sulphur for the list of respective studies please refer to Volume 2 of the RAR.					

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the new Annex II studies

All endpoints used in the environmental fate risk assessment were taken from the peer review conclusion for prothioconazole (EFSA, 2007), and the peer review conclusion for sulphur (EFSA, 2008). Therefore, no new studies are submitted for this product.

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