FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: BAS 768 00 F

Product name(s): Revytur

Chemical active substance(s):

Mefentrifluconazole, 25 g/L
Sulfur, 600 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: BASF

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Version history

When	What
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04/2023	Dossier sent for evaluation
08/2023	zRMS evaluation of dRR
11/2023	Update dRR – BASF DocID 2023/2053305
12/2023	Final version prepared by zRMS after Commenting period

Table of Contents

7 Metabolism and residue data (KCA section 6) 5

7.1 Summary and zRMS Conclusion 5
7.1.1 Critical GAP(s) and overall conclusion 5
7.1.2 Summary of the evaluation 8
7.1.2.1 Summary for mefentrifluconazole 9
7.1.2.2 Summary for Sulfur (BAS 175 F) 10
7.1.2.3 Summary for active substance 3 10
7.1.2.4 Summary for BAS 768 00 F 10
7.2 Mefentrifluconazole 11
7.2.1 Stability of Residues (KCA 6.1) 12
7.2.1.1 Stability of residues during storage of samples 12
7.2.1.2 Stability of residues in sample extracts (KCA 6.1) 15
7.2.2 Nature of residues in plants, livestock and processed commodities 16
7.2.2.1 Nature of residue in primary crops (KCA 6.2.1) 16
7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1) 18
7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1) 20
7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1) 21
7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5) 21
7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1) 25
7.2.3 Magnitude of residues in plants (KCA 6.3) 26
7.2.3.1 Summary of European data and new data supporting the intended uses 26
7.2.3.2 Conclusion on the magnitude of residues in plants 30
7.2.4 Magnitude of residues in livestock 33
7.2.4.1 Dietary burden calculation 33
7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3) 38
7.2.4.3 Dietary burden calculation in Triazole derived metabolites 44
7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3) 61
7.2.5.1 Available data for all crops under consideration 61
7.2.5.2 Conclusion on processing studies 63
7.2.6 Magnitude of residues in representative succeeding crops 64
7.2.6.1 Field rotational crop studies (KCA 6.6.2) 64
7.2.7 Other / special studies (KCA 6.10, KCA 6.10.1) 66
7.2.8 Estimation of exposure through diet and other means (KCA 6.9) 66
7.2.8.1 Input values for the consumer risk assessment 66
7.2.8.2 Conclusion on consumer risk assessment 77
7.3 Sulfur 81
7.3.1 Stability of Residues (KCA 6.1) 82
7.3.1.1 Stability of residues during storage of samples 82
7.3.1.2 Stability of residues in sample extracts (KCA 6.1) 83
7.3.2 Nature of residues in plants, livestock and processed commodities 84
7.3.2.1 Nature of residue in primary crops (KCA 6.2.1) 84
7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1) 86
7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1) 87
7.3.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1) 87

7.3.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5) 88
7.3.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1) 88
7.3.3 Magnitude of residues in plants (KCA 6.3) 89
7.3.4 Magnitude of residues in livestock 89
7.3.4.1 Dietary burden calculation 89
7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3) 89
7.3.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3) 89
7.3.5.1 Conclusion on processing studies 89
7.3.6 Magnitude of residues in representative succeeding crops 90
7.3.6.1 Field rotational crop studies (KCA 6.6.2) 90
7.3.7 Other / special studies (KCA 6.10, KCA 6.10.1) 90
7.3.8 Estimation of exposure through diet and other means (KCA 6.9) 90
7.4 Active substance 3 90
7.5 Combined exposure and risk assessment 91
7.5.1 Acute consumer risk assessment from combined exposure 91
7.5.2 Chronic consumer risk assessment from combined exposure 92
7.6 References 97

Appendix 1 Lists of data considered in support of the evaluation 99

Appendix 2 Detailed evaluation of the additional studies relied upon 100

A 2.1 Mefentrifluconazole 100
A 2.2 Sulfur 130
A 2.3 Active substance 3 131

Appendix 3 Pesticide Residue Intake Model (PRIMo) 132

Appendix 4 Additional information provided by the applicant 150

7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

The applicant's dRR text was not rewritten by the zRMS. In the resulting RR all comments /corrections/ add-ons were placed on the grey background.
BASF amendments that were not requested by zRMS but were prepared, were added within the present final RR on yellow.

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 768 00 F are presented in Table 7.1-2. They have been selected from the individual GAPs in the Central Zone for cereals. 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 MRLs of the active substance BAS 750 F (see Table 7.1-1) as laid down in Reg. (EU) 396/2005 is not expected.

Table 7.1-1: MRLs for the active substance (mefentrifluconazole) of BAS 768 00 F in cereals

Crop	Mefentrifluconazole (BAS 750 F)
	mg/kg
Wheat (triticale)	0.05
Barley	0.6

The chronic and the short-term intakes of BAS 750 F 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 uses.
Barley and Wheat are crops with no melliferous capacity according to SANTE/11956/2016 rev.9.
According to available data, no specific mitigation measures should apply.

Data gaps - none

Table 7.1-2: 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 G or I *****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**				**PHI**	**Conclusion:**
						Type	**Concentration of a.s**	**Method Kind**	**Growth stage & season**	**Number**	**Interval between applications (min)**	**kg as/hL**		**Water L/ha**		**kg as/ha**		
										min max		**min**	**max**	**min**	**max**	**min**	**max**	**(days)**	
1, 2, 3	Wheat TRZAW, TRZAS TRZDU, TRZSP	Central EU (DE, IE, PL, AT, NL)	BAS 768 00 F	F	*Zymoseptoria tritici - SEPTTR* *Blumeria graminis - ERYSGR* *Puccinia triticina - PUCCRT* *Puccinia striiformis - PUCCST* *P. tritici-repentis – PYRNTR* (IE only)	SC	(a) 25 g/L (b) 600 g/L	spraying	BBCH 30 - 59	2	14	(a) 0.033- (b) 0.800-	0.100 2.400	100-	300	(a) 0.100 (b) 2.400		F§	
7	Wheat TRZAW, TRZAS TRZDU, TRZSP	Central EU (CZ)	BAS 768 00 F	F	*Zymoseptoria tritici - SEPTTR* *Blumeria graminis - ERYSGR* *Puccinia triticina - PUCCRT* *Puccinia striiformis - PUCCST*	SC	(a) 25 g/L (b) 600 g/L	spraying	BBCH 30 - 59	1		(a) 0.033- (b) 0.800-	0.100 2.400	100-	300	(a) 0.100 (b) 2.400		F§	
4	Barley HORVW, HORVS	Central EU (DE, IE, AT, NL)	BAS 768 00 F	F	*Ramularia collo-cygni - RAMUCC* *Pyrenophora teres - PYRNTE* *Puccinia hordei - PUCCHD* *Rhynchosporium secalis - RHYNSE*	SC	(a) 25 g/L (b) 600 g/L	spraying	BBCH 30 - 59	2	14	(a) 0.033- (b) 0.800-	0.100 2.400	100-	300	(a) 0.100 (b) 2.400		F§	

1	2	3	4	5	6	7		8				9						10	11
GAP number (see part B.0)*	**Crop and/or situation ****	**Zone**	**Product**	**F G or I *****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**						**PHI**	**Conclusion:**
						Type	**Concentration of a.s**	**Method Kind**	**Growth stage & season**	**Number**		**Interval between applications (min)**	**kg as/hL**		**Water L/ha**		**kg as/ha**		**(days)**	
										min	**max**		**min**	**max**	**min**	**max**	**min**	**max**		
8	Barley HORVW, HORVS	Central EU (CZ)	BAS 768 00 F	F	*Ramularia collo-cygni - RAMUCC* *Pyrenophora teres - PYRNTE* *Puccinia hordei - PUCCHD* *Rhynchosporium secalis - RHYNSE*	SC	(a) 25 g/L (b) 600 g/L	spraying	BBCH 30 - 59		1		(a) 0.033- (b) 0.800-	0.100 2.400	100-	300	(a) 0.100 (b) 2.400		F§	
5, 6	Triticale TTLWI	Central EU (DE, IE, AT, NL, PL)	BAS 768 00 F	F	*Septoria species - SEPTSP* *Blumeria graminis - ERYSGR* *Puccinia triticina - PUCCRT* *Puccinia striiformis - PUCCST*	SC	(a) 25 g/L (b) 600 g/L	spraying	BBCH 30 - 59		2	14	(a) 0.033- (b) 0.800-	0.100 2.400	100-	300	(a) 0.100 (b) 2.400		F§	
9	Triticale TTLWI	Central EU (CZ)	BAS 768 00 F	F	*Septoria species - SEPTSP* *Blumeria graminis - ERYSGR* *Puccinia triticina - PUCCRT* *Puccinia striiformis - PUCCST*	SC	(a) 25 g/L (b) 600 g/L	spraying	BBCH 30 - 59		1		(a) 0.033- (b) 0.800-	0.100 2.400	100-	300	(a) 0.100 (b) 2.400		F§	

a.s.: Active substance
* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** Use also code numbers according to Annex I of Regulation (EU) No 396/2005
*** F: professional field use, G: professional greenhouse use, I: indoor application
F§ Defined by latest application timing.

Explanation for Column 11 “Conclusion”

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

7.1.2 Summary of the evaluation

The preparation BAS 768 00 F is composed of mefentrifluconazole (BAS 750 F) and sulfur (BAS 175 F).

Table 7.1-3: Toxicological reference values for the dietary risk assessment of BAS 750 F (Mefentrifluconazole) and BAS 175 F (Sulphur)

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 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
Sulphur					
ADI	Not applicable			EFSA (2008), 221, 1-70;	
ARfD	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

Table 7.1-4: Summary for BAS 750 F

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, 7	Wheat	Yes	Yes (8N, 9S)	Yes	Yes	Yes	No	No
4, 8	Barley	Yes	Yes/~~No~~ (9N, 9S)	Yes	Yes	Yes		No
5, 6, 9	Triticale (covered by wheat according to EU Reg. 2018/62)	Yes	Yes (8N, 9S)	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 BAS 750 F 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.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary. No acute risk has been identified for BAS 750 F in cereals. The use of BAS 768 00 F on cereals is therefore acceptable.

7.1.2.2 Summary for Sulfur (BAS 175 F)

During the evaluation of sulfur for Annex I Listing, the Rapporteur Member State (France) proposed in the Draft Assessment Report (2008) that no EU MRL should be set and that Sulfur be placed in Annex IV of Regulation (EC) No 396/2005. l. There is no MRL required for this active substance (Commission Regulation (EU) No 459/2010).

EFSA (2008) concluded:
"A consumer risk assessment is neither possible nor necessary, as the mammalian toxicology assessment has concluded that sulfur is of low toxicity, and it is not necessary to set an ADI or ARfD ….. The rapporteur Member State also tried to estimate total sulfur intake from food and water to evaluate general exposure. However, the PRAPeR 60 meeting of experts did not consider these estimates (not peer reviewed), but concluded that no dietary risk assessment needs to be carried out, since toxicological reference values were not set for sulfur."

7.1.2.3 Summary for active substance 3

Not relevant

7.1.2.4 Summary for BAS 768 00 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 768 00 F (KCA 6.8)

Crop	PHI for BAS 768 00 F proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for BAS 768 00 F proposed by zRMS	zRMS Comments (if different PHI proposed)
		BAS 750 F	BAS 175 F		
Wheat	F§	Yes	Yes	-	-
Barley	F§	Yes	Yes	-	-
Triticale	F§	Yes	Yes	-	-

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 768 00 F
Crop group	Led by BAS 750 F	Led by Sulfur	
Follow crops	NR	NR	

NR: not relevant

Assessment

7.2 Mefentrifluconazole

General data on mefentrifluconazole are summarized in the table below.

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)-2-(trifluoromethyl)phenyl]-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—methy1 sterols results in inhibition of growth and cell membrane disruption.
Systemic	Yes
Company (ies)	BASF SE*
Rapporteur Member State (RMS)	Spain 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/11312/2018 Rev. 2 2019 SANTE/11612/2018 Rev. 3 26 January 2021 (the Standing Committee on Plants, Animals, Food and Feed took note of the revision of the review report for the active substance mefentrifluconazole, to include the agreed reference values and residue definitions for the triazole derived metabolites)
Current MRL regulation	Regulation (EU) 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 Journal: conclusion on article 12	No
Current MRL applications on intended uses	Yes, but not for cereals (EFSA-Q-2021-00692)

* Notifier in the EU process to whom the a.s. belong(s)
** EFSA Journal 2018;16(7):5379- see list of references

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application. In the context of the Annex I inclusion process storage stability studies were 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 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)	
		12 months (TA)	
		12 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)	
		26 months (TA)	
		≤ 12 months (TAA)	
Forage/fodder crops (wheat forage)	High water content	24 months (BAS 750 F)	
		≤ 4 months (1,2,4-T)	
		53 months (TA)	
		53 months (TAA)	
Oilseeds (Soybean seed)	High oil content	24 months (BAS 750 F)	
		≤ 12 months (1,2,4-T)	
		26 months (TA)	
		26 months (TAA)	
		48 months (TLA)	
Oilseeds	High oil content	24 months (BAS 750 F)	

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
(Rapeseed/Canola seed)		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 (1,2,4-T)~~	
		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			
Bovine	Muscle	177 days (BAS 750 F)	EFSA, 2018a (BAS 750 F and M750F022) BASF DocID 2015/1106711 and BASF DocID 2015/1106710 EFSA, 2018b (TDMs) BASF Doc ID 1998/1002324
		178 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	Fat	180 days (BAS 750 F)	
		180 days (M750F022)	
		370 days (1,2,4-T)	
Bovine	Kidney	177 days (BAS 750 F)	
		178 days (M750F022)	
Bovine	Milk	177 days (BAS 750 F)	
		178 days (M750F022)	
		560 days (1,2,4-T)	

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
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)	

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 ≤18°C.

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 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 finalized TDM review (EFSA, 2018b) for which BASF was one of the members of the TDM group who submitted the studies. These studies were considered acceptable for 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 TDM review 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.

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. L0076/01 (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 was 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. (BASF DoclD: 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 which indicates stability of the different analytes in the extracts and final volumes in the matrices analyzed.

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 accepts the assessment proposal

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application. In the context of the Annex I inclusion process plant metabolism studies were 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	Chloro-phenyl-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 in-terval	EFSA, 2018a BASF DocID 2015/1073822
Cereals/grass crops	Wheat	Chloro-phenyl-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 and oilseeds	Soybean	Chloro-phenyl-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 in-terval	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 grape-vine (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.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application. In the context of the Annex I inclusion process one metabolism study in rotational crops was 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	Chloro-phenyl-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	Chloro-phenyl-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	
Cereals (small grain)	Wheat	Chloro-phenyl-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 plant 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.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application. In the context of the Annex I inclusion process one hydrolysis study was 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- 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 pasteurization, baking, brewing and boiling and sterilization".

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

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

Endpoints	
Plant groups covered	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 confirmed stable 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	BAS 750 F
Plant residue definition for risk assessment	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 submitted in the framework of this application. In the context of the Annex I inclusion process three animal metabolism studies (hen, goat, trout) were 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	
		Trifluoromethyphenylring (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	

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
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	
		Trifluoromethyphenylring (TFMP-ring)	1	0.40	12	Milk	Twice daily	
						Urine and faeces	Daily	
						Tissues	At sacrifice	
		Triazole ring (T-ring)	2	0.43	14	Milk	Twice daily	
						Urine and faeces	Daily	
						Tissues	At sacrifice	
Fish	Rainbow trout	Chlorophenyl ring (C-ring)	5	5.82 mg/kg DM	10-14	Faeces	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	Faeces	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, 2018)

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. TDMs 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.

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

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

	Endpoints
Animals covered	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	BAS 750 F
Animal residue definition for risk assessment	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 750F 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

zRMS accepts the assessment proposal

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

No new data are submitted in the framework of this application. In the context of the Annex I inclusion process four studies on the magnitude of residues of BAS 750 F were 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- 9: Summary of EU reported and new data supporting the intended uses of BAS 768 00 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 a) BAS 750 F b) Triazole derivative metabolites (TDMs) with a separate assessment of 1) TA, TLA, 2) TAA, 3) 1,2,4-T	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Wheat grain (covering triticale according to EU Reg 2018/62)	EFSA, 2018 BASF DocIDs 2014/1010809 and 2015/1099704 and 2017/1141927		GAP: 2 x 0.15 kg as/ha, BBCH 49, 69, PHI 35d, outdoor	0.01*	0.026**	0.034	0.05	yes
		N-EU	E/RA a): 4 x <0.01, 0.011, 0.014, 0.016, 0.024					
		S-EU	E/RA a): 7 x <0.01, 0.018, 0.026					
		N-EU	RA b) 1) 0.10, 0.12, 0.20, 0.22, 0.26, 0.26, 0.54, 1.21 2) 0.016, 0.019, 0.022, 0.023, 0.063, 0.1, 0.16, 0.42 3) 8 x <0.01	1) 0.26** 2) 0.06** 3) 0.01**	1) 1.21** 2) 0.42** 3) 0.01**	-	-	-
		S-EU	RA b) 1) 0.02, 0.13, 0.23, 0.26, 0.32, 0.33, 0.36, 0.37, 0.85 2) <0.01, 0.015, 0.023, 0.046, 0.068, 0.081, 0.091, 0.11, 0.2 3) 9 x <0.01					
	Supplementary Information BASF DocID	N-EU	GAP: 2x 0.1 kg as/ha, BBCH 30-59, PHI 56d, outdoor E/RA a): 4x <0.010	0.010	0.010	0.010	Highest residue covered by current MRL 0.05 mg/kg.	Yes

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 a) BAS 750 F b) Triazole derivative metabolites (TDMs) with a separate assessment of 1) TA, TLA, 2) TAA, 3) 1,2,4-T	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
	2021/2000402						No further considerations needed.	
		N-EU	GAP: 2x 0.1 kg as/ha, BBCH 30-59, PHI 56d, outdoor RA b): 1) 0.10, 0.15, 0.16, 0.19, 4x <0.010 2) 0.038, 0.080, *0.094*, *0.14* 3) 4x <0.010	1) 0.055 2) 0.087 3) 0.010	1) 0.190 2) 0.140 3) 0.010	-	-	
Wheat straw (covering triticale according to EU Reg 2018/62)	EFSA, 2018 BASF DocIDs 2014/1010809 and 2015/1099704 and 2017/1141927	N-EU	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	E/RA a): 0.5, 0.56, 1.6, 2.9, 3.1, 3.8, 4.6, 9.0, 18.0					
		N-EU	RA b) 1) 0.117, 0.118, 0.152, 0.161, 0.355, 0.483, 0.511, 0.642 2) 3 x <0.01, 0.014, 0.029, 0.086, 0.088, 0.16 3) 8 x <0.01	1) 0.25** 2) 0.03** 3) 0.01**	1) 1.51** 2) 0.16** 3) 0.01**	-	-	-
		S-EU	RA b) 1) 0.157, 0.164, 0.198, 0.23, 0.245, 0.37, 0.55, 0.705, 1.51 2) 3 x <0.01, 0.013, 0.031, 0.032, 0.054, 0.06, 0.081 3) 9 x <0.01					
	Supplementary Information BASF DocID	N-EU	GAP: 2x 0.1 kg as/ha, BBCH 39-59, PHI 56 d, outdoor E/RA a): 0.98, 1.3, 1.6, 2.1	1.45	2.1	Highest residue covered by pseudo MRL 30 mg/kg. No further considerations needed.		Yes

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 a) BAS 750 F b) Triazole derivative metabolites (TDMs) with a separate assessment of 1) TA, TLA, 2) TAA, 3) 1,2,4-T	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
	2021/2000402	N-EU	GAP: 2x 0.1 kg as/ha, BBCH 39-59, PHI 56 d, outdoor RA b): 1) 3x <0.010, *0.010*, 0.010, *0.033*, 0.046, 0.064 2) 0.012, *0.048*, *0.060*, *0.110* 3) 4x <0.010	1) 0.010 2) 0.054 3) 0.010	1) 0.064 2) 0.110 3) 0.010	-	-	
Barley grain	EFSA, 2018 BASF DocIDs 2014/1010808 and 2015/1099703 and 2017/1101701		GAP: 2 x 0.15 kg as/ha, BBCH 49, 69, PHI 35d, outdoor	0.1**	0.41**	0.548	0.6	yes
		N-EU	E/RA a): 0.014, 0.06, 0.071, 0.087, 0.1, 0.15, 0.15, 0.19, 0.28					
		S-EU	E/RA a): 0.03, 0.033, 0.07, 0.1, 0.1, 0.14, 0.16, 0.29, 0.41					
		N-EU	RA b) 1) 0.159, 0.187, 0.397, 0.514, 0.844, 1.186, 1.32, 2.6, 3.8 2) 0.019, 0.021, 0.025, 0.096, 0.11, 0.3, 0.34, 0.37, 0.5 3) 9 x <0.01	1) 0.33** 2) 0.09** 3) 0.01**	1) 3.8** 2) 0.5** 3) 0.01**	-	-	-
		S-EU	RA b) 1) 0.078, 0.09, 0.12, 0.126, 0.233, 0.24, 0.27, 0.701, 0.92 2) 3 x <0.01, 0.02, 0.081, 0.091, 0.011, 0.18, 0.2 3) 9 x <0.01					
	Supplementary Information BASF DocID 2021/2000401	N-EU	Trials GAP: 2x 0.1 kg as/ha, BBCH 30-59, PHI 56d, outdoor E/RA a): 0.026, 0.029, 0.058, 0.10	0.044	0.1	0.191	Highest residue covered by MRL 0.6 mg/kg. No further considerations needed.	yes
		N-EU	Trials GAP: 2x 0.1 kg as/ha, BBCH 30-59, PHI 56d, outdoor RA b)	1) 0.060 2) 0.092	1) 0.200 2) 0.120	-	-	

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 a) BAS 750 F b) Triazole derivative metabolites (TDMs) with a separate assessment of 1) TA, TLA, 2) TAA, 3) 1,2,4-T	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
			1) 0.11, 0.15, 0.18, 0.20, 4x <0.010 2) 0.029, 0.088, 0.096, 0.12 3) 4x <0.010	3) 0.010	3) 0.010			
Barley straw	EFSA, 2018 BASF DocIDs 2014/1010808 and 2015/1099703 and 2017/1101701	N-EU	E/RA a): 1.0, 1.7, 3.1, 3.9, 4.3, 4.3, 5.6, 6.8, 15.0	4.25**	18.0**	-	30	-
		S-EU	E/RA a): 0.39, 2.1, 2.2, 3.3, 4.2, 4.6, 6.4, 11.0, 18.0					
		N-EU	RA b) 1) 0.27, 0.423, 0.458, 0.57, 0.598, 0.897, 0.94, 1.171, 10.67 2) <0.01, 0.025, 0.026, 0.027, 0.035, 0.11, 0.12, 0.2, 0.33 3) 9 x <0.01	1) 0.33** 2) 0.04** 3) 0.01**	1) 10.67** 2) 0.33** 3) 0.01**	-	-	-
		S-EU	RA b) 1) 0.427, 0.413, 0.465, 0.54, 0.544, 0.584, 0.688, 0.842, 4.51 2) 4 x <0.01, 0.035, 0.045, 0.05, 0.095, 0.11 3) 9 x <0.01					
	Supplementary Information BASF DocID 2021/2000401	N-EU	Trials GAP: 2x 0.1 kg as/ha, BBCH 30-59, PHI 56d, outdoor E/RA a): 1.1, 1.2, 1.4, 3.7	1.3	3.7	Highest residue covered by pseudo MRL 30 mg/kg. No further considerations needed.		yes
		N-EU	Trials GAP: 2x 0.1 kg as/ha, BBCH 30-59, PHI 56d, outdoor RA b) 1) *0.011*, 0.014, *0.022*, 0.024, 0.014, 0.047, 0.056, 0.082 2) 0.016, 0.032, 0.036, *0.040* 3) 4x <0.010	1) 0.023 2) 0.034 3) 0.010	1) 0.082 2) 0.040 3) 0.010	-	-	

* Source of EU MRL: Commission Regulation (EU) 2021/590 of 12 April 2021 and EFSA 2018a.

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

In context of supplementary trials, untreated values (*cursive/italic*) 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

During the EU registration process for BAS 750 F, residue trials on wheat and barley from the representative formulation (BAS 750 01 F) were submitted and found acceptable. These trials were conducted with a more critical GAP (2x 150 g a.i/ha, BBCH 49 and BBCH 69) and are used in the present dossier as a worst-case scenario for BAS 750 F. In addition, residue trials conducted with an additional formulation (BAS 758 00 F) at a GAP of 2x100g a.i/ha (BBCH 49-59) are also included in the present dossier as supplementary information. It should be noted that several residue studies have been performed with BAS 750 F in cereals with more critical GAPs (e.g last application done at BBCH 69 instead of BBCH 59, see tables below) and the BAS 750 F values were always under the MRLs established and no risk for the consumers was identified in any of the formulations used.

Therefore, no new trials with BAS 768 00 F were conducted, because enough residue data (up to 44 trials) is available for BAS 750 F in cereals with different formulations. According to the available data, the intended uses on wheat, triticale, rye and barley are considered acceptable, for outdoor uses.

Please refer to additional document DocID 2023/2008877 for more information and for the summaries of the different studies summarized. Study reports can be requested, if needed.

According to appendix D of EU guidelines, extrapolation to triticale is possible with the trials on wheat.
The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.

zRMS accepts the assessment proposal

Table 7.2- 10: Summary of additional data supporting the intended uses of BAS 768 00 F in wheat

Formulation Code (Formulation Type)	Status of registration	GAP	Trials	DocID	Matrix	BAS 750 F Residue levels
BAS 752 03 F (EC)	Approved	2x 100 g ai/ha, BBCH 49, 69 (14 days)	3 NEU 1 SEU	2018/1086904	Grain	3×<0.01, 0.013
					Straw	1.5, 2.0, 3.1, 3.8,
BAS 752 00 F (EC)	Approved	2x 150 g ai/ha, BBCH 49, 69 (14 days)	4 NEU 4 SEU	2015/1106679	Grain	7×<0.01, 0.04
					Straw	0.49, 0.6, 0.88, 1.9, 3.2, 3.9, 4.2, 5.0
BAS 765 00 F (SC)	Approved	2x 100 g ai/ha, BBCH 49 – 69 (14 days)	4 SEU 4 NEU	2020/2093149	Grain	4× <0.01, 0.012, 0.021, 0.032, 0.036
					Straw	0.95, 1.0, 1.3, 1.5, 2.3, 2.5, 3.6, 3.8
BAS 751 00 F (EC)	Approved	2x 150 g ai/ha, BBCH 49, 69 (14 days)	4 SEU 4 NEU	2015/1106672	Grain	5 × <0.01, 0.011, 0.016, 0.023
					Straw	1.2, 1.4, 1.9, 2.3, 4.3, 5.6, 6.9, 7.1
BAS 763 00 F (SC)	Submitted	2x 100 g ai/ha, BBCH 30 – 69 (14 days)	8 NEU 8 SEU	2019/2075092 (Amendment N°1 2021/2023846), 2020/2103079	Grain	11× <0.01, 0.01, 0.01, 0.015, 0.05, 0.16
					Straw	0.24, 0.43, 0.45, 0.5, 0.53, 0.74, 1.2, 1.3, 1.4, 2.0, 2.2, 2.3, 2× 2.6, 3.3, 4.3,

Table 7.2- 11: Summary of additional data supporting the intended uses of BAS 768 00 F in barley

Formulation Code	Status of registration	GAP	Trials	DocID	Matrix	BAS 750 F Residue levels
BAS 752 03 F (EC)	Approved	2x 100 g ai/ha, BBCH 49, 69 (14 days)	3 NEU 1 SEU	2018/1086905	Grain	0.021, 0.045, 0.056, 0.13
					Straw	2× 1.4, 4.4, 4.8
BAS 752 00 F (EC)	Approved	2x 150 g ai/ha, BBCH 49, 69 (14 days)	4 NEU 4 SEU	2015/1106680	Grain	0.022, 0.029, 0.074, 0.10, 0.11, 0.14, 0.15, 0.30
					Straw	0.27, 0.52, 1.8, 2.4, 3.1, 3.2, 3.8, 3.9
BAS 765 00 F (SC)	Approved	2x 100 g ai/ha, BBCH 49 – 69 (14 days)	4 SEU 4 NEU	2020/2100869	Grain	0.038, 0.055, 0.068, 0.10, 0.13, 0.15, 0.26, 0.32
					Straw	0.50, 0.8, 1.2, 1.7, 3.0, 3.5, 4.4, 4.8
BAS 751 00 F (EC)	Approved	2x 150 g ai/ha, BBCH 49, 69 (14 days)	4 SEU 4 NEU	2015/1106678	Grain	0.053, 0.059, 0.11, 0.11, 0.13, 0.14, 0.17, 0.26
					Straw	1.5, 1.6, 1.8, 2.2, 3.3, 4.2, 4.3, 8.6
BAS 763 00 F (SC)	Submitted	2x 100 g ai/ha, BBCH 30 – 69 (14 days)	8 NEU 8 SEU	2019/2075091, 2020/2103078	Grain	<0.01, 0.017, 0.018, 0.026, 0.028, 0.029, 0.032, 0.043, 0.046, 0.046, 0.053, 0.059, 0.088, 0.09, 0.093, 0.28
					Straw	0.38, 2× 0.41, 0.45, 0.52, 0.58, 0.67, 0.73, 0.80, 0.88, 1.3, 1.3, 1.6, 1.7, 1.9, 2.7

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

During the EU registration process for BAS 750 F, a representative formulation BAS 750 01 F (containing 100 g/L BAS 750 F) was already evaluated for cereals (refer to EFSA, 2018a). In addition, other uses were also registered for BAS 750 F (refer to EFSA 2020). In this dossier, the residue data presented as worst case (BAS 750 01 F) is the same data submitted and evaluated in EFSA, 2018a. Therefore, no changes in the feed burden calculations are needed and the data from EFSA, 2018a supports the BAS 768 00 F formulation presented in this dossier.

However, in the context of an ongoing MRL application (EFSA-Q-2021-00692) supporting the dossier for product BAS 750 11 F, 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 and from the ongoing MRL application (EFSA-Q-2021-00692) as well as on crops included in previous submissions were taken into account as a worst-case scenario.

Table 7.2- 12: 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.*				
Barley straw	4.25	STMR / EFSA, 2018a	18.0	HR / EFSA, 2018a
Beet, sugar, tops	0.24	STMR/ EFSA, 2020	1.10	HR/ EFSA, 2020
Cabbage, heads, leaves (= residues in head cabbage)	0.013	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	0.019	HR, proposed in context of the MRL application (EFSA-Q-2021-00692)
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
Oat straw	4.25	STMR / EFSA, 2018a (extrapolation from barley)	18.0	HR / EFSA, 2018a (extrapolation from barley)
Rye straw	3.6	STMR / EFSA, 2018a (extrapolation from wheat)	18.0	HR / EFSA, 2018a (extrapolation from wheat)
Triticale straw	3.6	STMR / EFSA, 2018a (extrapolation from wheat)	18.0	HR / EFSA, 2018a (extrapolation from wheat)
Turnip, tops (leaves)	4.80	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot tops	6.10	HR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot tops
Wheat straw	3.6	STMR / EFSA, 2018a	18.0	HR / EFSA, 2018a
Carrot, culls (=roots)	0.017	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	0.055	HR, proposed in context of the MRL application (EFSA-Q-2021-00692)
Potato, culls (= roots)	0.01	STMR / EFSA, 2020	0.01	HR / EFSA, 2020
Swede, roots	0.017	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot roots	0.055	HR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot roots
Turnip, roots	0.017	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot roots	0.055	HR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot roots

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment/ Source	Input value (mg/kg)	Comment/ Source
Barley grain	0.1	STMR / EFSA, 2018a	0.1	STMR / EFSA, 2018a
Bean, seed (dry)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)
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
Cowpea, seed	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)
Lupin, seed	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)
Oat grain	0.1	STMR / EFSA, 2018a (extrapolation from barley)	0.1	STMR / EFSA, 2018a (extrapolation from barley)
Pea (field pea), seed (dry)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)
Rye grain	0.01	STMR / EFSA, 2018a (extrapolation from wheat)	0.01	STMR / EFSA, 2018a (extrapolation from wheat)
Soybean, seed	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)
Triticale grain	0.01	STMR / EFSA, 2018a (extrapolation from wheat)	0.01	STMR / EFSA, 2018a (extrapolation from wheat)
Wheat grain	0.01	STMR / EFSA, 2018a	0.01	STMR / EFSA, 2018a
Apple, wet pomace	0.25	$STMR_P$ (STMR 0.08 x PF 3.10) / EFSA, 2020	-	-
Beet, sugar, dried pulp	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	-	-
Beet, sugar, molasses	0.02	$STMR_P$ (STMR 0.02 x PF 0.88) / EFSA, 2020	-	-
Barley brewer's grain (dried)	0.24	$STMR_P$ (STMR 0.1 x PF 2.4) / EFSA, 2018a	-	-

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment/ Source	Input value (mg/kg)	Comment/ Source
Canola (rape seed), meal	0.02	$STMR_P$ (STMR 0.01 x PF 2.0)[a] / EFSA, 2020	-	-
Citrus, dried pulp	0.02	$STMR_P$ (STMR 0.145 x PF 0.11), proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Corn, field, milled by-pdts	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	-	-
Corn, field, gluten meal	0.03	$STMR_P$ (STMR 0.01 x PF 2.70)[c] / EFSA, 2020	-	-
Wheat distiller's grain (dried)	0.03	$STMR_P$ (STMR 0.01 x PF 2.7) / EFSA, 2018a	-	-
Flaxseed/linseed, meal	0.02	$STMR_P$ (STMR 0.01 x PF 2.0)[a], proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Lupin seed, meal	0.01	$STMR_P$ (STMR 0.01 x PF 1.1)[a], proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
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	-	-
Rape, meal	0.02	$STMR_P$ (STMR 0.01 x PF 2.0)[a] / EFSA, 2020	-	-
Soybean, meal	0.008	$STMR_P$ (STMR 0.01 x PF 0.83) /, proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Soybean, hulls	0.008	$STMR_P$ (STMR 0.01 x PF 0.83) /, proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Sunflower, meal	0.02	$STMR_P$ (STMR 0.01 x PF 2.0)[a] / EFSA, 2020	-	-
Wheat gluten meal	0.003	$STMR_P$ (STMR 0.01 x PF 0.3) / EFSA, 2018a	-	-

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment/ Source	Input value (mg/kg)	Comment/ Source
Wheat milled byproducts	0.01	$STMR_P$ (STMR 0.01 x PF 0.6) / EFSA, 2018a	-	-

HR = highest residue
STMR = Supervised Trials Median Residue
(a): Tentative processing factor derived based on a limited dataset.
(b): In the absence of specific processing factors supported by data, default processing factors were included in the calculation to consider the potential concentration of residues in these commodities.

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

Table 7.2- 13: 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*	0.158	0.203	turnip, tops (leaves)	8.48	yes
Dairy cattle*	0.129	0.242	barley, straw	6.28	yes
Ram/Ewe	0.165	0.412	barley, straw	12.4	yes
Lamb	0.210	0.525	barley, straw	12.36	yes
Breeding swine	0.005	0.017	beet, sugar, tops	0.76	yes
Finishing swine*	0.004	0.009	swede, roots	0.29	yes
Broiler poultry	0.009	0.011	swede, roots	0.16	yes
Layer poultry*	0.035	0.150	wheat, straw	2.19	yes
Turkey	0.008	0.011	swede, roots	0.15	yes

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

Feed intake level was estimated using the Excel calculator Animal model 2017.xls developed by EFSA. When considering residue data as it results from the crop uses supported in the present dossier, exceedance of the feed intake value of 0.004 mg/kg bw burden for parent **BAS 750 F** is observed for cattle, sheep, swine and poultry.

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.

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 were 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- 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]	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	0.158 (Dairy cattle)	0.242 (Dairy cattle)	0.035	3	0.01*	0.01*	0.01*	0.01*	0.02	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	0.158 (Dairy cattle)	0.242 (Dairy cattle)	0.035	3	0.017	0.018	0.017	0.018	0.11	0.20	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	0.158 (Dairy cattle)	0.242 (Dairy cattle)	0.035	3	0.031	0.034	0.031	0.034	0.17	0.35	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	0.158 (Dairy cattle)	0.242 (Dairy cattle)	0.035	3	0.012	0.014	0.012	0.014	0.04	0.11	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				

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	1.295	1.880	1.295	1.880				
Bovine milk	0.129 (Dairy cattle)	0.242 (Dairy cattle)	0.035	3	0.01*[e]	N/A	0.01*[e]	N/A	0.02	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				
			3.740	3	0.216 [e]	N/A	0.216 [e]	N/A				
Sheep meat	0.210 (Lamb)	0.525 (Lamb)	0.035	3	0.01*	0.01*	0.01*	0.01*	0.02	0.05	0.05	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	0.210 (Lamb)	0.525 (Lamb)	0.035	3	0.017	0.018	0.017	0.018	0.13	0.39	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	0.210 (Lamb)	0.525 (Lamb)	0.035	3	0.031	0.034	0.031	0.034	0.21	0.66	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	0.210 (Lamb)	0.525 (Lamb)	0.035	3	0.012	0.014	0.012	0.014	0.05	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				

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	1.295	1.880	1.295	1.880				
Sheep milk	0.165 (Ram/Ewe)	0.412 (Ram/Ewe)	0.035	3	0.01*[e]	N/A	0.01*[e]	N/A	0.02	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)	0.017 (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*				
			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)	0.017 (Breeding)	0.035	3	0.017	0.018	0.017	0.018	0.01	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)	0.017 (Breeding)	0.035	3	0.031	0.034	0.031	0.034	0.01	0.02	0.02	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)	0.017 (Breeding)	0.035	3	0.012	0.014	0.012	0.014	0.01	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				

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	1.295	1.880	1.295	1.880				
Poultry meat	0.005 (Breeding)	0.017 (Breeding)	0.010	3	0.01*	0.01*	0.062	0.062	0.01	0.01	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)	0.150 (Layer)	0.010	3	0.01*	0.01*	0.163	0.163	0.01	0.02	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 (Layer)	0.150 (Layer)	0.010	3	0.01*	0.01*	0.049	0.049	0.01	0.03	0.03	4.9
			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)	0.150 (Layer)	0.010	3	0.01*	0.01*	0.049	0.049	0.01	0.01	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				

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)				
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 calculation was done taking into account all registered uses and the future uses coming from the ongoing MRL application (EFSA-Q-2021-00692). In the case of swine liver a change of MRL was driven by the newest MRL application (EFSA-Q-2021-00692). All this data was considered here for the sake of completeness.

However, if the uses of the ongoing MRL application are not considered and only values from EFSA 2018a and 2020 are considered. Then no change of MRL in liver is needed and all values are cover.

In summary, there is no risk for animal MRLs to be exceeded with the proposed uses in this dossier (wheat and barley).

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 Tables 7.2-15, 7.2-17, 7.2-19 and 7.2-21. The results of the total maximum dietary burden calculations are reported in the tables below (Tables 7.2-16, 7.2-18, 7.2-20 and 7.2-22). A supplemental document, in which a detailed derivation of input values is presented (BASF DocID: 2023/2005936). For sake of being comprehensive residue data on crops included in the present submission from the ongoing MRL submission (EFSA-Q-2021-00692) as well as on crops included in previous submissions were taken into account as a worst-case scenario.

Regarding TDMs, overall livestock dietary burden calculations were recently performed by EFSA (EFSA, 2020), which cover the cereals use for BAS 768 00 F.

Table 7.2- 15: 1,2,4 input values for the dietary burden calculation (considering all uses)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment/ Source	Input value (mg/kg)	Comment/ Source
Risk assessment residue definition: 1,2,4-T[1]				
Barley straw	0.01	STMR	0.059	HR
Beet, sugar, tops	0.01	STMR	0.02	HR
Cabbage, heads, leaves (= residues in head cabbage)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	0.01	HR, proposed in context of the MRL application (EFSA-Q-2021-00692)
Corn, field, stover (fodder)	0.01	STMR	0.01	HR
Corn, pop, stover (fodder)	0.01	STMR	0.01	HR
Oat straw	0.01	STMR (extrapolation from barley)	0.059	HR (extrapolation from barley)
Rye straw	0.01	STMR (extrapolation from wheat)	0.01	HR (extrapolation from wheat)
Triticale straw	0.01	STMR (extrapolation from wheat)	0.01	HR (extrapolation from wheat)
Turnip, tops (leaves)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot tops	0.01	HR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot tops
Wheat straw	0.01	STMR	0.01	HR
Carrot, culls (=roots)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	0.01	HR, proposed in context of the MRL application (EFSA-Q-2021-00692)
Potato, culls (= roots)	0.01	STMR	0.01	HR
Swede, roots	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot roots	0.01	HR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot roots
Turnip, roots	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot roots	0.01	HR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot roots
Barley grain	0.01	STMR	0.01	STMR
Bean, seed (dry)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)
Corn, field (maize), grain	0.01	STMR	0.01	STMR
Corn, pop, grain	0.01	STMR	0.01	STMR

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment/ Source	Input value (mg/kg)	Comment/ Source
Cowpea, seed	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)
Lupin, seed	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)
Oat grain	0.01	STMR (extrapolation from barley)	0.01	STMR (extrapolation from barley)
Pea (field pea), seed (dry)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)
Rye grain	0.01	STMR (extrapolation from wheat)	0.01	STMR (extrapolation from wheat)
Soybean, seed	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)
Triticale grain	0.01	STMR (extrapolation from wheat)	0.01	STMR (extrapolation from wheat)
Wheat grain	0.01	STMR	0.01	STMR
Apple, wet pomace	0.01	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Beet, sugar, dried pulp	0.010	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Beet, sugar, ensiled pulp	0.010	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Beet, sugar, molasses	0.010	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Barley brewer's grain (dried)	0.010	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Canola (rape seed), meal	0.010	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Citrus, dried pulp	0.01	$STMR_P$ (STMR 0.01 x PF_d 1.0), proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Corn, field, milled by-pdts	0.010	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Corn, field, hominy meal	0.010	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Corn, field, gluten feed	0.010	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment/ Source	Input value (mg/kg)	Comment/ Source
Corn, field, gluten meal	0.010	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Wheat distiller's grain (dried)	0.010	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Flaxseed/linseed, meal	0.01	$STMR_P$ (STMR 0.01 x PF_d 1.0), proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Lupin seed, meal	0.01	$STMR_P$ (STMR 0.01 x PF 1.1)[(a)], proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Potato, process waste	0.010	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Potato, dried pulp	0.010	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Rape, meal	0.010	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Soybean, meal	0.01	$STMR_P$ (STMR 0.01 x PF_d 1.0), proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Soybean, hulls	0.01	$STMR_P$ (STMR 0.01 x PF_d 1.0), proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Sunflower, meal	0.010	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Wheat gluten meal	0.010	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Wheat milled byproducts	0.010	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-

HR = highest residue, STMR = Supervised Trials Median Residue

1 For source of input values, please refer to the supplemental document (BASF DocID 2023/2005936)

PF_d default processing factor. In the absence of specific processing factors supported by data, default processing factors were included in the calculation to consider the potential concentration of residues in these commodities. If residues in RAC < LOQ it is possible to entering the value of 1.0)

Table 7.2- 16: 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*	0.002	0.002	swede, roots	0.09	no
Dairy cattle*	0.002	0.003	swede, roots	0.07	no
Ram/Ewe	0.002	0.003	swede, roots	0.1	no
Lamb	0.003	0.003	swede, roots	0.08	no
Breeding swine	0.002	0.002	swede, roots	0.07	no
Finishing swine*	0.001	0.001	swede, roots	0.05	no
Broiler poultry	0.001	0.001	swede, roots	0.02	no
Layer poultry*	0.002	0.002	swede, roots	0.02	no
Turkey	0.001	0.001	swede, roots	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- 17: TA input values for the dietary burden calculation

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment/ Source	Input value (mg/kg)	Comment/ Source
Risk assessment residue definition: TA[1]				
Barley straw	0.087	STMR	0.71	HR
Beet, sugar, tops	0.032	STMR	0.07	HR
Cabbage, heads, leaves (= residues in head cabbage)	0.125	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	0.28	HR, proposed in context of the MRL application (EFSA-Q-2021-00692)
Corn, field, stover (fodder)	0.01	STMR	0.04	HR
Corn, pop, stover (fodder)	0.01	STMR	0.04	HR
Oat straw	0.087	STMR (extrapolation from barley)	0.71	HR (extrapolation from barley)
Rye straw	0.095	STMR (extrapolation from wheat)	0.83	HR (extrapolation from wheat)
Triticale straw	0.095	STMR (extrapolation from wheat)	0.83	HR (extrapolation from wheat)
Turnip, tops (leaves)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot tops	0.068	HR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot tops
Wheat straw	0.095	STMR	0.83	HR
Carrot, culls (=roots)	0.026	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	0.14	HR, proposed in context of the MRL application (EFSA-Q-2021-00692)
Potato, culls (= roots)	0.030	STMR	0.17	HR
Swede, roots	0.026	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot roots	0.14	HR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot roots
Turnip, roots	0.026	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot roots	0.14	HR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot roots
Barley grain	0.25	STMR	0.25	STMR
Bean, seed (dry)	0.30	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)	0.30	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)
Corn, field (maize), grain	0.08	STMR	0.08	STMR
Corn, pop, grain	0.08	STMR	0.08	STMR

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment/ Source	Input value (mg/kg)	Comment/ Source
Cowpea, seed	0.30	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)	0.30	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)
Lupin, seed	0.30	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)	0.30	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)
Oat grain	0.25	STMR (extrapolation from barley)	0.25	STMR (extrapolation from barley)
Pea (field pea), seed (dry)	0.30	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	0.30	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)
Rye grain	0.29	STMR (extrapolation from wheat)	0.29	STMR (extrapolation from wheat)
Soybean, seed	0.05	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	0.05	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)
Triticale grain	0.29	STMR (extrapolation from wheat)	0.29	STMR (extrapolation from wheat)
Wheat grain	0.29	STMR	0.29	STMR
Apple, wet pomace	0.35	$STMR_P$ (STMR 0.07 x PF_d 5.0)	-	-
Beet, sugar, dried pulp	0.27	$STMR_P$ (STMR 0.015 x PF_d 18)	-	-
Beet, sugar, ensiled pulp	0.05	$STMR_P$ (STMR 0.015 x PF_d 3.0)	-	-
Beet, sugar, molasses	0.17	$STMR_P$ (STMR 0.015 x PF 11.03)	-	-
Barley brewer's grain (dried)	0.01	$STMR_P$ (STMR 0.25 x PF 0.04)	-	-
Canola (rape seed), meal	0.42	$STMR_P$ (STMR 0.21 x PF_d 2.0)	-	-
Citrus, dried pulp	0.03	$STMR_P$ (STMR 0.01 x PF 2.61), proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Corn, field, milled by-pdts	0.08	$STMR_P$ (STMR 0.08 x PF_d 1.0)	-	-
Corn, field, hominy meal	0.48	$STMR_P$ (STMR 0.08 x PF_d 6.0)	-	-
Corn, field, gluten feed	0.20	$STMR_P$ (STMR 0.08 x PF_d 2.5)	-	-

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment/ Source	Input value (mg/kg)	Comment/ Source
Corn, field, gluten meal	0.08	$STMR_P$ (STMR 0.08 x PF_d 1.0)	-	-
Wheat distiller's grain (dried)	0.96	$STMR_P$ (STMR 0.29 x PF_d 3.3)	-	-
Flaxseed/linseed, meal	0.42	$STMR_P$ (STMR 0.21 x PF_d 2.0), proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Lupin seed, meal	0.33	$STMR_P$ (STMR 0.30 x PF_d 1.1), proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Potato, process waste	0.68	$STMR_P$ (STMR 0.034 x PF_d 20)	-	-
Potato, dried pulp	1.29	$STMR_P$ (STMR 0.034 x PF_d 38)	-	-
Rape, meal	0.42	$STMR_P$ (STMR 0.21 x PF_d 2.0)	-	-
Soybean, meal	0.07	$STMR_P$ (STMR 0.05 x PF_d 1.3), proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Soybean, hulls	0.65	$STMR_P$ (STMR 0.05 x PF_d 13), proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Sunflower, meal	0.12	$STMR_P$ (STMR 0.06 x PF_d 2.0)	-	-
Wheat gluten meal	0.06	$STMR_P$ (STMR 0.29 x PF 0.19)	-	-
Wheat milled byproducts	0.17	$STMR_P$ (STMR 0.29 x PF 0.58)	-	-

HR = highest residue, STMR = Supervised Trials Median Residue

1 For source of input values, please refer to the supplemental document (BASF DocID 2023/2005936)

PF_d default processing factor. In the absence of specific processing factors supported by data, default processing factors were included in the calculation to consider the potential concentration of residues in these commodities. If residues in RAC < LOQ it is possible to entering the value of 1.0)

Table 7.2- 18: 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*	0.055	0.070	potato, process waste	2.93	yes
Dairy cattle*	0.070	0.087	potato, process waste	2.25	yes
Ram/Ewe	0.075	0.090	potato, process waste	2.70	yes
Lamb	0.056	0.077	potato, process waste	1.82	yes
Breeding swine	0.030	0.043	potato, process waste	1.85	yes
Finishing swine*	0.015	0.029	swede, roots	0.95	yes
Broiler poultry	0.036	0.044	swede, roots	0.63	yes
Layer poultry*	0.034	0.044	swede, roots	0.64	yes
Turkey	0.024	0.034	potato, culls	0.48	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- 19: TAA input values for the dietary burden calculation

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment/ Source	Input value (mg/kg)	Comment/ Source
Risk assessment residue definition: TAA[1]				
Barley straw	0.045	STMR	0.33	HR
Beet, sugar, tops	0.01	STMR	0.013	HR
Cabbage, heads, leaves (= residues in head cabbage)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	0.01	HR, proposed in context of the MRL application (EFSA-Q-2021-00692)
Corn, field, stover (fodder)	0.01	STMR	0.02	HR
Corn, pop, stover (fodder)	0.01	STMR	0.02	HR
Oat straw	0.045	STMR (extrapolation from barley)	0.33	HR (extrapolation from barley)
Rye straw	0.03	STMR (extrapolation from wheat)	0.17	HR (extrapolation from wheat)
Triticale straw	0.03	STMR (extrapolation from wheat)	0.17	HR (extrapolation from wheat)
Turnip, tops (leaves)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot tops	0.013	HR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot tops
Wheat straw	0.03	STMR	0.17	HR
Carrot, culls (=roots)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	0.01	HR, proposed in context of the MRL application (EFSA-Q-2021-00692)
Potato, culls (= roots)	0.01	STMR	0.01	HR
Swede, roots	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot roots	0.01	HR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot roots
Turnip, roots	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot roots	0.01	HR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot roots
Barley grain	0.101	STMR	0.101	STMR
Bean, seed (dry)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)
Corn, field (maize), grain	0.01	STMR	0.01	STMR
Corn, pop, grain	0.01	STMR	0.01	STMR

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment/ Source	Input value (mg/kg)	Comment/ Source
Cowpea, seed	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)
Lupin, seed	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)
Oat grain	0.101	STMR (extrapolation from barley)	0.101	STMR (extrapolation from barley)
Pea (field pea), seed (dry)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)
Rye grain	0.068	STMR (extrapolation from wheat)	0.068	STMR (extrapolation from wheat)
Soybean, seed	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)
Triticale grain	0.068	STMR (extrapolation from wheat)	0.068	STMR (extrapolation from wheat)
Wheat grain	0.068	STMR	0.068	STMR
Apple, wet pomace	0.05	$STMR_P$ (STMR 0.01 x PF_d 5.0)	-	-
Beet, sugar, dried pulp	0.01	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Beet, sugar, ensiled pulp	0.01	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Beet, sugar, molasses	0.01	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Barley brewer's grain (dried)	0.01	$STMR_P$ (STMR 0.101 x PF 0.08)	-	-
Canola (rape seed), meal	0.01	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Citrus, dried pulp	0.01	$STMR_P$ (STMR 0.01 x PF_d 1.0), proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Corn, field, milled by-pdts	0.01	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Corn, field, hominy meal	0.01	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Corn, field, gluten feed	0.01	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment/ Source	Input value (mg/kg)	Comment/ Source
Corn, field, gluten meal	0.01	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Wheat distiller's grain (dried)	0.22	$STMR_P$ (STMR 0.068 x PF_d 3.3)	-	-
Flaxseed/linseed, meal	0.01	$STMR_P$ (STMR 0.01 x PF_d 1.0), proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Lupin seed, meal	0.01	$STMR_P$ (STMR 0.01 x PF_d 1.1), proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Potato, process waste	0.01	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Potato, dried pulp	0.01	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Rape, meal	0.01	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Soybean, meal	0.01	$STMR_P$ (STMR 0.01 x PF_d 1.3), proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Soybean, hulls	0.13	$STMR_P$ (STMR 0.01 x PF_d 13), proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Sunflower, meal	0.16	$STMR_P$ (STMR 0.06 x PF_d 2.0)	-	-
Wheat gluten meal	0.06	$STMR_P$ (STMR 0.068 x PF 0.95)	-	-
Wheat milled byproducts	0.04	$STMR_P$ (STMR 0.068 x PF 0.65)	-	-

HR = highest residue, STMR = Supervised Trials Median Residue

1 For source of input values, please refer to the supplemental document (BASF DocID 2023/2005936)

PF_d default processing factor. In the absence of specific processing factors supported by data, default processing factors were included in the calculation to consider the potential concentration of residues in these commodities. If residues in RAC < LOQ it is possible to entering the value of 1.0)

Table 7.2- 20: 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	0.005	barley straw	0.19	yes
Dairy cattle*	0.004	0.008	barley straw	0.20	yes
Ram/Ewe	0.004	0.009	barley straw	0.30	yes
Lamb	0.005	0.012	barley straw	0.28	yes
Breeding swine	0.003	0.003	distiller's grain	0.14	no
Finishing swine*	0.004	0.004	distiller's grain	0.14	yes
Broiler poultry	0.008	0.008	distiller's grain	0.11	yes
Layer poultry*	0.009	0.010	barley straw	0.14	yes
Turkey	0.007	0.007	distiller's grain	0.09	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- 21: TLA input values for the dietary burden calculation

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment/ Source	Input value (mg/kg)	Comment/ Source
Risk assessment residue definition: TLA[1]				
Barley straw	0.585	STMR	11.0	HR
Beet, sugar, tops	0.05	STMR	0.13	HR
Cabbage, heads, leaves (= residues in head cabbage)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	0.01	HR, proposed in context of the MRL application (EFSA-Q-2021-00692)
Corn, field, stover (fodder)	0.01	STMR	0.032	HR
Corn, pop, stover (fodder)	0.01	STMR	0.032	HR
Oat straw	0.585	STMR (extrapolation from barley)	11.0	HR (extrapolation from barley)
Rye straw	0.13	STMR (extrapolation from wheat)	1.5	HR (extrapolation from wheat)
Triticale straw	0.13	STMR (extrapolation from wheat)	1.5	HR (extrapolation from wheat)
Turnip, tops (leaves)	0.071	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot tops	0.28	HR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot tops
Wheat straw	0.13	STMR	1.5	HR
Carrot, culls (=roots)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	0.053	HR, proposed in context of the MRL application (EFSA-Q-2021-00692)
Potato, culls (= roots)	0.01	STMR	0.014	HR
Swede, roots	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot roots	0.053	HR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot roots
Turnip, roots	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot roots	0.053	HR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from carrot roots
Barley grain	0.09	STMR	0.09	STMR
Bean, seed (dry)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)
Corn, field (maize), grain	0.01	STMR	0.01	STMR
Corn, pop, grain	0.01	STMR	0.01	STMR

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment/ Source	Input value (mg/kg)	Comment/ Source
Cowpea, seed	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)
Lupin, seed	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692), extrapolation from pea, seed (dry)
Oat grain	0.09	STMR (extrapolation from barley)	0.09	STMR (extrapolation from barley)
Pea (field pea), seed (dry)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)
Rye grain	0.01	STMR (extrapolation from wheat)	0.01	STMR (extrapolation from wheat)
Soybean, seed	0.013	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	0.013	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)
Triticale grain	0.01	STMR (extrapolation from wheat)	0.01	STMR (extrapolation from wheat)
Wheat grain	0.01	STMR	0.01	STMR
Apple, wet pomace	0.05	$STMR_P$ (STMR 0.01 x PF_d 5.0)	-	-
Beet, sugar, dried pulp	0.01	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Beet, sugar, ensiled pulp	0.01	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Beet, sugar, molasses	0.01	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Barley brewer's grain (dried)	0.01	$STMR_P$ (STMR 0.09 x PF 0.07)	-	-
Canola (rape seed), meal	0.02	$STMR_P$ (STMR 0.01 x PF_d 2.0)	-	-
Citrus, dried pulp	0.03	$STMR_P$ (STMR 0.01 x PF 2.78), proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Corn, field, milled by-pdts	0.01	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Corn, field, hominy meal	0.06	$STMR_P$ (STMR 0.01 x PF_d 6.0)	-	-
Corn, field, gluten feed	0.03	$STMR_P$ (STMR 0.01 x PF_d 2.5)	-	-

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment/ Source	Input value (mg/kg)	Comment/ Source
Corn, field, gluten meal	0.01	$STMR_P$ (STMR 0.01 x PF_d 1.0)	-	-
Wheat distiller's grain (dried)	0.03	$STMR_P$ (STMR 0.01 x PF_d 3.3)	-	-
Flaxseed/linseed, meal	0.02	$STMR_P$ (STMR 0.01 x PF_d 2.0), proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Lupin seed, meal	0.01	$STMR_P$ (STMR 0.01 x PF_d 1.1), proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Potato, process waste	0.20	$STMR_P$ (STMR 0.01 x PF_d 20.0)	-	-
Potato, dried pulp	0.38	$STMR_P$ (STMR 0.01 x PF_d 38.0)	-	-
Rape, meal	0.02	$STMR_P$ (STMR 0.01 x PF_d 2.0)	-	-
Soybean, meal	0.02	$STMR_P$ (STMR 0.013 x PF_d 1.3), proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Soybean, hulls	0.17	$STMR_P$ (STMR 0.013 x PF_d 13.0), proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Sunflower, meal	0.02	$STMR_P$ (STMR 0.01 x PF_d 2.0)	-	-
Wheat gluten meal	0.02	$STMR_P$ (STMR 0.01 x PF_d 1.8)	-	-
Wheat milled byproducts	0.07	$STMR_P$ (STMR 0.01 x PF_d 7.0)	-	-

HR = highest residue, STMR = Supervised Trials Median Residue

1 For source of input values, please refer to the supplemental document (BASF DocID 2023/2005936)

PF_d default processing factor. In the absence of specific processing factors supported by data, default processing factors were included in the calculation to consider the potential concentration of residues in these commodities. If residues in RAC < LOQ it is possible to entering the value of 1.0)

Table 7.2- 22: 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*	0.022	0.109	barley straw	4.53	yes
Dairy cattle*	0.028	0.167	barley straw	4.33	yes
Ram/Ewe	0.035	0.269	barley straw	8.10	yes
Lamb	0.032	0.334	barley straw	7.86	yes
Breeding swine	0.010	0.015	potato, process waste	0.63	yes
Finishing swine*	0.005	0.010	swede, roots	0.34	yes
Broiler poultry	0.012	0.015	swede, roots	0.21	yes
Layer poultry*	0.012	0.055	barley, straw	0.81	yes
Turkey	0.006	0.009	swede, roots	0. 12	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, 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 are 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 accepts the assessment proposal

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 were submitted by the applicant. These studies are summarized in the table below. For a detailed assessment refer to the EFSA conclusion (2018).

Table 7.2- 23: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	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, 2018 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.	-	
Wheat/shorts		3.53 (BAS 750 F)	n.a.	-	
		3.54 (TA)	n.a.	-	
		2.00 (TAA)	n.a.	-	
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.	-	

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
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 by-products		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.	-	
Barley/pearled, pot barley	1 (3 trials)	0.12 (BAS 750 F)	n.a.	-	EFSA, 2018 BASF DocID 2014/1315282
		0.84 (TA)	n.a.	-	
		0.71 (TAA)	n.a.	-	
		0.52 (TLA)	n.a.	-	
Barley/flour		3.67 (BAS 750 F)	n.a.	-	
		1.20 (TA)	n.a.	-	
		2.11 (TAA)	n.a.	-	
		3.86 (TLA)	n.a.	-	
Barley/bran		5.00 (BAS 750 F)	n.a.	-	
		2.08 (TA)	n.a.	-	
		1.33 (TAA)	n.a.	-	
		0.64 (TLA)	n.a.	-	
Barley/brewing malt		0.5 (BAS 750 F)	n.a.	-	
		0.51 (TA)	n.a.	-	
		0.89 (TAA)	n.a.	-	
		0.23 (TLA)	n.a.	-	
Barley/malt sprouts		1.09 (BAS 750 F)	n.a.	-	
		1.72 (TA)	n.a.	-	
		2.71 (TAA)	n.a.	-	
		<0.07 (TLA)	n.a.	-	

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
Barley/beer		<0.04 (BAS 750 F)	n.a.	-	
		<0.04 (TA)	n.a.	-	
		0.15 (TAA)	n.a.	-	
		1.71 (TLA)	n.a.	-	
Barley/brewers grain (dried)		2.38 (BAS 750 F)	n.a.	-	
		<0.04 (TA)	n.a.	-	
		0.08 (TAA)	n.a.	-	
		<0.07 (TLA)	n.a.	-	
Barley/brewers yeast		0.19 (BAS 750 F)	n.a.	-	
		0.60 (TA)	n.a.	-	
		0.22 (TAA)	n.a.	-	
		0.30 (TLA)	n.a.	-	
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

two values = the mean processing factor was calculated, three or more values = the median processing factor was calculated

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 768 00 F.

zRMS accepts the assessment proposal

7.2.6 Magnitude of residues in representative succeeding crops

Cereals, as crops under consideration, can be grown in rotation. Data dealing with magnitude of residues in succeeding crops have been previously submitted and 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 with an application rate of 0.300 kg as/ha. This study is summarized in the table below. For a detailed assessment refer to the EFSA conclusion (2018a).

Table 7.2- 24: Summary of available studies in field rotational crops

Primary crop	Rate (kg a.s./ha) (GS at application or PHI)	Residue levels in succeeding crops			
		Succeeding crop group	Succeeding crop	Sowing intervals (DAT)*	Reference / Remarks
EU data					
None, bare soil application	1 x 0.300 (n.a.)	Leafy vegetables	Lettuce	30 ± 1 120 ± 3 365 ± 5	EFSA, 2018a BASF DocID 2015/1106682
			Spinach		
		Root and tuber vegetables	Radish		
			Carrot		
		Brassica vegetables	Cauliflower		
			Broccoli		
		Cereals	Wheat		
New data					
No new data					

n.a. not applicable, since residue definitions for risk assessment and for monitoring do not differ
* 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 <0.01 mg/kg (LOQ) in leafy vegetables (lettuce/spinach), root/tuber (carrot/radish), brassica vegetables (cauliower/ broccoli) and cereals (wheat). Study conditions with bare soil application of maximal annual application rate are representative of plateau concentration estimated for multi-year application.

The magnitude of both BAS 750 F and TDM was investigated under field conditions. Based on the results obtained in the magnitude of the residue study, no residues of BAS 750 F are expected in rotational crops for the use of BAS 750 F. The residue data obtained for the TDMs are comparable to the data on rotational crops considered in the TDM review. As for primary crop trials, slight variations in the levels of TDMs in rotational crops are not considered to have any significant impact on the risk assessment, and hence no further consideration is required.

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 accepts the assessment proposal

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 768 00 F. Barley and Wheat are crops with no melliferous capacity according to SANTE/11956/2016 rev.9.
Therefore, other special studies are not needed.

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

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

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 Reg. (EU) 2021/590 and the proposed MRLs of the MRL application (EFSA-Q-2021-00692) were used as input values.
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).

Table 7.2- 25: 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*				
Products of plant origin				
Citrus fruits	0.0102	STMR, extrapolation from orange, mandarin and lemon × peeling factor (PeF) (0.145 × 0.07) proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Hazelnuts/cobnuts	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Pistachios	0.08	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
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 7.2- 25: 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**
Table grapes	0.18	STMR, extrapolation from wine grapes (EFSA, 2020)	-	-
Wine grapes	0.18	STMR (EFSA, 2020)	-	-
Strawberries	0.19	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Other small fruits and berries	0.605	STMR, extrapolation from currants proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Table olives	0.525	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Kaki/Japanese Persimmons	0.08	STMR, extrapolation from apple and pear (EFSA, 2020), proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Potatoes	0.01	STMR (EFSA, 2020)	-	
Other root and tuber vegetables except sugar beets	0.017	STMR, extrapolation from carrots, proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Tomatoes	0.115	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Sweet peppers/bell peppers	0.21	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Aubergines/eggplants	0.115	STMR, extrapolation from tomato, proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Cucurbits with edible peel	0.049	STMR, extrapolation from cucumber and zucchini, proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Cucurbits with inedible peel	0.0126	STMR, extrapolation from melon × PeF (0.07 × 0.18)proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Sweet corn	0.01	STMR, extrapolation from corn (EFSA, 2020)	-	-

Table 7.2- 25: 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**
Flowering brassica	0.027	STMR, extrapolation from combined dataset broccoli and cauliflower, proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Brussels sprouts	0.068	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Head cabbages	0.013	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Roman rocket/rucola	2.45	STMR, extrapolation from spinach, proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Baby leaf crops (including brassica species)	2.45	STMR, extrapolation from spinach, proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Spinaches	2.45	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Herbs and edible flowers	2.45	STMR, extrapolation from spinach, proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Beans (without pods)	0.01	STMR, extrapolation from peas (without pods), proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Peas (without pods)	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Cardoons	0.60	STMR, extrapolation from celery, proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Celeries	0.60	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-

Table 7.2- 25: 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**
Florence fennels	0.60	STMR, extrapolation from celery, proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Globe artichokes	0.25	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Rhubarbs	0.60	STMR, extrapolation from celery, proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Pulses (dry)	0.01	STMR, extrapolation from peas, dry, proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Linseed	0.01	STMR, extrapolation from rape-seed (EFSA, 2020), proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Poppy seeds	0.01	STMR, extrapolation from rape-seed (EFSA, 2020), proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Sunflower seeds	0.01	STMR (EFSA, 2020)	-	
Rapeseeds / canola seeds	0.01	STMR (EFSA, 2020)	-	
Soyabeans	0.01	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Mustard seeds	0.01	STMR, extrapolation from rape-seed (EFSA, 2020), proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Gold of pleasure seeds	0.01	STMR, extrapolation from rape-seed (EFSA, 2020), proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Olives for oil production	0.355	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Barley	0.10	STMR (EFSA, 2018a)	0.10	STMR (EFSA, 2018a)
Maize/corn	0.01	STMR (EFSA, 2020)	-	
Oats	0.10	STMR, extrapolation from bar-ley (EFSA, 2018a)	0.10	STMR (EFSA, 2018a)*

Table 7.2- 25: 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**
Rye	0.01	STMR, extrapolation from wheat (EFSA, 2018a)	0.01	STMR (EFSA, 2018a)*
Wheat	0.01	STMR (EFSA, 2018a)	0.01 (0.01)	STMR (EFSA, 2018a)*
Hops	4.5	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
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)	-	
Swine: Others	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)	-	
Bovine: Others	0.09	STMR (EFSA, 2018a)	-	
Sheep: Meat	0.032	STMR (EFSA, 2018a)	-	
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)	-	
Sheep: Others	0.14	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)	-	
Goat: Others	0.14	STMR (EFSA, 2018a)	-	
Horse: Meat	0.024	STMR (EFSA, 2018a)	-	

Table 7.2- 25: 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**
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)	-	
Horse: Others	0.09	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)	-	
Poultry: Others	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)	-	
Milk and milk products: Others	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)	-	
Honey and other apiculture products	0.05	STMR, proposed in context of the MRL application (EFSA-Q-2021-00692)	-	-
Processed products of plant origin				
Barley / beer	-		0.004	$STMR_p$ (STMR* 0.1 x PF 0.04)
Barley / milling (flour)	-		0.367	$STMR_p$ (STMR* 0.1 x PF 3.67)
Barley / cooked	-		0.1	STMR*

Table 7.2- 25: 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**
Oat / milling (flakes)	-		0.1	STMR* (extrapolation from barley)
Oat / boiled	-		0.1	STMR* (extrapolation from barley)
Rye / milling (wholemeal)-baking			0.0079	$STMR_p$ (STMR* 0.01 x x PF 0.79) (extrapolation from wheat)
Rye / boiled			0.01	STMR* (extrapolation from wheat)
Wheat / bread (wholemeal)	-		0.0056	$STMR_p$ (STMR* 0.01 x x PF 0.56)
Wheat / bread/pizza	-		0.01	STMR*
Wheat / pasta	-		0.01	STMR*
Wheat / milling (wholemeal)-baking	-		0.0079	$STMR_p$ (STMR* 0.01 x x PF 0.79)
Wheat / milling (flour)	-		0.0029	$STMR_p$ (STMR* 0.01 x 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 pulses, oilseeds, oil fruits 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 Table 7.2-1.

The acute consumer risk assessment was performed considering the intended uses for this submission, and all uses included in the MRL application (EFSA-Q-2021-00692). 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 DocID 2023/2005936.

An overview of the input values is presented in the tables below. Note: for processing factors please refer to Table 7.2-23).

Table 7.2- 26: 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				
Products of plant origin				
Wheat	0.05	STMR / TDM review (STMR in this submission)	0.05	STMR* / TDM review
Rye	0.05	STMR / TDM review	0.05	STMR* / TDM review, extrapolation from wheat
Barley	0.05	STMR / TDM review	0.05	STMR* / TDM review
Oat	0.05	STMR / TDM review, extrapolation from barley	0.05	STMR* / TDM review, extrapolation from barley
Wheat / bread (wholemeal)	-		0.05	STMR* / TDM review
Wheat / bread/pizza	-		0.05	STMR* / TDM review
Wheat / pasta	-		0.05	STMR* / TDM review
Wheat / milling (wholemeal)-baking	-		0.05	STMR* / TDM review
Wheat / milling (flour)	-		0.05	STMR* / TDM review
Barley / beer	-		0.01	STMRp (STMR*/ TDM review 0.05 x default PF 0.2)
Barley / milling (flour)	-		0.05	STMR* / TDM review
Barley / cooked	-		0.05	STMR* / TDM review
Oat / milling (flakes)	-		0.05	STMR* / TDM review, extrapolation from barley
Oat / boiled	-		0.05	STMR* / TDM review, extrapolation from barley
Rye / milling (wholemeal)-baking			0.05	STMR* / TDM review, extrapolation from wheat
Rye / boiled			0.05	STMR* / TDM review, extrapolation from wheat
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 2023/2005936			
Risk assessment residue definition plant and animal: TA				
Products of plant origin				
Wheat	0.621	STMR / TDM review	0.621	STMR* / TDM review
Rye	0.621	STMR / TDM review, extrapolation from wheat	0.621	STMR* / TDM review, extrapolation from wheat
Barley	0.621	STMR / TDM review	0.621	STMR* / TDM review
Oat	0.621	STMR / TDM review, extrapolation from barley	0.621	STMR* / TDM review, extrapolation from barley

Table 7.2- 26: 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)	-		0.534	$STMR_p$ (STMR* 0.621 x PF 0.86)
Wheat / bread/pizza	-		0.621	STMR* / TDM review
Wheat / pasta	-		0.621	STMR* / TDM review
Wheat / milling (wholemeal)-baking	-		0.621	STMR* / TDM review
Wheat / milling (flour)	-		0.317	$STMR_p$ (STMR* 0.621 x PF 0.51)
Barley / beer	-		0.025	STMRp (STMR*/ TDM review 0.621 x PF 0.04)
Barley / milling (flour)	-		0.745	STMRp (STMR*/ TDM review 0.621 x PF 1.2)
Barley / cooked	-		0.621	STMR* / TDM review
Oat / milling (flakes)	-		0.621	STMR* / TDM review, extrapolation from barley
Oat / boiled	-		0.621	STMR* / TDM review, extrapolation from barley
Rye / milling (wholemeal)-baking			0.621	STMR* / TDM review, extrapolation from wheat
Rye / boiled			0.621	STMR* / TDM review, extrapolation from wheat
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 2023/2005936			
Risk assessment residue definition plant and animal TAA				
Products of plant origin				
Wheat	0.79	STMR / TDM review	0.79	STMR* / TDM review
Rye	0.79	STMR / TDM review, extrapolation from wheat	0.79	STMR* / TDM review, extrapolation from wheat
Barley	0.79	STMR / TDM review	0.79	STMR* / TDM review
Oat	0.79	STMR / TDM review, extrapolation from barley	0.79	STMR* / TDM review, extrapolation from barley
Wheat / bread (wholemeal)	-		0.94	$STMR_p$ (STMR* 0.79 x PF 1.19)
Wheat / bread/pizza	-		0.79	STMR* / TDM review
Wheat / pasta	-		0.79	STMR* / TDM review
Wheat / milling (wholemeal)-baking	-		0.79	STMR* / TDM review
Wheat / milling (flour)	-		0.64	$STMR_p$ (STMR* 0.79 x PF 0.81)

Table 7.2- 26: 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**
Barley / beer	-		0.119	STMRp (STMR*/ TDM review 0.79 x PF 0.15)
Barley / milling (flour)	-		1.67	STMRp (STMR*/ TDM review 0.79 x PF 2.11)
Barley / cooked	-		0.79	STMR* / TDM review
Oat / milling (flakes)	-		0.79	STMR* / TDM review, extrapolation from barley
Oat / boiled	-		0.79	STMR* / TDM review, extrapolation from barley
Rye / milling (wholemeal)-baking			0.79	STMR* / TDM review, extrapolation from wheat
Rye / boiled			0.79	STMR* / TDM review, extrapolation from wheat
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 2023/2005936			
Risk assessment residue definition plant and animal TLA				
Products of plant origin				
Wheat	0.022	STMR / TDM review	0.022	STMR* / TDM review
Rye	0.022	STMR / TDM review, extrapolation from wheat	0.022	STMR* / TDM review, extrapolation from wheat
Barley	0.076	STMR / TDM review	0.076	STMR*/ TDM review
Oat	0.076	STMR / TDM review, extrapolation from barley	0.076 (0.01)	STMR*/ TDM review, extrapolation from barley
Wheat / bread (wholemeal)	-		0.022	STMR* / TDM review
Wheat / bread/pizza	-		0.022	STMR* / TDM review
Wheat / pasta	-		0.022	STMR* / TDM review
Wheat / milling (wholemeal)-baking	-		0.022	STMR* / TDM review
Wheat / milling (flour)	-		0.022	STMR* / TDM review
Barley / beer	-		0.123	STMRp (STMR*/TDM review 0.076 x PF 1.71)
Barley / milling (flour)	-		0.293 (0.039)	STMRp (STMR*/TDM review 0.076 x PF 3.86)
Barley / cooked	-		0.076	STMR*/TDM review
Oat / milling (flakes)	-		0.076	STMR*/TDM review, extrapolation from barley

Table 7.2- 26: 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**
Oat / boiled	-		0.076	STMR*/TDM review, extrapolation from barley
Rye / milling (wholemeal)-baking			0.022	STMR* / TDM review, extrapolation from wheat
Rye / boiled			0.022	STMR* / TDM review, extrapolation from wheat
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 2023/2005936			

** 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

Extensive calculation sheets 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 Reg. (EU) 2021/590 and of the MRL application (EFSA-Q-2021-00692).

The summary of the chronic assessment is presented in Appendix 3. The ADI utilization ranges from 2% to 56% ADI. The highest TMDI was 56% ADI for the “NL toddler”, the highest contributor is spinach (14% 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 7.2-25.

The summary of the chronic assessment is presented in Appendix 3. The ADI utilization ranges from 0.6 to 15% of the ADI. The diet with the highest IEDI is "NL toddler" with 15% of the ADI. For this diet, the highest contributor is spinaches with 5% of the ADI. The diet with the second highest IEDI is “DE child” with 10% of the ADI, in which apples 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 7.2-26. A complete list of input values and their derivation can be found in the supplemental document with BASF DocID 2023/2005936.

The summary of the chronic assessment is presented in Appendix 3. The maximum ADI utilization is 86% (NL toddler) for 1,2,4-T, 6% (NL toddler) for TA and 1% (NL toddler) for TAA and TLA and 7% (NL toddler) for TA + TLA of the ADI. The highest contributor is milk (cattle) (78%) for 1,2,4 T, maize, corn (1%) for TA, maize, corn (0.6%) for TAA and milk (cattle) (0.8%) 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 7.2-25 for wheat (with extrapolation to rye) and barley (with extrapolation to oat).

The summary of the acute assessment is presented in Appendix 3. For children, the highest ARfD utilization was 0.4% for consumption of barley and second highest for wheat (0.10%). For adults, the highest ARfD utilization was 0.3% for consumption of barley and the second highest 0.06% for wheat.
For processed commodities, the highest ARfD utilization for children was 0.4% for consumption of barley/milling (flour) and second highest for oat/boiled (0.2%). For adults, the highest ARfD utilization was 0.1% for consumption of oat/boiled and second highest for barley/beer (0.10%).

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 7.2-26.

For unprocessed commodities, the highest ARfD utilization for children was 0.7% for 1,2,4-T for consumption of wheat, 3% for TA for consumption of wheat, 1% for TAA for consumption of wheat, 0.2% for TLA for consumption of barley and for 3.1% for TA + TLA (sum of %ARfD of TA and TLA for the crop with the highest contribution) for consumption of wheat. For adults, the highest ARfD utilization was 0.4% for 1,2,4-T for consumption of wheat, 2% for TA for consumption of wheat, 0.7% for TAA for consumption of wheat, 0.1% for TLA for consumption of barley and 2.06% for TA + TLA for consumption of wheat.

For processed commodities, the highest ARfD utilization for children was 0.6% for 1,2,4-T for consumption of wheat/milling (flour), 1% for TA for consumption of wheat/milling (flour), 0.8% for TAA for consumption of wheat/milling (flour), 0.2% for TLA for consumption of barley/milling (flour) and 1.1% for TA + TLA for consumption of wheat/milling (flour) (sum of %ARfD of TA and TLA for the crop with the highest contribution). For adults, the highest ARfD utilization was 0.4% for 1,2,4-T for consumption of barley/beer, 0.9% for TA for consumption of wheat/bread/pizza, 0.4% for TAA for consumption of barley/beer, 2% for TLA for consumption of barley/beer and 2.3% for TA + TLA for consumption of barley/beer.

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- 27: Consumer risk assessment

BAS 750 F	
TMDI (% ADI) according to EFSA PRIMo	Highest TMDI: 56% (NL toddler)
IEDI (% ADI) according to EFSA PRIMo	Highest IEDI: 15% (NL toddler)
IESTI (% ARfD) according to EFSA PRIMo*	unprocessed Highest IESTI: 0.4% (children, barley) 0.3% (adults, barley) processed Highest IESTI: 0.4% (children, barley / milling (flour)) 0.1% (adults, oat / boiled)
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: 86% (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)) 0.4% (adults, barley / beer)
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: 6% (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)) 0.4% (adults, barley / beer)
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: 0.2% (children, barley) 0.1% (adults, barley) processed Highest IESTI: 0.2% (children, barley / milling (flour)) 2% (adults, barley / beer)
NTMDI (% ADI) **	not applicable
NEDI (% ADI)**	not applicable
NESTI (% ARfD) **	not applicable
TA + TLA	
TMDI (% ADI) according to EFSA PRIMo	not applicable
IEDI (% ADI) according to EFSA PRIMo	Highest IEDI: 7% (NL toddler)
IESTI (% ARfD) according to EFSA PRIMo*	unprocessed Highest IESTI: 3.1% (children, wheat) 2.06% (adults, wheat) processed Highest IESTI: 1.1% (children, wheat/milling (flour)) 2.3% (adults, barley/beer)
NTMDI (% ADI) **	not applicable
NEDI (% ADI)**	not applicable
NESTI (% ARfD) **	not applicable

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

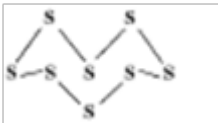
The proposed uses of mefentrifluconazole in the formulation BAS 768 00 F do not represent unacceptable acute and chronic risks for the consumer.

zRMS accepts the assessment proposal

7.3 Sulfur

General data on sulfur is summarized in the table below.

Table 7.3- 1: General information on sulfur

Active substance (ISO Common Name)	Sulfur (E-ISO, JMAF, ESA)
IUPAC	Sulfur
Chemical structure	
Molecular formula	S_8
Molar mass	32.064 (S)
Chemical group	Mineral (chalcogen)
Mode of action (if available)	Provides essential sulfur nutrients that enhance plant growth, and may also suppress certain mite species that also adversely affect plant yields.
Systemic	No
Company (ies)	Sulfur Task Force and Sulfur Working Group *
Rapporteur Member State (RMS)	France
Approval status	Approved Date of (25/06/2009) and reference to decision (REGULATION (EU) 540/2011)
Restriction (e.g. is restricted to use as "...")	see Approval Directive / Regulation
Review Report	SANCO/2676/08 – final 22/10/2009
Current MRL regulation	Regulation (EC) No 459/2010
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes, EFSA Journal 2016;14(4):4458
EFSA Journal: Conclusion on the peer review	Yes**
EFSA Journal: conclusion on article 12	No
Current MRL applications on intended uses	EFSA Journal 2016;14(4):4458: Statement of EFSA for substances that do not require MRL review

* Notifier in the EU process to whom the a.s. belong(s)
** EFSA Scientific Report (2008) 221,1-70 - 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

No new data submitted in the framework of this application.

The stability of residues for the active substance was reviewed during the Annex I inclusion process; elemental sulfur occurs widely in nature as stable deposits. It is known to be stable at or below ambient temperature. Elemental sulfur undergoes oxidation or reduction by specific microbial processes or when exposed directly to strong sunlight as a thin film surface.

Taking into consideration the stability of the molecular structure of the sulfur molecule (S_8), its inactivity towards oxidizing or reducing substances and the very low temperature of storage of the treated and untreated samples, ca. -20°C, it is considered that it is not necessary to carry out storage stability studies with crops containing residues of sulfur.

Unless exposed to specific sulfur-oxidizing micro-organisms under aqueous and aerobic conditions, residues of elemental sulfur dissolved in organic solvents (e.g. acetone or methanol) are expected to be stable at or below ambient temperature.

It can therefore be concluded that no storage stability studies are required to assess uses under con-sideration.

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			
--	--	Elemental Sulfur is stable.	EFSA Scientific Report (2008) 221, 34-70

Conclusion on stability of residues during storage

According to EFSA Scientific Report (2008) 221, 34-70: Elemental Sulfur is stable.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

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

Acc. to France, 2007: “Unless exposed to specific sulphur-oxidizing micro-organisms under aqueous and aerobic conditions, residues of elemental sulphur in organic solvents (e.g. acetone or methanol) are expected to be stable at or below ambient temperature.”

Conclusion on stability of residues in sample extracts

Acc. to France, 2007: “Unless exposed to specific sulphur-oxidizing micro-organisms under aqueous and aerobic conditions, residues of elemental sulphur in organic solvents (e.g. acetone or methanol) are expected to be stable at or below ambient temperature.”

zRMS accepts the assessment proposal

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

No new data submitted in the framework of this application.

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								
Cereals	Wheat	^{35}S-labelled micronized sulfur	Foliar application, G	10 mg [^{35}S]-sulfur/leaf	1	Different time intervals, up to seven days after application	--	France, 2007 EFSA, 2008

Summary of plant metabolism studies reported in the EU

EFSA (2008) concluded:
"Metabolism of elemental sulfur in the plant was studied following foliar application of [^{35}S]-labelled micronised sulfur to the surface of wheat leaves (10 mg [^{35}S]-sulfur/ leaf).

Individual leaves were sampled at different time intervals up to seven days after application and processed for analysis. Unincorporated sulfur was removed by surface washing prrevious to a solvent extraction of the leaf material. The rate of uptake by treated leaves was determined to be around 2 % of the applied [^{35}S]-labelled micronised sulfur.

Upon analysis of the leaf extracts, 13 radio-labelled compounds were separated, out of which sulfate, cysteine, cystine, methionine, and oxidised and reduced glutathion were identified. The unextractable fraction contained mainly proteins.

Of the extractable radioactivity (ERR), the amount incorporated in the pool of cysteine and cystine decreased from 35 % to 10 %, within 4 hours to 7 days after application. In contrary, the amount of [^{35}S]-sulfate increased from 10 % to 60 % of the ERR within the same period of time. No hydrogen sulfide was detected; however the authors could not exclude the hypothesis that the detected sulfate could originate from a secondary, fast oxidation of sulfide.

Based on the findings in wheat leaves, the authors proposed the metabolism of elemental sulfur applied to leaves of higher plants as follows: sulfur is not only incorporated into organic compounds, such as amino acids, peptides and proteins, but is also oxidised to sulfate. This oxidation of elemental sulfur to sulfate ions, directly or maybe through intermediate generation of sulfide, has been considered as a mechanism of detoxification.

Given the fact that the vast majority of the foliar applied elemental sulfur is not absorbed and metabolised by the plants, the rapporteur Member State has concluded that the pertinent residue on treated crops was elemental sulfur.

The mammalian toxicology assessment has concluded that sulfur is a substance of low toxicity, and it is not necessary to set an ADI or ARfD. Therefore, the meeting of experts in residues agreed that a residue definition for consumer risk assessment has not to be proposed with respect to the use of elemental sulfur on crops. In the absence of an ADI and ARfD, an elaboration on residue levels in food in order to compare consumer exposure to those toxicological reference values, is not required."

Summary of new plant metabolism studies

No new studies are submitted.

Conclusion on metabolism in primary crops

Metabolism study in wheat is available in the context of the EU evaluation process and explicit reference is made to the corresponding study already summarised and evaluated in the Draft Assessment Report (DAR) on sulphur (Public version, August 2007) and in EFSA, 2008.

Acc. to France, 2007: "*A metabolism study with radiolabelled elemental sulphur (^{35}S) in wheat showed that less than 2% of sulphur was taken up by the leaves of higher plants. This sulphur is metabolised to sulphate ions and incorporated as natural organic compounds such as cysteine, methionine and glutathione. It is not possible to distinguish between natural sulphur compounds and the sulphur linked to the treatment of the plants*."

zRMS accepts the assessment proposal

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.

Summary of plant metabolism studies reported in the EU

RMS, 2007: "*Elemental sulphur and its derivates occur naturally in soil and are absorbed by plants to provide a supply of essential plant and animal nutrients. It would not be easy to distinguish residues of elemental sulphur transferred into succeeding crops from natural and other applied sources. It is therefore considered unnecessary to carry out studies with sulphur residues transferring into succeeding crops.*"

EFSA Scientific Report (2008) 221, 13-70, concluded: "*The route of degradation of sulfur in soil was considered satisfactorily addressed by an open literature review. There is a natural cycle of oxidation and reduction reactions, which transform elemental sulfur into both organic and inorganic products Plants absorb sulfur via the roots as sulfate ions (SO_4^{2-}), formed by chemical or microbial oxidation of elemental sulfur or other forms of sulfur in the soil. In the plant, sulfate is reduced to sulphide, and subsequently incorporated in various sulfur-containing organic molecules, including plant proteins. This is a naturally driven process, and therefore the use of elemental sulfur as a plant protection product is not deemed to lead to any relevant residues in rotational crops.*"

Summary of new plant metabolism studies

No new data submitted in the framework of this application.

Conclusion on metabolism in rotational crops

Metabolism in rotational crops is intended to be not applicable.

No new data submitted in the framework of this application.

zRMS accepts the assessment proposal

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.

Conclusion on nature of residues in processed commodities

No new data submitted in the framework of this application.

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

Table 7.3- 4: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Cereals (Wheat)
Rotational crops covered	Not applicable
Metabolism in rotational crops similar to metabolism in primary crops?	Not applicable
Processed commodities	No study on the nature of the residue was performed in processed commodities
Residue pattern in processed commodities similar to pattern in raw commodities?	Not applicable
Plant residue definition for monitoring	None, EFSA Scientific Report (2008) 221, 32-70
Plant residue definition for risk assessment	None required, as no ADI and ARfD was set (EFSA Scientific Report (2008) 221, 32-70)
Conversion factor from enforcement to RA	None required, as no ADI and ARfD was set (EFSA Scientific Report (2008) 221, 32-70)

zRMS accepts the assessment proposal

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

Available data

No new data submitted in the framework of this application.

Summary of animal metabolism studies reported in the EU

EFSA (2008) concluded:
"No studies were submitted that investigate the fate of sulfur in livestock.
In the DAR the rapporteur Member State has made reference to an evaluation report by the European Medicines Agency (EMEA) on elemental sulfur, used as therapeutic agent in food-producing animals. The report concluded that residues in animal tissues from sulfur administration could not be regarded as being of any concern, neither in terms of human health nor effects on micro-organisms used during processing of food stuffs.
With respect to the assessment of plant protection uses of sulfur in terms of consumer safety, elaboration on residue levels in food of animal origin is not required, since no ADI and ARfD were set for sulfur."

It can therefore be concluded that no animal metabolism data are required to assess the use under consideration.

Summary of new animal metabolism studies

No new data for the product dossier considered to be required.

Conclusion on metabolism in livestock

It can be concluded that no animal metabolism data are required to assess the use under consideration.

No new data submitted in the framework of this application.

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

Table 7.3- 5: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Food producing animals (animal health and nutrition literature review) Sulfur is a natural product transformed into sulfate by all the animals
Time needed to reach a plateau concentration	Not applicable
Animal residue definition for monitoring	None, EFSA Scientific Report (2008) 221, 32-70
Animal residue definition for risk assessment	None required, EFSA Scientific Report (2008) 221, 32-70
Conversion factor	Not applicable, as no ADI and ARfD was set (EFSA Scientific Report (2008) 221, 32-70)
Metabolism in rat and ruminant similar	Not applicable
Fat soluble residue	Not applicable

zRMS accepts the assessment proposal

7.3.3 Magnitude of residues in plants (KCA 6.3)

No new data are submitted in the framework of this application.
During the evaluation of sulfur for Annex I Listing, the Rapporteur Member State (France) proposed in the Draft Assessment Report (2008) that no EU MRL should be set and that sulfur be placed in Annex IV of Regulation (EC) No 396/2005. l. There is no MRLs for this active substance (Commission Regulation (EU) No 459/2010). In Commission Regulation (EU) No 459/2010 it was stated: "*As regards sulphur, the Authority recommended in its conclusion not to continue to set MRLs for that pesticide because of its low toxicity. In view of that conclusion it is appropriate to delete the existing MRLs for that pesticide and to include it in Annex IV to Regulation (EC) No 396/2005*."
The mammalian toxicology assessment has concluded that sulfur is a substance of low toxicity, and it is not necessary to set an ADI or ARfD. Therefore, the meeting of experts in residues agreed that a residue definition for consumer risk assessment need not be proposed with respect to the use of elemental sulfur on crops. In the absence of an ADI and ARfD, an elaboration on residue levels in food in order to compare consumer exposure to those toxicological reference values, is not required.
According to the available data, the intended uses on wheat (triticale) and barley are considered acceptable for outdoor use.
zRMS accepts the assessment proposal

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

No new data/calculations submitted in the framework of this application.

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

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

Conclusion on feeding studies

An assessment of plant protection uses of sulfur in terms of consumer safety elaboration on residue levels in plants and food of animal origin is not required, since no toxicological reference values were set for sulfur.
zRMS accepts the assessment proposal

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

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

7.3.5.1 Conclusion on processing studies

No new data submitted in the framework of this application.
zRMS accepts the assessment proposal

7.3.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues (see 7.3.2.2), no study dealing with magnitude of residues in succeeding crops is needed.

7.3.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

No new data submitted in the framework of this application.

Conclusion on rotational crops studies

EFSA (2008) concluded:
"The route of degradation of sulfur in soil was considered satisfactorily addressed by an open literature review. There is a natural cycle of oxidation and reduction reactions, which transform elemental sulfur into both organic and inorganic products...
Plants absorb sulfur via the roots as sulfate ions (SO_4^{2-}), formed by chemical or microbial oxidation of elemental sulfur or other forms of sulfur in the soil. In the plant, sulfate is reduced to sulphide, and subsequently incorporated in various sulfur-containing organic molecules, including plant proteins. This is a naturally driven process, and therefore the use of elemental sulfur as a plant protection product is not deemed to lead to any relevant residues in rotational crops."

zRMS accepts the assessment proposal

7.3.7 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 768 00 F. Therefore, other special studies are not needed.

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

As ARfD was not deemed necessary, acute risk assessment is not relevant. EFSA (2008) concluded:

"A consumer risk assessment is neither possible nor necessary, as the mammalian toxicology assessment has concluded that sulfur is of low toxicity, and it is not necessary to set an ADI or ARfD ….. The rapporteur Member State also tried to estimate total sulfur intakes from food and water to evaluate general exposure. However, the PRAPeR 60 meeting of experts did not consider these estimates (not peer reviewed), but concluded that no dietary risk assessment needs to be carried out, since toxicological reference values were not set for sulfur."

zRMS accepts the assessment proposal

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

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). For sulfur, no ARfD is allocated. Consequently, no acute combined risk assessment was performed with sulfur.

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 768 00 F in barley and wheat (triticale). A HI <1 indicates absence of a health concern even if dose-addition of active ingredients is assumed.

Table 7.5-1: Acute consumer risk assessment from combined exposure

Crop	Active Ingredient	HQ (based on IESTI according to EFSA PRIMo)
Barley	Mefentrifluconazole (BAS 750 F)	0.004 (0.0006/0.15)
	1,2,4-Triazole (1,2,4-T)	0.003 (0.0003/0.1)
	Triazole alanine (TA)	0.012 (0.0035/0.3)
	Triazole acetic acid (TAA)	0.004 (0.0044/1.0)
	Triazole lactic acid (TLA)	0.001 (0.0004/0.3)
	Cumulative risk barley (HI)	**0.024**

Crop	Active Ingredient	HQ (based on IESTI according to EFSA PRIMo)
Wheat (triticale)	Mefentrifluconazole (BAS 750 F)	0.0007 (0.0001/0.15)
	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)	**0.050**

The Hazard Index is <1. Thus combined exposure to all active substances in BAS 768 00 F is not expected to present a consumer risk. No further refinement of the assessment is required.

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 harmonized 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 (barley and wheat (triticale) were performed 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 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 768 00 F in barley and wheat (triticale) 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.

zRMS accepts the assessment proposal

Table 7.5-2: Assessment of combined exposure of TA and TLA as a result of the intended use of BAS 768 00 F (barley, wheat (triticale))

Diet	Active Ingredient	HQ (based on IEDI according to EFSA PRIMo 3.1)
DE child	Triazole alanine	0.0108
	Triazole lactic acid	0.0004
	Cumulative risk (HI)	**0.0112**
DK child	Triazole alanine	0.0213
	Triazole lactic acid	0.0008
	Cumulative risk (HI)	**0.0222**
ES child	Triazole alanine	0.0092
	Triazole lactic acid	0.0003
	Cumulative risk (HI)	**0.0095**
FR infant	Triazole alanine	0.0016
	Triazole lactic acid	0.0001
	Cumulative risk (HI)	**0.0017**
FR toddler 2 - 3 yr	Triazole alanine	0.0065
	Triazole lactic acid	0.0002
	Cumulative risk (HI)	**0.0067**
FR child 3 - 15 yr	Triazole alanine	0.0097
	Triazole lactic acid	0.0004
	Cumulative risk (HI)	**0.0101**
IT toddler	Triazole alanine	0.0138
	Triazole lactic acid	0.0005
	Cumulative risk (HI)	**0.0143**
NL toddler	Triazole alanine	0.0098
	Triazole lactic acid	0.0004
	Cumulative risk (HI)	**0.0102**
NL child	Triazole alanine	0.0090
	Triazole lactic acid	0.0003
	Cumulative risk (HI)	**0.0093**

Table 7.5-2: Assessment of combined exposure of TA and TLA as a result of the intended use of BAS 768 00 F (barley, wheat (triticale))

Diet	Active Ingredient	HQ (based on IEDI according to EFSA PRIMo 3.1)
UK infant	Triazole alanine	0.0059
	Triazole lactic acid	0.0003
	Cumulative risk (HI)	**0.0062**
UK toddler	Triazole alanine	0.0083
	Triazole lactic acid	0.0003
	Cumulative risk (HI)	**0.0086**
DK adult	Triazole alanine	0.0034
	Triazole lactic acid	0.0001
	Cumulative risk (HI)	**0.0035**
ES adult	Triazole alanine	0.0059
	Triazole lactic acid	0.0003
	Cumulative risk (HI)	**0.0062**
FI adult	Triazole alanine	0.0024
	Triazole lactic acid	0.0001
	Cumulative risk (HI)	**0.0025**
FR adult	Triazole alanine	0.0046
	Triazole lactic acid	0.0002
	Cumulative risk (HI)	**0.0048**
IE adult	Triazole alanine	0.0055
	Triazole lactic acid	0.0002
	Cumulative risk (HI)	**0.0057**
IT adult	Triazole alanine	0.0086
	Triazole lactic acid	0.0003
	Cumulative risk (HI)	**0.0089**
LT adult	Triazole alanine	0.0047
	Triazole lactic acid	0.0002
	Cumulative risk (HI)	**0.0049**

Table 7.5-2: Assessment of combined exposure of TA and TLA as a result of the intended use of BAS 768 00 F (barley, wheat (triticale))

Diet	Active Ingredient	HQ (based on IEDI according to EFSA PRIMo 3.1)
NL general	Triazole alanine	0.0048
	Triazole lactic acid	0.0002
	Cumulative risk (HI)	**0.0051**
PL general	Triazole alanine	0.0000
	Triazole lactic acid	0.0000
	Cumulative risk (HI)	**0.0000**
PT general	Triazole alanine	0.0085
	Triazole lactic acid	0.0003
	Cumulative risk (HI)	**0.0088**
RO general	Triazole alanine	0.0105
	Triazole lactic acid	0.0004
	Cumulative risk (HI)	**0.0109**
SE general	Triazole alanine	0.0072
	Triazole lactic acid	0.0003
	Cumulative risk (HI)	**0.0075**
UK adult	Triazole alanine	0.0036
	Triazole lactic acid	0.0001
	Cumulative risk (HI)	**0.0037**
UK vegetarian	Triazole alanine	0.0044
	Triazole lactic acid	0.0002
	Cumulative risk (HI)	**0.0046**
GEMS/Food G06	Triazole alanine	0.0152
	Triazole lactic acid	0.0006
	Cumulative risk (HI)	**0.0158**
GEMS/Food G07	Triazole alanine	0.0104
	Triazole lactic acid	0.0005
	Cumulative risk (HI)	**0.0108**

Table 7.5-2: Assessment of combined exposure of TA and TLA as a result of the intended use of BAS 768 00 F (barley, wheat (triticale))

Diet	Active Ingredient	HQ (based on IEDI according to EFSA PRIMo 3.1)
GEMS/Food G08	Triazole alanine	0.0117
	Triazole lactic acid	0.0006
	Cumulative risk (HI)	**0.0123**
GEMS/Food G10	Triazole alanine	0.0097
	Triazole lactic acid	0.0005
	Cumulative risk (HI)	**0.0102**
GEMS/Food G11	Triazole alanine	0.0092
	Triazole lactic acid	0.0005
	Cumulative risk (HI)	**0.0097**
GEMS/Food G15	Triazole alanine	0.0116
	Triazole lactic acid	0.0006
	Cumulative risk (HI)	**0.0122**
DE general	Triazole alanine	0.0064
	Triazole lactic acid	0.0003
	Cumulative risk (HI)	**0.0067**
DE women 14 - 50 yr	Triazole alanine	0.0060
	Triazole lactic acid	0.0003
	Cumulative risk (HI)	**0.0063**
IE child	Triazole alanine	0.0024
	Triazole lactic acid	0.0001
	Cumulative risk (HI)	**0.0025**
FI 3 yr	Triazole alanine	0.0051
	Triazole lactic acid	0.0003
	Cumulative risk (HI)	**0.0054**
FI 6 yr	Triazole alanine	0.0041
	Triazole lactic acid	0.0000
	Cumulative risk (HI)	**0.0041**

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

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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.

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EFSA (European Food Safety Authority), 2020. Modification and setting of maximum residue levels for mefentrifluconazole in various crops. June 2020.

SANTE/11612/2018 Rev. 2, 26 January 2021. Review report for the active substance mefentrifluconazole.

Commission Regulation (EU) 2021/590 of 12 April 2021 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, boscalid, cow milk, etofenprox, ferric pyrophosphate, L-cysteine, lambda-cyhalothrin, maleic hydrazide, mefentrifluconazole, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate and triclopyr in or on certain products.

Validation of BASF Method Number L0076/09 for the determination of BAS 750 F in citrus (whole fruit), coffee (grain), dry beans (seed), soybeans (grain), tomato (whole fruit), wheat (grain) and wheat (straw) using LC-MS/MS, BASF Study Number 714673, Wesley Felipe de Paula José, BASF DocID 2015/3001681, 04. Sep. 2015.

Technical Procedure: BASF Method Number L0076/09, Method for the determination of BAS 421 F (Reg.No. 108406), BAS 480 F (Reg.No. 205259), BAS 500 F (Reg.No. 304428), M500F007 (Reg.No. 340266), BAS 510 F (Reg.No. 300355), BAS 550 F (Reg.No. 247723), BAS 555 F (Reg.No. 4056343), BAS 560 F (Reg.No. 4037710) and BAS 750 F (Reg.No. 5834378) in plant matrices by LC-MS/MS. B. Eilers, A. A. Guedez O., O. Rechel, C. Spangler, M. Kissel; BASF SE, 23 July 2019.

BASF method L0170/02; “Modification M004 of BCS residue analytical method 01062 for the determination of 1,2,4-triazole, triazolylalanine, triazole acetic acid and triazole lactic acid by LC/DMS/MS/MS in plant materials”; T. Class; Bayer CropScience AG; Monheim am Rhein. PTRL Europe study ID P 2383 G, 2011

Technical Procedure: BASF method L0170/02: “Method for the determination of 1,2,4-Triazole (T, Reg.No. 87084), Triazole alanine (TA, Reg.No. 270412), Triazole Acetic Acid (TAA, Reg.No. 137281) and Triazole Lactic Acid (TLA, Reg.No. 5050862) in plant matrices by LC-DMS/MS/MS”, T. Class; PTRL Europe, 16.04.2020.

Sulfur

France, 2008. Draft Assessment Report (DAR) on Sulphur prepared by the rapporteur Member State France in the framework of Regulation (EC) No 1107/2009, December 2008

EFSA (European Food Safety Authority), 2008. Conclusion on the peer review of the pesticide risk assessment of the active substance sulfur. EFSA Journal (2008) 221, 1-70. December 2008.

Commission Regulation (EU) 459/3010 of 27 May 2010 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 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for certain pesticides in or on certain products.

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 6.3.1/1	Erdmann, H.	2021	Study on the residue behaviour of BAS 750 F (Mefentrifluconazole), BAS 500 F (Pyraclostrobin) and BAS 560 F (Metrafenone) in barley after application of either BAS 758 00 F, BAS 750 01 F, BAS 500 06 F or BAS 560 00 F under field conditions in Northern Europe, 2020 2021/2000401 Agro-Check Dr. Teresiak & Erdmann GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	BASF
KCA 6.3.2/1	Erdmann, H.	2021	Study on the residue behaviour of BAS 750 F (Mefentrifluconazole), BAS 500 F (Pyraclostrobin) and BAS 560 F (Metrafenone) in wheat after application of either BAS 758 00 F, BAS 750 01 F, BAS 500 06 F or BAS 560 00 F under field conditions in Northern Europe, 2020 2021/2000402 Agro-Check Dr. Teresiak & Erdmann GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	BASF
KCA 6.7.1/1	Guedez Orozco, A.	2023	Mefentrifluconazole (BAS 750 F) - dRR summaries for residue trials performed with different formulations containing BAS 750 F for the draft Registration Report of BAS 768 00 F 2023/2008877 BASF 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 the reference list.

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Mefentrifluconazole

A 2.1.1 Stability of residues

No new data was 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 were submitted by the applicant. These studies are summarized in Chapter 07.02. 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 Barley

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, 2018a)	1 - 2	0.150 kg as/ha	14	BBCH 49- 69	35**
Intended cGAP (4,8*)	2	0.100 kg as/ha	14	BBCH 30 - 59	F§

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

** 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).

A 2.1.3.1.1 Study 1 – barley – BASF DocID 2021/2000401

Comments of zRMS:	The study has been accepted. The field and the analytical phase were performed satisfactorily. In the untreated control specimens, no residues of BAS 750 F were detected at or above the LOQ, 0.010 mg/kg. Bridging showed, that the new formulation BAS 758 00 F does not lead to higher residues than the respective solo formulation BAS 750 01 F. All validation parameters were within the required ranges. Both LC-MS/MS methods applied have the sufficient sensitivity and specificity. BASF method no. L0076/09 which determines the analytes by means of LC-MS/MS was used for Mefentrifluconazole. BASF method no. L0170/02 which determines the analytes by means of LC-DMS/MS/MS was used for the analysis of 1,2,4 Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA). Validation of the analytical methods was performed on plant matrices in separate studies. Significant matrix effects (> 20 %) were not observed. The method has a LOQ of 0.010 mg/kg. The LOD is 0.003 mg/kg. In this study LC-MS/MS was used for final determination of BAS 750 F (Mefentrifluconazole). Two transitions were used: 398 m/z -> 182 m/z (quantification) and 398 m/z -> 133 m/z (confirmation). LC-DMS-MS/MS was used for final determination of the triazole derivative metabolites 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA). The analytes were determined by LC-DMS-MS/MS, using two different HPLC columns/stationary phases and two transitions were applied: Transitions: 1,2,4-T (Reg.No. 87084) 70 m/z → 43 m/z; TAA (Reg.No. 137281) 128 m/z → 70 m/z; TA (Reg.No. 270412) 157 m/z → 70 m/z; TLA (Reg.No. 5050862) 158 m/z → 70 m/z; 1,2,4-T IS (Reg.No. 87084) 75 m/z → 46 m/z; TAA IS (Reg.No. 137281) 133 m/z → 75 m/z; TA IS (Reg.No. 270412) 162 m/z → 75 m/z; TLA IS (Reg.No. 5050862) 163 m/z → 75 m/z The analytical phase of the report was amended. No impact of Analytical Phase Report Amendment No. 1 on the results of the Analytical Phase. <u>Further details of the study are provided below:</u> 4 trials in barley were conducted in Northern Europe to determine the residues of BAS 750 F (Mefentrifluconazole) (*and BAS 500 F (Pyraclostrobin) and BAS 560 F (Metrafenone)*) after application of either the bridging formulation BAS 758 00 F (66.6 g Mefentrifluconazole /L, 80.0 g Pyraclostrobin /L, 100.0 g Metrafenone /L, EC) and registered solo formulation BAS 750 01 F (100.0 g Mefentrifluconazole /L, EC), (*and also BAS 500 06 F (200.0 g Pyraclostrobin /L, EC) or BAS 560 00 F (300.0 g Metrafenone /L, SC)*) in or on RAC. All trials consisted of 5 plots, however in the context of this assessment the data of the interest are originated from the plot 1 (control), plot 2 (treated with BAS 758 00 F) and plot 3 (treated with BAS 750 01 F). *Plot 4 (treated with BAS 500 06 F) and plot 5 (treated with BAS 560 00 F) are not related with the actives of the evaluated product.* The first application on plot 2 in all trials was made 13-15 days before application no. 2 (except of trial L200230). The second application was performed at BBCH 59. In all trials the first application on plot 3 was made at BBCH 49. The second application was made at BBCH 69. Samples were collected at BBCH 59 on plot 1 immediately before application no. 2 and directly after application no. 2 on plot 2 as whole plant no roots. On plot 1 samples were also collected at BBCH 69 immediately before application no. 2 and directly after application no. 2 on plot 3 as whole plant no roots. On plot 2 at 48-49 DALA the specimens were sampled as grain and straw. At 55-56 DALA samples were collected as grain and straw on plot 1 and 2. At 62-63 specimens were sampled as grain and straw on plot 2.

On plot 3 at 27-28 DALA specimens were collected as ears and rest of plant without roots or as grain and straw. At 34-35 DALA the specimens were sampled as grain and straw on plot 1 and 3. At 41-43 DALA barley specimens were collected as grain and straw on plot 3.
All barley samples of plot 1, 2 and 3 were analysed for BAS 750 F (Mefentrifluconazole), using the BASF Method L0076/09 with LOQ of 0.010 mg/kg.
The results of the average procedural recoveries for BAS 750 F in barley matrices at fortification levels between 0.010 and 10 mg/kg were at 78.7 % (see below table):

Matrix		Fortification Level [mg/kg]	BAS 750 F Mean [%]	SD [±]	RSD [%]	n
Barley	Whole plant no roots	0.010, 0.10 and 10	81.4	7.5	9.2	7
	Ears	0.010, 0.10 and 10	75.1	3.8	5.1	7
	Rest of plant without roots	0.010, 0.10 and 10	72.5	2.6	3.6	7
	Grain	0.010, 0.10 and 10	81.6	4.0	4.9	7
	Straw	0.010, 0.10 and 10	82.9	3.1	3.8	7
		Overall:	78.7	6.0	7.6	35

SD = standard deviation RSD = coefficient of variation n = number of recoveries

Overall and average recoveries were all in the range of 70 - 110 % and relative standard deviations (RSD) were < 20 %.
Further all barley samples of plot 1, 2 and 3 were analysed for triazoles: 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 LOQ of 0.010 mg/kg for each analyte. The results of the average procedural recoveries in plant matrices at fortification levels between 0.01 and 1.0 mg/kg were 89.2 % for 1,2,4-Triazole, 89.0 % for Triazole alanine, 97.5 % for Triazole acetic acid, 92.1 % for Triazole lactic acid as it is visualised in the table below (Procedural Recoveries for T, TA, TAA, and TLA).

Matrix		Recoveries of	Fortification Level [mg/kg]	Mean [%]	SD [±]	RSD [%]	n
Barley	Whole plant no roots	1,2,4-Triazole (T)	0.010, 0.10 and 1.0	90.6	6.3	6.9	8
	Ears		0.010, 0.10 and 1.0	88.9	12	13	8
	Rest of plant without roots		0.010, 0.10 and 1.0	88.5	12	13	8
	Grain		0.010, 0.10 and 1.0	94.7	3.7	3.9	10
	Straw		0.010, 0.10 and 1.0	82.2	4.9	6.0	8
			Overall:	89.2	8.9	10	42
Barley	Whole plant no roots	Triazole alanine (TA)	0.010, 0.10 and 1.0	91.3	13	14	8
	Ears		0.010, 0.10 and 1.0	92.2	4.8	5.2	8
	Rest of plant without roots		0.010, 0.10 and 1.0	93.6	4.6	4.9	8
	Grain		0.010, 0.10 and 1.0	92.4	9.5	10	10
	Straw		0.010, 0.10 and 1.0	74.4	3.0	4.0	8
			Overall:	89.0	10	12	42
Barley	Whole plant no roots	Triazole acetic acid (TAA)	0.010, 0.10 and 1.0	101	10	10	8
	Ears		0.010, 0.10 and 1.0	95.3	3.3	3.5	8
	Rest of plant without roots		0.010, 0.10 and 1.0	97.3	2.1	2.2	8
	Grain		0.010, 0.10 and 1.0	100	8.3	8.2	10
	Straw		0.010, 0.10 and 1.0	92.5	7.0	7.5	8
			Overall:	97.5	7.4	7.5	42
Barley	Whole plant no roots	Triazole lactic acid (TLA)	0.010, 0.10 and 1.0	99.9	12	12	8
	Ears		0.010, 0.10 and 1.0	94.8	2.0	2.2	8
	Rest of plant without roots		0.010, 0.10 and 1.0	91.4	4.3	4.8	8
	Grain		0.010, 0.10 and 1.0	95.7	7.4	7.7	10
	Straw		0.010, 0.10 and 1.0	77.7	2.6	3.4	8
			Overall:	92.1	10	11	42

SD = standard deviation RSD = coefficient of variation n = number of recoveries

Below is presented summary of TDMs residues in the untreated barley samples for 1,2,4-

Triazole (T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA):

Sampl. No.	Portion analyzed	Timing DALA	Timing Growth Stage (BBCH)	n	Range of Triazole residues and related analytes [mg/kg] 1,2,4-Triazole (T)	Triazole alanine (TA)	Triazole acetic acid (TAA)	Triazole lactic acid (TLA)
Plot 1 - untreated (in regard to plot 2)								
1	Whole plant no roots	0 DBLA	59	4	< 0.010	0.019 - 0.046	< 0.010 - 0.027	< 0.010 - 0.079
3	Grain	55 - 56	89	4	< 0.010	0.050 - 0.17	0.013 - 0.091	< 0.010
	Straw			4	< 0.010	< 0.010 - 0.022	< 0.010 - 0.040	< 0.010 - 0.056
Plot 1 – untreated (in regard to plot 3)								
1	Whole plant no roots	0 DBLA	69	4	< 0.010	0.014 - 0.051	< 0.010 - 0.026	< 0.010 - 0.065
3	Grain	34 - 35	85 - 87	4	< 0.010	0.035 - 0.16	0.011 - 0.085	< 0.010
	Straw			4	< 0.010	< 0.010 - 0.012	< 0.010 - 0.030	0.015 - 0.074

DALA = days after last application n = Number of specimens
DBLA = days before last application. In regard to plot 2 or plot 3.

Below is presented summary of TDMs residues in the treated barley samples for 1,2,4-Triazole (T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA):

Sampl. No.	Portion analyzed	Timing DALA	Timing Growth Stage (BBCH)	n	Range of Triazole residues and related analytes [mg/kg] 1,2,4-Triazole (T)	Triazole alanine (TA)	Triazole acetic acid (TAA)	Triazole lactic acid (TLA)
Plot 2 - treated with BAS 758 00 F (2x 1.5 L/ha)								
1	Whole plant no roots	0	59	4	< 0.010	0.033 - 0.043	< 0.010 - 0.027	0.033 - 0.069
2	Grain	48 - 49	87 - 89	4	< 0.010	0.11- 0.22	0.027 - 0.11	< 0.010
	Straw			4	< 0.010	< 0.010 - 0.015	0.013 - 0.040	0.021 - 0.063
3	Grain	55 - 56	89	4	< 0.010	0.10 - 0.20	0.025 - 0.12	< 0.010
	Straw			4	< 0.010	< 0.010 - 0.022	0.014 - 0.036	0.013 - 0.082
4	Grain	62 - 63	89	3	< 0.010	0.11 - 0.19	0.029 - 0.096	< 0.010
	Straw			3	< 0.010	< 0.010 - 0.024	0.016 - 0.032	0.014 - 0.068
Plot 3 – treated with BAS 750 01 F (2x 1.5 L/ha)								
1	Whole plant no roots	0	69	4	< 0.010	0.043 - 0.070	0.016 - 0.038	0.033 - 0.063
2	Ears	27 - 28	77 - 83	3	< 0.010	0.11 - 0.17	0.032 - 0.055	< 0.010
	Rest of plant without roots			3	< 0.010	< 0.010 - 0.013	0.012 - 0.024	0.057 - 0.071
	Grain	27	85	1	< 0.010	0.19	0.091	< 0.010
	Straw			1	< 0.010	< 0.010	0.025	0.062
3	Grain	34 - 35	85 - 87	4	< 0.010	0.17 - 0.22	0.046 - 0.11	< 0.010
	Straw			4	< 0.010	< 0.010 - 0.026	0.019 - 0.031	0.045 - 0.10
4	Grain	41 - 43	89	4	< 0.010	0.15 - 0.25	0.044 - 0.14	< 0.010
	Straw			4	< 0.010	0.012 - 0.040	0.018 - 0.066	0.024 - 0.073

DALA = days after last application n = Number of specimens

Residues of mefentrifluconazole

Plot 2: The residues of BAS 750 F analyzed in barley whole plant no roots specimens sampled immediately after the last application (59 BBCH) ranged from 1.4 to 3.7 mg/kg. In grain specimens collected at 48-49 DALA (87-89 BBCH) residues of BAS 750 F were found between 0.025 and 0.052 mg/kg. At 55-56 DALA (BBCH) and 62-63 DALA (89 BBCH) the residues were in a range from 0.026 to 0.10 mg/kg and from 0.021 to 0.040 mg/kg, respectively.

In straw specimens sampled at 48-49 DALA (87-89 BBCH) residues of BAS 750 F were analyzed between 0.60 and 2.4 mg/kg. At 55-56 DALA (89 BBCH) and 62-63 DALA (89 BBCH) residues of BAS 750 F were in a range from 0.86 to 3.7 mg/kg and from 1.1 to 2.8 mg/kg, respectively.

Plot 3: The residues of BAS 750 F analyzed in barley whole plant no roots specimens sampled immediately after the last application (69 BBCH) ranged from 1.5 to 5.5 mg/kg. In ears specimens collected at 27-28 DALA (77-83 BBCH) residues of BAS 750 F were analyzed between 0.54 and 1.7 mg/kg. Rest of plant without roots specimens taken at the same sampling event showed residues from 1.6 to 5.7 mg/kg. In grain specimens collected at 27 DALA (85 BBCH) a residue of BAS 750 F was found at 0.056 mg/kg. At 34-35 DALA (85-87 BBCH) and 41-43 DALA (89 BBCH) residues of BAS 750 F were analyzed in grain specimens from 0.049 to 0.17 mg/kg and from 0.054 to 0.18 mg/kg, respectively.
In straw specimens collected at 27 DALA (85 BBCH) a residue of BAS 750 F was found at 1.6 mg/kg. At 34-35 DALA (85-87 BBCH) and 41-43 DALA (89 BBCH) residues of BAS 750 F were analyzed in straw specimens in a range from 1.3 to 7.4 mg/kg and from 2.0 to 8.8 mg/kg, respectively.
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 758 00 F does not lead to higher residues than the respective solo formulation BAS 750 01 F (see below).

Sampl. No.	Portion analyzed	Timing DALA	Timing Growth stage (BBCH)	n	Range of Residues (mg/kg) BAS 750 F
Plot 2: treated with BAS 758 00 F (2x 1.5 L/ha)					
1	Whole plant no roots	0	59	4	1.4 - 3.7
2	Grain	48-49	87-89	4	0.025 - 0.052
	Straw			4	0.60 - 2.4
3	Grain	55-56	89	4	0.026 - 0.10
	Straw			4	0.86 - 3.7
4	Grain	62-63	89	3	0.021 - 0.040
	Straw			3	1.1 - 2.8
Plot 3: treated with BAS 750 01 F (2x 1.5 L/ha)					
1	Whole plant no roots	0	69	4	1.5 - 5.5
2	Ears	27-28	77-83	3	0.54 - 1.7
	Rest of plant without roots			3	1.6 - 5.7
	Grain	27	85	1	0.056
	Straw			1	1.6
3	Grain	34-35	85-87	4	0.049 - 0.17
	Straw			4	1.3 - 7.4
4	Grain	41-43	89	4	0.054 - 0.18
	Straw			4	2.0 - 8.8

DALA = days after last application n = Number of specimens
General: The limit of quantification (LOQ) is 0.010 mg/kg for BAS 750 F.

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

Analyte(s)	Portion analyzed	Max. Storage interval [days]
BAS 750 F	Barley / Whole plant (no roots)	293
	Barley / Ears	260
	Barley / Rest of plant without roots	260
	Barley / Grain	258
	Barley / Straw	254
BAS 500 F, M500F007 and BAS 560 F	Barley / Whole plant (no roots)	293
	Barley / Ears	260
	Barley / Rest of plant without roots	260
	Barley / Grain	230
	Barley / Straw	254
Triazole derivative metabolites (TDMs)	Barley / Whole plant (no roots)	167
	Barley / Ears	170
	Barley / Rest of plant without roots	170
	Barley / Grain	238
	Barley / Straw	149

Reference: CA 6.3.1/1

Report	Study on the residue behaviour of BAS 750 F (Mefentrifluconazole), BAS 500 F (Pyraclostrobin) and BAS 560 F (Metrafenone) in barley after application of either BAS 758 00 F, BAS 750 01 F, BAS 500 06 F or BAS 560 00 F under field conditions in Northern Europe, 2020
	Erdmann, H.-P., 2021
	Report No 876500, AC/BASF/20/02
	BASF DocID 2021/2000401
	Authority registration No
Guideline(s):	EC 1107/2009 of the European Parliament and of the Council of 21 Oct 2009
	EEC 7029/VI/95 rev. 5 (July 22 1997)
	OECD 509 (2009)
	SANCO 7525/VI/95 - rev.10.3, 13 June 2017
Deviations:	No
GLP:	yes
	(certified by Land Brandenburg Ministerium der Justiz und fuer Europa und fuer Verbraucherschutz, Potsdam, Germany)
Acceptability:	Yes

Table A 2: Application and sampling details for trials conducted in 2020

Region	No. of trials	Plot No.	No. of Appl.	F, G, I[2]	Method	Test Item	Active Substance	Application		Target Timing	
								Rate (kg a.s./ha)	Water vol. (L/ha)	Appl.	Sampl. (DALA)[1]
Northern Europe	4	2	2	F	foliar	BAS 758 00 F (EC)	Mefentrifluconazole Pyraclostrobin Metrafenone	0.10 0.12 0.15	200	1st application: 13-15 days before application no. 2* 2nd application BBCH 59	0 DALA (whole plant no roots) 48-49 DALA (grain and straw) 55-56 DALA (grain and straw) 62-63 DALA** (grain and straw)
		3	2	F	foliar	BAS 750 01 F (EC)	Mefentrifluconazole	0.15	200	1st application BBCH 49 2nd application BBCH 69	0 DALA (whole plant no roots) 27-28 DALA (ears and rest of plant w/o roots, grain and straw) 34-35 DALA (grain and straw) 41-43 DALA (grain and straw)
		4	2	F	foliar	BAS 500 06 F (EC)	Pyraclostrobin	0.25	200	1st application BBCH 49 2nd application BBCH 69	0 DALA (whole plant no roots) 27-28 DALA (ears and rest of plant w/o roots, grain and straw) 34-35 DALA (grain and straw) 41-43 DALA (grain and straw)
		5	2	F	foliar	BAS 560 00 F (SC)	Metrafenone	0.15	200	1st application BBCH 49 2nd application BBCH 69	0 DALA (whole plant no roots) 27-28 DALA (ears and rest of plant w/o roots, grain and straw) 34-35 DALA (grain and straw) 41-43 DALA (grain and straw)

1) days after last application, 2) Field, Glasshouse or Indoor; *except of trial L200230: 11 days before application no. 2, see deviation; **except of trial L200230: sampling no. 4 could not be performed, see deviation

Table A 3: Summary of recoveries of BAS 750 F in barley matrices

Matrix		Fortification level [mg/kg]	BAS 750 F			
			n	Mean [%]	SD [±]	RSD [%]
Barley	Whole plant no roots	0.010, 0.10 and 10	7	81.4	7.5	9.2
	Ears	0.010, 0.10 and 10	7	75.1	3.8	5.1
	Rest of plant without roots	0.010, 0.10 and 10	7	72.5	2.6	3.6
	Grain	0.010, 0.10 and 10	7	81.6	4.0	4.9
	Straw	0.010, 0.10 and 10	7	82.9	3.1	3.8
	Overall		**35**	**78.7**	**6.0**	**7.6**

SD = standard deviation, RSD = coefficient of variation, n = number of recoveries

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

Matrix		Fortification level [mg/kg]	1,2,4-Triazole (1,2,4-T)				Triazolylalanine (TA)				Triazole acetic acid (TAA)				Triazole lactic acid (TLA)			
			n	Mean [%]	SD [±]	RSD [%]	n	Mean [%]	SD [±]	RSD [%]	n	Mean [%]	SD [±]	RSD [%]	n	Mean [%]	SD [±]	RSD [%]
Barley	Whole plant no roots	0.010, 0.10 and 1.0	8	90.6	6.3	6.9	8	91.3	13	14	8	101	10	10	8	99.9	12	12
	Ears	0.010, 0.10 and 1.0	8	88.9	12	13	8	92.2	4.8	5.2	8	95.3	3.3	3.5	8	94.8	2.0	2.2
	Rest of plant without roots	0.010, 0.10 and 1.0	8	88.5	12	13	8	93.6	4.6	4.9	8	97..3	2.1	2.2	8	91.4	4.3	4.8
	Grain	0.010, 0.10 and 1.0	10	94.7	3.7	3.9	10	92.4	9.5	10	10	100	8.3	8.2	10	95.7	7.4	7.7
	Straw	0.010, 0.10 and 1.0	8	82.2	4.9	6.0	8	74.4	3.0	4.0	8	92.5	7.0	7.5	8	77.7	2.6	3.4
	Overall		**42**	**89.2**	**8.9**	**10**	**42**	**89.0**	**10**	**12**	**42**	**97.5**	**7.4**	**7.5**	**42**	**92.1**	**10**	**11**

SD = standard deviation, RSD = coefficient of variation, n = number of recoveries

Table A 5: Summary of residues of BAS 750 F and TDMs on barley in Northern Europe 2020 (treated samples)

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	Residues (mg/kg)					PHI (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				BAS 750 F	1,2,4-T	TA	TAA	TLA		
	(a)	(b)				(c)								(d)	(e)
2021/2000401 L200227 16833 Lentzke Brandenburg Germany EU-North 2020	Barley GC 0640 / Infinity	1. 04.10.2019 2. 13.05-21.05.2020 3. 13.07-14.07.2020	0.10	200	0.05	**Plot 2** 28.04.2020 12.05.2020	59	whole plant no roots grain straw grain straw grain straw	1.4 0.025 0.60 <u>0.026</u> 0.86 0.024 <u>1.1</u>	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0.043 0.22 <0.010 0.20 <0.010 0.19 <0.010	0.015 0.11 0.019 0.095 0.027 0.096 0.030	0.055 <0.010 0.049 <0.010 0.056 <0.010 0.042	0 49 49 56 56 62 62	2021/2000401 Plot 2: BAS 758 00 F EC Mefentrifluconazole 66.6 g/L Plot 3: BAS 750 01 F EC Mefentrifluconazole 100 g/L BASF method L0076/09 for Mefentrifluconazole and L0170/02 for Triazole Metabolites LOQ: 0.010 mg/kg Storage time for all commodities ≤293 days (Mefentrifluconazole), ≤238 days Triazole Metabolites Samples were analysed within the storage stability (see chapter 7.2.1)
			0.15	200	0.075	**Plot 3** 03.05.2020 21.05.2020	69	whole plant no roots grain straw grain straw grain straw	1.5 0.056 1.6 0.049 1.3 0.054 2.0	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0.062 0.19 <0.010 0.21 <0.010 0.23 0.012	0.024 0.091 0.025 0.11 0.023 0.13 0.035	0.061 <0.010 0.062 <0.010 0.049 <0.010 0.068	0 27 27 34 34 43 43	
2021/2000401 L200228 6562 KC Groesbeek Gelderland The Netherlands EU-North 2020	Barley GC 0640 / Rafaela	1. 14.10.2019 2. 09.05.-18.05.2020 3. 30.06.-08.07.2020	0.10	200	0.05	**Plot 2** 24.04.2020 07.05.2020	59	whole plant no roots grain straw grain straw grain straw	2.4 0.052 2.4 <u>0.058</u> <u>3.7</u> 0.040 2.8	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0.039 0.15 <0.010 0.15 0.014 0.14 0.014	0.015 0.088 0.024 0.088 0.032 0.072 0.032	0.069 <0.010 0.059 <0.010 0.082 <0.010 0.068	0 49 49 56 56 62 62	
			0.15	200	0.075	**Plot 3** 27.04.2020 18.05.2020	69	whole plant no roots ears rest of plant w/o roots grain straw grain straw	4.4 0.65 4.2 0.13 7.4 0.18 8.8	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0.043 0.11 <0.010 0.17 <0.010 0.15 0.014	0.019 0.055 0.012 0.086 0.019 0.087 0.035	0.063 <0.010 0.057 <0.010 0.064 <0.010 0.073	0 28 28 35 35 43 43	

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	Residues (mg/kg)					PHI (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				BAS 750 F	1,2,4-T	TA	TAA	TLA		
	(a)	(b)				(c)								(d)	(e)
2021/2000401 L200229 57810 Donnelay Grand Est / Moselle France EU-North 2020	Barley GC 0640 / Pixel	1. 10.10.2019 2. 07.05.-13.05.2020 3. 30.06.2020	0.10	200	0.05	**Plot 2** 22.04.2020 07.05.2020	59	whole plant no roots grain straw grain straw grain straw	3.7 0.038 1.2 <u>0.029</u> 1.1 0.021 <u>1.4</u>	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0.038 0.11 0.015 0.10 0.022 0.11 0.024	<0.010 0.027 0.013 0.025 0.014 0.029 0.016	0.033 <0.010 0.021 <0.010 0.013 <0.010 0.014	0 48 48 55 55 63 63	
			0.15	200	0.075	**Plot 3** 27.04.2020 13.05.2020	69	whole plant no roots ears rest of plant w/o roots grain straw grain straw	5.5 1.7 5.7 0.17 4.4 0.18 3.7	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0.070 0.16 0.013 0.21 0.026 0.25 0.034	0.016 0.032 0.017 0.046 0.019 0.044 0.018	0.033 <0.010 0.069 <0.010 0.045 <0.010 0.024	0 27 27 34 34 41 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	Residues (mg/kg)					PHI (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				BAS 750 F	1,2,4-T	TA	TAA	TLA		
(a)		(b)				(c)								(d)	(e)
2021/2000401 L200230 64-000 Kokorzyn Wielkopolska Poland EU-North 2020	Barley GC 0640 / Sandra	1. 24.09.2019 2. 08.05-15.05.2020 3. 08.07.2020	0.10	200	0.05	**Plot 2** 27.04.2020 08.05.2020	59	whole plant no roots grain straw grain straw	2.5 0.038 0.71 <u>0.10</u> <u>1.2</u>	<0.010 <0.010 <0.010 <0.010 <0.010	0.033 0.18 0.012 0.18 0.013	0.027 0.097 0.40 0.12 0.036	0.058 <0.010 0.063 <0.010 0.047	0 48 48 55 55	
			0.15	200	0.075	**Plot 3** 29.04.2020 15.05.2020	69	whole plant no roots ears rest of plant w/o roots grain straw grain straw	3.6 0.54 1.6 0.12 2.8 0.11 4.2	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0.043 0.17 0.012 0.22 0.011 0.25 0.040	0.038 0.054 0.024 0.11 0.031 0.14 0.066	0.061 <0.010 0.071 <0.010 0.10 <0.010 0.072	0 28 28 34 34 41 41	

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
*Plot 2: treated with BAS 758 00 F; Plot 3: treated with BAS 750 01 F

Table A 6: Summary of residues of BAS 750 F and TDMs on barley in Northern Europe 2020 (untreated samples)

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	Residues (mg/kg)					PHI (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				BAS 750 F	1,2,4-T	TA	TAA	TLA		
(a)		(b)				(c)								(d)	(e)
2021/2000401 L200227 16833 Lentzke Brandenburg Germany EU-North 2020	Barley AS 0640 / Infinity	1. 04.10.2019 2. 13.05-21.05.2020 3. 13.07-14.07.2020	-	-	-	**Plot 1[1)]**	-	whole plant no roots grain straw	<0.010 <0.010 <0.010	<0.010 <0.010 <0.010	0.046 0.17 0.011	0.019 0.091 0.040	0.079 <0.010 0.039	0 DBLA 56 56	2021/2000401 BASF method L0076/09 for Mefentrifluconazole and L0170/02 for Triazole Metabolites LOQ: 0.010 mg/kg Storage time for all commodities ≤293 days (Mefentrifluconazole), ≤238 days Triazole Metabolites Samples were analysed within the storage stability (see chapter 7.2.1)
						Plot 1[2)]		whole plant no roots grain straw	<0.010 <0.010 <0.010	<0.010 <0.010 <0.010	0.051 0.16 <0.010	0.019 0.078 0.026	0.055 <0.010 0.044	0 DBLA 34 34	
2021/2000401 L200228 6562 KC Groesbeek Gelderland / Groesbeek The Netherlands EU-North 2020	Barley AS 0640 / Rafaela	1. 14.10.2019 2. 09.05.-18.05.2020 3. 30.06.-08-07.2020	-	-	-	**Plot 1[1)]**	-	whole plant no roots grain straw	<0.010 <0.010 <0.010	<0.010 <0.010 <0.010	0.031 0.095 <0.010	<0.010 0.057 0.023	0.053 <0.010 0.056	0 DBLA 56 56	
						Plot 1[2)]		whole plant no roots grain straw	<0.010 <0.010 <0.010	<0.010 <0.010 <0.010	0.038 0.096 <0.010	0.015 0.058 0.014	0.065 <0.010 0.050	0 DBLA 35 35	
2021/2000401 L200229 57810 Donnelay Grand Est / Moselle France EU-North 2020	Barley AS 0640 / Pixel	1. 10.10.2019 2. 07.05-13.05.2020 3. 30.06.2020	-	-	-	**Plot 1[1)]**	-	whole plant no roots grain straw	<0.010 <0.010 <0.010	<0.010 <0.010 <0.010	0.019 0.050 0.012	<0.010 0.013 <0.010	<0.010 <0.010 <0.010	0 DBLA 55 55	
						Plot 1[2)]		whole plant no roots grain straw	<0.010 <0.010 <0.010	<0.010 <0.010 <0.010	0.014 0.035 <0.010	<0.010 0.011 <0.010	<0.010 <0.010 0.015	0 DBLA 34 34	

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 treat-ment or date	Portion an-alyzed	Residues (mg/kg)					PHI (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				BAS 750 F	1,2,4-T	TA	TAA	TLA		
	(a)	(b)				(c)								(d)	(e)
2021/2000401 L200230 64-000 Kokorzyn Wielkopolska Poland EU-North 2020	Barley AS 0640 / Sandra	1. 24.09.2019 2. 08.05.- 15.05.2020 3. 08.07.2020	-	-	-	**Plot 1[1)]**	-	whole plant no roots grain straw	<0.010 <0.010 <0.010	<0.010 <0.010 <0.010	0.032 0.15 0.022	0.027 0.079 0.036	0.057 <0.010 0.034	0 DBLA 55 55	
						Plot 1[2)]		whole plant no roots grain straw	<0.010 <0.010 <0.010	<0.010 <0.010 <0.010	0.034 0.13 0.012	0.026 0.085 0.030	0.053 <0.010 0.074	0 DBLA 34 34	

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

[1)] Days after last application on plot 2. DBLA: Days before last application on plot 2.
[2)] Days after last application on plot 3. DBLA: Days before last application on plot 3.

A 2.1.3.2 Wheat (triticale)

Table A 7: 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)	1 - 2	0.150 kg as/ha	14	BBCH 49- 69	35**
Intended cGAP (1, 2, 3, 5, 6, 7, 9*)	2	0.100 kg as/ha	14	BBCH 30 - 59	F§

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

** 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).

A 2.1.3.2.1 Study 2 – wheat – BASF DocID 2021/2000402

Comments of zRMS:	The study has been accepted. 4 trials in Northern Europe were conducted in order to determine the magnitude of residues of BAS 750 F (Mefentrifluconazole), *BAS 500 F (Pyraclostrobin)*, *BAS 560 F (Metrafenone)*, 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in wheat under field conditions after two applications of either BAS 758 00 F, BAS 750 01 F, BAS 500 06 F or BAS 560 00 F. Amendment No. 2 was prepared to the Report of the Analytical Phase however, it was not applicable to the actives of the interest and not affected the study. The detailed data applying to other actives than the active being the subject of the assessment were omitted here. The field and the analytical phase were performed satisfactorily. The following analytical methods were used and adapted for residue analysis: BASF Method L0076/09 was adapted for BAS 750 F using LC-MS/MS to achieve a LOQ of 0.010 mg/kg. BASF Method L0170/02 was adapted for TDMs using LC-DMS-MS/MS to achieve a LOQ) of 0.010 mg/kg per analyte. Validation of the analytical methods was performed on plant matrices in separate studies. For all analytical methods concurrent procedural recoveries, performed with fortified untreated specimens at levels covering the working range from LOQ to 10xLOQ, were analysed together with the field specimens. Overall and average recoveries were all in the range of 70 – 110 % and relative standard deviations (RSD) were < 20 %. Both LC-MS/MS methods applied have the sufficient sensitivity and specificity. Two transitions were used for BAS 750 F: 398 m/z -> 182 m/z (quantification) and 398 m/z -> 133 m/z (confirmation). For TDMs the following transitions were applied:

Transitions:	1,2,4-T (Reg.No. 87084)	70 m/z → 43 m/z
	TAA (Reg.No. 137281)	128 m/z → 70 m/z
	TA (Reg.No. 270412)	157 m/z → 70 m/z
	TLA (Reg.No. 5050862)	158 m/z → 70 m/z
	1,2,4-T IS (Reg.No. 87084)	75 m/z → 46 m/z
	TAA IS (Reg.No. 137281)	133 m/z → 75 m/z
	TA IS (Reg.No. 270412)	162 m/z → 75 m/z
	TLA IS (Reg.No. 5050862)	163 m/z → 75 m/z

Summary of procedural recoveries for residue analysis – BAS 750 F

Matrix		Fortification Level [mg/kg]	BAS 750 F 398 m/z -> 182 m/z			
			Mean [%]	SD [±]	RSD [%]	n
Wheat	Whole plant (no roots)	0.010, 0.10 and 10	87.7	13	15	9
	Ears	0.010, 0.10 and 10	91.5	3.3	3.6	7
	Rest of plant without roots	0.010, 0.10 and 10	93.1	2.9	3.1	7
	Grain	0.010, 0.10 and 1.0	97.7	9.3	9.5	7
	Straw	0.010, 0.10 and 10	85.5	4.6	5.4	11
		Overall:	90.4	8.7	9.6	41

n: Number of results included in calculation. SD: Standard Deviation. RSD: Relative Standard Deviation.

Summary of procedural recoveries for residue analysis – 1,2,4-T

Matrix		Fortification Level [mg/kg]	1,2,4-Triazole (1,2,4-T) 70 m/z -> 43 m/z			
			Mean [%]	SD [±]	RSD [%]	n
Wheat	Whole plant (no roots)	0.010, 0.10 and 1.0	95.5	7.1	7.5	8
	Ears	0.010, 0.10 and 1.0	92.9	7.8	8.4	10
	Rest of plant without roots	0.010, 0.10 and 1.0	90.7	8.7	9.6	10
	Grain	0.010, 0.10 and 1.0	88.3	13	15	8
	Straw	0.010, 0.10 and 1.0	78.6	6.2	7.8	8
		Overall:	89.4	10	11	44

n: Number of results included in calculation. SD: Standard Deviation. RSD: Relative Standard Deviation.

Summary of procedural recoveries for residue analysis - TLA

Matrix		Fortification Level [mg/kg]	Triazole lactic acid (TLA) 158 m/z -> 70 m/z			
			Mean [%]	SD [±]	RSD [%]	n
Wheat	Whole plant (no roots)	0.010, 0.10 and 1.0	96.3	12	13	8
	Ears	0.010, 0.10 and 1.0	85.5	8.7	10	10
	Rest of plant without roots	0.010, 0.10 and 1.0	89.0	8.6	9.7	10
	Grain	0.010, 0.10 and 1.0	83.2	8.9	11	8
	Straw	0.010, 0.10 and 1.0	77.7	6.2	8.0	8
		Overall:	85.5	10	12	44

n: Number of results included in calculation. SD: Standard Deviation. RSD: Relative Standard Deviation.

Summary of procedural recoveries for residue analysis - TAA

Matrix		Fortification Level [mg/kg]	Triazole acetic acid (TAA) 128 m/z -> 70 m/z			
			Mean [%]	SD [±]	RSD [%]	n
Wheat	Whole plant (no roots)	0.010, 0.10 and 1.0	99.4	7.3	7.4	8
	Ears	0.010, 0.10 and 1.0	98.3	10	10	10
	Rest of plant without roots	0.010, 0.10 and 1.0	98.4	4.6	4.7	10
	Grain	0.010, 0.10 and 1.0	94.6	5.2	5.5	8
	Straw	0.010, 0.10 and 1.0	94.7	9.7	10	8
		Overall:	97.2	7.6	7.9	44

n: Number of results included in calculation. SD: Standard Deviation. RSD: Relative Standard Deviation.

Summary of procedural recoveries for residue analysis - TA

Matrix		Fortification Level [mg/kg]	Triazole alanine (TA) 157 m/z -> 70 m/z			
			Mean [%]	SD [±]	RSD [%]	n
Wheat	Whole plant (no roots)	0.010, 0.10 and 1.0	93.9	8.2	8.8	8
	Ears	0.010, 0.10 and 1.0	93.2	5.5	5.9	10
	Rest of plant without roots	0.010, 0.10 and 1.0	91.6	4.0	4.3	10
	Grain	0.010, 0.10 and 1.0	87.1	11	13	8
	Straw	0.010, 0.10 and 1.0	75.5	3.9	5.1	8
		Overall:	88.7	9.3	11	44

n: Number of results included in calculation. SD: Standard Deviation. RSD: Relative Standard Deviation.

The following tables summarize the residue results of treated specimens:

Summary of Residues in Treated Samples for BAS 750 F in Wheat

Sampling No.	Portion analysed		Timing DALA[1)]	Growth stage (BBCH)	n	Range of residues BAS 750 F [mg/kg]
Plot 2: treated twice with BAS 758 00 F						
1	Wheat	Whole plant (no roots)	0	59	4	1.5 - 2.5
2		Grain	48 - 50	87 - 89	4	< 0.010
		Straw			4	0.75 - 2.1
3		Grain	55 - 57	87 - 89	4	< 0.010
		Straw			4	0.77 - 2.1
4		Grain	63 - 64	89	4	< 0.010
		Straw			4	0.98 - 1.3
Plot 3: treated twice with BAS 750 01 F						
1	Wheat	Whole plant (no roots)	0	69	4	2.2 - 3.5
2		Ears	34	83	1	0.35
		Rest of plant without roots			1	3.1
		Grain	34 - 35	85 - 89	3	< 0.010
		Straw			3	3.6 - 5.3
3		Grain	41 - 42	87 - 89	4	< 0.010 - 0.012
		Straw			4	2.7 - 7.8
4		Grain	48 - 49	89	4	< 0.010 - 0.011
		Straw			4	3.8 - 5.6

[1)]: days after last application. n: Number of results included in calculation.

Summary of Residues in Treated Samples for TDMs

Sampling No.	Portion analysed		Timing 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]	Triazole alanine (TA) [mg/kg]
Plot 2: treated twice with BAS 758 00 F									
1	Wheat	Whole plant (no roots)	0	59	4	< 0.010	< 0.010 - 0.042	< 0.010 - 0.029	0.010 - 0.034
2		Grain	49-50	85-89	4	< 0.010	0.035 - 0.10	< 0.010	0.10 - 0.17
		Straw			4	< 0.010	< 0.010 - 0.077	0.010 - 0.050	< 0.010 - 0.011
3		Grain	56-57	87-89	4	< 0.010	0.038 - 0.10	< 0.010	0.10 - 0.19
		Straw			4	< 0.010	0.012 - 0.078	0.010 - 0.064	< 0.010
4		Grain	63-64	89	4	< 0.010	0.036 - 0.097	< 0.010	0.086 - 0.16
		Straw			4	< 0.010	< 0.010 - 0.078	< 0.010 - 0.042	< 0.010
Plot 3: treated twice with BAS 750 01 F									
1	Wheat	Whole plant (no roots)	0	69	4	< 0.010	< 0.010 - 0.047	< 0.010 - 0.029	0.014 - 0.056
2		Ears	34	83	1	< 0.010	0.055	< 0.010	0.15
		Rest of plant without roots			1	< 0.010	0.019	0.044	< 0.010
		Grain	34 - 35	85-89	3	< 0.010	0.041 - 0.14	< 0.010	0.15 - 0.21
		Straw			3	< 0.010	< 0.010 - 0.10	0.014 - 0.068	< 0.010 - 0.013
3		Grain	41 - 42	87-89	4	< 0.010	0.040 - 0.10	< 0.010	0.16 - 0.22
		Straw			4	< 0.010	0.016 - 0.076	0.016 - 0.048	< 0.010 - 0.015
4		Grain	48 - 49	89	4	< 0.010	0.041 - 0.14	< 0.010	0.15 - 0.22
		Straw			4	< 0.010	0.014 - 0.10	0.010 - 0.066	< 0.010 - 0.016

[1)]: days after last application. n: Number of results included in calculation.

Summary of Residues in Untreated Samples for TDMs

Sampling No.	Portion analysed		Timing 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]	Triazole Alanine (TA) [mg/kg]
Plot 1: Untreated (in regard to plot 2)									
1	Wheat	Whole plant (no roots)	0 DBLA	59	4	< 0.010	< 0.010 - 0.058	< 0.010 - 0.045	< 0.010 - 0.040
3	Wheat	Grain	55 - 57	87-89	4	< 0.010	0.021 - 0.14	< 0.010	0.045 - 0.14
		Straw			4	< 0.010	< 0.010 - 0.11	< 0.010 - 0.041	< 0.010 - 0.010
Plot 1: Untreated (in regard to plot 3)									
1	Wheat	Whole plant (no roots)	0 DBLA	69	4	< 0.010	< 0.010 - 0.057	< 0.010 - 0.034	< 0.010 - 0.042
2	Wheat	Ears	34	83	1	< 0.010	0.038	< 0.010	0.075
		Rest of plant without roots			1	< 0.010	0.016	0.023	< 0.010
		Grain	34 - 35	85-89	3	< 0.010	0.019 - 0.11	< 0.010	0.038 - 0.13
		Straw			3	< 0.010	< 0.010 - 0.098	< 0.010 - 0.040	< 0.010 - 0.017

[1)]: days after last application. DBLA: days before last application. In regard to plot 2 or plot 3.
n: Number of results included in calculation.

Further details: Each trial consisted of 5 plots: plot 1 (untreated, control), plot 2 (treated with BAS 758 00 F), plot 3 (treated with BAS 750 01 F), plot 4 (treated with BAS 500 06 F) and plot 5 (treated with BAS 560 00 F).

The treatment on plot 2 in all trials was performed using formulation BAS 758 00 F (EC formulation, nominal content 66.6 g BAS 750 F /L, 80.0 g BAS 500 F /L and 100.0 g BAS 560 F /L) 2 times at a single rate of 1.5 L of formulated product/ha, equals to 0.1 kg a.i./ha of BAS 750 F, 0.12 kg a.i./ha of BAS 500 F and 0.15 kg a.i./ha of BAS 560 F. The application timings were at 13-14 days before BBCH 59 (except of trial L200225: 19 days before BBCH 59) and at BBCH 59 with a spray volume of 200 L/ha.

The treatment on plot 3 in all trials was performed using formulation BAS 750 01 F (EC formulation, nominal content 100.0 g BAS 750 F /L) 2 times at a single rate of 1.5 L of formulated product/ha, equals to 0.15 kg a.i./ha of BAS 750 F. The application timings were at BBCH 49 and at BBCH 69 with a spray volume of 200 L/ha.

For plot 1 and plot 2: specimens of wheat were collected at the day of last application (on plot 1 immediately pre application of plot 2 (0 DBLA) and on plot 2 immediately post application (0 DALA)) as whole plant no roots. At 48-50 DALA (plot 2), 55-57 DALA (plot 1 and 2) and 63-64 DALA (plot 2) wheat specimens were collected as grain and straw.

For plot 1, plot 3, plot 4 and plot 5: specimens of wheat were collected at the day of last application (on plot 1 immediately pre application of plot 3 to 5 (0 DBLA) and on plots 3, 4 and 5 immediately post application (0 DALA)) as whole plant no roots. At 34-35 DALA (plots 1, 3,4 and 5), 41-42 DALA (plots 3, 4 and 5) and 48-49 DALA (plots 3, 4 and 5) wheat specimens were collected as ears and rest of plant without roots or grain and straw.
All wheat specimens of plot 1 (untreated) and plot 2 (treated) were analysed for BAS 750 F (Mefentrifluconazole), BAS 500 F (Pyraclostrobin) and its metabolite

M500F007, BAS 560 F (Metrafenone) and 1,2,4-T, TA, TAA and TLA.
All treated wheat specimens of plot 3 were analysed for BAS 750 F (Mefentrifluconazole) and 1,2,4-T, TA, TAA and TLA.

Residues of BAS 750 F (Mefentrifluconazole):
Plot 2: The residues of BAS 750 F analyzed in wheat whole plant no roots specimens sampled immediately after the last application (59 BBCH) ranged from 1.5 to 2.5 mg/kg. In grain specimens collected at 48-50 DALA (87-89 BBCH), 55-57 DALA (87-89 BBCH) and 63-64 DALA (89 BBCH) no residues of BAS 750 F were found at or above the LOQ (0.010 mg/kg). In straw specimens sampled at 48-50 DALA (87-89 BBCH) residues of BAS 750 F were analyzed between 0.75 and 2.1 mg/kg. At 55-57 DALA (87-89 BBCH) and 63-64 DALA (89 BBCH) residues of BAS 750 F were in a range from 0.77 to 2.1 mg/kg and from 0.98 to 1.3 mg/kg, respectively.

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 2.2 to 3.5 mg/kg. In ears specimens collected at 34 DALA (83 BBCH) a residue of BAS 750 F was found at 0.35 mg/kg. Rest of plant without roots specimens taken at the same sampling event showed a residue of BAS 750 F of 3.1 mg/kg. In grain specimens sampled at 34-35 DALA (85-89 BBCH) no residues of BAS 750 F were found at or above the LOQ (0.010 mg/kg). At 41-42 DALA (87-89 BBCH) and 48-49 DALA (89 BBCH) residues were analyzed from < 0.010 to 0.012 mg/kg and from < 0.010 to 0.011 mg/kg, respectively.

In straw specimens sampled at 34-35 DALA (85-89 BBCH) residues of BAS 750 F ranged from 3.6 to 5.3 mg/kg. At 41-42 DALA (87-89 BBCH) and 48-49 DALA (89 BBCH) residues were analyzed from 2.7 to 7.8 mg/kg and from 3.8 to 5.6 mg/kg, respectively.

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 758 00 F does not lead to higher residues than the respective solo formulation BAS 750 01 F.

The maximum storage interval between sampling and analysis (extraction) of the treated specimens were as follows:

Matrix	Analyte				
	BAS 750 F	BAS 500 F	M500F007	BAS 560 F	Triazole derivative metabolites
Wheat - Whole plant no roots	264 days	264 days	264 days	257 days	161 days
Wheat - Ears	227 days	227 days	227 days	227 days	162 days
Wheat - Rest of plant without roots	224 days	224 days	224 days	224 days	162 days
Wheat - Grain	199 days	199 days	199 days	199 days	162 days
Wheat - Straw	203 days	203 days	203 days	203 days	134 days

Reference:	CA 6.3.2/1
Report	Study on the residue behaviour of BAS 750 F (Mefentrifluconazole), BAS 500 F (Pyraclostrobin) and BAS 560 F (Metrafenone) in wheat after application of either BAS 758 00 F, BAS 750 01 F, BAS 500 06 F or BAS 560 00 F under field conditions in Northern Europe, 2020
	Erdmann, H. P., 2021
	Report No 876499, AC/BASF/20/03
	BASF DocID 2021/2000402
	Authority registration No
Guideline(s):	EEC 7029/VI/95 rev. 5 (July 22 1997)
	OECD 509 Crop Field Trial (2009)
	SANCO 7525/VI/95 - rev.10.3, 13 June 2017
Deviations:	No
GLP:	yes
	(certified by Land Brandenburg Ministerium der Justiz und fuer Europa und fuer Verbraucherschutz, Potsdam, Germany)
Acceptability:	Yes

Table A 8: Application and sampling details for trials conducted in 2020

Region	No. of trials	Plot No.	No. of Appl.	F,G, I[2]	Method	Test Item	Active Substance	Application		Target Timing	
								Rate (kg a.s./ha)	Water vol. (L/ha)	Appl.	Sampl. (DALA)[1]
Northern Europe	4	2	2	F	foliar	BAS 758 00 F (EC)	Mefentrifluconazole Pyraclostrobin Metrafenone	0.10 0.12 0.15	200	1st application: 13-14 days before application no. 2* 2nd application BBCH 59	0 DALA (whole plant no roots) 48-50, 55-57, 63-64 DALA (grain and straw)
		3	2	F	foliar	BAS 750 01 F (EC)	Mefentrifluconazole	0.15	200	1st application BBCH 49 2nd application BBCH 69	0 DALA (whole plant no roots) 34-35 DALA (ears and rest of plant w/o roots, grain and straw) 41-42 DALA (grain and straw) 48-49 DALA (grain and straw)
		4	2	F	foliar	BAS 500 06 F (EC)	Pyraclostrobin	0.25	200	1st application BBCH 49 2nd application BBCH 69	0 DALA (whole plant no roots) 34-35 DALA (ears and rest of plant w/o roots, grain and straw) 41-42 DALA (grain and straw) 48-49 DALA (grain and straw)
		5	2	F	foliar	BAS 560 00 F (SC)	Metrafenone	0.15	200	1st application BBCH 49 2nd application BBCH 69	0 DALA (whole plant no roots) 34-35 DALA (ears and rest of plant w/o roots, grain and straw) 41-42 DALA (grain and straw) 48-49 DALA (grain and straw)

1) days after last application, 2) Field, Glasshouse or Indoor
*except of trial L200225: 19 days before application no. 2, see deviation

Table A 9: Summary of recoveries of BAS 750 F in wheat matrices

Matrix		Fortification level [mg/kg]	BAS 750 F			
			n	Mean [%]	SD [±]	RSD [%]
Wheat	Whole plant no roots	0.010, 0.10 and 10	9	87.7	13	15
	Ears	0.010, 0.10 and 10	7	91.5	3.3	3.6
	Rest of plant without roots	0.010, 0.10 and 10	7	93.1	2.9	3.1
	Grain	0.010, 0.10 and 1.0	7	97.7	9.3	9.5
	Straw	0.010, 0.10 and 10	11	85.5	4.6	5.4
	Overall		**41**	**90.4**	**8.7**	**9.6**

SD = standard deviation, RSD = coefficient of variation, n = number of recoveries

Table A 10: Summary of recoveries of metabolites 1,2,4-triazole, TA, TAA and TLA in wheat matrices

Matrix		Fortification level [mg/kg]	1,2,4-Triazole (1,2,4-T)				Triazole alanine (TA)				Triazole acetic acid (TAA)				Triazole lactic acid (TLA)			
			n	**Mean [%]**	**SD [±]**	**RSD [%]**	**n**	**Mean [%]**	**SD [±]**	**RSD [%]**	**n**	**Mean [%]**	**SD [±]**	**RSD [%]**	**n**	**Mean [%]**	**SD [±]**	**RSD [%]**
Wheat	Whole plant no roots	0.010, 0.10 and 10	8	95.5	7.1	7.5	8	93.9	8.2	8.8	8	99.4	7.3	7.4	8	96.3	12	13
	Ears	0.010, 0.10 and 10	10	92.9	7.8	8.4	10	93.2	5.5	5.9	10	98.3	10	10	10	85.5	8.7	10
	Rest of plant without roots	0.010, 0.10 and 10	10	90.7	8.7	9.6	10	91.6	4.0	4.3	10	98.4	4.6	4.7	10	89.0	8.6	9.7
	Grain	0.010, 0.10 and 1.0	8	88.3	13	15	8	87.1	11	13	8	94.6	5.2	5.5	8	83.2	8.9	11
	Straw	0.010, 0.10 and 10	8	78.6	6.2	7.8	8	75.5	3.9	5.1	8	94.7	9.7	10	8	77.7	6.2	8.0
	Overall		**44**	**89.4**	**10**	**11**	**44**	**88.7**	**9.3**	**11**	**44**	**97.2**	**7.6**	**7.9**	**44**	**85.5**	**10**	**12**

SD = standard deviation, RSD = coefficient of variation, n = number of recoveries

Table A 11: Summary of residues of BAS 750 F and TDMs on wheat in Northern Europe 2020 (treated samples)

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	Residues (mg/kg)					PHI (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				BAS 750 F	1,2,4-T	TA	TAA	TLA		
(a)		(b)				(c)								(d)	(e)
2021/2000402 L200223 16833 Lentzke Brandenburg Germany EU-North 2020	Wheat GC 0654 / Linus	1. 21.10.2019 2. 02.06- 16.06.2020 3. 20.07- 03.08.2020	0.10	200	0.05	**Plot 2** 18.05.2020 01.06.2020	59	whole plant no roots grain straw grain straw grain straw	1.7 <0.010 2.0 <0.010 <1.6 <0.010 1.3	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0.034 0.16 0.011 0.16 <0.010 0.16 <0.010	0.042 0.10 0.077 0.10 0.078 0.097 0.078	0.029 <0.010 0.040 <0.010 0.046 <0.010 0.040	0 49 49 56 56 63 63	2021/2000402 Plot 2: BAS 758 00 F EC Mefentrifluconazole 66.6 g/L Plot 3: BAS 750 01 F EC Mefentrifluconazole 100 g/L BASF method L0076/09 for Mefentrifluconazole and L0170/02 for Triazole Metabolites LOQ: 0.010 mg/kg Storage time for all commodities ≤264 days (Mefentrifluconazole), ≤162 days Triazole Metabolites Samples were analysed within the storage stability (see chapter 7.2.1)
			0.15	200	0.075	**Plot 3** 25.05.2020 16.06.2020	69	whole plant no roots grain straw graiw straw grain straw	2.8 <0.010 5.3 0.012 7.8 0.011 5.6	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0.039 0.19 <0.010 0.18 <0.010 0.22 0.010	0.047 0.14 0.10 0.10 0.076 0.14 0.10	0.029 <0.010 0.068 <0.010 0.044 <0.010 0.061	0 35 35 41 41 48 48	
2021/2000402 L200224 6599 AV Ven-Zelderheide Limburg The Netherlands EU-North 2020	Wheat GC 0654 / Bennington	1. 25.11.2019 2. 02.06- 12.06.2020 3. 31.07- 03.08.2020	0.10	200	0.05	**Plot 2** 18.05.2020 31.05.2020	59	whole plant no roots grain straw grain straw grain straw	1.5 <0.01 0.80 <0.010 <1.3 <0.010 1.2	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0.030 0.15 0.010 0.15 <0.010 0.13 <0.010	0.019 0.061 0.029 0.066 0.034 0.061 0.033	0.018 <0.010 0.026 <0.010 0.025 <0.010 0.031	0 50 50 57 57 64 64	
			0.15	200	0.075	**Plot 3** 20.05.2020 12.06.2020	69	whole plant no roots grain straw grain straw grain straw	3.5 <0.010 3.6 <0.010 4.5 <0.010 3.8	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0.056 0.21 0.013 0.22 0.015 0.21 0.016	0.031 0.093 0.043 0.093 0.045 0.097 0.049	0.025 <0.010 0.041 <0.010 0.039 <0.010 0.041	0 35 35 42 42 49 49	

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	Residues (mg/kg)					PHI (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				BAS 750 F	1,2,4-T	TA	TAA	TLA		
	(a)	(b)				(c)								(d)	(e)
2021/2000402 L200225 64-020 Jasień Wielkopolska Poland EU-North 2020	Wheat GC 0654 / Arkadia	1. 15.10.2019 2. 03.06- 10.06.2020 3. 04.08.2020	0.10	200	0.05	**Plot 2** 13.05.2020 01.06.2020	59	whole plant no roots grain straw grain straw grain straw	2.0 <0.010 2.1 <u><0.010</u> <u>2.1</u> <0.010 1.2	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0.010 0.10 <0.010 0.10 <0.010 0.086 <0.010	<0.010 0.035 <0.010 0.038 0.012 0.036 <0.010	<0.010 <0.010 0.010 <0.010 0.010 <0.010 <0.010	0 49 49 56 56 64 64	
			0.15	200	0.075	**Plot 3** 26.05.2020 10.06.2020	69	whole plant no roots grain straw grain straw grain straw	3.4 <0.010 4.5 <0.010 5.9 <0.010 5.2	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0.014 0.15 <0.010 0.16 <0.010 0.15 <0.010	<0.010 0.041 <0.010 0.040 0.016 0.041 0.014	<0.010 <0.010 0.014 <0.010 0.016 <0.010 0.010	0 34 34 42 42 49 49	

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	Residues (mg/kg)					PHI (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				BAS 750 F	1,2,4-T	TA	TAA	TLA		
	(a)	(b)				(c)								(d)	(e)
2021/2000402 L200226 67170 Kriegsheim Grand Est France EU-North 2020	Wheat GC 0654 / Absalon	1. 18.10.2019 2. 13.05-20.05.2020 3. 06.07.2020	0.10	200	0.05	**Plot 2** 30.04.2020 13.05.2020	59	whole plant no roots grain straw grain straw grain straw	2.5 <0.010 0.75 <u><0.010</u> 0.77 <0.010 <u>0.98</u>	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0.031 0.17 <0.010 0.19 <0.010 0.14 <0.010	0.027 0.069 0.025 0.080 0.039 0.063 0.034	0.018 <0.010 0.050 <0.010 0.064 <0.010 0.042	0 48 48 55 55 64 64	
			0.15	200	0.075	**Plot 3** 05.05.2020 20.05.2020	69	whole plant no roots grain straw graiw straw grain straw	2.2 0.35 3.1 <0.010 2.7 <0.010 4.1	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0.045 0.15 <0.010 0.19 <0.010 0.21 0.011	0.043 0.055 0.019 0.082 0.024 0.080 0.040	0.026 <0.010 0.044 <0.010 0.048 <0.010 0.066	0 34 34 41 41 48 48	

(a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included
*Plot 2: treated with BAS 758 00 F; Plot 3: treated with BAS 750 01 F

Table A 12: Summary of residues of BAS 750 F and TDMs on wheat in Northern Europe 2020 (untreated samples)

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	Residues (mg/kg)					PHI (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				BAS 750 F	1,2,4-T	TA	TAA	TLA		
(a)		(b)				(c)								(d)	(e)
2021/2000402 L200223 16833 Lentzke Brandenburg Germany EU-North 2020	Wheat GC 0654 / Linus	1. 21.10.2019 2. 02.06-16.06.2020 3. 20.07-03.08.2020	-	-	-	**Plot 1[1)]**	-	whole plant no roots grain straw	<0.010 <0.010 <0.010	<0.010 <0.010 <0.010	0.040 0.14 <0.010	0.058 0.14 0.11	0.045 <0.010 0.041	0 DBLA 56 56	2021/2000402 BASF method L0076/09 for Mefentrifluconazole and L0170/02 for Triazole Metabolites LOQ: 0.010 mg/kg Storage time for all commodities ≤264 days (Mefentrifluconazole), ≤162 days Triazole Metabolites Samples were analysed within the storage stability (see chapter 7.2.1)
						Plot 1[2)]	-	whole plant no roots grain straw	<0.010 <0.010 <0.010	<0.010 <0.010 <0.010	0.042 0.12 <0.010	0.057 0.11 0.098	0.034 <0.010 0.040	0 DBLA 35 35	
2021/2000402 L200224 6599 AV Ven-Zelderheide Limburg The Netherlands EU-North 2020	Wheat GC 0654 / Bennington	1. 25.11.2019 2. 02.06-12.06.2020 3. 31.07-03.08.2020	-	-	-	**Plot 1[1)]**	-	whole plant no roots grain straw	<0.010 <0.010 <0.010	<0.010 <0.010 <0.010	0.030 0.13 <0.010	0.020 0.094 0.060	0.023 <0.010 0.033	0 DBLA 57 57	
						Plot 1[2)]	-	whole plant no roots grain straw	<0.010 <0.010 <0.010	<0.010 <0.010 <0.010	0.036 0.13 0.017	0.028 0.080 0.038	0.026 <0.010 0.024	0 DBLA 35 35	
2021/2000402 L200225 64-020 Jasień Wielkopolska Poland EU-North 2020	Wheat GC 0654 / Arkadia	1. 15.10.2019 2. 03.06-10.06.2020 3. 04.08.2020	-	-	-	**Plot 1[1)]**	-	whole plant no roots grain straw	<0.010 <0.010 <0.010	<0.010 <0.010 <0.010	<0.010 0.045 <0.010	<0.010 0.021 <0.010	<0.010 <0.010 <0.010	0 DBLA 56 56	
						Plot 1[2)]	-	whole plant no roots grain straw	<0.010 <0.010 <0.010	<0.010 <0.010 <0.010	<0.010 0.038 <0.010	<0.010 0.019 <0.010	<0.010 <0.010 <0.010	0 DBLA 34 34	

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	Residues (mg/kg)					PHI (days)	Details on trial
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				BAS 750 F	1,2,4-T	TA	TAA	TLA		
	(a)	(b)				(c)								(d)	(e)
2021/2000402 L200226 67170 Kriegs-heim Grand Est France EU-North 2020	Wheat GC 0654 / Absalon	1. 18.10.2019 2. 13.05-20.05.2020 3. 06.07.2020	-	-	-	**Plot 1[1)]**	-	whole plant no roots grain straw	<0.010 <0.010 <0.010	<0.010 <0.010 <0.010	0.018 0.11 0.010	0.018 0.058 0.048	0.013 <0.010 0.041	0 DBLA 55 55	
						Plot 1[2)]	-	whole plant no roots grain straw	<0.010 <0.010 <0.010	<0.010 <0.010 <0.010	0.026 0.075 <0.010	0.030 0.038 0.016	0.020 <0.010 0.023	0 DBLA 34 34	

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

1) Days after last application on plot 2. DBLA: Days before last application on plot 2.
2) Days after last application on plot 3. DBLA: Days before last application on plot 3.

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 was submitted in the framework of this application. In the context of the Annex I inclusion process two processing studies in wheat and barley were submitted by the applicant. These studies are summarized in Chapter 07.02. For a detailed assessment refer to the EFSA conclusion (2018a) and the DAR.

A 2.1.6 Magnitude of residues in representative succeeding crops

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 were submitted by the applicant. This study is summarized in Chapter 07.02. For a detailed assessment refer to the EFSA conclusion (2018a) and the DAR.

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

The active substance BAS 750 F and its formulation BAS 768 00 F are intended to be used in cereal crops. No “other study” is provided.

A 2.2 Sulfur

A 2.2.1 Stability of residues

No new studies submitted within this dossier.

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

No new studies submitted within this dossier.

A 2.2.3 Magnitude of residues in plants

A 2.2.3.1 Barley

Table A 13: 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, 2008)	1-2	4.8-6.4 kg a.s./ha	14 days	BBCH 25-77	35**
Intended cGAP (4, 8*)	2	0.200 kg a.s./ha	14 days	BBCH 30 - 59	F§

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

A 2.2.3.2 Wheat (triticale)

Table A 14: 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, 2008)	1-2	4.8-6.4 kg a.s./ha	14 days	BBCH 25-77	35**
Intended cGAP (1, 2, 3, 5, 6, 7, 9*)	2	0.200 kg a.s./ha	14 days	BBCH 30 - 59	F§

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

No new studies submitted within this dossier.

A 2.2.4 Magnitude of residues in livestock

No new studies submitted within this dossier.

A 2.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

No new studies submitted within this dossier.

A 2.2.6 Magnitude of residues in representative succeeding crops

No new studies submitted within this dossier.

A 2.2.7 Other/Special Studies (KCA 6.10, KCA 6.10.1)

No new studies submitted within this dossier.

A 2.3 Active substance 3

Not relevant.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

BAS 750 F-TMDI calculations

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

Mefentrifluconazole (BAS 750 F)

LOQs (mg/kg) range from: 0.01 to: 0.05

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)
56%	NL toddler	19.47	14%	Spinaches	12%	Apples	5%	Milk: Cattle	0.7%	24%
39%	DE child	13.57	14%	Apples	4%	Spinaches	4%	Table grapes	0.3%	13%
28%	NL child	9.73	7%	Apples	5%	Spinaches	3%	Table grapes	0.3%	11%
24%	GEMS/Food G08	8.27	7%	Olives for oil production	3%	Wine grapes	2%	Barley	0.4%	14%
22%	GEMS/Food G06	7.57	4%	Tomatoes	3%	Olives for oil production	3%	Table grapes	0.3%	14%
21%	GEMS/Food G11	7.18	3%	Wine grapes	2%	Celeries	2%	Olives for oil production	0.5%	11%
20%	IE adult	7.17	3%	Wine grapes	3%	Spinaches	2%	Rhubarbs	0.4%	12%
20%	GEMS/Food G07	6.84	4%	Wine grapes	3%	Olives for oil production	1%	Tomatoes	0.4%	9%
18%	GEMS/Food G15	6.36	3%	Wine grapes	2%	Olives for oil production	1%	Sweet peppers/bell peppers	0.4%	8%
17%	GEMS/Food G10	5.90	3%	Olives for oil production	2%	Tomatoes	1%	Wine grapes	0.4%	10%
16%	FR child 3 15 yr	5.69	2%	Spinaches	2%	Milk: Cattle	2%	Apples	0.3%	7%
16%	ES child	5.59	6%	Olives for oil production	2%	Spinaches	1%	Apples	0.3%	10%
16%	DE women 14-50 yr	5.53	3%	Apples	2%	Wine grapes	1%	Milk: Cattle	0.2%	5%
16%	FR toddler 2 3 yr	5.46	4%	Apples	3%	Spinaches	3%	Milk: Cattle	0.2%	7%
15%	DE general	5.42	3%	Apples	2%	Wine grapes	1%	Milk: Cattle	0.2%	5%
15%	PT general	5.40	6%	Wine grapes	2%	Olives for oil production	1%	Apples	0.2%	5%
15%	RO general	5.22	4%	Wine grapes	2%	Tomatoes	2%	Apples	0.2%	5%
13%	FR infant	4.56	5%	Spinaches	2%	Apples	1%	Milk: Cattle	0.1%	3%
13%	FR adult	4.55	6%	Wine grapes	1%	Spinaches	0.9%	Apples	0.2%	4%
13%	ES adult	4.50	4%	Olives for oil production	1%	Spinaches	1%	Wine grapes	0.1%	7%
13%	NL general	4.47	3%	Spinaches	2%	Apples	2%	Wine grapes	0.2%	6%
12%	DK child	4.09	3%	Apples	1%	Cucumbers	1%	Milk: Cattle	0.2%	4%
11%	UK infant	4.02	3%	Milk: Cattle	2%	Apples	0.5%	Cauliflowers	0.2%	3%
11%	UK toddler	3.81	2%	Apples	2%	Milk: Cattle	0.7%	Currants (red, black and white)	0.2%	4%
11%	SE general	3.68	1%	Spinaches	1%	Apples	1%	Milk: Cattle	0.2%	6%
10%	FI 3 yr	3.38	1%	Spinaches	1%	Apples	1.0%	Oat	0.3%	6%
10%	IT toddler	3.37	2%	Tomatoes	1%	Spinaches	1%	Apples	0.1%	5%
10%	IT adult	3.36	2%	Spinaches	1%	Tomatoes	0.9%	Apples	0.1%	6%
8%	UK vegetarian	2.69	2%	Wine grapes	0.7%	Tomatoes	0.7%	Spinaches	0.1%	3%
8%	DK adult	2.63	2%	Wine grapes	1%	Apples	0.6%	Tomatoes	0.1%	2%
7%	FI 6 yr	2.44	1%	Spinaches	0.7%	Apples	0.7%	Strawberries	0.2%	4%
7%	PL general	2.40	2%	Apples	1%	Tomatoes	0.8%	Table grapes	0.1%	2%
7%	UK adult	2.40	3%	Wine grapes	0.5%	Tomatoes	0.5%	Apples	0.1%	2%
6%	FI adult	1.94	0.8%	Coffee beans	0.8%	Wine grapes	0.7%	Apples	0.3%	2%
5%	LT adult	1.61	2%	Apples	0.7%	Tomatoes	0.3%	Milk: Cattle	0.1%	2%
2%	IE child	0.73	0.4%	Apples	0.3%	Milk: Cattle	0.2%	Currants (red, black and white)	0.0%	0.9%

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) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

BAS 750 F-IEDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Mefentrifluconazole (BAS 750 F)

LOQs (mg/kg) range from: **0.01** to: **0.05**

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)
15%	NL toddler	5.23	5%	Spinaches	2%	Apples	2%	Milk: Cattle	0.3%	7%
10%	DE child	3.41	3%	Apples	1%	Spinaches	0.7%	Table grapes	0.2%	4%
8%	NL child	2.63	2%	Spinaches	1%	Apples	0.7%	Milk: Cattle	0.2%	3%
5%	GEMS/Food G06	1.87	1%	Tomatoes	0.5%	Table grapes	0.4%	Olives for oil production	0.2%	3%
5%	IE adult	1.80	0.9%	Spinaches	0.6%	Wine grapes	0.4%	Rhubarbs	0.3%	3%
5%	GEMS/Food G08	1.79	0.8%	Olives for oil production	0.5%	Wine grapes	0.4%	Tomatoes	0.2%	3%
5%	GEMS/Food G11	1.75	0.6%	Spinaches	0.5%	Wine grapes	0.5%	Celeries	0.2%	3%
5%	GEMS/Food G07	1.65	0.8%	Wine grapes	0.4%	Tomatoes	0.3%	Olives for oil production	0.2%	2%
5%	FR child 3 15 yr	1.58	0.7%	Spinaches	0.7%	Milk: Cattle	0.4%	Apples	0.2%	2%
4%	GEMS/Food G15	1.55	0.5%	Wine grapes	0.4%	Tomatoes	0.3%	Sweet peppers/bell peppers	0.1%	2%
4%	FR toddler 2 3 yr	1.54	1%	Spinaches	0.8%	Milk: Cattle	0.7%	Apples	0.1%	2%
4%	GEMS/Food G10	1.51	0.4%	Tomatoes	0.4%	Olives for oil production	0.3%	Spinaches	0.2%	2%
4%	DE women 14-50 yr	1.37	0.6%	Apples	0.4%	Wine grapes	0.4%	Milk: Cattle	0.1%	1%
4%	RO general	1.35	0.9%	Wine grapes	0.6%	Tomatoes	0.3%	Milk: Cattle	0.0%	1%
4%	DE general	1.34	0.6%	Apples	0.4%	Wine grapes	0.4%	Milk: Cattle	0.1%	1%
4%	ES child	1.32	0.7%	Olives for oil production	0.6%	Spinaches	0.4%	Milk: Cattle	0.2%	2%
4%	FR infant	1.29	2%	Spinaches	0.5%	Milk: Cattle	0.4%	Apples	0.0%	2%
4%	NL general	1.23	1%	Spinaches	0.3%	Apples	0.3%	Wine grapes	0.1%	2%
3%	UK infant	1.14	1%	Milk: Cattle	0.4%	Apples	0.2%	Eggs: Chicken	0.1%	0.7%
3%	PT general	1.13	1%	Wine grapes	0.3%	Tomatoes	0.3%	Olives for oil production	0.1%	0.9%
3%	FR adult	1.09	1%	Wine grapes	0.4%	Spinaches	0.2%	Apples	0.1%	1.0%
3%	SE general	1.08	0.5%	Spinaches	0.4%	Milk: Cattle	0.3%	Bovine: Muscle/meat	0.1%	2%
3%	UK toddler	1.05	0.6%	Milk: Cattle	0.4%	Apples	0.2%	Currants (red, black and white)	0.1%	1.0%
3%	ES adult	1.04	0.5%	Spinaches	0.4%	Olives for oil production	0.3%	Tomatoes	0.1%	2%
3%	DK child	1.01	0.5%	Apples	0.4%	Milk: Cattle	0.2%	Cucumbers	0.1%	0.8%
3%	IT adult	0.88	0.7%	Spinaches	0.4%	Tomatoes	0.2%	Apples	0.1%	2%
2%	IT toddler	0.85	0.5%	Tomatoes	0.4%	Spinaches	0.2%	Apples	0.1%	1%
2%	FI 3 yr	0.83	0.5%	Spinaches	0.2%	Apples	0.2%	Strawberries	0.1%	1%
2%	FI adult	0.67	0.8%	Coffee beans	0.2%	Tomatoes	0.2%	Wine grapes	0.8%	0.6%
2%	UK vegetarian	0.65	0.4%	Wine grapes	0.2%	Spinaches	0.2%	Tomatoes	0.1%	0.8%
2%	DK adult	0.64	0.5%	Wine grapes	0.2%	Apples	0.2%	Tomatoes	0.0%	0.5%
2%	FI 6 yr	0.62	0.4%	Spinaches	0.2%	Strawberries	0.1%	Tomatoes	0.1%	1%
2%	UK adult	0.60	0.6%	Wine grapes	0.1%	Tomatoes	0.1%	Spinaches	0.0%	0.6%
2%	PL general	0.57	0.5%	Apples	0.3%	Tomatoes	0.2%	Table grapes	0.0%	0.6%
1%	LT adult	0.48	0.4%	Apples	0.2%	Tomatoes	0.1%	Milk: Cattle	0.0%	0.4%
0.6%	IE child	0.20	0.1%	Milk: Cattle	0.1%	Apples	0.1%	Currants (red, black and white)	0.0%	0.2%

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) is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

BAS 750 F-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)
0.4%	Barley	0.6 / 0.1	0.56	0.3%	Barley	0.6 / 0.1	0.48
0.10%	Wheat	0.05 / 0.01	0.14	0.06%	Wheat	0.05 / 0.01	0.08
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

BAS 750 F-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)
0.4%	Barley / milling (flour)	0.6 / 0.37	0.66	0.1%	Barley / beer	0.6 / 0	0.14
0.2%	Barley / cooked	0.6 / 0.1	0.36	0.03%	Wheat / bread/pizza	0.05 / 0.01	0.04
0.0%	Wheat / milling (flour)	0.05 / 0	0.04	0.03%	Wheat / pasta	0.05 / 0.01	0.04
0.0%	Wheat / milling (wholemea	0.05 / 0.01	0.03	0.01%	Wheat / bread	0.05 / 0.01	0.02
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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 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-T - IEDI calculations

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

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

to:

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)
86%	NL toddler	19.83	78%	Milk: Cattle	2%	Maize/corn	1%	Bovine: Muscle/meat		1%
55%	UK infant	12.57	50%	Milk: Cattle	1%	Bovine: Muscle/meat	0.6%	Wheat		0.6%
43%	FR toddler 2 3 yr	10.00	38%	Milk: Cattle	1%	Bovine: Muscle/meat	0.7%	Wheat		0.7%
38%	NL child	8.84	32%	Milk: Cattle	2%	Sugar beet roots	1%	Bovine: Muscle/meat		0.8%
37%	FR child 3 15 yr	8.40	30%	Milk: Cattle	2%	Bovine: Muscle/meat	1.0%	Wheat		1%
32%	UK toddler	7.25	27%	Milk: Cattle	2%	Bovine: Muscle/meat	0.9%	Wheat		0.8%
30%	DE child	6.94	26%	Milk: Cattle	0.9%	Wheat	0.9%	Oranges		1%
24%	FR infant	5.43	22%	Milk: Cattle	0.4%	Bovine: Muscle/meat	0.3%	Sugar beet roots		0.3%
23%	SE general	5.31	16%	Milk: Cattle	5%	Bovine: Muscle/meat	0.7%	Wheat		0.6%
22%	DK child	5.17	16%	Milk: Cattle	2%	Bovine: Muscle/meat	1%	Swine: Muscle/meat		0.3%
22%	ES child	4.95	16%	Milk: Cattle	2%	Bovine: Muscle/meat	1.0%	Wheat		0.9%
20%	DE women 14-50 yr	4.63	16%	Milk: Cattle	1.0%	Sugar beet roots	0.5%	Swine: Muscle/meat		0.7%
20%	DE general	4.61	16%	Milk: Cattle	0.9%	Sugar beet roots	0.6%	Swine: Muscle/meat		0.6%
19%	RO general	4.40	15%	Milk: Cattle	1%	Wheat	0.7%	Swine: Muscle/meat		0.5%
15%	GEMS/Food G11	3.44	10%	Milk: Cattle	0.8%	Bovine: Muscle/meat	0.8%	Soyabeans		1%
15%	NL general	3.37	11%	Milk: Cattle	0.9%	Bovine: Muscle/meat	0.6%	Sugar beet roots		0.5%
14%	GEMS/Food G15	3.29	9%	Milk: Cattle	1.0%	Wheat	0.8%	Swine: Muscle/meat		1%
14%	GEMS/Food G07	3.18	8%	Milk: Cattle	1%	Bovine: Muscle/meat	0.9%	Wheat		1%
12%	GEMS/Food G08	2.83	7%	Milk: Cattle	1%	Swine: Muscle/meat	0.9%	Wheat		1%
12%	GEMS/Food G10	2.81	7%	Milk: Cattle	1%	Bovine: Muscle/meat	0.9%	Wheat		1%
10%	ES adult	2.21	6%	Milk: Cattle	0.9%	Bovine: Muscle/meat	0.5%	Wheat		0.6%
9%	IE adult	2.15	6%	Milk: Cattle	0.5%	Wheat	0.5%	Bovine: Muscle/meat		1.0%
9%	DK adult	2.09	7%	Milk: Cattle	0.6%	Bovine: Muscle/meat	0.5%	Swine: Muscle/meat		0.2%
9%	FR adult	2.00	6%	Milk: Cattle	0.7%	Bovine: Muscle/meat	0.5%	Wheat		0.3%
8%	GEMS/Food G06	1.87	3%	Milk: Cattle	2%	Wheat	0.3%	Sugar beet roots		1%
7%	LT adult	1.63	5%	Milk: Cattle	0.5%	Swine: Muscle/meat	0.3%	Bovine: Muscle/meat		0.2%
6%	UK adult	1.34	4%	Milk: Cattle	0.8%	Bovine: Muscle/meat	0.4%	Wheat		0.3%
6%	UK vegetarian	1.27	4%	Milk: Cattle	0.4%	Wheat	0.2%	Oranges		0.4%
5%	IE child	1.23	5%	Milk: Cattle	0.3%	Wheat	0.1%	Swine: Muscle/meat		0.1%
2%	PT general	0.45	0.9%	Wheat	0.2%	Potatoes	0.1%	Oranges		0.4%
2%	IT toddler	0.44	1%	Wheat	0.1%	Oranges	0.1%	Tomatoes		0.3%
1%	IT adult	0.30	0.9%	Wheat	0.1%	Oranges	0.1%	Tomatoes		0.3%
1%	FI 3 yr	0.27	0.3%	Wheat	0.2%	Potatoes	0.1%	Rye		0.3%
1.0%	FI 6 yr	0.22	0.2%	Wheat	0.2%	Potatoes	0.1%	Rye		0.3%
0.6%	FI adult	0.14	0.2%	Rye	0.1%	Oranges	0.1%	Wheat		0.2%
0.5%	PL general	0.11	0.1%	Potatoes	0.1%	Apples	0.1%	Head cabbages		0.2%

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.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

1,2,4-T - 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 No. of commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** 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)
0.7%	Wheat	0 / 0.05	0.72	0.4%	Wheat	0 / 0.05	0.42
0.3%	Barley	0 / 0.05	0.28	0.2%	Barley	0 / 0.05	0.24
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

1,2,4-T - IESTI calculations – Raw 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	0.4%	Barley / beer	0 / 0.01	0.36
0.3%	Wheat / milling (wholemeal)	0 / 0.05	0.28	0.2%	Wheat / bread/pizza	0 / 0.05	0.22
0.2%	Barley / cooked	0 / 0.05	0.18	0.2%	Wheat / pasta	0 / 0.05	0.19
0.1%	Barley / milling (flour)	0 / 0.05	0.09	0.2%	Wheat / bread (wholemeal)	0 / 0.05	0.17
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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 1,2,4-T is unlikely to present a public health risk.

For processed commodities, no exceedance of the ARfD/ADI was identified.

TA - IEDI calculations

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

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)
6%	NL toddler	16.51	1%	Maize/corn	0.8%	Wheat	0.8%	Milk: Cattle		0.7%
4%	GEMS/Food G10	10.98	1%	Soyabeans	0.8%	Wheat	0.2%	Potatoes		2%
4%	GEMS/Food G06	10.94	1%	Wheat	0.4%	Soyabeans	0.3%	Maize/corn		1%
4%	GEMS/Food G08	10.89	0.8%	Wheat	0.7%	Soyabeans	0.3%	Olives for oil production		1%
4%	GEMS/Food G11	10.52	1%	Soyabeans	0.7%	Wheat	0.2%	Potatoes		2%
3%	GEMS/Food G07	10.21	0.9%	Wheat	0.6%	Soyabeans	0.2%	Potatoes		1%
3%	GEMS/Food G15	10.13	0.9%	Wheat	0.6%	Soyabeans	0.2%	Potatoes		1%
3%	DK child	9.35	1%	Rye	0.9%	Wheat	0.2%	Bovine: Muscle/meat		0.3%
3%	DE child	9.07	0.9%	Wheat	0.4%	Oranges	0.3%	Apples		0.9%
3%	NL child	8.90	0.9%	Wheat	0.3%	Milk: Cattle	0.2%	Potatoes		0.5%
3%	FR child 3 15 yr	8.56	1.0%	Wheat	0.4%	Oranges	0.3%	Milk: Cattle		0.7%
3%	RO general	7.86	1%	Wheat	0.2%	Sunflower seeds	0.2%	Potatoes		0.4%
3%	ES child	7.51	0.9%	Wheat	0.3%	Olives for oil production	0.2%	Oranges		0.7%
2%	SE general	7.03	0.7%	Bovine: Muscle/meat	0.7%	Wheat	0.3%	Potatoes		0.4%
2%	UK infant	6.97	0.5%	Wheat	0.5%	Milk: Cattle	0.2%	Maize/corn		0.4%
2%	UK toddler	6.52	0.8%	Wheat	0.3%	Milk: Cattle	0.2%	Potatoes		0.5%
2%	FR toddler 2 3 yr	6.51	0.6%	Wheat	0.4%	Milk: Cattle	0.2%	Bovine: Muscle/meat		0.5%
2%	PT general	5.99	0.8%	Wheat	0.3%	Potatoes	0.1%	Soyabeans		0.5%
2%	IE adult	5.96	0.5%	Wheat	0.1%	Potatoes	0.1%	Oranges		0.7%
2%	IT toddler	5.44	1%	Wheat	0.1%	Tomatoes	0.1%	Potatoes		0.3%
2%	DE women 14-50 yr	5.04	0.4%	Wheat	0.2%	Oranges	0.2%	Milk: Cattle		0.5%
2%	DE general	5.02	0.4%	Wheat	0.2%	Oranges	0.2%	Milk: Cattle		0.4%
2%	NL general	4.73	0.4%	Wheat	0.1%	Potatoes	0.1%	Milk: Cattle		0.3%
2%	ES adult	4.60	0.5%	Wheat	0.1%	Olives for oil production	0.1%	Oranges		0.5%
1%	IT adult	3.71	0.3%	Wheat	0.1%	Tomatoes	0.0%	Peaches		0.2%
1%	FI 3 yr	3.64	0.3%	Potatoes	0.2%	Wheat	0.1%	Rye		0.3%
1%	FR adult	3.52	0.5%	Wheat	0.1%	Bovine: Muscle/meat	0.1%	Oranges		0.2%
1%	LT adult	3.19	0.2%	Rye	0.2%	Wheat	0.2%	Potatoes		0.1%
1.0%	FI 6 yr	2.90	0.2%	Potatoes	0.2%	Wheat	0.1%	Rye		0.3%
0.9%	FR infant	2.77	0.2%	Milk: Cattle	0.2%	Wheat	0.1%	Potatoes		0.2%
0.9%	UK vegetarian	2.77	0.4%	Wheat	0.1%	Oranges	0.1%	Potatoes		0.3%
0.9%	DK adult	2.73	0.2%	Wheat	0.1%	Rye	0.1%	Bovine: Muscle/meat		0.2%
0.9%	UK adult	2.59	0.3%	Wheat	0.1%	Bovine: Muscle/meat	0.1%	Potatoes		0.2%
0.5%	FI adult	1.62	0.1%	Rye	0.1%	Potatoes	0.1%	Wheat		0.2%
0.5%	PL general	1.44	0.2%	Potatoes	0.1%	Tomatoes	0.0%	Apples		0.2%
0.4%	IE child	1.29	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Potatoes		0.1%

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.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

TA - 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
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%	Barley	0 / 0.62	3.5

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
1%	Barley	0 / 0.62	3.0

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

TA - 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 (wholemeal)	0 / 0.53	3.0	0.8%	Wheat / pasta	0 / 0.62	2.4
0.8%	Barley / cooked	0 / 0.62	2.3	0.6%	Wheat / bread (wholemeal)	0 / 0.53	1.9
0.4%	Barley / milling (flour)	0 / 0.75	1.3	0.3%	Barley / beer	0 / 0.02	0.89
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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.

TAA - IEDI calculations

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

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	13.10	0.6%	Maize/corn	0.3%	Wheat	0.2%	Milk: Cattle		0.0%
0.9%	DK child	9.05	0.4%	Rye	0.3%	Wheat	0.1%	Milk: Cattle		0.0%
0.8%	GEMS/Food G06	7.56	0.6%	Wheat	0.1%	Maize/corn	0.0%	Soyabeans		0.0%
0.6%	DE child	6.01	0.3%	Wheat	0.1%	Milk: Cattle	0.1%	Rye		0.0%
0.6%	GEMS/Food G15	5.95	0.4%	Wheat	0.1%	Barley	0.1%	Maize/corn		0.0%
0.6%	GEMS/Food G08	5.90	0.3%	Wheat	0.1%	Barley	0.0%	Rye		0.0%
0.6%	NL child	5.81	0.3%	Wheat	0.1%	Milk: Cattle	0.0%	Sugar beet roots		0.0%
0.6%	FR child 3 15 yr	5.78	0.4%	Wheat	0.1%	Milk: Cattle	0.0%	Maize/corn		0.0%
0.6%	RO general	5.77	0.4%	Wheat	0.1%	Maize/corn	0.0%	Milk: Cattle		0.0%
0.5%	IT toddler	5.43	0.5%	Wheat	0.0%	Apples	0.0%	Oranges		0.0%
0.5%	GEMS/Food G10	5.34	0.3%	Wheat	0.1%	Maize/corn	0.0%	Barley		0.1%
0.5%	GEMS/Food G07	5.30	0.3%	Wheat	0.0%	Barley	0.0%	Milk: Cattle		0.0%
0.5%	UK infant	5.09	0.2%	Wheat	0.2%	Milk: Cattle	0.1%	Maize/corn		0.0%
0.5%	GEMS/Food G11	4.86	0.3%	Wheat	0.1%	Barley	0.0%	Soyabeans		0.1%
0.5%	ES child	4.79	0.4%	Wheat	0.0%	Milk: Cattle	0.0%	Maize/corn		0.0%
0.5%	UK toddler	4.57	0.3%	Wheat	0.1%	Milk: Cattle	0.0%	Sugar beet roots		0.0%
0.4%	FR toddler 2 3 yr	4.36	0.2%	Wheat	0.1%	Milk: Cattle	0.0%	Sugar beet roots		0.0%
0.4%	PT general	4.05	0.3%	Wheat	0.0%	Maize/corn	0.0%	Wine grapes		0.0%
0.4%	SE general	3.69	0.3%	Wheat	0.0%	Milk: Cattle	0.0%	Rye		0.0%
0.4%	DE general	3.58	0.1%	Wheat	0.0%	Milk: Cattle	0.0%	Rye		0.0%
0.4%	DE women 14-50 yr	3.50	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Rye		0.0%
0.3%	IT adult	3.41	0.3%	Wheat	0.0%	Apples	0.0%	Oranges		0.0%
0.3%	IE adult	2.84	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Maize/corn		0.0%
0.3%	ES adult	2.87	0.2%	Wheat	0.0%	Barley	0.0%	Milk: Cattle		0.0%
0.3%	NL general	2.79	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Barley		0.0%
0.2%	FR adult	2.40	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Wine grapes		0.0%
0.2%	FI 3 yr	2.18	0.1%	Wheat	0.1%	Rye	0.0%	Oat		0.0%
0.2%	LT adult	2.17	0.1%	Rye	0.1%	Wheat	0.0%	Milk: Cattle		0.0%
0.2%	UK vegetarian	2.05	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Oranges		0.0%
0.2%	DK adult	1.76	0.1%	Wheat	0.0%	Rye	0.0%	Milk: Cattle		0.0%
0.2%	FI 6 yr	1.73	0.1%	Wheat	0.0%	Rye	0.0%	Oat		0.0%
0.2%	UK adult	1.72	0.1%	Wheat	0.0%	Milk: Cattle	0.0%	Wine grapes		0.0%
0.2%	FR infant	1.58	0.1%	Milk: Cattle	0.1%	Wheat	0.0%	Sugar beet roots		0.0%
0.1%	IE child	1.14	0.1%	Wheat	0.0%	Milk: Cattle	0.0%	Apples		0.0%
0.1%	FI adult	1.05	0.1%	Rye	0.0%	Wheat	0.0%	Oat		0.0%
0.0%	PL general	0.16	0.0%	Apples	0.0%	Potatoes	0.0%	Table grapes		0.0%

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.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

TAA - 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)
1%	Wheat	0 / 0.79	11	0.7%	Wheat	0 / 0.79	6.6
0.4%	Barley	0 / 0.79	4.4	0.4%	Barley	0 / 0.79	3.8

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

TAA - 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	0.4%	Barley / beer	0 / 0.12	4.3
0.5%	Wheat / milling (wholemeal)	0 / 0.94	5.2	0.3%	Wheat / bread/pizza	0 / 0.79	3.5
0.3%	Barley / milling (flour)	0 / 1.67	3.0	0.3%	Wheat / bread (wholemeal)	0 / 0.94	3.3
0.3%	Barley / cooked	0 / 0.79	2.9	0.3%	Wheat / pasta	0 / 0.79	3.0
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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.

TLA - IEDI calculations

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

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 : ---

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	3.86	0.8%	Milk: Cattle	0.1%	Apples	0.1%	Maize/corn		0.1%
0.7%	UK infant	2.06	0.5%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat		0.0%
0.6%	DE child	1.92	0.3%	Milk: Cattle	0.1%	Apples	0.0%	Oranges		0.1%
0.6%	NL child	1.90	0.3%	Milk: Cattle	0.1%	Apples	0.0%	Wheat		0.1%
0.6%	FR toddler 2 3 yr	1.77	0.4%	Milk: Cattle	0.0%	Apples	0.0%	Wheat		0.1%
0.6%	FR child 3 15 yr	1.67	0.3%	Milk: Cattle	0.0%	Oranges	0.0%	Wheat		0.1%
0.5%	UK toddler	1.36	0.3%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes		0.0%
0.4%	DK child	1.25	0.2%	Milk: Cattle	0.0%	Rye	0.0%	Wheat		0.0%
0.4%	GEMS/Food G11	1.23	0.1%	Milk: Cattle	0.1%	Soyabeans	0.0%	Potatoes		0.1%
0.4%	GEMS/Food G08	1.16	0.1%	Milk: Cattle	0.0%	Soyabeans	0.0%	Wheat		0.1%
0.4%	GEMS/Food G15	1.15	0.1%	Milk: Cattle	0.0%	Soyabeans	0.0%	Wheat		0.1%
0.4%	GEMS/Food G07	1.14	0.1%	Milk: Cattle	0.0%	Soyabeans	0.0%	Wheat		0.1%
0.4%	RO general	1.13	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes		0.0%
0.4%	ES child	1.11	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Oranges		0.1%
0.4%	GEMS/Food G10	1.11	0.1%	Milk: Cattle	0.1%	Soyabeans	0.0%	Wheat		0.1%
0.4%	SE general	1.08	0.2%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.0%	Potatoes		0.1%
0.3%	DE general	1.05	0.2%	Milk: Cattle	0.0%	Apples	0.0%	Oranges		0.0%
0.3%	DE women 14-50 yr	1.04	0.2%	Milk: Cattle	0.0%	Apples	0.0%	Oranges		0.1%
0.3%	FR infant	0.95	0.2%	Milk: Cattle	0.0%	Apples	0.0%	Potatoes		0.0%
0.3%	GEMS/Food G06	0.91	0.1%	Wheat	0.0%	Tomatoes	0.0%	Milk: Cattle		0.1%
0.3%	NL general	0.82	0.1%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples		0.0%
0.2%	IE adult	0.73	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Wine grapes		0.1%
0.2%	ES adult	0.63	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Barley		0.0%
0.2%	FR adult	0.57	0.1%	Milk: Cattle	0.0%	Wine grapes	0.0%	Wheat		0.0%
0.2%	PT general	0.53	0.0%	Potatoes	0.0%	Wine grapes	0.0%	Wheat		0.0%
0.2%	DK adult	0.52	0.1%	Milk: Cattle	0.0%	Wine grapes	0.0%	Swine: Muscle/meat		0.0%
0.2%	LT adult	0.49	0.1%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples		0.0%
0.1%	FI 3 yr	0.38	0.0%	Potatoes	0.0%	Oat	0.0%	Cucumbers		0.0%
0.1%	UK vegetarian	0.38	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Wine grapes		0.0%
0.1%	UK adult	0.38	0.0%	Milk: Cattle	0.0%	Wine grapes	0.0%	Wheat		0.0%
0.1%	IT toddler	0.34	0.0%	Wheat	0.0%	Tomatoes	0.0%	Apples		0.0%
0.1%	FI 6 yr	0.29	0.0%	Potatoes	0.0%	Oat	0.0%	Wheat		0.0%
0.1%	IT adult	0.26	0.0%	Wheat	0.0%	Tomatoes	0.0%	Apples		0.0%
0.1%	IE child	0.25	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes		0.0%
0.1%	PL general	0.23	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes		0.0%
0.1%	FI adult	0.17	0.0%	Potatoes	0.0%	Apples	0.0%	Tomatoes		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.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

TLA - 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. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the

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)
0.2%	Barley	0 / 0.09	0.51	0.1%	Barley	0 / 0.09	0.44
0.1%	Wheat	0 / 0.02	0.32	0.06%	Wheat	0 / 0.02	0.18
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

TLA - 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)
0.2%	Barley / milling (flour)	0 / 0.29	0.53	2%	Barley / beer	0 / 0.13	4.7
0.1%	Barley / cooked	0 / 0.08	0.28	0.03%	Wheat / bread/pizza	0 / 0.02	0.10
0.1%	Wheat / milling (flour)	0 / 0.02	0.27	0.03%	Wheat / pasta	0 / 0.02	0.08
0.0%	Wheat / milling (wholemeal)	0 / 0.02	0.12	0.03%	Wheat / bread (wholemeal)	0 / 0.02	0.08
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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.

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	DE child	DK child	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	LT adult
Triazole alanine																					
Barley	0.621	STMR																			
Wheat (triticale)	0.621	STMR																			
			µg/kg bw/day	3.1112	6.1631	2.7557	0.4880	1.9168	2.8647	4.1340	2.8125	2.6684	1.6274	2.4457	1.0250	1.7636	0.6481	1.3839	1.5236	2.5739	1.3590
			mg/kg bw/day	0.0031	0.0062	0.0028	0.0005	0.0019	0.0029	0.0041	0.0028	0.0027	0.0016	0.0024	0.0010	0.0018	0.0006	0.0014	0.0015	0.0026	0.0014
			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
			HQ	**0.0104**	**0.021**	**0.009**	**0.002**	**0.006**	**0.010**	**0.014**	**0.009**	**0.009**	**0.005**	**0.008**	**0.003**	**0.006**	**0.002**	**0.005**	**0.005**	**0.009**	**0.005**
Triazole lactic acid																					
Barley	0.076	STMR																			
Wheat (triticale)	0.022	STMR																			
			µg/kg bw/day	0.1108	0.2183	0.0977	0.0173	0.0681	0.1020	0.1470	0.1088	0.0951	0.0577	0.0874	0.0363	0.0891	0.0240	0.0491	0.0546	0.0917	0.0514
			mg/kg bw/day	1E-04	2E-04	1E-04	2E-05	7E-05	1E-04	1E-04	1E-04	1E-04	6E-05	9E-05	4E-05	9E-05	2E-05	5E-05	5E-05	9E-05	5E-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
			HQ	**0.0004**	**0.001**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
Cummulative risk HI				**0.011**	**0.021**	**0.010**	**0.002**	**0.007**	**0.010**	**0.014**	**0.010**	**0.009**	**0.006**	**0.008**	**0.004**	**0.006**	**0.002**	**0.005**	**0.005**	**0.009**	**0.005**

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	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																					
Barley	0.621	STMR																			
Wheat (triticale)	0.621	STMR																			
			µg/kg bw/day	1.4258	0.0000	2.5368	3.1464	2.1714	1.0614	1.2960	4.5595	3.0280	3.4541	2.8664	2.7382	3.4494	1.8469	1.7478	0.7246	1.1852	1.0208
			mg/kg bw/day	0.0014	0.0000	0.0025	0.0031	0.0022	0.0011	0.0013	0.0046	0.0030	0.0035	0.0029	0.0027	0.0034	0.0018	0.0017	0.0007	0.0012	0.0010
			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
			HQ	**0.005**	**0.000**	**0.008**	**0.010**	**0.007**	**0.004**	**0.004**	**0.015**	**0.010**	**0.012**	**0.010**	**0.009**	**0.011**	**0.006**	**0.006**	**0.002**	**0.004**	**0.003**
Triazole lactic acid																					
Barley	0.076	STMR																			
Wheat (triticale)	0.022	STMR																			
			µg/kg bw/day	0.0663	0.0000	0.0915	0.1115	0.0769	0.0390	0.0470	0.1654	0.1398	0.1705	0.1333	0.1390	0.1642	0.0929	0.0721	0.0259	0.0455	0.0394
			mg/kg bw/day	7E-05	0E+00	9E-05	1E-04	8E-05	4E-05	5E-05	2E-04	1E-04	2E-04	1E-04	1E-04	2E-04	9E-05	7E-05	3E-05	5E-05	4E-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	1.3
			HQ	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**	**0.001**	**0.000**	**0.001**	**0.000**	**0.000**	**0.001**	**0.000**	**0.000**	**0.000**	**0.000**	**0.000**
Cummulative risk HI				**0.005**	**0.000**	**0.009**	**0.011**	**0.007**	**0.004**	**0.004**	**0.016**	**0.011**	**0.012**	**0.010**	**0.010**	**0.012**	**0.006**	**0.006**	**0.003**	**0.004**	**0.003**

Sulfur

EFSA (2008) concluded:
"*A consumer risk assessment is neither possible nor necessary, as the mammalian toxicology assessment has concluded that sulfur is of low toxicity, and it is not necessary to set an ADI or ARfD. Therefore, a consumer risk assessment is neither possible nor necessary*."

Active Substance 3
Not relevant

Appendix 4 Additional information provided by the applicant

Not relevant.