

FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: FGG01

Product name: Lozzare Pro, Miller Pro, Palator Pro

Chemical active substance:

Boscalid, 500 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: 08/05/2024

MS Finalisation date: 11/2024, 03/2025

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Version history

When	What
08 May 2024	V0 – 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.
29.11.2024	Assessment by ZRMS.
Feb 2025	V1 – Updated version following zRMS comments. Additional PEC modelling for sunflower.
03.2025	Assessment updated verion by ZRMS.

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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 LOZZARE PRO (FGG01) in the central zone member states Austria, Belgium, Czech Republic, Hungary, the Netherlands, Poland (zRMS), Romania, Slovakia and Slovenia according to Regulation (EC) No 1107/2009.

The product is a water dispersible granule (WG) formulated fungicide containing 500 g/kg of the active substance boscalid. It is intended to be used as fungicide to control different pests in various crops.

The review report for boscalid (SANCO/3919/2007 – rev. 5, dated 21 January 2008) is considered to provide the relevant review information or a reference to where such information can be found.

The Annex I Inclusion Directive for boscalid (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.

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).

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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 Groundwater
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g 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	AT, BE, CZ, SI	Grapevine, wine & table	F	<i>Botrytis cinerea</i> (BOTRI)	Spraying overall	BBCH 60-85	a) 1 per use b) 1 per crop / season	-	a) 1.0 kg/ha b) 1.0 kg/ha	a) 500 g/ha b) 500 g/ha	100-1000	21	0.72 kg product / 10000 m² LWA (optional)	A
2	AT, BE, CZ, SI, PL	Grapevine, wine & table	F	<i>Uncinula necator</i> , Powdery mildew (UNCINE)	Spraying overall	BBCH 15-81	a) 3 per use b) 3 per crop / season	10-14	a) 0.2 kg/ha b) 1.0 kg/ha	a) 100 g/ha b) 300 g/ha	100-1000	21	0.14 kg product / 10000 m² LWA 0.02 kg/100 L (optional)	A
3	AT, BE, CZ, HU, NL, PL , RO, SK	Oilseed rape (winter and spring)	F	<i>Sclerotinia sclerotiorum</i> (SCLESC)	Spraying overall	BBCH 57-69	a) 1 per use b) 1 per crop / season	-	a) 0.5 kg/ha b) 0.5 kg/ha	a) 250 g/ha b) 250 g/ha	100-300	35	-	A
4	AT, BE, CZ, NL, SK, HU, RO	Oilseed rape (winter and spring)	F	<i>Alternaria</i> species (ALTESP)	Spraying overall	BBCH 57-69	a) 1 per use b) 1 per crop / season	-	a) 0.5 kg/ha b) 0.5 kg/ha	a) 250 g/ha b) 250 g/ha	100-300	35	-	A
5	HU, PL , RO, SK,	Oilseed rape (winter and	F	<i>Leptosperia maculans</i> (LEPTMA)	Spraying overall	BBCH 13-57	a) 1 per use	-	a) 0.5 kg/ha	a) 250 g/ha	100-300	35	-	A

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	AT, CZ	spring)					b) 1 per crop / season		b) 0.5 kg/ha	b) 250 g/ha				
6	AT, BE, CZ, NL, PL	Beans and peas (fresh)	F	<i>Botrytis</i> (BOTRSP)	Spraying overall	BBCH 60-69	a) 2 per use b) 2 per crop / season	7	a) 1.0 kg/ha b) 2.0 kg/ha	a) 500 g/ha b) 1000 g/ha	150-600	7	-	
7	AT, BE, CZ	Beans and peas (fresh)	F	<i>Sclerotinia</i> (SCLESP)	Spraying overall	BBCH 60-69	a) 2 per use b) 2 per crop / season	7	a) 1.0 kg/ha b) 2.0 kg/ha	a) 500 g/ha b) 1000 g/ha	150-600	7	-	
Minor crops – Art.51														
8	PL	Spring rape gold of pleasure, winter turnip rape, mustard, sunflower, poppy linseed, flax, hemp, borage	F	<i>Alternaria</i> species (ALTESP) <i>Sclerotinia sclerotiorum</i> (SCLESC)	Spraying overall	BBCH 57-69	a) 1 per use b) 1 per crop / season	-	a) 0.5 kg/ha b) 0.5 kg/ha	a) 250 g/ha b) 250 g/ha	100-300	35	-	A
9	PL	Spring rape gold of pleasure, winter turnip rape, mustard, poppy linseed, flax, hemp, borage	F	<i>Leptosperia maculans</i> (LEPTMA)	Spraying overall	BBCH 13-57	a) 1 per use b) 1 per crop / season	-	a) 0.5 kg/ha b) 0.5 kg/ha	a) 250 g/ha b) 250 g/ha	100-300	35	-	A
10	PL	Grapevine, wine & table	F	<i>Botrytis cinerea</i> (BOTRI)	Spraying overall	BBCH 60-85	a) 1 per use b) 1 per crop / season	-	a) 1.0 kg/ha b) 1.0 kg/ha	a) 500 g/ha b) 500 g/ha	100-1000	21	0.72 kg product / 10000 m ² LWA (optional)	A
11	PL	Beans for fresh seeds, Broad bean	F	<i>Sclerotinia</i> (SCLESP) <i>Botrytis cinerea</i> (BOTRI)	Spraying overall	BBCH 60-69	a) 2 per use	7	a) 1.0 kg/ha b) 2.0 kg/ha	a) 500 g/ha b) 1000 g/ha	150-600	7	-	A

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		French beans, Peas for fresh seeds, edible podded peas					b) 2 per crop / season							
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* 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

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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 or 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	EU (North & South)	Grapes	F	<i>Botrytis</i>	Spraying	BBCH 68 - 81	1	NA	1.2	0.600	1000-1600	28	-
3&4&5	EU	Oilseed rape	F	<i>Sclerotinia</i> , <i>Alternaria</i> , <i>Phoma</i>	Spraying	BBCH 30, BBCH 63 - 65	2	4-6 weeks	0.5	0.250	200-400	-	-
6&7	EU (North & South)	Peas	F	<i>Botrytis</i> , <i>Sclerotinia</i>	Spraying	BBCH 60 - 69	2	7-10	1.0	0.500	400	7	-
6&7	EU (North & South)	Beans	F	<i>Botrytis</i> , <i>Sclerotinia</i>	Spraying	BBCH 60 - 69	2	7-10	1.0	0.500	300	7	-

* 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

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.

8.3 Rate of degradation in soil (KCP 9.1.1)

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

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

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 tables below summarise 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 %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	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.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

The anaerobic rate of degradation in soil of 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 DT₅₀ 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.

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 was evaluated in the context of the Annex I inclusion process. No additional studies were performed.

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	DT90 (d) actual	Kinetic parameters	St. (r 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.

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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)	DT50 (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	-	
Geom. mean (n=3)				131		
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

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

The accumulation in soil of boscalid 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**.

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 was evaluated in the context of the Annex I inclusion process. No additional studies were performed.

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

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

Boscalid							
Soil name	Soil type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (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		

8.5.1 Column leaching (KCP 9.1.2.1)

Refer to Point 8.5 above.

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

Reliable adsorption coefficient values were obtained for the active substance in the adsorption/desorption study. 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.

8.5.2 Lysimeter studies (KCP 9.1.2.2)

Refer to Point 8.5 above.

8.5.3 Field leaching studies (KCP 9.1.2.3)

Refer to Point 8.5 above.

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.

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 dark aerobic natural sediment water systems, the dissipation of boscalid in the water phase of both systems was mainly bayed 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 DT₅₀ values of 9 days and 3 days for system A and B, respectively. Appropriate DT₅₀ 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 CO₂ 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 DT₅₀ 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 and ecotoxicological relevance.

For PEC_{SW} calculations a DT₅₀ 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 DT₅₀ 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 line with the current guidance from FOCUS surface water, which states that system values are needed (unless it is proven that the DT₅₀ 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
Kellmetschweiler (System A)	8.5 / 6.8	-- ^a	-- ^a	--	9	133	Graphic	--	--	Y / SANCO/3919/2007 – rev. 5
Kellmetschweiler (System B)	8.1 / 7.5	-- ^a	-- ^a	--	3	43	Graphic	--	--	
Kellmetschweiler (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-14C]-boscalid) However, this metabolite was of transient nature. Additionally, this compound is of no toxicological and ecotoxicological relevance.	Y / SANCO/3919/2007 – rev. 5

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.

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.

8.7.2 Active substance

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 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 were 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]

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

$PEC_{soil,max,d}$	Maximum concentration following last application	$[\mu\text{g kg}^{-1}]$
k	Degradation rate in soil $(\ln(2)/DT_{50})$	$[\text{d}^{-1}]$
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	$[\mu\text{g kg}^{-1}]$
$PEC_{soil,plateau}$	Plateau concentration at steady state	$[\mu\text{g kg}^{-1}]$
$PEC_{soil,max}$	Maximum concentration	$[\mu\text{g kg}^{-1}]$

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 8.7-2**.

The PEC_{soil} calculations were performed for use in grapevine (vine and fresh) (1×500 g a.s./ha, post-emergence) and fresh beans (2×500 g a.s./ha, post-emergence), as a worst case in terms of a total soil loading for single and multiple applications, respectively. The two uses cover use to oilseed rape as well as all other GAP uses of FGG01.

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

Use No.	1	6
FOCUS Crop	Vines	Beans (field + vegetable)
Application rate (g a.s./ha)	Active substance boscalid: 500 g/ha	Active substance boscalid: 500 g/ha
Number of applications / interval	1 / -	2 / 7
Application timing	BBCH 60-85	BBCH 60-69
Crop interception (%)	60%	70%
Depth of soil layer (relevant for plateau concentration) (cm)	5 cm (no tillage)	20 cm (tillage)

Table 8.7-2: Input parameters related to application for $PEC_{soil,plateau}$ calculations

Use No.	1	6
Total annual application rate (g a.s./ha)	500 g a.s./ha	1000 g a.s./ha
Minimum accumulation factor in soil as derived from a field accumulation study	95%	95%
Depth of the considered soil cultivation layer	5 cm	20 cm
Density of the soil layer	1.5 g/cm ³	1.5 g/cm ³

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Table 8.7-3: Input parameter for active substance boscalid for PEC_{soil} calculation

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT ₅₀ (days)	Value in accordance to EU endpoint y/n/ 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

Table 8.7-4: PEC_{soil} for boscalid on grapevine (vine and fresh) (1 × 500 g a.s./ha, post-emergence)

PEC_{soil} (mg/kg)		Grapevine (vine and fresh)			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.267	-	-	--
Short term	24h	0.266	0.266	-	--
	2d	0.266	0.266	-	--
	4d	0.265	0.266	-	--
Long term	7d	0.263	0.265	-	--
	14d	0.259	0.263	-	--
	21d	0.256	0.261	-	--
	28d	0.252	0.259	-	--
	42d	0.245	0.256		
	50d	0.241	0.254	-	--
	100d	0.218	0.241	-	-
Plateau concentration(5 cm)					
FOCUS Approach:		0.242	-	-	-
Additional Approach:		0.633			
$PEC_{accumulation}$ ($PEC_{act} + PEC_{soil\ plateau}$)					
FOCUS Approach:		0.509	-	-	-
Additional Approach:		0.900			

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Table 8.7-5: PEC_{soil} for boscalid on fresh beans (2 × 500 g a.s./ha, post-emergence)

PEC _{soil} (mg/kg)		Fresh beans			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.200	-	0.397	-
Short term	24h	0.200	0.200	0.396	0.397
	2d	0.199	0.200	0.396	0.396
	4d	0.198	0.199	0.394	0.396
Long term	7d	0.197	0.199	0.392	0.394
	14d	0.194	0.197	0.386	0.392
	21d	0.192	0.196	0.381	0.389
	28d	0.189	0.194	0.375	0.386
	42d	0.184	0.192	0.365	0.381
	50d	0.181	0.190	0.359	0.378
	100d	0.163	0.181	0.324	0.359
Plateau concentration (20 cm)					
FOCUS Approach:		0.045	-	0.090	-
Additional approach:		0.158		0.317	
PEC _{accumulation} (PEC _{act} + PEC _{soil plateau})					
FOCUS Approach:		0.245	-	0.486	-
Additional approach:		0.360		0.714	

The risk assessment presented above for use on grapevine and beans covers all other uses in the GAP table. The soil loading, when considering the worst case crop-interception, is higher for the presented uses on grapevine and beans than for any of the other uses. Therefore the presented PEC_{soil} calculations cover all uses in the GAP.

zRMS comments:

PECs calculations have been accepted. The calculations cover proposed GAP. Soil parameters used for the calculations were considered at the EU level. Accumulated concentration was calculated for the boscalid by assuming distribution of plateau concentration through either plough layer .
No PEC_{soil} calculations were performed for metabolites of boscalid because metabolites no were found in amounts greater than 10% of the applied parent (DAR 2002). The crop interception assumed in calculations is in line with the most recent version of the FOCUS Groundwater Guidance of 2014.

The PECs results are presented in Table 8.7-4 and Table 8.7-5.

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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 in groundwater (PEC _{gw}) – Boscalid 50 WG (FGG01) -
Document No:	GW-213-220810-01
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

Use No.	1	2
FOCUS Crop	Vines	Vines
Application rate (g a.s./ha)	Boscalid: 500 g a.s./ha	Boscalid: 100 g a.s./ha
Number of applications / interval (d)	1 / -	3 / 10
Application timing	BBCH 60-85	BBCH 15-81
Absolute application date	Refer to Table 8.8-2 below	Refer to Table 8.8-2 below
Crop interception (%)	Early: 60% Late: 75%	Early: 60% Late: 75%
Frequency of application	annual	annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3	

n.r. not relevant

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Table 8.8-2: Input parameters related to application for PEC_{gw} calculations (continued)

Use No.	3-5	6-7
FOCUS Crop	Oilseed rape, summer Oilseed rape, winter	Beans (field + vegetable) Peas
Application rate (g a.s./ha)	Boscalid: 250 g a.s./ha	Boscalid: 500 g a.s./ha
Number of applications / interval (d)	1 / -	2 / 7
Application timing	BBCH 57-69 BBCH 13-57	BBCH 60-69
Absolute application date	Refer to Table 8.8-3 below	Refer to Table 8.8-4 below
Crop interception (%)	Early: 40% Intermediate & late: 80%	Beans: 70% Peas: 85%
Frequency of application	annual	annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3 FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5	

n.r. not relevant

Table 8.8-3: Application dates used for groundwater risk assessment

Scenario	Application dates (absolute)			
	Vines, 1 × 500 g a.s./ha		Vines, 3 × 100 g a.s./ha	
	BBCH 60 (early)	BBCH 85 (late)	BBCH 15 (early)	BBCH 81 (late)
Châteaudun	21/06	09/10	22/04 & 02/05 & 12/05	31/08 & 10/09 & 20/09
Hamburg	20/06	03/10	14/05 & 24/05 & 03/06	23/08 & 02/09 & 12/09
Kremsmünster	20/06	03/10	14/05 & 24/05 & 03/06	23/08 & 02/09 & 12/09
Piacenza	21/06	09/10	22/04 & 02/05 & 12/05	31/08 & 10/09 & 20/09
Porto	15/06	15/09	08/04 & 18/04 & 28/04	17/08 & 27/08 & 03/09
Sevilla	21/05	19/10	14/04 & 24/04 & 04/05	26/08 & 05/09 & 15/09
Thiva	26/05	22/09	03/04 & 13/04 & 23/04	11/08 & 21/08 & 31/08

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Table 8.8-3: Application dates used for groundwater risk assessment

Scenario	Application dates (absolute)					
	Oilseed rape, 1 × 250 g a.s./ha					
	Summer			Winter		
	BBCH 13 (early)	BBCH 57 (interm.)	BBCH 69 (late)	BBCH 13 (early)	BBCH 57 (interm.)	BBCH 69 (late)
Châteaudun	16/03 ^a	05/06 ^a	22/06 ^a	12/09	14/04	14/05
Hamburg	06/04 ^a	01/06 ^a	28/06 ^a	07/09	02/05	30/05
Jokioinen	24/05	02/07	22/07	-	-	-
Kremsmünster	06/04 ^a	01/06 ^a	28/06 ^a	07/09	02/05	30/05
Okehampton	03/04	12/05	13/06	19/08	27/04	25/05
Piacenza	-	-	-	10/10	09/04	05/05
Porto	28/03	26/05	26/06	25/09	03/04	14/05

^a Crop not defined, a surrogate crop “spring cereals” was used (AGES, 2022)

Table 8.8-4: Application dates used for groundwater risk assessment

Scenario	Application dates (absolute)	
	Beans, 2 × 500 g a.s./ha	Peas, 2 × 500 g a.s./ha
	Last application at BBCH 69	Last application at BBCH 69
Châteaudun	-	21/06 & 28/06
Hamburg	17/07 & 24/07	17/07 & 24/07
Jokioinen	-	10/07 & 17/07
Kremsmünster	17/07 & 24/07	-
Okehampton	30/06 & 07/07	21/06 & 28/06
Porto	09/06 & 16/06	-
Thiva	08/05 & 15/05 (1 st crop) 17/08 & 24/08 (2 nd crop)	-

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Table 8.8-5: 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 Normalized to 20°C using Q₁₀ of 2.2

Table 8.8-6: PEC_{GW} for boscalid following application of FGG01 on vines (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
Grapevines, wine & table, early and late applications (1 × 500 g a.s./ha)	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001
Grapevines, wine & table, early and late applications (3 × 100 g a.s./ha)	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001
	Porto	< 0.001	< 0.001

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	Sevilla	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001

Table 8.8-7: PEC_{GW} for boscalid following application of FGG01 on oilseed rape (winter and spring) (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
Oilseed rape, summer, early interm. and late applications (post-emergence, 1 × 250 g a.s./ha)	Châteaudun^a	< 0.001	< 0.001
	Hamburg^a	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Kremsmünster^a	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
Oilseed rape, winter, early, interm. and late applications (post-emergence, 1 × 250 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

^a Crop not defined, a surrogate crop “spring cereals” was used (AGES, 2022)

Table 8.8-8: PEC_{GW} for boscalid following application of FGG01 on beans and peas (fresh) (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
Beans (post-emergence, 2 × 500 g a.s./ha)	Hamburg	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001
	Porto	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001
Peas (post-emergence, 2 × 500 g a.s./ha)	Châteaudun	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001

Additional PEC_{GW} modelling for the use on sunflower is presented here considering application at BBCH 61-73. 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 substance are the same as used for modelling other uses and are as presented in **Table 8.8-5**.

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

Use No.	8 - sunflower
FOCUS Crop	Maize, as surrogate for sunflower
Application rate (g a.s./ha)	Boscalid: 250 g a.s./ha
Number of applications / interval (d)	1 / -
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)	62.5
Frequency of application	Annual
Models used for calculation	FOCUS PELMO 6.6.4 and FOCUS PEARL 5.5.5

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

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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	04/09
Hamburg	01/08	22/08
Kremsmünster	01/08	22/08
Okehampton	18/07	20/08
Piacenza	03/08	08/09
Porto	17/08	04/09
Sevilla	17/06	05/07
Thiva	18/06	25/07

Early and late applications were modelled and results are presented in **Table 8.8-11**.

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 × 250 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:

PECgw calculations have been accepted. The calculations cover proposed uses in GAP. The crop interception assumed in calculations is in line with the most recent version of the FOCUS Groundwater Guidance of 2014. In simulations PUF value of 0 was assumed for all compounds, in line with recommendations of the most recent version of the FOCUS Groundwater Guidance.

According to DAR in field studies no metabolite was found in amounts greater than 10% of the applied parent, therefore no PECgw calculations are performed for metabolites of boscalid. No MACRO calculations was required (PECgw < 0.001 µg/L).

Based on Focus PEARL and PELMO simulations. Calculated PECgw values are far below the threshold concentration of 0.1 µg/L for all scenarios and crops.

Boscalid is not predicted to leach into ground water above the critical 0.1 µg/L threshold following a 26-year period of application to vines, winter and spring oilseed rape, beans, peas.

No unacceptable risk for groundwater was identified.

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 in Surface Water and Sediment (PEC _{sw} and PEC _{sed}) – Boscalid 50 WG (FGG01) -.
Document No:	SW-213-220810-01
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.

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

Plant protection product	FGG01	
FOCUS Crop	Vines, late applications	Vines, early applications Vines, late applications
Application rate (g a.s./ha)	Boscalid: 500	Boscalid: 100
Number of applications/interval (d)	1 / -	3 / 10
Application timing	BBCH 60-85	BBCH 15-81
Application period (Step 2)	Oct.-Feb., Mar.-May & June-Sep.	Early: Oct.-Feb., Mar.-May Late: June-Sep.
Crop interception (Step 2)	Full canopy	Early: Minimal crop cover Late: Full canopy
Application window (Step 3)	Please see Tables 8.9.2-2 Length of application window 30 d	Please see Tables 8.9.2-2 Length of application window 50 d
FOCUS Locations	Step 1: not relevant Step 2: north and south EU Step 3: D6, R1, R2, R3 and R4	Step 1: not relevant Step 2: north and south EU Step 3: D6, R1, R2, R3 and R4
Application method (Step 3)	Air blast	Air blast
CAM (Chemical application method) (Step 3)	2	2
Soil depth (cm) (Step 3)	4	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	

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

Plant protection product	FGG01	
FOCUS Crop	Oilseed rape, summer Oilseed rape, winter	Oilseed rape, summer Oilseed rape, winter
Application rate (g a.s./ha)	Boscalid: 250	Boscalid: 250
Number of applications / interval (d)	1 / -	1 / -
Application timing	BBCH 57-69	BBCH 13-57
Application period (Step 2)	Mar.-May & June-Sep.	Oct.-Feb., Mar.-May & June-Sep.
Crop interception (Step 2)	Full canopy	Minimal crop cover
Application window (Step 3)	Please see Table 8.9.2-3 and Table 8.9.2-4 Length of application window 30 d	Please see Table 8.9.2-3 and Table 8.9.2-4 Length of application window 30 d
FOCUS locations	Step 1: not relevant Step 2: north and south EU Step 3: OSRS: D1, D3, D4 , D5, R1 OSRW: D2, D3, D4 , D5, R1 , R3	Step 1: not relevant Step 2: north and south EU Step 3: OSRS: D1, D3, D4 , D5, R1 OSRW: D2, D3, D4, D5, R1 , R3
Application method (Step 3)	Ground spray	Ground spray
CAM (Chemical application method) (Step 3)	2	2
Soil depth (cm) (Step 3)	4	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	

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

Plant protection product	FGG01
FOCUS Crop	Legumes ^a
Application rate (g/ha)	Boscalid: 500
Number of applications/interval (d)	2 / 7
Application timing	BBCH 60-69
Application period (Step 2)	Mar.-May, June-Sep.
Crop interception (Step 2)	Full canopy
Application window (Step 3)	Please see Table 8.9.2-5 Length of application window 37 d
FOCUS locations	Step 1: not relevant Step 2: north and south EU Step 3: D3, D4, D5, D6, R1, R2, R3, R4
Application method	Ground spray
CAM (Chemical application method)	2
Soil depth (cm)	4
Models used for calculation	STEP 1-2 v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXSWA v5.5

^a Covering use in fresh beans and peas

Table 8.9.2-2: FOCUS Step 3 scenario related input parameters for PEC_{SW/SED} calculations for the application of LOZZARE PRO, vines

Scenario	Application window used in modelling ^a			
	Vines, 1 × 500 g/ha		Vines, 3 × 100 g/ha	
	Early (from BBCH 60)	Late (up to BBCH 85)	Early (from BBCH 15)	Late (up to BBCH 85)
D6	02/04 (92) – 02/05 (122)	24/08 (236) – 23/09 (266)	17/02 (48) – 08/04 (98)	04/08 (214) – 23/09 (266)
R1 ^b	06/06 (157) – 06/07 (187)	31/08 (243) – 30/09 (273)	29/04 (119) – 18/06 (169)	11/08 (223) – 30/09 (273)
R2	15/06 (166) – 15/07 (196)	16/08 (228) – 15/09 (258)	08/04 (98) – 28/05 (148)	27/07 (208) – 15/09 (258)
R3	21/06 (172) – 21/07 (202)	09/09 (252) – 09/10 (282)	22/04 (112) – 11/06 (162)	20/08 (232) – 09/10 (282)
R4	06/06 (157) – 06/07 (187)	06/08 (218) – 05/09 (248)	02/04 (92) – 22/05 (142)	17/07 (198) – 05/09 (248)

^a Application date for BBCH 15, 60, 85 is taken from AppDate v3.06 and adjusted for the application window

^b Used also for D3 scenario, required according to Belgian national requirements (FPS Health, Food Chain Safety and Environment, 2021)

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Table 8.9.2-3: FOCUS Step 3 scenario related input parameters for PEC_{SW/SED} calculations for the application of LOZZARE PRO, oilseed rape, winter

Scenario	Application window used in modelling ^a		
	Oilseed rape, winter, 1 × 250 g/ha (BBCH 57-69)	Oilseed rape, winter, 1 × 250 g/ha (BBCH 13-57)	
	Summer (from BBCH 57) ^b	Autumn (from BBCH 13)	Spring (up to BBCH 57)
D2	31/05 (151) – 30/06 (181)	20/09(263) – 20/10 (293)	01/05 (121) – 31/05 (151)
D3	11/05 (131) – 10/06 (161)	07/09 (250) – 07/10 (280)	11/04 (101) – 11/05 (131)
D4	22/05 (142) – 21/06 (172)	08/09 (251) – 08/10 (281)	22/04 (112) – 22/05 (142)
D5	30/04 (120) – 30/05 (150)	25/09 (268) – 25/10 (298)	31/03 (90) – 30/04 (120)
R1	19/05 (139) – 18/06 (169)	09/09 (252) – 09/10 (282)	19/04 (109) – 19/05 (139)
R3	13/04 (103) – 13/05 (133)	10/10 (283) – 09/11 (313)	14/03 (73) – 13/04 (103)

^a Application date for BBCH 13 and 57 taken from AppDate v3.06 and adjusted for the application window

^b Application window sufficiently long to cover the proposed BBCH range of 57-69.

Table 8.9.2-4: FOCUS Step 3 scenario related input parameters for PEC_{SW/SED} calculations for the application of LOZZARE PRO, oilseed rape, spring

Scenario	Application window used in modelling ^a		
	Oilseed rape, spring, 1 × 250 g/ha	Oilseed rape, spring, 1 × 250 g/ha	
	Summer (from BBCH 57) ^b	Spring (from BBCH 13)	Summer (up to BBCH 57)
D1	01/07 (182) – 31/07 (212)	23/05 (143) – 22/06 (173)	01/06 (152) – 01/07 (182)
D3	10/06 (161) – 10/07 (191)	16/04 (106) – 16/05 (136)	11/05 (131) – 10/06 (161)
D4	14/06 (165) – 14/07 (195)	05/05 (125) – 04/06 (155)	15/05 (135) – 14/06 (165)
D5	20/05 (140) – 19/06 (170)	21/03 (80) – 20/04 (110)	20/04 (110) – 20/05 (140)
R1	03/06 (154) – 03/07 (184)	15/04 (105) – 15/05 (135)	04/05 (124) – 03/06 (154)
R3	15/05 (135) – 14/06 (165) ^c	25/04 (115) – 25/05 (145) ^d	-

^a Application date for BBCH 13, 57 is taken from AppDate v3.06 and adjusted for the application window

^b Application window sufficiently long to cover the proposed BBCH range of 57-69

^c Crop not defined, a surrogate crop “legumes” was used with application window starting at BBCH 55 (AGES, 2022)

^d Crop not defined, a surrogate crop “legumes” was used (AGES, 2022) and covers the whole application window for this crop

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Table 8.9.2-5: FOCUS Step 3 scenario related input parameters for PEC_{SW/SED} calculations for the application of LOZZARE PRO, beans and peas ^a

Scenario	Application window used in modelling ^a
	Fresh beans and peas, 2 × 500 g/ha (from BBCH 60)
D3	15/06 (166) – 22/07 (203)
D4	20/06 (171) – 27/07 (208)
D5	30/05 (150) – 06/07 (187)
D6	20/05 (140) – 26/06 (177)
R1	12/06 (163) – 19/07 (200)
R2	20/05 (140) – 26/06 (177)
R3	20/05 (140) – 26/06 (177)
R3	20/05 (140) – 26/06 (177)

^a Legumes used as a representative crop

^b Application date for BBCH 60 taken from AppDate v3.06 and adjusted for the application window

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Table 8.9.2-6: 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 _{foc} (mL/g)	743 (geomean, n=6)	Y / SANCO/3919/2007 – rev. 5 Geomean K _{foc} , according to EFSA Journal 2014;12(5):3662, 38 pp.
K _{fom} (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)	
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
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)	
Maximum occurrence observed (% molar basis with respect to the parent)	-	-
Formation fraction in soil:	-	-

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

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PEC_{sw/sed}

Table 8.9.2-7: FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} for active substance boscalid following one application to vines at 500 g a.s./ha

Scenario FOCUS	Season of application	Max PEC _{SW} (µg/L)	Dominant entry route	21 d- PEC _{SW, twa} (µg/L)	Max PEC _{SED} (µg/kg)
Step 1	-	97.104	Runoff/Drainage	n.r.	666.854
Step 2					
Northern Europe	March-May	14.440	Spraydrift	n.r.	97.657
	June-September	14.440	Spraydrift	n.r.	97.657
	October-February	24.289	Spraydrift	n.r.	170.781
Southern Europe	March-May	21.006	Spraydrift	n.r.	146.406
	June-September	17.723	Spraydrift	n.r.	122.032
	October-February	21.006	Spraydrift	n.r.	146.406

n.r. not required

Table 8.9.2-8: FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} for active substance boscalid following three applications to vines at 100 g a.s./ha

Scenario FOCUS	Season of application	Max PEC _{SW} (µg/L) ^a	Dominant entry route	21 d- PEC _{SW, twa} (µg/L)	Max PEC _{SED} (µg/kg) ^a
Step 1	-	52.933	Runoff/Drainage	n.r.	380.375
Step 2					
Northern Europe	March-May	7.054 (2.499)	Spraydrift	n.r.	97.657 (17.913)
	June-September	7.618 (2.888)	Spraydrift	n.r.	97.657 (19.531)
	October-February	15.493 (5.454)	Runoff/Drainage	n.r.	170.781 (39.850)
Southern Europe	March-May	12.680 (4.469)	Spraydrift	n.r.	146.406 (32.538)
	June-September	9.494 (3.545)	Spraydrift	n.r.	122.032 (24.406)
	October-February	12.680 (4.469)	Runoff/Drainage	n.r.	146.406 (32.538)

n.r. not required

^a Values in brackets are respective single applications

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Table 8.9.2-9: FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} for active substance boscalid following one application to oilseed rape (winter and spring) at 250 g a.s./ha

Scenario FOCUS	Season of application	Max PEC _{SW} (µg/L) ^a	Dominant entry route	21 d- PEC _{SW, twa} (µg/L)	Max PEC _{SED} (µg/kg) ^a
Step 1	-	44.161	Runoff/Drainage	n.r.	317.164
Step 2 – BBCH 57-69					
Northern Europe	March-May	3.405	Spraydrift	n.r.	23.638
	June-September	3.405	Spraydrift	n.r.	23.638
Southern Europe	March-May	5.457	Runoff/Drainage	n.r.	38.872
	June-September	4.431	Runoff/Drainage	n.r.	31.255
Step 2 – BBCH 13-57					
Northern Europe	March-May	6.277	Spraydrift	n.r.	44.966
	June-September	3.405	Spraydrift	n.r.	23.638
Southern Europe	March-May	11.202	Runoff/Drainage	n.r.	81.528
	June-September	4.431	Runoff/Drainage	n.r.	31.255

n.r. not required

a Values in brackets are respective single applications

Table 8.9.2-10: FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} for active substance boscalid following two applications to fresh beans and peas (surrogate crop: legumes) at 500 g a.s./ha

Scenario FOCUS	Season of application	Max PEC _{SW} (µg/L) ^a	Dominant entry route	21 d- PEC _{SW, twa} (µg/L)	Max PEC _{SED} (µg/kg) ^a
Step 1	-	176.645	Runoff/Drainage	n.r.	1270
Step 2					
Northern Europe	March-May	14.381 (7.631)	Spraydrift	n.r.	101.073 (53.370)
	June-September	14.381 (7.631)	Spraydrift	n.r.	101.073 (53.370)
Southern Europe	March-May	24.060 (12.555)	Runoff/Drainage	n.r.	172.943 (89.932)
	June-September	19.220 (10.093)	Runoff/Drainage	n.r.	137.008 (71.651)

n.r. not required

a Values in brackets are respective single applications

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Table 8.9.2-11: Maximum PEC_{SW} and PEC_{SED} actual of boscalid after one application to vines at 500 g a.s./ha (FOCUS Step 3)

Scenario FOCUS	Waterbody	Max PEC _{SW} (µg/L)	Dominant entry route	21 d- PEC _{SW,TWA} (µg/L)	Max PEC _{SED} (µg/kg)
Vines, early applications, 1 × 500 g a.s./ha					
D3 ^a	ditch	8.531	drift	n.r.	6.150
D6	ditch	8.522	drift	n.r.	6.631
R1	pond	0.353	runoff	n.r.	2.180
R1	stream ^b	6.269	drift	n.r.	2.147
R1	stream ^b	6.288	drift	n.r.	0.939
R2	stream	8.429	drift	n.r.	1.157
R3	stream	8.828	drift	n.r.	1.882
R4	stream	6.287	drift	n.r.	1.286
Vines, late applications, 1 × 500 g a.s./ha					
D3 ^a	ditch	8.537	drift	n.r.	6.609
D6	ditch	8.574	drift	n.r.	13.55
R1	pond	0.305	drift	n.r.	1.679
R1	stream ^b	6.288	drift	n.r.	0.942
R1	stream ^b	6.288	drift	n.r.	0.939
R2	stream	8.429	drift	n.r.	0.887
R3	stream	8.863	drift	n.r.	3.893
R4	stream	6.287	drift	n.r.	2.217

n.r. not relevant

^a Crop not defined, a surrogate crop “pome/stone fruit, early applications” was used, with the mean deposition mass in TOXSWA corrected for crop “vines, late application” (FPS Health, Food Chain Safety and Environment, 2021)

^b Covering D4 scenario, runoff entries (water and substance flow) were switched off during modelling (AGES, 2022)

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Table 8.9.2-12: Maximum PEC_{SW} and PEC_{SED} actual of boscalid after three early applications to vines at 100 g a.s./ha (FOCUS Step 3)

Scenario FOCUS	Waterbody	Max PEC _{SW} (µg/L)	Dominant entry route	21 d- PEC _{SW,TWA} (µg/L)	Max PEC _{SED} (µg/kg)
Vines, early applications, 3 × 100 g a.s./ha					
D6	ditch	0.870	drainage	n.r.	1.116
D3 ^a	ditch	0.518	drift	n.r.	0.588
R1	pond	0.046	runoff	n.r.	0.359
R1	stream ^b	1.086	runoff	n.r.	0.759
R1	stream ^b	0.374	drift	n.r.	0.077
R2	stream	0.587	runoff	n.r.	0.817
R3	stream	0.528	drift	n.r.	0.274
R4	stream	2.199	runoff	n.r.	2.126
D6	ditch	0.870	drainage	n.r.	1.116
Vines, early applications, 1 × 100 g a.s./ha					
D3 ^a	ditch	0.565	drift	n.r.	0.367
R1	stream ^b	0.415	drift	n.r.	0.064
R3	stream	0.582	drift	n.r.	0.124

n.r. not relevant

^a Crop not defined, a surrogate crop “pome/stone fruit, early applications” was used, with the mean deposition mass in TOXSWA corrected for crop “vines, early application” (FPS Health, Food Chain Safety and Environment, 2021)

^b Covering D4 scenario, runoff entries (water and substance flow) were switched off during modelling (AGES, 2022)

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Table 8.9.2-13: Maximum PEC_{SW} and PEC_{SED} actual of boscalid after three late applications to vines at 100 g a.s./ha (FOCUS Step 3)

Scenario FOCUS	Waterbody	Max PEC _{SW} (µg/L)	Dominant entry route	21 d- PEC _{SW,TWA} (µg/L)	Max PEC _{SED} (µg/kg)
Vines, late applications, 3 × 100 g a.s./ha					
D3 ^a	ditch	1.493	drift	n.r.	2.834
D6	ditch	1.849	drift	n.r.	5.529
R1	pond	0.123	drift	n.r.	0.854
R1	stream ^b	1.072	drift	n.r.	0.236
R1	stream ^b	1.072	drift	n.r.	0.236
R2	stream	1.436	drift	n.r.	0.436
R3	stream	1.512	drift	n.r.	2.115
R4	stream	1.587	runoff	n.r.	1.105
Vines, late applications, 1 × 100 g a.s./ha					
D3 ^a	ditch	1.707	drift	n.r.	1.425
D6	ditch	1.714	drift	n.r.	2.922
R1	pond	0.061	drift	n.r.	0.367
R1	stream ^b	1.257	drift	n.r.	0.192
R1	stream ^b	1.257	drift	n.r.	0.191
R2	stream	1.685	drift	n.r.	0.208
R3	stream	1.772	drift	n.r.	0.869

n.r. not relevant

^a Crop not defined, a surrogate crop “pome/stone fruit, early applications” was used, with the mean deposition mass in TOXSWA corrected for crop “vines, late application” (FPS Health, Food Chain Safety and Environment, 2021)

^b Covering D4 scenario, runoff entries (water and substance flow) were switched off during modelling (AGES, 2022)

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Table 8.9.2-14: Maximum PEC_{SW} and PEC_{SED} actual of boscalid after one summer application to oilseed rape (winter and spring) at 250 g a.s./ha (FOCUS Step 3)

Scenario FOCUS	Waterbody	Max PEC _{SW} (µg/L)	Dominant entry route	21 d- PEC _{SW,TWA} (µg/L)	Max PEC _{SED} (µg/kg)
Winter oilseed rape, 1 × 250 g a.s./ha (BBCH 57-69)					
D2	ditch	2.886	drainage	n.r.	19.48
D2	stream	1.932	drift	n.r.	11.62
D3	ditch	1.586	drift	n.r.	1.095
D4	pond	0.166	drainage	n.r.	1.579
D4	stream	1.334	drift	n.r.	0.507
D5	pond	0.180	drainage	n.r.	1.754
D5	stream	1.477	drift	n.r.	0.441
R1	pond	0.165	runoff	n.r.	1.335
R1	stream	1.153	runoff	n.r.	2.833
R3	stream	1.534	runoff	n.r.	2.144
Spring oilseed rape, 1 × 250 g a.s./ha (BBCH 57-69)					
D1	ditch	2.530	drainage	n.r.	22.26
D1	stream	1.596	drainage	n.r.	12.41
D3	ditch	1.588	drift	n.r.	1.189
D4	pond	0.193	drainage	n.r.	1.725
D4	stream	1.369	drift	n.r.	0.558
D5	pond	0.393	drainage	n.r.	3.382
D5	stream	1.476	drift	n.r.	0.921
R1	pond	0.311	runoff	n.r.	1.939
R1	stream	1.316	runoff	n.r.	2.958
R3 ^a	stream	1.395	runoff	n.r.	1.055

n.r. not relevant

a Crop not defined, a surrogate crop “legumes” was used

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Table 8.9.2-15: Maximum PEC_{SW} and PEC_{SED} actual of boscalid after one application to oilseed rape (winter) at 250 g a.s./ha (FOCUS Step 3)

Scenario FOCUS	Waterbody	Max PEC _{SW} (µg/L)	Dominant entry route	21 d- PEC _{SW,TWA} (µg/L)	Max PEC _{SED} (µg/kg)
Winter oilseed rape, autumn application, 1 × 250 g a.s./ha (BBCH 13-57)					
D2	ditch	10.28	drainage	n.r.	47.24
D2	stream	6.405	drainage	n.r.	27.61
D3	ditch	1.589	drift	n.r.	1.283
D4	pond	0.586	drainage	n.r.	4.967
D4	stream	1.369	drift	n.r.	1.723
D5	pond	0.406	drainage	n.r.	3.856
D5	stream	1.477	drift	n.r.	0.998
R1	pond	0.140	runoff	n.r.	1.171
R1	stream	1.297	runoff	n.r.	0.679
R3	stream	2.395	runoff	n.r.	2.423
Winter oilseed rape, spring application, 1 × 250 g a.s./ha (BBCH 13-57)					
D2	ditch	5.037	drainage	n.r.	28.90
D2	stream	3.148	drainage	n.r.	17.00
D3	ditch	1.582	drift	n.r.	0.882
D4	pond	0.294	drainage	n.r.	2.693
D4	stream	1.255	drift	n.r.	0.908
D5	pond	0.242	drainage	n.r.	2.527
D5	stream	1.284	drift	n.r.	0.607
R1	pond	0.151	runoff	n.r.	1.162
R1	stream	1.055	runoff	n.r.	0.914
R3	stream	1.462	drift	n.r.	1.555

n.r. not relevant

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Table 8.9.2-16: Maximum PEC_{SW} and PEC_{SED} actual of boscalid after one application to oilseed rape (spring) at 250 g a.s./ha (FOCUS Step 3)

Scenario FOCUS	Waterbody	Max PEC _{SW} (µg/L)	Dominant entry route	21 d- PEC _{SW,TWA} (µg/L)	Max PEC _{SED} (µg/kg)
Spring oilseed rape, spring application, 1 × 250 g a.s./ha (BBCH 13-57)					
D1	ditch	4.112	drainage	n.r.	36.50
D1	stream	2.745	drainage	n.r.	20.43
D3	ditch	1.583	drift	n.r.	0.911
D4	pond	0.380	drainage	n.r.	3.396
D4	stream	1.297	drift	n.r.	1.164
D5	pond	0.271	drainage	n.r.	2.617
D5	stream	1.258	drift	n.r.	0.650
R1	pond	0.181	runoff	n.r.	1.501
R1	stream	1.563	runoff	n.r.	1.076
R3 ^a	stream	1.280	drift	n.r.	0.741
Spring oilseed rape, summer application, 1 × 250 g a.s./ha (BBCH 13-57)					
D2	ditch	4.089	drainage	n.r.	36.22
D2	stream	2.728	drainage	n.r.	20.27
D3	ditch	1.585	drift	n.r.	0.996
D4	pond	0.323	drainage	n.r.	2.839
D4	stream	1.297	drift	n.r.	0.965
D5	pond	0.258	drainage	n.r.	2.372
D5	stream	1.378	drift	n.r.	0.594
R1	pond	0.235	runoff	n.r.	1.790
R1	stream	1.869	runoff	n.r.	1.547

n.r. not relevant

a Crop not defined, a surrogate crop “legumes” was used (AGES, 2022)

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Table 8.9.2-17: Maximum PEC_{SW} and PEC_{SED} actual of boscalid after two applications to fresh beans and peas (surrogate crop: legumes) at 500 g a.s./ha (FOCUS Step 3)

Scenario FOCUS	Waterbody	Max PEC _{SW} (µg/L)	Dominant entry route	21 d- PEC _{SW,TWA} (µg/L)	Max PEC _{SED} (µg/kg)
Fresh beans and peas, 2 × 500 g/ha					
D3	ditch	2.279	drift	n.r.	1.868
D4	pond	2.841	drainage	n.r.	21.21
D4	stream	3.556	drainage	n.r.	8.278
D5	pond	0.969	drainage	n.r.	10.27
D5	stream	2.207	drift	n.r.	2.354
D6	ditch	5.984	drainage	n.r.	7.593
R1	pond	0.704	runoff	n.r.	5.962
R1	stream	5.926	runoff	n.r.	5.975
R2	stream	2.117	runoff	n.r.	6.221
R3	stream	4.652	runoff	n.r.	3.563
R4	stream	9.504	runoff	n.r.	6.144
Fresh beans and peas, 1 × 500 g/ha					
D3	ditch	2.619	drift	n.r.	1.483
D5	stream	2.550	drift	n.r.	1.806

n.r. not relevant

Additional PEC_{SW} modelling for the use on sunflower is presented here considering application at BBCH 61-73. 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)⁴. D3 and D4 are also representative for the central zone and to cover these two scenarios, additional modelling use maize as a surrogate crop is presented. The application details are presented below in **Tables 8.9.2-18 and 8.9.2-19**.

Input parameters related to the active substance are the same as used for modelling other uses and are as presented in **Table 8.9.2-6**.

⁴ 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

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Table 8.9.2-18: Input parameters for application to sunflower for PEC_{SW/SED} calculations

Plant protection product	FGG01	
FOCUS Crop	Sunflower	Maize, as surrogate for D3 and D4
Application rate (g a.s./ha)	Boscalid: 250	
Number of applications/interval (d)	1 / -	
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 8.9.2-19 Length of application window 30 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	

Table 8.9.2-19: FOCUS Step 3 scenario related input parameters for PEC_{SW/SED} calculations for the application of LOZZARE PRO, oilseed rape, winter

Scenario	Dates according to AppDate v3.06 ^a	Application window used in modelling ^b
	Maize (as surrogate), 1 × 250 g/ha (BBCH 61-73)	
D3	BBCH 61: 11/08; BBCH 73: 28/08	11/08 (223) – 10/09 (253)
D4	BBCH 61: 19/08; BBCH 73: 29/08	19/08 (231) – 18/09 (261)
	Sunflower, 1 × 250 g/ha (BBCH 61-73)	
D5	BBCH 61: 12/07; BBCH 73: 02/08	12/07 (193) – 11/08 (223)
R1	BBCH 61: 07/07; BBCH 73: 30/07	07/07 (188) – 06/08 (218)
R3	BBCH 61: 28/06; BBCH 73: 02/08	28/06 (179) – 28/07 (209)
R4	BBCH 61: 22/06; BBCH 73: 16/07	22/06 (173) – 22/07 (203)

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

^b 30-day application window sufficiently long to cover the BBCH range of 61-73

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FOCUS Step 1-2 and Step 3 were modelled and results are presented in **Tables 8.8-20** (Step 1-2) and **8.8-21** (Step 3).

Table 8.9.2-20: FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} for active substance boscalid following one application to sunflower at 250 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					
Step 1	-	44.161	Runoff/Drainage	n.r.	311.035
Step 2					
Northern Europe	March-May	3.405	Runoff/Drainage	n.r.	23.638
	June-September	3.405	Runoff/Drainage	n.r.	23.638
Southern Europe	March-May	5.457	Runoff/Drainage	n.r.	38.872
	June-September	4.431	Runoff/Drainage	n.r.	31.255

n.r. not required

Table 8.9.2-21: Maximum PEC_{SW} and PEC_{SED} actual of boscalid after one application to sunflower at 250 g a.s./ha (FOCUS Step 3)

Scenario FOCUS	Waterbody	Max PEC _{SW} (µg/L)	Dominant entry route	21 d- PEC _{SW, TWA} (µg/L)	Max PEC _{SED} (µg/kg)
Sunflower, 1 × 250 g a.s./ha (BBCH 61-73)					
D3 ^a	ditch	1.311	drift	n.r.	0.840
D4 ^a	pond	0.231	drainage	n.r.	2.116
D4 ^a	stream	1.052	drift	n.r.	0.708
D5	pond	0.084	drainage	n.r.	0.843
D5	stream	1.281	drift	n.r.	0.341
R1	pond	0.209	runoff	n.r.	1.948
R1	stream	1.300	runoff	n.r.	1.316
R3	stream	1.580	runoff	n.r.	4.490
R4	stream	2.346	drift	n.r.	2.105

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

n.r. not relevant

Comments zRMS:

The surface water modelling has been performed using parameters for boscalid have been taken from SANCO/3919 /2007-rev. 5 21 January 2008.
 PECsw/sed calculations have been accepted. The calculations cover proposed GAP.
 Due the fact that crop vines is not define in program, a surrogate crop “pome/stone fruit, early applications” was used, with the mean deposition mass in TOXSWA corrected for crop “vines, early application” (FPS Health, Food Chain Safety and Environment, 2021)b. Covering D4 scenario (AGES, 2022) even when dominant entry route is runoff, as this would indicate that emissions via drift would be even lower.

FOCUS Step 4

Not required.

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

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 volatilization with subsequent deposition should be considered.

Comments zRMS:

Accepted.

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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 in groundwater (PECgw) – Boscalid 50 WG (FGG01) - GW-213-220810-01 Vali Consulting GmbH, Weinheim, Germany non GLP Unpublished	N	UPL Europe
KCP 9.2.5/01	Šulc, A.	2024b	Report on Predicted Environmental Concentrations of boscalid in Surface Water and Sediment (PECsw and PECsed) - Boscalid 50 WG (FGG01) - SW-213-220810-01 Vali Consulting GmbH, Weinheim, Germany non GLP Unpublished	N	UPL Europe

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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
-	-	-	-	-	-

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

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Appendix 2 Detailed evaluation of the new Annex II studies

A 2.1 Study 1

Comments of zRMS:	The calculation of PEC _{gw} are considered acceptable.
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Reference:	KCP 9.2.4.1/01
Report	Report on calculation of Predicted Environmental Concentrations of boscalid in groundwater (PEC _{gw}) – Boscalid 50 WG (FGG01) -. Šulc A., 2024a, Report No.: GW-213-220810-01
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 LOZZARE PRO (FGG01) according to the FOCUS GW report (2014) and the FOCUS Generic Guidance (2023) in order to predict concentration of residues in groundwater.

LOZZARE PRO (FGG01) is a fungicide containing 500 g/kg of boscalid. It is applied post-emergence to vines, winter and spring oilseed rape, beans and peas.

PEC_{GW} values for boscalid 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. All the scenarios relevant were parameterised using maximum application rates of the product.

Application details are summarised in **Tables 8.8-1 to 8.8-4**.

The PEC_{GW} values of boscalid have been assessed with the endpoints established in the EU review. The boscalid review report (SANCO/3919/2007 – rev. 5) is considered to provide the relevant review information or a reference to where such information can be found.

As K_{OC} of boscalid is between 100 and 2000 mL/g, two FOCUS step 3 simulations were conducted with alternating whole system and default DT₅₀ values. From both simulations, only highest PEC_{SW} and PEC_{SED} are presented.

The input parameters for boscalid are presented in **Table 8.8-5**.

Results and discussions

Results are reported in **Table 8.8-6 to 8.8-8**.

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.

Boscalid is not predicted to leach into ground water above the critical 0.1 µg/L threshold following a 26-year period of application to vines, winter and spring oilseed rape, beans and peas.

Conclusion

From the results estimated by two FOCUS recommended models, it can be foreseen that no risk is anticipated for groundwater for the active substance when boscalid is used according to the proposed GAP in vines, winter and spring oilseed rape, beans and peas.

The results indicate that any contamination of groundwater at concentrations relevant for the environment and for consumer exposure by the active substance boscalid must not be expected following the GAP proposed uses of LOZZARE PRO (FGG01).

A 2.2 Study 2

Comments of zRMS:	The calculation of PEC _{sw/sed} are considered acceptable.
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Reference:	KCP 9.2.5/01
Report	Report on Predicted Environmental Concentrations of Boscalid in Surface Water and Sediment (PEC _{sw} and PEC _{sed}) – Boscalid 50 WG (FGG01) -. Šulc, A., 2024b, Report No.: SW-213-220810-01
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 LOZZARE PRO (FGG01) according to the FOCUS SW report (2001) and the FOCUS Generic Guidance (2015).

LOZZARE PRO (FGG01) is a fungicide containing 500 g/kg of boscalid. It is applied post-emergence to vines, winter and spring oilseed rape, beans and peas.

PEC_{SW} and PEC_{SED} values for boscalid 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 active substance boscalid, 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 8.9.2-1**.

The PEC_{SW} and PEC_{SED} values of boscalid have been assessed with the endpoints established in the EU review. The boscalid review report (SANCO/3919/2007 – rev. 5) is 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 8.9.2-6**.

Results and discussions

The results of FOCUS Step 1 and 2 calculations are summarised in **Tables 8.9.2-7 to 8.9.2-10**.

The results of FOCUS Step 3 calculations are presented in **Tables 8.9.2-11 to 8.9.2-17**.

Conclusion

For the active substance boscalid FOCUS Step 1-2 and Step 3 calculations were conducted. The obtained PEC values are suitable for ecotoxicological risk assessments for the proposed uses of boscalid in vines, winter and spring oilseed rape, beans and peas.

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, grapevines, one application at 500 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: 18/12/2023, 12:00:35
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)*: 5
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): 500
Crop interception (%): 60

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme: Parent compound without metabolites

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

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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): 0.2667 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	0.2661	0.2664	0	1
2	0.2656	0.2661	0	2
4	0.2645	0.2656	0	4
7	0.2629	0.2648	0	7
14	0.2592	0.2629	0	14
21	0.2555	0.2610	0	21
28	0.2519	0.2592	0	28
42	0.2448	0.2556	0	42
50	0.2409	0.2535	0	50
100	0.2176	0.2413	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 5 cm(mg/kg): 0.2419**

(** 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): 0.2419

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for Programcheck over 5 cm considering accumulation* (mg/kg) 0.5086
 (* a tillage depth of 5 cm was considered for calculating the background concentration)

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

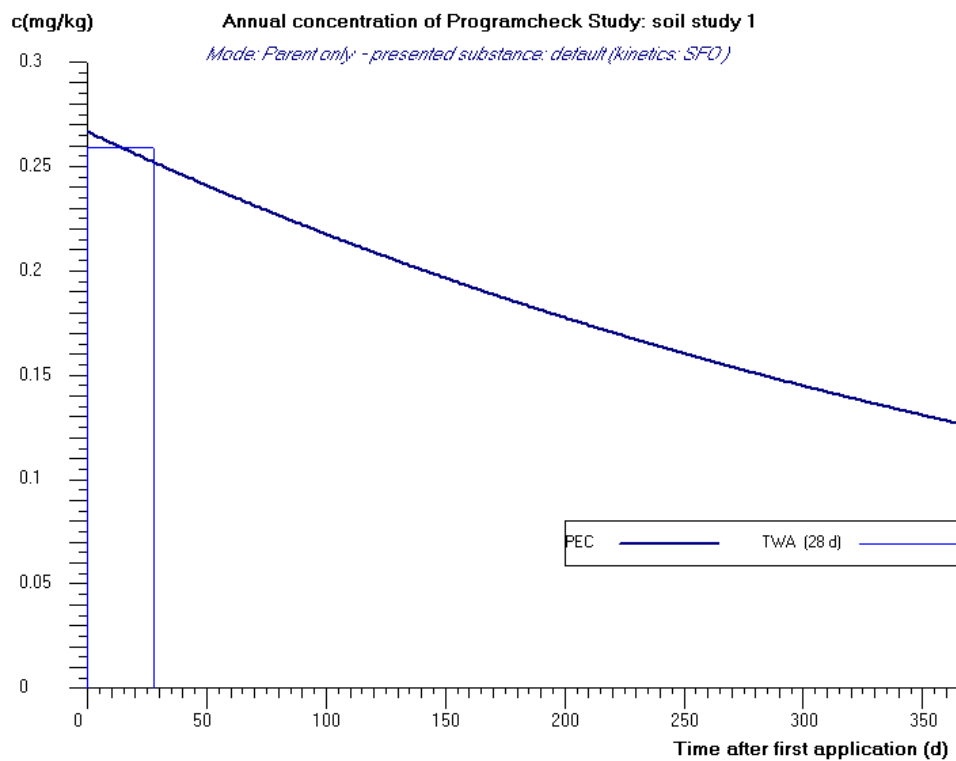
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Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.5080	0.5083	0	1
2	0.5075	0.5080	0	2
4	0.5064	0.5075	0	4
7	0.5048	0.5067	0	7
14	0.5011	0.5048	0	14
21	0.4974	0.5030	0	21
28	0.4938	0.5011	0	28
42	0.4867	0.4975	0	42
50	0.4828	0.4955	0	50
100	0.4595	0.4832	0	100

(* a tillage depth of 5 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, beans, two post-emergence applications at 500 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: 18/12/2023, 12:07:05

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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): 500
Time between two applications (d): 7
Crop interception (%): 70

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): 0.3972 occurring on day 7

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	0.3964	0.3968	7	8
2	0.3956	0.3964	7	9
4	0.3939	0.3956	7	11
7	0.3916	0.3944	7	14
14	0.3860	0.3916	7	21
21	0.3805	0.3888	7	28
28	0.3752	0.3861	7	35
42	0.3646	0.3807	7	49
50	0.3587	0.3776	7	57
100	0.3240	0.3594	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 Programcheck over 20 cm(mg/kg): 0.0901**

(** 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): 0.0901

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for Programcheck over 5 cm considering accumulation* (mg/kg) 0.4872
 (* 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	0.4864	0.4868	7	8
2	0.4856	0.4864	7	9
4	0.4840	0.4856	7	11
7	0.4816	0.4844	7	14
14	0.4761	0.4816	7	21
21	0.4706	0.4789	7	28
28	0.4652	0.4761	7	35
42	0.4547	0.4707	7	49
50	0.4488	0.4677	7	57
100	0.4141	0.4494	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)

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GRAPHIC REPRESENTATION OF THE CALCULATION

