

# FINAL REGISTRATION REPORT

## **Part B**

### **Section 7**

#### **Metabolism and Residues**

Detailed summary of the risk assessment

Product code: FGG01

Product name(s): Lozzare Pro, Miller Pro, Palator Pro

Chemical active substance:

Boscalid, 500 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

#### **CORE ASSESSMENT**

(Article 33 application for a new product registration)

Applicant: UPL Holdings Coöperatief U.A

Submission date: 08/05/2024

MS Finalisation date: 11/2024 03/2025

## Version history

When	What
08 May 2024	V0 – Version from applicant for submission to z-RMS Poland in the frame of the PPP Authorization according to Article 33 of Regulation (EC) No 1107/2009.
11/2024	ZRMS assessment
March 2025	Revision after commenting stage

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

### 7.1 Summary and zRMS Conclusion

#### Storage stability

In the framework of the peer review, storage stability of boscalid was demonstrated for a period of 16 months in commodities with high acid content (grape) and 24 months in commodities with high water content (cabbage, peach, pea), high oil content (rape seed), dry commodities (wheat grain) and cereal straw.

Boscalid and M510F01 in milk, muscle, fat, liver, kidney and egg for up to 5 months was demonstrated, when stored deep frozen.

Additionally, the applicant provided new storage stability study for honey for up to 5 months.

The storage period submitted in the original monograph and the additional study are sufficient to cover the storage period of the intended GAP table for this application.

#### Metabolism in plants and animals

Plant residue definition for monitoring Boscalid (Regulation n°2022/1324)

Plant residue definition for risk assessment Boscalid (EFSA 2014)

#### Magnitude of residues in plants

Grapevine, wine & table

Proposed GAP:

1 application; BBCH 60-85; 0.50 kg as/ha; PHI: 21 days (use No 1 and 10)

3 applications (interval 10-14 days); BBCH 15-81; 0.10 kg as/ha (application rate); PHI: 21 days (use No 2)

Applicant refers to the unprotected data from the DAR:

Trials GAP: 1 x 0.6 kg as/ha, BBCH 60-81, PHI 21d, outdoor

Residues (NEU): 0.24, 0.28, 0.39, 0.50, 2x 0.78, 0.88, 1.03 mg/kg

Number of trials is sufficient.

#### Uses No 1 and 10:

The trials are overdosed but the difference is within  $\pm 25$  % (acceptable deviation according to the SANTE/2019/12752 Rev01) and can support the proposed uses.

The data submitted show that no exceedance of the EU MRLs for grape will occur. Uses are accepted.

#### Use No 2:

The GAP of the proposed application differs in 2 parameters from the GAP of the field trials (number of treatments per season and dose). According to the current requirements (SANTE/2019/12752 Rev01), the allowable differences are 1 parameter.

However, the applicant submitted his position paper justifying the acceptance of field studies to support the proposed use (presented below).

*Based on SANTE/2019/12752*

On pg 11, pt 3.1 it says:

*“However, based on an expert judgment, minor deviations on more than one parameter may be accepted in exceptional and specific cases, especially if the deviation is not expected to have a major influence on the residue level in the harvested products (e.g. trial conducted with applications at 1100 g/ha and a 16 day PHI may be considered in compliance with a GAP defined as 1000 g/ha with a 14 day PHI)”*

Moreover on pg 13:

*“3.6. Deviations of residue trials regarding number of applications*

*In order to encompass the least favourable trial conditions, the trials must be carried out with the maximum number of applications defined in the cGAP. Where a PPP is applied in several applications, generally, the last application prior to harvest is the one that has the highest impact on the final residue in the harvested crop. The applications in fruits and fruiting vegetables prior to flowering are most of the time of less importance.*

*Generally, a deviation of the number of applications compared to the GAP is also acceptable under the following conditions:*

*II. If the number of applications in the residue trials is lower than the number of applications defined in the GAP by more than 25% and if it can be demonstrated that additional applications (e.g. at an early growth stage, rapid decline of residues after treatment) are unlikely to contribute significantly to the final residues.”*

*In our case we have 3 x 0.1 kg a.s./ha, BBCH 15-81, PHI 21*

*cGAP used in residue studies: 1 x 0.6 kg a.s./ha, BBCH 79-81, PHI 21*

*Therefore, we can argue that according to SANTE/12752 minor deviations on more than one parameter may be accepted in exceptional and specific cases especially if the deviation is not expected to have a major influence on the residue level in the harvested product which is the case here. Intended application is to be used with twice lower dose rate from the one used in residue studies. Moreover, intended application is to be used with 3 number of applications with last application at BBCH81 the latest, which is comparable with application done in residue trials (BBCH 79-81). Following SANTE/12752 deviation of the number of applications compared to the GAP is acceptable if the number of applications in the residue trials is lower than the number of applications defined in the GAP by more than 25% and if it can be demonstrated that additional applications (e.g. at an early growth stage) are unlikely to contribute significantly to the final residues which is the case here (intended application is between BBCH 15-81).*

*To conclude, SANTE/12752 states, Where a PPP is applied in several applications, generally, the last application prior to harvest is the one that has the highest impact on the final residue in the harvested crops. The application in fruits and fruiting vegetables prior flowering are most of the time of less importance. In our case, last application prior to harvest which has the highest impact on the final residue in the harvested crops presented in residue studies is done with dose rate twice higher from intended one and it shows acceptable results.*

Taking the above into account, the evaluator considers that the recognition of the applicant's arguments may be considered at the level of the Member States.

Poland agreed with the applicant's position. The available trials can support the use No 2. Use is accepted.

Field studies from the southern zone were not used in the assessment.

Oilseed rape (winter and spring),

gold of pleasure, winter turnip rape, mustard, sunflower, poppy, linseed, flax, hemp, borage

Proposed GAP:

1 application; BBCH 57-69 and BBCH 13-57; 250 g as/ha, PHI: 35

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.

Trials are overdosed (two application instead 1).  
Trials GAP (oilseed rape): 2 x 0.25 kg as/ha, BBCH 57-81, PHI 35d, outdoor  
Results (NEU): <LOQ, 0.016, 0.041, 0.074, 0.081, 0.12, 0.16, 0.22 mg/kg  
Trials can be accepted as worst case scenario.  
Sufficient trials are available to support the proposed use on oilseed rape.  
The data submitted show that no exceedance of the EU MRLs for oilseed rape will occur.  
According to the SANTE/2019/12752 Rev01 extrapolation from oilseed rape to gold of pleasure, winter turnip rape, mustard, sunflower, poppy, linseed, flax, hemp and borage is accepted.  
Uses are accepted. Field studies from the southern zone were not used in the assessment.

401000	Oilseeds	MRL
401010	Linseeds	1
401020	Peanuts/groundnuts	1
401030	Poppy seeds	1
401040	Sesame seeds	1
401050	Sunflower seeds	1
401060	Rapeseeds/canola seeds	1
401070	Soyabeans	3
401080	Mustard seeds	1
401090	Cotton seeds	1
401100	Pumpkin seeds	1
401110	Safflower seeds	1
401120	Borage seeds	1
401130	Gold of pleasure seeds	1
401140	Hemp seeds	1
401150	Castor beans	1
401990	Others (2)	0,06

Beans and peas (fresh),  
broad bean, french beans, peas and beans for fresh seeds, edible podded peas  
Proposed GAP:  
2 applications (interval: 7 days); BBCH 60-69; 500 g as/ha (application rate), PHI: 7  
New studies on the magnitude of residue have been submitted by the applicant in the framework of this application.  
Trials GAP (beans (fresh with pods)): 2 x 0.5 kg as/ha, BBCH 65-87, PHI 7d, outdoor  
Residues (NEU, beans with pods): 0.19, 0.25, 0.26, 0.28, 0.36, 0.61, 0.76, 2.0 mg/kg  
According to the SANTE/2019/12752 Rev01 extrapolation from beans (fresh with pods) to fresh peas with pods, french beans, edible podded peas is accepted. Number of trials is sufficient. The data submitted show that no exceedance of the EU MRLs for beans and peas with pods and without pods will occur.  
Uses are accepted.  
~~Extrapolation from beans with pod to peas and beans for seeds is not possible. Uses on broad bean and peas and beans for fresh seeds pulses are not accepted.~~  
Legumes: accepted fresh with pods only.  
Field studies from the southern zone were not used in the assessment.

Crops in the GAP table were not presented clearly. The applicant is obliged use code numbers according to Annex I of Regulation (EU) No 396/2005.

The lack of a precisely defined plant causes misunderstanding.

According to the SANTE/2019/12752 Rev01 extrapolation from beans and peas with pods to all group of legumes (application is made before the forming of the edible part of the plant) is acceptable.

zRMS agrees to use of the PPP in the protection of legumes with and without pods.

### **Magnitude of residues in livestock**

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.

STMR and HR from the new residue trials are less than used in dietary burden calculation for art.12 review (EFSA Journal 2014;12(7):3799). Additional data are not required.

### **Processing studies**

Studies investigating the magnitude of residues in processed commodities of different crops were reported in the framework of the peer review (DAR, 2002). Data are considered acceptable to derive robust processing factors for different crops.

New studies have been submitted by the applicant in the framework of this application. The objective of the study was to determine the residue level of boscalid in processing fractions of oilseed rape. The same levels of boscalid residue in processed commodities was found in the raw agricultural commodity, generating a processing factor of 1.0 for raw and crude oil.

Further processing studies are not required, as they are not expected to affect the outcome of the risk assessment.

### **Magnitude of residues in representative succeeding crops**

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 recalculated the MRL proposals to take into account such residues.*

Waiting periods before planting following succeeding crops: not required.

Additional data are not required.

### **Other / special studies**

New studies have been submitted by the applicant in the framework of this application.

Trials were performed in protected oilseed rape located in representative areas of honey production. Protected oilseed rape was treated with two foliar applications with Boscalid 500 g/Kg WG formulation (code FGG01) at a dose rate of 500 g boscalid/ha (equivalent to 1 kg product/ha) and nominal 300 L/ha water spray volume. The applications targeted a 7±1 day retreatment interval with the second application performed during the flowering period (BBCH 60-69). Residues of boscalid found in honey ranged from < 0.01 to 0.0455 mg/kg. The new data was input into the MRL calculator and the calculated EU MRL was 0.1 mg/kg, indicating that no exceedance of the MRL on honey (0.15 mg/kg – Reg (EU) no. 2021/590) will occur after the application of the plant protection product FGG01.



The results are acceptable. No risk for consumers is expected.

#### **Consumer risk assessment**

The proposed uses of boscalid in the formulation FGG01 do not represent unacceptable acute and chronic risks for the consumer.

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

#### **Selection of critical uses and justification**

The critical GAPs with respect to consumer intake and risk assessment for the preparation FGG01 are presented in Table 7.1-1. A list of all intended uses within the Central EU registration zone is given in Part B, Section 0.

#### **Overall conclusion**

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

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

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

According to available data, no specific mitigation measures should apply.

#### **Data gaps**

Noticed data gaps are:

- ~~Residue trials for beans or peas without pods.~~

Acceptance of use No2 left to decisions at Member State level. In Poland this use was accepted.

**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	12	13	14
Use- No. (e)	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha ( <sup>(i)</sup> )
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	AT, BE, CZ, SI	Grapevine, wine & table 0151010 0151020	F	<i>Botrytis cinerea</i> (BOTRI)	Spraying overall	BBCH 60-85	a) 1 per use  b) 1 per crop / season	-	a) 1.0  b) 1.0	a) 500  b) 500	100- 1000	21	0.72 kg product / 10000 m² LWA (optional) A
2	AT, BE, CZ, SI, PL	Grapevine, wine & table 0151010 0151020	F	<i>Uncinula necator</i> , <i>Powdery mildew</i> (UNCINE)	Spraying overall	BBCH 15-81	a) 3 per use  b) 3 per crop / season	10-14	a) 0.2  b) 1.0	a) 100 a  b) 300	100- 1000	21	0.14 kg product / 10000 m² LWA 0.02 kg/100 L (optional) R For decisions in the Member States.
3	AT, BE, CZ, HU, NL, PL, RO, SK	Oilseed rape (winter and spring) 0401060	F	<i>Sclerotinia sclerotiorum</i> (SCLESC)	Spraying overall	BBCH 57-69	a) 1 per use  b) 1 per crop / season	-	a) 0.5  b) 0.5	a) 250  b) 250	100- 300	35	A
4	AT, BE, CZ, NL, SK, HU, RO	Oilseed rape (winter and spring) 0401060	F	<i>Alternaria species</i> (ALTESP)	Spraying overall	BBCH 57-69	a) 1 per use  b) 1 per crop / season	-	a) 0.5  b) 0.5	a) 250  b) 250	100- 300	35	A
5	HU, PL, RO, SK, AT, CZ	Oilseed rape (winter and spring) 0401060	F	<i>Leptosperia maculans</i> (LEPTMA)	Spraying overall	BBCH 13-57	a) 1 per use  b) 1 per crop / season	-	a) 0.5  b) 0.5	a) 250  b) 250	100- 300	35	A
6	AT, BE, CZ, NL, PL	Beans and peas (fresh with pods and without pods) 0260010	F	Botrytis (BOTRSP)	Spraying overall	BBCH 60-69	a) 2 per use  b) 2 per crop / season	7	a) 1.0  b) 2.0	a) 500  b) 1000	150- 600	7	A Accepted fresh with pods only and without pods

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. (e)	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha ( <sup>(i)</sup> )
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha  min / max		
		0260030 026020 026040											(legumes)
7	AT, BE, CZ	Beans and peas (fresh with pods and without pods)  0260010 0260030 026020 026040	F	Sclerotinia (SCLESP)	Spraying overall	BBCH 60-69	a) 2 per use  b) 2 per crop / season	7	a) 1.0  b) 2.0	a) 500  b) 1000	150- 600	7	A Accepted fresh with pods only and without pods (legumes)
Minor uses according to Article 51 (zonal uses)													
8	PL	Spring rape (0401060) gold of pleasure (0401130), winter turnip rape (0401060), mustard (0401080), sunflower (0401050), poppy (0401030) linseed (0401010), flax (0401010), hemp (0401140), borage (0401120)	F	<i>Alternaria</i> species (ALTESP) <i>Sclerotinia sclerotiorum</i> (SCLESC)	Spraying overall	BBCH 57-69	a) 1 per use  b) 1 per crop / season	-	a) 0.5  b) 0.5	a) 250  b) 250	100- 300	35	A
9	PL	Spring rape (0401060) gold of pleasure (0401130), winter turnip rape (0401060), mustard (0401080), poppy (0401030) linseed (0401010), flax (0401010),	F	<i>Leptosperia maculans</i> (LEPTMA)	Spraying overall	BBCH 13-57	a) 1 per use  b) 1 per crop / season	-	a) 0.5  b) 0.5	a) 250  b) 250	100- 300	35	A

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. (e)	Member state(s)	Crop and/ or situation  (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks:  e.g. g safener/synergist per ha (i)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
		hemp (0401140), borage (0401120)											
10	PL	Grapevine, wine & table 0151010 0151020	F	<i>Botrytis cinerea</i> (BOTRI)	Spraying overall	BBCH 60-85	a) 1 per use b) 1 per crop / season	-	a) 1.0 b) 1.0	a) 500 b) 500	100- 1000	21	0.72 kg product / 10000 m <sup>2</sup> LWA (optional) A
11	PL	Beans for fresh seeds (fresh beans without pods - 026020), Broad bean French beans (0260010), Peas for fresh seeds (fresh peas without pods - 026040), edible podded peas (0260030)  accepted all group of legumes	F	<i>Sclerotinia</i> (SCLESP) <i>Botrytis cinerea</i> (BOTRI)	Spraying overall	BBCH 60-69	a) 2 per use b) 2 per crop / season	7	a) 1.0 b) 2.0	a) 500 b) 1000	150- 600	7	A Accepted fresh with pods only and without pods (legumes)

\* 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 FGG01 is a wettable granule (WG) formulation composed of boscalid 500g/kg.

**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 - Parent compound (if applicable)					
ADI	EC SANCO/3919/2007- rev.5, 21 January 2008	2008	0.04	Rat 2-year oral feed	100
ARfD	EC SANCO/3919/2007- rev.5, 21 January 2008	2008	Not necessary	low acute toxicity and lack of developmental toxicity concerns	

### 7.1.2.1 Summary for Boscalid

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

Use- No.*	Crop	Plant me- tabolism covered?	Sufficient residue trials?	PHI suffi- ciently supported?	Sample sto- rage cov- ered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for con- sumers identified?
1, 2, 10	Grapevine, wine & table	Yes	Yes	Yes	Yes	Yes	No	No
3, 4, 5	Oilseed rape (winter and spring)	Yes	Yes	Yes	Yes	Yes	No	No
6, 7, 11	Beans and peas (fresh with pods and without pods)	Yes	Yes	Yes	Yes	Yes	No	No
8, 9	Minor oilseeds	Yes	Yes	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

Additional data on the magnitude of residue in oilseed rape and beans with pods were submitted for the framework of this application. No additional data is required to cover the intended uses of the framework of this application.

The effects of processing on the nature of boscalid residues was investigated for oil production. No specific processing factor was derived and therefore not considered for risk assessment.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was

calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

No acute risk has been identified for the use of FGG01 on the intended crops treated according to the proposed GAP table.

### 7.1.2.2 Summary for FGG01

**Table 7.1-4: Information on FGG01 (KCA 6.8)**

Crop	PHI for FGG01 proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for FGG01 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Boscalid		
Grapevine, wine & table	21 days	Yes		
Oilseed rape (winter and spring)	35 days	Yes		
Beans and peas (fresh with pods and without pods)	7 days	Yes		
Minor oilseeds	35 days	Yes		

NR: not relevant

\* Purpose of withholding period to be specified

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

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for FGG01
Crop group	Led by boscalid	

NR: not relevant

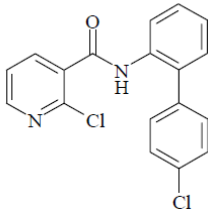
### Assessment

To be fulfilled by the zRMS.

## 7.2 Boscalid

General data on boscalid are summarized in the table below (last updated 2023/05/05)

**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)	C2: carboxamides, Group 7 - SDHI - Succinate DeHydrogenase Inhibitors.
Systemic	No
Company (ies)	BASF AG *
Rapporteur Member State (RMS)	Germany Slovakia (original RMS was Germany)
Approval status	<p>Approved                      Date of (01/08/2008) and reference to decision (COMMISSION DIRECTIVE 2008/44/EC - REGULATION (EU) No 2023/918).</p> <p>Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances  <a href="https://eur-lex.europa.eu/legal-content/PL/TXT/?uri=CELEX%3A02011R0540-20240201">https://eur-lex.europa.eu/legal-content/PL/TXT/?uri=CELEX%3A02011R0540-20240201</a></p> <p>Commission Implementing Regulation (EU) 2023/918 of 4 May 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aclonifen, ametoctradin, beflubutamid, benthiavalicarb, boscalid, captan, clethodim, cycloxydim, cyflumetofen, dazomet, diclofop, dimethomorph, ethephon, fenazaquin, fluopicolide, fluoxastrobin, flurochloridone, folpet, formetanate, Helicoverpa armige-</p>



	ra nucleopolyhedrovirus, hymexazol, indolylbutyric acid, mandipropamid, metalaxyl, metaldehyde, metam, metazachlor, metribuzin, milbemectin, paclobutrazol, penoxsulam, phenmedipham, pirimiphos-methyl, propamocarb, proquinazid, prothioconazole, S-metolachlor, Spodoptera littoralis nucleopolyhedrovirus, Trichoderma asperellum strain T34 and Trichoderma atroviride strain I-1237 <a href="https://eur-lex.europa.eu/eli/reg_impl/2023/918/oj">https://eur-lex.europa.eu/eli/reg_impl/2023/918/oj</a>
Restriction	See Approval Directive / Regulation Only uses as fungicide may be authorised
Review Report	SANCO/3919 /2007-rev. 5, 21/01/2008
Current MRL regulation	Regulation (EC) No 2022/1324
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes**
EFSA Journal: Conclusion on the peer review	No
Current MRL applications on intended uses	None

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

\*\* EFSA Journal 2014;12(7):3799 - 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

The frozen stability of boscalid (formerly named as: nicobifen) storage at < -18°C was determined in representative commodities for high water content (cabbage, peach and pea), high acid content (grape), high oil content (oilseed rape), high starch content (wheat grain), and dry feed item (wheat straw). Data has been generated within the scope of boscalid Annex I inclusion (Germany, 2002) and during the renewal framework, the studies were re-evaluated (Slovakia, 2018).

For animal commodities the frozen stability of boscalid and its metabolite M510F01 at < -18°C was determined in ruminants (muscle, liver, fat and milk) and poultry (egg) over 5-months period (Germany, 2002). Furthermore, during the renewal framework, the studies were re-evaluated and considered as acceptable (Slovakia, 2018).

The summary information on boscalid stability in plant and animal matrices is described below in Table 7.2-2.

One additional storage stability study on honey over a 5-month period is presented in the framework of this application (Flore, 2022, KCP 7.2.1/01). The detailed assessment of the new study is presented in Appendix 2 (A 2.1.1.1.1.1)

Procedural recoveries in all matrices were acceptable. No residues above the LOQ of 0.02 mg/kg could be detected in the corresponding control samples.

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
<b>Data relied on in EU</b>			
<b>Plant products – Boscalid, parent only</b>			
Cabbage	High water content	24 months	Germany, 2002
Peach	High water content	24 months	Germany, 2002
Pea	High water content	24 months	Germany, 2002
Grape	High acid content	16 months	Germany, 2002
Oilseed rape	High oil content	24 months	Germany, 2002
Wheat grain	High starch content	24 months	Germany, 2002
Cereal straw	Dry feed item	24 months	Germany, 2002
<b>Animal products – Boscalid and M510F01</b>			
Ruminant (cow)	Muscle	5 months	EFSA, 2014
Ruminant (cow)	Liver	5 months	EFSA, 2014
Ruminant (cow)	Fat	5 months	EFSA, 2014
Ruminant (cow)	Milk	5 months	EFSA, 2014
Poultry (hen)	Egg	5 months	EFSA, 2014
<b>New data</b>			
<b>Animal Products – Boscalid</b>			
Honey	Honey	5 months	Flore S., 2022, report No S22-01684

### Conclusion on stability of residues during storage

Available data demonstrates that residues of boscalid are stable for up to 24 months in the raw agricultural commodities cabbage, peach, peas, oilseed rape, wheat grain and cereal straw. On grape stability has been demonstrated over a period of 16 months. In animal matrices (ruminants and poultry), the frozen stability of boscalid and its metabolite M510F01 have been demonstrated for up to 5 months.

In addition, the new study has demonstrated stability of boscalid in honey for up to 5 months.

The storage period submitted in the original monograph and the additional study are sufficient to cover the storage period of the intended GAP table for this application.

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

##### Available data

Extraction efficiency of the solvents systems was demonstrated. Residue amounts of boscalid extracted from samples of wheat whole plant (high water content matrix), wheat grains (dry matrix) and oilseed rape seeds (high oil content matrix) with incurred residues were compared when extracting with different solvent systems as used in pre and post registration methods and when extracting with different solvent systems as were used in metabolism studies in accordance to the technical guideline on the evaluation of extraction efficiency of residue analytical methods, SANTE/2017/10632, rev. 4.

Extraction efficiency is summarized under dRR part B5, KCP 5.1/02 (Rastogi, T. Cross-Validation - Comparing Amounts of Boscalid extracted from Samples of Plant Origin with incurred Residues using three different Solvent Systems, Study Number: S22-00983)

All methods were validated in accordance with SANTE /2020/12830, rev. 2. In none of the extracts investigated any degradation was observed. From the data available, it can be concluded that boscalid is stable in sample extracts or solutions when stored during residue analysis.

### Conclusion on stability of residues in sample extracts

Boscalid is stable in all sample extracts and solutions when stored during the residues analysis. The stability of the residue in sample extracts can be considered as covered by available data for the same period as the sample extracts of residue trials.

## 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

The metabolism of boscalid in primary crops has been assessed in the original monograph (Germany, 2002). Crops belonging to the group of fruit crop (grape), pulse and oilseed (beans) and leafy vegetable (lettuce), were evaluated for the elucidation of the metabolic pathway of boscalid.

Furthermore, metabolism study on root and tuber vegetable (carrot) with seed treatment application<sup>1</sup> was performed to support the framework of the boscalid renewal (Slovakia, 2018). The summary information is described below in Table 7.2-3.

No new data are 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 (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	Grape	U- <sup>14</sup> C-diphenyl; 3- <sup>14</sup> C- pyridine	F	0.8	3	45	Foliar treatment	Germany, 2002
Pulses and oilseeds	Bean	U- <sup>14</sup> C-diphenyl; 3- <sup>14</sup> C- pyridine	G	0.7 0.5	3	18 0, 14, 53 <sup>(b)</sup>	Foliar treatment	Germany, 2002
Leafy vegetables	Lettuce	U- <sup>14</sup> C-diphenyl; 3- <sup>14</sup> C- pyridine	G	0.5 0.7	3	0, 14, 53 <sup>(b)</sup> 18	Foliar treatment	Germany, 2002
Root and tuber vegetables	Carrot	3- <sup>14</sup> C -pyridine	G				Seed treatment	Slovakia, 2018

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)

<sup>1</sup> New data developed by BASF to support the AIR III renewal of boscalid.

(b): whole plant, forage and bean straw, respectively

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

Metabolism studies assessed in the original monograph reveals that <sup>14</sup>C-boscalid labelled at two position is metabolised by two key transformation steps, hydroxylation of the aromatic ring system reaction followed by glutathione conjugation on grapes, lettuce and beans.

The relevant residue in grapes consisted of parent boscalid (92.7–96.4% TRR). Boscalid was also the main component in lettuce and in green beans/pods, amounting to 99.3% and 97% of the TRR, respectively. No other metabolites were clearly below 10% TRR.

The metabolism of boscalid in carrot (after seed treatments) was qualitatively and quantitatively comparable with the previously assessed study in fruit crops, root crops and leafy vegetables. Labelled material leads to the conclusion that the residue consists of the parent compound boscalid only.

### Conclusion on metabolism in primary crops

The metabolic pathway of boscalid is similar in all crop groups investigated. The residue definition for risk assessment and enforcement was set as parent boscalid only.

The metabolic behaviour of boscalid in primary crops is sufficiently addressed.

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

### Available data

During the original monograph of boscalid (Germany, 2022), a confined metabolism study in rotational crops was performed and considered acceptable. Two different labelled forms [U-<sup>14</sup>C-diphenyl] and [3-<sup>14</sup>C- pyridine] of boscalid were applied to bare soil followed by planting of rotational crops (radish, lettuce and wheat). The summary information is described below in Table 7.2-4.

No new data are 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)	Remarks	
EU data								
Leafy vegetables	Lettuce	U- <sup>14</sup> C-diphenyl; 3- <sup>14</sup> C-pyridine	Bare soil, G	2.1	30, 120, 270, 365	Mature crops	Bare soil application - Loamy sand	Germany, 2001
Root and tuber vegetables	Radish							
Cereals	Wheat							

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

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

The major compound detected in the rotational crop matrices tested was the parent. The TRR in the lettuce leaves ranged from 0.014 to 0.072 mg/kg, on radish roots from 0.009 to 0.09 mg/kg and on wheat grain ≤ 0.028 mg/kg. The highest TRR was found in wheat straw (0.81-7.99 mg/kg), followed by wheat forage (0.19-1.47 mg/kg) and radish leaves (0.09-0.30 mg/kg). The significantly levels detected in these

three matrices after plant back intervals (PBIs) of 270 and 365 days indicate that residues of boscalid may occur above the LOQ (0.05 mg/kg) in edible parts of other crops than investigated.

Further investigations were performed on the residue situation of boscalid in rotational crops. Confined study was submitted with DAR addendum and already evaluated at EU level (Germany, 2006). The field rotational crop study was performed in wheat, and it is summarized under data point KCA 6.6.2.

### Conclusion on metabolism in rotational crops

The proposed metabolic pathway in succeeding crops involves hydroxylation and conjugation reactions. 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. The metabolic behaviour in rotational crops is sufficiently addressed.

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

#### Available data

The effects of processing nature of boscalid were investigated in the framework of the annex I inclusion (Germany, 2002). The standard hydrolysis study simulating the effect on the nature of boscalid residues under representative processing conditions of pasteurisation, boiling and sterilisation was assessed. Tested conditions are described below in Table 7.2-5.

No new data are 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) (%)	Reference
<b>EU data</b>		
<b>Pasteurisation</b> (20 minutes, 90°C, pH 4)	Parent (99.3%)	Germany, 2002
<b>Baking, boiling, brewing</b> (60 minutes, 100°C, pH 5)	Parent (100.2%)	Germany, 2002
<b>Sterilisation</b> (20 minutes, 120°C, pH 6)	Parent (99.1%)	Germany, 2002

### Conclusion on nature of residues in processed commodities

The study demonstrates that food processes such as brewing, cooking, sterilisation or pasteurisation, will not impact on the nature of boscalid residues. No degradation of boscalid was observed under the standard hydrolysis conditions. The relevant residue for enforcement and risk assessment in processed commodities is therefore expected to be the same as for primary crops (Germany, 2002).

### 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**

<b>Endpoints</b>	
Plant groups covered	Fruits and fruiting vegetable (Grape) Pulses and oilseeds (Bean) Leafy vegetables (Lettuce) Root and tuber vegetables (Carrot)

Rotational crops covered	Leafy vegetables (Lettuce) Root and tuber vegetables (Radish) Cereals (Wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Boscalid is stable under standard hydrolysis conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Parent only (SANCO/3919 /2007)
Plant residue definition for risk assessment	Parent only (SANCO/3919 /2007)
Conversion factor from enforcement to RA	Not applicable

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

#### Available data

During the original monograph of boscalid, metabolism studies in animals were performed and considered acceptable. Furthermore, during the renewal framework, the studies were re-evaluated and considered as acceptable but not sufficient. There is a lack of information regarding the fate of pyridine moiety in ruminants and poultry liver. Therefore, a new hen metabolism study using 3-<sup>14</sup>C-pyridine was submitted by the applicant. However, the renewal assessment had already been completed by the RMS (Slovakia, 2018) and the details of the study and evaluation are not available.

The summary information is described below in Table 7.2-7. 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	Germany, 2002
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	[U- <sup>14</sup> C-diphenyl]	10	0.80 - 1.14	10	Eggs	daily	Germany, 2002
						Excreta	daily	
						Tissues	at sacrifice	
			3- <sup>14</sup> C-pyridine	Not given	Not given	Not given	Not given	Not given
Fish	Rainbow	[ <sup>14</sup> C-	Not	20 µg/L;	28	Muscle (edible)	daily	Germany,

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
	trout	diphenyl] and pyridine- <sup>15</sup> N, 2- <sup>13</sup> C]	informed	200 g/L		Viscera (non-edible)	daily	2002
						Whole fish	at sacrifice	

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

The metabolism and distribution of radioactive labelled boscalid [U-<sup>14</sup>C-diphenyl] was investigated in lactating goats and laying hens. Most of the radioactivity was excreted after administrated in both animal types showing no accumulation of U-<sup>14</sup>C-diphenyl-boscalid in goat milk, eggs, and tissues.

Boscalid and its metabolite M510F01 were the main residues found in animal tissues and products of hens and goats. Exception for liver (ruminant and pig) where the main component of the residue was the sum of boscalid, its metabolite M510F01 and its bound residues (M510F53 and M510F52), expressed as boscalid. Please note that the residue definition for poultry is still considered as provisional due the absence of data in the second radiolabelling (pyridine moiety) (EFSA, 2014).

No new data are submitted within the scope of this application regarding the fate of pyridine moiety in ruminants and poultry liver. The applicant for this dossier decided to wait for the member state assessment of the study submitted by BASF during the framework of the renewal, to avoid repeating animal studies due to animal welfare concerns.

No metabolism study was performed in pigs, since the metabolite patterns in rodents (rats) and ruminants (goats) did not differ significantly. For details on the rodent's metabolite patterns please refer to the toxicological and metabolism dossier (dRR Part B6).

Furthermore, the metabolism of boscalid in fish (rainbow trout) was assessed according to OECD 305 and SANCO/11187/2013. The results showed a maximum bioaccumulation factor (BCF) of 125 after 28 days in rainbow trout. However, boscalid and its metabolite showed a half-life of 1 day and after 3.3 days the TRR eliminated represent 90%, showing that the risks of bioaccumulation in fish and other aquatic organisms is unlikely due to the rapid excretion of the parent and its metabolite M510F01 and M510F05.

### Conclusion on metabolism in livestock

The available studies are valid, but not sufficient to address the metabolism of boscalid in livestock. An additional study performed by BASF to address the fate of pyridine moiety in poultry liver is pending of evaluation.

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

	Endpoints
Animals covered	Lactating goats
	Laying hens
	Fish
Time needed to reach a plateau concentration	2-3 days in milk
	6 days in eggs
Animal residue definition for monitoring	muscle, fat, milk and eggs: parent liver and kidney: sum of boscalid and its metabolite M510F01

	Reg. (EU) 2022/1324
Animal residue definition for risk assessment	muscle, fat, milk and eggs: parent kidney: sum of boscalid and its metabolite M510F01 liver: sum of boscalid, its metabolite M510F01 and its bound residues (measured as M510F53 and M510F52). EFSA Journal 2014;12(7):3799
Conversion factor	Not applicable
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes (log P <sub>ow</sub> =2.96)

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

The magnitude of residues on the intended uses are partially covered by unprotected data generated within the scope of boscalid Annex I inclusion, submitted as part of the DAR addendum (Germany, 2002 and 2006), within data submitted during the consultation of Member States (France, 2014; Germany, 2014; Netherlands, 2014), data submitted as part of the renewal process AIR III (Slovakia, 2018) and own data performed by the applicant for the framework of this application.

The representative product of boscalid for the applications mentioned at EU-level is a WG formulation with code BAS 510 01 F (trade name Cantus). The data protection period of the study reports developed with this formulation submitted in support of the initial authorisation of boscalid at member state level have already expired, in accordance with Article 59(1) of Regulation 1107/2009 (10 years for the initial product authorisation). Trials performed for the purpose of the renewal of boscalid are still under protection, therefore own trials have been performed to complement the data package.

The new trials were performed with the intended WG formulation FGG01 in order to complete the data package. The list of intended uses for which this dossier is applied for, are described below, and summarised in Table 7.2-9.

#### 7.2.3.1 Grapes (wine and table) (uses no. 1, 2 and 10)

The intended uses on grapes (wine and table) are covered by unprotected residue data of the reference product BAS 510 01 F (trade name Cantus, WG) provided in support of the initial Annex I approval of boscalid (Germany, 2006 – addendum 1 of the DAR).

A total of 17 decline trials (8 NEU and 9 SEU) were performed during the season 2002 and 2003 in different representative wine growing areas. The tested product is a WG formulation (BAS 510 01 F) and was applied once at growth stages BBCH 79 to 85 with an application rate of 600 g boscalid/ha and a spray volume of 800 L/ha. Grape samples were taken immediately after the last treatment (0 DAA), 21 days (= PHI), 28 days and 35 days after application.

The residue levels of boscalid were analysed in the whole fruit. Quantification was performed by HPLC-MS/MS detection. Samples were stored for up to 213 days at < -18°C between sampling and extraction. The limit of quantification was 0.01 mg/kg and the residues levels of boscalid at the proposed PHI of 21 days, ranged between 0.12 and 1.26 mg/kg.

The tested product was a WG formulation containing 500 g/kg of boscalid and therefore comparable to the intended formulation FGG01. According to SANTE 2019/12752, a sufficient number of trials were available to cover the intended uses on grapes. The distribution of the trials is also properly addressed. Therefore, the available unprotected data package can be considered sufficient to support intended uses number 1, 2 and 10 in the GAP for FGG01. An MRL exceedance above the current value of 5 mg/kg (Reg. (EU) No 149/2008) is not expected since the unprotected data was used to set the MRL on grapes.



### **7.2.3.2 Oilseed rape (uses no. 3, 4 and 5)**

The intended uses on oilseed rape (winter and spring) are covered by by new trials performed with the intended formulation FGG01. A total of 16 new trials (8 NEU and 8 SEU) were performed during 2022 and 2023 with the intended formulation FGG01 and are submitted in the framework of this application.

New trials were located on oilseed rape representative countries, Bulgaria, Italy, Spain, south of France, north of France, Germany, United Kingdom, and Poland (8 SEU and 8 NEU). The crops were treated twice with the formulation FGG01 (WG – boscalid 500 g/kg) via foliar application at a dose rate of 250 g boscalid/ha (equivalent to 500 g product/ha). The initial application (A1) was made at least 14±1 day before the second application (A2) to the treated plots at BBCH 67-81. The second application (A2) was performed 35 days before crop harvest and no later than BBCH 81. Moreover, one additional plot was added in two of the new trials performed in 2022 (NEU and SEU), in which an exaggerated dose of 5 N (1250 g boscalid/ha - 2.5 kg product/ha) was applied. From these trials additional samples were generated for the determination of boscalid in the processed fractions. Raw samples were sent to the processing test site for the preparation of the processed fractions, raw oil, press cake and crude oil. The details of the processed phase are described on data point 7.2.5.

Eight of the new trials were performed as decline trials and whole plant samples were collected at 0, 7, 14 and 21 and seed at 35 days after last application (DALA), which represents the normal commercial harvest. The remaining eight trials were performed as harvest trials and seed samples were collected at 35 DALA, which represents the intended PHI.

The residue level of boscalid was analysed in the whole plant and seed. Quantification was performed by LC-MS/MS detection. Samples were stored for up to 311 days at < -18°C between sampling and extraction. The limit of quantification was 0.01 mg/kg.

Residues of boscalid in the whole plant ranged from 0.4 to 4.7 mg/kg and residues of boscalid found in treated seed ranged from <LOQ to 0.78 mg/kg. The detailed assessment of the new studies is presented in Appendix 2 (A 2.1.3.1.1 and A 2.1.3.1.1)

According to SANTE 2019/12752, a sufficient number of trials were available to cover the intended uses on oilseed rape. The distribution of the trials is also properly addressed. Therefore, the new trials can be considered sufficient to support intended uses number 3, 4 and 5 in the GAP for FGG01.

An MRL exceedance above the current value of 1 mg/kg (Reg. (EU) No 520/2011) is not expected since the maximum highest residue (HR) measured in seed was 0.78 mg/kg. The new data was input into the MRL calculator (please refer to the excel spreadsheet named as: OECD Calculator\_FGG01\_intended uses) and the calculated EU MRL was 0.9 mg/kg, indicating that no exceedance of the MRL will occur.

### **7.2.3.3 Beans and Peas (uses no. 6, 7 and 11)**

The intended uses on beans and peas are covered by sixteen new trials (8 NEU and 8 SEU) performed in beans with pods during 2022 and 2023 with the intended formulation FGG01 and are submitted in the framework of this application. New trials were located in bean representative countries, Germany, United Kingdom, Poland, north of France, south of France, Italy, Spain, and Bulgaria (3 NEU and 4 SEU). The crops were treated twice with the formulation FGG01 (WG – boscalid 500 g/kg) via foliar application at a dose rate of 500 g boscalid/ha (equivalent to 1 kg product/ha). The initial application (A1) was made at least 14±1 days before the second application (A2) to the treated plots at BBCH 65-87. The second application (A2) was performed 7 days before crop harvest and no later than BBCH 87.

Eight of the new trials were performed as decline trials and whole plant samples were collected at 0, 1, 3, 5 and at 7 days after last application (DALA) the samples were split into bean and rest of the plant. The remaining eight trials were performed as harvest trials and beans and rest of the plant samples were collected at 7 DALA, which represents the intended PHI.

The residue level of boscalid was analysed in the whole plant and in bean with pod. Quantification was performed by LC-MS/MS detection. Samples were stored for up to 264 days at < -18°C between sampling and extraction. The limit of quantification was 0.01 mg/kg.

Residues of boscalid found in treated beans ranged from 0.19 to 2.0 mg/kg. The detailed assessment of the new studies is presented in Appendix 2 (A 2.1.3.2.1 and A 2.1.3.2.1).

According to SANTE 2019/12752, the residue data for the intended use on beans and peas can be extrapolated between the crops, therefore a sufficient number of trials were available to cover the intended uses on beans and peas in the EU. The distribution of the trials is also properly addressed. Therefore, the new trials can be considered sufficient to support intended uses number 6, 7 and 11 in the GAP for FGG01. An MRL exceedance above the current value for beans of 5 mg/kg (Reg. (EC) No 2016/1) is not expected since the maximum highest residue (HR) measured in beans was 2.0 mg/kg. The new data performed in beans was input into the MRL calculator (please refer to the excel spreadsheet named as: OECD Calculator\_FGG01\_intended uses), and the calculated EU MRL was 3 mg/kg for beans and peas, indicating that no exceedance of the MRL will occur.

#### **7.2.3.4 Spring rape, Gold-of-pleasure, Mustard, Poppy, Linseed, Flax, Oilseed turnip, common hemp, borage (uses no. 8 and 9)**

The available data described above in data point 7.2.3.2 used to cover the intended use on oilseed rape can be used to cover the intended use in these minor oilseeds, extrapolation according to SANTE/2019/12752 is possible. The unprotected residue data and the new data performed on oilseed rape are sufficient to cover the intended uses no. 8 and 9.

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

**Table 7.2-9: Summary of EU reported (representative formulation) and new data supporting the intended uses of FGG01 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
Grapes (wine and table)	Germany, 2006	N-EU 144241	GAP on which EU a.s. assessment is based: 1 x 0.6 kg as/ha, BBCH 60-81, PHI 21d, outdoor E/RA: 0.24, 0.28, 0.39, 0.50, 2x 0.78, 0.88, 1.03	<del>2.381</del> 0.64	1.03	2.381	5	Yes
		<del>S-EU</del> 44235 02/02/PF	<del>GAP on which EU a.s. assessment is based: 1 x 0.6 kg as/ha, BBCH 60-81, PHI 21d, outdoor E/RA: 0.19, 0.23, 0.24, 0.26, 0.34, 0.41, 0.71, 1.12, 1.47</del>	<del>1.794</del>	<del>1.47</del>	<del>1.830</del>	<del>5</del>	<del>Yes</del>
	Overall supporting data for eGAP (Germany, 2006)	EU	GAP on which EU a.s. assessment is based: 1 x 0.6 kg as/ha, BBCH 60-81, PHI 21d, outdoor E/RA: 0.19, 0.23, 2x 0.24, 0.26, 0.28, 0.34, 0.39, 0.41, 0.50, 0.71, 2x 0.78, 0.88, 1.03 1.12, 1.47	2.096	1.47	2.096	5	Yes
Oilseed rape	New trials	N-EU	GAP on which assessment is based: 2 x 0.25 kg as/ha, BBCH 57-81, PHI 35d, outdoor E/RA: <LOQ, 0.016, 0.041, 0.074, 0.081, 0.12, 0.16, 0.22	<del>0.096</del> 0.078	<del>0.78</del> 0.22	0.893	1	Yes
		<del>S-EU</del>	<del>GAP on which assessment is based: 2 x 0.25 kg as/ha, BBCH 57-81, PHI 35d, outdoor E/RA: 0.056, 0.069, 0.082, 0.11, 0.22, 0.24, 0.25, 0.78</del>					
Beans (fresh with pods) ➔ peas	New trials	N-EU	GAP on which assessment is based: 2 x 0.5 kg as/ha, BBCH 65-87, PHI 7d, outdoor E/RA: 0.19, 0.25, 0.26, 0.28, 0.36, 0.61, 0.76, 2.0	<del>0.370</del> 0.32	2.00	2.825	5 (with pods) 3 (without pods)	Yes
		<del>S-EU</del>	<del>GAP on which assessment is based: 2 x 0.5 kg as/ha, BBCH 65-84, PHI 7d, outdoor</del>					

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	STM (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
			E/RA: 0.23, 0.25, 0.28, 0.38, 0.39, 0.89, 1.4, 1.5					

\* Source of EU MRL: Reg. (EC) No 149/2008; Reg. (EC) No 520/2011; Reg. (EC) No 2016/1; Reg. (EU) 2016/156; Reg. (EU) 2022/1324

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

All the intended uses are considered acceptable for outdoor uses within the available data. The assessment of this dossier has been performed using unprotected data submitted for boscalid Annex I inclusion (DAR and DAR addendum - Germany, 2002 and 2006), within data submitted during the consultation of different member States (France, 2014; Germany, 2014; Netherlands, 2014), as well as data submitted for the renewal process AIR III (Slovakia, 2018). The intended uses on oilseed rape and green beans with pod are covered by own data performed by the applicant for the framework of this application.

The data considered for this application shows that no exceedance of the MRL will occur (please refer to the excel spreadsheet named as: OECD Calculator\_FGG01\_intended uses), and all the intended uses are considered acceptable.

## 7.2.4 Magnitude of residues in livestock

### 7.2.4.1 Dietary burden calculation

A livestock dietary burden calculation was performed considering the input values derived in the EU Review of boscalid and the residue levels found in oilseed rape and beans as described above. Processing factors were used for the processed feed commodities when required. **Animal model 2017 was used for the dietary burden calculation and** the input values for a livestock burden calculation are listed in Table 7.2-10 below. The results of the calculations are reported in Table 7.2-11.

**Table 7.2-10: Input values for the dietary burden calculation (considering the uses discussed in the EU Review for the active substance and the uses under consideration)**

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Boscalid				
Cabbage heads, leaves	1.10	Median residue	2.82	Highest residue
Kale	1.10	Median residue	4.10	Highest residue
Apple pomace	2.52	Median residue x PF	2.52	Median residue x 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 x PF	0.52	Median residue x 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	Median residue
Turnips	0.09	Median residue	0.28	Highest residue
Rapessed meal	0.08	Median residue x PF	0.08	Median residue x PF
Linseed meal	0.10	Median residue x 2	0.10	Median residue x 2
Sunflower seed meal	0.32	Median residue x 2	0.32	Median residue x 2

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Soya bean	0.05	Median residue	0.05	Median residue
Soya bean meal	0.01	Median residue x PF	0.01	Median residue x PF
Peanuts meal	0.10	Median residue x 2	0.10	Median residue x 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)
Boscalid					
Beef cattle*	9.65	0.335	Wheat straw	13.97	Y
Dairy cattle*	8.78	0.504	Wheat straw	13.09	Y
Ram/ewe	16.43	0.849	Wheat straw	25.50	Y
Lamb	16.56	1.071	Wheat straw	25.19	Y
Breeding swine	2.09	0.094	Kale	4.09	Y
Finishing swine*	1.36	0.041	Barley grain	1.36	Y
Broiler poultry	1.23	0.087	Brewer's grain	1.23	Y
Layer poultry*	5.19	0.503	Wheat	7.35	Y
Turkey	0.99	0.071	Brewer's grain	0.99	Y

\* These categories correspond to those (formerly) assessed at EU level.

The calculated dietary burdens for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Further investigation of residues is therefore required in all commodities of animal origin.

Moreover, it is relevant to describe that further consideration on the occurrence of residues in rotational crops has been considered on the calculation during the boscalid renewal framework. A slight increase of the dietary burden compared to the primary crop use has been detected. The calculated dietary burdens still exceed the trigger value of 0.1 mg/kg DM for all groups of livestock, confirming that further investigation of residues in all commodities of animal origin is required.

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

### Available data

Intended use on oilseed rape, pea, beans, linseed and flax of this dossier is fed to all livestock animals (cattle, sheep, swine and poultry) in the EU according to ENV/JM/MONO (2013).

A feeding study on laying hens was performed in the framework of boscalid for the Annex I inclusion (DAR addendum, Germany, 2006). The study was performed with four groups, three containing twelve laying hens and one (dosed with the high dose level) containing 20 laying hens of at least 40 weeks old. One group was kept as control; one group was treated with boscalid at level 1 mg/kg food dry weight (equivalent to 0.06 mg/kg/bw), and the other received 5x (medium) and 20x (high) this dose. All treatments were performed during 29 consecutive days. Eggs were taken every 2-4 days from the previous dosed day (-1) up to 38 days after first treatment. The birds were sacrificed within 24h after the last treatment and liver, muscle and fat samples were taken. Residues of boscalid and its metabolite M510

F01 were analysed in all samples.

Analysis of whole egg samples collected through the dosing period showed that no residues of boscalid and its metabolite M510 F01 above the limit of quantification, 0.01 mg/kg and 0.02 mg/kg, respectively were found in egg from the treated hens at 1x and 5x. The highest tested dose (20 mg/kg diet) showed increasing residue level along with the time. It was estimated that a plateau had been reached within the two weeks of dosing. The highest residue level of boscalid was 0.037 mg/kg at the 20 mg/kg dose level tested group.

No residues of boscalid and its metabolite M510 F01 above LOQ were detected in any of the hen matrices (muscle, liver and fat) treated at 1 mg/kg food dry weight. For muscle no residue above LOQ was detected in all treatment. Mean residues of boscalid and its metabolite M510 F01 above LOQ were detected in liver and fat from the mid and high dose groups. For liver, residues ranged from 0.11 to 0.18 mg/kg in the mid-dose group and from 0.14 to 0.20 mg/kg in the high-dose group. For fat, mean residues of 0.009 mg/kg and 0.171 mg/kg were detected in the mid and high dose, respectively.

The dose levels used in the feeding study were sufficient to cover the calculated burdens. Significant residues in edible matrices of poultry, except muscle, are expected and an MRL for poultry products has been derived with the Reg. (EU) no. 2016/156. The existing study on poultry is out of protection and it is still accepted during the framework of the boscalid renewal (Slovakia, 2018 – AIR III). Therefore, it is still reliable to support the framework of this application. No MRL exceedance is expected for poultry products after crop treatments according to the intended GAP table of the product FGG01.

Two feeding studies in lactating dairy cows were performed to address the magnitude of residues in ruminants. The first study was performed for the framework of boscalid for the Annex I inclusion (DAR, Germany, 2002) and the second was developed for the framework of boscalid renewal (Slovakia, 2018).

The unprotected DAR study tested 14 cows in the ranged weight of 480 - 735 kg. Cows were divided into 4 groups (3 cows/group), one group was kept as control and cows in the other group were fed twice daily with 1.5, 4.5 and 18 mg/kg diet of boscalid for 28±1 days. Two additional cows were fed with the highest dose, one developed mastitis and was discarded from the study and the other was kept on normal diet for another 7 days, for the monitoring of the residue decline after withdrawal of the test compound. Cows were milked twice daily and on the 21<sup>st</sup> day of the study a larger amount of milk was sampled and separated into skim milk and cream. The cows were sacrificed within 24h after the last treatment and liver, kidney, muscle, and fat samples were taken. Residues of boscalid and its metabolite M510 F01 were analysed in all samples.

No residues of boscalid and its metabolites M510 F01 and M510F 02 were found in milk samples from the control and low dose groups. In a few samples of the group tested at medium dose boscalid was detected above the LOQ (0.01 mg/kg) and no residues of its metabolites (M510 F01 and M510F 02) were detected. Samples from the highest tested dose reveals a regular occurrence of boscalid from the first day onwards, with the plateau been reached within two weeks (0.04-0.05 mg/kg). Analysis of the samples from the withdrawn animal showed that residues are rapidly excreted, since no residues in milk were observed after three days from when the dosing had stopped.

Residues consisting of boscalid and its metabolite M510 F01 and M510F 02 could be quantified only in liver and kidney. In all other matrices boscalid was the only quantifiable residue. In muscle, only one sample from the high dose group showed residues of boscalid above the LOQ (0.0326 mg/kg), all others were < 0.025 mg/kg. In fat, one sample of the low dose group showed residues higher than the LOQ (0.0526 mg/kg) and the samples from the medium and high dose showed residues of boscalid in the range of 0.084 - 0.267 mg/kg. In liver and kidney only metabolites M510F01 and M510F02 were found in samples from the medium dose group. In the high dose group, boscalid as well its metabolites were determined. Additionally, liver was analysed for bound residues by microwave treatment and residues (0.09 mg/kg boscalid) were detected in the high dose group. As residues were detected in milk (skim and cream), fat, liver and kidney at the high dose level tested (18 mg/kg), this study is not considered sufficient to cover the highest dose level calculated from dietary burden for ruminants (25.5 mg/kg DM for raw/ewe).

In order to cover the dose level calculated from dietary burden for ruminants, a new study has been

submitted in the framework of boscalid renewal (Slovakia, 2018 – AIR III). A total of 13 cows in the ranged weight of 500 - 640 kg were divided into three groups, one group (3 cows) was kept as control and the cows in the other groups were fed twice daily with 35 mg/kg diet of boscalid (3 cows) and 105 mg/kg diet of boscalid (7 cows) for 29 days. From the 7 cows treated with the high dose, one has been discarded, 3 were used for the dose assessment and 3 for the monitoring of the residue decline after withdrawal of the test compound. Cows were milked twice daily and on the 22<sup>nd</sup>, 28<sup>th</sup> and 42<sup>nd</sup> day of the study a larger amount of milk was sampled and separated into skim milk and cream. The cows were sacrificed within 24 hours after the last treatment and liver, kidney, muscle, and fat (omental, perirenal and subcutaneous) samples were taken, except for the three animals in the depuration experiment which were terminated, one each on days 36, 39 and 43, of the study to determine residue decline of the test compound.

No residues of boscalid and its metabolites M510 F01 were found in milk samples from the control. For the low dose group residues of boscalid ranged from < 0.01 to 0.023 mg/kg (parent) and was < 0.01 mg/kg for the metabolite (M510 F01). Samples from the highest tested dose reveals a regular occurrence of boscalid from the first day onwards, with a peak on day 7 of the study, with the plateau been reached in the following days. Residues of boscalid were below the LOQ (< 0.01 mg/kg) in skim milk samples from all dosing groups and the maximum residues of boscalid in cream milk were 0.072 and 0.492 mg/kg for the low and high-dose groups, respectively. Analysis of the samples from the withdrawal animal showed that residues are rapidly excreted, since no residues in milk were observed after two days from when the dosing had stopped. After 14 days of dosing ceased the residues of boscalid in skim and cream milk (samples from the withdrawal animal) were below the LOQ.

For the cows' tissues, the maximum combined residues (boscalid and metabolite) were 0.11 and 0.24 mg/kg in liver and kidney from the low and high dose groups, respectively. No residues were detected in muscle samples. In fat, the maximum residues of boscalid were found in perirenal fat at 0.22 and 0.25 mg/kg for the low and high dose groups, respectively. From the withdrawal animals, used for the decline assessment, residues of boscalid declined to below the LOQ in all tissue samples after 10 days of dosing ceased.

Feeding studies on pigs are not developed or required since the metabolic pathways in rats and cows (ruminants) are comparable and can be extrapolated to pigs. For details on the rodent's metabolite patterns please refer to the toxicological and metabolism (dRR Part B6).

Although the log of Po/w is 2.9, which is close to 3 (Germany, 2002), the bioconcentration study showed there is no risk of boscalid accumulation in fish or other aquatic organisms due to the rapid excretion of the parent compound and its metabolite. The results showed an elimination of more than 90% of the radioactivity in 3.3 days.

No new data were submitted in the framework of this application. For the overview of the available data describe above and the comparison to the expected residues please refer to table 3-11 described on EFSA Journal 2014;12(7):3799.

### Conclusion on feeding studies

The existing study on poultry is out of protection and it is still accepted during the framework of the boscalid renewal (Slovakia, 2018 – AIR III), therefore, it is still reliable to support the framework of this application.

The existing study on ruminants from the DAR is out of protection and it is still accepted during the framework of the boscalid renewal (Slovakia, 2018). However, it was not sufficient to cover the highest dose level calculated from dietary burden for ruminants (25.5 mg/kg DM for raw/ewe). The new study described in the renewal dossier (Slovakia, 2018) tested higher doses and are in accordance with the maximum dose level calculated. The applicant of this dossier already considered the necessity of obtain access to the study developed with higher doses by the applicant of the active substance, BASF SE, in order to avoid the study repetition due to animal welfare.

Feeding studies are valid but not sufficient. Further investigations for poultry and ruminants are necessary due to the absence of data in the second radiolabelling (pyridine moiety). Additional data has been requested by EFSA (2014) and Slovakia (2018) to address the fate of the pyridine moiety in animals'



commodities.

As a final conclusion, the data-gap mentioned above does not impact the framework of this application, since the requested uses do not modify the theoretical maximum daily intake for animals and, according to the 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)

Data on processing studies has been generated and reviewed within the scope of boscalid Annex I inclusion (Germany, 2002) and during the renewal process of boscalid (Slovakia, 2018). Processing studies were performed on grapes, peas and oilseed rape and were considered acceptable. According to OECD guideline 508, only procedures for the representatives uses on grapes (wet pomace, juice, must and wine) and oilseed rape (meal and oil) are considered as essential (category 1). Processing procedures for cooked and canned peas were assessed as additional data.

The magnitude of residues in processed commodities of grapes (4 trials) and peas (4 trials) are covered by unprotected data generated within the scope of boscalid Annex I inclusion (Germany, 2002). The formulations code tested in the processing studies performed for Annex I inclusion was BAS 510 01 F, which is a WG formulation which contains 500 g/kg of boscalid. The data protection period of the study reports developed with this formulation submitted in support of the initial approval of boscalid on 08/11/2002 have already expired, in accordance with Article 59(1) of Regulation 1107/2009 (10 years for the initial product authorisation). Trials to assess the procedure of oil production performed for the purpose of the renewal of boscalid are still under protection, therefore a letter of access will be required to complement the data package.

### 7.2.5.1 Available data for all crops under consideration

Intended crops grapes and peas are covered by processing studies performed during the boscalid Annex I inclusion (Germany, 2002) and oilseed rape can be covered by a study performed during the renewal process of boscalid (Slovakia, 2018) and new processing study data performed in the framework of this application.

**Table 7.2-12: Overview of the available processing studies**

Processed commodity	Number of studies	Median PF *	Median CF	Comments	Reference
<b>EU data</b>					
Residue definition: Boscalid					
<b>Grape</b>					
Dried fruit	4	2.4	n.a.	-	Germany, 2002
Juice	4	0.4	n.a.	-	Germany, 2002
Wet pomace	4	2.5	n.a.	-	Germany, 2002
Must (cold)	4	0.45	n.a.	-	Germany, 2002
Must (after heating)	4	0.32	n.a.	-	Germany, 2002
Wine (from must, cold)	4	0.35	n.a.	-	Germany, 2002
Wine (from must, heated)	4	0.24	n.a.	-	Germany, 2002
<b>Peas</b>					
Cooked/canned	4 <b>1</b>	< 0.36	n.a.	-	Germany, 2002
<b>Rape seed</b>					

Processed commodity	Number of studies	Median PF *	Median CF	Comments	Reference
Refined oil	4	1.29	n.a.	-	Slovakia, 2018
Meal (press cake)	4	0.56	n.a.	-	Slovakia, 2018
Oil (crude)	4	1.11	n.a.	-	Slovakia, 2018
<b>New data</b>					
Residue definition: Boscalid					
<b>Rape seed</b>					
Refined oil	2	2.05	n.a.	-	North L., 2022, report No S22-01575
Meal (press cake)	2	0.23	n.a.	-	
Oil (crude)	2	1.85	n.a.	-	

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

### 7.2.5.2 Conclusion on processing studies

Following treatment on grapes, the concentration of boscalid did not derived concentration factors < 1 in the consumer products (juice, must or wine). The same has been observed for the canned pea production. Residue levels in refined oil and crude oil processed fractions were > 1. Median processing factors of 2.4 and 2.5 were calculated for dried fruit and wet pomace.

Median processing factors of 1.29 and 2.05 were calculated for refined oil in the EU protected study and own study, respectively. And of 1.11 and 1.85 for the crude oil preparation in the EU protected study and own study, respectively. For meal a median processing factor < 1 (0.56 and 0.23) was calculated. Further processing studies are not required, 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. Considering available data dealing with nature of residues (see 0), residue of boscalid may occur in plants due to uptake from soil. Therefore, study dealing with magnitude of residues in succeeding crops is required.

The existing studies on the magnitude of residues in rotational crops under practical conditions from the DAR (Germany, 2002) and addendum 1 of the DAR (Germany, 2006), provided in support of the initial Annex I approval of boscalid, are out of protection and are still accepted during the framework of the boscalid renewal (Slovakia, 2018). Moreover, new studies were performed in EU and US with the aim to elucidate the transfer of boscalid residues from soil to succeeding crops.

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

##### Available data

In addition to the confined rotational crop study referenced in data point 7.2.2.2, two rotational crop field trials were evaluated as part of the peer review (Germany, 2002).

In one trial, a total of 3.8 kg of boscalid was applied over two years to vegetables, during the first year an amount of 2.1 kg was applied to lettuce (2 × 0.3 kg boscalid/ha – 0.75N) and green beans (3 × 0.5 kg boscalid/ha – 1.5N) and during the second year an amount of 1.7 kg applied to carrots (3 × 0.3 kg boscalid/ha – 1.7N) and cabbage -flower (2 × 0.4 kg boscalid/ha – 1N). The following year, spring wheat was sown in the same plot and no treatment with boscalid-containing products were applied to the plots.

In the second trial, boscalid was applied on winter rape (0.5 kg boscalid/ha – 1N) and, 365 days after harvest, wheat was sown on the same plot. Residues levels of boscalid were found in wheat forage and wheat straw after two years of treatment. Although the applied dose was higher than the intended dose, these field studies demonstrate uptake of boscalid residues via roots into succeeding crops.

No new studies for residues in succeeding crops have been submitted by the applicant in the framework of this application.

**Table 7.2-12: Summary of available studies in field rotational crops**

Primary crop	Rate (g 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 and green beans	2100	Cereals	Spring wheat	365	Germany, 2002
Carrots and cauliflower	1700	Cereals	Spring wheat	365	Germany, 2002
Oilseed rape	250	Cereals	Winter wheat	365	Germany, 2002

### Conclusion on rotational crops studies

The available studies on rotational crops clearly indicate that there is a potential for residues in crops grown in rotation. To avoid possible problems with residues in crops which are not treated with plant protection products containing boscalid, both in the monitoring and in the consumer dietary risk assessment, special measures are proposed. A general default MRL of 0.5 mg/kg was proposed in Addendum 1 to the DAR (Germany, 2006) for all rotational crop commodities in order to take into account the soil contamination and for completion with residue legislation in the context of article 12 (2) of Regulation (EC) No 396/2005. However, the member state suggested a more adjusted approach for different crop groups. Therefore, it is necessary to establish MRLs which are high enough to cover possible residues in most rotational crops.

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

Part of the intended uses of this dossier are considered as relevant for nectar production and collection by honeybees according to SANTE/11956/2016 rev.9. Although boscalid is a non-systemic active substance with low water solubility, which indicates that transfer from flowers to honey is considered unlikely, intended crops can be treated during the flowering period and boscalid residue levels in the honey must be addressed.

Therefore, in a new study by Knoll (2022), KCP 7.2.7/01, four trials (2 NEU and 2 SEU) were performed to determine the residues levels in honey to support the intended uses on melliferous crops (grapes). Trials were performed in protected oilseed rape located in representative areas of honey production (Germany (2) and Spain (2)) during 2022. Each trial contained one untreated and one treated plot, which were treated according to the GAP table. In order to represent the worst-case scenario, two foliar applications targeted a minimum of 6 days interval with the second application performed during flowering (BBCH 60-69). Honey samples were collected from the combs, ranging from 3 to 27 days after the last application, to cover the critical period.

The residue levels of boscalid were analysed in honey following the validated analytical procedure S22-00776 described in the analytical methods section of this dossier (please refer to study Sahvorost, N., 2002 - KCP 5.1.2/01 summarized in dRR Part B5). Quantification was performed by LC-MS/MS detection. Samples were stored for up to 19 days at < -18°C between sampling and extraction. The limit

of quantification was 0.01 mg/kg. Residues of boscalid found in honey ranged from < 0.01 mg/kg (LOQ) to 0.0455 mg/kg. The detailed assessment of the new studies is presented in Appendix 2 (A 2.1.7.1).

An MRL exceedance above the current value for honey of 0.1 mg/kg (Reg. (EC) No 2021/590) is not expected since the maximum highest residue (HR) measured in honey was 0.046 mg/kg. The new data performed was input into the MRL calculator, and the calculated EU MRL was 0.1 mg/kg for honey, indicating that no exceedance of the MRL will occur.

The available data for boscalid sufficiently address aspects of the residue situation that might arise from the use of FGG01. Therefore, other special studies are not needed.

## 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.

### 7.2.8.1 Input values for the consumer risk assessment

The median residue level for raw agricultural commodity derived from the submitted trials and the median residues derived by EFSA in previous assessments (EFSA, 2014, 2015, 2019, 2020) were the values used in the calculation. Input values for the consumer risk assessment are in Table 7.2-15 below.

**Table 7.2-13: Input values for the consumer risk assessment**

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition: Boscalid		
Citrus fruit	0.07	STMR*PeF (EFSA, 2014)
Almonds	0.05	STMR (EFSA, 2014)
Brazil nuts	0.05	STMR (EFSA, 2014)
Cashew nuts	0.05	STMR (EFSA, 2014)
Chestnuts	0.05	STMR (EFSA, 2014)
Coconuts	0.05	STMR (EFSA, 2014)
Hazelnuts/cobnuts	0.05	STMR (EFSA, 2014)
Macadamia	0.05	STMR (EFSA, 2014)
Pecans	0.05	STMR (EFSA, 2014)
Pine nut kernels	0.05	STMR (EFSA, 2014)
Pistachios	0.27	STMR (EFSA, 2014)
Walnuts	0.05	STMR (EFSA, 2014)
Other tree nuts	0.05	STMR (EFSA, 2014)
Apple	0.42	STMR (EFSA, 2014)
Pear	0.42	STMR (EFSA, 2014)
Quince	0.42	STMR (EFSA, 2014)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Apricots	0.77	STMR (EFSA, 2014)
Cherries (sweet)	1.51	STMR (EFSA, 2014)
Peaches	0.77	STMR (EFSA, 2014)
Plums	1.21	STMR (EFSA, 2014)
Table and wine grapes	1.42	STMR (EFSA, 2014)
Strawberries	1.95	STMR (EFSA, 2014)
Cane fruit	2.53	STMR (EFSA, 2014)
Blueberries	3.60	STMR (EFSA, 2014)
Cranberries	3.60	STMR (EFSA, 2014)
Currants (red, black and white)	3.60	STMR (EFSA, 2014)
Gooseberries (green, red and yellow)	3.60	STMR (EFSA, 2014)
Mediterranean medlars	3.60	STMR (EFSA, 2014)
Elderberries	3.60	STMR (EFSA, 2014)
Other small fruits and berries	3.60	STMR (EFSA, 2014)
Rose hips	2.60	STMR*PeF (EFSA, 2014)
Mulberries (black and white)	2.60	STMR*PeF (EFSA, 2014)
Azarole/Mediterranean medlar	2.60	STMR*PeF (EFSA, 2014)
Kiwi fruits (green, red, yellow)	0.07	STMR*PeF (EFSA, 2014)
Bananas	0.05	STMR*PeF (EFSA, 2014)
Granate apples/pomegranates	2.00	MRL(EFSA, 2020)
Potatoes	0.31	STMR (EFSA, 2014)
Root and tuber vegetables except beetroots and Jerusalem artichokes	0.31	STMR (EFSA, 2014)
Beetroots	0.38	STMR (EFSA, 2014)
Jerusalem artichokes	2.0	EU MRL
Garlic	2.40	STMR (EFSA, 2014)
Onions	2.40	STMR (EFSA, 2014)
Shallots	2.40	STMR (EFSA, 2014)
Spring onions/green onions and Welsh onions	2.30	STMR (EFSA, 2014)
Tomatoes	0.40	STMR (EFSA, 2014)
Sweet peppers/bell peppers	0.57	STMR (EFSA, 2014)
Aubergines/egg plants	0.40	STMR (EFSA, 2014)
Okra/lady's fingers	0.57	STMR (EFSA, 2014)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Other solanaceae	0.57	STMR (EFSA, 2014)
Cucurbits - edible peel	0.73	STMR (EFSA, 2014)
Cucurbits - inedible peel	0.40	STMR (EFSA, 2014)
Flowering brassica and head brassica, except head cabbage	1.52	STMR (EFSA, 2014)
Head cabbage	1.10	STMR (EFSA, 2014)
Leafy brassica	3.65	STMR (EFSA, 2014)
Kohlrabi	1.52	STMR (EFSA, 2014)
Lettuce and other salad plants including Brassicaceae and spinaches	5.60	STMR (EFSA, 2014)
Purslanes, chards/beet leaves, grape leaves and watercress	3.65	STMR (EFSA, 2014)
Witloofs/Belgian endives	8.55	STMR (EFSA, 2014)
Herbs and edible flowers	14.45	STMR (EFSA, 2014)
Beans (with pods)	0.66	STMR (EFSA, 2014)
Beans (without pods)	0.50	STMR (EFSA, 2015)
Peas (with pods)	0.66	STMR (EFSA, 2014)
Peas (without pods)	0.50	STMR (EFSA, 2015)
Lentils (fresh)	3.00	STMR (EFSA, 2014)
Asparagus	0.10	STMR (EFSA, 2014)
Cardoons	0.10	STMR (EFSA, 2014)
Celeries	2.18	STMR (EFSA, 2014)
Florence fennels	2.18	STMR (EFSA, 2014)
Globe artichokes	1.23	STMR (EFSA, 2014)
Leeks	2.35	STMR (EFSA, 2014)
Rhubarbs	0.10	STMR (EFSA, 2014)
Dry pulses, except lupins/lupini beans	0.13	STMR (EFSA, 2014)
Lupins/lupini beans	0.12	STMR (EFSA, 2014)
Oilseeds, except soyabeans	0.15	STMR (EFSA, 2014)
Soyabeans	0.12	STMR (EFSA, 2014)
Barley, oats	1.07	STMR (EFSA, 2014)
Rye, wheat	0.17	STMR (EFSA, 2014)
Buckwheat, maize, millet, rice, sorghum, other cereals	0.05	STMR (EFSA, 2014)
Coffee beans	0.05	STMR (EFSA, 2014)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Herbal infusions from dried flowers and dried leaves	0.05	STMR (EFSA, 2014)
Herbal infusions from dried roots	0.09	STMR (EFSA, 2014)
Hops	24.51	STMR (EFSA, 2014)
Spices	0.05	STMR (EFSA, 2014)
Sugar cane	0.21	STMR (EFSA, 2014)
Swine meat and fat	0.03	STMR (EFSA, 2014)
Ruminants meat	0.05	STMR (EFSA, 2014)
Ruminants fat	0.12	STMR (EFSA, 2014)
Poultry meat and fat	0.03	STMR (EFSA, 2014)
Milk	0.02	STMR (EFSA, 2014)
Bird's eggs	0.01	STMR (EFSA, 2014)
Swine kidney	0.05	STMR (EFSA, 2014)
Ruminants' kidney	0.09	STMR (EFSA, 2014)
Poultry liver	0.06	STMR (EFSA, 2014)
Swine liver	0.08	STMR (EFSA, 2014)
Ruminants' liver	0.11	STMR (EFSA, 2014)
Honey and other apiculture products	0.15	MRL (EFSA, 2019)

### 7.2.8.2 Conclusion on consumer risk assessment

A first-tier chronic consumer risk assessment was performed for boscalid based on available data described in Table 7.2-15 and using the EFSA PRIMo model rev 3.1.

With the current EFSA model the chronic risk assessment ranges from 4 to 71% of ADI (see Table 7.2-16 and appendix 1). The diet with the highest TMDI is “NL toddler” with 71% of ADI. For this diet, the highest contributor are apples with 11% of ADI. The diet with the second highest TMDI is “DE child” with 50% of ADI, in which apples still the major contributor with 13% of ADI.

According to the presented TMDI calculation a chronic intake of boscalid residues is unlikely to present a public health concern. The proposed uses of boscalid in the formulation 500 g/kg WG do not represent unacceptable chronic risks for the consumer. An extensive calculation sheet is presented in Appendix 3 (A 3.1). The chronic consumer intake for the representative uses is estimated to be below the ADI (= 71%). As an ARfD was not deemed necessary, acute risk assessment is not relevant. Results are listed in table 7.2-16.

**Table 7.2-14: Consumer risk assessment**

TMDI (% ADI) according to EFSA PRIMo rev. 3.1	71 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo	-
IESTI (% ARfD) according to EFSA PRIMo*	-

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

The proposed uses of boscalid in the formulation FGG01 do not represent unacceptable acute and chronic

risks for the consumer.

**zRMS:**

STMR from the new trials of grape, fresh bean and oilseed rape are less than used in EFSA calculation. Therefore, no recalculation using these values is required. ADI will not be exceeded.

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

Not relevant. The product contains only one active substance.

### **7.4 References**

Germany, 2002. Draft Assessment Report on boscalid (formerly nicobifen) prepared by the rapporteur Member State Germany in the framework of Directive 91/414/EEC, November 2002.

Germany, 2006. Addendum 1 to the Draft Assessment Report on boscalid (formerly nicobifen) prepared by the rapporteur Member State Germany in the framework of Directive 91/414/EEC, January, 2006

Slovakia, 2018. Draft Renewal Assessment Report on boscalid (formerly nicobifen) prepared by the rapporteur Member State Slovakia according to Reg no. 1107/2009, November 2002

FAO (Food and Agriculture Organization of the United Nations), 2006. Boscalid. In: Pesticide residues in food – 2006. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues. FAO Plant Production and Protection Paper 187, 68-86 pp.

FAO (Food and Agriculture Organization of the United Nations), 2008. In: Pesticide residues in food – 2008. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues. FAO Plant Production and Protection Paper 193, 99-68 pp.

FAO (Food and Agriculture Organisation of the United Nations), 2009a. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 2nd Ed. FAO Plant Production and Protection Paper 197, 264 pp.

FAO (Food and Agriculture Organization of the United Nations), 2009b. Pesticide residues in food – 2009. Evaluation. Part I. Residues. FAO Plant Production and Protection Paper 198, 134-145 pp.

FAO (Food and Agriculture Organization of the United Nations), 2010. Boscalid. In: Pesticide residues in food – 2010. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues. FAO Plant Production and Protection Paper 200, 55-59.

European Food Safety Authority; Modification of the existing MRLs for boscalid in various crops. EFSA Journal 2010;8(9):1780. 51 pp. <https://doi:10.2903/j.efsa.2010.1780>

European Food Safety Authority, 2014. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for boscalid according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(7):3799, 127 pp. <https://doi:10.2903/j.efsa.2014.3799>



EFSA (European Food Safety Authority), 2015. Reasoned opinion on the modification of the existing maximum residue levels (MRLs) for boscalid in beans and peas with pods. EFSA Journal 2015;13(3):4045, 19 pp. <https://doi:10.2903/j.efsa.2015.4045>

EFSA (European Food Safety Authority), 2019. Reasoned opinion on the modification of the existing maximum residue level for boscalid in honey. EFSA Journal 2019;17(11):5897, 25 pp. <https://doi.org/10.2903/j.efsa.2019.5897>

Germany, 2014a. Evaluation Report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing MRLs for boscalid, February 2014.

Germany, 2014b. Evaluation Report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing MRLs for boscalid, May 2014.

Netherlands, 2014. Evaluation Report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing MRLs for boscalid, January 2014.

United Kingdom, 2014. Evaluation Report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing MRLs for boscalid, January 2014.

## 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
KCA 6.1	Flore, S.	2022	Storage Stability of Boscalid in Honey under Deep Frozen Conditions Report no. S22-01684 – UPL/2022/0340 Eurofins Agroscience Services EcoChem GmbH, Germany GLP Unpublished	N	UPL
KCA 6.3, KCA 6.10	Davolos, CC.	2024	OECD calculator for oilseed rape, beans with pod and honey for the active substance boscalid based on the use of the FGG01 formulation. File name: OECD Calculator_FGG01_intended uses Unpublished	N	UPL
KCA 6.3.2/01; KCA 6.5.2	North, L.	2023	Determination of residues of Boscalid after two applications of Boscalid 500 WG in Oilseed rape and its processed fractions at 4 sites in Northern Europe and 4 sites in Southern Europe 2022 Report no. S22-01574 – UPL/2022/0442 Eurofins Agroscience Services Ltd., United Kingdom GLP Unpublished	N	UPL
KCA 6.3.2/02	North, L.	2024	Determination of residues of Boscalid after two applications of Boscalid 500 WG in Oilseed rape at 4 sites in Northern Europe and 4 sites in Southern Europe 2023 Report no. S23-00040 - UPL/2023/0503 Eurofins Agroscience Services Ltd., United Kingdom GLP Unpublished	N	UPL
KCA 6.3.3/01	North, L.	2023	Determination of residues of Boscalid after two applications of Boscalid 500 WG in Beans with pods at 3 sites in Northern Europe and 4 sites in Southern Europe 2022 Report no. S22-01575 – UPL/2022/0403	N	UPL

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
			Eurofins Agroscience Services Ltd., United Kingdom GLP Unpublished		
KCA 6.3.3/02	North, L.	2024	Determination of residues of Boscalid after two applications of Boscalid 500 WG in Beans with pods at 5 sites in Northern Europe and 4 sites in Southern Europe 2023 Report no. S23-00041 – UPL/2023/0507 Eurofins Agroscience Services Ltd., United Kingdom GLP Unpublished	N	UPL
KCA 6.4	Davolos, CC.	2024	Animal burden calculation of boscalid based on the use of the FGG01 formulation. File name: boscalid_mrl_guidelines_animal_model_2017 Unpublished	N	UPL
KCA 6.9	Davolos, CC.	2024	Dietary Risk Assessment of boscalid based on the use of the FGG01 formulation. File name: Chronic_EFSA_PRIMo_rev3.1_boscalid Unpublished	N	UPL
KCA 6.10	Knoll, M.	2022	Boscalid 500 WG: Determination of Residues of Boscalid in Honey after two Applications in Winter Oilseed Rape at Four Sites in Northern and Southern Europe in 2022 Report no. S22-00761 – UPL/2022/0377 Eurofins Agroscience Services EcoChem GmbH, Germany GLP Unpublished	N	UPL

**List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review**

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCA 6.1	Funk H., Mackenroth, C.	2001	Investigation of the Stability of Residues of BAS 510 F in Plant Matrices under Storage Conditions. Report No. 2001/1015028; RIP2002-192 GLP Unpublished	N	BASF
KCA 6.2.1	Rabe U., Schlueter H.	2001	Metabolism of 14C-BAS 510 F in grapevine BASF AG Agrarzentrum Limburgerhof; Limburgerhof; Germany Fed.Rep. Report No. 2000/1014860 GLP Unpublished	N	BASF
KCA 6.2.1	Hamm R.T.	1999	BAS 510 F in lettuce Report No. 1999/11240 GLP Unpublished	N	BASF
KCA 6.2.1	Veit P.	2001	Metabolism of 14C-BAS 510 F in beans Report No. 2000/1014861 GLP Unpublished	N	BASF
KCA 6.2.2	████████	2000	The Metabolism of 14C-BAS 510F in Lactating Goat. Report No. 000/1012353; RIP2001-331 GLP Unpublished	Y	BASF
KCA 6.2.2	████████	2000	14C-BAS 510 F- Absorption, Distribution and Excretion after Repeated Oral Administration in Lactating Goats. Report No. BASF DocID: 2000/1017221; RIP2001-330GLP Unpublished	Y	BASF
KCA 6.2.2	████████	2001	Nature of Residues of 14C-BAS 510 F in Laying Hens. Report No. 2000/5154; RIP2001-332 GLP	Y	BASF

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
			Unpublished		
KCA 6.3.1	Beck, J.	2003	Study on the residue behavior of Boscalid (BAS 510 F) in grapes (wine) after application of BAS 510 01 F under field conditions in Germany, France, Italy and Spain, 2002 Report no. 2003/1001357 GLP Unpublished	N	BASF
KCA 6.3.1	Moreno, S.	2003	Study on the residue behavior of Boscalid (BAS 510 F) in grapes (wine) after application of BAS 510 01 F under field conditions in Spain, 2002 Report no. 2003/1001279 GLP Unpublished	N	BASF
KCA 6.3.1	Schulz, H.	2004	Study on the residue behavior of BAS 510 F in vines after application of BAS 510 01 F under field conditions in France (N & S), Spain, Italy and Germany, 2003 Report no. 2004/1015915 GLP Unpublished	N	BASF
KCA 6.3.2	Raunft, E.	2001	Study on the residue behavior of BAS 510 F in winter rape after treatment with BAS 510 01 F under field conditions in Germany, Sweden and Great Britain, 2000. Report no. BASF DocID 2000/1014851 GLP Unpublished	N	BASF
KCA 6.3.2	Peny, A.	2001	Residue study in oil seed rape following treatment with the preparation BAS 510 01 F under field conditions in France in 2000. Report no. BASF DocID 2000/1014877 GLP Unpublished	N	BASF
KCA 6.3.2	Schulz, H.	2005	Study on the residue behavior of BAS 510 F in spring rape after treatment with BAS 510 01 F under field conditions in Germany, England and Sweden, 2004 Report no. BASF DocID 2005/1004971	N	BASF

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
			GLP Unpublished		
KCA 6.3.2	Oxspring S.,	2007	Study on the residue behaviour of BAS 510 F in spring oilseed rape after treatment with BAS 510 01 F under field conditions in Southern Europe during 2006 Report no. BASF DocID 2007/1007952 GLP Unpublished	N	BASF
KCA 6.3.2	Schaeufele, M.	2009	Residue study (decline) with BAS 664 AS F, BAS 510 01 F and BAS 555 00 F applied to oilseed rape in Germany and Northern France in 2008 Report no. BASF DocID 2008/1074165 GLP Unpublished	N	BASF
KCA 6.3.3	Heck, W.	2000	Study on the residue behavior of BAS 510 F in peas after treatment with BAS 510 01 F under field conditions in Germany, Denmark and Sweden, 1999 Report no. BASF DocID 2000/1014848 GLP Unpublished	N	BASF
KCA 6.3.3	Schulz, H.	2000	Determination of the residue of BAS 510 F in peas following treatment with BAS 510 01 F under field conditions in France 1999 Report no. BASF DocID 2000/1014879 GLP Unpublished	N	BASF
KCA 6.3.3	Heck W., Mackenroth C.	2001	Study on the residue behavior of BAS 510 F in peas after treatment with BAS 510 01 F under field conditions in Germany, Denmark, France and Sweden, 2000 Report no. BASF DocID 2000/1014852 GLP Unpublished	N	BASF
KCA 6.3.3	Perny, A.	2001	Residue study in green peas following treatment with the preparation BAS 510 01 F under field conditions in France in 2000	N	BASF

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
			Report no. BASF DocID 2000/1014878 GLP Unpublished		
KCA 6.3.3	Klaas, P.	2008	Study on the residue behavior of BAS 510 F in green beans after treatment with BAS 510 01 F under field conditions in Germany, the Netherlands, United Kingdom and Northern France, 2007. Report no. BASF DocID 2008/1028266 GLP Unpublished	N	BASF
KCA 6.3.3	Schulz, H.	2011	Study on the residue behavior of Boscalid in green beans after treatment with BAS 510 01 F under field conditions in Germany, the Netherlands, Northern France, Belgium, Southern France, Greece, Italy and Spain, 2009 Report no. BASF DocID 2010/1165744 GLP Unpublished	N	BASF
KCA 6.3.3	Meyer M.,	2011	Study on the residue behaviour of Boscalid in green beans after treatment with BAS 510 01 F under field conditions in Southern Europe (Southern France, Greece, Italy and Spain) and Northern Europe (Belgium), 2010 Report no. BASF DocID 2011/1251203 GLP Unpublished	N	BASF
KCA 6.4.1	██████████	2002	A meat and egg magnitude of the residue study with BAS 510 F in laying hens. Report no. 2002/5002466 GLP Unpublished	Y	BASF
KCA 6.4.2	██████████	2001	Residues in milk and edible tissues following oral administration of BAS 510 F to lactating dairy cattle. Report no. 2000/1017228 GLP Unpublished	Y	BASF
KCA 6.4.2	██████████	2008	A meat and milk magnitude of the residue study with BAS 510 F in lactating dairy cows	Y	BASF

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
			Report no. 2008/7015330 GLP Unpublished		
KCA 6.5.1	Scharf J.	1998	Hydrolysis of BAS 510 F at 90°C, 100°C, and 120°C Report no. 1998/10878 GLP Unpublished	N	BASF
KCA 6.5.3	Meumann H. et al.	2000	Study on the residue behaviour of BAS 510 F in grape process fractions after treatment with BAS 510 01 F under field conditions in Germany, 1999 Report no. 2000/1012412 GLP Unpublished	N	BASF
KCA 6.5.3	Scharm M.	2001	Determination of the residue of Reg. no. 300 355 in peas and processed products following treatment with BAS 510 01 F under field conditions in Germany 2000 Report no. 2000/1014885 GLP Unpublished	N	BASF
KCA 6.5.3	Versoi P.L., Abdel-Baky S.	2001	The magnitude of BAS 510 F residues in canola seed processed fractions. Report no. 2001/5001064 GLP Unpublished	N	BASF
KCA 6.6.1	Hamm R.T., Veit P.	2001	Confined rotational crop study with <sup>14</sup> C-BAS 510 F Report no. 2000/1014862 GLP Unpublished	N	BASF
KCA 6.6.2	Funk H., Mackenroth C.	2001	Determination of the residues of BAS 510 F in wheat obtained from the trial year 2000 Report no. 2000/1014853, RIP2001-374 GLP Unpublished	N	BASF



<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
KCA 6.6.2	Funk H., Mackenroth C.	2001	Report amendment no. 1 to final report: Determination of the residues of BAS 510 F in wheat obtained from the trial year 2000. Report no. 2001/1000989, RIP2001-375 GLP Unpublished	N	BASF
KCA 6.6.2	Jeannine M. J,	2002	Cereal Grains and Soybean Field Rotational Study for BAS 510 F, Report no. 2002/5001341 GLP Unpublished	N	BASF
KCA 6.6.2	Jeannine M. J,	2002	Field Rotational Study for BAS 510 F on Grasses, Alfalfa and Clover as Livestock Feed Crops Report no. 2002/5002063 GLP Unpublished	N	BASF
KCA 6.6.2	David W. Haughey, Samy Abdel-Baky	2001	Limited Rotational Crop Study for the Use of BAS 510 F Report no. 2001/5000966 GLP Unpublished	N	BASF
KCA 6.6.2	Versoi, P., Abdel-Baby, S.	2001	Magnitude of the Residue of BAS 510 F in Peas and Beans Planted as Rotational Crops and of BAS 500 F in Peas and Beans When Applied as a Foliar Spray Report no. 2001/5003311 GLP Unpublished	N	BASF
KCA 6.6.2	Raymond C. L.	2002	Sugar Beet, Garden Beet and Turnip Field Rotational Crop Study for BAS 510 02 F Residues. Report no. 2002/5004273 GLP Unpublished	N	BASF
KCA 6.6.2	Beck, J., Lehmann, A. Grote, C., Mackenroth, C.	2003	Study on the residue behaviour of Boscalid (BAS 510 F) on succeeding crops after application of BAS 510 01 F on bare soil and cultivation of potatoes under field conditions in Denmark, France, Germany and Great Britain, 2002	N	BASF

<b>Data point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Company Report No. Source (where different from company) GLP or GEP status Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Owner</b>
			Report no. 2003/1001358 GLP Unpublished		
KCA 6.6.2	Schroth E., Martin T.	2008	Study on the residue behaviour of BAS 510 F on the rotational crop: Carrots, after the application to the soil of BAS 510 01 F under field conditions in France (South), Germany, Netherlands and Spain, 2007 Report no. 2008/1036949 GLP Unpublished	N	BASF
KCA 6.6	Hamm, T.R.; Veit, P.	2001	Confined Rotational Crop Study with 14CBAS 510 F. BASF DocID.: 2000/1014862 - RIP2001-373 GLP Unpublished	N	BASF

**List of data submitted by the applicant and not relied on**

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

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

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

## 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

##### A 2.1.1.1.1.1 Study 1

Comments of zRMS:	Study is accepted. The study was performed in accordance with applicable guidelines. No deficiencies were found.
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Reference:	KCA 6.1
Report	Storage stability of boscalid in honey under deep frozen conditions, Flore S., 2022, report no. S22-01684, document no. UPL/2022/0340.
Guideline(s):	Yes (OECD 506; SANTE/2020/12830, rev.1 and ENV/MC/CHEM(98)17).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

### Materials and methods

Honey specimens were homogenized by thoroughly stirring with a spatula and stored at  $\leq -18^{\circ}\text{C}$  in the dark until fortification and extraction. Samples were fortified with boscalid at 0.10 mg/kg (10 x LOQ), and after homogenization they were stored at  $\leq -18^{\circ}\text{C}$ . Fortified samples were analysed after 0 and 30 and 149 days of storage.

The analytical method is based on multi-residue method QuEChERS and involved an extraction of the samples with acetonitrile, followed by addition of water. After centrifugation an aliquot of the extract was cleaned by dispersive SPE with PSA and magnesium sulphate. Final sample extracts were diluted with water:acetonitrile (1:1) and final determination was performed by LC-MS/MS. The primary analytical method was fully validated for honey in the study S22-00776 (Sahvorost, N., 2022 - submitted as KCP 5.2/01) summarized in dRR Part B5, and a partial validation in honey was performed in study S22-00761 (Knoll, M. 2022, submitted as KCP 7.2.1/01).

### Results and discussions

The recoveries and stability results are given in Table A 2.1.1.1.1-1.

After 149 days of storage 70% of the initial amount of boscalid in honey was determined indicating that residues are stable for at least 5 months of storage at  $-18^{\circ}\text{C}$ .

**Table A 2.1.1.1.1-1: Summary of concurrent recoveries of boscalid from honey.**

Matrix	Spike level (mg/kg)	Storage Interval (days)	Sample size (n)	Individual procedural recoveries (%)	Mean ± std dev
Boscalid					
Honey	0.10	0	2	105, 105	105
	0.10	30	2	91, 97	94 ±3
	0.10	149	2	108, 106	107 ±1

**Table A 2.1.1.1.1-2: Stability of boscalid residues in honey following storage at -18°C**

Matrix	Spike level (mg/kg)	Storage interval (days)	Individual recovered residues (mg/kg)	Individual recoveries (%)
Boscalid				
Honey	0.10	0	0.105, 0.105	105
	0.10	30	0.091, 0.097	94
	0.10	149	0.108, 0.106	107

## Conclusion

According to EC guideline 7032/VI/95, residues can be regarded as stable if the mean recovery at a given storage period does not fall below 70% of the initial value. Results from this study indicate that residues of boscalid are stable in honey for at up 149 days (5 months) of storage at  $\leq -18^{\circ}\text{C}$ .

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

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

### A 2.1.2.1 Nature of residue in plants

No additional data.

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

No additional data.

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

No additional data.

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

No additional data.

### A 2.1.2.2 Nature of residues in livestock

No additional data.

### A 2.1.3 Magnitude of residues in plants

#### A 2.1.3.1 Oilseed rape

**Table A 2.1.3.1-1: Comparison of intended and critical EU GAPs**

Type of GAP	Number of applications	Application rate per treatment (kg boscalid/ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, Germany, 2002 and EFSA, 2014)	1-2	0.25	8-12	61-69	35
Intended cGAP (number 03 and 04)	1	0.25	n.a.	57-69	35

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

#### A 2.1.3.1.1 Study 1

Comments of zRMS:	Study is accepted. The study was performed in accordance with applicable guidelines. No deficiencies were found. Trials from southern Europe were not included in the assessment.
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Reference:	KCA 6.3.2/02 and KCA 6.5.1
Report	Determination of residues of Boscalid after two applications of Boscalid 500 WG in Oilseed rape and its processed fractions at 4 sites in Northern Europe and 4 sites in Southern Europe 2022, North, L., report no. S22-01574, document no. UPL/2022/0442.
Guideline(s):	Yes (OECD 506; OECD 508; SANTE/2020/12830, rev.1 and ENV/MC/CHEM(98)17).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

#### Materials and methods

The objective of the study was to determine the residue level of boscalid in oilseed rape. Eight trials were conducted on field oilseed rape during 2022 in Northern Europe (4 NEU) and Southern Europe (4 SEU). Test sites were in United Kingdom, Germany, Poland, France (2 trials), Italy, Spain and Bulgaria. Half of the trials (4NEU and 4SEU) were performed as decline trials and half as harvest.

Oilseed rape fields were treated with two foliar applications with Boscalid 500 g/Kg WG formulation (code FGG01) at a dose rate of 250 g boscalid/ha (equivalent to 0.5 kg product/ha) and 200-400 L/ha water spray volume. The applications targeted a 14±1 day retreatment interval with the second application performed during BBCH 67-81.

Specimens consisted of oilseed rape whole plant and seed. In the decline trials, specimens were taken at 0 days after last application (DALA), at 7 DALA, 14 DALA, 21 DALA and 35 DALA, which represents the normal commercial harvest. Specimen from the harvest trials was taken at normal commercial harvest (35 DALA).

## Results and discussions

Specimens were analysed for residues of boscalid by following the validated analytical procedure developed at Eurofins AgroSciences services described in study no. S22-06799 (see study Rastogi, 2022, KCP 5.2/01 summarised in dRR Part B5). Extraction was performed with the mixture of methanol, water and hydrochloric acid (70:25:5). After cleaning, the extract was reconstituted in methanol/water (1:1). Quantification was performed by LC-MS/MS detection. Samples were stored for up to 311 days at < -18°C between sampling and extraction.

The limit of quantification (LOQ) for the analysis of boscalid in oilseed rape was 0.01 mg/kg with a limit of detection (LOD) of 0.003 mg/kg. No residues of boscalid above the limit of detection were found in any of the untreated specimens.

Overall mean recovery efficiencies for boscalid in oilseed rape within this study were within the required range of 70 – 120%. The relative standard deviation was less than 20% at all fortification levels, thus demonstrating sufficient accuracy and precision of the method in accordance with SANTE/2020/12830, rev.1. Calibration curves were established with satisfactory linearity ( $r > 0.995$ ).

Residues in treated oilseed rape samples ranged from 0.016 mg/kg to 0.25 mg/kg. Detailed results are described in Table A 2.1.3.1-2.

**Table A 2.1.3.1-2: Summary of study no. S22-01574 - 8 trials (4 NEU and 4 SEU)**

KCA 6.3.2/01

Reference:

Report Determination of residues of Boscalid after two applications of Boscalid 500 WG in Oilseed rape and its processed fractions at 4 sites in Northern Europe and 4 sites in Southern Europe 2022, North, L., report no. S22-01574, document no UPL/2022/0442

GLP: Yes Sample storage conditions: Up to 311 days; -18°C

Crop: Oilseed rape Analytical method: S22-06799, validated

Succeeding crop: - Limit of Quantification (mg/kg): 0.01 mg/kg

Indoor/Outdoor: Field Limit of Detection (mg/kg): 0.003 mg/kg

Formulation: FGG01 Residues calculated as: Boscalid

Content of active substance (g/kg or g/L):

500 g/kg

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl						
	(a)	(b)				(c)				(d)	(e)
S22-01574-01 Bickerstaffe, Lancashire, UK	Oilseed rape / Ramses	15 Aug 2021 Not applicable 15 Jul 2022	-	-	-	-	-	Whole plant	< 0.01	0	
								Seed	< 0.01	35	
			256	307	83.4	27 May 2022	79	Whole plant	2.3	0	
			260	312	83.3	10 Jun 2022		Whole plant	2.5*	0	
								Whole plant	2.4	7	
								Whole plant	2.6*	7	
								Whole plant	2.4	14	
								Whole plant	3.0*	14	
								Whole plant	1.2	21	
								Whole plant	1.2*	21	
								Whole plant	<u>0.22</u>	35	
								Seed			
S22-01574-02 Bernau,	Oilseed rape / Ludger	01 Sep 2021 05-28 May 2022	-	-	-	-	-	Whole plant	< 0.01	0	
								Seed	< 0.01	35	



								Whole plant	3.1	0	
								Whole plant	3.5*	0	
								Whole plant	2.4	7	
								Whole plant	2.0*	7	
								Whole plant	1.8	14	
								Whole plant	1.7*	14	
								Whole plant	0.84	21	
								Whole plant	0.97*	21	
								Whole plant	0.16	35	
								Seed			
S22-01574-03	Oilseed rape / Derrick	25 Aug 2021 07-27 May 2022 21 Jul 2022	-	-	-	-	-	Seed	< 0.01	36	
Obrzycko, Wielkopolskie, Poland			266 258	426 413	62.4 62.5	01 Jun 2022 15 Jun 2022	80	Seed	0.074	36	
S22-01574-04	Oilseed rape / Temptation	01 Sep 2021 01-30 Apr 2022 05 Jul 2022	-	-	-	-	-	Seed	< 0.01	35	
Sermersheim, Bas-Rhin, France			256 242	307 290	83.4 83.4	17 May 2022 31 May 2022	80	Seed	0.016	35	
S22-01574-05	Oilseed rape / Implement	19 Sep 2021 Not applicable 25 Jul 2022	-	-	-	-	-	Whole plant	<0.01	0	
Torraba de los Frailes, Aragon, Spain			303 294	303 294	83.5 83.3	06 Jun 2022 20 Jun 2022	71-75	Seed	<0.01	35	
								Whole plant	4.5	0	
								Whole plant	3.3*	0	
								Whole plant	3.8	7	
								Whole plant	0.36*	7	
								Whole plant	2.4	14	
								Whole plant	2.1*	14	
								Whole plant	2.7	21	
								Whole plant	2.7*	21	
								Whole plant	0.25	35	
								Seed			
S22-01574-06	Oilseed rape / Miranda	20 Oct 2021 16 Apr - 15 May	-	-	-	-	-	Whole plant	<0.01	0	
								Seed	<0.01	35	

			258 235	310 282	83.2 83.3	26 Apr 2022 10 May 2022	67	Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Whole plant Seed	3.6 4.7* 2.3 2.3* 1.7 1.7* 1.5 1.4* 0.22	0 0 7 7 14 14 21 21 35	
S22-01574-07	Oilseed rape / DK Immozt CL	12 Oct 2021 03-15 May 2022 13 Jul 2022	- 259 261	- 362 365	- 71.5 71.5	- 25 May 2022 08 Jun 2022	- 79	Seed Seed	<0.01 0.024	35 35	
S22-01574-08	Oilseed rape / Expacito	02 Sep 2021 Not recorded 21 Jun 2022	- 256 261	- 205 209	- 125 125	- 03 May 2022 17 May 2022	- 79-81	Seed Seed	<0.01 0.082	35 35	

- (a) According to CODEX Classification / Guide  
(b) Only if relevant  
(c) Year must be indicated  
(d) Days after last application (Label pre-harvest interval, PHI, underline)  
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included  
(\*) Retain samples

### A 2.1.3.1.2 Study 2

Comments of zRMS:	Study is accepted. The study was performed in accordance with applicable guidelines. No deficiencies were found. Trials from southern Europe were not included in the assessment.
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Reference:	KCA 6.3.2/02
Report	Determination of residues of Boscalid after two applications of Boscalid 500 WG in Oilseed rape at 4 sites in Northern Europe and 4 sites in Southern Europe 2023, North, L., report no. S23-00040, document no. UPL/2023/0503.
Guideline(s):	Yes (OECD 506; OECD 508; SANTE/2020/12830, rev.1 and ENV/MC/CHEM(98)17).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

#### Materials and methods

The objective of the study was to determine the residue level of boscalid in oilseed rape. Eight trials were conducted on field oilseed rape during 2023 in Northern Europe (4 NEU) and Southern Europe (4 SEU). Test sites were in United Kingdom, Germany, Poland, France (2 trials), Italy, Spain, and Bulgaria. Half of the trials (4NEU and 4SEU) were performed as decline trials and half as harvest.

Oilseed rape fields were treated with two foliar applications with Boscalid 500 g/Kg WG formulation (code FGG01) at a dose rate of 250 g boscalid/ha (equivalent to 0.5 kg product/ha) and 100-400 L/ha water spray volume. The applications targeted a 14±1 day retreatment interval with the second application performed during BBCH 69-80.

Specimens consisted of oilseed rape whole plant and seed. In the decline trials, specimens were taken at 0 days after last application (DALA), at 7 DALA, 14 DALA, 21 DALA and 35 DALA, which represents the normal commercial harvest. Specimen from the harvest trials was taken at normal commercial harvest (35 DALA).

#### Results and discussions

Specimens were analysed for residues of boscalid by following the validated analytical procedure developed at Eurofins AgroSciences services described in study no. S22-06799 (see study Rastogi, 2022, KCP 5.2/01 summarised in dRR Part B5). Extraction was performed with the mixture of methanol, water and hydrochloric acid (70:25:5). After cleaning, the extract was reconstituted in methanol/water (1:1). Quantification was performed by LC-MS/MS detection. Samples were stored for up to 121 days at < -18°C between sampling and extraction.

The limit of quantification (LOQ) for the analysis of boscalid in oilseed rape was 0.01 mg/kg with a limit of detection (LOD) of 0.003 mg/kg. No residues of boscalid above the limit of detection were found in any of the untreated specimens.

Overall mean recovery efficiencies for boscalid in oilseed rape within this study were within the required range of 70 – 120%. The relative standard deviation was less than 20% at all fortification levels, thus demonstrating sufficient accuracy and precision of the method in accordance with SANTE/2020/12830, rev.1. Calibration curves were established with satisfactory linearity ( $r > 0.995$ ).

Residues in treated oilseed rape samples ranged from <0.01 mg/kg (<LOQ) to 0.78 mg/kg. Detailed results are described in Table A 2.1.3.2-1.

**Table A 2.1.3.2-3: Summary of study no. S23-00040 - 8 trials (4 NEU and 4 SEU)**

KCA 6.3.2/02

Reference:

Report: Determination of residues of Boscalid after two applications of Boscalid 500 WG in Oilseed rape and its processed fractions at 4 sites in Northern Europe and 4 sites in Southern Europe 2022, North, L., report no. S22-01574, document no UPL/2022/0442

GLP: Yes Sample storage conditions: Up to 121 days; -18°C

Crop: Oilseed rape Analytical method: S22-06799, validated

Succeeding crop: - Limit of Quantification (mg/kg): 0.01 mg/kg

Indoor/Outdoor: Field Limit of Detection (mg/kg): 0.003 mg/kg

Formulation: FGG01 Residues calculated as: Boscalid

Content of active substance (g/kg or g/L):

500 g/kg

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treat- ment or no. of treatments and last date	Growth stage at last treat- ment or date	Portion analyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl						
(a)	(b)					(c)				(d)	(e)
S23-00040-01 64-530, Obrzycko, Wielkopolskie, Poland	Oilseed rape / Quincy	27 Aug 2022 Not applicable 20 Jul 2023	-	-	-	-	-	Whole plant	< 0.01	0	
								Seed	< 0.01	35	
			285	228	125	01 Jun 2023	72	Whole plant	3.3	0	
			252	201	125	15 Jun 2023	75	Whole plant	1.2	7	
								Whole plant	0.63	14	
S23-00040-02 LE651SE, Lount, Leicestershire, UK	Oilseed rape / Campus	06 Sep 2022 15 Apr – 22 May 2023 21 Jul 2023	-	-	-	-	-	Whole plant	< 0.01	0	
								Seed	< 0.01	35	
			240	192	125	02 Jun 2023	71-73	Whole plant	4.6	0	
			242	193	125	16 Jun 2023	79-80	Whole plant	0.74	7	
								Whole plant	0.90	14	
								Whole plant	0.78	21	
								Seed	0.041	35	

S23-00040-03 45390 Aulney-la-Rivière, Loiret, Northern France	Oilseed rape / LF Aviron	16 Aug 2022 03 Apr – 12 May 2023 28 Jun 2023	-	-	-	-	-	Seed	< 0.01	28	
			253 246	202 196	125 125	17 May 2023 31 May 2023	72 78	Seed	<u>0.012</u>	28	
S23-00040-04 21784, Geversdorf, Niedersachsen, Germany	Oilseed rape / PT 303	22 Aug 2022 Not available 02 Aug 2023	-	-	-	-	-	Seed	< 0.01	28	
			248 244	297 293	83 83	12 Jun 2023 26 Jun 2023	79 79	Seed	<LOQ	28	
S23-00040-05 40057, Granarolo dell'Emilia Emilia Romagna, Italy	Oilseed rape / Expectation (DEKALB)	20 Sep 2022 05-24 Apr 12 Jun 2023	-	-	-	-	-	Whole plant	<0.01	0	
			-	-	-	-	-	Seed	<0.01	35	
			271 240	325 288	83 83	24 Apr 2023 08 May 2023	69 75	Whole plant	3.0	0	
								Whole plant	0.46	7	
								Whole plant	0.26	14	
S23-00040-06 82-290, La Ville Dieu du Tem- ple, Tarn et Garonne, Southern France	Oilseed rape / DK expacito	15 Sep 2022 Not applicable 28 Jun 2023	-	-	-	-	-	Whole plant	<0.01	0	
			-	-	-	-	-	Seed	<0.01	35	
			257 254	205 203	125 125	11 May 2023 25 May 2023	71 80	Whole plant	7.0	0	
								Whole plant	4.6	7	
								Whole plant	6.5	14	
S23-00040-07 44492, Allueva, Aragon, Spain	Oilseed rape / click CL	20 Feb 2023 Not applicable 15 Aug 2023	-	-	-	-	-	Seed	<0.01	35	
			271 254	325 325	83 83	27 Jun 2023 11 Jul 2023	67 75	Seed	<u>0.78</u>	35	
S23-00040-08 2068, Polyantsi, Sofia, Bulgaria	Oilseed rape / DK immortal CL	16 Aug 2022 03 Apr – 12 May 2023 28 Jun 2023	-	-	-	-	-	Seed	<0.01	35	
			247 227	346 360	71 71	02 Jun 2023 16 Jun 2023	67 71 75	Seed	<u>0.069</u>	35	

- (a) According to CODEX Classification / Guide
- (b) Only if relevant
- (c) Year must be indicated
- (d) Days after last application (Label pre-harvest interval, PHI, underline)
- (e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
- (\*) Retain samples

### A 2.1.3.2 Beans with pods

**Table A 3: Comparison of intended and critical EU GAPs**

Type of GAP	Number of applications	Application rate per treatment (kg boscalid/ha)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, Germany, 2002 and EFSA, 2014)	2	0.500	7-15	60-69	7
Intended cGAP (number 05 and 06)	2	0.500	7	60-69	7

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

#### A 2.1.3.2.1 Study 1

Comments of zRMS:	Study is accepted The study was performed in accordance with applicable guidelines. No deficiencies were found. Trials from southern Europe were not included in the assessment.
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Reference:	KCA 6.3.2/01
Report	Determination of residues of Boscalid after two applications of Boscalid 500 WG in Beans with pods at 3 sites in Northern Europe and 4 sites in Southern Europe 2022, North, L., report no. S22-01575, document no. UPL/2022/0403.
Guideline(s):	Yes (OECD 506; OECD 508; SANTE/2020/12830, rev.1 and ENV/MC/CHEM(98)17).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

### Materials and methods

The objective of the study was to determine the residue level of boscalid in beans with pods. Seven trials were conducted on beans with pods field during 2022 in Northern Europe (3 NEU) and Southern Europe (4 SEU). Test sites were in United Kingdom, Germany, France (2 trials), Italy, Spain and Bulgaria. Four trials (2 NEU and 2 SEU) were performed as decline trials and three as harvest.

Beans fields were treated with two foliar applications with Boscalid 500 g/Kg WG formulation (code FGG01) at a dose rate of 500 g boscalid/ha (equivalent to 1 kg product/ha) and 150-600 L/ha water spray volume. The applications targeted a 7±1 day retreatment interval with the second application performed during BBCH 65-87.

Specimens consisted of beans whole plant, beans and rest of the plant. In the decline trials, specimens were taken at 0 days after last application (DALA), at 1 DALA, 3 DALA, 5 DALA and 7 DALA, which represents the normal commercial harvest. Specimen from the harvest trials was taken at normal commercial harvest (7 DALA).

## Results and discussions

Specimens were analysed for residues of boscalid by following the validated analytical procedure developed at Eurofins AgroSciences services described in study no. S22-06799 (see study Rastogi, 2022, KCP 5.2/01 summarised in dRR Part B5). Extraction was performed with the mixture of methanol, water and hydrochloric acid (70:25:5). After cleaning, the extract was reconstituted in methanol/water (1:1). Quantification was performed by LC-MS/MS detection. Samples were stored for up to 264 days at < -18°C between sampling and extraction.

The limit of quantification (LOQ) for the analysis of boscalid in beans was 0.01 mg/kg with a limit of detection (LOD) of 0.003 mg/kg. No residues of boscalid above the limit of detection were found in any of the untreated specimens.

Overall mean recovery efficiencies for boscalid in beans with pods within this study were within the required range of 70 – 120%. The relative standard deviation was less than 20% at all fortification levels, thus demonstrating sufficient accuracy and precision of the method in accordance with SANTE/2020/12830, rev.1. Calibration curves were established with satisfactory linearity ( $r > 0.995$ ).

Residues in treated beans samples ranged from 0.28 mg/kg to 2 mg/kg. Detailed results are described in Table A 2.1.3.2-2.



**Table A 2.1.3.2-2: Summary of study no. S22-01575 - 7 trials (4 NEU and 4 SEU)**

Reference: KCP 7.2.3.4/01  
Report: Determination of residues of Boscalid after two applications of Boscalid 500 WG in Beans with pods at 3 sites in Northern Europe and 4 sites in Southern Europe 2022, North, L., report no. S22-01575, document no UPL/2022/0403  
GLP: Yes Sample storage conditions: Up to 264 days; -18°C  
Crop: Beans with pods Analytical method: S22-06799, validated  
Succeeding crop: - Limit of Quantification (mg/kg): 0.01 mg/kg  
Indoor/Outdoor: Field Limit of Detection (mg/kg): 0.003 mg/kg  
Formulation: FGG01 Residues calculated as: Boscalid  
Content of active substance (g/kg or g/L): 500

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treat- ments and last date	Growth stage at last treatment or date	Portion ana- lyzed	Residues (mg/kg)	PHI (days)	Details on trial
			g a.s./ ha	Water (l/ha)	g a.s./hl						
(a)	(b)					(c)				(d)	(e)
S22-01575-01  Lampertheim, Hessen, Germany	Beans with pods / Bentley	15 Jun 2022 10 Aug – 01 Sep 2022 06 Sep 2022	-	-	-	-	-	Whole plant Bean	< 0.01 < 0.01	0 7	
			467	373	125	23 Aug 2022	65-75	Whole plant	23	0	
			521	417	125	30 Aug 2022	69-85	Whole plant	6.6	1	
								Whole plant	7.3	3	
								Whole plant	5.1	5	
								Bean	<u>0.61</u>	7	
								Rest of plant	11	7	
S22-01575-02  91660 Mereville, Essonne, France	Beans with pods / Montcalm	25 May 2022 05-26 Jul 2022 26 Jul 2022	-	-	-	-	-	Whole plant Bean	< 0.01 < 0.01	7 7	
			531	212	250	12 Jul 2022	65-71	Whole plant	94	0	
			517	207	250	19 Jul 2022	65-73	Whole plant	50	1	
								Whole plant	18	3	
								Whole plant	20	5	
								Bean	0.35	7	
								Bean*	<u>0.19*</u>	7	
								Rest of plant	21	7	
S22-01575-03	Beans with	29 Apr 2022	-	-	-	-	-	Whole plant	< 0.01	7	

DE738DG, Melbourne, Derbyshire, UK	pods / Hodesto	Na.. 09 Aug 2022						Bean	< 0.01	7	
			546 533	218 213	250 250	26 Jul 2022 02 Aug 2022	85-87 87	Bean Bean* Rest of plant Rest of plant*	2.0 2.1* 40 19	7 7 7 7	
S22 01575 05 82100 Castelsarrasin, Tarn et Garonne, France	Beans with pods / Compass	13 Jun 2022 n.a. 23 Aug 2022	-	-	-	-	-	Whole plant Bean	< 0.01 < 0.01	7 7	
			499 518	200 207	250 250	09 Aug 2022 16 Aug 2022	65 67-72	Whole plant Whole plant Whole plant Whole plant Bean Bean* Rest of plant Rest of plant*	37 16 17 14 0.55 0.39* 18 8.4*	0 1 3 5 7 7 7 7	
S22 01575 06 4018 Faenza, Emilia-romagna, Italy	Beans with pods / Borlotti	15 Jul 2022 20-31 Aug 2022 26 Sep 2022	-	-	-	-	-	Whole plant Bean	< 0.01 < 0.01	7 7	
			533 514	320 308	167 167	12 Sep 2022 19 Sep 2022	71 73	Whole plant Whole plant Whole plant Whole plant Bean Rest of plant	11 9.5 6.3 5.9 0.38 7.4	0 1 3 5 7 7	
S22 01575 07 111160, Barbate, Andalu- cia, Spain	Beans with pods / Prime	10 Aug 2022 n.a. 25 Oct 2022	-	-	-	-	-	Whole plant Bean	< 0.01 < 0.01	7 7	
			458 514	458 514	100 100	11 Oct 2022 18 Oct 2022	69-71 67-77	Bean Rest of plant	0.28 30	7 7	
S22 01575 08 5570, Lennitsa, Lovech Bulgaria	Beans with pods / Gina	16 May 2022 20 Jun - 05 Jul 2022 28 Jul 2022	-	-	-	-	-	Whole plant Bean	< 0.01 < 0.01	7 7	
			533 504	427 403	125 125	14 Jul 2022 21 Jul 2022	77 84	Bean Rest of plant	1.5 44	7 7	

- (a) According to CODEX Classification / Guide  
(b) Only if relevant  
(c) Year must be indicated

- (d) Days after last application (Label pre-harvest interval, PHI, underline)  
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included  
(\*) Retain samples

### A 2.1.3.2.2 Study 2

Comments of zRMS:	Study is accepted
	The study was performed in accordance with applicable guidelines. No deficiencies were found. Trials from southern Europe were not included in the assessment.

Reference:	KCA 6.3.2/02
Report	Determination of residues of Boscalid after two applications of Boscalid 500 WG in Beans with pods at 5 sites in Northern Europe and 4 sites in Southern Europe 2023, North, L., report no. S23-00041, document no. UPL/2023/0507.
Guideline(s):	Yes (OECD 506; OECD 508; SANTE/2020/12830, rev.1 and ENV/MC/CHEM(98)17).
Deviations:	No
GLP:	Yes
Acceptability:	Yes

#### Materials and methods

The objective of the study was to determine the residue level of boscalid in beans with pods. Nine trials were conducted on beans with pods field during 2023 in Northern Europe (5 NEU) and Southern Europe (4 SEU). Test sites were in United Kingdom, Poland (2 trials), Germany, France (2 trials), Italy, Spain and Bulgaria. Three trials (1 NEU and 2 SEU) were performed as decline trials and five as harvest.

Beans fields were treated with two foliar applications with Boscalid 500 g/Kg WG formulation (code FGG01) at a dose rate of 500 g boscalid/ha (equivalent to 1 kg product/ha) and 150-600 L/ha water spray volume. The applications targeted a 7±1 day retreatment interval with the second application performed during BBCH 65-87.

Specimens consisted of beans whole plant, beans and rest of the plant. In the decline trials, specimens were taken at 0 days after last application (DALA), at 1 DALA, 3 DALA, 5 DALA and 7 DALA, which represents the normal commercial harvest. Specimen from the harvest trials was taken at normal commercial harvest (7 DALA).

#### Results and discussions

Specimens were analysed for residues of boscalid by following the validated analytical procedure developed at Eurofins AgroSciences services described in study no. S22-06799 (see study Rastogi, 2022, KCP 5.2/01 summarised in dRR Part B5). Extraction was performed with the mixture of methanol, water and hydrochloric acid (70:25:5). After cleaning, the extract was reconstituted in methanol/water (1:1). Quantification was performed by LC-MS/MS detection. Samples were stored for up to 156 days at < -18°C between sampling and extraction.

The limit of quantification (LOQ) for the analysis of boscalid in beans was 0.01 mg/kg with a limit of detection (LOD) of 0.003 mg/kg. No residues of boscalid above the limit of detection were found in any of the untreated specimens.

Overall mean recovery efficiencies for boscalid in beans with pods within this study were within the required range of 70 – 120%. The relative standard deviation was less than 20% at all fortification levels, thus demonstrating sufficient accuracy and precision of the method in accordance with SANTE/2020/12830, rev.1. Calibration curves were established with satisfactory linearity ( $r > 0.995$ ).

Residues in treated beans samples ranged from 0.25 mg/kg to 1.4 mg/kg. Detailed results are described in

Table A 2.1.3.2-3.

**Table A 2.1.3.2-3: Summary of study no. S23-00041 - 9 trials (5 NEU and 4 SEU)**

Reference: KCA 6.3.3/02  
Report: Determination of residues of Boscalid after two applications of Boscalid 500 WG in Beans with pods at 5 sites in Northern Europe and 4 sites in Southern Europe 2023, North, L., report no. S23-00041, document no UPL/2023/0507  
GLP: Yes Sample storage conditions: Up to 156 days; -18°C  
Crop: Beans with pods Analytical method: S22-06799, validated  
Succeeding crop: - Limit of Quantification (mg/kg): 0.01 mg/kg  
Indoor/Outdoor: Field Limit of Detection (mg/kg): 0.003 mg/kg  
Formulation: FGG01 Residues calculated as: Boscalid  
Content of active substance (g/kg or g/L): 500

Trial No./ Location/ EU zone/ Year	Commodity/ Variety  (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest  (b)	Application rate per treatment			Dates of treatment or no. of treat- ments and last date  (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days)  (d)	Details on trial  (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl						
S23-00041-01  Lampertheim, Hessen, Germany	Beans with pods / Bentley	06 Apr 2023 10-20 Jun 2023 03 Jul 2023	-	-	-	-	-	Whole plant Bean	< 0.01 < 0.01	0 7	
			527	422	125	19 Jun 2023	69	Whole plant	15	0	
			515	412	125	26 Jun 2023	71-73	Whole plant	6.2	1	
								Whole plant	4.1	3	
								Whole plant	3.6	5	
								Bean	<u>0.25</u>	7	
								Rest of plant	15	7	
S23-00041-02  64514 Przekaw, Wiellcopolskie, Poland	Beans with pods / Unidor	05 Jun 2023 Not applicable 24 Aug 2023	-	-	-	-	-	Whole plant Bean	< 0.01 < 0.01	7 7	
			490	196	250	10 Aug 2023	79	Whole plant	19	0	
			503	201	250	17 Aug 2023	81	Whole plant	14	1	
								Whole plant	12	3	
								Whole plant	12	5	
								Bean	<u>0.76</u>	7	
								Rest of plant	37	7	

S23-00041-04 28140, Dambron, Eure et Loire, France	Beans with pods / Flagrano	09 Jun 2023 17 Jul-10 Aug 2023 14 Aug 2023	-	-	-	-	-	Whole plant	< 0.01	7	
			461 510	277 306	166 167	31 Jul 2023 07 Aug 2023	62-65 67-72	Bean Rest of plant	<u>0.26</u> 8.0	7 7	
S23-00041-05 62-110, Damaslawek, Wiellcopololair, Poland	Beans with pods / Eureka	17 May 2023 Not applicable 02 Aug 2023	-	-	-	-	-	Whole plant	< 0.01	7	
			509 507	204 203	250 250	19 Jul 2023 26 Jul 2023	75 77	Bean Rest of plant	0.36 <u>3.6</u>	7 7	
S23-00041-06 31360, Fumes, Castilla y Leon, Spain	Beans with pods / Stanley	27 Jul 2023 Not applicable 04 Oct 2023	-	-	-	-	-	Whole plant	< 0.01	7	
			513 519	308 311	167 167	09 Aug 2022 16 Aug 2022	71-73 73-75	Whole plant	14	0	
								Whole plant	13	1	
								Whole plant	5.4	3	
								Whole plant	3.3	5	
								Bean	<u>0.23</u>	7	
S23-00041-07 4018 Faenzaza, Emilia romagna, Italy	Beans with pods / Gioli	15 Jul 2023 20-30 Aug 2023 03 Oct 2023	-	-	-	-	-	Rest of plant	6.2	7	
			522 517	313 310	167 167	09 Aug 2022 16 Aug 2022	73 73-75	Whole plant	< 0.01	7	
								Bean	< 0.01	7	
								Whole plant	11	0	
								Whole plant	9.5	1	
								Whole plant	6.3	3	
S23-00041-08 82400, Espalais, Tarn et Garonne, France	Beans with pods / Compass	01 Jun 2023 Not available 09 Aug 2023	-	-	-	-	-	Whole plant	5.9	5	
								Whole plant	<u>0.38</u>	7	
								Rest of plant	7.4	7	
			508 521	203 208	250 250	26 Jul 2023 02 Aug 2023	61-73 61-77	Whole plant	< 0.01	7	
								Bean	< 0.01	7	
								Rest of plant	<u>0.89</u> 37	7 7	

S23-00041-09 5570, Lennitsa, Lovech Bulgaria	Beans with pods / Gina	28 Apr 2023	-	-	-	-	-	Whole plant	< 0.01	7	
		10 Jun 01 Jul 2023	-	-	-	-	-	Bean	< 0.01	7	
		04 Aug 2023	521 517	365 362	143 143	21 Jul 2023 28 Jul 2023	77 78	Bean	1.4 79	7 7	
								Rest of plant			
S23-00041-10 WR6 5JX, Worcester, Worcestershire, UK	Beans with pods / Venice	01 Jul 2023	-	-	-	-	-	Whole plant	< 0.01	7	
		Not applicable 28 Sep 2023	-	-	-	-	-	Bean	< 0.01	7	
			456 486	273 292	167 166	14 Sep 2023 21 Sep 2023	79 79	Bean	0.28	7	
								Rest of plant	5.0	7	

- (a) According to CODEX Classification / Guide  
(b) Only if relevant  
(c) Year must be indicated

- (d) Days after last application (Label pre-harvest interval, PHI, underline)  
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included  
(\*) Retain samples

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

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

No additional data.

## **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 additional data.

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

#### **A 2.1.5.2.1 . Study 1**

Comments of zRMS:	Study is accepted
	The study was performed in accordance with applicable guidelines. No deficiencies were found. Trials from southern Europe were not included in the assessment.

Reference: KCA 6.3.2/02 and KCA 6.5.1

Report Determination of residues of Boscalid after two applications of Boscalid 500 WG in Oilseed rape and its processed fractions at 4 sites in Northern Europe and 4 sites in Southern Europe 2022, North, L., report no. S22-01574, document no. UPL/2022/0442.

Guideline(s): Yes (OECD 506; OECD 508; SANTE/2020/12830, rev.1 and ENV/MC/CHEM(98)17).

Deviations: No

GLP: Yes

Acceptability: Yes

### **Materials and methods**

The objective of the study was to determine the residue level of boscalid in processing fractions of oilseed rape. Two trials were conducted on oilseed rape during 2022 in Northern Europe (Germany) and Southern Europe (North-France).

Oilseed rape fields were treated with two foliar applications with Boscalid 500 g/Kg WG formulation (code FGG01) at a dose rate of 1250 g boscalid/ha (equivalent to 5N dose) and 200-400 L/ha water spray volume. The applications targeted a 14±1 day retreatment interval with the second application performed during BBCH 67-81. Specimen was taken at normal commercial harvest (35 DALA) and processed into raw oil, press cake and crude oil.



## Results and discussions

Specimens were analysed for residues of boscalid by following the validated analytical procedure developed at Eurofins AgroSciences services described in study no. S22-06799 (see study Rastogi, 2022, KCP 5.2/01 summarised in dRR Part B5). Extraction was performed with the mixture of methanol, water and hydrochloric acid (70:25:5). After cleaning, the extract was reconstituted in methanol/water (1:1). Quantification was performed by LC-MS/MS detection. Samples were stored for up to 273 days at < -18°C between sampling and extraction.

The limit of quantification (LOQ) for the analysis of boscalid in oilseed rape was 0.01 mg/kg with a limit of detection (LOD) of 0.003 mg/kg. No residues of boscalid above the limit of detection were found in any of the untreated specimens .

Overall mean recovery efficiencies for boscalid in oilseed rape within this study were within the required range of 70 – 120%. The relative standard deviation was less than 20% at all fortification levels, thus demonstrating sufficient accuracy and precision of the method in accordance with SANTE/2020/12830, rev.1. Calibration curves were established with satisfactory linearity ( $r > 0.995$ ).

The same levels of boscalid residue in processed commodities was found in the raw agricultural commodity, generating a processing factor of 1.0 for raw and crude oil. Detailed results are described in Table A 2.1.5.2.1-1.

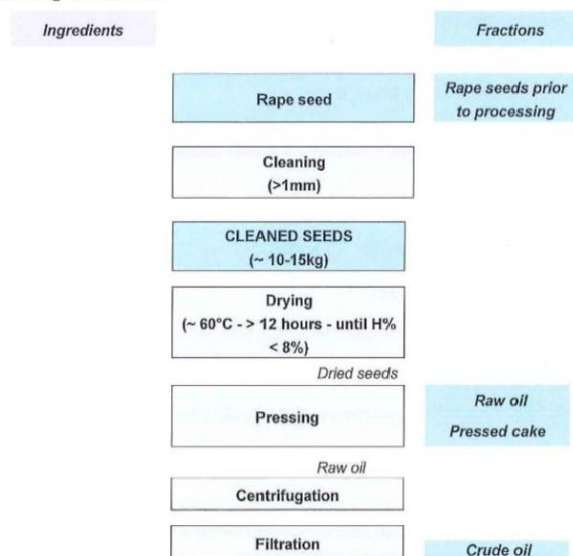
**Table A 4: Residue data from Oilseed rape processing study with boscalid**

RAC	Residues in RAC (unwashed sample, mg/kg)	PHI (days)	Processed commodity	Residue (mg/kg)	PF*	Comments/Reference
Oilseed rape	2.4	35	Raw oil Press cake Crude oil	2.5 0.23 2.3	1.0 0.10 0.96	-
	1.4	35	Raw oil Press cake Crude oil	1.6 0.24 1.4	1.1 0.17 1.0	-

\* processing factor

**Figure A 1: Processing flowchart for crude oil**

### 6.2. Processing to crude oil



## Conclusion

No specific processing factor was determined for the processing of oil seed rape into oil, since the same levels of boscalid residues in processed products (raw and crude oil) was found in the raw agricultural product. No specific processing factors were used for dietary exposure assessments and no specific MRL was derived for oil.

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

No additional data.

### A 2.1.7 Other/Special Studies

#### A 2.1.7.1 Study 1

Comments of zRMS:	Study is accepted
	The study was performed in accordance with applicable guidelines. No deficiencies were found

Reference:	KCA 6.10
Report	Boscalid 500 WG: Determination of residues of boscalid in honey after two applications in winter oilseed rape at four sites in Northern and Southern Europe in 2022, Knoll M., 2022, report no. S22-00761, document no. UPL/2022/0377
Guideline(s):	Yes (OECD 509 (published in June 2021 and SANTE/2020/12830, rev.1)
Deviations:	Yes (without impact)
GLP:	Yes
Acceptability:	Yes

## Materials and methods

The objective of the study was to determine the residue level of boscalid in honey. Four trials were conducted on protected oilseed rape during 2022 in Northern Europe (2 NEU) and Southern Europe (2 SEU). Test sites were in Germany and Spain.

Protected oilseed rape was treated with two foliar applications with Boscalid 500 g/Kg WG formulation (code FGG01) at a dose rate of 500 g boscalid/ha (equivalent to 1 kg product/ha) and nominal 300 L/ha water spray volume. The applications targeted a 7±1 day retreatment interval with the second application performed during the flowering period (BBCH 60-69).

## Results and discussions

Specimens were analysed for residues of boscalid by following the validated analytical procedure developed at Eurofins AgroSciences services described in study no. S22-00776 (see study Sahvorost, 2022, KCP 5.2/01 summarised in dRR Part B5). Extraction was performed with acetonitrile, after addition of water. Cleaning was performed by dispersive SPE with primary/secondary amine (PSA), the extract was reconstituted in methanol/water (1:1) with 0.5% formic acid. Quantification was performed by LC-MS/MS detection. Samples were stored for up to 19 days at < -18°C between sampling and extraction.

The limit of quantification (LOQ) for the analysis of boscalid in honey was 0.01 mg/kg. No residues of boscalid above the limit of detection were found in any of the untreated specimens.

Overall mean recovery efficiencies for boscalid in honey within this study were within the required range of 70 – 120%. The relative standard deviation was less than 20% at all fortification levels, thus demonstrating sufficient accuracy and precision of the method in accordance with SANTE/2020/12830, rev.1. Calibration curves were established with satisfactory linearity ( $r > 0.995$ ).

Residues in treated honey samples ranged from  $< 0.01$  mg/kg to 0.0455 mg/kg. Detailed results are described in Table A 2.1.7.1-1.

**Table A 2.1.7.1-1: Summary of study no. S22-00761 - 4 trials (2 NEU and 2 SEU)**

KCP 7.2.7/01

Reference:

Report Boscalid 500 WG: Determination of residues of boscalid in honey after two applications in winter oilseed rape at four sites in Northern and Southern Europe in 2022, Knoll M., 2022, report no. S22-00761, document no. UPL/2022/0377

GLP: Yes Sample storage conditions: Up to 19 days; -18°C  
Crop: Honey\* Analytical method: S22-00776, validated  
Succeeding crop: - Limit of Quantification (mg/kg): 0.01 mg/kg  
Indoor/Outdoor: Protected – DE and ES Limit of Detection (mg/kg): 0.003 mg/kg  
Formulation: FGG01 Residues calculated as: Boscalid  
Content of active substance (g/kg or g/L): 500 g/kg

Location including Postal Code	Commodity / Variety (a)	Date of Sowing or Planting (b)	Application rate per treatment		Dates of treatment (c)	Growth stage at Application (A) and at Sampling		Portion analysed	Residues (mg/kg)	PHI Days (d)	Details on trial (e)
			g a.s./ha	water (L/ha)		A	S		Boscalid		
Eggenstein-Leopoldshafen, Baden-Württemberg, 76344 Germany	Honey*	08 Sep 2021	--	--	Untreated	-	65	Honey*	<0.01	n.a.	Analytical procedure S22-00776
			488.5	293.1	Treated	63	65	Honey*	0.0273	3 DALA	
			505.4	303.2	A1= 13 April 2022 A2= 19 April 2022	63	65	Honey*	0.0273	3 DALA	
Pforzheim, Baden-Württemberg, 75177 Germany	Honey*	07 Sep 2021	--	--	Untreated	-	67	Honey*	<0.01	n.a.	Analytical procedure S22-00776
			495.3	297.2	Treated	63	67	Honey*	0.0455	8 DALA	
			492.4	295.4	A1= 19 April 2022 A2= 27 April 2022	63	67	Honey*	0.0455	8 DALA	
Valdeganga, Cestille le Maniche 02150 Spain	Honey*	24 Sep 2021	--	--	Untreated	-	69	Honey*	<0.01	n.a.	Analytical procedure S22-00776
			486.5	291.9	Treated	63	69	Honey*	0.0133	27 DALA	
			471.0	282.6	A1= 07 Apr 2022 A2= 14 Apr 2022	64-65	69	Honey*	0.0133	27 DALA	
Almansa, Albacete, 02640	Honey*	27 Oct 2021	--	--	Untreated	-	68-69	Honey*	<0.01	n.a.	Analytical procedure S22-00776

Spain			499.3 502.4	299.6 301.4	Treated A1= 15 Apr 2022 A2= 21 Apr 2022	66-70 62-73	68-69	Honey*	<0.01	21 DALA	
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DALA = Days After Last Application to the Treated Plot

\* The honey was produced by bees with access to a flowering OSR crop only

n.a.: not applicable. Untreated and treated plots samples were collected at the same day

The limit of quantification (LOQ) was 0.01 mg/kg for the analyte.


Sample residues below the validated LOQ are reported as <0.01 mg/kg. All other residues are reported to 4 decimal place.

## **Conclusion**

Residues of boscalid found in honey ranged from < 0.01 to 0.0455 mg/kg from bees that visit treated oilseed rape fields after being treated with FGG01 according to the intended GAP table. The new data was input into the MRL calculator and the calculated EU MRL was 0.1 mg/kg, indicating that no exceedance of the MRL on honey (0.15 mg/kg – Reg (EU) no. 2021/590) will occur after the application of the plant protection product FGG01.

## Appendix 3 Pesticide Residue Intake Model (PRIMo)

### A 3.1 TMDI calculations

 European Food Safety Authority EFSA PRIMo revision 3.1; 2021/01/06			<b>Boscalid</b>			Input values					
			LOG <sub>10</sub> (mg/kg) range from: <b>0.01</b> to: <b>0.01</b>								
			<b>Toxicological reference values</b>					Details - chronic risk assessment		Supplementary results - chronic risk assessment	
			ADI (mg/kg bw/day): <b>0.04</b>			ARfD (mg/kg bw): <b>not necessary</b>			Details - acute risk assessment/children		Details - acute risk assessment/adults
Source of ADI: <b>08/44/EC</b>			Source of ARfD: <b>08/44/EC</b>								
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/IEDI calculation (based on average food consumption)	71%	NL toddler	28.21	11%	Apples	10%	Spinaches	5%	Table grapes	0.0%	
	50%	DE child	19.31	13%	Apples	5%	Table grapes	3%	Spinaches	0.0%	
	37%	NL child	14.34	6%	Apples	4%	Table grapes	4%	Spinaches	0.0%	
	36%	GEMS/Food G08	14.59	4%	Wine grapes	3%	Onions	3%	Potatoes		
	35%	GEMS/Food G06	14.07	5%	Onions	4%	Table grapes	4%	Tomatoes		
	35%	GEMS/Food G10	13.89	5%	Lettuces	4%	Onions	2%	Potatoes		
	35%	GEMS/Food G07	13.83	5%	Wine grapes	3%	Lettuces	3%	Potatoes		
	34%	IE adult	13.74	4%	Wine grapes	3%	Sweet potatoes	2%	Potatoes	0.0%	
	33%	GEMS/Food G15	13.23	4%	Wine grapes	3%	Onions	3%	Potatoes		
	33%	GEMS/Food G11	13.16	4%	Wine grapes	3%	Potatoes	2%	Barley		
	30%	SE general	12.01	6%	Lettuces	3%	Potatoes	3%	Onions	0.0%	
	30%	RO general	11.87	6%	Wine grapes	5%	Onions	4%	Head cabbages	0.0%	
	27%	PT general	10.82	3%	Wine grapes	4%	Potatoes	2%	Onions		
	25%	FR child 3-15 yr	9.35	2%	Wheat	2%	Apples	2%	Other lettuce and other salad plants	0.0%	
	23%	NL general	9.33	2%	Spinaches	2%	Wine grapes	2%	Potatoes	0.0%	
	23%	DK child	9.35	3%	Cucumbers	2%	Apples	2%	Rye	0.0%	
	23%	FR toddler 2-3 yr	9.25	3%	Apples	2%	Spinaches	2%	Leeks	0.0%	
	22%	IT adult	8.93	5%	Lettuces	2%	Other lettuce and other salad plants	2%	Wheat		
	22%	FR adult	8.74	8%	Wine grapes	2%	Other lettuce and other salad plants	0.3%	Wheat	0.0%	
	22%	ES adult	8.72	7%	Lettuces	1%	Wine grapes	1%	Barley	0.0%	
	21%	DE general	8.53	3%	Wine grapes	3%	Apples	1%	Barley	0.0%	
	21%	DE women 14-50 yr	8.53	3%	Wine grapes	3%	Apples	2%	Lettuces	0.0%	
	21%	IT toddler	8.50	4%	Lettuces	3%	Wheat	2%	Other lettuce and other salad plants		
	21%	FI 3 yr	8.31	4%	Potatoes	2%	Onions	2%	Cucumbers		
	21%	ES child	8.30	6%	Lettuces	2%	Wheat	1%	Potatoes	0.0%	
	18%	FR infant	7.24	4%	Spinaches	2%	Apples	2%	Leeks	0.0%	
	18%	UK infant	7.08	3%	Potatoes	2%	Milk: Cattle	2%	Apples	0.0%	
	18%	UK toddler	7.01	3%	Potatoes	2%	Apples	2%	Wheat	0.0%	
	16%	FI 6 yr	6.48	3%	Potatoes	2%	Onions	1%	Strawberries		
	15%	UK vegetarian	6.00	3%	Wine grapes	2%	Lettuces	1%	Onions	0.0%	
14%	PL general	5.65	3%	Potatoes	2%	Apples	2%	Onions			
13%	DK adult	5.34	3%	Wine grapes	1%	Lettuces	1%	Apples	0.0%		
13%	UK adult	5.23	4%	Wine grapes	2%	Lettuces	1%	Potatoes	0.0%		
11%	FI adult	4.31	2%	Lettuces	1%	Wine grapes	0.3%	Potatoes			
11%	LT adult	4.28	2%	Potatoes	2%	Apples	1%	Head cabbages	0.0%		
4%	IE child	1.57	0.5%	Wheat	0.5%	Potatoes	0.3%	Apples	0.0%		
<b>Conclusions:</b> The estimated long-term dietary intake (TMDI/IEDI/IEDI) was below the ADI. The long-term intake of residues of Boscalid is unlikely to present a public health concern. DISCLAIMER: Dietary data from the UK were included in PRIMo when the UK was a member of the European Union.											

### **A 3.2 IEDI calculations**

IEDI was not calculated for boscalid since the TMDI does not exceed 100% of the ADI.

### **A 3.3 IESTI calculations - Raw commodities**

IESTI was not calculated for boscalid since no ARfD has been set.

### **A 3.4 IESTI calculations - Processed commodities**

IESTI was not calculated for boscalid since no ARfD has been set.



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

No additional information