

# REGISTRATION REPORT

## **Part B**

### **Section 8**

#### **Environmental Fate**

Detailed summary of the risk assessment

Product code: GLOB1811F

Product name: RASPUT

Chemical active substance:

Boscalid, 500 g/kg

**Poland – Art. 33**

#### **CORE ASSESSMENT**

**(authorization)**

Applicant: Globachem NV

Submission date: June 2021

**MS Finalisation date: 18/03/2022**

## Version history

When	What
December 2021	First zRMS PL evaluation
March 2022	RR finalized by zRMS after commenting period

## Table of Contents

<b>8</b>	<b>Fate and behaviour in the environment (KCP 9).....</b>	<b>4</b>
8.1	Critical GAP and overall conclusions.....	5
8.2	Metabolites considered in the assessment.....	7
8.3	Rate of degradation in soil (KCP 9.1.1).....	8
8.3.1	Aerobic degradation in soil (KCP 9.1.1.1) .....	8
8.3.2	Anaerobic degradation in soil (KCP 9.1.1.1).....	8
8.4	Field studies (KCP 9.1.1.2).....	9
8.4.1	Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)... ..	9
8.4.2	Soil accumulation testing (KCP 9.1.1.2.2) .....	10
8.5	Mobility in soil (KCP 9.1.2) .....	10
8.5.1	Column leaching (KCP 9.1.2.1).....	11
8.5.2	Lysimeter studies (KCP 9.1.2.2).....	11
8.5.3	Field leaching studies (KCP 9.1.2.3) .....	11
8.6	Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3) .....	12
8.7	Predicted Environmental Concentrations in soil (PEC <sub>soil</sub> ) (KCP 9.1.3) .....	12
8.7.1	Justification for new endpoints .....	12
8.7.2	Active substance(s) and relevant metabolite(s) .....	12
8.7.2.1	Boscalid and its metabolites.....	14
8.7.2.2	PEC <sub>soil</sub> of GLOB1811F.....	15
8.8	Predicted Environmental Concentrations in groundwater (PEC <sub>gw</sub> ) (KCP 9.2.4) .....	15
8.8.1	Justification for new endpoints .....	15
8.8.2	Boscalid and relevant metabolites (KCP 9.2.4.1).....	16
8.9	Predicted Environmental Concentrations in surface water (PEC <sub>sw</sub> ) (KCP 9.2.5) .....	19
8.9.1	Justification for new endpoints .....	19
8.9.2	Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5) .....	19
8.10	Fate and behaviour in air (KCP 9.3, KCP 9.3.1) .....	28
<b>Appendix 1</b>	<b>Lists of data considered in support of the evaluation.....</b>	<b>29</b>
<b>Appendix 2</b>	<b>Detailed evaluation of the new Annex II studies.....</b>	<b>30</b>
<b>Appendix 3</b>	<b>Additional information provided by the applicant (e.g. detailed modelling data).....</b>	<b>30</b>

## 8 Fate and behaviour in the environment (KCP 9)

### **Review Comments:**

This application was submitted by Globachem NV for approval of Rasput (GLOB1811F) a water dispersible granule (WG) containing 500 g/kg boscalid for use as a fungicide in oilseed rape in Poland.

Boscalid was included on Annex I of Directive 91/414/EEC on 1 of August 2008 under Inclusion Directive 2008/44/EC.

This Part B document only reviews data (Annex III) and additional information that has not previously been considered within the EU review process.

Since this document is based on the information provided by the applicant, all review comments, additions and corrections have been made using commenting boxes or highlighted in grey. Any incorrect data or text not evaluated by the zRMS has been crossed out.

## 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 destina- tion / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g saf- ener/ syner- gist 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	kg 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	CEU	Oilseed rape (Winter & Spring)	F	<i>Sclerotina scleroti- orum</i>	Foliar Spray	BBCH 55- 69	a) 2 b) 2	14	a) 0.5 b) 1	a) 0.25 b) 0.5	100-400	-	Maximum 2 applica- tions of 0.2 to 0.5 kg product/ ha per season per crop for all diseases	A
2	CEU	Oilseed rape (Winter & Spring)	F	<i>Alternaria brassicae</i>	Foliar Spray	BBCH 55- 69	a) 2 b) 2	14	a) 0.5 b) 1	a) 0.25 b) 0.5	100-400	-	Maximum 2 applica- tions of 0.2 to 0.5 kg product/ ha per season per crop for all diseases	A
3	CEU	Oilseed rape (Winter & Spring)	F	<i>Leptosphaeria macu- lans</i>	Foliar Spray	BBCH 20- 59	a) 2 b) 2	14	a) 0.5 b) 1	a) 0.25 b) 0.5	100-400	-	Maximum 2 applica- tions of 0.2 to 0.5 kg product/ ha per season per crop for all diseases	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, Gpn or I**	Pests or Group of pests controlled (additionally: develop- mental 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	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	EU (North & South)	Grape	F	<i>Botrytis</i>	Spraying	68 – 81	1	-	0.038 – 0.060	0.600	1000 – 1600	28	
2	EU	Oilseed Rape	F	<i>Sclerotinia, Alternaria, Phoma</i>	Spraying	30, 63 – 65	2	4 – 6 weeks	0.062 – 0.125	0.250	200 – 400	-	
3	EU (North & South)	Peas	F	<i>Botrytis, Sclerotinia</i>	Spraying	60 – 69	2	7 – 10	0.125	0.500	400	7	
4	EU (North & South)	Beans	F	<i>Botrytis, Sclerotinia</i>	Spraying	60 - 69	2	7 - 10	0.166	0.500	300	7	

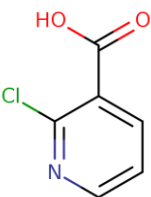
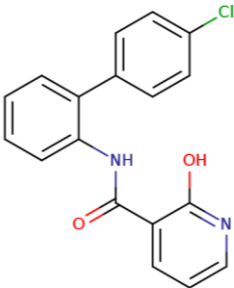
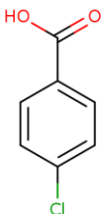
\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

\*\* 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

Evaluator comment: GLOB1811F /Rasput is intended to be used in protection of oilseed rape in field in Poland, therefore the assessment has been done only for this use.

## 8.2 Metabolites considered in the assessment

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

Metabolite	Molar mass	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
M510F47	157.6		Soil: anaerobic conditions <div> <div>3d</div> <div>2.6%</div> </div> <div> <div>62d</div> <div>6%</div> </div> <div> <div>90d</div> <div>5.9%</div> </div> <div> <div>120d</div> <div>6.7%</div> </div>	-
M510F49	324.8		Soil: aerobic conditions <div> <div>127d</div> <div>9%</div> </div> <div> <div>181d</div> <div>9%</div> </div> <div> <div>273d</div> <div>12.6%</div> </div> <div> <div>371d</div> <div>14.5%</div> </div>	-
M510F64	156.56		Sediment: outdoor conditions <div> <div>3 d:</div> <div>7.3 %</div> </div> <div> <div>14 d:</div> <div>9 %</div> </div> <div> <div>30 d:</div> <div>9.4 %</div> </div> <div> <div>120 d:</div> <div>1.9 %</div> </div>	-

### 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)

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

Boscalid, Laboratory studies, aerobic conditions										
Soil name	Soil type	pH (CaCl <sub>2</sub> )	t.oC	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Bruch West	Loamy sand	7.4	20	40	108	360	-	-	-	Y/Germany, 2002; Review Report, 2008
Li 35 b	Loamy sand	6.6	20	40	322	-	-	-	-	
Lufa 2.2	Loamy sand	5.6	20	40	384	-	-	-	-	
US soil	Sandy loam	7.0	20	40	376	-	-	-	-	
Minto (Canada)	Loam	7.7	20	40	133	442	-	-	-	
Geometric mean							232			
pH-dependency: y/n							n			

#### 8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

**Table 8.3-2: Summary of anaerobic degradation rates for Boscalid - laboratory studies**

Boscalid, Laboratory studies, anaerobic conditions										
Soil name	Soil type	pH (CaCl <sub>2</sub> )	t.oC	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Bruch West	Loamy sand	7.4	20	Flooded	261	-	-	-	-	Y/Germany, 2002; Review Report, 2008
Bruch West	Loamy sand	7.4	20	Flooded	345	-	-	-	-	
Geom. mean (n=2)							300			
pH-dependency: y/n							n			



**Table 8.3-3: Summary of anaerobic degradation rates for Boscalid - laboratory studies**

Boscalid, Laboratory studies, anaerobic conditions									
Soil type	pH (CaCl <sub>2</sub> )	t.oC	MWHC %	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2/10kPa	Chi2 (%)	Kinetic model	Evaluated on EU level y/n/ Reference
Sandy loam	7.2	20	Flooded	477.4	-	-	0.7	DFOP	Y/Germany, 2002; Boscalid RAR 2018
Sandy loam	7.5	20	Flooded	594.5	-	-	0.9	DFOP	
Geom. mean							Not calculated		
pH-dependency: y/n							-		

Evaluator Comments: No new data. Information in Section 8.3 is available in dossier of active substance boscalid and can be extrapolated to formulation. Therefore no studies have been conducted. EU agreed data were correctly reported.

## 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)

#### 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 <sub>2</sub> )	Depth (cm)	DissT50 (d) actual	DT90 (d) actual	Kinetic parameters	St. (x <sup>2</sup> )	Method of calculation	Evaluated on EU level y/n/ Reference
Silty loam	Germany, Stetten	7.5	-	90 49 28	-	-	-	-	Y/Germany, 2002; Review Report, 2008
Silty sand	Germany, Schifferstadt	5.4	-	208 175 147	-	-	-	-	
Sandy loam	Spain, Manzanilla	7.4	-	27	-	-	-	-	
Sandy loam	Spain, Alcala del Rio	7.7	-	78	-	-	-	-	
Loamy sand	Germany, Grossharrie	6.1	-	144	-	-	-	-	
Loamy sand	Sweden, Bjärred	5.5	-	-	-	-	-	-	
Maximum (n=9)				208	-				

## 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 (x)	Depth (cm)	DT50 (d) 20°C	Fit, Kinetic	Evaluated on EU level y/n/ Reference
Silty loam	Germany, Stetten	7.5	-	106	-	Y/Germany, 2002; Review Report, 2008
Silty sand	Germany, Schifferstadt	5.4	-	212	-	
Sandy loam	Spain, Manzanilla	7.4	-	-	-	
Sandy loam	Spain, Alcala del Rio	7.7	-	-	-	
Loamy sand	Germany, Grossharrie	6.1	-	98	-	
Arithmetic mean / Geometric mean (n=3)				139 / 107		
pH-dependency y/n				n		

### 8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Two soil accumulation studies were peer reviewed (Review Report 2008):

1. Germany, 1999-2003, loamy sand/sandy loam, application to vines (3 x 700 g as/ha = 2100 g as/ha); measured maximum plateau: mean 2900 g as/ha (138% of applied rate)
2. Germany, sandy loam, 1998-2004 and ongoing, 3-year rotation with vegetables (2100 g as/ha), vegetables (1700 g as/ha) and cereals (no application); measured maximum: 2545 g as/ha (150% of applied rate in the preceding year).

Evaluator Comments: No new data. Information in Section 8.4 is available in dossier of active substance boscalid and can be extrapolated to formulation. Therefore no studies have been conducted. EU agreed data were correctly reported.

### 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.

**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 y/n/ Reference
LUFA 2.2	Sand /	2.5	5.8	27.8	1110	0.875	Y/Germany,

Boscalid							
Soil name	Soil type	OC (%)	pH (-)	Kf (mL/g)	Kfoc (mL/g)	1/n (-)	Evaluated on EU level y/n/ Reference
	loamy sand						2002; Review Report, 2008; RAR Boscalid 2018
Bruch West	Loamy sand	1.5	7.5	7.6	507	0.870	
Li 35b	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	Silty loamy sand	0.5	5.2	3.3	655	0.860	
Canada 95024	Sandy loam	3.4	7.5	26.4	776	0.851	
Geometric mean					743		
Arithmetic mean (n=6)					771.5	0.864	
pH-dependency y/n					n		

### 8.5.1 Column leaching (KCP 9.1.2.1)

**Table 8.5-2: Summary of soil column leaching for Boscalid**

Boscalid					
Soil name	Soil type	OC (%)	pH (CaCl <sub>2</sub> )	Leachate (Total)	Evaluated on EU level y/n/ Reference
Lufa 2.1, Speyer, Germany	Sand	0.6	6.0	0.04% AR	Y/Germany, 2002; Review Report, 2008

### 8.5.2 Lysimeter studies (KCP 9.1.2.2)

No lysimeter study was provided during the EU Review of ~~Pyraclostrobin and Boscalid~~.

### 8.5.3 Field leaching studies (KCP 9.1.2.3)

No field leaching study was provided during the EU Review of ~~Pyraclostrobin and Boscalid~~.

Evaluator Comments: No new data. Information in Section 8.5 is available in dossier of active substance boscalid and can be extrapolated to formulation. Therefore no studies have been conducted. EU agreed data were correctly reported.

## 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.

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

Boscalid Distribution (max. water/sediment x % after x days)										
Wa- ter/sediment system	pH wa- ter/ sed.	DegT5 0 whole syst. (d)	DegT9 0 whole syst. (d)	Kinet- ic, Fit	DissT5 0 water (d)	DissT9 0 water (d)	Kinet- ic, Fit	DissT5 0 sed. (d)	Kinet- ic, Fit	Evaluated on EU level y/n/ Refer- ence
Pond system	8.5	>100	-	-	9	133	-	-	-	Y/Germany , 2002; Review Report, 2008
River system	8.1	>100	-	-	3	43	-	-	-	
Geometric mean (n=2)		>100	-		5.2	75.62		-		-

Evaluator Comments: No new data. Information in Section 8.6 is available in dossier of active substance boscalid and can be extrapolated to formulation. Therefore no studies have been conducted. However, in this Section the applicant should indicate in the summary on degradation in water/sediment systems the study of accumulation of boscalid in sediment (Platz, K., 2004). It was included in Addendum 1 to the Draft Assessment Report of 08 November 2002 of boscalid (30 January 2006). According to this study the maximum amount of boscalid in sediment after long-term application estimated on the basis of the standard laboratory study is reached at about 8 years after first application. The estimated maximum plateau amount of boscalid in sediment is 217% of the seasonal applied application rate. Additionally, the modelled concentration curve of boscalid after long-term application estimated on the basis of the higher tier outdoor water sediment study shows that there is no accumulation risk of the parent compound in sediment. The maximum amount in sediment after long-term application of boscalid was estimated with 27.2% of the seasonal application rate.

Predicted Environmental Concentrations in soil (PEC<sub>soil</sub>) (KCP 9.1.3)

### 8.6.1 Justification for new endpoints

There is no deviation from the EU agreed endpoints.

### 8.6.2 Active substance(s) and relevant metabolite(s)

**Table 8.7-1: Input parameters related to application for PEC<sub>soil</sub> calculations**

Use No.	1, 2, 3
Crop	Oilseed rape
Application rate (g as/ha)	500
Number of applications/interval	1*

Crop interception (%)	80
Depth of soil layer (relevant for plateau concentration) (cm)	5 cm (no tillage)

\* As a worst case situation, 1 application with a double dose was considered instead of 2 with a minimum interval of 14 days.

**Table 8.7-2: Input parameter for active substance and relevant metabolites for PEC<sub>soil</sub> calculation**

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
Boscalid	343.21	-	208 212 d (Maximum normalized, field studies)	Review Report 2008

The PEC soil calculations were performed with the FOCUS model for a standard soil considering a dry soil bulk density of 1.5 g/cm<sup>3</sup> and 5 cm soil depth.

PEC<sub>s</sub> immediately after application were calculated using FOCUS guidance<sup>1</sup> (i.e. current guidance) with the following equation:

$$PEC_{S, ini} = [A * (1 - f_{int})] / (100 * d * bd)$$

where: A = application rate

f<sub>int</sub> = fraction intercepted by plant cover

d = depth of the soil

bd = bulk soil density (g/cm<sup>3</sup>)

The actual PEC<sub>s</sub> at specific times (t) are calculated with the formula:

$$PEC_{S, actual} = PEC_{S, ini} * e^{-k \cdot t}$$

where: k = ln(2)/DT<sub>50</sub>;

t: time period.

The maximum ('moving window') time weighted average (TWA) PEC values are found by calculating a set of TWA PECs over a time window that is moved along the time axis. The average PEC within a day is calculated by:

$$PEC_{TWA} = PEC_{S, ini} \cdot (1 - e^{-k \cdot t}) / (k \cdot t)$$

Although field DT<sub>50</sub> > 3 months and field DT<sub>90</sub> > 1 year were observed for Boscalid, soil accumulation studies with annual applications showed no accumulation of Boscalid after up to 10 years use (see Annex point 8.4.2). However for the sake of completeness, PEC<sub>accumulation</sub> was calculated for Boscalid as follows:

$$PEC_{accumulation} = \text{Maximum } PEC_s \text{ after 1 year of treatment} / (1 - e^{-ki})$$

where k = ln2/DT<sub>50</sub> = ln2/265

i is the interval between the treatments (365 days)

$$PEC_{accumulation} = PEC_{S, ini} + PEC_{soil \text{ background}}$$

<sup>1</sup> 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.

These  $PEC_{soil, accumulation}$  are used in the risk assessment in Part B, Section 9.

### 8.6.2.1 Boscalid and its metabolites

**Table 8.7-3:  $PEC_{soil}$  for Boscalid on Oilseed rape**

$PEC_{soil}$ (mg/kg)		Oilseed rape	
		Single application	
		Actual	TWA
Initial		0.133	-
Short term	24h	0.133	0.133
	2d	0.132	0.133
	4d	0.132	0.132
Long term	7d	0.130	0.132
	14d	0.127	0.130
	21d	0.124	0.129
	28d	0.1210 0.122	0.127
	50d	0.113	0.123
	100d	0.096	0.113 0.114
Plateau concentration (5 cm) after year 3-5		0.056 0.058	
$PEC_{accumulation}$ ( $PEC_{act} + PEC_{soil plateau}$ )		0.1895 0.191	

Modelling Comments: The applicant used the acceptable equations according to guidelines FOCUS Soil Group. The assumptions of calculations are acceptable except the value  $DT_{50}$ . The maximum normalized value obtained from field studies should be used for calculations. Therefore the evaluator has recalculated the  $PEC_{soil}$  using  $DT_{50}$  value =212d.

It was assumed that the active substance was distributed in the top 5 cm soil layer with a soil bulk density of 1.5 g/mL.

The predicted environmental concentrations in soil ( $PEC_{soil}$ ) of boscalid were calculated according to FOCUS Guidance Soil persistence models using:

- the worst case: 1 application with a double dose instead of 2 application with a minimum interval of 14 days i.e. application rate for boscalid 500g as/ha, considering 80% interception for oilseed rape.

The calculated initial  $PEC$ s values are presented in Table 8.7-3 for boscalid.

Additionally, according to DAR (2002) no  $PEC_{soil}$  calculations are performed for metabolites of boscalid because in the field studies no metabolite is found in amounts greater than 10% of the applied parent.

$PEC_{soil}$  (boscalid): Agreed  $PEC_s$  for boscalid after recalculated :

**Boscalid:**

Initial  $PEC_{soil}$ : **0.133 mg/kg**

$PEC_{soil,plateau}$ : **0.058 mg/kg**

$PEC_{accumulation}$ : **0.191 mg/kg**

$PEC_{soil}$  are appropriate to be used for the subsequent risk assessment for soil organisms.

### 8.6.2.2 $PEC_{soil}$ of GLOB1811F

**Table 8.7-4:  $PEC_{soil}$  for GLOB1811F on Oilseed rape**

Active substance/ reparation	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)
Boscalid/ boscalid 50% WG	1000	1.333*	1.243* 1.289*	5	0.561* 0.58*	1.8948* 1.913*

\*Without interception

Modelling Comments: Modelling was conducted according to standard procedures recommended by FOCUS for  $PEC_{soil}$  calculation for the formulation.

The assumptions of calculations are acceptable except the value  $DT_{50}$ . The maximum normalized value obtained from field studies should be used for calculations. Therefore the evaluator has recalculated the  $PEC_{soil}$  using  $DT_{50}$  value =212d

The calculated initial  $PEC$ s values are presented in Table 8.7-3 for formulation GLOB1811F/Rasput.

$PEC_{soil}$  (product): Agreed  $PEC$ s for GLOB1811F/Rasput after recalculated:

#### **GLOB1811F/Rasput:**

Initial  $PEC_{soil}$ : **1.33 mg/kg**

$PEC_{soil,plateau}$ : **0.58 mg/kg**

$PEC_{accumulation}$ : **1.913 mg/kg**

$PEC_{soil}$  are appropriate to be used for the subsequent risk assessment for soil organisms.

## 8.7 Predicted Environmental Concentrations in groundwater ( $PEC_{gw}$ ) (KCP 9.2.4)

### 8.7.1 Justification for new endpoints

There is no deviation from the EU agreed endpoints.

## 8.7.2 Boscalid and relevant metabolites (KCP 9.2.4.1)

**Table 8.8-1: Input parameters related to application for PEC<sub>gw</sub> calculations**

Use No.	1,2, 3
Crop	OSR
Application rate (g as/ha)	250
Number of applications/interval (d)	2/14
Relative application date	Not applicable. Absolute application dates determined through Table 8.8-2: Application dates used for groundwater risk assessment v3.06 shown in Table 8.8-2.
Crop interception (%)	80
Frequency of application	annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3,

**Table 8.8-2: Application dates used for groundwater risk assessment**

Scenario	Application dates (absolute)			
	Winter Oilseed Rape	Spring Oilseed Rape	Winter Oilseed Rape	Spring Oilseed Rape
	Early application: BBCH 20 (Use No. 3)		Late application: BBCH 55 (Use No. 1,2)	
Châteaudun	29/09, 13/10	-	10/04, 24/04	-
Hamburg	17/09, 1/10	-	1/05, 15/05	-
Jokioinen	-	1/06, 15/06	-	29/06, 13/07
Kremsmünster	17/09, 1/10	-	30/04, 14/05	-
Okehampton	29/08, 12/09	11/04, 25/04	25/04, 9/05	9/05, 23/05
Piacenza	20/10, 3/11	-	5/04, 19/04	-
Porto	3/11, 17/11	9/04, 23/04	23/03, 6/04	22/05, 5/06

**Table 8.8-3: Input parameters related to active substance Boscalid and metabolites for PEC<sub>gw</sub> calculations**

Compound	Boscalid	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	343.2	Review Report, 2008
Water solubility (mg/L): (20°C)	4.6	Review Report, 2008
Saturated vapour pressure (Pa):	$7.2 \times 10^{-7}$ at 20°C	Review Report, 2008
DT <sub>50</sub> in soil (d)	212	Review Report, 2008
Temperature correction function Reference temperature [°C] PRZM: Q <sub>10</sub> [-]	20 2.58	Review Report, 2008
Moisture correction function	pF 2	Review Report, 2008



Compound	Boscalid	Value in accordance with EU endpoint y/n/ Reference*
Reference moisture [-] PRZM/MACRO: moisture exponent [-]	0.7	
Transformation rate	-	Review Report, 2008
K <sub>foc</sub> (mL/g) K <sub>om</sub> (L/kg)	771.5 (n=6) 447.5	Review Report, 2008
1/n	0.864 (n=6)	Review Report, 2008
Plant uptake factor	0	FOCUS recommendation
Formation fraction (conservative estimate based on max. occurrence in soil)	-	Review Report, 2008

\* Delete row in case of no pH dependency

**Table 8.8-4: PEC<sub>gw</sub> for Boscalid and metabolites on Oilseed rape early application (with FOCUS PEARL 4.4.4 and PELMO 5.5.3)**

Crop	Scenario	80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)			
		Boscalid			
		Winter		Spring	
		PEARL	PELMO	PEARL	PELMO
OSR 2 x 250 g a.s./ha 80/80 BBCH 20	Châteaudun	0.0000000 0.000 (using K <sub>om</sub> = 430.7 mL/g)	0.000 0.000 (using K <sub>om</sub> = 430.7 mL/g)	-	-
	Hamburg	0.0000970 <0.001 (using K <sub>om</sub> = 430.7 mL/g)	0.003 0.008 (using K <sub>om</sub> = 430.7 mL/g)	-	-
	Jokioinen	-	-	0.000000	0.000
	Kremsmünster	0.0000000 0.000 (using K <sub>om</sub> = 430.7 mL/g)	0.001 0.003 (using K <sub>om</sub> = 430.7 mL/g)	-	-
	Okehampton	0.001020	0.025	0.0000260	0.007
	Piacenza	0.0000520	0.002	-	-
	Porto	0.0000030	0.004	0.0000010	0.003
	Sevilla	-	-	-	-
	Thiva	-	-	-	-

**Table 8.8-5: PEC<sub>gw</sub> for Boscalid and metabolites on Oilseed rape late application (with FOCUS PEARL 4.4.4 and PELMO 5.5.3)**

Crop	Scenario	80 <sup>th</sup> Percentile PEC <sub>gw</sub> at 1 m Soil Depth (µg/L)			
		Boscalid			
		Winter		Spring	
		PEARL	PELMO	PEARL	PELMO
OSR 2 x 250 g a.s./ha 80/80 BBCH 55	Châteaudun	0.000000 0.000 (using Kom = 430.7 mL/g)	0.000 0.000 (using Kom = 430.7 mL/g)	-	-
	Hamburg	0.0000740 <0.001 (using Kom = 430.7 mL/g)	0.003 0.008 (using Kom = 430.7 mL/g)	-	-
	Jokioinen	-	-	0.000000	0.000
	Kremsmünster	0.0000000 0.000 (using Kom = 430.7 mL/g)	0.001 0.003 (using Kom = 430.7 mL/g)	-	-
	Okehampton	0.0000760	0.020	0.00000260	0.007
	Piacenza	0.0000340	0.002	-	-
	Porto	0.0000010	0.002	0.0000010	0.003
	Sevilla	-	-	-	-
	Thiva	-	-	-	-

Modelling Comments: The applicant has used appropriate models for ground water FOCUS-PEARL 4.4.4 FOCUS-PELMO 5.5.3. PEC<sub>gw</sub> values were calculated for two application of 250 g boscalid /ha to winter and spring oilseed rape. Input parameters used in FOCUS ground water modeling for boscalid are correct except K<sub>foc</sub> (mL/g) values. The applicant used arithmetic mean instead of geometric mean. According to *EFSA 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) there is the recommendation to use the geomean Kom or Koc not only to the soil exposure assessment but also to other exposure assessments e.g. leaching to groundwater and to surface water. Therefore for calculations should be applied Koc = 742.6 mL/g or Kom = 430.7 mL/g. The applicant used arithmetic means of Koc = 771.5 mL/g or Kom = 447.51 mL/g. therefore the evaluator recalculated the results for scenarios relevant for Poland. The recalculated PEC<sub>gw</sub> values were similar to those calculated by the applicant.

Thus the results of predicted environmental concentration in groundwater for boscalid submitted by applicant are acceptable. The evaluation refers **not** only to scenarios relevant for Poland: Châteaudun, Hamburg, Kremsmünster **but to all scenarios presented in this document.**

**However,** each Member State **may additionally** assess the PEC<sub>gw</sub> results for its respective scenarios at the national level, **if needed.**

According to DAR in field studies no metabolite was found in amounts greater than 10% of the applied parent. Therefore no PEC<sub>gw</sub> calculations are performed for metabolites of boscalid.

PEC<sub>gw</sub> (boscalid): Based on Focus PEARL and PELMO simulations, PEC<sub>gw</sub> for boscalid are below the trigger value 0.1 µg/L in all modelled scenarios for Poland.  
No unacceptable risk for groundwater is identified.

## 8.8 Predicted Environmental Concentrations in surface water (PEC<sub>sw</sub>) (KCP 9.2.5)

### 8.8.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

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

**Table 8.9-1: Input parameters related to application for PEC<sub>sw/sed</sub> calculations**

Plant protection product	GLOB1811F	
Use No.	1,2,3	
Crop	Winter Oilseed rape	Spring oilseed rape
Application rate (kg as/ha)	0.250	
Number of applications/interval (d)	2/14	
Application window (STEP 1 and 2 only)	June-Sep, Oct-Feb	March-May, June-Sep
Application method	Ground spray	
CAM (Chemical application method)	CAM 2	
Soil depth (cm)	4	
Models used for calculation	FOCUS STEP 1-2 v3.2 FOCUS SWASH v3.1 5.3, FOCUS PRZM v3.3-4.3.1, FOCUS MACRO v5.5.3 5.5.4, FOCUS TOXWA v3.3-4.3.1 5.5.3, SWAN v5.0.1	

**Table 8.9-2: FOCUS Step 3 Scenario related input parameters for PEC<sub>sw/sed</sub> calculations for the application of GLOB1811F**

Uses simulated	Crop	Scenario	Emergence date	Harvest date	Number of applica- tions	Dose rate (g a.s./ha)	Interval between applications	Input for the applica- tion timing		Application dates chosen by the mod- el
								1 <sup>st</sup> applica- tion	Last appli- cation	
1, 2	Oilseed rape, winter	D2	15/09	15/06	2	250 g a.s./ha	14	22/05	05/07	23/05, 6/06
		D3	2/09	20/07				2/05	15/06	4/05, 22/05
		D4	3/09	9/08				12/05	25/06	30/05, 16/06
		D5	20/09	5/07				23/04	6/06	23/04, 11/05
		R1	4/09	10/07				15/05	28/06	15/05, 31/05
		R3	5/10	5/06				9/04	23/05	11/04, 25/04
		D2	15/09	15/06	1		-	22/05	21/06	23/05
		D3	2/09	20/07				2/05	1/06	4/05
		D4	3/09	9/08				12/05	11/06	30/5
		D5	20/09	5/07				23/04	23/05	23/04
		R1	4/09	10/07				15/05	14/06	13/06
		R3	5/10	5/06				9/04	9/05	11/04
	Oilseed rape, spring	D1	19/05	8/09	2		14	28/06	11/08	2/07, 4/08
		D3	10/04	25/08				7/06	21/07	23/06, 8/07
		D4	1/05	31/08				11/06	25/07	4/07, 18/07
		D5	15/03	30/07				16/05	29/06	27/05, 10/06
		R1	10/04	15/08				31/05	14/07	13/06, 5/07
		D1	19/05	8/09	1		-	28/06	28/07	2/07
		D3	10/04	25/08				7/06	7/07	23/06
		D4	1/05	31/08				11/06	11/07	4/07
		D5	15/03	30/07				16/05	15/06	27/05
		R1	10/04	15/08				31/05	30/06	13/06

Uses simulated	Crop	Scenario	Emergence date	Harvest date	Number of applica- tions	Dose rate (g a.s./ha)	Interval between applications	Input for the applica- tion timing		Application dates chosen by the mod- el
								1 <sup>st</sup> applica- tion	Last appli- cation	
3	Oilseed rape, winter	D2	15/09	15/06	2	250 g a.s./ha	14	30/09	13/11	9/10, 3/11
		D3	2/09	20/07				17/09	31/10	26/07, 10/10
		D4	3/09	9/08				18/09	1/11	28/09, 26/10
		D5	20/09	5/07				5/10	18/11	31/10, 14/11
		R1	4/09	10/07				19/09	2/11	19/09, 6/10
		R3	5/10	5/06				20/10	3/12	27/10, 15/11
		D2	15/09	15/06	1		-	30/09	30/10	9/10
		D3	2/09	20/07				17/09	17/10	26/09
		D4	3/09	9/08				18/09	18/10	28/09
		D5	20/09	5/07				5/10	4/11	5/10
		R1	4/09	10/07				19/9	19/10	19/09
		R3	5/10	5/06				20/10	19/11	27/10
	Oilseed rape, spring	D1	19/05	8/09	2		14	31/05	14/07	17/06, 2/07
		D3	10/04	25/08				27/04	10/06	4/05, 22/05
		D4	1/05	31/08				14/05	27/06	30/05, 16/06
		D5	15/03	30/07				3/04	17/05	8/04, 22/04
		R1	10/04	15/08				25/04	08/06	26/04, 10/05
		D1	19/05	8/09	1		-	31/05	30/06	17/06
		D3	10/04	25/08				27/04	27/05	4/05
		D4	1/05	31/08				14/05	13/06	30/05
		D5	15/03	30/07				3/04	3/05	8/04
		R1	10/04	15/08				25/04	25/05	26/04

**Table 8.9-3: Input parameters related to active substance Boscalid and metabolites for PEC<sub>sw/sed</sub> calculations STEP 1/2 and 3(/4) (if necessary)**

Compound	Boscalid	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	343.2	EFSA, 2008
Saturated vapour pressure (Pa)	$7.2 \times 10^{-7}$ at 20°C	EFSA, 2008
Water solubility (mg/L)	4.6	EFSA, 2008
Diffusion coefficient in water (m <sup>2</sup> /d)	not required for Step 1+2/ $4.3 \times 10^{-5}$	EFSA, 2008
Diffusion coefficient in air (m <sup>2</sup> /d)	not required for Step 1+2/0.43	EFSA, 2008
K <sub>foc</sub> (mL/g)	771.5 (n = 6) 447.51	EFSA, 2008
Freundlich Exponent 1/n	0.864 (n = 6)	EFSA, 2008
Plant Uptake	0	FOCUS recommendation
Wash-Off factor from Crop (1/mm)	not required for Step 1+2/ 0.05 (MACRO) 0.50 (PRZM)	-
DT <sub>50,soil</sub> (d)	212 (geomean, n =8)	EFSA, 2008
Temperature correction function Reference temperature [°C] PRZM: Q <sub>10</sub> [-]	20 2.58	EFSA, 2008
Moisture correction function Reference moisture [-] PRZM/MACRO: moisture exponent [-]	pF 2 0.7	EFSA, 2008
DT <sub>50,water</sub> (d)	1000	EFSA, 2008
DT <sub>50,sed</sub> (d)	1000	EFSA, 2008
DT <sub>50,whole system</sub> (d)	1000	EFSA, 2008
Maximum occurrence observed (% molar basis with respect to the parent)	79.9	EFSA, 2008
Formation fraction in soil:	-	EFSA, 2008

**PEC<sub>sw/sed</sub>**

**Multiple applications:**

**Table 8.9-4: FOCUS Step 1,2 and 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Boscalid following multiple applications of GLOB1811F to Winter oilseed rape**

Scenario FOCUS	Waterbody	Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	21d- PEC <sub>sw, twa</sub> (µg/L)	Max PEC <sub>sed</sub> (µg/kg)*	Max PEC <sub>sed, accu</sub> (µg/kg)
<b>Step 1</b>	---	86.754	Drift	83.867	650.868	2911.755
<b>Step 2</b>						
Northern Europe	March-May	18.248	Drift	17.723	137.561	615.398
	June-Sept	18.248	Drift	17.723	137.561	615.398
	Oct-Feb	42.030	Drift	41.333	320.914	1435.655
Southern Europe	March-May	34.103	Drift	33.463	259.796	1162.236
	June-Sept	26.175	Drift	25.593	198.678	888.817
	Oct-Feb	34.103	Drift	33.463	259.796	1162.236
<b>Step 3</b>						
<b>Early application (BBCH 20)</b>						
D2	ditch	24.080	Drainage	10.250	114.900	1129.591
D2	stream	15.020	Drainage	5.221	66.470	653.472
D3	ditch	1.392	Drift	0.249	1.584	13.771
D4	pond	2.255	Drainage	2.178	18.510	192.317
D4	stream	3.627	Drainage	1.403	6.685	69.457
D5	pond	1.123	Drainage	1.044	13.260	106.418
D5	stream	1.876	Drainage	0.439	2.740	21.990
R1	pond	0.352	Run-off	0.302	2.928	25.455
R1	stream	3.427	Run-off	0.113	1.708	14.849
R3	stream	4.423	Run-off	0.391	7.145	45.267
<b>Late application (BBCH 55)</b>						
D2	ditch	7.311	Drainage	3.658	53.930	530.190
D2	stream	4.556	Drainage	2.141	31.100	305.747
D3	ditch	1.387	Drift	0.176	1.239	10.771
D4	pond	0.733	Drainage	0.708	6.830	70.963
D4	stream	1.183	Drift	0.456	2.283	23.720
D5	pond	0.765	Drainage	0.719	8.715	69.942
D5	stream	1.277	Drift	0.245	1.788	14.350
R1	pond	0.599	Run-off	0.520	5.131	44.607
R1	stream	3.518	Run-off	0.179	5.240	45.554
R3	stream	4.029	Run-off	0.303	3.699	23.435

**Table 8.9-5: FOCUS Step 1,2 and 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Boscalid following multiple applications of GLOB1811F to Spring oilseed rape**

Scenario FOCUS	Waterbody	Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	21d- PEC <sub>sw, twa</sub> (µg/L)	Max PEC <sub>sed</sub> (µg/kg)*	Max PEC <sub>sed, accu</sub> (µg/kg)
Step 1	---	86.7541	Drift	83.8665	650.8679	2911.755
Step 2						
Northern Europe	March-May	18.2476	Drift	17.7230	137.5605	615.398
	June-Sept	18.2476	Drift	17.7230	137.5605	615.398
	Oct-Feb	42.0299	Drift	41.3331	320.9136	1435.655
Southern Europe	March-May	34.1025	Drift	33.4631	259.7959	1162.236
	June-Sept	26.1750	Drift	25.5930	198.6782	888.817
	Oct-Feb	34.1025	Drift	33.4631	259.7959	1162.236
Step 3						
Early application (BBCH 20)						
D1	ditch	8.624	Drainage	8.324	77.170	872.572
D1	stream	5.766	Drainage	5.187	42.550	481.119
D3	ditch	1.386	Drift	0.161	1.136	9.876
D4	pond	1.292	Drainage	1.249	11.410	118.549
D4	stream	1.872	Drainage	0.811	3.915	40.676
D5	pond	1.087	Drainage	1.022	11.550	92.695
D5	stream	1.461	Drainage	0.386	2.441	19.590
R1	pond	0.501	Run-off	0.443	4.809	41.807
R1	stream	4.232	Run-off	0.273	2.842	24.707
Late application (BBCH 55)						
D1	ditch	6.108	Drainage	5.795	55.090	622.910
D1	stream	3.983	Drainage	3.608	30.500	344.868
D3	ditch	1.391	Drift	0.232	1.509	13.119
D4	pond	0.988	Drainage	0.956	8.924	92.720
D4	stream	1.799	Drainage	0.604	2.856	29.674
D5	pond	1.157	Drainage	1.091	11.450	91.892
D5	stream	1.456	Drainage	0.440	2.569	20.618
R1	pond	0.592	Run-off	0.549	6.767	58.830
R1	stream	3.427	Run-off	0.263	4.367	37.965



**Single application:**

**Table 8.9-6: FOCUS Step 1,2 and 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Boscalid following single application of GLOB1811F to Winter oilseed rape**

Scenario FOCUS	Waterbody	Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	21d- PEC <sub>sw, twa</sub> (µg/L)	Max PEC <sub>sed</sub> (µg/kg)*	Max PEC <sub>sed, accu</sub> (µg/kg)
<b>Step 1</b>	---	43.3771	Drift	41.9333	325.4339	1455.877
<b>Step 2</b>						
Northern Europe	March-May	9.4697	Drift	9.1776	71.2297	318.657
	June-Sept	9.4697	Drift	9.1776	71.2297	318.657
	Oct-Feb	21.6329	Drift	21.2528	165.0042	738.171
Southern Europe	March-May	17.5785	Drift	17.2277	133.746	598.333
	June-Sept	13.5241	Drift	13.2027	102.4879	458.495
	Oct-Feb	17.5785	Drift	17.2277	133.746	598.333
<b>Step 3</b>						
<b>Early application (BBCH 20)</b>						
D2	ditch	11.880	Drainage	4.974	59.880	588.685
D2	stream	7.410	Drainage	2.668	34.540	339.566
D3	ditch	1.589	Drift	0.142	1.304	11.336
D4	pond	0.899	Drainage	0.868	8.047	83.608
D4	stream	1.697	Drainage	0.554	2.719	28.250
D5	pond	0.497	Drainage	0.464	6.505	52.206
D5	stream	1.476	Drift	0.218	1.270	10.192
R1	pond	0.155	Run-off	0.133	1.420	12.345
R1	stream	1.356	Run-off	0.048	0.737	6.411
R3	stream	2.466	Run-off	0.160	2.563	16.238
<b>Late application (BBCH 55)</b>						
D2	ditch	3.898	Drainage	2.371	29.540	290.410
D2	stream	2.428	Drainage	1.070	16.540	162.606
D3	ditch	1.585	Drift	0.098	1.024	8.902
D4	pond	0.309	Drainage	0.298	3.128	32.500
D4	stream	1.333	Drift	0.190	0.982	10.200
D5	pond	0.358	Drainage	0.334	4.052	32.519
D5	stream	1.412	Drift	0.114	0.843	6.769
R1	pond	0.295	Run-off	0.249	2.759	23.986
R1	stream	2.324	Run-off	0.101	4.521	39.304
R3	stream	2.568	Run-off	0.142	3.383	21.433

**Table 8.9-7: FOCUS Step 1,2 and 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for Boscalid following single application of GLOB1811F to Spring oilseed rape**

Scenario FOCUS	Waterbody	Max PEC <sub>sw</sub> (µg/L)	Dominant entry route	21d- PEC <sub>sw, twa</sub> (µg/L)	Max PEC <sub>sed</sub> (µg/kg)*	Max PEC <sub>sed</sub> , accu (µg/kg)
Step 1	---	43.3771	Drift	41.9333	325.4339	1455.877
<b>Step 2</b>						
Northern Europe	March-May	9.4697	Drift	9.1776	71.2297	318.657
	June-Sept	9.4697	Drift	9.1776	71.2297	318.657
	Oct-Feb	21.6329	Drift	21.2528	165.0042	738.171
Southern Europe	March-May	17.5785	Drift	17.2277	133.746	598.333
	June-Sept	13.5241	Drift	13.2027	102.4879	458.495
	Oct-Feb	17.5785	Drift	17.2277	133.746	598.333
<b>Step 3</b>						
<b>Early application (BBCH 20)</b>						
D1	ditch	5.318	Drainage	5.084	48.680	550.432
D1	stream	3.503	Drainage	3.168	27.350	309.250
D3	ditch	1.584	Drift	0.092	0.985	8.562
D4	pond	0.649	Drainage	0.627	6.051	62.869
D4	stream	1.297	Drift	0.405	1.987	20.645
D5	pond	0.550	Drainage	0.514	5.854	46.981
D5	stream	1.263	Drift	0.194	1.262	10.128
R1	pond	0.229	Run-off	0.203	2.434	21.160
R1	stream	1.828	Run-off	0.120	1.276	11.093
<b>Late application (BBCH 55)</b>						
D1	ditch	0.341	Drainage	0.330	3.339	34.692
D1	stream	1.368	Drift	0.207	1.038	10.785
D3	ditch	0.411	Drainage	0.381	4.222	33.884
D4	pond	1.476	Drift	0.140	0.951	7.635
D4	stream	0.290	Run-off	0.270	3.612	31.401
D5	pond	2.313	Run-off	0.106	3.537	30.749
D5	stream	3.137	Drainage	2.958	29.400	332.430
R1	pond	1.982	Drainage	1.841	16.420	185.663
R1	stream	1.588	Drift	0.126	1.209	10.511

Modelling Comments: Predicted environmental concentrations in surface water (PEC<sub>sw</sub>) and sediment (PEC<sub>sed</sub>) has been calculated for boscalid after application of the product GLOB1811F/RASPUT to spring and winter oilseed rape, considering the pathways spray drift, drainage and runoff.

The PEC<sub>sw</sub> and PEC<sub>sed</sub> were calculated in compliance with relevant FOCUS scenarios in stepwise procedure (Steps 1, 2 and 3). In the Step 3 the evaluator assessed **not** only scenarios relevant for Poland: D3,

D4 and R1 but all scenarios submitted by applicant. However, each Member State may additionally assess the PEC<sub>sw</sub> and PEC<sub>sed</sub> results for its respective scenarios at the national level, if needed.

The presented modelling input parameters are acceptable except K<sub>foc</sub> (mL/g) values. The applicant used arithmetic mean instead of geometric mean. According to *EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT<sub>50</sub> values of active substances of plant protection products and transformation products of these active substances in soil* (EFSA Journal 2014;12(5):3662) there is the recommendation to use the geometric mean K<sub>oc</sub> or K<sub>om</sub> not only to the soil exposure assessment but also to other exposure assessments e.g. leaching to groundwater and to surface water. Therefore for calculations should be applied K<sub>oc</sub> = 742.6 mL/g or K<sub>om</sub> = 430.7 mL/g. The applicant used arithmetic means of K<sub>oc</sub> = 771.5 mL/g or K<sub>om</sub> = 447.51 mL/g.. However, it is not expected that differences can have a significant effect on the surface water modelling results. Calculations were carried out for twofold application of boscalid to spring and winter oilseed rape taking into account the application rate according to GAP.

According to DAR (2002) in aquatic studies no metabolite was found in amounts greater than 10% of the applied parent. Therefore no PEC<sub>sw/sed</sub> calculations are performed for metabolites of boscalid.

Calculations of PEC<sub>sw</sub> and PEC<sub>sed</sub> values are acceptable.

#### **Presented calculations may be used for risk assessment.**

PEC<sub>sw/sed</sub> (boscalid): The predicted concentrations in surface water and sediment of boscalid are appropriate to be used for the subsequent risk assessment for aquatic and sediment organisms.

However the relevance and acceptability of FOCUS Step 3 results may be additionally be considered at each Member State level, if needed.

#### **PEC<sub>sw/sed</sub> of GLOB1811F**

The PEC<sub>sw</sub> of the formulation GLOB1811F was also calculated for all crops, based on two applications at a rate of 500 g f.p./ha for oilseed rape. The calculator tool from the FOCUS SWASH model was used for this purpose. These PEC<sub>sw</sub> were calculated for the ditch, pond and stream scenarios. On top, to allow for the 20% spray drift contribution from the upstream catchment in the case of streams, the drift values of the calculator have been multiplied with a factor 1.2 for the stream scenario. The ditch scenario remains the worst-case in any case. The results of these calculations are provided below in table 8.9-12 below.

**Table 8.9-15: Maximum PEC<sub>sw</sub> for GLOB1811F**

Cropping scenario	FOCUS scenario	FOCUS values
		Max. PEC <sub>sw</sub> (µg/L)
Winter oilseed rape	Ditch	2.8063
	Pond	0.0896
	Stream	2.0616
		2.4739*
Spring oilseed rape	Ditch	2.8063
	Pond	0.0896
	Stream	2.0616
		2.4739*

\*taking into account the 20% contribution from the upstream catchment

**Modelling Comments:** Modelling was conducted according to standard procedures recommended by FOCUS for PEC<sub>sw</sub> calculation for the formulation. The PEC<sub>sw</sub> results obtained for product are correct.

However the PEC<sub>sed</sub> accumulation for formulation has not been submitted. The evaluator calculated this value using the following equation:

$$PEC_{sed}(\mu g/kg dw) = \frac{\%Drift_{soil} \times Application\ rate\ (g/ha) \times \%Active\ substance\ in\ sediment}{1000 \times sediment\ density\ (g/cm^3) \times sediment\ height\ (cm)}$$

The application of GLOB1811F/Rasput is 1000g/ha per season for oilseed rape. The maximum percentage of boscalid in the sediment is 79.9 %. The height of the sediment was assumed to be 5 cm and the sediment density was assumed to be 1.3 g/cm<sup>3</sup>.

PEC<sub>sed</sub> = 34.05 µg/kg

Taking into account the maximum accumulation value of 217 % in sediment as calculated in DAR the PEC<sub>sed</sub> accumulation value for formulation was received:

PEC<sub>sed, accu, max</sub> = 73.89 µg/kg

PEC<sub>sw/sed</sub> (product): PEC<sub>sw/sed</sub> can be used for the subsequent risk assessment for aquatic and sediment organisms.

## 8.9 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

**Table 8.10-1 Boscalid summary of atmospheric degradation and behaviour**

Compound	Boscalid
Direct photolysis in air	Photolytically stable in water. Photolysis in air not expected. Not stable under influence of radicals.
Quantum yield of direct phototransformation	<2.45 x 10 <sup>-4</sup>
Photochemical oxidative degradation in air	DT <sub>50</sub> : < 1.1d AOPWIN Version 1.88, [OH radicals] = 8 x 10 <sup>5</sup> cm <sup>-3</sup>
Volatilisation	Vapour pressure (Pa): 7.2 x 10 <sup>-7</sup> (20°C) Henry's Law Constant (Pa.m <sup>3</sup> /mol): 5.178 x 10 <sup>-5</sup>
Metabolites	-

The vapour pressure at 20 °C of Boscalid is < 10<sup>-5</sup> Pa. Hence Boscalid is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by Boscalid due to volatilization with subsequent deposition should not be considered.

Evaluator comment: Agreed with Applicant

## 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	XXX, J-P	2021a	Boscalid 50 WG - Estimations of the predicted environmental concentration in groundwater (PEC <sub>gw</sub> ) of Boscalid following the application of GLOB1811F on oilseed rape. Globachem NV, Report GLOB1811F – GW – Central EU Not GLP Unpublished	N	Globachem NV
KCP 9.2.5	XXX, J-P	2021b	Difenoconazole 500 SC – Estimation of the Predicted Environmental concentrations in surface water (PEC <sub>sw</sub> ) and sediments (PEC <sub>sed</sub> ) for Boscalid following the application of GLOB1811F on oilseed rape. Globachem NV, Report GLOB1811F – SW/SED – Central EU Not GLP Unpublished	N	Globachem NV

## **Appendix 2      Detailed evaluation of the new Annex II studies**

### **A 2.1              Study 1**

Comments of zRMS: Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information

Reference:	Data point
Report	Title, author(s), year, report No, document No, Authority registration No
Guideline(s):	Yes/No (If yes, give guidelines; If no, give justification, e.g., “ no guidelines available” or “ methods used comparable to guideline(s) xxx” )
Deviations:	Yes/No (If yes, describe deviations from test guidelines)
GLP:	Yes/No (If no, give justification, e.g., state that GLP was not compulsory at the time the study was performed)
Acceptability:	Yes/No/Supplementary

#### **Materials and methods**

#### **Results and discussions**

#### **Conclusion**

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