

# REGISTRATION REPORT

## **Part B**

### **Section 7**

#### **Metabolism and Residues**

Detailed summary of the risk assessment

Product code: GLOB1811F

Product name(s): RASPUT

Chemical active substance:

Boscalid, 500 g/kg

**Poland – Art. 33**

#### **CORE ASSESSMENT**

**(authorization)**

Applicant: Globachem NV

Submission date: June 2021

**MS Finalisation date: 01/06/2022**

## Version history

When	What
December 2021	First zRMS PL evaluation
March 2022	RR finalized by zRMS after commenting period
June 2022	Correction to the national label

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## 7 Metabolism and residue data (KCA section 6)

### 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.

### 7.1 Summary and zRMS Conclusion

#### 7.1.1 Critical GAP(s) and overall conclusion

##### Selection of critical uses and justification

The critical GAP with respect to consumer intake and risk assessment for the preparation GLOB1811F is presented in Table 7.1-1. It has been selected from the individual GAPs in the NEU for oilseed rape. A list of all intended uses within the NEU is given in Part B, Section 0.

##### Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL for boscalid as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of boscalid residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, Poland as zRMS agrees with the authorization of the intended use(s).

According to available data, a period of 365 days before planting new crops is recommended in order to reduce risk for succeeding crops.

##### Data gaps

No data gaps have been noticed.

**Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)**

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	Crop and/ or situation **	Zone	Product code	F, Fn, Fpn G, Gn, Gpn or I***	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Conclusion
						Type	Conc. of as	method kind	growth stage & season	number min max	interval between applications (min)	kg product/ha min max	water L/ha min max	kg as/ha min max		
1	OSR	CEU	GLOB1811F	F	<i>Sclerotina sclerotiorum</i>	WG	500 g/kg	Foliar Spray	BBCH 55-69	22	14	a) 0.5 b) 1	100-400	c) 0.25 d) 0.5	-	A
2	OSR	CEU	GLOB1811F	F	<i>Alternaria brassicae</i>	WG	500 g/kg	Foliar Spray	BBCH 55-69	22	14	a) 0.5 b) 1	100-400	c) 0.25 d) 0.5	-	A
3	OSR	CEU	GLOB1811F	F	<i>Leptosphaeria maculans</i>	WG	500 g/kg	Foliar Spray	BBCH 20-59	22	14	a) 0.5 b) 1	100-400	c) 0.25 d) 0.5	-	A

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

\*\* Use also code numbers according to Annex I of Regulation (EU) No 396/2005

\*\*\* 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 11 “Conclusion”

A	Exposure acceptable without risk mitigation measures, safe use
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable, no safe use

## 7.1.2 Summary of the evaluation

The preparation GLOB1811F is composed of boscalid 50% WG.

**Table 7.1-2: Toxicological reference values for the dietary risk assessment of Boscalid**

Reference value	Source	Year	Value	Study relied upon	Safety factor
Boscalid					
ADI	EC	2008	0.04 mg/kg bw/d	Rat 2-yr oral feed	100
ARfD	EC	2008	Not allocated	-	-

### 7.1.2.1 Summary for Boscalid

**Table 7.1-3: Summary for Boscalid**

Use-No.	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Oilseed rape	Yes	Yes (10 trials DAR, 2002)	Yes	Yes	Yes	No	No

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

According to the available data, the use requested in oilseed rape is considered acceptable. The proposed use is supported by the results of residue trials presented in EFSA Reasoned opinion on the review of the existing maximum residue levels (MRLs) for boscalid (2014). The assessment of a sufficient number of trials indicates that residue level is below of the current MRL – 1 mg/kg (Reg.(EU) 2021/590 (11 x 0.05 mg/kg and 1 x 0.07 mg/kg).

### 7.1.2.2 Summary for GLOB1811F

**Table 7.1-4: Information on GLOB1811F (KCA 6.8)**

Crop	PHI for GLOB1811F proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for GLOB1811F proposed by zRMS	zRMS Comments (if different PHI proposed)
		Boscalid		
Oilseed rape	NR	NR	NR	

NR: not relevant

\* Purpose of withholding period to be specified

\*\* F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

**Table 7.1-5: Waiting periods before planting succeeding crops**

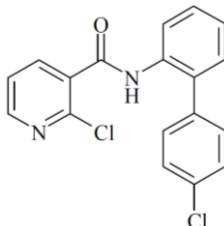
Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for GLOB1811F
Crop group	Led by Boscalid	
Leafy vegetables	<del>30 days</del> 365 days NR	Do not grow leafy vegetables in the treated field less than 365 days after application of GLOB1811F. NR
Root vegetables	<del>30 days</del> 365 days NR	Do not grow root vegetables in the treated field less than 365 days after application of GLOB1811F. NR
Fruiting vegetables	NR	NR
Bulb vegetables	<del>30 days</del> 365 days NR	Do not grow small grain in the treated field less than 365 days after application of GLOB1811F. NR
Stone fruits	NR	Do not grow bulb vegetables in the treated field less than 365 days after application of GLOB1811F. NR

NR: not relevant

## 7.2 Boscalid

General data on Boscalid are summarized in the table below (last updated 2017/01/24)

**Table 7.2-1: General information on Boscalid**

Active substance (ISO Common Name)	Boscalid
IUPAC	2-Chloro-N-(4'-chlorobiphenyl-2-yl)nicotinamide
Chemical structure	
Molecular formula	C <sub>18</sub> H <sub>12</sub> Cl <sub>2</sub> N <sub>2</sub> O
Molar mass	343.21 g/mol
Chemical group	Pyridine-carboxamides
Mode of action (if available)	Succinate dehydrogenase inhibitor
Systemic	Yes
Company	BASF AG.
Rapporteur Member State (RMS)	Slovakia (original RMS was Germany)
Approval status	Approved Date of (01/08/2008) and reference to decision (COMMISSION DIRECTIVE 2008/44/EC - REGULATION (EU) No 540/2011) <a href="http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008L0044&amp;from=EN">http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008L0044&amp;from=EN</a> <a href="http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0540&amp;from=EN">http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0540&amp;from=EN</a> <u>Extension of the approval period – Reg.(EU) 2021/745</u>
Restriction	Only uses as fungicide may be authorised
Review Report	SANCO/3919 /2007-rev. 5 21 January 2008
Current MRL regulation	<del>Reg. (EU) 2016/156</del> Reg. (EU) 2021/590
Peer review of MRLs according to Article 12 of Reg. No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Pending
EFSA Journal: conclusion on article 12	Yes
Current MRL applications on intended uses	EFSA-Q-2008-500 (Germany) Status: Reasoned opinion available (EFSA Journal 2014;12(7):3799)

\* Notifier in the EU process to whom the a.s. belong(s)

\*\* If yes: EFSA, YYYY - see list of references



## 7.2.1 Stability of Residues (KCA 6.1)

### 7.2.1.1 Stability of residues during storage of samples

#### Available data

No new data submitted in the framework of this application.

**Table 7.2-2: Summary of stability data achieved at  $\leq -18^{\circ}\text{C}$  (unless stated otherwise)**

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
<b>Data relied on in EU</b>			
<b>Plant products</b>			
Cabbage, peach and pea	High water content	24 months	DAR, 2002 EFSA, 2014
Grape	High acid content	16 months	DAR, 2002 EFSA, 2014
Rape seed	High lipid content	24 months	DAR, 2002 EFSA, 2014
Wheat grain and straw	Dry commodities / high starch content	24 months	DAR, 2002 EFSA, 2014
<b>Animal Products</b>			
Ruminant	Liver	5 months	DAR, 2002 EFSA, 2014
Ruminant	Milk	5 months	DAR, 2002 EFSA, 2014
Ruminant	Muscle	5 months	DAR, 2002 EFSA, 2014
Ruminant	Fat	5 months	DAR, 2002 EFSA, 2014
Ruminant	Kidney	5 months	DAR, 2002 EFSA, 2014
Poultry	Egg	5 months	DAR, 2002 EFSA, 2014

#### Conclusion on stability of residues during storage

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

*Storage stability of Boscalid was demonstrated for a period of 16 months at  $-18^{\circ}\text{C}$  in commodities with high acid content (grape) and 24 months at  $-18^{\circ}\text{C}$  in commodities with high water content (cabbage, peach, pea), high oil content (rape seed), dry commodities (wheat grain) and cereal straw. Degradation of residues during storage of the trial samples is therefore not expected. Storage stability of Boscalid and M510F01 in milk, muscle, fat, liver, kidney and egg for up to 5 months was demonstrated, when stored deep frozen.*

### 7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

No data was submitted and required at EU level during the EU Review of Boscalid.

## 7.2.2 Nature of residues in plants, livestock and processed commodities

### 7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

#### Available data

No new data submitted in the framework of this application.

**Table 7.2-3: Summary of plant metabolism studies**

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	Grape	U- <sup>14</sup> C-diphenyl and 3- <sup>14</sup> C-pyridine	foliar treatment, F	0.8	3	45	-	DAR, 2002 EFSA, 2014
Leafy vegetables	Lettuce		foliar treatment, G	0.7	3	18	-	DAR, 2002 EFSA, 2014
Pulses and oilseeds	Bean		foliar treatment, G	0.5	3	0 <sup>(a)</sup> , 14 <sup>(b)</sup> , 53 <sup>(c)</sup>	-	DAR, 2002 EFSA, 2014

(a) whole plant

(b) forage, green beans, pods and seeds

(c) bean straw, bean dry pods and dry seeds

### Summary of plant metabolism studies reported in the EU

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

*Metabolism of Boscalid was investigated for foliar treatment on fruits and fruiting vegetables (grapes), on pulses and oilseeds (beans) and on leafy vegetables (lettuce), using U-14C-diphenyl and 3-14C-pyridine labelled Boscalid (DAR, 2002).*

*In grapes, the highest TRR was identified in leaves and stalks (63.4 and 19.6 mg eq/kg respectively), whereas only 2 mg eq/kg was found in grapes (fruits). Unchanged parent Boscalid was the main component of the TRR in all plant parts, ranging from 92.7 % in grape fruits to 96.4 % in stalks. In lettuce, Boscalid was almost not metabolised. The residues in beans (edible part) were much lower compared to the rest of the plant. When separating greens beans into pods and seeds, the major part of radioactivity was found in pods (0.9 mg eq/kg) rather than in seeds (0.2 mg eq/kg). Residue levels were also higher in dry pods (6.1 mg eq/kg) than in dry seeds (0.2 mg eq/kg). Parent Boscalid was identified as the major compound of the TRR in bean leaves and forage (>98 %), in green beans and green pods (97 %), in bean straw (≥94 %), in dry pods (80-95 %) and in dry seeds (72 %). The cleavage products chlorophenylaminobenzene and 2-chloronicotinic acid were also identified in green beans and seeds but only in low concentrations (< 0.01 mg eq/kg). The metabolism studies showed that the metabolic pathway is similar in all crops.*

## Conclusion on metabolism in primary crops

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

*Consequently, the residue for enforcement and risk assessment in all plant commodities is defined as boscalid only. Validated analytical methods for enforcement of the proposed residue definition are available, except for hops, spices and herbal infusions. The conclusions reached by EFSA reflect the views of the RMS and are also in line with those of the JMPR (FAO, 2006).*

### 7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

#### Available data

No new data submitted in the framework of this application.

**Table 7.2-4: Summary of metabolism studies in rotational crops**

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Re- marks	
EU data								
Leafy vegetables	Lettuce	U- <sup>14</sup> C-diphenyl and 3- <sup>14</sup> C-pyridine	Bare soil, G	2.1	30, 120, 270, 365	Mature crops	-	DAR, 2002 EFSA, 2014
Root and tuber vegetables	Radish						-	DAR, 2002 EFSA, 2014
Cereals	Wheat						-	DAR, 2002 EFSA, 2014

\* Outdoor/field application (F) or glasshouse/protected/indoor application (G)

#### Summary of plant metabolism studies reported in the EU

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

*The metabolism of Boscalid in rotational crops – lettuce, radish, wheat – has been evaluated (DAR, 2002). One confined rotational crop study investigating the nature of residues following different plant-back intervals is available.*

*The highest TRR values were observed in radish leaves (0.34 mg eq/kg; 30 DAT, pyridine study) and in wheat straw (9.83 mg eq/kg, 30 DAT, diphenyl study and 4.01 mg eq/kg, 120 DAT, pyridine study). The highest TRR in lettuce amounted to 0.16 mg eq/kg (120 DAT, pyridine study), in radish root to 0.098 mg eq/kg (270 DAT, diphenyl study) and 0.066 mg eq/kg (365 DAT, pyridine study) and in wheat grain to 0.285 mg eq/kg (120 DAT, pyridine study) and 0.243 mg eq/kg (120 DAT, diphenyl study).*

*Except in wheat grain, parent boscalid was the major component of the TRR in all crops. Levels of the parent compound ranged from 50 % TRR in wheat straw (270 DAT, pyridine label) to 93 % TRR in wheat forage (270 DAT, pyridine label), and in lettuce leaves from 55.6 % TRR (270 DAT, diphenyl label) to 94.1 % TRR (365 DAT, diphenyl label). In wheat grain, the concentration of parent was low (between 1.9 % TRR at 270 DAT with the pyridine label and 16.8 % TRR at 30 DAT with the diphenyl label). Most of the radioactive residues in grain were not extractable (65 to 96 % TRR) and were detected in the starch fraction (36.2 to 48.4 % TRR, 0.06-0.12 mg eq/kg, pyridine label). The metabolite M510F61 (sugar conjugate of hydroxylated boscalid) was the only metabolite identified at levels exceeding 10 % TRR, in*

wheat forage (18.1 % TRR, diphenyl label, 270 DAT) and in radish leaves (21.2 % TRR for diphenyl label, 270 DAT and 11.2-15.5 % TRR, 365 DAT).

### Conclusion on metabolism in rotational crops

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

*The proposed metabolic pathway in succeeding crops involves hydroxylation and conjugation reactions. A part of the residue was also incorporated into and/or associated with natural products, such as starch, cellulose and lignin. The parent compound is therefore the main substance of concern in rotational crops and no metabolites of concern were identified in soil. Consequently, metabolic patterns in primary and rotational crops are found to be similar and a specific residue definition for rotational crops is not deemed necessary.*

### 7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

#### Available data

No new data submitted in the framework of this application.

**Table 7.2-5: Nature of the residues in processed commodities**

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)* Diphenyl-label	Reference
<b>EU data</b>		
<b>Pasteurisation</b> (20 minutes, 90°C, pH 4)	Parent (99.3%)	DAR, 2002 EFSA, 2014
<b>Baking, boiling, brewing</b> (60 minutes, 100°C, pH 5)	Parent (100.2%)	DAR, 2002 EFSA, 2014
<b>Sterilisation</b> (20 minutes, 120°C, pH 6)	Parent (91.1%)	DAR, 2002 EFSA, 2014

\* Total applied radioactivity after test

### Conclusion on nature of residues in processed commodities

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

*The effect of processing on the nature of Boscalid was investigated in the framework of the peer review. Studies were conducted simulating representative hydrolytic conditions for pasteurisation (20 minutes at 90°C, pH 4), boiling/brewing/baking (60 minutes at 100°C, pH 5) and sterilisation (20 minutes at 120°C, pH 6). From these studies, it was concluded that these processing conditions are not expected to have a significant impact on the composition of residues in matrices of plant origin (DAR, 2002). The relevant residue for enforcement and risk assessment in processed commodities is therefore expected to be the same as for primary crops.*

#### 7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

**Table 7.2-6: Summary of the nature of residues in commodities of plant origin**

Endpoints	
Plant groups covered	Fruits and fruiting vegetables (grapes) Leafy vegetables (lettuce) Pulses and oilseeds (bean)
Rotational crops covered	Root and tuber vegetables (Radish) Leafy vegetables (Lettuce) Cereals (Wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	a.s. is stable under standard hydrolysis conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Boscalid (Regulation n°2016/156) (Regulation n°2021/590)
Plant residue definition for risk assessment	Boscalid (EFSA 2014)
Conversion factor from enforcement to RA	None (DAR, 2002; EFSA, 2014)

#### 7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

##### Available data

No new data submitted in the framework of this application.

**Table 7.2-7: Summary of animal metabolism studies**

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	U- <sup>14</sup> C-diphenyl	2	1.46 - 1.73	5	Milk	Twice daily	DAR, 2002 EFSA, 2014
						Urine and faeces	Daily	
						Tissues	After sacrifice	
Laying poultry	Hens	U- <sup>14</sup> C-diphenyl	10	0.80 - 1.14	10	Eggs	Daily	DAR, 2002 EFSA, 2014
						Excreta	Daily	
						Tissues	After sacrifice	

## Summary of plant metabolism studies reported in the EU

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

*The nature of Boscalid residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (DAR, 2002). Reported metabolism studies include one study in lactating goats and one study in laying hens, both using [ $^{14}$ C-diphenyl] labelled Boscalid.*

*Lactating goats were dosed with 1.46 - 1.73 mg/kg bw per day of Boscalid. These dose levels represent at least 0.7 (including uptake of residues from previously treated soil) and 1 (resulting from the primary crop use only) time the maximum dietary burden of meat ruminant.*

*Boscalid is extensively excreted (89-93 % AR), with a relatively low transfer of residues to tissues (0.4-0.6 % AR in liver, 0.01-0.02 % AR for muscle, fat and kidney) and milk (0.06-0.15 % AR). The highest TRR was found in liver (2.59 mg eq/kg). Other TRR values were 0.27 mg eq/kg in kidney, 0.04 mg eq/kg in milk, 0.036 mg eq/kg in fat and 0.012 mg eq/kg in muscle.*

*Boscalid was the most abundant compound in fat (0.012 mg eq/kg; 34.6 % TRR) and represented a major part of the residue in muscle (0.002 mg eq/kg; 20.4 % TRR). It was also detected in liver (0.129 mg eq/kg; 5 % TRR), milk (0.001 mg eq/kg; 3.2 % TRR) and kidney (0.007 mg eq/kg; 2.5 % TRR). The metabolite M510F01 was the most abundant compound in muscle (0.003 mg eq/kg; 20.6 % TRR) and represented a major part of the residue in fat (0.009 mg eq/kg; 26.3 % TRR). It was also detected in liver (0.074 mg eq/kg; 2.9 % TRR), milk (0.006 mg eq/kg; 14.9 % TRR) and kidney (0.023 mg eq/kg; 8.6 % TRR). M510F02, the glucuronide conjugate of M510F01, is the most abundant compound in kidney (0.136 mg eq/kg; 50.3 % TRR) and was also detected in muscle (0.001 mg eq/kg; 11.9 % TRR) and milk (0.002 mg eq/kg, 6.4 % TRR).*

*Non-extractable residues accounted for 85 % TRR (2.2 mg eq/kg) in liver. Further extraction was conducted with either a mixture of acetic acid and acetone or with formic acid. Extraction released either M510F53 (43.6 % TRR; 1.13 mg eq/kg) or M510F52 (35.4 % TRR; 0.92 mg eq/kg), respectively for each solvent. Other compounds were detected but these compounds were demonstrated to be formed from extractable residues only (DAR, 2002). Therefore, only M510F53 and M510F52 are deemed to be representative of the bound residues in liver. It demonstrated that those residues mainly included components containing the unchanged diphenyl moiety, but also that a cleavage on the amine bound of Boscalid cannot be excluded. Consequently, as it is likely that bound residues are released during cooking of liver and that compounds comprising the pyridine moiety will have a different behaviour than the ones containing the diphenyl moiety, further investigation on the fate of the pyridine moiety in ruminant liver is still required.*

*Laying hens were dosed with 0.80 – 1.14 mg/kg bw per day of Boscalid. These dose levels represent at least 3.5 (including uptake of residues from previously treated soil) and 4.4 (resulting from the primary crop use only) times the maximum dietary burden of poultry.*

*Boscalid is extensively excreted (97.7 % AR), with a relatively low transfer of residues to tissues (0.04 % AR in liver, 0.003-0.004 % AR for muscle and fat) and eggs (0.12 % AR). The highest TRR was found in liver (0.17 mg eq/kg). Other TRR values were 0.058 mg eq/kg in eggs (with a maximum of 0.08 mg eq/kg), 0.025 mg eq/kg in fat and 0.003 mg eq/kg in muscle. A plateau is reached in eggs at day 6 (0.07 mg eq/kg).*

*Boscalid is the main compound in fat (0.023 mg eq/kg; 93.3 % TRR) and eggs (0.02 mg eq/kg; 35.5 % TRR). M510F01 was detected in eggs (0.015 mg eq/kg; 26.9 % TRR) and liver (0.009 mg eq/kg; 5.6 % TRR) and its conjugate M510F02 was detected in muscle (0.001 mg eq/kg; 11.9 % TRR) and eggs (0.01 mg eq/kg, 17.3 % TRR). Liver was only analysed using the microwave extraction used in the metabolism study on goats (only with formic acid). The results are similar to those observed in goats, M510F52 being the main compound (0.071 mg eq/kg; 42 % TRR). Therefore, further investigation on the fate of the pyri-*



*dine moiety in poultry liver is also required.*

*The metabolism studies on both ruminant and poultry show that parent compound, its hydroxy metabolite M510F01 and its conjugate are the main components of the residue in animal tissues and products, except in liver where the bound residues (measured as M510F53 and M510F52) were found to be the main components of the residue but the actual identity of those bound residues was not elucidated. The general metabolic pathways in rodents and ruminants were found to be comparable; the findings in ruminants can therefore be extrapolated to pigs.*

### Conclusion on metabolism in livestock

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

*During the Member States' consultation, it was agreed that conjugates of M510F01 are difficult to analyse routinely and that, based on the findings from metabolism study, Boscalid and M510F01 (free form) are deemed to be sufficient markers in liver and kidney. Nevertheless, as the available livestock feeding studies do not provide separate results for M510F01 and its conjugates, it is not possible to exclude conjugates of M510F01 from the enforcement residue definition in liver and kidney without additional data. Therefore, the relevant residue for enforcement is defined as Boscalid in muscle, fat, milk and eggs and as the sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates expressed as Boscalid in liver and kidney.*

*For risk assessment in liver, bound residues (measured as M510F53 and M510F52, but expressed as Boscalid) should also be included, but data is sufficient to derive a conversion factor for ruminant and pig livers only and supplementary data on the nature and magnitude of the bound residues in poultry liver are required. Since log Po/w of Boscalid is close to 3 (DAR, 2002) and residues in fat were found to be higher than in muscle, EFSA concludes that the residue in commodities of animal origin is fat soluble.*

*Validated analytical methods are available in all animal commodities.*

*The definition for enforcement derived by the JMPR is the same in muscle, fat, milk and eggs, but differs for liver and kidney, for which the residue definition is limited to Boscalid only (FAO, 2006). However, EFSA considers that the residue definition derived by JMPR for liver and kidney is not adequate, based on the results of the available feeding studies.*

### 7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

**Table 7.2-8: Summary on the nature of residues in commodities of animal origin**

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	2-3 days in milk
	6 days in eggs
Animal residue definition for monitoring	Boscalid in muscle, fat milk and eggs; Sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates expressed as Boscalid in liver and kidney; (Regulation n°2016/156) (Regulation n°2021/590)
Animal residue definition for risk assessment	Boscalid in muscle, fat milk and eggs; Sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates expressed as Boscalid in liver and kidney; Sum of Boscalid and its hydroxy metabolite M510F01 including its

	conjugates and the bound residues (measured as M510F52 or M510F53) expressed as Boscalid in Liver (ruminant and pig); (EFSA 2014)
Conversion factor	<del>None</del> 1.5 for ruminant and pig liver (EFSA, 2014)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes



## 7.2.3 Magnitude of residues in plants (KCA 6.3)

### 7.2.3.1 Summary of European data and new data supporting the intended uses

No new data are submitted in the framework of this application.

**Table 7.2-9: Summary of EU reported and new data supporting the intended uses of GLOB1811F and conformity to existing MRL**

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Oilseed rape	DAR 2002	C-EU	GAP on which EU a.s. assessment is based: 2 x 0.25 kg as/ha (0,5 kg pf/ha), interval 7-10 days between application, at BBCH 55-69, no PHI, outdoor  <b>10x &lt;0.05.</b>	N/A				
Oilseed rape	EFSA 2014	N-EU	2 x 0.25 kg as/ha (0,5 kg pf/ha), interval 8-12 days between application, at BBCH 61-69, no PHI, outdoor  <b>11x &lt;0.05; 0.07</b>	0.05	0.07	R <sub>ber</sub> = 0.1 R <sub>max</sub> = 0.07 MRL <sub>OECD</sub> = 0.07	1	yes

\*LOQ= 0,05 mg/kg

### 7.2.3.2 Conclusion on the magnitude of residues in plants

To cover the use of oilseed rape, ten residue trials are available in the DAR (DAR, 2002. *Draft Assessment Report of Boscalid. 8 November 2002*), carried out with a GAP more critical than proposed by Globachem NV (smaller interval between applications). Residue levels of Boscalid remained below the LOQ (0,05 mg/kg), which is covered by the EU-agreed MRL of 1 mg/kg in rapeseeds/canola. Therefore, it is possible to assume that for the proposed uses no exceedance of the MRL will occur.

In EFSA Reasoned opinion on the review of the existing maximum residue levels (MRLs) for boscalid (2014) a sufficient number of rape seed residue trials for central zone is presented. The residue level was: 11 x 0.05 mg/kg and 1 x 0.07 mg/kg, which is below the current MRL – 1 mg/kg (Reg.(EU) 2021/590. As the proposed GAP is within the GAP included in EFSA opinion, the requested application is accepted.

## 7.2.4 Magnitude of residues in livestock

### 7.2.4.1 Dietary burden calculation

Boscalid is authorised for use on several crops that might be fed to livestock. The median and maximum dietary burdens were therefore calculated for different groups of livestock. For dietary burden calculation the input values of EFSA Journal (2014) were used and a worst case calculation has been performed.

**Table 7.2-10: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration)**

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Boscalid				
Cabbage	1.10	Median residue	2.82	Highest residue
Kale	1.10	Median residue	4.10	Highest residue
Apple pomace	2.52	Median residue × PF	2.52	Median residue × PF
Wheat, rye grain	0.12	Median residue	0.12	Median residue
Barley, oat grain	1.07	Median residue	1.07	Median residue
Wheat, rye bran	0.52	Median residue × PF	0.52	Median residue × PF
Wheat straw	33.7	Median residue	52.7	Highest residue
Barley, oat straw	15.0	Median residue	26.9	Highest residue
Rye straw	19.6	Median residue	39.5	Highest residue
Peas (dry)	0.13	Median residue	0.13	Median residue
Beans(dry)	0.13	Median residue	0.13	Median residue
Potatoes	0.05	Median residue	0.05	Highest residue
Turnips	0.09	Median residue	0.28	Highest residue
Rape seed meal	0.08	Median residue × PF	0.08	Median residue × PF

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Linseed meal	0.10	Median residue $\times$ 2	0.10	Median residue $\times$ 2
Sunflower seed meal	0.32	Median residue $\times$ 2	0.32	Median residue $\times$ 2
Soya bean	0.05	Median residue	0.05	Median residue
Soya bean meal	0.01	Median residue $\times$ PF	0.01	Median residue $\times$ PF
Peanuts meal	0.10	Median residue $\times$ 2	0.10	Median residue $\times$ 2

**Table 7.2-11: Results of the dietary burden calculation**

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: Boscalid					
Dairy cattle	0.41	0.86	Wheat straw	23.8	<b>Y</b>
Beef cattle	0.99	1.77	Wheat straw	41.2	<b>Y</b>
Layer poultry	0.09	0.18	Kale	2.92	<b>Y</b>
Finishing swine	0.09	0.26	Kale	6.38	<b>Y</b>

#### 7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

##### Available data

No new data were submitted in the framework of this application.

The livestock burden calculation was performed by zRMS using the new Animal model 2017 tool and, as result feeding studies are required as a significant intake for ruminants, poultry and pigs is expected (> 0.004 mg/Kg bw (Reg. (EU) 283/2013).

New data requirements		<input type="checkbox"/> Regulation (EU) No 283/2013						
Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0,439	0,615	14,69	19,14	Dairy cattle	Wheat	straw	Yes
Cattle (dairy only)	0,439	0,615	11,42	15,99	Dairy cattle	Wheat	straw	Yes
Sheep (all diets)	0,811	1,186	19,08	27,91	Lamb	Wheat	straw	Yes
Sheep (ewe only)	0,630	0,922	18,89	27,66	Ram/Ewe	Wheat	straw	Yes
Swine (all diets)	0,075	0,127	3,25	5,51	Swine (breeding)	Kale	leaves	Yes
Poultry (all diets)	0,355	0,507	5,19	7,41	Poultry layer	Wheat	straw	Yes
Poultry (layer only)	0,355	0,507	5,19	7,41	Poultry layer	Wheat	straw	Yes

Animals	Median burden (mg/kg bw)	Maximum burden (mg/kg bw)	Above 0.004 mg/kg bw	Maximum burden (mg/kg DM)
Beef cattle	0.352	0.459	yes	19.14
Dairy cattle	0.439	0.615		15.99
Ram/Ewe	0.629	0.922	yes	27.7
Lamb	0.810	1.186		27.91
Pig (breeding)	0.075	0.127	yes	5.51
Pig (finishing)	0.042	0.044		1.48
Poultry broiler	0.095	0.104	yes	1.47
Poultry layer	0.355	0.507		7.41
Turkey	0.075	0.084		1.18

In the EFSA Journal (2014) the dietary burden uptake was also recalculated using as input values the combined residues from primary and rotational crops. Considering the occurrence of residues in rotational crops a slight increase of dietary burden was shown compared to the calculation performed using only the residues from primary crops. Hence, regardless of the residues occurring in rotational crops, further investigation of residues is required in all commodities of animal origin.

The feeding studies were performed and reported and were considered sufficient for deriving MRLs in livestock. Significant residues in edible matrices of livestock are expected, and MRL and risk assessment values for these commodities can be proposed. Considering however that further investigation in ruminant and poultry liver are still required, all MRL and risk assessment values in liver are tentative only.

**Table 7.2-12: Overview of the values derived from livestock feeding studies**

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) <sup>(a)</sup>	Highest residue (mg/kg) <sup>(b)</sup>	Calculated MRL (mg/kg)	CF for RA <sup>(c)</sup>
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)	No	Result for enforce-ment		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (DAR, 2002; EFSA, 2014)												
Enforcement residue definition: <ul style="list-style-type: none"><li>muscle, fat: boscalid</li><li>kidney, liver: sum of boscalid and its hydroxy metabolite M510F01 (free and conjugated), expressed as boscalid</li></ul> Risk assessment residue definition: <ul style="list-style-type: none"><li>muscle, fat: boscalid</li><li>kidney: sum of boscalid and its hydroxy metabolite M510F01 (free and conjugated), expressed as boscalid</li><li>liver: sum of boscalid, its hydroxy metabolite M510F01 (free and conjugated) and its bound residue (measured as M510F53 or M510F52), expressed as boscalid</li></ul>												
Pig meat	0.09	0.26	1.22	3	<0.025	<0.025	<0.025	<0.025	0.025	0.025	0.025*	1.00
			3.36	3	<0.025	<0.025	<0.025	<0.025				
Pig fat			1.22	9	0.15	0.22	0.15	0.22	0.025	0.05	0.05	1.00
			3.36	9	0.17	0.25	0.17	0.25				
Pig liver			1.22	3	0.09	0.11	-	-	0.005	0.05	0.05* (tentative)	1.50 <sup>(h)</sup>
			3.36	3	0.20	0.24	-	-				
Pig kidney			1.22	3	0.11	0.11	0.11	0.11	0.05	0.05	0.05*	1.00
			3.36	3	0.18	0.24	0.18	0.24				
Ruminant meat	0.99	1.77	1.22	3	<0.025	<0.025	<0.025	<0.025	0.025	0.025	0.025*	1.00
			3.36	3	<0.025	<0.025	<0.025	<0.025				
Ruminant fat					1.22	9	0.15	0.22	0.15	0.22	0.12	0.23

			3.36	9	0.17	0.25	0.17	0.25				
Ruminant liver			1.22	3	0.09	0.11	-	-				
			3.36	3	0.20	0.24	-	-				
Ruminant kidney			1.22	3	0.11	0.11	0.11	0.11	0.09	0.14	0.15	1.00
			3.36	3	0.18	0.24	0.18	0.24				
Poultry meat	0.09	0.18	0.06	3	<0.025	<0.025	<0.025	<0.025	0.025	0.025	0.025*	1.00
			0.32	3	<0.025	<0.025	<0.025	<0.025				
			1.26	3	<0.025	<0.025	<0.025	<0.025				
Poultry fat			0.06	3	<0.025	<0.025	<0.025	<0.025	0.03	0.06	0.06	1.00
			0.32	3	0.06	0.10	0.06	0.10				
			1.26	3	0.14	0.17	0.14	0.17				
Poultry liver			0.06	3	<0.05	0.05	0.08	0.05	0.06	0.11	0.15 (tentative)	1.00
			0.32	3	0.14	0.18	0.14	0.18				
			1.26	3	0.41	0.47	0.41	0.47				
Milk	0.41	0.86	1.22	30	0.01 <sup>(d)</sup>	N/A	0.01 <sup>(d)</sup>	N/A	0.01	0.01	0.01*	1.00
			3.36	60	0.05 <sup>(e)</sup>	N/A	0.05 <sup>(e)</sup>	N/A				
Eggs	0.09	0.18	0.06	30	<0.01 <sup>(f)</sup>	N/A	<0.01 <sup>(f)</sup>	N/A	0.01	0.01	0.01*	1.00
			0.32	30	<0.01 <sup>(f)</sup>	N/A	<0.01 <sup>(f)</sup>	N/A				
			1.26	30	0.02 <sup>(g)</sup>	N/A	0.02 <sup>(g)</sup>	N/A				

N/A: Not applicable – only the mean values are considered for calculating MRLs in milk.

n.r.: Not reported

(\*): Indicates that the MRL is set at the limit of analytical quantification.

(F): MRL is expressed as mg/kg of fat contained in the whole product.

(a): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).

(b): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).

(c): The median conversion factor for enforcement to risk assessment.

- (d): Mean residue level from day 1 until day 28 (3 cows, 10 sampling days).
- (e): Mean residue level from day 1 until day 28 (6 cows, 10 sampling days).
- (f): Mean residue level from day 1 until day 28 (3 hens, 10 sampling days).
- (g): Mean residue level from day 1 until day 28 (5 hens, 10 sampling days).
- (h): Tentative conversion factor derived from a separate ruminant feeding study.

### **Conclusion on feeding studies**

The requested uses (or the new mode of calculation) modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

## 7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

### 7.2.5.1 Available data for all crops under consideration

No new data were submitted in the framework of this application.

**Table 7.2-13: Overview of the available processing studies**

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
<b>EU data</b>					
Processing factors recommended (sufficiently supported by data)					
Apples, juice	6	0.08	1.00		PROFile
Apples, wet pomace	6	6.00	1.00		PROFile
Apples, dry pomace	4	18.35	1.00		PROFile
Apples, sauce	4	0.90	1.00		PROFile
Cherries, canned	4	0.52	1.00		EFSA, 2010
Cherries, jam	4	0.11	1.00		EFSA, 2010
Cherries, juice	4	0.39	1.00		EFSA, 2010
Plums, dried (prunes)	4	2.60	1.00		EFSA, 2010
Plums, jam	4	1.40	1.00		EFSA, 2010
Table grapes, dried (raisins)	4	2.40	1.00		DAR, 2002
Wine grapes, juice	4	0.40	1.00		DAR, 2002
Wine grapes, wet pomace	4	2.50	1.00		DAR, 2002
Strawberries, jam	4	0.44	1.00		PROFile
Strawberries, sauce	4	0.25	1.00		PROFile
Strawberries, canned	4	0.80	1.00		PROFile
Kiwi, peeled	4	0.06	1.00		PROFile
Carrots, canned	4	0.12	1.00		EFSA, 2010
Carrots, cooked	4	0.12	1.00		EFSA, 2010
Carrots, juice	4	0.12	1.00		EFSA, 2010
Tomatoes, unpeeled and canned	4	0.05	1.00		EFSA, 2010
Tomatoes, peeled and canned	4	0.05	1.00		EFSA, 2010
Tomatoes, paste	4	0.30	1.00		EFSA, 2010
Tomatoes, juice	4	0.17	1.00		EFSA, 2010



Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
Gherkins, canned	4	0.56	1.00		EFSA, 2010
Head cabbage, cooked	4	0.07	1.00		EFSA, 2010
Head cabbage, canned	4	0.07	1.00		EFSA, 2010
Head cabbage, sauerkraut	4	0.17	1.00		EFSA, 2010
Head cabbage, sauerkraut juice	4	0.07	1.00		EFSA, 2010
Rape seed, refined oil	4	1.26	1.00		EFSA, 2010
Rape seed, meal/press cake	4	0.56	1.00		EFSA, 2010
Barley, brewing malt	4	0.48	1.00		PROFile
Barley, beer	4	0.02	1.00		PROFile
Barley, pot/pearl	4	0.34	1.00		PROFile
Wheat, whole-meal flour	4	1.21	1.00		PROFile
Wheat, whole-meal bread	4	0.81	1.00		PROFile
Wheat, white flour	4	0.34	1.00		PROFile
Wheat, bran	4	4.32	1.00		PROFile
Indicative processing factors (limited dataset)					
Peas cooked/canned	1	<0.36	1.00		DAR, 2002
Rape seed, crude oil	2	1.11	1.00		EFSA, 2010
Soya bean, refined oil	2	0.40	1.00		EFSA, 2010
Soya bean, meal	2	0.16	1.00		EFSA, 2010

\* The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.

\*\* The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

### 7.2.5.2 Conclusion on processing studies

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

*Studies investigating the magnitude of residues in processed commodities of grapes and peas were also reported in the framework of the peer review (DAR, 2002). After boscalid was included in Annex I to Directive 91/414/EEC, studies investigating the magnitude of residues in processed commodities of apples, cherries, plums, strawberries, kiwi, carrots, tomatoes, gherkins, head cabbage, rape seed, soya bean, barley and wheat were evaluated by EFSA or by the RMS.*

*It is acknowledged that for most of the studies the exact details on the processing conditions are not available (meaning that the available studies might not be representative for any type of processing). Nevertheless, data are considered acceptable to derive robust processing factors for all processed commodities, except for some processed commodities of soya bean, rape seed and peas, where the number of available studies is not adequate; a minimum of 3 processing studies is normally required.*

*Meanwhile, further processing studies are not required for the time being as they are not expected to affect the outcome of the risk assessment.*

## 7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Data dealing with magnitude of residues in succeeding crops are available and are summarized hereafter.

### 7.2.6.1 Field rotational crop studies (KCA 6.6.2)

#### Available data

No new data submitted in the framework of this application.

**Table 7.2-14: Summary of available studies in field rotational crops**

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
EU data					
Lettuce followed by green beans	2.1 kg a.s./ha (2 x 0.3 kg a.s./ha followed by 3 x 0.5 kg a.s./ha)	Cereals	Spring wheat	365, 365, 365 (3-year crop rotation)	DAR, 2002 EFSA, 2014
Carrots followed by cauliflower	1.7 kg a.s./ha (3 x 0.3 kg a.s./ha followed by 2 x 0.4 kg a.s./ha)	Cereals	Spring wheat	365, 365, 365 (3-year crop rotation)	DAR, 2002 EFSA, 2014
Winter oilseed rape	0.5 kg a.s./ha	Cereals	Winter wheat*	365	DAR, 2002 EFSA, 2014

\* Sampling not performed under GLP

The rotational crop field trials were evaluated in the framework of the peer review and afterwards by EFSA (2014). Boscalid was applied the first year to lettuce (2 × 0.3 kg a.s./ha) and green beans (3 × 0.5 kg a.s./ha) and the second year to carrots (3 × 0.3 kg a.s./ha) and cauliflower (2 × 0.4 kg a.s./ha). The third year, wheat was sown in the same field. In the second field trial, boscalid was applied on winter rape (0.5 kg a.s./ha) and, 365 days after harvest, wheat was sown on the same plot.

Only wheat was analysed for residues, indicating that boscalid residues were not found above the LOQ in wheat grain when wheat was planted as a succeeding crop after vegetables or rape.

Furthermore, a number of field rotational crop studies have been performed in the US and the EU to provide a broader perspective on residue levels found in rotational crop studies conducted under natural conditions. They were already evaluated by EFSA (2014). Application rates ranged between 2.0 to 2.15 kg a.s./ha on a bare soil (or with strawberry as primary crop, in one study). In these studies, the following plants were grown as successive crops: root and tuber, leaves and tops, corn, brassica, seeds and grains. The results indicate no exceedances of current MRLs in rotational crops.

#### Conclusion on rotational crops studies

Conclusions drawn from EFSA Journal 2014;12(7):3799 are reported below:

*Occurrence of Boscalid residues in rotational crops was already investigated during the peer review. It is concluded that metabolic patterns in primary and succeeding crops are similar and that a potential for*

accumulation of Boscalid residues in crops grown in rotation is expected. EFSA is aware that instead of defining risk mitigating measures, risk managers may have the interest to establish MRLs accommodating for the uptake of residues from previously treated soils, EFSA therefore re-calculated the MRL proposals to take into account such residues. However, these MRLs are subject to a higher degree of uncertainty; Member States may therefore also consider the establishment of appropriate risk mitigation measures in order to prevent the presence of residues in rotational crops. Furthermore, residue trials after repeated application in permanent crops would be desirable as well.

In the opinion of zRMS a period of 365 days before planting new crops should be considered in order to reduce risk for succeeding crops.

Taking into account the following information:

no exceedance of MRLs in primary crops (rape),

similar metabolism of boscalid in primary and succeeding crops,

no exceedance of MRLs in rotational crops after application of a dose significantly higher than the requested dose (2.0-2.15 kg/ha v. 1.0 kg/ha),

it can be concluded that specific plant-back restrictions related to the use of Rasput are not required, provided that the product is used according to GAP.

#### 7.2.7 Other / special studies (KCA6.10, 6.10.1)

According to Regulation (EU) No. 283/2013 studies to determine the residue level in pollen and bee products are required to determine the residue in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at blossom.

A Guidance Document SANTE/11956/2016 rev. 9 (14 September 2018) 'Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey' is available and implemented by 1 January 2020.

According to this Guidance further data on crop or field/tunnel trials are required when residue in honey are expected considering the proposed uses and the properties of the active substance.

Following the different steps in this Guidance, residue in honey can be expected after pesticide application under one of the following conditions:

Residues in honey can occur:

- When a substance is applied during the flowering stage (BBCH 60-69) of a crop which is foraged by bees (the so-called melliferous crops which are attractive to bees and from which it is possible to produce honey)
- When a substance with systemic properties is applied prior to the flowering stage (before BBCH 60), including treatment of seeds, of a crop which is foraged by bees .
- from uses on non-target plants (in-field weeds and adjacent plants) when a substance is applied during the flowering period from April to September.
- from succeeding crops after application of a persistent and systemic active substance
- via honeydew collected from plant-sucking insects in forestry (such as *Picea* spp., *Abies* spp, *Pinus* spp. and *Quercus* spp.)

GLOB1811F, containing 500 g/kg Boscalid, is a fungicide with intended use on oilseed rape at BBCH 69 at the latest. According to SANTE/11956/2016 rev. 9 Appendix II, the intended crop oilseed rape is considered as a melliferous crop and GLOB1811F is applied during the flowering stage of oilseed rape.

Next to the exposure of bees to the crop itself, the exposure of bees to non-target plants (in-field flowering weeds and flowering adjacent plants (off-field flowering weeds)) need to be considered. However, if realistic farming practices (e.g. tillage and herbicide applications) are considered, weeds are not usually prevalent in arable fields. This is also confirmed by a recent publication (Maynard *et al*, 2014), where it was shown that less than 2% of all weeds recorded in arable crops (wheat, oilseed rape, sugar beet, sunflower, potatoes, maize, peas and beans) are at flowering growth stage. For arable crops, it can therefore be considered that the exposure of bees to in-field flowering weeds is not a realistic and relevant scenario as flowering weeds are not present in the field in significant quantities in realistic conditions.

Relating to exposure of bees to the intended melliferous crop oilseed rape itself and the potential to expect residue in honey, the applicant refers to monitoring data. In the minutes of the SCOPAFF meeting (san-te.ddg2.g.5(2019)6930972) the Commission refers to the EFSA residue monitoring programs for the years 2013-2017 and which are outlined in EFSA Scientific Reports. Those reports provide an insight into the official control activities carried out by EU Member States and provide data analysis regarding pesticide residue occurrence in the most important food products consumed including honey. During the SCOPAFF meeting, the Commission gave an overview of these findings and concluded that only a limited number of substances were found regularly in honey and that for most of them the MRLs in honey were not exceeded in any of the samples analysed.

In these monitoring results, a total of 1,590 samples of honey were analysed for boscalid residues in the reference period from 2013 to 2017. Samples originated from 25 different EU Member States and from 15 non-EU countries; most of the samples (61%, 972 samples) were from Germany. For 11% of the samples, the origin was unknown. The validated LOQs for the analytical methods used in the analysis ranged from 0.002 to 0.5 mg/kg. Overall, 27 samples (2%) contained quantifiable boscalid residues (residues above the LOQ). The highest boscalid residue measured in honey in the reference period accounted for 0.082 mg/kg, which is lower than the recently set MRL of 0.15 mg/kg in honey (Reg. (EU) 2021/590). Therefore, it can be concluded that no residues of Boscalid are expected to occur in honey after the use of GLOB1811F according to the intended GAP. No further data on crop or field/tunnel trials would be necessary.

Furthermore, reference can be made to several unprotected (non-GLP) studies on honey residues in oilseed rape after exposure to Boscalid (submitted in the dRAR (2018) and for the MRL review (EFSA, 2019)) as supportive information.

Crop	Application and sampling details					Residues (mg/kg)	Reference
	Method	Rate (kg a.s./ha)	No	BBCH	Sampling (DAT)		
Winter oilseed rape	foliar treatment, indoor (tunnel test)	0.25	1	59 (before flowering)	21 26	< 0.05 < 0.05	dRAR, 2018 EFSA, 2019 XXX U. & XXX C. (2004a)
				65 (full flowering, evening)	8 13	< 0.05 < 0.05	
				65 (full flowering, during foraging)	7 12	0.064 < 0.05	
Winter oilseed rape	Foliar treatment, out-	0.25	1	n.r.	28	< 0.05	dRAR, 2018 EFSA, 2019
					42	< 0.05	

	door				17	< 0.05	XXX U. & XXX C. (2004b)
					15	< 0.05	
					22	< 0.05	
					29	< 0.05	

In XXX U. & XXX C. (2004a), one residue trial was conducted under semi-field conditions, i.e. using tunnel tents. Three different scenarios were tested: in the first one, boscalid (500 g/ha) was applied before flowering (BBCH 59). In the second scenario, the crop was treated at full flowering (BBCH 65) and the bee colonies were placed in the tunnels the day after the treatment. In the third scenario, the crop was also treated at full flowering, with the bee colonies being present in the tunnels already during the application of boscalid. From all scenarios, honey samples were taken twice after the start of the bee exposure. The first sampling was carried out 21, 8 or 7 days after the respective treatment, the second one after the end of flowering period which was 26, 13 and 12 days after application.

In the first and second scenario, boscalid residues in honey were all below the LOQ (0.05 mg/kg). Only in scenario three (treatment of oilseed rape during foraging activity of the bees) quantifiable residues were determined (i.e. 0.064 mg/kg) seven days after the treatment.

In XXX U. & XXX C. (2004b), six additional residue trials were performed in Germany in which beehives were located near fields of oilseed rape which was treated with boscalid during flowering (application rate 200–250 g/ha). These studies were conducted in open field. Honey samples were taken 15–42 days after the application of boscalid.

In none of the trials, quantifiable residues of boscalid were found in honey.

zRMS comment: the presented data indicates that 1 application of boscalid at the rate of 0.25 as/ha to oilseed rape shortly before flowering and at full flowering does not cause the presence of residues in honey above MRL. It could be assumed that the application of 2 doses (according to proposed GAP) will not lead to exceedance of boscalid residues in honey as the residues below LOQ were measured on 8 DAT (interval between application in required GAP is 14 days).

## 7.2.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

As ARfD was not deemed necessary, acute risk assessment is not relevant.

The chronic risk assessment based on current MRLs (Reg.(EU) 2021/590) significantly exceeds ADI and represents the worst case. Therefore the refinement based on median residue (EFSA, 2014) was carried out as a realistic scenario.

### 7.2.8.1 Input values for the consumer risk assessment

**Table 7.2-15: Input values for the consumer risk assessment**

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition: Boscalid		

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Tree nuts except pistachios, pine nuts and coconuts	0.05	Median residue
Pistachios	0.27	Median residue
Apples, Pears, Quinces	0.42	Median residue
Apricots	0.77	Median residue (tentative)
Cherries	1.51	Median residue
Peaches	0.77	Median residue
Plums	0.29	Median residue
Table and wine grapes	1.42	Median residue
Strawberries	1.90	Median residue
Cane fruits	2.47	Median residue
Other small fruit and berries, except rose hips, mulberries and elderberries	3.60	Median residue
Rose hips, mulberries and elderberries	2.60	Median residue
Kiwi	0.08	Median residue × PF
Bananas	0.05	Median residue
Potatoes, Sweet potatoes, Yams, Arrowroot	0.05	Median residue
Beetroot	0.33	Median residue
Carrots, Horseradish	0.19	Median residue × PF
Celeriac	0.34	Median residue
Jerusalem artichokes	2.00	Median residue
Parsnips, Parsley root, Salsify, Turnips	0.09	Median residue
Radishes	0.28	Median residue
Garlic, Onions, Shallots	0.20	Median residue
Spring onions	2.30	EU MRL
Tomatoes, Aubergines (egg plants)	0.35	Median residue
Peppers	0.51	Median residue
Cucurbits with edible peel	0.68	Median residue
Cucurbits with inedible peel	0.35	Median residue

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Broccoli	1.55	Median residue
Cauliflower	1.55	Median residue
Brussels sprouts	0.30	Median residue
Head cabbage	1.10	Median residue
Chinese cabbage	1.10	Median residue
Kale	1.10	Median residue (tentative)
Kohlrabi	0.04	Median residue
Lettuce and similar	5.60	Median residue
Spinach	5.60	Median residue
Beet leaves (chard)	30.0	Median residue
Witloof	1.16	Median residue
Fresh herbs, except basil	5.60	Median residue
Basil	14.5	Median residue
Beans (fresh, with pods)	0.64	EU MRL
Beans (fresh, without pods)	0.11	Median residue
Peas (fresh, with pods)	0.64	Median residue
Peas (fresh, without pods)	0.11	Median residue
Lentils (fresh)	3.00	Median residue
Asparagus	0.05	Median residue (tentative)
Celery	2.18	Median residue
Fennel	2.18	Median residue
Globe artichokes	1.18	Median residue
Leek	2.30	Median residue
Beans (dry)	0.13	Median residue
Lentils (dry)	0.13	Median residue
Peas (dry)	0.13	Median residue
Linseed	0.05	Median residue
Peanuts	0.05	Median residue
Poppy seed	0.05	Median residue
Sunflower seed	0.16	Median residue
Rape seed	0.15	Median residue
Soya bean	0.05	Median residue
Mustard seed	0.05	Median residue
Borage	0.05	Median residue



Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Gold of pleasure	0.05	Median residue
Barley grain, Oats grain	1.07	Median residue
Wheat grain, Rye grain	0.12	Median residue
Herbal infusions (dried, roots)	0.95	Median residue (tentative)
Hops (dried)	24.5	Median residue (tentative)
Swine meat	0.03	$0.8 \times \text{Median muscle}$
Swine fat (free of lean meat)	0.03	$+ 0.2 \times \text{Median fat}$
Ruminant meat	0.05	Median residue
Ruminant fat	0.12	$0.8 \times \text{Median muscle}$
Poultry meat	0.03	$+ 0.2 \times \text{Median fat}$
Poultry fat	0.03	Median residue
Ruminant milk	0.01*	$0.8 \times \text{Median muscle}$
Birds' eggs	0.01*	$+ 0.2 \times \text{Median fat}$
Risk assessment residue definition: sum of boscalid and its hydroxy metabolite M510F01 (free and conjugated), expressed as boscalid		
Swine kidney	0.05*	Median residue
Ruminant kidney	0.09	Median residue
Poultry liver	0.06	Median residue (tentative)
Risk assessment residue definition: sum of boscalid, its hydroxy metabolite M510F01 (free and conjugated) and its bound residue (measured as M510F53 or M510F52), expressed as boscalid		
Swine liver	0.08	Median residue (tentative) $\times$ CF
Ruminant liver	0.11	Median residue (tentative) $\times$ CF

## 7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

**Table 7.2-1: Consumer risk assessment**

TMDI (% ADI) according to EFSA PRIMo	278.8 % (based on WHO Cluster diet B)
IEDI (% ADI) according to EFSA PRIMo	68.8 % (based on DE child)
IENTI (% ARfD) according to EFSA PRIMo*	Not relevant
NTMDI (% ADI) **	-
NEDI (% ADI)**	-
NESTI (% ARfD) **	-

\* include raw and processed commodities if both values are required for PRIMo

\*\* if national model is available



The proposed uses of Boscalid in the formulation Boscalid 50% WG do not represent unacceptable chronic risks for the consumer.

Consumer risk assessment has been recalculated by zRMS.

#### **Chronic exposure:**

The calculation of the TMDI was performed taking into account all the crops to which the Boscalid may be applied. At this scope crops assessed according to EFSA Journal 2014;12(7):3799 have been considered.

TMDI (% ADI) according to EFSA PRIMo 3.1	47% (based on NL Toddler)
IEDI (% ADI) according to EFSA PRIMo	-
IESTI (% ARfD) according to EFSA PRIMo*	-
NTMDI (% ADI) **	-
NEDI (% ADI)**	-
NESTI (% ARfD) **	-

\* include raw and processed commodities if both values are required for PRIMo

\*\* if national model is available

The estimated long-term dietary intake is below the ADI.

The diet with the highest TMDI is NL toddler population with 47% of ADI. For this diet, the highest contributors are apples with 11% of ADI and spinaches with 10% of ADI. The proposed use of Boscalid in the formulation GLOB1811F does not represent unacceptable chronic risks for the consumer.

No acute exposure assessment performed (no ARfD value established).

### **7.3 Combined exposure and risk assessment**

Not relevant. The product contains only one active substance.

### **7.4 References**

Germany, 2002. Draft Assessment Report of Boscalid. 8 November 2002.

European Commission, 2008. Review report for the active substance Boscalid. SANCO/3919/2007-rev. 5, 21 January 2008.

EFSA, 2014. Review of the existing Maximum Residue Levels (MRLs) for Boscalid according to Article 12 of Regulation 396/2005. EFSA Journal 2014;12(7):3799.

EFSA, 2019. Modification of the existing maximum residue level for boscalid in honey. EFSA Journal 2019;17(11):5897

## **Appendix 1 Lists of data considered in support of the evaluation**

## **Appendix 2 Detailed evaluation of the additional studies relied upon**

### **A 2.1           Boscalid**

#### **A 2.1.1           Stability of residues**

##### **A 2.1.1.1        Stability of residues during storage of samples**

##### **A 2.1.1.1.1     Storage stability of residues in plant products**

No new data were submitted in the framework of this application.

##### **A 2.1.1.1.2     Storage stability of residues in animal products**

No new data were submitted in the framework of this application.

#### **A 2.1.2           Nature of residues in plants, livestock and processed commodities**

##### **A 2.1.2.1        Nature of residue in plants**

##### **A 2.1.2.1.1     Nature of residue in primary crops**

No new data were submitted in the framework of this application.

##### **A 2.1.2.1.2     Nature of residue in rotational crops**

No new data were submitted in the framework of this application.

##### **A 2.1.2.1.3     Nature of residues in processed commodities**

No new data were submitted in the framework of this application.

##### **A 2.1.2.2        Nature of residues in livestock**

No new data were submitted in the framework of this application.

#### **A 2.1.3           Magnitude of residues in plants**

No additional studies were necessary/provided.

#### **A 2.1.4           Magnitude of residues in livestock**

##### **A 2.1.4.1        Livestock feeding studies**

No new data were submitted in the framework of this application.

**A 2.1.5      Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)**

**A 2.1.5.1      Distribution of the residue in peel/pulp**

No new data were submitted in the framework of this application.

**A 2.1.5.2      Processing studies on a core set of representative processes**

No new data were submitted in the framework of this application.

**A 2.1.6      Magnitude of residues in representative succeeding crops**


No new data were submitted in the framework of this application.

**A 2.1.7      Other/Special Studies**

No new data were submitted in the framework of this application.

## **Appendix 3 Pesticide Residue Intake Model (PRIMo)**

### **A 3.1 TMDI calculations**

 European Food Safety Authority EFSA PRIMo revision 3.1; 2019/03/19		<b>Boscalid (F)</b>				Input values					
		LOQs (mg/kg) range from: to:				Details - chronic risk assessment		Supplementary results - chronic risk assessment			
		<b>Toxicological reference values</b>				Details - acute risk assessment/children		Details - acute risk assessment/adults			
		ADI (mg/kg bw/day): <b>0.04</b>		ARfD (mg/kg bw): <b>not necessary</b>							
Source of ADI:		Source of ARfD:		Year of evaluation:		Year of evaluation:					
Year of evaluation:		Year of evaluation:		Year of evaluation:		Year of evaluation:					
Comments:											
<b>Normal mode</b>											
<b>Chronic risk assessment: JMPR methodology (IEDI/TMDI)</b>											
				No of diets exceeding the ADI: ---							
	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI(NED/IEDI) calculation (based on average food consumption)	47%	NL toddler	18,68	11%	Apples	10%	Spinaches	5%	Pears		
	32%	DE child	12,89	13%	Apples	3%	Spinaches	2%	Strawberries		
	22%	NL child	8,74	6%	Apples	4%	Spinaches	2%	Strawberries		
	16%	FR toddler 2 3 yr	6,37	3%	Apples	2%	Spinaches	2%	Leeks		
	15%	GEMS/Food G11	6,16	2%	Barley	2%	Apples	2%	Leeks		
	15%	FR infant	6,08	4%	Spinaches	2%	Chards/beet leaves	2%	Apples		
	15%	GEMS/Food G15	6,03	2%	Head cabbages	2%	Barley	1%	Wheat		
	15%	ES child	5,93	6%	Chards/beet leaves	1%	Wheat	1%	Apples		
	15%	IE adult	5,83	2%	Spinaches	1%	Basil and edible flowers	0,9%	Strawberries		
	14%	GEMS/Food G08	5,74	2%	Barley	1%	Apples	1%	Head cabbages		
	14%	GEMS/Food G06	5,71	3%	Tomatoes	2%	Wheat	1,0%	Apples		
	14%	ES adult	5,61	6%	Chards/beet leaves	1%	Barley	1%	Spinaches		
	14%	GEMS/Food G07	5,49	2%	Barley	1%	Wheat	1%	Apples		
	14%	IT toddler	5,47	5%	Chards/beet leaves	2%	Wheat	1%	Tomatoes		
	14%	SE general	5,45	2%	Head cabbages	1%	Chards/beet leaves	1%	Apples		
	14%	FR child 3 15 yr	5,43	2%	Apples	1%	Spinaches	1%	Wheat		
	13%	GEMS/Food G10	5,27	2%	Barley	1%	Tomatoes	1%	Wheat		
	13%	IT adult	5,26	5%	Chards/beet leaves	1%	Spinaches	1%	Wheat		
	13%	RO general	5,19	4%	Head cabbages	2%	Tomatoes	2%	Wheat		
	12%	DK child	4,72	2%	Apples	2%	Rye	1%	Wheat		
	12%	DE general	4,66	3%	Apples	1%	Barley	0,6%	Spinaches		
	12%	NL general	4,62	2%	Spinaches	2%	Apples	0,8%	Barley		
	11%	DE women 14-50 yr	4,41	3%	Apples	0,7%	Spinaches	0,6%	Tomatoes		
	10%	FI 3 yr	4,02	2%	Strawberries	2%	Oat	1,0%	Apples		
	10%	UK infant	3,97	2%	Apples	1%	Strawberries	1,0%	Cauliflowers		
	9%	UK toddler	3,51	2%	Apples	1%	Wheat	0,9%	Strawberries		
	8%	FR adult	3,06	0,8%	Apples	0,7%	Spinaches	0,7%	Leeks		
	7%	PT general	2,86	1%	Wheat	1%	Apples	0,8%	Tomatoes		
	7%	FI 6 yr	2,86	1%	Strawberries	0,8%	Oat	0,8%	Spinaches		
	7%	PL general	2,81	2%	Apples	1%	Head cabbages	0,8%	Tomatoes		
	6%	LT adult	2,40	2%	Apples	1%	Head cabbages	0,5%	Tomatoes		
	6%	UK vegetarian	2,29	0,6%	Apples	0,6%	Wheat	0,5%	Tomatoes		
	5%	DK adult	1,92	1%	Apples	0,5%	Tomatoes	0,3%	Pears		
	4%	UK adult	1,73	0,5%	Wheat	0,4%	Apples	0,4%	HOPS (dried)		
4%	FI adult	1,62	0,7%	Strawberries	0,6%	Apples	0,5%	Tomatoes			
2%	IE child	0,77	0,3%	Wheat	0,3%	Apples	0,2%	Broccoli			
<b>Conclusion:</b> The estimated long-term dietary intake (TMDI(NED/IEDI)) was below the ADI. The long-term intake of residues of Boscalid (F) is unlikely to present a public health concern.											

**A 3.2 IEDI calculations**

**A 3.3 IESTI calculations - Raw commodities**

**A 3.4 IESTI calculations - Processed commodities**

#### **Appendix 4 Additional information provided by the applicant**

No additional data submitted.