FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: Protiokonazol 300 EC

Product name(s): HERA 300 EC

Chemical active substance:

prothioconazole, 300 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Pestila Spółka z ograniczoną odpowiedzialnością

Submission date: October 2023

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Version history

When	What
February 2024	ZRMs evaluated dRR submitted by Applicant.
July 2024	The final Registration Report

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8 Fate and behaviour in the environment (KCP 9)

8.1 Critical GAP and overall conclusions

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. [(e)]	**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 [(f)]	**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			PECgw
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	Poland	Winter wheat	F	Controlled diseases - for details please refer to dRR Part B0 and B3	broadcast spraying	BBCH 29-65 Spring, post emergence	1 a) 1 b) 2	14	0.5 – 0.65 L/ha a) 0.65 L/ha b) 1.3 L/ha	150-195 g Prothioconazole a) 195 g Prothioconazole b) 390 g Prothioconazole	100-400 L/ha	35		A
2	Poland	Spring wheat	F		broadcast spraying	BBCH 29-65 Spring, post emergence	1 a) 1 b) 2	14	0.5 – 0.65 L/ha a) 0.65 L/ha b) 1.3 L/ha	150-195 g Prothioconazole a) 195 g Prothioconazole b) 390 g Prothioconazole	100-400 L/ha	35		A
3	Poland	Winter triticale	F		broadcast spraying	BBCH 29-65 Spring, post emergence	1 a) 1 b) 2	14	0.5 – 0.65 L/ha a) 0.65 L/ha b) 1.3 L/ha	150-195 g Prothioconazole a) 195 g Prothioconazole b) 390 g Prothioconazole	100-400 L/ha	35		A
4	Poland	Spring triticale	F		broadcast spraying	BBCH 29-65 Spring, post emergence	1 a) 1 b) 2	14	0.5 – 0.65 L/ha a) 0.65 L/ha b) 1.3 L/ha	150-195 g Prothioconazole a) 195 g Prothioconazole b) 390 g Prothioconazole	100-400 L/ha	35		A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. (e)	**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 (f)	**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			PECgw
Zonal uses (field or outdoor uses, certain types of protected crops)														
5	Poland	Spring barley	F		broadcast spraying	BBCH 29-65 Spring, post emergence	1 a) 1 b) 2	14	0.5 – 0.65 L/ha a) 0.65 L/ha b) 1.3 L/ha	150-195 g Prothioconazole a) 195 g Prothioconazole b) 390 g Prothioconazole	100-400 L/ha	35		A
6	Poland	Winter barley	F		broadcast spraying	BBCH 29-65 Spring, post emergence	1 a) 1 b) 2	14	0.5 – 0.65 L/ha a) 0.65 L/ha b) 1.3 L/ha	150-195 g Prothioconazole a) 195 g Prothioconazole b) 390 g Prothioconazole	100-400 L/ha	35		A
7	Poland	Rye	F		broadcast spraying	BBCH 29-65 Spring, post emergence	1 a) 1 b) 2	14	0.5 – 0.65 L/ha a) 0.65 L/ha b) 1.3 L/ha	150-195 g Prothioconazole a) 195 g Prothioconazole b) 390 g Prothioconazole	100-400 L/ha	35		A
8	Poland	Winter oilseed rape	F		broadcast spraying	BBCH 13-19 Autumn, post emergence	1 a) 1 b) 1	not relevant	0.5 – 0.6 L/ha a) 0.6 L/ha b) 0.6 L/ha	150-180 g Prothioconazole a) 180 g Prothioconazole b) 180 g Prothioconazole	100-400 L/ha	56		A
9	Poland	Winter oilseed rape	F		broadcast spraying	BBCH 61-72 Spring, post emergence	1 a) 1 b) 2	21	0.5 – 0.6 L/ha a) 0.6 L/ha b) 1.2 L/ha	150-180 g Prothioconazole a) 180 g Prothiocona-	100-400 L/ha	56		A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. (e)	**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 (f)	**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			PECgw
Zonal uses (field or outdoor uses, certain types of protected crops)														
										zole b) 360 g Prothioconazole				
Minor uses according to Article 51 (Zonal uses)														
10	Poland	Spring oilseed rape	F	Controlled diseases - for details please refer to dRR Part B0 and B3	broadcast spraying	BBCH 16-69 Spring Post-emergence	a)1 b)2	14-21	0.5 – 0.6 L/ha a) 0.6 L/ha b) 1.2 L/ha	150-180 g Prothioconazole a) 180 g Prothioconazole b) 360 g Prothioconazole	100-400 L/ha	56		A

Remarks table heading:

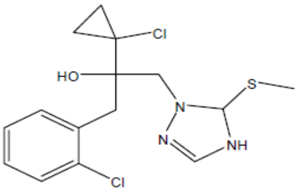
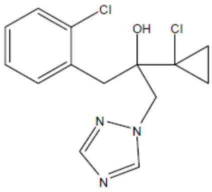
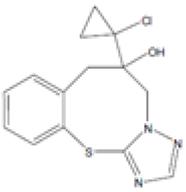
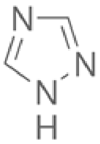
(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 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
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

8.2 Metabolites considered in the assessment

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 Prothioconazole-S-Methyl CAS 178928-71-7	358.3		Soil: 14.6% (lab) Sediment: 77%	PECsoil PECgw PECsw
M04: JAU 6476-desthio Prothioconazole-desthio CAS 120983-64-4	312.2		Soil: 57.1% (field) Total system: 54.6% Water: 32.3% Sediment: 26.9%	PECsoil PECgw PECsw
M12: Prothioconazole-thiazocine	307.8		Water: 14.1% AR, day 5 under photolysis conditions	PECsw
M13: 1,2,4-triazole	69.1		Soil: 0.001% Water: 37.2%	PECsw

8.3 Rate of degradation in soil (KCP 9.1.1)

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

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

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

Prothioconazole, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.°C**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Laacher Hof	Sandy Loam	6.6	20	48	0.07	5.3	-	-	FOMC	Yes, EFSA (2007)
Stanley	Silty Clay Loam	5.9	20	48	0.7	78.2	-	-	FOMC	Yes, EFSA (2007)
Hofchen	Silt	6.8	20	50	0.30	0.99	-	-	SFO	Yes, EFSA (2007)
Byromville	Loamy Sand	6.1	20	50	1.27	4.22	-	-	SFO	Yes, EFSA (2007)
Median (n=)4					0.5					
Geometric mean (n=4)					**0.37**					
pH-dependency: No										

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

Prothioconazole-S-methyl (M01), Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.°C**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Hofchen	Loamy Silt	6.5	20	40	5.9	19.6	-	-	SFO	Yes, EFSA (2007)
Laacher Hof AIII	Loamy Silt	6.7	20	40	27.2	90.2	-	-	SFO	Yes, EFSA (2007)
Laacher Hof AXXa	Sandy Loam	6.3	20	40	8.2	27.2	-	-	SFO	Yes, EFSA (2007)
Stanley	Silty Clay	5.2	20	40	46	153	-	-	SFO	Yes, EFSA (2007)
Geometric mean (n=4)					**15.7**					

Prothioconazole-S-methyl (M01), Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.°C**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
pH-dependency: No										

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

Prothioconazole-desthio (M04), Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.°C**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Hofchen	Loamy Silt	6.5	20	40	34.0	113.0	-	-	SFO	Yes, EFSA (2007)
Laacher Hof A III	Loamy Silt	6.7	20	40	29.6	59.2	-	-	SFO	Yes, EFSA (2007)
Laacher Hof A XXa	Sandy Loam	6.3	20	40	7.0	23.2	-	-	SFO	Yes, EFSA (2007)
Stanley	Silty Clay	5.2	20	40	18.6	61.9	-	-	SFO	Yes, EFSA (2007)
Geometric mean (n=4)					**19.0**					
pH-dependency: No										

Table 8.3.1-4: Summary of aerobic degradation rates for 1, 2, 4-triazole (M13) - laboratory studies

1, 2, 4-triaziole, Laboratory studies, aerobic conditions									
Soil type	**pH**	**t.°C**	**MWHC %**	**DT50 slow phase (d)**	**DT50 fast phase (d)**	**DT50 (d) 20°C pF2/10kPa**	**g**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Sandy loam	6.4	20	40	59.2	0.9	-	0.683	DFOP	y/CRD, UK, December 2013, Briefing note for the 13 December 2013 SCFAH, Agenda Item Pt. A 06.01- Amended DT50 values for the 1,2,4-triazole metabolite
Loamy sand	5.8	20	40	247.6	1.5	-	0.580	DFOP	
Silt loam	6.7	20	40	20.6	0.8	-	0.443	DFOP	
Geometric mean (n=3)				**67.1**	1.0	-	0.569	DFOP	

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Not relevant. No significant degradation of parent and no specific metabolites under anaerobic conditions.

8.4 Field studies (KCP 9.1.1.2)

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

Field studies with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

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

Soil type	Location	pH ($CaCl_2$)	Depth (cm)	DT_{50} (days) actual	DT_{90} (days) actual	St. (X^2)	DT_{50} (days) Norm[b]	Method of calculation	Evaluated on EU level y/n/ Reference
Loamy Silt/ Silt loam	Germany	6.25	0 – 10	1.9	6.4	-	1.2	1st Order	Yes, EFSA (2007)
Sandy Clay loam/ Sandy clay loam	Great Britain	7.56	0 – 10	1.6	5.5	-	0.8	1st Order	Yes, EFSA (2007)
Weak loamy silt/ Silt	France (North)	6.42	0 – 10	1.3	4.4	-	1.6	1st Order	Yes, EFSA (2007)
Sandy clay loam/ Sandy clay loam	Great Britain	7.56	0 – 10	**2.8 max**	9.3	-	1.4	1st Order	Yes, EFSA (2007)
Weak loamy silt/ Silt	France (North)	6.42	0 – 10	1.4	4.5	-	1.6	1st Order	Yes, EFSA (2007)
Sandy loamy silt/ silt loam	France (South)	7.61	0 – 10	1.7	5.6	-	1.1	1st Order	Yes, EFSA (2007)
Weak loamy sand/ sandy loam	Italy	7.56	0 – 10	1.6	5.4	-	1.5	1st Order	Yes, EFSA (2007)
Loamy sand/ Sandy loam	Germany	6.32	0 – 10	1.5	5.1	-	0.6	1st Order	Yes, EFSA (2007)
						Geometric mean (n=8)	**1.2**		
						pH-dependency	not reported		

[b] normalised for 20°C; not normalised for moisture content

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

Soil type	Location	pH ($CaCl_2$)	Depth (cm)	DT_{50} (days) actual	DT_{90} (days) actual	St. (X^2)	DT_{50} (days) Norm[b]	f.f kf/kdp	Method of calculation	Evaluated on EU level y/n/ Reference
Loamy Silt/ Silt loam	Germany	6.25	0 – 10	16.3	54.1	-	10.3	-	1st Order	Yes, EFSA (2007)
Sandy Clay loam	Great Britain	7.56	0 – 10	54.7	182	-	27.0	-	1st Order	Yes, EFSA (2007)
Weak loamy silt/ Silt	France (North)	6.42	0 – 10	47.6	158	-	27.5	-	1st Order	Yes, EFSA (2006)
Sandy clay loam	Great Britain	7.56	0 – 10	50.2	167	-	23.4	-	1st Order	Yes, EFSA (2007)
Weak loamy	France (North)	6.42	0 – 10	36.8	122	-	20.1	-	1st Order	Yes, EFSA (2007)

Soil type	Location	pH (CaCl2)	Depth (cm)	DT_{50} (days) actual	DT_{90} (days) actual	St. (X^2)	DT_{50} (days) Norm[b]	f.f kf/kdp	Method of calculation	Evaluated on EU level y/n/ Reference
silt/ Silt										
Sandy loamy silt/ silt loam	France (South)	7.61	0 – 10	**72.3**	240	-	61.9	-	1st Order	Yes, EFSA (2007)
Weak loamy sand/ sandy loam	Italy	7.56	0 – 10	30.5	101	-	20.7	-	1st Order	Yes, EFSA (2007)
Loamy sand/ Sandy loam	Germany	6.32	0 – 10	27.9	92.6	-	15.2	-	1st Order	Yes, EFSA (2007)
Geometric mean (n=8)							**22.7**			
pH-dependency: not reported										

[b] normalised for 20°C; not normalised for moisture content

Table 8.4.1-3: Summary of aerobic degradation rates for relevant metabolite(s) - field studies: Modelling endpoints

1, 2, 4-triazole (M13), Field studies – Modelling endpoints									
Soil type (bare soil with grass sown immediately after application with exception of Spain site where no grass sown)	**Location**	**pH**	**Depth (cm)**	**DT50 slow phase (d) 20°C, pF2**	**DT50 fast phase (d) 20°C, pF2**	**“g”**	**St. (x^2)**	**Method of calc.**	**Evaluated on EU level y/n/ Reference**
Silt loam	Germany	6.4	0 – 30	70.7	2.5	0.655	18.8	DFOP	Yes, CRD, UK, December 2013, Briefing note for the 13 December 2013 SCFAH, Agenda Item Pt. A 06.01- Amended DT50 values for the 1,2,4-triazole metabolite
Silty clay loam	Italy	7.6	0 – 40	59.8	1.4	0.364	10.6	DFOP	
Sandy loam	UK	7.4	0 – 40	25.1	0.5	0.458	18.1	DFOP	
Loam	Spain	5.8	0 – 30	126.0	4.6	0.489	12.7	DFOP	
Geometric mean (n=4) (arithmetic mean for “g” value)				60.5	1.68	0.489	-	DFOP	
pH-dependency:				No					

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Not relevant. See point 8.4.1. Soil accumulation studies are not required for prothioconazole and prothioconazole-desthio (M04) as DT_{90} values do not exceed one year.

8.5 Mobility in soil (KCP 9.1.2)

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

8.5.1 Laboratory studies (KCP 9.1.2.1)

The mobility of prothioconazole and its metabolites prothioconazole-S-methyl (M01) and prothioconazole-desthio (M04) in soil was evaluated during the EU review and is summarised in the EFSA Conclusion (EFSA Scientific Report (2007) 106, 1-98). No additional studies have been performed.

K_d and K_{oc} values for prothioconazole could not be determined in batch equilibrium studies due to the instability of the compound in these systems. Instead, a column leaching test and an aged column leaching study were conducted to obtain information concerning the leaching potential of prothioconazole. Batch equilibrium studies were conducted for the soil metabolites prothioconazole-S-methyl (M01) and prothioconazole-desthio (M04).

Table 8.5.1-1: Summary of soil adsorption/desorption for prothioconazole

Prothioconazole[a]							
Soil name	**Soil type**	**OC (%)**	**pH (H_2O)**	**Kd (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Byromville	Loamy sand	0.86	6.7	15.2	1765	0.9	Y, EFSA (2007)
				Maximum (n=1)	1765	0.9	
				pH-dependency:	-		

[a] Determined on the basis of an aged column leaching study

Table 8.5.1-2: Summary of soil adsorption/desorption for prothioconazole-S-methyl (M01)

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	Y, EFSA (2007)
Hofchen	Silt	2.14	7.1	64.1	2995.0	0.88	Y/EFSA (2007)
Stanley	Silty Clay Loam	1.66	5.9	41.2	2484.0	0.91	Yes, EFSA (2007)
Byromville	Loamy Sand	0.79	6.8	15.6	1973.6	0.85	Yes, EFSA (2007)
				Arithmetic mean	2556.3	0.88	
				Geomean (n=4)	2526	-	
				pH-dependency: No			

Table 8.5.1-3: Summary of soil adsorption/desorption for prothioconazole-desthio (M04)

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	Yes, EFSA (2007)
Hofchen	Silt	2.14	7.1	13.38	625.3	0.83	Yes, EFSA (2007)
Stanley	Silty Clay Loam	1.66	5.9	8.90	536.4	0.83	Yes, EFSA (2007)
Byromville	Loamy Sand	0.79	6.8	4.13	523.0	0.80	Yes, EFSA (2007)
Arithmetic mean					575.4	0.81	
Geomean (n=4)					573.5	-	
pH-dependency: No							

Table 8.5.1-4: Summary of soil adsorption/desorption for 1,2,4-triazole (M13, from PTZ)

1,2,4-triazole (M13, from PTZ)							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Data not given in EFSA Scientific Report				not stated	43-202	0.827-1.016	y/ EFSA & DAR
Arithmetic mean (n=4)					89	0.9155	
Geomean (n=4)					83	-	
pH-dependency y/n					No pH dependence		

8.5.2 Column leaching (KCP 9.1.2.1)

The leaching behaviour of prothioconazole was investigated in a column leaching study with four soils (loamy sand, sandy loam, silt, silty clay loam). Formulated product containing radiolabelled prothioconazole was applied at a max. use rate of 200 g a.s./ha to leaching columns. In order to achieve the equivalent of 200 mm rainfall, 393 ml of water with a flow rate of 0.139 ml/min was delivered to the column. Leachates were collected in two fractions and analysed. Because of low radioactive residues (<1% AR), the leachate fractions were not investigated by analytical methods.

An aged column leaching study was carried out with prothioconazole with a sandy loam soil. The test substance, formulated product containing radiolabelled prothioconazole, was applied to the soil at a max. rate of 200 g a.s./ha. The soil was incubated at 20°C for a total of 30 hours. Following incubation, the aged soil samples were applied to soil columns, which were then irrigated at 1000 mm. The leaching period was five days. Leachate was collected in fractions and analysed. 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. Distribution of prothioconazole and the two metabolites was used to estimate K_d and K_{oc} values for the compounds. The K_{oc} for prothioconazole was estimated to be 1765 (ml/g).

8.5.3 Lysimeter studies (KCP 9.1.2.2)

Not relevant. No studies submitted.

8.5.4 Field leaching studies (KCP 9.1.2.3)

Not relevant. No studies submitted.

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

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

Water/sediment studies were carried out with prothioconazole to investigate the degradation of the substance in aqueous systems under aerobic conditions, results of which are presented in the table below.

Data on the aqueous photolysis of prothioconazole were also presented in the DAR. The DT_{50} values determined were 44.3 hrs and 51.4 hrs for phenyl- and triazole-labelled test substance respectively. The mean environmental half-live was 47.7 hours, corresponding to a predicted under solar summer conditions (June) of 7.1 and 11 days in Arizona (USA) and Athens (Greece) respectively. Dark control samples of prothioconazole were stable, confirming that photolysis was the main process of degradation. Prothioconazole-desthio (M04, 55.7% AR), prothioconazole-thiazocine (M12, 14.1% AR) and 1,2,4-triazole (M13, 11.9% AR) were detected as major metabolites. While degradation of the parent substance is expected to be influenced by light in aqueous systems, the photodegradation of prothioconazole-desthio (M04) is not expected to contribute to the overall degradation based on quantum yield analysis (Φ of 0.00449). It was concluded that prothioconazole-thiazocine (M12) will not be formed under realistic environmental conditions at any significant amounts, based on data from the water/sediment and photolysis studies. The UV-absorption data in the environmentally relevant pH range showed that 1,2,4-triazole (M13) dissolved in aqueous solution does not absorb any light at wavelengths above 290 nm.

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

Prothioconazole Distribution (max. sediment: phenyl-label 21.0 – 23.4%; triazole-label 18.3 – 22.6%)										
Water/sediment system	**pH water/ sed.**	**DT50 whole syst. (d)**	**DT90 whole syst. (d)**	**Kinetic, Fit**	**DT50 water (d)**	**DT90 water (d)**	**Kinetic, Fit**	**DT50 sed. (d)**	**Kin etic, Fit**	**Evaluated on EU level y/n/ Reference**
Honninger Weiher	7.84/ 6.6	2.8	76.4	Hockey Stick	0.8	2.7	1st Order	-	-	Yes, EFSA (2007)
Angler Weiher	7.45/ 8.5	1.6	23.6	Hockey Stick	1.0	3.4	1st Order	-	-	Yes, EFSA (2007)
Mineralisation and non-extractable residues										

Water/sediment system	pH water/ sed.	Mineralisation x % after n d. (end of the study)	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)	Evaluated on EU level y/n/ Reference
Honninger Weiher (phenyl label)	7.84/6.6	14.7% (121 d)	-	50.8% (121 d)	Yes, EFSA (2007)
Angler Weiher (phenyl label)	7.45/8.5	29.0% (121 d)	-	31.3% (121 d)	Yes, EFSA (2007)
Honninger Weiher (triazole label)	7.84/6.6	1.9% (121 d)	-	52.2% (121 d)	Yes, EFSA (2007)
Angler Weiher (triazole label)	7.45/8.5	1.9% (121 d)	-	18.9% (121 d)	Yes, EFSA (2007)

Table 8.6-2: Summary of observed metabolites

Prothioconazole-S-methyl (M01) Water/sediment system	Max. in sediment 77% after 240 d	DAR & EFSA (2007)
Prothioconazole-desthio (M04) Water/sediment system	Max. in water 55.7 %after 11 d Max. in sediment 26.9 % after 14 d	DAR & EFSA (2007)
1,2,3-triazole (M13) Water/sediment system	Max. in water 37.2 % after 121 d	EFSA (2007)

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

8.7.1 Justification for new endpoints

Not relevant. No new endpoints proposed.

8.7.2 Active substance and relevant metabolites

The predicted environmental concentrations in soil (PECs) of prothioconazole and its metabolites were calculated using Excel sheet according to recommendations by the "FOCUS" group (FOCUS report, 29.02.1997). Calculations were based on a simple first tier approach. Input parameters related to application and active substance/metabolites data for PECs calculation are summarized below.

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

Use No.	1-6			7	8
Crop	winter cereals and spring cereals			winter oilseed rape	
Application rate (g as/ha)	195	195	195	180	180
Number of applications/interval	2/14	2/14	2/14	1/-	2/21
Crop interception (%)	20 (BBCH 29)	80 (BBCH 30-39)	90 (BBCH 40-65)	40 (BBCH 13-19)	80 (BBCH 61-72)
Depth of soil layer (relevant for plateau concentration) (cm)	5 (no tillage)	5 (no tillage)	5 (no tillage)	5 (no tillage)	5 (no tillage)

Soil density (g/cm^3)	1.5	1.5	1.5	1.5	1.5

Table 8.7.2-2: Input parameter for active substance 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 (max. from field)	Yes, EFSA (2007)
Prothioconazole-S-Methyl (M01)	358.3	14.6	46 (max. from lab)	Yes, EFSA (2007)
Prothioconazole-desthio (M04)	312.2	57.1	72.3 (max. from field)	Yes, EFSA (2007)

Table 8.7.2-3: PEC$_{soil}$ for prothioconazole in winter and spring cereals

PEC$_{soil}$ (mg/kg)		2x195 g a.s./ha, interval: 14d, BBCH 29				2x195 g a.s./ha, interval: 14d, BBCH 30-39				2x195 g a.s./ha, interval: 14d, BBCH 40-65			
		Single application		Multiple applications		Single application		Multiple applications		Single application		Multiple applications	
		Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
Initial		0.208	-	0.215	-	0.052	-	0.054	-	0.026	-	0.027	-
Short term	24h	0.162	0.184	0.167	0.190	0.041	0.046	0.042	0.048	0.020	0.023	0.021	0.024
	2d	0.127	0.164	0.131	0.169	0.032	0.041	0.033	0.042	0.016	0.021	0.016	0.021
	4d	0.077	0.132	0.080	0.136	0.019	0.033	0.020	0.034	0.010	0.017	0.010	0.017
Long term	7d	0.037	0.099	0.038	0.102	0.009	0.025	0.009	0.025	0.005	0.012	0.005	0.013
	14d	0.007	0.058	0.007	0.060	0.002	0.015	0.002	0.015	0.001	0.007	0.001	0.007
	21d	0.001	0.040	0.001	0.041	0.000	0.010	0.000	0.010	0.000	0.005	0.000	0.005
	28d	0.000	0.030	0.000	0.031	0.000	0.007	0.000	0.008	0.000	0.004	0.000	0.004
	50d	0.000	0.017	0.000	0.017	0.000	0.004	0.000	0.004	0.000	0.002	0.000	0.002
	100d	0.000	0.008	0.000	0.009	0.000	0.002	0.000	0.002	0.000	0.001	0.000	0.001
Plateau concentration (5cm) after 10 years		-	-	-	-	-	-	-	-	-	-	-	-
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		-	-	-	-	-	-	-	-	-	-	-	-

PEC_{soil} of metabolites

Table 8.7.2-4: PEC_{soil} for prothioconazole-S-Methyl (M01) in winter and spring cereals

PEC_{soil} (mg/kg)		2x195 g a.s./ha, interval: 14d, BBCH 29				2x195 g a.s./ha, interval: 14d, BBCH 30-39				2x195 g a.s./ha, interval: 14d, BBCH 40-65			
		Single application		Multiple applications		Single application		Multiple applications		Single application		Multiple applications	
		Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
Initial		0.032	-	0.057	-	0.008	-	0.014	-	0.004	-	0.007	-
Short term	24h	0.031	0.031	0.056	0.057	0.008	0.008	0.014	0.014	0.004	0.004	0.007	0.007
	2d	0.031	0.031	0.055	0.056	0.008	0.008	0.014	0.014	0.004	0.004	0.007	0.007
	4d	0.030	0.031	0.054	0.056	0.007	0.008	0.013	0.014	0.004	0.004	0.007	0.007
Long term	7d	0.028	0.030	0.051	0.054	0.007	0.007	0.013	0.014	0.004	0.004	0.006	0.007
	14d	0.026	0.028	0.046	0.052	0.006	0.007	0.012	0.013	0.003	0.004	0.006	0.006
	21d	0.023	0.027	0.042	0.049	0.006	0.007	0.010	0.012	0.003	0.003	0.005	0.006
	28d	0.021	0.026	0.038	0.047	0.005	0.006	0.009	0.012	0.003	0.003	0.005	0.006
	50d	0.015	0.022	0.027	0.040	0.004	0.006	0.007	0.010	0.002	0.003	0.003	0.005
	100d	0.007	0.016	0.013	0.030	0.002	0.004	0.003	0.007	0.001	0.002	0.002	0.004
Plateau concentration (5cm) after 10 years		-	-	-	-	-	-	-	-	-	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-	-	-	-	-	-	-	-	-	-	-

Table 8.7.2-5: PEC$_{soil}$ for prothioconazole-desthio (M04) in winter and spring cereals

PEC$_{soil}$ (mg/kg)		2x195 g a.s./ha, interval: 14d, BBCH 29				2x195 g a.s./ha, interval: 14d, BBCH 30-39				2x195 g a.s./ha, interval: 14d, BBCH 40-65			
		Single application		Multiple applications		Single application		Multiple applications		Single application		Multiple applications	
		Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
Initial		0.108	-	0.202	-	0.027	-	0.050	-	0.013	-	0.025	-
Short term	24h	0.107	0.107	0.200	0.201	0.027	0.027	0.050	0.050	0.013	0.013	0.025	0.025
	2d	0.106	0.107	0.198	0.200	0.026	0.027	0.050	0.050	0.013	0.013	0.025	0.025
	4d	0.104	0.106	0.194	0.198	0.026	0.026	0.049	0.050	0.013	0.013	0.024	0.025
Long term	7d	0.101	0.104	0.189	0.195	0.025	0.026	0.047	0.049	0.013	0.013	0.024	0.024
	14d	0.094	0.101	0.177	0.189	0.024	0.025	0.044	0.047	0.012	0.013	0.022	0.024
	21d	0.088	0.098	0.165	0.183	0.022	0.024	0.041	0.046	0.011	0.012	0.021	0.023
	28d	0.082	0.094	0.154	0.177	0.021	0.024	0.039	0.044	0.010	0.012	0.019	0.022
	50d	0.067	0.086	0.125	0.160	0.017	0.021	0.031	0.040	0.008	0.011	0.016	0.020
	100d	0.041	0.069	0.077	0.130	0.010	0.017	0.019	0.032	0.005	0.009	0.010	0.016
Plateau concentration (5cm) after 10 years		-	-	-	-	-	-	-	-	-	-	-	-
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		-	-	-	-	-	-	-	-	-	-	-	-

Table 8.7.2-6: PEC_{soil} for prothioconazole in winter oilseed rape

PEC_{soil} (mg/kg)		180 g a.s./ha, BBCH 13-19				2x180 g a.s./ha, interval: 21d, BBCH 61-72			
		Single application		Multiple applications		Single application		Multiple applications	
		Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
Initial		0.144	-	-	-	0.048	-	0.048	-
Short term	24h	0.112	0.128	-	-	0.037	0.043	0.038	0.043
	2d	0.088	0.114	-	-	0.029	0.038	0.029	0.038
	4d	0.053	0.091	-	-	0.018	0.030	0.018	0.031
Long term	7d	0.025	0.068	-	-	0.008	0.023	0.009	0.023
	14d	0.005	0.040	-	-	0.002	0.013	0.002	0.013
	21d	0.001	0.028	-	-	0.000	0.009	0.000	0.009
	28d	0.000	0.021	-	-	0.000	0.007	0.000	0.007
	50d	0.000	0.012	-	-	0.000	0.004	0.000	0.004
	100d	0.000	0.006	-	-	0.000	0.002	0.000	0.002
Plateau concentration (5cm) after 10 years		-	-	-	-	-	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-	-	-	-	-	-	-

Table 8.7.2-7: PEC_{soil} for prothioconazole-S-Methyl (M01) in winter oilseed rape

PEC_{soil} (mg/kg)		180 g a.s./ha, BBCH 13-19				2x180 g a.s./ha, interval: 21d, BBCH 61-72			
		Single application		Multiple applications		Single application		Multiple applications	
		Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
Initial		0.022	-	-	-	0.007	-	0.013	-
Short term	24h	0.022	0.022	-	-	0.007	0.007	0.012	0.013
	2d	0.021	0.022	-	-	0.007	0.007	0.012	0.012
	4d	0.021	0.021	-	-	0.007	0.007	0.012	0.012
Long term	7d	0.020	0.021	-	-	0.007	0.007	0.011	0.012
	14d	0.018	0.020	-	-	0.006	0.007	0.010	0.011
	21d	0.016	0.019	-	-	0.005	0.006	0.009	0.011
	28d	0.014	0.018	-	-	0.005	0.006	0.008	0.010
	50d	0.010	0.015	-	-	0.003	0.005	0.006	0.009
	100d	0.005	0.011	-	-	0.002	0.004	0.003	0.007
Plateau concentration (5cm) after 10 years		-	-	-	-	-	-	-	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-	-	-	-	-	-	-

Table 8.7.2-8: PEC$_{soil}$ for prothioconazole-desthio (M04) in winter oilseed rape

PEC$_{soil}$ (mg/kg)		180 g a.s./ha, BBCH 13-19				2x180 g a.s./ha, interval: 21d, BBCH 61-72			
		Single application		Multiple applications		Single application		Multiple applications	
		Actual	TWA	Actual	TWA	Actual	TWA	Actual	TWA
Initial		0.075	-	-	-	0.025	-	0.045	-
Short term	24h	0.074	0.074	-	-	0.025	0.025	0.045	0.045
	2d	0.073	0.074	-	-	0.024	0.025	0.044	0.045
	4d	0.072	0.073	-	-	0.024	0.024	0.043	0.044
Long term	7d	0.070	0.072	-	-	0.023	0.024	0.042	0.044
	14d	0.065	0.070	-	-	0.022	0.023	0.039	0.042
	21d	0.061	0.068	-	-	0.020	0.023	0.037	0.041
	28d	0.057	0.065	-	-	0.019	0.022	0.035	0.040
	50d	0.046	0.059		-	0.015	0.020	0.028	0.036
	100d	0.029	0.048	-	-	0.010	0.016	0.017	0.029
Plateau concentration (5cm) after 10 years		-	-	-	-	-	-	-	-
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		-	-	-	-	-	-	-	-

8.7.2.1 PEC$_{soil}$ of formulation

PECs for formulation was obtained from PECs for prothioconazole taking into account content of active substance and density of the formulation Protiokonazol 300 EC. TWA PECs, $_{background}$ PECs and accumulation PECs are not relevant for formulation.

Table 8.7.2-1: PECs for formulation after application to winter cereals, spring cereals and winter oilseed rape

Formulation	Application rate (g/ha)	PEC$_{act}$ (mg/kg)	PECact * (mg formulation/kg)
Protiokonazol 300 EC	2 x 195	0.215	0.689

* application rate calculated on the basis of density 1.033 g/ml

ZRMS comments:

The calculations PECsoil has been accepted for the active substance prothioconazole and its metabolites M01 and M04. The input parameters used in calculations were taken from the endpoints available in the EFSA conclusion on Scientific Report (2007) 106, 1-98. Interception is appropriate to the proposed BBCH of crops (guidance 2014).

Maximum PEC$_{soil}$ values are:
Prothioconazole: 0.215(mg/kg)
Prothioconazole-S-methyl : 0.022 (mg/kg)
Prothiuoconazole-desthio: 0.072 (mg/kg)

Protiokonazol 300 EC: 0.689 (mg formulation/kg)

The acceptable predicted environmental concentrations of prothioconazole and its metabolites in soil are appropriate to be used for the subsequent risk assessment.

8.8 Predicted Environmental Concentrations in groundwater (PEC$_{gw}$) (KCP 9.2.4)

8.8.1 Justification for new endpoints

Not relevant. No new endpoints proposed.

8.8.2 Active substance and relevant metabolites (KCP 9.2.4)

PECgw for active substance and its metabolites after application to winter cereals, spring cereals, winter oilseed rape were calculated with PELMO 6.6.4 and PEARL 5.5.5 for FOCUS groundwater scenarios. Application timing for each crop/scenario was settled with AppDate 3.06. Input parameters related to application and active substance and metabolites data for PECgw calculation are summarized below.

Table 8.8.2-1: Input parameters related to application for PEC$_{gw}$ calculations

Use No.	1,3,6	2,4,5	7	8

Crop	Winter cereals (BBCH 29)	Spring cereals (BBCH 29)	Winter oilseed rape (BBCH 13)	Winter oilseed rape (BBCH 61)
Application rate (g as/ha)	195	195	180	180
Number of applica-tions/interval (d)	2/14	2/14	1/-	2/21
Relative application date	-	-	-	-
Crop interception (%)	20	20	40	80
Frequency of applica-tion	annual			
Models used for calcu-lation	FOCUS PEARL 5.5.5, FOCUS PELMO 6.6.4			

Table 8.8.2-2: Application dates used for groundwater risk assessment

Scenario	Application dates (absolute)*				
	Crops				
	Winter cereals (BBCH 29)	**Spring cereals (BBCH 29**	**Maize* (BBCH 30)**	**Winter oilseed rape 1 application (BBCH 13)**	**Winter oilseed rape 2 applications (BBCH 61)**
Châteaudun	14.04 - 28.08	15.04 - 29.04	-	12.09	23.04 -14.05
Hamburg	03.05 - 17.05	26.04 - 10.05	-	07.09	08.05 - 29.05
Jokioinen	13.05 - 27.05	04.06 - 28.06	-	-	-
Kremsmünster	23.04 - 07.05	26.04 - 10.05	-	7.09	08.05 - 29.05
Okehampton	20.04 - 04.05	21.04 - 05.05	-	19.08	03.05 - 24.05
Piacenza	18.03 - 02.04	-	10.06 - 24.06	10.10	17.04 - 08.05
Porto	27.01 - 10.02	15.04 - 29.04	-	25.09	23.04 -14.05
Sevilla	04.01 - 18.01	-	10.04 - 24.04	-	-
Thiva	15.01 - 29.01	-	09.05 - 23.05	-	-

*as surrogate for spring cereals, interception 50%

Table 8.8.2-3: 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/
Molecular weight (g/mol)	344.26	358.3	312.2	Yes, EFSA (2007)
Water solubility (mg/l) at 20°C:	300	1000 (default)	1000 (default)	Yes, EFSA (2007)

Saturated vapour pressure (Pa) at 20°C:	0 Pa at 20°C (used as DT_{50} derived from field study)	1 x 10^{-10} Pa at 20°C (default)	1 x 10^{-10} Pa at 20°C (default)	Yes, EFSA (2007)
DT_{50} in soil (d)	1.2 (field, geomean, n =8)	15.7 (lab, geomean, n =4)	22.7 (field, geomean, n =8)	Yes, EFSA (2007)
Transformation rate	0.57762 (to M01)	0.04415 (to M04)	0.030535 (to sink)	Calculated for PELMO; ($ln(2)/DT_{50}$) x FFm
K_{foc} (mL/g)/K_{fom}	1765 / 1023.8 (aged leaching study, n = 1)	2525.9 /1465.1 (geomean, n = 4)	573.5 / 332.7 (geomean, n = 4)	Yes, EFSA (2007)
1/n	0.9 (default)	0.88 (arithmetic mean, n = 4)	0.81 (arithmetic mean, n = 4)	Yes, EFSA (2007)
Plant uptake factor	0	0	0	Yes, EFSA (2007)
Formation fraction	-	1 from parent (worst case)	1 from M01 (worst case)	-

Table 8.8.2-4: PEC_{gw} for prothioconazole and metabolites on winter and spring cereals and winter oilseed rape (PELMO 6.6.4 and PEARL 5.5.5)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)					
		FOCUS PELMO			FOCUS PEARL		
		Prothio-conazole	S-methyl	Desthio	Prothio-conazole	S-methyl	Desthio
Winter Cereals	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Spring Cereals	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Maize*	Piacenza	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

Winter oilseed rape (1 application)	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Winter oilseed rape (2 applications)	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

*as surrogate for spring cereals

For all scenarios PECgw values for prothioconazole and its metabolites are below the trigger value of 0.1 µg/L.

ZRMS comments:

The calculations PECgw has been accepted for the active substance prothioconazole and its metabolites M01 and M04. For active substance and its relevant metabolites PEC_{gw} calculations were performed with FOCUS new versions of models: FOCUS PEARL 5.5.5 and FOCUS PELMO 6.6.4. The input parameters used in calculations were taken from the endpoints available in the EFSA conclusion on Scientific Report (2007) 106, 1-98. Geometric mean K_{foc} for all compounds were derived from the datasets presented in the EFSA Scientific Report (2007) 106, 1-98 for consistency with current EU Guidance. The interception is appropriate to the proposed BBCH of crops (guidance 2014). In simulations PUF value of 0 was assumed for all compounds, in line with recommendations of the most recent version of the FOCUS Groundwater Guidance.

The PECgw values for active substance prothioconazole and its metabolites are below the trigger value 0.1 µg/L in all existing scenarios.
The the results indicate safely uses for the recommended use in GAP.

Nevertheless, additional simulations may be required by the sMS that do not accept calculations performed using FOCUS models.

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

8.9.1 Justification for new endpoints

Not relevant. No new endpoints proposed.

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

PECsw for prothioconazole and its metabolites after application to winter cereals, spring cereals and winter oilseed rape were calculated with FOCUS STEPS 1-2 v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3, SWAN v.5.0.1. Application timing for each crop/scenario was settled with AppDate 3.06. Input parameters related to application and active substance/metabolites data for PECsw calculation are summarized below.

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

Use No.	1,3,6	2,4,5	7	8
Crop	Winter cereals	Spring cereals	Winter oilseed rape	Winter oilseed rape
Application rate (g as/ha)	195	195	180	180
Number of applications/interval (d)	2/14	2/14	1/-	2/21
Application window	March – May, June-September (relevant for STEP 1 and 2 only)	March – May, June-September (relevant for STEP 1 and 2 only)	June-September, October-February (relevant for STEP 1 and 2 only)	March – May, June-September (relevant for STEP 1 and 2 only)
Interception	minimal crop cover (relevant for STEP 1 and 2 only)			
Application method	ground spray			
CAM (Chemical application method)	foliar linear			
Soil depth (cm)	4			
Models used for calculation	STEPS 1-2 in FOCUS v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3, SWAN v5.0.1			

Table 8.9.2-2: FOCUS Step 3 Scenario related input parameters for $PEC_{sw/sed}$ calculations

Crop	Scenario	Application window used in modelling	
		DD/MM	Julian day
Winter cereals BBCH 29-65	D1	24/03 - 17/08	83 - 229
	D2	03/04 - 19/08	93 - 231
	D3	15/04 - 10/09	105 - 253
	D4	17/03 - 14/08	76 - 226
	D5	14/03 - 08/07	73 - 189
	D6	10/02 - 28/05	41 - 148
	R1	23/04 - 02/08	113 - 214
	R3	18/03 - 02/07	77 - 183
	R4	20/01 - 08/07	20 - 189
Spring cereals BBCH 29-65	D1	26/05 – 22/08	146 -234
	D3	26/04 – 01/08	116 – 213
	D4	17/05 – 13/08	137 – 225
	D5	08/04 – 09/07	98 - 190
	R4	08/04 – 09/07	98 - 190

Crop	Scenario	Application window used in modelling	
Maize* BBCH 30-65	D6	09/05 – 30/07	129 - 211
	R1	05/06 – 14/09	156- 257
	R2	06/06 – 22/09	157 - 265
	R3	30/05 – 04/09	150 - 247
Winter oilseed rape (1 application) BBCH 13-19	D2	20/09 – 29/10	263 -302
	D3	07/09 – 16/10	250 – 289
	D4	08/09 – 17/10	251 - 290
	D5	25/09 – 3/11	268 - 307
	R1	09/09 – 18/10	252 - 291
	R3	10/10 – 18/11	283 - 322
Winter oilseed rape (2 applications) BBCH 61-72	D2	16/06 – 17/08	167 - 229
	D3	27/05 -06/08	147 - 218
	D4	07/06 – 28/08	158 - 240
	D5	12/05 – 22/07	132 - 203
	R1	27/05 – 02/08	147 - 214
	R3	22/04 – 28/06	112 - 179

*as surrogate for spring cereals

Table 8.9.2-3: Input parameters related to active substance prothioconazole and metabolites for $PEC_{sw/sed}$ calculations STEP 1, 2, 3 and 4

Compound	prothioconazole	prothioconazole-S-methyl (M01)	prothioconazole-desthio (M04)	1,2,4-triazole (M13)	Value in accordance with EU endpoint y/n/ Reference
Molecular weight (g/mol)	344.26	358.3	312.2	69.065	Yes, EFSA (2007)
Saturated vapour pressure (Pa)	not required for Step 1+2/ $4 \cdot 10^{-7}$ (20ºC)	not required for Step 1+2	$1 \cdot 10^{-10}$ (20ºC) (default)	not required for Step 1+2	Yes, EFSA (2007)
Water solubility (mg/L)	300 (20ºC)	1000 (default)	1000 (default)	730000	Yes, EFSA (2007)
Diffusion coefficient in water (m²/d)	not required for Step 1+2/ 4.3×10^{-5}	not required for Step 1+2	not required for Step 1+2/ 4.3×10^{-5}	not required for Step 1+2	Yes, EFSA (2007)
Diffusion coefficient in air (m²/d)	not required for Step 1+2/0.43	not required for Step 1+2	not required for Step 1+2/0.43	not required for Step 1+2	Yes, EFSA (2007)
K_{foc} /K_{om} (mL/g)	1765 / 1023.8 (aged leaching study, n = 1)	2525.9 /1465.1 (geomean, n = 4)	573.5 / 332.7 (geomean, n = 4)	83/48.1 (geomean, n=4)	Yes, EFSA (2007)
Freundlich Exponent 1/n	0.9 (default)	not required for Step 1+2	0.81 (arithmetic mean, n = 4)	not required for Step 1+2	Yes, EFSA (2007)
Plant Uptake	not required for Step 1+2/ 0 (default)	not required for Step 1+2	not required for Step 1+2/ 0 (default)	not required for Step 1+2	Yes, EFSA (2007)
Wash-Off factor from Crop (1/mm)	not required for Step 1+2/ 0.05 (MACRO) 0.50 (PRZM)	not required for Step 1+2	not required for Step 1+2/ 0.05 (MACRO) 0.50 (PRZM)	not required for Step 1+2	Yes, EFSA (2007)
$DT_{50,soil}$ (d)	1.2 (field, geomean, n =8)	15.7 (lab, geomean, n =4)	22.7 (field, geomean, n =8)	60.5 (field, geomean, n =4)	Yes, EFSA (2007)
$DT_{50,water}$ (d)	1 (lab. max., n=2)	1000 (default)	1000 (default)	1000 (default)	Yes, EFSA (2007)
$DT_{50,sed}$ (d)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	Yes, EFSA (2007)
$DT_{50,whole\ system}$ (d)	1.6 (lab. max., n=2)	1000 (default)	1000 (default)	1000 (default)	Yes, EFSA (2007)
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 14.6% Sediment: 77%	Soil: 57.1% Total system: 54.6% Water: 32.3% Sediment: 26.9%	Soil: 0.001% Water: 37.2%	Yes, EFSA (2007)
Formation	-	-	0.571 (soil)	-	

fraction:			1 (water) 1 (sediment)		

PEC$_{sw/sed}$

Table 8.9.2-4: FOCUS Step 1 and 2 PEC$_{sw}$ and PEC$_{sed}$ for prothioconazole following application of Protiokonazol 300 EC to winter and spring cereals and winter oilseed rape

Scenario FOCUS	Waterbody	Max PEC$_{sw}$ (µg/L)	Dominant entry route	PEC$_{sw}$ TWA21 (µg/L)	Max PEC$_{sed}$ (µg/kg)
Winter and spring cereals					
Step 1	NR	21.1770	NR	2.2312	342.1223
Step 2 Northern Europe March-May	NR	1.6045	NR	0.1910	10.8237
Step 2 Northern Europe June-September	NR	1.6045	NR	0.1910	10.8237
Step 2 Southern Europe March-May	NR	1.6045	NR	0.2663	17.6144
Step 2 Southern Europe June-September	NR	1.6045	NR	0.2287	14.2190
Winter oilseed rape, 1 application					
Step 1	NR	19.5480	NR	2.0595	315.8052
Step 2 Northern Europe June-September	NR	1.6554	NR	0.1576	7.7020
Step 2 Northern Europe October-February	NR	1.6554	NR	0.2201	13.3417
Step 2 Southern Europe June-September	NR	1.6554	NR	0.1784	9.5819
Step 2 Southern Europe October-February	NR	1.6554	NR	0.1993	11.4618
Winter oilseed rape, 2 applications					
Step 1	NR	19.5480	NR	2.0595	315.8052
Step 2 Northern Europe March-May	NR	1.4676	NR	0.1452	7.3061
Step 2 Northern Europe June-September	NR	1.4676	NR	0.1452	7.3061
Step 2 Southern Europe March-May	NR	1.4676	NR	0.1869	11.0659
Step 2 Southern Europe June-September	NR	1.4676	NR	0.1661	9.1860

Metabolites of prothioconazole

Table 8.9.2-5: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for prothioconazole-S-methyl (M01) following application of Protiokonazol 300 EC to winter and spring cereals and winter oilseed rape

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	PEC_{sw} TWA21 (µg/L)	Max PEC_{sed} (µg/kg)
Winter and spring cereals					
Step 1	NR	31.2490	NR	28.8752	732.8282
Step 2 Northern Europe March-May	NR	1.6575	NR	1.3321	35.2663
Step 2 Northern Europe June-September	NR	1.6575	NR	1.3321	35.2663
Step 2 Southern Europe March-May	NR	2.4207	NR	2.2060	55.9658
Step 2 Southern Europe June-September	NR	2.0106	NR	1.7989	45.6160
Winter oilseed rape, 1 application					
Step 1	NR	14.4226	NR	13.3270	338.2284
Step 2 Northern Europe June-September	NR	1.3266	NR	0.6434	16.2526
Step 2 Northern Europe October-February	NR	1.3266	NR	1.0673	29.1635
Step 2 Southern Europe June-September	NR	1.3266	NR	0.7847	20.5562
Step 2 South Europe October-February	NR	1.3266	NR	0.9260	24.8598
Winter oilseed rape, 2 applications					
Step 1	NR	28.8452	NR	26.6540	676.4568
Step 2 Northern Europe March-May	NR	1.5283	NR	0.9525	24.1180
Step 2 Northern Europe June-September	NR	1.5283	NR	0.9525	24.1180
Step 2 Southern Europe March-May	NR	1.5669	NR	1.3740	34.8220
Step 2 Southern Europe June-September	NR	1.5283	NR	1.1281	29.4700

Table 8.9.2-6: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for prothioconazole-desthio (M04) following application of Protiokonazol 300 EC to winter and spring cereals and winter oilseed rape

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	PEC_{sw} TWA21 (µg/L)	Max PEC_{sed} (µg/kg)
Winter and spring cereals					
Step 1	NR	76.4002	NR	75.1012	433.4414
Step 2 Northern Europe March-May	NR	6.9715	NR	6.7765	39.0994
Step 2 Northern Europe June-September	NR	6.9715	NR	6.7765	39.0994
Step 2 Southern Europe March-May	NR	12.9114	NR	12.6734	73.1408
Step 2 Southern Europe June-September	NR	9.9414	NR	9.7250	56.1201
Winter oilseed rape, 1 application					
Step 1	NR	35.2617	NR	34.6621	200.0499
Step 2 Northern Europe June-September	NR	2.6118	NR	2.5170	14.5195
Step 2 Northern Europe October-February	NR	5.7172	NR	5.6000	32.3168
Step 2 Southern Europe June-September	NR	3.6470	NR	3.5447	20.4520
Step 2 Southern Europe October-February	NR	4.6821	NR	4.5723	26.3844
Winter oilseed rape, 2 applications					
Step 1	NR	70.5233	NR	69.3242	400.0998
Step 2 Northern Europe March-May	NR	4.0051	NR	3.8430	22.1661
Step 2 Northern Europe June-September	NR	4.0051	NR	3.8430	22.1661
Step 2 Southern Europe March-May	NR	7.0601	NR	6.8759	39.6746
Step 2 Southern Europe June-September	NR	5.5326	NR	5.3595	30.9204

Table 8.9.2-7: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for 1,2,4-triazole (M13) following application of Protiokonazol 300 EC to winter and spring cereals and winter oilseed rape

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	PEC_{sw} TWA21 (µg/L)	Max PEC_{sed} (µg/kg)
Winter and spring cereals					
Step 1	NR	9.0038	NR	8.9127	7.4458
Step 2 Northern Europe March-May	NR	0.3054	NR	0.2961	0.2473
Step 2 Northern Europe June-September	NR	0.3054	NR	0.2961	0.2473
Step 2 Southern Europe March-May	NR	0.3921	NR	0.3822	0.3192
Step 2 Southern Europe June-September	NR	0.3487	NR	0.3392	0.2832
Winter oilseed rape, 1 application					
Step 1	NR	4.1556	NR	4.1136	3.4365
Step 2 Northern Europe June-September	NR	0.1628	NR	0.1579	0.1318
Step 2 Northern Europe October-February	NR	0.2348	NR	0.2294	0.1916
Step 2 Southern Europe June-September	NR	0.1868	NR	0.1817	0.1517
Step 2 Southern Europe October-February	NR	0.2108	NR	0.2056	0.1717
Winter oilseed rape, 2 applications					
Step 1	NR	8.3112	NR	8.2271	6.8731
Step 2 Northern Europe March-May	NR	0.2493	NR	0.2411	0.2013
Step 2 Northern Europe June-September	NR	0.2493	NR	0.2411	0.2013
Step 2 Southern Europe March-May	NR	0.2974	NR	0.2887	0.2411
Step 2 Southern Europe June-September	NR	0.2734	NR	0.2649	0.2212

PEC_{sw} values for the aqueous photolysis product prothioconazole thiazocine (M12) were calculated by multiplying the peak parent PEC_{sw} by the maximum observed metabolite level in the photolysis study (14.1%) and correcting for molecular weight difference (307.8/344.3). The PEC_{sw} values were only calculated from the highest FOCUS Step 1-2 parent value for cereals and oilseed rape.

Table 8.9.2-8: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} prothioconazole thiazocine (M12) following application of Protiokonazol 300 EC to winter and spring cereals and winter oilseed rape

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	PEC_{sw} TWA21 (µg/L)	Max PEC_{sed} (µg/kg)
Winter and spring cereals					
Step 1	NR	2.66941	NR	1.12347	43.1253
Step 2 Northern Europe March-May	NR	0.20225	NR	0.03732	1.3644
Step 2 Northern Europe June-September	NR	0.20225	NR	0.03732	1.3644
Step 2 Southern Europe March-May	NR	0.20225	NR	0.04818	2.2203
Step 2 Southern Europe June-September	NR	0.20225	NR	0.04276	1.7923
Winter oilseed rape, 1 application					
Step 1	NR	2.46407	NR	0.51853	39.8080
Step 2 Northern Europe June-September	NR	0.20867	NR	0.01990	0.9709
Step 2 Northern Europe October-February	NR	0.20867	NR	0.02892	1.6818
Step 2 Southern Europe June-September	NR	0.20867	NR	0.02290	1.2078
Step 2 Southern Europe October-February	NR	0.20867	NR	0.02592	1.4448
Winter oilseed rape, 2 applications					
Step 1	NR	2.46407	NR	1.03704	39.8080
Step 2 Northern Europe March-May	NR	0.18499	NR	0.03039	0.9210
Step 2 Northern Europe June-September	NR	0.18499	NR	0.03039	0.9210
Step 2 Southern Europe March-May	NR	0.18499	NR	0.03639	1.3949
Step 2 Southern Europe June-September	NR	0.18499	NR	0.03339	1.1579

Table 8.9.2-9: FOCUS Step 3 PEC_{sw} and PEC_{sed} for prothioconazole and for prothioconazole-desthio (M04) following application of Protiokonazol 300 EC to winter and spring cereals and winter oilseed rape

Crop	Location	Water body	Max PEC_{sw} (µg/L)	Max PEC_{sed} (µg/kg)	Max PEC_{sw} (µg/L)	Max PEC_{sed} (µg/kg)
			prothioconazole		prothioconazole-desthio (M04)	
Winter cereals	D1	ditch	1.093	1.778	0.01404	0.1610
	D1	stream	0.9211	0.1757	0.008877	0.09294
	D2	ditch	1.096	1.530	0.09891	0.2247
	D2	stream	0.9562	1.074	0.06217	0.1035
	D3	ditch	1.082	0.7536	< 1e-6	< 1e-6
	D4	pond	0.03538	0.1038	0.001830	0.01516
	D4	stream	0.8161	0.03495	0.008691	0.007649
	D5	pond	0.03620	0.08887	0.000108	0.001298
	D5	stream	0.9422	0.07744	0.000881	0.000223
	D6	ditch	1.086	0.9524	0.000329	0.000088
	R1	pond	0.03490	0.09314	0.05796	0.6155
	R1	stream	0.7061	1.212	**0.3619**	0.8821
	R3	stream	0.9948	0.9749	**0.7972**	1.003
	R4	stream	0.7071	0.1327	**1.309**	0.7363
Spring cereals	D1	ditch	1.094	1.269	0.03250	0.4021
	D1	stream	0.9461	0.5231	0.02040	0.2452
	D3	ditch	1.082	0.7578	< 1e-6	< 1e-6
	D4	pond	0.03492	0.04842	0.003576	0.02840
	D4	stream	0.9217	0.1762	0.01631	0.01456
	D5	pond	0.03620	0.08879	0.000117	0.001394
	D5	stream	0.9296	0.06479	0.000939	0.000238
	R4	stream	0.7073	0.8668	**0.5127**	0.8334
Maize *	D6	ditch	0.8824	0.4000	0.001190	0.000845
	R1	pond	0.05429	0.1363	0.2278	1.863
	R1	stream	0.6110	1.850	1.114	2.229
	R2	stream	0.8189	0.3750	**0.4041**	1.456
	R3	stream	0.8634	0.3764	**0.8274**	0.9767
Winter oilseed rape (1 application)	D2	ditch	1.156	1.274	**0.6636**	1.113
	D2	stream	1.028	1.138	**0.4149**	0.5231
	D3	ditch	1.146	0.7292	< 1e-6	< 1e-6
	D4	pond	0.03939	0.04838	0.01029	0.07463
	D4	stream	0.9868	0.1946	0.06491	0.03962
	D5	pond	0.03940	0.03892	0.001606	0.02029
	D5	stream	1.065	0.2590	0.01817	0.003321

	R1	pond	0.03937	0.04442	0.02771	0.2835
	R1	stream	0.7545	0.1108	0.3047	0.1810
	R3	stream	1.055	0.4954	**0.5778**	0.8869
Winter oilseed rape (2 applications)	D2	ditch	1.012	1.148	0.2775	0.4742
	D2	stream	0.8906	1.015	0.1800	0.2185
	D3	ditch	1.002	0.7760	< 1e-6	< 1e-6
	D4	pond	0.03222	0.03975	0.007864	0.05828
	D4	stream	0.8534	0.1931	0.04939	0.03071
	D5	pond	0.03223	0.03935	0.000373	0.004320
	D5	stream	0.9207	0.2611	0.004073	0.000728
	R1	pond	0.03230	0.08540	0.04153	0.4724
	R1	stream	0.6529	1.251	**0.8306**	1.028
	R3	stream	0.9172	0.3430	**0.5393**	0.3980

*as surrogate for spring cereals

Table 8.9.2-10: FOCUS Step 4 PEC_{sw} and PEC_{sed} for prothioconazole-desthio (M04) following application of Protiokonazol 300 EC to winter and spring cereals and winter oilseed rape

Vegetative buffer zone:		**Step 3**	**5m**	**10 m**	**10 m**
No-spray buffer:		**Step 3**	**5 m (VFS)**	**10 m (VFS)**	**10-12 m**
Crop	**Location Water body**	**Max PEC_{sw} (µg/L)**	**Max PEC_{sw} (µg/L)**	**Max PEC_{sw} (µg/L)**	**Max PEC_{sw} (µg/L)**
Winter cereals	D1 ditch	0.01404	0.01404	0.01404	0.01404
	D1 stream	0.008877	0.008877	0.008877	0.008877
	D2 ditch	0.09891	0.09891	0.09891	0.09891
	D2 stream	0.06217	0.06217	0.06217	0.06217
	D3 ditch	< 1e-6	< 1e-6	< 1e-6	< 1e-6
	D4 pond	0.001830	0.001830	0.001830	0.001830
	D4 stream	0.008691	0.008691	0.008691	0.008691
	D5 pond	0.000108	0.000108	0.000108	0.000108
	D5 stream	0.000887	0.000887	0.000887	0.000887
	D6 ditch	0.000329	0.000329	0.000329	0.000329
	R1 pond	0.05796	0.005467	0.000004	0.02326
	R1 stream	**0.3619**	0.04900	0.000048	0.1646
	R3 stream	**0.7972**	**0.3345**	0.2109	0.3638
	R4 stream	**1.309**	0.1479	0.05133	0.5954
Spring cereals	D1 ditch	0.03250	0.03250	-	-
	D1 stream	0.02040	0.02040	-	-
	D3 ditch	< 1e-6	< 1e-6	-	-
	D4 pond	0.003576	0.003576	-	-

	D4 stream	0.01631	0.01631	-	-
	D5 pond	0.000117	0.000117	-	-
	D5 stream	0.000939	0.000939	-	-
	R4 stream	**0.5127**	0.1428	-	-
Maize*	D6 ditch	0.001190	0.001190	-	-
	R1 pond	0.2278	0.04445	-	-
	R1 stream	1.114	0.1794	-	-
	R2 stream	**0.4041**	0.000765	-	-
	R3 stream	**0.8274**	0.1383	-	-
Winter oilseed rape (1 application)	D2 ditch	**0.6636**	**0.6636**	**0.6636**	**0.6636**
	D2 stream	**0.4149**	**0.4149**	**0.4149**	**0.4149**
	D3 ditch	< 1e-6	< 1e-6	< 1e-6	< 1e-6
	D4 pond	0.01029	0.01029	0.01029	0.01029
	D4 stream	0.06491	0.06491	0.06491	0.06491
	D5 pond	0.001606	0.001606	0.001606	0.001606
	D5 stream	0.01817	0.01817	0.01817	0.01817
	R 1pond	0.02771	0.004822	0.001986	0.02449
	R1 stream	0.3047	0.03702	0.001986	0.1337
	R3 stream	**0.5778**	0.2111	0.1401	0.2631
Winter oilseed rape (2 applications)	D2 ditch	0.2775	0.2775	-	-
	D2 stream	0.1800	0.1800	-	-
	D3 ditch	< 1e-6	< 1e-6	-	-
	D4 pond	0.007864	0.007864	-	-
	D4 stream	0.04939	0.04939	-	-
	D5 pond	0.000373	0.000373	-	-
	D5 stream	0.004073	0.004073	-	-
	R1 pond	0.04153	0.002539	-	-
	R1 stream	**0.8306**	0.02609	-	-
	R3 stream	**0.5393**	0.004260	-	-

*as surrogate for spring cereals

ZRMS comments:

The calculations PECsw/sed has been accepted for the active substance prothioconazole and its metabolites M01 and M04.
The input parameters used in calculations were taken from the endpoints available in the EFSA conclusion on Scientific Report (2007) 106, 1-98. Interception is appropriate to the proposed BBCH of crops (guidance 2014).
PECsw/sed calculations performed at Step 1-2 and Step 3 and Step 4 for the active substance PECsw/sed have been accepted. Input parameters and PECsw/sed calculations can be considered acceptable.

The PECsw calculations have been approved for applications proposed in GAP. PECsw and PECsed calculations were carried out according to the FOCUS guidance recommendations.

Other approaches for simulating run-off mitigation reductions and sediment *(e.g. VSFMod)* and according to the *Austrian Environmental Agency (AGES)* are not recommended for the Core Assessment. Applicant should check

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

Table 8.10-1 Summary of atmospheric degradation and behaviour

Compound	Prothioconazole
Direct photolysis in air	Not studied – no data requested
Photochemical oxidative degradation in air	Not measured – no data requested
Volatilisation	Half-life: 1.1 hours Chemical lifetime: 1.6 hours derived by the Atkinson model, OH (12h) concentration assumed = $1.5x10^{6}$
Metabolites	Vapour pressure (Pa): << 4×10^{-7} Henry's Law Constant (Pa.m3/mol): << 3×10^{-5}
	Prothioconazole-desthio: Half-life: 14.2 hours Chemical lifetime: 20.5 hours Calculated according to Atkinson (AOPWIN v. 1.87, 12 hour day, $1.5x10^{6}$ OH radicals/cm^{3})

The vapour pressure at 20°C of the active substance prothioconazole is < 10^{-5} Pa. Hence the active substance prothioconazole is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance prothioconazole due to volatilization with subsequent deposition is not relevant.

ZRMS comments:

The data on atmospheric degradation and behaviour in air for prothioconazole provided by the Applicant are considered acceptable. The prothioconazole is regarded as non-volatile and, consequently, exposure of adjacent surface waters and terrestrial ecosystems by prothioconazole due to volatilization with subsequent deposition is not expected.

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2.4	Hara-Skrzypiec A.	2022	Protiokonazol 300 EC Calculation of predicted environmental concentrations of prothioconazole and its metabolites in ground-water using the FOCUS groundwater scenarios (FOCUS PEARL, FOCUS PELMO) Company Report No: EST/20/2022 ESTICON Sp. z o.o. GLP: No Published: No	N	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**
KCP 9.2.5	Hara-Skrzypiec A.	2022	Protiokonazol 300 EC Calculation of Predicted Environmental Concentrations of prothioconazole and its metabolites in surface water using the FOCUS scenarios (Steps 1, 2, 3 and 4) Company Report No: EST/19/2022 ESTICON Sp. z o.o. GLP: No Published: No	N	Pestila Sp. z o.o.* ProAgri Sp. z o.o.**

*Pestila Spółka z ograniczoną odpowiedzialnością (short name: Pestila Sp. z o. o.)
** ProAgri Spółka z ograniczoną odpowiedzialnością (short name: ProAgri Sp. z o.o.)
Please note that Pestila Sp. z o. o. and ProAgri International Sp. z o.o. are co-sponsors of the studies for Prothioconaole 300 EC and have the same rights for using data in registration processes without Letter of access issuing.

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

The following tables are to be completed by MS

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

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

Appendix 2 Detailed evaluation of the new Annex II studies

Not relevant.

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

Not relevant.