

REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: GPF515 / FGE03

Product name: Boscalid / Prothioconazole 350 / 200 WG

Chemical active substance:

Boscalid, 350 g/kg

Prothioconazole, 200 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Article 33 application for a new product registration)

Applicant: UPL Holdings Coöperatief U.A.

Submission date: November 2024, update March 2025

MS Finalisation date: June 2025 (initial Core Assessment)

August 2025 (final Core Assessment)

Version history

When	What
November 2024	V01 – Version from applicant for submission to z-RMS Poland in the frame of the PPP Authorization according to Article 33 of Regulation (EC) No 1107/2009.
March 2025	Updated dRR (additional PEC_{soil} , PEC_{gw} , $PEC_{sw/sed}$ calculation for use in sunflower at zRMS request).
May 2025	Additional PEC_{sw} calculations at Step 4 for boscalid for use in sunflower
June 2025	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency. Following the evaluation and before sending the document for commenting, all coloured highlighting was removed, from the parts updated by the Applicant, for better legibility.
August 2025	Final report (Core Assessment updated following the commenting period). No additional information or assessments after the commenting period.

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8 Fate and behaviour in the environment (KCP 9)

This document reviews the environmental fate studies and modelling for the first authorisation of the product Boscalid / Prothioconazole 350 / 200 WG (GPF515 / FGE03) in the central zone member states Czech Republic, Hungary and Poland according to Regulation (EC) No 1107/2009.

The product is a water dispersible granule (WG) formulated fungicide containing 350 g/kg of the active substance boscalid and 200 g/kg active substance prothioconazole. It is intended to be used as fungicide to control *Sclerotinia* in oilseed rape along with some minor uses including sunflower.

The review reports for boscalid (SANCO/3919/2007 – rev. 5, dated 21 January 2008) and prothioconazole (SANCO/3923 /07 – final, dated 10 December 2007) are considered to provide the relevant review information or a reference to where such information can be found.

The Annex I Inclusion Directive for boscalid and prothioconazole (2008/44/EC) provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on boscalid, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States must pay particular attention to:

- the long term risk to birds and soil organisms,
- the risk of accumulation in soil if the substance is used in perennial crops or in succeeding crops in crop rotation.

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on prothioconazole, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States must pay particular attention to:

- the protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied, where appropriate,

Conditions of use shall include adequate risk mitigation measures, where appropriate.

These concerns have been addressed within the current submission.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

Appendix 2 of this document contains the detailed information of the new studies.

Information on the detailed composition of the formulation can be found in the confidential dossier of this submission (Registration Report - Part C).

8.1 Critical GAP and overall conclusions

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/ 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 product/ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	CZ	Oilseed rape (winter and spring) (<i>Brassica napus</i>) BRSNN	F	Sclerotinia (<i>Sclerotinia sclerotiorum</i>) SCLESC	Spraying overall	BBCH 61-69	a) 1 b) 1	-	a) 0.7 b) 0.7	a) boscalid: 245 prothioconazole: 140 b) boscalid: 245 prothioconazole: 140	100-400	35	-	A
	HU	Oilseed rape (winter and spring) (<i>Brassica napus</i>) BRSNN	F	Sclerotinia (<i>Sclerotinia sclerotiorum</i>) SCLESC	Spraying overall	BBCH 61-69	a) 1 b) 1	-	a) 0.7 b) 0.7	a) boscalid: 245 prothioconazole: 140 b) boscalid: 245 prothioconazole: 140	100-400	35	-	A
2	CZ	Oilseed rape (winter and spring) (<i>Brassica napus</i>) BRSNN	F	Sclerotinia (<i>Sclerotinia sclerotiorum</i>) SCLESC	Spraying overall	BBCH 61-73	a) 2 b) 2	14	a) 0.7 b) 1.4	a) boscalid: 245 prothioconazole: 140 b) boscalid: 490 prothioconazole: 280	100-400	35	-	A
	HU	Oilseed rape (winter and spring) (<i>Brassica napus</i>) BRSNN	F	Sclerotinia (<i>Sclerotinia sclerotiorum</i>) SCLESC	Spraying overall	BBCH 61-73	a) 2 b) 2	14	a) 0.7 b) 1.4	a) boscalid: 245 prothioconazole: 140 b) boscalid: 490 prothioconazole: 280	100-400	35	-	A
	PL	Oilseed rape (winter) (<i>Brassica napus</i>) BRSNN	F	Sclerotinia (<i>Sclerotinia sclerotiorum</i>) SCLESC	Spraying overall	BBCH 61-73	a) 2 b) 2	14	a) 0.7 b) 1.4	a) boscalid: 245 prothioconazole: 140 b) boscalid: 490 prothioconazole: 280	100-400	35	-	A

Minor uses according to Article 51 (zonal uses)														
3	PL	Spring rape gold of pleasure, winter turnip rape, mustard, sunflower, poppy linseed, flax, hemp, borage	F	Scelrotinia (<i>Sclerotinia sclerotiorum</i>) SCLESC	Spraying overall	BBCH 61-73	a) 2 per use b) 2 per crop / season	14	a) 0.7 kg/ha b) 1.4 kg/ha	a) 245 g/ha boscalid 140 g/ha prothioconazole b) 490 g/ha boscalid 280 g/ha prothioconazole	100-400	35	-	A

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

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

Explanation for column 15 “Conclusion”

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

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14
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
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product/ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1 & 2	EU	Oilseed rape	F	<i>Sclerotinia, alternaria, Phoma</i>	Spraying	BBCH 30, BBCH 63 - 65	2	4-6 weeks	0.5	0.250	200-400	-	Critical use covering also minor uses n.3 of the GAP

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

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

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. *	Member state(s)	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
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1 & 2	North EU	Rape	F	<i>Sclerotinia, botrytis, alternaria, leptosphaeria</i>	Overall spraying	Start BBCH 53	1-2 #	Ref. to growth stage	0.7	0.175	200-400	56	# timing , no. of applications depends on national conditions Critical use covering also minor uses n.3 of the GAP

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

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

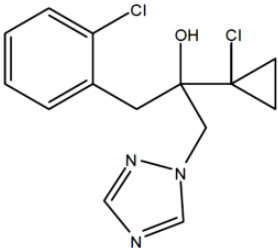
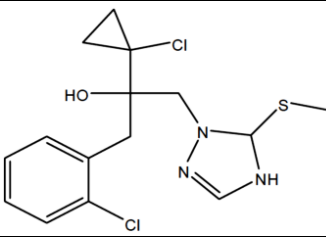
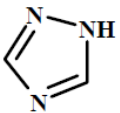
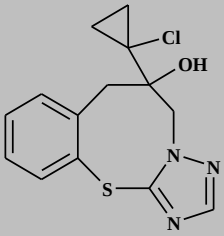
8.2 Metabolites considered in the assessment

Active substance boscalid

Boscalid metabolite M510F64 occurred at amounts > 5% in 2 sequential measurements in the higher-tier outdoor water/sediment study presented for the original approval of boscalid. Metabolite M510F64 reached maximum 9.4% TAR after 30 days in the water phase. However, as indicated in the Monograph (2002) the data available from the open literature indicated, that this metabolite is by orders of magnitude less toxic than the active substance and therefore of no ecotoxicological relevance. Thus, this compound is of no toxicological and ecotoxicological relevance. Following the approaches taken for the currently authorised products containing boscalid, no exposure assessment was presented for metabolite M510F64. No other metabolites of boscalid potentially relevant for exposure assessment have been observed.

Active substance prothioconazole

Table 8.2-1: Metabolites of active substance 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} since the GAP is not covered by EU assessment
Prothioconazole-S-methyl (M01) (JAU-S-methyl)	358.3 g/mol		Soil: 14.6% Water/sediment: 77% (anaerobic) water/sediment 12.7 % (aerobic)	PEC _{SOIL} , PEC _{GW} , PEC _{SW/SED} since the GAP is not covered by EU assessment
1,2,4-triazole (M13)	69.065 g/mol		Water: 37.2% Sediment: 4.6% Whole system: 41.8%	PEC _{SW/SED} since the GAP is not covered by EU assessment
JAU 6476-thiazocine (prothioconazole-thiazocine, M12)	307.8		Aqueous photolysis study: 14.1% on day 5	Considered not relevant in EFSA (2007)

zRMS comments:

According to EU Review Report SANCO/3919/2007-rev.5, no relevant metabolites of boscalid are formed in soil or aquatic systems.
Information regarding prothioconazole metabolites is in general in line with EU agreed endpoints reported in EFSA Scientific Report (2007) 106, with some minor corrections.
Information on metabolite JAU 6476-thiazocine has been added by the zRMS, as this metabolite was found at >10% in aqueous photolysis study. However, it was considered not relevant for the exposure assessment during EU review.

8.3 Rate of degradation in soil (KCP 9.1.1)

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

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 Boscalid and its metabolites

The aerobic rate of degradation in soil of boscalid was evaluated in the context of the Annex I inclusion process. No additional studies were performed.

The table below summarises the DT₅₀ values for boscalid, taken from the review report for boscalid (SANCO/3919/2007 – rev. 5, dated 21 January 2008).

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

Boscalid, laboratory studies, aerobic conditions										
Soil name	Soil type (USDA)	pH (CaCl ₂)	t.oC	MWHC %	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa	Chi ² (%)	Kinetic model	Evaluated on EU level / Reference
Bruch West	Sandy loam	7.4	20	40	108	360	108	n.r.	1 st order	Y / SANCO/3919/2007 – rev. 5
Li 35 b	Loamy sand	6.6	20	40	322	n.r.	322	n.r.	1 st order	
Lufa 2.2	Loamy sand	5.6	20	40	384	n.r.	384	n.r.	1 st order	
US soil	Loamy sand	7.0	20	40	376	n.r.	376	n.r.	1 st order	
Minto (Canada)	Loam	7.7	20	40	133	442	133	n.r.	1 st order	
Geometric mean / Median (n=5)							232 / 322			
pH-dependency:							No			

n.r. not reported

No major metabolites of boscalid were found in aerobic metabolism studies.

zRMS comments:

Soil degradation data for boscalid presented in table above are in line with the EU Review Report SANCO/3919/2007-rev.5.

8.3.1.2 Prothioconazole and its metabolites

The aerobic rate of degradation in soil of prothioconazole was evaluated in the context of the Annex I inclusion process. No additional studies were performed.

The tables below summarise the DT₅₀ values for prothioconazole and its metabolites, taken from the Prothioconazole DAR (2005) and EFSA Conclusions (EFSA Scientific Report (2007) 106, 1-98).

Table 8.3-2: Summary of aerobic degradation rates for prothioconazole - laboratory studies

Prothioconazole, laboratory studies, aerobic conditions										
Soil name	Soil type (x)	pH (CaCl ₂)	t.oC	MWHC %	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa	Chi ² (%)	Kinetic model	Evaluated on EU level / Reference
Laacher Hof	Sandy loam	6.6	20	34.42	0.08	5.3	-	-	FOMC	Y / DAR, 2005 and LoEP
Stanley	Silty clay loam	5.9	20	56.25	0.7	89.2	-	-	FOMC	
Höfchen	Silt	6.8	20	63.1	0.3	0.99	-	-	SFO	
Byromville	Loamy sand	6.1	20	49 ^a	1.27	4.22	-	-	SFO	
Geometric mean/Median (n=4):					0.37 / 0.5					
pH-dependency:					No					

LoEP = EFSA Scientific Report (2007) 106, 1-98

^a % of 1/3 bar moisture

For selection of endpoints for PEC calculation for prothioconazole please refer to section 8.4.1.

Table 8.3-3: Summary of aerobic degradation rates for prothioconazole-S-methyl (M01) - laboratory studies

Prothioconazole-S-methyl (M01), Laboratory studies, aerobic conditions										
Soil name	Soil type (x)	pH (CaCl ₂)	t.oC	MWHC %	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa	Chi ² (%)	Kinetic model	Evaluated on EU level / Reference
Höfchen	Loamy silt	6.5	20	63.1	5.9	19.6	-	-	1 st order SFO	Y / DAR, 2005 and LoEP
Laacher Hof	Loamy silt	6.7	20	36.4	27.2	90.2	-	-	1 st order SFO	
Laacher Hof	Sandy loam	6.3	20	34.4	8.2	27.2	-	-	1 st order SFO	
Stanley	Silty clay	5.2	20	43.8	46.0	153	-	-	1 st order SFO	
Geometric mean/Median (n=4):					15.7 / 17.7					
pH-dependency:					No					

LoEP = EFSA Scientific Report (2007) 106, 1-98

For selection of endpoint for PEC_{soil} calculation the worst-case unnormalized half-life (46 d at 20°C) is proposed for prothioconazole-S-methyl (M01). For PEC_{sw} and PEC_{GW} calculation the geometric mean of the unnormalized half-life values (15.7 d at 20°C) is proposed.

Table 8.3-4: Summary of aerobic degradation rates for prothioconazole-desthio (M04) - laboratory studies

Prothioconazole-desthio (M04), laboratory studies, aerobic conditions										
Soil name	Soil type (x)	pH (CaCl ₂)	t.oC	MWHC %	DT50 (d)	DT90 (d)	DT ₅₀ (d) 20°C pF2/10kPa	Chi ² (%)	Kinetic model	Evaluated on EU level / Reference
Höfchen	Loamy silt	6.5	20	63.1	34.0	113.0	-	-	1 st order SFO	Y / DAR, 2005 and LoEP
Laacher Hof	Loamy silt	6.7	20	36.4	29.6	59.2 ~~98.3~~	-	-	1 st order SFO	
Laacher Hof	Sandy loam	6.3	20	34.4	7.0	23.2	-	-	1 st order SFO	
Stanley	Silty clay	5.2	20	43.8	18.6	61.9	-	-	1 st order SFO	
Geometric mean/Median (n=4):					19.0 / 24.1					
pH-dependency:					No					

LoEP = EFSA Scientific Report (2007) 106, 1-98

For selection of endpoints for PEC calculation for prothioconazole-desthio (M04) please refer to section 8.4.1.

zRMS comments:

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

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)

The anaerobic rate of degradation in soil of prothioconazole and boscalid was evaluated in the context of the Annex I inclusion process. No additional studies were performed.

In anaerobic soil conditions boscalid was found to be very persistent, resulting DT_{50} values at 20°C were 261 days and 345 days, respectively. One metabolite (M510F47) was detected with the pyridine-labelled test item which reached a maximum of 6.7% (120 days); however, significant amounts > 5% were formed only after extended periods of anaerobic conditions (≥ 60 days), which are not expected to occur under conditions of normal agricultural use.

Soil degradation under anaerobic conditions was not investigated for prothioconazole. However, an anaerobic aquatic metabolism study was submitted. Results indicated a relatively rapid breakdown of parent to prothioconazole-S-methyl (M01), which seemed to accumulate. However, it was considered that, under the representative uses proposed, prothioconazole will not be exposed to anaerobic conditions and, therefore, it is unlikely there would be significant formation of prothioconazole-S-methyl (M01) under field conditions.

The same point is valid for the current application and uses of FGE03 where anaerobic conditions are not expected to occur considering the timing of application. This combined with the relatively quick degradation of prothioconazole and metabolites in the field means anaerobic conditions are not expected to be relevant.

zRMS comments:

Anaerobic soil degradation data for boscalid are in line with the EU Review Report SANCO/3919/2007-rev.5.

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 FGE03 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)

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

The field dissipation of boscalid and prothioconazole was evaluated in the context of the Annex I inclusion process. No additional studies were performed.

8.4.1.1 Boscalid and its metabolites

Field soil dissipation studies have been performed to investigate the degradation and dissipation of boscalid in soil. In total, acceptable trials were conducted at 5 sites: 3 trials in Germany and 2 in Spain. In the two trials conducted in Germany (Stetten and Schifferstadt), three different application rates were used.

Under field conditions slow degradation of boscalid was observed. No major metabolites of boscalid were found in field dissipation studies. Boscalid did not show a tendency to move into deeper layers of soil. It was mostly detected in the top 10 cm soil layer. In all trials a DT₉₀ could not be reached within one year after application.

For selection of endpoint for PEC_{soil} calculation the worst-case field half-life (212 d at 20°C) was standardised to 15°C with Q₁₀ of 2.2 and resulted in DT₅₀ of 314.5 d (at 15°C). Afterwards, for approval of boscalid containing products, a DT₅₀ of 340.5 d was proposed to be used for PEC_{soil} calculation (worst-case field half-life of 212 days (20°C) recalculated to 15°C using a Q₁₀ value of 2.58).

Furthermore, normalisation of field data for boscalid was performed with Q₁₀ of 2.2 and an arithmetic mean DT₅₀ value of 139 was considered a reasonable conservative estimate for prediction of the degradation of boscalid in the field. Thus, for PEC_{GW} and PEC_{SW} calculation a DT₅₀ of 139 days was used.

Triggering endpoints

Table 8.4-1: Summary of aerobic degradation rates for boscalid - field studies: Triggering endpoints

Boscalid, field studies – Triggering endpoints									
Soil type	Location	pH (CaCl ₂)	Depth (cm)	DissT50 (d) actual	DT ₉₀ (d) actual	Kinetic parameters	St. (x ²)	Method of calculation	Evaluated on EU level / Reference
Silty loam	Stetten (DE)	7.5	n.r.	90 *	n.c.	- **	0.952	- **	Y / SANCO/3919/2007 – rev. 5
Silty sand	Schifferstadt (DE)	5.4	n.r.	208 *	n.c.	- **	0.956	- **	
Sandy loam	Manzanilla (ES)	7.4	n.r.	27	n.c.	- **	0.88	- **	
Sandy loam	Alcala del Rio (ES)	7.7	n.r.	78	n.c.	- **	0.81	- **	
Loamy sand	Grossharrie (DE)	6.1	n.r.	144	n.c.	- **	0.87	- **	
Maximum (n=5)				208	-				

n.r. not reported n.c. not calculated

* Application rate was 300 g/ha

** A fit according to simple first order was not possible. The DT₅₀ values were determined graphically.

Modelling endpoints

Table 8.4-2: Summary of aerobic degradation rates for boscalid - field studies: Modelling endpoints

Boscalid, field studies – Modelling endpoints						
Soil type	Location	pH (CaCl ₂)	Depth (cm)	DT ₅₀ (d) 20°C, pF2 *	Fit, kinetic	Evaluated on EU level / Reference
Silty loam	Stetten (DE)	7.5	n.r.	106 #	n.r.	Y / SANCO/3919/2007 – rev. 5
Silty sand	Schifferstadt (DE)	5.4	n.r.	212 #	n.r.	
Sandy loam	Manzanilla (ES)	7.4	n.r.	- ##	n.r.	
Sandy loam	Alcala del Rio (ES)	7.7	n.r.	- ##	n.r.	
Loamy sand	Grossharrie (DE)	6.1	n.r.	98	n.r.	
Arithmetic mean (n=3)				139	-	
pH-dependency				No		

n.r. not reported

* For correction of the temperature a Q₁₀ of 2.2 was used

3 application rates were considered as replicates and the results of the 3 replicates are averaged

Because of the high standard deviations of the degradation rate a reasonable calculation of the half-life is not possible

zRMS comments:

Field degradation data for boscalid are in line with the EU Review Report SANCO/3919/2007-rev.5.

8.4.1.2 Prothioconazole and its metabolites

Field dissipation of prothioconazole has been investigated in eight studies at different sites in northern Europe (Germany, Great Britain and France) and southern Europe (France, Italy). Four of the sites were not cropped and the remaining four were sown with spring barley just prior to the application of the test substance directly to the soil surface. Analyses from each site were conducted on samples from depths up to 50 cm. Soil residues were restricted to the top 10 cm soil horizon. Neither prothioconazole nor the two metabolites M01 and M04 were detected below this soil layer at any sampling interval in any study.

For selection of endpoints for PEC_{soil} calculation, the worst-case field half-life of 2.8 d is proposed for prothioconazole. For PEC_{SW} and PEC_{GW} calculation, the geometric mean of the normalised half-life values (1.2 d) is proposed.

For metabolite prothioconazole-desthio (M04), for PEC_{soil} calculation, the worst-case field half-life of 72.3 d is proposed. For PEC_{SW} and PEC_{GW} calculation, the geometric mean of the normalised half-life values (22.7 d) is proposed.

Triggering endpoints

Table 8.4-3: Summary of aerobic degradation rates for prothioconazole - field studies: Triggering endpoints

Prothioconazole, field studies – Triggering endpoints									
Soil type (USDA)	Location	pH (CaCl ₂)	Depth (cm)	DissT50 (d) actual	DT ₉₀ (d) actual	Kinetic parameters	St. (R ²)	Method of calculation	Evaluated on EU level / Reference
Silt loam	Burscheid (DE)	6.25	0-10	1.9	6.4	-	1.00	1 st order	Y / DAR, 2005 and LoEP
Sandy clay loam	Thurston (GB)	7.56	0-10	1.6	5.5	-	1.00	1 st order	
Silt	Fresne (North FR)	6.42	0-10	1.3	4.4	-	1.00	1 st order	
Sandy clay loam	Thurston (GB)	7.56	0-10	2.8	9.3	-	0.99	1 st order	
Silt	Fresne (North FR)	6.42	0-10	1.4	4.5	-	1.00	1 st order	
Silt loam	Etienne (South FR)	7.61	0-10	1.7	5.6	-	0.99	1 st order	
Sandy loam	Pradelle (IT)	7.56	0-10	1.6	5.4	-	0.99	1 st order	
Sandy loam	Monheim (DE)	6.32	0-10	1.5	5.1	-	1.00	1 st order	
Maximum (n=8)				2.8	9.3	-			

LoEP = EFSA Scientific Report (2007) 106, 1-98

Table 8.4-4: Summary of aerobic degradation rates for prothioconazole-desthio (M04) - field studies: Triggering endpoints

Prothioconazole-desthio (M04), field studies – Triggering endpoints										
Soil type (USDA)	Location	pH (CaCl ₂)	Depth (cm)	DissT50 (d) actual	DT ₉₀ (d) actual	f.f.	Kinetic parameters	St. (R ²)	Method of calc.	Evaluated on EU level / Reference
Silt loam	Burscheid (DE)	6.25	0-10	16.3 ^a	54.1 ^a	-	-	0.98	1 st order	Y / DAR, 2005 and LoEP
Sandy clay loam	Thurston (GB)	7.56	0-10	54.7	182	-	-	0.96	1 st order	
Silt	Fresne (North FR)	6.42	0-10	47.6	158	-	-	0.94	1 st order	
Sandy clay loam	Thurston (GB)	7.56	0-10	50.2	167	-	-	0.91	1 st order	
Silt	Fresne (North FR)	6.42	0-10	36.8	122	-	-	0.93	1 st order	
Silt loam	Etienne (South FR)	7.61	0-10	72.3	240	-	-	0.91	1 st order	
Sandy loam	Pradelle (IT)	7.56	0-10	30.5	101	-	-	0.98	1 st order	
Sandy loam	Monheim (DE)	6.32	0-10	27.9 ^a	92.6 ^a	-	-	0.98	1 st order	
Maximum (n=8)				72.3	240	-	-			

LoEP = EFSA Scientific Report (2007) 106, 1-98

Modelling endpoints

Table 8.4-5: Summary of aerobic degradation rates for prothioconazole - field studies: Modelling endpoints

Prothioconazole, field studies – Modelling endpoints						
Soil type (USDA)	Location	pH (CaCl ₂)	Depth (cm)	DT ₅₀ (d) 20°C, pF2	Fit, kinetic	Evaluated on EU level / Reference
Silt loam	Burscheid (DE)	6.25	0-10	1.2	1 st order	Y / DAR, 2005 and LoEP
Sandy clay loam	Thurston (GB)	7.56	0-10	0.8	1 st order	
Silt	Fresne (North FR)	6.42	0-10	1.6	1 st order	
Sandy clay loam	Thurston (GB)	7.56	0-10	1.4	1 st order	
Silt	Fresne (North FR)	6.42	0-10	1.6	1 st order	
Silt loam	Etienne (South FR)	7.61	0-10	1.1	1 st order	
Sandy loam	Pradelle (IT)	7.56	0-10	1.5	1 st order	
Sandy loam	Monheim (DE)	6.32	0-10	0.6	1 st order	
Geometric mean (n=8)				1.2	-	
pH-dependency:				No	-	

LoEP = EFSA Scientific Report (2007) 106, 1-98

Table 8.4-6: Summary of aerobic degradation rates for prothioconazole-desthio (M04) - field studies: Modelling endpoints

Prothioconazole-desthio (M04), field studies – Modelling endpoints							
Soil type (USDA)	Location	pH (CaCl ₂)	Depth (cm)	DT ₅₀ (d) 20°C, pF2	f.f.	Fit, Kinetic	Evaluated on EU level y/n/ Reference
Silt loam	Burscheid (DE)	6.25	0-10	10.3	-	1 st order	Y / DAR, 2005 and LoEP
Sandy clay loam	Thurston (GB)	7.56	0-10	27.0	-	1 st order	
Silt	Fresne (North FR)	6.42	0-10	27.5	-	1 st order	
Sandy clay loam	Thurston (GB)	7.56	0-10	23.4	-	1 st order	
Silt	Fresne (North FR)	6.42	0-10	20.1	-	1 st order	
Silt loam	Etienne (South FR)	7.61	0-10	61.9	-	1 st order	
Sandy loam	Pradelle (IT)	7.56	0-10	20.7	-	1 st order	
Sandy loam	Monheim (DE)	6.32	0-10	15.2	-	1 st order	
Geometric mean (n=8)				22.7	-	-	
pH-dependency				No	-	-	

LoEP = EFSA Scientific Report (2007) 106, 1-98

zRMS comments:

The triggering endpoints for prothioconazole and metabolite JAU 5479-desthio provided in Tables 8.4-3 and 8.4-6 above are in line with data reported in EFSA Scientific Report (2007) 106 and prothioconazole DAR of 2005. For relevant endpoints considered in exposure assessment, please refer to points 8.7 (soil), 8.8 (groundwater) and 8.9 (surface water) of this document.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

The accumulation in soil of boscalid and prothioconazole was evaluated in the context of the Annex I inclusion process. No additional studies were performed.

The accumulation behaviour of boscalid under field conditions was investigated in two trials conducted at two sites in Germany over a 5-year-period (1998 to 2003) after application onto vines (3 × 700 g a.s./ha) and over a 7-year-period (1998-2004, interim results) after 3-year crop rotation (vegetables (2100 g a.s./ha), vegetables (1700 g a.s./ha) and cereals (no application)). The trials indicated a potential for accumulation in soil with plateau levels in spring before the first yearly application event 95% (application onto grapes) and 150% (application onto vegetables) of the total yearly application rate.

This was considered also for the assessment of PEC_{soil, accumulation}, please refer to **Point 8.7**.

For prothioconazole, no data on soil accumulation was submitted for the Annex I inclusion and is not considered required. The field soil dissipation DT₉₀ values for prothioconazole and prothioconazole-desthio (M04) are below the trigger of 1 year (see **Table 8.4-3** and **Table 8.4-4**). For prothioconazole-S-methyl (M01), no field studies are triggered (DT_{50 lab} < 60 days, see **Table 8.3-3**).

zRMS comments:

Information regarding the accumulation study is in line with the EU Review Report for boscalid, SANCO/3919/2007-rev.5.
No EU agreed data from soil accumulation studies with prothioconazole are available in EFSA Scientific Report (2007) 106.
Potential for soil accumulation with boscalid and prothioconazole is thus addressed in calculation of soil exposure in point 8.7 of this report.

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.

The mobility in soil of boscalid and prothioconazole was evaluated in the context of the Annex I inclusion process. No additional studies were performed.

8.5.1 Boscalid and its metabolites

Boscalid can be classified as slightly mobile in soil. The adsorption to soil was not pH dependent.

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

Boscalid							
Soil name	Soil type	OC (%)	pH (-)	K _f (mL/g)	K _{foc} (mL/g)	1/n (-)	Evaluated on EU level / Reference
LUFA 2.2	Sand / Loamy sand	2.5	5.8	27.8	1110	0.875	Y / SANCO/3919/2007 – rev. 5
Bruch West	Sandy loam	1.5	7.5	7.6	507	0.870	
Li 35 b	Loamy sand	1.1	6.5	6.5	594	0.839	
USA 538-30-5	Loamy sand	0.4	5.8	3.9	987	0.887	
USA 538-31-2	Loam	0.5	5.2	3.3	655	0.860	
CAN-95024	Sandy clay loam	3.4	7.5	26.4	776	0.851	
Arithmetic mean (n=6)					771.5	0.864	N / Geomean according to EFSA Journal 2014;12(5):3662, 38 pp.
Geometric mean (n=6)					743	-	
pH-dependency					No		

zRMS comments:

Soil mobility data for boscalid presented in Table 8.5-1 are in line with the EU Review Report SANCO/3919/2007-rev.5.

In addition to the arithmetic mean K_{foc}, also geometric mean value was calculated on the basis of the EU agreed data. The zRMS confirms that the geometric mean K_{foc} reported in table above is correct.

8.5.2 Prothioconazole and its metabolites

Adsorption coefficient for prothioconazole could not be determined via standard batch equilibrium studies due to the instability of the compound in these systems. Therefore, the distribution of prothioconazole in an aged column leaching study was used to estimate adsorption (see section 8.5.3).

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

Table 8.5-2: Summary of soil adsorption/desorption for prothioconazole-S-methyl (M01)

Prothioconazole-S-methyl (M01)							
Soil name	Soil type	OC (%)	pH (H ₂ O)	K _d (mL/g)	K _{foc} (mL/g)	1/n (-)	Evaluated on EU level / Reference
Laacher Hof	Sandy loam	2.02	7.2	56.0	2772.4	0.87	Y / DAR, 2005 and LoEP
Höfchen	Silt	2.14	7.1	64.1	2995.0	0.88	
Stanley	Silty clay loam	1.66	5.9	41.2	2484.0	0.91	
Byromville	Loamy sand	0.79	6.8	15.6	1973.6	0.85	
Arithmetic mean (n=4)					2556.3	0.88	N / Geomean according to EFSA Journal 2014;12(5):3662, 38 pp.
Geometric mean (n=4)					2525.9	-	
pH-dependency					No		

LoEP = EFSA Scientific Report (2007) 106, 1-98

Table 8.5-3: Summary of soil adsorption/desorption for prothioconazole-desthio (M04)

Prothioconazole-desthio (M04)							
Soil Name	Soil Type	OC (%)	pH (H ₂ O)	K _d (mL/g)	K _{foc} (mL/g)	1/n (-)	Evaluated on EU level / Reference
Laacher Hof	Sandy loam	2.02	7.2	12.46	616.8	0.79	Y / DAR, 2005 and LoEP
Höfchen	Silt	2.14	7.1	13.38	625.3	0.83	
Stanley	Silty clay loam	1.66	5.9	8.90	536.4	0.83	
Byromville	Loamy sand	0.79	6.8	4.13	523.0	0.80	
Arithmetic mean (n=4)					575.4	0.81	
Geometric mean (n=4)					573.53	-	N / Geomean according to EFSA Journal 2014;12(5):3662, 38 pp.
pH-dependency					No		

LoEP = EFSA Scientific Report (2007) 106, 1-98

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

1,2,4-triazole							
Soil Name	Soil Type	OC (%)	pH (H ₂ O)	K _f (mL/g)	K _{foc} (mL/g)	1/n (-)	Evaluated on EU level / Reference
Alpaugh, USA	Sandy loam	0.70	8.8	0.833	120	0.897	Y / EFSA Scientific Report (2008) 176, 1-109 Conclusion on the peer review of tebuconazole
Hollister, USA	Clay loam	1.74	6.9	0.748	43	0.827	
Lawrenceville, USA	Silty clay loam	0.70	7.0	0.722	104	0.922	
Pachappa, USA	Sandy loam	0.81	6.9	0.720	89	1.016	
Arithmetic mean (n=4)					89	0.916	
Geometric mean (n=4)					83	-	N / Geomean according to EFSA Journal 2014;12(5):3662, 38 pp.
pH-dependency					No		

zRMS comments:

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

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

8.5.3 Column leaching (KCP 9.1.2.1)

Refer to Point 8.5 above.

Column leaching studies of boscalid and prothioconazole were evaluated in the context of the Annex I inclusion process. No additional studies were performed.

Active substance boscalid

Reliable adsorption coefficient values were obtained for the active substance in the adsorption/desorption study (see Section 8.5.1 above). Nevertheless, column leaching in one soil without ageing was performed along with the aged column leaching study. The results of the aged and non-aged soil column leaching experiments showed that boscalid is not mobile in soil. There is no risk of displacement of boscalid into deeper soil layers.

Active substance prothioconazole

Adsorption coefficient for prothioconazole could not be determined via standard batch equilibrium studies due to the instability of the compound in these systems. Therefore, the distribution of prothioconazole in an aged column leaching study was used to estimate K_d and K_{OC} values. Phenyl- ^{14}C radiolabelled prothioconazole was applied on a loamy sand soil and incubated at 20°C 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- ^{14}C radiolabelled prothioconazole was further investigated in a non-aged soil column leaching study in 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).

zRMS comments:

Information on column leaching studies for boscalid is in line with conclusions derived at the EU level.

Results of column leaching and aged residues leaching of prothioconazole are reported in EFSA Scientific Report (2007) 106, however are not necessary for purposes of evaluation of FGE03, as based on results of the groundwater modelling no unacceptable leaching of prothioconazole or its metabolites is expected.

It is noted that at the EU level no respective soil adsorption-desorption studies were performed with prothioconazole and the K_{oc} 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 K_{oc} 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.

8.5.4 Lysimeter studies (KCP 9.1.2.2)

For boscalid and prothioconazole, no lysimeter data have been submitted for Annex I inclusion. The results of the PEC_{GW} simulations as given under point 8.8 indicate a low leaching risk of boscalid and of prothioconazole and its metabolites. Therefore, lysimeter studies are not required.

zRMS comments:

The lysimeter studies were not required during the EU review of both active substances. The leaching potential of boscalid and prothioconazole and their metabolites following application of FGE03 is addressed in groundwater modelling presented in point 8.8 of this document.

8.5.5 Field leaching studies (KCP 9.1.2.3)

For boscalid and prothioconazole, no field leaching studies have been submitted for Annex I inclusion. The results of the PEC_{GW} simulations as given under point 8.8 indicate a low leaching risk of boscalid and of prothioconazole and its metabolites. Therefore, lysimeter studies are not required.

zRMS comments:

The field leaching studies were not required during the EU review of both active substances. The leaching potential of boscalid and prothioconazole and their metabolites following application of FGE03 is addressed in groundwater modelling presented in point 8.8 of this document.

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

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

8.6.1 Boscalid and its metabolites

The distribution and degradation of boscalid was studied in three aquatic systems: two systems in an indoor/dark study and one system in an outdoor study.

In laboratory incubations in two dark aerobic natural sediment water systems, the dissipation of boscalid in the water phase of both systems was mainly based on sorption process. The highest amount of boscalid in sediment was observed in test system B with 79.9% TAR. The amount of bound residues in the sediment was low; a maximum value of 12.9% was observed in system A at day 100 after treatment. The decay in the water phase was determined graphically (non SFO) with DT_{50} values of 9 days and 3 days for systems A and B, respectively. Appropriate DT_{50} values that describe the degradation processes in water and sediment could not be deduced from the water/sediment study conducted in the dark.

Under natural conditions, boscalid will be degraded to CO_2 or will be bound to the sediment. The maximum concentration in sediment was observed at day 103 with 28.2% TAR. The kinetic evaluation of the observations resulted in a single first-order DT_{50} describing degradation in the water phase of 32 days, as provided in the Addendum to the DAR. Compared to the standard laboratory studies, the degradation under natural conditions is enhanced. This is accompanied by the appearance of an additional metabolite (M510 F64) that was not detected in the other studies. However, this metabolite was of transient nature, and is of no toxicological or ecotoxicological relevance.

For PEC_{SW} calculations, a DT_{50} in the water phase of 32 days is proposed in the DAR Addendum (2007). However, in more recent registration reports for boscalid containing products, a DT_{50} value of 90 days is proposed to be used as a whole system half-life ($n = 1$, higher tier outdoor study, recalculation by Ctgb (authorisation 14735N)). This is to be in line with the current guidance from FOCUS surface water, which states that system values are needed (unless it is proven that the DT_{50} water and sediment represent

real degradation values instead of dissipation values). Although the background calculation leading to this DT value are not available to the applicant, as a conservative approach, and in line with current approaches and registrations, the same value of 90 day is used here.

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

Boscalid distribution (max. water/sediment 79.9% after 100 days)										
Water/sediment system	pH water/sed.	DegT50 whole syst. (d)	DegT90 whole syst. (d)	Kinetic, Fit	DissT50 water (d)	DissT90 water (d)	Kinetic, Fit	DissT50 sed. (d)	Kinetic, Fit	Evaluated on EU level / Reference
Kellmetschweiher (System A)	8.5 / 6.8	-- ^a	-- ^a	--	9	133	Graphic	--	--	Y / SANCO/3919/2007 – rev. 5
Kellmetschweiher (System B)	8.1 / 7.5	-- ^a	-- ^a	--	3	43	Graphic	--	--	
Kellmetschweiher (Outdoor)	8.8 / -	110 ^{b, c}	370 ^b	Graphic	32	n.c.	SFO	n.c.	--	
Geometric mean (n=x)		--	--		n.c.	n.c.		--		

n.c. not calculated

a Values by far exceeding the duration of the experiment, for both systems and both labelling positions

b 46% of a.s. after 120 days in water and sediment

c 90 d according to FOCUS Kinetic guidance (Ctgb recalculation, registration authorisation 14735N)

Table 8.6-2: Summary of observed metabolites

Metabolite	Water/sediment system	Evaluated on EU level / Reference
M510 F64 Water/sediment system	Max. in water 9.4% after 30 d (outdoor conditions, [diphenyl-U- ¹⁴ C]-boscalid) However, this metabolite was of transient nature. Additionally, this compound is of no toxicological or ecotoxicological relevance.	Y / SANCO/3919/2007 – rev. 5

zRMS comments:

Information on degradation of boscalid in water/sediment systems is in line with the EU Review Report SANCO/3919/2007-rev.5 and Vol. 3 of the Monograph (2002). It is noted that according to SANCO/3919/2007 – rev. 5 the accumulation of boscalid in sediment reach plateau after 8 yr: 217 % (calculation).

8.6.2 Prothioconazole and its metabolites

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

Prothioconazole dissipated rapidly in both systems and the DT₅₀ values for the water phase were calculated using first order kinetics (DT₅₀ water = 0.8 – 1.0 day). Bi-phasic kinetics (“Hockey Stick”) were applied to evaluate the entire water/sediment system (DT₅₀ whole system = 1.6 – 2.8 days).

A water/sediment study under anaerobic conditions is available. The amounts of ¹⁴CO₂ and organic volatile radioactive substances were very low (< 0.1% AR throughout the study). The DT₅₀ values of prothioconazole were calculated to be 2.5 days for the water layer and 72 days for the entire system and

followed first-order reaction kinetics. Prothioconazole-S-methyl (M01) was identified as a major metabolite in the sediment (maximum 77.0% AR by day 240).

In the Final Addendum to the DAR (2008), the study of Schad (2001) was re-evaluated and new worst case whole system DT₅₀ of 24.1 d was derived. This endpoint is considered suitable to be used for PEC_{SW/SED} risk assessment.

Table 8.6-3: Summary of degradation in water/sediment of prothioconazole

Prothioconazole distribution (max. water/sediment 23.4% after 1 day)										
Water/sediment system	pH water/sed.	DegT50 whole syst. (d)	DegT90 whole syst. (d)	Kinetic, Fit	DissT50 water (d)	DissT90 water (d)	Kinetic, Fit	DissT50 sed. (d)	Kinetic, Fit	Evaluated on EU level / Reference
Hönniger Weiher	7.84 / 6.6	2.8	76.4	HS	0.8	2.7	1 st order	-	-	Y / DAR, 2005 and LoEP
Angler Weiher	7.45 / 8.5	1.6	23.6	HS	1.0	3.4	1 st order	-	-	
Geometric mean (n=2)		2.1	-		-	-		-		FOCUS (2006)

LoEP = EFSA Scientific Report (2007) 106, 1-98

Table 8.6-4: Summary of observed metabolites

Metabolite	Water/sediment system	Evaluated on EU level / Reference
Prothioconazole-desthio (M04)	In water: 32.3% after 7 d In sediment: 26.9% after 14 d In total system: 54.6% after 7 d (32.3% water + 22.3% sediment) DT ₅₀ in water/sediment system: 49.9 d (total system value, n=2)	Y / DAR, 2005 and LoEP
Prothioconazole-S-methyl (M01)	In sediment: 77% after 240 d (anaerobe) DT ₅₀ in water/sediment system: 40.2 (total system value, n=2)	
1,2,4-triazole (M13)	In water: 37.2% after 121 d In sediment: 4.6% after 121 d In total system: 41.8% after 121 d	

LoEP = EFSA Scientific Report (2007) 106, 1-98

zRMS comments:

Degradation data for prothioconazole and its 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.

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

8.7.1 Justification for new endpoints

The following deviation from the EU agreed endpoints is considered.

Boscalid

Endpoint	EU agreed endpoint (SANCO/3919/2007 – rev. 5)	Endpoint used in the present risk assessment	Remark
DT _{50,field} (d)	314.5 (Maximum at 15°C, field study, Q ₁₀ = 2.2)	340.5 (Maximum at 15°C, field study, Q ₁₀ = 2.58)	Worst-case field half-life of 212 days (20°C) recalculated to 15°C using a Q ₁₀ value of 2.58.

Prothioconazole

Not applicable as no new endpoints differing from EU agreed endpoints used.

zRMS comments:

It is noted that DT₅₀ value of 340.5 days considered in soil exposure calculation for boscalid was longer than maximum value of 208 days reported in EU Review Report SANCO/3919/2007-rev.5 or 314.5 days calculated at 15°C. This value is the maximum EU agreed field DT₅₀ of 212 days standardised to 15°C with consideration of Q₁₀ of 2.58. As this value is longer than all EU agreed, it is accepted for PEC_{soil} calculations as representing worst case.

8.7.2 Active substances and relevant metabolites

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

Use No.	1	2	3
FOCUS Crop	Oilseed rape, winter and Oilseed rape, summer		Sunflower
Application rate (g a.s./ha)	Boscalid: 245 g a.s./ha Prothioconazole: 140 g a.s./ha (0.7 kg product/ha)		
Number of applications/interval	1 / -	2 / 14	2 / 14
Application timing	BBCH 61-69	BBCH 61-73	BBCH 61-73
Crop interception (%)	80%		75
Application rate considering interception (g a.s./ha)	Boscalid: 49 g a.s./ha Prothioconazole: 28 g a.s./ha		Boscalid: 61.25 g a.s./ha Prothioconazole: 35 g a.s./ha
Depth of soil layer (relevant for plateau concentration) (cm)	20 cm (tillage)		

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

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT ₅₀ (days)	Value in accordance to EU endpoint / Reference
Boscalid	Not required	-	340.5 SFO, maximum at 15°C, field study, Q ₁₀ = 2.58	N / Worst-case field half-life of 212 days (20°C) recalculated to 15°C using a Q ₁₀ value of 2.58
Prothioconazole	344.3	-	2.8 SFO, maximum field, non-normalised	Y / EFSA LoEP
Prothioconazole-S-methyl (M01) (JAU-S-methyl)	358.3	14.6	46 SFO, maximum lab, 20°C, not normalised for pF2	
Prothioconazole-desthio (M04) (JAU-desthio)	312.2	57.1	72.3 SFO kinetics, maximum field, non-normalised	

LoEP = EFSA Scientific Report (2007) 106, 1-98

zRMS comments:

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

Input parameters presented in Table 8.7-2 are in line with EU agreed parameters for prothioconazole reported in EFSA Scientific Report (2007) 106 and the value of 340.5 days considered in soil exposure calculation for boscalid is longer than EU agreed, thus it is accepted for PEC_{soil} calculations as representing worst case.

8.7.2.1 Boscalid

The PEC_{soil} of boscalid has been assessed with the FOCUS guidelines (FOCUS, 1997¹), FOCUS groundwater interception values (EFSA, 2014²) and the recalculated EU agreed DT₅₀ value from field dissipation studies. The PEC_{soil} were calculated with the model ESCAPE v.2.0 (26 November 2019). The reports from this modelling are included in Appendix 3.

The PEC_{soil,accumulation} was also assessed as the soil dissipation DT₉₀ values for boscalid were above 1 year. As a standard approach according to FOCUS the overall accumulation PEC in soil PEC_{soil,accu} after application over many years is determined following **Equation 1** and **Equation 2**.

Equation 1: Calculation of PEC_{soil,plateau}

$$PEC_{soil,plateau} = \frac{PEC_{soil,max,d}}{1 - e^{-kt}} \cdot e^{-kt}$$

with:	PEC _{soil,plateau}	Plateau concentration at steady state	[mg kg ⁻¹]
	PEC _{soil,max,d}	Maximum concentration following last application	[µg kg ⁻¹]
	k	Degradation rate in soil (ln(2)/DT ₅₀)	[d ⁻¹]
	t	Time interval between growing seasons (365 d)	[d]

Equation 2: Calculation of PEC_{soil,accu}

$$PEC_{soil,accu} = PEC_{soil,plateau} + PEC_{soil,max}$$

with:	PEC _{soil,accu}	Maximum concentration in soil for the accumulation risk assessment	[µg kg ⁻¹]
	PEC _{soil,plateau}	Plateau concentration at steady state	[µg kg ⁻¹]
	PEC _{soil,max}	Maximum concentration	[µg kg ⁻¹]

Additionally, PEC_{soil,plateau} was estimated by using a percentage rate deducted from two accumulation field studies (Addendum 1 to DAR, 2002), and using the parameters presented in **Table 8.7-3**.

¹ FOCUS (1997) Soil persistence models and EU Registration - The Final Report of the Soil Modelling Workgroup of FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use) – 29 February 1997.

² EFSA 2014 European Food Safety Authority. Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662, 38 pp., doi:10.2903/j.efsa.2014.3662

Table 8.7-3: Input parameters related to application for PEC_{soil},plateau calculations

Use No.	1, 2 & 3
Total annual application rate (g a.s./ha)	Boscalid: 245 g/ha or 490 g/ha
Minimum accumulation factor in soil as derived from a field accumulation study	95%
Depth of the considered soil cultivation layer	20 cm
Density of the soil layer	1.5 g/cm ³

Table 8.7-4: PEC_{soil} for boscalid on oilseed rape (winter and spring) (post-emergence, 2 × 245 g a.s./ha)

PEC _{soil} (mg/kg)		Oilseed rape (winter and spring)			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.065	-	0.129	-
Short term	24h	0.065	0.065	0.129	0.129
	2d	0.065	0.065	0.128	0.129
	4d	0.065	0.065	0.127	0.128
Long term	7d	0.064	0.065	0.125	0.128
	14d	0.064	0.064	0.123	0.127
	21d	0.063	0.064	0.122	0.126
	28d	0.062	0.064	0.118	0.125
	50d	0.059	0.062	0.116	0.124
	100d	0.053	0.059	0.105	0.117
Plateau concentration (20 cm)					
FOCUS Approach:		0.015	-	0.029	-
Additional approach:		0.078		0.155	
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})					
FOCUS Approach:		0.080	-	0.158	-
Additional approach:		0.143		0.287	

Table 8.7-5: PEC_{soil} for boscalid on sunflower (post-emergence, 2 × 245 g a.s./ha)

PEC _{soil} (mg/kg)		Sunflower			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.082	-	0.161	-
Short term	24h	0.082	0.082	0.161	0.161
	2d	0.081	0.082	0.160	0.161
	4d	0.081	0.081	0.160	0.160
Long term	7d	0.081	0.081	0.159	0.160
	14d	0.079	0.081	0.157	0.159
	21d	0.078	0.00	0.154	0.158
	28d	0.077	0.079	0.152	0.157
	50d	0.074	0.078	0.146	0.153
	100d	0.067	0.074	0.131	0.146
Plateau concentration (20 cm)					
FOCUS Approach:		0.019	-	0.037	-
Additional approach:		0.078		0.155	
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})					
FOCUS Approach:		0.101	-	0.198	-
Additional approach:		0.160		0.316	

zRMS comments:

The soil exposure for boscalid has been independently validated by the zRMS using FOCUS methods and DT₅₀ of 340.5 days as representing worst case.

The calculated PEC_{SOIL} values for boscalid were similar with these obtained by the Applicant and therefore results reported in tables above may be used for the soil risk assessment purposes.

Regard to the additional approach taken by the Applicant in order to calculate accumulated PEC_{soil} values, it is considered correct since the results of the accumulation study performed in field study were EU agreed and are thus not questioned by the zRMS.

8.7.2.2 Prothioconazole and its metabolites

Table 8.7-6: PEC_{soil} for prothioconazole on oilseed rape (winter and spring) (post-emergence, 2×140 g a.s./ha)

PEC_{soil} (mg/kg)		Oilseed rape (winter and spring)			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.037	-	0.039	-
Short term	24h	0.029	0.033	0.030	0.034
	2d	0.023	0.030	0.024	0.031
	4d	0.014	0.024	0.014	0.026
Long term	7d	0.007	0.018	0.007	0.020
	14d	0.001	0.011	0.001	0.012
	21d	< 0.001	0.007	< 0.001	0.014
	28d	< 0.001	0.005	< 0.001	0.011
	50d	< 0.001	0.003	< 0.001	0.006
	100d	< 0.001	0.002	< 0.001	0.003
Plateau concentration (20 cm)		-	-	-	-
$PEC_{accumulation}$ ($PEC_{act} + PEC_{soil\ plateau}$)		-	-	-	-

Table 8.7-7: PEC_{soil} for prothioconazole-S-methyl (M01) on oilseed rape (winter and spring) (post-emergence, 2×140 g prothioconazole/ha)

PEC_{soil} (mg/kg)		Oilseed rape (winter and spring)			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.005	-	0.009	-
Short term	24h	0.005	0.005	0.009	0.009
	2d	0.005	0.005	0.009	0.009
	4d	0.005	0.005	0.009	0.009
Long term	7d	0.005	0.005	0.008	0.009
	14d	0.004	0.005	0.008	0.009
	21d	0.004	0.005	0.007	0.009
	28d	0.003	0.004	0.006	0.008
	50d	0.002	0.004	0.005	0.007
	100d	0.001	0.003	0.002	0.006
Plateau concentration (20 cm)		-	-	-	-
$PEC_{accumulation}$ ($PEC_{act} + PEC_{soil\ plateau}$)		-	-	-	-

Table 8.7-8: PEC_{soil} for prothioconazole-desthio (M04) on oilseed rape (winter and spring) (post-emergence, 2×140 g prothioconazole/ha)

PEC_{soil} (mg/kg)		Oilseed rape (winter and spring)			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.017	-	0.033	-
Short term	24h	0.017	0.017	0.033	0.033
	2d	0.017	0.017	0.033	0.033
	4d	0.017	0.017	0.032	0.033
Long term	7d	0.016	0.017	0.032	0.033
	14d	0.015	0.017	0.030	0.032
	21d	0.014	0.016	0.028	0.032
	28d	0.014	0.016	0.026	0.031
	50d	0.011	0.015	0.021	0.029
	100d	0.007	0.012	0.013	0.024
Plateau concentration (20 cm)		-	-	-	-
$PEC_{accumulation}$ ($PEC_{act} + PEC_{soil\ plateau}$)		-	-	-	-

Table 8.7-9: PEC_{soil} for prothioconazole on sunflower (post-emergence, 2 × 140 g a.s./ha)

PEC _{soil} (mg/kg)		Sunflower			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.047	-	0.048	-
Short term	24h	0.036	0.042	0.038	0.043
	2d	0.028	0.037	0.029	0.038
	4d	0.017	0.030	0.018	0.032
Long term	7d	0.008	0.022	0.009	0.025
	14d	0.002	0.013	0.002	0.015
	21d	< 0.001	0.009	< 0.001	0.018
	28d	< 0.001	0.007	< 0.001	0.014
	50d	< 0.001	0.004	< 0.001	0.008
	100d	< 0.001	0.002	< 0.001	0.004
Plateau concentration (20 cm)		-	-	-	-
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		-	-	-	-

Table 8.7-10: PEC_{soil} for prothioconazole-S-methyl (M01) on sunflower (post-emergence, 2 × 140 g prothioconazole/ha)

PEC _{soil} (mg/kg)		Sunflower			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.006	-	0.011	-
Short term	24h	0.006	0.006	0.011	0.011
	2d	0.006	0.006	0.011	0.011
	4d	0.006	0.006	0.011	0.011
Long term	7d	0.006	0.006	0.011	0.011
	14d	0.005	0.006	0.010	0.011
	21d	0.005	0.006	0.009	0.011
	28d	0.004	0.005	0.008	0.010
	50d	0.003	0.005	0.006	0.009
	100d	0.001	0.004	0.003	0.007
Plateau concentration (20 cm)		-	-	-	-
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		-	-	-	-

Table 8.7-11: PEC_{soil} for prothioconazole-desthio (M04) on sunflower (post-emergence, 2 × 140 g prothioconazole/ha)

PEC _{soil} (mg/kg)		Sunflower			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.021	-	0.034	-
Short term	24h	0.021	0.021	0.034	0.034
	2d	0.021	0.021	0.034	0.034
	4d	0.021	0.021	0.034	0.034
Long term	7d	0.021	0.021	0.033	0.034
	14d	0.019	0.021	0.031	0.034
	21d	0.018	0.021	0.029	0.033
	28d	0.017	0.020	0.027	0.032
	50d	0.014	0.019	0.022	0.030
	100d	0.009	0.015	0.014	0.025
Plateau concentration (20 cm)		-	-	-	-
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})		-	-	-	-

zRMS comments:

The soil exposure for prothioconazole and its metabolites has been independently validated by the zRMS using FOCUS methods and using EU agreed endpoints and the pseudo-application rates of metabolites derived with consideration of the parent rate, molar ratio and peak occurrence in soil.

The calculated PEC_{soil} values for prothioconazole and its metabolites were similar to those obtained by the Applicant and therefore results reported in Tables 8.7-6 to 8.7-11 above may be used for the soil risk assessment purposes.

8.7.2.3 PEC_{soil} of FGE03

Table 8.7-12: PEC_{soil} for FGE03 on oilseed rape (winter and spring) (post-emergence, 1 × 0.7 kg/ha and 2 × 0.7 kg/ha), 80% crop interception

Active substance/ preparation	Application rate (g/ha)	PEC _{act} (mg/kg)	PEC _{twa21 d} (mg/kg)	Tillage depth (cm)	PEC _{soil,plateau} (mg/kg)	PEC _{accu} = PEC _{act} + PEC _{soil,plateau} (mg/kg)
FGE03	700	0.187	0.185	n.a.	n.a.	n.a.
FGE03	1400	0.373	0.371	n.a.	n.a.	n.a.

n.a. not applicable

Table 8.7-13: PEC_{soil} for FGE03 on sunflower (post-emergence, 1 × 0.7 kg/ha and 2 × 0.7 kg/ha), 75% crop interception

Active substance/ preparation	Application rate (g/ha)	PEC _{act} (mg/kg)	PEC _{twa21 d} (mg/kg)	Tillage depth (cm)	PEC _{soil,plateau} (mg/kg)	PEC _{accu} = PEC _{act} + PEC _{soil,plateau} (mg/kg)
FGE03	700	0.233	0.232	n.a.	n.a.	n.a.
FGE03	1400	0.467	0.463	n.a.	n.a.	n.a.

n.a. not applicable

zRMS comments:

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

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

8.8.1 Justification for new endpoints

Not relevant.

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

Report:	KCP 9.2.4.1/01, Šulc A., 2024a
Title:	Report on calculation of Predicted Environmental Concentrations of boscalid, prothioconazole and their metabolites in groundwater (PEC _{gw}) - FGE03 (GPF515) / Central Zone -
Document No:	GW-213-220810CZ-01
Guidelines:	SANCO/13144/2010, version 3, 10 October 2014 Generic Guidance for Tier 1 FOCUS Ground Water Assessment, version 2.4, March 2023
GLP	Not applicable, computer modelling study. No laboratory work was conducted.

Study summary is presented under Appendix A2.1.

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

FOCUS Crop	Oilseed rape, winter and Oilseed rape, summer	
Application rate (g a.s./ha)	Boscalid: 245 g a.s./ha Prothioconazole: 140 g a.s./ha (0.7 kg product/ha)	
Number of applications / interval (d)	1 / -	2 / 14
Application timing	BBCH 61-69	BBCH 61-73
Absolute application date	Refer to Tables 8.8-2 and 8.8-3 below	
Crop interception (%)	80%	
Application rate considering interception (g a.s./ha)	Boscalid: 49 g a.s./ha Prothioconazole: 28 g a.s./ha	
Frequency of application	Annual	
Models used for calculation	FOCUS PEARL v5.5.5 and FOCUS PELMO v. 6.6.4 v5.5.3	

Table 8.8-2: Application dates used for groundwater risk assessment for single application to oilseed rape

Scenario	Application dates (absolute), single application			
	Oilseed rape, winter		Oilseed rape, summer	
	Early, BBCH 61	Late, BBCH 69	Early, BBCH 61	Late, BBCH 69
Châteaudun	23/04	14/05	-	-
Hamburg	08/05	30/05	-	-
Jokioinen	-	-	07/07	22/07
Kremsmünster	08/05	30/05	-	-
Okehampton	03/05	25/05	18/05	13/06
Piacenza	17/04	05/05	-	-
Porto	23/04	14/05	03/06	26/06

Table 8.8-3: Application dates used for groundwater risk assessment for two applications to oilseed rape

Scenario	Application dates (absolute), two applications			
	Oilseed rape, winter		Oilseed rape, summer	
	Early, BBCH 61	Late, BBCH 73	Early, BBCH 61	Late, BBCH 73
Châteaudun	23/04 & 07/05	11/05 & 25/05	-	-
Hamburg	08/05 & 22/05	27/05 & 10/06	-	-
Jokioinen	-	-	07/07 & 21/07	15/07 & 29/07
Kremsmünster	08/05 & 22/05	27/05 & 10/06	-	-
Okehampton	03/05 & 17/05	22/05 & 05/06	18/05 & 01/06	12/06 & 26/06
Piacenza	17/04 & 01/05	30/04 & 14/05	-	-
Porto	23/04 & 07/05	11/05 & 25/05	03/06 & 17/06	23/06 & 07/07

zRMS comments:

The application pattern assumed in simulations is in line with the critical Central Zone GAP as presented in Table 8.1-1. Assumed crop interception corresponded with BBCH stages at which product FGE03 is intended to be applied.

Application dates presented in tables above were checked by the zRMS using AppDate ver. 3.06 tool and are considered acceptable.

Potential leaching in Central Zone scenarios not defined for spring oilseed rape is considered to be covered by simulations performed for winter oilseed rape.

8.8.2.1 Boscalid

Table 8.8-4: Input parameters related to active substance boscalid for PEC_{gw} calculations

Compound	Boscalid	Value in accordance with EU endpoint / Reference
Molecular weight (g/mol)	343.21	Y / SANCO/3919/2007 – rev. 5
Water solubility (mg/l)	4.64 at 20°C 6.69 at 30°C	Y / SANCO/3919/2007 – rev. 5 Extrapolated ^a
Saturated vapour pressure (Pa)	7.2×10^{-7} at 20°C 2.6×10^{-6} at 30°C	Y / SANCO/3919/2007 – rev. 5 Extrapolated ^a
DT ₅₀ in soil (d)	139 (arithmetic mean, normalisation to 20°C ^b , n =3)	Y / SANCO/3919/2007 – rev. 5
Transformation rate	To CO ₂ :0.0049867	N / Calculated from the DT ₅₀ in soil of 139 d
K _{foc} (mL/g)	743 (geometric mean, n = 6)	Y / SANCO/3919/2007 – rev. 5 Geomean according to EFSA Journal 2014;12(5):3662, 38 pp.
K _{fom} (mL/g)	431	K _{foc} / 1.724
1/n	0.864 (arithmetic mean, n = 6)	Y / SANCO/3919/2007 – rev. 5
Plant uptake factor	0	FOCUS default (worst case assumption)
Formation fraction	-	-

^a Calculated with the extrapolation routine in the EVA3 rev2h tool (2017)

^b Normalised to 20°C using Q₁₀ of 2.2

Table 8.8-5: PEC_{gw} for boscalid following early or late application of FGE03 on winter or spring oilseed rape (FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5)

Crop	Scenario	80 th Percentile PEC_{GW} at 1 m Soil Depth ($\mu\text{g/L}$)	
		Boscalid FOCUS PELMO 6.6.4	Boscalid FOCUS PEARL 5.5.5
Winter oilseed rape, early or late applications ($2 \times 245 \text{ g a.s./ha}$)	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
Spring oilseed rape, early or late applications ($2 \times 245 \text{ g a.s./ha}$)	Jokioinen	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Porto	< 0.001	< 0.001

Calculation of PEC_{GW} with FOCUS MACRO 5.5.4 was not considered required as PEC_{GW} concentrations with FOCUS PEARL and FOCUS PELMO were < 0.001 $\mu\text{g/L}$ for all scenarios and substances.

zRMS comments:

Input parameters for boscalid presented in Tables 8.8-4 and used in the modelling are in line with with the currently agreed EU endpoints.

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

The groundwater modelling was independently validated by the zRMS in additional modelling with FOCUS PEARL 5.5.5 and FOCUS PELMO 6.6.4 using the same parameters and the same PEC_{gw} values were obtained.

Overall, no unacceptable leaching of boscalid is expected following application of FGE03 according to the intended use pattern.

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

8.8.2.2 Prothioconazole and its metabolites

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

Compound	Prothioconazole	Value in accordance with EU endpoint / Reference
Molecular weight (g/mol)	344.3	Y / EFSA LoEP, 2007
Water solubility (mg/L)	300 at 20°C 600 at 30°C	Y / EFSA LoEP, 2007
Saturated vapour pressure (Pa)	1.0×10^{-20} at 20°C 3.62×10^{-20} at 30°C Set to low value as soil DT ₅₀ is derived from field study where influence of vapour pressure is already reflected. Minimum value rather than '0' used to satisfy model requirement of entering a numerical value.	N / EFSA LoEP, 2007 EFSA value is 4.0×10^{-7} at 20°C
DT ₅₀ in soil (d)	1.2 Field, geometric mean, normalisation to 20°C ^a , n = 8	Y / EFSA LoEP, 2007
Formation fractions	To M01: 0.146 To M04: 0.6 To CO ₂ : 0.254	Y / DAR (2005) used for PELMO results presented in EFSA LoEP (2007)
Transformation rate	To M01: 0.084333 To M04: 0.346574 To CO ₂ : 0.146716	N / Calculated from the DT ₅₀ in soil
K _{fOC} (mL/g)	1765 Based on aged soil column leaching study	Y / EFSA LoEP, 2007 Geomean according to EFSA Journal 2014;12(5):3662, 38 pp.
K _{fOM} (mL/g)	1023.8	K _{fOC} / 1.724
1/n	0.9 FOCUS default	Y / EFSA LoEP, 2007
Plant uptake factor	0	FOCUS default (worst case assumption)
Formation fraction	-	-

^a Q₁₀ = 2.2

Table 8.8-7: Input parameters related to metabolites prothioconazole-S-methyl (M01) and prothioconazole-desthio (M04) for PEC_{gw} calculations

Compound	Prothioconazole-S-methyl (M01)	Prothioconazole-desthio (M04)	Value in accordance with EU endpoint / Reference
Molecular weight (g/mol)	358.3	312.2	Y / EFSA LoEP, 2007
Water solubility (mg/L)	1000 at 20°C (default)	1000 at 20°C (default)	Y / EFSA LoEP, 2007 Extrapolated ^a
Saturated vapour pressure (Pa)	1×10^{-10} at 20°C (default)	1×10^{-10} at 20°C (default)	Y / EFSA LoEP, 2007 Extrapolated ^a
DT ₅₀ in soil (d)	15.7 Lab, geometric mean, 20°C, n = 4	22.7 Field, geometric mean, normalisation to 20°C ^b , n = 8	Y / EFSA LoEP, 2007
Formation fraction	To M04: 1.0	-	Y / DAR (2005) used for PELMO results presented in EFSA LoEP (2007)
Transformation rate	To M04: 0.044150	To CO ₂ : 0.030535	N / Calculated from the DT ₅₀ in soil
K _{fOC} (mL/g)	2525.9 Geometric mean, n = 4	573.5 Geometric mean, n = 4	Y / EFSA LoEP, 2007 Geomean according to EFSA Journal 2014;12(5):3662, 38 pp.
K _{fOM} (mL/g)	1465.1	332.7	K _{fOC} / 1.724
1/n	0.88 Arithmetic mean, n = 4	0.81 Arithmetic mean, n = 4	Y / EFSA LoEP, 2007
Plant uptake factor	0	0	FOCUS default (worst case assumption)

^a Calculated with the extrapolation routine in the EVA3 rev2h tool (2017)

^b Q₁₀ = 2.2

Table 8.8-8: PEC_{gw} for prothioconazole and metabolites M01 & M04 following early or late application of FGE03 on winter or spring oilseed rape (FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)	
		Prothioconazole & metabolites M01 & M04 FOCUS PELMO 6.6.4	Prothioconazole & metabolites M01 & M04 FOCUS PEARL 5.5.5
Winter oilseed rape, early or late applications (2 × 140 g a.s./ha)	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
Spring oilseed rape, early or late applications (2 × 140 g a.s./ha)	Jokioinen	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Porto	< 0.001	< 0.001

zRMS comments:

Input parameters for prothioconazole and its metabolites presented in Tables 8.8-6 and 8.8-7 and used in the modelling are in general in line with the EU agreed endpoints reported in EFSA Scientific Report (2007) 106.

In simulations PUF value of 0 was assumed for all compounds, which is in line with recommendations of the most recent version of the FOCUS Groundwater Guidance (2023). The groundwater modelling was independently validated by the zRMS in additional modelling with FOCUS PEARL 5.5.5 and FOCUS PELMO 6.6.4 using the EU agreed input parameters and application dates as suggested by AppDate 3.06.

Obtained results were in good agreement with these derived by the Applicant for prothioconazole and its metabolites presented in Table 8.8-8

Overall, no unacceptable leaching of prothioconazole and its metabolites is expected following application of FGE03 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.

Additional PEC_{GW} modelling for the use on sunflower is presented here considering application at BBCH 61-73 at the same application rate as for oilseed rape, i.e. 0.7 kg product/ha, equivalent to 245 g boscalid/ha and 140 g prothioconazole/ha. Maize was modelled as a surrogate crop as sunflower is defined for FOCUS scenarios Piacenza and Sevilla, both of which are not representative for the central zone according to the central zone working document for fate and behaviour (2018)³. Maize however is defined for the four FOCUS groundwater scenarios representative for the central zone, i.e. Châteaudun, Hamburg, Kremsmünster and Okehampton. The application details are presented below in **Tables 8.8-9** and **8.8-10**.

Input parameters related to the active substances are the same as used for modelling oilseed rape and are as presented in **Table 8.8-4** (boscalid) and in **Tables 8.8-6** (prothioconazole) and **8.8-7** (prothioconazole metabolites).

Table 8.8-9: Input parameters related to application to sunflower for PEC_{GW} calculations

Use No.	3 - sunflower
FOCUS Crop	Maize, as surrogate for sunflower
Application rate (g a.s./ha)	Boscalid: 245 g a.s./ha Prothioconazole: 140 g a.s./ha
Number of applications / interval (d)	2 / 14
Application timing	BBCH 61-73
Absolute application date	Refer to Table 8.8-10 below
Crop interception (%)	75%
Application rate considering interception (g a.s./ha)	Boscalid: 61.25 g a.s./ha Prothioconazole: 35 g a.s./ha
Frequency of application	Annual
Models used for calculation	FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5

Table 8.8-10: Application dates used for groundwater risk assessment for use on sunflower with maize as a surrogate crop

Scenario	Application dates (absolute)	
	Maize (as surrogate for sunflower), 1 × 250 g a.s./ha	
	BBCH 61	BBCH 73
Châteaudun	17/08 & 31/08	21/08 & 04/09
Hamburg	01/08 & 15/08	08/08 & 22/08
Kremsmünster	01/08 & 15/08	08/08 & 22/08
Okehampton	18/07 & 01/08	06/08 & 20/08
Piacenza	03/08 & 17/08	25/08 & 08/09
Porto	17/08 & 31/08	21/08 & 04/09
Sevilla	17/06 & 01/07	21/06 & 05/07
Thiva	18/06 & 02/07	11/07 & 25/07

Early and late applications were modelled and results are presented in **Table 8.8-11** for boscalid and in **Table 8.8-12** for prothioconazole and its metabolites.

³ Working document of the central zone in the authorisation of plant protection products. Section 8, Environmental fate and behaviour. Version 1 rev. 1 – June 2018

Table 8.8-11: PEC_{GW} for boscalid following application of FGG01 on sunflower (using maize as a surrogate FOCUS crop) (FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)	
		FOCUS PELMO 6.6.4	FOCUS PEARL 5.5.5
Sunflower (maize as surrogate) 1 × 245 g a.s./ha, BBCH 61-73 Results for early and late applications	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001

Table 8.8-12: PEC_{GW} for prothioconazole and metabolites M01 & M04 following application of FGG01 on sunflower (using maize as a surrogate FOCUS crop) (FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)	
		FOCUS PELMO 6.6.4	FOCUS PEARL 5.5.5
Sunflower (maize as surrogate) 1 × 140 g a.s./ha, BBCH 61-73 Results for early and late applications	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001

All PEC_{GW} concentrations are far below the trigger of 0.1 µg/L indicating safe use.

zRMS comments:

It is noted that the Central Zone GAP includes several minor crops: spring rape, gold of pleasure, winter turnip rape, mustard, sunflower, poppy, linseed, flax, hemp, borage. The winter oilseed rape (major crop) is relevant surrogate crop for all minor crops except of sunflower, as the sunflower is available for FOCUS modelling. Nevertheless not all scenarios relevant to the central zone are defined for sunflower, thus the Applicant was requested to provide simulations performed for maize as surrogate crop for both active substances boscalid and prothioconazole and its metabolites.

The application pattern assumed in simulations and presented in Table 8.8-9 is in line with the critical Central Zone GAP as presented in Table 8.1-1. Assumed crop interception corresponded with BBCH 61 for sunflower.

Application dates presented in Table 8.8-10 were checked by the zRMS using AppDate ver. 3.06 tool and are considered acceptable.

The groundwater modelling was independently validated by the zRMS in additional modelling with FOCUS PEARL 5.5.5 and FOCUS PELMO 6.6.4 using the EU agreed input parameters for both active substances and application dates as suggested by AppDate 3.06 for maize. It is noted that relevant in central zone, scenario Piacenza is defined for sunflower, thus zRMS performed additional simulations for this scenario and obtained PEC_{gw} values were far below 0.1 µg/L as for maize used as a surrogate crop.

Obtained results were in good agreement with these derived by the Applicant being below the trigger value of 0.1 µg/L for all scenarios and for both active substances boscalid and prothioconazole and its metabolites.

Overall, no unacceptable leaching of both active substances is expected following the use of FGE03 on sunflower.

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

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

8.9.1 Justification for new endpoints

Not relevant.

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

Report:	KCP 9.2.5/01, Šulc, A., 2024b
Title:	Report on Predicted Environmental Concentrations of boscalid, prothioconazole and their metabolites in Surface Water and Sediment (PEC _{sw} and PEC _{sed}) - FGE03 (GPF515) / Central Zone -.
Document No:	SW-213-220810CZ-01
Guidelines:	SANCO/4802/2001, version 2, May 2003 Generic Guidance for FOCUS Surface Water Scenarios, version 1.4, May 2015
GLP	Not applicable, computer modelling study. No laboratory work was conducted.

Study summary is presented under Appendix A2.2.

Application data

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

Plant protection product	FGE03	
FOCUS Crop	Oilseed rape, winter and Oilseed rape, spring	
Application rate (g a.s./ha)	Boscalid: 245 g a.s./ha Prothioconazole: 140 g a.s./ha (0.7 kg product/ha)	
Number of applications/interval (d)	1 / -	2 / 14
Application timing	BBCH 61-69	BBCH 61-73
Application period (Step 2)	Mar.-May & June-Sep.	
Crop interception (Step 2)	Full canopy	
Application window (Step 3)	Please see Table 8.9-2 (winter) or Table 8.9-3 (spring) Length of application window 30 d	Please see Table 8.9-2 (winter) or Table 8.9-3 (spring) Length of application window 44 d
FOCUS Locations	Step 1: not relevant Step 2: north and south EU Step 3: Winter oilseed rape: D2, D3, D4, D5, R1, R3 Spring oilseed rape: D1, D3, D4, D5, R1	
Application method (Step 3)	Ground spray	
CAM (Chemical application method) (Step 3)	2	
Soil depth (cm) (Step 3)	4	
Models used for calculation	STEP 1-2 v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXSWA v5.5	

Table 8.9-1: FOCUS Step 3 scenario related input parameters for PEC_{SW/SED} calculations for the application of FGE03, oilseed rape, winter

Scenario	Application window used in modelling ^a	
	Oilseed rape, winter, 1 × 0.7 kg product/ha (BBCH 61-69)	Oilseed rape, winter, 2 × 0.7 kg product/ha (BBCH 61-73)
~~D2~~	~~16/06 (167) – 16/07 (197)~~	~~16/06 (167) – 30/07 (211)~~
D3	27/05 (147) – 26/06 (177)	27/05 (147) – 10/07 (191)
D4	07/06 (158) – 07/07 (188)	07/06 (158) – 21/07 (202)
D5	12/05 (132) – 11/06 (162)	12/05 (132) – 25/06 (176)
R1	27/05 (147) – 26/06 (177)	27/05 (147) – 10/07 (191)
R3	22/04 (112) – 22/05 (142)	22/04 (112) – 05/06 (156)

^a Application date for BBCH 61 taken from AppDate v3.06 and adjusted for the application window

Table 8.9-3: FOCUS Step 3 scenario related input parameters for PEC_{SW/SED} calculations for the application of FGE03, oilseed rape, spring

Scenario	Application window used in modelling ^a	
	Oilseed rape, spring, 1 × 0.7 kg product/ha (BBCH 61-69)	Oilseed rape, spring, 2 × 0.7 kg product/ha (BBCH 61-73)
~~D1~~	~~06/07 (187) – 05/08 (217)~~	~~06/07 (187) – 19/08 (231)~~
D3	17/06 (168) – 17/07 (198)	17/06 (168) – 31/07 (212)
D4	20/06 (171) – 20/07 (201)	20/06 (171) – 03/08 (215)
D5	27/05 (147) – 26/06 (177)	27/05 (147) – 10/07 (191)
R1	09/06 (160) – 09/07 (190)	09/06 (160) – 23/07 (204)

^a Application date for BBCH 61 is taken from AppDate v3.06 and adjusted for the application window

zRMS comments:

The application pattern assumed in surface water simulations is in general in line with Central Zone GAP presented in Table 8.1-1.

The application windows presented in tables above were checked by the zRMS using AppDate ver. 3.06 tool and are considered acceptable. Since only relevant scenarios in the central zone were validated, therefore D1 and D2 scenarios were struck through as not relevant.

8.9.2.1 Boscalid

Table 8.9-4: Input parameters related to active substance boscalid for PEC_{SW/SED} calculations STEP 1-3

Compound	Boscalid	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	343.21	Y / SANCO/3919/2007 – rev. 5
Saturated vapour pressure (Pa)	7.2×10^{-7} (20°C)	
Water solubility (mg/L)	4.6 (20°C)	
Diffusion coefficient in water (m ² /d)	4.3×10^{-5}	Default
Diffusion coefficient in air (m ² /d)	0.43	Default
K _{IOC} (mL/g)	743 (geomean, n=6)	Y / SANCO/3919/2007 – rev. 5 Geomean K _{IOC} , according to EFSA Journal 2014;12(5):3662, 38 pp.
K _{IOM} (mL/g)	431	
Freundlich Exponent 1/n	0.864 (arithmetic mean, n=6)	
Plant Uptake	0	FOCUS default
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	FOCUS default
DT _{50,soil} (d)	139 (arithmetic mean, normalisation to 20°C ^a , n =3)	Y / SANCO/3919/2007 – rev. 5
DT _{50,water} (d)	Step 2: 90 Step 3: 90 / 1000 ^b	N / data from SANCO/3919/2007 – rev. 5, recalculation performed by CtgB for registration of BAS 516 09 F ⁴
DT _{50,sed} (d)	Step 2: 1000 Step 3: 1000 / 90 ^b	
DT _{50,whole system} (d)	90 ^c (higher-tier outdoor study, n=1)	

a Normalised to 20°C using Q₁₀ of 2.2

b As K_{IOC} is between 100 and 2000 mL/g, two FOCUS step 3 simulations to be conducted with alternating whole system and default DT₅₀ values. This is in accordance with FOCUS SW guidance (v 1.4, May 2015).

c Used at FOCUS Step 1-2

PEC_{SW/SED}

Table 8.9-5: FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} for active substance boscalid following one or two applications to oilseed rape (winter and spring) at 245 g a.s./ha

Scenario	Season of application	Max PEC _{SW} (µg/L)	Dominant entry route	21 d-PEC _{SW, twa} (µg/L)	Max PEC _{SED} (µg/kg)
FOCUS					
1 × 245 g a.s./ha, BBCH 61-69					
Step 1	-	43.278	Runoff/Drainage	n.r.	310.821
Step 2					
Northern Europe	March-May	3.337	Spray drift	n.r.	23.166
	June-September	3.337	Spray drift	n.r.	23.166
Southern Europe	March-May	5.348	Runoff/Drainage	n.r.	38.095
	June-September	4.342	Runoff/Drainage	n.r.	30.630
2 × 245 g a.s./ha, BBCH 61-73 ^a					
Step 1	-	86.556	Runoff/Drainage	n.r.	609.628
Step 2					
Northern Europe	March-May	6.151	Spray drift	n.r.	42.925
	June-September	36.151	Spray drift	n.r.	42.925
Southern Europe	March-May	10.037	Runoff/Drainage	n.r.	71.777
	June-September	8.094	Runoff/Drainage	n.r.	57.351

n.r. not required

a Respective single applications are covered by the use above

⁴ Product Insure Duo, registration number 16032 N

Table 8.9-6: FOCUS Step 3 maximum PEC_{SW} and PEC_{SED} actual of boscalid after two or one applications to oilseed rape (winter) at 245 g a.s./ha ^a

Scenario FOCUS	Waterbody	Max PEC _{SW} (µg/L)	Dominant entry route	21 d- PEC _{SW,TWA} (µg/L)	Max PEC _{SED} (µg/kg)
Oilseed rape, winter, 2 × 245 g boscalid/ha					
D2	ditch	7.398	drainage	n.r.	39.5
D2	stream	4.614	drainage	n.r.	23.64
D3	ditch	1.362	drift	n.r.	1.406
D4	pond	0.533 ^b	drainage	n.r.	4.527
D4	stream	1.202	drainage	n.r.	1.539
D5	pond	0.597 ^b	drainage	n.r.	6.282
D5	stream	1.252	drift	n.r.	1.490
R1	pond	0.275 ^b	runoff	n.r.	2.377 ^b
R1	stream	3.144	runoff	n.r.	3.977
R3	stream	2.666 ^b	runoff	n.r.	1.599
Oilseed rape, winter, 1 × 245 g boscalid/ha					
D2	ditch	2.321	drainage	n.r.	14.47
D2	stream	1.746 ^b	drift	n.r.	9.332
D3	ditch	1.555	drift	n.r.	1.103
D4	pond	0.152 ^b	drainage	n.r.	1.381
D4	stream	1.341	drift	n.r.	0.446
D5	pond	0.206 ^b	drainage	n.r.	1.956
D5	stream	1.447	drift	n.r.	0.498
R1	pond	0.161 ^b	runoff	n.r.	1.308
R1	stream	1.128 ^b	runoff	n.r.	2.777
R3	stream	1.442	drift	n.r.	0.709

n.r. not relevant

a Respective single application also presented, covering use #2

b Combination of DT_{50, water} = 1000 d and DT_{50, sediment} = 90 d

Please note that in accordance with the central zone working document on efate⁵, the D2 scenario is not relevant for the central zone and, therefore, PEC values for this scenario are not considered in the aquatic risk assessment.

⁵ Working Document of the Central Zone in the Authorisation of Plant Protection Products - Part B section 8 - Environmental fate and behaviour. Version 1 rev. 1 – June 2018

Table 8.9-7: FOCUS Step 3 maximum PEC_{SW} and PEC_{SED} actual of boscalid after two or one applications to oilseed rape (spring) at 245 g a.s./ha ^a

Scenario FOCUS	Waterbody	Max PEC _{SW} (µg/L)	Dominant entry route	21 d- PEC _{SW,TWA} (µg/L)	Max PEC _{SED} (µg/kg)
Oilseed rape, spring, 2 × 245 g boscalid/ha					
~~D1~~	~~ditch~~	~~5.466~~	~~drainage~~	~~n.r.~~	~~51.13~~
~~D1~~	~~stream~~	~~3.666~~	~~drainage~~	~~n.r.~~	~~28.90~~
D3	ditch	1.363	drift	n.r.	1.451
D4	pond	0.730 ^b	drainage	n.r.	6.061
D4	stream	1.433	drainage	n.r.	2.080
D5	pond	0.515 ^b	drainage	n.r.	4.468
D5	stream	1.251	drift	n.r.	1.178
R1	pond	0.675 ^b	runoff	n.r.	4.086
R1	stream	2.483	runoff	n.r.	6.399
Oilseed rape, spring, 1 × 245 g boscalid/ha					
~~D1~~	~~ditch~~	~~2.470~~	~~drainage~~	~~n.r.~~	~~21.88~~
~~D1~~	~~stream~~	~~1.558~~	~~drift~~	~~n.r.~~	~~12.18~~
D3	ditch	1.556	drift	n.r.	1.166
D4	pond	0.205 ^b	drainage	n.r.	1.837
D4	stream	1.341	drift	n.r.	0.599
D5	pond	0.386 ^b	drainage	n.r.	3.220
D5	stream	1.446	drift	n.r.	0.879
R1	pond	0.304 ^b	runoff	n.r.	1.903
R1	stream	1.287	runoff	n.r.	2.902

n.r. not relevant

a Respective single application also presented, covering use #2

b Combination of DT_{50, water} = 1000 d and DT_{50, sediment} = 90 d

Please note that in accordance with the central zone working document on efate⁶, the D1 scenario is not relevant for the central zone and, therefore, PEC values for this scenario are not considered in the aquatic risk assessment.

zRMS comments:

The input parameters considered by the Applicant in surface water modelling for boscalid and presented in Table 8.9- 4 are in line with the currently agreed EU endpoints.

The only exception is consideration of the geometric mean instead of arithmetic mean K_{foc} value for boscalid. This deviation is, however, agreed by the zRMS as the geometric mean K_{foc} values are lower than arithmetic mean values and represent thus worst case in terms of the water column exposure. Moreover, consideration of geometric mean K_{foc} values is in line with current EFSA recommendations. The geometric mean values calculated by the Applicant were based on the currently EU agreed individual values and are confirmed to be correct.

At Step 3 simulations PUF value of 0 was assumed, and it is in line with current recommendations.

⁶ Working Document of the Central Zone in the Authorisation of Plant Protection Products - Part B section 8 - Environmental fate and behaviour. Version 1 rev. 1 – June 2018

The performed calculations were independently validated by the zRMS in additional modelling using the same parameters. Obtained PEC_{sw} and PEC_{sed} were in good agreement with values calculated by the Applicant and for some scenarios were insignificantly higher. Since only relevant scenarios in the central zone were validated, therefore results presented for D1 and D2 scenarios were struck through as not relevant. Surface water exposure presented in Tables 8.9-5 to 8.9-7 may be used in the aquatic risk assessment.

Simulations performed for winter oilseed rape (major crop) are considered to cover the surface water exposure for following minor crops: gold of pleasure, winter turnip rape, mustard, poppy, linseed, flax, hemp, borage.

Additional calculation for use in sunflower were performed by the Applicant and results are presented in Tables 8.9-19 and 8.9-24. The performed calculations for use on sunflower (minor crop) were independently validated by the zRMS in additional modelling. Since for sunflower not all relevant in the central zone scenarios are defined, maize was used as the surrogate crop for missing D3 and D4 scenarios and it is accepted by the zRMS. Obtained PEC_{sw} and PEC_{sed} results were in good agreement with values calculated by the Applicant and presented in Tables: 8.9-19 and 8.9-24. Since additional calculations at Step 4 for boscalid were necessary for finalisation of the aquatic risk assessment, thus the Applicant performed additional simulations at Step 4 considering vegetated filter strip of 10 and 15m. However, according to recommendations of the FOCUS work group on landscape and mitigation (SANCO/10422/2005) vegetated filter buffer zones of 10 and 20 m are recommended for run-off reduction as reasonable worst-case assumption, therefore result for 15 m was not considered and was thus struck through. Independent validation performed by the zRMS in additional simulations for vegetated filter strip at 10 m resulted with the same values as these reported by the Applicant in table below and may be used for the risk assessment purposes.

FOCUS STEP 4 Max PEC_{sw} ($\mu\text{g/L}$) for boscalid after two or one applications to winter and spring oilseeds rape and sunflower – additional calculations performed by the Applicant

STEP 4		PEC_{sw} ($\mu\text{g/L}$)		
Run-off reduction in line with FOCUS L&M		10 m		15m
		Winter oilseed rape 2 x 245 g a.s./ha	Spring oilseed rape 2 x 245 g a.s./ha	
R1	Stream	1.421	1.131	-
R3	Stream	1.209	-	-
		Sunflower 2 x 245 g a.s./ha	Sunflower 1 x 245 g a.s./ha	Sunflower 2 x 245 g a.s./ha
R1	Stream	1.402	-	-
R3	Stream	1.186	-	-
R4	Stream	1.781	1.043	0.242

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 Prothioconazole and its metabolites

Table 8.9-8: Input parameters related to active substance prothioconazole for PEC_{SW/SED} calculations STEP 1-4

Compound	Prothioconazole	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	344.3	Y / EFSA LoEP, 2007
Saturated vapour pressure (Pa)	4.0×10^{-7} (20°C)	
Water solubility (mg/L)	300 (20°C)	
Diffusion coefficient in water (m ² /d)	4.3×10^{-5}	Default
Diffusion coefficient in air (m ² /d)	0.43	Default
K _{fOC} (mL/g)	1765 (based on aged soil column leaching study)	Y / EFSA LoEP, 2007
K _{fOM} (mL/g)	1023.8 (K _{fOC} / 1.724)	
Freundlich exponent 1/n	0.9 (FOCUS default)	
Plant uptake	0	FOCUS default
Wash-off factor from crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	FOCUS default
DT _{50, soil} (d)	1.2 (field, geometric mean, normalisation to 20°C ^a , n = 8)	Y / EFSA LoEP, 2007
DT _{50, water} (d)	Step 2: 24.1 (worst case, first order whole system value) Step 3: 24.1 (set 1) / 1000 (set 2) ^b	Y / EFSA LoEP, 2007
DT _{50, sed} (d)	Step 2: 1000 Step 3: 1000 (set 1) / 24.1 (set 2) ^b	
DT _{50, whole system} (d)	24.1, worst case, n = 2, first order, 20°C ^c	

^a Normalized to 20°C using Q₁₀ of 2.2

^b As K_{oc} is between 100 and 2000 mL/g, two FOCUS step 3 simulations to be conducted with alternating whole system and default DT₅₀ values. This is in accordance with FOCUS SW guidance (v 1.4, May 2015).

^c Used at FOCUS Step 1-2

Table 8.9-9: Input parameters of the metabolite prothioconazole-desthio (M04) for PEC_{SW/SED} calculations, STEP 1-3

Compound	Prothioconazole-desthio (M04)	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	312.2	Y / EFSA LoEP, 2007
Saturated vapour pressure (Pa)	1×10^{-10} at 20°C (default)	
Water solubility (mg/L)	1000 at 20°C (default)	
Diffusion coefficient in water (m ² /d)	4.3×10^{-5}	Default
Diffusion coefficient in air (m ² /d)	0.43	Default
K _{IOC} (mL/g)	573.5 (geometric mean, n = 4)	Y / EFSA LoEP, 2007 Geomean K _{IOC} , according to EFSA Journal 2014;12(5):3662, 38 pp.
K _{IOM} (mL/g)	332.7 (K _{IOC} / 1.724)	
Freundlich exponent 1/n	0.81 (arithmetic mean, n = 4)	
Plant uptake	0	FOCUS default
Wash-off factor from crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	FOCUS default
DT _{50, soil} (d)	22.7 (field, geometric mean, normalisation to pF2 & 20°C ^a , n = 8)	Y / EFSA LoEP, 2007
DT _{50, water} (d)	Step 2: 49.9 (whole system value) Step 3: 1000 (set 1) / 49.9 (set 2) ^b	Y / DAR 2005
DT _{50, sed} (d)	Step 2: 1000 Step 3: 49.9 (set 1) / 1000 (set 2) ^b	
DT _{50, whole system} (d)	49.9 ^c (worst case, whole system, 1 st order kinetics)	
Max. occurrence (%) / formation fraction in soil	57.1% / 0.6	Y / EFSA LoEP, 2007
Max. occurrence (%) / formation fraction in water	32.3% / 1	Y / EFSA LoEP, 2007
Max. occurrence (%) / formation fraction in sediment	26.9% / 1	Y / EFSA LoEP, 2007
Max. occurrence (%) in water/sediment system	54.6%	Y / DAR, 2005; EFSA LoEP, 2007

a Normalized to 20°C using Q₁₀ of 2.2

b As K_{oc} is between 100 and 2000 mL/g, two FOCUS step 3 simulations to be conducted with alternating whole system and default DT₅₀ values. This is in accordance with FOCUS SW guidance (v 1.4, May 2015). As a worst case, for the first set of modelling, the system DT₅₀ set to the water compartment for the parent is simulated with the default 1000 d DT₅₀ set to the water compartment for the metabolite.

c Used at FOCUS Step 1-2

Table 8.9-10: Input parameters related to metabolites prothioconazole-S-methyl (M01) and 1,2,4-triazole (M13) for PEC_{SW/SED} calculations, Step 1-2

Parameter	Prothioconazole-S-methyl (M01)	1,2,4-triazole (M13)	Value in accordance with EU endpoint y/n/ Reference
Physical-Chemical parameters			
Molecular weight [g/mol]	358.3	69.1	Y / EFSA LoEP, 2007
Water solubility [mg/L]	1000 at 20°C (default)	730000 at 25°C	M01: Y / EFSA LoEP, 2007 M13: Y / EFSA LoEP, 2014 ^a
Degradation in soil			
DT ₅₀ soil [days]	15.7 (lab, geometric mean, 20°C, n = 4)	1000 (default)	Y / EFSA LoEP, 2007
Max. occurrence in soil [%]	14.6	2.0	Y / EFSA LoEP, 2007; DAR, 2005
Sorption to soil			
K _{FOC} [mL/g]	2525.9 (geometric mean, n = 4)	83 (geometric mean, n = 4)	N / EFSA LoEP, 2007 (M01) & 2014 (M13) Geomean according to EFSA Journal 2014;12(5):3662, 38 pp.
Degradation in aquatic system			
DT ₅₀ total system [d] (Step 1)	1000	1000	Y / EFSA LoEP, 2007
DT ₅₀ water [d] (Step 2)	1000	1000	N / EFSA LoEP, 2007
DT ₅₀ sediment [d] (Step 2)	1000	1000	Y / EFSA LoEP, 2007
Maximum occurrence observed [%]	Water/sediment: Not found in aerobic study 12.7 (aerobic in whole system) 77 (anaerobic in sediment)	Water/sediment: 37.2% (water) 41.8% (in whole system)	Y / EFSA LoEP, 2007; DAR, 2005

^a EFSA Journal 2014;12(1):3485 on tebuconazole, p 54

PEC_{SW/SED}

Table 8.9-11: FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} for active substance prothioconazole following one or two applications to oilseed rape (winter and spring) at 140 g a.s./ha

Scenario	Season of application	Max PEC _{SW} (µg/L)	Dominant entry route	21 d-PEC _{SW, twa} (µg/L)	Max PEC _{SED} (µg/kg)
FOCUS					
1 × 140 g a.s./ha, BBCH 61-69					
Step 1	-	15.204	Runoff/Drainage	n.r.	245.626
Step 2					
Northern Europe	March-May	1.288	Spray drift	n.r.	7.652
	June-September	1.288	Spray drift	n.r.	7.652
Southern Europe	March-May	1.288	Spray drift	n.r.	8.870
	June-September	1.288	Spray drift	n.r.	8.261
2 × 140 g a.s./ha, BBCH 61-73 ^a					
Step 1	-	30.408	Runoff/Drainage	n.r.	491.253
Step 2					
Northern Europe	March-May	1.505	Spray drift	n.r.	11.746
	June-September	1.505	Spray drift	n.r.	11.746
Southern Europe	March-May	1.505	Spray drift	n.r.	12.964
	June-September	1.505	Spray drift	n.r.	12.355

n.r. not required

^a Respective single applications are covered by the use above

Table 8.9-12: FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} for prothioconazole metabolite prothioconazole-S-methyl (M01) following one or two applications to oilseed rape (winter and spring) at 140 g prothioconazole/ha

Scenario	Season of application	Max PEC _{SW} (µg/L)	Dominant entry route	21 d-PEC _{SW, t_{wa}} (µg/L)	Max PEC _{SED} (µg/kg)
FOCUS					
1 × 140 g a.s./ha, BBCH 61-69					
Step 1	-	3.21 1.623	Runoff/Drainage	n.r.	77.60 41.003
Step 2					
Northern Europe	March-May	0.17 0.068	Runoff/Drainage	n.r.	2.87 1.718
	June-September	0.17 0.068	Runoff/Drainage	n.r.	2.87 1.718
Southern Europe	March-May	0.20 0.136	Runoff/Drainage	n.r.	4.77 3.437
	June-September	0.17 0.102	Runoff/Drainage	n.r.	3.82 2.577
2 × 140 g a.s./ha, BBCH 61-73 ^a					
Step 1	-	6.41 3.247	Runoff/Drainage	n.r.	155.20 82.006
Step 2					
Northern Europe	March-May	0.20 0.105	Runoff/Drainage	n.r.	4.54 2.644
	June-September	0.20 0.105	Runoff/Drainage	n.r.	4.54 2.644
Southern Europe	March-May	0.32 0.209	Runoff/Drainage	n.r.	7.36 5.289
	June-September	0.26 0.157	Runoff/Drainage	n.r.	5.95 3.967

n.r. not required

a Respective single applications are covered by the use above

Table 8.9-13: FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} for prothioconazole metabolite prothioconazole-desthio (M04) following one or two applications to oilseed rape (winter and spring) at 140 g prothioconazole/ha

Scenario	Season of application	Max PEC _{SW} (µg/L)	Dominant entry route	21 d-PEC _{SW, t_{wa}} (µg/L)	Max PEC _{SED} (µg/kg)
FOCUS					
1 × 140 g a.s./ha, BBCH 61-69					
Step 1	-	27.423	Runoff/Drainage	n.r.	153.613
Step 2					
Northern Europe	March-May	1.075	Runoff/Drainage	n.r.	5.837
	June-September	1.075	Runoff/Drainage	n.r.	5.837
Southern Europe	March-May	1.746	Runoff/Drainage	n.r.	9.682
	June-September	1.411	Runoff/Drainage	n.r.	7.759
2 × 140 g a.s./ha, BBCH 61-73 ^a					
Step 1	-	54.845	Runoff/Drainage	n.r.	307.225
Step 2					
Northern Europe	March-May	1.736	Runoff/Drainage	n.r.	9.413
	June-September	1.736	Runoff/Drainage	n.r.	9.413
Southern Europe	March-May	2.802	Runoff/Drainage	n.r.	15.522
	June-September	2.269	Runoff/Drainage	n.r.	12.468

n.r. not required

a Respective single applications are covered by the use above

Table 8.9-14: FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} for prothioconazole metabolite 1,2,4-triazole (M13) following one or two applications to oilseed rape (winter and spring) at 140 g prothioconazole/ha

Scenario	Season of application	Max PEC _{SW} (µg/L)	Dominant entry route	21 d-PEC _{SW, t_{wa}} (µg/L)	Max PEC _{SED} (µg/kg)
FOCUS					
1 × 140 g a.s./ha, BBCH 61-69					
Step 1	-	3.63 3.402	Runoff/Drainage	n.r.	3.00 2.814
Step 2					
Northern Europe	March-May	0.113	Spray drift	n.r.	0.092
	June-September	0.113	Spray drift	n.r.	0.092
Southern Europe	March-May	0.137	Spray drift	n.r.	0.111
	June-September	0.125	Spray drift	n.r.	0.101
2 × 140 g a.s./ha, BBCH 61-73 ^a					
Step 1	-	7.27 6.804	Runoff/Drainage	n.r.	6.01 5.627
Step 2					
Northern Europe	March-May	0.189	Spray drift	n.r.	0.153
	June-September	0.189	Spray drift	n.r.	0.153
Southern Europe	March-May	0.222	Spray drift	n.r.	0.180
	June-September	0.206	Spray drift	n.r.	0.166

n.r. not required

a Respective single applications are covered by the use above

Table 8.9-15: Maximum PEC_{SW} and PEC_{SED} actual of prothioconazole and prothioconazole-desthio (M04), after two or one applications to oilseed rape (winter) at 140 g a.s./ha (FOCUS Step 3) ^a

Scenario FOCUS	Waterbody	Prothioconazole			Prothioconazole-desthio (M04)	
		Max PEC _{SW} (µg/L)	Dominant entry route	Max PEC _{SED} (µg/kg)	Max PEC _{SW} (µg/L) ^b	Max PEC _{SED} (µg/kg)
Oilseed rape, winter, 2 × 140 g prothioconazole/ha						
D2	ditch	1.195	drift	4.843	0.232	2.355
D2	stream	1.045	drift	4.077	0.212	1.690
D3	ditch	0.778	drift	0.961	0.044 0.014	0.221
D4	pond	0.044	drift	0.248	0.010 0.015	0.245
D4	stream	0.662	drift	0.187	0.022 0.008	0.032
D5	pond	0.044	drift	0.252	0.010 0.016	0.301
D5	stream	0.714	drift	0.260	0.032 0.014	0.045
R1	pond	0.048	drift	0.286	0.040 0.016	0.275
R1	stream	0.506	drift	0.978	0.614 0.005	0.524
R3	stream	0.711	drift	0.276	0.408 0.022	0.097
Oilseed rape, winter, 1 × 140 g prothioconazole/ha						
D2	ditch	0.896	drift	2.856	0.129	1.555
D2	stream	0.798	drift	2.450	0.120	1.153
D3	ditch	0.887	drift	0.726	0.036 0.011	0.109
D4	pond	0.031	drift	0.155	0.007 0.009	0.157
D4	stream	0.765	drift	0.160	0.026 0.009	0.019
D5	pond	0.031	drift	0.162	0.006 0.010	0.193
D5	stream	0.826	drift	0.223	0.036 0.015	0.027
R1	pond	0.034	runoff	0.212	0.056 0.011	0.200
R1	stream	0.584	drift	0.983	0.173 0.006	0.510
R3	stream	0.823	drift	0.194	0.216 0.019	0.025

n.r. not relevant

a Respective single application also presented, covering use #2

b The PEC_{SW} of prothioconazole-desthio (M04) is the critical PEC_{SW} for the aquatic risk assessment. In all cases, it is resulting from the combination of parent DT_{50, water} = 24.1 d & DT_{50, sediment} = 1000 d with metabolite DT_{50, water} = 1000 d & DT_{50, sediment} = 49.9 d.

Please note that in accordance with the central zone working document on efate⁷, the D2 scenario is not relevant for the central zone and, therefore, PEC values for this scenario are not considered in the aquatic risk assessment.

Table 8.9-16: Maximum PEC_{SW} and PEC_{SED} actual of prothioconazole and prothioconazole-desthio (M04), after two or one applications to oilseed rape (spring) at 140 g a.s./ha (FOCUS Step 3) ^a

Scenario FOCUS	Waterbody	Prothioconazole			Prothioconazole-desthio (M04)	
		Max PEC _{SW} (µg/L)	Dominant entry route	Max PEC _{SED} (µg/kg)	Max PEC _{SW} (µg/L) ^b	Max PEC _{SED} (µg/kg)
Oilseed rape, spring, 2 × 140 g prothioconazole/ha						
D1	ditch	1.182	drift	4.568	0.169	2.095
D1	stream	0.678	drift	0.526	0.023	0.079
D3	ditch	0.779	drift	0.998	0.047 0.015	0.220
D4	pond	0.044	drift	0.248	0.010 0.015	0.240
D4	stream	0.662	drift	0.187	0.022 0.008	0.032
D5	pond	0.044	drift	0.252	0.010 0.016	0.302
D5	stream	0.714	drift	0.259	0.032 0.014	0.044
R1	pond	0.060	runoff	0.421	0.126 0.021	0.390
R1	stream	0.506	drift	1.974	0.519 0.008	1.074
Oilseed rape, spring, 1 × 140 g prothioconazole/ha						
D1	ditch	0.896	drift	2.679	0.101	1.339
D1	stream	0.783	drift	0.445	0.026	0.050
D3	ditch	0.888	drift	0.771	0.043 0.013	0.122
D4	pond	0.031	drift	0.155	0.009	0.154
D4	stream	0.765	drift	0.160	0.026 0.009	0.019
D5	pond	0.031	drift	0.162	0.006 0.010	0.193
D5	stream	0.825	drift	0.220	0.036 0.015	0.026
R1	pond	0.044	runoff	0.258	0.052 0.012	0.236
R1	stream	0.585	drift	1.216	0.207 0.008	0.607

n.r. not relevant

^a Respective single application also presented, covering use #2

^b The PEC_{SW} of prothioconazole-desthio (M04) is the critical PEC_{SW} for the aquatic risk assessment. In all cases, it is resulting from the combination of parent DT_{50, water} = 24.1 d & DT_{50, sediment} = 1000 d with metabolite DT_{50, water} = 1000 d & DT_{50, sediment} = 49.9 d.

⁷ Working Document of the Central Zone in the Authorisation of Plant Protection Products - Part B section 8 - Environmental fate and behaviour. Version 1 rev. 1 – June 2018

Please note that in accordance with the central zone working document on efate⁸, the D1 scenario is not relevant for the central zone and, therefore, PEC values for this scenario are not considered in the aquatic risk assessment.

Sunflower

Additional PEC_{SW} modelling for the use on sunflower is presented here considering application at BBCH 61-73 at the same application rate as for oilseed rape, i.e. 0.7 kg product/ha, equivalent to 245 g boscalid/ha and 140 g prothioconazole/ha.. The crop sunflower is defined for FOCUS scenarios D5, R1, R3 and R4, all of which are representative for the central zone according to the central zone working document for fate and behaviour (2018). D3 and D4 are also representative scenarios for the central zone and to cover these two scenarios, additional modelling using maize as a surrogate crop is presented. The application details are presented below in **Tables 8.9-17** and **8.9-18**.

Input parameters related to the active substances are the same as used for modelling oilseed rape and are as presented in **Table 8.9-4** (boscalid) and in **Tables 8.9-8** (prothioconazole), **8.9.2-9** (prothioconazole-S-methyl (M01)) and **8.9.2-10** (prothioconazole-S-methyl (M01) and 1,2,4-triazole (M13)).

Table 8.9-17: Input parameters for application to sunflower for PEC_{SW/SED} calculations

Plant protection product	FGE03	
FOCUS Crop	Sunflower	Maize, as surrogate for D3 and D4
Application rate (g a.s./ha)	Boscalid: 245 g a.s./ha Prothioconazole: 140 g a.s./ha	
Number of applications/interval (d)	2 / 14	
Application timing	BBCH 61-73	
Application period (Step 2)	Mar.-May & June-Sep.	
Crop interception (Step 2)	Full canopy	
Application window (Step 3)	Please see Tables 8.9.2-18 Length of application window: 1 application: 30 d 2 applications 44 d	
FOCUS Locations	Step 1: not relevant Step 2: north and south EU Step 3: D5, R1, R3 and R4	Step 1: not relevant Step 2: north and south EU Step 3: D3 & D4
Application method (Step 3)	Ground spray	
CAM (Chemical application method) (Step 3)	2	
Soil depth (cm) (Step 3)	4	
Models used for calculation	STEP 1-2 v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXSWA v5.5	

⁸ Working document of the central zone in the authorisation of plant protection products. Section 8, Environmental fate and behaviour. Version 1 rev. 1 – June 2018

Table 8.9-18: FOCUS Step 3 scenario related input parameters for PEC_{SW/SED} calculations for the application of FGE03, sunflower

Scenario	Dates according to AppDate v3.06 ^a	Application window used in modelling	
		Single application	Two applications
	Maize (as surrogate), BBCH 61-73		
D3	BBCH 61: 11/08; BBCH 73: 28/08	11/08 (223) – 10/09 (253)	15/07 (196) – 28/08 (240)
D4	BBCH 61: 19/08; BBCH 73: 29/08	19/08 (231) – 18/09 (261)	16/07 (197) – 29/08 (241)
	Sunflower, BBCH 61-73		
D5	BBCH 61: 12/07; BBCH 73: 02/08	12/07 (193) – 11/08 (223)	19/06 (170) – 02/08 (214)
R1	BBCH 61: 07/07; BBCH 73: 30/07	07/07 (188) – 06/08 (218)	16/06 (167) – 30/07 (211)
R3	BBCH 61: 28/06; BBCH 73: 02/08	28/06 (179) – 28/07 (209)	19/06 (170) – 02/08 (214)
R4	BBCH 61: 22/06; BBCH 73: 16/07	22/06 (173) – 22/07 (203)	02/06 (153) – 16/07 (197)

^a Application date for BBCH 61 and 73 taken from AppDate v3.06

The application dates are taken from the AppDate tool and, for single applications, are set to start from BBCH 61 and are sufficiently long to cover the BBCH range of 61-73. For two applications, the second application is set to take place at the last application stage of BBCH 73 and the application window works backwards 44 days to the first application. This more than covers the application window.

FOCUS Step 1-2 results are presented in the following tables:

- **Tables 8.9-19** – Boscalid, one and two applications to sunflower
- **Tables 8.9-20** – Prothioconazole, one and two applications to sunflower
- **Tables 8.9-21** – Prothioconazole metabolite prothioconazole-S-methyl (M01), one and two applications to sunflower
- **Tables 8.9-22** – Prothioconazole metabolite prothioconazole-desthio (M04), one and two applications to sunflower
- **Tables 8.9-23** – Prothioconazole metabolite 1,2,4-triazole (M13), one and two applications to sunflower

Table 8.9-19: FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} for active substance boscalid following two applications to sunflower at 245 g a.s./ha

Scenario	Season of application	Max PEC _{SW} (µg/L) Multiple / single application	Dominant entry route	21 d-PEC _{SW, twa} (µg/L)	Max PEC _{SED} (µg/kg) Multiple / single application
FOCUS					
Sunflower, 2 × 245 g a.s./ha, BBCH 61-73					
Step 1	-	86.556	Runoff/Drainage	n.r.	621.642
Step 2					
Northern Europe	March-May	6.151 / 3.337	Runoff/Drainage	n.r.	42.925 / 23.166
	June-September	6.151 / 3.337	Runoff/Drainage	n.r.	42.925 / 23.166
Southern Europe	March-May	10.037 / 5.348	Runoff/Drainage	n.r.	71.777 / 38.095
	June-September	8.094 / 4.342	Runoff/Drainage	n.r.	57.351 / 30.630

n.r. not required

Table 8.9-20: FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} for active substance prothioconazole following two applications to sunflower at 140 g a.s./ha

Scenario FOCUS	Season of application	Max PEC _{SW} (µg/L) Multiple / single application	Dominant entry route	21 d- PEC _{SW, twa} (µg/L)	Max PEC _{SED} (µg/kg) Multiple / single application
Sunflower, 2 × 140 g a.s./ha, BBCH 61-73					
Step 1	-	30.408	Runoff/Drainage	n.r.	491.253
Step 2					
Northern Europe	March-May	1.505 / 1.288	Spray drift	n.r.	11.746 / 7.652
	June-September	1.505 / 1.288	Spray drift	n.r.	11.746 / 7.652
Southern Europe	March-May	1.505 / 1.288	Spray drift	n.r.	12.964 / 8.870
	June-September	1.505 / 1.288	Spray drift	n.r.	12.355 / 8.261

n.r. not required

Table 8.9-21: FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} for prothioconazole metabolite prothioconazole-S-methyl (M01) following two applications to sunflower at 140 g prothioconazole/ha

Scenario FOCUS	Season of application	Max PEC _{SW} (µg/L) Multiple / single application	Dominant entry route	21 d- PEC _{SW, twa} (µg/L)	Max PEC _{SED} (µg/kg) Multiple / single application
Sunflower, 2 × 140 g a.s./ha, BBCH 61-73					
Step 1	-	6.41 3.247	Runoff/Drainage	n.r.	155.20 82.006
Step 2					
Northern Europe	March-May	0.20 / 0.17 0.105 / 0.068	Runoff/Drainage	n.r.	4.54 / 2.87 2.644 / 1.718
	June-September	0.20 / 0.17 0.105 / 0.068	Runoff/Drainage	n.r.	4.54 / 2.87 2.644 / 1.718
Southern Europe	March-May	0.32 / 0.20 0.209 / 0.136	Runoff/Drainage	n.r.	7.36 / 4.77 5.289 / 3.437
	June-September	0.26 / 0.17 0.157 / 0.102	Runoff/Drainage	n.r.	5.95 / 3.82 3.967 / 2.577

n.r. not required

Table 8.9-22: FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} for prothioconazole metabolite prothioconazole-desthio (M04) following two applications to sunflower at 140 g prothioconazole/ha

Scenario FOCUS	Season of application	Max PEC _{SW} (µg/L) Multiple / single application	Dominant entry route	21 d- PEC _{SW, twa} (µg/L)	Max PEC _{SED} (µg/kg) Multiple / single application
Sunflower, 2 × 140 g a.s./ha, BBCH 61-73					
Step 1	-	54.845	Runoff/Drainage	n.r.	307.225
Step 2					
Northern Europe	March-May	1.736 / 1.075	Runoff/Drainage	n.r.	9.413 / 5.837
	June-September	1.736 / 1.075	Runoff/Drainage	n.r.	9.413 / 5.837
Southern Europe	March-May	2.802 / 1.746	Runoff/Drainage	n.r.	15.522 / 9.682
	June-September	2.269 / 1.411	Runoff/Drainage	n.r.	12.468 / 7.759

n.r. not required

Table 8.9-23: FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} for prothioconazole metabolite 1,2,4-triazole (M13) following one or two applications to sunflower at 140 g prothioconazole/ha

Scenario FOCUS	Season of application	Max PEC _{SW} (µg/L) Multiple / single application	Dominant entry route	21 d- PEC _{SW, TWA} (µg/L)	Max PEC _{SED} (µg/kg) Multiple / single application
Sunflower, 2 × 140 g a.s./ha, BBCH 61-73					
Step 1	-	7.27 6.894	Runoff/Drainage	n.r.	6.01 5.627
Step 2					
Northern Europe	March-May	0.189 / 0.113	Spray drift	n.r.	0.153 / 0.092
	June-September	0.189 / 0.113	Spray drift	n.r.	0.153 / 0.092
Southern Europe	March-May	0.222 / 0.137	Spray drift	n.r.	0.180 / 0.111
	June-September	0.206 / 0.125	Spray drift	n.r.	0.166 / 0.101

n.r. not required

FOCUS Step 3 results are presented in the following tables:

- **Tables 8.9-24** – Boscalid, two and one applications to sunflower
- **Tables 8.9-25** – prothioconazole and prothioconazole-desthio (M04), two and one applications to sunflower

Table 8.9-24: FOCUS Step 3 maximum PEC_{SW} and PEC_{SED} actual of boscalid after two or one applications to sunflower at 245 g a.s./ha^a

Scenario FOCUS	Waterbody	Max PEC _{SW} (µg/L)	Dominant entry route	21 d- PEC _{SW, TWA} (µg/L)	Max PEC _{SED} (µg/kg)
Sunflower, 2 × 245 g boscalid/ha					
D3 ^a	ditch	1.115 ^b	drift	n.r.	0.868 ^c
D4 ^a	pond	0.925 ^b	drainage	n.r.	7.481 ^c
D4 ^a	stream	1.607 ^b	drainage	n.r.	2.679 ^c
D5	pond	0.278 ^b	drainage	n.r.	2.578 ^c
D5	stream	1.081 ^b	drift	n.r.	0.660 ^c
R1	pond	0.535 ^b	runoff	n.r.	4.560 ^c
R1	stream	3.090 ^b	runoff	n.r.	5.517 ^c
R3	stream	2.599 ^b	runoff	n.r.	6.454 ^c
R4	stream	3.917 ^b	runoff	n.r.	3.637 ^c
Sunflower, 1 × 245 g boscalid/ha					
D3 ^a	ditch	1.285 ^b	drift	n.r.	0.824 ^c
D4 ^a	pond	0.225 ^b	drainage	n.r.	2.064 ^c
D4 ^a	stream	1.031 ^b	drift	n.r.	0.690 ^c
D5	pond	0.082 ^b	drainage	n.r.	0.821 ^c
D5	stream	1.256 ^b	drift	n.r.	0.334 ^c
R1	pond	0.205 ^b	runoff	n.r.	1.914 ^c
R1	stream	1.271 ^b	runoff	n.r.	1.290 ^c
R3	stream	1.544 ^b	runoff	n.r.	4.409 ^c
R4	stream	2.294 ^b	runoff	n.r.	2.062 ^c

n.r. not relevant

^a Maize run as a surrogate for D3 & D4 scenarios

^b Combination of DT_{50, water} = 1000 d and DT_{50, sediment} = 90 d

^c Combination of DT_{50, water} = 90 d and DT_{50, sediment} = 1000 d

Table 8.9-25: Maximum PEC_{SW} and PEC_{SED} actual of prothioconazole and prothioconazole-desthio (M04), after two or one applications to sunflower at 140 g a.s./ha (FOCUS Step 3) ^a

Scenario FOCUS	Waterbody	Prothioconazole			Prothioconazole-desthio (M04)	
		Max PEC _{SW} (µg/L)	Dominant entry route	Max PEC _{SED} (µg/kg)	Max PEC _{SW} (µg/L) ^b	Max PEC _{SED} (µg/kg)
Sunflower, 2 × 140 g prothioconazole/ha						
D3 ^a	ditch	0.636	drift	0.575	0.029 0.009	0.113
D4 ^a	pond	0.037	drift	0.240	0.009 0.011	0.206
D4 ^a	stream	0.564	drift	0.083	0.027 0.006	0.011
D5	pond	0.042	drift	0.242	0.015	0.269
D5	stream	0.617	drift	0.225	0.029 0.012	0.039
R1	pond	0.058	runoff	0.357	0.095 0.019	0.341
R1	stream	0.437	drift	1.450	0.544 0.007	0.750
R3	stream	0.617	drift	0.645	0.421 0.017	0.383
R4	stream	0.437	drift	0.453	0.677 0.011	0.245
Sunflower, 1 × 140 g prothioconazole/ha						
D3 ^a	ditch	0.733	drift	0.532	0.033 0.010	0.071
D4 ^a	pond	0.030	drift	0.164	0.030 0.006	0.123
D4 ^a	stream	0.588	drift	0.022	0.015 0.006	0.002
D5	pond	0.030	drift	0.151	0.009	0.172
D5	stream	0.716	drift	0.193	0.034 0.014	0.024
R1	pond	0.031	drift	0.175	0.014 0.009	0.186 0.169
R1	stream	0.502	drift	0.366	0.164 0.006	0.166
R3	stream	0.716	runoff	0.483	0.222 0.019	0.283
R4	stream	0.508	drift	0.285	0.462 0.010	0.137

n.r. not relevant

a Maize run as a surrogate for D3 & D4 scenarios

b The PEC_{SW} of prothioconazole-desthio (M04) is the critical PEC_{SW} for the aquatic risk assessment. In all cases, it is resulting from the combination of parent DT_{50, water} = 24.1 d & DT_{50, sediment} = 1000 d with metabolite DT_{50, water} = 1000 d & DT_{50, sediment} = 49.9 d.

zRMS comments:

Input parameters presented in Table 8.9-8 to 8.9-10 used in the surface water modelling for prothioconazole and its metabolites are in general in line with EU agreed endpoints with following remarks:

- For prothioconazole DT_{50} in water/sediment of 24.1 days was used instead of 1.0 day agreed in the course of the EU review. Nevertheless, this deviation is not expected to have significant impact on the obtained results.
- For the metabolite JAU 6476 S-Methyl in the aerobic water/sediment study the maximum occurrence of 12.7% in the whole system is observed, while in the anaerobic study 77% only in sediment. Thus, respective information were added to the Table 8.9-10 and used in the independent zRMS calculations for this metabolite at Step 1-2.
- For the metabolite 1,2,4-triazole - the maximum occurrence of 41.8% was observed in the whole system. Respective information were added to the Table 8.9-10 and used in the independent zRMS calculations for this metabolite at Step 1-2.
- For metabolites JAU 6476 S-methyl and JAU 6476-desthio and 1,2,4-Triazole the geometric instead of arithmetic mean K_{foc} values were used. However, this deviation is agreed by the zRMS, as the geometric mean K_{foc} values are lower than arithmetic mean values and represent thus worst case in terms of the potential leaching. Moreover, consideration of geometric mean K_{foc} values is in line with current EFSA recommendations.

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

Simulations performed for winter oilseed rape (major crop) are considered to cover the surface water exposure for minor crops: gold of pleasure, winter turnip rape, mustard, poppy, linseed, flax, hemp, borage.

Since for sunflower not all relevant to the central zone scenarios are defined maize was used as the surrogate crop for missing D3 and D4 scenarios and it is accepted by the zRMS. The application pattern presented in Table 8.9-17 assumed in surface water simulations for sunflower is in line with Central Zone GAP presented in Table 8.1-1, and the application windows presented in Table 8.9-18 were checked by the zRMS using AppDate ver. 3.06 tool and are considered acceptable.

The surface water exposure at Step 1-3 was independently validated by the zRMS in additional modelling using the same parameters as indicated above and only relevant scenarios in the central zone were validated, therefore results presented for D1 and D2 scenarios were struck through as not relevant.

Results obtained by the zRMS of PEC_{sw} and PEC_{sed} for prothioconazole were in good agreement with values calculated by the Applicant. Overall, values presented in tables: 8.9-11, 8.9-15, 8.9-16 and 8.9-20 may be used further in the aquatic risk assessment.

Results obtained by the zRMS for prothioconazole metabolite JAU 6476 S-Methyl at Step 1-2 were considerably higher comparing to these obtained by the Applicant since higher maximum occurrence in the whole system (12.7%) was considered by the zRMS calculations. Thus, values reported in Tables 8.9-12 and 8.9-21 were corrected by the zRMS and may be used for purposes of the aquatic risk assessment.

Results for prothioconazole metabolite 1,2,4-triazole calculated by the zRMS at Steps 1 were higher to these obtained by the Applicant since higher maximum occurrence in the whole system (41.8%) was considered by the zRMS. Thus, values reported in Tables 8.9-14 and 8.9-23 were corrected by the zRMS and may be used for purposes of the aquatic risk assessment.

Results for prothioconazole metabolite JAU 6476-desthio obtained by the zRMS at Step 1-2 were in good agreement with values calculated by the Applicant. Whereas at Step 3 PEC_{sw} values calculated by the zRMS in independent modelling were considerably higher comparing to these obtained by the Applicant. Thus, values reported in Tables 8.9-15, 8.9-16 and 8.9-25 were corrected by the zRMS. Since obtained PEC_{sw} values at Step 3 were above the RAC of 0.334 $\mu\text{g/L}$ for metabolite JAU 6476-desthio, additional Step 4 calculations with consideration of 10 m vegetative strips were performed mainly for R1 stream, R3 stream and R4 stream scenarios.

Step 4 simulations were performed according to recommendations of the FOCUS work group on landscape and mitigation factors. Obtained results are presented in table below and may be used in the aquatic risk assessment.

FOCUS STEP 4 Max PEC_{sw} (µg/L) for metabolite JAU 6476-desthio considering application of 140 g a.s./ha at BBCH 61 for winter and spring oilseeds rape and sunflower

STEP 4		PEC _{sw} (µg/L)	
Run-off reduction in line with FOCUS L&M		10 m	
		Winter oilseed rape 2 x 140 g a.s./ha	Spring oilseed rape 2 x 140 g a.s./ha
R1	Stream	0.278	0.237
R3	Stream	0.182	-
		Sunflower 2 x 140 g a.s./ha	Sunflower 1 x 140 g a.s./ha
R1	Stream	0.247	-
R3	Stream	0.192	-
R4	Stream	0.307	0.210

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

8.9.2.3 PEC_{sw/sed} of FGE03 (GPF515)

Since the formulation contains more than one active substance, the PEC_{sw} of the formulation was calculated based on the single application of formulation (0.7 kg/ha).

The PEC for surface water were calculated with FOCUS drift calculator v.1 in FOCUS SWASH v 5.3; for stream (upstream catchment area not accounted for).

Table 8.9-18: PEC_{sw} of FGE03

Crop	Application rate [g/ha]	Number of applications / interval	Areal mean deposition [% of application rate]	Distance [m]	PEC _{sw} [µg/L]
All uses, worst case single application	700	1 / -	1.4304	1	4.49 2.238

zRMS comments:

Recalculation of the surface water exposure to the formulated product performed by the zRMS using Spray Drift Calculator and application rate of 700 g/ha resulted with slightly higher PEC_{sw} values for 1 m distance

Obtained PEC_{sw} results for the formulated product calculated by the zRMS for different buffer distances are presented in table below:

Application rate [g product/ha] ^A	Crop	Drift buffer [m]	Drift rate [%]	Initial PEC _{sw} [µg product/L]
700	Field crop: oilseed rape / sunflower	1 application (90 th percentile drift)		
		1	2.77	4.49
		3	0.95	1.90
		5	0.59	1.22
		10	0.29	0.65

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

Active substance boscalid

Table 8.10-1: Summary of atmospheric degradation and behaviour - boscalid

Compound	Boscalid
Direct photolysis in air	Photolytically stable in water. Photolysis in air not expected. Not stable under influence of radicals, (see DT ₅₀ photochemical oxidative degradation).
Quantum yield of direct phototransformation	$< 2.45 \times 10^{-4}$
Photochemical oxidative degradation in air	DT ₅₀ : < 1.1 d AOPWIN Version 1.88, [OH radicals] = $8 \times 10^5 \text{ cm}^{-3}$
Volatilisation	Vapour pressure (Pa): 7.2×10^{-7} Henry's Law Constant (Pa.m ³ /mol): 5.178×10^{-5}
Metabolites	No data available.

The vapour pressure at 20 °C of the active substance boscalid is $< 10^{-5}$ Pa. Hence the active substance boscalid is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance boscalid due to volatilisation with subsequent deposition does not need to be considered.

Active substance prothioconazole

Table 8.10-2 Summary of atmospheric degradation and behaviour - 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	<u>Prothioconazole:</u> Half-life: 1.1 hours Chemical lifetime: 1.6 hours Calculated according to Atkinson (AOPWIN v. 1.87, 12 hour day, 1.5×10^6 OH radicals/cm ³) <u>Prothioconazole-desthio (M04):</u> Half-life: 14.2 hours Chemical lifetime: 20.5 hours Calculated according to Atkinson (AOPWIN v. 1.87, 12 hour day, 1.5×10^6 OH radicals/cm ³)
Volatilisation	Vapour pressure (Pa): $< 4 \times 10^{-7}$ Pa at 20°C Henry's Law Constant (Pa.m ³ /mol): $< 3 \times 10^{-5}$ Pa.m ³ /mol at 20°C 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	No data available.

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

zRMS comments:

Provided above information is in line with EU agreed data reported in the EU Review Report SANCO/3919/2007-rev.5 and in EFSA Scientific Report (2007) 106, 1-98 for boscalid and prothioconazole. Taking into account the low vapour pressure ($< 10^{-5}$ Pa) and DT₅₀ in air < 2 days, boscalid and prothioconazole are not expected to be subject to volatilisation and the long- or short-range transport. Taking this into account the contamination of the atmosphere with boscalid and prothioconazole from the intended uses of FGE03 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 9.2.4.1/01	Šulc, A.	2024a	Report on calculation of Predicted Environmental Concentrations of boscalid, prothioconazole and their metabolites in groundwater (PEC _{gw}) - FGE03 (GPF515) / Central Zone - GW-213-220810CZ-01 Vali Consulting GmbH, Rossdorf, Germany non GLP Unpublished	N	UPL Europe
KCP 9.2.5/01	Šulc, A.	2024b	Report on Predicted Environmental Concentrations of boscalid, prothioconazole and their metabolites in Surface Water and Sediment (PEC _{sw} and PEC _{sed}) - FGE03 (GPF515) / Central Zone - SW-213-220810CZ-01 Vali Consulting GmbH, Rossdorf, Germany non GLP Unpublished	N	UPL Europe

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
All endpoints for the active substances and their metabolites were taken from the EU review of boscalid and of prothioconazole.					

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the new Annex II studies

A 2.1 Study 1

Comments of zRMS:	The ground water modelling for boscalid and prothioconazole and its metabolites has been accepted by the zRMS. For evaluation of the input parameters, please refer to points 8.8.2.1 for boscalid and 8.8.2.2 for prothioconazole.
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Reference:	KCP 9.2.4.1/01
Report	Report on calculation of Predicted Environmental Concentrations of boscalid, prothioconazole and their metabolites in groundwater (PEC _{GW}) - FGE03 (GPF515) / Central Zone -. Šulc A., 2024a, Report No.: GW-213-220810CZ-01
Guideline(s):	SANCO/13144/2010, version 3, 10 October 2014 Generic Guidance for Tier 1 FOCUS Ground Water Assessment, version 2.4, March 2023
Deviations:	Not relevant
GLP:	Not applicable, computer modelling study. No laboratory work was conducted.
Acceptability:	Yes

Materials and methods

A PEC_{GW} calculation was performed for the product FGE03 (GPF515) according to the FOCUS GW report (2014) and the FOCUS Generic Guidance (2023) in order to predict concentration of residues in groundwater.

FGE03 is a WG formulated fungicide containing 350 g/kg of boscalid and 200 g/kg prothioconazole. It is applied to winter and spring oilseed rape from BBCH 61-69 (single application) or from BBCH 61-73 (two applications) at an application rate of 0.7 kg product/ha. This is equivalent to 245 g/ha boscalid and 140 g/ha prothioconazole per application.

PEC_{GW} values for boscalid and for prothioconazole and its metabolites M01 and M04 are derived from calculations using the modelling software FOCUS PEARL 5.5.5 and FOCUS PELMO 6.6.4. FOCUS MACRO 5.5.4 should be modelled for the Châteaudun scenario when FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5 calculations give PEC_{GW} above 0.001 µg/L. All crop-relevant FOCUS site scenarios were considered within the present calculations and were parameterised using maximum application rates of the product.

Application details are summarised in **Tables 8.8-1 to 8.8-3**.

The PEC_{GW} values have been assessed with the endpoints established in the EU review. The review report for boscalid (SANCO/3919/2007 – rev. 5) and the EFSA conclusions and LoEP for prothioconazole (EFSA Scientific Report (2007) 106, 1-98) are considered to provide the relevant review information or a reference to where such information can be found.

The input parameters for boscalid are presented in **Table 8.8-4** and for prothioconazole and metabolites M01 and M04 in **Tables 8.8-6 and 8.8-7**.

Results and discussions

Results are reported in **Table 8.8-5** for boscalid and **8.8-8** for prothioconazole and metabolites M01 and M04.

Boscalid, prothioconazole and the prothioconazole metabolites prothioconazole-S-methyl (M01) & prothioconazole-desthio (M04) are not predicted to leach into ground water above the critical 0.1 µg/L threshold following a 26-year period of application to winter and spring oilseed rape.

Calculation of PEC_{GW} with FOCUS MACRO 5.5.4 was not considered required as PEC_{GW} concentrations with FOCUS PEARL and FOCUS PELMO were < 0.001 µg/L for all scenarios and substances.

Conclusion

From the results estimated by FOCUS recommended models, it can be foreseen that no risk is anticipated for groundwater for the active substances or metabolites when the product is used according to the proposed GAP in winter and spring oilseed rape.

The results indicate that any contamination of groundwater at concentrations relevant for the environment and for consumer exposure by the active substances boscalid and prothioconazole and metabolites must not be expected following the GAP proposed uses of FGE03 (GPF515).

A 2.2 Study 2

Comments of zRMS:	The surface water modelling for boscalid and prothioconazole and its metabolites has been partly accepted by the zRMS. For detailed evaluation please refer to points 8.9.2.1 for boscalid and 8.9.2.2 for prothioconazole.
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Reference:	KCP 9.2.5/01
Report	Report on Predicted Environmental Concentrations of boscalid, prothioconazole and their metabolites in Surface Water and Sediment (PEC _{sw} and PEC _{sed}) - FGE03 (GPF515) / Central Zone -. Šulc, A., 2024b, Report No.: SW-213-220810CZ-01
Guideline(s):	SANCO/4802/2001, version 2, May 2003 Generic Guidance for FOCUS Surface Water Scenarios, version 1.4, May 2015
Deviations:	Not relevant
GLP:	Not applicable, computer modelling study. No laboratory work was conducted.
Acceptability:	Yes

Materials and methods

A PEC_{SW} calculation was performed for the product FGE03 (GPF515) according to the FOCUS SW report (2001) and the FOCUS Generic Guidance (2015).

FGE03 (GPF515) is a fungicide containing 350 g/kg of boscalid and 200 g/kg prothioconazole. It is applied to winter and spring oilseed rape from BBCH 61-69 (single application) or from BBCH 61-73 (two applications) at an application rate of 0.7 kg product/ha. This is equivalent to 245 g/ha boscalid and 140 g/ha prothioconazole per application.

PEC_{SW} and PEC_{SED} values for boscalid and for prothioconazole and its metabolites for FOCUS evaluation steps 1 and 2 were calculated using the modelling software STEPS 1-2 (version 3.2). Within the scope of evaluation steps 3 and 4 with boscalid, prothioconazole and its metabolite prothioconazole-desthio (M04), for every main entry route, different software was used as recommended, i.e. FOCUS SWASH 5.3, Drift

calculator 1.1 (spray drift), MACRO 5.5.4 (drainage) and PRZM 4.3.1 (runoff). Based on the different pesticide inputs calculated, TOXSWA 5.5 was used to simulate the fate of pesticide entries in typical surface water bodies and finally to calculate maximum as well as actual and time weighted average concentrations in water layer and sediment for different dates or periods.

Application data are summarised in **Table 8.9-1**.

The PEC_{SW} and PEC_{SED} values have been assessed with the endpoints established in the EU review. The review report for boscalid (SANCO/3919/2007 – rev. 5) and the EFSA conclusions and LoEP for prothioconazole (EFSA Scientific Report (2007) 106, 1-98) are considered to provide the relevant review information or a reference to where such information can be found.

The input parameters for boscalid are presented in **Table 8.9-4**. For boscalid, its metabolite M510F64 occurred at amounts >5% in 2 sequential measurements in the higher-tier outdoor water/sediment study presented for the original approval of boscalid. Metabolite M510F64 reached maximum 9.4% TAR after 30 days in the water phase. Additionally this compound is of no toxicological and ecotoxicological relevance. Following the approaches taken for the currently authorised products containing boscalid, no exposure assessment was presented for metabolite M510F64. No other metabolites potentially relevant for exposure assessment have been observed.

The input parameters for prothioconazole and its metabolites in **Tables 8.9-8 to 8.9-10**. For parent prothioconazole and metabolite prothioconazole-desthio (M04), the K_{OC} values are between 100 and 2000 mL/g and guidance indicates that 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. This would result in four possible combinations for parent and metabolite modelling:

Substance	Endpoint	Possible combinations			
Parent	DT ₅₀ (water)	System DT ₅₀	System DT ₅₀	Default DT ₅₀	Default DT ₅₀
	DT ₅₀ (sediment)	Default DT ₅₀	Default DT ₅₀	System DT ₅₀	System DT ₅₀
Metabolite	DT ₅₀ (water)	System DT ₅₀	Default DT ₅₀	System DT ₅₀	Default DT ₅₀
	DT ₅₀ (sediment)	Default DT ₅₀	System DT ₅₀	Default DT ₅₀	System DT ₅₀

It is clear that for the water compartment, simulating the shorter system DT₅₀ for the parent combined with the longer default DT₅₀ for the metabolite will result in worst case PEC_{SW} for the metabolite. As the aquatic risk assessment is driven by the metabolite and its risk to water and not sediment, this worst case combination was chosen for modelling – set 1 in **Tables 8.9-8 and 8.9-9**. The opposite combination of longer default DT₅₀ for the parent combined with the shorter system DT₅₀ for the metabolite was simulated to provide worst case PEC_{SED} values – set 2 in **Tables 8.9-8 and 8.9-9**.

Results and discussions

The results of FOCUS Step 1 and 2 calculations are summarised in **Tables 8.9-5 (boscalid), 8.9-11 (prothioconazole), 8.9-12 (prothioconazole-S-methyl (M01)), 8.9-13 (prothioconazole-desthio (M04)) and 8.9-14 (1,2,4-triazole (M13))**.

The results of FOCUS Step 3 calculations are presented in **Tables 8.9-6 to 8.9-7 (boscalid) and 8.9-15 to 8.9-16 (prothioconazole and prothioconazole-desthio (M04))**.

Conclusion

For the active substance boscalid FOCUS Step 1-2 and Step 3 were conducted. For the active substance prothioconazole and its metabolite prothioconazole-desthio (M04), FOCUS Step 1-2 and Step 3 were conducted. For the other metabolites of prothioconazole, i.e. prothioconazole-S-methyl (M01) and 1,2,4-triazole (M13), FOCUS Step 1-2 were conducted.

The obtained PEC values are suitable for ecotoxicological risk assessments for the proposed uses of FGE03 in winter and spring oilseed rape.

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

A 3.1 ESCAPE v2.0 output file

A 3.1.1 Boscalid, oilseed rape, one application at 245 g a.s./ha

ESCAPE Estimation of Soil Concentrations After Pesticide Applications

developed by Michael Klein

Program version: 2.0 (26 November 2019)
Date of this simulation: 10/05/2024, 11:56:33
Calculation problem: Programcheck

PROGRAM SETTINGS

Calculation mode: Residues from different applications are considered separately over one year
Application mode: Single annual application pattern (calculation period 1 year)

SCENARIO DATA USED IN THE CALCULATION

Name of the scenario: Programcheck
Name of the soil: Borstel
Soil density (kg/L): 1.5
Soil depth (cm): 5
Tillage depth (cm)*: 20
Organic carbon content (%): 1.5
Field capacity (Vol%): 29.2
Wilting point (Vol%): 6.4

Climatic conditions: 20 °C constant
(* for calculation of background concentrations)

APPLICATION PATTERN USED IN THE CALCULATION

Crop rotation: every year
Application date: 1 Mar
Application rate (g/ha): 245
Crop interception (%): 80

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme: Parent compound without metabolites

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

Soil study: soil study 1
Metabolism scheme: Parent compound without metabolites
Kinetics for Programcheck: Single First order (SFO)
DT50 (d): 340.5
Rate constant (1/d): 0.002
Q10-factor: 2.58
Walker-exponent: 0.7
Ref. temperature (°C): 20

RESULTS OF THE CALCULATION

Metabolism scheme: Parent compound without metabolites

RESULTS FOR: Programcheck

Calculations over one year

Maximum annual total soil concentration for Programcheck over 5 cm(mg/kg): 0.0653 occurring on day 0

Calculated time dependent total soil concentrations over 5 cm for Programcheck after one year (mg/kg)

Time(d)	PECact*	PECTwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0652	0.0653	0	1
2	0.0651	0.0652	0	2
4	0.0648	0.0651	0	4
7	0.0644	0.0649	0	7
14	0.0635	0.0644	0	14
21	0.0626	0.0640	0	21
28	0.0617	0.0635	0	28
42	0.0600	0.0626	0	42
50	0.0590	0.0621	0	50
100	0.0533	0.0591	0	100

(* PECact values are related to the time after the first application)

Calculation of background concentrations after many years

Final Background concentration in total soil for Programcheck over 20 cm(mg/kg): 0.0148**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): 0.0148

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for Programcheck over 5 cm considering accumulation* (mg/kg) 0.0802

(* a tillage depth of 20 cm was considered for calculating the background concentration)

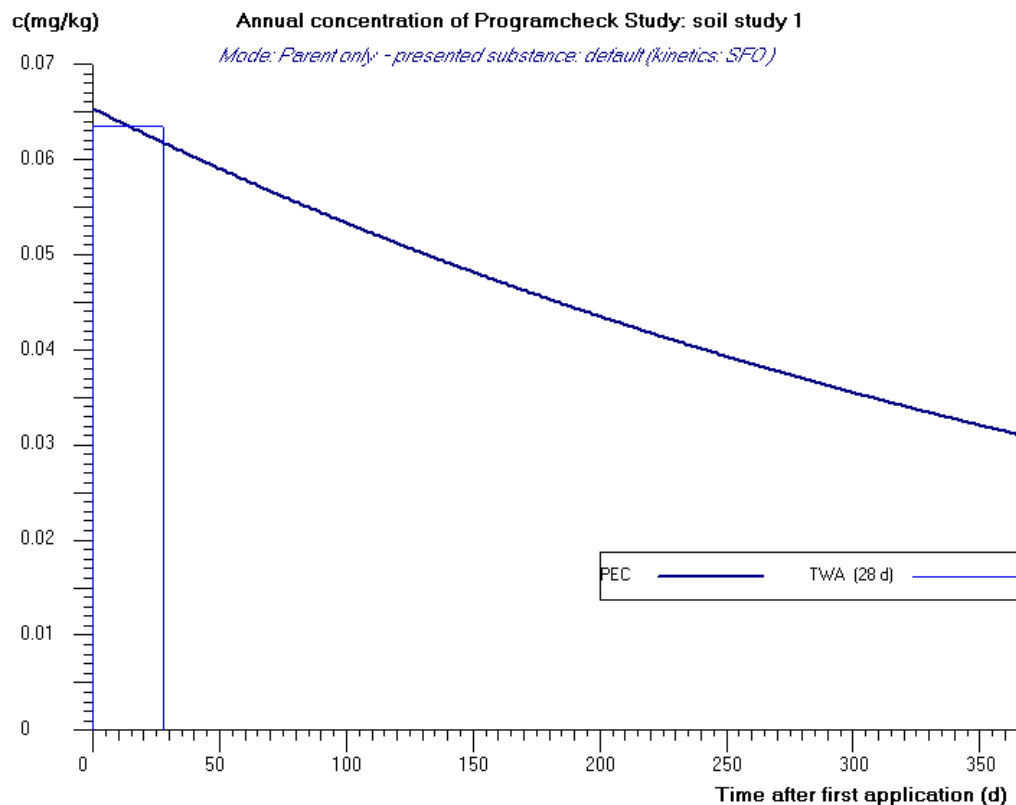
Calculated time dependent total soil concentrations over 5 cm for Programcheck(mg/kg) considering accumulation*

Time(d)	PECact**	PECTwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0800	0.0801	0	1
2	0.0799	0.0800	0	2
4	0.0796	0.0799	0	4
7	0.0792	0.0797	0	7
14	0.0783	0.0792	0	14
21	0.0774	0.0788	0	21
28	0.0765	0.0783	0	28
42	0.0748	0.0774	0	42
50	0.0738	0.0769	0	50
100	0.0681	0.0739	0	100

(* a tillage depth of 20 cm was considered for calculating the background concentration)

(** PECact values are related to the time after the first application)

GRAPHIC REPRESENTATION OF THE CALCULATION



A 3.1.2 Boscalid, oilseed rape, two applications at 245 g a.s./ha

ESCAPE Estimation of Soil Concentrations After Pesticide Applications

developed by Michael Klein

Program version: 2.0 (26 November 2019)
 Date of this simulation: 04/07/2024, 14:43:18
 Calculation problem: Programcheck

PROGRAM SETTINGS

Calculation mode: Residues from different applications are considered separately over one year
 Application mode: Single annual application pattern (calculation period 1 year)

SCENARIO DATA USED IN THE CALCULATION

Name of the scenario:	Programcheck
Name of the soil:	Borstel
Soil density (kg/L):	1.5
Soil depth (cm):	5
Tillage depth (cm)*:	20
Organic carbon content (%):	1.5
Field capacity (Vol%):	29.2
Wilting point (Vol%):	6.4

Climatic conditions: 20 °C constant
 (* for calculation of background concentrations)

APPLICATION PATTERN USED IN THE CALCULATION

Crop rotation: every year

Number of Applications : 2

1st Application date: 1 Mar

Application rate (g/ha): 245

Time between two applications (d): 14

Crop interception (%): 80

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme: Parent compound without metabolites

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

Soil study: soil study 1

Metabolism scheme: Parent compound without metabolites

Kinetics for Programcheck: Single First order (SFO)

DT50 (d): 340.5

Rate constant (1/d): 0.002

Q10-factor: 2.58

Walker-exponent: 0.7

Ref. temperature (°C): 20

RESULTS OF THE CALCULATION

Metabolism scheme: Parent compound without metabolites

RESULTS FOR: Programcheck

Calculations over one year

Maximum annual total soil concentration for Programcheck over 5 cm(mg/kg): 0.1288 occurring on day 14

Calculated time dependent total soil concentrations over 5 cm for Programcheck after one year (mg/kg)

Time(d)	PECact*	PECTwa	Begin TWAframe(d)	End TWAframe(d)
1	0.1286	0.1287	14	15
2	0.1283	0.1286	14	16
4	0.1278	0.1283	14	18
7	0.1270	0.1279	14	21
14	0.1252	0.1270	14	28
21	0.1234	0.1261	14	35
28	0.1217	0.1252	14	42
42	0.1183	0.1235	14	56
50	0.1164	0.1225	14	64
100	0.1051	0.1166	14	114

(* PECact values are related to the time after the maximum concentration)

Calculation of background concentrations after many years

Final Background concentration in total soil for Programcheck over 20 cm(mg/kg): 0.0292**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): 0.0292

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for Programcheck over 5 cm considering accumulation* (mg/kg) 0.1581

(* a tillage depth of 20 cm was considered for calculating the background concentration)

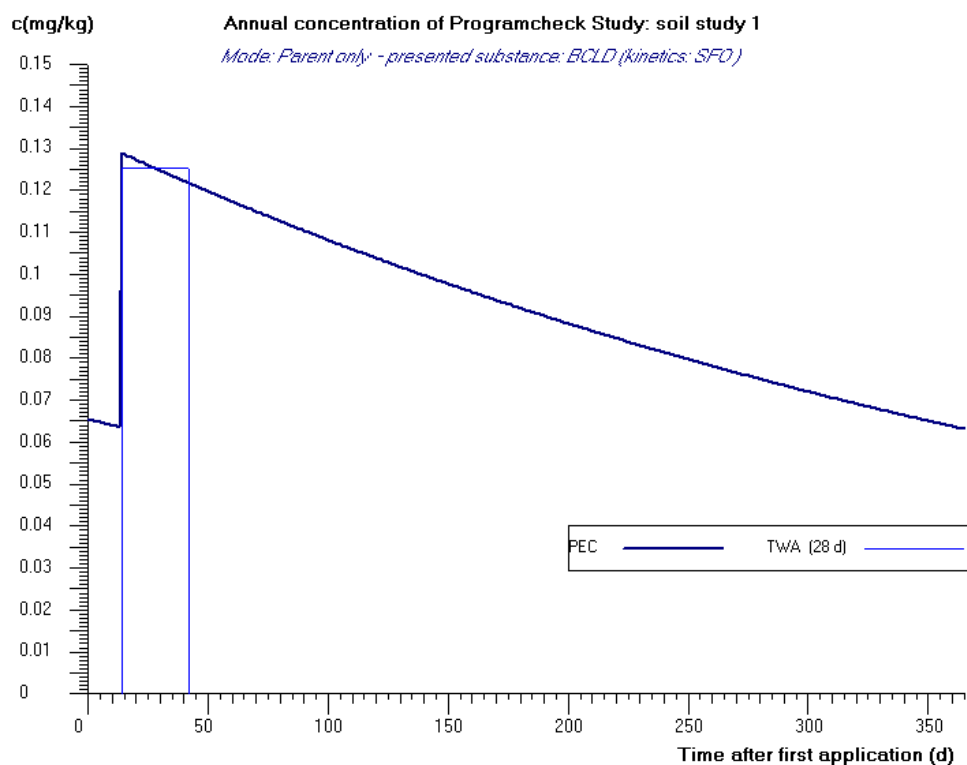
Calculated time dependent total soil concentrations over 5 cm for Programcheck(mg/kg) considering accumulation*

Time(d)	PECact**	PECTwa	Begin TWAframe(d)	End TWAframe(d)
1	0.1578	0.1579	14	15
2	0.1575	0.1578	14	16
4	0.1570	0.1575	14	18
7	0.1562	0.1571	14	21
14	0.1544	0.1562	14	28
21	0.1527	0.1553	14	35
28	0.1509	0.1544	14	42
42	0.1475	0.1527	14	56
50	0.1456	0.1517	14	64
100	0.1343	0.1458	14	114

(* a tillage depth of 20 cm was considered for calculating the background concentration)

(** PECact values are related to the time after the maximum concentration)'

GRAPHIC REPRESENTATION OF THE CALCULATION



A 3.1.3 Prothioconazole and metabolites, oilseed rape, one application at 140 g a.s./ha

ESCAPE Estimation of Soil Concentrations After Pesticide Applications

developed by Michael Klein

Program version: 2.0 (26 November 2019)
Date of this simulation: 10/05/2024, 12:33:21
Calculation problem: Programcheck

PROGRAM SETTINGS

Calculation mode: Residues from different applications are considered separately over one year
Application mode: Single annual application pattern (calculation period 1 year)

SCENARIO DATA USED IN THE CALCULATION

Name of the scenario: Programcheck
Name of the soil: Borstel
Soil density (kg/L): 1.5
Soil depth (cm): 5
Tillage depth (cm)*: 20
Organic carbon content (%): 1.5
Field capacity (Vol%): 29.2
Wilting point (Vol%): 6.4

Climatic conditions: 20 °C constant
(* for calculation of background concentrations)

APPLICATION PATTERN USED IN THE CALCULATION

Crop rotation: every year
Application date: 1 Mar
Application rate (g/ha): 140
Crop interception (%): 80

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme: Active compound and two parallel metabolites

Compound	Molecular mass(g/mol)	KOC(L/kg)	Formation (%)
PTCZ	344.3		
methyl	358.3	2525.9	14.6
desthio	312.2	573.5	57.1

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

Soil study: soil study 1

Metabolism scheme: Active compound and two parallel metabolites

Kinetics for PTCZ: Single First order (SFO)
DT50 (d): 2.8
Rate constant (1/d): 0.2476
Q10-factor: 2.58
Walker-exponent: 0.7
Ref. temperature (°C): 20

Kinetics for methyl: Single First order (SFO)
DT50 (d): 46
Rate constant (1/d): 0.0151
Q10-factor: 2.58
Walker-exponent: 0.7
Ref. temperature (°C): 20

Kinetics for desthio: Single First order (SFO)
DT50 (d): 72.3
Rate constant (1/d): 0.0096
Q10-factor: 2.58
Walker-exponent: 0.7
Ref. temperature (°C): 20

RESULTS OF THE CALCULATION

Metabolism scheme: Active compound and two parallel metabolites

RESULTS FOR: PTCZ

Calculations over one year

Maximum annual total soil concentration for PTCZ over 5 cm(mg/kg): 0.0373 occurring on day 0

Calculated time dependent total soil concentrations over 5 cm for PTCZ after one year (mg/kg)

Time(d)	PECact*	PECTwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0291	0.0332	0	1
2	0.0228	0.0296	0	2
4	0.0139	0.0238	0	4
7	0.0066	0.0178	0	7
14	0.0012	0.0105	0	14
21	0.0002	0.0072	0	21
28	<0.0001	0.0054	0	28
42	<0.0001	0.0036	0	42
50	<0.0001	0.0030	0	50
100	<0.0001	0.0015	0	100

(* PECact values are related to the time after the first application)

Calculation of background concentrations after many years

Final Background concentration in total soil for PTCZ over 20 cm(mg/kg): <0.0001**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): <0.0001

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for PTCZ over 5 cm considering accumulation* (mg/kg) 0.0373

(* a tillage depth of 20 cm was considered for calculating the background concentration)

Calculated time dependent total soil concentrations over 5 cm for PTCZ(mg/kg) considering accumulation*

Time(d)	PECact**	PECTwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0291	0.0332	0	1
2	0.0228	0.0296	0	2
4	0.0139	0.0238	0	4
7	0.0066	0.0178	0	7
14	0.0012	0.0105	0	14
21	0.0002	0.0072	0	21
28	<0.0001	0.0054	0	28
42	<0.0001	0.0036	0	42
50	<0.0001	0.0030	0	50
100	<0.0001	0.0015	0	100

(* a tillage depth of 20 cm was considered for calculating the background concentration)

(** PECact values are related to the time after the first application)

RESULTS FOR: methyl

Calculations over one year

Maximum annual total soil concentration for methyl over 5 cm(mg/kg): 0.0048 occurring on day 12^

(^ This is 3.07 % of the theoretical maximum concentration of the metabolite)

Calculated time dependent total soil concentrations over 5 cm for methyl after one year (mg/kg)

Time(d)	PECact*	PECTwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0048	0.0048	12	13
2	0.0047	0.0048	11	13
4	0.0047	0.0048	10	14
7	0.0045	0.0047	9	16

14	0.0041	0.0046	7	21
21	0.0037	0.0045	6	27
28	0.0033	0.0044	5	33
42	0.0027	0.0040	3	45
50	0.0024	0.0039	3	53
100	0.0011	0.0029	1	101

(* PECact values are related to the time after the maximum concentration)

Calculation of background concentrations after many years

Final Background concentration in total soil for methyl over 20 cm(mg/kg): <0.0001**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): <0.0001

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for methyl over 5 cm considering accumulation* (mg/kg) 0.0048
(* a tillage depth of 20 cm was considered for calculating the background concentration)

Calculated time dependent total soil concentrations over 5 cm for methyl(mg/kg) considering accumulation*

Time(d)	PECact**	PECTwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0048	0.0048	12	13
2	0.0047	0.0048	11	13
4	0.0047	0.0048	10	14
7	0.0045	0.0047	9	16
14	0.0041	0.0046	7	21
21	0.0037	0.0045	6	27
28	0.0033	0.0044	5	33
42	0.0027	0.0040	3	45
50	0.0024	0.0039	3	53
100	0.0011	0.0029	1	101

(* a tillage depth of 20 cm was considered for calculating the background concentration)

(** PECact values are related to the time after the maximum concentration)

RESULTS FOR: desthio

Calculations over one year

Maximum annual total soil concentration for desthio over 5 cm(mg/kg): 0.0170 occurring on day 14^

(^ This is 12.58 % of the theoretical maximum concentration of the metabolite)

Calculated time dependent total soil concentrations over 5 cm for desthio after one year (mg/kg)

Time(d)	PECact*	PECTwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0170	0.0170	13	14
2	0.0170	0.0170	13	15
4	0.0168	0.0170	12	16
7	0.0164	0.0170	11	18
14	0.0154	0.0167	9	23
21	0.0144	0.0164	7	28
28	0.0135	0.0161	6	34
42	0.0118	0.0153	5	47
50	0.0109	0.0148	4	54
100	0.0068	0.0123	2	102

(* PECact values are related to the time after the maximum concentration)

Calculation of background concentrations after many years

Final Background concentration in total soil for desthio over 20 cm(mg/kg): 0.0001**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): 0.0001

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for desthio over 5 cm considering accumulation* (mg/kg) 0.0172
(* a tillage depth of 20 cm was considered for calculating the background concentration)

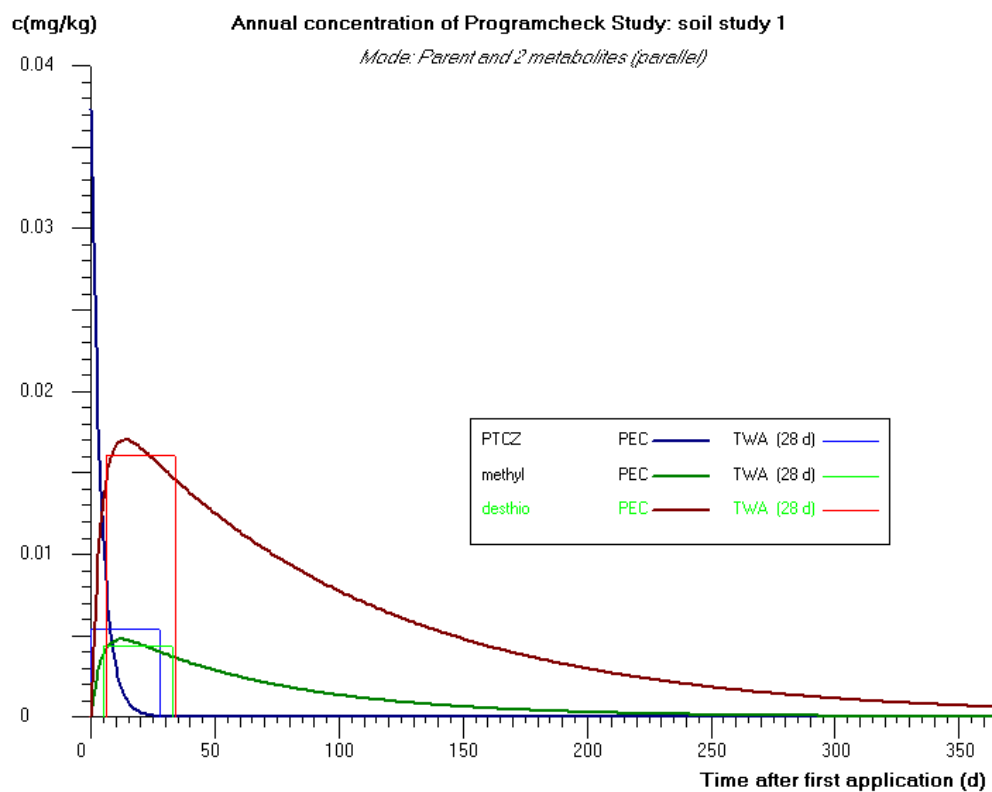
Calculated time dependent total soil concentrations over 5 cm for desthio(mg/kg) considering accumulation*

Time(d)	PECact**	PECTwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0171	0.0172	13	14
2	0.0171	0.0172	13	15
4	0.0169	0.0171	12	16
7	0.0165	0.0171	11	18
14	0.0156	0.0169	9	23
21	0.0146	0.0166	7	28
28	0.0136	0.0162	6	34
42	0.0120	0.0154	5	47
50	0.0111	0.0150	4	54
100	0.0069	0.0124	2	102

(* a tillage depth of 20 cm was considered for calculating the background concentration)

(** PECact values are related to the time after the maximum concentration)

GRAPHIC REPRESENTATION OF THE CALCULATION



A 3.1.4

Prothioconazole and metabolites, oilseed rape, two applications at 140 g a.s./ha

ESCAPE **Estimation of Soil Concentrations After Pesticide Applications**

developed by Michael Klein

Program version: 2.0 (26 November 2019)
Date of this simulation: 04/07/2024, 14:53:08
Calculation problem: Programcheck

PROGRAM SETTINGS

Calculation mode: Residues from different applications are considered separately over one year
Application mode: Single annual application pattern (calculation period 1 year)

SCENARIO DATA USED IN THE CALCULATION

Name of the scenario: Programcheck
Name of the soil: Borstel
Soil density (kg/L): 1.5
Soil depth (cm): 5
Tillage depth (cm)*: 20
Organic carbon content (%): 1.5
Field capacity (Vol%): 29.2
Wilting point (Vol%): 6.4

Climatic conditions: 20 °C constant
(* for calculation of background concentrations)

APPLICATION PATTERN USED IN THE CALCULATION

Crop rotation: every year
Number of Applications : 2
1st Application date: 1 Mar
Application rate (g/ha): 140
Time between two applications (d): 14
Crop interception (%): 80

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme: Active compound and two parallel metabolites

Compound	Molecular mass(g/mol)	KOC(L/kg)	Formation (%)
methyl	344.3		
desthio	358.3	2525.9	14.6
	312.2	573.5	57.1

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

Soil study: soil study 1
Metabolism scheme: Active compound and two parallel metabolites

Kinetics for : Single First order (SFO)
DT50 (d): 2.8
Rate constant (1/d): 0.2476
Q10-factor: 2.58
Walker-exponent: 0.7
Ref. temperature (°C): 20

Kinetics for methyl: Single First order (SFO)
DT50 (d): 46
Rate constant (1/d): 0.0151
Q10-factor: 2.58

Walker-exponent: 0.7
Ref. temperature (°C): 20

Kinetics for desthio: Single First order (SFO)
DT50 (d): 72.3
Rate constant (1/d): 0.0096
Q10-factor: 2.58
Walker-exponent: 0.7
Ref. temperature (°C): 20

RESULTS OF THE CALCULATION

Metabolism scheme: Active compound and two parallel metabolites

RESULTS FOR:

Calculations over one year

Maximum annual total soil concentration for over 5 cm(mg/kg): 0.0385 occurring on day 14

Calculated time dependent total soil concentrations over 5 cm for after one year (mg/kg)

Time(d)	PECact*	PECTwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0301	0.0343	14	15
2	0.0235	0.0305	14	16
4	0.0143	0.0255	13	17
7	0.0068	0.0201	13	20
14	0.0012	0.0121	13	27
21	0.0002	0.0140	0	21
28	<0.0001	0.0113	0	28
42	<0.0001	0.0077	0	42
50	<0.0001	0.0064	0	50
100	<0.0001	0.0032	0	100

(* PECact values are related to the time after the maximum concentration)

Calculation of background concentrations after many years

Final Background concentration in total soil for over 20 cm(mg/kg): <0.0001**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): <0.0001

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for over 5 cm considering accumulation* (mg/kg) 0.0385

(* a tillage depth of 20 cm was considered for calculating the background concentration)

Calculated time dependent total soil concentrations over 5 cm for (mg/kg) considering accumulation*

Time(d)	PECact**	PECTwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0301	0.0343	14	15
2	0.0235	0.0305	14	16
4	0.0143	0.0255	13	17
7	0.0068	0.0201	13	20
14	0.0012	0.0121	13	27
21	0.0002	0.0140	0	21
28	<0.0001	0.0113	0	28
42	<0.0001	0.0077	0	42
50	<0.0001	0.0064	0	50
100	<0.0001	0.0032	0	100

(* a tillage depth of 20 cm was considered for calculating the background concentration)

(** PECact values are related to the time after the maximum concentration)

RESULTS FOR: methyl

Calculations over one year

Maximum annual total soil concentration for methyl over 5 cm(mg/kg): 0.0089 occurring on day 24[^]
([^] This is 5.76 % of the theoretical maximum concentration of the metabolite)

Calculated time dependent total soil concentrations over 5 cm for methyl after one year (mg/kg)

Time(d)	PECact*	PECTwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0089	0.0089	23	24
2	0.0089	0.0089	23	25
4	0.0087	0.0089	22	26
7	0.0084	0.0089	21	28
14	0.0077	0.0087	19	33
21	0.0069	0.0085	17	38
28	0.0062	0.0082	16	44
42	0.0050	0.0076	15	57
50	0.0045	0.0072	14	64
100	0.0021	0.0056	3	103

(* PECact values are related to the time after the maximum concentration)

Calculation of background concentrations after many years

Final Background concentration in total soil for methyl over 20 cm(mg/kg): <0.0001**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): <0.0001

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for methyl over 5 cm considering accumulation* (mg/kg) 0.0090
(* a tillage depth of 20 cm was considered for calculating the background concentration)

Calculated time dependent total soil concentrations over 5 cm for methyl(mg/kg) considering accumulation*

Time(d)	PECact**	PECTwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0089	0.0090	23	24
2	0.0089	0.0090	23	25
4	0.0087	0.0089	22	26
7	0.0084	0.0089	21	28
14	0.0077	0.0087	19	33
21	0.0069	0.0085	17	38
28	0.0062	0.0082	16	44
42	0.0050	0.0076	15	57
50	0.0045	0.0072	14	64
100	0.0021	0.0056	3	103

(* a tillage depth of 20 cm was considered for calculating the background concentration)

(** PECact values are related to the time after the maximum concentration)

RESULTS FOR: desthio

Calculations over one year

Maximum annual total soil concentration for desthio over 5 cm(mg/kg): 0.0327 occurring on day 25[^]

([^] This is 24.16 % of the theoretical maximum concentration of the metabolite)

Calculated time dependent total soil concentrations over 5 cm for desthio after one year (mg/kg)

Time(d)	PECact*	PECTwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0327	0.0327	25	26
2	0.0326	0.0327	24	26
4	0.0323	0.0327	23	27
7	0.0316	0.0326	22	29
14	0.0298	0.0321	20	34

21	0.0279	0.0315	19	40
28	0.0261	0.0309	18	46
42	0.0228	0.0294	16	58
50	0.0211	0.0285	16	66
100	0.0131	0.0236	7	107

(* PECact values are related to the time after the maximum concentration)

Calculation of background concentrations after many years

Final Background concentration in total soil for desthio over 20 cm(mg/kg): 0.0003**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): 0.0003

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for desthio over 5 cm considering accumulation* (mg/kg) 0.0330

(* a tillage depth of 20 cm was considered for calculating the background concentration)

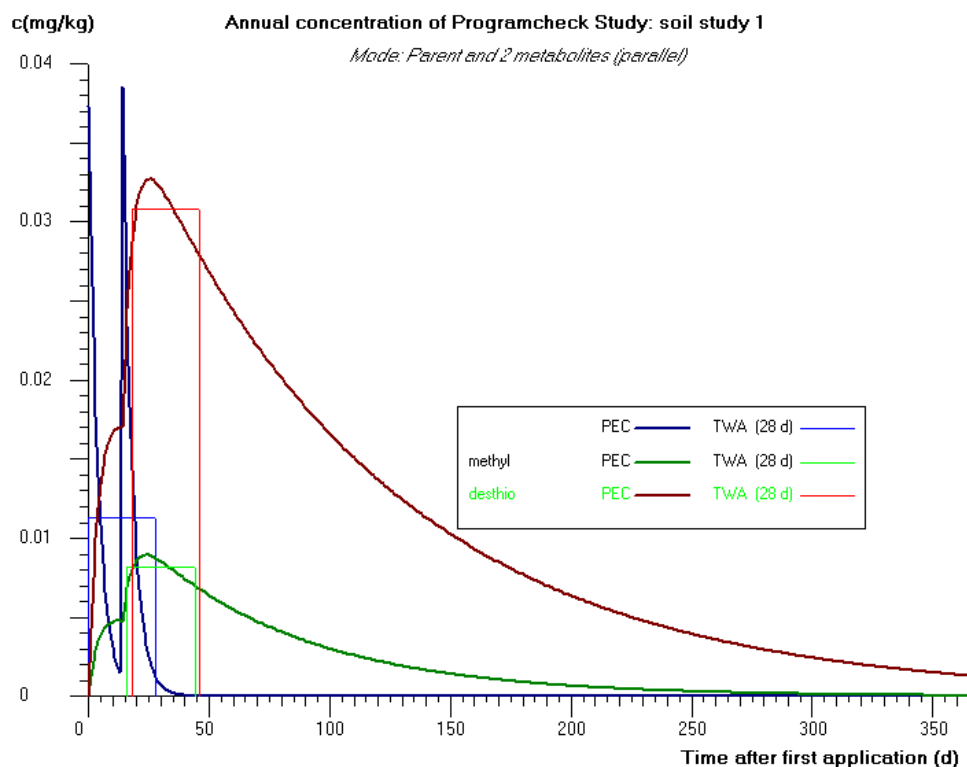
Calculated time dependent total soil concentrations over 5 cm for desthio(mg/kg) considering accumulation*

Time(d)	PECact**	PECTwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0330	0.0330	25	26
2	0.0329	0.0330	24	26
4	0.0326	0.0329	23	27
7	0.0319	0.0328	22	29
14	0.0300	0.0324	20	34
21	0.0281	0.0318	19	40
28	0.0263	0.0311	18	46
42	0.0231	0.0296	16	58
50	0.0214	0.0288	16	66
100	0.0133	0.0239	7	107

(* a tillage depth of 20 cm was considered for calculating the background concentration)

(** PECact values are related to the time after the maximum concentration)

GRAPHIC REPRESENTATION OF THE CALCULATION



A 3.1.5 Boscalid, sunflower, one application at 245 g a.s./ha

ESCAPE Estimation of Soil Concentrations After Pesticide Applications

developed by Michael Klein

Program version: 2.0 (26 November 2019)
 Date of this simulation: 28.02.2025, 17:16:56
 Calculation problem: Programcheck

PROGRAM SETTINGS

Calculation mode: Residues from different applications are considered separately over one year
 Application mode: Single annual application pattern (calculation period 1 year)

SCENARIO DATA USED IN THE CALCULATION

Name of the scenario: new application pattern1
 Name of the soil: Borstel
 Soil density (kg/L): 1.5
 Soil depth (cm): 5
 Tillage depth (cm)*: 20
 Organic carbon content (%): 1.5
 Field capacity (Vol%): 29.2
 Wilting point (Vol%): 6.4

Climatic conditions: 20 °C constant
 (* for calculation of background concentrations)

APPLICATION PATTERN USED IN THE CALCULATION

Crop rotation: every year

Application date: 1 May
 Application rate (g/ha): 245
 Crop interception (%): 75

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme: Parent compound without metabolites

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

Soil study: soil study 1
 Metabolism scheme: Parent compound without metabolites
 Kinetics for Programcheck: Single First order (SFO)
 DT50 (d): 340.5
 Rate constant (1/d): 0.002
 Q10-factor: 2.58
 Walker-exponent: 0.7
 Ref. temperature (°C): 20

RESULTS OF THE CALCULATION

Metabolism scheme: Parent compound without metabolites

RESULTS FOR: Programcheck

Calculations over one year

Maximum annual total soil concentration for Programcheck over 5 cm(mg/kg): 0.0817 occurring on day 0

Calculated time dependent total soil concentrations over 5 cm for Programcheck after one year (mg/kg)

Time(d)	PECact*	PECTwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0815	0.0816	0	1
2	0.0813	0.0815	0	2
4	0.0810	0.0813	0	4
7	0.0805	0.0811	0	7
14	0.0794	0.0805	0	14
21	0.0782	0.0799	0	21
28	0.0771	0.0794	0	28
42	0.0750	0.0783	0	42
50	0.0738	0.0776	0	50
100	0.0666	0.0739	0	100

(* PECact values are related to the time after the first application)

Calculation of background concentrations after many years

Final Background concentration in total soil for Programcheck over 20 cm(mg/kg): 0.0185**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): 0.0185

Calculations of concentrations considering accumulation after many years of application

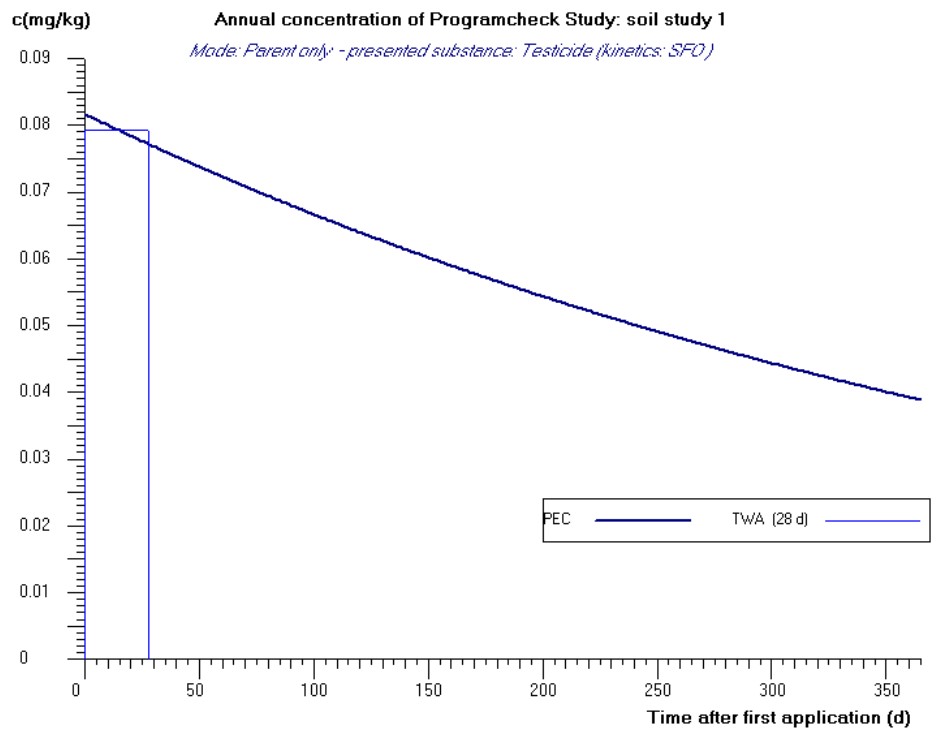
Maximum total soil concentration for Programcheck over 5 cm considering accumulation* (mg/kg) 0.1002
 (* a tillage depth of 20 cm was considered for calculating the background concentration)

Calculated time dependent total soil concentrations over 5 cm for Programcheck(mg/kg) considering accumulation*

Time(d)	PECact**	PECTwa	Begin TWAframe(d)	End TWAframe(d)
1	0.1000	0.1001	0	1

2	0.0999	0.1000	0	2
4	0.0995	0.0999	0	4
7	0.0990	0.0996	0	7
14	0.0979	0.0990	0	14
21	0.0968	0.0985	0	21
28	0.0957	0.0979	0	28
42	0.0935	0.0968	0	42
50	0.0923	0.0962	0	50
100	0.0851	0.0924	0	100
(* a tillage depth of 20 cm was considered for calculating the background concentration)				
(** PECact values are related to the time after the first application)				

GRAPHIC REPRESENTATION OF THE CALCULATION



A 3.1.6 **Boscalid, sunflower, two applications at 245 g a.s./ha**

ESCAPE
Estimation of Soil Concentrations After Pesticide Applications

developed by Michael Klein

Program version: 2.0 (26 November 2019)
Date of this simulation: 28.02.2025, 17:21:09
Calculation problem: Programcheck

PROGRAM SETTINGS

Calculation mode: Residues from different applications are considered separately over one year
Application mode: Single annual application pattern (calculation period 1 year)

SCENARIO DATA USED IN THE CALCULATION

Name of the scenario: new application pattern1
Name of the soil: Borstel
Soil density (kg/L): 1.5
Soil depth (cm): 5
Tillage depth (cm)*: 20
Organic carbon content (%): 1.5
Field capacity (Vol%): 29.2
Wilting point (Vol%): 6.4

Climatic conditions: 20 °C constant
(* for calculation of background concentrations)

APPLICATION PATTERN USED IN THE CALCULATION

Crop rotation: every year
Number of Applications : 2
1st Application date: 1 May
Application rate (g/ha): 245
Time between two applications (d): 14
Crop interception (%): 75

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme: Parent compound without metabolites

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

Soil study: soil study 1
Metabolism scheme: Parent compound without metabolites
Kinetics for Programcheck: Single First order (SFO)
DT50 (d): 340.5
Rate constant (1/d): 0.002
Q10-factor: 2.58
Walker-exponent: 0.7
Ref. temperature (°C): 20

RESULTS OF THE CALCULATION

Metabolism scheme: Parent compound without metabolites

RESULTS FOR: Programcheck

Calculations over one year

Maximum annual total soil concentration for Programcheck over 5 cm(mg/kg): 0.1610 occurring on day 14

Calculated time dependent total soil concentrations over 5 cm for Programcheck after one year (mg/kg)

Time(d)	PECact*	PECTwa	Begin TWAframe(d)	End TWAframe(d)
1	0.1607	0.1609	14	15
2	0.1604	0.1607	14	16
4	0.1597	0.1604	14	18
7	0.1588	0.1599	14	21
14	0.1565	0.1588	14	28
21	0.1543	0.1576	14	35
28	0.1521	0.1565	14	42
42	0.1478	0.1543	14	56
50	0.1455	0.1531	14	64
100	0.1314	0.1457	14	114

(* PECact values are related to the time after the maximum concentration)

Calculation of background concentrations after many years

Final Background concentration in total soil for Programcheck over 20 cm(mg/kg): 0.0365**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): 0.0365

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for Programcheck over 5 cm considering accumulation* (mg/kg) 0.1976
(* a tillage depth of 20 cm was considered for calculating the background concentration)

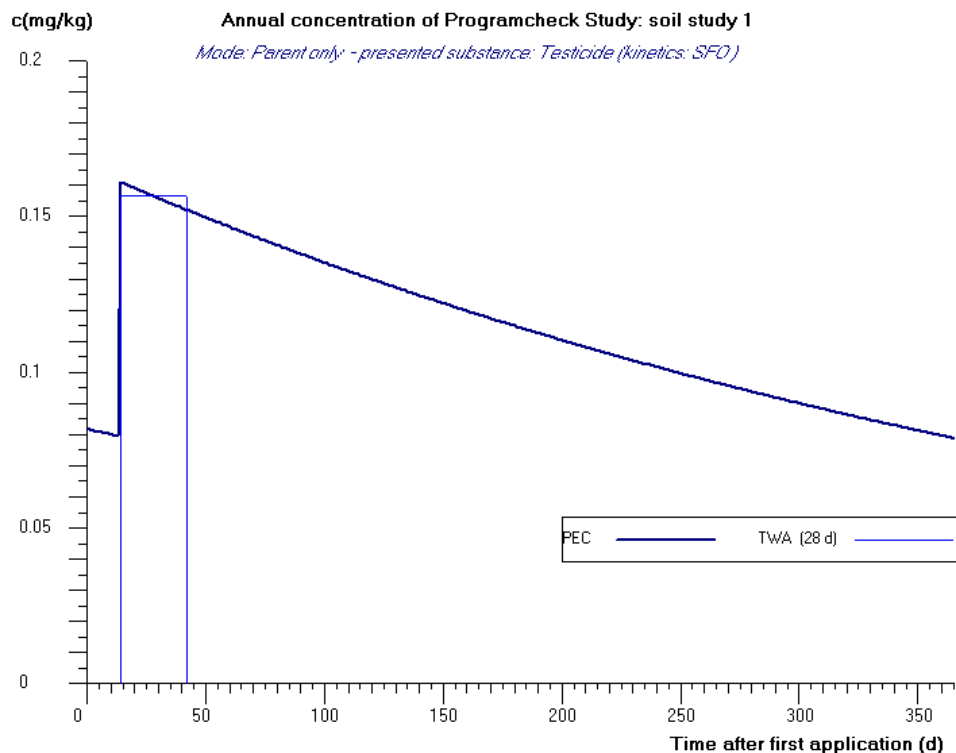
Calculated time dependent total soil concentrations over 5 cm for Programcheck(mg/kg) considering accumulation*

Time(d)	PECact**	PECTwa	Begin TWAframe(d)	End TWAframe(d)
1	0.1972	0.1974	14	15
2	0.1969	0.1972	14	16
4	0.1963	0.1969	14	18
7	0.1953	0.1964	14	21
14	0.1930	0.1953	14	28
21	0.1908	0.1942	14	35
28	0.1886	0.1931	14	42
42	0.1844	0.1909	14	56
50	0.1820	0.1896	14	64
100	0.1679	0.1822	14	114

(* a tillage depth of 20 cm was considered for calculating the background concentration)

(** PECact values are related to the time after the maximum concentration)

GRAPHIC REPRESENTATION OF THE CALCULATION



A 3.1.7 Prothioconazole and metabolites, sunflower, one application at 245 g a.s./ha

ESCAPE **Estimation of Soil Concentrations After Pesticide Applications**

developed by Michael Klein

Program version: 2.0 (26 November 2019)
Date of this simulation: 28.02.2025, 17:31:48
Calculation problem: Programcheck

PROGRAM SETTINGS

Calculation mode: Residues from different applications are considered separately over one year
Application mode: Single annual application pattern (calculation period 1 year)

SCENARIO DATA USED IN THE CALCULATION

Name of the scenario: new application pattern1
Name of the soil: Borstel
Soil density (kg/L): 1.5
Soil depth (cm): 5
Tillage depth (cm)*: 20
Organic carbon content (%): 1.5
Field capacity (Vol%): 29.2
Wilting point (Vol%): 6.4

Climatic conditions: 20 °C constant
(* for calculation of background concentrations)

APPLICATION PATTERN USED IN THE CALCULATION

Crop rotation: every year
Application date: 1 May
Application rate (g/ha): 140
Crop interception (%): 75

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme:	Active compound and two parallel metabolites		
Compound	Molecular mass(g/mol)	KOC(L/kg)	Formation (%)
PTCZ	344.3		
methyl	358.3	2525.9	14.6
desthio	312.2	573.5	57.1

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

Soil study:	soil study 1
Metabolism scheme:	Active compound and two parallel metabolites
Kinetics for PTCZ:	Single First order (SFO)
DT50 (d):	2.8
Rate constant (1/d):	0.2476
Q10-factor:	2.58
Walker-exponent:	0.7
Ref. temperature (°C):	20
Kinetics for methyl:	Single First order (SFO)
DT50 (d):	46
Rate constant (1/d):	0.0151
Q10-factor:	2.58
Walker-exponent:	0.7
Ref. temperature (°C):	20
Kinetics for desthio:	Single First order (SFO)
DT50 (d):	72.3
Rate constant (1/d):	0.0096
Q10-factor:	2.58

Walker-exponent: 0.7
Ref. temperature (°C): 20

RESULTS OF THE CALCULATION

Metabolism scheme: Active compound and two parallel metabolites

RESULTS FOR: PTCZ

Calculations over one year

Maximum annual total soil concentration for PTCZ over 5 cm(mg/kg): 0.0467 occurring on day 0

Calculated time dependent total soil concentrations over 5 cm for PTCZ after one year (mg/kg)

Time(d)	PECact*	PECTwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0364	0.0415	0	1
2	0.0284	0.0370	0	2
4	0.0173	0.0298	0	4
7	0.0082	0.0223	0	7
14	0.0015	0.0131	0	14
21	0.0003	0.0090	0	21
28	<0.0001	0.0068	0	28
42	<0.0001	0.0045	0	42
50	<0.0001	0.0038	0	50
100	<0.0001	0.0019	0	100

(* PECact values are related to the time after the first application)

Calculation of background concentrations after many years

Final Background concentration in total soil for PTCZ over 20 cm(mg/kg): <0.0001**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): <0.0001

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for PTCZ over 5 cm considering accumulation* (mg/kg) 0.0467

(* a tillage depth of 20 cm was considered for calculating the background concentration)

Calculated time dependent total soil concentrations over 5 cm for PTCZ(mg/kg) considering accumulation*

Time(d)	PECact**	PECTwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0364	0.0415	0	1
2	0.0284	0.0370	0	2
4	0.0173	0.0298	0	4
7	0.0082	0.0223	0	7
14	0.0015	0.0131	0	14
21	0.0003	0.0090	0	21
28	<0.0001	0.0068	0	28
42	<0.0001	0.0045	0	42
50	<0.0001	0.0038	0	50
100	<0.0001	0.0019	0	100

(* a tillage depth of 20 cm was considered for calculating the background concentration)

(** PECact values are related to the time after the first application)

RESULTS FOR: methyl

Calculations over one year

Maximum annual total soil concentration for methyl over 5 cm(mg/kg): 0.0060 occurring on day 12^

(^ This is 3.07 % of the theoretical maximum concentration of the metabolite)

Calculated time dependent total soil concentrations over 5 cm for methyl after one year (mg/kg)

Time(d)	PECact*	PECTwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0060	0.0060	12	13
2	0.0059	0.0060	11	13

4	0.0058	0.0059	10	14
7	0.0056	0.0059	9	16
14	0.0051	0.0058	7	21
21	0.0046	0.0056	6	27
28	0.0042	0.0054	5	33
42	0.0034	0.0050	3	45
50	0.0030	0.0048	3	53
100	0.0014	0.0036	1	101

(* PECact values are related to the time after the maximum concentration)

Calculation of background concentrations after many years

Final Background concentration in total soil for methyl over 20 cm(mg/kg): <0.0001**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): <0.0001

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for methyl over 5 cm considering accumulation* (mg/kg) 0.0060
(* a tillage depth of 20 cm was considered for calculating the background concentration)

Calculated time dependent total soil concentrations over 5 cm for methyl(mg/kg) considering accumulation*

Time(d)	PECact**	PECTwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0060	0.0060	12	13
2	0.0059	0.0060	11	13
4	0.0058	0.0059	10	14
7	0.0057	0.0059	9	16
14	0.0051	0.0058	7	21
21	0.0046	0.0056	6	27
28	0.0042	0.0054	5	33
42	0.0034	0.0050	3	45
50	0.0030	0.0048	3	53
100	0.0014	0.0036	1	101

(* a tillage depth of 20 cm was considered for calculating the background concentration)

(** PECact values are related to the time after the maximum concentration)

RESULTS FOR: desthio

Calculations over one year

Maximum annual total soil concentration for desthio over 5 cm(mg/kg): 0.0213 occurring on day 14^

(^ This is 12.58 % of the theoretical maximum concentration of the metabolite)

Calculated time dependent total soil concentrations over 5 cm for desthio after one year (mg/kg)

Time(d)	PECact*	PECTwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0213	0.0213	13	14
2	0.0212	0.0213	13	15
4	0.0210	0.0213	12	16
7	0.0205	0.0212	11	18
14	0.0193	0.0209	9	23
21	0.0181	0.0205	7	28
28	0.0169	0.0201	6	34
42	0.0148	0.0191	5	47
50	0.0137	0.0186	4	54
100	0.0085	0.0153	2	102

(* PECact values are related to the time after the maximum concentration)

Calculation of background concentrations after many years

Final Background concentration in total soil for desthio over 20 cm(mg/kg): 0.0002**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): 0.0002

Calculations of concentrations considering accumulation after many years of application

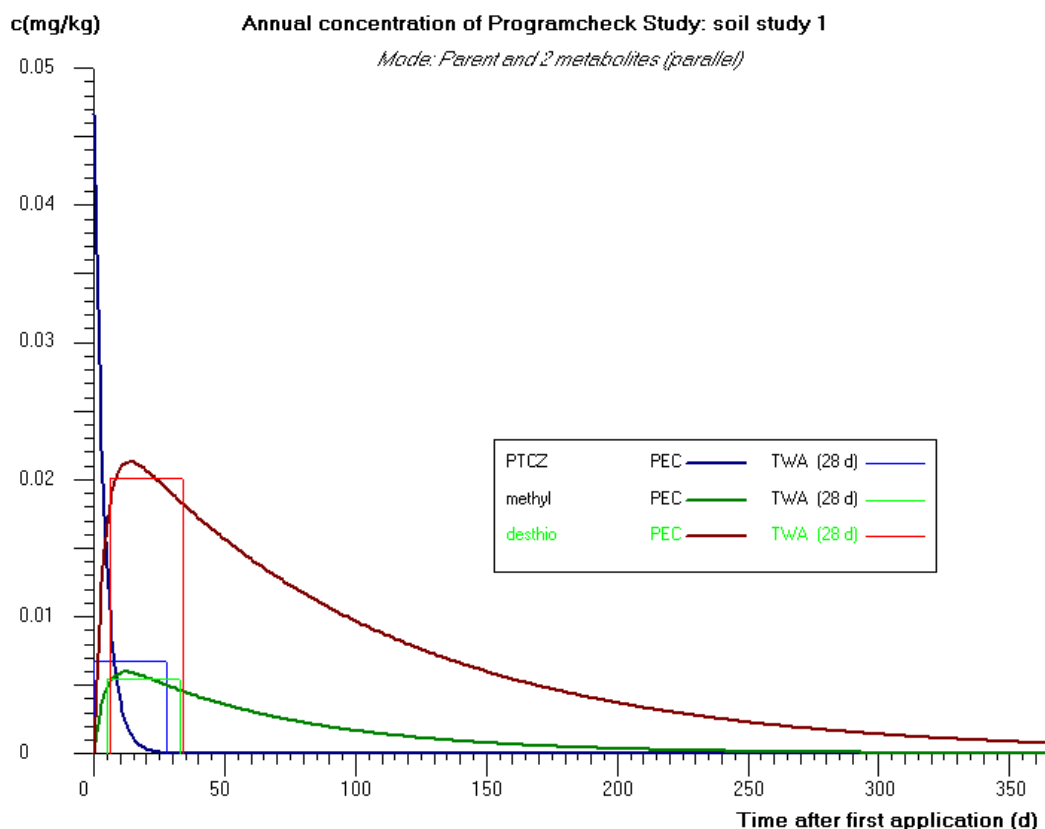
Maximum total soil concentration for desthio over 5 cm considering accumulation* (mg/kg) 0.0215
(* a tillage depth of 20 cm was considered for calculating the background concentration)

Calculated time dependent total soil concentrations over 5 cm for desthio(mg/kg) considering accumulation*

Time(d)	PECact**	PECTwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0214	0.0215	13	14
2	0.0214	0.0215	13	15
4	0.0211	0.0214	12	16
7	0.0207	0.0214	11	18
14	0.0195	0.0211	9	23
21	0.0182	0.0207	7	28
28	0.0171	0.0203	6	34
42	0.0149	0.0193	5	47
50	0.0138	0.0187	4	54
100	0.0086	0.0155	2	102

(* a tillage depth of 20 cm was considered for calculating the background concentration)
(** PECact values are related to the time after the maximum concentration)

GRAPHIC REPRESENTATION OF THE CALCULATION



A 3.1.8 Prothioconazole and metabolites, sunflower, two applications at 245 g a.s./ha

ESCAPE
Estimation of Soil Concentrations After Pesticide Applications

developed by Michael Klein

Program version: 2.0 (26 November 2019)
Date of this simulation: 28.02.2025, 17:36:16
Calculation problem: Programcheck

PROGRAM SETTINGS

Calculation mode: Residues from different applications are considered separately over one year
Application mode: Single annual application pattern (calculation period 1 year)

SCENARIO DATA USED IN THE CALCULATION

Name of the scenario: new application pattern1
Name of the soil: Borstel
Soil density (kg/L): 1.5
Soil depth (cm): 5
Tillage depth (cm)*: 20
Organic carbon content (%): 1.5
Field capacity (Vol%): 29.2
Wilting point (Vol%): 6.4

Climatic conditions: 20 °C constant
(* for calculation of background concentrations)

APPLICATION PATTERN USED IN THE CALCULATION

Crop rotation: every year
Number of Applications : 2
1st Application date: 1 May
Application rate (g/ha): 140
Time between two applications (d): 14
Crop interception (%): 75

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme:	Active compound and two parallel metabolites		
Compound	Molecular mass(g/mol)	KOC(L/kg)	Formation (%)
PTCZ	344.3		
methyl	358.3	2525.9	14.6
desthio	312.2	573.5	57.1

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

Soil study: soil study 1

Metabolism scheme: Active compound and two parallel metabolites

Kinetics for PTCZ: Single First order (SFO)
DT50 (d): 2.8
Rate constant (1/d): 0.2476
Q10-factor: 2.58
Walker-exponent: 0.7
Ref. temperature (°C): 20

Kinetics for methyl: Single First order (SFO)
DT50 (d): 46
Rate constant (1/d): 0.0151
Q10-factor: 2.58
Walker-exponent: 0.7
Ref. temperature (°C): 20

Kinetics for desthio: Single First order (SFO)
DT50 (d): 72.3
Rate constant (1/d): 0.0096
Q10-factor: 2.58
Walker-exponent: 0.7

Ref. temperature (°C): 20

RESULTS OF THE CALCULATION

Metabolism scheme: Active compound and two parallel metabolites

RESULTS FOR: PTCZ

Calculations over one year

Maximum annual total soil concentration for PTCZ over 5 cm(mg/kg): 0.0481 occurring on day 14

Calculated time dependent total soil concentrations over 5 cm for PTCZ after one year (mg/kg)

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0376	0.0428	14	15
2	0.0293	0.0382	14	16
4	0.0179	0.0319	13	17
7	0.0085	0.0252	13	20
14	0.0015	0.0152	13	27
21	0.0003	0.0175	0	21
28	<0.0001	0.0141	0	28
42	<0.0001	0.0096	0	42
50	<0.0001	0.0080	0	50
100	<0.0001	0.0040	0	100

(* PECact values are related to the time after the maximum concentration)

Calculation of background concentrations after many years

Final Background concentration in total soil for PTCZ over 20 cm(mg/kg): <0.0001**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): <0.0001

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for PTCZ over 5 cm considering accumulation* (mg/kg) 0.0481

(* a tillage depth of 20 cm was considered for calculating the background concentration)

Calculated time dependent total soil concentrations over 5 cm for PTCZ(mg/kg) considering accumulation*

Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0376	0.0428	14	15
2	0.0293	0.0382	14	16
4	0.0179	0.0319	13	17
7	0.0085	0.0252	13	20
14	0.0015	0.0152	13	27
21	0.0003	0.0175	0	21
28	<0.0001	0.0141	0	28
42	<0.0001	0.0096	0	42
50	<0.0001	0.0080	0	50
100	<0.0001	0.0040	0	100

(* a tillage depth of 20 cm was considered for calculating the background concentration)

(** PECact values are related to the time after the maximum concentration)

RESULTS FOR: methyl

Calculations over one year

Maximum annual total soil concentration for methyl over 5 cm(mg/kg): 0.0112 occurring on day 24^

(^ This is 5.76 % of the theoretical maximum concentration of the metabolite)

Calculated time dependent total soil concentrations over 5 cm for methyl after one year (mg/kg)

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0112	0.0112	23	24
2	0.0111	0.0112	23	25

4	0.0109	0.0112	22	26
7	0.0105	0.0111	21	28
14	0.0096	0.0109	19	33
21	0.0086	0.0106	17	38
28	0.0078	0.0102	16	44
42	0.0063	0.0095	15	57
50	0.0056	0.0090	14	64
100	0.0026	0.0070	3	103

(* PECact values are related to the time after the maximum concentration)

Calculation of background concentrations after many years

Final Background concentration in total soil for methyl over 20 cm(mg/kg): <0.0001**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): <0.0001

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for methyl over 5 cm considering accumulation* (mg/kg) 0.0112
(* a tillage depth of 20 cm was considered for calculating the background concentration)

Calculated time dependent total soil concentrations over 5 cm for methyl(mg/kg) considering accumulation*

Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0112	0.0112	23	24
2	0.0111	0.0112	23	25
4	0.0109	0.0112	22	26
7	0.0106	0.0111	21	28
14	0.0096	0.0109	19	33
21	0.0086	0.0106	17	38
28	0.0078	0.0102	16	44
42	0.0063	0.0095	15	57
50	0.0056	0.0090	14	64
100	0.0026	0.0070	3	103

(* a tillage depth of 20 cm was considered for calculating the background concentration)

(** PECact values are related to the time after the maximum concentration)

RESULTS FOR: desthio

Calculations over one year

Maximum annual total soil concentration for desthio over 5 cm(mg/kg): 0.0341 occurring on day 25^

(^ This is 20.14 % of the theoretical maximum concentration of the metabolite)

Calculated time dependent total soil concentrations over 5 cm for desthio after one year (mg/kg)

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0341	0.0341	25	26
2	0.0340	0.0341	24	26
4	0.0336	0.0340	23	27
7	0.0330	0.0339	22	29
14	0.0310	0.0335	20	34
21	0.0290	0.0329	19	40
28	0.0271	0.0321	18	46
42	0.0237	0.0306	16	58
50	0.0220	0.0297	16	66
100	0.0136	0.0246	7	107

(* PECact values are related to the time after the maximum concentration)

Calculation of background concentrations after many years

Final Background concentration in total soil for desthio over 20 cm(mg/kg): 0.0003**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): 0.0003

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for desthio over 5 cm considering accumulation* (mg/kg) 0.0344
(* a tillage depth of 20 cm was considered for calculating the background concentration)

Calculated time dependent total soil concentrations over 5 cm for desthio(mg/kg) considering accumulation*

Time(d)	PECact**	PECTwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0344	0.0344	25	26
2	0.0343	0.0344	24	26
4	0.0340	0.0344	23	27
7	0.0333	0.0342	22	29
14	0.0313	0.0338	20	34
21	0.0294	0.0332	19	40
28	0.0275	0.0325	18	46
42	0.0241	0.0309	16	58
50	0.0223	0.0300	16	66
100	0.0139	0.0249	7	107

(* a tillage depth of 20 cm was considered for calculating the background concentration)
(** PECact values are related to the time after the maximum concentration)

GRAPHIC REPRESENTATION OF THE CALCULATION

