REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: BAS 762 02 F

Product name(s): Revydas

Chemical active substance(s):

Mefentrifluconazole, 100 g/L
Boscalid, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: BASF

Submission date: March 2021

MS Finalisation date: November 2021 (initial Core Assessment)

April 2022 (final Core Assessment)

Version history

When	What
March 2021	Initial dRR – BASF DocID 2021/2002158
November 2021	Initial zRMS assessment. The report in the dRR format has been prepared by the Applicant , therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through and shaded for transparency~~.
April 2022	Final report (Core Assessment after the commenting period) Additional information/assessments included by the zRMS in the report in response to comments recieved from the cMS and the Applicant are highlighted in yellow, while not agreed use pattern is ~~struck through and shaded~~.

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

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 BAS 762 02 F are presented in Table 7.1-1. They have been selected from the individual GAPs in the Central zone for oilseed rape, sunflower and wheat. A list of all intended uses within the Central zone is given in Part B, Section 0.

Overall conclusion
The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.05 mg/kg (sunflower seeds), 0.06 mg/kg (oilseed rape/rapeseeds/canola seeds) and 0.05 mg/kg (wheat) for mefentrifluconazole and 1.0 mg/kg (sunflower seeds and oilseed rape/rapeseeds/canola seeds) and 0.8 mg/kg (wheat) for boscalid as laid down in Reg. (EU) 396/2005 is not expected.

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

As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended use(s). Based on the data available, no specific mitigation measures should apply.

Data gaps
Noticed data gaps are: None

~~According to the EFSA Journal 2018;16(7):5379 following data gap in residue area has been identified during the peer review process:~~

- ~~Data or information addressing residue levels of mefentrifluconazole and its metabolites in pollen and in bee products for human consumption, obtained from primary and rotational crops.~~

~~In our opinion, the above data gap should also be fulfilled in this application to support the intended uses of BAS 762 02 F / Revydas.~~

The residue study for the determination of mefentrifluconazole residues in honey (BASF DocID: 2020/2109990, Report Amendment N°1 DocID: 2021/2038566) has been provided by Applicant and added to the Registration Report for BAS 762 02 F / Revydas.

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

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min) (days)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		
1	**Oilseed Rape, winter and spring (BRSNN)**	**AT, BE, DE, PL, IE**	**BAS 762 02 F**	**F**	***Sclerotinia sclerotiorum (SCLESC) Alternaria spp. (ALTESP) Erysiphe cruciferarum (ERYSCR) Neopseudocercosporella brassicae (MYCOBR)***	**SC**	**a) 100 g/L b) 200 g/L**	**Spraying**	**57 - 75**	**1**	**-**	**a) 0.025 - 0.1 b) 0.05 - 0.2**	**100-400**	**a) 0.1 b) 0.2**	**F**	F is defined by latest application timing. **A**
2	Oilseed Rape, winter and spring (BRSNN)	HU, RO, SI, SK	BAS 762 02 F	F	*Sclerotinia sclerotiorum (SCLESC) Alternaria spp. (ALTESP)*	SC	a) 100 g/L b) 200 g/L	Spraying	57 - 75	1	-	a) 0.015 - 0.1 b) 0.03 - 0.2	100-400	a) 0.06 - 0.1 b) 0.12 - 0.2	F	dose rate range 0.6 - 1.0 L/ha F is defined by latest application timing. **A**
3	Oilseed Rape, winter and spring (BRSNN)	CZ	BAS 762 02 F	F	*Sclerotinia sclerotiorum (SCLESC) Alternaria spp. (ALTESP) Erysiphe cruciferarum (ERYSCR) Neopseudocercosporella brassicae (MYCOBR)*	SC	a) 100 g/L b) 200 g/L	Spraying	57 - 75	1	-	a) 0.015 - 0.1 b) 0.03 - 0.2	100-400	a) 0.06 - 0.1 b) 0.12 - 0.2	F	dose rate range 0.6 - 1.0 L/ha F is defined by latest application timing. **A**

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min) (days)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		
4	**Sunflower (HELAN)**	**AT, DE, PL**	**BAS 762 02 F**	**F**	***Diaporthe helianthi (DIAPHE)*** ***Plenodomus lindquistii (LEPTLI)*** ***Sclerotinia sclerotiorum (SCLESC)*** ***Alternaria helianthi (ALTEHE)***	**SC**	**a) 100 g/L** **b) 200 g/L**	**Spraying**	**31 - 69**	**1 - 2**	**7**	**a) 0.025 - 0.1** **b) 0.05 - 0.2**	**100-400**	**a) 0.1** **b) 0.2**	**F**	1st appl. BBCH 31-59 2nd appl. BBCH 61-69. F is defined by latest application timing. **A**
5	Sunflower (HELAN)	HU, RO, SI, SK, CZ	BAS 762 02 F	F	*Diaporthe helianthi (DIAPHE)* *Plenodomus lindquistii (LEPTLI)* *Sclerotinia sclerotiorum (SCLESC)* *Alternaria helianthi (ALTEHE)*	SC	a) 100 g/L b) 200 g/L	Spraying	31 - 69	1 - 2	7	a) 0.015 - 0.1 b) 0.03 - 0.2	100-400	a) 0.06 - 0.1 b) 0.12 - 0.2	F	dose rate range 0.6 - 1.0 L/ha 1st appl. BBCH 31-59 2nd appl. BBCH 61-69. F is defined by latest application timing. **A**

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min) (days)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		
6	Sunflower (HELAN)	CZ	BAS 762 02 F	F	*Diaporthe helianthi (DIAPHE)* *Plenodomus lindquistii (LEPTLI)* *Sclerotinia sclerotiorum (SCLESC)* *Alternaria helianthi (ALTEHE)*	SC	a) 100 g/L b) 200 g/L	Spraying	31 - 69	1	-	a) 0.015 - 0.1 b) 0.03 - 0.2	100-400	a) 0.06 - 0.1 b) 0.12 - 0.2	F	dose rate range 0.6 - 1.0 L/ha F is defined by latest application timing. **A**
7	**wheat (winter and spring)**	**DE, AT**	**BAS 762 02 F**	**F**	***Oculimacula spp. - PSDCHE*** ***Septoria tritici - SEPTTR*** ***Blumeria graminis - ERYSGR***	**SC**	**a) 100 g/L** **b) 200 g/L**	**Spraying**	**30 - 49**	**1**	**-**	**a) 0.033 - 0.1** **b) 0.066 - 0.2**	**100 - 300**	**a) 0.1** **b) 0.2**	**56**	For eyespot control, only one application at BBCH 30-32 **A**
8	wheat (winter and spring)	CZ	BAS 762 02 F	F	Oculimacula spp. - PSDCHE Septoria tritici - SEPTTR Blumeria graminis - ERYSGR	SC	a) 100 g/L b) 200 g/L	Spraying	30 - 49	1	-	a) 0.02 - 0.1 b) 0.04 - 0.2	100 - 300	a) 0.06 - 0.1 b) 0.12 - 0.2	56	dose rate range 0.6 - 1.0 L/ha **A**
9	**wheat (winter and spring)**	**PL**	**BAS 762 02 F**	**F**	***Oculimacula spp. - PSDCHE*** ***Septoria tritici - SEPTTR*** ***Blumeria graminis - ERYSGR***	**SC**	**a) 100 g/L** **b) 200 g/L**	**Spraying**	**30 - 49**	**1**	**-**	**a) 0.033 - 0.1** **b) 0.066 - 0.2**	**100 - 300**	**a) 0.1** **b) 0.2**	**56**	**A**

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

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

critical GAPs are highlighted in **bold**

a) Mefentrifluconazole

b) Boscalid

Explanation for Column 11 “Conclusion”

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

7.1.2 Summary of the evaluation

The formulated product BAS 762 02 F contains the active ingredients mefentrifluconazole (BAS 750 F) and boscalid (BAS 510 F). Their toxicological endpoints are summarized below. As also being relevant, the set endpoints for the triazole derivative metabolites (TDMs) are shown in the table.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of BAS 750 F, TDMs and BAS 510 F

Reference value	Source	Year	Value	Study relied upon	Safety factor
Mefentrifluconazole - Parent compound					
ADI*	EFSA, 2018a	2018	0.035 mg/kg bw per day	18-month carcinogenicity study in mice	100
ARfD*	EFSA, 2018a	2018	0.15 mg/kg bw	Developmental toxicity study in rabbits	100
1,2,4-Triazole (1,2,4-T) - TDM					
ADI	EFSA, 2018b	2018	0.023 mg/kg bw per day	Newly submitted rat 12-month study	300
ARfD	EFSA, 2018b	2018	0.1 mg/kg bw	Rabbit developmental study	300
Triazole alanine (TA) - TDM					
ADI	EFSA, 2018b	2018	0.3 mg/kg bw per day	Newly submitted rabbit developmental study	100
ARfD	EFSA, 2018b	2018	0.3 mg/kg bw	Newly submitted rabbit developmental study	100
Triazole acetic acid (TAA) - TDM					
ADI	EFSA, 2018b	2018	1 mg/kg bw per day	Newly submitted rat 2-generation and rabbit developmental studies	100
ARfD	EFSA, 2018b	2018	1 mg/kg bw	Newly submitted rat 2-generation and rabbit developmental studies	100
Triazole lactic acid (TLA) - TDM					
ADI	EFSA, 2018b	2018	0.3 mg/kg bw per day	Newly submitted rabbit developmental study	100
ARfD	EFSA, 2018b	2018	0.3 mg/kg bw	Newly submitted rabbit developmental study	100
Boscalid - Parent compound					
ADI	08/44/EC	2008	0.04 mg/kg bw per day	2 years rat oral feed	100
ARfD	08/44/EC	2008	Not necessary		Not applicable

* Toxicological reference values are applicable to the metabolites M750F015, M750F016 and M750F017 (major rat metabolites); M750F019 (conjugate of major rat metabolites); M750F022; M750F023, M750F024, M750F025 (fatty acid conjugates of M750F022); and M750F043 (sulfate conjugate of M750F022)

7.1.2.1 Summary for Mefentrifluconazole (BAS 750 F)

Table 7.1-3: Summary for mefentrifluconazole

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, 2, 3	Oilseed rape	Yes	Yes	Yes	Yes	Yes	No	No
4, 5, 6	Sunflower	Yes	Yes	Yes	Yes	Yes		No
7, 8, 9	Wheat	Yes	Yes	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 mefentrifluconazole residues have been investigated. Data on effects of processing on the amount of residue have been submitted.
These data were considered for risk assessment.

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

No new MRLs or mitigation measures have been proposed.

No acute risk has been identified for the crops of concern. The use of BAS 762 02 F on oilseed rape, sunflower and wheat is therefore acceptable.

7.1.2.2 Summary for boscalid

Table 7.1-4: 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, 2, 3	Oilseed rape	Yes	Yes	Yes	Yes	Yes	No	No
4, 5, 6	Sunflower	Yes	Yes	Yes	Yes	Yes		No
7, 8, 9	Wheat	Yes	Yes	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. These data were considered for risk assessment.

No new MRLs or mitigation measures have been proposed.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

No chronic risk has been identified for boscalid in oilseed rape, sunflower and wheat. An acute consumer risk assessment was not performed because an ARfD is not set for boscalid. The use of BAS 762 02 F on these crops is therefore acceptable.

7.1.2.3 Summary for active substance 3

Not relevant.

7.1.2.4 Summary for BAS 762 02 F

Waiting periods prior to planting succeeding crops are not required. Withholding period/PHI is detailed in the following table.

Table 7.1-5: Information on BAS 762 02 F (KCA 6.8)

Crop	PHI for BAS 762 02 F proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for BAS 762 02 F proposed by zRMS	zRMS Comments (if different PHI proposed)
		mefentrifluconazole	boscalid		
Oilseed rape	F**	Yes	Yes	F**	
Sunflower	F**	Yes	Yes	F**	
Wheat	56 days	Yes	Yes	56 days	

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 7.1-6: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops			Overall waiting period proposed by zRMS for BAS 762 02 F
Crop group	Led by mefentrifluconazole	Led by boscalid	
Follow crops	NR	NR	NR

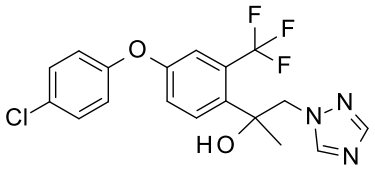
NR: not relevant

Assessment

7.2 Mefentrifluconazole

General data on mefentrifluconazole are summarized in the table below (last updated 2021/01/27).

Table 7.2-1: General information on mefentrifluconazole

Active substance (ISO Common Name)	Mefentrifluconazole (ISO provisionally approved) (BAS 750 F)
IUPAC	(2RS)-2-[4-(4-chlorophenoxy)-α,α,α-trifluoro-o-tolyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol
Chemical structure	
Molecular formula	$C_{18}H_{15}ClF_3N_3O_2$
Molar mass	397.8 g/mol
Chemical group	Azole
Mode of action (if available)	Blocking of ergosterol biosynthesis through inhibition of cytochrome P450 sterol 14α-demethylase (CYP51). The depletion of ergosterol and accumulation of non-functional 14α-methyl sterols results in inhibition of growth and cell membrane disruption.
Systemic	Yes
Company (ies)	BASF SE*
Rapporteur Member State (RMS)	ES Original RMS: United Kingdom Co-RMS: FR/AT
Approval status	Approved 20/03/2019 Reg. (EU) No 2019/337
Restriction (e.g. is restricted to use as "...")	N.A.
Review Report	~~SANTE/11612/2018 Rev.2 25 January 2019~~ SANTE/11612/2018 Rev. 3, 25 January 2019, 26 January 2021
Current MRL regulation	~~Reg (EU) No 2019/977~~ Reg (EU) No 2021/590
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Not yet available
EFSA Journal : Conclusion on the peer review	Yes**, EFSA 2018a
EFSA Journal: conclusion on article 12	No
Current MRL applications on intended uses	No

* Notifier in the EU process to whom the a.s. belong(s)
** EFSA Journal 2018;16(7):5379 - see list of references
N.A. not applicable

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 was submitted in the framework of this application. In the context of the Annex I inclusion process three storage stability studies have been submitted by the applicant. These studies are summarized in the table below. For a detailed assessment refer to the EFSA Conclusion (2018a and b).

Table 7.2-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products (parent BAS 750 F & metabolites 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA), triazole lactic acid (TLA))			
Fruiting vegetables (Tomato fruit)	High water content	24 months (BAS 750 F)	EFSA, 2018a (BAS 750 F) BASF DocID 2016/1112644 (BAS 750 F) and BASF DocID 2015/7005764 (TLA) EFSA, 2018b (TDMs)
		6 months (1,2,4-T)	
		53 months (TA)	
		53 months (TAA)	
Pome fruits (Apple fruit)	High water content	24 months (BAS 750 F)	
		6 months (1,2,4-T)	
		53 months (TA)	
		53 months (TAA)	
Leafy vegetables (Lettuce head)	High water content	48 months (TLA)	
Brassica vegetables (Mustard greens)	High water content	6 months (1,2,4-T)	
		53 months (TA)	
		53 months (TAA)	
Leaves of root and tuber vegetables (Radish tops)	High water content	12 months (1,2,4-T)	
		53 months (TA)	
		53 months (TAA)	
Forage/fodder crops (wheat forage)	High water content	24 months (BAS 750 F)	
		6 months (1,2,4-T)	
		53 months (TA)	
		53 months (TAA)	

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Oilseeds (Soybean seed)	High oil content	24 months (BAS 750 F)	
		12 months (1,2,4-T)	
		26 months (TA)	
		53 months (TAA)	
		48 months (TLA)	
Oilseeds (Rape seed/Canola seed)	High oil content	24 months (BAS 750 F)	
		not stable (1,2,4-T)	
		not stable (TA)	
		53 months (TAA)	
		48 months (TLA)	
Dry legume vegetables/Pulses (Dried peas seed, Dried bean seed)	High protein content	24 months (BAS 750 F)	
		15 months (TA)	
		25 months (TAA)	
		48 months (TLA)	
Cereal grain (Wheat grain, Barley grain)	High starch content	24 months (BAS 750 F)	
		12 months (1,2,4-T)	
		26 months (TA)	
		26 months (TAA)	
		48 months (TLA)	
Starchy roots (Potato tuber)	High starch content	24 months (BAS 750 F)	
Grapes fruit	High acid content	24 months (BAS 750 F)	
Citrus fruits (Lemon fruit, Orange fruit)	High acid content	24 months (BAS 750 F)	
		48 months (TLA)	
Cereal straw (wheat)	Other	24 months (BAS 750 F)	
		12 months (1,2,4-T)	
		53 months (TA)	
		40 months (TAA)	
Animal Products (parent BAS 750 F & metabolite M750F022 & 1,2,4-triazole (1,2,4-T))			
Bovine	Muscle	177 days (BAS 750 F)	EFSA, 2018a (BAS 750 F) BASF DocID 2015/1106711 and BASF DocID 2015/1106710 EFSA, 2018b (TDMs)
		178 days (M750F022)	
		370 days (1,2,4-T)	
Bovine	Fat	180 days (BAS 750 F)	
		180 days (M750F022)	
		370 days (1,2,4-T)	
Bovine	Liver	177 days (BAS 750 F)	
		178 days (M750F022)	
		370 days (1,2,4-T)	
Bovine	Kidney	177 days (BAS 750 F)	

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
		178 days (M750F022)	
Bovine	Milk	177 days (BAS 750 F)	
		178 days (M750F022)	
		560 days (1,2,4-T)	
Poultry	Egg	177 days (BAS 750 F)	
		178 days (M750F022)	
		370 days (1,2,4-T)	
Bovine	Cream	177 days (BAS 750 F)	
		178 days (M750F022)	
New data			
No new data			

Conclusion on stability of residues during storage

BAS 750 F

BAS 750 F has been demonstrated to be stable in all five crop groups; high water (tomato fruit, apple fruit), high oil (soybean seed, rape seed), high protein (dried pea seed, dried bean seed), high starch (wheat grain, potato tuber) and high acid (grape fruit, lemon fruit) for a period of 730 days (~24 months) when stored at ≤-18ºC.

As at least one crop has been considered in all five crop groups, it can be concluded that sufficient data is available to support the storage stability of BAS 750 F in all plant commodities for at least 730 days. Additionally, as there is no observed decline in residues across these commodities, specific storage stability data is not required for processed commodities.

BAS 750 F has been demonstrated to be stable in cow tissue (liver, kidney, muscle and fat), milk and cream and hen egg for at least 177 days when stored under deep frozen conditions.

Metabolites

M750F022 is a metabolite formed at relatively high levels in animal commodities. M750F022 has been demonstrated to be stable in cow tissue (liver, kidney, muscle and fat), milk and cream and hen egg for at least 178 days when stored under deep frozen conditions.

Triazole derivative metabolites (TDMs) are formed during the metabolism of BAS 750 F in plant and animal commodities. The TDMs are 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid. Frozen storage stability of these metabolites was considered as part of the TDM peer review (EFSA, 2018b) for which BASF was one of the members of the TDM group who submitted the studies. These studies were considered acceptable in the TDM review. This table includes the studies in which the longest storage period was considered (other studies covering shorter time scales were also presented in the review). During the initial TDM review in 2015 only an interim storage stability study was available for triazole lactic acid (TLA). To support the duration of sample storage in studies considered for BAS 750 F, the full study for TLA has been submitted, and is evaluated in the EFSA conclusions 2018a and 2018b. This study demonstrates that TLA is stable in wheat grain, navy bean, orange, canola seed, and lettuce matrices for at least 48 months when stored under deep frozen conditions. As at least one crop has been considered in all five crop groups, it can be considered that sufficient data is available to support the storage stability of TLA in all plant commodities for at least 48 months.

zRMS comments:
Studies on the storage stability of mefentrifluconazole under frozen conditions were assessed in the framework of the EU pesticides peer review (EFSA, 2018). The parent compound showed to be stable for at least 24 months in all plant category groups. zRMS-PL agrees with the conclusion presented by the Applicant on the stability of mefentrifluconazole and M750F022 in plant and animal matrices.

Triazole derivative metabolites (TDMs) are formed during the metabolism of BAS 750 F in plant and animal commodities. The TDMs are 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid. Frozen storage stability of these metabolites was considered as part of the TDM review (Triazole Derivative Metabolites Addendum – Confirmatory Data, February 2018 amended following discussions at the toxicology and residues expert meetings (Pesticides Peer Review Meetings no. 162 and 171 respectively)) for which BASF was one of the members of the TDM group who submitted the studies. These studies were considered acceptable in the TDM review.
Storage stability data are available in high water content, high starch content and high oil content matrices.
Additionally zRMS-PL added below the Table 7.2-2a on the storage stability data on TDMs in plant and animal matrices according to the EFSA Journal 2018;16(7):5376 (EFSA, 2018b).

Table 7.2-2a: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise) according to the Peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted. (EFSA, 2018b)

Plant products (Category)	**Commodity**	**T** (°C)	**Stability** (Month/year)			
			1,2,4-T	TA	TAA	TLA
High water content	Tomatoes	≤ 18	≤ 6	53	53	-
	Apples	≤ 18	≤ 6	12	12	-
	Lettuce	≤ 18	-	-	-	48
	Mustard greens	≤ 18	≤ 6	53	53	-
	Radish tops	≤ 18	≤ 12	26	≤ 12	-
	Wheat forage	≤ 18	≤ 4	53	53	-
High oil content	Soybean	≤ 18	≤ 12	26	26	48
	Rape seed	≤ 18	Not stable	Not stable	53	48
High protein content	Dried Pea, beans	≤ 18	-	15	25	48
High starch content	Wheat grain Barley grain	≤ 18	≤ 12	26	26	48
	Potato	≤ 18	-	-	-	-
High acid content	Grapes	≤ 18	-	-	-	-
	Lemon, orange	≤ 18	-	-	-	48
Other	Wheat straw	≤ 18	≤ 12	53	40	No data

Animal	**Commodity**	**T** (°C)	**Stability** (Month/year)			
			1,2,4-T	TA	TAA	TLA
Bovine	Muscle	≤ 18	12	-	-	-
	Liver	≤ 18	12	-	-	-
	Fat	≤ 18	12	-	-	-
	Milk	≤ 18	18	12	12	-
Poultry	Egg	≤ 18	12	12	12	-

Sufficient stability data are available to support the residue data presented in the present dossier.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

No new data was submitted in the framework of this application. In the context of the Annex I inclusion process sufficient information has been submitted by the applicant. For a detailed assessment refer to the

EFSA conclusion (2018a).

For plant matrices, stability tests for BAS 750 F in extracts and final volume solutions were done within the validation study of analytical BASF Method No. L0076/09 (BASF DocID 2015/3001681). Stability tests were conducted in six representative matrices (tomato whole fruit, citrus whole fruit, dry beans seed, wheat grain, soybean grain and coffee grain). BAS 750 F showed to be stable for up to 8 days.
For animal matrices, stability tests for BAS 750 F were done during the validation study of BASF analytical Method No. L0272/01 (BASF DocID: 2015/1106707). Stability tests for extracts and final volumes were conducted in seven representative animal matrices (bovine meat, bovine milk, bovine cream, bovine fat, bovine liver, bovine kidney, hen egg). BAS 750 F showed to be stable under refrigerator conditions up to 7 days.

Additionally, stability tests for M750F022 were done during the validation study of the BASF analytical Method No. L0309/01 (BASF DocID: 2015/1106706). The stability of extracts and final volumes was investigated after 7 days of storage at approximately 4°C for extracts and after 3 and 7 days of storage at approximately 4°C for final volumes. The results showed that M750F022 was stable over the tested time period of 7 days, except for cow kidney, which is only stable for three days.

Additionally, the residue samples were always run together with fortification samples. Results of the fortifications were always in the acceptable range of 70-120%, which indicates stability of the different analytes in the extracts and final volumes in the matrices analysed.

Conclusion on stability of residues in sample extracts
The analytes BAS 750 F, M750F022 and the triazole metabolites were stable in the extracts and final volumes of the residue samples.

zRMS comments:
Information given by the Applicant is sufficient and zRMS-Poland agrees with presented above conclusions.
No further data are required.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data
No new data was submitted in the framework of this application. In the context of the Annex I inclusion process three plant metabolism studies have been submitted by the applicant. These studies are summarized in the table below. For a detailed assessment refer to the EFSA conclusion (2018a).

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruit crops	Grape	Chlorophenyl-ring (C-ring) Triazole-ring (T-ring)	Foliar spray applications, F*	0.150	3	Leaf, stalk and grape fruits: "-0" (21 DAT)[1)], 12	10 day interval	EFSA, 2018a BASF DocID 2015/1073822
Cereals/grass crops	Wheat	Chlorophenyl-ring (C-ring) Triazole-ring (T-ring)	Foliar spray applications, G**	0.150	2	Forage: -6 (=15)[3)] Grain: 35 Straw: 35	application: BBCH 49 and 69, 21 day interval	EFSA, 2018a BASF DocID 2015/1001872

Pulses/Oilseeds	Soybean	Chlorophenyl-ring (C-ring) Triazole-ring (T-ring)	Foliar spray applications, G**	0.125	3	Forage: -17 (=19 DAT)[2)] Seed: 47/48 Hull: 47/48 Rest of plant: 47/48 Green pods: 47/48	application: BBCH 60, 72 and 77, 18 day interval	EFSA, 2018a, BASF DocID 2014/1224012
New data								
No new data								

(a) Outdoor/field application (F) or glasshouse/protected/indoor application (G)
DAT = days after last treatment
* cultivated on outdoor test plots, test area 0.4 m^2, under natural climatic conditions
** cultivated indoor (plastic containers located in vegetation hall/greenhouse/pythotron)
[1)] immediately prior to the last (=third) application (DALA"-0") corresponding to 21 after the first application
[2)] 19 days after the first application (19 DAT) corresponding to directly prior to the second application, and 17 days prior to last application (-17 DALA).
[3)] only one application: 15 days after the first application (= 15 DAT) corresponding to 6 days prior to last application (DALA= -6)

Summary of plant metabolism studies reported in the EU

EFSA, 2018a: Metabolism was investigated using two radiolabels (BAS 750 F labelled in the C-ring or in the T-ring). Results obtained with both labels show a consistent picture of BAS 750 F metabolism. Investigations were done in three plant species, wheat (cereal crop group), soybean (pulses and oilseed crop group), and grapevine (fruits/fruiting vegetable crop group), foliar applied with BAS 750 F and reflecting the cGAP (critical GAP). Comparable results were obtained for all three crop groups.

In most matrices the unchanged parent is the predominant component of the residue (>60% of the radioactive residue), notably in forage (wheat, soybean), leaf/stalk (grapevine), straw/hull/chaff (wheat, soybean), green pod (soybean) and grape (grapevine). The enantiomer ratio of the two BAS 750 F isomers remains unchanged (racemic mixture).

In wheat grain and soybean seed, the predominant component of the residue is the group of TDM, with triazole alanine as the most abundant compound (formed via cleavage of the T-bridge). In these matrices unchanged parent is present at very low levels if at all.

Other metabolites were formed via two main pathways:

- Initial hydroxylation of the chlorophenyl or propyl-triazole moiety and a subsequent conjugation with glucose, followed by malonylation of the glucose moiety or additional hydroxylation of the chlorophenyl ring (M750F018, 019, 020, 026, 027).
- Conjugation of the hydroxyl group of the propyl-triazole moiety of BAS 750 F followed by malonylation or conjugation with another glucose molecule (M750F011, 012, 013, 014, 028).

Absence of detectable cleavage at the ether bridge between C-ring and TFMP-ring (trifluoromethylphenyl-ring, linking C-ring and T-ring) confirms that results obtained with C-labelled samples also provide comprehensive information on the metabolic fate of the TFMP-ring.

Conclusion on metabolism in primary crops

It can be concluded from the available metabolism studies that for the compound BAS 750 F a plant typical metabolic pathway exists. This has been shown for three different crops (grape, soybean, wheat) after foliar application.

zRMS comments:

The metabolism of mefentrifluconazole in primary crops was evaluated at the EU level. Information given by the Applicant is sufficient.

According to the EFSA Journal 2020;18(7):6193:

"The metabolism of mefentrifluconazole in primary crops has been investigated in fruit crops, pulses/ oilseeds and cereals/grass in the framework of the EU pesticides peer review (EFSA, 2018c). After foliar applications, parent mefentrifluconazole was the predominant residue (> 60% total radioactive residue (TRR)) in tested plant parts,

except in wheat grains and soybean seeds. The triazole derivative metabolites (TDMs) were formed in significantly higher amounts in these commodities (77% TRR in wheat grain and 82% TRR in soyabean seed), with triazole alanine (TA) as the most abundant compound. A preferential metabolism or uptake of one of the two mefentrifluconazole enantiomers was not observed in plants. The available plant metabolism studies sufficiently address primary crop metabolism for the crops under assessment."

Regarding TDMs, the conclusions are published in EFSA Journal 2018;16(7):5376: "*Primary crops metabolism data are reported for a total of 16 approved triazole compounds,[2] and 2 triazole active substances that are not approved at EU level (bitertanol, flusilazole), on fruit crops, cereals (straw and grain), pulses and oilseeds and root crops. (…) Based on the metabolism data in primary and rotational crops that were compiled from the assessment of the 18 triazole active substances the triazole active substances were shown to degrade into the common metabolites 1,2,4-T, TA, TLA and TAA, known as TDMs.*
Besides the parent compound that was identified at significant residue levels in all crop groups, TA was predominantly found in the organs of storage (79% total radioactive residue (TRR) in potato tuber, 31–88% TRR in oil seeds, 8–69% TRR in cereal grains) but also in cereal straw (1–16% TRR) and in fruit crops (up to 80% TRR). TAA was only detected at significant proportions in cereal grain and straw (5–35% and 7–41% TRR, respectively) and TLA in fruit crops (up to 67% TRR) and in cereal straw (up to 43% TRR). 1,2,4-T was detected at lower levels in all crop parts (up to 12% TRR)."

The residue definitions for plant agreed for monitoring and risk assessment (EFSA Journal 2020;18(7):6193):
Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites, the following residue definitions for enforcement and risk assessment were proposed in the EU pesticides peer review (EFSA, 2018c):
Residue definition for enforcement: Mefentrifluconazole
The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned enforcement residue definition.
Residue definition for risk assessment:
• Mefentrifluconazole
• Triazole alanine (TA) and triazole lactic acid (TLA)
• Triazole acetic acid (TAA)
• 1,2,4-triazole (1,2,4-T)

No additional metabolism studies are necessary to support the intended uses for BAS 762 02 F / Revydas.

[2] Epoxiconazole, penconazole, tebuconazole, fenbuconazole, flutriafol, paclobutrazole, metconazole, fluquiconazole, difenoconazole, tetraconazole, propiconazole, ipconazole

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data was submitted in the framework of this application. In the context of the Annex I inclusion process one metabolism study in rotational crops has been submitted by the applicant. This study is summarized in the table below. For a detailed assessment refer to the EFSA conclusion (2018a).

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 (DAP)Δ	Remarks	
EU data								
Root/tuber crops	White radish	Chlorophenyl-ring (C-ring)	G	0.300	30 120 365	68 57 61	One application to bare soil	EFSA, 2018a BASF DocID 2015/1001871
		Triazole-ring (T-ring)			31 122 364	70 59 61	One application to bare soil	
Leafy crops	Spinach	Chlorophenyl-ring (C-ring)	G	0.300	30 120 365	28-41 33-41 27-40	One application to bare soil	

		Triazole-ring (T-ring)			31 122 364	25-44 32-43 33-46	One application to bare soil	
Cereal (small grain)	Wheat	Chlorophenyl-ring (C-ring)	G	0.300	30 120 365	49-105 50-144 55-137	One application to bare soil	
		Triazole-ring (T-ring)			31 122 364	53-105 52-148 54-138	One application to bare soil	
New data								
No new data								

* Outdoor/field application (F) or glasshouse/protected/indoor application (G)
** DAT=days after soil treatment (soil aging interval)
Δ DAP=days after planting/sowing (cultivation interval)

Summary of rotational crop metabolism studies reported in the EU
EFSA, 2018a: To investigate residues in rotational crops, a nature of the residue study has been conducted in different crops representing three different crop categories, namely leafy vegetables, root and tuber vegetables and cereals. BAS 750 F was applied at 300 g ai/ha to bare soil, corresponding to a BAS 750 F concentration in soil of 0.1 mg/kg (soil depth 20 cm, soil density 1.5 g/cm^3). The rotational crops were cultivated after soil aging intervals of 30, 120 and 365 days, samples were taken at both mature and immature growth stages.
Based on results obtained in the nature of the residue study conducted with two labels (C-label, T-label), the residue in rotational crops is identified as unchanged parent BAS 750 F as well as the triazole derivative metabolites (TDM). The ratio of R- and S-enantiomers of BAS 750 F residue in plant remained unchanged compared with the test substance, indicating absence of preferential metabolism or uptake.

Conclusion on metabolism in rotational crops
Overall, the metabolism in rotational crops is similar to metabolism in primary crops with no rotational crop specific metabolites.

zRMS comments:
The metabolism of mefentrifluconazole in rotational crops was evaluated at the EU level. Information given by the Applicant is sufficient.

According to the EFSA Journal 2020;18(7):6193:
"Mefentrifluconazole is intended to be used in the EU on several crops (potatoes, oilseeds, maize, sugar beets) that can be grown in rotation with other crops. The metabolism of mefentrifluconazole in rotational crops has been investigated in leafy crops, root and tuber crops and cereals during the EU pesticides peer review (EFSA, 2018c). Mefentrifluconazole and the TDMs were identified as relevant residues in rotational crops. Overall the metabolic pathway in rotational crops was found to be similar as in primary crops."
For rotational crops, the same residue definitions as primary crops were proposed.

With regard to TDMs the conclusions are published in EFSA Journal 2018;16(7):5376: "*For the rotational crops, metabolism data are available on leafy crops, root crops and cereal grain and straw for a total of 12[3] approved triazole active substances and one non approved triazole active substance (flusilazole). (…) Similar metabolic patterns were depicted both in primary and in rotational crops."*

No additional metabolism studies are necessary to support the intended uses for BAS 762 02 F / Revydas.

[3] Epoxiconazole, penconazole, tebuconazole, fenbuconazole, flutriafol, paclobutrazole, metconazole, fluquiconazole, difenoconazole, tetraconazole, propiconazole, ipconazole.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data
No new data was submitted in the framework of this application. In the context of the Annex I inclusion

process one hydrolysis study has been submitted by the applicant. This study is summarized in the table below. For a detailed assessment refer to the EFSA conclusions (2018a and b).

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

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	109.1% (BAS 750 F)	EFSA, 2018a (BAS 750 F) BASF DocID 2014/1170665 EFSA, 2018b (TDMs)
	103.5% (1,2,4-T)	
	100.4% (TA)	
	99.4% (TAA)	
	102.6% (TLA)	
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	108.7% (BAS 750 F)	
	104.0% (1,2,4-T)	
	100.0% (TA)	
	101.0% (TAA)	
	104.1% (TLA)	
Sterilisation (20 minutes, 120°C, pH 6)	105.6% (BAS 750 F)	
	99.4% (1,2,4-T)	
	99.8% (TA)	
	100.5% (TAA)	
	96.4% (TLA)	
New data		
No new data		

Conclusion on nature of residues in processed commodities

EFSA, 2018 a, b: In the nature of the residues processing study, under conditions representative of pasteurisation (pH 4, 90 °C, 20 min), baking, boiling, brewing (pH 5, 100 °C, 60 min) and sterilisation (pH 6, 120 °C, 20 min) BAS 750 F was stable. No degradation product exceeding 2% of total radioactivity was detected and no change in the isomer ratio was observed. BAS 750 F can be regarded as stable to hydrolysis and the nature of the residue is not affected by processing operations. Stability of TDMs under high temperature hydrolysis is also stated in EFSA conclusion, 2018b:

"The TDMs remained stable under the standard hydrolysis conditions simulating processing of pasteurisation, baking, brewing and boiling and sterilisation."

zRMS comments:

The effect of processing on the nature of parent mefentrifluconazole was investigated in the framework of the EU pesticides peer review EFSA Journal 2018;16(7):5379). The standard hydrolysis studies showed that the active substance is hydrolytically stable under processing conditions simulating pasteurisation, baking, brewing/boiling and sterilisation.

In the framework of the assessment of the EU peer review of TDMs, EFSA concluded that triazole alanine (TA), 1,2,4-triazole (1,2,4-T), triazole acetic acid (TAA) and triazole lactic acid (TLA) remain stable under the standard hydrolysis conditions (EFSA Journal 2018;16(7):5376).

Information given by the Applicant is sufficient.

No additional data are necessary to support the intended uses for BAS 762 02 F / Revydas.

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 (EFSA, 2018a)

Endpoints	
Plant groups covered	Fruit crops (grape) Cereals/grass crops (wheat) Pulses/oilseeds (soybean)
Rotational crops covered	Confined metabolism studies on root/tuber crops (white radish), leafy crops (spinach), cereals/small grains (wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes. BAS 750 F and TDMs, no other components identified.
Processed commodities	Parent BAS 750 F and TDMs confirmed stability under hydrolytic conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes. Residues not susceptible to degradation under standard processing conditions
Plant residue definition for monitoring (RD-Mo)	BAS 750 F
Plant residue definition for risk assessment (RD-RA)	a) BAS 750 F b) triazole derivative metabolites (TDMs) with a separate assessment of: 1) TA and TLA 2) TAA 3) 1,2,4-Triazole
Conversion factor from enforcement to RA	Not applicable

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

Available data

No new data was submitted in the framework of this application. In the context of the Annex I inclusion process three animal metabolism studies (hen, goat, trout) have been submitted by the applicant. These studies are summarized in the table below. For a detailed assessment refer to the EFSA conclusion (2018a).

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								
Laying poultry	Hens	Chlorophenyl ring (C-ring)	10	1.11	14	Eggs	24 h prior to first dose administration, twice daily, additionally, whole eggs still in oviduct after termination	EFSA, 2018a BASF DocID 2015/1001001
						Excreta	24 h prior to first dose administration, once daily	
						Tissues	at sacrifice	
		Trifluoromethyl-phenyl ring (TFMP-ring)	10	1.15	14	Eggs	24 h prior to first dose administration, twice daily, additionally, whole eggs still in oviduct after termination	
						Excreta	24 h prior to first dose administration, once daily	
						Tissues	at sacrifice	
		Triazole ring (T-ring)	10	1.11	14	Eggs	24 h prior to first dose administration, twice daily, additionally, whole eggs still in oviduct after termination	
						Excreta	24 h prior to first dose administration, once daily	
						Tissues	at sacrifice	
Lactating ruminants	Goat	Chlorophenyl ring (C-ring)	2	0.36	14	Milk	twice daily	EFSA, 2018a BASF DocID 2015/1078841
						Urine and faeces	daily	
						Tissues	at sacrifice	
		Trifluoromethyl-phenyl ring (TFMP-ring)	1	0.40	12	Milk	twice daily	
						Urine and faeces	daily	
						Tissues	at sacrifice	
		Triazole ring	2	0.43	14	Milk	twice daily	

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	
		(T-ring)				Urine and faeces	daily	
						Tissues	at sacrifice	
Fish	Rainbow trout	Chlorophenyl ring (C-ring)	5	5.82 mg/kg DM	10-14	Feces	daily prior to and after feeding	EFSA, 2018a (study submitted as part of EU AI dossier) BASF DocID 2015/1106141
						Filet, filet with skin and liver	6 hours after the last dose	
		Triazole ring (T-ring)	5	5.4 mg/kg DM	10-14	Feces	daily prior to and after feeding	
						Filet, filet with skin and liver	6 hours after the last dose	
New data								
No new data								

Summary of animal metabolism studies reported in the EU

EFSA, 2018a: Metabolism was investigated using three radiolabels (BAS 750 F labelled in the C-ring, TFMP-ring or in the T-ring). Results obtained with all labels show a consistent picture of BAS 750 F metabolism. Investigations were done in laying hen and lactating goat, as well as in rat to support toxicology studies. For goat and hen, the residue was rapidly and extensively eliminated via excreta, and reached a plateau in milk and egg within 7 days. Comparable results were obtained for all three animals, indicating common basic metabolite routes.

In poultry matrices the metabolite M750F022 (and its fatty acid conjugates) is the predominant component of the residue, with unmodified parent BAS 750 F and 1,2,4-triazole also present as significant components. In goat matrices, unmodified parent BAS 750 F and 1,2,4-triazole were the predominant components of the residue, with M750F022 present at much lower levels.

The metabolic pathway is largely based on two main transformation steps in livestock animals:

- hydroxylation at the C-ring (followed by conjugation) (M750F016, 034, 015, 041, 063)
- cleavage at the T-bridge (followed by conjugation) (M750F022-025, 038, 043, 064)

In addition, minor transformation steps were observed in livestock animals:

- cleavage at the ether bridge (followed by conjugation)
- hydroxylation at the T-ring
- hydroxylation of the methyl group (at quaternary C-atom, followed by conjugation)

Differences seen in species and/or matrices are the result of quantitative differences of transformation reactions as well as species-typical conjugation reactions (sulphation, glucuronidation, methylation, glutathione conjugation).

The parent BAS 750 F was applied as a racemic mixture of two enantiomers. Chiral analysis of BAS 750 F revealed a significant change of the ratio in most goat matrices, with proportion of the R-enantiomer of 70-80% in cream, muscle, liver, kidney and fat. In contrast, the racemate was maintained in goat faeces, indicating a preferential metabolism of the S-enantiomer. Such a change was not observed in poultry, but a comparable change was observed in rats (see section CA B.6).

Conclusion on metabolism in livestock

In conclusion, the major components of the residue in goat were identified as unchanged parent BAS 750 F and the TDM which together represent a large proportion of the residue. TDM exceed parent in all matrices except fat. Considering the non-TDM residue, parent represents 85% TRR in muscle and fat, >45% of TRR in milk and liver, 28-46% TRR in kidney. The cleavage product M750F022 was present at much lower levels (<7% TRR, except one kidney sample). For both parent and M750F022 presence of several downstream transformation products indicate effective further metabolic transformation. Overall, metabolism of BAS 750 F in lactating goats, and by extrapolation in ruminant livestock, can be considered well-elucidated.

In conclusion, the major components of the residue in hen were identified as 1,2,4-triazole, metabolite M750F022 together with its fatty acid conjugates, parent BAS 750 F as well as a liver-specific metabolite (M750F034). Overall, metabolism of BAS 750 F in laying hen can be considered well-elucidated.

In conclusion, a metabolism study in fish upon dietary exposure to BAS 750 F showed that parent BAS 750 F and 1,2,4-triazole were the major residues in fish matrices.

zRMS comments:

Information given by the Applicant is sufficient.

In EFSA Journal 2020;18(7):6193, EFSA concluded that the metabolism of mefentrifluconazole after repeated oral administration has been investigated in hens, goats and trout in the framework of the EU pesticides peer review (EFSA, 2018). Parent mefentrifluconazole was the dominant residue in goat and trout edible commodities and the metabolite M750F022 (with its fatty acid conjugates) in poultry. Beside parent, significant amounts were observed of 1,2,4-triazole only. Chiral analysis of mefentrifluconazole revealed a significant change of the ratio in most goat matrices (70–80% R-enantiomer in cream, muscle, liver, kidney, fat); but in the faeces, the racemate was maintained. Such a change was not observed in poultry and was not analysed for in fish.

For commodities of animal origin, the following residue definitions for enforcement and risk assessment were proposed in the EU pesticides peer review (EFSA, 2018):

Residue definition for enforcement: Mefentrifluconazole

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition.

In livestock, the residue definition for risk assessment should include mefentrifluconazole, the metabolite M750F022 and its fatty acid conjugates (in poultry) and, separately, the triazole derivative metabolites (TA, TLA, TAA, 1,2,4-T) as agreed during the EU peer review of confirmatory data for TDMs (EFSA Journal 2018;16(7):5376).

For fish, the residue definition for risk assessment is provisional and includes parent mefentrifluconazole and 1,2,4-triazole, separately.

No additional data are necessary to support the intended uses for BAS 762 02 F / Revydas.

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 (EFSA, 2018a)

Endpoints	
Animals covered	Laying hen
	Goat/Cow
	Fish
Time needed to reach a plateau concentration	Eggs: 5-7 days
	Milk: 5-8 days
Animal residue definition for monitoring (RD-Mo)	BAS 750 F
Animal residue definition for risk assessment (RD-RA)	animal except poultry: a) BAS 750 F b) triazole derivative metabolites (TDMs) with a separate assessment of: 1) 1,2,4-triazole 2) TA and TLA 3)TAA for ruminant matrices. poultry: a) sum of BAS 750 F, metabolite M750F022 and fatty acid conjugates of M750F022, expressed as parent b) triazole derivative metabolites (TDMs) with a separate assessment of: 1) 1,2,4-triazole 2) TA and TLA 3) TAA fish: a) BAS 750 F b) 1,2,4-triazole* *In future TA, TAA and TLA, (of which metabolism in fish is currently unknown), may also need to be included in the RD–RA as demonstrated appropriate for other animals i.e. ruminant and poultry.
Conversion factor	Poultry only: Muscle: 6.2, Fat: 16.3, Liver: 4.9, Egg: 4.9
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

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 BAS 762 02 F 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: BAS 750 F RA = according to risk assessment residue definition: a) BAS 750 F b) triazole derivative metabolites (TDMs) with a separate assessment of 1) TA, 2) TLA, 3) TAA, 4) 1,2,4-T	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Oilseed rape (rapeseeds / canola seeds)	EFSA, 2020 BASF DocIDs 2017/1023368 and 2018/1086903	N-EU	GAP on which MRL assessment is based: 2x 0.15 kg as/ha, BBCH 13-75, PHI n.a., outdoor E/RA a): 7x <0.01, 0.02	0.01	0.05	-	0.06 (proposed, EFSA, 2020)	-
		S-EU	GAP on which MRL assessment is based: 2x 0.15 kg as/ha, BBCH 13-75, PHI n.a., outdoor E/RA a): 5x <0.01, 0.02, 0.03, 0.05					
		N-EU	GAP on which MRL assessment is based: 2x 0.15 kg as/ha, BBCH 13-75, PHI n.a., outdoor RA b): 1) 0.03, 0.05, 0.09, 0.17, 0.34, 0.51, 0.94, 1.20 2) 6x <0.01, 0.01, 0.03 3) 8x <0.01 4) 8x <0.01	1) 0.13 2) 0.01 3) 0.01 4) 0.01	1) 1.20 2) 0.03 3) 0.01 4) 0.01	-	-	-
		S-EU	GAP on which MRL assessment is based: 2x 0.15 kg as/ha, BBCH 13-75, PHI n.a., outdoor RA b): 1) 0.02, 2x 0.06, 2x 0.08, 0.16, 0.20, 0.40 2) 8x <0.01 3) 8x <0.01 4) 8x <0.01					
	New trials BASF DocID	N-EU	Trials GAP: 1x 0.1 kg as/ha, BBCH 75, PHI F, outdoor E/RA a): 7x <0.01, 0.055	0.01**	0.06**	Highest residue covered by proposed MRL 0.06		Yes

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition: BAS 750 F RA = according to risk assessment residue definition: a) BAS 750 F b) triazole derivative metabolites (TDMs) with a separate assessment of 1) TA, 2) TLA, 3) TAA, 4) 1,2,4-T	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
	2019/1016882 and 2020/2006193	S-EU	Trials GAP: 1x 0.1 kg as/ha, BBCH 75, PHI F, outdoor E/RA a): 4x <0.01, 2x 0.011, 0.014, 0.027			mg/kg. No further considerations needed.		
		N-EU	Trials GAP: 1x 0.1 kg as/ha, BBCH 75, PHI F, outdoor RA b): 1) 0.18, 0.33, 0.58, 0.94, 0.98, 1.4, 1.6, 3.8 2) <0.01, 0.015, 0.019, 0.031, 0.034, 0.050, 0.054, 0.21 3) 5x<0.010, 0.011, 0.023, 0.056 4) 8x <0.01	1) 0.58** 2) 0.03** 3) 0.01** 4) 0.01**	1) 3.8** 2) 0.21** 3) 0.06** 4) 0.01**	-	-	-
		S-EU	Trials GAP: 1x 0.1 kg as/ha, BBCH 75, PHI F, outdoor RA b): 1) 0.075, 0.11, 0.13, 0.36, 0.46, 0.58, 0.61, 1.1 2) 3x <0.01, 0.018, 0.023, 0.029, 0.030, 0.033 3) 7x <0.01, 0.011 4) 8x <0.01					
Sunflower seeds	EFSA, 2020 BASF DocID 2017/1018091 and 2018/1013070	N-EU	GAP on which MRL assessment is based: 2x 0.11 kg as/ha, BBCH 31-69, PHI n.a., outdoor E/RA a): 6x <0.01, 0.01, 0.02	0.01	0.04	-	0.05 (proposed, EFSA, 2020)	Yes
		S-EU	GAP on which MRL assessment is based: 2x 0.11 kg as/ha, BBCH 31-69, PHI n.a., outdoor E/RA a): 3x <0.01, 0.01, 3x 0.02, 0.04					
		N-EU	GAP on which MRL assessment is based: 2x 0.11 kg as/ha, BBCH 31-69, PHI n.a., outdoor RA b): 1) 0.03, 2x 0.04, 0.05, 2x 0.06, 0.08, 0.14 2) 8x <0.01 3) 0.02, 2x 0.03, 3x 0.06, 0.08, 0.09 4) 8x <0.01	1) 0.06 2) 0.01 3) 0.06 4) 0.01	1) 0.26 2) 0.01 3) 0.29 4) 0.01	-	-	-
		S-EU	GAP on which MRL assessment is based: 2x 0.11 kg as/ha, BBCH 31-69, PHI n.a., outdoor RA b):					

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition: BAS 750 F RA = according to risk assessment residue definition: a) BAS 750 F b) triazole derivative metabolites (TDMs) with a separate assessment of 1) TA, 2) TLA, 3) TAA, 4) 1,2,4-T	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
			1) 2x 0.03, 0.04, 2x 0.06, 0.07, 0.11, 0.26 2) 7x <0.01, 0.01 3) 2x 0.04, 0.05, 0.06, 0.07, 0.08, 0.15, 0.29 4) 8x <0.01					
	New trials BASF DocID 2018/1205796 2019/2075093 (+Amendment 2020/2108977)	N-EU	Trials GAP: 2x 0.1 kg as/ha, BBCH 59-69, PHI F, outdoor E/RA a): 6x <0.01, 0.037, 0.042	0.01**	0.04**	Highest residue covered by proposed MRL 0.05 mg/kg. No further considerations needed.		Yes
		S-EU	Trials GAP: 2x 0.1 kg as/ha, BBCH 59-69, PHI F, outdoor E/RA a): 6x <0.01, 0.010, 0.012					
		N-EU	Trials GAP: 2x 0.1 kg as/ha, BBCH 59-69, PHI F, outdoor RA b): 1) 0.018, 0.044, 0.045, 0.048, 0.094, 0.12, 0.16, 0.23 2) 8x <0.01 3) 0.016, 0.023, 0.042, 0.090, 0.098, 0.11, 0.19, 0.23 4) 8x <0.01	1) 0.05** 2) 0.01** 3) 0.08** 4) 0.01**	1) 0.31** 2) 0.01** 3) 0.61** 4) 0.01**	-	-	-
		S-EU	Trials GAP: 2x 0.1 kg as/ha, BBCH 59-69, PHI F, outdoor RA b): 1) 0.021, 0.035, 0.041, 0.043, 0.051, 0.058, 0.22, 0.31 2) 7x <0.01, 0.01 3) 0.027, 0.032, 0.033, 0.045, 0.065, 0.091, 0.34, 0.61 4) 8x <0.01					
Wheat grain	EFSA, 2018a BASF DocIDs 2014/1010809 and 2015/1099704 and 2017/1141927	N-EU	GAP on which EU a.s. assessment is based: 2x 0.15 kg as/ha, BBCH 49-69, PHI 35d***, outdoor E/RA a): 4x <0.01, 0.011, 0.014, 0.016, 0.024	0.01**	0.026**	-	0.05	Yes
		S-EU	GAP on which EU a.s. assessment is based: 2x 0.15 kg as/ha, BBCH 49-69, PHI 35d***, outdoor E/RA a): 7x <0.01, 0.018, 0.026					
		N-EU	GAP on which EU a.s. assessment is based: 2x 0.15 kg as/ha, BBCH 49-69, PHI 35d***, outdoor RA b): 1)# 0.10, 0.12, 0.20, 0.22, 0.26, 0.26, 0.54, 1.21	1) 0.26** 2) 3) 0.06** 4) 0.01**	1) 1.21** 2) 3)	-	-	-

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition: BAS 750 F RA = according to risk assessment residue definition: a) BAS 750 F b) triazole derivative metabolites (TDMs) with a separate assessment of 1) TA, 2) TLA, 3) TAA, 4) 1,2,4-T	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
			2) 3) 0.016, 0.019, 0.022, 0.023, 0.063, 0.1, 0.16, 0.42 4) 8x <0.01		0.42** 4) 0.01**			
		S-EU	GAP on which EU a.s. assessment is based: 2x 0.15 kg as/ha, BBCH 49-69, PHI 35d***, outdoor RA b): 1)# 0.02, 0.13, 0.23, 0.26, 0.32, 0.33, 0.36, 0.37, 0.85 2) 3) <0.01, 0.015, 0.023, 0.046, 0.068, 0.081, 0.091, 0.11, 0.2 4) 9x <0.01					
	New trials BASF DocID 2019/1016888	N-EU	Trials GAP: 1x 0.1 kg as/ha, BBCH 49, PHI 42-69d, outdoor E/RA a): 4x <0.01	0.01	0.01	Highest residue covered by current MRL 0.05 mg/kg. No further considerations needed.		Yes
		S-EU	Trials GAP: 1x 0.1 kg as/ha, BBCH 49, PHI 56-57d, outdoor E/RA a): 4x <0.01					
Wheat straw	EFSA, 2018a BASF DocIDs 2014/1010809 and 2015/1099704 and 2017/1141927	N-EU	GAP on which EU a.s. assessment is based: 2x 0.15 kg as/ha, BBCH 49-69, PHI 35d***, outdoor E/RA a): 1.9, 2.3, 3.4, 3.6, 3.9, 4.9, 5.5, 10	3.6**	18.0**	-	30	Yes
		S-EU	GAP on which EU a.s. assessment is based: 2x 0.15 kg as/ha, BBCH 49-69, PHI 35d***, outdoor E/RA a): 0.5, 0.56, 1.6, 2.9, 3.1, 3.8, 4.6, 9.0, 18.0					
		N-EU	GAP on which EU a.s. assessment is based: 2x 0.15 kg as/ha, BBCH 49-69, PHI 35d***, outdoor RA b): 1)# 0.117, 0.118, 0.152, 0.161, 0.355, 0.483, 0.511, 0.642 2) 3) 3x <0.01, 0.014, 0.029, 0.086, 0.088, 0.16 4) 8x <0.01	1) 0.25** 2) 3) 0.03** 4) 0.01**	1) 1.51** 2) 3) 0.16** 4) 0.01**	-	-	-
		S-EU	GAP on which EU a.s. assessment is based: 2x 01.5 kg as/ha, BBCH 49-69, PHI 35d***, outdoor RA b):					

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	**Evaluation** **GAP** **Residue levels (mg/kg)** **E = according to enforcement residue definition: BAS 750 F** **RA = according to risk assessment residue definition:** **a) BAS 750 F** **b) triazole derivative metabolites (TDMs) with a separate assessment of 1) TA, 2) TLA, 3) TAA, 4) 1,2,4-T**	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
			1) # 0.157, 0.164, 0.198, 0.23, 0.245, 0.37, 0.55, 0.705, 1.51 2) 3) 3x <0.01, 0.013, 0.031, 0.032, 0.054, 0.06, 0.081 4) 9x <0.01					
	New trials BASF DocID 2019/1016888	N-EU	Trials GAP: 1x 0.1 kg as/ha, BBCH 49, PHI 42-69d, outdoor E/RA a): 0.36, 0.40, 1.0, 1.7	0.69	1.7	Highest residue covered by pseudo MRL 30 mg/kg. No further considerations needed.		Yes
		S-EU	Trials GAP: 1x 0.1 kg as/ha, BBCH 49, PHI 56-57d, outdoor E/RA a): 0.11, 0.66, 0.72, 1.0					

EFSA 2018a: residues are reported as the sum of TA and TLA measurements

* Source of EU MRL: Reg. (EU) 2019/977

** U-test confirms that the NEU and SEU data sets are not statistically different, hence they are combined in each case to provide overall STMR and HR values. (test was performed for parent residues only)

*** general note regarding the intended PHI of 35 days: the time interval between the second application and harvest may vary depending on geographical and weather conditions. As soon the last application is made at the latest BBCH stage foreseen in the cGAP (BBCH 69), residue trials are considered valid even if the PHI of 35 days is not met.

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

General note: in context of EFSA (2018a and 2020), for TA, TLA, TAA and 1,2,4-T only the residue values from treated plots were reported. In context of the new trials, untreated values were considered for further calculations if they were higher than the values from the treated plots.

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on oilseed rape, sunflower and wheat are considered acceptable for outdoor uses. The extrapolation rules between crops have been applied according to SANTE/2019/12752.
The newly conducted residue trials have been conducted either with formulation BAS 762 00 F and/or BAS 762 02 F according to the critical GAPs. As both formulations are SC formulations, they can be considered to be equivalent and a similar residue behaviour is expected (see 3.4, Deviations of residue trials regarding the formulation in SANTE/2019/12752). In case both formulations have been used in the same trial, the more critical residue value has been chosen for derivation of the overall HR and STMR values and their MRL compliance.
The data submitted show that no exceedance of the current or proposed mefentrifluconazole MRLs for the intended uses (oilseed rape including turnip rape and oil radish, sunflower and wheat) is expected. The highest residue values from all new residue trials conducted are below the currently established or proposed EU MRLs, therefore a safe use of mefentrifluconazole for the intended uses of BAS 762 02 F can be assumed.
In the presented wheat residue trials, only parent mefentrifluconazole was measured. The triazole derivative metabolites (TDMs) 1) TA, 2) TLA, 3) TAA, 4) 1,2,4-T are covered by the recent EFSA Conclusion (EFSA, 2018a) in the course of which wheat applications with a more critical GAP (2x 0.15 kg as/ha, PHI 35 days) compared to this submission (1x 0.1 kg as/ha, PHI 56-57 days) were evaluated. It has been shown previously that TDM residue levels directly correlate with the residue level of parent mefentrifluconazole, consequently the TDM residues resulting from wheat trials presented in this submission are covered by the risk envelope presented by EFSA, 2018a.

zRMS comments:
Information given by the Applicant is sufficient.
Wheat, sunflower seed and oilseed rape are the major crops in northern Europe (Technical Guidelines SANTE/2019/12752). A minimum of eight trials are required.

1. Wheat
The intended GAP for mefentrifluconazole for wheat in central Europe is 1 x 0.100 kg a.i./ha at BBCH 30-49 with PHI of 56 days.
New study on the magnitude of residue have been submitted by the Applicant in the framework of this application:
1. BASF DocID 2019/1016888– 4 NEU trials and 4 SEU trials;
Eight residue trials were conducted in Germany, Poland, Southern France, Spain, The Netherlands, United Kingdom, Italy and Greece during the 2018 season. In this study one application, applied at growth stage BBCH 49 were made at a nominal rate of 0.1 kg ai/ha for mefentrifluconazole.
Residues of mefentrifluconazole in samples of wheat grain at BBCH 89 were < 0.010 mg/kg.

In SANTE/2019/12752 it is concluded that in '<LOQ residue' situation, the number of independent trials may be reduced. The number of trials shall not be below the minimum of three per zone for minor crops and four per zone for major crops. So sufficient trials are available to support the proposed use in wheat.

The trials are supported by valid storage stability data for wheat and validated analytical methods.
The residues arising from the proposed uses will not exceed the MRLs established for mefentrifluconazole for wheat (0.05 mg/kg) in Reg. (EC) No 2021/590.

In the presented wheat residue trials, only parent mefentrifluconazole was measured. zRMS-PL agrees with conclusion presented by Applicant, that *The triazole derivative metabolites (TDMs) 1) TA, 2) TLA, 3) TAA, 4) 1,2,4-T are covered by the recent EFSA Conclusion (EFSA, 2018a) in the course of which wheat applications with a more critical GAP (2x 0.15 kg as/ha, PHI 35 days) compared to this submission (1x 0.1 kg as/ha, PHI 56-57 days) were evaluated. It has been shown previously that TDM residue levels directly correlate with the residue level of parent mefentrifluconazole, consequently the TDM residues resulting from wheat trials presented in this submission are covered by the risk envelope presented by EFSA, 2018a.*

2. Oilseed rape
The intended GAP for mefentrifluconazole for oilseed rape in central Europe is 1 x 0.100 kg a.i./ha at BBCH 57-75 with PHI as not relevant.
Sufficient trials are available to support the proposed use in oilseed rape.

New studies on the magnitude of residue have been submitted by the Applicant in the framework of this application:
1. BASF DocID 2019/1016882 – 4 NEU trials and 4 SEU trials;
Eight residue trials were conducted in Germany, The Netherlands, Denmark, Northern and Southern France, Greece, Italy and Spain during the 2018 season. In this study one application, applied at growth stage BBCH 75 were made at a nominal rate of 0.1 kg ai/ha for mefentrifluconazole.
Residues of mefentrifluconazole in samples of oilseed rape seed at BBCH 89 (38-54 DALA) were < 0.010 mg/kg.
In the analytical phase S18-04978 of this study all specimens were analysed additionally for residues of the Triazole metabolites 1,2,4-Triazole, Triazolylalanine, Triazole acetic acid and Triazole lactic.
Residues of 1,2,4-Triazole in samples of oilseed rape seed at BBCH 89 (38-54 DALA) were < 0.010 mg/kg.
Residues of Triazolylalanine in samples of oilseed rape seed at BBCH 89 (38-54 DALA) were between 0.28-1.4 mg/kg.
Residues of Triazole lactic acid in samples of oilseed rape seed at BBCH 89 (38-54 DALA) were between 0.01-0.034 mg/kg.
Residues of Triazole acetic acid in samples of oilseed rape seed at BBCH 89 (38-54 DALA) were between <0.01-0.011 mg/kg.

2. BASF DocID 2020/2006193 – 4 NEU trials and 4 SEU trials;
Eight residue trials were conducted in Northern and Southern Europe during the 2019 season. In this study one application, applied at growth stage BBCH 75 were made at a nominal rate of 0.1 kg ai/ha for mefentrifluconazole.
Residues of mefentrifluconazole in samples of oilseed rape seed at BBCH 89 (38-54 DALA) were between < 0.010 -0.055 mg/kg.
In this study all specimens were analysed additionally for residues of the Triazole metabolites 1,2,4-Triazole, Triazolylalanine, Triazole acetic acid and Triazole lactic.
Residues of 1,2,4-Triazole in samples of oilseed rape seed at BBCH 89 (38-54 DALA) were < 0.010 mg/kg.
Residues of Triazolylalanine in samples of oilseed rape seed at BBCH 89 (38-54 DALA) were between 0.18-3.8 mg/kg.
Residues of Triazole lactic acid in samples of oilseed rape seed at BBCH 89 (38-54 DALA) were between <0.01-0.21 mg/kg.
Residues of Triazole acetic acid in samples of oilseed rape seed at BBCH 89 (38-54 DALA) were between <0.01-0.056 mg/kg.

The trials are supported by valid storage stability data for oilseed rape and validated analytical methods.
The residues arising from the proposed uses will not exceed the MRLs established for mefentrifluconazole for oilseed rape (0.06 mg/kg) in Reg. (EC) No 2021/590.

3. Sunflower seed
The intended GAP for mefentrifluconazole for sunflower seed in central Europe is 2 x 0.100 kg a.i./ha with 7 days between application at BBCH 31-69 with PHI as not relevant.
Sufficient trials are available to support the proposed use in sunflower seed.
New studies on the magnitude of residue have been submitted by the Applicant in the framework of this application:
1. BASF DocID 2018/120579– 4 NEU trials and 4 SEU trials;
Eight residue trials were conducted in Northern and Southern Europe during the 2018 season. In this study two times application, applied at BBCH 59 and the second application at BBCH 69, were made at a nominal rate of 0.1 kg ai/ha for mefentrifluconazole.
Residues of mefentrifluconazole in treated seed specimens taken at BBCH 89 ranged between < 0.010 mg/kg and 0.042 mg/kg.
In this study all specimens were analysed additionally for residues of the Triazole metabolites 1,2,4-Triazole, Triazolylalanine, Triazole acetic acid and Triazole lactic.
Residues of 1,2,4-Triazole in samples of oilseed rape seed at BBCH 89 were < 0.010 mg/kg.
Residues of Triazolylalanine in samples of oilseed rape seed at BBCH 89 were between 0.015 and 0.12 mg/kg.
Residues of Triazole lactic acid in samples of oilseed rape seed at BBCH 89 were <0.01 mg/kg.
Residues of Triazole acetic acid in samples of oilseed rape seed at BBCH 89 were between 0.015 and 0.11 mg/kg.

2. BASF DocID 2019/2075093 – 4 NEU trials and 4 SEU trials;
Eight residue trials were conducted in Northern and Southern Europe during the 2019 season. In this study two times application, applied at BBCH 59-61 and the second application at BBCH 69, were made at a nominal rate of 0.1 kg ai/ha for mefentrifluconazole.
Residues of mefentrifluconazole in treated seed specimens taken at BBCH 89 were < 0.010 mg/kg.
In this study all specimens were analysed additionally for residues of the Triazole metabolites 1,2,4-Triazole, Triazolylalanine, Triazole acetic acid and Triazole lactic.
Residues of 1,2,4-Triazole in samples of oilseed rape seed at BBCH 89 were < 0.010 mg/kg.

Residues of Triazolylalanine in samples of oilseed rape seed at BBCH 89 were between 0.018 and 0.23 mg/kg.
Residues of Triazole lactic acid in samples of oilseed rape seed at BBCH 89 were <0.01 mg/kg.
Residues of Triazole acetic acid in samples of oilseed rape seed at BBCH 89 were between 0.016 and 0.23 mg/kg.

The trials are supported by valid storage stability data for sunflower and validated analytical methods.
The residues arising from the proposed uses will not exceed the MRLs established for mefentrifluconazole for sunflower seed (0.05 mg/kg) in Reg. (EC) No 2021/590.

No additional data are required.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

In the context of a recently submitted and already evaluated MRL application (please refer to EFSA, 2020), the anticipated maximum dietary burden for poultry, pigs and ruminants (dairy cattle and beef cattle) have been calculated using the current version of the OECD feed burden calculator (using the OECD methodology) considering all BAS 750 F uses. For sake of being comprehensive residue data on crops included in the present submission as well as on crops included in previous submissions were taken into account as a worst-case scenario.

Table 7.2-10: Input values for the dietary burden calculation (considering the uses authorized in the country of the zRMS/authorized within the zone/evaluated in Art. 12 procedure and the uses under consideration)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment/ Source	Input value (mg/kg)	Comment/ Source
Enforcement residue definition: *parent BAS 750 F* Risk assessment residue definition: *animal except poultry: parent BAS 750 F, poultry: sum of parent BAS 750 F, metabolite M750F022 and fatty acid conjugates of M750F022, expressed as parent equivalents.* (Values in brackets are based on calculations with residue values from Table 7.2-9)				
Apple, wet pomace	0.25	$STMR_P$ (STMR 0.08 x PF 3.10) / EFSA, 2020	0.25	$STMR_P$ (STMR 0.08 x PF 3.10) / EFSA, 2020
Beet, sugar, tops	0.24	STMR/ EFSA, 2020	1.10	HR/ EFSA, 2020
Beet, sugar, dried pulp	0.10	$STMR_P$ (STMR 0.02 x PF 4.75) / EFSA, 2020	0.10	$STMR_P$ (STMR 0.02 x PF 4.75) / EFSA, 2020
Beet, sugar, ensiled pulp	0.02	$STMR_P$ (STMR 0.02 x PF 0.88) / EFSA, 2020	0.02	$STMR_P$ (STMR 0.02 x PF 0.88) / EFSA, 2020
Beet, sugar, molasses	0.02	$STMR_P$ (STMR 0.02 x PF 0.88) / EFSA, 2020	0.02	$STMR_P$ (STMR 0.02 x PF 0.88) / EFSA, 2020
Corn, field (maize), grain	0.01	STMR/ EFSA, 2020	0.01	STMR/ EFSA, 2020
Corn, pop, grain	0.01	STMR/ EFSA, 2020	0.01	STMR/ EFSA, 2020
Corn, field, stover (fodder)	0.13	STMR/ EFSA, 2020	0.61	HR / EFSA, 2020
Corn, pop, stover (fodder)	0.13	STMR/ EFSA, 2020	0.61	HR / EFSA, 2020
Corn, field, milled byproducts	0.09	$STMR_P$ (STMR 0.01 x PF 8.8) / EFSA, 2020	-	-
Corn, field, hominy meal	0.02	$STMR_P$ (STMR 0.01 x PF 1.70)[(c)] / EFSA, 2020	-	-
Corn, field, gluten feed	0.03	$STMR_P$ (STMR 0.01 x PF 2.70)[(c)] / EFSA, 2020	-	-

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment/ Source	Input value (mg/kg)	Comment/ Source
Corn, field, gluten meal	0.03	$STMR_P$ (STMR 0.01 x PF 2.70)[(c)] / EFSA, 2020	-	-
Potato, culls (= roots)	0.01	STMR / EFSA, 2020	0.01	HR / EFSA, 2020
Potato, process waste	0.005	$STMR_P$ (STMR 0.01 x PF 0.45) / EFSA, 2020	-	-
Potato, dried pulp	0.02	$STMR_P$ (STMR 0.01 x PF 2.43) / EFSA, 2020	-	-
Canola (rape seed), meal	0.02[1] (0.02)	$STMR_P$ (STMR 0.01 x PF 2.0)[(a)] / EFSA, 2020 (STMR in this submission 0.01 x PF 2.0)	0.02[1] (0.02)	$STMR_P$ (STMR 0.01 x PF 2.0)[(a)] / EFSA, 2020 (STMR in this submission 0.01 x PF 2.0)
Rape, meal	0.02[1] (0.02)	$STMR_P$ (STMR 0.01 x PF 2.0)[(a)] / EFSA, 2020 (STMR in this submission 0.01 x PF 2.0)	0.02[1] (0.02)	$STMR_P$ (STMR 0.01 x PF 2.0)[(a)] / EFSA, 2020 (STMR in this submission 0.01 x PF 2.0)
Sunflower, meal	0.02[1] (0.02)	$STMR_P$ (STMR 0.01 x PF 2.0)[(a)] / EFSA, 2020 (STMR in this submission 0.01 x PF 2.0)	0.02[1] (0.02)	$STMR_P$ (STMR 0.01 x PF 2.0)[(a)] / EFSA, 2020 (STMR in this submission 0.01 x PF 2.0)
Wheat grain	0.01[1] (0.01)	STMR / EFSA, 2018a (STMR in this submission)	0.01[1] (0.01)	STMR / EFSA, 2018a (STMR in this submission)
Wheat straw	3.6[1] (0.69)	STMR / EFSA, 2018a (STMR in this submission)	18.0[1] (1.7)	HR / EFSA, 2018a (HR in this submission)
Wheat gluten meal	0.003[1] (0.003)	$STMR_P$ (STMR 0.01 x PF 0.3) / EFSA, 2018a (STMR in this submission 0.01 x PF 0.3)	-	-
Wheat milled byproducts	0.01[1] (0.006)	$STMR_P$ (STMR 0.01 x PF 0.6) / EFSA, 2018a (STMR in this submission 0.01 x PF 0.6)	-	-
Wheat distiller's grain (dried)	0.03[1] (0.027)	$STMR_P$ (STMR 0.01 x PF 2.7) / EFSA, 2018a (STMR in this submission 0.01 x PF 2.7)	-	-
Rye grain	0.01	STMR / EFSA, 2018a	0.01	STMR / EFSA, 2018a
Rye straw	3.6	STMR / EFSA, 2018a	18.0	HR / EFSA, 2018a
Triticale grain	0.01	STMR / EFSA, 2018a	0.01	STMR / EFSA, 2018a
Triticale straw	3.6	STMR / EFSA, 2018a	18.0	HR / EFSA, 2018a
Barley grain	0.1	STMR / EFSA, 2018a	0.1	STMR / EFSA, 2018a
Barley straw	4.25	STMR / EFSA, 2018a	18.0	HR / EFSA, 2018a

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment/ Source	Input value (mg/kg)	Comment/ Source
Barley brewers grain (dried)	0.24	$STMR_P$ (STMR 0.1 x PF 2.4) / EFSA, 2018a	-	-
Oat grain	0.1	STMR / EFSA, 2018a	0.1	STMR / EFSA, 2018a
Oat straw	4.25	STMR / EFSA, 2018a	18.0	HR / EFSA, 2018a

HR = highest residue
STMR = Supervised Trials Median Residue
(a): In the absence of specific processing factors supported by data, default processing factors of 2 (oilseed meal), 18 and 3 (sugar beet dried and ensiled pulp, respectively) were included in the calculation to consider the potential concentration of residues in these commodities.
(b): Since residues in RAC and in processed products were below the LOQ (please refer to EFSA, 2020), a processing factor was not applied. Concentration of residues is not expected.
(c): Tentative processing factor derived based on a limited dataset.
[1] STMRs and HRs of EFSA, 2018a and 2020 cover also data from new trials submitted in this dossier

The results of the total maximum dietary burden calculations are reported in the table below.

Table 7.2-11: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Enforcement residue definition: *parent BAS 750 F* Risk assessment residue definition: *animal except poultry: parent BAS 750 F, poultry: sum of parent BAS 750 F, metabolite M750F022 and fatty acid conjugates of M750F022, expressed as parent equivalents*					
Beef cattle*	0.038	0.150	barley straw	6.25	yes
Dairy cattle*	0.060	0.238	barley straw	6.18	yes
Ram/Ewe	0.099	0.407	barley straw	12.20	yes
Lamb	0.126	0.520	barley straw	12.23	yes
Breeding swine	0.005	0.014	beet, sugar, tops	0.60	yes
Finishing swine*	0.004	0.004	barley, grain	0.12	no
Broiler poultry	0.008	0.008	barley, grain	0.11	yes
Layer poultry*	0.035	0.147	wheat straw	2.15	yes
Turkey	0.008	0.008	barley, grain	0.11	yes
Fish (carp)	-	-	-	0.061	no
Fish (trout)	-	-	-	0.042	no

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

Regarding the dietary burden for parent **BAS 750 F**, all calculated maximum dietary burdens (mg/kg bw/d) are covered by the recent calculation (EFSA, 2020).

Regarding fish, in context of EFSA 2020 calculations were made for BAS 750 F. As all input values are covered, no further considerations are needed.

zRMS comments:
Information given by the Applicant is sufficient.
Several crops under consideration and/or their by-products can be used as feed items for livestock and fish. Therefore, the potential of transfer of residues in products of animal origin was investigated.
For livestock, calculations were based on the OECD feeding stuff tables (OECD, 2013).
Applicant presented dietary burden calculation which are covered by the recent calculation evaluated in MRL application by EFSA in 2020 (EFSA Journal 2020;18(7):6193).

According to the EFSA Journal 2020;18(7):6193:
EFSA updated the livestock dietary burdens conducted in the framework of the EU pesticides peer review (EFSA, 2018c) with the input values for apple pomace and for potatoes, maize, sweet corn and sugar beet products and by-products. In the absence of specific processing factors, EFSA used the default processing factors of 2 for oilseed meal and 3 and 18 for dried pulp and ensiled pulp of sugar beets, respectively. When the specific processing studies showed that residues in the raw commodity and in the processed product were below the LOQ, no default processing factor was applied because residues are not expected to concentrate in the by-product.
For parent mefentrifluconazole, the revised dietary burden exceeded the trigger value of 0.004 mg/ kg body weight (bw) per day for all livestock animal species; compared with the previous calculations, the calculated dietary burden is in the same order of magnitude except for poultry and breeding swine where the estimated dietary burden is slightly higher; the main contributors to the diet are wheat grain and sugar beet tops, respectively.
Regarding TDMs, the calculated intakes exceeded the trigger value of 0.004 mg/kg bw per day for TA, TLA and TAA. The calculations demonstrated that the livestock exposure to the residues of these three metabolites resulting from the existing and intended uses of mefentrifluconazole are lower than the indicative dietary burdens calculated in the framework of the review of the confirmatory data on TDMs. These calculations considered the contribution of TDM residues in animal commodities from the uses of a number of triazole pesticides (EFSA, 2018b). Given that residues of 1,2,4 triazole is not significant in the livestock diets (< 0.004 mg/kg bw per day) further consideration is not required.

<u>Fish</u>
The results of the dietary burden calculations of mefentrifluconazole,10 one for rainbow trout and one for common

carp, were provided (Austria, 2019). The trigger value of 0.1 mg/kg dry matter (DM) was not exceeded for both species. Consequently, a feeding study that estimates MRLs in fish is unnecessary.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

No new data was submitted in the framework of this application. In the context of the Annex I inclusion process two feeding studies in hen and cow have been submitted by the applicant. These studies are summarized in the table below. For a detailed assessment refer to the EFSA conclusion (2018a).

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)[(b)]	Highest residue (mg/kg)[(c)]	Calculated MRL (mg/kg)	CF for RA[(d)]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)[(a)]	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (current Excel calculator *Animal model.2017.xls* developed by EFSA applied)												
EFSA, 2018a, BASF DocIDs 2015/1106667, 2016/1001326 and 2015/1107649												
Enforcement residue definition: *parent BAS 750 F* and risk assessment residue definition: *animal except poultry: parent BAS 750 F, poultry: sum of parent BAS 750 F, metabolite M750F022 and fatty acid conjugates of M750F022, expressed as parent*												
Bovine meat	0.060 (Dairy cattle)	0.238 (Dairy cattle)	0.035	3	0.01*	0.01*	0.01*	0.01*	0.01	0.03	0.03	1.0
			0.193	3	0.01*	0.01*	0.01*	0.01*				
			1.042	3	0.073	0.105	0.073	0.105				
			3.740	3	0.163	0.221	0.163	0.221				
Bovine fat	0.060 (Dairy cattle)	0.238 (Dairy cattle)	0.035	3	0.017	0.018	0.017	0.018	0.06	0.19	0.2	1.0
			0.193	3	0.049	0.059	0.049	0.059				
			1.042	3	0.649	0.900	0.649	0.900				
			3.740	3	1.711	2.290	1.711	2.290				
Bovine liver	0.060 (Dairy cattle)	0.238 (Dairy cattle)	0.035	3	0.031	0.034	0.031	0.034	0.09	0.34	0.4	1.0
			0.193	3	0.150	0.182	0.150	0.182				
			1.042	3	0.993	1.400	0.993	1.400				
			3.740	3	3.030	3.580	3.030	3.580				
Bovine kidney	0.060 (Dairy cattle)	0.238 (Dairy cattle)	0.035	3	0.012	0.014	0.012	0.014	0.02	0.10	0.15	1.0
			0.193	3	0.048	0.074	0.048	0.074				
			1.042	3	0.291	0.505	0.291	0.505				
			3.740	3	1.295	1.880	1.295	1.880				
Bovine milk	0.060 (Dairy cattle)	0.238 (Dairy cattle)	0.035	3	0.01*[(e)]	N/A	0.01*[(e)]	N/A	0.01	0.02	0.03	1.0
			0.193	3	0.01* [(e)]	N/A	0.01* [(e)]	N/A				
			1.042	3	0.08 [(e)]	N/A	0.08 [(e)]	N/A				

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)[b]	Highest residue (mg/kg)[c]	Calculated MRL (mg/kg)	CF for RA[d]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)[a]	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
			3.740	3	0.216 [e]	N/A	0.216 [e]	N/A				
Sheep meat	0.126 (Lamb)	0.520 (Lamb)	0.035	3	0.01*	0.01*	0.01*	0.01*	0.02	0.05	0.06	1.0
			0.193	3	0.01*	0.01*	0.01*	0.01*				
			1.042	3	0.073	0.105	0.073	0.105				
			3.740	3	0.163	0.221	0.163	0.221				
Sheep fat	0.126 (Lamb)	0.520 (Lamb)	0.035	3	0.017	0.018	0.017	0.018	0.09	0.38	0.4	1.0
			0.193	3	0.049	0.059	0.049	0.059				
			1.042	3	0.649	0.900	0.649	0.900				
			3.740	3	1.711	2.290	1.711	2.290				
Sheep liver	0.126 (Lamb)	0.520 (Lamb)	0.035	3	0.031	0.034	0.031	0.034	0.14	0.65	0.7	1.0
			0.193	3	0.150	0.182	0.150	0.182				
			1.042	3	0.993	1.400	0.993	1.400				
			3.740	3	3.030	3.580	3.030	3.580				
Sheep kidney	0.126 (Lamb)	0.520 (Lamb)	0.035	3	0.012	0.014	0.012	0.014	0.03	0.25	0.3	1.0
			0.193	3	0.048	0.074	0.048	0.074				
			1.042	3	0.291	0.505	0.291	0.505				
			3.740	3	1.295	1.880	1.295	1.880				
Sheep milk	0.099 (Ram/Ewe)	0.407 (Ram/Ewe)	0.035	3	0.01*[e]	N/A	0.01*[e]	N/A	0.01	0.03	0.04	1.0
			0.193	3	0.01* [e]	N/A	0.01* [e]	N/A				
			1.042	3	0.08 [e]	N/A	0.08 [e]	N/A				
			3.740	3	0.216 [e]	N/A	0.216 [e]	N/A				
Pig meat	0.005 (Breeding)	0.014 (Breeding)	0.035	3	0.01*	0.01*	0.01*	0.01*	0.01	0.01	0.01*	1.0
			0.193	3	0.01*	0.01*	0.01*	0.01*				

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)[(b)]	Highest residue (mg/kg)[(c)]	Calculated MRL (mg/kg)	CF for RA[(d)]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)[(a)]	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
			1.042	3	0.073	0.105	0.073	0.105				
			3.740	3	0.163	0.221	0.163	0.221				
Pig fat	0.005 (Breeding)	0.014 (Breeding)	0.035	3	0.017	0.018	0.017	0.018	0.002	0.01	0.01*	1.0
			0.193	3	0.049	0.059	0.049	0.059				
			1.042	3	0.649	0.900	0.649	0.900				
			3.740	3	1.711	2.290	1.711	2.290				
Pig liver	0.005 (Breeding)	0.014 (Breeding)	0.035	3	0.031	0.034	0.031	0.034	0.005	0.013	0.015	1.0
			0.193	3	0.150	0.182	0.150	0.182				
			1.042	3	0.993	1.400	0.993	1.400				
			3.740	3	3.030	3.580	3.030	3.580				
Pig kidney	0.005 (Breeding)	0.014 (Breeding)	0.035	3	0.012	0.014	0.012	0.014	0.002	0.01	0.01*	1.0
			0.193	3	0.048	0.074	0.048	0.074				
			1.042	3	0.291	0.505	0.291	0.505				
			3.740	3	1.295	1.880	1.295	1.880				
Poultry meat	0.035 (Layer)	0.147 (Layer)	0.010	3	0.01*	0.01*	0.062	0.062	0.06	0.07	0.015	6.2
			0.096	3	0.01*	0.01*	0.062	0.062				
			0.296	3	0.01*	0.01*	0.062	0.062				
			0.984	3	0.016	0.027	0.099	0.167				
Poultry fat	0.035 (Layer)	0.147 (Layer)	0.010	3	0.01*	0.01*	0.163	0.163	0.16	0.36	0.03	16.3
			0.096	3	0.01*	0.01*	0.163	0.163				
			0.296	3	0.022	0.025	0.359	0.408				
			0.984	3	0.167	0.250	2.722	4.075				
Poultry liver	0.035	0.147	0.010	3	0.01*	0.01*	0.049	0.049	0.05	0.13	0.03	4.9

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)[(b)]	Highest residue (mg/kg)[(c)]	Calculated MRL (mg/kg)	CF for RA[(d)]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)[(a)]	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
	(Layer)	(Layer)	0.096	3	0.013	0.017	0.064	0.083				
			0.296	3	0.015	0.021	0.074	0.103				
			0.984	3	0.038	0.060	0.186	0.294				
Eggs	0.035 (Layer)	0.147 (Layer)	0.010	3	0.01*	0.01*	0.049	0.049	0.05	0.05	0.015	4.9
			0.096	3	0.01*	0.01*	0.049	0.049				
			0.296	3	0.01*	0.01*	0.049	0.049				
			0.984	3	0.035	0.042	0.172	0.206				
New data												
No new data												

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): Based on a xx kg animal consuming xx kg feed DM/day.
(b): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).
(c): 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).
(d): The median conversion factor for enforcement to risk assessment.
(e): Mean residue level from day 3 until day 28 (3 cows, 9 sampling days).

Conclusion on feeding studies

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

The current Excel calculator *Animal model 2017.xls* developed by EFSA was used and therefore new MRLs of BAS 750 F in swine liver and milk were proposed in context of submissions for product BAS 750 11 F in Core C and S. Both submissions were recently evaluated and MRLs were raised accordingly (EFSA, 2020).

zRMS comments:

Information given by the Applicant is sufficient.

EFSA in EFSA Journal 2020;18(7):6193 concluded that *„Feeding studies with mefentrifluconazole in ruminants and poultry were assessed in the framework of the EU pesticides peer review of this active substance (EFSA, 2018c). The metabolic pathway in ruminants was comparable to that in rats, so the results of the ruminant feeding study may be extrapolated to pigs and other domestic animals (OECD, 2007e). Based on the updated dietary burden calculations and the results of the feeding studies, EFSA concludes that the setting of an MRL in liver of swine and an increase of the existing MRLs in kidney of cattle and in milk of ruminants is required.*

A modification of the existing MRLs for the other tissues of ruminants and of poultry tissues and eggs is not necessary.

The requested uses modify the theoretical maximum daily intake for animals, but regarding available feeding data, there is no risk for animal MRL to be exceeded.

7.2.4.3 Dietary burden calculation in Triazole derived metabolites

Austria 2019:
As the dietary burden in the TDM review did not account for residues of TDMs arising from treatment with BAS 750 F, additional dietary burden calculations have been undertaken in the DAR (UK, 2018) in the framework of the active substance approval to address these residues specifically. The dietary burden calculation has been performed according to the approach presented in the OECD Guidance document on residues in livestock, series on pesticides No 73 for a total of 9 animal species, fish excluded.

All feed items, which might be treated with the active substance have been considered. In this calculation the registered as well as the proposed uses of BAS 750 F are considered. A separate calculation has been made for each TDM (1,2,4-T, TA, TAA and TLA).
Even in the absence of maintenance treatments with triazole-containing plant protection products, many residue trials showed measurable residues of TDMs in the control samples. These residues are attributed to the use of triazole-containing plant products on the test plots during previous seasons. Therefore, the levels of TDM residues measured in the treated samples are considered to properly reflect the residues that result from the test item and from the use of triazole-containing plant protection products during previous growing seasons. Whenever the residues measured in the control samples exceeded the levels found in the corresponding treated samples, the residues in the control samples were taken into account (instead of the residues in the corresponding treated samples) for the calculation of the median and highest residue levels (STMR and HR).

In summary, the available data package is considered to adequately reflect the residue levels in crops because it covers:
- Treatment programmes involving several triazole-containing plant protection products.
- Residues that may result from the use of triazole-containing plant protection products during previous seasons.

In context of EFSA (2020) overall livestock burden calculations were performed for all TDMs of concern.

For the input values, please refer to Table 7.2-13 and the supplemental document, in which a detailed derivation of input values is presented (BASF DocID 2021/2001338).
The results of the total maximum dietary burden calculations are reported in the tables below (Table 7.2-14 to Table 7.2-17).

Regarding TDMs, overall livestock dietary burden calculations were recently performed by EFSA (EFSA, 2020). As in context of the present submission only oilseed rape, sunflower and wheat are foreseen as intended crops, in the following the input values for 1,2,4-T, TA, TAA and TLA in oilseed rape, sunflower and wheat matrices are shown and compared to the derived values as shown in Table 7.2-9 (values in brackets). The worst case was used for dietary burden calculations only.

Table 7.2-13: TDM input values for the dietary burden calculation (considering the uses under consideration)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment/ Source[1]	Input value (mg/kg)	Comment/ Source[1]
Risk assessment residue definition: 1,2,4-T (values in brackets are based on calculations with residue values from Table 7.2-9)				
Canola (rape seed), meal	0.01 (0.01)	STMR[1] (STMR in this submission)	-	-
Rape, meal	0.01 (0.01)	STMR[1] (STMR in this submission)	-	-
Sunflower, meal	0.01 (0.01)	STMR[1] (STMR in this submission)	-	-
Wheat grain	0.01	STMR[1]	0.01	STMR[1]
Wheat straw	0.01	STMR[1]	0.01	HR[1]
Wheat gluten meal	0.01	STMR[1]	-	-
Wheat milled byproducts	0.01	STMR[1]	-	-
Wheat distiller's grain (dried)	0.01	STMR[1]	-	-
Risk assessment residue definition: *TA* (values in brackets are based on calculations with residue values from Table 7.2-9)				
Canola (rape seed), meal	1.16 (1.16)	$STMR_P$ (STMR 0.58 x PF 2.0)[1] (STMR in this submission 0.58 x PF 2.0)	-	-
Rape, meal	1.16 (1.16)	$STMR_P$ (STMR 0.58 x PF 2.0)[1] (STMR in this submission 0.58 x PF 2.0)	-	-
Sunflower, meal	0.12 (0.10)	$STMR_P$ (STMR 0.06 x PF 2.0)[1] (STMR in this submission 0.05 x PF 2.0)	-	-
Wheat grain	0.28	STMR[1]	0.28	STMR[1]
Wheat straw	0.035	STMR[1]	0.83	HR[1]
Wheat gluten meal	0.05	$STMR_P$ (STMR 0.28 x PF 0.19)[1]	-	-
Wheat milled byproducts	0.16	$STMR_P$ (STMR 0.28 x PF 0.58)[1]	-	-
Wheat distiller's grain (dried)	0.92	$STMR_P$ (STMR 0.28 x PF 3.3)[1]	-	-
Risk assessment residue definition: *TAA* (values in brackets are based on calculations with residue values from Table 7.2-9)				
Canola (rape seed), meal	0.02 (0.02)	$STMR_P$ (STMR 0.01 x PF 2.0)[1] (STMR in this submission 0.01 x PF 2.0)	-	-
Rape, meal	0.02 (0.02)	$STMR_P$ (STMR 0.01 x PF 2.0)[1] (STMR in this submission 0.01 x PF 2.0)	-	-

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment/ Source[1]	Input value (mg/kg)	Comment/ Source[1]
Sunflower, meal	0.12 (0.16)	$STMR_P$ (STMR 0.062 x PF 2.0)[1] (STMR in this submission 0.08 x PF 2.0)	-	-
Wheat grain	0.085	STMR[1]	0.085	STMR[1]
Wheat straw	0.047	STMR[1]	0.17	HR[1]
Wheat gluten meal	0.08	$STMR_P$ (STMR 0.085 x PF 0.95)[1]	-	-
Wheat milled byproducts	0.05	$STMR_P$ (STMR 0.085 x PF 0.63)[1]	-	-
Wheat distiller's grain (dried)	0.28	$STMR_P$ (STMR 0.085 x PF 3.3)[1]	-	-
Risk assessment residue definition: *TLA* (values in brackets are based on calculations with residue values from Table 7.2-9)				
Canola (rape seed), meal	0.05 (0.05)	$STMR_P$ (STMR 0.026 x PF 2.0)[1] (STMR in this submission 0.026 x PF 2.0)	-	-
Rape, meal	0.05 (0.05)	$STMR_P$ (STMR 0.026 x PF 2.0)[1] (STMR in this submission 0.026 x PF 2.0)	-	-
Sunflower, meal	0.02 (0.02)	$STMR_P$ (STMR 0.01 x PF 2.0)[1] (STMR in this submission 0.01 x PF 2.0)	-	-
Wheat grain	0.01	STMR[1]	0.01	STMR[1]
Wheat straw	0.077	STMR[1]	1.50	HR[1]
Wheat gluten meal	0.02	$STMR_P$ (STMR 0.01 x PF 1.8)[1]	-	-
Wheat milled byproducts	0.07	$STMR_P$ (STMR 0.01 x PF 7.0)[1]	-	-
Wheat distiller's grain (dried)	0.03	$STMR_P$ (STMR 0.01 x PF 3.3) [1]	-	-

HR = highest residue, STMR = Supervised Trials Median Residue

1 For Source, please refer to the supplemental document (BASF DocID 2021/2001338)

Table 7.2-14: Results of the dietary burden calculation for 1,2,4-T

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
1,2,4-T					
Beef cattle*	0.001	0.002	potato process waste	0.07	no
Dairy cattle*	0.002	0.003	beet, sugar, tops	0.07	no
Ram/Ewe	0.002	0.002	potato process waste	0.1	no
Lamb	0.002	0.003	potato process waste	0.07	no
Breeding swine	0.001	0.001	beet, sugar, tops	0.05	no
Finishing swine*	0.001	0.001	potato, culls	0.03	no
Broiler poultry	0.001	0.001	potato, culls	0.02	no
Layer poultry*	0.001	0.001	beet, sugar, tops	0.02	no
Turkey	0.001	0.001	potato, culls	0.02	no

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

For all animal species considered, the maximum dietary burden of 1,2,4-Triazole resulting from treatment with BAS 750 F is below the trigger value of 0.004 mg/kg bw/day. Thus, no further consideration of the residues in animal commodities is required.

Table 7.2-15: Results of the dietary burden calculation for TA

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
TA					
Beef cattle*	0.012	0.020	rape meal	0.82	yes
Dairy cattle*	0.012	0.024	potato culls	0.63	yes
Ram/Ewe	0.013	0.030	rape meal	0.90	yes
Lamb	0.018	0.037	rape meal	0.86	yes
Breeding swine	0.011	0.018	canola meal	0.78	yes
Finishing swine*	0.015	0.024	canola meal	0.78	yes
Broiler poultry	0.034	0.038	canola meal	0.55	yes
Layer poultry*	0.027	0.036	canola meal	0.53	yes
Turkey	0.035	0.045	canola meal	0.62	yes

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

The maximum dietary burden of TA (triazole alanine) resulting from treatment with BAS 750 F exceeds the trigger value of 0.004 mg/kg bw/day for all animal species considered, thus further consideration of the residues in animal commodities is required.

Table 7.2-16: Results of the dietary burden calculation for TAA

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
TAA					
Beef cattle*	0.003	0.006	barley straw	0.25	yes
Dairy cattle*	0.004	0.009	barley straw	0.24	yes
Ram/Ewe	0.004	0.013	barley straw	0.40	yes
Lamb	0.006	0.016	barley straw	0.38	yes
Breeding swine	0.004	0.004	distiller's grain	0.16	no
Finishing swine*	0.005	0.005	distiller's grain	0.16	yes
Broiler poultry	0.008	0.008	distiller's grain	0.12	yes
Layer poultry*	0.009	0.011	barley straw	0.16	yes
Turkey	0.007	0.007	distiller's grain	0.10	yes

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

The maximum dietary burden of TAA (triazole acetic acid) resulting from treatment with BAS 750 F exceeds the trigger value of 0.004 mg/kg bw/day for all animal species considered except for breeding swine, thus further consideration of the residues in animal commodities is required.

Table 7.2-17: Results of the dietary burden calculation for TLA

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
TLA					
Beef cattle*	0.007	0.091	barley straw	3.80	yes
Dairy cattle*	0.011	0.147	barley straw	3.81	yes
Ram/Ewe	0.015	0.250	barley straw	7.50	yes
Lamb	0.019	0.319	barley straw	7.50	yes
Breeding swine	0.003	0.004	beet, sugar, tops	0.16	no
Finishing swine*	0.003	0.003	beet, sugar, dried pulp	0.11	no
Broiler poultry	0.006	0.006	barley, grain	0.09	yes
Layer poultry*	0.008	0.048	barley, straw	0.70	yes
Turkey	0.005	0.005	barley, grain	0.07	yes

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

The maximum dietary burden of TLA (triazole lactic acid) resulting from treatment with BAS 750 F exceeds the trigger value of 0.004 mg/kg bw/day for all animal species considered except for swine, thus further consideration of the residues in animal commodities is required.

As recently already concluded by EFSA (EFSA, 2020), regarding TDMs, the calculated intakes exceeded the trigger value of 0.004 mg/kg bw per day for TA, TLA and TAA. The calculations demonstrated that the livestock exposure to the residues of these three metabolites resulting from the existing and intended uses of mefentrifluconazole are lower than or identical to the burdens that were calculated in context of EFSA 2018b and EFSA 2020. Given that residues of 1,2,4-triazole is not significant in the livestock diets (<0.004 mg/kg bw per day) further consideration is not required.
The following statement made by EFSA (EFSA, 2020) is still considered appropriate: *[…] Although the calculations for the TDMs were not provided, considering the results of the dietary burden calculations performed with parent mefentrifluconazole in livestock and the residue levels of TDMs in feed which may occur from the intended applications, it can be reasonably assumed that significant residues of the individual TDMs (> 0.1 mg/kg DM) are not likely in the total diet of fish.*

zRMS comments:
Information given by the Applicant is sufficient. Calculations reported in the EFSA conclusions on the EU MRL review (EFSA Journal 2020;18(7):6193) are still valid. EFSA concluded that "*The magnitude of residues of each TDM in animal matrices was estimated based on the ruminants and poultry feeding studies conducted with TAA and TA; feeding studies with TLA and 1,2,4-T are not available. Thus, the data gap identified in the EU peer review of confirmatory data for TDMs is not yet addressed. Provisionally, transfer factors were derived from the feeding studies with TAA and TA to estimate the residue concentration for TLA and 1,2,4-T, respectively (EFSA, 2018b).*"
No additional data are required.

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. In the context of the Annex I inclusion process two processing studies in wheat and barley have been submitted by the applicant. And one processing study for soybean (oilseeds) has been submitted and was evaluated in EFSA, 2020. These studies are summarized in the table below. For a detailed assessment refer to the EFSA conclusion (2018a) and to EFSA, 2020.

Table 7.2-18: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **[(a)]	Comments	Reference
EU data					
Enforcement residue definition: *parent BAS 750 F* *Risk assessment residue definition:* *a) BAS 750 F* *b) triazole derivative metabolites (TDMs) with a separate assessment of: 1) TA and TLA, 2) TAA, 3) 1,2,4-T*					
wheat/bran	1 (3 trials)	2.94 (BAS 750 F)	n.a.	-	EFSA, 2018a BASF DocID 2014/1315283
		2.86 (TA)	n.a.		
		1.35 (TAA)	n.a.		
wheat/flour		<0.29 (BAS 750 F)	n.a.		
		0.51 (TA)	n.a.		
		0.81 (TAA)	n.a.		
wheat/germ		1.12 (BAS 750 F)	n.a.		
		0.97 (TA)	n.a.		
		0.70 (TAA)	n.a.		
wheat/middlings		2.26 (BAS 750 F)	n.a.		
		2.74 (TA)	n.a.		
		1.42 (TAA)	n.a.		

Processed commodity	Number of studies	Median PF *	Median CF **[(a)]	Comments	Reference
wheat/shorts		3.53 (BAS 750 F)	n.a.		
		3.54 (TA)	n.a.		
		2.00 (TAA)	n.a.		

Processed commodity	Number of studies	Median PF *	Median CF **[(a)]	Comments	Reference
wheat/gluten		0.55 (BAS 750 F)	n.a.		
		0.51 (TA)	n.a.		
		1.15 (TAA)	n.a.		
wheat/gluten feed meal		<0.29 (BAS 750 F)	n.a.		
		0.19 (TA)	n.a.		
		0.95 (TAA)	n.a.		
wheat/starch		<0.29 (BAS 750 F)	n.a.		
		<0.03 (TA)	n.a.		
		<0.05 (TAA)	n.a.		
wheat/whole meal flour		0.79 (BAS 750 F)	n.a.		
		1.0 (TA)	n.a.		
		0.90 (TAA)	n.a.		
wheat/whole grain bread		0.56 (BAS 750 F)	n.a.		
		0.86 (TA)	n.a.		
		1.19 (TAA)	n.a.		
wheat/milled byproducts		0.62 (BAS 750 F)	n.a.		
		0.58 (TA)	n.a.		
		0.65 (TAA)	n.a.		
wheat/aspirated grain fraction		38.46 (BAS 750 F)	n.a.		
		0.69 (TA)	n.a.		
		0.63 (TAA)	n.a.		
wheat/silage, wet		1.19 (BAS 750 F)	n.a.		
wheat/silage, wilted		1.88 (BAS 750 F)	n.a.		
soybean, flour	1 (3 trials)	tentative[1,2] (BAS 750 F)	n.a.		EFSA, 2020 BASF DocID 2015/7005934
		1.41 (TA)	n.a.		
		1.33 (TAA)	n.a.		
		1.20 (TLA)	n.a.		

Processed commodity	Number of studies	Median PF *	Median CF **[(a)]	Comments	Reference
soybean, soymilk/soy drink		tentative[1,2] (BAS 750 F)	n.a.		
		<0.16 (TA)	n.a.		
		<0.50 (TAA)	n.a.		
		<0.20 (TLA)	n.a.		
soybean, tofu		tentative[1,2] (BAS 750 F)	n.a.		
		0.13 (TA)	n.a.		
		<0.50 (TAA)	n.a.		
		<0.20 (TLA)	n.a.		
soybean, soy sauce		tentative[1,2] (BAS 750 F)	n.a.		
soybean, miso		tentative[1,2] (BAS 750 F)	n.a.		
soybean, refined oil		tentative[1,2] (BAS 750 F)	n.a.		
		<0.06 (TA)	n.a.		
		<0.50 (TAA)	n.a.		
		<0.20 (TLA)	n.a.		
soybean, hulls		tentative[1,2] (BAS 750 F)	n.a.		
		0.50 (TA)	n.a.		
		0.50 (TAA)	n.a.		
		1.20 (TLA)	n.a.		
soybean, meal (toasted)		tentative[1,2] (BAS 750 F)	n.a.		
		1.67 (TA)	n.a.		
		1.33 (TAA)	n.a.		
		1.0 (TLA)	n.a.		
soybean, aspirated grain fraction		188 (BAS 750 F)	n.a.		
		1.0 (TA)	n.a.		
		1.0 (TAA)	n.a.		
		0.83 (TLA)	n.a.		
soybean, pollard		tentative[1,2] (BAS 750 F)	n.a.		
		0.91 (TA)	n.a.		
		1.0 (TAA)	n.a.		
		1.0 (TLA)	n.a.		

Processed commodity	Number of studies	Median PF *	Median CF **[(a)]	Comments	Reference
New data					
No new data					

* 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.
[(a)]: n.a. not applicable, since residue definitions for risk assessment and for monitoring do NOT differ
1) based on the residues of one trial
2) tentative PF is derived based on a limited data set
1,2,4-T = 1,2,4-triazole, TA = triazole alanine, TAA = triazole acetic acid, TLA = triazole lactic acid

7.2.5.2 Conclusion on processing studies

The processing studies for BAS 750 F are sufficient to cover the intended use of BAS 762 02 F.

zRMS comments:
Sufficient data for the nature and magnitude of residues of mefentrifluconazole and the TDMs in processed wheat and barley commodities was available in the DAR (UK, 2018).
zRMS-PL agrees with the Applicant summary on process factors for soybean (oilseeds). According to the "Evaluation report on MRLs for Mefentrifluconazole in various commodities" (Austria, 18 July 2019):
"*Residues of BAS 750 F in treated soybean seed samples collected 21 to 23 days after the last application ranged between <0.01 to 0.13 mg/kg. Aspirated grain fraction samples derived from these soybean seed samples bore parent BAS 750 F residues between 1.21 to 2.51 mg/kg. Residues of parent BAS 750 F were <0.01 mg/kg in all processed fractions with the exception of one crude oil sample where the residues were 0.012 mg/kg. A comparison of the residues in the processed RAC samples with those in each processed fraction indicated that parent BAS 750 F residues concentrated in aspirated grain fractions by 188 times (median processing factor). The compound did not concentrate in any other processed soybean fractions.*
Triazole derived metabolite residues were <0.01 to 0.38 mg/kg in/on soybean seed RAC samples harvested targeting crop maturity. The aspirated grain fraction samples derived from the soybean seed samples bore triazole derived metabolite residues ranging from <0.01 to 0.28 mg/kg. Processing factors for the triazole derived metabolites were not calculated."
No additional data are required.

7.2.6 Magnitude of residues in representative succeeding crops

Crops included in this submission can be grown in rotation. Data dealing with magnitude of residues in succeeding crops are available and have been submitted. They are summarized hereafter.

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

Available data
No new data was submitted in the framework of this application. In the context of the Annex I inclusion process one study for residues in succeeding crops has been submitted by the applicant. This study is summarized in the table below. For a detailed assessment refer to the EFSA conclusion (2018a).

Table 7.2-19: Summary of available studies in field rotational crops

Primary crop	Rate (kg as/ha) (GS at application or PHI)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)*	Reference / Remarks
EU data					
None, bare soil application	1x 0.300 (n.a.)	Leafy vegetables	Lettuce	30 ± 1 120 ± 3 365 ± 5	EFSA, 2018a BASF DocID 2015/1106682
			Spinach		
		Root and tuber	Radish		

Primary crop	Rate (kg as/ha) (GS at application or PHI)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)*	Reference / Remarks
		vegetables	Carrot		
		Brassica vegetables	Cauliflower		
			Broccoli		
		Cereals	Wheat		
New data					
No new data					

n.a. not applicable
* replant interval (days)

Conclusion on rotational crops studies

No significant residues of BAS 750 F were found in representative rotational crops with BAS 750 F being <0.01 mg/kg (LOQ) in leafy vegetables (lettuce/spinach), root/tuber (carrot/radish), brassica vegetables and cereals (wheat). Study conditions with bare soil application of maximal annual application rate are representative of plateau concentration estimated for multi-year application.

Residues of 1,2,4-T do not exceed the LOQ of 0.01 mg/kg for different representative succeeding crops at any plant back interval (30, 120, 365 days).
Residues of TAA do not exceed the LOQ of 0.01 mg/kg for root and tuber, brassica and leafy crops at any plant back interval (30, 120, 365 days). Residues of TAA were detected in wheat at all plant back intervals (up to 0.35 mg/kg in treated wheat grain, up to 0.15 mg/kg in straw, most controls contained background levels but lower than treated samples).

Residues of TA were detected in all commodities at all plant back intervals. Residues were highest in wheat commodities and leafy crops (up to 0.52 mg/kg in treated wheat grain; up to 0.35 mg/kg in flowering brassica; most controls contained background levels but lower than treated samples).
Residues of TLA were detected in all commodities except leafy crops at all plant back intervals. Residues were highest in wheat commodities (up to 0.16 mg/kg in treated wheat straw; most controls contained background levels but commonly lower than treated samples).

In conclusion, for the use of BAS 750 F supported in the present dossier, no replant restrictions are required. As no significant residues of BAS 750 F are expected, the default MRL of 0.01 mg/kg is appropriate for rotational crops.

zRMS comments:
Mefentrifluconazole exhibited high to very high persistence in soil (DT_{90} 616–> 1,000 days), and accumulation following subsequent years of treatment is expected.
EFSA concluded in EFSA Journal 2018;16(7):5379 that *In rotational crop residue trials in wheat, radish, carrot, cauliflower, broccoli, lettuce and spinach in NEU and SEU at a dose level which covers the expected plateau concentration of BAS 750 F in soil,* ***residues of BAS 750 F above LOQ were not found*** *while residues of TDM except 1,2,4-T regularly exceeded the LOQ. The residue levels obtained for the TDM are comparable to the residues in rotational crops considered for other triazole active substances in the TDM review.*
It should be noted that *Taking into account multiple applications of different triazole pesticides per crop or per season, the EU peer review of TDMs concluded that the possible uptake of TDMs in crops via soil previously treated with triazole pesticides cannot be excluded and TDM residues in rotational crops have to be considered in the risk assessment (EFSA, 2018b). However, due to the lack of a comprehensive overview on all authorised uses of the different triazole active substances and expected soil concentration for TDMs, a reliable estimation of the TDM residues expected in rotational crops grown in soil containing residues of TDMs at the soil plateau concentration cannot be performed.*

In conclusion, no residues of mefentrifluconazole are expected in rotational crops. No mitigation measure is deemed necessary.
No additional data are required.

7.2.7 Other / special studies (KCA 6.10, KCA 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of BAS 762 02 F. Therefore, other special studies are not needed.

zRMS comments:.
EFSA concluded in EFSA Journal 2018;16(7):5379 that *With regard to the requirement for residue data in pollen and bee products for human consumption a waiver was submitted that was considered as insufficient evidence to conclusively rule out occurrence of residues of BAS 750 F or its metabolites in pollen and in bee products for human consumption (data gap).*
~~No new study was submitted in the framework of this dossier and residue data in pollen and bee products for human consumption are still required.~~
A residue study for the determination of mefentrifluconazole and its metabolites residues in honey has been performed (BASF DocID: 2020/2109990, Report Amendment N°1 DocID: 2021/2038566) and has been provided by Applicant.
No residues (<0.05 mg/kg) of mefentrifluconazole and 1,2,4-Triazole (T), Triazolylalanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) were found in any honey samples collected at 67-69 BBCH (14 DALA).
Therefore, the data is sufficient for the registration of BAS 762 02 F / Revydas.
More details are presented in Appendix 2.

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).

7.2.8.1 Input values for the consumer risk assessment

For sake of being comprehensive, residue data from all previous submissions were taken into account as a worst-case scenario of the chronic risk assessment.
In context of TMDI calculations, the (default) MRLs as reported in EU Reg ~~2019/977~~ 2021/590 were used as input values ~~as well as the MRLs proposed by EFSA (EFSA, 2020).~~
The following table summarizes the input values from plant and animal commodities used for the chronic (IEDI) and acute (IESTI) dietary risk assessment (according to EFSA PRIMO model vers. 3.1).
The PRIMo 3.1 xls-spreadsheets used are attached to this submission to facilitate evaluation (TMDI: BASF DocID 2021/2001331, IEDI: BASF DocID 2021/2001332 and IESTI: BASF DocID 2021/2001333).

Table 7.2-20: Input values for the consumer risk assessment

Commodity	Chronic risk assessment (normal mode)		Acute risk assessment (refined calculation mode)	
	Input (mg/kg)	**Comment**	**Input** (mg/kg)	**Comment**
Risk assessment residue definition plant and animal except poultry: parent BAS 750 F *Risk assessment residue definition poultry: sum of parent BAS 750 F, metabolite M750F022 and fatty acid conjugates of M750F022, expressed as parent equivalents* (Values in brackets are based on calculations with residue values from Table 7.3-9)				
Products of plant origin				
Pome fruits	0.08	STMR, extrapolation from apple and pear (EFSA, 2020)	-	
Apricots	0.15	STMR (EFSA, 2020)	-	
Cherries	0.48	STMR (EFSA, 2020)	-	
Peaches	0.15	STMR (EFSA, 2020)	-	
Plums	0.11	STMR (EFSA, 2020)	-	
Table grapes	0.18	STMR, extrapolation from wine grapes (EFSA, 2020)	-	
Wine grapes	0.18	STMR (EFSA, 2020)	-	
Potatoes	0.01	STMR (EFSA, 2020)	-	
Sweet corn	0.01	STMR, extrapolation from corn (EFSA, 2020)	-	
Sunflower seeds	0.01 (0.01)	STMR (EFSA, 2020) (STMR in this submission)	0.01 (0.01)	STMR (EFSA, 2020)* (STMR* in this submission)
Rapeseeds / canola seeds	0.01 (0.01)	STMR (EFSA, 2020) (STMR in this submission)	0.01 (0.01)	STMR (EFSA, 2020)* (STMR* in this submission)
Barley	0.10	STMR (EFSA, 2018a)	-	
Maize/corn	0.01	STMR (EFSA, 2020)	-	
Oats	0.1	STMR (EFSA, 2018a)	0.1	STMR (EFSA, 2018a)
Rye	0.01	STMR (EFSA, 2018a)	0.01	STMR (EFSA, 2018a)*
Wheat	0.01 (0.01)	STMR (EFSA, 2018a) (STMR in this submission)	0.01 (0.01)	STMR (EFSA, 2018a)* (STMR* in this submission)
Sugar beet roots	0.02	STMR (EFSA, 2020)	-	
Products of animal origin				
Risk assessment residue definition plant and animal except poultry: parent BAS 750 F				
Swine: Meat	0.01	STMR (EFSA, 2018a)	-	
Swine: Fat free of lean meat	0.01	STMR (EFSA, 2018a)	-	
Swine: Liver	0.01	STMR (EFSA, 2018a)	-	
Swine: Kidney	0.01	STMR (EFSA, 2018a)	-	
Swine: Edible offal	0.01	STMR (EFSA, 2018a)	-	
Bovine: Meat	0.024	STMR (EFSA, 2018a)	-	
Bovine: Fat	0.06	STMR (EFSA, 2018a)	-	
Bovine: Liver	0.09	STMR (EFSA, 2018a)	-	
Bovine: Kidney	0.02	STMR (EFSA, 2018a)	-	
Bovine: Edible offal	0.02	STMR (EFSA, 2018a)	-	
Sheep: Meat	0.032	STMR (EFSA, 2018a)	-	

Table 7.2-20: Input values for the consumer risk assessment

Commodity	Chronic risk assessment (normal mode)		Acute risk assessment (refined calculation mode)	
	Input (mg/kg)	**Comment**	**Input** (mg/kg)	**Comment**
Sheep: Fat	0.09	STMR (EFSA, 2018a)	-	
Sheep: Liver	0.14	STMR (EFSA, 2018a)	-	
Sheep: Kidney	0.03	STMR (EFSA, 2018a)	-	
Sheep: Edible offal	0.03	STMR (EFSA, 2018a)	-	
Goat: Meat	0.032	STMR (EFSA, 2018a)	-	
Goat: Fat	0.09	STMR (EFSA, 2018a)	-	
Goat: Liver	0.14	STMR (EFSA, 2018a)	-	
Goat: Kidney	0.03	STMR (EFSA, 2018a)	-	
Goat: Edible offal	0.03	STMR (EFSA, 2018a)	-	
Horse: Meat	0.024	STMR (EFSA, 2018a)	-	
Horse: Fat	0.06	STMR (EFSA, 2018a)	-	
Horse: Liver	0.09	STMR (EFSA, 2018a)	-	
Horse: Kidney	0.02	STMR (EFSA, 2018a)	-	
Horse: Edible offal	0.02	STMR (EFSA, 2018a)	-	
Poultry: Meat	0.062	STMR (EFSA, 2018a)	-	
Poultry: Fat	0.163	STMR (EFSA, 2018a)	-	
Poultry: Liver	0.05	STMR (EFSA, 2018a)	-	
Poultry: Kidney	0.05	STMR (EFSA, 2018a)	-	
Poultry: Edible offal	0.05	STMR (EFSA, 2018a)	-	
Milk and milk products: Cattle	0.01	STMR (EFSA, 2018a)	-	
Milk and milk products: Sheep	0.01	STMR (EFSA, 2018a)	-	
Milk and milk products: Goat	0.01	STMR (EFSA, 2018a)	-	
Milk and milk products: Horse	0.01	STMR (EFSA, 2018a)	-	
Birds' eggs	0.05	STMR (EFSA, 2018a)	-	
Eggs: Chicken	0.05	STMR (EFSA, 2018a)	-	
Eggs: Duck	0.05	STMR (EFSA, 2018a)	-	
Eggs: Goose	0.05	STMR (EFSA, 2018a)	-	
Eggs: Quail	0.05	STMR (EFSA, 2018a)	-	
Other eggs	0.05	STMR (EFSA, 2018a)	-	
Processed products of plant origin				
Sunflower seeds / oils	-		0.02 (0.02)	$STMR_p$ (STMR* 0.01 x default PF 2.0) (STMR* in this submission 0.01 x default PF 2.0)
Rapeseeds / oils	-		0.02 (0.02)	$STMR_p$ (STMR* 0.01 x default PF 2.0) (STMR* in this submission 0.01 x default PF 2.0)

Table 7.2-20: Input values for the consumer risk assessment

Commodity	Chronic risk assessment (normal mode)		Acute risk assessment (refined calculation mode)	
	Input (mg/kg)	**Comment**	**Input** (mg/kg)	**Comment**
Wheat / bread (wholemeal)	-		0.0056 (0.0056)	$STMR_p$ (STMR* 0.01 x x PF 0.56) (STMR* in this submission 0.01 x PF 0.56)
Wheat / bread/pizza	-		0.01 (0.01)	STMR* (STMR* in this submission)
Wheat / pasta	-		0.01 (0.01)	STMR* (STMR* in this submission)
Wheat / milling (wholemeal)-baking	-		0.0079 (0.0079)	$STMR_p$ (STMR* 0.01 x x PF 0.79) (STMR* in this submission 0.01 x PF 0.79)
Wheat / milling (flour)	-		0.0029 (0.0029)	$STMR_p$ (STMR* 0.01 x x PF 0.29) (STMR* in this submission 0.01 x PF 0.29)

Note, in absence of specific data, STMR and HR values for liver are also used for edible offal and/or kidney
** for oilseeds and cereals the HR is only relevant for post-harvest uses. For other cases, the acute exposure is calculated with the STMR (EFSA PRIMO model vers. 3.1)*
*** for milk, the acute exposure is calculated with the STMR (EFSA PRIMO model vers. 3.1)*
**** for jam, the acute exposure is calculated with the STMR (EFSA PRIMO model vers. 3.1)*

Separate consumer risk assessments are performed for triazole derivative metabolites (TDMs) 1,2,4-T, TA, TAA and TLA. Toxicological reference values have been established for each triazole derivative metabolites during the EU peer review of confirmatory data for TDMs (EFSA, 2018b). The set endpoints for the TDMs are shown in the table Table 7.1-2. The PRIMo 3.1 xls-spreadsheets used are attached to this submission to facilitate evaluation (1,2,4-T: BASF DocID 2021/2001337, TA: BASF DocID 2021/2001334, TAA: BASF DocID 2021/2001335 and TLA: BASF DocID 2021/2001336).

For the chronic consumer risk assessment, the STMR values for 1,2,4-T, TA, TAA and TLA derived during the TDM risk assessment (United Kingdom, 2018b Appendix E) were compared to STMRs after use of BAS 750 F, please refer to the supplemental document with BASF DocID 2021/2001338. In general, all STMR values derived from residues following BAS 750 F treatment resulted in lower values than those used in the TDM review with one exception (barley/oat, grain for TLA).

The acute consumer risk assessment was performed considering the intended use for oilseed rape, sunflower and wheat. STMR and HR values derived in the TDM review (United Kingdom, 2018b Appendix E) were compared to the residue values following application of BAS 750 F, please refer to the supplemental document with BASF DocID 2021/2001338. In general, STMR/HR values derived from residues following BAS 750 F treatment resulted in higher values compared to those used in TDM review for oilseed rape (HR for TA and TLA), and barley/oats, grain (HR for TA and STMR/HR for TLA).

An overview of the input values (intended uses only) is presented in the table below, details are provided in the supplemental document with BASF DocID 2021/2001338. Note: for processing factors please refer to Table 7.2-18).

Table 7.2-21: Input values for the consumer risk assessment for TDMs

Commodity	Chronic risk assessment (normal mode)		Acute risk assessment (refined calculation mode)	
	Input (mg/kg)	**Comment**	**Input** (mg/kg)	**Comment**
Risk assessment residue definition plant and animal: 1,2,4-T (Values in brackets are based on calculations with residue values from Table 7.2-9)				
Products of plant origin				
Sunflower seeds	0.05 (0.01)	STMR / TDM review (STMR in this submission)	0.05 (0.01)	STMR* / TDM review (STMR* in this submission)
Rapeseeds / canola seeds	0.05 (0.01)	STMR / TDM review (STMR in this submission)	0.05 (0.01)	STMR* / TDM review (STMR* in this submission)
Wheat	0.05	STMR / TDM review	0.05	STMR* / TDM review
Sunflower seeds / oils	-		0.10 (0.02)	$STMR_p$ (STMR* 0.05 x default PF 2.0) (STMR* in this submission 0.01 x default PF 2.0)
Rapeseeds / oils	-		0.10 (0.02)	$STMR_p$ (STMR* 0.05 x default PF 2.0) (STMR* in this submission 0.01 x default PF 2.0)
Wheat / bread (wholemeal)	-		0.05	STMR*
Wheat / bread/pizza	-		0.05	STMR*
Wheat / pasta	-		0.05	STMR*
Wheat / milling (wholemeal)-baking	-		0.05	STMR*
Wheat / milling (flour)	-		0.05	STMR*
Products of animal origin and all other products of plant origin	Derived in context of the TDM review, for details please refer to the supplemental document with BASF DocID 2021/2001338			
Risk assessment residue definition plant and animal: TA (Values in brackets are based on calculations with residue values from Table 7.2-9)				
Products of plant origin				
Sunflower seeds	1.04 (0.05)	STMR / TDM review (STMR in this submission)	1.04 (0.05)	STMR* / TDM review (STMR* in this submission)
Rapeseeds / canola seeds	1.04 (0.58)	STMR / TDM review (STMR in this submission)	1.04 (0.58)	STMR* / TDM review (STMR* in this submission)
Wheat	0.621	STMR / TDM review	0.621	STMR* / TDM review
Sunflower seeds / oils	-		2.08 (0.10)	$STMR_p$ (STMR* 1.04 x default PF 2.0) (STMR* in this submission 0.05 x default PF 2.0)
Rapeseeds / oils	-		2.08 (1.16)	$STMR_p$ (STMR* 1.04 x default PF 2.0) (STMR* in this submission 0.58 x default PF 2.0)
Wheat / bread (wholemeal)	-		0.534	$STMR_p$ (STMR* 0.621 x PF 0.86)
Wheat / bread/pizza	-		0.621	STMR*
Wheat / pasta	-		0.621	STMR*

Table 7.2-21: Input values for the consumer risk assessment for TDMs

Commodity	Chronic risk assessment (normal mode)		Acute risk assessment (refined calculation mode)	
	Input (mg/kg)	**Comment**	**Input** (mg/kg)	**Comment**
Wheat / milling (wholemeal)-baking	-		0.621	STMR*
Wheat / milling (flour)	-		0.317	$STMR_p$ (STMR* 0.621 x PF 0.51)
Risk assessment residue definition plant and animal TAA (Values in brackets are based on calculations with residue values from Table 7.2-9)				
Products of plant origin				
Sunflower seeds	0.12 (0.08)	STMR / TDM review (STMR in this submission)	0.12 (0.08)	STMR* / TDM review (STMR* in this submission)
Rapeseeds / canola seeds	0.12 (0.01)	STMR / TDM review (STMR in this submission)	0.12 (0.01)	STMR* / TDM review (STMR* in this submission)
Wheat	0.79	STMR / TDM review	0.79	STMR* / TDM review
Sunflower seeds / oils	-		0.24 (0.16)	$STMR_p$ (STMR* 0.12 x default PF 2.0) (STMR* in this submission 0.08 x default PF 2.0)
Rapeseeds / oils	-		0.24 (0.02)	$STMR_p$ (STMR* 0.12 x default PF 2.0) (STMR* in this submission 0.01 x default PF 2.0)
Wheat / bread (wholemeal)	-		0.94	$STMR_p$ (STMR* 0.79 x PF 1.19)
Wheat / bread/pizza	-		0.79	STMR*
Wheat / pasta	-		0.79	STMR*
Wheat / milling (wholemeal)-baking	-		0.79	STMR*
Wheat / milling (flour)	-		0.64	$STMR_p$ (STMR* 0.79 x PF 0.81)
Products of animal origin and all other products of plant origin	Derived in context of the TDM review, for details please refer to the supplemental document with BASF DocID 2021/2001338			
Risk assessment residue definition plant and animal TLA (Values in brackets are based on calculations with residue values from Table 7.2-9)				
Products of plant origin				
Sunflower seeds	0.065 (0.01)	STMR / TDM review (STMR in this submission)	0.065 (0.01)	STMR* / TDM review (STMR* in this submission)
Rapeseeds / canola seeds	0.065 (0.03)	STMR / TDM review (STMR in this submission)	0.065 (0.03)	STMR* / TDM review (STMR* in this submission)
Wheat	0.022	STMR / TDM review	0.022	STMR* / TDM review
Sunflower seeds / oils	-		0.13 (0.02)	$STMR_p$ (STMR* 0.065 x default PF 2.0) (STMR* in this submission 0.01 x default PF 2.0)
Rapeseeds / oils	-		0.13 (0.06)	$STMR_p$ (STMR* 0.065 x default PF 2.0) (STMR* in this submission 0.03 x default PF 2.0)

Table 7.2-21: Input values for the consumer risk assessment for TDMs

Commodity	Chronic risk assessment (normal mode)		Acute risk assessment (refined calculation mode)	
	Input (mg/kg)	**Comment**	**Input** (mg/kg)	**Comment**
Wheat / bread (wholemeal)	-		0.022	STMR*
Wheat / bread/pizza	-		0.022	STMR*
Wheat / pasta	-		0.022	STMR*
Wheat / milling (wholemeal)-baking	-		0.022	STMR*
Wheat / milling (flour)	-		0.022	STMR*
Products of animal origin and all other products of plant origin	Derived in context of the TDM review, for details please refer to the supplemental document with BASF DocID 2021/2001338			

** for oilseeds and cereals the HR is only relevant for post-harvest uses. For other cases, the acute exposure is calculated with the STMR (EFSA PRIMO model vers. 3.1)*

7.2.8.2 Conclusion on consumer risk assessment

Results of the extensive calculations are presented in Appendix 3.

TMDI Calculation

BAS 750 F

The TMDI calculation was performed with the current EFSA model (version 3.1) using an ADI of 0.035 mg/kg bw/day applying default and established MRLs of EU Reg ~~2019/977~~ 2021/590.

The summary of the chronic assessment is presented in Appendix 3. The ADI utilization ranges from 1 to ~~32~~31% ADI. The highest TMDI was ~~32~~31% ADI for the "NL toddler", the highest contributor are apples (12% ADI).

The TMDI is well below the ADI for all European sub-population groups, therefore no health effects due to chronic exposure are expected.

IEDI Calculation

BAS 750 F

The IEDI calculation was performed with the current EFSA model (version 3.1) using an ADI of 0.035 mg/kg bw/day and STMRs as listed in Table 7.2-20.

The summary of the chronic assessment is presented in Appendix 3. The ADI utilization ranges from 0.4 to 7% of the ADI. The diet with the highest IEDI is "NL toddler" with 7% of the ADI. For this diet, the highest contributor is apple with 2% of the ADI. The diet with the second highest IEDI is "DE child" with 6% of the ADI, in which also apple is the major contributor with 3% of the ADI.

The IEDI is well below the ADI for all European sub-population groups, therefore no health effects due to chronic exposure are expected.

TDMs

The IEDI calculation was performed with the current EFSA model (version 3.1) using an ADI of 0.023 mg/kg bw/day for 1,2,4-T, 0.3 mg/kg bw/day for TA and TLA and 1 mg/kg bw/day for TAA. Input values (intended uses) are listed in Table 7.2-21. A complete list of input values and their derivation can be found in the supplemental document with BASF DocID 2021/2001338.

The summary of the chronic assessment is presented in Appendix 3. The maximum ADI utilization is 48% (NL toddler) for 1,2,4-T, 4% (NL toddler) for TA and 1% (NL toddler) for TAA and TLA of the ADI. The highest contributor is milk (cattle) (42%) for 1,2,4 T, maize, corn (1%) for TA, maize, corn (0.6%) for TAA and milk (cattle) (0.6%) for TLA.

The IEDI is well below the ADI for all European sub-population groups, therefore no health effects due to chronic exposure are expected.

IESTI Calculation

BAS 750 F

A refined IESTI calculation was performed with the current EFSA model (version 3.1) using an ARfD of 0.15 mg/kg bw/day and STMRs as listed in Table 7.2-20 for oilseed rape, sunflower and wheat.

The summary of the acute assessment is presented in Appendix 3. For children, the highest ARfD utilization was 0.10% for consumption of wheat and second highest for sunflower seed (0.042%). For adults, the highest ARfD utilization was 0.06% for consumption of wheat.
For processed commodities, the highest ARfD utilization was 0.02% for consumption of wheat/milling (flour and wholemeal) and sunflower seeds/oils for children and 0.03% for adults for consumption of wheat/bread/pizza and wheat/pasta.

In both cases the IESTI is well below the ARfD for all commodities and European sub-population groups, therefore no health effects due to acute exposure are expected.

TDMs

A refined calculation was performed with the current EFSA model (version 3.1) using an ARfD of 0.1 mg/kg bw/day for 1,2,4-T, 0.3 mg/kg bw/day for TA and TLA and 1 mg/kg bw/day for TAA. Input values are listed in Table 7.2-21.

The summary of the acute assessment is presented in Appendix 3.

The summary of the acute assessment is presented in Appendix 3. For children, the highest ARfD utilization was for consumption of wheat: 0.7% for 1,2,4-T, 3% for TA, 1% for TAA and 0.1% for TLA. For adults, the highest ARfD utilization was for consumption of wheat: 0.4% for 1,2,4-T, 2% for TA, 0.7% for TAA and 0.06% for TLA.

For processed commodities, the highest ARfD utilization was for consumption of wheat / milling (flour): 0.6% for 1,2,4-T, 1% for TA, 0.8% for TAA and 0.1% for TLA for children. For adults, the highest ARfD utilization was for consumption of wheat / bread/pizza: 0.2% for 1,2,4-T, 0.9% for TA, 0.3% for TAA and 0.03% for TLA.

In all cases the IESTI is well below ARfD for all commodities and European sub-population groups, therefore no health effects due to acute exposure are expected.

Table 7.2-22: Consumer risk assessment

BAS 750 F	
TMDI (% ADI) according to EFSA PRIMo	Highest TMDI: 3231% (NL toddler)
IEDI (% ADI) according to EFSA PRIMo	Highest IEDI: 7% (NL toddler)
IESTI (% ARfD) according to EFSA PRIMo*	unprocessed Highest IESTI: 0.10% (children, wheat) 0.06% (adults, wheat) processed Highest IESTI: 0.02% (children, wheat / milling (flour and wholemeal) and sunflower seeds / oils) 0.03% (adults, wheat / bread/pizza and wheat / pasta)
NTMDI (% ADI) **	not applicable
NEDI (% ADI)**	not applicable
NESTI (% ARfD) **	not applicable
1,2,4-T	
TMDI (% ADI) according to EFSA PRIMo	not applicable
IEDI (% ADI) according to EFSA PRIMo	Highest IEDI: 48% (NL toddler)
IESTI (% ARfD) according to EFSA PRIMo*	unprocessed Highest IESTI: 0.7% (children, wheat) 0.4% (adults, wheat) processed Highest IESTI: 0.6% (children, wheat / milling (flour)) 0.2% (adults, wheat / bread/pizza and wheat / pasta)
NTMDI (% ADI) **	not applicable
NEDI (% ADI)**	not applicable
NESTI (% ARfD) **	not applicable
TA	
TMDI (% ADI) according to EFSA PRIMo	not applicable
IEDI (% ADI) according to EFSA PRIMo	Highest IEDI: 4% (NL toddler)
IESTI (% ARfD) according to EFSA PRIMo*	unprocessed Highest IESTI: 3% (children, wheat) 2% (adults, wheat processed Highest IESTI: 1% (children, wheat / milling (flour)) 0.9% (adults, wheat / bread/pizza)
NTMDI (% ADI) **	not applicable
NEDI (% ADI)**	not applicable
NESTI (% ARfD) **	not applicable
TAA	
TMDI (% ADI) according to EFSA PRIMo	not applicable
IEDI (% ADI) according to EFSA PRIMo	Highest IEDI: 1% (NL toddler)
IESTI (% ARfD) according to EFSA PRIMo*	unprocessed Highest IESTI: 1% (children, wheat) 0.7% (adults, wheat) processed Highest IESTI: 0.8% (children, wheat / milling (flour)) 0.3% (adults, wheat / bread/pizza)

NTMDI (% ADI) **	not applicable
NEDI (% ADI)**	not applicable
NESTI (% ARfD) **	not applicable
TLA	
TMDI (% ADI) according to EFSA PRIMo	not applicable
IEDI (% ADI) according to EFSA PRIMo	Highest IEDI: 1% (NL toddler)
IESTI (% ARfD) according to EFSA PRIMo*	unprocessed Highest IESTI: 0.1% (children, wheat) 0.06% (adults, wheat) processed Highest IESTI: 0.1% (children, wheat / milling (flour)) 0.03% (adults, wheat / bread/pizza and wheat / pasta)
NTMDI (% ADI) **	not applicable
NEDI (% ADI)**	not applicable
NESTI (% ARfD) **	not applicable

* includes raw and processed commodities if both values are required for PRIMo
** if national model is available

The proposed uses of mefentrifluconazole (BAS 750 F) in the formulation BAS 762 02 F do not represent unacceptable acute and chronic risks for the consumer.

zRMS comments:
In meantime the values of EU MRLs for mefentrifluconazole were changed. Assessments of the potential chronic dietary consumer risk resulting from exposure to residues mefentrifluconazole were updated and were performed using revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo) and the current EU MRLs values laid down in Regulation (EU) 2021/590.
The calculation of the TMDI using EFSA model (version 3.1) and all MRLs according to current Reg. (EU) No 2021/590 led to a utilisation of the ADI of 31% with the NL toddler being the population group with the highest value. For this diet, the highest contributor is Apples with 12% of the ADI. The intended uses will not result in a consumer chronic exposure exceeding the ADI.

A refined IESTI calculation was performed with the EFSA Pesticide Residues Intake Model (PRIMo 3.1) using an ARfD of 0.15 mg/kg bw/day and STMRs as listed in Table 7.2-20 for oilseed rape, sunflower and wheat. For children, the highest ARfD utilization was 0.10% for consumption of wheat and second highest for sunflower seed (0.042%). For adults, the highest ARfD utilization was 0.06% for consumption of wheat.
The intended uses will not result in a consumer acute exposure exceeding the ARfD.
Updated extensive calculation sheets are presented in Appendix 3.

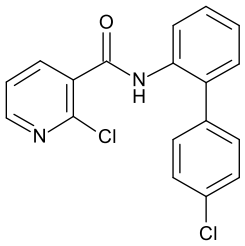
Separate consumer risk assessments are performed for triazole derivative metabolites (TDMs): 1,2,4-T, TA, TAA and TLA.

The proposed uses of mefentrifluconazole and triazole derivative metabolites (TDMs) in the product BAS 762 02 F / Revydas do not represent unacceptable chronic and acute risks for the consumer.
No further studies are required to support the proposed uses.

7.3 Boscalid

General data on boscalid are summarized in the table below (last updated 2021/01/25).

Table 7.3-1: General information on boscalid

Active substance (ISO Common Name)	Boscalid
IUPAC	2-chloro-N-(4′-chloro[1,1′-biphenyl]-2-yl)pyridine-3-carboxamide
Chemical structure	
Molecular formula	$C_{18}H_{12}Cl_2N_2O$
Molar mass	343.21 g/mol
Chemical group	Carboxamide fungicides
Mode of action (if available)	Boscalid is a member of the fungicide group succinate dehydrogenase inhibitors (SDHI) and the mode of action at the molecular level is the inhibition of the enzyme succinate dehydrogenase (SDH), also known as complex II in the mitochondrial electron transport chain. Through its inhibition of complex II, boscalid disrupts fungal growth by preventing energy production and also by eliminating the availability of the chemical building blocks for the synthesis of other essential cellular components.
Systemic	Yes
Company (ies)	BASF SE*
Rapporteur Member State (RMS)	Germany/Slovakia**
Approval status	Approved 01.08.2008 Commission Directive 2008/44/EC and Commission Implementing Regulation (EU) No. 540/2011
Restriction	~~No~~ Only uses as fungicide may be authorised.
Review Report	SANCO/3919/2007 – rev. 5 21/01/2008
Current MRL regulation	Regulation (EC) No ~~2016/156~~ 2021/590
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal: Conclusion on the peer review	No***
EFSA Journal: conclusion on article 12	Yes****
Current MRL applications on intended uses	No

* Notifier in the EU process to whom the a.s. belong(s)
** RMS Slovakia: in AI renewal process since 2016, co-RMS: France
*** Not officially peer reviewed by EFSA
**** EFSA, 2014 - see list of references

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 Stability of residues during storage of samples

Available data

The storage stability of boscalid in plant and animal matrices was already evaluated and is summarized in the table below. No new data were submitted in the framework of this application.

Table 7.3-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Grapes	High acid content	BAS 510 F: 16 months	*2000/1014860* EFSA, 2014
Cabbage (head), peach (fruit), pea	High water content	BAS 510 F: 24 months	*2001/1015028* Germany, 2002; EFSA, 2014
Oilseed rape	High oil content	BAS 510 F: 24 months	*2001/1015028* Germany, 2002; EFSA, 2014
Wheat (grain)	Dry commodities	BAS 510 F: 24 months	*2001/1015028* Germany, 2002; EFSA, 2014
Sugar beet (root)	High starch commodity	BAS 510 F: 24 months	*2001/1015028* Germany, 2002; EFSA, 2014
Wheat (green plant)	-	BAS 510 F: 24 months	*2001/1015028* Germany, 2002; EFSA, 2014
Wheat (straw)	-	BAS 510 F: 24 months	*2001/1015028* Germany, 2002; EFSA, 2014
Animal Products			
Ruminant	Milk	BAS 510 F: 5 months M510F01: 5 months	*2000/1017229* Germany, 2002; EFSA, 2014
Ruminant	Muscle	BAS 510 F: 5 months M510F01: 5 months	*2000/1017229* Germany, 2002; EFSA, 2014
Ruminant	Liver	BAS 510 F: 5 months M510F01: 5 months	*2000/1017229* Germany, 2002; EFSA, 2014

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Ruminant	Fat	BAS 510 F: 5 months M510F01: 5 months	*2000/1017229* Germany, 2002; EFSA, 2014
Ruminant	Kidney	BAS 510 F: 5 months M510F01: 5 months	*2000/1017229* Germany, 2002; EFSA, 2014
Poultry	Egg	BAS 510 F: 5 months M510F01: 5 months	*2000/1017229* Germany, 2002; EFSA, 2014
New data			
No new data			

Conclusion on stability of residues during storage
Storage stability of boscalid in various plant and animal matrices was evaluated during the MRL review according to Art 12. Following conclusion is taken from EFSA's reasoned opinion (EFSA, 2014). Their conclusion is as follows:
"The potential degradation of residues during storage of the residues trials samples was also assessed. In the framework of the peer review, 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 (Germany, 2002).
…
Studies demonstrated storage stability of boscalid and M510F01 in milk, muscle, fat, liver, kidney and egg for up to 5 months when stored deep frozen (Germany, 2002). "

All samples reported were stored in compliance with the above reported storage conditions. Degradation of residues during storage of the trial samples is therefore not expected.

zRMS comments:
In the EFSA Journal 2014;12(7):3799 it is stated that the potential degradation of residues during storage of the residues trials samples was also assessed. In the framework of the peer review, 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 (Germany, 2002).
Studies demonstrated storage stability of boscalid and M510F01 in milk, muscle, fat, liver, kidney and egg for up to 5 months when stored deep frozen (Germany, 2002).

The studies on the magnitude of residues are valid with regard to storage stability.
Sufficient stability data are available to support the residue data presented in the present dossier. No additional data are required.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data
For the active substance boscalid, investigations were performed using sample extracts out of ^{14}C-metabolism studies and fortified samples during the validation of the residue analytical methods. In none of the extracts investigated any degradation was observed. Further details are provided within the method studies in section 5.

No new study on the stability of residues in sample extracts was conducted.

Conclusion on stability of residues in sample extracts
From the data available it can be concluded that boscalid is stable in sample extracts or solutions when stored during residue analysis.

zRMS comments:
Information presented by Applicant above have been accepted and are sufficient to support the proposed uses. No additional data are required .

7.3.2 Nature of residues in plants, livestock and processed commodities

7.3.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

A new metabolism study has been submitted by the applicant in context of EFSA's request for additional information (Sept 2019) and is referenced here for completion purposes. The study is summarized in the table below; a complete OECD summary can be found in Appendix 2.

Table 7.3-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G [(a)]	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	Grape	U-^{14}C-diphenyl and 3-^{14}C-pyridine	Foliar treatment, F	0.8	3	45	-	*2000/1014860* Germany, 2002; EFSA, 2014
Leafy vegetables	Lettuce	U-^{14}C-diphenyl and 3-^{14}C-pyridine	Foliar treatment, G	0.7	3	18	-	*1999/11240* Germany, 2002; EFSA, 2014
Pulses and oilseeds	Bean	U-^{14}C-diphenyl and 3-^{14}C-pyridine	Foliar treatment, G	0.5	3	0[(b)], 14[(c)], 53[(d)]	-	*2000/1014861* Germany, 2002; EFSA, 2014
New data submitted in context of renewal process (EFSA's request for additional information, September 2019)								
Pulses and oilseeds	Bean	U-^{14}C-diphenyl	Foliar treatment, G	0.523	3	-3[(e)], 13 [(f)]	-	*2017/1143721* XXX D. & Jung K., 2017, A 2.2.2.1.1.1

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)
(b): Whole plant
(c): Forage, green beans, pods and seeds
(d): Bean straw, bean dry pods and dry seeds
(e): Bean pods and rest of plant
(f): Bean pods, hulls, seeds and rest of plant

Summary of plant metabolism studies reported in the EU
The following summary of the plant metabolism studies is taken from EFSA's MRL review according to Article 12 (EFSA, 2014):

"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 metabolized. The residues in beans (edible part) were much lower compared to the rest of the plant. When separating greens beans into pods and seeds, the major part of radioactivity was found in pods (0.9 mg eq/kg) rather than in seeds (0.2 mg eq/kg). Residue levels were also higher in dry pods (6.1 mg eq/kg) than in dry seeds (0.2 mg eq/kg). Parent boscalid was identified as the major compound of the TRR in bean leaves and forage (>98%), in green beans and green pods (97%), in bean straw (≥94%), in dry pods (80-95%) and in dry seeds (72%). The cleavage products chlorophenylaminobenzene and 2-chloronicotinic acid were also identified in green beans and seeds but only in low concentrations (<0.01 mg eq/kg). The metabolism studies showed that the metabolic pathway is similar in all crops."

The origin of chlorophenylaminobenzene (M510F62) in the bean metabolism study is currently discussed in the ongoing re-evaluation process of boscalid, as the occurrence of M510F62 at day 0 and the decrease at the later sampling points indicate that it was already present in the application formulation and is not the result of a metabolic reaction. This was confirmed by the new bean metabolism study submitted in September 2019 in context of the AIR renewal process of boscalid (see below).

Summary of new plant metabolism studies
The origin of chlorophenylaminobenzene (M510F62) was checked in a separate bean metabolism study, which has been submitted in September 2019 in context of EFSA's request for additional information. This study is consequently not yet contained in the draft RAR. A complete OECD summary of that study is given in Appendix 2 for completion purposes. In the new bean metabolism study (BASF DocID 2017/1143721) special care was taken that M510F62 was not applied via the application formulation as impurity into the test system and could later on not be identified in any analyzed plant sampled, thus M510F62 could not be confirmed as plant metabolite.

Conclusion on metabolism in primary crops
Generally, it can be concluded that the metabolic pathway is similar in all crop groups investigated. Based on the above findings, following foliar treatment the residue for enforcement and risk assessment in all plant commodities is defined as the parent compound boscalid only (EFSA, 2014). These conclusions are also in line with those of the JMPR (FAO, 2009).

zRMS comments:
In EFSA Journal 2014;12(7):3799 it is stated that 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-^{14}C-diphenyl and 3-^{14}C-pyridine labelled boscalid (Germany, 2002). The metabolism studies showed that the metabolic pathway is similar in all crops.

A new bean metabolism study using ^{14}C-dipheny-labeled boscalid (DocID 2017/1143721) has been recently submitted by the Applicant in context of EFSA's request for additional information (Sept 2019) and is referenced here for completion purposes. This study is not yet assessed in the RAR and not yet contained in the publicly available draft RAR, because information about new study was provided to the RMS in stage when the evaluation has already been done.
In our opinion the evaluation of metabolism study should be carried out at the EU level and the active substance level. However, it should be noted that Applicant submitted this study as additional information. This study was conducted for support the argumentation that M510F62 were introduced into the bean metabolism study as impurity in the application solution.
Based on the study (DocID 2017/1143721) results, it can concluded that in all bean matrices investigated, boscalid constituted the dominant residue. 2-(4-chlorophenyl)aniline, designated in a previous metabolism study as metabolite M510F62, was not detected. Taking into the study results account it can confirm that the metabolic pathway is similar in all crops.

Information presented by Applicant above have been accepted and are sufficient to support the proposed uses.

Definition:
The residue for enforcement and risk assessment in all plant commodities is defined as boscalid only.

No additional data are required .

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

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

Table 7.3-4: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Lettuce	U-^{14}C-diphenyl and 3-^{14}C-pyridine	Bare soil, G	2.1	30, 120, 270, 365	Mature crops	-	*2000/1014862, 2002/1004122* (Amendment) Germany, 2002; EFSA, 2014
Root and tuber vegetables	Radish						-	
Cereals/Small grain	Wheat						-	
New data								
No new data								

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

Summary of rotational crop metabolism studies reported in the EU
The following summary of the rotational crop metabolism studies is taken from the EFSA MRL review according to article 12 (EFSA, 2014):
"The metabolism of boscalid in rotational crops – lettuce, radish, wheat – has been evaluated (Germany, 2002). One confined rotational crop study investigating the nature of residues following different plant-back intervals is available. The characteristics of this study are summarized in the Table 7.3-4.
The highest TRR values were observed in radish leaves (0.34 mg/kg; 30 DAT, pyridine study) and in wheat straw (9.83 mg/kg, 30 DAT, diphenyl study and 4.01 mg/kg, 120 DAT, pyridine study). The highest TRR in lettuce amounted to 0.16 mg/kg (120 DAT, pyridine study), in radish root to 0.098 mg/kg (270 DAT, diphenyl study) and 0.066 mg/kg (365 DAT, pyridine study) and in wheat grain to 0.285 mg/kg (120 DAT, pyridine study) and 0.243 mg/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/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 rotational crop metabolism studies
Not applicable, as no new data are submitted.

Conclusion on metabolism in rotational crops

"The proposed metabolic pathway in succeeding crops involves hydroxylation and conjugation reactions. A part of the residue was also incorporated into and/or associated with natural products, such as starch, cellulose and lignin. The parent compound is therefore the main substance of concern in rotational crops and no metabolites of concern were identified in soil. Consequently, metabolic patterns in primary and rotational crops are found to be similar and a specific residue definition for rotational crops is not deemed necessary." (EFSA, 2014)

zRMS comments:
The metabolism of boscalid in rotational crops was found to be similar to the primary crops and a specific residue definition for rotational crops is not deemed necessary (EFSA, 2014).
The metabolism of boscalid in plants is sufficiently addressed and no additional metabolism studies are necessary to support the proposed uses of the product BAS 762 02 F / Revydas.

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Table 7.3-5: Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	Parent (99.3%)	*1998/10878* Germany, 2002; EFSA, 2014
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Parent (100.2%)	
Sterilisation (20 minutes, 120°C, pH 6)	Parent (99.1%)	
New data		
No new data		

Conclusion on nature of residues in processed commodities

The effect of processing on the nature of boscalid was investigated in the framework of the peer review (EFSA, 2014). 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 (Germany, 2002). The relevant residue for enforcement and risk assessment in processed commodities is therefore expected to be the same as for primary crops (EFSA, 2014).

zRMS comments:
In EFSA Journal 2014;12(7):3799 it is stated that 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 in processed commodities, boscalid residues were shown to be stable during processing by pasteurisation, baking/brewing/boiling and sterilisation. Boscalid can be regarded as stable to hydrolysis. These processing conditions are not expected to have a significant impact on the composition of residues in matrices of plant origin (Germany, 2002).

7.3.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA

6.7.1)

Table 7.3-6: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Grapes (fruits), lettuce (leafy vegetables), beans (pulses and oilseeds)
Rotational crops covered	Lettuce (leafy vegetables), radish (root and tuber vegetables), wheat (cereals/small grain)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Boscalid is stable under standard hydrolysis conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Parent compound (boscalid) (EC, 2008)
Plant residue definition for risk assessment	Parent compound (boscalid) (EC, 2008)
Conversion factor from enforcement to RA	1 (Germany, 2002, EFSA, 2014)

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

Available data

The nature of boscalid residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (Germany, 2002) and was confirmed in the Article 12 review reported in the EFSA Reasoned Opinion 2014 (EFSA, 2014). Reported metabolism studies include one study in lactating goats and one study in laying hens, both using [U-^{14}C-diphenyl] labelled boscalid. The characteristics of these studies are summarized in the table below.

A new metabolism study has been submitted by the applicant in context of EFSA's request for additional information (Sept 2019) and is referenced here for completion purposes. The study is summarized in the table below; a complete OECD summary can be found in Appendix 2.

Table 7.3-7: 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	*2000/1012353*, *2000/1017221*, *2019/2046268* (Amendment)* Germany, 2002; EFSA, 2014
						Urine and feces	Daily	
						Tissues	After sacrifice	
Laying poultry	Hens	U-^{14}C-diphenyl	10	0.80 - 1.14	10	Eggs	Daily	*2000/5154* Germany, 2002; EFSA, 2014
						Excreta	Daily	
						Tissues	After sacrifice	
Fish	Bioaccumulation and metabolism study in rainbow trout: There is no risk of accumulation in fish or other aquatic organisms because of the rapid excretion of the parent compound and its metabolites.							*2000/1017222* Germany, 2002
New data submitted in context of renewal process (EFSA's request for additional information, September 2019)								
Laying	Hens	3-^{14}C-	10	0.78 – 1.05	13	Eggs	Daily	*2019/1077444*

poultry		pyridine				Excreta	Daily	XXX J. & XXX C., 2019, A 2.2.2.2.1 *2019/1075236* XXX J. & XXX N., 2019, A 2.2.2.2.2
						Tissues	After sacrifice	

*Amendment: correction of typo in footnote 2 of table 15 in study report (0.067 mg/kg → 0.046 mg/kg), submitted in context of EFSA's request for additional information, September 2019. Amendment is available upon request.

Summary of animal metabolism studies reported in the EU

The following summary of the livestock metabolism studies is adopted from the EFSA MRL review according to Article 12 (EFSA, 2014):

Lactating goats were dosed with 1.46-1.73 mg/kg bw/d of boscalid. Including the uptake of residues in crops from previously treated soil, these dose levels represent at least 0.7 times the maximum dietary burden of meat ruminant (2.04 mg/kg bw/d) and 1.0 times of dairy ruminants (1.43 mg/kg bw/d).

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

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

Non-extractable residues accounted for 85% TRR (2.2 mg/kg) in liver. The same microwave extraction method used in the metabolism study on hen was applied using harsh conditions with either a mixture of acetonitrile and acetic acid or with formic acid. This microwave method allowed the differentiation between extractable and bound residues of BAS 510 F by the formation of M510F01, M510F49 and M510F51 (originating from extractable residues) and either M510F53 (43.6% TRR) or M510F52 (35.4% TRR) for the respective solvent. The bound parent (measured as cleavage product M510F53 and M510F52) is therefore the main compound in the liver. In BASF's opinion, the metabolites M510F52 and M510F53 were not formed under biotic conditions and are used as a marker for bound residues.

Laying hens were dosed with 0.80–1.14 mg/kg bw/d of boscalid. Including uptake of residues in crops from previously treated soil, these dose levels represent at least 3.5 times the maximum dietary burden of poultry.

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

Boscalid is the main compound in fat (0.023 mg/kg; 93.3% TRR) and eggs (0.02 mg/kg; 35.5% TRR). M510F01 was detected in eggs (0.015 mg/kg; 26.9% TRR) and liver (0.009 mg/kg; 5.6%TRR) and its conjugate M510F02 was detected in muscle (0.001 mg/kg; 11.9% TRR) and eggs (0.01 mg/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/kg; 42% TRR).

Taken together, in hens dosed with 12.5 mg/kg feed, the residues in eggs, fat, and muscle mainly consisted of unchanged parent. In eggs, beside the parent compound also its hydroxy metabolite M510F01 including conjugates were present. Low extractability could be observed in liver due to a high level of bound residues. By application of a specially developed microwave method under harsh conditions it was possible to differentiate between extractable and bound residues of BAS 510 F by the formation of M510F01, M510F49 and M510F51 (originating from extractable residues) and M510F52 (originating from bound residues), respectively. The bound parent (measured as cleavage product M510F52) is therefore the main compound in the liver. The bound residues mainly resulted from a substitution of the chlorine of the pyridine system by thiol groups of liver proteins and binding parent to the protein.

Summary of new animal metabolism studies
As requested by EFSA (EFSA, 2014), an additional poultry metabolism study using ^{14}C-pyridine-labeled boscalid has been performed and consequently submitted in context of EFSA's request for additional information by the applicant in September 2019. After conduct of the study, further identification work on the generic metabolite M510F65 has been performed to define a precise structure (M510F02). As the two studies have been submitted recently, they are consequently not yet contained in the draft RAR. Complete OECD summaries of both studies are given in Appendix 2.

Briefly, the primary metabolite M510F01 results from hydroxylation of the parent compound and is found in all relevant matrices. Conjugation of this metabolite with glucuronic acid leads to M510F02, which is present in liver, egg yolk and egg white (and bile). A cleavage of parent molecule could not be identified in any of the analysed samples. The release of bound residues was achieved by applying solubilization methods mimicking the human digestive system (protease, pepsin, pancreatin) and can thus be considered to be similar to human capabilities to release residues from the samples. Any remaining bound radioactivity (max. 9.6 %TRR and 0.042 mg/kg in liver) is thus regarded as non-bioavailable. The further identification work using high resolution HPLC-MS/MS allowed the structure elucidation of the aglycon, revealing that the conjugated metabolite, being previously identified as M510F65 within the hen metabolism study, is M510F02.

The results of the new hen metabolism study using ^{14}C-pyridine-labeled boscalid are in good agreement with the previous conducted metabolism study in laying hens using a ^{14}C-diphenyl label.

Conclusion on metabolism in livestock
The general metabolic pathways in rodents and ruminants were found to be comparable; the findings in ruminants can therefore be extrapolated to pigs. Parent compound, its hydroxy metabolite M510F01 and its conjugate M510F02 are the main residues in animal tissues and products. In the already EU peer reviewed metabolism studies, bound residues (measured as cleavage product M510F53 and M510F52) were found to be the main residue in liver. 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. As confirmed by EFSA (2014) for risk assessment in liver, bound residues (measured as M510F53 and M510F52, but expressed as boscalid) should be included, but data is only sufficient to derive a conversion factor (CF) of 1.5 for ruminant and pig livers.

The new livestock metabolism study employing soft extraction methods throughout the study revealed parent, M510F01 and M510F02 as metabolites, having minor amounts of non-bioavailable, bound liver residues left (<10%TRR). Considering the new data, the current animal residue definition for risk assessment should be reassessed in context of the ongoing renewal process.

zRMS comments:
According to the EFSA Journal 2014;12(7):3799 there are available metabolism studies include one study in lactating goats and one study in laying hens, both using [U-^{14}C-diphenyl] labelled boscalid. 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.
During the Member States' consultation, it was agreed that conjugates of M510F01 are difficult to analyse routinely and that, based on the findings from metabolism study, boscalid and M510F01 (free form) are deemed to be sufficient markers in liver and kidney. Nevertheless, as the available livestock feeding studies do not provide separate results for M510F01 and its conjugates, it is not possible to exclude conjugates of M510F01 from the enforcement residue definition in liver and kidney without additional data. Therefore, the relevant residue for enforcement is defined as boscalid in muscle, fat, milk and eggs and as the sum of boscalid and its hydroxy metabolite M510F01 including its conjugates expressed as boscalid in liver and kidney. For risk assessment in liver, bound residues (measured as M510F53 and M510F52, but expressed as boscalid) should also be included, but data is sufficient to derive a conversion factor for ruminant and pig livers only and supplementary data on the nature and magnitude of the bound residues in poultry liver are required. Since log Po/w of boscalid is close to 3 (Germany, 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.

A new poultry metabolism study using ^{14}C-pyridine-labeled boscalid (BASF DocID 2019/1077444) has been recently submitted by the Applicant in context of EFSA's request for additional information (Sept 2019) and is referenced here for completion purposes. This study is not yet assessed in the RAR and not yet contained in the publicly available draft RAR, because information about new study was provided to the RMS in stage when the evaluation has already been done.

In our opinion the evaluation of new poultry metabolism and the setting residue definition should be carried out at the EU level and the active substance level, not at the level of plant protection product registration in the Central Zone. However, it should be noted that Applicant submitted this study as additional information.
Based on the studies results (BASF DocID 2019/1077444 and BASF DocID 2019/1075236), it can concluded that the new hen metabolism study using ^{14}C-pyridine-labeled boscalid are in good agreement with the previous conducted metabolism study in laying hens using a ^{14}C-diphenyl label.

Information presented by Applicant above have been accepted and are sufficient to support the proposed uses.

Definition:
Enforcement residue definition for animal commodities:
- muscle, fat, milk and eggs: parent boscalid (BAS 510 F);
- kidney, liver: sum of boscalid and its hydroxy metabolite M510F01 (free and conjugated), expressed as boscalid
Risk assessment residue definition for animal commodities:
- parent boscalid (BAS 510 F);
- liver (poultry) and kidney: sum of parent boscalid (BAS 510 F) and hydroxylation product M510F01 (including its conjugates), expressed as boscalid;
- liver (ruminant and pig): sum of parent boscalid (BAS 510 F),and hydroxylation product M510F01 (including its conjugates) and the bound residues (measured as M510F52 or M510F53), expressed as boscalid.
No additional data are required .

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

Table 7.3-8: 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 weeks in milk
	6 days in eggs

Animal residue definition for monitoring	Parent boscalid (BAS 510 F); Liver and kidney: sum of boscalid and its hydroxy metabolite M510F01 (free and conjugated), expressed as boscalid
Animal residue definition for risk assessment	Parent boscalid (BAS 510 F); Liver and kidney: sum of boscalid and its hydroxy metabolite M510F01 (free and conjugated), expressed as boscalid); Liver (ruminant and pig): sum of boscalid, its hydroxy metabolite M510F01 (free and conjugated) and its bound residue (measured as M510F53 or M510F52), expressed as boscalid
Conversion factor	Not applicable*
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes (log Pow = 2.96), in livestock feeding study residues in fat were found to be higher than in muscle

* It should be noted that EFSA derived a conversion factor in context of Art. 12 evaluation of boscalid (EFSA 2014). However, submitting a new livestock metabolism and feeding study in context of the ongoing Annex I inclusion process, BASF could show that a conversion factor is not deemed to be necessary. Therefore, input values from the MRLs for animal commodities proposed within the Annex I renewal have been used for risk assessment purposes in context of this submission.

7.3.3 Magnitude of residues in plants (KCA 6.3)

7.3.3.1 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 7.3-9: Summary of EU reported and new data supporting the intended uses of BAS 762 02 F and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Oilseed rape (rapeseeds / canola seeds)	EFSA, 2014	N-EU	GAP on which MRL assessment is based: 2x 0.25 kg as/ha, BBCH 61-69, PHI n.a., outdoor E/RA: 11x <0.05, 0.07	0.05	0.07	-	1	
		S-EU	GAP on which MRL assessment is based: 1x 0.25 kg as/ha, BBCH n.a., PHI 35d, outdoor E/RA: 3x <0.05	-	-	-		-
		Import (US)	GAP on which MRL assessment is based: 2x 0.294 kg as/ha, BBCH n.a., PHI 21, outdoor E/RA: 3x <0.05, 2x 0.08, 0.11, 0.19, 0.28, 0.30, 0.34, 0.48, 0.51	0.15	0.51	-		
	New trials BASF DocID 2019/1016882 2020/2006193	N-EU	Trials GAP: 1x 0.2 kg as/ha, BBCH 75, PHI F, outdoor E/RA: <0.01, 0.013, 0.015, 0.019, 0.022, 0.023, 0.033, 0.30	0.03**	0.30**	Highest residue covered by current MRL 1.0 mg/kg. No further considerations needed.		Yes
		S-EU	Trials GAP: 1x 0.2 kg as/ha, BBCH 75, PHI F, outdoor E/RA: <0.01, 0.021, 0.032, 0.058, 0.059, 0.065, 0.070, 0.13					
Sunflower seeds	EFSA, 2014	N-EU	GAP on which MRL assessment is based: 2x 0.1 kg as/ha, BBCH 18-79, PHI 35d, outdoor E/RA: 2x <0.01, 2x 0.01, 0.02, 2x <0.05, 0.11, 0.33	0.02	0.33		1	
		S-EU	GAP on which MRL assessment is based: 2x 0.1 kg as/ha, BBCH 20-65, PHI 35d, outdoor E/RA: <0.01, 0.02, 2x <0.05	0.04	0.05			-
		Import (US)	GAP on which MRL assessment is based: 2x 0.444 kg as/ha, BBCH n.a., PHI 21d, outdoor E/RA: <0.05, 0.11, 0.13, 0.15, 0.17, 0.23, 0.24, 0.54	0.16	0.54			

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
	New trials BASF DocID 2018/1205796, 2019/2075093 (+Amendment 2020/2108977)	N-EU	Trials GAP: 2x 0.2 kg as/ha, BBCH 69, PHI F, outdoor E/RA: 4x <0.01, 0.011, 0.021, 0.25, 0.3	0.02**	0.30**	Highest residue covered by current MRL 1.0 mg/kg. No further considerations needed.		Yes
		S-EU	Trials GAP: 2x 0.2 kg as/ha, BBCH 69, PHI F, outdoor E/RA: <0.01, 0.036, 0.045, 0.077 <0.01, 0.010, 0.023, 0.051					
Wheat grain	EFSA, 2014	N-EU	GAP on which MRL assessment is based: 2x 0.35 kg as/ha, BBCH 69, PHI 35d, outdoor E/RA: 0.05, 0.06, 0.11, 2x 0.12, 0.18, 0.24, 0.27, 0.31	0.12	0.31		0.8	-
		S-EU	GAP on which MRL assessment is based: 2x 0.35 kg as/ha, BBCH 69, PHI 35d, outdoor E/RA: 3x 0.05, 0.19	0.05	0.19	-		-
	New trials BASF DocID 2019/1016888	N-EU	Trials GAP: 1x 0.2 kg as/ha, BBCH 49, PHI 42-69d, outdoor E/RA: 4x <0.01	0.01**	0.033**	Highest residue covered by current MRL 0.8 mg/kg. No further considerations needed.		Yes
		S-EU	Trials GAP: 1x 0.2 kg as/ha, BBCH 49, PHI 56-57d, outdoor E/RA: 3x <0.01, 0.033					

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 straw	EFSA, 2014	N-EU	GAP on which MRL assessment is based: 2x 0.35 kg as/ha, BBCH 69, PHI 35d, outdoor E/RA: 13.44, 15.2, 15.08, 17.6, 19.62, 20.77, 30.51, 32.9, 39.5	19.62	39.5		150 (pseudo MRL)	-
		S-EU	GAP on which MRL assessment is based: 2x 0.35 kg as/ha, BBCH 69, PHI 35d, outdoor E/RA: 24.06, 31.75, 35.72, 52.70	33.74	52.70	-		-
	New trials BASF DocID 2019/1016888	N-EU	Trials GAP: 1x 0.2 kg as/ha, BBCH 49, PHI 42-69d, outdoor E/RA: 1.5, 1.8, 3.4, 4.6	3.30	4.90	Highest residue covered by pseudo MRL 150 mg/kg. No further considerations needed.		Yes
		S-EU	Trials GAP: 1x 0.2 kg as/ha, BBCH 49, PHI 56-57d, outdoor E/RA: 0.89, 3.2, 4.4, 4.9					

* Source of EU MRL: Reg. (EU) ~~2016/156~~ 2021/590

** U-test confirms that the NEU and SEU data sets are not statistically different, hence they are combined in each case to provide overall STMR and HR values.

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

7.3.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on oilseed rape, sunflower and wheat are considered acceptable for outdoor uses. The extrapolation rules between crops have been applied according to SANTE/2019/12752.
The newly conducted residue trials have been conducted either with formulation BAS 762 00 F and/or BAS 762 02 F according to the critical GAPs. As both formulations are SC formulations, they can be considered to be equivalent and a similar residue behavior is expected (see 3.4, Deviations of residue trials regarding the formulation in SANTE/2019/12752). In case both formulations have been used in the same trial, the more critical residue value has been chosen for derivation of the overall HR and STMR values and their MRL compliance.
The data submitted show that no exceedance of the current or proposed boscalid MRLs for the intended uses (oilseed rape, sunflower and wheat) is expected. The highest residue values from all new residue trials conducted are below the currently established or proposed EU MRLs, therefore a safe use of boscalid for the intended uses of BAS 762 02 F can be assumed.

zRMS comments:
Information given by the Applicant is sufficient.
Wheat, sunflower seed and oilseed rape are the major crops in northern Europe (Technical Guidelines SANTE/2019/12752). A minimum of eight trials are required.

1. Wheat
The intended GAP for boscalid for wheat in central Europe is 1 x 0.200 kg a.i./ha at BBCH 30-49 with PHI of 56 days.
New study on the magnitude of residue have been submitted by the Applicant in the framework of this application:
1. BASF DocID 2019/1016888– 4 NEU trials and 4 SEU trials;
Eight residue trials were conducted in Germany, Poland, Southern France, Spain, The Netherlands, United Kingdom, Italy and Greece during the 2018 season. In this study one application, applied at growth stage BBCH 49 were made at a nominal rate of 0.2 kg ai/ha for boscalid.
Residues of boscalid in samples of wheat grain at BBCH 89 were between < 0.010 mg/kg (4 trials).

In SANTE/2019/12752 it is concluded that in '<LOQ residue' situation, the number of independent trials may be reduced. The number of trials shall not be below the minimum of three per zone for minor crops and four per zone for major crops. So sufficient trials are available to support the proposed use in wheat.

The trials are supported by valid storage stability data for wheat and validated analytical methods.
The residues arising from the proposed uses will not exceed the MRLs established for boscalid for wheat (0.8 mg/kg) in Reg. (EC) No 2021/590.

2. Oilseed rape
The intended GAP for boscalid for oilseed rape in central Europe is 1 x 0.200 kg a.i./ha at BBCH 57-75 with PHI as not relevant.
Sufficient trials are available to support the proposed use in oilseed rape.
New studies on the magnitude of residue have been submitted by the Applicant in the framework of this application:
1. BASF DocID 2019/1016882 – 4 NEU trials and 4 SEU trials;
Eight residue trials were conducted in Germany, The Netherlands, Denmark, Northern and Southern France, Greece, Italy and Spain during the 2018 season. In this study one application, applied at growth stage BBCH 75 were made at a nominal rate of 0.2 kg ai/ha for boscalid.
Residues of boscalid in samples of oilseed rape seed at BBCH 89 (38-54 DALA) were between < 0.010 and 0.065 mg/kg.

2. BASF DocID 2020/2006193 – 4 NEU trials and 4 SEU trials;
Eight residue trials were conducted in Northern and Southern Europe during the 2019 season. In this study one application, applied at growth stage BBCH 75 were made at a nominal rate of 0.2 kg ai/ha for boscalid.
Residues of boscalid in samples of oilseed rape seed at BBCH 89 (38-54 DALA) were between 0.015 -0.30 mg/kg.

The trials are supported by valid storage stability data for oilseed rape and validated analytical methods.
The residues arising from the proposed uses will not exceed the MRLs established for boscalid for oilseed rape (1 mg/kg) in Reg. (EC) No 2021/590.

3. Sunflower seed
The intended GAP for boscalid for sunflower seed in central Europe is 2 x 0.200 kg a.i./ha with 7 days between application at BBCH 31-69 with PHI as not relevant.
Sufficient trials are available to support the proposed use in sunflower seed.
New studies on the magnitude of residue have been submitted by the Applicant in the framework of this application:
1. BASF DocID 2018/120579– 4 NEU trials and 4 SEU trials;
Eight residue trials were conducted in Northern and Southern Europe during the 2018 season. In this study two times application, applied at BBCH 59 and the second application at BBCH 69, were made at a nominal rate of 0.2 kg ai/ha for boscalid.
Residues of boscalid in treated seed specimens taken at BBCH 89 ranged between < 0.010 mg/kg and 0.30 mg/kg.

2. BASF DocID 2019/2075093 – 4 NEU trials and 4 SEU trials;
Eight residue trials were conducted in Northern and Southern Europe during the 2019 season. In this study two times application, applied at BBCH 59-61 and the second application at BBCH 69, were made at a nominal rate of 0.2 kg ai/ha for boscalid.
Residues of boscalid in treated seed specimens taken at BBCH 89 were < 0.010 – 0.051 mg/kg.

The trials are supported by valid storage stability data for sunflower and validated analytical methods.
The residues arising from the proposed uses will not exceed the MRLs established for boscalid for sunflower seed (1 mg/kg) in Reg. (EC) No 2021/590.

No additional data are required.

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

In 2014, the calculation of the overall feed burden has been performed by EFSA in context of the MRL re-evaluation according to EEC 396/2005, Article 12 (EFSA 2014). The results are shown in the table below.

Table 7.3-10: Results of the dietary burden calculation including uptake of residues from previously treated soil by EFSA (EFSA 2014)

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition boscalid					
Dairy ruminants	0.41	1.43	Grass, fresh	39.9	Y
Meat ruminants	0.99	2.04	Wheat straw	47.5	Y
Poultry	0.09	0.23	Kale	3.66	Y
Pigs	0.09	0.37	Grass silage	9.31	Y

A comparison of input values is given in the table below to show that the target uses considered in this application (oilseed rape, sunflower and wheat) are well covered by the previous feed burden calculations done by EFSA (2014) and the resulting MRL values derived for animal matrices. Thus, no further consideration regarding residues in animal commodities and respective MRLs is needed in context of this submission.

Table 7.3-11: Comparison of input values for the dietary burden calculation considering primary crops and uptake of residues from previously treated soil (EFSA, 2014)

Commodity[1]	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: boscalid (Values in brackets are based on calculations with residue values from Table 7.3-9)				
1 – Forages				
Wheat, straw	33.7 (3.51)	STMR wheat straw (PC) (EFSA, 2014) (STMR wheat straw (PC) in this submission[2] 3.3 + STMR straws and fodder (cereals, RC) 0.21 (EFSA, 2014)	52.7 (11.7)	HR wheat straw (PC) (EFSA, 2014) (HR wheat straw (PC) in this submission[2] 4.9 + HR straws and fodder (cereals, RC) 6.8 (EFSA, 2014)
2 – Roots & Tubers				
-				
3 – Cereal Grain/Crops Seeds				
Wheat, grain	0.17 (0.06)	STMR wheat/rye grain + cereal grain (PC+RC) (EFSA, 2014) (0.01 STMR (PC) in this submission[2] + 0.05 STMR cereal grain (RC), EFSA 2014)	0.17 (0.06)	STMR wheat/rye grain + cereal grain (PC+RC) (EFSA, 2014) (0.01 STMR (PC) in this submission[2] + 0.05 STMR cereal grain (RC), EFSA 2014)
4 – By-Products				
Canola (Rape seed), meal*	0.15 x 0.56 (0.03 x 0.56)	STMR rape seed (PC) x PF (EFSA, 2014) (STMR (PC) in this submission[2] x PF)	0.15 x 0.56 (0.03 x 0.56)	STMR rape seed (PC) x PF (EFSA, 2014) (STMR (PC) in this submission[2] x PF)
Distiller's grain*	0.17 x 3.3 (0.06 x 3.3)	STMR wheat/rye grain + cereal grain (PC+RC) x $PF_{default}$ (EFSA, 2014) (0.01 STMR (PC) in this submission[2] + 0.05 STMR cereal grain (RC) x $PF_{default}$, EFSA 2014)	0.17 x 3.3 (0.06 x 3.3)	STMR wheat/rye grain + cereal grain (PC+RC) x $PF_{default}$ (EFSA, 2014) (0.01 STMR (PC) in this submission[2] + 0.05 STMR cereal grain (RC) x $PF_{default}$, EFSA 2014)
Rape, meal*	0.15 x 0.56 (0.03 x 0.56)	STMR rape seed (PC) x PF (EFSA, 2014) (STMR (PC) in this submission[2] x PF)	0.15 x 0.56 (0.03 x 0.56)	STMR rape seed (PC) x PF (EFSA, 2014) (STMR (PC) in this submission[2] x PF)
Sunflower, meal*	0.16 x 2 (0.02 x 2)	STMR sunflower seed (PC) x $PF_{default}$ (EFSA, 2014) (STMR (PC) in this submission[2] x $PF_{default}$)	0.16 x 2 (0.02 x 2)	STMR sunflower seed (PC) x $PF_{default}$ (EFSA, 2014) (STMR (PC) in this submission[2] x $PF_{default}$)
Wheat, gluten meal*	0.17 x 1.8 (0.06 x 1.8)	STMR wheat/rye grain + cereal grain (PC+RC) x $PF_{default}$ (EFSA, 2014) (0.01 STMR (PC) in this submission[2] + 0.05 STMR cereal grain (RC) x $PF_{default}$, EFSA 2014)	0.17 x 1.8 (0.06 x 1.8)	STMR wheat/rye grain + cereal grain (PC+RC) x $PF_{default}$ (EFSA, 2014) (0.01 STMR (PC) in this submission[2] + 0.05 STMR cereal grain (RC) x $PF_{default}$, EFSA 2014)

Commodity[1]	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Wheat, milled by products*	0.17 x 7 (0.06 x 7)	STMR wheat/rye grain + cereal grain (PC+RC) x $PF_{default}$ (EFSA, 2014) (0.01 STMR (PC) in this submission[2] + 0.05 STMR cereal grain (RC) x $PF_{default}$, EFSA 2014)	0.17 x 7 (0.06 x 7)	STMR wheat/rye grain + cereal grain (PC+RC) x $PF_{default}$ (EFSA, 2014) (0.01 STMR (PC) in this submission[2] + 0.05 STMR cereal grain (RC) x $PF_{default}$, EFSA 2014)

1 See EFSA Journal 2014;12(7):3799 (considering uptake of residues from previously treated soil)
2 STMR/HR from new trials, covering Northern and Southern residue data as worst case scenario (see Table 7.3-9)
* to be considered according to EFSA animal model (2017)
RC Residues in rotational crop considered
PC Residues in primary crop considered

zRMS comments:
In the context of this document, new dietary burden calculations were performed. Details are provided below:

It is an EU data requirement (Commission Regulation (EU) No 283/2013, 1 March 2013) and guideline requirement (OECD 505, Residues in Livestock) to estimate the dietary intakes for poultry, dairy cattle, beef cattle and pigs, if residues are likely in crops or part of crops fed to animals.

The median and maximum dietary burdens were calculated for different groups of livestock according to OECD guidance documents 64 & 32 (2009) and 73 (2013), which have now also been agreed upon at European level (EFSA; Animal Model calculation spreadsheet from 2017). The input values for all relevant commodities have been selected according to the recommendations of JMPR (FAO, 2009) and are summarized in Table 7.2-12. In general, STMR and HR values from supervised field trials were used as inputs. In addition, all boscalid uses in Europe and also residues in rotational crops have been considered as a worst-case scenario in these calculations.
This approach is over-conservative as it assumes that all crops fed to livestock have been grown in rotation after boscalid use at the maximum seasonal application rate for several consecutive years. Thus, the usage of STMR values as input values of rotational residues for dietary burden calculation is considered to be sufficient conservative. Nevertheless, to be comparable with the dietary burden calculation performed by EFSA in context of the Art. 12 MRL review, HR and STMR values, as derived by EFSA have been used for rotational residues (EFSA, 2014). In case new commodities were included in Animal model 2017 compared to 2014, extrapolations were done in the same conservative approach as EFSA has previously conducted in their assessment. Default processing factors were applied according EFSA Animal Model 2017, except for OSR meal where an empiric processing factor of 0.56 is available. It should be noted that the usage of default processing factors for residues from rotational crops is an over-estimation. As only rotational residues are considered, an even distribution of residues throughout the commodity (e.g. grain) is expected and thus no concentration of residues in the by-product collection would be expected. Nevertheless, default processing factors were applied in the calculations as outlined in the table below.

Table 7.3-12: Input values for the dietary burden calculation considering primary crops and uptake of residues from previously treated soil (EFSA, 2014)

Commodity[1]	Maximum dietary burden		Median dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: boscalid				
1 – Forages				
Alfalfa forage (green)	1.46	HR forages (pulses/oilseeds, RC) (EFSA, 2014)	0.08	STMR forages (pulses/oilseeds, RC) (EFSA, 2014)
Alfalfa, hay (fodder)	1.46 x 2.5	HR forages (pulses/oilseeds, RC) x $PF_{default}$ (EFSA, 2014)	0.08 x 2.5	STMR forages (pulses/oilseeds, RC) x $PF_{default}$ (EFSA, 2014)
Alfalfa, meal	1.46 x 2.5	HR forages (pulses/oilseeds, RC) x $PF_{default}$ (EFSA, 2014)	0.08 x 2.5	STMR forages (pulses/oilseeds, RC) x $PF_{default}$ (EFSA, 2014)
Alfalfa, silage	1.46 x 1.1	HR forages (pulses/oilseeds, RC) x $PF_{default}$ (EFSA, 2014)	0.08 x 1.1	STMR forages (pulses/oilseeds, RC) x $PF_{default}$ (EFSA, 2014)
Barley, forage[2]	6.80	HR straws and fodder (cereals, RC) (EFSA, 2014)	0.21	STMR straws and fodder (cereals, RC) (EFSA, 2014)

Barley, straw	6.80	HR straws and fodder (cereals, RC) (EFSA, 2014)	0.21	STMR straws and fodder (cereals, RC) (EFSA, 2014)
Barley, silage[2]	6.80 x 1.3	HR straws and fodder (cereals, RC) x $PF_{default}$ (EFSA, 2014)	0.21 x 1.3	STMR straws and fodder (cereals, RC) x $PF_{default}$ (EFSA, 2014)
Bean, vines (fodder green)[2]	1.46	HR forages (pulses/oilseeds, RC) (EFSA, 2014)	0.08	STMR forages (pulses/oilseeds, RC) (EFSA, 2014)
Beet, mangel, fodder	0.84	HR fodder beet leaves (EFSA, 2014)	0.05	STMR fodder beet leaves (EFSA, 2014)
Beet, sugar, tops	0.84	HR fodder beet leaves (EFSA, 2014)	0.05	STMR fodder beet leaves (EFSA, 2014)
Cabbage heads, leaves	2.82	HR brassica (PC+RC) (EFSA, 2014)	1.1	STMR brassica (PC+RC) (EFSA, 2014)
Clover (fresh), forage	1.46	HR forages (pulses/oilseeds, RC) (EFSA, 2014)	0.08	STMR forages (pulses/oilseeds, RC) (EFSA, 2014)
Clover, hay	1.46 x 3.0	HR forages (pulses/oilseeds, RC) x $PF_{default}$ (EFSA, 2014)	0.08 x 3.0	STMR forages (pulses/oilseeds, RC) x $PF_{default}$ (EFSA, 2014)
Clover, silage	1.46 x 1.0	HR forages (pulses/oilseeds, RC) x $PF_{default}$ (EFSA, 2014)	0.08 x 1.0	STMR forages (pulses/oilseeds, RC) x $PF_{default}$ (EFSA, 2014)
Corn, forage	6.80	HR straws and fodder (cereals, RC) (EFSA, 2014)	0.21	STMR straws and fodder (cereals, RC) (EFSA, 2014)
Corn, field, stover	6.80	HR straws and fodder (cereals, RC) (EFSA, 2014)	0.21	STMR straws and fodder (cereals, RC) (EFSA, 2014)
Corn, pop, stover	6.80	HR straws and fodder (cereals, RC) (EFSA, 2014)	0.21	STMR straws and fodder (cereals, RC) (EFSA, 2014)
Cowpea, forage	1.46	HR forages (pulses/oilseeds, RC) (EFSA, 2014)	0.08	STMR forages (pulses/oilseeds, RC) (EFSA, 2014)
Cowpea, hay	1.46 x 2.9	HR forages (pulses/oilseeds, RC) x $PF_{default}$ (EFSA, 2014)	0.08 x 2.9	STMR forages (pulses/oilseeds, RC) x $PF_{default}$ (EFSA, 2014)
Grass, forage (fresh)	6.80	HR straws and fodder (cereals, RC) (EFSA, 2014)	0.21	STMR straws and fodder (cereals, RC) (EFSA, 2014)
Grass, hay	6.80 x 3.5	HR straws and fodder (cereals, RC) x $PF_{default}$ (EFSA, 2014)	0.21 x 3.5	STMR straws and fodder (cereals, RC) x $PF_{default}$ (EFSA, 2014)
Grass, silage	6.80 x 1.6	HR straws and fodder (cereals, RC) x $PF_{default}$ (EFSA, 2014)	0.21 x 1.6	STMR straws and fodder (cereals, RC) x $PF_{default}$ (EFSA, 2014)
Kale, leaves (forage)	4.1	HR brassica (PC+RC) (EFSA, 2014)	1.1	STMR brassica (PC+RC) (EFSA, 2014)
Lespedeza, forage	1.46	HR forages (pulses/oilseeds, RC) (EFSA, 2014)	0.08	STMR forages (pulses/oilseeds, RC) (EFSA, 2014)
Lespedeza, hay	1.46 x 4.0	HR forages (pulses/oilseeds, RC) x $PF_{default}$ (EFSA, 2014)	0.08 x 4.0	STMR forages (pulses/oilseeds, RC) x $PF_{default}$ (EFSA, 2014)
Millet, forage[2]	6.80	HR straws and fodder (cereals, RC) (EFSA, 2014)	0.21	STMR straws and fodder (cereals, RC) (EFSA, 2014)
Millet, straw	6.80	HR straws and fodder (cereals, RC) (EFSA, 2014)	0.21	STMR straws and fodder (cereals, RC) (EFSA, 2014)
Oat, forage[2]	6.80	HR straws and fodder (cereals, RC) (EFSA, 2014)	0.21	STMR straws and fodder (cereals, RC) (EFSA, 2014)
Oat, hay[2]	6.80 x 3	HR straws and fodder (cereals, RC) x $PF_{default}$ (EFSA, 2014)	0.21 x 3	STMR straws and fodder (cereals, RC) x $PF_{default}$ (EFSA, 2014)
Oat, straw	6.80	HR straws and fodder (cereals, RC) (EFSA, 2014)	0.21	STMR straws and fodder (cereals, RC) (EFSA, 2014)
Pea, vines (green)[2]	1.46	HR forages (pulses/oilseeds, RC) (EFSA, 2014)	0.08	STMR forages (pulses/oilseeds, RC) (EFSA, 2014)
Pea, hay (hay or fodder)[2]	1.46 x 3.5	HR forages (pulses/oilseeds, RC) x $PF_{default}$ (EFSA, 2014)	0.08 x 3.5	STMR forages (pulses/oilseeds, RC) x $PF_{default}$ (EFSA, 2014)
Pea, silage[2]	1.46 x 1.6	HR forages (pulses/oilseeds, RC) x $PF_{default}$ (EFSA, 2014)	0.08 x 1.6	STMR forages (pulses/oilseeds, RC) x $PF_{default}$ (EFSA, 2014)
Rape, forage[2]	1.46	HR forages (pulses/oilseeds, RC) (EFSA, 2014)	0.08	STMR forages (pulses/oilseeds, RC) (EFSA, 2014)

Rice, straw	6.80	HR straws and fodder (cereals, RC) (EFSA, 2014)	0.21	STMR straws and fodder (cereals, RC) (EFSA, 2014)
Rye, forage[2]	6.80	HR straws and fodder (cereals, RC) (EFSA, 2014)	0.21	STMR straws and fodder (cereals, RC) (EFSA, 2014)
Rye, straw	6.80	HR straws and fodder (cereals, RC) (EFSA, 2014)	0.21	STMR straws and fodder (cereals, RC) (EFSA, 2014)
Sorghum, forage[2]	6.80	HR straws and fodder (cereals, RC) (EFSA, 2014)	0.21	STMR straws and fodder (cereals, RC) (EFSA, 2014)
Sorghum, stover	6.80	HR straws and fodder (cereals, RC) (EFSA, 2014)	0.21	STMR straws and fodder (cereals, RC) (EFSA, 2014)
Sorghum, silage	6.80 x 0.6	HR straws and fodder (cereals, RC) x $PF_{default}$ (EFSA, 2014)	0.21 x 0.6	STMR straws and fodder (cereals, RC) x $PF_{default}$ (EFSA, 2014)
Soybean, forage[2]	1.46	HR forages (pulses/oilseeds, RC) (EFSA, 2014)	0.08	STMR forages (pulses/oilseeds, RC) (EFSA, 2014)
Pea, hay (hay or fodder)[2]	1.46 x 1.5	HR forages (pulses/oilseeds, RC) x $PF_{default}$ (EFSA, 2014)	0.08 x 1.5	STMR forages (pulses/oilseeds, RC) x $PF_{default}$ (EFSA, 2014)
Pea, silage[2]	1.46 x 0.5	HR forages (pulses/oilseeds, RC) x $PF_{default}$ (EFSA, 2014)	0.08 x 0.5	STMR forages (pulses/oilseeds, RC) x $PF_{default}$ (EFSA, 2014)
Trefoil, forage[2]	1.46	HR forages (pulses/oilseeds, RC) (EFSA, 2014)	0.08	STMR forages (pulses/oilseeds, RC) (EFSA, 2014)
Trefoil, hay[2]	1.46 x 2.8	HR forages (pulses/oilseeds, RC) x $PF_{default}$ (EFSA, 2014)	0.08 x 2.8	STMR forages (pulses/oilseeds, RC) x $PF_{default}$ (EFSA, 2014)
Triticale, straw	6.80	HR straws and fodder (cereals, RC) (EFSA, 2014)	0.21	STMR straws and fodder (cereals, RC) (EFSA, 2014)
Turnip, tops (leaves)	0.84	HR fodder beet leaves (EFSA, 2014)	0.05	STMR fodder beet leaves (EFSA, 2014)
Vetch, forage	1.46	HR forages (pulses/oilseeds, RC) (EFSA, 2014)	0.08	STMR forages (pulses/oilseeds, RC) (EFSA, 2014)
Vetch, hay	1.46 x 2.8	HR forages (pulses/oilseeds, RC) x $PF_{default}$ (EFSA, 2014)	0.08 x 2.8	STMR forages (pulses/oilseeds, RC) x $PF_{default}$ (EFSA, 2014)
Wheat, forage[2]	6.80	HR straws and fodder (cereals, RC) (EFSA, 2014)	0.21	STMR straws and fodder (cereals, RC) (EFSA, 2014)
Wheat, hay[2]	6.80 x 3.5	HR straws and fodder (cereals, RC) x $PF_{default}$ (EFSA, 2014)	0.21 x 3.5	STMR straws and fodder (cereals, RC) x $PF_{default}$ (EFSA, 2014)
Wheat, straw	4.90	HR (this document)	3.30	STMR (this document)
2 – Roots & Tubers				
Carrot, culls	0.75	HR carrots (PC+RC) (EFSA, 2014)	0.24	STMR carrots (PC+RC) (EFSA, 2014)
Cassava/tapioca, roots	0.37	HR cassava (RC) (EFSA, 2014)	0.05	STMR cassava (RC) (EFSA, 2014)
Potatoes, culls	0.42	HR potatoes (PC+RC) (EFSA, 2014)	0.10	STMR potatoes (PC+RC) (EFSA, 2014)
Swede	0.65	HR turnips (PC+RC) (EFSA, 2014)	0.14	STMR turnips (PC+RC) (EFSA, 2014)
Turnip	0.65	HR turnips (PC+RC) (EFSA, 2014)	0.14	STMR turnips (PC+RC) (EFSA, 2014)
3 – Cereal Grain/Crops Seeds				
Barley, grain	1.07	STMR barley grain (PC) (EFSA, 2014)	1.07	STMR barley grain (PC) (EFSA, 2014)
Bean, seed (dry)	0.13	STMR bean/pea dry (PC+RC) (EFSA, 2014)	0.13	STMR bean/pea dry (PC+RC) (EFSA, 2014)
Corn, field, grain	0.05	STMR cereal grain (RC) (EFSA, 2014)	0.05	STMR cereal grain (RC) (EFSA, 2014)
Corn, pop, grain	0.05	STMR cereal grain (RC) (EFSA, 2014)	0.05	STMR cereal grain (RC) (EFSA, 2014)
Cotton, undelinted seed	0.05	STMR seed (pulses and oilseeds, RC) (EFSA, 2014)	0.05	STMR seed (pulses and oilseeds, RC) (EFSA, 2014)

Cowpea, seed	0.05	STMR seed (pulses and oilseeds, RC) (EFSA, 2014)	0.05	STMR seed (pulses and oilseeds, RC) (EFSA, 2014)
Lupin, seed	0.05	STMR seed (pulses and oilseeds, RC) (EFSA, 2014)	0.05	STMR seed (pulses and oilseeds, RC) (EFSA, 2014)
Millet, grain	0.05	STMR cereal grain (RC) (EFSA, 2014)	0.05	STMR cereal grain (RC) (EFSA, 2014)
Oat, grain	1.07	STMR oat grain (PC) (EFSA, 2014)	1.07	STMR oat grain (PC) (EFSA, 2014)
Pea, seed (dry)	0.13	STMR bean/pea dry (PC+RC) (EFSA, 2014)	0.13	STMR bean/pea dry (PC+RC) (EFSA, 2014)
Rye, grain	0.17	STMR rye, grain (PC+RC) (EFSA, 2014)	0.17	STMR rye, grain (PC+RC) (EFSA, 2014)
Sorghum, grain	0.05	STMR cereal grain (RC) (EFSA, 2014)	0.05	STMR cereal grain (RC) (EFSA, 2014)
Soybean, seed	0.10	STMR soybean seed (PC+RC) (EFSA, 2014)	0.10	STMR soybean seed (PC+RC) (EFSA, 2014)
Triticale, grain	0.17	STMR triticale, grain (PC+RC) (EFSA, 2014)	0.17	STMR triticale, grain (PC+RC) (EFSA, 2014)
Wheat, grain	0.01	STMR wheat grain (this document)	0.01	STMR wheat grain (this document)
4 – By-Products				
Sugar beet, dried pulp	0.05 x 18	STMR sugar beet (RC) x $PF_{default}$ (EFSA, 2014)	0.05 x 18	STMR sugar beet (RC) x $PF_{default}$ (EFSA, 2014)
Sugar beet, ensiled pulp	0.05 x 3	STMR sugar beet (RC) x $PF_{default}$ (EFSA, 2014)	0.05 x 3	STMR sugar beet (RC) x $PF_{default}$ (EFSA, 2014)
Sugar beet, molasses	0.05 x 28	STMR sugar beet (RC) x $PF_{default}$ (EFSA, 2014)	0.05 x 28	STMR sugar beet (RC) x $PF_{default}$ (EFSA, 2014)
Brewer's grain	1.07 x 3.3	STMR barley grain x $PF_{default}$ (this document)	1.07 x 3.3	STMR barley grain x $PF_{default}$ (this document)
Canola (Rape seed), meal	0.15 x 0.56	STMR rape seed (PC+RC) x PF (EFSA, 2014)	0.15 x 0.56	STMR rape seed (PC+RC) x PF (EFSA, 2014)
Corn, milled by-pdts	0.05 x 1	STMR cereal grain (RC) x $PF_{default}$ (EFSA, 2014)	0.05 x 1	STMR cereal grain (RC) x $PF_{default}$ (EFSA, 2014)
Corn, hominy meal	0.05 x 6	STMR cereal grain (RC) x $PF_{default}$ (EFSA, 2014)	0.05 x 6	STMR cereal grain (RC) x $PF_{default}$ (EFSA, 2014)
Corn, gluten feed	0.05 x 2.5	STMR cereal grain (RC) x $PF_{default}$ (EFSA, 2014)	0.05 x 2.5	STMR cereal grain (RC) x $PF_{default}$ (EFSA, 2014)
Corn, gluten meal	0.05 x 1	STMR cereal grain (RC) x $PF_{default}$ (EFSA, 2014)	0.05 x 1	STMR cereal grain (RC) x $PF_{default}$ (EFSA, 2014)
Cotton, meal	0.05 x 1.3	STMR cotton seed (RC) x $PF_{default}$ (EFSA, 2014)	0.05 x 1.3	STMR cotton seed (RC) x $PF_{default}$ (EFSA, 2014)
Distiller's grain	0.05 x 3.3	STMR cereal grain (RC) x $PF_{default}$ (EFSA, 2014)	0.05 x 3.3	STMR cereal grain (RC) x $PF_{default}$ (EFSA, 2014)
Flaxseed/linseed, meal	0.10 x 2	STMR linseed (PC+RC) x $PF_{default}$ (EFSA, 2014)	0.10 x 2	STMR linseed (PC+RC) x $PF_{default}$ (EFSA, 2014)
Lupin seed, meal	0.05 x 1.1	STMR lupin seed (RC) x $PF_{default}$ (EFSA, 2014)	0.05 x 1.1	STMR lupin seed (RC) x $PF_{default}$ (EFSA, 2014)
Peanut, meal	0.10 x 2	STMR peanut seed (PC+RC) x $PF_{default}$ (EFSA, 2014)	0.10 x 2	STMR peanut seed (PC+RC) x $PF_{default}$ (EFSA, 2014)
Potato, process waste	0.10 x 20	STMR potatoes (PC+RC) x $PF_{default}$ (EFSA, 2014)	0.10 x 20	STMR potatoes (PC+RC) x $PF_{default}$ (EFSA, 2014)
Potato, dried pulp	0.10 x 38	STMR potatoes (PC+RC) x $PF_{default}$ (EFSA, 2014)	0.10 x 38	STMR potatoes (PC+RC) x $PF_{default}$ (EFSA, 2014)
Rape, meal	0.15 x 0.56	STMR rape seed (PC+RC) x PF (EFSA, 2014)	0.15 x 0.56	STMR rape seed (PC+RC) x PF (EFSA, 2014)
Rice, bran/pollard	0.05 x 10	STMR cereal grain (RC) x $PF_{default}$ (EFSA, 2014)	0.05 x 10	STMR cereal grain (RC) x $PF_{default}$ (EFSA, 2014)

Safflower, meal	0.05 x 2	STMR safflower seed (RC) x $PF_{default}$ (EFSA, 2014)	0.05 x 2	STMR safflower seed (RC) x $PF_{default}$ (EFSA, 2014)
Soybean, meal	0.10 x 1.3	STMR soybean seed (PC+RC) x $PF_{default}$ (EFSA, 2014)	0.10 x 1.3	STMR soybean seed (PC+RC) x $PF_{default}$ (EFSA, 2014)
Soybean, hulls	0.10 x 13	STMR soybean seed (PC+RC) x $PF_{default}$ (EFSA, 2014)	0.10 x 13	STMR soybean seed (PC+RC) x $PF_{default}$ (EFSA, 2014)
Sunflower, meal	0.16 x 2	STMR sunflower seed (PC+RC) x $PF_{default}$ (EFSA, 2014)	0.16 x 2	STMR sunflower seed (PC+RC) x $PF_{default}$ (EFSA, 2014)
Wheat, gluten meal	0.01 x 1.8	STMR wheat grain x $PF_{default}$ (this document)	0.01 x 1.8	STMR wheat grain x $PF_{default}$ (this document)
Wheat, milled by products	0.01 x 7	STMR wheat grain x $PF_{default}$ (this document)	0.01 x 7	STMR wheat grain x $PF_{default}$ (this document)

1 See EFSA Journal 2014;12(7):3799 (considering uptake of residues from previously treated soil)
2 Bean, vines (fodder green), pea vines, hay and silage and rape and cereal forage are only relevant if a specific GAP on forage is proposed. No specific GAP intended for forage production is proposed but residues from rotational crops are considered (EFSA Journal 2014;12(7):3799).
RC Residues in rotational crop considered
PC Residues in primary crop considered

The results of the calculations using the EU animal model 2017 are presented in the table below. The calculated dietary burdens for livestock exceed the trigger value of 0.004 mg/kg bw/day for all species.

Table 7.3-13: Results of the dietary burden calculation (EFSA Animal Model 2017)

Relevant groups	Dietary burden (a) expressed in				Most critical diet (b)	Most critical commodity (c)		Trigger exceeded (Yes/No) 0.004 mg/kg bw
	mg/kg bw per day		mg/kg DM					
	Median	Maximum	Median	Maximum				
Risk assessment residue definition: boscalid								
Cattle (all diets)	0.277 (0.99)	0.845 (2.04)	8.69	21.97 (47.5)	Dairy cattle	Grass	forage (fresh)	Yes
Cattle (dairy only)	0.277 (0.41)	0.845 (1.43)	7.19	21.97 (39.9)	Dairy cattle	Grass	forage (fresh)	Yes
Sheep (all diets)	0.286	0.889	8.57	26.67	Ram/Ewe	Grass	forage (fresh	Yes
Sheep (ewe only)	0.286	0.889	8.57	26.67	Ram/Ewe	Grass	forage (fresh)	Yes
Swine (all diets)	0.115 (0.09)	0.268 (0.37)	4.99	11.62 (9.31)	Swine (breeding)	Grass	silage	Yes
Poultry (all diets)	0.138 (0.10)	0.329 (0.23)	2.01	4.81 (3.66)	Poultry layer	Wheat	forage	Yes
Poultry (layer only)	0.138 (0.10)	0.329 (0.23)	2.01	4.81 (3.66)	Poultry layer	Wheat	forage	Yes

(a): Values in brackets are results of the dietary burden calculation including uptake of residues from previously treated soil by EFSA (EFSA, 2014)
(b): 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"
(c): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as "mg/kg bw per day".

Comparing the dietary burdens calculated with the new EU animal model 2017 using very conservative assumptions with the values calculated by EFSA in context of the MRL review according to Article 12 of Regulation (EC) No 396/2005 (values provided in brackets in the table above), it can be seen that these residue intakes are lower or well in the range of previously calculated values. It is therefore concluded that the existing MRLs in animal commodities will not be exceeded by the intended uses of BAS 762 02 F / Revydas.

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

The uses under consideration are well covered by the input levels for rape meal, sunflower meal, wheat grain and wheat straw, which have been used for calculations of dietary burden for livestock by EFSA (EFSA, 2014). The additional contribution via canola (rape seed) meal, sunflower meal, wheat gluten meal, wheat milled byproducts and wheat distiller's grain, which should be considered additionally according to EFSA animal model (2017), is negligible as these commodities are not belonging to the main contributing feed commodities amongst all boscalid relevant feed items. Thus, no further consideration regarding residues in animal commodities and respective MRLs is needed in context of this submission. Nevertheless, for sake of completeness, information related to livestock feeding studies is provided below.

Available data

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

A lactating cow feeding study and a laying hen feeding study for boscalid were peer-reviewed during the Annex I inclusion process and were considered to be acceptable. However, as the dose levels were insufficient to cover the calculated dietary burden for ruminants, a new feeding study was submitted during Member State consultation in the context of the Article 12 review of the existing MRLs and evaluated (EFSA, 2014).

Two groups of lactating cows, each consisting of three animals (three additional animals for the highest dose, to conduct a depuration follow-up) were dosed for 28 consecutive days with boscalid at levels of 35.8 and 116.3 mg/kg in the diet (equivalent to 1.22 and 3.36 mg/kg bw). The samples were analysed for boscalid and for M510F01, including its conjugates. In milk, a plateau level was reached after two weeks for ruminants exposed to the highest dose level.

In the Article 12 review, EFSA considered the available data as sufficient for deriving MRLs in livestock. These MRLs were derived in compliance with the latest recommendations on this matter (FAO, 2009).

The studies also cover the feed intake arising from the intended uses of BAS 762 02 F, as the specific input values derived in context of the present dossier are covered by the input values used by EFSA in their assessment.

Conclusion on feeding studies

Considering the input levels for dietary burden calculation of the intended uses with BAS 762 02 F (oilseed rape, sunflower and wheat) it could be shown that the use is well covered by already registered boscalid containing products on these crops. Thus, there is no risk for animal MRLs to be exceeded.

zRMS comments:

The calculated dietary burdens for boscalid were found to be above the trigger value of 0.004 mg/kg bw per day for all animal species. Further investigation of residues in animal commodities is therefore required.

Because the newly calculated dietary burdens are in compliance with previously calculated values, these MRL calculations are still considered valid. The data are summarised in the table below.

Table 7.3-14: Overview of the values derived from livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[b]	Highest residue (mg/kg)[c]	Established MRL (mg/kg)[d]	MRL compliance
	Med. (mg/kg bw/d)[a]	Max. (mg/kg bw/d)[a]	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 (EFSA, 2014)												
Ruminant meat	0.99 (0.283)	2.04 (0.845)	1.22	3	<0.025	<0.025	<0.025	<0.025	0.025	0.025	0.01*	Yes
			3.56	3	<0.025	<0.025	<0.025	<0.025				
Ruminant fat			1.22	3	0.15	0.22	0.15	0.22	0.12	0.23	0.3	Yes
			3.56	3	0.17	0.25	0.17	0.25				
Ruminant liver			1.22	3	0.09	0.11	0.135	0.165	0.08	0.16	0.2	Yes
			3.56	3	0.20	0.24	0.30	0.375				

Ruminant kidney			1.22	3	0.11	0.11	0.11	0.11	0.025	0.076	0.2	Yes
			3.56	3	0.18	0.24	0.18	0.24				
Milk	0.41 (0.283)	1.43 (0.845)	1.22	3	0.01[(e)]	N/A	0.01[(e)]	N/A	0.01	0.02	0.02	Yes
			3.56	5	0.05[(f)]	N/A	0.05[(f)]	N/A				
EU data (EFSA, 2014)												
Pig meat	0.09 (0.107)	0.37 (0.263)	1.22	3	<0.025	<0.025	<0.025	<0.025	0.025	0.025	0.01*	Yes
			3.56	3	<0.025	<0.025	<0.025	<0.025				
Pig fat			1.22	3	0.15	0.22	0.15	0.22	0.025	0.07	0.07	Yes
			3.56	3	0.17	0.25	0.17	0.25				
Pig liver			1.22	3	0.09	0.11	0.135	0.165	0.05	0.05	0.05*	Yes
			3.56	3	0.20	0.24	0.30	0.375				
Pig kidney			1.22	3	0.11	0.11	0.11	0.11	0.05	0.05	0.05*	Yes
			3.56	3	0.18	0.24	0.18	0.24				
EU data (EFSA, 2014)												
Poultry meat	0.10 (0.108)	0.23 (0.286)	0.06	3	<0.025	<0.025	<0.025	<0.025	0.025	0.025	0.01*	Yes
			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	0.07	0.08	Yes
			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	<0.05	0.05	0.06	0.14	0.15	Yes
			0.32	3	0.14	0.18	0.14	0.18				
			1.26	3	0.41	0.47	0.41	0.47				
Eggs			0.06	3	<0.01[(g)]	N/A	<0.01[(g)]	N/A	0.01	0.01	0.01*	Yes
			0.32	3	<0.01[(g)]	N/A	<0.01[(g)]	N/A				
			1.26	5	0.02[(h)]	N/A	0.02[(h)]	N/A				

N/A: Not applicable – only the mean values are considered for calculating MRLs in milk and eggs.
n.r.: Not reported
(*): Indicates that the MRL is set at the limit of analytical quantification.
(a): Values from EFSA 2014; new calculated values provided in brackets.
(b): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).
(c): 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).
(d): The MRL for all meat matrices was set at the default LOQ of 0.01 mg/kg (Reg. (EU) 2021/590), although the LOQ of the analytical method used in the feeding studies was 0.025 m/kg. Nevertheless, MRL exceedances are not expected because all residues were below LOQ, also at highly exaggerated feeding levels in the studies.
(e): Mean residue level from day 1 until day 28 (3 cows, 10 sampling days).
(f): Mean residue level from day 1 until day 28 (5 cows, 10 sampling days).
(g): Mean residue level from day 1 until day 28 (3 hens, 10 sampling days).
(h): Mean residue level from day 1 until day 28 (5 hens, 10 sampling days).

No further data are required.

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

7.3.5.1 Available data for all crops under consideration

Data/information on processing studies was reviewed during the approval of active substance boscalid and were considered acceptable.

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

Table 7.3-15: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
Enforcement residue definition: boscalid					
Rape seed, crude oil	2	1.11***	1.00		*2001/5001064* EFSA, 2014
Rape seed, meal/press cake	4	0.56	1.00		
Rape seed, refined oil	4	1.26	1.00		
Wheat, whole-meal flour	4	1.21	1.00		*2003/1000945* EFSA, 2014
Wheat, whole meal bread	4	0.81	1.00		
Wheat, white flour	4	0.34	1.00		
Wheat, bran	4	4.32	1.00		
New data					
No new data available.					

* 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.
*** Indicative processing factor, due to limited dataset (EFSA 2014)

7.3.5.2 Conclusion on processing studies

The existing processing studies and derived processing factors are considered appropriate to support the use of formulation BAS 762 02 F in oilseed rape, sunflower and wheat. No risk to consumers is expected to arise from processed commodities of the crops under assessment, which have been previously treated with the plant protection product.

zRMS comments:
No new data were submitted in the framework of this application. Data presented by Applicant in point 7.3.5 have been accepted and are sufficient to support the proposed uses.
The relevant residue for enforcement and risk assessment in processed commodities is therefore expected to be the same as for primary crops.
No additional data are required.

7.3.6 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/have been submitted and are summarized hereafter.

7.3.6.1 Field rotational crop studies (KCA 6.6.2)

The GAPs of the uses under consideration are with maximum 2 applications of 200 g a.s./ha (boscalid) below the corresponding registered critical EU GAPs with 2 applications of 267 g a.s./ha each (EFSA, 2014). Using the risk envelope approach, it is proposed that the assessments conducted for the EU registration of boscalid and the recent Article 12 MRL evaluation will cover the proposed use of BAS 762 02 F in oilseed rape, sunflower and wheat. Thus, no further consideration regarding field rotational crop studies is needed in context of this submission, nevertheless, for sake of completeness, information related to this topic is provided below.

Available data

No new data submitted in the framework of this application.

Besides the confined rotational crop study reported in chapter 7.2.2, two rotational crop field trials were evaluated in the framework of the peer review (Germany, 2002; EFSA, 2014). Furthermore, a number of field rotational crop studies have been performed in the US and the EU to provide a broader perspective on residue levels found in rotational crop studies conducted under natural conditions. They were already evaluated by EFSA in the context of the Article 12 review (EFSA, 2014). Application rates supported in the framework of the MRL review ranged between 0.25 and 2.15 kg a.s./ha. The maximum seasonal application rate foreseen for product BAS 762 02 F is 2 x 0.200 kg a.s./ha (boscalid) and therefore in the lower part of the range, which has already been considered by EFSA.

Additional studies for residues in succeeding crops have been submitted in the frame of the Annex I renewal process and are currently under evaluation in the peer review process (EFSA evaluation pending). All relevant studies are summarized in the table below.

Table 7.3-16: Summary of available studies in field rotational crops

Primary crop	Rate (kg a.s./ha)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
EU data					
1st year: Lettuce & green beans 2nd year: Carrots & cauliflower	Total: 2.1 2x 0.3, 3x 0.5 Total: 1.7 3x 0.3, 2x 0.4	Cereals	Spring wheat (plant without root, straw, grain)	365	*2000/1014853*, *2001/1000989*-amendment Germany, 2002; EFSA, 2014
Winter rape	1x 0.5	Cereals	Winter wheat (straw, grain)	365	
Bare soil application	Total: 2.04 1× 0.8, 2× 0.62	Cereals	Wheat	14±1	*2002/5001341*, EFSA, 2014 (FAO, 2010)
			Corn, field		
			Corn, sweet		
			Sorghum, grain		
			Rice		
		Oilseeds and pulses	Soya bean		
	Total: 2.04	Fodder crops	Grasses	14±1	*2002/5002063*,

Primary crop	Rate (kg a.s./ha)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
Bare soil application	1x 0.8, 2x 0.62		Alfalfa		EFSA, 2014
			Clover		
strawberry	Total: 2.04 5x 0.42	Cereals	Wheat	14, 30, and 45±1	*2001/5000966* EFSA, 2014
		Leafy vegetables and Brassicas	Cabbage		
		Root and Tuber	Radish		
Bare soil application	Total: 2.04 1x 0.8, 2x 0.62	Oilseeds and pulses	Peas	14±1	*2001/5003311* EFSA, 2014
			Beans		
Bare soil application	Total: 2.04 1x 0.8, 2x 0.62	Root and Tuber	Sugar beets	14±1	*2002/5004273* EFSA, 2014
			Garden beets		
			Turnips		
Bare soil application	1x 2.1	Root and Tuber	Potato	29 ± 1	*2003/1001358* EFSA, 2014
Bare soil application	1x 2.1	Root and Tuber	Carrot	30 ± 1	*2008/1036949* EFSA, 2014

Primary crop	Rate (kg a.s./ha)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)	Reference / Remarks
New data submitted in context of renewal process (already included in publicly available draft RAR)					
Bare soil application	1x 2.1	Fruits and fruiting vegetables	Zucchini (fruit)	30±1	*2015/1117845*
			Cucumber (fruit)		
			Tomato (fruit)		
		Leafy vegetables and Brassicas	Lettuce (leaves)		
Boscalid-containing aged soil, treated over three years	1.8; 0.75; 1.8	Cereals	Wheat (whole plant, grain, straw)	1	*2009/1069175*
		Root and Tuber	Radish (roots, leaves)	1	
		Leafy vegetables and Brassicas	Spinach (leaves)	15	
New data					
No new data available.					

GS not available

Conclusion on rotational crops studies

Boscalid is known to be persistent in soil. It is possible that boscalid residues are found not only in target crops but also in succeeding crops. These should be considered when setting MRLs. During Article 12 review, EFSA performed an estimate whether or not a significant uptake of boscalid residues from the soil is expected which would contribute to the residue levels for the annual crops under consideration (EFSA, 2014). Where a significant residue uptake could not be excluded, the MRL proposal presented by EFSA took into account the additional residue via soil uptake. This approach was pursued by the European Commission with the current EU MRLs (Reg. (EU) ~~2016/156~~ 2021/590) and is supported by the data presented. The MRLs derived using this approach were taken into account for the risk assessments conducted within this dossier (see chapter 7.3.8). Taking this and the relatively low application rate into account it can be concluded that specific plant-back restrictions related to the use of BAS 762 02 F are not required, provided that the product is used according to GAP.

zRMS comments:

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

Crops under evaluation are expected to be grown in rotation. In EFSA Journal 2014;12(7):3799 it is stated that according to the soil degradation studies evaluated in the framework of the peer review, the DT_{90} value of boscalid is expected to exceed one year, which is higher than the trigger value of 100 days (EC, 2008). According to the European guidelines on rotational crops (EC, 1997b), further investigation of residues in rotational crops is therefore relevant. Moreover, as the DT_{90} value exceeds one year, boscalid is likely to accumulate in soils treated for several consecutive years and particular attention has to be paid to the plateau concentration expected in soil after several years of applications.

Evaluator agrees with conclusions on rotational crops studies presented by Applicant in point 7.3.6. It should be noted that the critical GAPs of the uses under consideration are with two applications of 200 g boscalid/ha below the critical EU GAPs with 2 applications of 350 g a.s./ha. Using the risk envelope approach, it is proposed that the assessments conducted for the EU registration of boscalid will cover the proposed uses of BAS 762 02 F / Revydas in wheat, sunflower and oilseed rape as well. Furthermore the derived MRLs by EFSA were implemented by the European Commission with the in force regulation: Reg (EU) 2021/590. The assessment of EFSA is still applicable in context of this registration report BAS 762 02 F / Revydas. Therefore specific plant-back restrictions related to the use of BAS 762 02 F / Revydas are not required, provided that the product is used according to GAP.

Additional studies for residues in succeeding crops have been submitted in the frame of the Annex I renewal process and are currently under evaluation in the peer review process (EFSA conclusion pending).
No additional data are required.

7.3.7 Other / special studies (KCA 6.10, KCA 6.10.1)

The available data for the active substance sufficiently addresses aspects of the residue situation that might arise from the use of BAS 762 02 F. Therefore, other special studies are not needed.
In respect to honey, an MRL application for boscalid residues in honey has been submitted in the past, for which EFSA's reasoned opinion has been published. The proposed MRL (0.15 mg/kg) is based on oilseed rape honey residue data (BASF DocIDs *2006/1002522*, *2018/1192746* (Amendment), *2004/1006463*, *2004/1006464*), using oilseed rape as surrogate crop for all melliferous crops with boscalid registrations. The proposed MRL also covers boscalid residues found in EU pesticide monitoring programmes between 2013 and 2017 (EFSA, 2019).

7.3.8 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 Table 7.1-2). For this assessment, an ADI (Acceptable Daily Intake) of 0.04 mg/kg/bw-day was used for the chronic dietary assessment. As an ARfD was not deemed necessary, the conduction of an acute risk assessment is not relevant.

7.3.8.1 Input values for the consumer risk assessment

Assessments of the potential chronic dietary consumer risk resulting from exposure to residues of boscalid (BAS 510 F) were performed using the EFSA Pesticide Residues Intake Model (PRIMo) rev. 3.1. The (unrefined) risk assessment (TMDI) was based on the current EU MRLs laid down in Regulation (EC) ~~2016/156~~ 2021/590. ~~In case a new MRL has was proposed in the meantime (e.g. confirmatory MRL dossier (2018)), the newly proposed value was considered.~~ Additionally, as a more refined assessment is required (IEDI), STMRs taken from the corresponding EFSA reasoned opinions, instead of the MRLs, are included in the assessment, considering the combined assessment of primary uses and uptake of residues from previously treated soil.
The PRIMo 3.1 xls-spreadsheets used are attached to this submission to facilitate evaluation (TMDI: BASF DocID 2021/2001884 and IEDI: BASF DocID 2021/2001885).

Table 7.3-17: Input values for the consumer risk assessment

Commodity	Chronic risk assessment (IEDI)	
	Input value (mg/kg)	**Comment MRL – Reg. (EU) 2021/590**
Risk assessment residue definition: boscalid (values in brackets are based on calculations with residue values from Table 7.3-9, adjusted, in case needed, with the potential uptake of rotational residues (EFSA Journal 2014;12(7):3799))		
Citrus fruits	0.05	Median Residue (CXL)
Tree nuts except pistachios	0.05*	EU MRL
Pistachios	0.27	Median residue (EFSA, 2014)
Pome fruits, except apples, pears, quinces	0.01*	EU MRL
Apples, pears, quinces	0.42	Median residue (EFSA, 2014)
Stone fruits, except apricots, cherries, peaches, plums	0.01*	EU MRL
Apricots	0.77	Median residue (EFSA, 2014)
Cherries (sweet)	1.51	Median residue (EFSA, 2014)
Peaches	0.77	Median residue (EFSA, 2014)
Plums	0.29	Median residue (EFSA, 2014)
Table and wine grapes	1.42	Median residue (EFSA, 2014)
Strawberries	1.90	Median residue (EFSA, 2014)

Commodity	Chronic risk assessment (IEDI)	
	Input value (mg/kg)	**Comment MRL – Reg. (EU) 2021/590**
Risk assessment residue definition: boscalid (values in brackets are based on calculations with residue values from Table 7.3-9, adjusted, in case needed, with the potential uptake of rotational residues (EFSA Journal 2014;12(7):3799))		
Cane fruits	2.47	Median residue (EFSA, 2014)
Other small fruit and berries, except rose hips, mulberries and elderberries	3.60	Median residue (EFSA, 2014)
Rose hips, mulberries and elderberries	2.60	Median residue (EFSA, 2014)
Miscellaneous fruits with edible peel	0.01*	EU MRL
Miscellaneous fruits with inedible peel, small, except kiwi	0.01*	EU MRL
Kiwi fruits (green, red, yellow)	0.08	Median residue × PF (EFSA, 2014)
Miscellaneous fruits with inedible peel, large except bananas and granate apples/pomegranates	0.01*	EU MRL
Bananas	0.05	Median residue (EFSA, 2014)
Granate apples/pomegranates	0.50	Median residue (EFSA, 2020)
Potatoes	0.1	Median residue (EFSA, 2014)
Tropical root and tuber vegetables except sweet potatoes, yams, arrowroots	2	EU MRL
Sweet potatoes, yams, arrowroots	0.1	Median residue (EFSA, 2014)
Beetroot	0.38	Median residue (EFSA, 2014)
Carrots, horseradish	0.24	Median residue (EFSA, 2014)
Celeriac, turnip rooted celeries	0.39	Median residue (EFSA, 2014)
Jerusalem artichokes	2	EU MRL
Parsnips, parsley root, salsify, turnips	0.14	Median residue (EFSA, 2014)
Radishes	0.33	Median residue (EFSA, 2014)
Other root and tuber vegetables: swedes/rutabaga, others	2	EU MRL
Garlic, onions, shallots	0.20	Median residue (EFSA, 2014)
Spring onions/green onions and welsh onions	2.30	Median residue (EFSA, 2014)
Bulb vegetables, others	0.5	EU MRL
Tomatoes, aubergines (egg plants)	0.40	Median residue (EFSA, 2014)
Sweet peppers/bell peppers	0.56	Median residue (EFSA, 2014)
Okra/lady finger, other Solanaceae	3	EU MRL
Cucurbits with edible peel	0.73	Median residue (EFSA, 2014)
Cucurbits with inedible peel	0.40	Median residue (EFSA, 2014)
Sweet corn	0.05	EU MRL
Other fruiting vegetables	0.9	EU MRL
Broccoli	1.55	Median residue (EFSA, 2014)
Cauliflower	1.55	Median residue (EFSA, 2014)
Other flowering brassica	5	EU MRL
Brussels sprouts	0.30	Median residue (EFSA, 2014)
Head cabbage	1.10	Median residue (EFSA, 2014)
Other head brassica	5	EU MRL

Commodity	Chronic risk assessment (IEDI)	
	Input value (mg/kg)	**Comment MRL – Reg. (EU) 2021/590**
Risk assessment residue definition: boscalid (values in brackets are based on calculations with residue values from Table 7.3-9, adjusted, in case needed, with the potential uptake of rotational residues (EFSA Journal 2014;12(7):3799))		
Chinese cabbage	1.10	Median residue (EFSA, 2014)
Kale	1.10	Median residue (EFSA, 2014)
Other leafy brassica	9	EU MRL
Kohlrabi	1.38	STMR related to the MRL (8 mg/kg) proposed within the confirmatory MRL dossier 2018 (Current EU MRL: 5 mg/kg, STMR 0.08 mg/kg (EFSA, 2014))
Lettuce and salad plants	5.60	Median residue (EFSA, 2014) UK model: used for beansprouts
Spinaches	5.60	Median residue (EFSA, 2014)
Purslane	5.60	STMR related to the MRL (50 mg/kg) proposed within the confirmatory MRL dossier 2018 (Current EU MRL: 0.9 mg/kg, STMR 0.05 mg/kg)
Beet leaves (chard)	5.60	STMR related to the MRL (50 mg/kg) proposed within the confirmatory MRL dossier 2018 (Current EU MRL: 30 mg/kg, no STMR given (ESA, 2014))
Other spinach and similar	5.60	STMR related to the MRL (50 mg/kg) proposed within the confirmatory MRL dossier 2018 (Current EU MRL: 0.9 mg/kg, no STMR given (ESA, 2014))
Vine leaves (grape leaves)	0.01*	EU MRL
Water cress	0.01*	EU MRL
Witloofs/Belgian endives	1.16	Median residue (EFSA, 2014)
Herbs and edible flowers, except basil	5.60	Median residue (EFSA, 2014)
Basil	14.5	Median residue (EFSA, 2014)
Beans (with pods)	1.28	STMR related to the MRL (6 mg/kg) proposed within the Annex I renewal (Current EU MRL: 5 mg/kg, STMR 0.66 mg/kg (EFSA, 2015))
Beans (without pods)	0.11	Median residue (EFSA, 2014)
Peas (with pods)	1.28	STMR related to the MRL (6 mg/kg) proposed within the Annex I renewal (Current EU MRL: 5 mg/kg, STMR 0.66 mg/kg (EFSA, 2015))
Peas (without pods)	0.11	Median residue (EFSA, 2014)
Lentils (fresh)	3	EU MRL
Other legume vegetables	0.06	EU MRL
Asparagus	0.10	Median residue (EFSA, 2014)
Cardoons	0.9	EU MRL
Celeries	2.25	STMR related to the MRL (20 mg/kg) proposed within the confirmatory MRL dossier 2018 (Current EU MRL: 9 mg/kg, STMR 0.05 mg/kg (EFSA, 2014))

Commodity	Chronic risk assessment (IEDI)	
	Input value (mg/kg)	**Comment MRL – Reg. (EU) 2021/590**
Risk assessment residue definition: boscalid (values in brackets are based on calculations with residue values from Table 7.3-9, adjusted, in case needed, with the potential uptake of rotational residues (EFSA Journal 2014;12(7):3799))		
Florence fennels	2.25	STMR related to the MRL (20 mg/kg) proposed within the confirmatory MRL dossier 2018 (Current EU MRL: 9 mg/kg, STMR 0.05 mg/kg (EFSA, 2014))
Globe artichokes	1.23	Median residue (EFSA, 2014)
Leek	2.35	Median residue (EFSA, 2014)
Rhubarb	0.9	EU MRL
Bamboo shoots	0.01*	EU MRL
Palm hearts	0.01*	EU MRL
Other stem vegetables	0.5	EU MRL
Fungi	0.01*	EU MRL
Algae	0.01*	EU MRL
Beans	0.13	Median residue (EFSA, 2014)
Lentils	0.13	Median residue (EFSA, 2014)
Peas	0.13	Median residue (EFSA, 2014)
Lupins	3	EU MRL
Other pulses	3	EU MRL
Linseeds	0.10	Median residue (EFSA, 2014)
Peanuts/groundnuts	0.10	Median residue (EFSA, 2014)
Poppy seeds	0.10	Median residue (EFSA, 2014)
Sesame seed	1	EU MRL
Sunflower seed	0.16 (0.02)	Median residue (EFSA, 2014) (Median residue in this submission)
Rape seed /canola seeds	0.15 (0.03)	Median residue (EFSA, 2014) (Median residue in this submission)
Soya beans	0.10	Median residue (EFSA, 2014)
Mustard seed	0.10	Median residue (EFSA, 2014)
Cotton seed	1	EU MRL
Pumpkin seeds	1	EU MRL
Safflower	1	EU MRL
Borage seeds	0.10	Median residue (EFSA, 2014)
Gold of pleasure seeds	0.10	Median residue (EFSA, 2014)
Hemp seed	1	EU MRL
Castor beans	1	EU MRL
Other oilseeds	0.06	EU MRL
Oil fruits	0.01*	EU MRL
Cereals, except barley, oats, wheat, rye grain	0.15	EU MRL
Barley	1.07	Median residue (EFSA, 2014)
Oats	1.07	Median residue (EFSA, 2014)

Commodity	Chronic risk assessment (IEDI)	
	Input value (mg/kg)	**Comment MRL – Reg. (EU) 2021/590**
Risk assessment residue definition: boscalid (values in brackets are based on calculations with residue values from Table 7.3-9, adjusted, in case needed, with the potential uptake of rotational residues (EFSA Journal 2014;12(7):3799))		
Wheat	~~0.17~~ (0.06)	~~Median residue (EFSA, 2014)~~ (Median residue in this submission 0.01 + Median residue in rotational crop, EFSA 2014 0.05)
Rye	0.17	Median residue (EFSA, 2014)
Teas	0.01*	EU MRL
Coffee beans	0.05*	EU MRL
Herbal infusions (from flowers)	0.9	EU MRL
Herbal infusions (from leaves and herbs)	0.9	EU MRL
Herbal infusions (roots)	0.95	Median residue (EFSA, 2014)
Herbal infusions (any other parts of the plant)	0.01*	EU MRL
Cocoa beans	0.01*	EU MRL
Carobs/Saint John's breads)	0.01*	EU MRL
Hops	24.5	Median residue (EFSA, 2014)
Seed spices	0.9	EU MRL
Fruit spices	0.9	EU MRL
Bark spices	0.9	EU MRL
Root and rhizome spices except horseradish	0.4	EU MRL
Horseradish, root spices	2	EU MRL
Spices (bud, flower stigma, aril)	0.9	EU MRL
Sugar beet roots	0.05	Median residue (EFSA, 2014)
Sugar canes	7	EU MRL
Chicory roots	0.4	EU MRL
Other sugar plants	0.5	EU MRL
Swine, muscle	~~0.03~~ 0.01	~~MRL proposed within the Annex I renewal~~ (Current EU MRL: 0.01* mg/kg)
Swine, fat tissue	0.07	EU MRL
Swine, edible offal	0.07	EU MRL
Other swine products	0.05*	EU MRL
Bovine, muscle	~~0.03~~ 0.01	~~MRL proposed within the Annex I renewal~~ (Current EU MRL: 0.01* mg/kg)
Bovine, fat tissue	0.3	EU MRL
Bovine, edible offal	0.3	EU MRL
Other bovine products	0.05*	EU MRL
Sheep, muscle	~~0.03~~ 0.01	~~MRL proposed within the Annex I renewal~~ (Current EU MRL: 0.01* mg/kg)
Sheep, fat tissue	0.3	EU MRL
Sheep, edible offal	0.3	EU MRL

Commodity	Chronic risk assessment (IEDI)	
	Input value (mg/kg)	**Comment MRL – Reg. (EU) 2021/590**
Risk assessment residue definition: boscalid (values in brackets are based on calculations with residue values from Table 7.3-9, adjusted, in case needed, with the potential uptake of rotational residues (EFSA Journal 2014;12(7):3799))		
Other sheep products	0.05*	EU MRL
Goat, muscle	~~0.03~~ 0.2	~~MRL proposed within the Annex I renewal (~~Current EU MRL: 0.01* mg/kg~~)~~
Goat, fat tissue	0.3	EU MRL
Goat, edible offal	0.3	EU MRL
Other goat products	0.05*	EU MRL
Equine, muscle	~~0.03~~ 0.01	~~MRL proposed within the Annex I renewal (~~Current EU MRL: 0.01* mg/kg~~)~~
Equine, fat tissue	0.3	EU MRL
Equine, edible offal	0.3	EU MRL
Other equine products	0.05*	EU MRL
Poultry, muscle	~~0.03~~ 0.01	~~MRL proposed within the Annex I renewal (~~Current EU MRL: 0.01* mg/kg~~)~~
Poultry, fat tissue	~~0.2~~ 0.08	~~Proposed MRL (confirmatory MRL dossier 2018) (~~Current EU MRL: 0.08 mg/kg~~)~~
Poultry, edible offal	~~0.3~~ 0.15	~~MRL proposed within the Annex I renewal (~~Current EU MRL: 0.15 mg/kg~~)~~
Other poultry products	0.05*	EU MRL
Other farm animals, muscle	~~0.03~~ 0.01	~~MRL proposed within the Annex I renewal (~~Current EU MRL: 0.01* mg/kg~~)~~
Other farm animals, fat tissue	0.3	EU MRL
Other farm animals, edible offal	0.3	EU MRL
Other farm animal products, other	0.05*	EU MRL
Milk and cream	0.02	EU MRL
Birds' eggs	~~0.15~~ 0.01	~~Proposed MRL (confirmatory MRL dossier 2018) (~~Current EU MRL: 0.01* mg/kg~~)~~
Honey	0.15	~~Proposed MRL (EFSA, 2019) (~~Current EU MRL ~~0.05*~~ 0.15 mg/kg~~)~~
Amphibians and reptiles	0.01*	EU MRL
Snails	0.01*	EU MRL
Other terrestrial animal products	0.01*	EU MRL
Risk assessment residue definition: sum of boscalid and its hydroxy metabolite M510F01 (free and conjugated), expressed as boscalid		
Swine, kidney	0.05*	EU MRL
Bovine, kidney	0.2	EU MRL
Sheep, kidney	0.2	EU MRL
Goat, kidney	0.2	EU MRL
Equine, liver	0.2	EU MRL

Commodity	Chronic risk assessment (IEDI)	
	Input value (mg/kg)	Comment MRL – Reg. (EU) 2021/590
Risk assessment residue definition: boscalid (values in brackets are based on calculations with residue values from Table 7.3-9, adjusted, in case needed, with the potential uptake of rotational residues (EFSA Journal 2014;12(7):3799))		
Equine, kidney	0.2	EU MRL
Poultry, kidney	0.05*	EU MRL
Poultry, liver	~~0.3~~ 0.15	~~MRL proposed within the Annex I renewal (~~Current EU MRL: 0.15 mg/kg~~)~~
Other farm animals, liver	0.2	EU MRL
Other farm animals, kidney	0.2	EU MRL
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	0.05*	EU MRL
Bovine, liver	0.2	EU MRL
Sheep, liver	0.2	EU MRL
Goat, liver	0.2	EU MRL

(*) Indicates lower limit of analytical determination

7.3.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Taking into account residues in food commodities of plant and animal origin, the TMDI / IEDI calculation was performed with the current EFSA model (version 3.1) using an ADI of 0.04 mg/kg bw/day and input values as listed in table above.

A long-term consumer intake concern was not identified for any of the European diets incorporated in the EFSA PRIMo model. The total chronic intake calculated accounted for 69% of the ADI (NL toddler). An acute consumer risk assessment was not performed because an ARfD is not set for boscalid.

Table 7.3-18: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo 3.1	~~400~~ 398% (NL toddler), highest contributing commodity: spinaches (90%)
IEDI (% ADI) according to EFSA PRIMo 3.1	69% (NL toddler), highest contributing commodity: apples (11%)
IESTI (% ARfD) according to EFSA PRIMo 3.1*	Not applicable, as no ARfD was allocated
NTMDI (% ADI) **	Not necessary
NEDI (% ADI)**	Not necessary
NESTI (% ARfD) **	Not necessary

* include raw and processed commodities if both values are required for PRIMo
** if national model is available

The risk assessment presented above has been performed with the STMR values for oilseed rape, sunflower and wheat which have been derived in the recent MRL review (EFSA 2014). As the residues resulting from the use of BAS 762 02 F on oilseed rape, sunflower and wheat are below the uses already evaluated in context of MRL review, no unacceptable chronic risk for the consumer is expected.

zRMS comments:
In meantime the values of EU MRLs for boscalid were changed. The calculation of the TMDI using EFSA model (version 3.1) and all MRLs according to current Reg. (EU) No 2021/590 led to a utilisation of the ADI of 398%

with the NL toddler being the population group with the highest value. For this diet, the highest contributor is spinaches with 90% of the ADI.

The refined assessment of chronic risk is required as TMDI calculations exceeded 100% of the ADI. IEDI calculation has been performed with the STMRs values taken from the corresponding EFSA reasoned opinions, instead of the MRLs, are included in the assessment, considering the combined assessment of primary uses and uptake of residues from previously treated soil. The input values are presented in Table 7.3 17, corrected by zRMS according to the current MRLs values (Reg. (EU) 2021/590).

The total chronic intake calculated accounted for 69% of the ADI (NL toddler) with apples (11%) as highest contributing commodity. Therefore the intended uses will not result in a consumer chronic exposure exceeding the ADI.
Updated extensive calculation sheets are presented in Appendix 3.
Since the setting of an ARfD was not deemed necessary for boscalid, no acute consumer risk assessment was performed.
The proposed uses of boscalid in the product BAS 762 02 F / Revydas do not represent unacceptable chronic and acute risks for the consumer.
No further studies are required to support the proposed uses.

7.4 Active substance 3

Not relevant.

7.5 Combined exposure and risk assessment

From a scientific point of view, it is regarded necessary to take into account potential combination effects. However, the evaluation of cumulative or synergistic effects as requested by Art. 4 (3b) of Regulation (EC) No. 1107/2009 should only be performed when harmonised "scientific methods accepted by the Authority to assess such effects are available."
Currently, no EU-harmonized guidance is available on the risk assessment of combined exposure to multiple active substances; this approach is not mandatory at EU level.

7.5.1 Acute consumer risk assessment from combined exposure

~~Triazole alanine and Triazole lactic acid share the same residue definition a combined risk assessment has been performed.~~

A combined risk assessment has been performed for parent mefentrifluconazole and the triazole derivative metabolites (TDMs: 1,2,4-Triazole, Triazole alanine, Triazole acetic acid and Triazole lactic acid).

In the absence of agreed guidance on estimating combined acute exposure, an indicative Hazard Index (HI) can be derived in order to show specifically for the intended use, that the combined exposure from parent BAS 750 F and the triazole derivative metabolites (TDMs) is very low. For the present estimation, dose-addition of parent BAS 750 F and the TDMs is assumed. Such an approach most likely results in an over-estimating of the exposure and risk, i.e. for cases where BAS 750 F and the TDMs differ in phenomenological effects or mode(s)/mechanisms of action. Therefore, at this stage this assessment can only be considered indicative.
Briefly, the Hazard Quotient (HQ) is calculated for BAS 750 F and the TDMs. The HQ is defined as the acute exposure (IESTI) divided by the acute toxicological reference value (ARfD). Summation of these HQ (irrespective of having in fact a common toxicological target) yields the (indicative) Hazard Index for the intended use BAS 762 02 F in sunflower, rape seeds/canola seeds and wheat. A HI <1 indicates absence of a health concern even if dose-addition of active ingredients is assumed.

Table 7.5-1: Indicative acute consumer risk assessment due to combined exposure

Crop	Active Ingredient	HQ (based on IESTI according to EFSA PRIMo)
Sunflower	Mefentrifluconazole (BAS 750 F)	0.0002 (0.00003/0.15)
	1,2,4-Triazole (1,2,4-T)	0.0020 (0.0002/0.1)
	Triazole alanine (TA)	0.0110 (0.0033/0.3)
	Triazole acetic acid (TAA)	0.0004 (0.0004/1.0)
	Triazole lactic acid (TLA)	0.0007 (0.0002/0.3)
	Cumulative risk sunflower (HI)	**0.0143**
Rape seeds / Canola seeds	Mefentrifluconazole (BAS 750 F)	0.0001 (0.00001/0.15)
	1,2,4-Triazole (1,2,4-T)	0.0010 (0.0001/0.1)
	Triazole alanine (TA)	0.0047 (0.0014/0.3)
	Triazole acetic acid (TAA)	0.0002 (0.0002/1.0)
	Triazole lactic acid (TLA)	0.0003 (0.0001/0.3)
	Cumulative risk rape seeds / canola seeds (HI)	**0.0063**
Wheat	Mefentrifluconazole (BAS 750 F)	0.0007 (0.0001/0.15)

Crop	Active Ingredient	HQ (based on IESTI according to EFSA PRIMo)
	1,2,4-Triazole (1,2,4-T)	0.0070 (0.0007/0.1)
	Triazole alanine (TA)	0.0300 (0.0090/0.3)
	Triazole acetic acid (TAA)	0.0114 (0.0114/1.0)
	Triazole lactic acid (TLA)	0.0010 (0.0003/0.3)
	Cumulative risk wheat (HI)	**0.0501**

7.5.2 Chronic consumer risk assessment from combined exposure

The uses under consideration provide only a minor contribution to the overall chronic exposure of consumers to pesticide residues. The issue requires a more universal consideration and possibly the generic usage of monitoring data. A harmonised approach is not yet available, and currently no specific consideration is warranted in the scope of this evaluation.

Using the EFSA PRIMo model (version 3.1) the combined chronic risk for Triazole alanine and Triazole lactic acid was assessed. Calculations for estimated worst-case chronic exposure based on STMRs in target crops (sunflower, rape seeds/canola seeds and wheat) was calculated in section 7.3.8.

Briefly, the Hazard Quotient (HQ) is calculated for TA and TLA in the formulated product which are chronically toxic. For TA and TLA, the HQ of is defined as the chronic exposure (IEDI) divided by the chronic toxicological reference value (ADI). Summation of these HQ (irrespective of having in fact a common toxicological target) yields the (indicative) Hazard Index (HI) for the intended use of BAS 762 02 F in sunflower seeds, rape seeds/canola seeds and wheat grain. A HI <1 indicates absence of a health concern even if dose-addition of active ingredients is assumed.

In the following table the calculated worst-case dietary exposure (relative to the toxicological reference value) is listed for each sub-population group of the EFSA PRIMo model (version 3.1). The overview shows that even if dose-addition would be postulated (summation of the exposure values) an overall chronic exposure would not pose a chronic health concern (value well below 1.0 for all sub-population groups). Extensive calculation sheets are presented in Appendix 3.

Table 7.5-2: Assessment of combined exposure of TA and TLA as a result of the intended use of BAS 762 02 F (sunflower, rape seeds/canola seeds and wheat)

Diet	Active Ingredient	HQ (based on IEDI according to EFSA PRIMo 3.1)
DE child	Triazole alanine	0.009
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.009**
DK child	Triazole alanine	0.009
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.009**
ES child	Triazole alanine	0.010
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.010**
FR infant	Triazole alanine	0.002
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.002**
FR toddler 2 - 3 yr	Triazole alanine	0.007
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.007**
FR child 3 - 15 yr	Triazole alanine	0.010
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.011**
IT toddler	Triazole alanine	0.014
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.014**
NL toddler	Triazole alanine	0.012
	Triazole lactic acid	0.001
	Cumulative risk (HI)	**0.013**
NL child	Triazole alanine	0.011
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.012**

Table 7.5-2: Assessment of combined exposure of TA and TLA as a result of the intended use of BAS 762 02 F (sunflower, rape seeds/canola seeds and wheat)

Diet	Active Ingredient	HQ (based on IEDI according to EFSA PRIMo 3.1)
UK infant	Triazole alanine	0.005
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.006**
UK toddler	Triazole alanine	0.008
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.008**
DK adult	Triazole alanine	0.002
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.002**
ES adult	Triazole alanine	0.005
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.005**
FI adult	Triazole alanine	0.001
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.001**
FR adult	Triazole alanine	0.005
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.005**
IE adult	Triazole alanine	0.005
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.006**
IT adult	Triazole alanine	0.009
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.009**
LT adult	Triazole alanine	0.002
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.002**

Table 7.5-2: Assessment of combined exposure of TA and TLA as a result of the intended use of BAS 762 02 F (sunflower, rape seeds/canola seeds and wheat)

Diet	Active Ingredient	HQ (based on IEDI according to EFSA PRIMo 3.1)
NL general	Triazole alanine	0.006
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.006**
PL general	Triazole alanine	0.000
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.000**
PT general	Triazole alanine	0.009
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.009**
RO general	Triazole alanine	0.013
	Triazole lactic acid	0.001
	Cumulative risk (HI)	**0.013**
SE general	Triazole alanine	0.007
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.007**
UK adult	Triazole alanine	0.003
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.004**
UK vegetarian	Triazole alanine	0.004
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.004**
GEMS/Food G06	Triazole alanine	0.016
	Triazole lactic acid	0.001
	Cumulative risk (HI)	**0.016**
GEMS/Food G07	Triazole alanine	0.012
	Triazole lactic acid	0.001
	Cumulative risk (HI)	**0.012**

Table 7.5-2: Assessment of combined exposure of TA and TLA as a result of the intended use of BAS 762 02 F (sunflower, rape seeds/canola seeds and wheat)

Diet	Active Ingredient	HQ (based on IEDI according to EFSA PRIMo 3.1)
GEMS/Food G08	Triazole alanine	0.011
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.012**
GEMS/Food G10	Triazole alanine	0.010
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.010**
GEMS/Food G11	Triazole alanine	0.008
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.008**
GEMS/Food G15	Triazole alanine	0.012
	Triazole lactic acid	0.001
	Cumulative risk (HI)	**0.012**
DE general	Triazole alanine	0.004
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.004**
DE women 14 - 50 yr	Triazole alanine	0.005
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.005**
IE child	Triazole alanine	0.002
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.002**
FI 3 yr	Triazole alanine	0.003
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.003**
FI 6 yr	Triazole alanine	0.002
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.002**

Note: due to the rounding rules it may happen, that the presented HI (calculated from unrounded HQs differs slightly from the sum of rounded HQs)

7.6 References

Mefentrifluconazole

United Kingdom, 2017. Draft assessment report (DAR) prepared according to the Commission Regulation (EU) No. 1107/2009, BAS 750 F Mefentrifluconazole, April 2017

United Kingdom, 2018a. Revised Draft Assessment Report (DAR) on BAS 750 F (mefentrifluconazole) prepared by the rapporteur Member State the United Kingdom in the framework of Regulation (EC) No 1107/2009, April 2018

United Kingdom, 2018b. Triazole Derivate Metabolites, addendum – confirmatory data prepared by the rapporteur Member State, the United Kingdom in the framework of Regulation (EC) No 1107/2009, revised version of February 2018.

EFSA (European Food Safety Authority), 2018a. Conclusion on the peer review of the pesticide risk assessment of the active substance BAS 750 F (mefentrifluconazole). EFSA Journal 2018;16(7):5379. July 2018.

EFSA (European Food Safety Authority), 2018b. Peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data submitted. EFSA Journal 2018;16(7):5376. June 2018.

EFSA (European Food Safety Authority), 2020. Reasoned Opinion on the modification and setting of maximum residue levels for mefentrifluconazole in various crops. EFSA Journal 2020;18(7):6193. June 2020

Commission Regulation (EU) 2019/977 of 13 June 2019 amending Annexes II and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aclonifen, Beauveria bassiana strain PPRI 5339, Clonostachys rosea strain J1446, fenpyrazamine, mefentrifluconazole and penconazole in or on certain products. OJ L 159, 17.6.2019, p. 1–25. http://data.europa.eu/eli/reg/2019/977/oj

EC (European Commission), 2020. SANTE/2019/12752 TECHNICAL GUIDELINES ON DATA REQUIREMENTS FOR SETTING MAXIMUM RESIDUE LEVELS, COMPARABILITY OF RESIDUE TRIALS AND EXTRAPOLATION OF RESIDUE DATA ON PRODUCTS FROM PLANT AND ANIMAL ORIGIN (Repealing and replacing the existing Guidance Document SANCO 7525/VI/95 Rev. 10.3)

EC (European Commission), 2018 SANTE/10257/2017 ANNEX D052119/01 replacing Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council

Boscalid

Commission Directive 2008/44/EC of 04 April 2008 amending Council Directive 91/414/EEC to include benthiavalicarb, boscalid, carvone, fluoxastrobin, *Paecilomyces lilacinus* and prothioconazole as active substances

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

Commission Implementing Regulation (EU) No 2018/917 of 27 June 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances alpha-cypermethrin, beflubutamid, benalaxyl, benthiavalicarb, bifenazate, boscalid, bromoxynil, captan, carvone, chlorpropham, cyazofamid, desmedipham, dimethoate, dimethomorph, diquat, ethephon, ethoprophos, etoxazole, famoxadone, fenamidone, fenamiphos, flumioxazine, fluoxastrobin, folpet, foramsulfuron, formetanate, Gliocladium catenulatum strain: J1446, isoxaflutole, metalaxyl-m, methiocarb, methoxyfenozide, metribuzin, milbemectin, oxasulfuron, Paecilomyces lilacinus strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole, pymetrozine and s-metolachlor

Commission Implementing Regulation (EU) No 2019/707 of 7 May 2019 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances alpha-cypermethrin, beflubutamid, benalaxyl, benthiavalicarb, bifenazate, boscalid, bromoxynil, captan, cyazofamid, desmedipham, dimethoate, dimethomorph, diuron, ethephon, etoxazole, famoxadone, fenamiphos, flumioxazine, fluoxastrobin, folpet, foramsulfuron, formetanate, metalaxyl-m, methiocarb, metribuzin, milbemectin, Paecilomyces lilacinus strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole, s-metolachlor and tebuconazole

Commission Regulation (EU) 2016/156 of 18 January 2016 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for boscalid, clothianidin, thiamethoxam, folpet and tolclofos-methyl in or on certain products

EC (European Commission), 2020. SANTE/2019/12752 TECHNICAL GUIDELINES ON DATA REQUIREMENTS FOR SETTING MAXIMUM RESIDUE LEVELS, COMPARABILITY OF RESIDUE TRIALS AND EXTRAPOLATION OF RESIDUE DATA ON PRODUCTS FROM PLANT AND ANIMAL ORIGIN (Repealing and replacing the existing Guidance Document SANCO 7525/VI/95 Rev. 10.3)

EC (European Commission), 2018 SANTE/10257/2017 ANNEX D052119/01 replacing Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council

EC (European Commission), 2008. Review report for the active substance boscalid. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 22 January 2008 in view of the inclusion of boscalid in Annex I of Council Directive 91/414/EEC. SANCO/3919/2007-rev.5, 21 January 2008.

EFSA (European Food Safety Authority), 2010. Scientific and technical support for preparing a EU position in the 42nd Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2010;8(11):1560. [51 pp.]. doi:10.2903/j.efsa.2010.1560.

EFSA (European Food Safety Authority), 2011. Scientific support for preparing an EU position in the 43rd Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2011;9(9):2360. [123 pp.] doi:10.2903/j.efsa.2011.2360.

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

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

EFSA (European Food Safety Authority), 2020. Reasoned opinion on the modifcation of the existing maximum residue level for boscalid in pomegranates. EFSA Journal 2020;18(9):6236, 22 pp. https://doi.org/10.2903/j.efsa.2020.6236

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

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

Germany, 2002. Draft assessment report on the active substance boscalid prepared by the rapporteur Member State Germany in the framework of Council Directive 91/414/EEC, November 2002.

Germany, 2006. Addendum to the draft assessment report on the active substance boscalid prepared by the rapporteur Member State Germany in the framework of Council Directive 91/414/EEC, May 2006.

Slovakia, 2018. Draft Renewal Assessment Report prepared according to the Commission Regulation (EU) N° 1107/2009, March 2019.

EC (European Commission), 2020. SANTE/2019/12752 TECHNICAL GUIDELINES ON DATA REQUIREMENTS FOR SETTING MAXIMUM RESIDUE LEVELS, COMPARABILITY OF RESIDUE TRIALS AND EXTRAPOLATION OF RESIDUE DATA ON PRODUCTS FROM PLANT AND ANIMAL ORIGIN (Repealing and replacing the existing Guidance Document SANCO 7525/VI/95 Rev. 10.3)

EC (European Commission), 2018 SANTE/10257/2017 ANNEX D052119/01 replacing Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.2.1/1	XXX, D.	2017	Additional investigations of the metabolism of 14C-BAS 510 F in beans 2017/1143721 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCA 6.2.2/1	XXX, C., XXX, J.	2019	The Metabolism of [14C-pyridin]- BAS 510 F (Reg. No. 300355) in Laying Hens 2019/1077444 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	Yes	BASF
KCA 6.2.2/2	XXX, N., XXX, J.	2019	Further investigation of metabolite M510F65 (identified in hen metabolism study 773275) 2019/1075236 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	Yes	BASF
KCA 6.3.1/1	XXX, H.	2019	Study on the residue behaviour of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) in oilseed rape after application of BAS 762 00 F under field conditions in Germany, The Netherlands, Denmark, Northern and Southern France, Greece, Italy and 2019/1016882 Agro-Check Dr. Teresiak & XXX GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	BASF
KCA 6.3.1/2	XXX, H.	2020	Study on the residue behaviour of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) in oilseed rape after application of either BAS 762 02 F or BAS 762 00 F under field conditions in Northern and Southern Europe, 2019 2020/2006193 Agro-Check Dr. Teresiak & XXX GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3.1/3	XXX, H.	2021	Final Report- Amendment No. 1 Study on the residue behaviour of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) in oilseed rape after application of either BAS 762 02 F or BAS 762 00 F under field conditions in Northern and Southern Europe, 2019 2021/2001354 Agro-Check Dr. Teresiak & XXX GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	BASF
KCA 6.3.2/1	XXX, O.	2019	Study on the residue behaviour of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) on sunflower after treatment with BAS 762 00 F under field conditions in Northern and Southern Europe, season 2018 2018/1205796 Agricultura y Ensayo S.L., Alcala de Guadaira, Spain yes Unpublished	No	BASF
KCA 6.3.2/2	XXX, O.	2020	Study on the residue behaviour of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) on sunflower after treatment with BAS 762 00 F or BAS 762 02 F under field conditions in Northern and Southern Europe, season 2019 2019/2075093 Agricultura y Ensayo S.L., Alcala de Guadaira, Spain yes Unpublished	No	BASF
KCA 6.3.2/3	XXX, O.	2020	Amendment No. 1: Study on the residue behaviour of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) on sunflower after treatment with BAS 762 00 F or BAS 762 02 F under field conditions in Northern and Southern Europe, season 2019 2020/2108977 Agricultura y Ensayo S.L., Alcala de Guadaira, Spain yes Unpublished	No	BASF
KCA 6.3.3/1	XXX, H.	2019	Study on the residue behaviour of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) in wheat after application of either BAS 762 00 F, BAS 750 01 F or BAS 549 02 F under field conditions in Germany, Poland, Southern France, Spain, The Netherla 2019/1016888 Agro-Check Dr. Teresiak & XXX GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.10	XXX, M.	2021	Determination of residues of BAS 750 F (Mefentrifluconazole) in oilseed rape and rapeseed honey (unripe) after one application of BAS 750 05 F under simi-field conditions in Germany, 2018 BASF DocID 2020/2109990 yes Unpublished	No	BASF
KCA 6.10	XXX, M.	2021	Amendment N°1 to final report Determination of residues of BAS 750 F (Mefentrifluconazole) in oilseed rape and rapeseed honey (unripe) after one application of BAS 750 05 F under simi-field conditions in Germany, 2018 BASF DocID 2021/2038566 yes Unpublished	No	BASF
KCA 6.9/1	Anonymous	2021	BAS 750 F_EFSA_PRIMo_rev3.1_TMDI 2021/2001331 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCA 6.9/2	Anonymous	2021	BAS 750 F_EFSA_PRIMo_rev3.1_IEDI 2021/2001332 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCA 6.9/3	Anonymous	2021	BAS 750 F_EFSA_PRIMo_rev3.1_IESTI_core C 2021/2001333 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCA 6.9/4	Anonymous	2021	TA_EFSA_PRIMo_rev3.1_IEDI_IESTI_core C 2021/2001334 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.9/5	Anonymous	2021	TAA_EFSA_PRIMo_rev3.1_IEDI_IESTI_core C 2021/2001335 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCA 6.9/6	Anonymous	2021	TLA_EFSA_PRIMo_rev3.1_IEDI_IESTI_core C 2021/2001336 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCA 6.9/7	Anonymous	2021	124T_EFSA_PRIMo_rev3.1_IED_IESTI_core C 2021/2001337 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCA 6.9/8	Anonymous	2021	BAS 510 F_EFSA_PRIMo_rev3.1_TMD 2021/2001884 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCA 6.9/9	Anonymous	2021	BAS 510 F_EFSA_PRIMo_rev3.1_IED 2021/2001885 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCA 6.9/10	XXX, A.	2021	Supplemental document - 1,2,4-T, TA, TAA, TLA - Derivation of input values for the livestock dietary burden and the risk assessments for formulation BAS 762 02 F 2021/2001338 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF

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

Please refer to Part A

List of data submitted by the applicant and not relied on

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

List of data relied on 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	Vertebrate study Y/N	Owner
-	-	-	-	-	-

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Mefentrifloconazole

A 2.1.1 Stability of residues

No new data submitted in the framework of this application. In the context of the Annex I inclusion process one storage stability study in plant products and two storage stability studies in animal products have been submitted by the applicant. These studies are summarized in chapter 7.2. For a detailed assessment refer to the EFSA conclusion (2018a) and the DAR (UK, 2018).

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

No new data submitted in the framework of this application. In the context of the Annex I inclusion process three plant metabolism studies (grapes, soybeans, wheat), one metabolism study in rotational crops (spinach, white radish, wheat), one hydrolysis study and two animal metabolism studies (goat, hen) have been submitted by the applicant. These studies are summarized in chapter 7.2. For a detailed assessment refer to the EFSA conclusion (2018a) and the DAR (UK, 2018).

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Oilseed rape

Table A 1: 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 (EFSA, 2020)	2	0.150 kg as/ha	14	BBCH 13-75	n.a.
Intended cGAP (1*)	1	0.100 kg as/ha	-	BBCH 57-75	F

* 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 – oilseed rape - BASF DocID 2019/1016882

Comments of zRMS:

During the 2018 growing season, 8 trials in oilseed rape were conducted in different representative growing areas in Germany, The Netherlands, Denmark, Northern and Southern France, Greece, Italy and Spain to determine the residue level of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) after application of BAS 762 00 F in or on Raw Agricultural Commodities (RAC).
The trials consisted of two plots: plot 1 (control) and plot 2 (treated with BAS 762 00 F). BAS 762 00 F (100 g BAS 750 F/L, 200 g BAS 510 F/L, SC) was applied in all trials once at a single rate of 1.0 L/ha formulated product, equals to 0.100 kg a.i./ha of BAS 750 F and 0.200 kg a.i./ha of BAS 510 F on plot 2 with a water volume of 200 L/ha.
In all trials the application was made at BBCH 75.
Oilseed rape specimens were collected shortly before application (plot 1) and directly after application (plot 2) as whole plant (no roots). At BBCH 83 the specimens were sampled as pods with seeds and rest of plant without roots and at BBCH 89 as seed.
Commercial harvest was reached in all trials between 38 and 54 DALA.
All oilseed rape specimens of plot 1 and 2 were analyzed for BAS 750 F using the BASF Method L0076/09 and for BAS 510 F using the BASF Method L0076/09. Each method has a limit of quantitation of 0.010 mg/kg. The results of the average procedural recoveries in oilseed rape matrices at fortification levels between 0.010 and 2.5 mg/kg were 86.6% for BAS 750 F and 81.7% for BAS 510 F.
Further all specimens were analyzed for 1,2,4-Triazole (T), Triazolylalanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) using BASF method no. L0170/02. The method has a limit of quantitation of 0.010 mg/kg for each analyte. The mean of the concurrent recoveries was within the acceptable range of 70 - 110% for all analytes.

The residues of **BAS 750 F** analyzed in oilseed rape whole plant (no roots) specimens sampled immediately after the application ranged from 0.24 to 0.86 mg/kg.
At BBCH 83 (26-39 DALA) residues decreased to a range of < 0.010 to 0.17 mg/kg in pods with seeds specimens and to a range of < 0.010 to 0.061 mg/kg in rest of plant without roots specimens.
At BBCH 89 (38-54 DALA) seed specimens were collected and the residues of BAS 750 F were between < 0.010 and 0.011 mg/kg.
In the untreated control specimens, no residues of BAS 750 F were detected at or above the limit of quantitation (LOQ, 0.010 mg/kg).

In the analytical phase S18-04978 of this study all specimens were analysed additionally for residues of the Triazole metabolites 1,2,4-Triazole, Triazolylalanine, Triazole acetic acid and Triazole lactic.

Summary of Residues of Triazole Metabolites **after application with BAS 762 00 F** in treated Oilseed Rape Specimens:

Portion analysed	Plot No.	DALA [1]	Growth stage (BBCH)	n [2]	Residues of 1,2,4-Triazole [3] [mg/kg]	Triazolylalanine [3] [mg/kg]	Triazole Lactic Acid [3] [mg/kg]	Triazole Acetic Acid [3] [mg/kg]
Whole Plant (No Roots)	2	0	75	8	< 0.010	0.020 - 0.27	< 0.010 - 0.031	< 0.010 - 0.014
Pods with Seeds		26 - 39	83	8	< 0.010	0.053 - 0.63	0.010 - 0.070	< 0.010 - 0.039
Rest of Plant without Roots				8	< 0.010	< 0.010 - 0.038	< 0.010	< 0.010
Seed		38 - 54	89	8	< 0.010	0.037 – 1.4	< 0.010 - 0.034	< 0.010 – 0.011

1) DALA = Days after last Application
2) n = number of samples
3) The limit of detection (LOD) is 0.003 mg/kg and the limit of quantitation (LOQ) is 0.010 mg/kg)

Summary of Residues of Triazole Metabolites in **untreated** Oilseed Rape Specimens:

Portion analysed	Plot No.	DALA [1]	Growth stage (BBCH)	n [2]	Residues of 1,2,4-Triazole [3] [mg/kg]	Residues of Triazolylalanine [3] [mg/kg]	Residues of Triazole Lactic Acid [3] [mg/kg]	Residues of Triazole Acetic Acid [3] [mg/kg]
Whole Plant (No Roots)	1	0 DBLA	75	8	< 0.010	0.022 - 0.27	< 0.010 - 0.017	< 0.010
Pods with Seeds		26 - 39	83	8	< 0.010	0.045 - 0.72	< 0.010 - 0.085	< 0.010 - 0.052
Rest of Plant without Roots				8	< 0.010	< 0.010 - 0.018	< 0.010	< 0.010
Seed		38 - 54	89	8	< 0.010	0.075 - 1.2	< 0.010 - 0.031	< 0.010

1) DALA = Days after last Application, DBLA = Days before last application
2) n = number of samples
3) The limit of detection (LOD) is 0.003 mg/kg and the limit of quantitation (LOQ) is 0.010 mg/kg)

The maximum storage interval from harvest until analysis was 166 days for BAS 750 F (Mefentrifluconazole). The maximum storage interval from harvest until analysis for all samples was 146 days for Triazole Metabolites. Seed samples were anaylzed within 48 days latest.
Data indicates that residues of BAS 750 F were stable during the period of frozen storage prior to analysis.

The study is acceptable.

Reference: CA 6.3.1/1

Report: Study on the residue behaviour of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) in oilseed rape after application of BAS 762 00 F under field conditions in Germany, The Netherlands, Denmark, Northern and Southern France, Greece, Italy and Spain, 2018
XXX, H. P., 2019
Report No 825503, AC/BASF/18/03
BASF DocID 2019/1016882
Authority registration No

Guideline(s): Regulation (EC) No. 1107/2009 of the European Parliament and the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
European Community Guideline 7029/VI/95 - rev.5, 22/07/97: General recommendations for the design preparation and realization of residue trials.
European Community Guideline SANCO 7525/VI/95 - Rev. 10.3, 13 June 2017: Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs.
OECD Guideline for the testing of chemicals – Crop Field Trials: OECD/OCDE 509. Adopted 7 September 2009

Deviations: No

GLP: yes
(certified by Ministry of Justice, European Affairs and Consumer Protection, Brandenburg, Germany)

Acceptability: Yes

Table A 2: Summary of recoveries (study 1 (2019/1016882), oilseed rape)

Matrix		Fortification level [mg/kg]	BAS 750 F			
			n	Mean [%]	SD [±]	RSD [%]
Oilseed rape	Whole plant*	0.010, 0.10 and 2.5	7	85.5	7.7	9.0
	Pods with seeds	0.010, 0.10 and 1.25	7	86.4	3.6	4.1
	Rest of plant**	0.010, 0.10	6	83.2	6.8	8.1
	Seed	0.010, 0.10	6	91.5	6.0	6.6
	Overall		26	86.6	6.5	7.6

* No roots
** Without roots

Table A 3: Summary of recoveries (study 1 (2019/1016882), oilseed rape)

Matrix		Fortification level [mg/kg]	1,2,4-Triazole (1,2,4-T)				Triazolylalanine (TA)				Triazole lactic acid (TLA)				Triazole acetic acid (TAA)			
			n	Mean [%]	SD [±]	RSD [%]	n	Mean [%]	SD [±]	RSD [%]	n	Mean [%]	SD [±]	RSD [%]	n	Mean [%]	SD [±]	RSD [%]
Oilseed rape	Whole plant*	0.01 and 0.10 (and 0.30, TA)	10	102	8.9	8.7	11	88.9	16	18	10	87.3	7.5	8.6	10	105	4.8	4.6
	Pods with seeds	0.01 and 0.10 (and 0.80, TA)	10	104	8.8	8.4	11	90.7	5.6	6.2	10	99.8	8.6	8.6	10	104	5.2	5.0
	Rest of plant**	0.01 and 0.10	10	89.8	12	14	10	89.3	7.7	8.7	10	89.4	4.5	5.0	10	103	1.4	1.4
	Seed	0.01 and 0.10 (and 1.5, TA)	10	102	7.8	7.7	11	91.0	15	17	10	93.2	13	14	10	100	10	10
	Overall		**40**	**99.4**	**11**	**11**	**43**	**90**	**12**	**13**	**40**	**92.4**	**10**	**9.3**	**40**	**103**	**6.2**	**6.1**

* No roots
** Without roots

Table A 4: Summary of the study 1 (2019/1016882), oilseed rape

Trial No./ Location/ EU zone/ Year	Commodity / Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)					DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 750 F	1,2,4-Triazole (1,2,4-T)	Triazolylalanine (TA)	Triazole lactic acid (TLA)	Triazole acetic acid (TAA)		
	(a)	(b)				(c)									(d)	(e)
L180106 Germany EU-North 2018	Oilseed rape SO0495 PR 46W20	1. 22.08.2017 2. 20.04.2018-14.05.2018 3. 16.07.2018	100	200	50	1 25.05.2018	BBCH 75	Whole plant (no roots)	75	0.55	<0.010	0.13	<0.010	<0.010	0	**BAS 762 00 F** SC **Mefentrifluconazole 100 g/L** Boscalid 200 g/L BASF method L0076/09 for Mefentrifluconazole and L0170/02 for Triazole Metabolites
								Pods with seeds	83	0.049	<0.010	0.63	0.058	0.025	28	
								Rest of plant without roots	83	0.061	<0.010	0.017	<0.010	<0.010	28	
								Seed	89	<0.010	<0.010	0.48	0.015	<0.010	52	
L180107 The Netherlands EU-North 2018	Oilseed rape SO0495 Temptation	1. 06.09.2017 2. 14.04.2018-15.05.2018 3. 09.07.2018	100	200	50	1 30.05.2018	BBCH 75	Whole plant (no roots)	75	0.55	<0.010	0.25	<0.010	<0.010	0	
								Pods with seeds	83	0.060	<0.010	0.59	0.070	0.023	28	
								Rest of plant without roots	83	0.036	<0.010	0.024	<0.010	<0.010	28	
								Seed	89	<0.01	<0.010	1.4	0.034	0.011	40	

Trial No./ Location/ EU zone/ Year	Commodity / Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)					DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 750 F	1,2,4-Triazole (1,2,4-T)	Triazolylalanine (TA)	Triazole lactic acid (TLA)	Triazole acetic acid (TAA)		
	(a)	(b)				(c)									(d)	(e)
L180108 Denmark EU-North 2018	Oilseed rape SO0495 Trezzor	1. 05.09.2017 2. 03.05.2018-18.05.2018 3. 19.07.2018	100	200	50	1 30.05.2018	BBCH 75	Whole plant (no roots)	75	0.24	<0.010	0.051	<0.010	<0.010	0	LOQ: 0.010 mg/kg No residues above the LOQ for BAS 750 F in any of the analysed untreated specimens. Storage time for all commodities ≤166 days (Mefentrifluconazole), ≤146 days Triazole Metabolites Samples were analysed within the proven storage stability (see chapter 7.2.1)
								Pods with seeds	83	0.054	<0.010	0.10	0.022	<0.010	30	
								Rest of plant without roots	83	0.055	<0.010	<0.010	<0.010	<0.010	30	
								Seed	89	<0.010	<0.010	0.28	0.010	<0.010	50	
L180109 France EU-North 2018	Oilseed rape SO0495 Expansion	1. 26.08.2017 2. 25.04.2018-10.05.2018 3. 02.07.2018	100	200	50	1 15.05.2018	BBCH 75	Whole plant (no roots)	75	0.59	<0.010	0.14	0.014	<0.010	0	
								Pods with seeds	83	0.052	<0.010	0.51	0.057	0.034	38	
								Rest of plant without roots	83	0.030	<0.010	<0.010	<0.010	<0.010	38	
								Seed	89	<0.010	<0.010	0.94	0.020	<0.010	48	
L180110 France EU-South 2018	Oilseed rape SO0495 Alicante	1. 23.08.2017 2. 12.04.2018-23.04.2018 3. 01.07.2018	100	200	50	1 24.05.2018	BBCH 75	Whole plant (no roots)	75	0.85	<0.010	0.27	0.031	0.014	0	
								Pods with seeds	83	<0.010	<0.010	0.56	0.062	0.039	26	
								Rest of plant without roots	83	<0.010	<0.010	0.038	<0.010	<0.010	26	
								Seed	89	<0.010	<0.010	0.61	0.023	<0.010	47	
L180111 Greece EU-South 2018	Oilseed rape SO0495 Exception	1. 21.09.2017 2. 01.04.2018-20.04.2018 3. 13.06.2018	100	200	50	1 05.05.2018	BBCH 75	Whole plant (no roots)	75	0.49	<0.010	0.020	<0.010	<0.010	0	
								Pods with seeds	83	0.061	<0.010	0.053	0.010	<0.010	27	
								Rest of plant without roots	83	0.024	<0.010	<0.010	<0.010	<0.010	27	
								Seed	89	<0.010	<0.010	0.037	<0.010	<0.010	39	
L180112 Italy EU-South 2018	Oilseed rape SO0495 DK Exclusiv	1. 30.09.2017 2. 10.04.2018-30.04.2018 3. 13.06.2018-14.06.2018	100	200	50	1 07.05.2018	BBCH 75	Whole plant (no roots)	75	0.86	<0.010	0.085	<0.010	<0.010	0	
								Pods with seeds	83	0.17	<0.010	0.18	0.020	<0.010	31	
								Rest of plant without roots	83	0.048	<0.010	<0.010	<0.010	<0.010	31	
								Seed	89	<0.010	<0.010	0.34	0.012	<0.010	38	

Trial No./ Location/ EU zone/ Year	Commodity / Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)					DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 750 F	1,2,4-Triazole (1,2,4-T)	Triazolylalanine (TA)	Triazole lactic acid (TLA)	Triazole acetic acid (TAA)		
	(a)	(b)				(c)									(d)	(e)
L180113 Spain EU-South 2018	Oilseed rape SO0495 Omega-9	1. 06.11.2017 2. 22.03.2018-16.04.2018 3. 30.05.2018	100	200	50	1 06.04.2018	BBCH 75	Whole plant (no roots)	63-75[f]	0.79	<0.010	0.033	<0.010	<0.010	0	
								Pods with seeds	83	0.052	<0.010	0.094	0.015	<0.010	39	
								Rest of plant without roots	83	0.020	<0.010	<0.010	<0.010	<0.010	39	
								Seed	89	0.011	<0.010	0.11	<0.010	<0.010	54	

_ underlined residue values were used for calculations. In case both formulations have been used in the same trial, the more critical residue value has been chosen. Also, if higher residues appeared at a later PHI, the more critical value has been chosen.

(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, underlined)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(f) Main growth stage 75

Table A 5: Summary of the study 1 (2019/1016882), oilseed rape, untreated

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)					DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 750 F	1,2,4-Triazole (1,2,4-T)	Triazolylalanine (TA)	Triazole lactic acid (TLA)	Triazole acetic acid (TAA)		
	(a)	(b)				(c)									(d)	(e)
L180106 Germany EU-North 2018	Oilseed rape SO0495 PR 46W20	1. 22.08.2017 2. 20.04.2018-14.05.2018 3. 16.07.2018	-	-	-	- Plot 1	-	Whole plant (no roots)	75	<0.010	<0.010	0.15	<0.010	<0.010	0	**BAS 762 00 F** SC **Mefentrifluconazole 100 g/L** Boscalid 200 g/L BASF method L0076/09 for Mefentrifluconazole and L0170/02 for Triazole Metabolites LOQ: 0.010 mg/kg
								Pods with seeds	83	<0.010	<0.010	0.52	0.052	0.020	28	
								Rest of plant without roots	83	<0.010	<0.010	0.015	<0.010	<0.010	28	
								Seed	89	<0.010	<0.010	0.58	0.019	<0.010	52	
L180107 The Netherlands EU-North 2018	Oilseed rape SO0495 Temptation	1. 06.09.2017 2. 14.04.2018-15.05.2018 3. 09.07.2018	-	-	-	- Plot 1	-	Whole plant (no roots)	75	<0.010	<0.010	0.27	0.013	<0.010	0	
								Pods with seeds	83	<0.010	<0.010	0.61	0.063	0.021	28	
								Rest of plant without roots	83	<0.010	<0.010	0.018	<0.010	<0.010	28	
								Seed	89	<0.010	<0.010	1.2	0.031	<0.010	40	
L180108 Denmark EU-North 2018	Oilseed rape SO0495 Trezzor	1. 05.09.2017 2. 03.05.2018-18.05.2018 3. 19.07.2018	-	-	-	- Plot 1	-	Whole plant (no roots)	75	<0.010	<0.010	0.069	<0.010	<0.010	0	
								Pods with seeds	83	<0.010	<0.010	0.14	0.024	<0.010	30	
								Rest of plant without roots	83	<0.010	<0.010	<0.010	<0.010	<0.010	30	
								Seed	89	<0.010	<0.010	0.33	0.015	<0.010	50	
L180109 France EU-North 2018	Oilseed rape SO0495 Expansion	1. 26.06.2017 2. 25.04.2018-10.05.2018 3. 02.07.2018	-	-	-	- Plot 1	-	Whole plant (no roots)	75	<0.010	<0.010	0.15	0.017	<0.010	0	
								Pods with seeds	83	<0.010	<0.010	0.72	0.085	0.052	38	
								Rest of plant without roots	83	<0.010	<0.010	<0.010	<0.010	<0.010	38	
								Seed	89	<0.010	<0.010	0.90	0.031	<0.010	48	
L180110 France EU-South 2018	Oilseed rape SO0495 Alicante	1. 23.08.2017 2. 12.04.2018-23.04.2018 3. 01.07.2018	-	-	-	- Plot 1	-	Whole plant (no roots)	75	<0.010	<0.010	0.11	0.012	<0.010	0	
								Pods with seeds	83	<0.010	<0.010	0.36	0.040	0.016	26	
								Rest of plant without roots	83	<0.010	<0.010	0.016	<0.010	<0.010	26	
								Seed	89	<0.010	<0.010	0.51	0.018	<0.010	47	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)					DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 750 F	1,2,4-Triazole (1,2,4-T)	Triazolylalanine (TA)	Triazole lactic acid (TLA)	Triazole acetic acid (TAA)		
	(a)	(b)				(c)									(d)	(e)
L180111 Greece EU-South 2018	Oilseed rape SO0495 Exception	1. 21.09.2017 2. 01.04.2018-20.04.2018 3. 13.06.2018	-	-	-	- Plot 1	-	Whole plant (no roots)	75	<0.010	<0.010	0.025	<0.010	<0.010	0	
								Pods with seeds	83	<0.010	<0.010	0.055	<0.010	<0.010	27	
								Rest of plant without roots	83	<0.010	<0.010	<0.010	<0.010	<0.010	27	
								Seed	89	<0.010	<0.010	0.075	<0.010	<0.010	39	
L180112 Italy EU-South 2018	Oilseed rape SO0495 DK Exclusiv	1. 30.09.2017 2. 10.04.2018-30.04.2018 3. 13.06.2018-14.06.2018	-	-	-	- Plot 1	-	Whole plant (no roots)	75	<0.010	<0.010	0.063	<0.010	<0.010	0	
								Pods with seeds	83	<0.010	<0.010	0.30	0.033	0.015	31	
								Rest of plant without roots	83	<0.010	<0.010	<0.010	<0.010	<0.010	31	
								Seed	89	<0.010	<0.010	0.46	0.018	<0.010	38	
L180113 Spain EU-South 2018	Oilseed rape SO0495 Omega-9	1. 06.11.2017 2. 22.03.2018-16.04.2018 3. 30.05.2018	-	-	-	- Plot 1	-	Whole plant (no roots)	63-75[f]	<0.010	<0.010	0.022	<0.010	<0.010	0	
								Pods with seeds	83	<0.010	<0.010	0.045	<0.010	<0.010	39	
								Rest of plant without roots	83	<0.010	<0.010	<0.010	<0.010	<0.010	39	
								Seed	89	<0.010	<0.010	0.092	<0.010	<0.010	54	

_ underlined residue values were used for calculations. In case both formulations have been used in the same trial, the more critical residue value has been chosen. Also, if higher residues appeared at a later PHI, the more critical value has been chosen.

(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, underlined)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(f) Main growth stage 75

A 2.1.3.1.2 Study 2 – oilseed rape - BASF DocID 2020/2006193

Comments of zRMS:	During the 2019 growing season, 8 trials in oilseed rape were conducted in different representative growing areas in Northern and Southern Europe to determine the residue level of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) after application of BAS 762 02 F or BAS 762 00 F in or on Raw Agricultural Commodities (RAC). Four trials (L190326, L190327, L190332 and L190333) consisted of three plots: plot 1 (control), plot 2 (treated with BAS 762 02 F) and plot 3 (treated with BAS 762 00 F) Four trials ((L190328, L190329, L190330 and L190331) consisted of two plots: plot 1 (control) and plot 2 (treated with BAS 762 02 F). BAS 762 02 F (100 g BAS 750 F/L, 200 g BAS 510 F/L, SC) was applied in all trials once at a single rate of 1.0 L/ha formulated product, equals to 0.100 kg a.i./ha of BAS 750 F and 0.200 kg a.i./ha of BAS 510 F on plot 2 with a spray volume of 200 L/ha. BAS 762 00 F (100 g BAS 750 F/L, 200 g BAS 510 F/L, SC) was applied in four trials once at a single rate of 1.0 L/ha formulated product, equals to 0.100 kg a.i./ha of BAS 750 F and 0.200 kg a.i./ha of BAS 510 F on plot 3 with a spray volume of 200 L/ha. In all trials the application was made at BBCH 75. Trials L190326, L190327, L190332 and L190333 Oilseed rape specimens were collected shortly before application (plot 1) and directly after application (plot 2 and plot 3) as whole plant (no roots). At BBCH 83 the specimens were sampled as pods with seeds and rest of plant without roots. At 89 BBCH oilseed rape specimens were collected as seed. Trials L190328, L190329, L190330 and L190331 Oilseed rape specimens were collected shortly before application (plot 1) and directly after application (plot 2) as whole plant (no roots). At BBCH 83 the specimens were sampled as pods with seeds and rest of plant without roots. At BBCH 89 oilseed rape specimens were collected as seed. Commercial harvest was reached in all trials between 28 and 66 DALA. All oilseed rape specimens were analyzed for BAS 750 F using the adapted BASF Method L0076/09. The method has a limit of quantitation of 0.010 mg/kg. The results of the average procedural recoveries in oilseed rape matrices at fortification levels between 0.010 and 20 mg/kg were 85.2% for BAS 750 F. Further all specimens were analyzed for 1,2,4-Triazole (T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) using the adapted BASF method no. L0170/02. The method has a limit of quantitation of 0.010 mg/kg for each analyte. The mean of the concurrent recoveries was within the acceptable range of 70 - 110% for all analytes. Plot 2 - treated with BAS 762 02 F: The residues of BAS 750 F analyzed in oilseed rape whole plant (no roots) specimens sampled immediately after the application ranged from 0.41 to 1.6 mg/kg. At BBCH 83 (22-42 DALA) residues decreased to 0.041 - 0.57 mg/kg in pods with seeds specimens and were between 0.036 and 0.32 mg/kg in rest of plant without roots specimens. In seed specimens taken at BBCH 89 (28-66 DALA) residues of BAS 750 F were between < 0.010 and 0.055 mg/kg. Plot 3 - treated with BAS 762 00 F: The residues of BAS 750 F analyzed in oilseed rape whole plant (no roots) specimens sampled immediately after the application ranged from 0.52 to 0.96 mg/kg. At BBCH 83 (22-42 DALA) residues decreased to 0.032 - 0.093 mg/kg in pods with seeds specimens and to 0.035 - 0.076 mg/kg in rest of plant without roots specimens. In seed specimens taken at BBCH 89 (31-61 DALA) residues of BAS 750 F were < 0.010 mg/kg. In the untreated control specimens, no residues of BAS 750 F were detected at or above the limit of quantitation (LOQ, 0.010 mg/kg). Summary of Residues in Treated Samples for TDMs

Sampling No.	Portion analysed		Timing: Plot	Timing: DALA[1)]	Growth stage (BBCH)	n	Range of residues: 1,2,4-Triazole (1,2,4-T) [mg/kg]	Triazole alanine (TA) [mg/kg]	Triazole acetic acid (TAA) [mg/kg]	Triazole lactic acid (TLA) [mg/kg]
Plot 2: treated twice with BAS 762 02 F										
1	Oilseed Rape	Whole Plant (No Roots)	2	0	75	8	< 0.010	< 0.010 - 0.46	< 0.010 - 0.013	< 0.010 - 0.020
2		Pods with Seeds		22 – 42	83	8	< 0.010	0.029 - 1.3	< 0.010 - 0.049	< 0.010 - 0.083
		Rest of Plant without Roots		22 – 42	83	8	< 0.010	< 0.010 - 0.11	< 0.010	< 0.010
3		Seed		28 – 66	89	8	< 0.010	0.13 - 3.8	< 0.010 - 0.056	< 0.010 - 0.21
Plot 3: treated twice with BAS 762 00 F										
1	Oilseed Rape	Whole Plant (No Roots)	3	0	75	4	< 0.010	0.088 - 0.18	< 0.010	< 0.010
2		Pods with Seeds		22 – 42	83	4	< 0.010	0.15 - 0.68	< 0.010 - 0.034	< 0.010 - 0.062
		Rest of Plant without Roots		22 – 42	83	4	< 0.010	0.024 - 0.084	< 0.010	< 0.010
3		Seed		31 – 61	89	4	< 0.010	0.31 - 0.98	< 0.010	0.021 - 0.050

[1)]: days after last application.

Summary of Residues in Untreated Samples for TDMs

Sampling No.	Portion analysed		Timing: Plot	Timing: DALA[1)]	Growth stage (BBCH)	n	Range of residues: 1,2,4-Triazole (1,2,4-T) [mg/kg]	Triazole alanine (TA) [mg/kg]	Triazole acetic acid (TAA) [mg/kg]	Triazole lactic acid (TLA) [mg/kg]
1	Oilseed Rape	Whole Plant (No Roots)	1	0 DBLA	75	8	< 0.010	< 0.010 - 0.41	< 0.010 - 0.011	< 0.010 - 0.020
2		Pods with Seeds		22 – 42	83	8	< 0.010	< 0.010 - 1.3	< 0.010 - 0.043	< 0.010 - 0.098
		Rest of Plant without Roots		22 – 42	83	8	< 0.010	< 0.010 - 0.047	< 0.010	< 0.010
3		Seed		28 – 66	89	8	< 0.010	0.019 - 3.5	< 0.010 - 0.042	< 0.010 - 0.17

[1)]: days after last application. DBLA: days before last application.

The maximum storage interval from harvest until analysis for the treated specimens is summarized below:

Analyte	Portion analyzed	Max. Storage interval [days]
BAS 750 F	Whole Plant (No Roots)	189
	Pods with Seeds	152
	Rest of Plant without Roots	158
	Seed	131
BAS 510 F	Whole Plant (No Roots)	189
	Pods with Seeds	231
	Rest of Plant without Roots	158
	Seed	211
Triazole derivative metabolites (TDMs)	Whole Plant (No Roots)	314
	Pods with Seeds	283
	Rest of Plant without Roots	283
	Seed	70

The study is acceptable.

The document BASF Doc ID 2020/2006193 is only valid in combination with document BASF Doc ID 2021/2001354.The amendment (BASF DocID 2021/2001354) was provided by Applicant. The amendment corrects the harvest dates for the trials L190327-to L190333 due to a formatting error, they were given as numerical values in the final

	report instead as dates.

Reference:	CA 6.3.1/2
Report	Study on the residue behaviour of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) in oilseed rape after application of either BAS 762 02 F or BAS 762 00 F under field conditions in Northern and Southern Europe, 2019 XXX, H. P., 2020 Report No 825504, AC/BASF/19/03 BASF DocID 2020/2006193 Authority registration No
Guideline(s):	Regulation (EC) No. 1107/2009 of the European Parliament and the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC European Community Guideline 7029/VI/95 - rev.5, 22/07/97: General recommendations for the design preparation and realization of residue trials. European Community Guideline SANCO 7525/VI/95 - Rev. 10.3, 13 June 2017: Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. OECD Guideline for the testing of chemicals – Crop Field Trials: OECD/OCDE 509. Adopted 7 September 2009
Deviations:	No
GLP:	yes (certified by Ministry of Justice, European Affairs and Consumer Protection, Brandenburg, Germany)
Acceptability:	Yes

Reference:	CA 6.3.1/3
Report	Final Report- Amendment No. 1 Study on the residue behaviour of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) in oilseed rape after application of either BAS 762 02 F or BAS 762 00 F under field conditions in Northern and Southern Europe, 2019 XXX, H. P., 2021 Report No 825504, AC/BASF/19/13 BASF DocID 2021/2001354 Authority registration No
Guideline(s):	Regulation (EC) No. 1107/2009 of the European Parliament and the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC European Community Guideline 7029/VI/95 - rev.5, 22/07/97: General recommendations for the design preparation and realization of residue trials. European Community Guideline SANCO 7525/VI/95 - Rev. 10.3, 13 June 2017: Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. OECD Guideline for the testing of chemicals – Crop Field Trials: OECD/OCDE 509. Adopted 7 September 2009
Deviations:	No

GLP:	yes (certified by Ministry of Justice, European Affairs and Consumer Protection, Brandenburg, Germany)
Acceptability:	Yes

Table A 6: Summary of recoveries (study 2 (2020/2006193), oilseed rape)

Matrix		Fortification level [mg/kg]	BAS 750 F			
			n	Mean [%]	SD [±]	RSD [%]
Oilseed rape	Whole plant*	0.010, 0.10 and 20	10	86.9	5.5	6.3
	Pods with seeds	0.010, 0.10, 1.0 and 10	9	84.2	3.7	4.5
	Rest of plant**	0.010, 0.10 and 20	7	80.2	4.9	6.1
	Seed	0.010, 0.10 and 1.0	9	88.0	9.7	11
	Overall		35	85.2	6.8	8.0

* No roots
** Without roots

Table A 7: Summary of recoveries (study 2 (2020/2006193), oilseed rape)

Matrix		Fortification level [mg/kg]	1,2,4-Triazole (1,2,4-T)				Triazolylalanine (TA)				Triazole lactic acid (TLA)				Triazole acetic acid (TAA)			
			n	Mean [%]	SD [±]	RSD [%]	n	Mean [%]	SD [±]	RSD [%]	n	Mean [%]	SD [±]	RSD [%]	n	Mean [%]	SD [±]	RSD [%]
Oilseed rape	Whole plant*	0.010, 0.10 and 1.0	9	92.7	9.7	10	9	96.7	13	13	9	95.9	10	11	9	97.3	6.2	6.3
	Pods with seeds	0.010, 0.10, 1.0 and 5.0	11	95.1	9.3	9.8	11	91.6	11	12	11	93.4	10	11	11	98.8	8.6	8.7
	Rest of plant**	0.010, 0.10 and 1.0	9	91.3	6.9	7.6	9	102	10	10	9	99.8	6.3	6.4	9	101	8.0	8.0
	Seed	0.010, 0.10, 1.0 and 5.0	18	84.1	9.4	11	18	91.0	12	13	18	99.2	11	11	18	99.8	8.7	8.7
	Overall		**47**	**89.7**	**9.9**	**11**	**47**	**94.3**	**12**	**13**	**47**	**97.3**	**10**	**10**	**47**	**99.3**	**7.9**	**8.0**

* No roots
** Without roots

Table A 8: Summary of the study 2 (2020/2006193), oilseed rape

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)					DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 750 F	1,2,4-Triazole (1,2,4-T)	Triazolylalanine (TA)	Triazole lactic acid (TLA)	Triazole acetic acid (TAA)		
	(a)	(b)				(c)									(d)	(e)
L190326 Germany EU-North 2018	Oilseed rape SO0495 PT 264	1. 28.08.2018 2. 18.04.-18.05.2019 3. 10.07.-15.07.2019	100	200	50	1 23.05.2019 Plot 2	BBCH 75	Whole plant (no roots)	75	0.84	<0.010	0.073	<0.010	<0.010	0	**BAS 762 02 F** SC Plot 2 & **BAS 762 00 F** SC Plot 3 **Mefentrifluconazole 100 g/L** Boscalid 200 g/L BASF method L0076/09 for Mefentrifluconazole and L0170/02 for Triazole Metabolites LOQ: 0.010 mg/kg
								Pods with seeds	83	0.19	<0.010	0.31	0.033	0.014	33	
								Rest of plant without roots	83	0.14	<0.010	0.034	<0.010	<0.010	33	
								Seed	89	<u><0.010</u>	<u><0.010</u>	0.73	0.038	<u><0.010</u>	48	
		1. 28.08.2018 2. 18.04.-18.05.2019 3. 10.07.-15.07.2019				1 23.05.2019 Plot 3	BBCH 75	Whole plant (no roots)	75	0.96	<0.010	0.088	<0.010	<0.010	0	
								Pods with seeds	83	0.089	<0.010	0.37	<0.010	0.017	33	
								Rest of plant without roots	83	0.062	<0.010	0.030	<0.010	<0.010	33	
								Seed	89	<0.010	<0.010	<u>0.98</u>	<u>0.050</u>	<0.010	48	
L190327 Belgium EU-North 2018	Oilseed rape SO0495 Memori	1. 06.09.2018 2. 17.04.-13.05.2019 3. 23.07.2019	100	200	50	1 23.05.2019 Plot 2	BBCH 75	Whole plant (no roots)	75	0.84	<0.010	0.14	<0.010	<0.010	0	No residues above the LOQ for BAS 750 F in any of the analysed untreated specimens. Storage time for all
								Pods with seeds	83	0.041	<0.010	0.55	0.050	0.025	42	
								Rest of plant without roots	83	0.052	<0.010	0.073	<0.010	<0.010	42	
								Seed	89	<0.010	<0.010	0.93	0.037	<u>0.023</u>	61	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)					DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 750 F	1,2,4-Triazole (1,2,4-T)	Triazolylalanine (TA)	Triazole lactic acid (TLA)	Triazole acetic acid (TAA)		
	(a)	(b)				(c)									(d)	(e)
		1. 06.09.2018 2. 17.04.-13.05.2019 3. 23.07.2019				1 23.05.2019 Plot 3	BBCH 75	Whole plant (no roots)	75	0.57	<0.010	0.15	<0.010	<0.010	0	commodities ≤189 days (Mefentrifluconazole), ≤314 days Triazole Metabolites Samples were analysed within the proven storage stability (see chapter 7.2.1)
								Pods with seeds	83	0.032	<0.010	0.68	0.062	0.034	42	
								Rest of plant without roots	83	0.049	<0.010	0.084	<0.010	<0.010	42	
								Seed	89	<0.010	<0.010	0.79	0.040	0.012	61	
L190328 Poland EU-North 2018	Oilseed rape SO0495 Kuga	1. 25.08.2018 2. 10.05.-28.05.2019 3. 10.07.2019	100	200	50	1 30.05.2019 Plot 2	BBCH 75	Whole plant (no roots)	75	0.77	<0.010	0.46	0.020	0.013	0	
								Pods with seeds	83	0.15	<0.010	1.3	0.077	0.049	22	
								Rest of plant without roots	83	0.13	<0.010	0.11	<0.010	<0.010	22	
								Seed	89	0.055	<0.010	3.8	0.21	0.056	33	
L190329 Denmark EU-North 2018	Oilseed rape SO0495 DK Exalte	1. 22.08.2018 2. 02.05.-19.05.2019 3. 10.07.-13.08.2019	100	200	50	1 08.06.2019 Plot 2	BBCH 75	Whole plant (no roots)	75	0.75	<0.010	0.029	<0.010	<0.010	0	
								Pods with seeds	83	0.046	<0.010	0.074	<0.010	<0.010	30	
								Rest of plant without roots	83	0.044	<0.010	<0.010	<0.010	<0.010	30	
								Seed	89	<0.010	<0.010	0.18	<0.010	<0.010	66	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)					DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 750 F	1,2,4-Triazole (1,2,4-T)	Triazolylalanine (TA)	Triazole lactic acid (TLA)	Triazole acetic acid (TAA)		
	(a)	(b)				(c)									(d)	(e)
L190330 France EU-South 2019	Oilseed rape SO0495 Memori CS	1. 12.09.2018 2. 19.03.-26.04.2019 3. ~~12~~13.06.2019	100	200	50	1 03.05.2019 Plot 2	BBCH 75	Whole plant (no roots)	75	0.79	<0.010	0.16	<0.010	<0.010	0	
								Pods with seeds	83	0.15	<0.010	0.42	0.083	0.026	31	
								Rest of plant	83	0.036	<0.010	<0.010	<0.010	<0.010	31	
								without roots	89	0.011	<0.010	1.1	0.030	0.011	41	
								Seed								
L190331 Greece EU-South 2019	Oilseed rape SO0495 Puncher	1. 26.10.2018 2. 15.04.-30.04.2019 3. 12.06.2019	100	200	50	1 14.05.2019 Plot 2	BBCH 75	Whole plant (no roots)	75	1.4	<0.010	<0.010	<0.010	<0.010	0	
								Pods with seeds	83	0.57	<0.010	0.029	<0.010	<0.010	22	
								Rest of plant	83	0.32	<0.010	<0.010	<0.010	<0.010	22	
								without roots	89	0.027	<0.010	0.13	<0.010	<0.010	28	
								Seed								
L190332 Italy EU-South 2019	Oilseed rape SO0495 PT279CL	1. 03.10.2018 2. 25.04.-10.05.2019 3. 21.06.2019	100	200	50	1 21.05.2019 Plot 2	BBCH 75	Whole plant (no roots)	75	0.41	<0.010	0.16	<0.010[(1)]	<0.010	0	
								Pods with seeds	83	0.26	<0.010	0.25	0.023	<0.010	22	
								Rest of plant	83	0.11	<0.010	<0.010	<0.010	<0.010	22	
								without roots	89	<0.010	<0.010	0.53	0.029	<0.010	31	
								Seed								

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)					DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 750 F	1,2,4-Triazole (1,2,4-T)	Triazolylalanine (TA)	Triazole lactic acid (TLA)	Triazole acetic acid (TAA)		
	(a)	(b)				(c)									(d)	(e)
		1. 03.10.2018 2. 25.04.-10.05.2019 3. 21.06.2019				1 21.05.2019 Plot 3	BBCH 75	Whole plant (no roots)	75	0.52	<0.010	0.18	<0.010[(1)]	<0.010	0	
								Pods with seeds	83	0.093	<0.010	0.22	0.023	<0.010	22	
								Rest of plant without roots	83	0.076	<0.010	<0.010	<0.010	<0.010	22	
								Seed	89	<0.010	<0.010	0.58	0.027	<0.010	31	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)					DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 750 F	1,2,4-Triazole (1,2,4-T)	Triazolylalanine (TA)	Triazole lactic acid (TLA)	Triazole acetic acid (TAA)		
	(a)	(b)				(c)									(d)	(e)
L190333 Spain EU-South 2019	Oilseed rape SO0495 Omega-9	1. 29.11.2018 2. 02.04.-30.04.2019 3. 27.05.2019	100	200	50	1 03.04.2019 Plot 2	BBCH 75	Whole plant (no roots)	75	1.6	<0.010	0.15	<0.010[1]	<0.010	0	
								Pods with seeds	83	0.44	<0.010	0.20	0.036[1]	<0.010	30	
								Rest of plant without roots	83	0.18	<0.010	0.032[1]	<0.010[1]	<0.010	30	
								Seed	89	<u>0.014</u>	<u><0.010</u>	<u>0.36</u>	0.032	<u><0.010</u>	50	
		1. 29.11.2018 2. 02.04.-30.04.2019 3. 27.05.2019				1 03.04.2019 Plot 3	BBCH 75	Whole plant (no roots)	75	0.82	<0.010	0.17	<0.010[1]	<0.010	0	
								Pods with seeds	83	0.076	<0.010	0.15	0.026[1]	<0.010	30	
								Rest of plant without roots	83	0.035	<0.010	0.024[1]	<0.010[1]	<0.010	30	
								Seed	89	<0.010	<0.010	0.31	0.021	<0.010	50	

_ underlined residue values were used for calculations. In case both formulations have been used in the same trial, the more critical residue value has been chosen. Also, if higher residues appeared at a later PHI, the more critical value has been chosen.

(1) Analysed with confirmation method
(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, underlined)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Table A 9: Summary of the study 2 (2020/2006193), oilseed rape, untreated

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)					DALA	Details on trial
			g a.s. / ha	Water (L/ha)	g a.s./hL					BAS 750 F	1,2,4-Triazole (1,2,4-T)	Triazolylalanine (TA)	Triazole lactic acid (TLA)	Triazole acetic acid (TAA)		
	(a)	(b)				(c)									(d)	(e)
L190326 Germany EU-North 2018	Oilseed rape SO0495 PT 264	1. 28.08.2018 2. 18.04.-18.05.2019 3. 10.07.-15.07.2019	-	-	-	- Plot 1	-	Whole plant (no roots)	75	<0.010	<0.010	0.064	<0.010	<0.010	0	**BAS 762 02 F** SC Plot 2 & **BAS 762 00 F** SC Plot 3 **Mefentrifluconazole 100 g/L** Boscalid 200 g/L BASF method L0076/09 for Mefentrifluconazole and L0170/02 for Triazole Metabolites LOQ: 0.010 mg/kg
								Pods with seeds	83	<0.010	<0.010	0.28	0.025	0.011	33	
								Rest of plant without roots	83	<0.010	<0.010	0.024	<0.010	<0.010	33	
								Seed	89	<0.010	<0.010	0.11	0.032	<0.010	48	
L190327 Belgium EU-North 2018	Oilseed rape SO0495 Memori	1. 06.09.2018 2. 17.04.-13.05.2019 3. 23.07.2019	-	-	-	- Plot 1	-	Whole plant (no roots)	75	<0.010	<0.010	0.10	<0.010	<0.010	0	
								Pods with seeds	83	<0.010	<0.010	0.50	0.034	0.018	42	
								Rest of plant without roots	83	<0.010	<0.010	0.047	<0.010	<0.010	42	
								Seed	89	<0.010	<0.010	1.6	0.054	0.020	61	
L190328 Poland EU-North 2018	Oilseed rape SO0495 Kuga	1. 25.08.2018 2. 10.05.-28.05.2019 3. 10.07.2019	-	-	-	- Plot 1	-	Whole plant (no roots)	75	<0.010	<0.010	0.41	0.020	0.011	0	
								Pods with seeds	83	<0.010	<0.010	1.3	0.098	0.043	22	
								Rest of plant without roots	83	<0.010	<0.010	0.045	<0.010	<0.010	22	
								Seed	89	<0.010	<0.010	3.5	0.17	0.042	33	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)					DALA	Details on trial
			g a.s. / ha	Water (L/ha)	g a.s./hL					BAS 750 F	1,2,4-Triazole (1,2,4-T)	Triazolylalanine (TA)	Triazole lactic acid (TLA)	Triazole acetic acid (TAA)		
	(a)	(b)				(c)									(d)	(e)
L190329 Denmark EU-North 2018	Oilseed rape SO0495 DK Exalte	1. 22.08.2018 2. 02.05.-19.05.2019 3. 10.07.-13.08.2019	-	-	-	- Plot 1	-	Whole plant (no roots)	75	<0.010	<0.010	0.025	<0.010	<0.010	0	
								Pods with seeds	83	<0.010	<0.010	0.052	<0.010	<0.010	30	
								Rest of plant without roots	83	<0.010	<0.010	<0.010	<0.010	<0.010	30	
								Seed	89	<0.010	<0.010	0.019	<0.010	<0.010	66	
L190330 France EU-South 2019	Oilseed rape SO0495 Memori CS	1. 12.09.2018 2. 19.03.-26.04.2019 3. ~~12~~13.06.2019	-	-	-	- Plot 1	-	Whole plant (no roots)	75	<0.010	<0.010	0.14	<0.010	<0.010	0	
								Pods with seeds	83	<0.010	<0.010	0.30	0.062	0.015	31	
								Rest of plant without roots	83	<0.010	<0.010	<0.010	<0.010	<0.010	31	
								Seed	89	<0.010	<0.010	0.60	0.027	<0.010	41	
L190331 Greece EU-South 2019	Oilseed rape SO0495 Puncher	1. 26.10.2018 2. 15.04.-30.04.2019 3. 12.06.2019	-	-	-	- Plot 1	-	Whole plant (no roots)	75	<0.010	<0.010	<0.010	<0.010	<0.010	0	
								Pods with seeds	83	<0.010	<0.010	<0.010	<0.010	<0.010	22	
								Rest of plant without roots	83	<0.010	<0.010	<0.010	<0.010	<0.010	22	
								Seed	89	<0.010	<0.010	0.047	<0.010	<0.010	28	
L190332 Italy EU-South 2019	Oilseed rape SO0495 PT279CL	1. 03.10.2018 2. 25.04.-10.05.2019 3. 21.06.2019	-	-	-	- Plot 1	-	Whole plant (no roots)	75	<0.010	<0.010	0.081	<0.010(1)	<0.010	0	
								Pods with seeds	83	<0.010	<0.010	0.11	<0.010	<0.010	22	
								Rest of plant without roots	83	<0.010	<0.010	0.021	<0.010	<0.010	22	
								Seed	89	<0.010	<0.010	0.29	0.014	<0.010	31	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)					DALA (d)	Details on trial (e)
			g a.s. / ha	Water (L/ha)	g a.s./hL					BAS 750 F	1,2,4-Triazole (1,2,4-T)	Triazolylalanine (TA)	Triazole lactic acid (TLA)	Triazole acetic acid (TAA)		
L190333 Spain EU-South 2019	Oilseed rape SO0495 Omega-9	1. 29.11.2018 2. 02.04.-30.04.2019 3. 27.05.2019	-	-	-	- Plot 1	-	Whole plant (no roots)	75	<0.010	<0.010	0.17	<0.010(1)	<0.010	0	
								Pods with seeds	83	<0.010	<0.010	0.23	0.029(1)	<0.010	30	
								Rest of plant without roots	83	<0.010	<0.010	0.027(1)	<0.010(1)	<0.010	30	
								Seed	89	<0.010	<0.010	0.33	0.033	<0.010	50	

_ underlined residue values were used for calculations. In case both formulations have been used in the same trial, the more critical residue value has been chosen. Also, if higher residues appeared at a later PHI, the more critical value has been chosen.

(1) Analysed with confirmation method
(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, underlined)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

A 2.1.3.2 Sunflower

Table A 10: 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 (EFSA, 2020)	2	0.110 kg as/ha	14	BBCH 31-69	n.a.
Intended cGAP (4*)	2	0.100 kg as/ha	7	BBCH 31-69	F

* 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 - sunflower - BASF DocID 2018/120579

Comments of zRMS:	Eight field trials L180264 (Germany), L180265 (North France), L180266 (Belgium), L180267 (Hungary), L180268 (South France), L180269 (Greece), L180270 (Italy) and L180271 (Spain)) were conducted during the growing season of 2018 in order to determine the magnitude of residues of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) in sunflower after treatment with BAS 762 00 F. All field trials consisted of two plots - one untreated plot (Plot 1) and one treated plot (Plot 2). BAS 762 00 F (100 g BAS 750 F/L, 200 g BAS 510 F/L, SC) was applied two times on plot 2. The applications took place at a rate of 1.0 L of formulated product/ha, equals to nominal 0.1 kg a.i./ha BAS 750 F and 0.2 kg a.i./ha BAS 510 F. The first application took place at BBCH 59 and the second application at BBCH 69 each with a spray volume of 200 L/ha. Sunflower specimens of whole plant (no roots) were collected at 0 DBLA (days before last application) and at 0 DALA (days after last application) (BBCH 69). Specimens of flower head and rest of plant without roots were collected at BBCH 79-83 (6 – 21 DALA). Specimens of seeds were collected at BBCH 89 (27 – 58 DALA). In this analytical phase (S18-04977), all specimens of sunflower were analysed for BAS 750 F and BAS 510 F according to BASF analytical method no. L0076/09. Residues of the Triazole metabolites 1,2,4-Triazole, Triazolylalanine, Triazole acetic acid and Triazole lactic acid were analysed according to BASF analytical method no. L0170/02. The final determination of the analytes in the untreated and treated specimens was performed by single extraction and single injection with liquid chromatography and mass spectrometric detection (LC-MS/MS) for BAS 750 F and BAS 510 F. For Triazole metabolites 1,2,4-Triazole, Triazolylalanine, Triazole acetic acid and Triazole lactic acid, determination was performed by single extraction and single injection with liquid chromatography and ion mobility mass spectrometric detection (LC-DMS/MS/MS). The limit of quantitation (LOQ) was 0.010 mg/kg for all analytes. The mean of the concurrent recoveries was within the acceptable range of 70 - 110% for all analytes. The BAS 750 F residues in treated whole plant (no roots) specimens taken 0 DALA (days after last application) ranged between 0.43 mg/kg and 1.0 mg/kg. The BAS 750 F residues in treated flower head specimens taken at BBCH 79-83 (6-21 DALA) ranged between 0.024 mg/kg and 0.21 mg/kg. The BAS 750 F residues in treated rest of plant without roots specimens taken at BBCH 79-83 (6-21 DALA) ranged between 0.077 mg/kg and 1.3 mg/kg. The BAS 750 F residues in treated seed specimens taken at BBCH 89 (27-58 DALA) ranged between < 0.010 mg/kg and 0.042 mg/kg. No residues of BAS 750 F at or above the limit of quantitation were detected in the untreated specimens of this study. The following residues of Triazole metabolites were found in the treated samples:

Summary of Residues of Triazole Metabolites after Application with BAS 762 00 F in treated Sunflower Specimens

Portion analysed	Plot No.	DALA [1]	Growth stage (BBCH)	n [2]	Residues of 1,2,4-Triazole [3] [mg/kg]	Residues of Triazolyl-alanine [3] [mg/kg]	Residues of Triazole Lactic Acid [3] [mg/kg]	Residues of Triazole Acetic Acid [3] [mg/kg]
Whole Plant (No Roots)	2	0	69	8	< 0.010	< 0.010 - 0.062	< 0.010 - 0.090	< 0.010 - 0.092
Flower Head		6 – 21	79-83	8	< 0.010	< 0.010 - 0.18	< 0.010 - 0.035	< 0.010 - 0.20
Rest of Plant without Roots				8	< 0.010	< 0.010	< 0.010 – 0.18	< 0.010 – 0.084
Seed		27 - 58	89	8	< 0.010	0.015 – 0.31	< 0.010 - 0.010	0.015 – 0.61

1) DALA = Days after last Application
2) n = number of samples
3) The limit of quantitation (LOQ) is 0.010 mg/kg

The following residues of Triazole metabolites were found in the untreated samples:

Summary of Residues of Triazole Metabolites in untreated Sunflower Specimens

Portion analysed	Plot No.	DALA [1]	Growth stage (BBCH)	n [2]	Residues of 1,2,4-Triazole [3] [mg/kg]	Residues of Triazolyl-alanine [3] [mg/kg]	Residues of Triazole Lactic Acid [3] [mg/kg]	Residues of Triazole Acetic Acid [3] [mg/kg]
Whole Plant (No Roots)	1	0 DBLA	69	8	< 0.010	< 0.010 - 0.065	< 0.010 - 0.077	< 0.010 - 0.074
Flower Head		6 – 21	79-83	8	< 0.010	< 0.010 - 0.16	< 0.010 - 0.038	< 0.010 - 0.15
Rest of Plant without Roots				8	< 0.010	< 0.010	< 0.010 – 0.14	< 0.010 - 0.046
Seed		27 - 58	89	8	< 0.010	< 0.010 - 0.22	< 0.010	< 0.010 - 0.32

1) DALA = Days after last Application, DBLA = Days before last application
2) n = number of samples
3) The limit of quantitation (LOQ) is 0.010 mg/kg

The maximum storage interval from harvest to the sample extraction was 123 days for BAS 750 F and BAS 510 F. Storage stability of BAS 750 F and BAS 510 F was shown for 24 months.
The maximum storage interval from harvest to the sample extraction was for sunflower (seed) 20 days, for sunflower (flower head and rest of plant without roots) 110 days and for sunflower (whole plant no roots) 130 days for the Triazole metabolites.

The study is acceptable.

Reference: CA 6.3.2/1

Report: Study on the residue behaviour of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) on sunflower after treatment with BAS 762 00 F under field conditions in Northern and Southern Europe, season 2018
XXX, O., 2019
Report No 825505, 18/01/PF
BASF DocID 2018/1205796
Authority registration No

Guideline(s): Regulation (EC) no. 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.
European Community Guidelines 7029/VI/95 – Rev. 5, 22/07/97: Appendix B- General Recommendations for the design, preparation and realization of residue trials.
OECD 509 – OECD Guideline for the testing of Chemicals Crop Field Trials 7th September 2009.
European Community Guideline SANCO 7525/VI/95 - rev.10.3, 13 June 2017: Comparability, extrapolation, group tolerances and data requirements for setting MRLs.

International guidelines for distribution and pesticides application. AEPLA, FAO 1985.
Directive 2004/10/EC of the European Parliament and of the Council of 11th February 2004
OECD Principles of Good Laboratory Practice and Compliance Monitoring Number 1. 'OECD Principles on Good Laboratory Practice'. ENV/MC/CHEM(98)17.
OECD Principles of Good Laboratory Practice and Compliance Monitoring Number 4. 'Quality Assurance and GLP'. ENV/JM/MONO(99)20.
OECD Principles of Good Laboratory Practice and Compliance Monitoring Number 6 (Revised). 'The Application of the GLP Principles to field studies'. ENV/JM/MONO (99)22.
OECD Principles of Good Laboratory Practice and Compliance Monitoring Number 13. Consensus Document of the Working Group on Good Laboratory Practice 'The application of OECD Principles of GLP to the Organisation and
Management of Multi-site studies'. ENV/JM/MONO(2002)/9.
R.D. 1369/2000 on 19th of July, whereby the Principles of Good Laboratory Practices and their application to the conduction of non-clinical studies on chemical substances and products are established.
Relevant national GLP-Regulations of Test site countries.

Deviations: No

GLP: yes
(certified by ENAC, Entidad Nacional de Acreditación, Madrid Spain)

Acceptability: Yes

Table A 11: Summary of recoveries (study 1 (2018/1205796), sunflower)

Matrix		Fortification level [mg/kg]	BAS 750 F			
			n	Mean [%]	SD [±]	RSD [%]
Sunflower	Whole plant*	0.01, 0.10 and 5.0	7	85.6	3.5	4.0
	Flower head	0.01, 0.10 and 1.25	7	84.5	3.2	3.7
	Rest of plant*	0.01, 0.10 and 8.5	7	84.3	1.7	2.0
	Seed	0.01 and 0.10	6	89.5	13	14
	Overall		27	85.7	6.5	7.5

* No roots
** Without roots

Table A 12: Summary of recoveries (study 1 (2018/1205796), sunflower)

Matrix		Fortification level [mg/kg]	1,2,4-Triazole (1,2,4-T)				Triazolylalanine (TA)				Triazole lactic acid (TLA)				Triazole acetic acid (TAA)			
			n	Mean [%]	SD [±]	RSD [%]	n	Mean [%]	SD [±]	RSD [%]	n	Mean [%]	SD [±]	RSD [%]	n	Mean [%]	SD [±]	RSD [%]
Sunflower	Whole plant*	0.01 and 0.10	10	95.5	10	11	10	87.3	6.4	7.4	10	94.8	11	11	10	104	4.1	3.9
	Flower head	0.01 and 0.10 (and 0.20, TA and TAA)	10	97.4	14	15	11	94.5	5.3	5.6	10	106	4.5	4.2	11	101	8.1	8.0
	Rest of plant*	0.01 and 0.10 (and 0.30, TLA)	10	87.6	11	12	10	91.4	4.3	4.7	11	96.1	6.5	6.7	10	100	5.0	5.0
	Seed	0.01 and 0.10 (and 0.7, TA and TAA)	10	98.7	4.7	4.8	11	87.9	5.5	6.2	10	100	8.6	8.6	11	98.2	8.4	8.5
	Overall		**40**	**94.8**	**11**	**12**	**42**	**90.3**	**6.0**	**6.6**	**41**	**99.1**	**8.6**	**8.7**	**42**	**101**	**6.8**	**6.7**

* No roots
** Without roots

Table A 13: Summary of the study 1 (2018/1205796), sunflower

Trial No./ Location / EU zone/ Year	Commodity / Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)					DALA	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL					BAS 750 F	1,2,4-Triazole (1,2,4-T)	Triazolylalanine (TA)	Triazole lactic acid (TLA)	Triazole acetic acid (TAA)		
	(a)	(b)				(c)									(d)	(e)
L180264 Germany EU-North 2019	Sunflower SO 0702 SY Valeo	1. 10.04.2018 2. 27.06.2018-16.07.2018 3. 12.09.2018	100	200	50	2 16.07.2018	BBCH 69	Whole plant (no roots)	69	0.43	<0.010	<0.010	<0.010	<0.010	0	**BAS 762 00 F** SC **Mefentrifluconazole 100 g/L** Boscalid 200 g/L BASF method L0076/09 for Mefentrifluconazole and L0170/02 for Triazole Metabolites LOQ: 0.010 mg/kg No residues of BAS 750 F above the LOQ in any of the analyzed untreated specimens. Storage time for all commodities ≤130 days Samples were analysed within the
								Flower head	79	0.21	<0.010	0.015	<0.010	0.027	8	
								Rest of plant without roots	79	0.99	<0.010	<0.010	0.015	<0.010	8	
								Seed	89	<0.010	<0.010	0.094	<0.010	0.090	58	
L180265 France EU-North 2018	Sunflower SO 0702 ES IDILLIC	1. 27.04.2018 2. 30.06.2018-17.07.2018 3. 03.09.2018	100	200	50	2 03.08.2018	BBCH 69	Whole plant (no roots)	69	0.76	<0.010	<0.010	<0.010	<0.010	0	
								Flower head	79-83	0.12	<0.010	<0.010	<0.010	0.017	12	
								Rest of plant without roots	79-83	1.3	<0.010	<0.010	<0.010	<0.010	12	
								Seed	89	0.042	<0.010	0.015	<0.010	0.023	27	
L180266 Belgium EU-North 2018	Sunflower SO 0702 Es Novamis CL	1. 10.04.2018 2. 02.07.2018-16.07.2018 3. 10.09.2018	100	200	50	2 18.07.2018	BBCH 69	Whole plant (no roots)	69	0.55	<0.010	<0.010	<0.010	<0.010	0	
								Flower head	79	0.12	<0.010	<0.010	<0.010	<0.010	12	
								Rest of plant without roots	79	0.84	<0.010	<0.010	<0.010	<0.010	12	
								Seed	89	<0.010	<0.010	0.026	<0.010	0.015	54	
L180267 Hungary EU-North 2018	Sunflower SO 0702 P64LE25	1. 10.05.2018 2. 01.07.2018-10.08.2018 3. 25.10.2018	100	200	50	2 10.08.2018	BBCH 69	Whole plant (no roots)	69	0.71	<0.010	0.027	0.010	0.020	0	
								Flower head	79	0.057	<0.010	0.031	<0.010	0.041	14	
								Rest of plant without roots	79	0.71	<0.010	<0.010	0.010	<0.010	14	
								Seed	89	0.037	<0.010	0.12	<0.010	0.11	52	

Trial No./ Location / EU zone/ Year (a)	Commodity / Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment: g a.s./ ha	Water (L/ha)	g a.s./h L	Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg): BAS 750 F	1,2,4-Triazole (1,2,4-T)	Triazolylalanine (TA)	Triazole lactic acid (TLA)	Triazole acetic acid (TAA)	DALA (d)	Details on trial (e)
L180268 France EU-South 2018	Sunflower SO 0702 LG 5678	1. 02.05.2018 2. 10.07.2018-30.07.2018 3. 19.09.2018	100	200	50	2 30.07.2018	BBCH 69	Whole plant (no roots)	69	1.0	<0.010	<0.010	<0.010	<0.010	0	proven storage stability (see chapter 7.2.1)
								Flower head	79	0.071	<0.010	0.012	<0.010	0.014	17	
								Rest of plant without roots	79	0.60	<0.010	<0.010	<0.010	<0.010	17	
								Seed	89	0.010	<0.010	0.041	<0.010	0.032	49	
L180269 Greece EU-South 2018	Sunflower SO 0702 Neoma	1. 04.04.2018 2. 08.06.2018-28.06.2018 3. 10.08.2018-20.08.2018	100	200	50	2 21.06.2018	BBCH 69	Whole plant (no roots)	69	0.45	<0.010	<0.010	<0.010	<0.010	0	
								Flower head	79	0.024	<0.010	<0.010	<0.010	<0.010	20	
								Rest of plant without roots	79	0.077	<0.010	<0.010	<0.010	<0.010	20	
								Seed	89	<0.010	<0.010	0.035	<0.010	0.045	54	
L180270 Italy EU-South 2018	Sunflower SO 0702 LG5687HO	1. 18.05.2018 2. 03.07.2018-17.07.2018 3. 30.08.2018	100	200	50	2 17.07.2018	BBCH 69	Whole plant (no roots)	69	0.57	<0.010	0.065	0.090	0.092	0	
								Flower head	79	0.056	<0.010	0.18	0.035	0.20	6	
								Rest of plant without roots	79	0.44	<0.010	<0.010	0.18	0.084	6	
								Seed	89	<0.010	<0.010	0.31	0.010	0.61	44	

Trial No./ Location / EU zone/ Year	Commodity / Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)					DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 750 F	1,2,4-Triazole (1,2,4-T)	Triazolylalanine (TA)	Triazole lactic acid (TLA)	Triazole acetic acid (TAA)		
	(a)	(b)				(c)									(d)	(e)
L180271 Spain EU-South 2018	Sunflower SO 0702 LG5461	1. 09.04.2018 2. 27.06.2018-02.07.2018 3. 24.08.2018	100	200	50	2 09.07.2018	BBCH 69	Whole plant (no roots)	69	0.74	<0.010	<0.010	<0.010	<0.010	0	
								Flower head	79	0.16	<0.010	0.015	<0.010	0.033	21	
								Rest of plant without roots	79	0.79	<0.010	<0.010	<0.010	<0.010	21	
								Seed	89	<u><0.010</u>	<u><0.010</u>	<u>0.051</u>	<u><0.010</u>	<u>0.091</u>	45	

_ underlined residue values were used for calculations. In case both formulations have been used in the same trial, the more critical residue value has been chosen. Also, if higher residues appeared at a later PHI, the more critical value has been chosen.

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

Table A 14: Summary of the study 1 (2018/1205796), sunflower, untreated

Trial No./ Location / EU zone/ Year (a)	Commodity / Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment: g a.s./ha	Application rate per treatment: Water (L/ha)	Application rate per treatment: g a.s./hL	Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg): BAS 750 F	Residues (mg/kg): 1,2,4-Triazole (1,2,4-T)	Residues (mg/kg): Triazolylalanine (TA)	Residues (mg/kg): Triazole lactic acid (TLA)	Residues (mg/kg): Triazole acetic acid (TAA)	DALA (d)	Details on trial (e)
L180264 Germany EU-North 2019	Sunflower SO 0702 SY Valeo	1. 10.04.2018 2. 27.06.2018-16.07.2018 3. 12.09.2018	-	-	-	- Plot 1	-	Whole plant (no roots)	69	<0.010	<0.010	<0.010	<0.010	<0.010	0	**BAS 762 00 F** SC Mefentrifluconazole 100 g/L **Boscalid 200 g/L** BASF method L0076/09 for Mefentrifluconazole and L0170/02 for Triazole Metabolites LOQ: 0.010 mg/kg
								Flower head	79	<0.010	<0.010	<0.010	<0.010	0.012	8	
								Rest of plant without roots	79	<0.010	<0.010	<0.010	<0.010	<0.010	8	
								Seed	89	<0.010	<0.010	0.037	<0.010	0.046	53	
L180265 France EU-North 2018	Sunflower SO 0702 ES IDILLIC	1. 27.04.2018 2. 30.06.2018-17.07.2018 3. 03.09.2018	-	-	-	- Plot 1	-	Whole plant (no roots)	69	<0.010	<0.010	<0.010	<0.010	<0.010	0	
								Flower head	79-83	<0.010	<0.010	<0.010	<0.010	0.014	12	
								Rest of plant without roots	79-83	<0.010	<0.010	<0.010	<0.010	<0.010	12	
								Seed	89	<0.010	<0.010	0.048	<0.010	0.098	27	
L180266 Belgium EU-North 2018	Sunflower SO 0702 Es Novamis CL	1. 10.04.2018 2. 02.07.2018-16.07.2018 3. 10.09.2018	-	-	-	- Plot 1	-	Whole plant (no roots)	69	<0.010	<0.010	<0.010	<0.010	<0.010	0	
								Flower head	79	<0.010	<0.010	<0.010	<0.010	<0.010	12	
								Rest of plant without roots	79	<0.010	<0.010	<0.010	<0.010	<0.010	12	
								Seed	89	<0.010	<0.010	0.045	<0.010	0.023	54	

Trial No./ Location / EU zone/ Year	Commodity / Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)					DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 750 F	1,2,4-Triazole (1,2,4-T)	Triazolylalanine (TA)	Triazole lactic acid (TLA)	Triazole acetic acid (TAA)		
	(a)	(b)				(c)									(d)	(e)
L180267 Hungary EU-North 2018	Sunflower SO 0702 P64LE25	1. 10.05.2018 2. 01.07.2018-10.08.2018 3. 25.10.2018	-	-	-	- Plot 1	-	Whole plant (no roots)	69	<0.010	<0.010	<0.010	<0.010	<0.010	0	
								Flower head	79	<0.010	<0.010	<0.010	<0.010	<0.010	14	
								Rest of plant without roots	79	<0.010	<0.010	<0.010	<0.010	<0.010	14	
								Seed	89	<0.010	<0.010	0.015	<0.010	0.026	52	
L180268 France EU-South 2018	Sunflower SO 0702 LG 5678	1. 02.05.2018 2. 10.07.2018-30.07.2018 3. 19.09.2018	-	-	-	- Plot 1	-	Whole plant (no roots)	69	<0.010	<0.010	<0.010	<0.010	<0.010	0	
								Flower head	79	<0.010	<0.010	<0.010	<0.010	<0.010	17	
								Rest of plant without roots	79	<0.010	<0.010	<0.010	<0.010	<0.010	17	
								Seed	89	<0.010	<0.010	<0.010	<0.010	<0.010	49	
L180269 Greece EU-South 2018	Sunflower SO 0702 Neoma	1. 04.04.2018 2. 08.06.2018-28.06.2018 3. 10.08.2018-20.08.2018	-	-	-	- Plot 1	-	Whole plant (no roots)	69	<0.010	<0.010	<0.010	<0.010	<0.010	0	
								Flower head	79	<0.010	<0.010	<0.010	<0.010	<0.010	20	
								Rest of plant without roots	79	<0.010	<0.010	<0.010	<0.010	<0.010	20	
								Seed	89	<0.010	<0.010	<0.010	<0.010	<0.010	54	
L180270 Italy EU-South 2018	Sunflower SO 0702 LG5687HO	1. 18.05.2018 2. 03.07.2018-17.07.2018 3. 30.08.2018	-	-	-	- Plot 1	-	Whole plant (no roots)	69	<0.010	<0.010	0.065	0.077	0.074	0	
								Flower head	79	<0.010	<0.010	0.16	0.038	0.15	6	
								Rest of plant without roots	79	<0.010	<0.010	<0.010	0.14	0.046	6	
								Seed	89	<0.010	<0.010	0.22	<0.010	0.32	44	

Trial No./ Location / EU zone/ Year	Commodity / Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)					DALA	Details on trial
			g a.s./ha	Water (L/ha)	g a.s./hL					BAS 750 F	1,2,4-Triazole (1,2,4-T)	Triazolylalanine (TA)	Triazole lactic acid (TLA)	Triazole acetic acid (TAA)		
	(a)	(b)				(c)									(d)	(e)
L180271 Spain EU-South 2018	Sunflower SO 0702 LG5461	1. 09.04.2018 2. 27.06.2018-02.07.2018 3. 24.08.2018	-	-	-	- Plot 1	-	Whole plant (no roots)	69	<0.010	<0.010	<0.010	<0.010	<0.010	0
								Flower head	79	<0.010	<0.010	<0.010	<0.010	0.018	21
								Rest of plant without roots	79	<0.010	<0.010	<0.010	<0.010	<0.010	21
								Seed	89	<0.010	<0.010	0.037	<0.010	0.061	45

_ underlined residue values were used for calculations. In case both formulations have been used in the same trial, the more critical residue value has been chosen. Also, if higher residues appeared at a later PHI, the more critical value has been chosen.

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

A 2.1.3.2.2 Study 2 - sunflower - BASF DocID 2019/2075093

Comments of zRMS:	During the 2019 growing season eight trials were conducted in order to determine the magnitude of residues of Mefentrifluconazole (BAS 750 F), Boscalid (BAS 510 F), 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in sunflower under field conditions after two applications of either BAS 762 00 F or BAS 762 02 F in in Germany (L190443), France (L190444 and L190447), Netherlands (L190445), Austria (L190446), Greece (L190448), Italy (L190449) and in Spain (L190450). Trials L190443, L190444, L190449 and L190450 consisted of three plots: plot 1 (untreated), plot 2 (treated with BAS 762 02 F) and plot 3 (treated with BAS 762 00 F). Trials L190445, L190446, L190447 and L190448 consisted of two plots: plot 1 (untreated), plot 2 (treated with BAS 762 02 F). The treatment on plot 2 of all trials was performed using formulation BAS 762 02 F two times at a target rate of 1.0 L of formulated product/ha (SC formulation, nominal content 100 g BAS 750 F /L and 200 g BAS 510 F /L), corresponding to 0.10 kg a.i./ha of BAS 750 F and 0.20 kg a.i./ha of BAS 510 F. The application timing was at BBCH 59-61 and BBCH 69. The treatment on plot 3 (for trial L190443, L190444, L190449 and L190450) was performed using formulation BAS 762 00 F two times at a target rate of 1.0 L of formulated product/ha (SC formulation, nominal content 100 g BAS 750 F /L and 200 g BAS 510 F /L), corresponding to 0.10 kg a.i./ha of BAS 750 F and 0.20 kg a.i./ha of BAS 510 F. The application timing was at BBCH 59-61 and BBCH 69. Specimens of sunflower were collected as whole plant (no roots) at the day of last application (0 DALA), (on plot 1 before the application, 0 DBLA), as flower head and rest of plant without roots on BBCH 79 and as seed on BBCH 89. All sunflower specimens (whole plant (no roots), flower head, rest of plant without roots, seed) were analysed for Mefentrifluconazole (BAS 750 F), Boscalid (BAS 510 F) and triazole (1,2,4-T, TA, TAA, TLA). The following analytical methods were used and adapted (considering lab and matrix specific requirements) for residue analysis: - BASF Method L0076/09 was adapted for BAS 750 F and BAS 510 F using LC-MS/MS to achieve a limit of quantification (LOQ) of 0.010 mg/kg. - BASF Method L0170/02 was adapted for triazole derivative metabolites (TDMs) 1,2,4-Triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA), and triazole lactic acid (TLA) using LC-DMS-MS/MS to achieve a limit of quantification (LOQ) of 0.010 mg/kg per analyte. Overall and average recoveries were all in the range of 70 – 110 % and relative standard deviations (RSD) were < 20 %. Mefentrifluconazole (BAS 750 F) residues ranged from 0.67 – 2.4 mg/kg (plot 2) and 1.3 – 1.8 mg/kg (plot 3) for sunflower whole plant (no roots) collected directly after application, 0 DALA (BBCH 69). At BBCH 79, residues of Mefentrifluconazole (BAS 750 F) ranged from 0.019 – 0.34 mg/kg (plot 2) and 0.059 – 0.30 mg/kg (plot 3) for sunflower flower head specimens and from 0.23 – 3.4 mg/kg (plot 2) and 0.24 – 3.3 mg/kg (plot 3) for sunflower rest of plant without roots specimens. At BBCH 89, residues of Mefentrifluconazole (BAS 750 F) ranged from <0.010 – 0.012 mg/kg (plot 2) and for <0.010 – 0.010 mg/kg (plot 3) sunflower seed specimens. None of the untreated samples of this study had any residue of Mefentrifluconazole (BAS 750 F) exceeding the respective LOQ (0.010 mg/kg). Summary of Residues in Untreated Samples for TDMs

Sampling No.	Portion analysed		Plot	DALA[1)]	Growth stage (BBCH)	n	Range of residues			
							1,2,4-Triazole (1,2,4-T) [mg/kg]	Triazole acetic acid (TAA) [mg/kg]	Triazole lactic acid (TLA) [mg/kg]	Triazolyl-alanine (TA) [mg/kg]
1	Sunflower	Whole plant (no roots)	1	0 DBLA	69	8	<0.010	<0.010 - 0.067	<0.010 - 0.058	<0.010 - 0.067
2		Flower head	1	4 - 20	79	8	<0.010	<0.010 - 0.072	<0.010 - 0.017	<0.010 - 0.052
		Rest of plant without roots				8	<0.010	<0.010 - 0.013	<0.010 - 0.029	<0.010
3		Seed	1	41 - 58	89	8	<0.010	<0.010 - 0.34	<0.010	<0.010 - 0.22

1): days after last application. DBLA: days before last application.

Summary of Residues in Treated Samples for TDMs (Plot 2)

Sampling No.	Portion analysed		Plot	DALA[1)]	Growth stage (BBCH)	n	Range of residues			
							1,2,4-Triazole (1,2,4-T) [mg/kg]	Triazole acetic acid (TAA) [mg/kg]	Triazole lactic acid (TLA) [mg/kg]	Triazolyl-alanine (TA) [mg/kg]
1	Sunflower	Whole plant (no roots)	2	0	69	8	<0.010	<0.010 - 0.019	<0.010 - 0.028	<0.010 - 0.020
2		Flower head	2	4 - 20	79	8	<0.010	<0.010 - 0.043	<0.010 - 0.012	<0.010 - 0.052
		Rest of plant without roots				8	<0.010	<0.010 - 0.012	<0.010 - 0.026	<0.010
3		Seed	2	41 - 58	89	8	<0.010	0.016 - 0.20	<0.010	0.018 - 0.20

1): days after last application.

Summary of Residues in Treated Samples for TDMs (Plot 3)

Sampling No.	Portion analysed		Plot	DALA[1)]	Growth stage (BBCH)	n	Range of residues			
							1,2,4-Triazole (1,2,4-T) [mg/kg]	Triazole acetic acid (TAA) [mg/kg]	Triazole lactic acid (TLA) [mg/kg]	Triazolyl-alanine (TA) [mg/kg]
1	Sunflower	Whole plant (no roots)	3	0	69	4	<0.010	<0.010 - 0.030	<0.010 - 0.031	<0.010 - 0.032
2		Flower head	3	4 - 14	79	4	<0.010	<0.010 - 0.095	<0.010 - 0.011	<0.010 - 0.069
		Rest of plant without roots				4	<0.010	<0.010 - 0.023	<0.010 - 0.051	<0.010
3		Seed	3	41 - 58	89	4	<0.010	0.027 - 0.23	<0.010	0.021 - 0.23

1): days after last application.

The study is acceptable.

Reference: CA 6.3.2/2

Report: Study on the residue behaviour of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) on sunflower after treatment with BAS 762 00 F or BAS 762 02 F under field conditions in Northern and Southern Europe, season 2019
XXX, O., 2020
Report No 825506, 19/09/PF
BASF DocID 2019/2075093
Authority registration No

Guideline(s): Regulation (EC) no. 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection

products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.
European Community Guidelines 7029/VI/95 – Rev. 5, 22/07/97: Appendix B- General Recommendations for the design, preparation and realization of residue trials.
OECD 509 – OECD Guideline for the testing of Chemicals Crop Field Trials 7th September 2009.
European Community Guideline SANCO 7525/VI/95 - rev.10.3, 13 June 2017: Comparability, extrapolation, group tolerances and data requirements for setting MRLs.
Directive 2004/10/EC of the European Parliament and of the Council of 11th February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances.
OECD Principles of Good Laboratory Practice and Compliance Monitoring Number 1. 'OECD Principles on Good Laboratory Practice'. ENV/MC/CHEM(98)17.
OECD Principles of Good Laboratory Practice and Compliance Monitoring Number 4. 'Quality Assurance and GLP'. ENV/JM/MONO(99)20.
OECD Principles of Good Laboratory Practice and Compliance Monitoring Number 6 (Revised). 'The Application of the GLP Principles to field studies'. ENV/JM/MONO (99)22.
OECD Principles of Good Laboratory Practice and Compliance Monitoring Number 13. Consensus Document of the Working Group on Good Laboratory Practice 'The application of OECD Principles of GLP to the Organisation and Management of Multi-site studies'. ENV/JM/MONO(2002)/9.
Spanish R.D. 1369/2000 on 19th of July, whereby the Principles of Good Laboratory Practices and their application to the conduction of non-clinical studies on chemical substances and products are established.
Relevant national GLP-Regulations of Test site countries.

Deviations: No

GLP: yes
(certified by ENAC, Entidad Nacional de Acreditación, Madrid Spain)

Acceptability: Yes

Reference: CA 6.3.2/3

Report: Amendment no. 1 to Final Report - Study on the residue behaviour of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) on sunflower after treatment with BAS 762 00 F or BAS 762 02 F under field conditions in Northern and Southern Europe, season 2019
XXX, O., 2020
Report No 825506, 19/09/PF
BASF DocID 2020/2108977
Authority registration No

Guideline(s): Regulation (EC) no. 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.
European Community Guidelines 7029/VI/95 – Rev. 5, 22/07/97: Appendix B- General Recommendations for the design, preparation and realization of

residue trials.
OECD 509 – OECD Guideline for the testing of Chemicals Crop Field Trials 7th September 2009.
European Community Guideline SANCO 7525/VI/95 - rev.10.3, 13 June 2017: Comparability, extrapolation, group tolerances and data requirements for setting MRLs.
Directive 2004/10/EC of the European Parliament and of the Council of 11th February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances.
OECD Principles of Good Laboratory Practice and Compliance Monitoring Number 1. 'OECD Principles on Good Laboratory Practice'. ENV/MC/CHEM(98)17.
OECD Principles of Good Laboratory Practice and Compliance Monitoring Number 4. 'Quality Assurance and GLP'. ENV/JM/MONO(99)20.
OECD Principles of Good Laboratory Practice and Compliance Monitoring Number 6 (Revised). 'The Application of the GLP Principles to field studies'. ENV/JM/MONO (99)22.
OECD Principles of Good Laboratory Practice and Compliance Monitoring Number 13. Consensus Document of the Working Group on Good Laboratory Practice 'The application of OECD Principles of GLP to the Organisation and Management of Multi-site studies'. ENV/JM/MONO(2002)/9.
Spanish R.D. 1369/2000 on 19th of July, whereby the Principles of Good Laboratory Practices and their application to the conduction of non-clinical studies on chemical substances and products are established.
Relevant national GLP-Regulations of Test site countries.

Deviations: No

GLP: yes
(certified by ENAC, Entidad Nacional de Acreditación, Madrid Spain)

Acceptability: Yes

Table A 15: Summary of recoveries (study 2 (2019/2075093), sunflower)

Matrix		Fortification level [mg/kg]	BAS 750 F			
			n	Mean [%]	SD [±]	RSD [%]
Sunflower	Whole plant*	0.01, 0.10, 10.0 and 20.0	7	92.3	7.5	8.1
	Flower head	0.01, 0.10, 10.0 and 20.0	12	95.9	4.9	5.1
	Rest of plant*	0.01, 0.10, 10.0 and 20.0	9	93.3	9.2	9.9
	Seed	0.01, 0.10 and 1.0	12	83.0	7.9	9.6
	Overall		40	91.8	8.5	9.3

* No roots
** Without roots

Table A 16: Summary of recoveries (study 2 (2019/2075093), sunflower)

Matrix		Fortification level [mg/kg]	1,2,4-Triazole (1,2,4-T)				Triazolylalanine (TA)				Triazole lactic acid (TLA)				Triazole acetic acid (TAA)			
			n	Mean [%]	SD [±]	RSD [%]	n	Mean [%]	SD [±]	RSD [%]	n	Mean [%]	SD [±]	RSD [%]	n	Mean [%]	SD [±]	RSD [%]
Sunflower	Whole plant*	0.01, 0.10 and 1.0	19	103	8.4	8.2	19	93.3	11	12	19	89.0	9.5	11	19	90.6	9.5	11
	Flower head	0.01, 0.10 and 1.0	11	98.7	9.2	9.3	11	99.9	10	10	11	93.2	10	11	11	85.9	8.6	10
	Rest of plant*	0.01, 0.10 and 1.0	12	96.6	11	11	12	92.9	10	11	12	89.3	12	14	12	87.6	8.6	9.8
	Seed	0.01, 0.10 and 1.0	15	99.4	9.1	9.1	15	95.2	6.8	7.1	15	92.3	8.0	8.7	15	86.1	8.5	9.8
	Overall		**57**	**99.7**	**9.4**	**9.4**	**57**	**95.0**	**9.9**	**10**	**57**	**90.7**	**9.8**	**11**	**57**	**87.9**	**8.9**	**10**

* No roots
** Without roots

Table A 17: Summary of the study 2 (2019/2075093), sunflower

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)					DALA	Details on trial
			g a.s. / ha	Water (L/ha)	g a.s./hL					BAS 750 F	1,2,4-Triazole (1,2,4-T)	Triazolylalanine (TA)	Triazolelactic acid (TLA)	Triazole acetic acid (TAA)		
(a)		(b)				(c)									(d)	(e)
L190443 Germany EU-North 2019	Sunflower SO 0702 Vivacio	1. 10.04.2019 2. 03.07.2019-22.07.2019 3. 18.09.2019-21.09.2019	100	200	50	2 22.07.2019 (plot 2)	BBCH 69	Whole plant (no roots)	69	1.4	<0.010	0.020	0.028	0.019	0	**BAS 762 02 F** (SC, plot 2) **BAS 762 00 F** (SC, plot 3) **Mefentrifluconazole 100 g/L** Boscalid 200 g/L BASF method L0076/09 for Mefentrifluconazole and L0170/02 for Triazole Metabolites LOQ: 0.010 mg/kg
								Flower head	79	0.27	<0.010	0.052	0.011	0.043	4	
								Rest of plant without roots	79	1.4	<0.010	<0.010	0.023	<0.010	4	
								Seed	89	<0.010	<0.010	0.20	<0.010	0.20	58	
			100	200	50	2 22.07.2019 (plot 3)	BBCH 69	Whole plant (no roots)	69	1.8	<0.010	0.032	0.031	0.022	0	
								Flower head	79	0.27	<0.010	0.010	<0.010	<0.010	4	
								Rest of plant without roots	79	1.3	<0.010	<0.010	0.026	<0.010	4	
								Seed	89	<0.010	<0.010	0.23	<0.010	0.23	58	
L190444 France EU-North 2019	Sunflower SO 0702 RGT Buffalo	1. 08.04.2019 2. 07.07.2019-19.07.2019 3. 11.09.2019	100	200	50	2 19.07.2019 (plot 2)	BBCH 69	Whole plant (no roots)	69	2.2	<0.010	<0.010	0.017	0.013	0	
								Flower head	79	0.28	<0.010	0.031	<0.010	0.039	14	
								Rest of plant without roots	79	3.4	<0.010	<0.010	0.026	0.012	14	
								Seed	89	<0.010	<0.010	0.089	<0.010	0.084	54	
			100	200	50	2 19.07.2019 (plot 3)	BBCH 69	Whole plant (no roots)	69	1.4	<0.010	0.028	0.028	0.030	0	
								Flower head	79	0.27	<0.010	0.069	0.011	0.095	14	
								Rest of plant without roots	79	3.3	<0.010	<0.010	0.051	0.023	14	
								Seed	89	<0.010	<0.010	0.16	<0.010	0.19	54	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)					DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 750 F	1,2,4-Triazole (1,2,4-T)	Triazolylalanine (TA)	Triazolelactic acid (TLA)	Triazole acetic acid (TAA)		
	(a)	(b)				(c)									(d)	(e)
L190445 Netherland EU-North 2019	Sunflower SO 0702 ES Biba	1. 11.05.2019 2. 05.07.2019-07.08.2019 3. 20.09.2019	100	200	50	2 07.08.2019 (plot 2)	BBCH 69	Whole plant (no roots)	69	0.67	<0.010	<0.010	0.016	<0.010	0	
								Flower head	79	0.025	<0.010	<0.010	<0.010	<0.010	12	
								Rest of plant without roots	79	0.23	<0.010	<0.010	<0.010	<0.010	12	
								Seed	89	<0.010	<0.010	0.044	<0.010	0.042	44	
L190446 Austria EU-North 2019	Sunflower SO 0702 ES Biba	1. 18.04.2019 2. 05.07.2019-26.07.2019 3. 18.09.2019	100	200	50	2 23.07.2019 (plot 2)	BBCH 69	Whole plant (no roots)	69	1.2	<0.010	<0.010	<0.010	<0.010[2)]	0	
								Flower head	79	0.081	<0.010	<0.010	<0.010	<0.010[2)]	15	
								Rest of plant without roots	79	0.44	<0.010	<0.010	<0.010	<0.010[2)]	15	
								Seed	89	<0.010	<0.010	0.018	<0.010	0.016	55	
L190447 France EU-South 2019	Sunflower SO 0702 MAS 87 OL	1. 08.05.2019 2. 21.07.2019-12.08.2019 3. 01.10.2019	100	200	50	2 12.08.2019 (plot 2)	BBCH 69	Whole plant (no roots)	69	2.2	<0.010	<0.010	<0.010	<0.010	0	No residues of BAS 750 F above the LOQ in any of the analyzed untreated specimens. Storage time for all commodities ≤232 days Samples were analysed within the proven storage stability (see chapter 7.2.1)
								Flower head	79	0.16	<0.010	<0.010	<0.010	<0.010[2)]	15	
								Rest of plant without roots	79	1.5	<0.010	<0.010	<0.010	<0.010[2)]	15	
								Seed	89	<0.010	<0.010	0.043	<0.010	0.033	45	
L190448 Greece EU-South 2019	Sunflower SO 0702 NK Neoma	1. 22.03.2019 2. 10.06.2019-20.06.2019 3. 01.08.2019-10.08.2019	100	200	50	2 21.06.2019 (plot 2)	BBCH 69	Whole plant (no roots)	69	1.6	<0.010	<0.010	<0.010	<0.010[2)]	0	
								Flower head	79	0.019	<0.010	0.011	0.010	0.015[2)]	20	
								Rest of plant without roots	79	0.43	<0.010	<0.010	<0.010	<0.010[2)]	20	
								Seed	89	<0.010	<0.010	0.058	<0.010	0.065	48	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)					DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 750 F	1,2,4-Triazole (1,2,4-T)	Triazolylalanine (TA)	Triazole lactic acid (TLA)	Triazole acetic acid (TAA)		
	(a)	(b)				(c)									(d)	(e)
L190449 Italy EU-South 2019	Sunflower SO 0702 LG5451H O CL	1. 29.04.2019 2. 11.07.2019-26.07.2019 3. end Aug - beg Sep 2019	100	200	50	2 26.07.2019 (plot 2)	BBCH 69	Whole plant (no roots)	69	0.92	<0.010	0.015	<0.010	<0.010[2)]	0	
								Flower head	79	0.088	<0.010	0.013	<0.010	0.016[2)]	11	
								Rest of plant without roots	79	0.39	<0.010	<0.010	<0.010	<0.010[2)]	11	
								Seed	89	<0.010	<0.010	0.036	<0.010	0.063	41	
			100	200	50	2 26.07.2019 (plot 3)	BBCH 69	Whole plant (no roots)	69	1.3	<0.010	<0.010	<0.010	<0.010	0	
								Flower head	79	0.059	<0.010	<0.010	<0.010	<0.010	11	
								Rest of plant without roots	79	0.24	<0.010	<0.010	<0.010	<0.010	11	
								Seed	89	<0.010	<0.010	0.036	<0.010	0.048	41	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)					DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 750 F	1,2,4-Triazole (1,2,4-T)	Triazolylalanine (TA)	Triazole lactic acid (TLA)	Triazole acetic acid (TAA)		
	(a)	(b)				(c)									(d)	(e)
L190450 Spain EU-South 2019	Sunflower SO 0702 LG 50531	1. 15.03.2019 2. 14.06.2019-27.06.2019 3. 14.08.2019	100	200	50	2 25.06.2019 (plot 2)	BBCH 69	Whole plant (no roots)	69	2.4	<0.010	<0.010	0.014	<0.010	0	
								Flower head	79	0.34	<0.010	<0.010	0.012	<0.010	13	
								Rest of plant without roots	79	1.6	<0.010	<0.010	<0.010	<0.010	13	
								Seed	89	0.012	<0.010	0.020	<0.010	0.022	48	
			100	200	50	2 26.07.2019 (plot 3)	BBCH 69	Whole plant (no roots)	69	1.4	<0.010	<0.010	0.020	<0.010	0	
								Flower head	79	0.30	<0.010	<0.010	<0.010	<0.010	13	
								Rest of plant without roots	79	1.9	<0.010	<0.010	<0.010	<0.010	13	
								Seed	89	0.010	<0.010	0.021	<0.010	0.027	48	

_ underlined residue values were used for calculations. In case both formulations have been used in the same trial, the more critical residue value has been chosen. Also, if higher residues appeared at a later PHI, the more critical value has been chosen.

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

Table A 18: Summary of the study 2 (2019/2075093), sunflower, untreated

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)				DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					1,2,4-Triazole (1,2,4-T)	Triazolylalanine (TA)	Triazole lactic acid (TLA)	Triazole acetic acid (TAA)		
	(a)	(b)				(c)								(d)	(e)
L190443 Germany EU-North 2019	Sunflower SO 0702 Vivacio	1. 10.04.2019 2. 03.07.2019-22.07.2019 3. 18.09.2019-21.09.2019	-	-	-	- Plot 1	-	Whole plant (no roots)	69	<0.010	0.014	0.029	0.013	0	**BAS 762 02 F** (SC, plot 2)
								Flower head	79	<0.010	0.041	<0.010	0.038	4	**BAS 762 00 F** (SC, plot 3)
								Rest of plant without roots	79	<0.010	<0.010	0.020	<0.010	4	
								Seed	89	<0.010	0.14	<0.010	0.15	58	BASF method L0076/09 for Mefentrifluconazole and L0170/02 for Triazole Metabolites
			-	-	-	- Plot 1	-	Whole plant (no roots)	69	<0.010	0.013	0.029	0.014	0	
								Flower head	79	<0.010	0.038	<0.010	0.041	4	
								Rest of plant without roots	79	<0.010	<0.010	0.020	<0.010	4	
								Seed	89	<0.010	0.15	<0.010	0.14	58	
L190444 France EU-North 2019	Sunflower SO 0702 RGT Buffalo	1. 08.04.2019 2. 07.07.2019-19.07.2019 3. 11.09.2019	-	-	-	- Plot 1	-	Whole plant (no roots)	69	<0.010	0.011	0.021	0.021	0	LOQ: 0.010 mg/kg
								Flower head	79	<0.010	0.035	<0.010	0.042	14	
								Rest of plant without roots	79	<0.010	<0.010	0.027	0.013	14	
								Seed	89	<0.010	0.072	<0.010	0.082	54	
			-	-	-	- Plot 1	-	Whole plant (no roots)	69	<0.010	0.021	0.021	0.011	0	
								Flower head	79	<0.010	0.042	<0.010	0.035	14	
								Rest of plant without roots	79	<0.010	0.013	0.027	<0.010	14	
								Seed	89	<0.010	0.082	<0.010	0.072	54	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)				DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					1,2,4-Triazole (1,2,4-T)	Triazolylalanine (TA)	Triazole lactic acid (TLA)	Triazole acetic acid (TAA)		
	(a)	(b)				(c)								(d)	(e)
L190445 Netherland EU-North 2019	Sunflower SO 0702 ES Biba	1. 11.05.2019 2. 05.07.2019-07.08.2019 3. 20.09.2019	-	-	-	- Plot 1	-	Whole plant (no roots)	69	<0.010	<0.010	0.010	<0.010	0	
								Flower head	79	<0.010	<0.010	<0.010	<0.010	12	
								Rest of plant without roots	79	<0.010	<0.010	<0.010	<0.010	12	
								Seed	89	<0.010	0.035	<0.010	0.037	44	
L190446 Austria EU-North 2019	Sunflower SO 0702 ES Biba	1. 18.04.2019 2. 05.07.2019-26.07.2019 3. 18.09.2019	-	-	-	- Plot 1	-	Whole plant (no roots)	69	<0.010	<0.010	<0.010	<0.010	0	
								Flower head	79	<0.010	<0.010	<0.010	<0.010	15	
								Rest of plant without roots	79	<0.010	<0.010	<0.010	<0.010	15	
								Seed	89	<0.010	<0.010	<0.010	<0.010	55	
L190447 France EU-South 2019	Sunflower SO 0702 MAS 87 OL	1. 08.05.2019 2. 21.07.2019-12.08.2019 3. 01.10.2019	-	-	-	- Plot 1	-	Whole plant (no roots)	69	<0.010	<0.010	<0.010	<0.010	0	
								Flower head	79	<0.010	<0.010	<0.010	<0.010	15	
								Rest of plant without roots	79	<0.010	<0.010	<0.010	<0.010	15	
								Seed	89	<0.010	0.015	<0.010	0.015	45	
L190448 Greece EU-South 2019	Sunflower SO 0702 NK Neoma	1. 22.03.2019 2. 10.06.2019-20.06.2019 3. 01.08.2019-10.08.2019	-	-	-	- Plot 1	-	Whole plant (no roots)	69	<0.010	<0.010	<0.010	<0.010	0	
								Flower head	79	<0.010	<0.010	<0.010	<0.010	20	
								Rest of plant without roots	79	<0.010	<0.010	<0.010	<0.010	20	
								Seed	89	<0.010	0.013	<0.010	0.019	48	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment: g a.s./ha	Water (L/ha)	g a.s./hL	Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg): 1,2,4-Triazole (1,2,4-T)	Triazolylalanine (TA)	Triazole lactic acid (TLA)	Triazole acetic acid (TAA)	DALA (d)	Details on trial (e)
L190449 Italy EU-South 2019	Sunflower SO 0702 LG5451HO CL	1. 29.04.2019 2. 11.07.2019-26.07.2019 3. end Aug - beg Sep 2019	-	-	-	- Plot 1	-	Whole plant (no roots)	69	<0.010	0.067	0.058	0.067	0	
								Flower head	79	<0.010	0.052	0.017	0.072	11	
								Rest of plant without roots	79	<0.010	<0.010	0.029	<0.010	11	
								Seed	89	<0.010	0.22	<0.010	0.34	41	
			-	-	-	- Plot 1	-	Whole plant (no roots)	69	<0.010	0.067	0.058	0.067	0	
								Flower head	79	<0.010	0.072	0.017	0.052	11	
								Rest of plant without roots	79	<0.010	<0.010	0.029	<0.010	11	
								Seed	89	<0.010	0.34	<0.010	0.22	41	
L190450 Spain EU-South 2019	Sunflower SO 0702 LG 50531	1. 15.03.2019 2. 14.06.2019-27.06.2019 3. 14.08.2019	-	-	-	- Plot 1	-	Whole plant (no roots)	69	<0.010	<0.010	0.019	<0.010	0	
								Flower head	79	<0.010	<0.010	<0.010	<0.010	13	
								Rest of plant without roots	79	<0.010	<0.010	<0.010	<0.010	13	
								Seed	89	<0.010	<0.010	<0.010	0.011	48	
			-	-	-	- Plot 1	-	Whole plant (no roots)	69	<0.010	<0.010	0.019	<0.010	0	
								Flower head	79	<0.010	<0.010	<0.010	<0.010	13	
								Rest of plant without roots	79	<0.010	<0.010	<0.010	<0.010	13	
								Seed	89	<0.010	0.011	<0.010	<0.010	48	

_ underlined residue values were used for calculations. In case both formulations have been used in the same trial, the more critical residue value has been chosen. Also, if higher residues appeared at a later PHI, the more critical value has been chosen.

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

A 2.1.3.1 Wheat

Table A 19: 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 (EFSA, 2018a)	2	0.150 kg as/ha	14	BBCH 30- 69	35
Intended cGAP (7, 9*)	1	0.100 kg as/ha	-	BBCH 30-49	56

A 2.1.3.1.1 Study 1 - wheat - BASF DocID 2019/1016888

Comments of zRMS:	During the 2018 growing season, 8 trials in wheat were conducted in different representative growing areas in Germany, Poland, Southern France, Spain, The Netherlands, United Kingdom, Italy and Greece to determine the residue level of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) after application of either BAS 762 00 F, BAS 750 01 F or BAS 549 02 F in or on Raw Agricultural Commodities (RAC). Four trials were set up as bridging trials (L180098 to L180101) which consisted of four plots: plot 1 (control), plot 2 (treated with BAS 762 00 F), plot 3 (treated with BAS 750 01 F) and plot 4 (treated with BAS 549 02 F). Four trials (L180102 to L180105) consisted of two plots: plot 1 (control), plot 2 (treated with BAS 762 00 F). BAS 762 00 F (100 g BAS 750 F/L, 200 g BAS 510 F/L, SC) was applied in all trials once at a single rate of 1.0 L/ha formulated product, equals to 0.100 kg a.i./ha of BAS 750 F and 0.200 kg a.i./ha of BAS 510 F on plot 2 with a water volume of 200 L/ha. BAS 750 01 F (100 g BAS 750 F/L, EC) was applied in four trials twice at a single rate of 1.5 L/ha formulated product, equals to 0.150 kg a.i./ha of BAS 750 F on plot 3 with a water volume of 200 L/ha. BAS 549 02 F (67 g BAS 480 F/L, 233 g BAS 510 F/L, SC) was applied in four trials twice at a single rate of 1.5 L/ha formulated product, equals to 0.1005 kg a.i./ha of BAS 480 F and 0.3495 kg a.i./ha of BAS 510 F on plot 4 with a water volume of 200 L/ha. In all trials the first application was made at BBCH 49. In the four bridging trials (plot 3 and 4) the second application was performed at BBCH 69. Trials L180098 to L180101 Wheat specimens were collected at BBCH 49 immediately before application no. 1 on plot 1 and directly after application no. 1 on plot 2 as whole plant no roots. At BBCH 69 specimens of plot 1 and 2 were collected before application no. 2 and directly after application no. 2 on plot 3 and 4 as whole plant no roots. At BBCH 83 the specimens of all plots were sampled as ears and rest of plant without roots. At 55-57 days after last application (DALA, related to plot 2) wheat specimens were collected on all plots either as ears and rest of plants without roots or as grain and straw. In one trial crop maturity was not reached at 56 ± 1 DALA and further samples were collected at BBCH 89 as grain and straw. In trial L180099 crop maturity was reached at 42 DALA already (related to plot 2), so that here sampling no. 4 omitted. Trials L180102 to L180105 Wheat specimens were collected at BBCH 49 immediately before application no. 1 on plot 1 and directly after application no. 1 on plot 2 as whole plant no roots. At BBCH 69 specimens were collected as whole plant no roots. At BBCH 83 the specimens were sampled as ears and rest of plant without roots. At 56-57 DALA, BBCH 89 was reached, wheat specimens were collected as grain and straw. Wheat specimens were analysed for BAS 750 F and BAS 510 F using the BASF Method L0076/09. The method has a limit of quantitation of 0.010 mg/kg. The results of the average procedural recoveries in wheat matrices at fortification levels between 0.010 and 40 mg/kg were at 84.6% for BAS 750 F and at 85.7% for BAS 510 F.

	Residues of BAS 750 F Plot 2: The residues of BAS 750 F analyzed in wheat whole plant no roots specimens sampled immediately after the last application (49 BBCH) ranged from 0.60 to 1.6 mg/kg. At 69 BBCH (12-23 DALA) residues decreased to 0.033 - 0.93 mg/kg. In ears specimens collected at 83 BBCH (27-43 DALA) and 85 BBCH (55 DALA) the residues of BAS 750 F were found from < 0.010 to 0.57 mg/kg and at 0.20 mg/kg, respectively. Rest of plant without roots specimens taken at the same sampling events showed residues of BAS 750 F from 0.059 to 2.3 mg/kg and at 0.77 mg/kg, respectively. In grain specimens sampled at 89 BBCH (42-69 DALA) residues of BAS 750 F were below the LOQ (0.010 mg/kg). In straw specimens sampled at 89 BBCH (42-69 DALA) residues of BAS 750 F ranged between 0.11 and 1.7 mg/kg. Plot 3: The residues of BAS 750 F analyzed in wheat whole plant no roots specimens sampled immediately after the last application (69 BBCH) ranged from 3.5 to 5.8 mg/kg. In ears specimens collected at 83 BBCH (14-23 DALA) and 85 BBCH (43 DALA) the residues of BAS 750 F were found from < 0.010 to 1.3 mg/kg and at 1.2 mg/kg, respectively. Rest of plant without roots specimens taken at the same sampling events showed residues of BAS 750 F from 2.1 to 4.3 mg/kg and at 3.9 mg/kg, respectively. In grain specimens sampled at 89 BBCH (29-57 DALA) residues of BAS 750 F were analyzed between < 0.010 and 0.034 mg/kg. In straw specimens sampled at 89 BBCH (29-57 DALA) residues of BAS 750 F ranged from 5.4 to 8.0 mg/kg. In the untreated control specimens, no residues of BAS 750 F were detected at or above the limit of quantitation (LOQ, 0.010 mg/kg). Bridging showed, that the new formulation BAS 762 00 F does not lead to higher residues that the respective solo formulation BAS 750 01 F. The maximum storage interval from harvest until analysis was 465 days for BAS 750 F (Mefentrifluconazole). Data indicates that residues of BAS 750 F were stable during the period of frozen storage prior to analysis. The study is acceptable.

Reference:	CA 6.3.3/1
Report	Study on the residue behaviour of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) in wheat after application of either BAS 762 00 F, BAS 750 01 F or BAS 549 02 F under field conditions in Germany, Poland, Southern France, Spain, The Netherlands, United Kingdom, Italy and Greece, 2018 XXX, H. P., 2020 Report No 857041, AC/BASF/18/01 BASF DocID 2019/1016888 Authority registration No
Guideline(s):	Regulation (EC) No. 1107/2009 of the European Parliament and the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC European Community Guideline 7029/VI/95 - rev.5, 22/07/97: General recommendations for the design preparation and realization of residue trials. European Community Guideline SANCO 7525/VI/95 - Rev. 10.3, 13 June 2017: Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. OECD Guideline for the testing of chemicals – Crop Field Trials: OECD/OCDE 509. Adopted 7 September 2009 GLP-Regulations of Test site countries
Deviations:	No
GLP:	yes (certified by Ministry of Justice, European Affairs and Consumer Protection, Brandenburg, Germany)
Acceptability:	Yes

Table A 20: Summary of recoveries (study 1 (2019/1016888), wheat)

Matrix		Fortification level [mg/kg]	BAS 750 F			
			n	Mean [%]	SD [±]	RSD [%]
Wheat	Whole plant*	0.010, 0.10, 2.0, 20	10	80.1	9.8	12
	Ears	0.010, 0.10, 5.0, 10	10	86.1	17	20
	Rest of plant**	0.010, 0.10, 5.0, 10, 20, 30	13	83.0	11	13
	Grain	0.010, 0.10, 1.0	7	77.8	11	14
	Straw	0.010, 0.10, 40	7	98.7	10	11
	Overall		47	84.6	13	16

* No roots
** Without roots

Table A 21: Summary of the study 1 (2019/1016888), wheat

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)	DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 750 F		
	(a)	(b)				(c)					(d)	(e)
L180098 Germany EU-North 2018	Wheat TRZAW GC0654 Tobak	1. 26.09.2017 2. 25.05.-01.06.2018 3. 20.07.2018	100	200	50	1 17.05.2018	BBCH 49	whole plant no roots whole plant no roots ears rest of plant without roots grain straw	49 69 83 83 89 89	0.60 0.88 0.012 0.50 <0.010 1.0	0 15 33 33 57 57	**BAS 762 00 F** SC **Mefentrifluconazole 100 g/L** Boscalid 200 g/L **f) BAS 750 01 F** SC **Mefentrifluconazole 100 g/L** BASF method L0076/09 LOQ: 0.01 mg/kg
			75 75	200 200	150 150	1 17.05.2018 2 01.06.2018	BBCH 49 BBCH 69	whole plant no roots ears rest of plant without roots grain straw	69 83 83 89 89	4.9[f] 0.30[f] 2.1[f] <0.010[f] 6.0[f]	0 18 18 42 42	
L180099 Poland EU-North 2018	Wheat TRZAW GC0654 Bamberka	1. 31.10.2017 2. 30.05.-10.06.2018 3. 20.08.2018	100	200	50	1 25.05.2018	BBCH 49	whole plant no roots whole plant no roots ears rest of plant without roots grain straw	49 69 83 83 89 89	1.3 0.33 0.047 0.27 <0.010 0.40	0 13 27 27 42 42	
			75 75	200 200	150 150	1 25.05.2018 2 07.06.2018	BBCH 49 BBCH 69	whole plant no roots ears rest of plant without roots grain straw	69 83 83 89 89	5.8[f] 0.66[f] 3.1[f] <0.010[f] 7.9[f]	0 14 14 29 29	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)	DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 750 F		
	(a)	(b)				(c)					(d)	(e)
L180100 France EU-South 2018	Wheat TRZAW GC0654 Solehio	1. 20.10.2017 2. 16.06.-20.06.2018 3. 16.08.2018	100	200	50	1 08.06.2018	BBCH 49	whole plant no roots whole plant no roots ears rest of plant without roots ears rest of plant without roots grain straw	49 69 83 83 85 85 89 89	1.6 0.54 0.26 0.58 0.20 0.77 <u><0.010</u> <u>0.66</u>	0 12 35 35 55 55 69 69	
			75 75	200 200	150 150	1 08.06.2018 2 20.06.2018	BBCH 49 BBCH 69	whole plant no roots ears rest of plant without roots ears rest of plant without roots grain straw	69 83 83 85 85 89 89	3.5[f] 1.3[f] 2.6[f] 1.2[f] 3.9[f] 0.012[f] 5.4[f]	0 23 23 43 43 57 57	
L180101 Spain EU-South 2018	Wheat TRZAW GC0654 Adagio	1. 17.11.2017 2. 05.05.-14.05.2018 3. 20.06.2018	100	200	50	1 25.04.2018	BBCH 49	whole plant no roots whole plant no roots ears rest of plant without roots grain straw	49 69 83 83 89 89	1.3 0.36 0.013 0.29 <u><0.010</u> <u>0.72</u>	0 19 36 36 56 56	No residues above the LOQ in any of the analyzed untreated specimens. Storage time for all commodities ≤465 days Samples were analysed within the storage stability (see chapter 7.2.1)
			75 75	200 200	150 150	1 25.04.2018 2 14.05.2018	BBCH 49 BBCH 69	whole plant no roots ears rest of plant without roots grain straw	69 83 83 89 89	5.2[f] <0.010[f] 4.3[f] 0.034[f] 8.0[f]	0 17 17 37 37	
L180102 The Netherlands EU-North 2018	Wheat TRZAW GC0654 Benchmark	1. 25.10.2017 2. 29.05.-11.06.2018 3. 18.07.2018	100	200	50	1 22.05.2018	BBCH 49	whole plant no roots whole plant no roots ears rest of plant without roots grain straw	49 69 83 83 89 89	1.1 0.20 <0.010 0.20 <u><0.010</u> <u>0.36</u>	0 20 41 41 57 57	
L180103 United Kingdom EU-North 2018	Wheat TRZAW GC0654 Belepi	1. 26.03.2018 2. 20.06.-29.06.2018 3. 05.08.2018	100	200	50	1 13.06.2018	BBCH 49	whole plant no roots whole plant no roots ears rest of plant without roots grain	49 69 83 83 89	1.1 0.93 0.57 2.3 <u><0.010</u>	0 16 36 36 56	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)	DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 750 F		
	(a)	(b)				(c)					(d)	(e)
								straw	89	1.7	56	
L180104 Italy EU-South 2018	Wheat TRZAW GC0654 Calabro	1. 18.11.2017 2. 19.05.-01.06.2018 3. 04.07.2018	100	200	50	1 09.05.2018	BBCH 49	whole plant no roots whole plant no roots ears rest of plant without roots grain straw	49 69 83 83 89 89	1.1 0.033 <0.010 0.059 <0.010 0.11	0 23 40 40 56 56	
L180104 Greece EU-South 2018	Wheat TRZAW GC0654 Cannavaro	1. 05.11.2017 2. 20.04.-30.04.2018 3. 11.06.2018	100	200	50	1 16.04.2018	BBCH 49	whole plant no roots whole plant no roots ears rest of plant without roots grain straw	49 69 83 83 89 89	1.4 0.79 0.012 0.72 <0.010 1.0	0 14 43 43 56 56	

_ underlined residue values were used for calculations. In case both formulations have been used in the same trial, the more critical residue value has been chosen. Also, if higher residues appeared at a later PHI, the more critical value has been chosen.

(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, underlined)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(f) Bridging trials with formulation BAS 750 01 F (SC) containing 100 g/L of BAS 750 F

A 2.1.4 Magnitude of residues in livestock

No new data submitted in the framework of this application. In the context of the Annex I inclusion process two feeding studies in hen and cow have been submitted by the applicant. These studies are summarized in chapter 7.2. For a detailed assessment refer to the EFSA conclusion (2018a) and the DAR (UK, 2018).

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

No new data submitted in the framework of this application. In the context of the Annex I inclusion process two cereal processing studies (conducted in wheat and barley) have been submitted by the applicant. And one processing study for soybean (oilseeds) has been submitted and was evaluated in EFSA, 2020. These studies are summarized in chapter 7.2. For a detailed assessment refer to the EFSA conclusion (2018a and 2020) and the DAR (UK, 2018).

A 2.1.6 Magnitude of residues in representative succeeding crops

No new data submitted in the framework of this application. In the context of the Annex I inclusion process one study for residues in succeeding crops has been submitted by the applicant. This study is summarized in chapter 7.2. For a detailed assessment refer to the EFSA conclusion (2018a) and the DAR (UK, 2018).

A 2.1.7 Other/Special Studies (KCA 6.10, KCA 6.10.1)

The active substance BAS 750 F and its formulation BAS 762 02 F are intended to be used in oilseed rape, sunflower and wheat. ~~No "other study" is provided.~~

A residue study for the determination of BAS 750 F residues in honey has been performed (BASF DocID: 2020/2109990, Report Amendment N°1 DocID: 2021/2038566) and has been provided by Applicant.

A 2.1.7.1.1 Study 1 - oilseed rape and rapeseed honey

Comments of zRMS:	Four field trials were conducted in Germany in order to determine the magnitude of residues of BAS 750 F (Mefentrifluconazole) and its metabolites T (1,2,4 Triazole), TA (triazolylalanine), TAA (triazole acetic acid) and TLA (triazole lactic acid) in oil-seed rape and rapeseed honey after one application of BAS 750 05 F under semi-field conditions. Each field trial consisted of a treated plot. In two field trials (L180272 and L180274) a control plot was also included. The test item BAS 750 05 F (75.0 g/L BAS 750 F (Mefentrifluconazole)), a suspension concentrate (SC), was foliar applied once on oilseed rape under semi-field conditions at growth stage BBCH 65, at a target rate of 2.0 L/ha formulated product (equals to 0.15 kg a.i./ha BAS 750 F (Mefentrifluconazole)). Treated oilseed rape (whole plant (no roots)) specimens were taken on the day of last application (once the spray solution was completely dried), as well as 14 days after last application (BBCH 67-69). Treated inflorescences and pollen specimens for analysis were sampled on the day of the last application (BBCH 65) (directly after last application in treated plots) as well as 1 day (BBCH 65), 2 (BBCH 65), 3 (BBCH 65), 4 (BBCH 65), 5 (BBCH 65), 10 (BBCH 65-67) and 14 (BBCH 67-69) days after last application. Treated bees for honey stomach and bees specimens were taken at 1, 3, 5 and 14 days after last application. At last sampling event also treated honey and wax specimens were taken. No residues (<0.05 mg/kg) of Mefentrifluconazole and 1,2,4-Triazole (T), Triazolylalanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) were found in any honey samples collected at 67-69 BBCH (14 DALA). No residues (<0.05 mg/kg) of 1,2,4-Triazole (T), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) were found in any pollen samples 14 days after last application.

	In pollen samples collected at 67-69 BBCH (14 DALA) the residues of Mefentrifluconazole and Triazolylalanine (TA) were found from 0.14 to 0.79 mg/kg and from 0.31 to 1.8 mg/kg, respectively. The study is acceptable.

Report:	Determination of residues of BAS 750 F (Mefentrifluconazole) in oilseed rape and rapeseed honey (unripe) after one application of BAS 750 05 F under simi-field conditions in Germany, 2018
	XXX, M.
	BASF DocID 2020/2109990
Guideline(s):	EC 1107/2009, EEC 7525/VI/95 rev. 10.3, OECD 509 (2009), SANTE/11956/2016 rev. 9
Deviations:	No
GLP:	Yes
	(certified by Saechsisches Staatsministerium fuer Umwelt und Landwirtschaft, Dresden, Germany)
Acceptability:	Yes

Report:	Amendment N°1 to final report Determination of residues of BAS 750 F (Mefentrifluconazole) in oilseed rape and rapeseed honey (unripe) after one application of BAS 750 05 F under simi-field conditions in Germany, 2018
	XXX, M.
	BASF DocID 2021/2038566
Guideline(s):	EC 1107/2009, EEC 7525/VI/95 rev. 10.3, OECD 509 (2009), SANTE/11956/2016 rev. 9
Deviations:	No
GLP:	Yes
	(certified by Saechsisches Staatsministerium fuer Umwelt und Landwirtschaft, Dresden, Germany)
Acceptability:	Yes

During the growing season of 2018, four trials in oilseed rape/rapeseed honey were conducted in different growing areas in Germany in order to determine the magnitude of the BAS 750 F (mefentrifluconazole) residues and its metabolites 1,2,4-triazole (1,2,4-T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA), after application of the formulated product BAS 750 05 F under semi-field conditions in or on Raw Agricultural Commodities (RAC).

For the analysis of BAS 750 F and the triazole metabolites (1,2,4-T, TA, TAA and TLA) analytical method No. L0170/03 was used which determines the analytes by means of LC-MS/MS.

Specimens were extracted with a mixture of methanol and water. For the determination of BAS 750 F, an aliquot was taken and filtered. Then the isotopically labelled internal standard was added for quantitation using HPLC-MS/MS. Another aliquot, for determination of 1,2,4-triazole (T), triazole alanine (TA), triazole acetic acid (TAA) and triazole lactic acid (TLA) was filtered, concentrated, and cleaned-up by a simple dispersive C18-SPE step. The analytes were determined by LC-DMS/MS/MS, using isotopically labelled internal standards for quantitation.
Higher residues were accordingly diluted to fit into the calibration curve and matrix effects were compensated by using labelled internal standards. The method has a limit of quantitation of 0.050 mg/kg for each analyte. The limit of detection for each analyte is at least 10 % of the LOQ and therefore corresponds to 0.005 mg/kg.

The mean procedural recoveries were 98.3% for BAS 750 F (mefentrifluconazole), 99.1% for 1,2,4-T, 103% for TA, 102% for TAA and 103% for TLA at fortification levels between 0.050 and 20 mg/kg for BAS 750 F and between 0.050 and 2.0 mg/kg for the triazole metabolites.
The detailed results are given in the tables below.

Table 3:Summary of recoveries of BAS 750 F in the different matrices

Matrix		Fortification Level [mg/kg]	BAS 750 F (m/z 398 → 182)			
			Mean [%]	SD [±]	RSD [%]	n
Oilseed rape	Whole Plant (No Roots)	0.05, 0.50 and 5.0	97.3	3.6	3.7	7
	Honey	0.05, 0.50 and 5.0	91.5	2.0	2.2	7
	Inflorescences	0.05, 0.50,5.0 and 20	98.9	7.3	7.4	8
	Pollen	0.05, 0.50,5.0 and 20	105	9.1	8.6	7
		Overall:	**98.3**	**7.7**	**7.8**	**29**

Table 4:Summary of recoveries of metabolites 1,2,4-triazole, TA, TAA and TLA in different matrices

Matrix		Fortification Level [mg/kg]	1,2,4 Triazole (Aquasil column)				TA (m/z 157→70)				TAA (Aquasil column)				TLA (Aquasil column)			
			Mean [%]	SD [±]	RSD [%]	n	Mean [%]	SD [±]	RSD [%]	n	Mean [%]	SD [±]	RSD [%]	n	Mean [%]	SD [±]	RSD [%]	n
Oilseed rape	Whole Plant (No Roots)	0.050 and 0.50	92.5	3.0	3.2	10	103	8.6	8.3	10	101	3.1	3.0	10	103	5.9	5.7	10
	Honey	0.050 and 0.50	99.6	7.5	7.5	10	100	5.3	5.2	10	101	5.3	5.3	10	106	4.9	4.6	10
	Inflorescences	0.050, 0.50 and 2.0	94.8	4.8	5.1	11	105	12	11	11	106	2.7	2.6	11	99.1	3.8	3.9	11
	Pollen	0.050, 0.50 and 2.0	106	4.2	4.0	17	103	12	12	17	101	6.7	6.6	17	103	18	18	17
		Overall:	**99.1**	**7.2**	**7.3**	**48**	**103**	**10**	**10**	**48**	**102**	**5.3**	**5.2**	**48**	**103**	**12**	**11**	**48**

TA = triazole alanine, TAA = triazole acetic acid, TLA = triazole lactic acid, SD = standard deviation, RSD = coefficient of variation, n = number of recoveries

Table 5: Residues of BAS 750 F (75 g/L, BAS 750 05 F, SC formulation) and TDM in in oilseed rape and rapeseed honey (treated samples, field conditions)

Report No. Location (EU-region) trial No	Commodity/ Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest	Method of treatment	Application rate per treatment			No. of treat-ments and last date	Growth stage at last date	Portion ana-lyzed	DALA[1)]	Residues (mg/kg)				
				kg as/hL	Water L/ha	kg as/ha					BAS 750 F	1,2,4-T	TA	TAA	TLA
2020/2109990 04319 Leipzig OT Hirschfeld Germany L180272	Oilseed rape SO 0495 BRSNN Arabella	1. 28.08.2017 2. 23.04.2018 – 14.05.2018 3. 14.05.2018	Foliar application	0.075	200	0.150	1 30.04.2018	65	Whole plant (no roots)	65	4.0	<0.050	0.19	<0.050	<0.050
									Whole plant (no roots)	69	1.6	<0.050	0.21	<0.050	<0.050
									Inflorescences	65	18	<0.050	1.8	<0.050	<0.050
									Inflorescences	65	12	<0.050	1.6	<0.050	<0.050
									Inflorescences	65	7.6	<0.050	1.8	<0.050	<0.050
									Inflorescences	65	2.9	<0.050	1.4	<0.050	<0.050
									Inflorescences	65	2.1	<0.050	1.5	<0.050	<0.050
									Inflorescences	65	1.4	<0.050	1.4	<0.050	<0.050
									Inflorescences	67	0.28	<0.050	1.8	<0.050	<0.050
									Inflorescences	69	0.14	<0.050	1.3	<0.050	<0.050
									Honey	69	<0.050	<0.050	<0.050	<0.050	<0.050
									Pollen	65	6.8	<0.050	1.9	<0.050	<0.050
									Pollen	65	2.4	<0.050	1.7	<0.050	<0.050
									Pollen	65	1.6	<0.050	1.4	<0.050	<0.050
									Pollen	65	0.92	<0.050	1.4	<0.050	<0.050
									Pollen	65	0.67	<0.050	1.5	<0.050	<0.050
									Pollen	65	0.80	<0.050	1.5	<0.050	<0.050
									Pollen	67	0.74	<0.050	1.4	<0.050	<0.050
									Pollen	69	0.79	<0.050	1.6	<0.050	<0.050
2020/2109990 04319 Leipzig OT Hirschfeld Germany L180273	Oilseed rape SO 0495 BRSNN Arabella	1. 28.08.2017 2. 23.04.2018 – 14.05.2018 3. 14.05.2018	Foliar application	0.075	200	0.150	1 30.04.2018	65	Whole plant (no roots)	65	3.2	<0.050	0.14	<0.050	<0.050
									Whole plant (no roots)	69	1.0	<0.050	0.16	<0.050	<0.050
									Inflorescences	65	20	<0.050	1.3	<0.050	<0.050
									Inflorescences	65	14	<0.050	1.4	<0.050	<0.050
									Inflorescences	65	12	<0.050	1.1	<0.050	<0.050
									Inflorescences	65	4.3	<0.050	1.2	<0.050	<0.050
									Inflorescences	65	2.0	<0.050	1.2	<0.050	<0.050
									Inflorescences	65	1.4	<0.050	1.1	<0.050	<0.050
									Inflorescences	67	0.28	<0.050	1.5	<0.050	<0.050
									Inflorescences	69	0.085	<0.050	1.7	<0.050	<0.050

									Honey	69	<0.050	<0.050	<0.050	<0.050	<0.050
									Pollen	65	5.4	<0.050	1.2	<0.050	<0.050
									Pollen	65	2.1	<0.050	1.2	<0.050	<0.050
									Pollen	65	0.57	<0.050	1.1	<0.050	<0.050
									Pollen	65	0.61	<0.050	1.2	<0.050	<0.050
									Pollen	65	0.23	<0.050	1.3	<0.050	<0.050
									Pollen	65	0.39	<0.050	1.2	<0.050	<0.050
									Pollen	67	0.29	<0.050	1.3	<0.050	<0.050
									Pollen	69	0.29	<0.050	1.8	<0.050	<0.050
2020/2109990 04617 Monstab Germany L180274	Oilseed rape SO 0495 BRSNN Bender	1. 25.08.2017 2. 22.04.2018 – 14.05.2018 3. 14.05.2018	Foliar application	0.075	200	0.150	1 30.04.2018	65	Whole plant (no roots)	65	3.6	<0.050	<0.050	<0.050	<0.050
									Whole plant (no roots)	67	1.3	<0.050	<0.050	<0.050	<0.050
									Inflorescences	65	17	<0.050	0.24	<0.050	<0.050
									Inflorescences	65	15	<0.050	0.24	<0.050	<0.050
									Inflorescences	65	9.5	<0.050	0.29	<0.050	<0.050
									Inflorescences	65	2.7	<0.050	0.18	<0.050	<0.050
									Inflorescences	65	1.2	<0.050	0.30	<0.050	<0.050
									Inflorescences	65	1.0	<0.050	0.29	<0.050	<0.050
									Inflorescences	65	0.33	<0.050	0.36	<0.050	<0.050
									Inflorescences	67	0.12	<0.050	0.51	<0.050	<0.050
									Honey	67	<0.050	<0.050	<0.050	<0.050	<0.050
									Pollen	65	12	<0.050	0.26	<0.050	<0.050
									Pollen	65	2.0	<0.050	0.28	<0.050	<0.050
									Pollen	65	0.28	<0.050	0.31	<0.050	<0.050
									Pollen	65	0.12	<0.050	0.33	<0.050	<0.050
									Pollen	65	0.087	<0.050	0.32	<0.050	<0.050
									Pollen	65	0.15	<0.050	0.28	<0.050	<0.050
									Pollen	67	0.14	<0.050	0.31	<0.050	<0.050
2020/2109990 04617 Monstab Germany L180275	Oilseed rape SO 0495 BRSNN Bender	1. 25.08.2017 2. 22.04.2018 – 14.05.2018 3. 14.05.2018	Foliar application	0.075	200	0.150	1 30.04.2018	65	Whole plant (no roots)	65	3.5	<0.050	0.057	<0.050	<0.050
									Whole plant (no roots)	67	1.5	<0.050	0.055	<0.050	<0.050
									Inflorescences	65	13	<0.050	0.28	<0.050	<0.050
									Inflorescences	65	11	<0.050	0.27	<0.050	<0.050
									Inflorescences	65	12	<0.050	0.28	<0.050	<0.050
									Inflorescences	65	3.1	<0.050	0.25	<0.050	<0.050
									Inflorescences	65	1.5	<0.050	0.32	<0.050	<0.050
									Inflorescences	65	0.98	<0.050	0.36	<0.050	<0.050

									Inflorescences	65	0.32	<0.050	0.32	<0.050	<0.050
									Inflorescences	67	0.15	<0.050	0.54	<0.050	<0.050
									Honey	67	<0.050	<0.050	<0.050	<0.050	<0.050
									Pollen	65	9.4	<0.050	0.28	<0.050	<0.050
									Pollen	65	1.7	<0.050	0.32	<0.050	<0.050
									Pollen	65	1.1	<0.050	0.34	<0.050	<0.050
									Pollen	65	0.25	<0.050	0.35	<0.050	<0.050
									Pollen	65	0.14	<0.050	0.33	<0.050	<0.050
									Pollen	65	0.24	<0.050	0.34	<0.050	<0.050
									Pollen	65	0.16	<0.050	0.29	<0.050	<0.050
									Pollen	67	0.19	<0.050	0.33	<0.050	<0.050

[1)] days after last application
1,2,4-T = 1,2,4-triazole, TA = triazole alanine, TAA = triazole acetic acid, TLA = triazole lactic acid.

Table 7.6-6: Residues of BAS 750 F (75 g/L, BAS 750 05 F, SC formulation) and TDM in in oilseed rape and rapeseed honey (untreated samples, field conditions)

Report No. Location (EU-region) trial No	Commodity/ Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest	Method of treatment	Application rate per treatment			No. of treat-ments and last date	Growth stage at last date	Portion analyzed	DALA[1)]	Residues (mg/kg)				
				kg as/hL	Water L/ha	kg as/ha					BAS 750 F	1,2,4-T	TA	TAA	TLA
2020/2109990 04319 Leipzig OT Hirschfeld Germany L180272	Oilseed rape SO 0495 BRSNN Arabella	1. 28.08.2017 2. 23.04.2018 – 14.05.2018 3. 14.05.2018	-	-	-	-	-	-	Whole plant (no roots)	65	<0.050	<0.050	0.083	<0.050	<0.050
									Inflores-cences	65	<0.050	<0.050	1.3	<0.050	<0.050
									Honey	69	<0.050	<0.050	<0.050	<0.050	<0.050
									Pollen	65	<0.050	<0.050	0.29	<0.050	<0.050
2020/2109990 04617 Monstab Germany	Oilseed rape SO 0495 BRSNN	1. 25.08.2017 2. 22.04.2018 – 14.05.2018	-	-	-	-	-	-	Whole plant (no roots)	65	<0.050	<0.050	<0.050	<0.050	<0.050

Table 7.6-6: Residues of BAS 750 F (75 g/L, BAS 750 05 F, SC formulation) and TDM in in oilseed rape and rapeseed honey (untreated samples, field conditions)

Report No. Location (EU-region) trial No	Commodity/ Variety	Date of 1. Sowing or planting 2. Flowering 3. Harvest	Method of treatment	Application rate per treatment			No. of treat-ments and last date	Growth stage at last date	Portion analyzed	DALA[1)]	Residues (mg/kg)				
				kg as/hL	Water L/ha	kg as/ha					BAS 750 F	1,2,4-T	TA	TAA	TLA
L180274	Bender	3. 14.05.2018							Inflores-cences	65	<0.050	<0.050	0.18	<0.050	<0.050
									Honey	67	<0.050	<0.050	<0.050	<0.050	<0.050
									Pollen	65	<0.050	<0.050	0.28	<0.050	<0.050

[1)] days after last application
[2)] days before last appliction
1,2,4-T = 1,2,4-triazole, TA = triazole alanine, TAA = triazole acetic acid, TLA = triazole lactic acid.
n.a. not applicable

A 2.2 Boscalid

A 2.2.1 Stability of residues

No new data.

A 2.2.2 Nature of residues in plants, livestock and processed commodities

A 2.2.2.1 Nature of residues in plants

A 2.2.2.1.1 Nature of residues in primary crops

A 2.2.2.1.1.1 Beans (rest of plant, pods, hulls, seed)

A new bean metabolism study using ^{14}C-dipheny-labeled boscalid has been recently submitted by the applicant in context of EFSA's request for additional information (Sept 2019) and is referenced here for completion purposes. This study is not yet contained in the publicly available draft RAR.

Comments of zRMS:	The metabolism in beans was conducted with ^{14}C-BAS 510 F to investigate the production-process-related impurity 2-(4-chlorophenyl)aniline (M510F62) as a potential legume biotransformation product. The active substance was applied to beans at a nominal rate of 3 x 500 g a.s./ha. Pods and rest of plant were harvested at -3 DALA and 13 DALA. At 13 DALA, pods were further separated into hulls and seeds. Based on the study results (DocID 2017/1143721), it can concluded that in all bean matrices investigated, boscalid constituted the dominant residue. 2-(4-chlorophenyl)aniline, designated in a previous metabolism study as metabolite M510F62, was not detected. The study is acceptable.

Reference:	CA 6.2.1/1
Report	Additional investigations of the metabolism of ^{14}C-BAS 510 F in beans, XXX, D., 2017 report No 834755 BASF DocID 2017/1143721 Authority registration No
Guideline(s):	EEC 7028/VI/95 rev. 3 Appendix A (EU): Metabolism and distribution in plants (draft of 22 July 1997), EPA 860.1000: Background - PMRA Section 97.2 (Canada): Residue Chemistry Guidelines: Plants and Lifestock (June 1997), EPA 860.1000: EPA Residue Chemistry Test Guidelines, EPA 860.1300: EPA Residue Chemistry Test Guidelines, EPA 860.1300: Nature of the Residue in Plants Livestock, JMAFF No 59 NohSan No 4200, OECD 501 - Metabolism in crops (adopted January 8 2007)
Deviations:	No
GLP:	yes (certified by Landesamt fuer Umwelt, Mainz, Germany)
Acceptability:	Yes

I. MATERIAL AND METHODS

A. MATERIALS

1. Test material: BAS 510 F

Description:	^{14}C-labeled at the diphenyl rings (diphenyl-U-C14); spec. activity 13.4 MBq/mg; Unlabeled BAS 510 F	
Lot/batch #:	Diphenyl-U-C14:	641-4009
	Unlabeled:	L71-168
Purity:	Diphenyl-U-C14:	radiochem. purity 99.6%, chem. purity 93%
	Unlabeled:	chem. purity 99%
CAS#:	188425-85-6	
Development code:	N/A	
Spiking levels:	Not reported	

2. Test commodity:

Crop:	Bean
Type:	Legume vegetables
Variety:	Hild's Maxi
Botanical name:	*Phaseolus vulgaris*
Crop parts(s) or processed Commodity:	Pods, rest of plant, hulls and seeds
Sample size:	Pods (130-1415 g) Rest of plant (574-2609 g) Hulls (1579 g) Seeds (332 g)

B. STUDY DESIGN AND METHODS

1. Test procedure

The study was carried out at the Agricultural Research Centre of BASF in Limburgerhof, Germany. The plant cultivation was conducted in a phytotron.

Bean seeds were sowed into six plastic containers filled with Bruch West soil. The crops were treated three times with radiolabeled boscalid at an application interval of 9-11 days. The test item was applied as SC formulations at a total actual application rate of 1568.5 g a.s./ha (3 x 522.8 g a.s./ha). Pods and rest of plant were harvested at -3 DALA and 13 DALA.

For the preparation of the application formulations, diphenyl-U-^{14}C-labeled (dissolved in acetonitrile) and unlabeled test item were mixed to obtain a ratio of approximately 1:1. The purity and stability of the application solutions were confirmed using HPLC and the identity was determined and verified by LC-MS/MS analysis (LC-MS/MS only for the second and third application solution). There was no indication of the existence of M510F62 in the application solution.

At -3 DALA, bean plants were thinned out and the harvested plant material was separated into pods and rest of plant. At harvest (BBCH 75-79; 13 DALA), pods were separated from whole plants and one part was separated by hand into seeds and hulls. Rest of plant were cut off with scissors above the ground and chopped.

2. Description of analytical procedures

Homogenized solid plant samples were weighed and combusted by means of an oxidizer. The limit of quantitation in mg/kg was calculated from the twofold background radioactivity level (dpm/g matrix) divided by the corresponding specific radioactivity. For the quantitation of radioactive residues in liquid samples a liquid scintillation counter (LSC) was used.

Homogenization/solvent extraction: Subsamples (pods, hulls and rest of plant collected 13 DALA) or whole samples (pods and rest of plant collected -3 DALA, seeds sampled 13 DALA) were homogenized. All samples were extracted three times with methanol and two times with water. After each extraction step, solid material was separated from the extract by centrifugation and filtration. The filtered supernatants (methanol extracts and water extracts) were pooled and adjusted to a defined volume, and aliquots thereof were radio-assayed. The residue after solvent extraction was dried in a fume hood, weighed, homogenized, and aliquots thereof were radio-assayed.

HPLC sample preparation: Prior to HPLC analysis the combined water extracts of pods (-3 and 13 DALA), hulls (13 DALA) and seeds (13 DALA) were concentrated, brought to a defined volume with the respective mobile phase. The combined methanol extracts of rest of plants (-3 and 13 DALA) were diluted with methanol before HPLC analysis. All other combined methanol or water extracts were directly analyzed by HPLC. The limit of quantitation for the quantitative HPLC methods was determined by a calibration curve and the limit of detection corresponds to the lowest calibration level accounting for 100.28 dpm/100 µL.

II. RESULTS AND DISCUSSION

1. Total radioactive residue (TRR)

In the present study, the TRR was calculated by summarizing the extractable radioactive residue (ERR) and the residual radioactive residue (RRR) after solvent extraction. For both labels, the measured TRR of the investigated matrices showed no major differences to the calculated TRR. The calculated TRR was set to 100%. The results are summarized in
Table A 22. The calculated TRR of rest of plant was 29.179 mg/kg (-3 DALA) and 52.051 mg/kg (13 DALA). The TRR in pods and seeds was lower and ranged from 0.789 mg/kg (pods, 13 DALA) to 1.196 mg/kg (pods, -3 DALA). Seeds were the matrix with the lowest residue level with 0.065 mg/kg.

Table A 22: Total radioactive residues (TRR) in bean samples following the application of boscalid

Matrix	DALA[1]	TRR measured[2] [mg/kg]	TRR calculated[3] [mg/kg]
Pods[4]	-3	1.016	1.196
Rest of plant[4]	-3	28.797	29.179
Pods	13	0.757	0.789
Hulls	13	0.833	0.802
Seeds	13	0.066	0.065
Rest of plant	13	49.388	52.051

1 Days after last application
2 Determined by direct combustion analysis
3 Calculated as the sum of ERR (extractable radioactive residue) and RRR (residual radioactive residue)
4 Samples were harvested 3 days before last application, only 2 x 522.8 g boscalid/ha had been applied

2. Extractability of radioactive residues

The extractability of the bean matrices with methanol and water is depicted in Table A 23. The extractability of radioactive residues of bean pods, hulls and rest of plant was very high and accounted for 98.5% TRR to 99.3% TRR. For bean seeds, the portions of extractable residues accounted for 70.2% TRR. For bean pods, hulls and rest of plant, the main part of the radioactive residues was extracted with methanol (≥97.8% TRR). The radioactive residues in the RRR were equal to or below 1.5% TRR and were not further investigated. For bean seeds, the portions of the radioactive residues extracted with methanol and water were 65.1% TRR and 5.1% TRR, respectively. The radioactive residues in the RRR accounted for 29.8% TRR and was not further investigated due to the low amounts of radioactive residues (0.019 mg/kg).

Table A 23: Extractability for radioactive residues of boscalid in bean samples

Matrix	DA-LA[1]	Methanol extract[2]		Water extract[2]		ERR[3]		RRR[4]		TRR calculated[5]
		[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]
Pods	-3	1.183	98.9	0.005	0.4	1.188	99.3	0.009	0.7	1.196
Rest of plant	-3	28.874	99.0	0.114	0.4	28.988	99.3	0.191	0.7	29.179
Pods	13	0.773	98.0	0.005	0.6	0.778	98.6	0.011	1.4	0.789
Hulls	13	0.785	97.8	0.005	0.7	0.790	98.5	0.012	1.5	0.802
Seeds	13	0.042	65.1	0.003	5.1	0.046	70.2	0.019	29.8	0.065
Rest of plant	13	51.374	98.7	0.275	0.5	51.649	99.2	0.402	0.8	52.051

1 Days after last application
2 Values measured from combined extracts
3 ERR (extractable radioactive residue) was calculated as sum of methanol and water extract
4 RRR (residual radioactive residue), after solvent extraction
5 Calculated as the sum of ERR + RRR was set to 100% TRR

3. Identification, characterization and quantification of radioactive residues in bean matrices

Peak assignment was based on comparison of the retention times and elution profiles with those of the reference items boscalid and 2-(4-chlorophenyl)aniline (M510F62). As the main portion of radioactive residues was recovered in bean rest of plant harvested at 13 DALA, the combined methanol extract was analyzed by LC-MS/MS and the obtained results confirmed the peak assignment.
A summary of identified and characterized radioactive residues is compiled in Table A 24. In none of the tested matrices at any time point 2-(4-chlorophenyl)aniline, designated in a previous metabolism study as metabolite M510F62, was detected in the methanol and water extract using two HPLC methods. This compound was further not detected in the methanol extract of rest of plant (13 DALA) by LC-MS/MS analysis.

Identification, characterization and quantitation of radioactive residues in pods (-3 DALA)

The methanol and water extract obtained from the pods sample at -3 DALA was analyzed by HPLC, where the unchanged parent boscalid was detected and quantified (sum of methanol and water extract: 1.188 mg/kg or 99.3% TRR).
In total, 1.188 mg/kg or 99.3% TRR was identified/characterized in the ERR, whereby one peak was characterized (<0.001 mg/kg or <0.1% TRR). The final residue was 0.009 mg/kg or 0.7% TRR and was not further investigated. The "grand total" accounted for 1.196 mg/kg or 100.0% TRR.

Identification, characterization and quantitation of radioactive residues in rest of plant (-3 DALA)

The methanol and water extract obtained from the rest of plant sample at -3 DALA was analyzed by HPLC, where the unchanged parent boscalid was detected and quantified (sum of methanol and water extract: 29.848 mg/kg or 102.3% TRR).
In total, 29.854 mg/kg or 102.3% TRR was identified/characterized in the ERR, whereby one peak was characterized (0.006 mg/kg or <0.1% TRR). The final residue was 0.191 mg/kg or 0.7% TRR and was not further investigated. The "grand total" accounted for 30.044 mg/kg or 103.0% TRR.

Identification, characterization and quantitation of radioactive residues in pods (13 DALA)
The methanol and water extract obtained from the pods sample at 13 DALA was analyzed by HPLC, where the unchanged parent boscalid was detected and quantified (sum of methanol and water extract: 0.761 mg/kg or 96.5% TRR).
In total, 0.778 mg/kg or 98.5% TRR was identified/characterized in the ERR, whereby one peak was characterized (0.016 mg/kg or 2.1% TRR). The final residue was 0.011 mg/kg or 1.4% TRR and was not further investigated. The "grand total" accounted for 0.789 mg/kg or 100.0% TRR.

Identification, characterization and quantitation of radioactive residues in hulls (13 DALA)
The methanol and water extract obtained from the hulls sample at 13 DALA was analyzed by HPLC, where the unchanged parent boscalid was detected and quantified (sum of methanol and water extract: 0.789 mg/kg or 98.3% TRR).
In total, 0.790 mg/kg or 98.5% TRR was identified/characterized in the ERR, whereby each characterized peak was below or equal to 0.001 mg/kg or 0.1% TRR. The final residue was 0.012 mg/kg or 1.5% TRR and was not further investigated. The "grand total" accounted for 0.802 mg/kg or 100.0% TRR.

Identification, characterization and quantitation of radioactive residues in seeds (13 DALA)
The methanol and water extract obtained from the seeds sample at 13 DALA was analyzed by HPLC, where the unchanged parent boscalid was detected and quantified (sum of methanol and water extract: 0.011 mg/kg or 17.3% TRR).
In total, 0.046 mg/kg or 70.1% TRR was identified/characterized in the ERR, whereby each characterized peak was below or equal to 0.011 mg/kg or 16.7% TRR. The final residue was 0.019 mg/kg or 29.8% TRR and was not further investigated. The "grand total" accounted for 0.065 mg/kg or 99.9% TRR.

Identification, characterization and quantitation of radioactive residues in rest of plant (13 DALA)
The methanol and water extract obtained from the rest of plant sample at 13 DALA was analyzed by HPLC, where the unchanged parent boscalid was detected and quantified (sum of methanol and water extract: 52.795 mg/kg or 101.4% TRR).
In total, 52.819 mg/kg or 101.5% TRR was identified/characterized in the ERR, whereby one peak was characterized (0.024 mg/kg or <0.1% TRR). The final residue was 0.402 mg/kg or 0.8% TRR and was not further investigated. The "grand total" accounted for 53.221 mg/kg or 102.2% TRR.

Table A 24: Summary of identified and characterized radioactive residues in bean matrices

Designation	Pods (-3 DALA)		Rest of plant (-3 DALA)		Pods (13 DALA)		Hulls (13 DALA)		Seeds (13 DALA)		Rest of plant (13 DALA)	
	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]
Boscalid (BAS 510 F)	1.188	99.3	29.848	102.3	0.761	96.5	0.789	98.3	0.011	17.3	52.795	101.4
M510F62	-	-	-	-	-	-	-	-	-	-	-	-
Total identified From ERR	1.188	99.3	29.848	102.3	0.761	96.5	0.789	98.3	0.011	17.3	52.795	101.4
Total characterized from ERR	<0.001	<0.1	0.006	<0.1	0.016	2.1	0.001	0.1	0.034	52.8	0.024	<0.1
Total identified and characterized	1.188	99.3	29.854	102.3	0.778	98.5	0.790	98.5	0.046	70.1	52.819	101.5
Final residue	0.009	0.7	0.191	0.7	0.011	1.4	0.012	1.5	0.019	29.8	0.402	0.8
Grand total	**1.196**	**100.0**	**30.044**	**103.0**	**0.789**	**100.0**	**0.802**	**100.0**	**0.065**	**99.9**	**53.221**	**102.2**

4. Metabolic pathway

In all bean matrices investigated, boscalid constituted the dominant residue. 2-(4-chlorophenyl)aniline, designated in a previous metabolism study as metabolite M510F62, was not detected.

5. Storage stability

All samples were analyzed within 6 months after sampling. Hence, no storage stability investigations were necessary.

III. CONCLUSION

The present study describes the metabolism of boscalid with particular regard to 2-(4-chlorophenyl)aniline (M510F62) as a potential legume biotransformation product. The active substance was applied to beans at a nominal rate of 3 x 522.8 g a.s./ha. Pods and rest of plant were harvested at -3 DALA and 13 DALA. At 13 DALA, pods were further separated into hulls and seeds.

The highest levels of radioactive residues were found in rest of plants at -3 DALA and 13 DALA (29.179 mg/kg and 52.051 mg/kg, respectively). The radioactive residue levels in the other matrices were between 0.789 mg/kg and 1.196 mg/kg, except for bean seeds (0.065 mg/kg).
The bean matrices were extracted with methanol and water. The extractability of radioactive residues of bean pods, hulls and rest of plant was very high (98.5-99.3% TRR). In bean seeds, the ERR accounted for 70.2% TRR. Most of the radioactive residues were extracted with methanol (65.1-99.0% TRR) and only minor amounts of residues were extracted with water (up to 5.1% TRR).
The radioactive residue after solvent extraction was generally low. The RRRs were equal to or below 1.5% of the TRR for bean pods, hulls and rest of plant. For bean seeds, the RRR accounted for 29.8% TRR and was not further investigated due to the low amounts of radioactive residues (0.019 mg/kg).

Peak assignment in the chromatograms was achieved by retention time comparison with the ^{14}C-reference items boscalid and M510F62. In addition, the methanol extract of rest of plant (13 DALA) was analyzed by LC-MS/MS.
The methanol and water extracts from all matrices mainly contained the unchanged parent compound boscalid with portions ranging from 96.5% to 102.3% TRR (sum of both extracts), except for seeds (sum of both extracts: 17.3% TRR). The remaining characterized radioactivity of seeds existed of several peaks, each below or equal to 0.011 mg/kg or 16.7 %TRR (most likely 2 non-separated peaks, see peak number 3 in figure 23 of study report). M510F62, which was previously identified in the extractables of the first bean metabolism study, was not detected in any matrix.

In all bean matrices investigated, boscalid constituted the dominant residue. 2-(4-Chlorophenyl)aniline, designated in a previous metabolism study as metabolite M510F62, was not detected. These findings strongly suggest a contamination of the application solution used in the previous study with 2-(4-chlorophenyl)aniline. 2-(4-Chlorophenyl)aniline is thus not generated during the metabolic processing of boscalid in beans and should therefore not be confirmed as plant metabolite of boscalid.

A 2.2.2.2 Nature of residues in livestock

A 2.2.2.2.1 Laying hen

A new poultry metabolism study using ^{14}C-pyridine-labeled boscalid has been recently submitted by the applicant in context of EFSA's request for additional information (Sept 2019) and is referenced here for completion purposes. This study is not yet contained in the publicly available draft RAR.

Comments of zRMS:	In the study (BASF DocID 2019/1077444) the nature of BAS 510 F degradation products in egg yolk, egg white, liver, muscle, fat, excreta and bile samples, which were generated in an externally conducted in-life phase was investigated. The primary metabolite M510F01 results from hydroxylation of the parent compound and is found in all matrices except bile. Conjugation of this metabolite with glucuronic acid leads to M510F02, present in liver, egg yolk, egg white and bile. Based on the study results (BASF DocID 2019/1077444), it can concluded that the new hen metabolism study using ^{14}C-pyridine-labeled boscalid are in good agreement with the previous conducted metabolism study in laying hens using a ^{14}C-diphenyl label. The study is acceptable.

Reference:	CA 6.2.2/1
Report	The Metabolism of [14C-pyridin]- BAS 510 F (Reg. No. 300355) in Laying Hens, XXX, C., XXX, J., 2019 report No 773275 BASF DocID 2019/1077444 Authority registration No
Guideline(s):	EEC 91/414 (7030(VI/95 Rev. 3), PMRA Residue Chemistry Guidelines Section 97.2 Nature of the Residue - Plants - Livestock (Canada), EPA 860.1000, EPA 860.1300, JMAFF 59 NohSan No 4200, OECD Test Guideline 503 - Metabolism in livestock
Deviations:	No
GLP:	yes (certified by Landesamt fuer Umwelt, Wasserwirtschaft und Gewerbeaufsicht, Mainz, Germany)
Acceptability:	Yes
Duplication (if vertebrate study)	No

I. MATERIAL AND METHODS

A. MATERIALS

1. Test material:	BAS 510 F		
Description:	^{14}C-labelled at position 3 of the pyridine ring (pyridin-3-C^{14}); spec. activity 5.11 MBq/mg; unlabeled BAS 510 F		
Lot/batch #:	pyridin-3-C14:	640-2301	
	Unlabeled:	L71-168	
Purity:	pyridin-3-C14:	radiochem. purity 99.5%, chem. purity 98.0%	
	Unlabeled:	chem. purity 99.0%	
CAS #:	188425-85-6		
Stability of test compound:	The stability of [^{14}C-pyridin]-BAS 510 F in the dose formulation was verified analytically prior to the first dosing occasion and 15 days post dose preparation.		

2. Test animals:	Laying hens
Species:	*Gallus gallus domesticus*
Gender:	Female
Weight at dosing:	1.5-2.0 kg
Number of animals:	10
Acclimatization period:	24 days
Diet:	Commercially available non-medicated concentrate ration, (Country Laygold Meal supplied by Harbro Limited, Markethill, Turriff, AB53 4PA.)
Water:	Tab water (*ad libitum*)
Housing:	Individual metabolism cages
Husbandry:	Husbandry conditions were in accordance with the current guidelines
Environmental conditions:	
Temperature:	20-21°C
Humidity:	24-59% relative humidity
Air changes:	Not reported
Photoperiod:	16 h light/ 8 h dark

B. STUDY DESIGN AND METHODS

1. Dosing regime:	Oral using a dosing gun
Amount of dose:	Nominal dose: 12 mg/kg per dry weight diet per day; mean actual doses (per dry weight diet per day): 12.601 mg/kg food consumed dry weight equivalent)
Food consumption:	17-175 g/day per bird (during application period)
Vehicle:	Gelatine capsule
Timing:	Once daily (in the morning)
Duration:	13 consecutive days

2. Sample collection:

Egg collection:	24 h prior to first dose administration, twice daily, additionally, whole eggs still in oviduct after termination
Excreta collection:	24 h prior to first dose administration, once daily
Interval from last dose to sacrifice:	Approximately 6 h
Tissues/organs collected and analyzed:	Egg white, egg yolk, muscle, fat, liver, excreta and bile
Matrices sampled for Balance Analysis:	Eggs (white, yolk and partially formed eggs), muscle (breast and thigh), fat (omental, renal and subcutaneous), liver, kidney, excreta, bile, blood, gastrointestinal tract and contents and cage wash

3. Test procedure

The in-life phase of this study was performed April 2016 to August 2016 (Charles River Laboratories Edinburgh Ltd), metabolism phase conducted from Sep 2016 to Feb 2017 (BASF SE). Ten laying hens were dosed at a nominal level of 12 mg/kg BAS 510 F per dry weight diet. The dose was administered orally in a gelatine capsule using a dosing gun, once daily for 13 consecutive days. Based on days 1 to 12, the mean achieved daily dose administered was 12.601 mg/kg food consumed (dry weight equivalent). The [^{14}C]-BAS 510 F dose formulation was prepared by mixing radiolabelled and non-radiolabelled test item in the ratio 1:1, leading to an actual specific activity of 2.51 MBq/mg. Approximately 6 h after administration of the final dose, the hens were sacrificed and the samples retained post mortem.

4. Sampling and storage

Excreta were collected prior to dose administration and at 24 h intervals thereafter until the time of sacrifice. The daily excreta samples were pooled, and the total weight recorded. Daily excreta samples were stored in a freezer set to maintain -20°C following collection.
Following each excreta collection, the cage was washed with the minimum amount of 1% detergent: water solution. The rinses were collected, pooled and the weight recorded. The cagewash was retained for total radioactivity analysis. Cage wash samples were stored at ambient temperature.
Eggs were collected from each metabolism cage twice daily (am and pm) from pre-dose (Day -1) until Day 13 (day of sacrifice). Eggs were separated into yolk and white and pooled on a daily basis, the total weight of each pool was recorded. Eggs collected in the afternoon during the dosing period were stored in a fridge set to maintain 4°C prior to total radioactivity analysis the following morning. Eggs collected in the morning were analyzed immediately with any afternoon eggs collected the previous day. Egg shells were retained but not analyzed. Egg samples were stored at 2-8°C prior to total radioactivity analysis, and following analysis stored in a freezer set to maintain -20°C.
At approximately 6 h post final dose the hens were sacrificed and edible tissues (liver, muscle and fat), partially formed eggs, bile, blood and the GI tract removed post mortem.

5. Description of analytical procedures

The radioactive content of the dose solution was determined by LSC analysis. The isotope ratio was determined by LC-MS analysis. Radiochemical purity of ^{14}C-BAS 510 F was confirmed by HPLC analysis.

The following samples were prepared for further use in the analytical phase and were measured for radioactivity: Excreta samples of days 8–12 were combined to produce a single excreta pool, egg yolk samples of days 8–12 were combined to produce a single egg yolk pool and an egg white pool of days 8–12 was prepared. A composite muscle sample was prepared by combining the breast muscle and leg and thigh muscle in a ratio of 1:1 by weight. Similarly, a composite fat sample was prepared by combining the omental fat and subcutaneous fat with skin in a ratio of 1:1 by weight. In addition, composite bile was measured for radioactivity and then used in the analytical phase. The radioactivity in each pool was determined by LSC analysis or combustion analysis followed by LSC.

Samples of the matrices egg white, egg yolk, liver, muscle, fat and excreta were each extracted with an appropriate solvent (acetonitrile or methanol). Aliquots of the residues after methanol extraction of liver and excreta were each extracted dichloromethane. The residues after this solvent extraction were extracted again with water. Aliquots of the residues after acetonitrile extraction of egg yolk and egg white were each extracted with water. Solubilization with enzymes of the residue after solvent extraction was conducted for egg yolk, liver and muscle. Aliquots of bile were directly subjected to HPLC analysis. Extracts were concentrated and analyzed by HPLC.

Generally, identification of metabolites was based on analysis by HPLC-MS/MS, on co-chromatography as well as chromatographic comparison of retention times of reference substances. In addition, various HPLC peaks were characterized by their chromatographic properties.

II. RESULTS AND DISCUSSION

General observations: all hens remained in good general health throughout the acclimatisation and dosing periods of the study. The hens were weighed during the acclimatisation and on study periods and the weights were shown to be consistent during the study.

1. Distribution of radioactive residues

Daily egg samples obtained on 13 consecutive days, separated into egg yolk and egg white, were measured for total radioactive residues (TRR). Residues in the egg reached a plateau maximum of 0.034 mg/kg for egg white and 0.150 mg/kg for egg yolk after 8 and 11 days, respectively (see Table A 25). These results indicating absence of accumulation of residues both in egg yolk and in egg white.

Table A 25: TRR in egg white and yolk after administration of [^{14}C-pyridin]-BAS 510 F to hen

Application day	TRR measured [mg/kg]	
	Egg white	Egg yolk
1	0.019	0.005
2	0.020	0.009
3	0.023	0.034
4	0.027	0.062
5	0.029	0.088
6	0.031	0.105
7	0.034	0.128
8	**0.034**[1]	0.142
9	0.031	0.143
10	0.028	0.137
11	0.031	**0.150**[1]
12	0.032	0.146
13[2]	0.031[2]	0.140[2]

1 Plateau maximum, indicated by bold typing; 2 day of sacrifice, no full 24 hour cycle

Approximately 92.5% of the total dose was recovered, the majority of which was present in the excreta (87.7%), followed by 4.6% in cage wash. Radioactivity associated with edible portions (eggs and tissues) accounted for *ca* 0.3% of the administered dose (see Table A 26).

Table A 26: Recovery of radioactivity following administration of [^{14}C-pyridin]-BAS 510 F to hens

Matrix	% Administered dose recovered in samples
Excreta	87.657
Cage wash	4.594
Egg yolk	0.086
Egg white	0.058
Liver[1]	0.111
Fat[1]	0.000
Muscle[1]	0.026
Bile	0.005
Total	**92.537**

1 Calculated from weight of tissue collected at necropsy

2. Total radioactive residues (TRR)

Total radioactive residues were calculated by summarizing the pooled acetonitrile or methanol extract (first extraction) and the residue after the first extraction (see Table A 27). The highest TRR was measured in excreta (11.063 mg/kg). In liver, with 0.439 mg/kg the TRR was lower; the TRR values of egg yolk and fat were 0.123 mg/kg and 0.095 mg/kg, respectively. The lowest TRR values were found for muscle and egg white (0.051 mg/kg and 0.030 mg/kg, respectively). Since bile was not extracted, the TRR measured from the in-life-phase report (33.976 mg/kg) was taken as 100% TRR.
Radioactive residue data measured during the in-life-phase for eggs, blood, bile and edible tissues are also provided in the table below. Residues in liver were 0.444 mg/kg. Residues in peritoneal fat and skin with fat accounted for 0.128 mg/kg and 0.075 mg/kg, respectively. Residues in breast muscle and leg and thigh muscle accounted for 0.021 mg/kg and 0.035 mg/kg, respectively. Residues in blood and bile accounted for 0.075 and 33.976 mg/kg, respectively.

The measured TRR values from the in-life-phase report were similar to the calculated TRR values (see Table A 25).

Table A 27: Total radioactive residues

Matrix	TRR measured[1]	TRR calculated[2]	
	[mg/kg]	[mg/kg]	% TRR
Peritoneal fat	0.128	-	-
Skin with fat	0.075	-	-
Composite fat (a)	0.090	0.095	100.0
Leg and thig muscle	0.035	-	-
Breast muscle	0.021	-	-
Composite muscle (b)	0.039	0.051	100.0
Liver	0.444	0.439	100.0
Egg yolk (c)	0.220	0.123	100.0
Egg white (c)	0.034	0.030	100.0
Blood	0.075	-	-
Excreta	12.179	11.063	100.0
Bile	33.976	33.976[3]	100.0

1 The TRR measured is taken from the in-life-phase report
2 The TRR calculated is calculated as sum of the result of the pooled extract of the first extraction and the result of the residue after that extraction.
3 Since bile was not extracted, the TRR measured from the in-life-phase report was taken as 100.0% TRR.
(a) Peritoneal fat: Skin with fat 1:1, by weight
(b) Breast muscle: Leg and thigh muscle 1:1, by weight
(c) Composite Day 8-12 (time points which fall on the plateau)

3. Extractability of radioactive residues

The extractability of the hen matrices is summarized in Table A 28. The major part of radioactivity was extracted with acetonitrile or methanol (62.5–94.1% TRR): 0.077 mg/kg or 62.5% TRR were extracted in this step from egg yolk, 0.026 mg/kg or 85.4% TRR from egg white, 0.286 mg/kg or 65.1% TRR from liver, 0.039 mg/kg or 77.5% TRR from muscle, 0.090 mg/kg or 94.1% TRR from fat and 10.022 mg/kg or 90.6% TRR from excreta. From liver and excreta, small amounts of radioactivity were additionally extracted with dichloromethane (1.4% TRR and 1.1% TRR, respectively). With water, subsequently 1.8% TRR and 1.0% TRR were extracted from liver and excreta, respectively. From egg yolk and egg white 9.9% TRR and 6.0% TRR were extracted with water, respectively.

Table A 28: Extractability of radioactive residues in hen matrices

Matrix	Acetonitrile or methanol extract[1]		Residue after first extraction[2]		Sum acetonitrile or methanol extract + residue after first extraction		Dichloro-methane extract		Water extract		ERR		RRR	
	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[%TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]
Egg yolk	0.077	62.5	0.046	37.5	0.123	100.0	n.a.	n.a.	0.012	9.9	0.089	72.4	0.035	28.3
Egg white	0.026	85.4	0.004	14.6	0.030	100.0	n.a.	n.a.	0.002	6.0	0.028	91.4	0.002	8.0
Liver	0.286	65.1	0.153	34.9	0.439	100.0	0.006	1.4	0.008	1.8	0.300	68.4	0.140	31.8
Muscle	0.039	77.5	0.011	22.5	0.051	100.0	n.a.	n.a.	n.a.	n.a.	0.039	77.5	0.011	22.5
Fat	0.090	94.1	0.006	5.8	0.095	100.0	n.a.	n.a.	n.a.	n.a.	0.090	94.1	0.006	5.8
Excreta	10.022	90.6	1.041	9.4	11.063	100.0	0.123	1.1	0.115	1.0	10.259	92.7	0.671	6.1

1 Values of pooled acetonitrile or methanol extract
2 The first extraction is the extraction with acetonitrile or methanol. The acetonitrile or methanol extract and the residue after the first extraction per definition add up to 100% TRR.
n.a. not applicable

4. Solubilization of radioactive residues

The residues after solvent extraction (RRR) of egg yolk, liver and muscle were subjected to further investigations. The results of the protease incubations of the residues after solvent extraction of the three matrices and the results of the pepsin and pancreatin incubations of liver are summarized in Table A 29. Protease released 0.029 mg/kg or 23.7% TRR from egg yolk, 0.095 mg/kg or 21.6% TRR from liver and 0.018 mg/kg or 35.5% TRR from muscle. The residues after protease solubilization were 0.009 mg/kg or 7.5% TRR and 0.004 mg/kg or 8.1% TRR for egg yolk and muscle, respectively. Since the residue after protease solubilization for liver was higher (0.058 mg/kg or 13.3% TRR), pepsin (artificial gastric juice) and pancreatin (artificial intestinal fluid) solubilizations were performed in order to test the bioavailability of the residues. Pepsin incubation released additional 0.009 mg/kg or 2.0% TRR and pancreatin solubilization 0.007 mg/kg or 1.7% TRR. The final residue of liver (0.042 mg/kg or 9.6% TRR), calculated from the residue after protease solubilization minus the pepsin and pancreatin solubilizates) can thus be considered not bioavailable.

Table A 29: Solubilization of the residual radioactive residues (RRR)

Designation	Matrix					
	Egg yolk		Liver		Muscle	
	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]
Residue after solvent extraction	0.035	28.3	0.140	31.8	0.011	22.5
Protease solubilizate	0.029	23.7	0.095	21.6	0.018	35.1
Residue after protease solubilization	0.009	7.5	0.058	13.3	0.004	8.1
Pepsin solubilizate	n.a.	n.a.	0.009	2.0	n.a.	n.a.
Pancreatin solubilizate	n.a.	n.a.	0.007	1.7	n.a.	n.a.
Sum of released residues	**0.029**	**23.7**	**0.111**	**25.3**	**0.018**	**35.1**
Final residue	0.009	7.5	0.042 1	9.6 [1]	0.004	8.1
Sum of released residues + final residue	**0.038**	**31.2**	**0.153**	**34.9**	**0.022**	**43.2**

1 The final residue for liver was calculated from the residue after protease solubilization minus the pepsin and pancreatin solubilizates.
n.a. not applicable

5. Identification and characterization of radioactive residues

An aliquot of the pooled methanol extract of excreta was used to generate two sub-fractions by HPLC fractionation, which were subjected to MS analyses for metabolite identification. Here, the parent compound BAS 510 F and, with an additional MS analysis using a reference item to specify the position of the hydroxyl group as position 5 of the biphenyl moiety, the metabolite M510F01 were identified. An aliquot of bile was subjected to MS analysis, where M510F65 was identified. The generic structure of M510F65 has been identified as the definite structure of M510F02 within an additional study (see DocID 2019/1075236; summary below).

Solvent extracts or sub-fractions thereof with a sufficient level of radioactive residues were analyzed by HPLC, generally with two methods. The peaks in the HPLC chromatograms that were used for quantification and confirmation were identified by comparison of their retention times with those of the reference items, using the same HPLC methods. In order to assign peaks correctly in the case of peak splitting, the acetonitrile extract of egg white was taken for co-chromatography experiments with bile using both quantifying and confirmatory HPLC methods.

Residues in extracts/solubilizates that were not analyzed by HPLC, were considered characterized by their partition/solubilization characteristics. A summary of identified and characterized residues is shown in Table A 30. A summary of all identified metabolites and their distribution is given in Table A 31.

Egg yolk

In the acetonitrile extract, the two prominent peaks were identified as the parent compound BAS 510 F, accounting for 0.042 mg/kg or 34.0% TRR, and as M510F01 accounting for 0.034 mg/kg or 27.4% TRR. In the water extract, the main peak was assigned to M510F02 and accounted for 0.010 mg/kg or 8.4% TRR. In the protease solubilizate, the only peak assigned in the quantitative HPLC run matches the retention time of M510F02 (0.029 mg/kg or 23.7% TRR); the confirmatory chromatogram shows several peaks around the expected retention time. Therefore, in the confirmatory chromatogram, one of the largest peaks and at the same time the one that matches the retention time best, was tentatively assigned to M510F02 (0.009 mg/kg or 6.9% TRR from the confirmatory chromatogram); additional peaks in the confirmatory HPLC chromatogram might belong to small amounts of further components and/or might show due to peak splitting (remaining peaks ≤0.009 mg/kg or 7.0% TRR from the confirmatory HPLC run).
In the ERR, the total amount identified and characterized was 0.089 mg/kg or 72.4% TRR. The level of radioactive residues after solvent extraction accounted for 0.035 mg/kg or 28.3% TRR and was therefore further solubilized; 0.029 mg/kg or 23.7% TRR were released by protease solubilization leading to a final residue of 0.009 mg/kg or 7.5% TRR. In the ERR and RRR, 0.115 mg/kg or 93.4% TRR were identified and 0.003 mg/kg or 2.6% TRR were characterized, which adds up to a total amount identified and characterized of 0.118 mg/kg or 96.0% TRR.

Egg white

In the acetonitrile extract, the two main peaks were identified as BAS 510 F (0.010 mg/kg or 34.3% TRR) and M510F01 (0.008 mg/kg or 28.1% TRR). The double peak eluting at 32.53 min/32.96 min was assigned to M510F02 and accounts for 0.005 mg/kg or 16.4% TRR.
The water extract contained 0.002 mg/kg or 6.0% TRR; thus, it was not further analyzed by HPLC. The residual radioactive residue after solvent extraction was also low and accounted for 0.002 mg/kg or 8.0% TRR and was therefore the final residue. In total, 0.024 mg/kg or 78.8% TRR were identified and 0.004 mg/kg or 12.6% TRR were characterized. The total amount identified and characterized was 0.028 mg/kg or 91.4% TRR.

Liver

In the methanol extract, the two prominent peaks were identified as M510F01, accounting for 0.155 mg/kg or 35.2% TRR, and as M510F02 accounting for 0.080 mg/kg or 18.2% TRR. Parent was also identified and accounted for 0.008 mg/kg or 1.8% TRR. The dichloromethane extract showed only one peak, which was characterized by its chromatographic behaviour.
In the protease solubilizate, the peak at 33.81 min/34.29 min was assigned to M510F02. This peak is sensitive to splitting; it accounted for 0.010 mg/kg or 2.2% TRR.
The results of the quantitative analysis of liver are summarized in
Table A 30 to
Table A 31. The water extract contained 0.008 mg/kg or 1.8% TRR; thus, it was not further analyzed by HPLC. The total amount identified and characterized from the ERR accounted for 0.300 mg/kg or 68.4% TRR. The residues in the pepsin and pancreatin solubilizates were too low for good chromatography and accounted for 0.009 mg/kg or 2.0% TRR and 0.007 mg/kg or 1.7% TRR, respectively. The final residue, which can thus be considered not bioavailable, was calculated from the residue after protease solubilization minus the pepsin and pancreatin solubilizates and accounted for 0.042 mg/kg or 9.6% TRR. In the ERR and RRR, 0.252 mg/kg or 57.5% TRR were identified and 0.159 mg/kg or 36.2% TRR were characterized. The total amount identified and characterized was 0.411 mg/kg or 93.7% TRR.

Muscle
In the methanol extract, BAS 510 F (0.015 mg/kg or 29.4% TRR) and M510F01 (0.005 mg/kg or 10.8% TRR) were identified.
In total, 0.020 mg/kg or 40.3% TRR were identified. In the ERR, 0.039 mg/kg or 77.5% TRR were identified and characterized; additional 0.018 mg/kg or 35.1% TRR were characterized in the RRR (there were 2 characterized peaks in the protease solubilizate, maximum: 0.009 mg/kg or 17.6% TRR). Together with the final residue, the total amount identified and characterized would add up to 0.061 mg/kg or 120.7% TRR; these discrepancies might result from inhomogeneities of the residue after solvent extraction.

Fat
In this extract, BAS 510 F was identified and accounted for 0.081 mg/kg or 84.9% TRR. M510F01 was also present, accounting for 0.005 mg/kg or 5.3% TRR.
In total, 0.086 mg/kg or 90.2% TRR were identified and 0.004 mg/kg or 4.0% TRR were characterized, which adds up to a total amount identified and characterized of 0.090 mg/kg or 94.1% TRR.

Excreta
In this extract, M510F01 was identified and accounted for 6.846 mg/kg or 61.9% TRR. BAS 510 F was also present, accounting for 2.694 mg/kg or 24.4% TRR.
The dichloromethane extract and the water extract contained ≤0.123 mg/kg or ≤1.1% TRR. In total, 9.540 mg/kg or 86.2% TRR were identified and 0.720 mg/kg or 6.5% TRR were characterized. The total amount identified and characterized was 10.259 mg/kg or 92.7% TRR.

Bile
The main component was identified as M510F02 and accounted for 32.041 mg/kg or 94.3% TRR. The characterized components accounted for 1.935 mg/kg or 5.7% TRR. The total amount identified and characterized was 33.976 mg/kg or 100% TRR.

Table A 30: Summary of identified and of characterized residues in hen matrices

Residue component	Matrix													
	Egg yolk		Egg white		Liver		Muscle		Fat		Excreta		Bile	
	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]
Extractable radioactivity														
BAS 510 F	0.042	34.0	0.010	34.3	0.008	1.8	0.015	29.4	0.081	84.9	2.694	24.4	n.d.	n.d.
M510F01	0.034	27.4	0.008	28.1	0.155	35.2	0.005	10.8	0.005	5.3	6.846	61.9	n.d.	n.d.
M510F02	0.010	8.4	0.005	16.4	0.080	18.2	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	32.041	94.3
Total identified from ERR	0.086	69.8	0.024	78.8	0.242	55.2	0.020	40.3	0.086	90.2	9.540	86.2	32.041	94.3
Total characterized from ERR by HPLC[1]	0.003 (1 + 2 peaks)	2.6	0.002 (2 peaks)	6.6	0.050 (3 + 1 peaks)	11.3	0.019 (5 peaks)	37.2	0.004 (1 peak)	4.0	0.482 (3 peaks)	4.4	1.935 (3 peaks)	5.7
Maximum unknown peak	0.001	1.1	0.001	4.6	0.017	3.8	0.007	13.2	0.004	4.0	0.303	2.7	0.930	2.7
Dichloromethane extract	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	0.123	1.1	n.a.	n.a.
Water extract	n.a.	n.a.	0.002	6.0	0.008	1.8	n.a.	n.a.	n.a.	n.a.	0.115	1.0	n.a.	n.a.
Total characterized from ERR	0.003	2.6	0.004	12.6	0.058	13.1	0.019	37.2	0.004	4.0	0.720	6.5	1.935	5.7
Total identified / characterized from ERR	0.089	72.4	0.028	91.4	0.300	68.4	0.039	77.5	0.090	94.1	10.259	92.7	33.976	100.0
Radioactivity released from non-extractable radioactivity														
By HPLC														
M510F02	0.009[2]	6.9[2]	-	-	0.010	2.2	n.d.	n.d.	-	-	-	-	-	-
Total identified from RRR	0.009[2]	6.9[2]	-	-	0.010	2.2	-	-	-	-	-	-	-	-
Total characterized from RRR by HPLC	0.020[2] (5 peaks)[2]	16.8[2]	-	-	0.085 (17 peaks)	19.3	0.018 (2 peaks)	35.1	-	-	-	-	-	-
Maximum unknown	0.009[2]	7.0[2]	-	-	0.010	2.4	0.009	17.6	-	-	-	-	-	-
By solubilization procedures														
Pepsin solubilizate	n.a.	n.a.	-	-	0.009	2.0	n.a.	n.a.	-	-	-	-	-	-
Pancreatin solubilizate	n.a.	n.a.	-	-	0.007	1.7	n.a.	n.a.	-	-	-	-	-	-
Total characterized from RRR by solubilization	0.020	16.8	-	-	0.101	23.1	0.018	35.1	-	-	-	-	-	-

Residue component	Matrix													
	Egg yolk		Egg white		Liver		Muscle		Fat		Excreta		Bile	
	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]	[mg/kg]	[% TRR]
Total identified / characterized from RRR by solubilization	0.029	23.7	n.a.	n.a.	0.111	25.3	0.018	35.1	n.a.	n.a.	n.a.	n.a.	-	-
Total identified and characterized	**0.029**	**23.7**	**0.028**	**91.4**	**0.411**	**93.7**	**0.057**	**112.6**	**0.090**	**94.1**	**10.259**	**92.7**	**33.976**	**100.0**
Final residue	0.009	7.5	0.002	8.0	0.042	9.6	0.004	8.1	0.006	5.8	0.671	6.1	-	-
Grand total	**0.127**	**103.5**	**0.030**	**99.4**	**0.453**	**103.2**	**0.061**	**120.7**	**0.095**	**100.0**	**10.930**	**98.8**	**33.976**	**100.0**

n.a. Not applicable
n.d. Not detected
1 In case several extracts were analyzed by HPLC, the number of not assigned peaks in the individual extract is given.
2 While the quantitative HPLC chromatogram shows only one peak (0.029 mg/kg or 37.1% TRR), in the confirmatory chromatogram six peaks are present in total, which leads to the fact that M510F02 accounts for only 0.009 mg/kg or 6.9%. In this table the results of the confirmatory HPLC chromatogram are shown.

Table A 31: Identified components in hen matrices

Designation	Egg yolk	Egg white	Liver	Muscle	Fat	Excreta	Bile
	[mg/kg] [%TRR]	[mg/kg] [%TRR]	[mg/kg] [%TRR]	[mg/kg] [%TRR]	[mg/kg] [%TRR]	[mg/kg] [%TRR]	[mg/kg] [%TRR]
BAS 510 F	0.042 34.0	0.009 29.1	0.008 1.8	0.015 29.4	0.081 84.9	2.694 24.4	-
M510F01	0.034 27.4	0.007 24.5	0.155 35.2	0.005 10.8	0.005 5.3	6.846 61.9	-
M510F02	0.039 32.1	0.003 9.6	0.090 20.5	-	-	-	32.041 94.3

6 Proposed metabolic pathway

The proposed metabolic pathway of boscalid in laying hens is shown in Figure A 1.
The primary metabolite M510F01 results from hydroxylation of the parent compound in position 5 of the biphenyl moiety and is found in all relevant matrices. Conjugation of this metabolite with glucuronic acid leads to M510F02, present in liver, egg yolk and egg white.

7 Storage stability

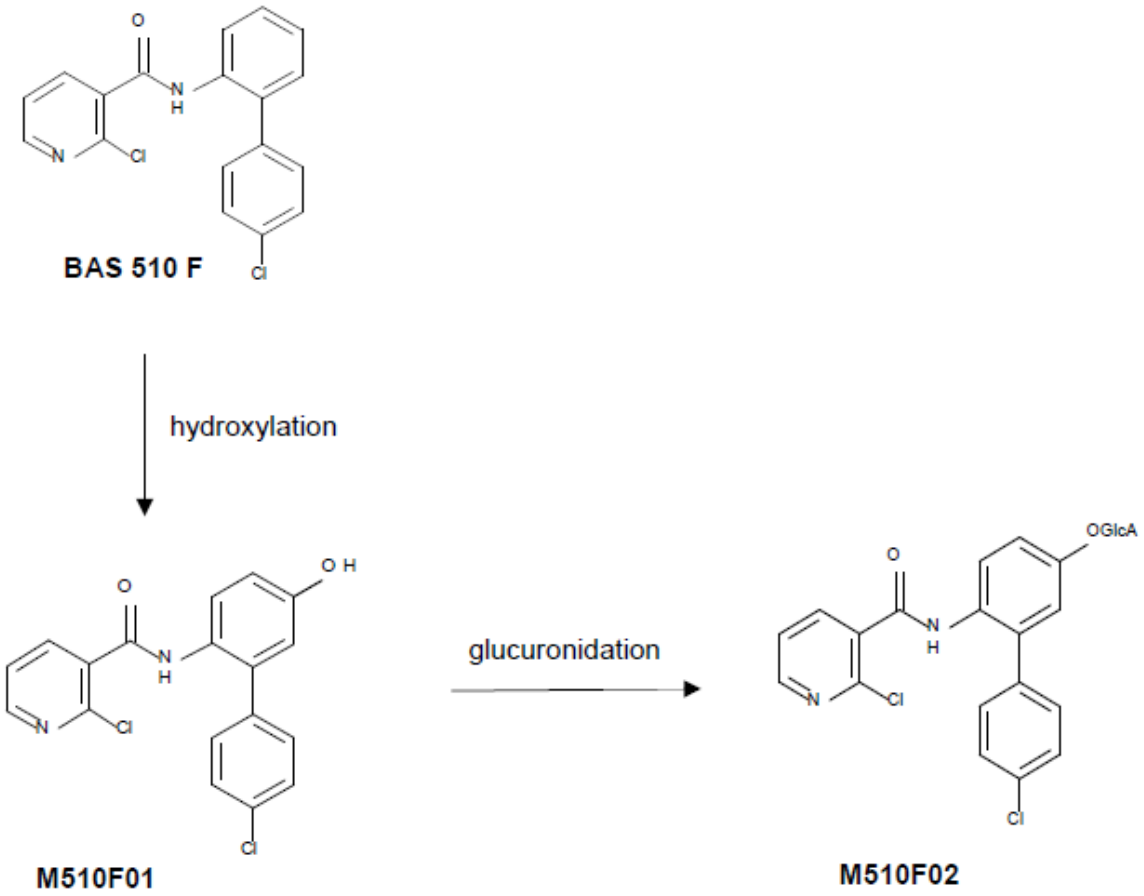
The intervals between sampling, extraction and analysis of the matrices (egg yolk, egg white, liver, muscle and fat) and the solvent extracts which were quantitatively analyzed and re-analyzed with HPLC.
The matrices were extracted within 113 and 148 days after sacrifice (sampling) of the hens and no further extractions were performed. Therefore, there was no need to conduct matrix stability experiments.
The extracts were analyzed within 148 and 149 days after sampling and re-analyzed within 229 and 233 days after sampling. The HPLC profiles of the late analyses were compared with those of the early analyses, which revealed that the samples were stable throughout the time of the study. For egg yolk and liver, shifts of the retention time were seen but since the pattern was confirmed, also the extracts of these matrices are proven to be stable upon storage.

III. CONCLUSION

The objective of the present study was to investigate the metabolic fate of ^{14}C-pyridine labelled BAS 510 F in egg yolk, egg white, liver, muscle, fat and excreta samples, which were generated in an externally conducted in-life phase.
Ten laying hens were dosed at a nominal level of 12 mg/kg BAS 510 F per dry weight diet. The dose was administered orally in a gelatine capsule using a dosing gun, once daily for 13 consecutive days.
The following samples were prepared for further use in the analytical phase and were measured for radioactivity: Excreta samples of days 8-12 were combined to produce a single excreta pool, egg yolk samples of days 8-12 were combined to produce a single egg yolk pool and an egg white pool of days 8-12 was prepared. A composite muscle sample was prepared by combining the breast muscle and leg and thigh muscle in a ratio of 1:1 by weight. Similarly, a composite fat sample was prepared by combining the omental fat and subcutaneous fat with skin in a ratio of 1:1 by weight. In addition, composite bile was measured for radioactivity and then used in the analytical phase.
The highest TRR was measured in excreta (11.063 mg/kg). In liver, with 0.439 mg/kg the TRR was lower; the TRR values of egg yolk and fat were 0.123 mg/kg and 0.095 mg/kg, respectively. The lowest TRR values were found for muscle and egg white (0.051 mg/kg and 0.030 mg/kg, respectively). The measured TRR values from the in-life-phase report were similar to the calculated TRR values.

The major part of radioactivity of the hen matrices was extracted with acetonitrile or methanol (62.5–94.1% TRR): 0.077 mg/kg or 62.5% TRR were extracted in this step from egg yolk, 0.026 mg/kg or 85.4% TRR from egg white, 0.286 mg/kg or 65.1% TRR from liver, 0.039 mg/kg or 77.5% TRR from muscle, 0.090 mg/kg or 94.1% TRR from fat and 10.022 mg/kg or 90.6% TRR from excreta. From liver and excreta, only small amounts of radioactivity were additionally extracted with dichloromethane and subsequently with water (1.0%–1.8% TRR for each extraction). From egg yolk and egg white, 9.9% TRR and 6.0% TRR were extracted with water, respectively.
The residues after solvent extraction of egg yolk, liver and muscle were subjected to further investigations. By solubilization with protease, 21.6–35.5% TRR were released. For liver, the residue after solubilization with protease, was subjected to solubilization with artificial gastric juice and subsequently with artificial intestinal fluid, which released further 1.7% and 2.0% TRR, respectively. The final residue of liver (0.042 mg/kg or 9.6% TRR) can thus be considered not bioavailable. The final residues of the other investigated matrices were low (max. 8.1% TRR or 0.009 mg/kg).
Three samples that each contained one of the three main components were used as reference items and were subjected to structure elucidation by MS analysis. Thereby, BAS 510 F, M510F01 and M510F65 were identified. (Further investigations in a separate study (see DocID 2019/1075236; summary below) with the generic metabolite M510F65 lead to the definite structure M510F02). Solvent extracts or sub-fractions thereof with a sufficient level of radioactive residues were analysed by HPLC, generally with two methods. The peaks in the HPLC chromatograms that were used for quantification and confirmation were identified by comparison of their retention times with those of the reference items, using the same HPLC methods. In order to assign peaks correctly in the case of peak splitting, the acetonitrile extract of egg white was taken for co-chromatography experiments with bile using both quantifying and confirmatory HPLC methods. BAS 510 F was identified as main component in egg yolk, egg white, muscle and fat (29.1-84.9% TRR). In liver and excreta, it accounted for 1.8% TRR and 24.4% TRR, respectively. Metabolite M510F01 was the main component in liver and excreta (35.2% TRR and 61.9% TRR, respectively). In the other matrices, it accounted for 5.3%–27.4% TRR. Bile contained almost exclusively metabolite M510F02 (94.3% TRR). This metabolite was also present in egg yolk, egg white and liver, accounting for 9.6-32.1% TRR. The three components BAS 510 F, M510F01 and M510F02 were all present in egg yolk, egg white and liver; looking at the identified components, the matrices muscle, fat and excreta contained only BAS 510 F and M510F01. The primary metabolite M510F01 results from hydroxylation of the parent compound and is found in all relevant matrices. Conjugation of this metabolite with glucuronic acid leads to M510F02, present in liver, egg yolk and egg white (and bile).
All matrices were extracted within the required six months after sacrifice of the hens and no re-extraction was performed; therefore, it was not necessary to investigate the stability of the residues in the matrix. By comparison of the HPLC profiles of early HPLC analyses of the pooled acetonitrile or methanol extracts of egg yolk, egg white, liver, muscle and fat with those of the corresponding late analyses, it was shown that the extracts were stable throughout the time of the study.
The results are in good agreement with the previous conducted metabolism study in laying hens using a biphenyl label.

Figure A 1 Proposed metabolic pathway of BAS 510 F in laying hens



A 2.2.2.2.2 Laying hen (identification of M510F65)

After conduct of the new hen metabolism study, further identification work on the generic metabolite M510F65, occurring in hen egg yolk, egg white, liver and bile has been performed. This study has been submitted by the applicant to EFSA in context of the data call in September 2019. This study is consequently not yet contained in the draft RAR.

Comments of zRMS:	The study is acceptable.

Reference:	CA 6.2.2/2
Report	Further investigation of metabolite M510F65 (identified in hen metabolism study 773275), XXX, N., XXX, J., 2019 report No 884023 BASF DocID 2019/1075236 Authority registration No
Guideline(s):	EEC 91/414 (1607/IV/97 Rev. 1), EEC 91/414 (7030(VI/95 Rev. 3), EEC 91/414 Annex II (Part A Section 6), PMRA Residue Chemistry Guidelines Section 97.2 Nature of the Residue - Plants - Livestock (Canada), EEC 91/414 Annex III (Part A Section 8), EPA 860.1300: EPA Residue Chemistry Test Guidelines
Deviations:	No
GLP:	yes (certified by Landesamt fuer Umwelt, Mainz, Germany)
Acceptability:	Yes
Duplication (if vertebrate study)	No

I. MATERIAL AND METHODS

A. MATERIALS

1.	**Test material:**	BAS 510 F	
	Description:	^{14}C-labelled at position 3 of the pyridine ring (pyridin-3-C^{14}); spec. activity 5.11 MBq/mg; unlabeled BAS 510 F	
	Lot/batch #:	Pyridin-3-C^{14}:	640-2301
		Unlabeled:	L71-168
	Purity:	Pyridin-3-C^{14}:	radiochem. purity 99.5%, chem. purity 98.0%
		Unlabeled:	chem. purity 99.0%
	CAS #:	188425-85-6	
	Development code:	N/A	
	Spiking levels:	Not reported	
2.	**Test animals:**	Laying hens	
	Species:	*Gallus gallus domesticus*	
	Gender:	Female	

B. STUDY DESIGN AND METHODS

1. Test procedure

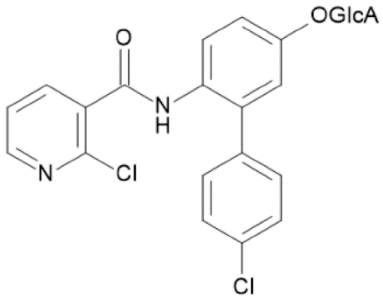
The application of the test item was performed during a previous conducted study on the metabolism of ^{14}C-boscalid in laying hen (for details of the test design see DocID 2019/1077444, summary above). The objective of the present study was the identification of the precise position of the glucuronic acid moiety of metabolite M510F65. Since M510F65 was present at very high levels in bile, this matrix was chosen for elucidation of the structure.
During the present study, all samples and extracts were stored in a freezer at -18°C or below and all investigations were completed within less than 3 weeks.

2. Description of analytical procedures

For the quantification of radioactivity in liquid samples, liquid scintillation counters (LSC) were used. Aliquots of liquid samples were mixed with a sufficient volume of a suitable scintillator prior to measurement. All data were corrected using appropriate quench curves.
Aliquots of bile were subjected to HPLC fractionation for isolation of M510F65. The fractions were combined and made up to a defined volume with acetonitrile. After LSC and HPLC analyses of aliquots, the sample was concentrated to dryness and stored in a freezer.
According to the validated method BASF 471/0, the residue was taken up in sodium acetate buffer and treated with β-glucuronidase / arylsulfatase for cleavage of the glucuronic acid. After incubation at 37°C in a rotary evaporator for 3 h, sodium chloride, hydrochloric acid and water were added and partitioned two times against ethyl acetate. Both ethyl acetate phases were combined and filled up to a defined volume with ethyl acetate. The volume of the water phase was determined. Aliquots of the ethyl acetate and water phases were subjected to LSC analysis. Further aliquots of the combined ethyl acetate phase were subjected to HPLC and HPLC-MS/MS analyses.

II. RESULTS AND DISCUSSION

Aliquots of hen bile were subjected to HPLC fractionation for isolation of M510F65. The combined fraction was incubated with β-glucuronidase / arylsulfatase for cleavage of the glucuronic acid group. The chromatograms obtained from analysis of aliquots before and after enzymatic treatment showed efficient cleavage of the glucuronic acid moiety.
HPLC-MS/MS investigation of the sample obtained after enzyme treatment revealed that the metabolite corresponding to the single peak was identified as metabolite M510F01. Additionally, the structure has been confirmed by the comparison of its spectroscopic and chromatographic data with those of an authentic reference substance.
Based on these results, it can be concluded that the metabolite, being previously identified as M510F65 within the hen metabolism study, is M510F02:



III. CONCLUSION

Metabolite M510F65 of boscalid was identified in several hen matrices within a previous hen metabolism study (see DocID 2019/1077444, summary above). Since the exact position of the glucuronic acid group in this molecule was not known, this study aims for further structure elucidation.
Sample preparation according to the validated BASF method 471/0 was applied for generation of the purified aglycon of M510F65. High resolution HPLC-MS/MS analysis allowed the structure elucidation of the aglycon revealing that the conjugated metabolite, being previously identified as M510F65 within the hen metabolism study, is M510F02.

A 2.2.3 Magnitude of residues in plants

A 2.2.3.1 Oilseed rape

Table A 32: 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 (EFSA, 2014)	2	0.250 kg as/ha	8-12 days	61-69	n.a.
Intended cGAP (1*)	1	0.200 kg as/ha	-	57-75	F

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

A 2.2.3.1.1 Study 1 – oilseed rape - BASF DocID 2019/1016882

Comments of zRMS:	During the 2018 growing season, 8 trials in oilseed rape were conducted in different representative growing areas in Germany, The Netherlands, Denmark, Northern and Southern France, Greece, Italy and Spain to determine the residue level of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) after application of BAS 762 00 F in or on Raw Agricultural Commodities (RAC). The trials consisted of two plots: plot 1 (control) and plot 2 (treated with BAS 762 00 F). BAS 762 00 F (100 g BAS 750 F/L, 200 g BAS 510 F/L, SC) was applied in all trials once at a single rate of 1.0 L/ha formulated product, equals to 0.100 kg a.i./ha of BAS 750 F and 0.200 kg a.i./ha of BAS 510 F on plot 2 with a water volume of 200 L/ha. In all trials the application was made at BBCH 75. Oilseed rape specimens were collected shortly before application (plot 1) and directly after application (plot 2) as whole plant (no roots). At BBCH 83 the specimens were sampled as pods with seeds and rest of plant without roots and at BBCH 89 as seed. Commercial harvest was reached in all trials between 38 and 54 DALA. All oilseed rape specimens of plot 1 and 2 were analyzed for BAS 750 F using the BASF Method L0076/09 and for BAS 510 F using the BASF Method L0076/09. Each method has a limit of quantitation of 0.010 mg/kg. The results of the average procedural recoveries in oilseed rape matrices at fortification levels between 0.010 and 2.5 mg/kg were 86.6% for BAS 750 F and 81.7% for BAS 510 F. The residues of **BAS 510 F** analyzed in oilseed rape whole plant (no roots) specimens sampled immediately after the application ranged from 0.55 to 2.0 mg/kg. At BBCH 83 (26-39 DALA) residues decreased to a range of < 0.010 to 1.2 mg/kg in pods with seeds specimens and to a range of < 0.010 to 0.27 mg/kg in rest of plant without roots specimens. At BBCH 89 (38-54 DALA) seed specimens were collected and the residues of BAS 510 F were between < 0.010 and 0.065 mg/kg. In all the untreated control specimens, no residues of BAS 510 F were detected at or above the limit of quantitation (LOQ, 0.010 mg/kg), except for trial L180107 were residues above the limit of quantitation were found (0.26 mg/kg in whole plant no roots, 0.011 mg/kg in pods with seeds and 0.080 mg/kg in rest of plant without roots specimens). The maximum storage interval from harvest until analysis for BAS 510 F (Boscalid) was 166 days. Data indicates that residues of BAS 510 F were stable during the period of frozen storage prior to analysis. The study is acceptable.

Reference:	CA 6.3.1/1
Report	Study on the residue behaviour of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) in oilseed rape after application of BAS 762 00 F under

	field conditions in Germany, The Netherlands, Denmark, Northern and Southern France, Greece, Italy and Spain, 2018 XXX, H. P., 2019 Report No 825503, AC/BASF/18/03 BASF DocID 2019/1016882 Authority registration No
Guideline(s):	Regulation (EC) No. 1107/2009 of the European Parliament and the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC European Community Guideline 7029/VI/95 - rev.5, 22/07/97: General recommendations for the design preparation and realization of residue trials. European Community Guideline SANCO 7525/VI/95 - Rev. 10.3, 13 June 2017: Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. OECD Guideline for the testing of chemicals – Crop Field Trials: OECD/OCDE 509. Adopted 7 September 2009
Deviations:	No
GLP:	yes (certified by Ministry of Justice, European Affairs and Consumer Protection, Brandenburg, Germany)
Acceptability:	Yes

Table A 33: Summary of recoveries (study 1 (2019/1016882), oilseed rape)

Matrix		Fortification level [mg/kg]	BAS 510 F			
			n	Mean [%]	SD [±]	RSD [%]
Oilseed rape	Whole plant*	0.010, 0.10 and 2.5	7	87.0	7.7	8.8
	Pods with seeds	0.010, 0.10 and 1.25	7	79.8	3.7	4.6
	Rest of plant**	0.010, 0.10 and 0.32	7	78.8	5.4	6.9
	Seed	0.010, 0.10	6	81.2	2.7	3.3
	Overall		27	81.7	6.0	7.3

* No roots
** Without roots

Table A 34: Summary of the study 1 (2019/1016882), oilseed rape

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)	DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 510 F		
	(a)	(b)				(c)					(d)	(e)
L180106 Germany EU-North 2018	Oilseed rape SO0495 PR 46W20	1. 22.08.2017 2. 20.04.2018-14.05.2018 3. 16.07.2018	200	200	100	1 25.05.2018	BBCH 75	Whole plant (no roots) Pods with seeds Rest of plant without roots Seed	75 83 83 89	1.2 0.24 0.27 <0.010	0 28 28 52	**BAS 762 00 F** SC Mefentrifluconazole 100 g/L **Boscalid 200 g/L** BASF method L0076/09 for Boscalid LOQ: 0.010 mg/kg
L180107 The Netherlands EU-North 2018	Oilseed rape SO0495 Temptation	1. 06.09.2017 2. 14.04.2018-15.05.2018 3. 09.07.2018	200	200	100	1 30.05.2018	BBCH 75	Whole plant (no roots) Pods with seeds Rest of plant without roots Seed	75 83 83 89	1.5 0.33 0.21 0.022	0 28 28 40	
L180108 Denmark EU-North 2018	Oilseed rape SO0495 Trezzor	1. 05.09.2017 2. 03.05.2018-18.05.2018 3. 19.07.2018	200	200	100	1 30.05.2018	BBCH 75	Whole plant (no roots) Pods with seeds Rest of plant without roots Seed	75 83 83 89	0.55 0.19 0.18 0.013	0 30 30 50	
L180109 France EU-North 2018	Oilseed rape SO0495 Expansion	1. 26.08.2017 2. 25.04.2018-10.05.2018 3. 02.07.2018	200	200	100	1 15.05.2018	BBCH 75	Whole plant (no roots) Pods with seeds Rest of plant without roots Seed	75 83 83 89	1.4 0.30 0.13 0.015	0 38 38 48	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)	DALA (d)	Details on trial (e)
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 510 F		
L180110 France EU-South 2018	Oilseed rape SO0495 Alicante	1. 23.08.2017 2. 12.04.2018-23.04.2018 3. 01.07.2018	200	200	100	1 24.05.2018	BBCH 75	Whole plant (no roots) Pods with seeds Rest of plant without roots Seed	75 83 83 89	2.0 <0.010 <0.010 <u><0.010</u>	0 26 26 47	No residues above the LOQ in any of the analyzed untreated specimens*. Storage time for all commodities ≤166 days Samples were analysed within the proven storage stability (see chapter 7.3.1)
L180111 Greece EU-South 2018	Oilseed rape SO0495 Exception	1. 21.09.2017 2. 01.04.2018-20.04.2018 3. 13.06.2018	200	200	100	1 05.05.2018	BBCH 75	Whole plant (no roots) Pods with seeds Rest of plant without roots Seed	75 83 83 89	1.2 0.38 0.12 <u>0.032</u>	0 27 27 39	
L180112 Italy EU-South 2018	Oilseed rape SO0495 DK Exclusiv	1. 30.09.2017 2. 10.04.2018-30.04.2018 3. 13.06.2018-14.06.2018	200	200	100	1 07.05.2018	BBCH 75	Whole plant (no roots) Pods with seeds Rest of plant without roots Seed	75 83 83 89	2.0 1.2 0.21 <u>0.021</u>	0 31 31 38	
L180113 Spain EU-South 2018	Oilseed rape SO0495 Omega-9	1. 06.11.2017 2. 22.03.2018-16.04.2018 3. 30.05.2018	200	200	100	1 06.04.2018	BBCH 75	Whole plant (no roots) Pods with seeds Rest of plant without roots Seed	63-75[f] 83 83 89	1.8 0.28 0.090 <u>0.065</u>	0 39 39 54	

_ underlined residue values were used for calculations. In case both formulations have been used in the same trial, the more critical residue value has been chosen. Also, if higher residues appeared at a later PHI, the more critical value has been chosen.

(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, underlined)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(f) Main growth stage 75
* except for trial L180107 were residues above the limit of quantitation were found (0.26 mg/kg in whole plant no roots, 0.011 mg/kg in pods with seeds and 0.080 mg/kg in rest of plant without roots specimens).

A 2.2.3.1.2 Study 2 – oilseed rape - BASF DocID 2020/2006193

Comments of zRMS:	During the 2019 growing season, 8 trials in oilseed rape were conducted in different representative growing areas in Northern and Southern Europe to determine the residue level of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) after application of BAS 762 02 F or BAS 762 00 F in or on Raw Agricultural Commodities (RAC). Four trials (L190326, L190327, L190332 and L190333) consisted of three plots: plot 1 (control), plot 2 (treated with BAS 762 02 F) and plot 3 (treated with BAS 762 00 F) Four trials ((L190328, L190329, L190330 and L190331) consisted of two plots: plot 1 (control) and plot 2 (treated with BAS 762 02 F). BAS 762 02 F (100 g BAS 750 F/L, 200 g BAS 510 F/L, SC) was applied in all trials once at a single rate of 1.0 L/ha formulated product, equals to 0.100 kg a.i./ha of BAS 750 F and 0.200 kg a.i./ha of BAS 510 F on plot 2 with a spray volume of 200 L/ha. BAS 762 00 F (100 g BAS 750 F/L, 200 g BAS 510 F/L, SC) was applied in four trials once at a single rate of 1.0 L/ha formulated product, equals to 0.100 kg a.i./ha of BAS 750 F and 0.200 kg a.i./ha of BAS 510 F on plot 3 with a spray volume of 200 L/ha. In all trials the application was made at BBCH 75. Trials L190326, L190327, L190332 and L190333 Oilseed rape specimens were collected shortly before application (plot 1) and directly after application (plot 2 and plot 3) as whole plant (no roots). At BBCH 83 the specimens were sampled as pods with seeds and rest of plant without roots. At 89 BBCH oilseed rape specimens were collected as seed. Trials L190328, L190329, L190330 and L190331 Oilseed rape specimens were collected shortly before application (plot 1) and directly after application (plot 2) as whole plant (no roots). At BBCH 83 the specimens were sampled as pods with seeds and rest of plant without roots. At BBCH 89 oilseed rape specimens were collected as seed. Commercial harvest was reached in all trials between 28 and 66 DALA. All oilseed rape specimens were analyzed for **BAS 510 F** using the adapted BASF Method L0076/09. The method has a limit of quantitation of 0.010 mg/kg. The results of the average procedural recoveries in oilseed rape matrices at fortification levels between 0.010 and 20 mg/kg were 87.1% for BAS 510 F. Plot 2 - treated with BAS 762 02 F: The residues of **BAS 510 F** analyzed in oilseed rape whole plant (no roots) specimens sampled immediately after the application ranged from 1.2 to 3.4 mg/kg. At BBCH 83 (22-42 DALA) residues decreased to values between 0.33 and 2.4 mg/kg in pods with seeds specimens and from 0.15 to 1.1 mg/kg in rest of plant without roots specimens. At BBCH 89 (28-66 DALA) seed specimens were collected and the residues of BAS 510 F were analyzed from 0.019 to 0.30 mg/kg. Plot 3 - treated with BAS 762 00 F: The residues of **BAS 510 F** analyzed in oilseed rape whole plant (no roots) specimens sampled immediately after the application ranged from 1.3 to 2.5 mg/kg. At BBCH 83 (22-42 DALA) residues decreased to values between 0.31 to 0.52 mg/kg in pods with seeds specimens and from 0.15 to 0.28 mg/kg in rest of plant without roots specimens. At BBCH 89 (31-61 DALA) seed specimens were collected and the residues of BAS 510 F were analyzed from 0.015 to 0.026 mg/kg. In the untreated control specimens, no residues of BAS 510 F were detected at or above the limit of quantitation (LOQ, 0.010 mg/kg). The maximum storage interval from harvest until analysis for the treated specimens is summarized below:

Analyte	Portion analyzed	Max. Storage interval [days]
BAS 750 F	Whole Plant (No Roots)	189
	Pods with Seeds	152
	Rest of Plant without Roots	158
	Seed	131
BAS 510 F	Whole Plant (No Roots)	189
	Pods with Seeds	231
	Rest of Plant without Roots	158
	Seed	211
Triazole derivative metabolites (TDMs)	Whole Plant (No Roots)	314
	Pods with Seeds	283
	Rest of Plant without Roots	283
	Seed	70

The study is acceptable.

Reference: CA 6.3.1/2

Report: Study on the residue behaviour of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) in oilseed rape after application of either BAS 762 02 F or BAS 762 00 F under field conditions in Northern and Southern Europe, 2019
XXX, H. P., 2020
Report No 825504, AC/BASF/19/03
BASF DocID 2020/2006193
Authority registration No

Guideline(s): Regulation (EC) No. 1107/2009 of the European Parliament and the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
European Community Guideline 7029/VI/95 - rev.5, 22/07/97: General recommendations for the design preparation and realization of residue trials.
European Community Guideline SANCO 7525/VI/95 - Rev. 10.3, 13 June 2017: Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs.
OECD Guideline for the testing of chemicals – Crop Field Trials: OECD/OCDE 509. Adopted 7 September 2009

Deviations: No

GLP: yes
(certified by Ministry of Justice, European Affairs and Consumer Protection, Brandenburg, Germany)

Acceptability: Yes

Table A 35: Summary of recoveries (study 2 (2020/2006193), oilseed rape)

Matrix		Fortification level [mg/kg]	BAS 510 F			
			n	Mean [%]	SD [±]	RSD [%]
Oilseed rape	Whole plant*	0.010, 0.10 and 10	8	86.7	2.6	3.0
	Pods with seeds	0.010, 0.10, 1.0 and 10	11	85.8	5.9	6.8
	Rest of plant**	0.010, 0.10 and 20	7	86.0	4.2	4.9
	Seed	0.010, 0.10 and 1.0	10	87.6	5.7	6.5
	Overall		36	87.1	5.0	5.8

* No roots
** Without roots

Table A 36: Summary of the study 2 (2020/2006193), oilseed rape

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)	DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 510 F		
	(a)	(b)				(c)					(d)	(e)
L190326 Germany EU-North 2019	Oilseed rape SO0495 PT 264	1. 28.08.2018 2. 18.04.-18.05.2019 3. 10.07.-15.07.2019	200	200	100	1 23.05.2019 Plot 2	BBCH 75	Whole plant (no roots) Pods with seeds Rest of plant without roots Seed	75 83 83 89	1.9 0.82 0.49 0.033	0 33 33 48	**BAS 762 02 F** (SC, plot 2) **BAS 762 00 F** (SC, plot 3) Mefentrifluconazole 100 g/L
			200	200	100	1 23.05.2019 Plot 3	BBCH 75	Whole plant (no roots) Pods with seeds Rest of plant without roots Seed	75 83 83 89	1.4 0.44 0.24 0.016	0 33 33 48	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)	DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 510 F		
	(a)	(b)				(c)					(d)	(e)
L190327 Belgium EU-North 2019	Oilseed rape SO0495 Memori	1. 06.09.2018 2. 17.04.-13.05.2019 3. 23.07.2019	200	200	100	1 23.05.2019 Plot 2	BBCH 75	Whole plant (no roots) Pods with seeds Rest of plant without roots Seed	75 83 83 89	1.9 0.34 0.23 <u>0.023</u>	0 42 42 61	**Boscalid 200 g/L** BASF method L0076/09 for Boscalid LOQ: 0.010 mg/kg No residues above the LOQ in any of the analyzed untreated specimens. Storage time for all commodities ≤231 days Samples were analysed within the storage stability (see chapter 7.3.1)
			200	200	100	1 23.05.2019 Plot 3	BBCH 75	Whole plant (no roots) Pods with seeds Rest of plant without roots Seed	75 83 83 89	1.8 0.31 0.25 0.015	0 42 42 61	
L190328 Poland EU-North 2019	Oilseed rape SO0495 Kuga	1. 25.08.2018 2. 10.05.-28.05.2019 3. 10.07.2019	200	200	100	1 30.05.2019 Plot 2	BBCH 75	Whole plant (no roots) Pods with seeds Rest of plant without roots Seed	75 83 83 89	1.7 0.81 0.51 <u>0.30*</u>	0 22 22 33	
L190329 Denmark EU-North 2019	Oilseed rape SO0495 DK Exalte	1. 22.08.2018 2. 02.05.-19.05.2019 3. 10.07.-13.08.2019	200	200	100	1 08.06.2019 Plot 2	BBCH 75	Whole plant (no roots) Pods with seeds Rest of plant without roots Seed	75 83 83 89	1.9 0.33 0.15 <u>0.019</u>	0 30 30 66	
L190330 France EU-South 2019	Oilseed rape SO0495 Memori CS	1. 12.09.2018 2. 19.03.-26.04.2019 3. 12.06.2019	200	200	100	1 03.05.2019 Plot 2	BBCH 75	Whole plant (no roots) Pods with seeds Rest of plant without roots Seed	75 83 83 89	2.7 0.87 0.17 <u>0.070</u>	0 31 31 41	
L190331 Greece EU-South 2019	Oilseed rape SO0495 Puncher	1. 26.10.2018 2. 15.04.-30.04.2019 3. 12.06.2019	200	200	100	1 14.05.2019 Plot 2	BBCH 75	Whole plant (no roots) Pods with seeds Rest of plant without roots Seed	75 83 83 89	3.2 2.4 1.1 <u>0.13</u>	0 22 22 28	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)	DALA (d)	Details on trial (e)
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 510 F		
L190332 Italy EU-South 2019	Oilseed rape SO0495 PT279CL	1. 03.10.2018 2. 25.04.-10.05.2019 3. 21.06.2019	200	200	100	1 21.05.2019 Plot 2	BBCH 75	Whole plant (no roots) Pods with seeds Rest of plant without roots Seed	75 83 83 89	1.2 1.6** 0.58 <u>0.059</u>	0 22 22 31	
			200	200	100	1 21.05.2019 Plot 3	BBCH 75	Whole plant (no roots) Pods with seeds Rest of plant without roots Seed	75 83 83 89	1.3 0.52 0.28 0.026	0 22 22 31	
L190333 Spain EU-South 2019	Oilseed rape SO0495 Omega-9	1. 29.11.2018 2. 02.04.-30.04.2019 3. 27.05.2019	200	200	100	1 03.04.2019 Plot 2	BBCH 75	Whole plant (no roots) Pods with seeds Rest of plant without roots Seed	75 83 83 89	3.4 1.8 0.59 <u>0.058</u>	0 30 30 50	
			200	200	100	1 03.04.2019 Plot 3	BBCH 75	Whole plant (no roots) Pods with seeds Rest of plant without roots Seed	75 83 83 89	2.5 0.40 0.15 0.017	0 30 30 50	

_ underlined residue values were used for calculations. In case both formulations have been used in the same trial, the more critical residue value has been chosen. Also, if higher residues appeared at a later PHI, the more critical value has been chosen.

(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, underlined)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
* mean (0.29, 0.30, 0.31)
** mean (1.5, 1.8, 1.7)

A 2.2.3.2 Sunflower

Table A 37: 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 (EFSA, 2014)	2	0.100 kg as/ha	21-30 days	18-79	35
Intended cGAP (4*)	2	0.200 kg as/ha	7 days	31-69	F

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

A 2.2.3.2.1 Study 1 - sunflower - BASF DocID 2018/1205796

Comments of zRMS:	Eight field trials L180264 (Germany), L180265 (North France), L180266 (Belgium), L180267 (Hungary), L180268 (South France), L180269 (Greece), L180270 (Italy) and L180271 (Spain)) were conducted during the growing season of 2018 in order to determine the magnitude of residues of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) in sunflower after treatment with BAS 762 00 F. All field trials consisted of two plots - one untreated plot (Plot 1) and one treated plot (Plot 2). BAS 762 00 F (100 g BAS 750 F/L, 200 g BAS 510 F/L, SC) was applied two times on plot 2. The applications took place at a rate of 1.0 L of formulated product/ha, equals to nominal 0.1 kg a.i./ha BAS 750 F and 0.2 kg a.i./ha BAS 510 F. The first application took place at BBCH 59 and the second application at BBCH 69 each with a spray volume of 200 L/ha. Sunflower specimens of whole plant (no roots) were collected at 0 DBLA (days before last application) and at 0 DALA (days after last application) (BBCH 69). Specimens of flower head and rest of plant without roots were collected at BBCH 79-83 (6 – 21 DALA). Specimens of seeds were collected at BBCH 89 (27 – 58 DALA). In this analytical phase (S18-04977), all specimens of sunflower were analysed for BAS 750 F and BAS 510 F according to BASF analytical method no. L0076/09. The final determination of the analytes in the untreated and treated specimens was performed by single extraction and single injection with liquid chromatography and mass spectrometric detection (LC-MS/MS) for BAS 750 F and BAS 510 F. The limit of quantitation (LOQ) was 0.010 mg/kg for all analytes. The mean of the concurrent recoveries was within the acceptable range of 70 - 110% for all analytes. The BAS 510 F residues in treated whole plant (no roots) specimens taken 0 DALA (days after last application) ranged between 2.0 mg/kg and 4.7 mg/kg. The BAS 510 F residues in treated flower head specimens taken at BBCH 79-83 (6-21 DALA) ranged between 0.29 mg/kg and 0.95 mg/kg. The BAS 510 F residues in treated rest of plant without roots specimens taken at BBCH 79-83 (6-21 DALA) ranged between 0.61 mg/kg and 8.1 mg/kg. The BAS 510 F residues in treated seed specimens taken at BBCH 89 (27-58 DALA) ranged between < 0.010 mg/kg and 0.30 mg/kg. No residues of BAS 510 F at or above the limit of quantitation were detected in the untreated specimens of this study. The maximum storage interval from harvest to the sample extraction was 123 days for BAS 750 F and BAS 510 F. Storage stability of BAS 750 F and BAS 510 F was shown for 24 months. The study is acceptable.

Reference: CA 6.3.2/1

Report	Study on the residue behaviour of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) on sunflower after treatment with BAS 762 00 F under field conditions in Northern and Southern Europe, season 2018 XXX, O., 2019 Report No 825505, 18/01/PF BASF DocID 2018/1205796 Authority registration No
Guideline(s):	Regulation (EC) no. 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. European Community Guidelines 7029/VI/95 – Rev. 5, 22/07/97: Appendix B- General Recommendations for the design, preparation and realization of residue trials. OECD 509 – OECD Guideline for the testing of Chemicals Crop Field Trials 7th September 2009. European Community Guideline SANCO 7525/VI/95 - rev.10.3, 13 June 2017: Comparability, extrapolation, group tolerances and data requirements for setting MRLs. International guidelines for distribution and pesticides application. AEPLA, FAO 1985. Directive 2004/10/EC of the European Parliament and of the Council of 11th February 2004 OECD Principles of Good Laboratory Practice and Compliance Monitoring Number 1. 'OECD Principles on Good Laboratory Practice'. ENV/MC/CHEM(98)17. OECD Principles of Good Laboratory Practice and Compliance Monitoring Number 4. 'Quality Assurance and GLP'. ENV/JM/MONO(99)20. OECD Principles of Good Laboratory Practice and Compliance Monitoring Number 6 (Revised). 'The Application of the GLP Principles to field studies'. ENV/JM/MONO (99)22. OECD Principles of Good Laboratory Practice and Compliance Monitoring Number 13. Consensus Document of the Working Group on Good Laboratory Practice 'The application of OECD Principles of GLP to the Organisation and Management of Multi-site studies'. ENV/JM/MONO(2002)/9. R.D. 1369/2000 on 19th of July, whereby the Principles of Good Laboratory Practices and their application to the conduction of non-clinical studies on chemical substances and products are established. Relevant national GLP-Regulations of Test site countries.
Deviations:	No
GLP:	yes (certified by ENAC, Entidad Nacional de Acreditación, Madrid Spain)
Acceptability:	Yes

Table A 38: Summary of recoveries (study 1 (2018/1205796), sunflower)

Matrix		Fortification level [mg/kg]	BAS 510 F			
			n	Mean [%]	SD [±]	RSD [%]
Sunflower	Whole plant*	0.01, 0.10 and 5.0	7	84.4	4.2	5.0
	Flower head	0.01, 0.10 and 1.25	7	91.2	5.1	5.6
	Rest of plant*	0.01, 0.10 and 8.5	7	88.5	5.7	6.4
	Seed	0.01, 0.10 and 0.40	9	84.4	8.9	11
	Overall		30	86.9	6.8	7.8

* No roots
** Without roots

Table A 39: Summary of the study 1 (2018/1205796), sunflower

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Growth stage at sampling (BBCH)	Residues (mg/kg)	DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 510 F		
	(a)	(b)				(c)					(d)	(e)
L180264 Germany EU-North 2019	Sunflower SO 0702 SY Valeo	1. 10.04.2018 2. 27.06.2018-16.07.2018 3. 12.09.2018	200	200	100	2 16.07.2018	BBCH 69	Whole plant (no roots) Flower head Rest of plant without roots Seed	69 79 79 89	2.3 0.95 5.0 <0.010	0 8 8 58	**BAS 762 00 F** SC Mefentrifluconazole 100 g/L **Boscalid 200 g/L**
L180265 France EU-North 2018	Sunflower SO 0702 ES IDILLIC	1. 27.04.2018 2. 30.06.2018-17.07.2018 3. 03.09.2018	200	200	100	2 03.08.2018	BBCH 69	Whole plant (no roots) Flower head Rest of plant without roots Seed	69 79-83 79-83 89	4.2 0.74 8.1 0.25	0 12 12 27	
L180266 Belgium EU-North 2018	Sunflower SO 0702 Es Novamis CL	1. 10.04.2018 2. 02.07.2018-16.07.2018 3. 10.09.2018	200	200	100	2 18.07.2018	BBCH 69	Whole plant (no roots) Flower head Rest of plant without roots Seed	69 79 79 89	2.7 0.59 4.2 <0.010	0 12 12 54	BASF method L0076/09 for Boscalid LOQ: 0.010 mg/kg No residues above the LOQ in any of the analysed untreated specimens. Storage time for all commodities ≤123 days Samples were analysed within the proven storage stability (see chapter 7.3.1)
L180267 Hungary EU-North 2018	Sunflower SO 0702 P64LE25	1. 10.05.2018 2. 01.07.2018-10.08.2018 3. 25.10.2018	200	200	100	2 10.08.2018	BBCH 69	Whole plant (no roots) Flower head Rest of plant without roots Seed	69 79 79 89	3.4 0.33 5.3 0.30	0 14 14 52	
L180268 France EU-South 2018	Sunflower SO 0702 LG 5678	1. 02.05.2018 2. 10.07.2018-30.07.2018 3. 19.09.2018	200	200	100	2 30.08.2018	BBCH 69	Whole plant (no roots) Flower head Rest of plant without roots Seed	69 79 79 89	4.7 0.44 3.7 0.077	0 17 17 49	
L180269 Greece EU-South 2018	Sunflower SO 0702 Neoma	1. 04.04.2018 2. 08.06.2018-28.06.2018 3. 10.08.2018-20.08.2018	200	200	100	2 21.06.2018	BBCH 69	Whole plant (no roots) Flower head Rest of plant without roots Seed	69 79 79 89	2.0 0.29 0.61 <0.010	0 20 20 54	
L180270 Italy EU-South 2018	Sunflower SO 0702 LG5687HO	1. 18.05.2018 2. 03.07.2018-17.07.2018 3. 30.08.2018	200	200	100	2 17.07.2018	BBCH 69	Whole plant (no roots) Flower head Rest of plant without roots Seed	69 79 79 89	2.9 0.40 3.7 0.045	0 6 6 44	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Growth stage at sampling (BBCH)	Residues (mg/kg)	DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 510 F		
	(a)	(b)				(c)					(d)	(e)
L180271 Spain EU-South 2018	Sunflower SO 0702 LG5461	1. 09.04.2018 2. 27.06.2018-02.07.2018 3. 24.08.2018	200	200	100	2 09.07.2018	BBCH 69	Whole plant (no roots) Flower head Rest of plant without roots Seed	69 79 79 89	3.3 0.77 4.3 <u>0.036</u>	0 21 21 45	

_ underlined residue values were used for calculations. In case both formulations have been used in the same trial, the more critical residue value has been chosen. Also, if higher residues appeared at a later PHI, the more critical value has been chosen.

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

A 2.2.3.2.2 Study 2 - sunflower - BASF DocID 2019/2075093

Comments of zRMS:	During the 2019 growing season eight trials were conducted in order to determine the magnitude of residues of Mefentrifluconazole (BAS 750 F), Boscalid (BAS 510 F), 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in sunflower under field conditions after two applications of either BAS 762 00 F or BAS 762 02 F in in Germany (L190443), France (L190444 and L190447), Netherlands (L190445), Austria (L190446), Greece (L190448), Italy (L190449) and in Spain (L190450). Trials L190443, L190444, L190449 and L190450 consisted of three plots: plot 1 (untreated), plot 2 (treated with BAS 762 02 F) and plot 3 (treated with BAS 762 00 F). Trials L190445, L190446, L190447 and L190448 consisted of two plots: plot 1 (untreated), plot 2 (treated with BAS 762 02 F). The treatment on plot 2 of all trials was performed using formulation BAS 762 02 F two times at a target rate of 1.0 L of formulated product/ha (SC formulation, nominal content 100 g BAS 750 F /L and 200 g BAS 510 F /L), corresponding to 0.10 kg a.i./ha of BAS 750 F and 0.20 kg a.i./ha of BAS 510 F. The application timing was at BBCH 59-61 and BBCH 69. The treatment on plot 3 (for trial L190443, L190444, L190449 and L190450) was performed using formulation BAS 762 00 F two times at a target rate of 1.0 L of formulated product/ha (SC formulation, nominal content 100 g BAS 750 F /L and 200 g BAS 510 F /L), corresponding to 0.10 kg a.i./ha of BAS 750 F and 0.20 kg a.i./ha of BAS 510 F. The application timing was at BBCH 59-61 and BBCH 69. Specimens of sunflower were collected as whole plant (no roots) at the day of last application (0 DALA), (on plot 1 before the application, 0 DBLA), as flower head and rest of plant without roots on BBCH 79 and as seed on BBCH 89. All sunflower specimens (whole plant (no roots), flower head, rest of plant without roots, seed) were analysed for Mefentrifluconazole (BAS 750 F), Boscalid (BAS 510 F) and triazole (1,2,4-T, TA, TAA, TLA). BASF Method L0076/09 was adapted for BAS 750 F and BAS 510 F using LC-MS/MS to achieve a limit of quantification (LOQ) of 0.010 mg/kg. Overall and average recoveries were all in the range of 70 – 110% and relative standard deviations (RSD) were < 20%. Boscalid (BAS 510 F) residues ranged from 1.6 – 5.2 mg/kg (plot 2) and 2.7 – 4.4 mg/kg (plot 3) for sunflower whole plant (no roots) collected directly after application, 0 DALA (BBCH 69). At BBCH 79, residues of Boscalid (BAS 510 F) ranged from 0.040 – 0.77 mg/kg (plot 2) and 0.26 – 0.70 mg/kg (plot 3) for sunflower flower head specimens and from 1.2 – 8.1 mg/kg (plot 2) and 1.3 – 8.4 mg/kg (plot 3) for sunflower rest of plant without roots specimens. At BBCH 89, residues of Boscalid (BAS 510 F) ranged from <0.010 – 0.051 mg/kg (plot 2) and 0.010 – 0.023 mg/kg (plot 3) for sunflower seed specimens. None of the untreated samples of this study had any residue of Boscalid (BAS 510 F) exceeding the respective LOQ (0.010 mg/kg). The study is acceptable.

Reference:	CA 6.3.2/2
Report	Study on the residue behaviour of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) on sunflower after treatment with BAS 762 00 F or BAS 762 02 F under field conditions in Northern and Southern Europe, season 2019 XXX, O., 2020 Report No 825506, 19/09/PF BASF DocID 2019/2075093 Authority registration No

Guideline(s):	Regulation (EC) no. 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. European Community Guidelines 7029/VI/95 – Rev. 5, 22/07/97: Appendix B- General Recommendations for the design, preparation and realization of residue trials. OECD 509 – OECD Guideline for the testing of Chemicals Crop Field Trials 7th September 2009. European Community Guideline SANCO 7525/VI/95 - rev.10.3, 13 June 2017: Comparability, extrapolation, group tolerances and data requirements for setting MRLs. Directive 2004/10/EC of the European Parliament and of the Council of 11th February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances. OECD Principles of Good Laboratory Practice and Compliance Monitoring Number 1. 'OECD Principles on Good Laboratory Practice'. ENV/MC/CHEM(98)17. OECD Principles of Good Laboratory Practice and Compliance Monitoring Number 4. 'Quality Assurance and GLP'. ENV/JM/MONO(99)20. OECD Principles of Good Laboratory Practice and Compliance Monitoring Number 6 (Revised). 'The Application of the GLP Principles to field studies'. ENV/JM/MONO (99)22. OECD Principles of Good Laboratory Practice and Compliance Monitoring Number 13. Consensus Document of the Working Group on Good Laboratory Practice 'The application of OECD Principles of GLP to the Organisation and Management of Multi-site studies'. ENV/JM/MONO(2002)/9. Spanish R.D. 1369/2000 on 19th of July, whereby the Principles of Good Laboratory Practices and their application to the conduction of non-clinical studies on chemical substances and products are established. Relevant national GLP-Regulations of Test site countries.
Deviations:	No
GLP:	yes (certified by ENAC, Entidad Nacional de Acreditación, Madrid Spain)
Acceptability:	Yes

Reference:	CA 6.3.2/3
Report	Amendment no. 1 to Final Report - Study on the residue behaviour of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) on sunflower after treatment with BAS 762 00 F or BAS 762 02 F under field conditions in Northern and Southern Europe, season 2019 XXX, O., 2020 Report No 825506, 19/09/PF BASF DocID 2020/2108977 Authority registration No
Guideline(s):	Regulation (EC) no. 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and

91/414/EEC.
European Community Guidelines 7029/VI/95 – Rev. 5, 22/07/97: Appendix B- General Recommendations for the design, preparation and realization of residue trials.
OECD 509 – OECD Guideline for the testing of Chemicals Crop Field Trials 7th September 2009.
European Community Guideline SANCO 7525/VI/95 - rev.10.3, 13 June 2017: Comparability, extrapolation, group tolerances and data requirements for setting MRLs.
Directive 2004/10/EC of the European Parliament and of the Council of 11th February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances.
OECD Principles of Good Laboratory Practice and Compliance Monitoring Number 1. 'OECD Principles on Good Laboratory Practice'. ENV/MC/CHEM(98)17.
OECD Principles of Good Laboratory Practice and Compliance Monitoring Number 4. 'Quality Assurance and GLP'. ENV/JM/MONO(99)20.
OECD Principles of Good Laboratory Practice and Compliance Monitoring Number 6 (Revised). 'The Application of the GLP Principles to field studies'. ENV/JM/MONO (99)22.
OECD Principles of Good Laboratory Practice and Compliance Monitoring Number 13. Consensus Document of the Working Group on Good Laboratory Practice 'The application of OECD Principles of GLP to the Organisation and Management of Multi-site studies'. ENV/JM/MONO(2002)/9.
Spanish R.D. 1369/2000 on 19th of July, whereby the Principles of Good Laboratory Practices and their application to the conduction of non-clinical studies on chemical substances and products are established.
Relevant national GLP-Regulations of Test site countries.

Deviations: No

GLP: yes
(certified by ENAC, Entidad Nacional de Acreditación, Madrid Spain)

Acceptability: Yes

Table A 40: Summary of recoveries (study 2 (2019/2075093), sunflower)

Matrix		Fortification level [mg/kg]	BAS 510 F			
			n	Mean [%]	SD [±]	RSD [%]
Sunflower	Whole plant*	0.01, 0.10, 10.0 and 20.0	12	93.5	5.7	6.1
	Flower head	0.01, 0.10, 10.0 and 20.0	9	93.5	5.7	6.1
	Rest of plant*	0.01, 0.10, 10.0 and 20.0	12	94.0	7.0	7.5
	Seed	0.01, 0.10 and 1.0	7	84.6	9.7	11.4
	Overall		40	92.5	7.8	8.4

* No roots
** Without roots

Table A 41: Summary of the study 2 (2019/2075093), sunflower)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Growth stage at sampling (BBCH)	Residues (mg/kg)	DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 510 F		
	(a)	(b)				(c)					(d)	(e)
L190443 Germany EU-North 2019	Sunflower SO 0702 Vivacio	1. 10.04.2019 2. 03.07.2019-22.07.2019 3. 18.09.2019-21.09.2019	200	200	100	2 22.07.2019 (plot 2)	BBCH 69	Whole plant (no roots) Flower head Rest of plant without roots Seed	69 79 79 89	3.4 0.68 3.7 <u>0.021</u>	0 4 4 58	**BAS 762 02 F** (SC, plot 2) **BAS 762 00 F** (SC, plot 3) Mefentrifluconazole 100 g/L
			200	200	100	2 22.07.2019 (plot 3)	BBCH 69	Whole plant (no roots) Flower head Rest of plant without roots Seed	69 79 79 89	4.4 0.66 3.4 0.021	0 4 4 58	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Growth stage at sampling (BBCH)	Residues (mg/kg)	DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 510 F		
	(a)	(b)				(c)					(d)	(e)
L190444 France EU-North 2019	Sunflower SO 0702 RGT Buffalo	1. 08.04.2019 2. 07.07.2019- 19.07.2019 3. 11.09.2019	200	200	100	2 19.07.2019 (plot 2)	BBCH 69	Whole plant (no roots) Flower head Rest of plant without roots Seed	69 79 79 89	4.6 0.70 8.1 0.010	0 14 14 54	**Boscalid 200 g/L** BASF method L0076/09 for Boscalid LOQ: 0.010 mg/kg No residues above the LOQ in any of the analyzed untreated specimens. Storage time for all commodities ≤139 days Samples were analysed within the proven storage stability (see chapter 7.3.1)
			200	200	100	2 19.07.2019 (plot 3)	200	Whole plant (no roots) Flower head Rest of plant without roots Seed	69 79 79 89	3.0 0.70 8.4 <u>0.011</u>	0 14 14 54	
L190445 Netherland EU-North 2019	Sunflower SO 0702 ES Biba	1. 11.05.2019 2. 05.07.2019- 07.08.2019 3. 20.09.2019	200	200	100	2 07.08.2019 (plot 2)	BBCH 69	Whole plant (no roots) Flower head Rest of plant without roots Seed	69 79 79 89	1.6 0.13 1.2 <u><0.010</u>	0 12 12 44	
L190446 Austria EU-North 2019	Sunflower SO 0702 ES Biba	1. 18.04.2019 2. 05.07.2019- 26.07.2019 3. 18.09.2019	200	200	100	2 23.07.2019 (plot 2)	BBCH 69	Whole plant (no roots) Flower head Rest of plant without roots Seed	69 79 79 89	2.8 0.28 2.1 <u><0.010</u>	0 15 15 55	
L190447 France EU-South 2019	Sunflower SO 0702 MAS 87 OL	1. 08.05.2019 2. 21.07.2019- 12.08.2019 3. 01.10.2019	200	200	100	2 12.08.2019 (plot 2)	BBCH 69	Whole plant (no roots) Flower head Rest of plant without roots Seed	69 79 79 89	5.1 0.44 5.7 <u>0.051</u>	0 15 15 45	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Growth stage at sampling (BBCH)	Residues (mg/kg)	DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 510 F		
	(a)	(b)				(c)					(d)	(e)
L190448 Greece EU-South 2019	Sunflower SO 0702 NK Neoma	1. 22.03.2019 2. 10.06.2019- 20.06.2019 3. 01.08.2019- 10.08.2019	200	200	100	2 21.06.2019 (plot 2)	BBCH 69	Whole plant (no roots) Flower head Rest of plant without roots Seed	69 79 79 89	4.2 0.040 1.3 <u><0.010</u>	0 20 20 48	
L190449 Italy EU-South 2019	Sunflower SO 0702 LG5451HO CL	1. 29.04.2019 2. 11.07.2019- 26.07.2019 3. end Aug - beg Sep 2019	200	200	100	2 26.07.2019 (plot 2)	BBCH 69	Whole plant (no roots) Flower head Rest of plant without roots Seed	69 79 79 89	2.0 0.31 1.7 <0.010	0 11 11 41	
			200	200	100	2 26.07.2019 (plot 3)	BBCH 69	Whole plant (no roots) Flower head Rest of plant without roots Seed	69 79 79 89	2.7 0.25 1.3 <u>0.010</u>	0 11 11 41	
L190450 Spain EU-South 2019	Sunflower SO 0702 LG 50531	1. 15.03.2019 2. 14.06.2019- 27.06.2019 3. 14.08.2019	200	200	100	2 25.06.2019 (plot 2)	BBCH 69	Whole plant (no roots) Flower head Rest of plant without roots Seed	69 79 79 89	5.2 0.77 4.2 0.015	0 13 13 48	
			200	200	100	2 26.07.2019 (plot 3)	BBCH 69	Whole plant (no roots) Flower head Rest of plant without roots Seed	69 79 79 89	3.2 0.69 4.7 <u>0.023</u>	0 13 13 48	

_ underlined residue values were used for calculations. In case both formulations have been used in the same trial, the more critical residue value has been chosen. Also, if higher residues appeared at a later PHI, the more critical value has been chosen.

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

A 2.2.3.3 Wheat

Table A 42: 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 (EFSA, 2014)	2	0.350 kg as/ha	n.a.	69	35
Intended cGAP (7, 9*)	1	0.200 kg as/ha	-	57-75	56

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

A 2.2.3.3.1 Study 1 - wheat - BASF DocID 2019/1016888

Comments of zRMS:	During the 2018 growing season, 8 trials in wheat were conducted in different representative growing areas in Germany, Poland, Southern France, Spain, The Netherlands, United Kingdom, Italy and Greece to determine the residue level of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) after application of either BAS 762 00 F, BAS 750 01 F or BAS 549 02 F in or on Raw Agricultural Commodities (RAC). Four trials were set up as bridging trials (L180098 to L180101) which consisted of four plots: plot 1 (control), plot 2 (treated with BAS 762 00 F), plot 3 (treated with BAS 750 01 F) and plot 4 (treated with BAS 549 02 F). Four trials (L180102 to L180105) consisted of two plots: plot 1 (control), plot 2 (treated with BAS 762 00 F). BAS 762 00 F (100 g BAS 750 F/L, 200 g BAS 510 F/L, SC) was applied in all trials once at a single rate of 1.0 L/ha formulated product, equals to 0.100 kg a.i./ha of BAS 750 F and 0.200 kg a.i./ha of BAS 510 F on plot 2 with a water volume of 200 L/ha. BAS 750 01 F (100 g BAS 750 F/L, EC) was applied in four trials twice at a single rate of 1.5 L/ha formulated product, equals to 0.150 kg a.i./ha of BAS 750 F on plot 3 with a water volume of 200 L/ha. BAS 549 02 F (67 g BAS 480 F/L, 233 g BAS 510 F/L, SC) was applied in four trials twice at a single rate of 1.5 L/ha formulated product, equals to 0.1005 kg a.i./ha of BAS 480 F and 0.3495 kg a.i./ha of BAS 510 F on plot 4 with a water volume of 200 L/ha. In all trials the first application was made at BBCH 49. In the four bridging trials (plot 3 and 4) the second application was performed at BBCH 69. Trials L180098 to L180101 Wheat specimens were collected at BBCH 49 immediately before application no. 1 on plot 1 and directly after application no. 1 on plot 2 as whole plant no roots. At BBCH 69 specimens of plot 1 and 2 were collected before application no. 2 and directly after application no. 2 on plot 3 and 4 as whole plant no roots. At BBCH 83 the specimens of all plots were sampled as ears and rest of plant without roots. At 55-57 days after last application (DALA, related to plot 2) wheat specimens were collected on all plots either as ears and rest of plants without roots or as grain and straw. In one trial crop maturity was not reached at 56 ± 1 DALA and further samples were collected at BBCH 89 as grain and straw. In trial L180099 crop maturity was reached at 42 DALA already (related to plot 2), so that here sampling no. 4 omitted. Trials L180102 to L180105 Wheat specimens were collected at BBCH 49 immediately before application no. 1 on plot 1 and directly after application no. 1 on plot 2 as whole plant no roots. At BBCH 69 specimens were collected as whole plant no roots. At BBCH 83 the specimens were sampled as ears and rest of plant without roots. At 56-57 DALA, BBCH 89 was reached, wheat specimens were collected as grain and straw. Wheat specimens were analysed for BAS 750 F and BAS 510 F using the BASF Method L0076/09. The method has a limit of quantitation of 0.010 mg/kg. The results of the average procedural recoveries in wheat matrices at fortification levels between 0.010 and 40 mg/kg were at 84.6% for BAS 750 F and at 85.7% for BAS 510 F. **Residues of BAS 510 F**

	Plot 2: The residues of BAS 510 F analyzed in wheat whole plant no roots specimens sampled immediately after the last application (49 BBCH) ranged from 1.4 to 3.9 mg/kg. After 12- 23 DALA (69 BBCH) residues were found from 0.39 to 6.1 mg/kg. In ears specimens collected at 83 BBCH (27-43 DALA) and 85 BBCH (55 DALA) the residues of BAS 510 F were found from 0.021 to 1.4 mg/kg and at 1.4 mg/kg, respectively. Rest of plant without roots specimens taken at the same sampling events showed residues of BAS 510 F from 0.49 to 3.4 mg/kg and at 2.9 mg/kg, respectively. In grain specimens sampled at 89 BBCH (42-69 DALA) residues of BAS 510 F were analyzed between < 0.010 and 0.033 mg/kg. In straw specimens sampled at 89 BBCH (42-69 DALA) residues of BAS 510 F ranged between 0.89 and 4.9 mg/kg. Plot 4: The residues of BAS 510 F analyzed in wheat whole plant no roots specimens sampled immediately after the last application (69 BBCH) ranged from 2.7 to 14 mg/kg. In ears specimens collected at 83 BBCH (14-23 DALA) and 85 BBCH (43 DALA) the residues of BAS 510 F were found from 0.78 to 3.5 mg/kg and at 7.0 mg/kg, respectively. Rest of plant without roots specimens taken at the same sampling events showed residues of BAS 510 F from 2.6 to 21 mg/kg and at 24 mg/kg, respectively. In grain specimens sampled at 89 BBCH (29-57 DALA) residues of BAS 510 F were between 0.029 and 0.16 mg/kg. In straw specimens sampled at 89 BBCH (29-57 DALA) residues of BAS 510 F ranged from 18 to 31 mg/kg. In the untreated control specimens, no residues of BAS 510 F were detected at or above the limit of quantitation (LOQ, 0.010 mg/kg). Bridging showed, that the new formulation BAS 762 00 F does not lead to higher residues that the respective registered formulation BAS 549 02 F. The maximum storage interval from harvest until analysis was 465 days for BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid). Data indicates that residues of BAS 750 F and BAS 510 F were stable during the period of frozen storage prior to analysis. The study is acceptable.

Reference:	CA 6.3.3/1
Report	Study on the residue behaviour of BAS 750 F (Mefentrifluconazole) and BAS 510 F (Boscalid) in wheat after application of either BAS 762 00 F, BAS 750 01 F or BAS 549 02 F under field conditions in Germany, Poland, Southern France, Spain, The Netherlands, United Kingdom, Italy and Greece, 2018 XXX, H. P., 2020 Report No 857041, AC/BASF/18/01 BASF DocID 2019/1016888 Authority registration No
Guideline(s):	Regulation (EC) No. 1107/2009 of the European Parliament and the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC European Community Guideline 7029/VI/95 - rev.5, 22/07/97: General recommendations for the design preparation and realization of residue trials. European Community Guideline SANCO 7525/VI/95 - Rev. 10.3, 13 June 2017: Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. OECD Guideline for the testing of chemicals – Crop Field Trials: OECD/OCDE 509. Adopted 7 September 2009 National relevant GLP-Regulations of Test site countries
Deviations:	No
GLP:	yes (certified by Ministry of Justice, European Affairs and Consumer Protection, Brandenburg, Germany)
Acceptability:	Yes

Table A 43: Summary of recoveries (study 1 (2019/1016888), wheat)

Matrix		Fortification level [mg/kg]	BAS 510 F			
			n	Mean [%]	SD [±]	RSD [%]
Wheat	Whole plant*	0.010, 0.10, 2.0, 20	10	84.1	11	13
	Ears	0.010, 0.10, 5.0, 10	10	88.7	13	15
	Rest of plant**	0.010, 0.10, 5.0, 10, 20, 30	13	84.3	11	13
	Grain	0.010, 0.10, 1.0	7	79.3	10	13
	Straw	0.010, 0.10, 40	7	92.6	10	11
	Overall		47	85.7	12	13

* No roots
** Without roots

Table A 44: Summary of the study 1 (2019/1016888), wheat

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)	DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 510 F		
	(a)	(b)				(c)					(d)	(e)
L180098 Germany EU-North 2018	Wheat TRZAW GC0654 Tobak	1. 26.09.2017 2. 25.05.-01.06.2018 3. 20.07.2018	200	200	100	1 17.05.2018	BBCH 49	whole plant no roots whole plant no roots ears rest of plant without roots grain straw	49 69 83 83 89 89	1.4 5.7 0.044 1.6 <0.010 3.4	0 15 33 33 57 57	**BAS 762 00 F** SC Mefentrifluconazole 100 g/L **Boscalid 200 g/L** **f) BAS 549 02 F** SC **Boscalid 233 g/L** Epoxiconazole 67 g/L BASF method L0076/09 LOQ: 0.01 mg/kg
			349.5 349.5	200 200	174.75 174.75	1 17.05.2018 2 01.06.2018	BBCH 49 BBCH 69	whole plant no roots ears rest of plant without roots grain straw	69 83 83 89 89	14[f] 0.78[f] 14[f] 0.029[f] 26[f]	0 18 18 42 42	
L180099 Poland EU-North 2018	Wheat TRZAW GC0654 Bamberka	1. 31.10.2017 2. 30.05.-10.06.2018 3. 20.08.2018	200	200	100	1 25.05.2018	BBCH 49	whole plant no roots whole plant no roots ears rest of plant without roots grain straw	49 69 83 83 89 89	3.0 1.2 0.19 1.1 <0.010 1.8	0 13 27 27 42 42	
						1		whole plant no roots	69	2.7[f]	0	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)	DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 510 F		
	(a)	(b)				(c)					(d)	(e)
			400	229	174.67	25.05.2018	BBCH 49	ears	83	1.5[f]	14	No residues above the LOQ in any of the analysed untreated specimens.
						2		rest of plant without roots	83	2.6[f]	14	
			349.5	200	174.75	07.06.2018	BBCH 69	grain	89	0.068[f]	29	
								straw	89	18[f]	29	
L180100 France EU-South 2018	Wheat TRZAW GC0654 Solehio	1. 20.10.2017 2. 16.06.-20.06.2018 3. 16.08.2018	200	200	100	1	BBCH 49	whole plant no roots	49	3.9	0	Storage time for all commodities ≤465 days Samples were analysed within the proven storage stability (see chapter 7.3.1)
						08.06.2018		whole plant no roots	69	4.3	12	
								ears	83	1.2	35	
								rest of plant without roots	83	2.6	35	
								ears	85	1.4	55	
								rest of plant without roots	85	2.9	55	
								grain	89	0.033	69	
								straw	89	4.9	69	
						1		whole plant no roots	69	7.4[f]	0	
			349.5	200	174.75	08.06.2018	BBCH 49	ears	83	3.5[f]	23	
						2		rest of plant without roots	83	21[f]	23	
			349.5	200	174.75	20.06.2018	BBCH 69	ears	85	7.0[f]	43	
								rest of plant without roots	85	24[f]	43	
								grain	89	0.13[f]	57	
								straw	89	31[f]	57	
L180101 Spain EU-South 2018	Wheat TRZAW GC0654 Adagio	1. 17.11.2017 2. 05.05.-14.05.2018 3. 20.06.2018	200	200	100	1	BBCH 49	whole plant no roots	49	2.9	0	
						25.04.2018		whole plant no roots	69	1.5	19	
								ears	83	0.048	36	
								rest of plant without roots	83	1.4	36	
								grain	89	<0.010	56	
								straw	89	3.2	56	
						1		whole plant no roots	69	10[f]	0	
			349.5	200	174.75	25.04.2018	BBCH 49	ears	83	1.9[f]	17	
						2		rest of plant without roots	83	16[f]	17	
			349.5	200	174.75	14.05.2018	BBCH 69	grain	89	0.16[f]	37	
								straw	89	24[f]	37	
L180102 The Netherlands EU-North 2018	Wheat TRZAW GC0654 Benchmark	1. 25.10.2017 2. 29.05.-11.06.2018 3. 18.07.2018	200	200	100	1	BBCH 49	whole plant no roots	49	2.6	0	
						22.05.2018		whole plant no roots	69	0.80	20	
								ears	83	0.024	41	
								rest of plant without roots	83	1.0	41	
								grain	89	<0.010	57	
								straw	89	1.5	57	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Growth stage at sampling (BBCH)	Residues (mg/kg)	DALA	Details on trial
			g a.s./ ha	Water (L/ha)	g a.s./hL					BAS 510 F		
	(a)	(b)				(c)					(d)	(e)
L180103 United Kingdom EU-North 2018	Wheat TRZAW GC0654 Belepi	1. 26.03.2018 2. 20.06.-29.06.2018 3. 05.08.2018	200	200	100	1 13.06.2018	BBCH 49	whole plant no roots whole plant no roots ears rest of plant without roots grain straw	49 69 83 83 89 89	2.4 6.1 1.4 3.4 <0.010 4.6	0 16 36 36 56 56	
L180104 Italy EU-South 2018	Wheat TRZAW GC0654 Calabro	1. 18.11.2017 2. 19.05.-01.06.2018 3. 04.07.2018	200	200	100	1 09.05.2018	BBCH 49	whole plant no roots whole plant no roots ears rest of plant without roots grain straw	49 69 83 83 89 89	2.6 0.39 0.021 0.49 <0.010 0.89	0 23 40 40 56 56	
L180104 Greece EU-South 2018	Wheat TRZAW GC0654 Cannavaro	1. 05.11.2017 2. 20.04.-30.04.2018 3. 11.06.2018	200	200	100	1 16.04.2018	BBCH 49	whole plant no roots whole plant no roots ears rest of plant without roots grain straw	49 69 83 83 89 89	3.0 5.9 0.065 2.0 <0.010 4.4	0 14 43 43 56 56	

– underlined residue values were used for calculations. In case both formulations have been used in the same trial, the more critical residue value has been chosen. Also, if higher residues appeared at a later PHI, the more critical value has been chosen.

(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, underlined)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
(f) Bridging trials with formulation BAS 549 02 F (SC)

A 2.2.4 Magnitude of residues in livestock

No new data.

A 2.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

No new data.

A 2.2.6 Magnitude of residues in representative succeeding crops

No new data.

A 2.2.7 Other/Special Studies (KCA 6.10, KCA 6.10.1)

No new data.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

Mefentrifluconazole

A 3.1 Mefentrifluconazole TMDI calculations – updated

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Mefentrifluconazole

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0,035	ARfD (mg/kg bw):	0,15
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

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 : ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	31%	NL toddler	11,01	12%	Apples	5%	Milk: Cattle	5%	Pears		
	26%	DE child	9,00	14%	Apples	4%	Table grapes	2%	Cherries (sweet)		
	17%	NL child	5,97	7%	Apples	3%	Table grapes	2%	Milk: Cattle		
	11%	PT general	3,77	6%	Wine grapes	1%	Apples	0,7%	Table grapes		
	10%	DE women 14-50 yr	3,67	3%	Apples	2%	Wine grapes	1%	Milk: Cattle		
	10%	RO general	3,66	4%	Wine grapes	2%	Apples	1,0%	Milk: Cattle		
	10%	DE general	3,66	3%	Apples	2%	Wine grapes	1%	Milk: Cattle		
	10%	GEMS/Food G07	3,61	4%	Wine grapes	1%	Apples	1%	Barley		
	10%	GEMS/Food G15	3,48	3%	Wine grapes	1%	Barley	1%	Apples		
	10%	GEMS/Food G08	3,46	3%	Wine grapes	2%	Barley	1%	Apples		
	10%	GEMS/Food G11	3,37	3%	Wine grapes	2%	Apples	1%	Barley		
	9%	FR adult	3,19	6%	Wine grapes	0,9%	Apples	0,4%	Milk: Cattle		
	9%	FR child 3 15 yr	3,19	2%	Milk: Cattle	2%	Apples	0,9%	Wine grapes		
	9%	FR toddler 2 3 yr	3,14	4%	Apples	3%	Milk: Cattle	0,6%	Wine grapes		
	9%	IE adult	3,12	3%	Wine grapes	0,8%	Apples	0,7%	Table grapes		
	8%	GEMS/Food G06	2,85	3%	Table grapes	1%	Apples	1%	Wheat		
	8%	DK child	2,82	3%	Apples	1%	Milk: Cattle	0,8%	Rye		
	8%	UK infant	2,82	3%	Milk: Cattle	2%	Apples	0,4%	Oat		
	7%	NL general	2,48	2%	Apples	2%	Wine grapes	0,7%	Milk: Cattle		
	7%	GEMS/Food G10	2,43	1%	Wine grapes	1%	Barley	0,9%	Apples		
	7%	UK toddler	2,37	2%	Apples	2%	Milk: Cattle	0,6%	Table grapes		
	6%	DK adult	1,95	2%	Wine grapes	1%	Apples	0,5%	Milk: Cattle		
	5%	ES child	1,92	1%	Apples	1%	Milk: Cattle	0,6%	Wheat		
	5%	ES adult	1,90	1%	Wine grapes	0,9%	Apples	0,8%	Barley		
	5%	SE general	1,62	1%	Apples	1%	Milk: Cattle	0,5%	Bovine: Muscle/meat		
	5%	UK adult	1,61	3%	Wine grapes	0,5%	Apples	0,3%	Milk: Cattle		
	5%	PL general	1,59	2%	Apples	0,8%	Table grapes	0,5%	Cherries (sweet)		
	4%	FR infant	1,54	2%	Apples	1%	Milk: Cattle	0,2%	Sugar beet roots		
	4%	IT toddler	1,53	1%	Apples	0,9%	Wheat	0,7%	Peaches		
	4%	UK vegetarian	1,49	2%	Wine grapes	0,7%	Apples	0,3%	Wheat		
	4%	FI 3 yr	1,42	1%	Apples	1,0%	Oat	0,6%	Table grapes		
	4%	IT adult	1,31	0,9%	Apples	0,8%	Peaches	0,6%	Wheat		
	4%	LT adult	1,30	2%	Apples	0,3%	Milk: Cattle	0,2%	Pears		
	3%	FI adult	1,11	0,8%	Coffee beans	0,8%	Wine grapes	0,7%	Apples		
	3%	FI 6 yr	0,99	0,7%	Apples	0,5%	Oat	0,4%	Table grapes		
	1%	IE child	0,43	0,4%	Apples	0,3%	Milk: Cattle	0,2%	Wheat		

A 3.2 IEDI calculations

European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

Mefentrifluconazole BAS 750 F (F)

LOQs (mg/kg) range from:	0.01	to:	0.01
Toxicological reference values			
ADI (mg/kg bw/day):	0.035	ARfD (mg/kg bw):	0.15
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

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: ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
7%	NL toddler	2.60	2%	Apples	2%	Milk: Cattle	1.0%	Pears		0.2%
6%	DE child	2.01	3%	Apples	0.7%	Table grapes	0.6%	Milk: Cattle		0.1%
4%	NL child	1.45	1%	Apples	0.7%	Milk: Cattle	0.5%	Table grapes		0.1%
3%	RO general	0.91	0.3%	Wine grapes	0.3%	Milk: Cattle	0.3%	Apples		0.1%
2%	FR child 3 15 yr	0.87	0.7%	Milk: Cattle	0.4%	Apples	0.2%	Sugar beet roots		0.1%
2%	DE women 14-50 yr	0.86	0.6%	Apples	0.4%	Wine grapes	0.4%	Milk: Cattle		0.1%
2%	DE general	0.86	0.6%	Apples	0.4%	Wine grapes	0.4%	Milk: Cattle		0.2%
2%	GEMS/Food G07	0.85	0.8%	Wine grapes	0.2%	Apples	0.2%	Poultry: Muscle/meat		0.3%
2%	UK infant	0.85	1%	Milk: Cattle	0.4%	Apples	0.2%	Eggs: Chicken		0.1%
2%	FR toddler 2 3 yr	0.84	0.8%	Milk: Cattle	0.7%	Apples	0.2%	Sugar beet roots		0.1%
2%	GEMS/Food G15	0.82	0.5%	Wine grapes	0.3%	Barley	0.3%	Apples		0.4%
2%	GEMS/Food G08	0.80	0.5%	Wine grapes	0.3%	Barley	0.3%	Apples		0.4%
2%	PT general	0.80	1%	Wine grapes	0.2%	Apples	0.2%	Peaches		0.1%
2%	GEMS/Food G11	0.77	0.5%	Wine grapes	0.4%	Apples	0.3%	Barley		0.4%
2%	DK child	0.72	0.5%	Apples	0.4%	Milk: Cattle	0.2%	Rye		0.3%
2%	FR adult	0.71	1%	Wine grapes	0.2%	Apples	0.1%	Milk: Cattle		0.1%
2%	IE adult	0.67	0.6%	Wine grapes	0.2%	Apples	0.1%	Peaches		0.1%
2%	UK toddler	0.67	0.6%	Milk: Cattle	0.4%	Apples	0.2%	Sugar beet roots		0.1%
2%	GEMS/Food G06	0.63	0.5%	Table grapes	0.2%	Apples	0.2%	Wheat		0.2%
2%	GEMS/Food G10	0.61	0.3%	Poultry: Muscle/meat	0.2%	Wine grapes	0.2%	Barley		0.3%
2%	NL general	0.61	0.3%	Apples	0.3%	Wine grapes	0.2%	Milk: Cattle		0.2%
2%	ES child	0.57	0.4%	Milk: Cattle	0.3%	Apples	0.2%	Poultry: Muscle/meat		0.1%
1%	ES adult	0.47	0.2%	Wine grapes	0.2%	Apples	0.2%	Barley		0.2%
1%	DK adult	0.46	0.5%	Wine grapes	0.2%	Apples	0.2%	Milk: Cattle		0.0%
1%	SE general	0.44	0.4%	Milk: Cattle	0.2%	Apples	0.1%	Eggs: Chicken		0.1%
1%	FR infant	0.42	0.5%	Milk: Cattle	0.4%	Apples	0.1%	Sugar beet roots		0.0%
1%	UK adult	0.38	0.6%	Wine grapes	0.1%	Apples	0.1%	Milk: Cattle		0.1%
1.0%	PL general	0.35	0.5%	Apples	0.2%	Table grapes	0.1%	Cherries (sweet)		
1.0%	LT adult	0.34	0.4%	Apples	0.1%	Milk: Cattle	0.1%	Potatoes		0.1%
1.0%	UK vegetarian	0.34	0.4%	Wine grapes	0.1%	Apples	0.1%	Milk: Cattle		0.1%
0.9%	IT toddler	0.31	0.2%	Apples	0.2%	Wheat	0.1%	Peaches		0.2%
0.9%	FI 3 yr	0.31	0.2%	Apples	0.2%	Oat	0.1%	Potatoes		0.1%
0.8%	IT adult	0.27	0.2%	Apples	0.2%	Peaches	0.1%	Wheat		0.1%
0.6%	FI 6 yr	0.22	0.1%	Apples	0.1%	Potatoes	0.1%	Oat		0.1%
0.5%	FI adult	0.17	0.2%	Wine grapes	0.1%	Apples	0.0%	Oat		0.0%
0.4%	IE child	0.13	0.1%	Milk: Cattle	0.1%	Apples	0.0%	Wheat		0.0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Mefentrifluconazole BAS 750 F (F) is unlikely to present a public health concern.

A 3.3 IESTI calculations - Raw commodities

Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children				**Results for adults**			
No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.10%	Wheat	0.05 / 0.01	0.14	0.06%	Wheat	0.05 / 0.01	0.08
0.02%	Sunflower seeds	0.05 / 0.01	0.03	0.01%	Sunflower seeds	0.05 / 0.01	0.01
0.01%	Rapeseeds/canola	0.06 / 0.01	0.01	0.00%	Rapeseeds/canola	0.06 / 0.01	0.01
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

A 3.4 IESTI calculations - Processed commodities

Processed commodities

Results for children				Results for adults			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.02%	Wheat / milling (flour)	0.05 / 0	0.04	0.03%	Wheat / bread/pizza	0.05 / 0.01	0.04
0.02%	Wheat / milling (wholeme:	0.05 / 0.01	0.03	0.03%	Wheat / pasta	0.05 / 0.01	0.04
0.02%	Sunflower seeds / oils	0.05 / 0.02	0.02	0.01%	Wheat / bread	0.05 / 0.01	0.02
0.00%	Rapeseeds / oils	0.06 / 0.02	0.01	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
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#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
Expand/collapse list							

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Mefentrifluconazole BAS 750 F (F) is unlikely to present a public health risk.

For processed commodities, no exceedance of the ARfD/ADI was identified.

1, 2, 4, Triazole

A 3.5 1, 2, 4, Triazole TMDI calculations

not applicable

A 3.6 IEDI calculations

European Food Safety Authority

EF SA PRIMo revision 3.1; 2019/03/19

1,2,4-T

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0,023	ARfD (mg/kg bw):	0,1
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

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 : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
48%	NL toddler	11,05	42%	Milk: Cattle	2%	Maize/corn	1%	Sugar beet roots		1,0%
30%	UK infant	6,80	27%	Milk: Cattle	0,9%	Bovine: Muscle/meat	0,6%	Wheat		0,6%
24%	FR toddler 2 3 yr	5,52	20%	Milk: Cattle	0,8%	Bovine: Muscle/meat	0,7%	Wheat		0,7%
22%	NL child	5,10	17%	Milk: Cattle	2%	Sugar beet roots	0,9%	Wheat		0,9%
20%	FR child 3 15 yr	4,71	16%	Milk: Cattle	1%	Bovine: Muscle/meat	1,0%	Wheat		1%
17%	UK toddler	4,00	14%	Milk: Cattle	0,9%	Bovine: Muscle/meat	0,9%	Wheat		0,9%
17%	DE child	3,82	14%	Milk: Cattle	0,9%	Wheat	0,5%	Apples		1%
14%	DK child	3,16	9%	Milk: Cattle	1%	Rye	1%	Swine: Muscle/meat		2%
13%	FR infant	2,96	12%	Milk: Cattle	0,3%	Sugar beet roots	0,2%	Bovine: Muscle/meat		0,2%
13%	SE general	2,95	9%	Milk: Cattle	3%	Bovine: Muscle/meat	0,7%	Wheat		0,8%
12%	ES child	2,80	9%	Milk: Cattle	1,0%	Bovine: Muscle/meat	1,0%	Wheat		1,0%
12%	DE general	2,66	9%	Milk: Cattle	0,9%	Sugar beet roots	0,6%	Swine: Muscle/meat		0,6%
12%	DE women 14-50 yr	2,65	9%	Milk: Cattle	1,0%	Sugar beet roots	0,5%	Wheat		0,6%
11%	RO general	2,59	8%	Milk: Cattle	1%	Wheat	0,6%	Swine: Muscle/meat		1%
9%	NL general	1,97	6%	Milk: Cattle	0,6%	Sugar beet roots	0,5%	Bovine: Muscle/meat		0,5%
8%	GEMS/Food G15	1,94	5%	Milk: Cattle	1,0%	Wheat	0,7%	Swine: Muscle/meat		1%
8%	GEMS/Food G11	1,91	5%	Milk: Cattle	0,8%	Wheat	0,6%	Swine: Muscle/meat		1,0%
8%	GEMS/Food G07	1,85	4%	Milk: Cattle	0,9%	Wheat	0,6%	Bovine: Muscle/meat		1%
7%	GEMS/Food G08	1,70	4%	Milk: Cattle	1%	Swine: Muscle/meat	0,9%	Wheat		1%
7%	GEMS/Food G10	1,58	4%	Milk: Cattle	0,9%	Wheat	0,6%	Bovine: Muscle/meat		1%
6%	ES adult	1,27	3%	Milk: Cattle	0,5%	Bovine: Muscle/meat	0,5%	Wheat		0,6%
5%	DK adult	1,23	4%	Milk: Cattle	0,5%	Swine: Muscle/meat	0,4%	Bovine: Muscle/meat		0,4%
5%	FR adult	1,17	3%	Milk: Cattle	0,5%	Wheat	0,4%	Bovine: Muscle/meat		0,5%
5%	IE adult	1,15	3%	Milk: Cattle	0,5%	Wheat	0,3%	Bovine: Muscle/meat		0,5%
5%	GEMS/Food G06	1,14	2%	Milk: Cattle	2%	Wheat	0,3%	Sugar beet roots		2%
4%	LT adult	1,00	3%	Milk: Cattle	0,5%	Swine: Muscle/meat	0,2%	Rye		0,5%
3%	UK adult	0,77	2%	Milk: Cattle	0,5%	Bovine: Muscle/meat	0,4%	Wheat		0,4%
3%	UK vegetarian	0,70	2%	Milk: Cattle	0,4%	Wheat	0,1%	Sugar beet roots		0,5%
3%	IE child	0,70	2%	Milk: Cattle	0,3%	Wheat	0,1%	Swine: Muscle/meat		0,3%
2%	IT toddler	0,36	1%	Wheat	0,0%	Potatoes	0,0%	Apples		1%
1%	PT general	0,34	0,9%	Wheat	0,2%	Potatoes	0,1%	Wine grapes		0,9%
1%	IT adult	0,23	0,9%	Wheat	0,0%	Apples	0,0%	Potatoes		0,9%
0,8%	FI 3 yr	0,19	0,3%	Wheat	0,2%	Potatoes	0,1%	Rye		0,4%
0,7%	FI 6 yr	0,15	0,2%	Wheat	0,2%	Potatoes	0,1%	Rye		0,4%
0,4%	FI adult	0,08	0,2%	Rye	0,1%	Wheat	0,1%	Potatoes		0,2%
0,3%	PL general	0,06	0,1%	Potatoes	0,1%	Apples	0,0%	Table grapes		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of 1,2,4-T is unlikely to present a public health concern.

A 3.7 IESTI calculations - Raw commodities

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.7%	Wheat	0 / 0.05	0.72
0.2%	Sunflower seeds	0 / 0.05	0.16
0.07%	Rapeseeds/canola	0 / 0.05	0.07

Expand/collapse list

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.4%	Wheat	0 / 0.05	0.42
0.05%	Sunflower seeds	0 / 0.05	0.05
0.03%	Rapeseeds/canola	0 / 0.05	0.03

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

A 3.8 IESTI calculations - Processed commodities

Processed commodities

Results for children				**Results for adults**			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.6%	Wheat / milling (flour)	0 / 0.05	0.60	0.2%	Wheat / bread/pizza	0 / 0.05	0.22
0.3%	Wheat / milling (wholeme	0 / 0.05	0.28	0.2%	Wheat / pasta	0 / 0.05	0.19
0.1%	Sunflower seeds / oils	0 / 0.1	0.12	0.2%	Wheat / bread	0 / 0.05	0.17
0.0%	Rapeseeds / oils	0 / 0.1	0.03	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
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#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
Expand/collapse list							

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of 1,2,4-T is unlikely to present a public health risk.

For processed commodities, no exceedance of the ARfD/ADI was identified.

Triazole alanine

A 3.9 Triazole alanine TMDI calculations

Not applicable.

A 3.10 IEDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

TA

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0,3	ARfD (mg/kg bw):	0,3
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

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 : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
4%	NL toddler	12,40	1%	Maize/corn	0,8%	Wheat	0,4%	Milk: Cattle		0,9%
3%	DK child	7,67	1%	Rye	0,9%	Wheat	0,1%	Potatoes		2%
2%	GEMS/Food G06	6,50	1%	Wheat	0,3%	Maize/corn	0,1%	Potatoes		2%
2%	NL child	6,17	0,9%	Wheat	0,2%	Potatoes	0,2%	Milk: Cattle		0,9%
2%	GEMS/Food G15	6,01	0,9%	Wheat	0,2%	Potatoes	0,2%	Sunflower seeds		1%
2%	GEMS/Food G08	6,00	0,8%	Wheat	0,2%	Potatoes	0,2%	Barley		1%
2%	RO general	5,94	1%	Wheat	0,2%	Sunflower seeds	0,2%	Potatoes		1%
2%	DE child	5,80	0,9%	Wheat	0,3%	Apples	0,2%	Rye		1%
2%	GEMS/Food G07	5,65	0,9%	Wheat	0,2%	Potatoes	0,2%	Rapeseeds/canola seeds		1%
2%	GEMS/Food G10	4,95	0,8%	Wheat	0,2%	Potatoes	0,1%	Maize/corn		1,0%
2%	FR child 3 15 yr	4,90	1,0%	Wheat	0,2%	Milk: Cattle	0,1%	Potatoes		1,0%
2%	IT toddler	4,62	1%	Wheat	0,1%	Potatoes	0,0%	Peaches		1%
2%	PT general	4,53	0,8%	Wheat	0,3%	Potatoes	0,1%	Sunflower seeds		0,8%
1%	GEMS/Food G11	4,28	0,7%	Wheat	0,2%	Potatoes	0,2%	Barley		0,9%
1%	UK infant	4,21	0,5%	Wheat	0,3%	Milk: Cattle	0,2%	Maize/corn		0,5%
1%	ES child	4,13	0,9%	Wheat	0,1%	Potatoes	0,1%	Milk: Cattle		0,9%
1%	UK toddler	4,02	0,8%	Wheat	0,2%	Potatoes	0,1%	Milk: Cattle		0,8%
1%	FR toddler 2 3 yr	3,71	0,6%	Wheat	0,2%	Milk: Cattle	0,1%	Potatoes		0,6%
1%	SE general	3,66	0,7%	Wheat	0,3%	Potatoes	0,1%	Bovine: Muscle/meat		0,7%
1%	DE general	3,19	0,4%	Wheat	0,1%	Rye	0,1%	Barley		0,6%
1%	NL general	3,11	0,4%	Wheat	0,1%	Potatoes	0,1%	Rapeseeds/canola seeds		0,5%
1%	DE women 14-50 yr	3,11	0,4%	Wheat	0,1%	Rye	0,1%	Milk: Cattle		0,6%
1%	IE adult	3,03	0,5%	Wheat	0,1%	Potatoes	0,1%	Sunflower seeds		0,5%
1,0%	IT adult	2,99	0,9%	Wheat	0,0%	Peaches	0,0%	Potatoes		0,9%
0,9%	FI 3 yr	2,69	0,3%	Potatoes	0,2%	Wheat	0,1%	Rye		0,4%
0,8%	ES adult	2,55	0,5%	Wheat	0,1%	Barley	0,1%	Potatoes		0,6%
0,8%	LT adult	2,39	0,2%	Rye	0,2%	Wheat	0,2%	Potatoes		0,5%
0,7%	FR adult	2,21	0,5%	Wheat	0,0%	Wine grapes	0,0%	Potatoes		0,5%
0,7%	FI 6 yr	2,13	0,2%	Potatoes	0,2%	Wheat	0,1%	Rye		0,3%
0,6%	UK vegetarian	1,83	0,4%	Wheat	0,1%	Potatoes	0,0%	Milk: Cattle		0,4%
0,6%	DK adult	1,68	0,2%	Wheat	0,1%	Rye	0,1%	Potatoes		0,3%
0,5%	UK adult	1,62	0,3%	Wheat	0,1%	Potatoes	0,0%	Wine grapes		0,4%
0,5%	FR infant	1,49	0,2%	Wheat	0,1%	Potatoes	0,1%	Milk: Cattle		0,2%
0,4%	FI adult	1,05	0,1%	Rye	0,1%	Potatoes	0,1%	Wheat		0,2%
0,3%	IE child	0,99	0,2%	Wheat	0,0%	Potatoes	0,0%	Milk: Cattle		0,2%
0,3%	PL general	0,93	0,2%	Potatoes	0,0%	Apples	0,0%	Plums		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of TA is unlikely to present a public health concern.

A 3.11 IESTI calculations - Raw commodities

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
3%	Wheat	0 / 0.62	9.0
1%	Sunflower seeds	0 / 1.04	3.3
0.5%	Rapeseeds/canola	0 / 1.04	1.4

Expand/collapse list

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Wheat	0 / 0.62	5.2
0.3%	Sunflower seeds	0 / 1.04	1.0
0.2%	Rapeseeds/canola	0 / 1.04	0.55

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

A 3.12 IESTI calculations - Processed commodities

Processed commodities

Results for children				**Results for adults**			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Wheat / milling (flour)	0 / 0.32	3.8	0.9%	Wheat / bread/pizza	0 / 0.62	2.7
1.0%	Wheat / milling (wholemea	0 / 0.53	3.0	0.8%	Wheat / pasta	0 / 0.62	2.4
0.8%	Sunflower seeds / oils	0 / 2.08	2.4	0.6%	Wheat / bread	0 / 0.53	1.9
0.2%	Rapeseeds / oils	0 / 2.08	0.61	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
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Expand/collapse list							

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of TA is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

Triazole acetic acid

A 3.13 Triazole acetic acid TMDI calculations

not applicable

A 3.14 IEDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

TAA

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	1	ARfD (mg/kg bw):	1
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

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: ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
1%	NL toddler	12,18	0,6%	Maize/corn	0,3%	Wheat	0,2%	Milk: Cattle		0,4%
0,9%	DK child	8,81	0,4%	Rye	0,3%	Wheat	0,0%	Milk: Cattle		0,8%
0,7%	GEMS/Food G06	7,14	0,6%	Wheat	0,1%	Maize/corn	0,0%	Milk: Cattle		0,6%
0,6%	RO general	5,54	0,4%	Wheat	0,1%	Maize/corn	0,0%	Milk: Cattle		0,4%
0,5%	GEMS/Food G15	5,50	0,4%	Wheat	0,1%	Barley	0,1%	Maize/corn		0,4%
0,5%	DE child	5,44	0,3%	Wheat	0,1%	Rye	0,1%	Milk: Cattle		0,4%
0,5%	GEMS/Food G08	5,36	0,3%	Wheat	0,1%	Barley	0,0%	Rye		0,4%
0,5%	IT toddler	5,35	0,5%	Wheat	0,0%	Apples	0,0%	Maize/corn		0,5%
0,5%	NL child	5,32	0,3%	Wheat	0,1%	Milk: Cattle	0,0%	Sugar beet roots		0,3%
0,5%	FR child 3 15 yr	5,22	0,4%	Wheat	0,1%	Milk: Cattle	0,0%	Maize/corn		0,4%
0,5%	GEMS/Food G07	4,79	0,3%	Wheat	0,0%	Barley	0,0%	Maize/corn		0,4%
0,5%	GEMS/Food G10	4,67	0,3%	Wheat	0,1%	Maize/corn	0,0%	Barley		0,4%
0,5%	UK infant	4,50	0,2%	Wheat	0,1%	Milk: Cattle	0,1%	Maize/corn		0,2%
0,4%	ES child	4,36	0,4%	Wheat	0,0%	Milk: Cattle	0,0%	Maize/corn		0,4%
0,4%	GEMS/Food G11	4,13	0,3%	Wheat	0,1%	Barley	0,0%	Milk: Cattle		0,3%
0,4%	UK toddler	4,13	0,3%	Wheat	0,1%	Milk: Cattle	0,0%	Sugar beet roots		0,3%
0,4%	PT general	3,90	0,3%	Wheat	0,0%	Maize/corn	0,0%	Wine grapes		0,3%
0,4%	FR toddler 2 3 yr	3,85	0,2%	Wheat	0,1%	Milk: Cattle	0,0%	Sugar beet roots		0,2%
0,3%	SE general	3,38	0,3%	Wheat	0,0%	Milk: Cattle	0,0%	Rye		0,3%
0,3%	IT adult	3,35	0,3%	Wheat	0,0%	Apples	0,0%	Maize/corn		0,3%
0,3%	DE general	3,29	0,1%	Wheat	0,0%	Rye	0,0%	Barley		0,2%
0,3%	DE women 14-50 yr	3,19	0,2%	Wheat	0,0%	Rye	0,0%	Milk: Cattle		0,2%
0,3%	ES adult	2,63	0,2%	Wheat	0,0%	Barley	0,0%	Milk: Cattle		0,2%
0,3%	IE adult	2,62	0,2%	Wheat	0,0%	Maize/corn	0,0%	Oat		0,2%
0,3%	NL general	2,57	0,2%	Wheat	0,0%	Milk: Cattle	0,0%	Barley		0,2%
0,2%	FR adult	2,24	0,2%	Wheat	0,0%	Milk: Cattle	0,0%	Wine grapes		0,2%
0,2%	LT adult	2,09	0,1%	Rye	0,1%	Wheat	0,0%	Milk: Cattle		0,2%
0,2%	FI 3 yr	2,08	0,1%	Wheat	0,1%	Rye	0,0%	Oat		0,2%
0,2%	UK vegetarian	1,91	0,2%	Wheat	0,0%	Milk: Cattle	0,0%	Wine grapes		0,2%
0,2%	FI 6 yr	1,65	0,1%	Wheat	0,0%	Rye	0,0%	Oat		0,1%
0,2%	DK adult	1,64	0,1%	Wheat	0,0%	Rye	0,0%	Milk: Cattle		0,1%
0,2%	UK adult	1,61	0,1%	Wheat	0,0%	Milk: Cattle	0,0%	Wine grapes		0,1%
0,1%	FR infant	1,33	0,1%	Wheat	0,1%	Milk: Cattle	0,0%	Sugar beet roots		0,1%
0,1%	IE child	1,08	0,1%	Wheat	0,0%	Milk: Cattle	0,0%	Apples		0,1%
0,1%	FI adult	0,99	0,1%	Rye	0,0%	Wheat	0,0%	Oat		0,1%
0,0%	PL general	0,13	0,0%	Apples	0,0%	Potatoes	0,0%	Table grapes		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of TAA is unlikely to present a public health concern.

A 3.15 IESTI calculations - Raw commodities

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Wheat	0 / 0.79	11
0.04%	Sunflower seeds	0 / 0.12	0.38
0.02%	Rapeseeds/canola	0 / 0.12	0.17

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.7%	Wheat	0 / 0.79	6.6
0.01%	Sunflower seeds	0 / 0.12	0.12
0.01%	Rapeseeds/canola	0 / 0.12	0.06

A 3.16 IESTI calculations - Processed commodities

Processed commodities

Results for children				**Results for adults**			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.8%	Wheat / milling (flour)	0 / 0.64	7.7	0.3%	Wheat / bread/pizza	0 / 0.79	3.5
0.5%	Wheat / milling (wholemea	0 / 0.94	5.2	0.3%	Wheat / bread	0 / 0.94	3.3
0.0%	Sunflower seeds / oils	0 / 0.24	0.28	0.3%	Wheat / pasta	0 / 0.79	3.0
0.0%	Rapeseeds / oils	0 / 0.24	0.07	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
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Expand/collapse list							

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of TAA is unlikely to present a public health risk.

For processed commodities, no exceedance of the ARfD/ADI was identified.

Triazole lactic acid

A 3.17 Triazole lactic acid TMDI calculations

not applicable

A 3.18 IEDI calculations

efsa
European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

TLA

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0,3	ARfD (mg/kg bw):	0,3
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

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 : --

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	1,0%	NL toddler	2,93	0,6%	Milk: Cattle	0,1%	Apples	0,1%	Maize/corn		0,0%
	0,5%	UK infant	1,50	0,4%	Milk: Cattle	0,0%	Potatoes	0,0%	Wheat		0,0%
	0,5%	NL child	1,42	0,2%	Milk: Cattle	0,1%	Apples	0,0%	Wheat		0,0%
	0,5%	DE child	1,36	0,2%	Milk: Cattle	0,1%	Apples	0,0%	Wheat		0,0%
	0,4%	FR toddler 2 3 yr	1,27	0,3%	Milk: Cattle	0,0%	Apples	0,0%	Wheat		0,0%
	0,4%	FR child 3 15 yr	1,15	0,2%	Milk: Cattle	0,0%	Wheat	0,0%	Apples		0,0%
	0,3%	UK toddler	0,98	0,2%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes		0,0%
	0,3%	DK child	0,94	0,1%	Milk: Cattle	0,0%	Rye	0,0%	Wheat		0,1%
	0,3%	RO general	0,84	0,1%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes		0,0%
	0,3%	DE general	0,75	0,1%	Milk: Cattle	0,0%	Apples	0,0%	Sugar beet roots		0,0%
	0,3%	GEMS/Food G15	0,75	0,1%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes		0,1%
	0,2%	SE general	0,75	0,1%	Milk: Cattle	0,0%	Bovine: Muscle/meat	0,0%	Potatoes		0,0%
	0,2%	ES child	0,74	0,1%	Milk: Cattle	0,0%	Wheat	0,0%	Bovine: Muscle/meat		0,0%
	0,2%	GEMS/Food G07	0,74	0,1%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes		0,0%
	0,2%	DE women 14-50 yr	0,74	0,1%	Milk: Cattle	0,0%	Apples	0,0%	Wheat		0,0%
	0,2%	GEMS/Food G08	0,72	0,1%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes		0,1%
	0,2%	GEMS/Food G11	0,69	0,1%	Milk: Cattle	0,0%	Potatoes	0,0%	Wheat		0,0%
	0,2%	FR infant	0,67	0,2%	Milk: Cattle	0,0%	Apples	0,0%	Potatoes		0,0%
	0,2%	NL general	0,60	0,1%	Milk: Cattle	0,0%	Potatoes	0,0%	Apples		0,0%
	0,2%	GEMS/Food G10	0,60	0,1%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes		0,0%
	0,2%	GEMS/Food G06	0,49	0,1%	Wheat	0,0%	Milk: Cattle	0,0%	Table grapes		0,1%
	0,2%	IE adult	0,45	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Wine grapes		0,0%
	0,1%	FR adult	0,42	0,0%	Milk: Cattle	0,0%	Wine grapes	0,0%	Wheat		0,0%
	0,1%	ES adult	0,42	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Barley		0,0%
	0,1%	PT general	0,40	0,0%	Potatoes	0,0%	Wine grapes	0,0%	Wheat		0,0%
	0,1%	DK adult	0,38	0,1%	Milk: Cattle	0,0%	Wine grapes	0,0%	Apples		0,0%
	0,1%	LT adult	0,37	0,0%	Milk: Cattle	0,0%	Potatoes	0,0%	Apples		0,0%
	0,1%	UK adult	0,27	0,0%	Milk: Cattle	0,0%	Wine grapes	0,0%	Wheat		0,0%
	0,1%	UK vegetarian	0,26	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Wine grapes		0,0%
	0,1%	FI 3 yr	0,25	0,0%	Potatoes	0,0%	Oat	0,0%	Apples		0,0%
	0,1%	IT toddler	0,23	0,0%	Wheat	0,0%	Apples	0,0%	Potatoes		0,0%
	0,1%	FI 6 yr	0,19	0,0%	Potatoes	0,0%	Oat	0,0%	Wheat		0,0%
	0,1%	IE child	0,18	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes		0,0%
	0,1%	PL general	0,17	0,0%	Potatoes	0,0%	Apples	0,0%	Table grapes		
	0,1%	IT adult	0,17	0,0%	Wheat	0,0%	Apples	0,0%	Peaches		0,0%
	0,0%	FI adult	0,10	0,0%	Potatoes	0,0%	Apples	0,0%	Rye		0,0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of TLA is unlikely to present a public health concern.

A 3.19 IESTI calculations - Raw commodities

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Wheat	0 / 0.02	0.32
0.07%	Sunflower seeds	0 / 0.07	0.21
0.03%	Rapeseeds/canola	0 / 0.07	0.09

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.06%	Wheat	0 / 0.02	0.18
0.02%	Sunflower seeds	0 / 0.07	0.07
0.01%	Rapeseeds/canola	0 / 0.07	0.03

A 3.20 IESTI calculations - Processed commodities

Processed commodities

Results for children				**Results for adults**			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Wheat / milling (flour)	0 / 0.02	0.27	0.03%	Wheat / bread/pizza	0 / 0.02	0.10
0.1%	Sunflower seeds / oils	0 / 0.13	0.15	0.03%	Wheat / pasta	0 / 0.02	0.08
0.0%	Wheat / milling (wholemea	0 / 0.02	0.12	0.03%	Wheat / bread	0 / 0.02	0.08
0.0%	Rapeseeds / oils	0 / 0.13	0.04	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
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#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
Expand/collapse list							

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of TLA is unlikely to present a public health risk.

For processed commodities, no exceedance of the ARfD/ADI was identified.

Boscalid

A 3.21 Boscalid TMDI calculations - updated

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Boscalid (F)

LOQs (mg/kg) ranges from: 0.01 to: 0.15

Toxicological reference values

ADI (mg/kg bw/day):	0.04	ARfD (mg/kg bw):	n.a.
Source of ADI:	2008/44/EC	Source of ARfD:	2008/44/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

Normal mode

Chronic risk assessment: JMPR methodology (IED/TMDI)

No of diets exceeding the ADI: 28

Exposure resulting fro

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 under assessme (in % of A
398 %	NL toddler	159.22	98%	Spinaches	54%	Apples	31%	Escaroles/broad-leaved endives	0.3 %	10%
261 %	DE child	104.33	62%	Apples	25%	Spinaches	20%	Oranges	0.5 %	9%
224 %	GEMSFood G11	89.69	34%	Sugar canes	28%	Soybeans	20%	Potatoes	0.1 %	15%
223 %	GEMSFood G10	89.29	41%	Lettuces	24%	Soybeans	23%	Sugar canes	0.1 %	14%
217 %	NL child	86.91	31%	Spinaches	29%	Apples	17%	Potatoes	0.3 %	8%
216 %	GEMSFood G08	86.32	29%	Sugar canes	27%	Tomatoes	14%	Wheat	0.1 %	15%
214 %	GEMSFood G05	85.48	28%	Sugar canes	25%	Lettuces	20%	Potatoes	0.1 %	17%
210 %	GEMSFood G07	84.11	30%	Lettuces	27%	Sugar canes	19%	Potatoes	0.1 %	14%
187 %	GEMSFood G15	74.99	23%	Sugar canes	18%	Potatoes	14%	Lettuces	0.1 %	17%
184 %	IE adult	73.63	18%	Sweet potatoes	16%	Wine grapes	16%	Wine grapes	0.2 %	5%
169 %	SE general	67.61	50%	Lettuces	21%	Potatoes	8%	Spinaches	0.4 %	6%
145 %	IT adult	57.95	47%	Lettuces	20%	Other lettuce and other salad plants	12%	Spinaches	0.0 %	6%
144 %	ES adult	57.68	67%	Lettuces	9%	Spinaches	6%	Oranges	0.2 %	10%
144 %	FR child 3-15 yr	57.64	17%	Oranges	14%	Other lettuce and other salad plants	13%	Spinaches	0.5 %	9%
141 %	ES child	56.23	52%	Lettuces	11%	Oranges	10%	Spinaches	0.3 %	9%
132 %	RO general	52.75	21%	Wine grapes	19%	Potatoes	18%	Head cabbages	0.2 %	10%
131 %	IT toddler	52.32	38%	Lettuces	14%	Other lettuce and other salad plants	13%	Wheat	0.0 %	13%
131 %	PT general	52.28	31%	Wine grapes	27%	Potatoes	13%	Lettuces	0.0 %	8%
130 %	NL general	52.11	19%	Spinaches	12%	Escaroles/broad-leaved endives	12%	Potatoes	0.2 %	7%
128 %	FR toddler 2-3 yr	51.11	20%	Spinaches	16%	Apples	10%	Beans (with pods)	0.3 %	6%
120 %	DE women 14-50 yr	48.13	14%	Lettuces	13%	Apples	10%	Wine grapes	0.2 %	6%
119 %	DK child	47.76	18%	Lettuces	16%	Cucumbers	12%	Potatoes	0.3 %	9%
115 %	DE general	46.16	12%	Apples	12%	Lettuces	10%	Wine grapes	0.2 %	9%
112 %	FI 3 yr	44.80	24%	Potatoes	10%	Cucumbers	8%	Spinaches	0.0 %	3%
108 %	FR adult	43.36	29%	Wine grapes	19%	Other lettuce and other salad plants	7%	Spinaches	0.2 %	4%
102 %	UK toddler	40.84	17%	Potatoes	10%	Oranges	9%	Apples	0.4 %	8%
102 %	FR infant	40.77	33%	Spinaches	10%	Potatoes	8%	Apples	0.1 %	2%
92 %	FI 6 yr	36.75	19%	Potatoes	10%	Lettuces	7%	Cucumbers	0.0 %	3%
87 %	UK infant	34.92	18%	Potatoes	8%	Apples	7%	Carrots	0.5 %	5%
82 %	UK vegetarian	32.92	18%	Lettuces	10%	Wine grapes	7%	Potatoes	0.1 %	4%
68 %	UK adult	27.33	15%	Lettuces	14%	Wine grapes	7%	Potatoes	0.1 %	4%
67 %	PL general	26.89	17%	Potatoes	10%	Apples	7%	Tomatoes	0.0 %	
66 %	DK adult	26.34	12%	Wine grapes	11%	Lettuces	6%	Potatoes	0.1 %	2%
63 %	FI adult	25.07	18%	Lettuces	6%	Potatoes	4%	Tomatoes	0.7 %	0.2%
60 %	LT adult	23.95	16%	Potatoes	9%	Apples	8%	Lettuces	0.1 %	3%
18 %	IE child	7.27	3%	Potatoes	2%	Wheat	2%	Apples	0.1 %	2%

Conclusion:

The estimated TMDI/NEDI/IEDI was in the ranges of 0 % to 398 % of the ADI.

For 28 diet(s) the ADI is exceeded.

A 3.22 IEDI calculations

European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

Boscalid

LOQs (mg/kg) range from:	0.01	to:	0.15
Toxicological reference values			
ADI (mg/kg bw/day):	0.04	ARfD (mg/kg bw):	n.a.
Source of ADI:	2008/44/	Source of ARfD:	2008/44/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 : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
69%	NL toddler	27.74	11%	Apples	10%	Spinaches	5%	Table grapes	0.4%	
63%	GEMS/Food G11	25.04	34%	Sugar canes	4%	Wine grapes	2%	Barley	0.3%	
58%	GEMS/Food G06	23.14	29%	Sugar canes	4%	Table grapes	4%	Tomatoes	0.1%	
56%	GEMS/Food G08	22.57	28%	Sugar canes	4%	Wine grapes	3%	Lettuces	0.3%	
56%	GEMS/Food G07	22.41	27%	Sugar canes	5%	Wine grapes	3%	Lettuces	0.3%	
50%	GEMS/Food G10	19.82	23%	Sugar canes	5%	Lettuces	2%	Wheat	0.3%	
49%	GEMS/Food G15	19.70	23%	Sugar canes	4%	Wine grapes	2%	Head cabbages	0.3%	
45%	DE child	18.09	13%	Apples	5%	Table grapes	3%	Spinaches	0.6%	
36%	NL child	14.45	6%	Apples	4%	Table grapes	4%	Spinaches	0.5%	
33%	IE adult	13.40	4%	Wine grapes	4%	Other leafy brassica	2%	Spinaches	0.3%	
23%	RO general	9.40	6%	Wine grapes	4%	Head cabbages	2%	Wheat	0.4%	
23%	FR child 3 15 yr	9.37	2%	Wheat	2%	Apples	2%	Other lettuce and other salad plan	0.8%	
23%	SE general	9.28	6%	Lettuces	2%	Head cabbages	1%	Wheat	0.7%	
22%	DE women 14-50 yr	8.77	3%	Wine grapes	3%	Apples	2%	Lettuces	0.3%	
22%	FR toddler 2 3 yr	8.66	3%	Apples	3%	Beans (with pods)	2%	Spinaches	0.5%	
22%	DE general	8.62	3%	Wine grapes	3%	Apples	1%	Barley	0.3%	
21%	IT adult	8.57	5%	Lettuces	2%	Other lettuce and other salad plants	2%	Wheat	0.0%	
21%	PT general	8.40	3%	Wine grapes	2%	Wheat	1%	Lettuces	0.0%	
21%	FR adult	8.28	6%	Wine grapes	2%	Other lettuce and other salad plants	0.9%	Wheat	0.4%	
20%	ES adult	8.19	7%	Lettuces	1%	Wine grapes	1%	Barley	0.4%	
20%	NL general	8.17	2%	Spinaches	2%	Wine grapes	2%	Apples	0.4%	
20%	DK child	8.16	3%	Cucumbers	2%	Apples	2%	Rye	0.7%	
20%	IT toddler	8.08	4%	Lettuces	3%	Wheat	2%	Other lettuce and other salad plan	0.0%	
19%	ES child	7.67	6%	Lettuces	2%	Wheat	1%	Apples	0.6%	
17%	FI 3 yr	6.80	2%	Cucumbers	2%	Strawberries	2%	Oat	0.0%	
17%	FR infant	6.69	4%	Spinaches	2%	Apples	2%	Beans (with pods)	0.1%	
15%	UK toddler	6.19	2%	Apples	2%	Wheat	1%	Currants (red, black and white)	0.5%	
15%	UK infant	6.12	2%	Milk: Cattle	2%	Apples	1%	Wheat	0.7%	
13%	FI 6 yr	5.23	1%	Strawberries	1%	Cucumbers	1%	Lettuces	0.0%	
13%	UK vegetarian	5.14	3%	Wine grapes	2%	Lettuces	0.9%	Wheat	0.1%	
12%	DK adult	4.67	3%	Wine grapes	1%	Lettuces	1%	Apples	0.3%	
12%	UK adult	4.60	4%	Wine grapes	2%	Lettuces	0.7%	Wheat	0.2%	
10%	FI adult	4.05	2%	Lettuces	1%	Wine grapes	0.7%	Coffee beans	0.7%	
10%	PL general	3.86	2%	Apples	1%	Table grapes	1%	Head cabbages	0.0%	
9%	LT adult	3.66	2%	Apples	1%	Head cabbages	0.9%	Lettuces	0.2%	
3%	IE child	1.28	0.5%	Wheat	0.3%	Apples	0.3%	Currants (red, black and white)	0.1%	

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Boscalid is unlikely to present a public health concern.

A 3.23 IESTI calculations - Raw commodities

Not applicable

A 3.24 IESTI calculations - Processed commodities

Not applicable

A 3.25 Further considerations on combined toxicity (chronic) – TA and TLA

Crop groups and examples of individual products within the groups to which the MRLs apply	pTMRL (mg/kg)		TMDI/IEDI is calculated with MRL STMR STMR-p; LOQ	ES child	FR infant	FR toddler 2 3 yr	FR child 3 15 yr	IT toddler	NL toddler	NL child	UK infant	UK toddler	DK adult	ES adult	FI adult	FR adult	IE adult	IT adult
Triazole alanine																		
Sunflower	1.04	STMR																
Rapeseed	1.04	STMR																
Wheat	0.621	STMR																
			µg/kg bw/day	2.8772	0.5135	2.0588	3.1068	4.1447	3.7419	3.4116	1.6274	2.4330	0.6978	1.5628	0.2116	1.4975	1.6328	2.5778
			mg/kg bw/day	0.0029	0.0005	0.0021	0.0031	0.0041	0.0037	0.0034	0.0016	0.0024	0.0007	0.0016	0.0002	0.0015	0.0016	0.0026
			ADI	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300
			HQ	**0.010**	**0.002**	**0.007**	**0.010**	**0.014**	**0.012**	**0.011**	**0.005**	**0.008**	**0.002**	**0.005**	**0.001**	**0.005**	**0.005**	**0.009**
Triazole lactic acid																		
Sunflower	0.065	STMR																
Rapeseed	0.065	STMR																
Wheat	0.022	STMR																
			µg/kg bw/day	0.1053	0.0189	0.0770	0.1169	0.1473	0.1676	0.1441	0.0577	0.0862	0.0247	0.0582	0.0078	0.0562	0.06346	0.0916
			mg/kg bw/day	1E-04	2E-05	8E-05	1E-04	1E-04	2E-04	1E-04	6E-05	9E-05	2E-05	6E-05	8E-06	6E-05	6E-05	9E-05
			ADI	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
			HQ	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.001**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
Cummulative risk HI				**0.010**	**0.002**	**0.007**	**0.011**	**0.014**	**0.013**	**0.012**	**0.006**	**0.008**	**0.002**	**0.005**	**0.001**	**0.005**	**0.006**	**0.009**

Crop groups and examples of individual products within the groups to which the MRLs apply	pTMRL (mg/kg)		TMDI/EDI is calculated with MRL STMR STMR-p; LOQ	LT adult	NL general	PL general	PT general	RO general	SE general	UK adult	UK vegetarian	GEMS/Food G06	GEMS/Food G07	GEMS/Food G08	GEMS/Food G10	GEMS/Food G11	GEMS/Food G15	DE general	DE women 14-50 yr	IE child	FI 3 yr	FI 6 yr
Triazole alanine																						
Sunflower	1.04	STMR																				
Rapeseed	1.04	STMR																				
Wheat	0.621	STMR																				
			µg/kg bw/day	0.6972	1.6913	0.0086	2.7332	3.8397	1.9882	1.0410	1.2718	4.7637	3.5924	3.3882	2.9463	2.3520	3.5857	1.2429	1.4134	0.7222	0.8321	0.6676
			mg/kg bw/day	0.0007	0.0017	0.0000	0.0027	0.0038	0.0020	0.0010	0.0013	0.0048	0.0036	0.0034	0.0029	0.0024	0.0036	0.0012	0.0014	0.0007	0.0008	0.0007
			ADI	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300	0.300
			HQ	**0.002**	**0.006**	**0.000**	**0.009**	**0.013**	**0.007**	**0.003**	**0.004**	**0.016**	**0.012**	**0.011**	**0.010**	**0.008**	**0.012**	**0.004**	**0.005**	**0.002**	**0.003**	**0.002**
Triazole lactic acid																						
Sunflower	0.065	STMR																				
Rapeseed	0.065	STMR																				
Wheat	0.022	STMR																				
			µg/kg bw/day	0.0259	0.0732	0.0005	0.1049	0.1548	0.0704	0.0369	0.0451	0.1761	0.1536	0.1431	0.1182	0.0864	0.1477	0.0460	0.0523	0.0256	0.0320	0.0254
			mg/kg bw/day	3E-05	7E-05	5E-07	1E-04	2E-04	7E-05	4E-05	5E-05	2E-04	2E-04	1E-04	1E-04	9E-05	1E-04	5E-05	5E-05	3E-05	3E-05	3E-05
			ADI	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	1.3
			HQ	**0.000**	**0.000**	**0.000**	**0.000**	**0.001**	**0.000**	**0.000**	**0.000**	**0.001**	**0.001**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
Cummulative risk HI				**0.002**	**0.006**	**0.000**	**0.009**	**0.013**	**0.007**	**0.004**	**0.004**	**0.016**	**0.012**	**0.012**	**0.010**	**0.008**	**0.012**	**0.004**	**0.005**	**0.002**	**0.003**	**0.002**

Appendix 4 Additional information provided by the applicant

Not applicable.