REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: ADM.03500.F.2.B

(alternative codes: ADM.3500.F.2.B; MCW-2075)

Product name(s): see part A

Chemical active substance(s):

Prothioconazole 250 g/L

Central zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorisation)

Applicant: Country organisation/representative
as specified in Part A

Submission date: June 2021

MS Finalisation date: October 2022 (initial Core Assessment)

March 2023 (final Core Assessment)

Version history

When	What
2021/06	Version 1 Applicant
October 2022	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.
March 2023	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Information no longer relevant is struck through and shaded.

DATA PROTECTION CLAIM

In order to present a dossier fully compliant with today's requirements (Reg. 284/2013), studies have been performed on ADM.03500.F.2.B. Under Article 59, Regulation 1107/2009/EC. On behalf of the Sponsor Company the applicant claims data protection for the studies conducted with ADM.03500.F.2.B. The data protection status and corresponding justification as valid for the respective country will be confirmed in the respective PART A.

STATEMENT FOR OWNERSHIP

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8 Fate and behaviour in the environment (KCP 9)

8.1 Critical GAP and overall conclusions

The critical GAP uses and application patterns considered in the risk assessments for soil, groundwater and surface water are specified under the respective chapters, i.e. 8.7 (soil), 8.8 (groundwater) and 8.9 (surface water).

For the conclusion in groundwater, the concerned critical GAP uses of ADM.03500.F.2.B are summarised in Table 8.1.1.

Table 8.1-1: Critical Central Zone GAP for ADM.03500.F.2.B ~~Concerned critical GAP uses of ADM.03500.F.2.B for the risk assessment in groundwater~~

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)														
1-4, 6-9, 11-15, 17-21, 28-31, 33-36, 38-40, 42, 43, 45, 46, 52-54, 169	DE, AT, BE, NL, IE, CZ, PL, SK, HU, SL	winter- & spring wheat, spring & winter barley triticale, rye, oats	F	*Septoria tritici, Drechslera tritici-repentis, Puccinia striiformis, Puccinia recondite, Fusarium + microdochium, Rhyncosporium secalis, Helminthosporium gramineum (Pyrenophora teres), Ramularia collo-cygni, Puccinia hordei*	foliar, spraying, overall	BBCH 30-69 spring	a) 1 b) 1	n.a.	a) 0.8 L/ha b) 0.8 L/ha	a) 200 b) 200	100 - 400	n.r.	For Germany: The use in wheat also covers the following crops: spelt,, one-grained wheat, emmer, durum wheat, Khorasan wheat and soft wheat according to the BVL crop tree	A
5, 10, 16, 22, 32, 37, 41, 44, 47, 55	DE, AT, BE, NL, IE, CZ, PL, SK, HU, SL	winter- & spring oilseed rape	F	*Sclerotinia sclerotiorum Alternaria spp.*	foliar, spraying, overall	BBCH 50-73 spring	a) 1 b) 1	n.a.	a) 0.7 L/ha b) 0.7 L/ha	a) 175 b) 175	100 - 400	n.r.		A

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
n.r.= not relevant, n.a.= not applicable

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

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

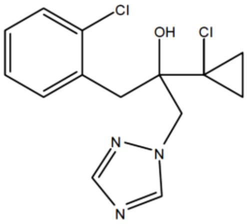
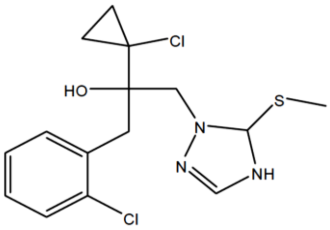
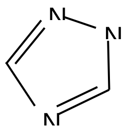
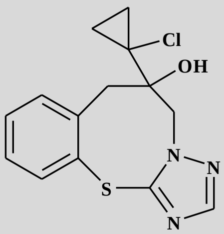
Member state(s)	Crop and/ or situation (a)	F, Fn, Fpn G, Gn, Gpn or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate			PHI (days) (l)	Remarks: e.g. g safener / synergist per ha (m)
				Type (d-f)	Conc. of a.s. (i)	Method / Kind (f-h)	Timing / Growth stage of crop & season (j)	Max. number a) per use b) per crop/season (k)	Min. interval between applications (days)	kg or L product/ha min max	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
EU North South	Wheat, rye, triticale	F	Rusts, Eyespot, Fusarium spp., Powd. Mildew, Rhynchospor., Septoria	EC	250 g/L	Overall spray	start 26-29 up to BBCH69	1 – 3 #	14 – 21 #		0.2	200-400	35	# timing, no. of applic. depends on national conditions
EU North South	Barley, oat	F	Rusts, Eyespot, Pyren. teres, Powd. Mildew, Fusarium spp., Rhynchospor.	EC	250 g/L	Overall spray	start 30 up to BBCH 61	1 – 2 #	14 – 21 #		0.2	200-400	35	# timing, no. of applic. depends on national conditions
EU North	Rape	F	Sclerotinia, Botrytis, Alternaria, Leptosphaeria	EC	250 g/L	Overall spray	start BBCH 53	1 – 2 #	14 – 28 #		0.175	200-400	56	# timing , no. of applic. depends on national conditions
EU North South	Wheat, rye, triticale, oat, barley	F	Fusarium spp., Bunt, Smut	FS	250 g/L	Seed Treatment	Pre sowing	1	n.a. (0)		*approx. 9-18 g as/ha (180 kg seed/ha)	200 – 400 ml water /dt	n.a.	*5 – 10 g as/dt seed

Remarks columns:

- * Uses for which risk assessment could not been concluded due to lack of essential data are marked grey
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
- (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
- (f) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
- (g) All abbreviations used must be explained
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
- (i) g/kg or g/L
- (j) Growth stage at 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
- (k) The minimum and maximum number of application possible under practical conditions of use must be provided
- (l) PHI - minimum pre-harvest interval
- (m) 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
Prothioconazole-desthio (M04) (JAU-desthio)	312.2 g/mol		soil: 57.1 % water: 32.3% sediment: 26.9% whole system: 54.6%	PEC_{SOIL}, PEC_{GW}, $PEC_{SW/SED}$: current GAP use not considered in the EU assessment (EFSA 2007), and FOCUS models are required for PEC_{GW} and PEC_{SW} calculations (soil metabolites now also need to be included in this modelling due to run-off entry)
Prothioconazole-S-methyl (M01) (JAU-S-methyl)	358.3 g/mol		soil: 14.6 % water/sediment (anaerobic): 77 % (~~anaerobic~~, in sediment, not detected in water) water/sediment (aerobic): 12.7% (whole system); 3.1% (water); 9.6% (sediment)	
1,2,4-triazole (M13)	69.065 g/mol		water: 37.2 % sediment: 4.6 % whole system: 41.8%	
JAU 6476-thiazocine (prothioconazole-thiazocine, M12)	307.8		Aqueous photolysis study: 14.1% on day 5	Considered not relevant in EFSA (2007)

zRMS comments:

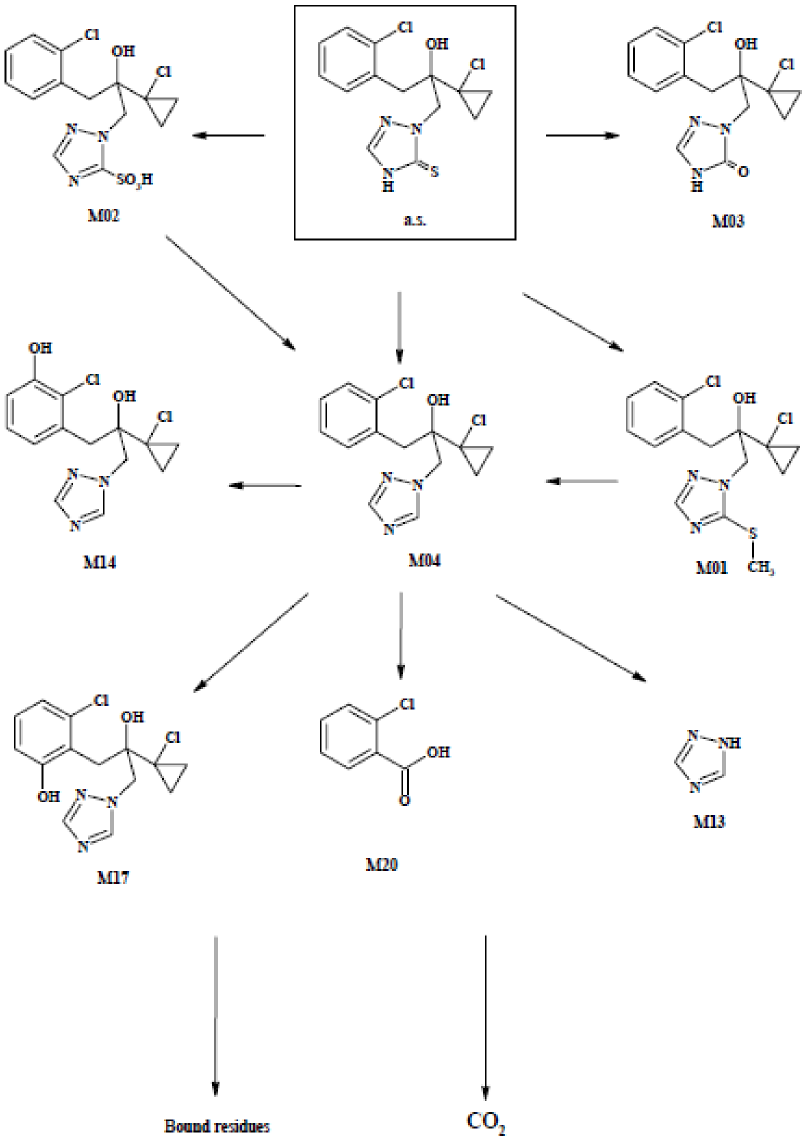
Information regarding prothioconazole metabolites is in general line with EU agreed endpoints reported in EFSA Scientific Report (2007) 106, with some minor corrections.

Information 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.

8.3 Rate of degradation in soil (KCP 9.1.1)

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

The aerobic route and rate of degradation of phenyl-UL-^{14}C and 3,5-triazole-^{14}C labelled prothioconazole under dark conditions was investigated in two laboratory studies. The results of the aerobic soil degradation studies were used to estimate the portion of the active substance degrading to prothioconazole-S-methyl (14.6 % at day 7, triazole label). The portion of active substance converted to prothioconazole-desthio (M04) was calculated to be 57.1%, based on the results of the eight field studies.
No other major metabolites were detected, although six minor metabolites were detected at levels in the range <0.1 to 5.5% AR. 1,2,4-triazole was only detected in relevant amounts in water/sediment studies (37.2 % in the water phase).



a.s. = prothioconazole
M01 = prothioconazole -S-methyl
M02 = prothioconazole -sulfonic acid
M03 = prothioconazole -triazolinone
M04 = prothioconazole -desthio
M13 = 1,2,4-triazole
M14 = prothioconazole -3-hydroxy-desthio
M17 = prothioconazole -6-hydroxy-desthio
M20 = 2-chlorobenzoic acid

Figure 8.3-1: Degradation scheme of prothioconazole and metabolites

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

Data on the rates of aerobic soil degradation of the active substance prothioconazole and its metabolites are available in the context of the respective EU evaluation process. For details see EFSA (2007)[1] and the DAR (2005)[2] for prothioconazole. Additional degradation data were not required as a result of the reviews.

8.3.1.1 Prothioconazole and its metabolites

Prothioconazole

A summary of the EU agreed aerobic soil degradation data of prothioconazole is given in Table 8.3-1.

Table 8.3-1: Summary of EU agreed aerobic degradation rates for prothioconazole - laboratory studies (according to DAR, 2005)

Prothioconazole, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t. °C**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi[2] (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Laacher Hof	sandy loam	6.6	20	34.2	0.07	5.3	-	-	1st order and FOMC	y/ DAR, 2005; EFSA, 2007
Stanley	silty clay loam	5.9	20	56.25	0.7	78.2	-	-		
Höfchen	silt	6.8	20	63.1	0.3	0.99	-	-		
Byromville	loamy sand	6.1	20	65*	1.27	4.22	-	-		
Geometric mean/Median (n=4)							0.37/0.5			
pH-dependency: y/n							n			

* % of 1/3 bar moisture

Un-normalised $DegT_{50}$ and $DegT_{90}$ values of prothioconazole in aerobic laboratory soils ranged from 0.07 to 1.27 days and 0.99 to 78.2 days, respectively. For modelling endpoints, please refer to field studies.

Metabolites

A summary of the EU agreed aerobic soil degradation data of prothioconazole metabolites is given in Table 8.3-2 and Table 8.3-4.

Table 8.3-2: Summary of EU agreed aerobic degradation rates for prothioconazole-S-methyl laboratory studies (according to DAR, 2005)

Prothioconazole-S-methyl, Laboratory studies, aerobic conditions										
Soil name	**Soil type (DIN)**	**pH ($CaCl_2$)**	**t. °C**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**$DegT_{50}$ (d) 20°C pF2/10kPa**	**Chi[2] (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Höfchen	loamy silt	6.5	20	63.1	5.9	19.6	-	-	1st order	y/ DAR, 2005; EFSA, 2007
Laacher Hof	loamy silt	6.7	20	36.4	27.2	90.2	-	-		
Laacher Hof	sandy loam	6.3	20	34.3	8.2	27.2	-	-		
Stanley	silty clay	5.2	20	43.8	**46.0**[1)]	153	-	-		
Geometric mean/Median (n = 4)							**15.7**[2)]/17.7			
pH-dependency: y/n							n			

bold figure used as EU agreed endpoint for PECsoil[1)], PEC_{GW}[2)] and $PEC_{SW/SED}$[2)] calculations

Un-normalised DT_{50} and DT_{90} values of prothioconazole-S-methyl ranged from 5.9–46.0 days and 19.6–

[1] EFSA (2007): EFSA Scientific Report (2007) 106, 1–98, Conclusion regarding the peer review of the pesticide risk assessment of the active substance prothioconazole. Issued on 12 July 2007.
[2] DAR (2005): Draft Assessment Report on Prothioconazole, Volume 3, Annex B, B.8, July 2005.

153 days, respectively. This results in a DT_{50} geometric mean of 15.7 days which is the EU agreed endpoint (EFSA, 2007) used for PEC_{GW} and $PEC_{SW/SED}$ calculations. Maximum unnormalized DT_{50} was used for PECsoil assessment.

Table 8.3-3: Summary of EU agreed aerobic degradation rates for prothioconazole-desthio laboratory studies (according to DAR, 2005)

Prothioconazole-desthio, Laboratory studies, aerobic conditions										
Soil name	**Soil type (DIN)**	**pH ($CaCl_2$)**	**t. °C**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**$DegT_{50}$ (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Höfchen	loamy silt	6.5	20	36.4	34.0	113.0	-	-	1st order	y/ DAR, 2005; EFSA, 2007
Laacher Hof	loamy silt	6.7	20	34.4	29.6	59.2	-	-		
Laacher Hof	sandy loam	6.3	20	43.8	7.0	23.2	-	-		
Stanley	silty clay	5.2	20	43.8	18.6	61.9	-	-		
Geometric mean/Median (n = 4)							19.0/24.1			
pH-dependency: y/n							n			

Un-normalised DT_{50} and DT_{90} values of prothioconazole-desthio ranged from 7.0–34.0 days and 23.2–113.0 days, respectively. For modelling endpoints, please refer to field studies.

Soil photolysis

Information on soil photolysis of the parent compound prothioconazole is available from the DAR (2005). It is summarised hereafter.

Table 8.3-4 Summary of agreed EU photolysis data of prothioconazole in laboratory soils (according to DAR, 2005)

Prothioconazole, Laboratory studies, soil photolysis										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t. °C**	**1/3 bar MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**$DegT_{50}$ (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Byromville	loamy sand	6.1	20	75	4.1 [a)] 14.7 [b)] 22.9 [e)]	13.7 [a)]	-	-	1st order	y/ DAR, 2005; EFSA, 2007

[a)] DT_{50}/DT_{90} experimental
[b)] predicted environmental half-life under solar summer conditions of Phoenix, AZ, USA in June
[c)] predicted environmental half-life under solar summer conditions of Athens, Greece in June

A soil photolysis study is available with phenyl-^{14}C-labelled prothioconazole. Results demonstrated prothioconazole to be degraded rapidly (prothioconazole amounted to 18.6% AR in the irradiated samples after 15 days, end of the study) on soil surface if irradiated by simulated sunlight. However, the fast degradation observed for the dark control (19.0% AR at 15d) revealed phototransformation not to be the dominant process of degradation. M04 (prothioconazole-desthio) appears at relatively high concentrations in both irradiated and dark control samples (maximum observed at day 7: 38.5% A.R. and 29.4% A.R respectively), indicating that photolysis will not significantly contribute to the overall degradation of prothioconazole in soil under environmental conditions. The first order DT_{50} value for the degradation of the active ingredient yielded 4.1 days, equated to 22.9 days under sola summer conditions of Athens (Greece) in June.

Table 8.3-5: Summary of agreed EU photolysis data of prothioconazole in laboratory soils (EFSA, 2007)

Soil photolysis	
Metabolites that may require further consideration for risk assessment	none

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.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Soil degradation under anaerobic conditions was not investigated. EFSA (2007) provides the following information on the anaerobic degradation of prothioconazole: Due to the fact that a seed treatment formulation was considered, an anaerobic aquatic metabolism study was submitted. The anaerobic study indicated relatively rapid breakdown of parent to JAU-S-methyl, which seems to accumulate. This might indicate that if prothioconazole was applied to an anaerobic soil there would be significant formation of JAU-S-methyl. However, the only major period of anaerobic conditions is likely to be in winter. According to the underlying GAP table no seed treatment is envisaged and the application of ADM.03500.F.2.B~~1.A~~ will only take place in spring/summer. Therefore, it is unlikely that there would be significant formation of JAU-S-methyl under field conditions.

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 ADM.03500.F.2.B does not include application as a seed treatment, so anaerobic route of exposure is not considered further, in line with EU conclusions.

8.4 Field studies (KCP 9.1.1.2)

The field dissipation rates of prothioconazole were evaluated during the EU review. The dissipation of prothioconazole was examined in eight studies under field conditions at four sites in Northern Europe and at two sites in Southern Europe. No additional studies have been performed.

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

See above. Soil dissipation data on prothioconazole and its metabolite is available from the DAR of the active substance prothioconazole (DAR, 2005). No additional studies have been performed. Studies on field dissipation rates with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.4.1.1 Prothioconazole and its metabolites

Dissipation of prothioconazole and prothioconazole-desthio was examined in eight studies under field conditions at four sites in Northern Europe and two sites in Southern Europe. Application of the test substance was directly onto bare soil. Details on soil type and study location are presented in Table 8.4-1 and Table 8.4-2.

Prothioconazole

The $DissT_{50field}$ values of prothioconazole were in the range of 1.3–2.8 days (DT_{90} = 4.4–9.3 days) (see Table 8.4-1) following 1st order kinetics. The maximum $DissT_{50}$ of 2.8 days is the EU agreed endpoint (EFSA, 2007) considered for PEC_{SOIL} calculations. Normalised field soil dissipation modelling endpoints of prothioconazole range between 0.6 to 1.6 days. For PECgw and PECsw modelling of prothioconazole the geometric mean of 1.2 days was used.

Table 8.4-1: Summary of EU agreed aerobic degradation rates for prothioconazole - field studies: Triggering and Modelling endpoints (according to DAR, 2005)

Prothioconazole, Field studies – Triggering endpoints (actual) and Modelling endpoints (normalised)									
Soil type DIN 19682 / USDA)	**Location**	**pH**	**Depth (cm)**	**$DissT_{50}$ (d) actual**	**DT_{90} (d) actual**	**DT_{50}, norm 20°C (d)**	**St. (r^2)**	**Method of calculation**	**Evaluated on EU level y/n/ Reference**
Loamy silt / Silt loam	51399 Burscheid, Trial Station Höfchen Germany	6.25	0-10	1.9	6.4	1.2	1.00	1st order	y/ DAR, 2005; EFSA, 2007
Sandy clay loam / Sandy clay loam	IP31 3SH Thurston, Bury St. Edmunds Elm Farm Development Station Great Britain	7.56	0-10	1.6	5.5	0.8	1.00		
Weak loamy silt / Silt	27700 Fresne l'Archeveque France (North)	6.42	0-10	1.3	4.4	1.6	1.00		
Sandy clay loam / Sandy clay loam	IP31 3SH Thurston, Bury St. Edmunds Elm Farm Development Station Great Britain	7.56	0-10	2.8	9.3	1.4	0.99		
Weak loamy silt / Silt	27700 Fresne l'Archeveque France (North)	6.42	0-10	1.4	4.5	1.6	1.00		
Sandy loamy silt / Silt loam	13103 St. Etienne du Gres France (South)	7.61	0-10	1.7	5.6	1.1	0.99		
Weak loamy sand / Sandy loam	37060 Pradelle Di Nogarole Rocca (VR) Italy	7.56	0-10	1.6	5.4	1.5	0.99		
Loamy sand / Sandy loam	40789 Monheim Trial Station Laacherhof Germany	6.32	0-10	1.5	5.1	0.6	1.00		
Maximum (n=8)				**2.8***	9.3	-			
Geomean (n=8)				-	-	**1.2#**			

bold figure represent the EU agreed endpoint considered for *PEC_{SOIL} calculations and #PECgw, PECsw simulations

Prothioconazole-desthio

The $DissT_{50field}$ of prothioconazole-desthio (see Table 8.4-2) ranged from 16.3 days to 72.3 days (DT_{90} = 54.1–240 days). The maximum $DissT_{50}$ of 54.7 days along with a conversion rate of 49.4% was considered as endpoint for PEC_{SOIL} calculations. Normalised field soil dissipation modelling endpoints of prothioconazole-desthio range between 10.3 to 61.9 days. For PECgw and PECsw modelling the geometric mean of 22.7 days along with a conversion rate of 57.1 % for prothioconazole-desthio was used.

Table 8.4-2: Summary of EU agreed aerobic degradation rates for prothioconazole -desthio field studies: Triggering and Modelling endpoints (according to DAR, 2005)

Prothioconazole-desthio, Field studies – Triggering endpoints (actual) & Modelling endpoints (normalised)									
Soil type DIN 19682 / USDA)	**Location**	**pH**	**Depth (cm)**	**$DissT_{50}$ (d) actual**	**DT_{90} (d) actual**	**DT_{50}, norm 20°C (d)**	**St.(r^2)**	**Method of calculation**	**Evaluated on EU level y/n/ Reference**
Loamy silt / Silt loam	51399 Burscheid, Trial Station Höfchen Germany	6.25	0-10	16.3 [a)]	54.1[a)]	10.3	0.98	1st order	y/ DAR 2005; EFSA, 2007
Sandy clay loam / Sandy clay loam	IP31 3SH Thurston, Bury St. Edmunds Elm Farm Development Station Great Britain	7.56	0-10	54.7	182	27.0	0.96		
Weak loamy silt / Silt	27700 Fresne l'Archeveque France (North)	6.42	0-10	47.6	158	27.5	0.94		
Sandy clay loam / Sandy clay loam	IP31 3SH Thurston, Bury St. Edmunds Elm Farm Development Station Great Britain	7.56	0-10	50.2	167	23.4	0.91		
Weak loamy silt / Silt	27700 Fresne l'Archeveque France (North)	6.42	0-10	36.8	122	20.1	0.93		
Sandy loamy silt / Silt loam	13103 St. Etienne du Gres France (South)	7.61	0-10	72.3 ~~[a)]~~	240	61.9	0.91		
Weak loamy sand / Sandy loam	37060 Pradelle Di Nogarole Rocca (VR) Italy	7.56	0-10	30.5	101	20.7	0.98		
Loamy sand / Sandy loam	40789 Monheim Trial Station Laacherhof Germany	6.32	0-10	27.9 [b)]	92.6 [b)]	15.2	0.98		
Maximum (n=8)				**72.3 ***	240	-			
~~Maximum (n=7)~~				~~54.7*~~	~~182~~	~~-~~			
Geomean (n=8)				-	-	**22.7#**			

~~a) excluded because this soil located in southern France is not considered relevant for application in the central zone~~
b) without day 0 sample, because maximum concentrations were found at later sampling dates
bold figure represent the EU agreed endpoint considered for *PEC_{SOIL} calculations and #PECgw, PECsw simulations

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.

The Applicant indicated that the maximum field DT_{50} of 54.7 d is an EU agreed endpoint relevant for PEC_{SOIL} calculations. This is, however, not true, since the maximum DT_{50} of 72.3 d was agreed at the EU level for soil exposure assessment and no differentiation was made between soils in particular climatic zones. Furthermore, the field DT_{50} values calculated for particular test sites within the EU do not seem to be significantly different and therefore should be merged. Taking this into account, exclusion of the degradation data from trials performed in Spain is not justified. To support such an exclusion the Applicant would have to provide detailed analysis demonstrating that DT_{50} in the Southern France soil is significantly different comparing to test sites within the Central Zone, which was not done.

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.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

According to EFSA (2007) no data on soil accumulation was submitted and none is required for prothioconazole and prothioconazole-desthio. This is substantiated by field soil dissipation studies resulting in DT_{90} values for prothioconazole and prothioconazole-desthio below the trigger of 1 year in any trial (see Table 8.4-1 and Table 8.4-2, Annex point 8.4.1).

zRMS comments:

According to information presented in EFSA Scientific Report (2007) 106, soil accumulation testing is not required for prothioconazole.

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.

Data on the mobility in soil are available for prothioconazole (DAR 2005; EFSA, 2007) and summarised in the following.

8.5.1 Prothioconazole and its metabolites

Prothioconazole

During the EU review adsorption coefficient for prothioconazole could not be determined via standard batch equilibrium studies due to the instability of the compound in these systems. Therefore, K_d and K_{oc} values of prothioconazole were estimated from aged column leaching studies.

Phenyl- UL-^{14}C radiolabelled prothioconazole was applied on a loamy sand soil and incubated at 20 ºC under aerobic conditions for 30 hours. The resulting values for prothioconazole were K_d = 15.2 and K_{oc} = 1765 mL/g (slightly mobile compound). At the end of the study, the extracted radioactivity was composed of 22.7% unchanged parent compound, the known metabolites from the soil metabolism study M04 (31.8% AR), M01 (8.1% AR) and prothioconazole-sulfonic acid (M02) (1.5%). The total radioactivity in the leachate accounted for only 1.1% AR of the applied radioactivity, and in the leachate fraction a radioactivity content of < 0.2% of the applied radioactivity was measured. The leaching behaviour of phenyl-UL-^{14}C radiolabelled prothioconazole was further investigated in a non-aged soil column leaching study on four soils. The level of radioactivity detected in the leachates was < 1% AR in all samples. Therefore, the leachate fractions were not analysed. The majority of the residue of the active substance was detected in the top 6 cm layer (14.6-40.7% AR in 0-6 cm layer, not detected in the 6-12 cm layer), this also being the case for the metabolites prothioconazole-S-methyl (5.5-11.2% AR in the 0-6 cm layer, not detected in the 6-12 cm layer) and prothioconazole-desthio (15.4-28.0% AR in the 0-6 cm layer, not detected in the 6-12 cm layer).

The sole K_{oc} value of 1765 mL/g along with a default 1/n (0.9) has been considered for the use in FOCUS PEC groundwater and PEC surface water/sediment modelling.

Metabolites

Adsorption/desorption data from four different soils are available for the major metabolite prothioconazole-S-methyl as shown in Table 8.5-1. K_f^{ads} values range from 15.6–64.1 mL/g. The K_{foc}^{ads} values range from 1973.6–2995.0 mL/g resulting in an arithmetic mean of **2556.3** mL/g, which is the EU agreed endpoint (EFSA, 2007) considered for PEC_{GW} and $PEC_{SW/SED}$ calculations. Freundlich coefficients vary from 0.85–0.91 with an arithmetic mean of **0.88** considered as EU agreed endpoint in PEC_{GW} and $PEC_{SW/SED}$

calculations. No soil pH dependent adsorption was observed.

The second major metabolite prothioconazole-desthio was investigated with the same soils. Results are presented in Table 8.5-1. K_f^{ads} values range from 4.1–13.4 mL/g. The K_{foc}^{ads} values range from 523.0–625.3 mL/g resulting in an arithmetic mean of **575.4** mL/g, which is the EU agreed endpoint (EFSA, 2007) considered for PEC_{GW} and $PEC_{SW/SED}$ calculations. Freundlich coefficients vary from 0.79–0.83 with an arithmetic mean of **0.81** considered as EU agreed endpoint in PEC_{GW} and $PEC_{SW/SED}$ calculations. No soil pH dependent adsorption was observed.

Table 8.5-1: Summary of EU agreed soil adsorption for prothioconazole-S-methyl (according to DAR, 2005; EFSA, 2007)

Prothioconazole-S-methyl							
Soil Name	**Soil Type (USDA)**	**OC (%)**	**pH (H_2O)**	**K_f^{ads} (mL/g)**	**K_{foc}^{ads} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Laacher Hof AXXa, Rhineland, Germany	sandy loam	2.02	7.2	56.0	2772.4	0.87	y/ DAR 2005; EFSA, 2007
Höfchen, Rhineland, Germany	silt	2.14	7.1	64.1	2995.0	0.88	
Stanley, Kansas, USA	silty clay loam	1.66	5.9	41.2	2484.0	0.91	
Byromville, Georgia, USA	loamy sand	0.79	6.8	15.6	1973.6	0.85	
Arithmetic mean (n = 4)					**2556.3**	**0.88**	
Median (n = 4)					2628.2	0.875	
Geometric mean (n=4)					2525.9	0.88	
pH-dependency y/n					n		

bold figures: used as endpoints for PEC_{GW} and $PEC_{SW/SED}$ calculations

Table 8.5-2: Summary of EU agreed soil adsorption for prothioconazole-desthio (according to EFSA, 2007)

Prothioconazole-desthio							
Soil Name	**Soil Type (USDA)**	**OC (%)**	**pH (H_2O)**	**K_f^{ads} (mL/g)**	**K_{foc}^{ads} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Laacher Hof AXXa, Rhineland, Germany	sandy loam	2.02	7.2	12.46	616.8	0.79	y/ DAR 2005; EFSA, 2007
Höfchen, Rhineland, Germany	silt	2.14	7.1	13.38	625.3	0.83	
Stanley, Kansas, USA	silty clay loam	1.66	5.9	8.90	536.4	0.83	
Byromville, Georgia, USA	loamy sand	0.79	6.8	4.13	523.0	0.80	
Arithmetic mean (n = 4)					**575.4**	**0.81**	
Median (n = 4)					576.60	0.82	
Geometric mean (n=4)					573.53	0.81	
pH-dependency y/n					n		

zRMS comments:

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

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. The results of the modelling simulation were validated by the zRMS with consideration of the EU agreed arithmetic mean values.

8.5.2 Column leaching (KCP 9.1.2.1)

Leaching behaviour of prothioconazole was investigated under laboratory conditions in four soils. The study was carried out according to SETAC Guidelines (1995), BBA Guideline Part IV, 4-2 (1986) and in accordance with the principles of GLP. 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:

In EFSA Scientific Report (2007) 106 results of column leaching and aged residues leaching are reported. Their results are, however, not necessary for purposes of evaluation of ADM.03500.F.2.B, as based on results of the groundwater modelling no unacceptable leaching of prothioconazole or its metabolites is expected.

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 the degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.
Data on the degradation of the active substance prothioconazole and its metabolites in water/sediment systems are available in the context of the respective EU evaluation process. For details see EFSA (2007) and the DAR (2005) for prothioconazole.

8.6.1 Prothioconazole and its metabolites

Information on the degradation of prothioconazole in water sediment systems was available for two aquatic systems, Hönniger Weiher and Angler Weiher. From the two systems a geometric mean $DegT_{50}$ of 2.1 days was calculated for the whole system (Table 8.6-1), which is considered as endpoint for $PEC_{SW/SED}$ modelling.

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

DAR 2005: Prothioconazole distribution (max. sediment 23.4% after 1 days)										
Water / sediment system	**pH water/ sed. (H_2O)**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic, Fit**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic, Fit**	**$DissT_{50}$ sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Hönniger Weiher	7.84 / 6.6	2.8	76.4	‘hockey stick’, r^2=0.953	0.8	2.7	1st order, r^2=0.947	n.c.	-	y/ DAR, 2005; EFSA, 2007
Angler Weiher	7.45 / 8.5	1.6	23.6	‘hockey stick’, r^2=0.998	1.0	3.4	1st order, r^2=0.999	n.c.	-	

DAR 2005: Prothioconazole distribution (max. sediment 23.4% after 1 days)										
Water / sediment system	**pH water/ sed. (H_2O)**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic, Fit**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic, Fit**	**$DissT_{50}$ sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n/ Reference**
Geometric mean (n=2)		**2.1**								FOCUS (2006)[3]

n.c.: not calculated; **bold figure:** used as endpoint for $PEC_{SW/SED}$ calculations

Table 8.6-2: Summary of observed metabolites

Metabolites in Water/sediment system	**Max occurrence [%]**	**DT_{50} in sediment/water system [d]**	**Evaluated on EU level**
Prothioconazole-desthio	in water 32.3 % after 7 d in sediment 26.9 % after 14 d	49.9 (whole system value, n=2)	y/ DAR, 2005; EFSA, 2007
Prothioconazole-S-methyl	in sediment 77% after 240 d (anaerob)	40.2 (whole system value, n=2)	
1,2,4-triazole	in water 37.2 % after 121 d in sediment 4.6 % after 121 d in whole system 41.8 % after 121 d	-	

Hydrolysis, phototransformation in water and ready biodegradability

The aqueous **hydrolysis** of prothioconazole was investigated in one study at different pH values at 50 °C. Prothioconazole was found to hydrolyse slowly at pH 7 and 9 (DT_{50} estimated greater than one year). At pH 4 and 25 °C the DT_{50} was estimated to be 120 days.

The aqueous **photolysis** of phenyl- and triazole-labelled prothioconazole was studied following SETAC Guidelines (1995), US EPA Guideline 162-1 (1982) in accordance with the principles of GLP. Test solutions made up in sterile aqueous solution at pH 7 with a concentration of approximately 4 mg/l were continuously exposed to simulated sunlight using a xenon light (290 nm UV filter). Exposure period was equated 65.0 solar summer days in June in Arizona (USA) and 100.7 days in Athens (Greece). Prothioconazole was completely photodegraded within the duration of the experiment. Determined mean experimental half-life was 47.7 h (44.3 h, k = 0.0157 h^{-1}, R^2 = 0.999 for the phenyl-labelled and 51.4 h, k = 0.0135 h^{-1}, R^2 = 0.999 for the triazole-labelled test substance).

In a second study quantum yields and direct photodegradation of prothioconazole was investigated according to ECETOC method (1981, 1984), Test Guideline ‘Phototransformation of chemicals in water, Part A (Berlin, 1992) and in accordance with the principles of GLP. Mean quantum yields of 0.0638 (pH 4) and 0.0047 (pH 9) were calculated for 50° latitude and a 0 – 5 cm water depth. Resulting assessed environmental direct photolysis half-lives were 50 to < 200 days at pH 4 and 7 to 20 days at pH 9 in the periods of main use.
In another study following the same methods and guidelines quantum yield of prothioconazole-desthio was investigated in pure water. Determined quantum yield was 0.00449. Quantum yield was used for the estimation of the environmental half-life using two different simulation models (GC-SLOAR and Frank & Klöpffer). Results indicated an insignificant contribution of direct photodegradation in water to the overall elimination of prothioconalzole-desthio in the environment.

In an aqueous photolysis study prothioconazole-thiazocine was observed in amounts > 10% AR. Data from the study were used to quantify the degradational behaviour by using ‘ACSL Optimize Software’ and first order kinetics. Environmental DT_{50} values assuming summer sunlight conditions in Athens, Greece were 125.3 days for phenyl- and 212.5 days for triazole-labelled prothioconazole.

For a realistic estimation of maximum amounts of prothioconazole-thiazocine in surface water under natural

[3] FOCUS (2006): Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration; Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005, version 2.0, 434 pp., June 2006

conditions information about the dissipation of prothioconazole from the water phase was combined with data about the photolysis of prothioconazole to its metabolite prothioconazole-thiazocine. It was suggested that due to the fast dissipation of prothioconazole from the water phase (longest DT_{50} = 1 day) and the slow photolytic degradation to prothioconazole-thiazocine (longest DT_{50} = 212.5 days) an amount of prothioconazole-thiazocine of 1 % of the amount of the active substance reaching surface water will not be exceeded under realistic environmental conditions. Therefore, prothioconazole-thiazocine was not regarded as a major aqueous metabolite by the study author.

In another study the molar extinction coefficient of 1,2,4-triazole was investigated according to Test Guideline 'Phototransformation of chemicals in water, Part A (Berlin, 1992) and in accordance with principles of GLP. UV-absorption data in the environmentally relevant pH range showed no absorption of light at wavelength above 290 nm by 1,2,4-triazole. Therefore, no contribution of direct photodegradation to the overall elimination of 1,2,4-triazole in the aqueous environment is to be expected.

Table 8.6-3: Summary of agreed EU hydrolysis, photolysis and ready biodegradability data on prothioconazole in water (EFSA, 2007)

Parameter	Endpoints
Hydrolysis of active substance and relevant metabolites	prothioconazole: DT_{50} at 50°C: pH 9 and 7: > 1 year, pH 4: 120 days DT_{50} at 25°C: pH 9, 7 and 4: > 1 year
Photolytic degradation of active substance and relevant metabolites	Aqueous photolysis study (25 °C, pH 7) prothioconazole: phenyl label - DT_{50} = 44.3 hrs (R^2 = 0.999) triazole label - DT_{50} = 51.4 hrs (R^2 = 0.999) mean = 47.7 hours (n=2) predicted environmental half-life under solar summer conditions (June) of Phoenix, AZ, USA of 7.1 days and 11 days at Athens mineralisation at study end (18 days) = 3.0% AR (phenyl label), 0.5% AR (triazole label) Dark controls: prothioconazole was stable in the dark control samples, confirming that photolysis was the main process of degradation. %AR at 18 days was 108.7% for the phenyl label and 107.1% for the triazole label. prothioconazole-desthio (M04): max 55.7% AR 11 d prothioconazole-thiazocine (M12): max 14.1% AR, 5d 1,2,4-triazole (M13): max 11.9% AR, 18d
Quantum yield	prothioconazole: Quantum yields Φ of 0.0638 (pH 4) and 0.0047 (pH 9) were calculated. Environmental direct photolysis half-lives were in the range 50 to >200 days at pH 4 and 7 to 20 days at pH 9 for the periods of main use. prothioconazole-desthio (M04): A quantum yield of Φ of 0.00449 was calculated. The resulting quantum yield and the UV absorption were used to estimate the environmental half-life of prothioconazole-desthio (M04) concerning direct photodegradation in water by two different simulation models (GC-SOLAR, half-life at 50^0 latitude and 0-1cm depth in the summer season: 269 days and Frank & Klöpffer, half-life at 50^0 latitude and 0-1cm depth > 1 year). 1,2,4-triazole (M13): 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.
Ready biodegradable (yes/no)	No data submitted, not required

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 metabolite 1,2,4-triazole.

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

According to the residue definition provided in the EFSA conclusion on prothioconazole (EFSA, 2007) the following residues are of concern for the exposure and risk assessment in soil:

Prothioconazole, prothioconazole-desthio (JAU-desthio), prothioconazole-S-methyl (JAU-S-methyl)

PEC_{SOIL} values were calculated in accordance to FOCUS (1997[4]).

8.7.1 Justification for new endpoints

PEC_{SOIL} calculation for prothioconazole and prothioconazole-desthio (JAU-Desthio), prothioconazole-S-methyl (JAU-S-methyl) were performed considering the endpoints agreed in the EU (EFSA, 2007).

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

PEC_{SOIL} calculations were performed for a realistic worst case application pattern of ADM.03500.F.2.B covering all intended GAP uses in the Central zone. The overall critical GAP use (please refer to Table 8.7-1) was based on the highest intended single application rate, i.e. 1 x 200 g a.s./ha, at BBCH 30. 80 % crop interception was considered for the treatment at BBCH 30. This application pattern represents an overall worst case of the intended GAP uses of ADM.03500.F.2.B in the Central zone, comprising the highest deposit rate (= application rate corrected for crop interception) per year, i.e. 1 x 40 g a.s./ha.

The input parameters for the risk envelope GAP use of ADM.03500.F.2.B~~1.A~~ for PEC_{soil} calculations are provided in Table 8.7-2.

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

Use No.[1]	1-22, 28-47, 52-55, 169 (all uses)
Crop	Cereals (also covering Oilseed rape)
Application rate (g a.s./ha)	Prothioconazole: 1 x 200 g
Number of applications/interval	-
Crop interception (%)	80 (FOCUS, 2014)
Frequency of application	Every year
Depth of soil layer (relevant for plateau concentration) (cm)	20

[1] Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

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

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT_{50} (days)	Value in accordance to EU endpoint y/n/ Reference
Prothioconazole	344.3	-	2.8 (SFO kinetics, maximum from field studies, un-normalised)	y/EFSA, 2007
JAU-S-Methyl	358.3	14.6	46 (SFO kinetics, maximum from lab studies, un-normalised)	y/EFSA, 2007
JAU-Desthio	312.2	57.1 ~~49.4*~~	72.3 (max. field, non-normalised, n= 3) ~~54.7 (SFO kinetics, maximum from field studies*, un-normalised)~~	y/EFSA, 2007~~*~~

~~*one soil located in southern Europe was excluded from calculations because it is not considered relevant for application in the central zone~~

[4] FOCUS (1997): Soil persistence models and EU Registration. The final report of the work of the Soil Modelling Work Group of FOCUS. February 1997.

8.7.2.1 Prothioconazole and its metabolites

Table 8.7-3: PEC$_{SOIL}$ for prothioconazole following 1 × 200 g a.s./ha to cereals (BBCH 30)

PEC$_{SOIL}$ (mg/kg)		**Cereals (BBCH 30)**			
		Single application		**Multiple applications**	
		Actual	**TWA**	**Actual**	**TWA**
Initial		0.053	-	-	-
Short term	24h	0.042	0.047	-	-
	2d	0.033	0.042	-	-
	4d	0.020	0.034	-	-
Long term	7d	0.009	0.025	-	-
	14d	0.002	0.015	-	-
	21d	0.000	0.010	-	-
	28d	0.000	0.008	-	-
	50d	0.000	0.004	-	-
	100d	0.000	0.002	-	-
Plateau concentration (20 cm) after year x		not triggered	-	-	-
PEC$_{SOIL,accumulation}$ (PEC$_{SOIL,act}$ +PEC$_{SOIL,plateau}$)		not triggered	-	-	-

PEC$_{soil}$ of metabolites

Table 8.7-4: PEC$_{SOIL}$ for JAU-Desthio and JAU-S-Methyl following 1 × 200 g a.s./ha to cereals

PEC$_{SOIL}$ (mg/kg)		**Cereals (BBCH 30)**			
		Single applications			
		JAU-Desthio		**JAU-S-Methyl**	
		Actual	**TWA**	**Actual**	**TWA**
Initial		~~0.024~~	~~-~~	0.008	-
Short term	24h	~~0.024~~	~~0.024~~	0.008	0.008
	2d	~~0.023~~	~~0.024~~	0.008	0.008
	4d	~~0.023~~	~~0.023~~	0.008	0.008
Long term	7d	~~0.022~~	~~0.023~~	0.007	0.008
	14d	~~0.020~~	~~0.022~~	0.007	0.007
	21d	~~0.018~~	~~0.021~~	0.006	0.007
	28d	~~0.017~~	~~0.020~~	0.005	0.007
	50d	~~0.013~~	~~0.018~~	0.004	0.006
	100d	~~0.007~~	~~0.014~~	0.002	0.004
Plateau concentration (5/20 cm) after year x		not triggered	-	not triggered	-
PEC$_{SOIL,accumulation}$ (PEC$_{SOIL,act}$ +PEC$_{SOIL,plateau}$)		not triggered	-	not triggered	-

zRMS comments:

The application pattern assumed in soil exposure assessment for prothioconazole is in line with the critical Central Zone GAP and it is thus agreed. It is noted that, the worst case application pattern of 1 x 200 g a.s./ha at BBCH 30 was considered, covering all intended uses presented in the Central Zone GAP (Table 8.1-1). Relevant crop interception of 80% in line with FOCUS groundwater guidance (2014) has been selected.

Input parameters presented in Table 8.7-2 are in general in line with EU agreed parameters reported in EFSA Scientific Report (2007) 106, with following exceptions:

- For metabolite JAU-Desthio the max occurrence of 49.4% and DT$_{50}$ of 54.7 days were taken into account, as one soil located in Southern Europe was excluded from the calculations as considered not relevant by the Applicant for application in the Central Zone. In opinion of the zRMS the max occurrence of 57.1% and DT$_{50}$ of 72.3 days should be used for PEC$_{SOIL}$ calculation as this values are EU agreed endpoints and exclusion of the degradation data from the Southern France soil should be supported by the respective statistical analysis demonstrating that the results in this soil are significantly different comparing to soils at other locations. For more details, please refer to point 8.4.1.1 above.

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 metabolite JAU-S-Methyl were similar to those obtained by the Applicant, and therefore results reported in tables above may be used for the soil risk assessment purposes.

The new calculation and results for the metabolite JAU-Desthio are presented in the table below, as they were different comparing to Applicants' results. The $PEC_{SOIL,ACCU}$ was not required as DT_{50} of the metabolite is below 100 days. The short- and long-term PEC_{SOIL} values are not reported below as they are not necessary for the risk assessment purposes. Only 21 TWA PEC_{SOIL} is provided as being required for evaluation of the risk of secondary poisoning for birds and mammals.

PEC_{SOIL} JAU-Desthio (mg/kg)	**Cereals (BBCH 30)**
	Single application
Initial	0.028
21-d TWA	0.025

8.7.2.2 PEC_{SOIL} of product ADM.03500.F.2.B

Table 8.7-5: PEC_{soil} for ADM.03500.F.2.B

Active substance/ reparation	Application rate (g/ha)	PEC_{act} (mg/kg)	PEC_{twa}21 d (mg/kg)	Tillage depth (cm)	$PEC_{soil,plateau}$ (mg/kg)	$PEC_{accu} = PEC_{act} + PEC_{soil,plateau}$ (mg/kg)
ADM.03500.F.2.B	864.0 ~~805.6~~	0.230* ~~0.215*~~	-	20	not triggered	

* based on a relative density of 1.08 ~~1.007~~ g/mL and the worst-case application rate of 0.8 L product/ha, considering a crop interception fraction of 0.8

zRMS comments:

~~PEC_{SOIL} value for the formulated product is agreed by the zRMS and may be used in the risk assessment for soil organisms.~~

PEC_{SOIL} value for the formulated product was recalculated by the zRMS since the relative density of the product is 1.08 g/mL, instead of the used value of 1.007 g/mL. Respective changes were introduced to the Table 8.7-5.

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

According to the residue definition provided in the EFSA conclusion on prothioconazole (EFSA, 2007) the following residues are of concern for the risk assessment in groundwater:
Prothioconazole, prothioconazole-desthio, (JAU-desthio), prothioconazole-S-methyl (JAU-S-methyl)

8.8.1 Justification for new endpoints

EU agreed endpoints, as defined in the List of Endpoints (LoEP) of the EFSA conclusion for prothioconazole (EFSA, 2007), were considered in the groundwater assessment for prothioconazole and its metabolites in accordance to the recommendations for the Central zone (2018). However, in addition to the EU agreed endpoints for the plant uptake factor of prothioconazole and its metabolites, a default value of 0.0 is used, which is in accordance to the recommendations of the latest FOCUS (2014b[5]) guidance. For vapour pressure and water solubility of metabolites the parent values are used in absence of data in the list of endpoints.

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

The following PEC_{GW} modelling for the active substance prothioconazole and its metabolites (using current model versions FOCUS PELMO 5.5.3 and/or FOCUS PEARL 4.4.4) has not previously been reviewed and a summary is provided in support of this assessment in Appendix 2 of this document. In accordance with the working document of the central zone the results of one of these models show the PEC_{GW} results to be <0.001 µg/l in all relevant scenarios for all substances triggering groundwater assessment, it is not necessary to perform simulation runs with the other model. Therefore, only FOCUS PEARL results are presented below.

The PEC_{GW} of prothioconazole and its metabolites have been assessed with FOCUS PEARL 4.4.4 following FOCUS (2014b) and the requirements of the Central zone (2018).

The exposure assessment in groundwater was based on various application patterns (Table 8.8-1) derived from GAP information.

Please note, that the highest resulting deposit rate (application rate corrected for crop interception) results in the maximum PEC_{GW}. That means, the maximum intended rates per treatment were set to the beginning of the intended application timing, where crop interception is lowest. Therefore, the defined application patterns in Table 8.8-1 represent the worst-case of application for the resulting maximum PEC_{GW} of prothioconazole and its metabolites for a specific GAP use.

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

Use No.[1	**1-4, 6-9, 11-15, 17-21, 28-31, 38-40, 42, 43, 45, 46, 52-54, 169**	**5, 10, 16, 22, 32, 41, 44, 47, 55**
Crop / $FOCUS_{GW}$ crop	Cereals, spring & winter	Oilseed rape, spring & winter
Application timing (BBCH / month)	30	50
Application rate (g/ha)	200	175
Number of applications/interval (d)	1/ -	1/ -
Absolute application dates	See Table 8.8-3	See Table 8.8-3
Crop interception (%)	80	80
Models used for calculation	FOCUS PEARL v4.4.4	FOCUS PEARL v4.4.4

[1 Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

[5] FOCUS (2014b): Generic Guidance for Tier 1 FOCUS Ground Water Assessments, Version 2.2, May 2014

8.8.2.1 Prothioconazole and its metabolites

The input parameters of prothioconazole and its metabolites utilised for PEC_{GW} modelling are summarised hereafter.

Table 8.8-2: Input parameters related to active substance prothioconazole and metabolites for PEC_{GW} calculations

Compound	Prothioconazole	JAU-desthio	JAU-S-methyl	Value in accordance with EU endpoint y/n/ Reference
Molecular weight (g/mol)	344.26	312.2	358.3	y/ EFSA, 2007
Water solubility (mg/L)	300 (20 °C)	300 (20 °C)	300 (20 °C)	Parent y/ EFSA, 2007 Metabolites: parent value
Saturated vapour pressure (Pa)	< 4x10E-07 (20 °C)	< 4x10E-07 (20 °C)	< 4x10E-07 (20 °C)	
DT_{50} in soil (d)	1.2 (norm.geomean from field studies), n=4	22.7 (norm.geomean from field studies), n=4	15.7 (geomean from lab studies), n=4	y/ EFSA, 2007
Q_{10} (-)	2.58	2.58	2.58	n/ FOCUS 2014 a, b
K_{foc} /K_{fom} (mL/g)	1765/1023.8 (sole value)	575.4/333.8 (arithmetic mean, n=4)	2556.3/1482.8 (arithmetic mean, n=4)	y/ EFSA, 2007
1/n	0.9 (default)	0.81 (arithmetic mean, n=4)	0.88 (arithmetic mean, n=4)	y/ EFSA, 2007
Plant uptake factor	0 (default)	0 (default)		n/ FOCUS, 2014b
Formation fraction	-	0.571	0.146	y/ EFSA, 2007

Table 8.8-3: FOCUS PEARL Scenario related input parameters for PECgw calculations for the application of ADM.03500.F.2.B

GAP use	FOCUS Scenario	Absolute application dates	
		Winter crop	Spring crop
Cereals, 1 x 200g (BBCH 30)	Châteaudun	15-April	16-April
	Hamburg	4-May	28-April
	Jokioinen	14-May	5-June
	Kremsmünster	24-April	27-April
	Okehampton	21-April	22-April
	Piacenza	19-March	-
	Porto	30-January	16-April
	Sevilla	6-January	-
	Thiva	18-January	-
Oilseed rape 1 x 175 g (BBCH 50)	Châteaudun	31-March	-
	Hamburg	27-April	-
	Jokioinen	-	24-June
	Kremsmünster	25-April	-
	Okehampton	20-April	04-May
	Piacenza	27-March	-
	Porto	23-Feburary	14-May

The 80th percentile annual average PEC_{GW} of prothioconazole and metabolites are provided in the following.

Table 8.8-4: Tier 1 PEC_{GW} for prothioconazole and metabolites

Crop / $FOCUS_{GW}$ Crop, Appl. no. & rate (g a.s./ha)	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L)					
		PEARL 4.4.4			no further model triggered		
		Prothio	Desthio	S-Methyl			
Cereals/ Winter cereals 1 × 200 g	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			
Cereals/ Spring cereals 1 × 200 g	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			
Oilseed rape winter 1 x 175 g	Châteaudun	< 0.001	< 0.001	< 0.001			
	Hamburg	< 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			
Oilseed rape spring 1 x 175 g	Jokioinen	< 0.001	< 0.001	< 0.001			
	Okehampton	< 0.001	< 0.001	< 0.001			
	Porto	< 0.001	< 0.001	< 0.001			

The results of the Tier 1 FOCUS PEARL show that PEC_{GW} results to be < 0.001 µg/L in all relevant scenarios for all substances (prothioconazole and its metabolites) triggering groundwater assessment, it is not necessary to perform simulation runs with the FOCUS PELMO or FOCUS MACRO model.

Important note: some Member States may request simulations performed with the missing model if the results of that specific model are deemed essential to comply with the national requirements.

Then the corresponding model simulations are presented in the national addenda.

zRMS comments:

The application pattern assumed in simulations is in line with the critical Central Zone GAP as presented in Table 8.1-1. Input parameters presented in Table 8.8-2 and used in the modelling are in line with the EU agreed endpoints reported in EFSA Scientific Report (2007) 106. Application dates presented in Table 8.8-3 were checked by the zRMS using AppDate ver. 3.06 tool and are considered acceptable.

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

Since all PEC_{GW} were <0.001 µg/L, simulations performed using single model are deemed sufficient, in line with indications of the Central Zone guidance document in area of efate (2018).

The performed calculations were 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 ADM.03500.F.2.B 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)

According to the residue definition provided in the EFSA conclusion on prothioconazole (EFSA, 2007), the following residues are of concern for the risk assessment in surface water and sediment:

Prothioconazole, JAU-desthio, JAU-S-methyl and 1,2,4-triazole

In contrast to EFSA (2007) PECsw/sed calculations are also performed for soil metabolite JAU-S-methyl since entry via run-off drainage to surface water could not be excluded considering FOCUS modelling.

8.9.1 Justification for new endpoints

Following the requirements for the Central zone (2018), EU agreed endpoints, as defined in the List of Endpoints (LoEP) of the EFSA conclusion for prothioconazole (EFSA, 2007), were considered in the assessment for prothioconazole and its metabolites. However, in addition to the EU agreed endpoints for the plant uptake factor of prothioconazole and its metabolites, a default value of 0.0 is used, which is in accordance to the recommendations of the latest FOCUS (2015[6]) and EFSA (2014[7]) guidance. For vapour pressure and water solubility of metabolites the parent values are used in absence of data in the list of endpoints. Furthermore, DT_{50} values for water/sediment (system) are needed for FOCUS modelling and taken from the DAR of prothioconazole (2005) in accordance with FOCUS (2006).

zRMS comments:
Detailed discussion regarding endpoints considered in surface water modelling and their acceptability is presented in the commenting boxes in point 8.9.2.1.

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

The following $PEC_{SW/SED}$ modelling for active substance prothioconazole and its metabolites (using current model versions STEPS 1-2 v3.2, FOCUS SWASH v5.3, FOCUS MACRO v5.5.4, FOCUS PRZM v4.3.1, FOCUS TOXSWA v5.5.3, SWAN v5.0) have not previously been reviewed and a summary is provided in support of this assessment in Appendix 2 of this document.

The exposure and risk assessment in surface water and sediment was based on the worst-case application patterns derived from GAP information. Modelling was performed considering the representative $FOCUS_{SW}$ crop groups winter and spring cereals, as well as oilseed rape spring and winter. For cereals the intended maximum seasonal application rate of 1 x 200 g a.s./ha was calculated for BBCH 30 and BBCH 69 and for oilseeds a maximum seasonal rate of 1 x 175 g a.s./ha was calculated for BBCH 50 and 73.

[6] FOCUS (2015): Generic Guidance for FOCUS Surface Water Scenarios, Version 1.4, May 2015
"FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC". Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2. 245 pp.
[7] EFSA (2013): EFSA Journal 2013;11(6):3291: Scientific Opinion on the report of the FOCUS groundwater working group (FOCUS, 2009): assessment of higher tiers.

Table 8.9-1: Input parameters related to application for PECSW/SED calculations

Plant protection product	ADM.03500.F.2.B		
Use No.[1]	6-9, 11-15, 28-31, 38-40, 42, 43, 45, 46	10, 16, 32, 41, 44, 47	
Crop / $FOCUS_{SW}$ crop	Cereals/ Winter and Spring cereals	Oilseed rape, winter & spring	
Application rate (g a.s./ha)	1 x 200 g	1 x 175 g	
No. of applications/interval (d)	1 / -	1 / -	
Application timing	post-emergence (BBCH 30–69)	post-emergence (BBCH 50–73)	-
Application window (relevant for STEP 1 and 2 only)	Mar.–May, June–Sep.	Mar.–May, June–Sep.	
Application method	Ground spray	Ground spray	
CAM (Chemical application method)	2	2	
Soil depth (cm)	4	4	
Models used for calculation	STEPS 1-2 v3.2, FOCUS SWASH v5.3, FOCUS MACRO v5.5.4, FOCUS PRZM v4.3.1, FOCUS TOXSWA v5.5.3, SWAN v5.0.0		

[1] Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0. (PEC calculations of missing numbers are handled in national addenda)

Start of the application windows were determined with AppDate version 3.06 for BBCH 30 (cereals) and BBCH 50 (oilseeds). For the later post-emergence scenarios the application window ends at BBCH 69 (cereals) and 73 (oilseeds) in accordance with AppDate 3.01. This version has been used as the function “suggested last application date” was not available in the current version. The considered application windows are presented in the table below.

Table 8.9-2: FOCUS STEP 3 Scenario related input parameters for $PEC_{SW/SED}$ calculations for the application of ADM.03500.F.2.B

Crop	Scenario	Application window used for modelling	
		BBCH stages	
		from BBCH 30*	up to BBCH 69
Winter cereals	D1	25-Mar - 15-May (84-135)	24-Jun – 24-Jul (175-205)
	D2	04-Apr - 25-May (94-145)	25-Jun – 25-Jul (176-206)
	D3	16-Apr - 06-Jun (106-157)	15-Jul – 14-Aug (196-226)
	D4	18-Mar - 08-May (77-128)	21-Jun – 21-Jul (172-202)
	D5	15-Mar - 05-May (74-125)	15-May - 14-Jun (135-165)
	D6	16-Feb - 08-Apr (47-98)	06-Apr - 06-May (96-126)
	R1	04-May - 24-Jun (124-175)	08-Jun – 08-Jul (159-189)
	R3	19-Mar - 09-May (78-129)	08-May - 07-Jun (128-158)
	R4	24-Jan - 16-Mar (24-75)	15-May - 14-Jun (135-165)
Spring cereals	D1	27-May - 17-Jul (147-198)	30-Jun – 30-Jul (181-211)
	D3	28-Apr - 18-Jun (118-169)	09-Jun – 09-Jul (160-190)
	D4	18-May - 08-Jul (138-189)	21-Jun – 21-Jul (172-202)
	D5	09-Apr - 30-May (99-150)	16-May - 15-Jun (136-166)
	R4	09-Apr - 30-May (99-150)	16-May - 15-Jun (136-166)
		from BBCH 50	**up to BBCH 73**
Oilseed rape winter	D2	28-Apr - 28-May (118-148)	11-Jun – 11-Jul (162-192)
	D3	09-Apr - 09-May (99-129)	30-May - 29-Jun (150-180)
	D4	18-Apr - 18-May (108-138)	13-Jun – 13-Jul (164-194)
	D5	05-Apr - 05-May (95-125)	15-May - 14-Jun (135-165)
	R1	07-May - 06-Jun (127-157)	26-May - 25-Jun (146-176)
	R3	29-Mar - 28-Apr (88-118)	21-Apr - 21-May (111-141)

Oilseed rape spring	D1	23-Jun – 23-Jul (174-204)	12-Jul – 12-Aug (193-223)
	D3	30-May – 29-Jun (150-180)	25-Jun – 25-Jul (176-206)
	D4	06-Jun – 06-Jul (157-187)	28-Jun – 28-Jul (179-209)
	D5	08-May - 07-Jun (128-158)	02-Jun – 02-Jul (153-183)
	R1	24-May – 23-Jun (144-174)	16-Jun – 16-Jul (167-197)

zRMS comments:

The application pattern presented in Table 8.9-1 assumed in simulations is in line with central Zone GAP as presented in Table 8.1-1.

According to information provided by the Applicant above, the beginning of the application windows was determined using AppDate 3.06. It seems, however, that version 3.01 was used to establish the relevant application windows. Although in line with the Central Zone guidance document in area of efate (2018)[8] the most recent version of the program should be used, in case of cereals and oilseed rape the only differences between 3.06 and 3.01 versions are dates in R1 scenario (for application to cereals from BBCH 30 and in winter oilseed rape from BBCH 50). The application windows presented in Table 8.9-2 are confirmed to be in line with AppDate 3.01, while dates presented in table below were determined by the zRMS using AppDate 3.06 and were taken into account in simulations performed in order to validate the Applicants' results. Please note that the most recent version of AppDate does not provide possibility for determination of the last possible date of application (this was available in version 3.01 and respective dates are presented in the last column of Table 8.9-2). It is noted that the Applicant considered 51 days application window for uses in cereals, but due to single application of ADM.03500.F.2.B intended in the Central Zone, the zRMS assumed 30 days windows.

Application windows assumed in the zRMS simulations performed for validation purposes

	Application window used for modelling			
Scenario	**Winter cereals from BBCH 30**	**Spring cereals from BBCH 30**	**Winter oilseed rape from BBCH 50**	**Spring oilseed rape from BBCH 50**
D1	25-Mar – 24Apr (84-114)	27-May - 26-Jul (147-177)	-	23-Jun – 23-Jul (174-204)
D2	04-Apr - 04-May (94-124)	-	28-Apr - 28-May (118-148)	-
D3	16-Apr – 16-May (106-136)	28-Apr - 28-May (118-148)	09-Apr - 09-May (99-129)	30-May – 29-Jun (150-180)
D4	18-Mar – 17-Apr (77-107)	18-May - 17-Jul (138-168)	18-Apr - 18-May (108-138)	06-Jun – 06-Jul (157-187)
D5	15-Mar – 14-Apr (74-104)	09-Apr - 09-May (99-129)	05-Apr - 05-May (95-125)	08-May - 07-Jun (128-158)
D6	16-Feb – 18-Mar (47-77)	-	-	-
R1	24-Apr – 24 May (114-144)	-	05-May-04-Jun (125-155)	24-May – 23-Jun (144-174)
R3	19-Mar – 18-Apr (78-108)	-	29-Mar - 28-Apr (88-118)	-
R4	24-Jan – 23-Feb (24-54)	09-Apr - 09-May (99-129)	-	-

The differences between Applicants' and zRMS application windows had no significant impact on the PEC_{SW} results discussed in the commenting boxes in point 8.9.2.1.

[8] Working document of the Central Zone in the authorization of plant protection products, Section 8, Environmental fate and behaviour, Version 1 rev., June 2018

8.9.2.1 Prothioconazole and its metabolites

Table 8.9-3: Step 1 in FOCUS input parameters considered for Prothioconazole and its metabolites JAU 6476-Desthio, JAU 6476 S-Methyl, 1,2,4- Triazole for the critical GAP uses in the central zone

Parameter		Compound	Value	Remark	Reference
Substance specific data					
Water solubility [mg/L]		Prothioconazole	300	Parent value (determined at 20 °C, pH 8)	EFSA Journal (2007) 106, 1-98 (prothioconazole)
		JAU 6476-Desthio	300		
		JAU 6476 S-Methyl	300		
		1,2,4- Triazole	300	assumed as for the other metabolites*	
K_{OC} [L/kg]		Prothioconazole	1765	sole value	EFSA Journal (2007) 106, 1-98 (prothioconazole)
		JAU 6476-Desthio	575.4	arithmetic mean, n=4	
		JAU 6476 S-Methyl	2556.3		
		1,2,4- Triazole	89	arithmetic mean, n=4	
DT_{50} in sediment/water system [d]		Prothioconazole	2.1	geomean (whole system) n=2 from EU agreed studies: DT_{50} from HS kinetics	EFSA Journal (2007) 106, 1-98 (prothioconazole), FOCUS (2006)
		JAU 6476-Desthio	49.9	max. whole system value (n=2)	DAR (2005)
		JAU 6476 S-Methyl	40.2		
		1,2,4- Triazole	1000	default value	FOCUS (2006)
Molecular Mass [g/mole]		Prothioconazole	344.3	-	EFSA Journal (2007) 106, 1-98 (prothioconazole)
		JAU 6476-Desthio	312.2		
		JAU 6476 S-Methyl	358.3		
		1,2,4- Triazole	69.1		
Maximum occurrence observed for the metabolite [%]	water/ sediment studies	JAU 6476-Desthio	54.6 ~~32.3~~	max for whole system ~~max. from 2 water sediment systems~~	EFSA Journal (2007) 106, 1-98 (prothioconazole)
		JAU 6476 S-Methyl	12.7 (aerobic) 77 (anaerobic)		
		1,2,4- Triazole	41.8 ~~37.2~~		
	soil	JAU 6476-Desthio	57.1		
		JAU 6476 S-Methyl	14.6		
		1,2,4- Triazole	0.0001	No soil metabolite (low value)	
Application pattern					
Application rate of a.i. [g/ha]		Prothioconazole	200 175		GAP
Number of applications per season			1	-	
Time between two applications [d]			-	-	
Crop type			Cereals	Winter and Spring	
			Oilseed rape	Winter and Spring	

* it is known from other documents/substances (eg epoxiconazole, tebuconazole, difenoconazole etc.) that the solubility for 1,2,4 -triazole is much higher: 730 000 mg/L (EFSA Journal 2014;12(1):3485 on tebnuconazole, p 53). However, this discrepancy will not affect the outcome of the aquatic risk assessment for 1,2,4- triazole

Table 8.9-4: Step 2 in FOCUS input parameters considered for Prothioconazole metabolites JAU 6476-Desthio, JAU 6476 S-Methyl, 1,2,4- Triazole, for the critical GAP uses in the central zone

Step 2				
Parameter		**Value**	**Remark**	**Reference**
Substance specific data				
DT_{50} in soil [d]	Prothioconazole	1.2	geomean (from field studies), n=8	EFSA (2007)
	JAU 6476-Desthio	22.7		
	JAU 6476 S-Methyl	15.7	geomean (from lab studies), n=4	
	1,2,4- Triazole	1000	default value (no soil metabolite)	FOCUS (2006)
DT_{50} in water [d]	Prothioconazole	2.1 (correct value: 1.0 d)	mean (whole system): DT_{50} from HS kinetics	EFSA Journal (2007) 106, 1-98 (prothioconazole), FOCUS (2006)
	JAU 6476-Desthio	49.9	max. whole system (n=2)	DAR (2005)
	JAU 6476 S-Methyl	40.2		
	1,2,4- Triazole	1000	default value	
DT_{50} in sediment [d]	Prothioconazole	2.1 (correct value: 1.0 d)	mean (whole system): DT_{50} from HS kinetics	See above, acc. to FOCUS: System decline DT_{50} for both compartments
	JAU 6476-Desthio	49.9	max. whole system (n=2)	
	JAU 6476 S-Methyl	40.2		
	1,2,4- Triazole	1000	default value	
Application pattern				
Crop interception	Intermediate Full canopy Full canopy	from BBCH 30-39 ~~69~~ (cereals) from BBCH 40-69 (cereals) from BBCH 50-73 (oilseeds)		FOCUS (2015), worst case
Region and season of application				
Northern Europe	Mar.–May, June–Sep.	Cereals, Oilseed rape (Spring and winter)		GAP

Table 8.9-5: Step 3 & 4 FOCUS SWASH input parameters considered for the critical GAP uses

Parameter	**Substance**	**Value**	**Remark**	**Reference**
General				
Molar mass [g/mol]	Prothioconazole	344.3	-	EFSA Journal (2007) 106, 1-98 (prothioconazole)
	JAU 6476-desthio	312.2		
Saturated vapour pressure [Pa]	Prothioconazole	4x10E-07	determined at 20 °C	
	JAU 6476-desthio	4x10E-07	parent value	
Molar enthalpy of vaporisation [J/mol]		95000	default value	FOCUS (2001)[9]
Solubility in water [mg/L]	Prothioconazole	300	determined at 20 °C	EFSA Journal (2007) 106, 1-98 (prothioconazole)
	JAU 6476-desthio	300	parent value	
Molar enthalpy of dissolution [J/mol]		27000	default value	FOCUS (2001)
Diffusion coefficient in water [m²/d]		4.3E-05	default value	
Diffusion coefficient in air [m²/d]		0.43	default value	
Sorption				
General K_{OM} [L/kg]	Prothioconazole	1024	calculated by SWASH based on K_{OC} divided by 1.724	
	JAU 6476-desthio	332.7		
General K_{OC} [L/kg]	Prothioconazole	1765	sole value (column leaching study)	EFSA Journal (2007) 106, 1-98 (prothioconazole)
	JAU 6476-desthio	575.4	arithmetic mean,	

[9] FOCUS (2001). “FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC“ Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2. 245 pp.

Parameter	Substance	Value	Remark	Reference
			n = 4	
Freundlich exponent [-]	Prothioconazole	0.9	default	
	JAU 6476-desthio	0.81	-	
Ref. concentration in liquid phase [g/m^3]		1	default value	-
Uptake and wash-off				
Factor for the uptake by plant roots in soil	All compounds	0	worst case	FOCUS (2014)
Wash off factor from crop	[1/mm]	0.05	MACRO	FOCUS (2001)
	[1/cm]	0.5	PRZM	
Transformation				
Conversion factor (parent → metabolite): 0.57 in soil, 0.323 in water/sediment				
Half-life time [d] – water	Prothioconazole	2.1 (value from LoEP: 1.0 d)	geomean (whole system): DT_{50} from HS kinetics	EFSA Journal (2007) 106, 1-98 (prothioconazole), FOCUS (2006)
	JAU 6476-desthio	1000 [1)] ~~49.9~~	max. (whole system), n=2	
sediment	Prothioconazole	1000	default (worst case)	FOCUS (2006)
	JAU 6476-desthio	49.9 [1)] ~~1000~~		
soil	Prothioconazole	1.2	geomean (from field studies, normalised), n=8	EFSA (2007)
	JAU 6476-desthio	22.7		
crop		10.00	default value	FOCUS (2001)
Activation energy [J/mol]		65400	default value	recommended by the PPR (2007) for EFSA
Exponent [1/K]		0.0948	default value	
Q_{10}fac [-]		2.58	default value	
Specifications on transformation in soil				
Exponent for the effect of water content [-]		0	MACRO, PRZM	FOCUS (2001)
Half life measured at pF		2	MACRO	
Half life measured at moisture content [%]		100.00	PRZM	-
Relative (% of FC)		yes	-	-

[1)] Combination giving worst case PEC_{SW} at Steps 3&4 (for details, see zRMS comment at the end of this chapter)

$PEC_{SW/SED}$ at Step 1&2 and Step 3&4

The STEP 1 & 2 and STEP 3 global maximum PEC_{SW} and PEC_{SED} values of prothioconazole and its metabolites for the worst-case application patterns of the intended GAP uses of ADM.03500.F.2.B are given in the following. For metabolite prothioconazole-desthio as well STEP 4 values are presented, where necessary. Non spraying buffer zones at 10 and 20 m distances are considered for drift and run-off reduction. The use of drift reducing nozzles (75, 90 %) is also accepted and presented as further mitigation option.

ACTIVE SUBSTANCE

Cereals

Table 8.9-6: FOCUS STEP 1, 2 & 3 PEC_{SW} and PEC_{SED} for prothioconazole following single application of 200 g a.s./ha to spring cereals BBCH 30

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	Dominant entry route	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
STEP 1	---	21.72	~~run-off/drainage~~	2.98	350.89
STEP 2					
Northern Europe	March-May	1.84	~~spray drift~~	0.19	7.81
	June-Sept	1.84	~~spray drift~~	0.19	7.81
STEP 3					
D1	Ditch	1.279	spray drift	0.299	1.917
D1	Stream	1.119	spray drift	0.044	0.592
D3	Ditch	1.265	spray drift	0.059	0.738
D4	Pond	0.044	spray drift	0.011	0.082
D4	Stream	1.034	spray drift	0.004	0.071
D5	Pond	0.044	spray drift	0.015	0.102
D5	Stream	1.062	spray drift	0.003	0.045
R4	Stream	0.836	spray drift	0.033	0.896

Table 8.9-7: FOCUS STEP 1, 2 & 3 PEC_{SW} and PEC_{SED} for prothioconazole following single application of 200 g a.s./ha to spring cereals BBCH 69

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	Dominant entry route	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
STEP 1	---	21.72	~~run-off/drainage~~	2.98	350.89
STEP 2					
Northern Europe	March-May	1.84	~~spray drift~~	0.19	7.81
	June-Sept	1.84	~~spray drift~~	0.19	7.81
STEP 3					
D1	Ditch	1.279	spray drift	0.212	1.538
D1	Stream	1.119	spray drift	0.042	0.567
D3	Ditch	1.268	spray drift	0.070	0.839
D4	Pond	0.044	spray drift	0.008	0.067
D4	Stream	1.090	spray drift	0.013	0.202
D5	Pond	0.044	spray drift	0.010	0.078
D5	Stream	1.178	spray drift	0.020	0.296
R4	Stream	0.836	spray drift	0.008	0.127

Table 8.9-8: FOCUS STEP 1, 2 & 3 PEC_{SW} and PEC_{SED} for prothioconazole following single application of 200 g a.s./ha to winter cereals BBCH 30

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	Dominant entry route	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
STEP 1	---	21.72	~~run-off/drainage~~	2.98	350.89
STEP 2					
Northern Europe	March-May	1.84	~~spray drift~~	0.19	7.81
	June-Sept	1.84	~~spray drift~~	0.19	7.81
STEP 3					
D1	Ditch	1.268	spray drift	0.101	1.078
D1	Stream	0.986	spray drift	0.003	0.042
D2	Ditch	1.280	spray drift	0.229	2.006
D2	Stream	1.131	spray drift	0.192	1.759
D3	Ditch	1.264	spray drift	0.057	0.726
D4	Pond	0.044	spray drift	0.019	0.124
D4	Stream	0.934	spray drift	0.002	0.028
D5	Pond	0.044	spray drift	0.015	0.101
D5	Stream	1.009	spray drift	0.002	0.029
D6	Ditch	1.249	spray drift	0.026	0.368
R1	Pond	0.044	spray drift	0.013	0.094
R1	Stream	0.829	spray drift	0.012	0.284
R3	Stream	1.170	spray drift	0.015	0.232
R4	Stream	0.836	spray drift	0.008	0.128

Table 8.9-9: FOCUS STEP 1, 2 & 3 PEC_{SW} and PEC_{SED} for prothioconazole following single application of 200 g a.s./ha to winter cereals BBCH 69

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	Dominant entry route	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
STEP 1	---	21.72	~~run-off/drainage~~	2.98	350.89
STEP 2					
Northern Europe	March-May	1.84	~~spray drift~~	0.19	7.81
	June-Sept	1.84	~~spray drift~~	0.19	7.81
STEP 3					
D1	Ditch	1.279	spray drift	0.279	1.917
D1	Stream	1.119	spray drift	0.044	0.592
D2	Ditch	1.281	spray drift	0.231	1.623
D2	Stream	1.139	spray drift	0.205	1.450
D3	Ditch	1.269	spray drift	0.076	0.876
D4	Pond	0.044	spray drift	0.008	0.067
D4	Stream	1.093	spray drift	0.015	0.220
D5	Pond	0.044	spray drift	0.010	0.078
D5	Stream	1.180	spray drift	0.020	0.306
D6	Ditch	1.270	spray drift	0.134	1.219
R1	Pond	0.044	spray drift	0.015	0.164
R1	Stream	0.836	spray drift	0.018	1.886
R3	Stream	1.171	spray drift	0.024	0.368
R4	Stream	0.836	spray drift	0.008	0.127

Oilseed rape

Table 8.9-10: FOCUS STEP 1, 2 & 3 PEC_{SW} and PEC_{SED} for prothioconazole following single application of 175 g a.s./ha to spring oilseed rape, BBCH 50

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	Dominant entry route	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
STEP 1	---	19.01	~~run-off/drainage~~	2.61	307.03
STEP 2					
Northern Europe	March-May	1.61	~~spray drift~~	0.13	4.06
	June-Sept	1.61	~~spray drift~~	0.13	4.06
STEP 3					
D1	Ditch	1.119	spray drift	0.244	1.685
D1	Stream	0.979	spray drift	0.039	0.519
D3	Ditch	1.180	spray drift	0.058	0.708
D4	Pond	0.038	spray drift	0.007	0.059
D4	Stream	0.957	spray drift	0.013	0.192
D5	Pond	0.038	spray drift	0.009	0.069
D5	Stream	0.967	spray drift	0.004	0.062
R1	Pond	0.038	spray drift	0.010	0.098
R1	Stream	0.731	spray drift	0.012	0.891

Table 8.9-11: FOCUS STEP 1, 2 & 3 PEC_{SW} and PEC_{SED} for prothioconazole following single application of 175 g a.s./ha to spring oilseed rape, BBCH 73

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	Dominant entry route	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
STEP 1	---	19.01	~~run-off/drainage~~	2.61	307.03
STEP 2					
Northern Europe	March-May	1.61	~~spray drift~~	0.13	4.06
	June-Sept	1.61	~~spray drift~~	0.13	4.06
STEP 3					
D1	Ditch	1.119	spray drift	0.202	1.418
D1	Stream	0.979	spray drift	0.037	0.503
D3	Ditch	1.110	spray drift	0.068	0.786
D4	Pond	0.038	spray drift	0.007	0.059
D4	Stream	0.957	spray drift	0.013	0.192
D5	Pond	0.038	spray drift	0.008	0.063
D5	Stream	1.032	spray drift	0.018	0.266
R1	Pond	0.038	spray drift	0.011	0.112
R1	Stream	0.7318	spray drift	0.016	1.244

Table 8.9-12: FOCUS STEP 1, 2 & 3 PEC_{SW} and PEC_{SED} for <u>prothioconazole</u> following single application of 175 g a.s./ha to winter oilseed rape, BBCH 50

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	Dominant entry route	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
STEP 1	---	19.01	~~run-off/drainage~~	2.61	307.03
STEP 2					
Northern Europe	March-May	1.61	~~spray drift~~	0.13	4.06
	June-Sept	1.61	~~spray drift~~	0.13	4.06
STEP 3					
D2	Ditch	1.120	spray drift	0.203	1.769
D2	Stream	0.997	spray drift	0.173	1.580
D3	Ditch	1.106	spray drift	0.051	0.649
D4	Pond	0.038	spray drift	0.016	0.106
D4	Stream	0.849	spray drift	0.002	0.032
D5	Pond	0.038	spray drift	0.013	0.089
D5	Stream	0.896	spray drift	0.002	0.029
R1	Pond	0.038	spray drift	0.012	0.084
R1	Stream	0.723	spray drift	0.010	0.273
R3	Stream	1.022	spray drift	0.013	0.197

Table 8.9-13: FOCUS STEP 1, 2 & 3 PEC_{SW} and PEC_{SED} for <u>prothioconazole</u> following single application of 175 g a.s./ha to winter oilseed rape, BBCH 75

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	Dominant entry route	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
STEP 1	---	19.01	~~run-off/drainage~~	2.61	307.03
STEP 2					
Northern Europe	March-May	1.61	~~spray drift~~	0.13	4.06
	June-Sept	1.61	~~spray drift~~	0.13	4.06
STEP 3					
D2	Ditch	1.120	spray drift	0.219	1.491
D2	Stream	0.997	spray drift	0.194	1.332
D3	Ditch	1.110	spray drift	0.067	0.779
D4	Pond	0.038	spray drift	0.007	0.058
D4	Stream	0.957	spray drift	0.013	0.192
D5	Pond	0.038	spray drift	0.009	0.069
D5	Stream	1.032	spray drift	0.018	0.268
R1	Pond	0.038	spray drift	0.010	0.112
R1	Stream	0.730	spray drift	0.012	1.224
R3	Stream	1.028	spray drift	0.016	0.237

METABOLITES

Prothioconazole-desthio/ Cereals

Table 8.9-14: FOCUS STEP 1-4 PEC_{SW} and PEC_{SED} for prothioconazole-desthio following single application of 200 g a.s./ha to spring cereals BBCH 30

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	Dominant entry route	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
STEP 1	---	39.12 ~~31.124~~	~~run-off/drainage~~	33.60 ~~26.798~~	219.86 ~~175.985~~
STEP 2					
Northern Europe	March-May	3.63 ~~3.279~~	~~spray drift~~	3.08 ~~2.803~~	20.14 ~~18.329~~
	June-Sept	3.63 ~~3.279~~	~~spray drift~~	3.08 ~~2.803~~	20.14 ~~18.329~~
STEP 3					
D1	Ditch	0.165	-	0.154	0.018
D1	Stream	0.063	-	0.004	0.074
D3	Ditch	0.041	-	0.003	0.038
D4	Pond	0.008	-	0.008	0.077
D4	Stream	0.027	-	< 0.001	0.004
D5	Pond	0.008	-	0.007	0.081
D5	Stream	0.037	-	< 0.001	0.002
R4	Stream	0.563	-	0.079	0.897

STEP 4		Max PEC_{SW} (µg/L) considering following mitigation:						
No spray buffer (m)		10	10	10	20	20	20	10
Vegetative strip (m)		none	none	none	none	none	none	10
Nozzle reduction		none	75%	90%	none	75%	90%	none
R4	Stream	0.563	0.563	0.563	0.563	0.563	0.563	0.256

Table 8.9-15: FOCUS STEP 1-4 PEC_{SW} and PEC_{SED} for prothioconazole-desthio following single application of 200 g a.s./ha to spring cereals BBCH 69

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	Dominant entry route	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
STEP 1	---	39.12 ~~31.124~~	~~run-off/drainage~~	33.60 ~~26.798~~	219.86 ~~175.985~~
STEP 2					
Northern Europe	March-May	1.72 ~~1.440~~	~~spray drift~~	1.42 ~~1.208~~	9.28 ~~7.896~~
	June-Sept	1.72 ~~1.440~~	~~spray drift~~	1.42 ~~1.208~~	9.28 ~~7.896~~
STEP 3					
D1	Ditch	0.191	-	0.170	1.051
D1	Stream	0.074	-	0.004	0.075
D3	Ditch	0.056	-	0.005	0.062
D4	Pond	0.008	-	0.008	0.077
D4	Stream	0.035	-	0.001	0.009
D5	Pond	0.008	-	0.008	0.079
D5	Stream	0.049	-	0.001	0.015
R4	Stream	0.027	-	0.001	0.119
STEP 4 not required					

Table 8.9-16: FOCUS STEP 1-4 PEC_{SW} and PEC_{SED} for prothioconazole-desthio following single application of 200 g a.s./ha to winter cereals BBCH 30

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	Dominant entry route	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
STEP 1	---	39.12 ~~31.124~~	~~run-off/drainage~~	33.60 ~~26.798~~	219.86 ~~175.985~~
STEP 2					
Northern Europe	March-May	3.63 ~~3.279~~	~~spray drift~~	3.08 ~~2.803~~	20.14 ~~18.329~~
	June-Sept	3.63 ~~3.279~~	~~spray drift~~	3.08 ~~2.803~~	20.14 ~~18.329~~
STEP 3					
D1	Ditch	0.021	-	0.004	0.052
D1	Stream	0.042	-	< 0.001	0.018
D2	Ditch	0.143	-	0.035	0.363
D2	Stream	0.150	-	0.039	0.410
D3	Ditch	0.020	-	0.001	0.018
D4	Pond	0.006	-	0.006	0.074
D4	Stream	0.024	-	< 0.001	0.003
D5	Pond	0.007	-	0.007	0.082
D5	Stream	0.036	-	< 0.001	0.001
D6	Ditch	0.011	-	< 0.001	0.005
R1	Pond	0.058	-	0.047	0.473
R1	Stream	0.506	-	0.038	0.678
R3	Stream	0.441	-	0.021	0.563
R4	Stream	0.651	-	0.032	0.432

STEP 4		Max PEC_{SW} (µg/L) considering following mitigation:						
No spray buffer (m)		10	10	10	20	20	20	10
Vegetative strip (m)		none	none	none	none	none	none	10
Nozzle reduction		none	75%	90%	none	75%	90%	none
R1	Stream	0.506	0.506	0.506	0.506	0.506	0.506	0.230
R3	Stream	0.441	0.441	0.441	0.441	0.441	0.441	0.201
R4	Stream	0.651	0.651	0.651	0.651	0.651	0.651	0.296

Table 8.9-17: FOCUS STEP 1-4 PEC_{SW} and PEC_{SED} for prothioconazole-desthio following single application of 200 g a.s./ha to winter cereals BBCH 69

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)		Dominant entry route		21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
STEP 1	---	39.12 ~~31.124~~		~~run-off/drainage~~		33.60 ~~26.798~~	219.86 ~~175.985~~
STEP 2							
Northern Europe	March-May	1.72 ~~1.440~~		~~spray drift~~		1.42 ~~1.208~~	9.28 ~~7.896~~
	June-Sept	1.72 ~~1.440~~		~~spray drift~~		1.42 ~~1.208~~	9.28 ~~7.896~~
STEP 3							
D1	Ditch	0.176		-		0.158	1.017
D1	Stream	0.063		-		0.003	0.066
D2	Ditch	0.186		-		0.173	1.225
D2	Stream	0.194		-		0.176	1.073
D3	Ditch	0.071		-		0.008	0.087
D4	Pond	0.009		-		0.008	0.078
D4	Stream	0.036		-		0.001	0.009
D5	Pond	0.008		-		0.008	0.079
D5	Stream	0.050		-		0.001	0.015
D6	Ditch	0.073		-		0.022	0.151
R1	Pond	0.074		-		0.061	0.529
R1	Stream	0.307		-		0.024	0.919
R3	Stream	0.456		-		0.019	0.277
R4	Stream	0.027		-		0.001	0.112
STEP 4		**Max PEC_{SW} (µg/L) considering following mitigation:**					
No spray buffer (m)		10	10	10	20	20	20	10
Vegetative strip (m)		none	none	none	none	none	none	10
Nozzle reduction		none	75%	90%	none	75%	90%	none
R3	Stream	0.456	0.456	0.456	0.456	0.456	0.456	0.162

Prothioconazole-desthio/ Oilseed rape

Table 8.9-18: FOCUS STEP 1-4 PEC_{SW} and PEC_{SED} for prothioconazole-desthio following single application of 175 g a.s./ha to spring oilseed rape, BBCH 50

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	Dominant entry route	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
STEP 1	---	34.23 ~~27.233~~	~~run-off/drainage~~	29.40 ~~23.448~~	192.38 ~~153.987~~
STEP 2					
Northern Europe	March-May	1.34 ~~1.010~~	~~spray drift~~	1.10 ~~0.918~~	7.17 ~~5.996~~
	June-Sept	1.34 ~~1.010~~	~~spray drift~~	1.10 ~~0.918~~	7.17 ~~5.996~~
STEP 3					
D1	Ditch	0.154	-	0.138	0.897
D1	Stream	0.055	-	0.000	0.519
D3	Ditch	0.040	-	0.000	0.042
D4	Pond	0.008	-	0.007	0.068
D4	Stream	0.031		0.001	0.008
D5	Pond	0.007	-	0.007	0.071
D5	Stream	0.034	-	0.000	0.002
R1	Pond	0.021	-	0.019	0.205
R1	Stream	0.187	-	0.000	0.419
STEP 4 not required					

Table 8.9-19: FOCUS STEP 1-4 PEC_{SW} and PEC_{SED} for prothioconazole-desthio following single application of 175 g a.s./ha to spring oilseed rape, BBCH 73

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	Dominant entry route	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
STEP 1	---	34.23 ~~27.233~~	~~run-off/drainage~~	29.40 ~~23.448~~	192.38 ~~153.987~~
STEP 2					
Northern Europe	March-May	1.34 ~~1.010~~	~~spray drift~~	1.10 ~~0.918~~	7.17 ~~5.996~~
	June-Sept	1.34 ~~1.010~~	~~spray drift~~	1.10 ~~0.918~~	7.17 ~~5.996~~
STEP 3					
D1	Ditch	0.161	-	0.202	0.933
D1	Stream	0.062	-	0.003	0.065
D3	Ditch	0.053	-	0.006	0.065
D4	Pond	0.008	-	0.007	0.068
D4	Stream	0.032	-	0.001	0.008
D5	Pond	0.007	-	0.007	0.070
D5	Stream	0.045	-	0.001	0.014
R1	Pond	0.083	-	0.072	0.549
R1	Stream	0.404	-	0.000	1.156

STEP 4		Max PEC_{SW} (µg/L) considering following mitigation:						
No spray buffer (m)		10	10	10	20	20	20	10
Vegetative strip (m)		none	none	none	none	none	none	10
Nozzle reduction		none	75%	90%	none	75%	90%	none
R1	Stream	0.404	0.404	0.404	0.404	0.404	0.404	0.184

Table 8.9-20: FOCUS STEP 1-4 PEC_{SW} and PEC_{SED} for prothioconazole-desthio following single application of 175 g a.s./ha to winter oilseed rape, BBCH 50

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	Dominant entry route	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
STEP 1	---	34.23 ~~27.233~~	~~run-off/drainage~~	29.40 ~~23.448~~	192.38 ~~153.987~~
STEP 2					
Northern Europe	March-May	1.34 ~~1.010~~	~~spray drift~~	1.10 ~~0.918~~	7.17 ~~5.996~~
	June-Sept	1.34 ~~1.010~~	~~spray drift~~	1.10 ~~0.918~~	7.17 ~~5.996~~
STEP 3					
D2	Ditch	0.124	~~spray drift~~	0.031	0.304
D2	Stream	0.138	~~spray drift~~	0.036	0.365
D3	Ditch	0.018	~~spray drift~~	0.001	0.016
D4	Pond	0.006	~~spray drift~~	0.006	0.069
D4	Stream	0.022	~~spray drift~~	0.000	0.002
D5	Pond	0.006	~~spray drift~~	0.006	0.073
D5	Stream	0.031	~~spray drift~~	0.000	0.001
R1	Pond	0.055 ~~0.049~~	~~spray drift~~	0.040	0.417
R1	Stream	0.402	~~spray drift~~	0.030	0.584
R3	Stream	0.373	~~spray drift~~	0.017	0.481

STEP 4		Max PEC_{SW} (µg/L) considering following mitigation:						
No spray buffer (m)		10	10	10	20	20	20	10
Vegetative strip (m)		none	none	none	none	none	none	10
Nozzle reduction		none	75%	90%	none	75%	90%	none
R1	Stream	0.402	0.402	0.402	0.402	0.402	0.402	0.182
R3	Stream	0.373	0.373	0.373	0.373	0.373	0.373	0.170

Table 8.9-21: FOCUS STEP 1-4 PEC_{SW} and PEC_{SED} for prothioconazole-desthio following single application of 175 g a.s./ha to winter oilseed rape, BBCH 73

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	Dominant entry route	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
STEP 1	---	34.23 ~~27.233~~	~~run-off/drainage~~	29.40 ~~23.448~~	192.38 ~~153.987~~
STEP 2					
Northern Europe	March-May	1.34 ~~1.010~~	~~spray drift~~	1.10 ~~0.918~~	7.17 ~~5.996~~
	June-Sept	1.34 ~~1.010~~	~~spray drift~~	1.10 ~~0.918~~	7.17 ~~5.996~~
STEP 3					
D2	Ditch	0.157	~~spray drift~~	0.148	1.069
D2	Stream	0.164	~~spray drift~~	0.150	0.947
D3	Ditch	0.045	~~spray drift~~	0.005	0.054
D4	Pond	0.008	~~spray drift~~	0.007	0.068
D4	Stream	0.032	~~spray drift~~	0.001	0.008
D5	Pond	0.007	~~spray drift~~	0.007	0.070
D5	Stream	0.043	~~spray drift~~	0.000	0.013
R1	Pond	0.025	~~spray drift~~	0.022	0.229
R1	Stream	0.226	~~spray drift~~	0.010	0.562
R3	Stream	0.283	~~spray drift~~	0.021	0.188
STEP 4 not required					

Prothioconazole-S-methyl/ Cereals

Table 8.9-22: FOCUS STEP 1, 2 PEC_{SW} and PEC_{SED} for prothioconazole-S-methyl following 1 × 200 g a.s./ha to spring cereals BBCH 30

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	~~Dominant entry route~~	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
STEP 1	---	15.891	~~run-off/drainage~~	12.403	368.549
STEP 2					
Northern Europe	March-May	1.474	~~spray drift~~	0.709	20.418
	June-Sept	1.474	~~spray drift~~	0.709	20.418

Table 8.9-23: FOCUS STEP 1, 2 PEC_{SW} and PEC_{SED} for prothioconazole-S-methyl following 1 × 200 g a.s./ha to spring cereals BBCH 69

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	~~Dominant entry route~~	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
STEP 1	---	15.891	~~run-off/drainage~~	12.403	370.650
STEP 2					
Northern Europe	March-May	1.474	~~spray drift~~	0.486	12.558
	June-Sept	1.474	~~spray drift~~	0.486	12.558

Table 8.9-24: FOCUS STEP 1, 2 PEC_{SW} and PEC_{SED} for prothioconazole-S-methyl following 1 × 200 g a.s./ha to winter cereals BBCH 30

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	~~Dominant entry route~~	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
STEP 1	---	15.891	~~run-off/drainage~~	12.403	368.549
STEP 2					
Northern Europe	March-May	1.474	~~spray drift~~	0.709	20.418
	June-Sept	1.474	~~spray drift~~	0.709	20.418

Table 8.9-25: FOCUS STEP 1, 2 PEC_{SW} and PEC_{SED} for <u>prothioconazole-S-methyl</u> following 1 × 200 g a.s./ha to winter cereals BBCH 69

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	~~Dominant entry route~~	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
STEP 1	---	15.891	~~run-off/drainage~~	12.403	370.650
STEP 2					
Northern Europe	March-May	1.474	~~spray drift~~	0.486	12.558
	June-Sept	1.474	~~spray drift~~	0.486	12.558

<u>Prothioconazole-S-methyl/ Oilseed rape</u>

Table 8.9-26: FOCUS STEP 1, 2 PEC_{SW} and PEC_{SED} for <u>prothioconazole-S-methyl</u> following 1 × 175 g a.s./ha to oil seed rape, spring BBCH 50/BBCH 73

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	~~Dominant entry route~~	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
STEP 1	---	13.905	~~run-off/drainage~~	10.853	324.319
STEP 2					
Northern Europe	March-May	1.290	~~spray drift~~	0.401	10.300
	June-Sept	1.290	~~spray drift~~	0.401	10.300

Table 8.9-27: FOCUS STEP 1, 2 PEC_{SW} and PEC_{SED} for <u>prothioconazole-S-methyl</u> following 1 × 175 g a.s./ha to oil seed rape, winter BBCH 50/BBCH 73

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	~~Dominant entry route~~	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
STEP 1	---	13.905	~~run-off/drainage~~	10.853	324.319
STEP 2					
Northern Europe	March-May	1.290	~~spray drift~~	0.401	10.300
	June-Sept	1.290	~~spray drift~~	0.401	10.300

<u>1,2,4-triazole / Cereals</u>

Table 8.9-28: FOCUS STEP 1, 2 PEC_{SW} and PEC_{SED} for <u>1,2,4-triazole</u> following 2 × 200 g a.s./ha to spring cereals BBCH 30

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	~~Dominant entry route~~	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
STEP 1	---	5.15 ~~4.587~~	~~run-off/drainage~~	5.10 ~~4.540~~	4.57 ~~3.960~~
STEP 2					
Northern Europe	March-May	0.22 ~~0.198~~	~~spray drift~~	0.22 ~~0.192~~	0.19 ~~0.172~~
	June-Sept	0.22 ~~0.198~~	~~spray drift~~	0.22 ~~0.192~~	0.19 ~~0.172~~

Table 8.9-29: FOCUS STEP 1, 2 PEC_{SW} and PEC_{SED} for <u>1,2,4-triazole</u> following 2 × 200 g a.s./ha to spring cereals BBCH 69

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	~~Dominant entry route~~	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
STEP 1	---	5.15 ~~4.587~~	~~run-off/drainage~~	5.10 ~~4.540~~	4.57 ~~4.067~~
STEP 2					
Northern Europe	March-May	0.17 ~~0.153~~	~~spray drift~~	0.17 ~~0.148~~	0.15 ~~0.132~~
	June-Sept	0.17 ~~0.153~~	~~spray drift~~	0.17 ~~0.148~~	0.15 ~~0.132~~

Table 8.9-30: FOCUS STEP 1, 2 PEC_{SW} and PEC_{SED} for 1,2,4-triazole following 2 × 200 g a.s./ha to winter cereals BBCH 30

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	~~Dominant entry route~~	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
STEP 1	---	5.15 ~~4.587~~	~~run-off/drainage~~	5.10 ~~4.540~~	4.57 ~~3.960~~
STEP 2					
Northern Europe	March-May	0.22 ~~0.198~~	~~spray drift~~	0.22 ~~0.192~~	0.19 ~~0.172~~
	June-Sept	0.22 ~~0.198~~	~~spray drift~~	0.22 ~~0.192~~	0.19 ~~0.172~~

Table 8.9-31: FOCUS STEP 1, 2 PEC_{SW} and PEC_{SED} for 1,2,4-triazole following 2 × 200 g a.s./ha to winter cereals BBCH 69

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	~~Dominant entry route~~	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
STEP 1	---	5.15 ~~4.587~~	~~run-off/drainage~~	5.10 ~~4.540~~	4.57 ~~4.067~~
STEP 2					
Northern Europe	March-May	0.17 ~~0.153~~	~~spray drift~~	0.17 ~~0.148~~	0.15 ~~0.132~~
	June-Sept	0.17 ~~0.153~~	~~spray drift~~	0.17 ~~0.148~~	0.15 ~~0.132~~

1,2,4-triazole / Oilseed rape

Table 8.9-32: FOCUS STEP 1, 2 PEC_{SW} and PEC_{SED} for 1,2,4-triazole following 1 × 175 g a.s./ha to oil seed rape, spring BBCH 50/BBCH 73

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	~~Dominant entry route~~	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
STEP 1	---	4.51 ~~4.014~~	~~run-off/drainage~~	4.46 ~~3.972~~	4.00 ~~3.558~~
STEP 2					
Northern Europe	March-May	0.15 ~~0.130~~	~~spray drift~~	0.14 ~~0.126~~	0.13 ~~0.113~~
	June-Sept	0.15 ~~0.130~~	~~spray drift~~	0.14 ~~0.126~~	0.13 ~~0.113~~

Table 8.9-33: FOCUS STEP 1, 2 PEC_{SW} and PEC_{SED} for 1,2,4-triazole following 1 × 175 g a.s./ha to oil seed rape, winter BBCH 50/BBCH 73

Scenario FOCUS	Waterbody	Max PEC_{SW} (µg/L)	~~Dominant entry route~~	21 d- $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
STEP 1	---	4.51 ~~4.014~~	~~run-off/drainage~~	4.46 ~~3.972~~	4.00 ~~3.558~~
STEP 2					
Northern Europe	March-May	0.15 ~~0.130~~	~~spray drift~~	0.14 ~~0.126~~	0.13 ~~0.113~~
	June-Sept	0.15 ~~0.130~~	~~spray drift~~	0.14 ~~0.126~~	0.13 ~~0.113~~

zRMS comments:

Input parameters used for surface water modelling for prothioconazole and its metabolites and presented in Tables 8.9-3 to 8.9-5 are in general in line with EU agreed endpoints with following remarks:

General:

- For cereals from BBCH 30-69 the intermediate crop interception was considered by the Applicant. However, according to FOCUS Surface Water Generic Guidance (2015), for cereals at BBCH 20-30 and BBCH 49-89 crop cover is defined as intermediate and full canopy, respectively. Therefore, respective corrections were introduced in Table 8.9-4. Nevertheless, as the intermediate crop interception represents worst case, its consideration for later BBCH stages is accepted by the zRMS for Step 1-2 calculations.

For prothioconazole:

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

For metabolite JAU 6476-desthio:

- Maximum occurrence of 32.3% was used for the whole system, however, this is relevant for the maximum observed in the water phase, while for the whole system 54.6% is the correct value. Respective changes were introduced in Table 8.9-3 and used in the independent zRMS calculations for this metabolite at Step 1-2.
- It is noted that at the EU level no separate DT_{50} values were determined for water and sediment compartments and DT_{50} of 49.9 days is relevant for the whole system. Nevertheless, in line with indications of the FOCUS Surface Water Generic Guidance (2015), at Steps 1&2 the whole system DT_{50} may be also attributed to particular compartments.
- 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 Applicants' 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

For the metabolite JAU 6476 S-Methyl

- The Applicant used the maximum occurrence in water/sediment system of 77%, but such formation of JAU 6476 S-Methyl was observed only in sediment in the anaerobic water/sediment study. In the aerobic water/sediment study the maximum occurrence of 12.7% was observed in the whole system. Nevertheless, as assumed 77% represents worst case, it was accepted by the zRMS for Step 1-2 calculations.

For the 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 8.9-3 and were used in the independent calculations at Step 1-2.

Considering all deviation mentioned above respective changes were introduced in Tables 8.9-3 to 8.9-5.

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

Step 4 simulations were performed according to recommendations of the FOCUS work group on landscape and mitigation factors and were validated by the zRMS for convenience of the concerned Member States that consider FOCUS simulations as Step 4 at the national level.

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

Prothioconazole:

Results for prothioconazole at Step 1-3 were in general in good agreement with results obtained by the Applicant, with following exceptions:

- Since in line with the FOCUS guidance at Step 1-2 for uses in cereals at BBCH >40 the zRMS considered crop interception corresponding with "full canopy", obtained $PEC_{SW/SED}$ were lower comparing to Applicants' values, as these were derived with consideration of the "intermediate crop cover" also for later BBCH stages. The results obtained by the Applicant may be used in the risk assessment as representing worst case.
- PEC_{SW} at Step 3-4 were the same, whereas PEC_{SED} values obtained by the zRMS were slightly higher due to modified combination of DT_{50} values considered in simulations performed for parent+metabolite (JAU 6476-desthio). However, observed differences were slight and with no impact on the outcome of the risk assessment, which was driven by exposure of aquatic species via the water column.

Overall, the surface water exposure reported in Tables 8.9-6 to 8.9-13 may be used in the aquatic risk assessment.

Metabolite JAU 6476-desthio:

- Since higher maximum occurrence in the whole system was considered by the zRMS at Steps 1-2 calculations, obtained results were automatically higher and Tables 8.9-14 to 8.9-21 were amended accordingly.
- $PEC_{SW/SED}$ calculated by the zRMS at Steps 3-4 for the correct input parameters were the same or lower comparing to these obtained by the Applicant.

Overall, the surface water exposure reported in Tables 8.9-14 to 8.9-21 (with corrected Step 1-2 results) may be used in the aquatic risk assessment.

Metabolite JAU 6476 S-Methyl

Results obtained by the zRMS for this compound at Step 1-2 were considerably lower comparing to these obtained by the Applicant due to much higher maximum occurrence assumed in Applicants' simulations. Overall, values in Tables 8.9-22 to 8.9-27 may be used further in the aquatic risk assessment.

Metabolite 1,2,4-triazole

PEC_{SW} and PEC_{SED} calculated by the zRMS at Step 1-2 were higher comparing to these obtained by the Applicant when higher maximum occurrence was taken into account. Values reported in Tables 8.9-28 to 8.9-33 were thus corrected by the zRMS and may be used for purposes of the aquatic risk assessment.

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

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

8.9.2.2 PEC$_{SW/SED}$ of ADM.03500.F.2.B

The product-based ~~Step 3~~ PEC$_{sw}$ via spray drift were calculated for the standard water body types ditch, pond and stream using the FOCUS drift calculator 1.1 implemented in the FOCUS SWASH 5.3 model.

~~The maximum application rate per treatment (805.6 g product/ha) corresponds to 0.8 L product/ha as worst-case application rate assuming a product density of 1.007 g/mL. Calculations were performed for a single application of the product in cereals. The maximum initial PEC$_{sw}$ from spray drift entry (Step 3) and for standard distances of 10 and 20 m are presented in the table below.~~

~~The maximum initial PECsw from spray drift entry (without mitigations) is calculated to be 5.176 µg product/L.~~

~~**Table 8.9-34: PEC$_{sw}$ of the product ADM.03500.F.2.B from spray drift entry following single application to FOCUS scenarios in arable crops**~~

~~Water body~~	~~Application rate (g product/ha)~~	~~No spray FOCUS buffer distances (m)~~	~~Drift entry (%)~~	~~PEC$_{sw}$ (µg prod./L) with nozzle reduction~~		
				~~0 %~~	~~75 %~~	~~90 %~~
~~Ditch~~	~~805.6*~~ ~~(single application)~~	~~Standard FOCUS buffer Step 3~~	~~1.9274~~	~~5.1757~~	~~1.2939~~	~~0.5176~~
		~~10~~	~~0.2771~~	~~0.7440~~	~~0.1860~~	~~0.0744~~
		~~20~~	~~0.1440~~	~~0.3866~~	~~0.0966~~	~~0.0387~~
~~Pond~~		~~Standard FOCUS buffer Step 3~~	~~0.2191~~	~~0.1765~~	~~0.0441~~	~~0.0176~~
		~~10~~	~~0.1363~~	~~0.1098~~	~~0.0274~~	~~0.0110~~
		~~20~~	~~0.0910~~	~~0.0733~~	~~0.0183~~	~~0.0073~~
~~Stream~~		~~Standard FOCUS buffer Step 3~~	~~1.4304~~	~~3.8410~~	~~0.9602~~	~~0.3841~~
		~~10~~	~~0.2771~~	~~0.7440~~	~~0.1860~~	~~0.0744~~
		~~20~~	~~0.1440~~	~~0.3866~~	~~0.0966~~	~~0.0387~~

~~* the rate of formulation is based on a specific density of 1.007 g/mL and the worst-case application rate of 0.8 L product/ha~~

zRMS comments:

~~The surface water exposure to formulation was validated by the zRMS using Spray Drift Calculator. Obtained results were in agreement with these reported in Table 8.9-34.~~

~~Performed calculations are relevant also for the application to oilseed rape.~~

~~Please note that no Step 3 PEC$_{SW}$ is calculated for the formulated products, since only spray drift is assumed as the route of entry of the formulation to water and no phys-chem or degradation data are taken into account. For this reason reference to Step 3 calculation has been struck through in the text and table above.~~

The surface water exposure to formulation was recalculated by the zRMS using Spray Drift Calculator since the relative density of the product is 1.08 g/mL, instead of the used value of 1.007 g/mL. Obtained results are reported in table below. Please note that performed calculations are relevant also for the application to oilseed rape.

Water body	Application rate (g product/ha)	No spray FOCUS buffer distances (m)	Drift entry (%)	PEC$_{sw}$ (µg prod./L) with nozzle reduction		
				0 %	75 %	90 %
Ditch	864.0* (single application)	Standard FOCUS buffer	1.9274	5.5509	1.3877	0.5551
		10	0.2771	0.7980	0.1995	0.0798
		20	0.1440	0.4146	0.1037	0.0415
Pond		Standard FOCUS buffer	0.2191	0.1893	0.0473	0.0189
		10	0.1363	0.1177	0.0294	0.0118
		20	0.0910	0.0786	0.0197	0.0079
Stream		Standard FOCUS buffer	1.4304	4.1194	1.0299	0.4119

		10	0.2771	0.7980	0.1995	0.0798
		20	0.1440	0.4146	0.1037	0.0415

* the rate of formulation is based on a specific density of 1.08 g/mL and the worst-case application rate of 0.8 L product/ha

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

Table 8.10-1 Summary of atmospheric degradation and behaviour of Prothioconazole

Compound	Prothioconazole
Direct photolysis in air	Not studied – no data requested
Quantum yield of direct phototransformation	Not studied – no data requested
Photochemical oxidative degradation in air	Prothioconazole: Half-life: 1.1 hours Chemical lifetime: 1.6 hours Calculated according to Atkinson (AOPWIN v. 1.87, 12 hour day, 1.5x106 OH radicals/cm3) prothioconazole-desthio *(M04)*: Half-life: 14.2 hours Chemical lifetime: 20.5 hours Calculated according to Atkinson (AOPWIN v. 1.87, 12 hour day, 1.5x106 OH radicals/cm3)
Volatilisation	Laboratory route and rate soil studies indicated that volatilisation of prothioconazole and prothioconazole-desthio (*M04*) is unlikely to take place because no volatiles were detected at levels above 0.1% AR.
Metabolites	*

* based on the results concerning vapour pressure, Henry Law constant and photo oxidative stability in ambient air, it can be concluded that neither emission of prothioconazole into the air, nor accumulation and contamination by wet or dry deposition are to be expected for the parent compound and its metabolite prothioconazole-desthio (M04).

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

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.

Taking this into account the contamination of the atmosphere with prothioconazole from the intended uses of ADM.03500.F.2.B is considered to be negligible.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2.4/01	Penne, C.	2021	Predicted environmental concentrations in groundwater (PEC_{gw}) of prothioconazole and its metabolites using FOCUS PELMO 5.5.3, FOCUS PEARL 4.4.4 and FOCUS MACRO 5.5.4 for critical GAP uses in the Central zone. Report no.: ADM-210615-01, sponsor no. 000108552 EBRC Consulting GmbH, Hannover, Germany Not GLP Unpublished	N	ADM
KCP 9.2.5/01	Penne, C.	2021	Predicted environmental concentrations in surface water (PEC_{sw}) and sediment (PEC_{sed}) of prothioconazole and its metabolites using STEPS 1-2 in FOCUS (v3.2), FOCUS SWASH 5.3 and SWAN v5.0 for critical GAP uses in the Central zone. Report no.: ADM-210615-02, sponsor no. 000108554 EBRC Consulting GmbH, Hannover, Germany Not GLP Unpublished	N	ADM

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 most of endpoints for prothioconazole and its relevant metabolites was taken from the EU review, for the list of respective studies please refer to Volume 2 of the monograph.					

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 Additional information provided by the applicant

A 2.1 KCP 9.2.4 Predicted Environmental Concentrations in groundwater (PEC_{GW})

Comments of zRMS:	The groundwater modelling performed by the Applicant was agreed by the zRMS. For discussion on input parameters and obtained results, please refer to point 8.8 of this document.

Reference:	KCP 9.2.4/ 01
Report	Predicted environmental concentrations in groundwater (PEC_{gw}) of prothioconazole and its metabolites using FOCUS PELMO 5.5.3, FOCUS PEARL 4.4.4 and FOCUS MACRO 5.5.4 for critical GAP uses in the Central zone. Penne, C. (2021), Report no.: ADM-210615-01, sponsor no. 000108552
Guideline(s):	Generic Guidance for Tier 1 FOCUS Ground Water Assessments, Version 2.2, May 2014 "Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU" Report of the FOCUS Ground Water Work Group, EC Document Reference Sanco/13144/2010 Version 1, June 2009, 604 pp. Working Document of the Central Zone in the Authorisation of Plant Protection Products - Section 8 Environmental Fate and Behaviour, Version 1.1, June 2018
Deviations:	None
GLP:	No (not applicable)
Acceptability:	Acceptable

In this report predicted environmental concentrations in groundwater (PECgw) of the active substance prothioconazole and its metabolites JAU-desthio and JAU-S-methyl are presented for critical GAP uses of ADM.03500.F. 2.B~~1.A~~ in cereals and oilseeds.

Tier 1 PECgw were calculated for worst-case application patterns using the models FOCUS PELMO 5.5.3, FOCUS PEARL 4.4.4 and FOCUS MACRO 5.5.4.

PECgw of all substances in all FOCUS models and all scenarios resulted in 80^{th} percentile annual average PECgw below the drinking water trigger of 0.1 µg/L at 1 m depth. Thus, none of the compounds leached to groundwater to any environmentally hazardous extent and no toxicological risks are indicated.

A 2.2 KCP 9.2.5 Predicted Environmental Concentrations in surface water (PEC_{SW})

Comments of zRMS:	The surface water modelling performed by the Applicant was in general agreed by the zRMS with exception of Step 1-2 performed for JAU 6476-desthio and 1,2,4-triazole. For discussion on input parameters and obtained results, please refer to point 8.9 of this document.

Reference:	KCP 9.2.5/ 01
Report	Predicted environmental concentrations in surface water (PEC_{sw}) and sediment (PEC_{sed}) of prothioconazole and metabolites using STEPS 1-2 in FOCUS (v3.2), FOCUS SWASH 5.3 and SWAN v5.0 for critical GAP uses in the Central zone. Penne, C. (2021), Report no.: ADM-210615-02, sponsor no. 000108554
Guideline(s):	Generic Guidance for FOCUS Surface Water Scenarios, Version 1.4, May 2015 "FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC". Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2. 245 pp Working Document of the Central Zone in the Authorisation of Plant Protection Products - Section 8 Environmental Fate and Behaviour, Version 1.1, June 2018
Deviations:	None
GLP:	No (not applicable)
Acceptability:	Partially acceptable (for details, please refer to point 8.9 of this report)

In this report predicted environmental concentrations in surface water (PECsw) and sediment (PECsed) of the active substance prothioconazole and its metabolites JAU-desthio, JAU-S-methyl and 1,2,4-triazole are presented for critical GAP uses of ADM.03500.F. 2.B~~1.A~~ in cereals and oilseeds.

PECsw and PECswd were calculated for worst-case application patterns using the models STEPS 1-2 in FOCUS (v3.2), FOCUS SWASH 5.3 and SWAN v5.0.0. PEC_{SW} and PEC_{SED} for the active substance prothioconazole were calculated up to FOCUS Step 3. Spray drift was the main entry route at Step 3.

For the metabolite JAU-desthio PEC_{SW} and PEC_{SED} calculations were calculated up to FOCUS Step 4. Run-off was the main entry route, which can be reduced to an acceptable level with a vegetative filter strip of 10m at Step 4.

For the metabolites JAU-S-methyl and 1,2,4-triazole PEC_{SW} and PEC_{SED} calculations were calculated only up to FOCUS Step 2.

Modelling was sufficient to achieve PEC_{SW} and PEC_{SED} levels acceptable for the eco-toxicological risk assessment.