

FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: BSK-FUN 500 SC

Product name(s): -

Chemical active substance:

boscalid, 500 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant:

Pestila Sp. z o. o. and ProAgri International Sp. z o. o.

Submission date: April 2024, update August 2024

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Version history

When	What
August 2024	Additional data provided by the Applicant
October 2024	ZRMS assessment
February 2025	The final Registration Report.
June 2025	Corrections made after the commenting period.

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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 wheat and oilseed rape matrices. The boscalid is stable for a period of 5 months storage at $\leq -18^{\circ}\text{C}$ in the dark in wheat (whole plant, straw and grain) and oilseed rape (whole plant, pods and seeds)

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

Winter wheat, triticale, barley, rye;
spring wheat, triticale, barley

Proposed GAP:

1 application, BBCH 30-49, 350 g as/ha, PHI: 56 days

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

Trials GAP (wheat): 1x 0.35 kg as/ha, BBCH 30-49, PHI 56d, outdoor

Residues: 0.0065, 0.0075, 0.0421, 0.0498, 0.0501, 0.0562, 0.0626, 0.0731 mg/kg (2 x <0.01, 0.04, 2 x 0.05, 2 x 0.06, 0.07 mg/kg)

Sufficient trials are available to support the proposed use on wheat.

According to SANTE/2019/12752 Rev.01 extrapolation from wheat to triticale, barley and rye is possible before forming the edible part.

The data submitted show that no exceedance of the EU MRLs for wheat, triticale, barley and rye will occur.

Winter oilseed rape

Proposed GAP:

2 applications; BBCH Autumn - BBCH 13-18 Spring - BBCH 31-57; 100 - 250 g as/ha, PHI: n/a
one in autumn, one in spring (30 days interval) or 2 in spring (14 days interval)

2 applications; BBCH 57-71 (spring, 14 days interval); 100 - 250 g as/ha, PHI: n/a

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

Trials GAP: 2 x 0.25 kg as/ha, BBCH 57-71, PHI NA, outdoor

2x< 0.002, 0.0071, 0.0144, 0.0182, 0.0253, 0.0532, 0.1070 mg/kg (3 x<0.01, 0.01, 0.02, 0.03, 0.05, 0.11 mg/kg)

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.

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. 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

Four new semi-field/tunnel studies in N-EU zone (Poland and N-France) and S-EU zone (S-France and Italy) in 2023-2024 have been performed on *Phacelia tanacetifolia* to investigate the magnitude of boscalid residues in honey. These trials consider a “worst case” situation (the most critical scenario was used on Phacelia plants representing a worst case in terms of residues in honey). All results are \leq LOQ, which is below MRL. The results are acceptable. No risk for consumers is expected.

Consumer risk assessment

The proposed uses of boscalid in the formulation BSK-FUN 500 SC do not represent unacceptable chronic

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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 BSK-FUN 500 SC are presented in Table 7.1-1. A list of all intended uses is given in Part B, Section 0.

Overall conclusion

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

The chronic intakes of boscalid residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, authority agrees with the authorization of the intended uses.

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

Data gaps

None

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Table 7.1-1: Intended uses (GAP)

1	2	3	4	5	6	7	8	10	11	12	13	14	
Use- No.	Member state(s)	Crop and/ or situation (crop desti- nation / pur- pose of crop)	F G 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. safener/syn- ergist per ha e.g. recom- mended or man- datory tank mix- tures	
					Method / Kind	Timing / Growth stage of crop & sea- son	Max. number (min. interval between appli- cations) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	Poland	Winter wheat	F	Septoria leaf blotch (<i>Zymoseptoria tritici</i>) SEPTTR Eyespot of cereals (<i>Oculimacula acuformis</i>) PSDCHA Brown rust of cereals (<i>Puccinia recon- dita</i>) PUCCRE	broadcast spraying	BBCH 30-49	1 a) 1 b) 1	0.7 L/ha a) 0.7 L/ha b) 0.7 L/ha	350 g as/ha a) 350 g as/ha b) 350 g as/ha	100-300 L/ha	56 days	A	
2	Poland	Spring wheat	F	Septoria leaf blotch (<i>Zymoseptoria tritici</i>) SEPTTR	broadcast spraying	BBCH 30-49	1 a) 1 b) 1	0.7 L/ha a) 0.7 L/ha b) 0.7 L/ha	350 g as/ha a) 350 g as/ha b) 350 g as/ha	100-300 L/ha	56 days	A	
3	Poland	Winter triti- cale	F	Septoria leaf blotch (<i>Zymoseptoria tritici</i>) SEPTTR	broadcast spraying	BBCH 30-49	1 a) 1 b) 1	0.7 L/ha a) 0.7 L/ha b) 0.7 L/ha	350 g as/ha a) 350 g as/ha b) 350 g as/ha	100-300 L/ha	56 days	A	
4	Poland	Spring triti- cale	F	Septoria leaf blotch (<i>Zymoseptoria tritici</i>) SEPTTR	broadcast spraying	BBCH 30-49	1 a) 1 b) 1	0.7 L/ha a) 0.7 L/ha b) 0.7 L/ha	350 g as/ha a) 350 g as/ha b) 350 g as/ha	100-300 L/ha	56 days	A	
5	Poland	Winter barley	F	Net blotch of barley (<i>Pyrenophora teres</i>) PYRNTE	broadcast spraying	BBCH 30-49	1 a) 1 b) 1	0.7 L/ha a) 0.7 L/ha b) 0.7 L/ha	350 g as/ha a) 350 g as/ha b) 350 g as/ha	100-300 L/ha	56 days	A	
6	Poland	Spring barley	F	Net blotch of barley (<i>Pyrenophora teres</i>) PYRNTE	broadcast spraying	BBCH 30-49	1 a) 1 b) 1	0.7 L/ha a) 0.7 L/ha b) 0.7 L/ha	350 g as/ha a) 350 g as/ha b) 350 g as/ha	100-300 L/ha	56 days	A	

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7	Poland	Winter oilseed rape	F	Black leg of crucifers (<i>Leptosphaeria maculans</i>) LEPTMA	broadcast spraying	Autumn BBCH 13-18 Spring BBCH 31-57	2 a) 1 b) 2 (30 days)	0.2-0.5 L/ha a) 0.5 L/ha b) 1 L/ha	100-250 g as/ha a) 250 g as/ha b) 500 g as/ha	100-400 L/ha	N/A	one in autumn, one in spring or 2 in spring, min. 14 days between applications A
8	Poland	Winter oilseed rape	F	Black leg of crucifers (<i>Leptosphaeria maculans</i>) LEPTMA	broadcast spraying	Spring BBCH 31-57	2 a) 1 b) 2 (14 days)	0.2-0.5 L/ha a) 0.5 L/ha b) 1 L/ha	100-250 g as/ha a) 250 g as/ha b) 500 g as/ha	100-400 L/ha	N/A	one in autumn, one in spring or 2 in spring, min. 14 days between applications A
9	Poland	Winter oilseed rape	F	Black leg of crucifers (<i>Leptosphaeria maculans</i>) LEPTMA Cottony rot <i>Sclerotinia sclerotiorum</i> SCLESC	broadcast spraying	BBCH 57-71	2 a) 1 b) 2 (14 days)	0.2-0.5 L/ha a) 0.5 L/ha b) 1 L/ha	100-250 g as/ha a) 250 g as/ha b) 500 g as/ha	100-400 L/ha	N/A	A
10	Poland	Winter rye	F	Leaf blotch of cereals (<i>Rhynchosporium secalis</i>) RHYNSE	broadcast spraying	BBCH 30-49	1 a) 1 b) 1	0.7 L/ha a) 0.7 L/ha b) 0.7 L/ha	350 g boscalid a) 350 g boscalid b) 350 g boscalid	100-300 L/ha	56 days	A

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

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

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

Explanation for Column 11 "Conclusion"

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

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7.1.2 Summary of the evaluation

The preparation BSK-FUN 500 SC is composed of boscalid.

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

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

7.1.2.1 Summary for boscalid

Table 7.1-3: Summary for boscalid

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1-4	Wheat (incl. trit-icale)	Yes	Yes (8)	Yes	Yes	Yes	No	No
5-6	Barley	Yes	Yes - extrapolation from wheat	Yes	Yes	Yes		No
10	Rye	Yes	Yes - extrapolation from wheat	Yes	Yes	Yes		No
7-9	Oilseed rape	Yes	Yes (8)	Yes	Yes	Yes		No

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

The effects of processing on the nature of boscalid residues have been investigated. Data on effects of processing on the amount of residue have been submitted.

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.

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7.1.2.2 Summary for BSK-FUN 500 SC

Table 7.1-4: Information on BSK-FUN 500 SC (KCA 6.8)

Crop	PHI for BSK-FUN 500 SC proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for BSK-FUN 500 SC proposed by zRMS	zRMS Comments (if different PHI proposed)
		Boscalid		
Cereals	56 days	Yes		
Oilseed rape	NR	NR		

NR: not relevant

* Purpose of withholding period to be specified

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

Table 7.1-5: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for BSK-FUN 500 SC
Crop group	Led by boscalid	
All	NR No minimum waiting periods are necessary to be considered neither in terms of phytotoxicity nor in terms of residues in succeeding crops. For more details, please refer to dRR Part B Section 3.	

NR: not relevant

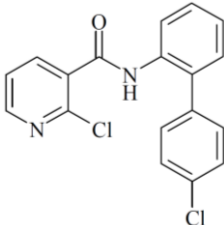
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Assessment

7.2 Boscalid

General data on boscalid are summarized in the table below

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 ₁₈ H ₁₂ Cl ₂ N ₂ O
Molar mass	343.21 g/mol
Chemical group	Pyridine-carboxamides
Mode of action (if available)	Succinate dehydrogenase inhibitors
Systemic	Yes
Company (ies)	BASF AG
Rapporteur Member State (RMS)	Slovakia (original RMS was Germany)
Approval status	<p>Approved Date of approval 01/08/2008</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 https://eur-lex.europa.eu/legal-content/PL/TXT/?uri=CELEX%3A02011R0540-20240201</p> <p>Commission Implementing Regulation (EU) 2020/869 of 24 June 2020 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances beflubutamid, benalaxyl, benthiavalicarb, bifenazate, boscalid, bromoxynil, captan, cyazofamid, dimethomorph, ethephon, etoxazole, famoxadone, fenamiphos, flumioxazine, fluoxastrobin, folpet, formetanate, metribuzin, milbemectin, Paecilomyces lilacinus strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole and S-metolachlor https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1593089089989&uri=CELEX:32020R0869</p>

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	<p>Commission Implementing Regulation (EU) 2021/745 of 6 May 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aluminium ammonium sulphate, aluminium silicate, beflubutamid, benthiavalicarb, bifenazate, boscalid, calcium carbonate, captan, carbon dioxide, cymoxanil, dimethomorph, ethephon, extract from tea tree, famoxadone, fat distillation residues, fatty acids C7 to C20, flumioxazine, fluoxastrobin, flurochloridone, folpet, formetanate, gibberellic acid, gibberellins, heptamaloxyloglucan, hydrolysed proteins, iron sulphate, metazachlor, metribuzin, milbemectin, Paecilomyces lilacinus strain 251, phenmedipham, phosmet, pirimiphos-methyl, plant oils/rape seed oil, potassium hydrogen carbonate, propamocarb, prothioconazole, quartz sand, fish oil, repellents by smell of animal or plant origin/ sheep fat, S-metolachlor, Straight Chain Lepidopteran Pheromones, tebuconazole and urea https://eur-lex.europa.eu/eli/reg_impl/2021/745/oj</p> <p>Commission Implementing Regulation (EU) 2022/708 of 5 May 2022 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2,5-dichlorobenzoic acid methylester, acetic acid, aclonifen, aluminium ammonium sulphate, aluminium phosphide, aluminium silicate, beflubutamid, benthiavalicarb, boscalid, calcium carbide, captan, cymoxanil, dimethomorph, dodemorph, ethephon, ethylene, extract from tea tree, fat distillation residues, fatty acids C7 to C20, fluoxastrobin, flurochloridone, folpet, formetanate, gibberellic acid, gibberellins, hydrolysed proteins, iron sulphate, magnesium phosphide, metam, metamitron, metazachlor, metribuzin, milbemectin, phenmedipham, pirimiphos-methyl, plant oils/clove oil, plant oils/rape seed oil, plant oils/spear mint oil, propamocarb, proquinazid, prothioconazole, pyrethrins, quartz sand, fish oil, repellents by smell of animal or plant origin/sheep fat, S-metolachlor, Straight Chain Lepidopteran Pheromones, sulcotrione, tebuconazole and urea https://eur-lex.europa.eu/eli/reg_impl/2022/708/oj</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 armigera 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 https://eur-lex.europa.eu/eli/reg_impl/2023/918/oj</p>
Restriction	Only uses as fungicide may be authorised
Review Report	SANCO/3919 /2007 - rev. 5, 21 January 2008

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Current MRL regulation	Reg. (EU) 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	Pending
EFSA Journal: conclusion on article 12	Yes
Current MRL applications on intended uses	NR

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

One new stability study has been submitted by the applicant in the framework of this application. Results are summarized in the Table below. The detailed assessment of this study is presented in Appendix 2.

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

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

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Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
			EFSA, 2014
New studies			
Wheat – whole plant	High water content	5 months	Sala A., Report no. LBN-0126-2023
Wheat – grain	High starch content	5 months	
Wheat – straw	Dry commodities	5 months	
Oilseed rape – whole plant	High water content	5 months	
Oilseed rape – pod	High water content	5 months	
Oilseed rape – seeds	High oil content	5 months	

Conclusion on stability of residues during storage

According to EFSA Journal 2014;12(7):3799:

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

Additionally, the applicant provided new storage stability study for wheat and oilseed rape matrices. The boscalid is stable for a period of 5 months storage at $\leq -18^{\circ}\text{C}$ in the dark in wheat (whole plant, straw and grain) and oilseed rape (whole plant, pods and seeds).

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

Wheat Final Report GBA-DPL-2023-14 (analytical part: LBN-0118-2023):

In order to check the stability of the analyte in the final extracts, aliquots of untreated sample extracts were spiked with known amounts of analyte at L5 calibration level). The stability in the extracts was tested for a period of 3 days (for Seeds and Whole Plant) and 5 days (for Straw) at $5 \pm 3^{\circ}\text{C}$ in dark conditions: after this period, the stored fortified extracts were analysed concurrently with the same matrix-matched standard solutions freshly prepared, used as reference. The measured instrumental responses were compared and the stability was expressed as the percentage ratio between the responses of the spiked extracts analysed after 3 days and 4 days, and the freshly spiked ones.

Extract	Analyte	Analyte area Freshly prepared standard	Analyte area Extract stored 3 days at $5 \pm 3^{\circ}\text{C}$	% Residual analyte (Stored/Fresh)	$\Delta\%$
Grain	Boscalid	1376	1287	93.5	-6.5
Whole Plant		5796	5700	98.3	-1.7
Straw		1128	982	87.1	-12.9

After 3 days in the dark at $5 \pm 3^{\circ}\text{C}$ (% Recovery Stored/Fresh):

- Straw: -12.9%

In order to check the stability of the analyte in the final extracts, aliquots of untreated sample extracts were spiked with known amounts of analyte at L5 calibration level). The stability in the extracts was tested for a period of 3 days (for Seeds and Whole Plant) and 4 days (for Pods) at $5 \pm 3^\circ\text{C}$ in dark conditions: after this period, the stored fortified extracts were analysed concurrently with the same matrix-matched standard solutions freshly prepared, used as reference. The measured instrumental responses were compared and the stability was expressed as the percentage ratio between the responses of the spiked extracts analysed after 3 days and 4 days, and the freshly spiked ones.

Extract	Analyte	Analyte area Freshly pre- pared standard	Analyte area Extract stored 3 days at 5 ± 3°C	% Residual ana- lyte (Stored/Fresh)	Δ%
Seeds	Boscalid	1979	1899	96.0	-4.0
Whole Plant		6846	6247	91.3	-8.7
Pods		1684	1360	80.8	-19.2

- Pods: -19.2%

The stability of the analyte in the extract can be considered proven for 3 days and 4 days at $5 \pm 3^\circ\text{C}$ in the dark since the recovery of the stored spiked sample is within the range of 70-120% measured against the freshly prepared one, as required by the SANTE/2020/12830 rev.2 guidance document.

No new data submitted in the framework of this application.

Crop Group	Crop	Label po- sition	Application and sampling details					Reference
			Method, F or G	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								

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Fruits and fruiting vegetable	Grape	U- ¹⁴ C-di-phenyl and 3- ¹⁴ C-pyridine	foliar treatment, F	0.8	3	45	-	DAR, 2002 EFSA, 2014
Leafy vegetables	Lettuce		foliar treatment, G	0.7	3	18	-	DAR, 2002 EFSA, 2014
Pulses and oilseeds	Bean		foliar treatment, G	0.5	3	0 ^(a) , 14 ^(b) , 53 ^(c)	-	DAR, 2002 EFSA, 2014

(a) whole plant

(b) forage, green beans, pods and seeds

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

Summary of plant metabolism studies reported in the EU

According to EFSA Journal 2014;12(7):3799:

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

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

Summary of new plant metabolism studies

Not relevant. No new plant metabolism studies have been submitted.

Conclusion on metabolism in primary crops

According to EFSA Journal 2014;12(7):3799:

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

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

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

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

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

Summary of plant metabolism studies in rotational crops reported in the EU

According to EFSA Journal 2014;12(7):3799:

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

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

Except in wheat grain, parent boscalid was the major component of the TRR in all crops. Levels of the parent compound ranged from 50 % TRR in wheat straw (270 DAT, pyridine label) to 93 % TRR in wheat forage (270 DAT, pyridine label), and in lettuce leaves from 55.6 % TRR (270 DAT, diphenyl label) to 94.1 % TRR (365 DAT, diphenyl label). In wheat grain, the concentration of parent was low (between 1.9 % TRR at 270 DAT with the pyridine label and 16.8 % TRR at 30 DAT with the diphenyl label). Most of the radioactive residues in grain were not extractable (65 to 96 % TRR) and were detected in the starch fraction (36.2 to 48.4 % TRR, 0.06-0.12 mg eq/kg, pyridine label). The metabolite M510F61 (sugar conjugate of hydroxylated boscalid) was the only metabolite identified at levels exceeding 10 % TRR, in wheat forage (18.1 % TRR, diphenyl label, 270 DAT) and in radish leaves (21.2 % TRR for diphenyl label, 270 DAT and 11.2-15.5 % TRR, 365 DAT).

Summary of new plant metabolism studies in rotational crops

Not relevant. No new plant metabolism studies in rotational crops have been submitted.

Conclusion on metabolism in rotational crops

According to EFSA Journal 2014;12(7):3799:

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

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necessary.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

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

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

* Total applied radioactivity after test

Conclusion on nature of residues in processed commodities

According to EFSA Journal 2014;12(7):3799:

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

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

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

Endpoints	
Plant groups covered	Fruits and fruiting vegetables (grapes) Leafy vegetables (lettuce) Pulses and oilseeds (bean)
Rotational crops covered	Root and tuber vegetables (Radish) Leafy vegetables (Lettuce) Cereals (Wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	a.s. is stable under standard hydrolysis conditions

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Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Boscalid (Reg. (EU) 2022/1324)
Plant residue definition for risk assessment	Boscalid (EFSA 2014)
Conversion factor from enforcement to RA	None (DAR, 2002; EFSA, 2014)

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

Available data

No new data submitted in the framework of this application.

Table 7.2-7: Summary of animal metabolism studies

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

Summary of plant metabolism studies reported in the EU

According to EFSA Journal 2014;12(7):3799:

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

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

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

Boscalid was the most abundant compound in fat (0.012 mg eq/kg; 34.6 % TRR) and represented a major part of the residue in muscle (0.002 mg eq/kg; 20.4 % TRR). It was also detected in liver (0.129 mg eq/kg; 5 % TRR), milk (0.001 mg eq/kg; 3.2 % TRR) and kidney (0.007 mg eq/kg; 2.5 % TRR). The metabolite M510F01 was the most abundant compound in muscle (0.003 mg eq/kg; 20.6 % TRR) and represented a

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major part of the residue in fat (0.009 mg eq/kg; 26.3 % TRR). It was also detected in liver (0.074 mg eq/kg; 2.9 % TRR), milk (0.006 mg eq/kg; 14.9 % TRR) and kidney (0.023 mg eq/kg; 8.6 % TRR). M510F02, the glucuronide conjugate of M510F01, is the most abundant compound in kidney (0.136 mg eq/kg; 50.3 % TRR) and was also detected in muscle (0.001 mg eq/kg; 11.9 % TRR) and milk (0.002 mg eq/kg; 6.4 % TRR).

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

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

Boscalid is extensively excreted (97.7 % AR), with a relatively low transfer of residues to tissues (0.04 % AR in liver, 0.003-0.004 % AR for muscle and fat) and eggs (0.12 % AR). The highest TRR was found in liver (0.17 mg eq/kg). Other TRR values were 0.058 mg eq/kg in eggs (with a maximum of 0.08 mg eq/kg), 0.025 mg eq/kg in fat and 0.003 mg eq/kg in muscle. A plateau is reached in eggs at day 6 (0.07 mg eq/kg). Boscalid is the main compound in fat (0.023 mg eq/kg; 93.3 % TRR) and eggs (0.02 mg eq/kg; 35.5 % TRR). M510F01 was detected in eggs (0.015 mg eq/kg; 26.9 % TRR) and liver (0.009 mg eq/kg; 5.6 % TRR) and its conjugate M510F02 was detected in muscle (0.001 mg eq/kg; 11.9 % TRR) and eggs (0.01 mg eq/kg; 17.3 % TRR). Liver was only analysed using the microwave extraction used in the metabolism study on goats (only with formic acid). The results are similar to those observed in goats, M510F52 being the main compound (0.071 mg eq/kg; 42 % TRR). Therefore, further investigation on the fate of the pyridine moiety in poultry liver is also required.

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

Summary of new animal metabolism studies

Not relevant. No new animal metabolism studies have been submitted.

Conclusion on metabolism in livestock

According to EFSA Journal 2014;12(7):3799:

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

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

Validated analytical methods are available in all animal commodities.

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

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

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

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	2-3 days in milk
	6 days in eggs
Animal residue definition for monitoring	Boscalid in muscle, fat milk and eggs; Sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates expressed as Boscalid in liver and kidney (Reg. (EU) 2022/1324)
Animal residue definition for risk assessment	Boscalid in muscle, fat milk and eggs; Sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates expressed as Boscalid in liver and kidney; Sum of Boscalid and its hydroxy metabolite M510F01 including its conjugates and the bound residues (measured as M510F52 or M510F53) expressed as Boscalid in Liver (ruminant and pig); (EFSA 2014)
Conversion factor	1.5 for ruminant and pig liver (EFSA, 2014)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes

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7.2.3 Magnitude of residues in plants (KCA 6.3)

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

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. These studies are summarized in the Table below. The detailed assessment of these studies is presented in Appendix 2.

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of BSK-FUN 500 SC 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
Wheat grain (incl. triticale)	New trials	N-EU	Trials GAP: 1x 0.35 kg as/ha, BBCH 30-49, PHI 56d, outdoor 0.0065, 0.0075, 0.0421, 0.0498, 0.0501, 0.0562, 0.0626, 0.0731	N/A				
	Overall supporting data for cGAP	N-EU	0.0065, 0.0075, 0.0421, 0.0498, 0.0501, 0.0562, 0.0626, 0.0731	0.05	0.0731	0.141	0.8	Yes
Barley grain extrapolation from wheat	New trials	N-EU	<i>Wheat</i> Trials GAP: 1x 0.35 kg as/ha, BBCH 30-49, PHI 56d, outdoor 0.0065, 0.0075, 0.0421, 0.0498, 0.0501, 0.0562, 0.0626, 0.0731	N/A				
	Overall supporting data for cGAP	N-EU	0.0065, 0.0075, 0.0421, 0.0498, 0.0501, 0.0562, 0.0626, 0.0731	0.05	0.0731	0.141	4	Yes

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Rye grain extrapolation from wheat	New trials	N-EU	<i>Wheat</i> Trials GAP: 1x 0.35 kg as/ha, BBCH 30-49, PHI 56d, outdoor 0.0065, 0.0075, 0.0421, 0.0498, 0.0501, 0.0562, 0.0626, 0.0731	N/A				
	Overall supporting data for cGAP	N-EU	0.0065, 0.0075, 0.0421, 0.0498, 0.0501, 0.0562, 0.0626, 0.0731	0.05	0.0731	0.141	0.8	Yes
Wheat straw (incl. triticale)	New trials	N-EU	Trials GAP: 1x 0.35 kg as/ha, BBCH 30-49, PHI 56d, outdoor 1.7415, 2.2672, 3.9345, 3.9848, 4.8975, 5.0612, 5.7310, 7.4445	N/A				
	Overall supporting data for cGAP	N-EU	1.7415, 2.2672, 3.9345, 3.9848, 4.8975, 5.0612, 5.7310, 7.4445	4.44	7.4445	-	-	-
Barley straw extrapolation from wheat	New trials	N-EU	<i>Wheat:</i> Trials GAP: 1x 0.35 kg as/ha, BBCH 30-49, PHI 56d, outdoor 1.7415, 2.2672, 3.9345, 3.9848, 4.8975, 5.0612, 5.7310, 7.4445	N/A				
	Overall supporting data for cGAP	N-EU	1.7415, 2.2672, 3.9345, 3.9848, 4.8975, 5.0612, 5.7310, 7.4445	4.44	7.4445	-	-	-
Rye straw extrapolation from wheat	New trials	N-EU	<i>Wheat:</i> Trials GAP: 1x 0.35 kg as/ha, BBCH 30-49, PHI 56d, outdoor 1.7415, 2.2672, 3.9345, 3.9848, 4.8975, 5.0612, 5.7310, 7.4445	N/A				
	Overall supporting data for cGAP	N-EU	1.7415, 2.2672, 3.9345, 3.9848, 4.8975, 5.0612, 5.7310, 7.4445	4.44	7.4445	-	-	-
Oilseed rape	New trials	N-EU	Trials GAP: 2 x 0.25 kg as/ha, BBCH 57-71, PHI NA, outdoor 2x< 0.002, 0.0071, 0.0144, 0.0182, 0.0253, 0.0532, 0.1070	N/A				

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	Overall supporting data for cGAP	N-EU	2x< 0.002, 0.0071, 0.0144, 0.0182, 0.0253, 0.0532, 0.1070	0.02	0.1070	0.172	1	Yes
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* Source of EU MRL: Reg. (EU) 2022/1324

7.2.3.2 Conclusion on the magnitude of residues in plants

Wheat (incl. triticale)

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. A total of 8 residue trials in Northern Europe were performed on wheat.

Sufficient trials are available to support the proposed use on wheat. The residue data are valid with regard to storage stability data.

The data submitted show that no exceedance of the EU MRL of 0.8 mg/kg for wheat will occur.

Barley

According to SANTE/2019/12752 Rev.01 extrapolation from wheat to barley is possible before forming the edible part. The anticipated application for barley is before forming the edible part (BBCH 30-49).

Sufficient trials on wheat are available to support the proposed use on barley. The residue data are valid with regard to storage stability data.

The data submitted show that no exceedance of the EU MRL of 4 mg/kg for barley will occur.

Rye

According to SANTE/2019/12752 Rev.01 extrapolation from wheat to rye is possible before or after forming the edible part. The anticipated application for rye is before forming the edible part (BBCH 30-49).

Sufficient trials on wheat are available to support the proposed use on rye. The residue data are valid with regard to storage stability data.

The data submitted show that no exceedance of the EU MRL of 0.8 mg/kg for rye will occur.

Oilseed rape

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. A total of 8 residue trials in Northern Europe were performed on oilseed rape.

Sufficient trials are available to support the proposed use on oilseed rape. The residue data are valid with regard to storage stability data.

The data submitted show that no exceedance of the EU MRL of 1 mg/kg for oilseed rape will occur.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Boscalid is authorised for use on several crops that might be fed to livestock. The median and maximum dietary burdens were therefore performed by EFSA (*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) for different groups of livestock using the agreed European methodology (EC, 1996).

Additionally, an applicant provided calculation performed by actual Animal Model 2017 using input values from EFSA Journal 2014;12(7):3799.

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

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: boscalid				
Cabbage	1.10	Median residue	2.82	Highest residue
Kale	1.10	Median residue	4.10	Highest residue
Apple pomace	2.52	Median residue \times PF	2.52	Median residue \times 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 \times PF	0.52	Median residue \times PF
Wheat straw	33.7	Median residue	52.7	Highest residue
Barley, oat straw	15.0	Median residue	26.9	Highest residue
Rye straw	19.6	Median residue	39.5	Highest residue
Peas (dry)	0.13	Median residue	0.13	Median residue
Beans(dry)	0.13	Median residue	0.13	Median residue
Potatoes	0.05	Median residue	0.05	Highest residue
Turnips	0.09	Median residue	0.28	Highest residue
Rape seed meal	0.08	Median residue \times PF	0.08	Median residue \times PF
Linseed meal	0.10	Median residue \times 2	0.10	Median residue \times 2
Sunflower seed meal	0.32	Median residue \times 2	0.32	Median residue \times 2
Soya bean	0.05	Median residue	0.05	Median residue
Soya bean meal	0.01	Median residue \times PF	0.01	Median residue \times PF
Peanuts meal	0.10	Median residue \times 2	0.10	Median residue \times 2

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Table 7.2-11: Results of the dietary burden calculation

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0,412	0,585	11,48	15,93	Dairy cattle	Wheat	straw	Yes
Cattle (dairy only)	0,412	0,585	10,71	15,22	Dairy cattle	Wheat	straw	Yes
Sheep (all diets)	0,743	1,118	18,89	27,66	Lamb	Wheat	straw	Yes
Sheep (ewe only)	0,630	0,922	18,89	27,66	Ram/Ewe	Wheat	straw	Yes
Swine (all diets)	0,075	0,127	3,25	5,51	Swine (breeding)	Kale	leaves	Yes
Poultry (all diets)	0,355	0,507	5,19	7,41	Poultry layer	Wheat	straw	Yes
Poultry (layer only)	0,355	0,507	5,19	7,41	Poultry layer	Wheat	straw	Yes

(a): When several diets are relevant (e.g. cattle, sheep and poultry "all diets"), the most critical diet is identified from the maximum dietary burdens expressed as "mg/kg bw per day"

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".

According to the new Animal model 2017 a significant intake for ruminants, poultry and pigs is expected (> 0.004 mg/Kg bw (Reg. (EU) 283/2013), thus feeding studies are required.

The dietary burden was calculated in the framework of the Article 12 procedure. The intended uses are covered by the uses assessed in EFSA Journal 2014;12(7):3799. STMR/HR values from the supervised residue trials presented in this submission are lower than were used as input values stated in EFSA Journal 2014;12(7):3799. No further calculation is needed. Nevertheless, the evaluator performed the calculations using the currently valid calculator (animal model 2017) for the proposed uses only.

2017) for the proposed uses only.

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0,063	0,102	1,64	2,65	Dairy cattle	Barley	straw	Yes
Cattle (dairy only)	0,063	0,102	1,64	2,65	Dairy cattle	Barley	straw	Yes
Sheep (all diets)	0,134	0,220	3,15	5,17	Lamb	Barley	straw	Yes
Sheep (ewe only)	0,105	0,172	3,15	5,17	Ram/Ewe	Barley	straw	Yes
Swine (all diets)	0,007	0,007	0,23	0,23	Swine (finishing)	Wheat	milled bypds	Yes
Poultry (all diets)	0,043	0,066	0,62	0,96	Poultry layer	Wheat	straw	Yes
Poultry (layer only)	0,043	0,066	0,62	0,96	Poultry layer	Wheat	straw	Yes

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.

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7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

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

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

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

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Ruminant fat			1.22	9	0.15	0.22	0.15	0.22	0.12	0.23	0.3	1.00
			3.36	9	0.17	0.25	0.17	0.25				
Ruminant liver			1.22	3	0.09	0.11	-	-	0.08	0.14	0.15 (tentative)	1.50 ^(h)
			3.36	3	0.20	0.24	-	-				
Ruminant kidney			1.22	3	0.11	0.11	0.11	0.11	0.09	0.14	0.15	1.00
			3.36	3	0.18	0.24	0.18	0.24				
Poultry meat	0.09	0.18	0.06	3	<0.025	<0.025	<0.025	<0.025	0.025	0.025	0.025*	1.00
			0.32	3	<0.025	<0.025	<0.025	<0.025				
			1.26	3	<0.025	<0.025	<0.025	<0.025				
Poultry fat			0.06	3	<0.025	<0.025	<0.025	<0.025	0.03	0.06	0.06	1.00
			0.32	3	0.06	0.10	0.06	0.10				
			1.26	3	0.14	0.17	0.14	0.17				
Poultry liver			0.06	3	<0.05	0.05	0.08	0.05	0.06	0.11	0.15 (tentative)	1.00
			0.32	3	0.14	0.18	0.14	0.18				
			1.26	3	0.41	0.47	0.41	0.47				
Milk	0.41	0.86	1.22	30	0.01 ^(d)	N/A	0.01 ^(d)	N/A	0.01	0.01	0.01*	1.00
			3.36	60	0.05 ^(e)	N/A	0.05 ^(e)	N/A				
Eggs	0.09	0.18	0.06	30	<0.01 ^(f)	N/A	<0.01 ^(f)	N/A	0.01	0.01	0.01*	1.00
			0.32	30	<0.01 ^(f)	N/A	<0.01 ^(f)	N/A				
			1.26	30	0.02 ^(g)	N/A	0.02 ^(g)	N/A				

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

n.r.: Not reported

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

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

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

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- (b): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).
- (c): The median conversion factor for enforcement to risk assessment.
- (d): Mean residue level from day 1 until day 28 (3 cows, 10 sampling days).
- (e): Mean residue level from day 1 until day 28 (6 cows, 10 sampling days).
- (f): Mean residue level from day 1 until day 28 (3 hens, 10 sampling days).
- (g): Mean residue level from day 1 until day 28 (5 hens, 10 sampling days).
- (h): Tentative conversion factor derived from a separate ruminant feeding study.

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Conclusion on feeding studies

The feeding studies were performed and reported and were considered sufficient for deriving MRLs 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.

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

7.2.5.1 Available data for all crops under consideration

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

Table 7.2-13: Overview of the available processing studies

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

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Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
Tomatoes, unpeeled and canned	4	0.05	1.00		EFSA, 2010
Tomatoes, peeled and canned	4	0.05	1.00		EFSA, 2010
Tomatoes, paste	4	0.30	1.00		EFSA, 2010
Tomatoes, juice	4	0.17	1.00		EFSA, 2010
Gherkins, canned	4	0.56	1.00		EFSA, 2010
Head cabbage, cooked	4	0.07	1.00		EFSA, 2010
Head cabbage, canned	4	0.07	1.00		EFSA, 2010
Head cabbage, sauerkraut	4	0.17	1.00		EFSA, 2010
Head cabbage, sauerkraut juice	4	0.07	1.00		EFSA, 2010
Rape seed, refined oil	4	1.26	1.00		EFSA, 2010
Rape seed, meal/press cake	4	0.56	1.00		EFSA, 2010
Barley, brewing malt	4	0.48	1.00		PROFile
Barley, beer	4	0.02	1.00		PROFile
Barley, pot/pearl	4	0.34	1.00		PROFile
Wheat, whole-meal flour	4	1.21	1.00		PROFile
Wheat, whole-meal bread	4	0.81	1.00		PROFile
Wheat, white flour	4	0.34	1.00		PROFile
Wheat, bran	4	4.32	1.00		PROFile
Indicative processing factors (limited dataset)					
Peas cooked/canned	1	<0.36	1.00		DAR, 2002
Rape seed, crude oil	2	1.11	1.00		EFSA, 2010
Soya bean, refined oil	2	0.40	1.00		EFSA, 2010
Soya bean, meal	2	0.16	1.00		EFSA, 2010

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

7.2.5.2 Conclusion on processing studies

According to EFSA Journal 2014;12(7):3799:

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

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

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

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

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application.

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

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

* Sampling not performed under GLP

Conclusion on rotational crops studies

According to EFSA Journal 2014;12(7):3799:

Occurrence of Boscalid residues in rotational crops was already investigated during the peer review. It is concluded that metabolic patterns in primary and succeeding crops are similar and that a potential for accumulation of Boscalid residues in crops grown in rotation is expected. EFSA is aware that instead of defining risk mitigating measures, risk managers may have the interest to establish MRLs accommodating for the uptake of residues from previously treated soils, EFSA therefore re-calculated the MRL proposals to take into account such residues. However, these MRLs are subject to a higher degree of uncertainty;

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Member States may therefore also consider the establishment of appropriate risk mitigation measures in order to prevent the presence of residues in rotational crops. Furthermore, residue trials after repeated application in permanent crops would be desirable as well.

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

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

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

According to this guidance further data on crop or field/tunnel trials are required when residue in honey are expected considering the proposed uses and the properties of the active substance. Following this guidance, residues in honey can occur:

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

Product BSK-FUN 500 SC is a fungicide with intended use on oilseed rape at flowering stage. According to SANTE/11956/2016 rev. 9, Appendix II, the oilseed rape is considered as a melliferous crop and residues in honey can occur. Regarding above, an applicant will provide the study on residues of boscalid in honey:

~~STUDY PLAN: Determination of Boscalid Residues in Honey Following Application on Phacelia with BSK-FUN 500 SC under semi field Conditions in Northern and Southern Europe in 2023, Study No. C3127. According to this study plan and its amendments, final report will be available in July 2024.~~

Four new semi-field/tunnel studies in N-EU zone (Poland and N-France) and S-EU zone (S-France and Italy) in 2023-2024 have been performed on *Phacelia tanacetifolia* to investigate the magnitude of boscalid residues in honey. These trials consider a “worst case” situation (the most critical scenario was used on Phacelia plants representing a worst case in terms of residues in honey). The results of these studies are summarized in the table below. The details are presented in Appendix 2.

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Table 7.2-15: Summary of new data on honey supporting the intended uses of BSK-FUN 500 SC

Commodity	Source	Residue zone	Evaluation GAP Residue levels (mg/kg)	STMR (mg/kg)	HR (mg/kg)	Un-rounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Phacelia (worst case) - residues in honey	New trials (report no. R C3127)	N-EU & S-EU	Trial GAP: 1x 600 g as/ha, BBCH 65, semi-field (tunnel) trial < 0.003 (LOD), 2x < 0.01 (LOQ), 0.01	N/A				
	Overall supporting data for honey	N-EU & S-EU	< 0.003 (LOD), 2x < 0.01 (LOQ), 0.01	0.01	0.01	0.022	0.15	Yes

*Source of EU MRL: Reg. (EU) 2022/1324

A semi-field/tunnel study (containing four trials) for determining the magnitude of residues of boscalid in honey was conducted in compliance with current guidelines. In four honey trials BSK-FUN 500 SC was applied at a rate 600 g as/ha at a flowering phase (BBCH 65).
All samples were analysed within 30 days from sampling, therefore there is no need to perform studies on the stability of residues during storage.
All results are ≤ LOQ, which is below actual MRL. The results are acceptable. No risk for consumers is expected.

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

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

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

The chronic risk assessment based on current MRLs (Reg. (EU) Reg. (EU) 2022/1324), represents the worst case scenario, significantly exceeds ADI. Therefore, the refinement based on median residue (EFSA, 2014) was carried out as a realistic scenario.

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-16: Input values for the consumer risk assessment

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition: boscalid		
Tree nuts except pistachios, pine nuts and coconuts	0.05	Median residue
Pistachios	0.27	Median residue

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Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Apples, Pears, Quinces	0.42	Median residue
Apricots	0.77	Median residue (tentative)
Cherries	1.51	Median residue
Peaches	0.77	Median residue
Plums	0.29	Median residue
Table and wine grapes	1.42	Median residue
Strawberries	1.90	Median residue
Cane fruits	2.47	Median residue
Other small fruit and berries, except rose hips, mulberries and elderberries	3.60	Median residue
Rose hips, mulberries and elderberries	2.60	Median residue
Kiwi	0.08	Median residue × PF
Bananas	0.05	Median residue
Potatoes, Sweet potatoes, Yams, Arrow-root	0.05	Median residue
Beetroot	0.33	Median residue
Carrots, Horseradish	0.19	Median residue × PF
Celeriac	0.34	Median residue
Jerusalem artichokes	2.00	Median residue
Parsnips, Parsley root, Salsify, Turnips	0.09	Median residue
Radishes	0.28	Median residue
Garlic, Onions, Shallots	0.20	Median residue
Spring onions	6	EU MRL*
Tomatoes, Aubergines (egg plants)	0.35	Median residue
Peppers	0.51	Median residue
Cucurbits with edible peel	0.68	Median residue
Cucurbits with inedible peel	0.35	Median residue
Broccoli	1.55	Median residue
Cauliflower	1.55	Median residue
Brussels sprouts	0.30	Median residue
Head cabbage	1.10	Median residue
Chinese cabbage	1.10	Median residue
Kale	1.10	Median residue (tentative)

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Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Kohlrabi	0.04	Median residue
Lettuce and similar	5.60	Median residue
Spinach	5.60	Median residue
Beet leaves (chard)	30.0	Median residue
Witloof	1.16	Median residue
Fresh herbs, except basil	5.60	Median residue
Basil	14.5	Median residue
Beans (fresh, with pods)	5	EU MRL*
Beans (fresh, without pods)	0.11	Median residue
Peas (fresh, with pods)	0.64	Median residue
Peas (fresh, without pods)	0.11	Median residue
Lentils (fresh)	3.00	Median residue
Asparagus	0.05	Median residue (tentative)
Celery	2.18	Median residue
Fennel	2.18	Median residue
Globe artichokes	1.18	Median residue
Leek	2.30	Median residue
Beans (dry)	0.13	Median residue
Lentils (dry)	0.13	Median residue
Peas (dry)	0.13	Median residue
Linseed	0.05	Median residue
Peanuts	0.05	Median residue
Poppy seed	0.05	Median residue
Sunflower seed	0.16	Median residue
Rape seed	0.15	Median residue
Soya bean	0.05	Median residue
Mustard seed	0.05	Median residue
Borage	0.05	Median residue
Gold of pleasure	0.05	Median residue
Barley grain, Oats grain	1.07	Median residue
Wheat grain, Rye grain	0.12	Median residue
Herbal infusions (dried, roots)	0.95	Median residue (tentative)

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

* Reg. (EU) 2022/1324

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-17: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	400 % (based on NL toddler diet)
IEDI (% ADI) according to EFSA PRIMo	70 % (based on NL toddler diet)
IESTI (% ARfD) according to EFSA PRIMo*	Not relevant.
NTMDI (% ADI) **	Not relevant.
NEDI (% ADI)**	Not relevant.
NESTI (% ARfD) **	Not relevant.

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

** if national model is available

Chronic and acute exposure calculations were performed using revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo rev. 3.1) provided on the internet homepage of EFSA (<https://www.efsa.europa.eu/>).

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This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population. The model was developed to calculate simultaneously the short-term (acute) and long-term (chronic) dietary exposure to pesticide residue in food according to internationally agreed methodologies. The exposure is compared to the toxicological reference values (i.e., the ADI and the ARfD).

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

The chronic risk assessment based on current MRLs (Reg. (EU) Reg. (EU) 2022/1324), represents the worst-case scenario, significantly exceeds ADI. Therefore, the refinement based on median residue (EFSA, 2014) was carried out as a realistic scenario. According to calculations the highest chronic exposure was calculated for NL toddler diet, representing 70% of the ADI. Since IEDI value is below 100%, further refinement is not required.

The proposed uses of boscalid in the formulation BSK-FUN 500 SC do not represent unacceptable chronic risks for the consumer.

zRMS:

STMR from the new trials of wheat 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.

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7.4 References

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

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

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

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Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.
 MS to blacken authors of vertebrate studies in the version made available to third parties/public.

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 6.3/01	Ptaszek R.	2024	Magnitude of the residue of Boscalid (188425-85-6) in wheat (Raw Agricultural Commodity - RAC) grown in open field conditions after one application of a formulated product BSK-FUN 500 SC- four harvest and four decline curve trials in Northern Europe GBA Polska Sp. z o.o. AGRO Services Study number: GBA-DPL-2023-14 GEP Unpublished	N	Pestila Sp. z o.o. and ProAgri International Sp. z o.o.
KCA 6.3/02	Ptaszek R.	2024	Magnitude of the residue of Boscalid (188425-85-6) in oilseed rape (Raw Agricultural Commodity - RAC) grown in open field conditions after one application of a formulated product BSK-FUN 500 SC - four harvest and four decline curve trials in Northern Europe GBA Polska Sp. z o.o. AGRO Services Study number: GBA-DPL-2023-15 GEP Unpublished	N	Pestila Sp. z o.o. and ProAgri International Sp. z o.o.
KCA 6.3/03	Sala A.	2023	Magnitude of the residue of Boscalid (188425-85-6) in wheat (Raw Agricultural Commodity – RAC) grown in open field conditions after one application of formulated product BSK-FUN 500 SC – four harvest and four decline curve trials in Northern Europe	N	Pestila Sp. z o.o. and ProAgri

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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. LBN-0118-2023 LabAnalysis s.r.l. GLP: Yes Published: No		International Sp. z o.o.
	Sala A.	2024	Final Report Amendment 1 Magnitude of the residue of Boscalid (188425-85-6) in wheat (Raw Agricultural Commodity – RAC) grown in open field conditions after one application of formulated product BSK-FUN 500 SC – four harvest and four decline curve trials in Northern Europe report no. LBN-0118-2023 LabAnalysis Life Science s.r.l. sede di Pavia GLP: Yes Published: No	N	Pestila Sp. z o.o. and ProAgri International Sp. z o.o.
KCA 6.3/04	Sala A.	2023	Magnitude of the residue of Boscalid (188425-85-6) in oilseed rape (Raw Agricultural Commodity – RAC) grown in open field conditions after two application of formulated product BSK-FUN 500 SC – four harvest and four decline curve trials in Northern Europe report no. LBN-0119-2023 LabAnalysis s.r.l. GLP: Yes Published: No	N	Pestila Sp. z o.o. and ProAgri International Sp. z o.o.
	Sala A.	2024	Final Report Amendment 1 Magnitude of the residue of Boscalid (188425-85-6) in oilseed rape (Raw Agricultural Commodity – RAC) grown in open field conditions after two application of formulated product BSK-FUN 500 SC – four harvest and four decline curve trials in Northern Europe report no. LBN-0119-2023 LabAnalysis Life Science s.r.l. sede di Pavia GLP: Yes Published: No	N	Pestila Sp. z o.o. and ProAgri International Sp. z o.o.

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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 6.1/01	Sala A.	2024	Freezer storage stability of Boscalid in Wheat and Oilseed rape samples Report No. LBN-0126-2023 LabAnalysis Life Science s.r.l. sede di Pavia GLP: Yes Published: No	N	Pestila Sp. z o.o. and ProAgri International Sp. z o.o.
KCA6.10, 6.10.1/01	Schneider E.	2024	Determination of Boscalid Residues in Honey Following Application on Phacelia with BSK-FUN 500 SC under semi field Conditions in Northern and Southern Europe in 2023-2024 Report No. R C3127 ANADIAG GLP: Yes Published: No	N	Pestila Sp. z o.o. and ProAgri International Sp. z o.o.

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
	Funk, Horst; Mackenroth, Christiane	2001	Investigation of the Stability of Residues of BAS 510 F in Plant Matrices under Storage Conditions. 2001/1015028 GLP, unpublished RIP2002-192	N	BASF
	Rabe, U.;	2001	Metabolism of BAS 510 F in Grapevine.	N	BASF

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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
	Schlüter, H.		BASF DocID: 2000/1014860 GLP, unpublished RIP2001-327		
	Hamm, R.T.	1999	Metabolism of BAS 510 F in Lettuce. BASF DocID: 1999/11240 GLP, unpublished RIP2001-328	N	BASF
	Veit, P.	2001	Metabolism of 14C-BAS 510 F in Beans. BASF DocID: 2000/1014861 GLP, unpublished RIP2001-329	N	BASF
	xxxxx	2001	The Metabolism of 14C-BAS 510F in Lactaing Goat. xxxxxxxxxxx DocID: 2000/1017221 GLP, unpublished RIP2001-331	N	BASF
	xxxxx	2000	14C-BAS 510 F- Absorption, Distribution and Excretion after Repeated Oral Administration in Lactating Goats. xxxxxxx DocID: 2000/1012353 GLP, unpublished RIP2001-330	N	BASF
	xxxxx	2000	Nature of Residues of 14C-BAS 510 F in Laying Hens. xxxxxxx Doc No.: 2000/5154 GLP, unpublished RIP2001-332	N	BASF
	xxxxx	2001	Investigation of the Stability of Residues of BAS 510 F and M510F01 in Sample Material of Animal	N	BASF

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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
			Origin under Usual Storage Conditions. xxxxxx DocID: 2000/1017229 GLP, unpublished RIP2001-354		
	xxxxx	2001	Residues in Milk and Edible Tissues Following Oral Administration of BAS 510 F to Lactating Dairy Cattle. xxxxxx DocID: 2000/1017228 GLP, unpublished RIP2001-352	N	BASF
	Scharf, J.	1998	Hydrolysis of BAS 510 F at 90°C, 100°C, and 120°C. BASF Doc.: 1998/10878 GLP, unpublished RIP2001-355	N	BASF
	Funk, H.; Mackenroth, C.	2001	Determination of the residues of BAS 510 F in wheat obtained from the trial year 2000. BASF DocID.: 2000/1000989 GLP, unpublished RIP2001-375	N	BASF
	Funk, H.; Mackenroth, C.	2000	Determination of the residues of BAS 510 F in wheat obtained from the trial year 2000. BASF DocID.: 2000/1014853 GLP, unpublished RIP2001-374	N	BASF
	Hamm, T.R.; Veit, P.	2001	Confined Rotational Crop Study with 14CBAS 510 F. BASF DocID.: 2000/1014862 GLP, unpublished RIP2001-373	N	BASF

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The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Boscalid

A 2.1.1 Stability of residues

A 2.1.1.1 Stability of residues during storage of samples

A 2.1.1.1.1 Storage stability of residues in plant products

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

A 2.1.1.1.1.1 Study 1

Comments of zRMS:	Study is accepted
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Reference:	KCA 6.1/01
Report	Freezer storage stability of Boscalid in Wheat and Oilseed rape samples, Sala A., 2024, report no. LBN-0126-2023
Guideline(s):	Yes OECD 506 SANTE/2020/12830 Rev.2
Deviations:	No
GLP:	Yes
Acceptability:	Yes

Materials and methods

The objective of this study was the evaluation of the storage stability in dark frozen conditions (temperature $\leq -18^{\circ}\text{C}$) of the analyte Boscalid in the following matrices:

Wheat:

- Whole plant
- Grain
- Straw

Oilseed rape

- Whole plant
- Pod
- Seeds

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The storage stability was evaluated over a period of 5 months storage at $\leq -18^{\circ}\text{C}$ in the dark. Untreated samples of the above matrices, devoid of any residue of boscalid were spiked with boscalid reference material at a 0.1 mg/kg spiking level and immediately stored at $\leq -18^{\circ}\text{C}$ in the dark. The samples used in the study were previously homogenized in frozen conditions in order to obtain comminuted samples (fine powder in case of wheat grain and oilseed rape seeds and small pellets in case of wheat whole plant, wheat straw, oilseed rape straw and oilseed rape pods).

The analytical determination was carried out applying the analytical method validated in the GLP studies coded LBN-0118-2023 and LBN-0119-2023 according to SANTE/2020/12830, Rev.2 guidance document. Details are provided in dRR Part B Section 5.

Results and discussions

Table A 1: Summary of concurrent recoveries of boscalid from below matrices

Recovery check name	Extraction date	Spiking level	Sample weight (g)	Spiking solution conc. (mg/L)	Spiking volume (µL)	Spiked conc. (mg/kg)	Final extract volume (mL)	Dilution factor	Expected conc. in the analysed extract (µg/L)	Measured conc. in the analysed extract (µg/L)	Measured conc. in the sample (mg/kg)	Recovery (%)
Wheat - whole plant												
WWP t0 RC1	06/12/2023	10xLOQ	5.01	10	50	0.100	20	1	25.0	24.4426	0.0976	97.8
WWP t0 RC2		10xLOQ	4.98	10	50	0.100	20	1	25.0	24.0425	0.0966	96.2
WWP t1 RC1	04/01/2024	10xLOQ	5.08	10	50	0.098	20	1	25.0	24.1115	0.0949	96.4
WWP t1 RC2		10xLOQ	5.11	10	50	0.098	20	1	25.0	24.6780	0.0966	98.7
WWP t3 RC1	11/03/2024	10xLOQ	4.99	10	50	0.100	20	1	25.0	22.8774	0.0917	91.5
WWP t3 RC2		10xLOQ	5.01	10	50	0.100	20	1	25.0	22.7509	0.0908	91.0
WWP t5 RC1	02/05/2024	10xLOQ	4.99	10	50	0.100	20	1	25.00	22.3081	0.0894	89.2
WWP t5 RC2		10xLOQ	5.06	10	50	0.099	20	1	25.00	21.4707	0.0849	85.9
Wheat - grain												
WGR t0 RC1	06/12/2023	10xLOQ	5.02	10	50	0.100	20	1	25.00	23.9046	0.0952	95.6
WGR t0 RC2		10xLOQ	5.02	10	50	0.100	20	1	25.00	22.8938	0.0912	91.6
WGR t1 RC1	04/01/2024	10xLOQ	5.01	10	50	0.100	20	1	25.00	22.9773	0.0917	91.9
WGR t1 RC2		10xLOQ	5.01	10	50	0.100	20	1	25.00	22.3935	0.0894	89.6
WGR t3 RC1	11/03/2024	10xLOQ	5.03	10	50	0.099	20	1	25.00	23.0911	0.0918	92.4
WGR t3 RC2		10xLOQ	5.05	10	50	0.099	20	1	25.00	24.3160	0.0963	97.3
WGR t5 RC1	02/05/2024	10xLOQ	4.98	10	50	0.100	20	1	25.00	24.1749	0.0971	96.7
WGR t5 RC2		10xLOQ	5.01	10	50	0.100	20	1	25.00	23.8440	0.0952	95.4
Wheat - straw												
WST t0 RC1	06/12/2023	10xLOQ	2.50	10	25	0.100	20	1	12.50	12.8138	0.1025	102.5
WST t0 RC2		10xLOQ	2.49	10	25	0.100	20	1	12.50	13.0162	0.1045	104.1
WST t1 RC1	04/01/2024	10xLOQ	2.49	10	25	0.100	20	1	12.50	12.2360	0.0983	97.9
WST t1 RC2		10xLOQ	2.50	10	25	0.100	20	1	12.50	11.7163	0.0937	93.7
WST t3 RC1	11/03/2024	10xLOQ	2.51	10	25	0.100	20	1	12.50	11.6574	0.0929	93.3
WST t3 RC2		10xLOQ	2.51	10	25	0.100	20	1	12.50	11.6455	0.0928	93.2
WST t5 RC1	02/05/2024	10xLOQ	2.51	10	25	0.100	20	1	12.50	12.0860	0.0963	96.7
WST t5 RC2		10xLOQ	2.51	10	25	0.100	20	1	12.50	11.0180	0.0878	88.1

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Oilseed rape - whole plant												
OSRWP t0 RC1	05/12/2023	10xLOQ	5.08	10	50	0.098	20	1	25.00	19.8853	0.078	79.5
OSRWP t0 RC2		10xLOQ	5.03	10	50	0.099	20	1	25.00	20.3085	0.081	81.2
OSRWP t1 RC1	04/01/2024	10xLOQ	5.09	10	50	0.098	20	1	25.00	23.5913	0.093	94.4
OSRWP t1 RC2		10xLOQ	4.94	10	50	0.101	20	1	25.00	24.5389	0.099	98.2
OSRWP t3 RC1	11/03/2024	10xLOQ	5.06	10	50	0.099	20	1	25.00	21.2708	0.084	85.1
OSRWP t3 RC2		10xLOQ	5.07	10	50	0.099	20	1	25.00	20.7036	0.082	82.8
OSRWP t5 RC1	02/05/2024	10xLOQ	4.94	10	50	0.101	20	1	25.00	23.2418	0.094	93.0
OSRWP t5 RC2		10xLOQ	5.02	10	50	0.100	20	1	25.00	21.4725	0.086	85.9
Oilseed rape - pods												
OSRPO t0 RC1	05/12/2023	10xLOQ	2.59	10	25	0.097	20	1	12.50	10.8513	0.084	86.8
OSRPO t0 RC2		10xLOQ	2.47	10	25	0.101	20	1	12.50	10.8341	0.088	86.7
OSRPO t1 RC1	04/01/2024	10xLOQ	2.48	10	25	0.101	20	1	12.50	11.9567	0.096	95.7
OSRPO t1 RC2		10xLOQ	2.47	10	25	0.101	20	1	12.50	12.2066	0.099	97.7
OSRPO t3 RC1	11/03/2024	10xLOQ	2.46	10	25	0.102	20	1	12.50	10.6732	0.087	85.4
OSRPO t3 RC2		10xLOQ	2.58	10	25	0.097	20	1	12.50	10.8662	0.084	86.9
OSRPO t5 RC1	02/05/2024	10xLOQ	2.56	10	25	0.098	20	1	12.50	11.6200	0.091	93.0
OSRPO t5 RC2		10xLOQ	2.45	10	25	0.102	20	1	12.50	12.3652	0.101	98.9
Oilseed rape - seeds												
OSRSE t0 RC1	05/12/2023	10xLOQ	4.99	10	50	0.100	20	1	25.00	22.6028	0.091	90.4
OSRSE t0 RC2		10xLOQ	4.97	10	50	0.101	20	1	25.00	22.4351	0.090	89.7
OSRSE t1 RC1	04/01/2024	10xLOQ	5.04	10	50	0.099	20	1	25.00	21.6314	0.086	86.5
OSRSE t1 RC2		10xLOQ	5.03	10	50	0.099	20	1	25.00	19.9018	0.079	79.6
OSRSE t3 RC1	11/03/2024	10xLOQ	5.01	10	50	0.100	20	1	25.00	21.9037	0.087	87.6
OSRSE t3 RC2		10xLOQ	5.01	10	50	0.100	20	1	25.00	24.4107	0.097	97.6
OSRSE t5 RC1	02/05/2024	10xLOQ	5.01	10	50	0.100	20	1	25.00	23.0942	0.092	92.4
OSRSE t5 RC2		10xLOQ	5.00	10	50	0.100	20	1	25.00	23.1395	0.093	92.6

Table A 2: Stability of boscalid residues in above matrices following storage at ≤-18°C

Matrix	Actual storage period (months/days)	Residue Level in Freezer Storage Stability Sample % of initial spiking level)	Residue Level in Freezer Storage Stability Sample % of initial spiking level (corrected for the recovery of the day)
Wheat			
Wheat Whole plant	0 months	98.9	102.2
	1 month (29 days)	93.6	95.9
	3 months (96 days)	88.1	96.5
	5 months (148 days)	88.3	100.8
Wheat Grain	0 months	96.5	103.1
	1 month (29 days)	91.4	100.7
	3 months (96 days)	92.1	97.2

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	5 months (148 days)	97.0	101.0
Wheat Straw	0 months	98.1	94.9
	1 month (29 days)	98.9	103.2
	3 months (96 days)	90.0	96.6
	5 months (148 days)	97.5	105.5
Oilseed rape			
Oilseed rape Whole plant	0 months	80.3	99.9
	1 month (30 days)	84.3	87.5
	3 months (97 days)	81.7	97.4
	5 months (149 days)	86.8	97.0
Oilseed rape Pods	0 months	91.0	104.9
	1 month (30 days)	86.5	89.5
	3 months (97 days)	85.6	99.3
	5 months (149 days)	92.1	96.0
Oilseed rape Seeds	0 months	91.5	101.6
	1 month (30 days)	85.0	102.2
	3 months (97 days)	91.3	98.6
	5 months (149 days)	88.5	95.7

Conclusion

The boscalid is stable for a period of 5 months storage at $\leq -18^{\circ}\text{C}$ in the dark in wheat (whole plant, straw and grain) and oilseed rape (whole plant, pods and seeds).

A 2.1.1.1.2 Storage stability of residues in animal products

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

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

A 2.1.2.1 Nature of residue in plants

A 2.1.2.1.1 Nature of residue in primary crops

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

A 2.1.2.1.2 Nature of residue in rotational crops

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

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A 2.1.2.1.3 Nature of residues in processed commodities

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

A 2.1.2.2 Nature of residues in livestock

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

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Wheat

Table A 3: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (DAR, Germany, 2002)	-	-	-	-	-
cGAP EU (Art. 12, EFSA, 2014)	2	350 g as/ha	-	BBCH 69	35
Intended cGAP (1 and 2*)	1	350 g as/ha	NA	BBCH 30-49	56

* 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. Trials are independent
-------------------	---

Reference:	KCA 6.3/01
Report	Magnitude of the residue of Boscalid (188425-85-6) in wheat (Raw Agricultural Commodity - RAC) grown in open field conditions after one application of a formulated product BSK-FUN 500 SC- four harvest and four decline curve trials in Northern Europe, Ptaszek R., 2024, Study number: GBA-DPL-2023-14
Guideline(s):	Yes OECD ENV/MC/CHEM(98)16, ENV/JM/MONO(2002)9, OECD 509, Environment Monograph No. 50 (1999), FAO, Rome 1990, 7029/VI/95 rev.5, SANTE/2019/12752, Council Decision [C(97)186/Final]
Deviations:	No
GLP:	Yes
Acceptability:	Yes

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Field phase:

The objective of the field phase of the study was to provide an analytical laboratory with treated specimens of wheat (RAC) resulting from one application at rate of 0.7 L/ha of BSK-FUN 500 SC (350 g a.s./ha of Boscalid). The study was carried out in open field conditions. All aspects of a field work will be performed in accordance with typical Good Agricultural Practices.

The application equipment consisted of a boom sprayer for foliar applications closely simulating commercial-type treatments. Before each application the spray equipment was calibrated using the volume/time method for liquid applications to deliver an average volume of spray mixture per unit time in the desired spray volume per hectare.

Crop & plot information

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Trial GBA-DPL-2023-14-D01	
Location (country/state-region)	Poland, Mazowieckie
Location reference (city and ZIP code)	Pomianowo, 09-164 Dzierżążnia
GPS Coordinates	52.619198362920585, 20.15942473043369
Crop (common, latin name, EPPO code)	Winter wheat, <i>Triticum aestivum</i> , TRZAW
Cultivar (Variety)	Asory
Cropping technique	Standard
Planting date	20.09.2022
Flowering period	20.06.2023
Harvest date	04.08.2023
Date of crop Destruction	04.08.2023
Number of plots	2
Plot size (m ²)	30
Plot width (m)	3
Plot length (m)	10
Distance between treated/untreated (m)	10
Number of rows/plot	N/A
Number of plants/plot	N/A
Distance between rows (m)	0.125
Distance between plants (m)	N/A
Plants/ha	N/A
Slope %	0
Soil type	Sand
pH	5.7
% organic matter	1.8
Remarks	N/A

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Trial GBA-DPL-2023-14-D02	
Location (country/state-region)	Poland, Kujawsko-Pomorskie
Location reference (city and ZIP code)	Murczyn, 88-400 Żnin
GPS Coordinates	52.8723857, 17.8171461
Crop (common, latin name, EPPO code)	Winter wheat, <i>Triticum aestivum</i> , TRZAW
Cultivar (Variety)	Asory
Cropping technique	Standard
Planting date	15.10.2022
Flowering period	15.06.2023
Harvest date	30.07.2023
Date of crop Destruction	30.07.2023
Number of plots	2
Plot size (m²)	30
Plot width (m)	3
Plot length (m)	10
Distance between treated/untreated (m)	10
Number of rows/plot	N/A
Number of plants/plot	N/A
Distance between rows (m)	0.125
Distance between plants (m)	N/A
Plants/ha	N/A
Slope %	0
Soil type	Sandy clay
pH	7.5
% organic matter	1.4
Remarks	N/A

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Trial GBA-DPL-2023-14-D03	
Location (country/state-region)	Poland, Pomorskie
Location reference (city and ZIP code)	Lasowice Wielkie, 82-200 Malbork
GPS Coordinates	54.0850180080461, 19.064920204518586
Crop (common, latin name, EPPO code)	Winter wheat, <i>Triticum aestivum</i> , TRZAW
Cultivar (Variety)	Arkadia
Cropping technique	Standard
Planting date	15.09.2022
Flowering period	18.06.2023
Harvest date	08.08.2023
Date of crop Destruction	08.08.2023
Number of plots	2
Plot size (m²)	30
Plot width (m)	3
Plot length (m)	10
Distance between treated/untreated (m)	10
Number of rows/plot	N/A
Number of plants/plot	N/A
Distance between rows (m)	0.125
Distance between plants (m)	N/A
Plants/ha	N/A
Slope %	0
Soil type	Silt
pH	6.1
% organic matter	2.4
Remarks	N/A

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Trial GBA-DPL-2023-14-D04	
Location (country/state-region)	Poland, Warmińsko-Mazurskie
Location reference (city and ZIP code)	Wielewo, 14-500 Braniewo
GPS Coordinates	54.32186623495725, 19.854112313362332
Crop (common, latin name, EPPO code)	Winter wheat, <i>Triticum aestivum</i> , TRZAW
Cultivar (Variety)	Fenomen
Cropping technique	Standard
Planting date	03.09.2022
Flowering period	18.06.2023
Harvest date	03.08.2023
Date of crop Destruction	03.08.2023
Number of plots	2
Plot size (m²)	30
Plot width (m)	3
Plot length (m)	10
Distance between treated/untreated (m)	10
Number of rows/plot	N/A
Number of plants/plot	N/A
Distance between rows (m)	0.125
Distance between plants (m)	N/A
Plants/ha	N/A
Slope %	0
Soil type	Sand
pH	6.2
% organic matter	2.4
Remarks	N/A

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Trial GBA-DPL-2023-14-D05	
Location (country/state-region)	Poland, Łódzkie
Location reference (city and ZIP code)	Żywocin, 97-320 Wolbórz
GPS Coordinates	51.5525025545391, 19.857403014678734
Crop (common, latin name, EPPO code)	Winter wheat, <i>Triticum aestivum</i> , TRZAW
Cultivar (Variety)	Artist
Cropping technique	Standard
Planting date	06.10.2022
Flowering period	10.06.2023
Harvest date	03.08.2023
Date of crop Destruction	03.08.2023
Number of plots	2
Plot size (m²)	45
Plot width (m)	3
Plot length (m)	15
Distance between treated/untreated (m)	10
Number of rows/plot	N/A
Number of plants/plot	N/A
Distance between rows (m)	0.125
Distance between plants (m)	N/A
Plants/ha	N/A
Slope %	0
Soil type	Clay
pH	6.2
% organic matter	2.3
Remarks	N/A

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Trial GBA-DPL-2023-14-D06	
Location (country/state-region)	Poland, Mazowieckie
Location reference (city and ZIP code)	Wikcinek, 96-513 Nowa Sucha
GPS Coordinates	52.14217236291455, 20.217750100953555
Crop (common, latin name, EPPO code)	Winter wheat, <i>Triticum aestivum</i> , TRZAW
Cultivar (Variety)	Euforia
Cropping technique	Standard
Planting date	10.10.2022
Flowering period	25.06.2023
Harvest date	24.07.2023
Date of crop Destruction	24.07.2023
Number of plots	2
Plot size (m ²)	45
Plot width (m)	3
Plot length (m)	15
Distance between treated/untreated (m)	20
Number of rows/plot	N/A
Number of plants/plot	N/A
Distance between rows (m)	0.12
Distance between plants (m)	N/A
Plants/ha	N/A
Slope %	0
Soil type	Sandy clay
pH	5.2
% organic matter	1.3
Remarks	N/A

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Trial GBA-DPL-2023-14-D07	
Location (country/state-region)	Poland, Mazowieckie
Location reference (city and ZIP code)	Żukówka, 05-870 Blonie
GPS Coordinates	52.1850411, 20.6255753
Crop (common, latin name, EPPO code)	Winter wheat, <i>Triticum aestivum</i> , TRZAW
Cultivar (Variety)	Arkadia
Cropping technique	Standard
Planting date	30.09.2022
Flowering period	18.06.2023
Harvest date	04.08.2023
Date of crop Destruction	04.08.2023
Number of plots	2
Plot size (m²)	45
Plot width (m)	3
Plot length (m)	15
Distance between treated/untreated (m)	10
Number of rows/plot	N/A
Number of plants/plot	N/A
Distance between rows (m)	N/A
Distance between plants (m)	N/A
Plants/ha	N/A
Slope %	0
Soil type	Clay
pH	5.8
% organic matter	1.9
Remarks	N/A

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Trial GBA-DPL-2023-14-D08	
Location (country/state-region)	Poland, Mazowieckie
Location reference (city and ZIP code)	Gogole Wielkie, 06-420 Golymin-Ośrodek
GPS Coordinates	52.84349419410551, 20.811554767263143
Crop (common, latin name, EPPO code)	Winter wheat, <i>Triticum aestivum</i> , TRZAW
Cultivar (Variety)	Delawar
Cropping technique	Standard
Planting date	25.09.2022
Flowering period	19.06.2023
Harvest date	04.08.2023
Date of crop Destruction	04.08.2023
Number of plots	2
Plot size (m²)	45
Plot width (m)	3
Plot length (m)	15
Distance between treated/untreated (m)	10
Number of rows/plot	N/A
Number of plants/plot	N/A
Distance between rows (m)	0.125
Distance between plants (m)	N/A
Plants/ha	N/A
Slope %	0
Soil type	Sandy clay
pH	5.9
% organic matter	2.3
Remarks	N/A

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Only one sampling took place within the trial GBA-DPL-2023-14-D01, GBA-DPL-2023-14-D02, GBA-DPL-2023-14-D03 and GBA-DPL-2023-14-D04. There were 5 samplings performed within the trials: GBA-DPL-2023-14-D05, GBA-DPL-2023-14-D06, GBA-DPL-2023-14-D07 and GBA-DPL-2023-14-D08.

Analytical phase:

The analytical phase was performed in LabAnalysis s.r.l. and summarised in report LBN-0118-2023. The analytical method was validated according to SANTE/2020/12830 Rev.2 (14/02/2023) guidance document. The samples were analysed by a HPLC-MS/MS system. For more details, please refer to dRR Part B Section 5.

LOQ = 0.01 mg/kg – each matrix

LOD = 0.002 mg/kg

The accuracy and precision results obtained are in compliance with SANTE/2020/12830 rev.2 requirements:

LOQ level (0.01 mg/kg)

Mean recovery 60 – 120%

RSD \leq 30%

10xLOQ level (0.1 mg/kg)

Mean recovery 70 – 120%

RSD \leq 20%

Results:

Summary of the field samples analysis is reported in the following table:

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Table A 4: Summary of the study GBA-DPL-2023-14 (8 trials)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treat- ment or date	Portion ana- lyzed	Residues (mg/kg)	DALA (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Boscalid		
GBA-DPL-2023-14- D01/Poland/N- EU/2023	Winter wheat/Asory	1. 20.09.2022 2. 20.06.2023 3. 04.08.2023	334.5	286.7	116.67	10.06.2023	BBCH 49	Straw Seeds	2.2672 <u>0.0498</u>	harvest harvest	HPLC-MS/MS LOQ = 0.01 mg/kg LOD = 0.002 mg/kg Storage period: Seeds: 60 days Straw: 65 days Whole plant: 119 days
GBA-DPL-2023-14- D02/Poland/N- EU/2023	Winter wheat/Asory	1. 15.10.2022 2. 15.06.2023 3. 30.07.2023	352	301.7	116.67	01.06.2023	BBCH 49	Straw Seeds	3.9848 <u>0.0075</u>	harvest harvest	HPLC-MS/MS LOQ = 0.01 mg/kg LOD = 0.002 mg/kg Storage period: Seeds: 60 days Straw: 65 days Whole plant: 119 days
GBA-DPL-2023-14- D03/Poland/N- EU/2023	Winter wheat/Arkadia	1. 15.09.2022 2. 18.06.2023 3. 08.08.2023	358	306.7	116.7	02.06.2023	BBCH 49	Straw Seeds	4.8975 <u>0.0065</u>	harvest harvest	HPLC-MS/MS LOQ = 0.01 mg/kg LOD = 0.002 mg/kg Storage period: Seeds: 60 days Straw: 65 days Whole plant: 119 days
GBA-DPL-2023-14- D04/Poland/N- EU/2023	Winter wheat/Fe- nomen	1. 03.09.2022 2. 18.06.2023 3. 03.08.2023	354	303.3	116.7	02.06.2023	BBCH 49	Straw Seeds	1.7415 <u>0.0501</u>	harvest harvest	HPLC-MS/MS LOQ = 0.01 mg/kg LOD = 0.002 mg/kg Storage period: Seeds: 60 days Straw: 65 days Whole plant: 119 days

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Trial No./ Location/ EU zone/ Year	Commodity/ Va- riety (a)	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treat- ment or date	Portion ana- lyzed	Residues (mg/kg)	DALA (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Boscalid		
GBA-DPL-2023-14- D05/Poland/N- EU/2023	Winter wheat/Artist	1. 06.10.2022 2. 10.06.2023 3. 03.08.2023	358	204.4	175.2	05.06.2023	BBCH 49	Whole plant Whole plant Whole plant Whole plant Straw Seeds	3.3445 2.2488 2.1326 3.8257 7.4445 <u>0.0562</u>	0 20 30 39 harvest harvest	HPLC-MS/MS LOQ = 0.01 mg/kg LOD = 0.002 mg/kg Storage period: Seeds: 60 days Straw: 65 days Whole plant: 119 days
GBA-DPL-2023-14- D06/Poland/N- EU/2023	Winter wheat/Euforia	1. 10.10.2022 2. 25.06.2023 3. 24.07.2023	381	217.8	174.9	10.06.2023	BBCH 49	Whole plant Whole plant Whole plant Whole plant Straw Seeds	2.8787 1.8023 3.7668 4.6565 5.0612 <u>0.0421</u>	0 19 31 38 harvest harvest	HPLC-MS/MS LOQ = 0.01 mg/kg LOD = 0.002 mg/kg Storage period: Seeds: 60 days Straw: 65 days Whole plant: 119 days
GBA-DPL-2023-14- D07/Poland/N- EU/2023	Winter wheat/Arkadia	1. 30.09.2022 2. 18.06.2023 3. 04.08.2023	354	202.2	175.0	09.06.2023	BBCH 49	Whole plant Whole plant Whole plant Whole plant Straw Seeds	2.7723 1.5766 1.7507 2.6003 5.7310 <u>0.0731</u>	0 20 28 39 harvest harvest	HPLC-MS/MS LOQ = 0.01 mg/kg LOD = 0.002 mg/kg Storage period: Seeds: 60 days Straw: 65 days Whole plant: 119 days
GBA-DPL-2023-14- D08/Poland/N- EU/2023	Winter wheat/Delawar	1. 25.09.2022 2. 19.06.2023 3. 04.08.2023	338.5	193.3	175.1	09.06.2023	BBCH 49	Whole plant Whole plant Whole plant Whole plant Straw Seeds	5.0587 4.7672 2.2603 3.1992 3.9345 <u>0.0626</u>	0 20 28 39 harvest harvest	HPLC-MS/MS LOQ = 0.01 mg/kg LOD = 0.002 mg/kg Storage period: Seeds: 60 days Straw: 65 days Whole plant: 119 days

- (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

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A 2.1.3.2 Oilseed rape

Table A 5: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage	PHI (days)
cGAP EU (DAR, Germany, 2002)	2	250 g as/ha	4-6 weeks	BBCH 30, 63 - 65	N/A
cGAP EU (Art. 12, EFSA, 2014)	2	250 g as/ha	8-12 days	BBCH 61-69	N/A
Intended cGAP (7*)	2	100-250 g as/ha	30 days	BBCH 13-18	N/A
Intended cGAP (8*)	2	100-250 g as/ha	14 days	BBCH 31-57	N/A
Intended cGAP (9*)	2	100-250 g as/ha	14 days	BBCH 57-71	N/A

* 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. Trials are independent
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Reference:	KCA 6.3/02
Report	Magnitude of the residue of Boscalid (188425-85-6) in oilseed rape (Raw Agricultural Commodity - RAC) grown in open field conditions after one application of a formulated product BSK-FUN 500 SC - four harvest and four decline curve trials in Northern Europe, Ptaszek R., 2024, Study number: GBA-DPL-2023-15
Guideline(s):	Yes OECD ENV/MC/CHEM(98)16, ENV/JM/MONO(2002)9, OECD 509, Environment Monograph No. 50 (1999), FAO, Rome 1990, 7029/VI/95 rev.5, SANTE/2019/12752, Council Decision [C(97)186/Final]
Deviations:	Yes Two deviations were reported. One for the trial GBA-DPL-2023-15-D02 and the other for the trial GBA-DPL-2023-15-D05.
GLP:	Yes
Acceptability:	Yes

Field phase:

The objective of the field phase of the study was to provide an analytical laboratory with treated specimens of winter oilseed rape (RAC) resulting from two applications at rate of 0.5 L/ha of BSK-FUN 500 SC (250 g a.s./ha of Boscalid). The study was carried out in open field conditions. All aspects of a field work was performed in accordance with typical Good Agricultural Practices.

The application equipment consisted of a boom sprayer for foliar

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applications closely simulating commercial-type treatments. Before each application the spray equipment was calibrated using the volume/time method for liquid applications to deliver an average volume of spray mixture per unit time in the desired spray volume per hectare.

Crop & plot information

Trial GBA-DPL-2023-15-D01	
Location (country/state-region)	Poland/Pomorskie
Location reference (city and ZIP code)	82-200 Malbork
GPS Coordinates	54.08472237386993, 19.064559802617893
Crop (common, latin name, EPPO code)	Winter oilseed rape, <i>Brassica napus</i> , BRSNW
Cultivar (Variety)	Momento
Cropping technique	Standard
Planting date	16.08.2022
Flowering period	01.06.2023
Harvest date	25.07.2023
Date of crop Destruction	25.07.2023
Number of plots	2
Plot size (m²)	30
Plot width (m)	3
Plot length (m)	10
Distance between treated/untreated (m)	10
Number of rows/plot	N/A
Number of plants/plot	N/A
Distance between rows (m)	0.125
Distance between plants (m)	N/A
Plants/ha	N/A
Slope %	0
Soil type	Silt
pH	5.7
% organic matter	2.2
Remarks	N/A

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Trial GBA-DPL-2023-15-D02	
Location (country/state-region)	Poland/Kujawsko-Pomorskie
Location reference (city and ZIP code)	88-400 Żnin
GPS Coordinates	52.868393830155405, 17.786990096295394
Crop (common, latin name, EPPO code)	Winter oilseed rape, <i>Brassica napus</i> , BRSNW
Cultivar (Variety)	Acapulco
Cropping technique	Standard
Planting date	15.08.2022
Flowering period	07.05.2023
Harvest date	24.07.2023
Date of crop Destruction	24.07.2023
Number of plots	2
Plot size (m²)	30
Plot width (m)	3
Plot length (m)	10
Distance between treated/untreated (m)	10
Number of rows/plot	N/A
Number of plants/plot	N/A
Distance between rows (m)	0.2
Distance between plants (m)	0.1
Plants/ha	600 000
Slope %	0
Soil type	Sandy clay
pH	5.7
% organic matter	1.9
Remarks	N/A

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Trial GBA-DPL-2023-15-D03	
Location (country/state-region)	Poland/Łódzkie
Location reference (city and ZIP code)	96-128 Słupia
GPS Coordinates	51.86600237794306, 19.990347072038134
Crop (common, latin name, EPPO code)	Winter oilseed rape, <i>Brassica napus</i> , BRSNW
Cultivar (Variety)	SY Glorietta
Cropping technique	Standard
Planting date	21.08.2022
Flowering period	17.06.2023
Harvest date	31.07.2023
Date of crop Destruction	31.07.2023
Number of plots	2
Plot size (m²)	30
Plot width (m)	3
Plot length (m)	10
Distance between treated/untreated (m)	10
Number of rows/plot	N/A
Number of plants/plot	N/A
Distance between rows (m)	0.125
Distance between plants (m)	0.04
Plants/ha	N/A
Slope %	0
Soil type	Sand
pH	6.2
% organic matter	1.5
Remarks	N/A

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Trial GBA-DPL-2023-15-D04	
Location (country/state-region)	Poland/Pomorskie
Location reference (city and ZIP code)	82-213 Miloradz
GPS Coordinates	54.052585169611376, 18.875913601181562
Crop (common, latin name, EPPO code)	Winter oilseed rape, <i>Brassica napus</i> , BRSNW
Cultivar (Variety)	Aliboom
Cropping technique	Standard
Planting date	18.08.2022
Flowering period	05.06.2023
Harvest date	25.07.2023
Date of crop Destruction	25.07.2023
Number of plots	2
Plot size (m ²)	30
Plot width (m)	3
Plot length (m)	10
Distance between treated/untreated (m)	10
Number of rows/plot	N/A
Number of plants/plot	N/A
Distance between rows (m)	0.125
Distance between plants (m)	N/A
Plants/ha	N/A
Slope %	0
Soil type	Silt
pH	6.2
% organic matter	2.4
Remarks	N/A

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Trial GBA-DPL-2023-15-D05	
Location (country/state-region)	Poland/Łódzkie
Location reference (city and ZIP code)	99-311 Bedlno
GPS Coordinates	52.12458606392088, 19.625031689177266
Crop (common, latin name, EPPO code)	Winter oilseed rape, <i>Brassica napus</i> , BRSNW
Cultivar (Variety)	Harvey
Cropping technique	Standard
Planting date	10.09.2022
Flowering period	05.05.2023
Harvest date	17.07.2023
Date of crop Destruction	17.07.2023
Number of plots	2
Plot size (m²)	45
Plot width (m)	3
Plot length (m)	15
Distance between treated/untreated (m)	10
Number of rows/plot	N/A
Number of plants/plot	N/A
Distance between rows (m)	0.25
Distance between plants (m)	0.12
Plants/ha	N/A
Slope %	0
Soil type	3B, Sand
pH	5.5
% organic matter	-
Remarks	N/A

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Trial GBA-DPL-2023-15-D06	
Location (country/state-region)	Poland/Łódzkie
Location reference (city and ZIP code)	97-320 Wolbórz
GPS Coordinates	51.53610768901381, 19.82857908636836
Crop (common, latin name, EPPO code)	Winter oilseed rape, <i>Brassica napus</i> , BRSNW
Cultivar (Variety)	Temptation
Cropping technique	Standard
Planting date	28.08.2022
Flowering period	14.05.2023
Harvest date	26.07.2023
Date of crop Destruction	26.07.2023
Number of plots	2
Plot size (m²)	45
Plot width (m)	3
Plot length (m)	15
Distance between treated/untreated (m)	10
Number of rows/plot	N/A
Number of plants/plot	N/A
Distance between rows (m)	0.125
Distance between plants (m)	N/A
Plants/ha	N/A
Slope %	0
Soil type	Sandy clay
pH	6.2
% organic matter	2.3
Remarks	N/A

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Trial GBA-DPL-2023-15-D07	
Location (country/state-region)	Poland/Mazowieckie
Location reference (city and ZIP code)	05-870 Blonie
GPS Coordinates	52.183640633086235, 20.626468809428395
Crop (common, latin name, EPPO code)	Winter oilseed rape, <i>Brassica napus</i> , BRSNW
Cultivar (Variety)	Aliboom
Cropping technique	Standard
Planting date	10.08.2022
Flowering period	08.05.2023
Harvest date	05.08.2023
Date of crop Destruction	05.08.2023
Number of plots	2
Plot size (m²)	45
Plot width (m)	3
Plot length (m)	15
Distance between treated/untreated (m)	10
Number of rows/plot	N/A
Number of plants/plot	N/A
Distance between rows (m)	0.125
Distance between plants (m)	N/A
Plants/ha	N/A
Slope %	0
Soil type	Clay
pH	5.9
% organic matter	6.3
Remarks	N/A

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Trial GBA-DPL-2023-15-D08	
Location (country/state-region)	Poland/Mazowieckie
Location reference (city and ZIP code)	09-140 Raciąż
GPS Coordinates	52.70860719951556, 20.13381288219856
Crop (common, latin name, EPPO code)	Winter oilseed rape, <i>Brassica napus</i> , BRSNW
Cultivar (Variety)	Ambassador
Cropping technique	Standard
Planting date	29.08.2022
Flowering period	18.06.2023
Harvest date	31.07.2023
Date of crop Destruction	31.07.2023
Number of plots	2
Plot size (m ²)	45
Plot width (m)	3
Plot length (m)	15
Distance between treated/untreated (m)	10
Number of rows/plot	N/A
Number of plants/plot	N/A
Distance between rows (m)	0.125
Distance between plants (m)	N/A
Plants/ha	N/A
Slope %	0
Soil type	Clay
pH	5.9
% organic matter	2.1
Remarks	N/A

Analytical phase:

The analytical phase was performed in LabAnalysis s.r.l. and summarised in report LBN-0119-2023. The analytical method was validated according to SANTE/2020/12830 Rev.2 (14/02/2023) guidance document. The samples were analysed by a HPLC-MS/MS system. For more details, please refer to dRR Part B Section 5.

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LOQ = 0.01 mg/kg – each matrix
LOD = 0.002 mg/kg

The accuracy and precision results obtained are in compliance with SANTE/2020/12830 rev.2 requirements:

LOQ level (0.01 mg/kg)
Mean recovery 60 – 120%
RSD \leq 30%

10xLOQ level (0.1 mg/kg)
Mean recovery 70 – 120%
RSD \leq 20%

Results:

Summary of the field samples analysis is reported in the following table:

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Table A 6: Summary of the study GBA-DPL-2023-15 (8 trials)

Trial No./ Location/ EU zone/ Year	Commodity/ Va- riety (a)	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treat- ment or date	Portion ana- lyzed	Residues (mg/kg)	DALA (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Boscalid		
GBA-DPL-2023-15- D01/Poland/N- EU/2023	Winter oilseed rape / Momento	1. 16.08.2022 2. 01.06.2023 3. 25.07.2023	250 250	300 300	83.3 83.3	02.06.2023 16.06.2023	BBCH 61 BBCH 71	Seeds	<u>0.0144</u>	harvest	HPLC-MS/MS LOQ = 0.01 mg/kg LOD = 0.002 mg/kg Storage period: Whole plant: 113 days Plant without pods: 88 days Pods: 89 days Seeds: 72 days
GBA-DPL-2023-15- D02/Poland/N- EU/2023	Winter oilseed rape / Acapulco	1. 15.08.2022 2. 07.05.2023 3. 24.07.2023	247 258.5	296.7 310	83.2 83.4	01.06.2023 15.06.2023	BBCH 61 BBCH 71	Seeds	<u>0.0532</u>	harvest	HPLC-MS/MS LOQ = 0.01 mg/kg LOD = 0.002 mg/kg Storage period: Whole plant: 113 days Plant without pods: 88 days Pods: 89 days Seeds: 72 days
GBA-DPL-2023-15- D03/Poland/N- EU/2023	Winter oilseed rape / SY Glo- rietta	1. 21.08.2022 2. 17.06.2023 3. 31.07.2023	233.5 258.5	282 310	82.8 83.4	14.06.2023 28.06.2023	BBCH 61 BBCH 71	Seeds	<u>0.0071</u>	harvest	HPLC-MS/MS LOQ = 0.01 mg/kg LOD = 0.002 mg/kg Storage period: Whole plant: 113 days Plant without pods: 88 days Pods: 89 days Seeds: 72 days
GBA-DPL-2023-15- D04/Poland/N- EU/2023	Winter oilseed rape / Aliboom	1. 18.08.2022 2. 05.06.2023 3. 25.07.2023	255.5 269.5	306.7 323.3	83.3 83.4	02.06.2023 16.06.2023	BBCH 61 BBCH 71	Seeds	<u>0.0182</u>	harvest	HPLC-MS/MS LOQ = 0.01 mg/kg LOD = 0.002 mg/kg

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Trial No./ Location/ EU zone/ Year	Commodity/ Va- riety (a)	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treat- ment or date	Portion ana- lyzed	Residues (mg/kg)	DALA (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Boscalid		
											Storage period: Whole plant: 113 days Plant without pods: 88 days Pods: 89 days Seeds: 72 days
GBA-DPL-2023-15- D05/Poland/N- EU/2023	Winter oilseed rape / Harvey	1. 10.09.2022 2. 05.05.2023 3. 17.07.2023	255.5 253	204.4 202.2	125 125.1	08.06.2023 22.06.2023	BBCH 65 BBCH 71	Whole plant Whole plant Whole plant Seeds	3.2041 2.4584 4.0169 <u>0.1070</u>	0 6 13 harvest	HPLC-MS/MS LOQ = 0.01 mg/kg LOD = 0.002 mg/kg Storage period: Whole plant: 113 days Plant without pods: 88 days Pods: 89 days Seeds: 72 days
GBA-DPL-2023-15- D06/Poland/N- EU/2023	Winter oilseed rape / Temptation	1. 28.08.2022 2. 14.05.2023 3. 26.07.2023	228 264	182.2 211.1	125.1 125.1	05.06.2023 19.06.2023	BBCH 61 BBCH 71	Whole plant Whole plant Whole plant Plant w/o pods Pods Seeds	2.5551 1.6895 1.7359 0.5313 2.3441 <u>0.0253</u>	0 7 18 25 25 harvest	HPLC-MS/MS LOQ = 0.01 mg/kg LOD = 0.002 mg/kg Storage period: Whole plant: 113 days Plant without pods: 88 days Pods: 89 days Seeds: 72 days
GBA-DPL-2023-15- D07/Poland/N- EU/2023	Winter oilseed rape / Aliboom	1. 10.08.2022 2. 08.05.2023 3. 05.08.2023	250 250	200 200	125 125	09.06.2023 23.06.2023	BBCH 62 BBCH 71	Whole plant Whole plant Whole plant Plant w/o pods Pods Seeds	2.1647 1.4214 2.0514 0.5260 3.5695 <u><0.002</u>	0 6 14 25 25 harvest	HPLC-MS/MS LOQ = 0.01 mg/kg LOD = 0.002 mg/kg Storage period: Whole plant: 113 days Plant without pods: 88 days Pods: 89 days Seeds: 72 days

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Trial No./ Location/ EU zone/ Year	Commodity/ Va- riety (a)	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treat- ment or date	Portion ana- lyzed	Residues (mg/kg)	DALA (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Boscalid		
GBA-DPL-2023-15- D08/Poland/N- EU/2023	Winter oilseed rape / Standard	1. 29.08.2022 2. 18.06.2023 3. 31.07.2023	261 261	208.9 208.9	124.9 124.9	10.06.2023 24.06.2023	BBCH 64 BBCH 71	Whole plant Whole plant Whole plant Plant w/o pods Pods Seeds	1.936 0.491 0.637 0.306 1.331 <u>≤0.002</u>	0 5 11 25 25 harvest	HPLC-MS/MS LOQ = 0.01 mg/kg LOD = 0.002 mg/kg Storage period: Whole plant: 113 days Plant without pods: 88 days Pods: 89 days Seeds: 72 days

- (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

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A 2.1.4 Magnitude of residues in livestock

A 2.1.4.1 Livestock feeding studies

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

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

A 2.1.5.1 Distribution of the residue in peel/pulp

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

A 2.1.5.2 Processing studies on a core set of representative processes

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

A 2.1.6 Magnitude of residues in representative succeeding crops

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

A 2.1.7 Other/Special Studies

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

A 2.1.7.1 Residues in Honey

A 2.1.7.1.1 Study 1

Comments of Evaluator: Study is accepted

Reference:	KCA 6.10, 6.10.1/01
Report	Determination of Boscalid Residues in Honey Following Application on Phacelia with BSK-FUN 500 SC under semi field Conditions in Northern and Southern Europe in 2023-2024; Schneider E., 2024; report no. R C3127
Guideline(s):	Yes - OECD – guideline for the testing of chemicals, 509; Crop field trial, 14/06/2021 - SANTE/11956/2016 rev.9 – Technical Guidelines for determining the magnitude of pesticide residue in honey and setting maximum Residue Levels in

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honey.

- Guideline 1607/VI/97 rev.2 to Directive 91/414/EEC and Regulations (EU) No. 283/2013 and 284/2013 implementing Regulation (EC)1107/2009, under consideration of the provisions of the Afssa saisine No 2007-SA-0209 – Document guide de fixation de LMR pour le miel.

Deviations:

Yes

Deviation No. 22/09/2023

Trial C3127 MA1:

The weight of sample C3127 MA1 / UH / A was 29.45 g instead of 100 g required by the study plan. The sample C3127 MA1 / UH / R was not collected.

The production of honey was not sufficient in the untreated plot.

The deviation has no impact on the integrity of the study as the taken amount of the untreated field specimens is sufficient for analyses to demonstrate that they have not been treated with a forbidden a.i. and as the treated field specimens were taken as requested by the study plan.

Deviation No. 23/11/2023

Trial C3127 PL1:

The age of the queens could not have been exactly determined (maybe > 2 years). The beekeeper did not have the exact age of the queens but it was approximately two years (from May 2021).

This deviation has no impact on the study as the age of the queens did not affect the strength of the colonies and the residue level.

GLP:

Yes

Acceptability:

Yes

Materials and methods

Field Phase of the study:

The objective of the study was to determine the residue levels of boscalid in honey from bees foraging on Phacelia following one foliar application at flowering of the formulated product BSK-FUN 500 SC (500 g boscalid/L) under semi-field conditions in Northern and Southern Europe in 2023-2024.

The study consisted of 2 phases: the field phase, and the analytical phase.

The study was conducted under semi-field conditions at two sites in Northern Europe and at two sites in Southern Europe.

On these sites, 2 tunnels covered with anti-insect nets were used: Phacelia was grown under both tunnels. At flowering, the crop was treated with BSK-FUN 500 SC at the rate of 1.2 L product/ha (600 g boscalid/ha) in one tunnel. In the second tunnel, the crop was kept untreated.

One honeybee colony was installed under each tunnel the day before the application and bees foraging was restricted to the tunnels. Honey was sampled (at commercial maturity), and the residue level of boscalid was determined by analysis.

Analytical Phase of the study:

The objective of the analytical phase was to determine the residue levels of boscalid in samples harvested during the field phase.

Samples were analysed within 30 days after sampling.

Residues are extracted from honey with water and acetonitrile/acetic acid 99.9/0.1 % mixture. After addition of magnesium sulphate and sodium chloride, the mixture is shaken intensively and centrifuged for phase separation. An aliquot of the organic phase is filtered through PET filter, transferred into a vial for LC-MS/MS analysis.

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The limit of detection (LOD) was expressed as lowest calibration standard.
The LOD was ≈ 0.7 ng/mL for boscalid in honey (corresponding to 0.003 mg/kg).
The LOQ was 0.01 mg/kg for boscalid in honey.
Details are described in dRR Part B Section 5 - validation study C3128).

Conclusion

Residues in control samples were non-detectable. The residue results for boscalid in the treated specimens are summarized below.

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Table A 7: Summary of the study R C3127 (4 trials)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or plant- ing 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treat- ment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion ana- lysed	Residues (mg/kg)	DAA (days) (d)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	kg a.s./hl				Boscalid		
Trial number C3127 MA1 / France, Donnelay (57810) / N- EU / 2023	Phacelia / Stala	1. 15.06.2023 2. 25.08.2023- 27.09.2023 3. n.a.	634.7	317	200.0	30.08.2023	65	Honey	NDR	22	Analytical Method: LC-MS/MS LOD = 0.003 mg/kg LOQ = 0.01 mg/kg Storage time of samples: 22 days NDR: No detectable residues (residues below the LOD)
Trial number C3127 PL1 / Poland, Góra Świętej Małgo- rzaty (99-122) / N-EU / 2023	Phacelia / Stala	1. 09.05.2023 2. 23.06.2023- 10.07.2023 3. n.a.	618.8	413	150.0	29.06.2023	65	Honey	<LOQ	11	Analytical Method: LC-MS/MS LOD = 0.003 mg/kg LOQ = 0.01 mg/kg Storage time of samples: 15 days
Trial number C3127 EF1 / France, Lalandusse (47330) / S- EU / 2023	Phacelia / Stala	1. 13.05.2023 2. 23.06.2023-n.a. 3. n.a.	577.4	289	200.0	30.06.2023	65	Honey	0.01	10	Analytical Method: LC-MS/MS LOD = 0.003 mg/kg LOQ = 0.01 mg/kg Storage time of samples: 15 days
Trial number C3127 IT2 / Italy, Tor- tona (15057) / S-EU / 2023	Phacelia / Boratus	1. 20.03.2023 2. 28.05.2023- 24.06.2023 3. n.a.	572.8	286	200.0	04.06.2023	65	Honey	<LOQ	14	Analytical Method: LC-MS/MS LOD = 0.003 mg/kg LOQ = 0.01 mg/kg Storage time of samples: 17 days

- (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)


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(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

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Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

 European Food Safety Authority EFSA PRIMo revision 3.1; 2021/01/06		<table><tr><th colspan="4">boscalid (F)</th></tr><tr><td colspan="2">LOQs (mg/kg) range from:</td><td colspan="2">to:</td></tr><tr><th colspan="4">Toxicological reference values</th></tr><tr><td>ADI (mg/kg bw/day):</td><td>0,04</td><td>ARID (mg/kg bw):</td><td>not necessary</td></tr><tr><td>Source of ADI:</td><td>EC</td><td>Source of ARID:</td><td>EC</td></tr><tr><td>Year of evaluation:</td><td>2008</td><td>Year of evaluation:</td><td>2008</td></tr></table>				boscalid (F)				LOQs (mg/kg) range from:		to:		Toxicological reference values				ADI (mg/kg bw/day):	0,04	ARID (mg/kg bw):	not necessary	Source of ADI:	EC	Source of ARID:	EC	Year of evaluation:	2008	Year of evaluation:	2008	<table><tr><th colspan="2">Input values</th></tr><tr><td>Details - chronic risk assessment</td><td>Supplementary results - chronic risk assessment</td></tr><tr><td>Details - acute risk assessment/children</td><td>Details - acute risk assessment/adults</td></tr></table>		Input values		Details - chronic risk assessment	Supplementary results - chronic risk assessment	Details - acute risk assessment/children	Details - acute risk assessment/adults
boscalid (F)																																					
LOQs (mg/kg) range from:		to:																																			
Toxicological reference values																																					
ADI (mg/kg bw/day):	0,04	ARID (mg/kg bw):	not necessary																																		
Source of ADI:	EC	Source of ARID:	EC																																		
Year of evaluation:	2008	Year of evaluation:	2008																																		
Input values																																					
Details - chronic risk assessment	Supplementary results - chronic risk assessment																																				
Details - acute risk assessment/children	Details - acute risk assessment/adults																																				
Comments:																																					
Normal mode																																					
Chronic risk assessment: JMPR methodology (IED/TMDI)																																					
		No of diets exceeding the ADI :				26				Exposure resulting from																											
	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor (in % of ADI)	Commodity / group of commodities	2nd contributor to (in % of ADI)	Commodity / group of commodities	3rd contributor to (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)																										
TMDI/IED calculation (based on average food consumption)	400%	NL toddler	159,92	90%	Spinaches	54%	Apples	31%	Escaroles/broad-leaved endives																												
	262%	DE child	104,99	62%	Apples	25%	Spinaches	20%	Oranges																												
	229%	GEMS/Food G11	91,59	34%	Sugar canes	28%	Soyabeans	20%	Potatoes																												
	227%	GEMS/Food G10	90,71	41%	Lettuces	24%	Soyabeans	23%	Sugar canes																												
	222%	GEMS/Food G06	89,86	29%	Sugar canes	27%	Tomatoes	14%	Wheat																												
	219%	NL child	87,70	31%	Spinaches	20%	Apples	17%	Potatoes																												
	217%	GEMS/Food G08	86,98	28%	Sugar canes	25%	Lettuces	20%	Potatoes																												
	216%	GEMS/Food G07	86,32	30%	Lettuces	27%	Sugar canes	19%	Potatoes																												
	198%	IE adult	79,35	18%	Sweet potatoes	16%	Wine grapes	16%	Wine grapes																												
	189%	GEMS/Food G15	75,62	23%	Sugar canes	18%	Potatoes	14%	Lettuces																												
	169%	SE general	67,47	50%	Lettuces	21%	Potatoes	8%	Spinaches																												
	146%	FR child 3 15 yr	58,42	17%	Oranges	14%	Other lettuce and other salad plants	13%	Spinaches																												
	145%	IT adult	58,02	47%	Lettuces	20%	Other lettuce and other salad plants	12%	Spinaches																												
	144%	ES adult	57,67	67%	Lettuces	9%	Spinaches	6%	Oranges																												
	140%	ES child	56,15	52%	Lettuces	11%	Oranges	10%	Spinaches																												
	134%	NL general	53,49	19%	Spinaches	12%	Escaroles/broad-leaved endives	12%	Potatoes																												
	132%	RO general	52,74	21%	Wine grapes	19%	Potatoes	18%	Head cabbages																												
	131%	IT toddler	52,42	36%	Lettuces	14%	Other lettuce and other salad plants	13%	Wheat																												
	131%	PT general	52,33	31%	Wine grapes	27%	Potatoes	13%	Lettuces																												
	128%	FR toddler 2 3 yr	51,24	20%	Spinaches	16%	Apples	10%	Beans (with pods)																												
	124%	DE women 14-50 yr	49,47	14%	Lettuces	13%	Apples	10%	Wine grapes																												
	122%	FR adult	48,92	29%	Wine grapes	19%	Other lettuce and other salad plants	14%	Tea (dried leaves of Camellia sine																												
	119%	DK child	47,61	18%	Lettuces	16%	Cucumbers	12%	Potatoes																												
	119%	DE general	47,47	12%	Apples	12%	Lettuces	10%	Wine grapes																												
	112%	FI 3 yr	44,80	24%	Potatoes	10%	Cucumbers	8%	Spinaches																												
	105%	UK toddler	41,81	17%	Potatoes	10%	Oranges	9%	Apples																												
	102%	FR infant	40,75	33%	Spinaches	10%	Potatoes	8%	Apples																												
	93%	UK infant	37,13	16%	Potatoes	8%	Potatoes	7%	Carrots																												
	92%	FI 6 yr	36,76	19%	Potatoes	10%	Lettuces	7%	Cucumbers																												
	87%	UK vegetarian	34,90	18%	Lettuces	10%	Wine grapes	7%	Potatoes																												
	74%	UK adult	29,45	15%	Lettuces	14%	Cucumbers	7%	Potatoes																												
	67%	PL general	26,98	17%	Potatoes	10%	Apples	7%	Tomatoes																												
	67%	DK adult	26,64	12%	Wine grapes	11%	Lettuces	6%	Potatoes																												
63%	FI adult	25,07	18%	Lettuces	6%	Potatoes	4%	Tomatoes																													
60%	LT adult	23,91	16%	Potatoes	9%	Apples	8%	Lettuces																													
18%	IE child	7,33	3%	Potatoes	2%	Wheat	2%	Apples																													
<p>Conclusion: The estimated TMDI/IED/IEDI was in the range of 0 % to 399,8 % of the ADI. For 26 diet(s) the ADI is exceeded. DISCLAIMER: Dietary data from the UK were included in PRIMo when the UK was a member of the European Union.</p>																																					

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A 3.2 IEDI calculations



European Food Safety Authority
EFSA PRIMo revision 3.1; 2021/01/06

boscalid (F)

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day): **0,04** ARID (mg/kg bw): **not necessary**

Source of ADI: **EC** Source of ARID: **EC**

Year of evaluation: **2008** Year of evaluation: **2008**

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

		No of diets exceeding the ADI : ***						Exposure resulting from			
	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	MRLs set at the LOQ (in % of ADI)	commodities not under assessment (in % of ADI)
TMDI/NEDI calculation (based on average food consumption)	70%	NL toddler	27,92	11%	Apples	10%	Beans (with pods)	10%	Spinaches		
	43%	DE child	17,05	13%	Apples	5%	Table grapes	3%	Spinaches		
	35%	NL child	14,18	6%	Apples	4%	Beans (with pods)	4%	Table grapes		
	27%	IE adult	10,69	4%	Wine grapes	2%	Beans (with pods)	2%	Spinaches		
	27%	FR toddler 2-3 yr	10,61	10%	Beans (with pods)	3%	Apples	2%	Spinaches		
	26%	ES adult	10,46	7%	Lettuces	6%	Chards/beet leaves	3%	Beans (with pods)		
	26%	GEMS/Food G07	10,28	5%	Wine grapes	3%	Lettuces	2%	Barley		
	25%	GEMS/Food G08	10,08	4%	Wine grapes	3%	Lettuces	2%	Barley		
	24%	GEMS/Food G11	9,62	4%	Wine grapes	2%	Barley	2%	Apples		
	24%	FR child 3-15 yr	9,61	6%	Beans (with pods)	2%	Apples	2%	Other lettuce and other salad plant		
	24%	ES child	9,59	6%	Chards/beet leaves	6%	Lettuces	3%	Beans (with pods)		
	24%	GEMS/Food G10	9,56	5%	Lettuces	2%	Barley	1%	Wine grapes		
	24%	IT adult	9,50	5%	Lettuces	5%	Chards/beet leaves	2%	Other lettuce and other salad plant		
	24%	GEMS/Food G06	9,47	4%	Table grapes	3%	Tomatoes	2%	Wheat		
	23%	GEMS/Food G15	9,15	4%	Wine grapes	2%	Head cabbages	2%	Barley		
	22%	SE general	8,96	6%	Lettuces	2%	Head cabbages	1%	Chards/beet leaves		
	22%	FR adult	8,77	8%	Wine grapes	3%	Beans (with pods)	2%	Other lettuce and other salad plant		
	22%	RO general	8,70	6%	Wine grapes	4%	Head cabbages	2%	Tomatoes		
	22%	FR infant	8,62	6%	Beans (with pods)	4%	Spinaches	2%	Chards/beet leaves		
	21%	IT toddler	8,58	5%	Chards/beet leaves	4%	Lettuces	2%	Wheat		
	21%	NL general	8,35	3%	Beans (with pods)	2%	Spinaches	2%	Wine grapes		
	19%	DE general	7,51	3%	Wine grapes	3%	Apples	1%	Barley		
	19%	DE women 14-50 yr	7,48	3%	Wine grapes	3%	Apples	2%	Lettuces		
	19%	PT general	7,43	9%	Wine grapes	1%	Lettuces	1%	Wheat		
	18%	DK child	7,08	3%	Cucumbers	2%	Apples	2%	Lettuces		
	15%	FI 3 yr	6,12	2%	Cucumbers	2%	Strawberries	2%	Oat		
	13%	UK toddler	5,03	2%	Apples	1%	Wheat	1%	Currants (red, black and white)		
	12%	UK vegetarian	4,73	3%	Wine grapes	2%	Lettuces	0,6%	Apples		
	12%	FI 6 yr	4,69	1%	Strawberries	1%	Cucumbers	1%	Lettuces		
	12%	UK infant	4,64	2%	Apples	1%	Strawberries	1,0%	Cauliflowers		
	11%	DK adult	4,38	3%	Wine grapes	1%	Lettuces	1%	Apples		
	11%	UK adult	4,27	4%	Wine grapes	2%	Lettuces	0,5%	Wheat		
	9%	PL general	3,61	2%	Apples	1%	Table grapes	1%	Head cabbages		
	9%	FI adult	3,50	2%	Lettuces	1%	Wine grapes	0,7%	Strawberries		
8%	LT adult	3,18	2%	Apples	1%	Head cabbages	0,9%	Lettuces			
3%	IE child	1,06	0,3%	Wheat	0,3%	Apples	0,3%	Currants (red, black and white)			

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of boscalid (F) 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.

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A 3.3 IESTI calculations - Raw commodities

Not relevant.

A 3.4 IESTI calculations - Processed commodities

Not relevant.

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Appendix 4 Additional information provided by the applicant

Not relevant.