FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: BAS 758 00 F

Product name(s): Revyflex Plus

Chemical active substance(s):

Mefentrifluconazole, 66.6 g/L

Metrafenone, 100 g/L

Pyraclostrobin, 80 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: BASF

Submission date: March 2022

MS Finalisation date: 27/01/2023

Version history

When	What
03/2022	Initial dRR – BASF DocID 2021/2050429
04/2022	Dossier sent for evaluation
10/2022	zRMS evaluation of dRR
December 2022	Post-commenting update by the applicant (BASF DocID 2022/2060894)
January 2023	Final version prepared by zRMS after Commenting period

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

It should be noted that the applicant's dRR was not rewritten by the ZRMS and the RR resulted from the evaluation was prepared by an insertion into the dRR of the ZRMS' comments on the grey background.

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 758 00 F are presented in Table 7.1-1. They have been selected from the individual GAPs in the Central zone for wheat and barley. A list of all intended uses within the Central zone is given in Part B, Section 0.

The proposed maximum total rates of mefentrifluconazole and pyraclostrobin (200g/ha and 240g/ha, respectively) are lower than the relevant rates for cereals already evaluated and authorized within the CEU (zRMS PL). For metrafenone the proposed maximum total active rate (300g/ha) is equal the rate supported by the EU GAPs for cereals and reported in EFSA Journal 2013;11(12):3498. The proposed highest BBCH and PHI are covered by the supported EU data. Thus, it can be seen right away that the proposed by the applicant GAP is likely approvable.

Mefentrifluconazole

In the context of this application mefentrifluconazole (BAS 750 F) is sufficiently stable in plant and animal matrices. Also properly stored BAS 750 F extracts are reported as sufficiently stable. The parent stability was also confirmed under hydrolytic conditions in processing.

Based on the sufficient metabolism studies the enforcement residue definition is the same in plant and animal matrices: the parent mefentrifluconazole. The residue definition for risk assessment in plant and animal matrices except the parent should include separately considered the TDMs. For animal matrices based on metabolism in livestock in addition M750F022 metabolite and its fatty acid conjugates expressed as the parent should be considered.

Based on the reported residue data, it can be concluded that the sufficient number of residue field trials in wheat and barley in NEU and SEU are available to support the representative use in cereals (EFSA Journal 2018;16(7):5379) for mefentrifluconazole.

In conclusion on crops rotation, as no significant residues of the parent in succeeding crops are expected, for the use of BAS 750 F supported by the applicant no restrictions for succeeding crops are required.

Since data obtained on the levels of TDM residues from use of BAS 750 F are comparable to the TDM data previously considered in the TDM review (November 2015), it is not considered necessary to undertake a new acute or chronic risk assessment for TDMs arising from the use of the product.

The *Animal model 2017* was used and therefore new MRLs of BAS 750 F in swine liver and milk were proposed in context of submissions for product BAS 750 11 F in Core C and recently were evaluated and MRLs were raised accordingly (EFSA, 2020). Regarding available feeding data, there is no risk for animal MRL to be exceeded.

According to the available data, the intended uses on cereals are considered acceptable, for outdoor uses. The extrapolation rules have been applied according to SANTE/2019/12752. The data submitted show that no exceedance of the current mefentrifluconazole MRLs for the intended uses (barley, wheat, rye, triticale, and oat) is expected.

It can be concluded that the proposed uses of mefentrifluconazole in the formulation BAS 758 00 F do not represent unacceptable acute and chronic risks for the consumer (see estimation scenarios of the applicant).

Metrafenone

Residues of metrafenone are stable for at least 24 months in wheat whole plants, grain, and straw. No studies assessing the stability of residues in products of animal origin were carried out since livestock feeding studies were not required.

Metabolism was sufficiently investigated in fruit, fruiting vegetables and cereals and has been previously reported in the DAR. The metabolism in rotational crops study shows that no detectable residues would be expected, field data are not required (UK, 2005; EFSA, 2006). Thus, it can be concluded that the residues in succeeding crops are unlikely when metrafenone is used in accordance with the intended GAP.

The requested uses (and the new mode of calculation) modify the livestock dietary burden for animals, but regarding available feeding data, there is no risk for the current MRLs for products of animal origin (0.01 mg/kg) to be exceeded.

In a standard nature of the residues study (OECD 507), metrafenone was not degraded during the simulation of pasteurisation, baking, boiling, brewing or sterilisation. Available processing data show that residues of metrafenone are reduced when barley is processed into pearl barley or beer but are concentrated into the bran fraction. Further processing studies are not required in this case as they are not expected to affect the outcome of the risk assessment (EFSA Journal 2013;11(12):3498).

According to the available data, the intended uses on cereals are considered acceptable, for outdoor uses. The shorter application interval has no effect on the residue levels in grain and straw. The data submitted show that no exceedance of the MRL will occur.

Since the GAP for BAS 758 00 F does not lead to higher residues in cereals than have already been assessed (GAP EU 2006 SANCO/10280/06 - rev. final; max BBCH 79, max 100g/ha, 35PHI), no additional consumer exposure assessments have been conducted. The proposed uses of metrafenone in the formulation BAS 758 00 F do not represent unacceptable chronic risks for the consumer.

Pyraclostrobin

Cereals are the group covered in stability and metabolism studies for primary, succeeding, and processed commodities. The storage stability in plant and animal matrices was already evaluated (18-25 months). The data available also demonstrates that pyraclostrobin is stable in sample extracts or solutions when properly stored during analysis.

The residue definition for risk assessment and enforcement for primary crops, rotational and processed commodities is the parent pyraclostrobin. The residue definition for risk assessment and enforcement for animal matrices is also the parent except a liver (not of poultry), milk and fat, where the residue is the sum of the parent and the metabolites 500M04, 500M85 expressed as pyraclostrobin.

The data on rotation shows that in succeeding crops significant residues are not expected. No accumulation of pyraclostrobin or its degradation products in the parts of plants used for human or animal consumption. Specific plant-back restrictions related to the use of pyraclostrobin are not required, provided that pyraclostrobin is applied in compliance with the intended GAP.

Considering the calculated dietary burden for the requested uses (the animal model 2017) no risk for animal MRLs to be exceeded is expected based on available feeding data.

The processing data demonstrates that processes like brewing, cooking, sterilization or pasteurization, will not impact the nature of pyraclostrobin residues. No risk to consumers is expected to arise from processed cereals, which have been previously treated with the plant protection product of concern consistently with the intended GAP.

According to the available data, the intended uses on cereals are considered acceptable, for outdoor uses. The extrapolation rules have been applied according to SANTE/2019/12752. The data submitted show that no exceedance of the current pyraclostrobin MRLs for the intended uses (barley, wheat, rye, triticale and oat) is expected. Concluding, the proposed uses of pyraclostrobin in the formulation BAS 758 00 F do not represent unacceptable acute and chronic risks for the consumer.

Overall conclusion

Thus, the data available for BAS 758 00 F are considered sufficient for risk assessment. An exceedance of the current MRL of 0.05 mg/kg (wheat, rye and triticale) and 0.6 mg/kg (barley and oat) for mefentrifluconazole and 0.07 mg/kg (wheat, rye and triticale) and 0.6 mg/kg (barley and oat) for metrafenone and 0.2 mg/kg (wheat, rye and triticale) and 1.0 mg/kg (barley and oat) for pyraclostrobin as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of mefentrifluconazole, metrafenone, pyraclostrobin, and TDMs residues are unlikely to present a public health concern.
The evaluation of cumulative or synergistic effects as requested by Art. 4 of Regulation (EC) No. 1107/2009 should only be performed when harmonised “scientific methods accepted by the Authority to assess such effects are available.” In the absence of agreed guidance on estimating combined acute and chronic exposure, an indicative Hazard Indexes (HIs) can be derived to show specifically for the intended uses, that the combined exposure from triazole derivative metabolites (TDMs) is very low. A HI <1 indicates absence of a health concern even if dose-addition of active ingredients is assumed and all HIs obtained by the applicant were below 1 (see paragraph 7.5).
As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended uses.

Current MRLs in cereals for the active substances of the product BAS 758 00 F

Crop	Mefentrifluconazole mg/kg	Metrafenone mg/kg	Pyraclostrobin mg/kg
Wheat/rye/triticale	0.05	0.07	0.2
Barley/oat	0.6	0.6	1.0

Based on the data available, no specific mitigation measures should apply.

Data gaps

Noticed data gaps are: None

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1-5 16-22	CEU	wheat TRZAW, TRZAS TRZDU, TRZSP barley HORVW HORVS rye SECCW SECCS SECCE triticale TTLWI TTLSO oat AVESA	F	*Oculimacula spp.* - PSDCHE *Blumeria graminis* - ERYSGR *Zymoseptoria tritici* - SEPTTR *Puccinia triticina* - PUCCRT *Puccinia striiformis* - PUCCST *P. tritici-repentis* – PYRNTR *Pyrenophora teres* - PYRNTE *R. secalis* - RHYNSE *R. collo-cygni* - RAMUCC *Puccinia hordei* – PUCCHD *Puccinia recondita* – PUCCRE *Septoria spp.* – SEPTSP *Puccinia coronata* – PUCCCA	Spraying (SP)	30 - 59	a) 2 b) 2	14	a) 1,5 b) 3	a) 0,100* / 0,150** / 0,120*** b) 0,200* / 0,300** / 0,240***	100 - 300	56	For eyespot control, only one application at BBCH 30-32
6-10	CEU	wheat TRZAW, TRZAS TRZDU, TRZSP barley HORVW HORVS rye SECCW SECCS SECCE triticale TTLWI TTLSO oat AVESA	F	*Oculimacula spp.* - PSDCHE *Blumeria graminis* - ERYSGR *Zymoseptoria tritici* - SEPTTR *Puccinia triticina* - PUCCRT *Puccinia striiformis* - PUCCST *P. tritici-repentis* – PYRNTR *Pyrenophora teres* - PYRNTE *R. secalis* - RHYNSE *R. collo-cygni* - RAMUCC *Puccinia hordei* – PUCCHD *Puccinia recondita* – PUCCRE *Septoria spp.* – SEPTSP *Puccinia coronata* – PUCCCA	Spraying (SP)	30 - 59	a) 1 b) 1	-	a) 1 - 1,5 b) 1 - 1,5	a) 0,100* / 0,150** / 0,120*** b) 0,100* / 0,150** / 0,120***	100 - 300	56	For eyespot control, only one application at BBCH 30-32
11-15	CEU	wheat TRZAW, TRZAS TRZDU, TRZSP barley HORVW HORVS rye	F	*Oculimacula spp.* - PSDCHE *Blumeria graminis* - ERYSGR *Zymoseptoria tritici* - SEPTTR *Puccinia triticina* - PUCCRT *Puccinia striiformis* - PUCCST *P. tritici-repentis* – PYRNTR	Spraying (SP)	30 - 59	a) 2 b) 2	14	a) 0,5 - 1 b) 0,5 - 2	a) 0,067* / 0,100** / 0,080*** b) 0,133* / 0,200** / 0,160***	100 - 300	56	For eyespot control, only one application at BBCH 30-32

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. (e)	**Mem-ber state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests con-trolled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between appli-cations (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Wa-ter L/ha min / max		
		SECCW SECCS SECCE triticale TTLWI TTLSO oat AVESA		*Pyrenophora teres* - PYRNTE *R. secalis* - RHYNSE *R. collo-cygni* - RAMUCC *Puccinia hordei* – PUCCHD *Puccinia recondita* – PUCCRE *Septoria spp.* – SEPTSP *Puc-cinia coronata* – PUCCCA									

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

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

critical GAPs are highlighted in **bold**

column 11: mefentrifluconazole / metrafenone / pyraclostrobin

* Mefentrifluconazole ** Metrafenone *** Pyraclostrobin

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 758 00 F is composed of mefentrifluconazole, metrafenone and pyraclostrobin.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of mefentrifluconazole, metrafenone and pyraclostrobin

Reference value	Source	Year	Value	Study relied upon	Safety factor
Mefentrifluconazole - Parent compound					
ADI*	EFSA, 2018a	2018	0.035 mg/kg bw per day	18-month carcinogenicity study in mice	100
ARfD*	EFSA, 2018a	2018	0.15 mg/kg bw	Developmental toxicity study in rabbits	100
1,2,4-Triazole (1,2,4-T) - TDM					
ADI	EFSA, 2018b	2018	0.023 mg/kg bw per day	Newly submitted rat 12-month study	300
ARfD	EFSA, 2018b	2018	0.1 mg/kg bw	Rabbit developmental study	300
Triazole alanine (TA) - TDM					
ADI	EFSA, 2018b	2018	0.3 mg/kg bw per day	Newly submitted rabbit developmental study	100
ARfD	EFSA, 2018b	2018	0.3 mg/kg bw	Newly submitted rabbit developmental study	100
Triazole acetic acid (TAA) - TDM					
ADI	EFSA, 2018b	2018	1 mg/kg bw per day	Newly submitted rat 2-generation and rabbit developmental studies	100
ARfD	EFSA, 2018b	2018	1 mg/kg bw	Newly submitted rat 2-generation and rabbit developmental studies	100
Triazole lactic acid (TLA) - TDM					
ADI	EFSA, 2018b	2018	0.3 mg/kg bw per day	Newly submitted rabbit developmental study	100
ARfD	EFSA, 2018b	2018	0.3 mg/kg bw	Newly submitted rabbit developmental study	100
Metrafenone - Parent compound					
ADI	EFSA, 2006	2006	0.25 mg/kg bw	Rat, 2-year	100
ARfD	EFSA, 2006	2006	Not allocated – not necessary	-	-
Pyraclostrobin - Parent compound					
ADI	04/30/EC	2004	0.03 mg/kg bw per day	Rat, chronic study	100
ARfD	04/30/EC	2004	0.03 mg/kg bw	Rabbit, developmental toxicity (maternal toxicity)	100

7.1.2.1 Summary for mefentrifluconazole (BAS 750 F)

Table 7.1-3: Summary for mefentrifluconazole

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1, 6, 11	Wheat	Yes	Yes (4 new trials NEU)	Yes	Yes	Yes	No	No
2, 7, 12	Barley	Yes	Yes (4 new trials NEU)	Yes	Yes	Yes		No
3, 8, 13	rye (extrapolation from wheat)	Yes	Yes (4 new trials NEU)	Yes	Yes	Yes		No
4, 9, 14	triticale (covered by wheat according to EU Reg. 2018/62)	Yes	Yes (4 new trials NEU)	Yes	Yes	Yes		No
5, 9, 15	oat (extrapolation from barley)	Yes	Yes (4 new trials NEU)	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
Note: the uses presented in column 1 belong to the cGAP and cover therefore all other GAPs for that crop as specified in Table 7.1 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.

7.1.2.2 Summary for metrafenone

Table 7.1-4: Summary for metrafenone

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?
1-22	Cereals	Yes	Yes/4 each in wheat and barley	Yes	Yes	Yes	No	No

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

7.1.2.3 Summary for Pyraclostrobin

Table 7.1-5: Summary for Pyraclostrobin

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, 6, 11	Wheat	Yes	Yes (4 new trials NEU)	Yes	Yes	Yes	No	No
2, 7 12	Barley	Yes	Yes (4 new trials NEU)	Yes	Yes	Yes		No
3, 8, 13	rye (extrapolation from wheat)	Yes	Yes (4 new trials NEU)	Yes	Yes	Yes		No
4, 9, 14	triticale (covered by wheat according to EU Reg. 2018/62)	Yes	Yes (4 new trials NEU)	Yes	Yes	Yes		No
5,9,15	oat (extrapolation from barley)	Yes	Yes (4 new trials NEU)	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
Note: the uses presented in column 1 belong to the cGAP and cover therefore all other GAPs for that crop as specified in Table 7.1 1

The effects of processing on the nature of pyraclostrobin 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 for the intended uses.

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

No acute risk has been identified for the crops of concern. The use of BAS 758 00 F for the intended uses is therefore acceptable.

7.1.2.4 Summary for BAS 758 00 F

Waiting periods prior to planting succeeding crops are not required. This is not relevant here since a pre-emergence use is not intended and application of BAS 758 00 F is directed to the crop only. Withholding period/PHI is detailed in the following table.

Table 7.1-6: Information on BAS 758 00 F (KCA 6.8)

Crop	PHI for BAS 758 00 F proposed by applicant	PHI/ Withholding period* sufficiently supported for			PHI for BAS 758 00 F proposed by zRMS	zRMS Comments (if different PHI proposed)
		mefentrifluconazole	metrafenone	pyraclostrobin		
Wheat	56 days	Yes	Yes	Yes	56	
Barley	56 days	Yes	Yes	Yes		
Rye	56 days	Yes	Yes	Yes		
Triticale	56 days	Yes	Yes	Yes		
Oat	56 days	Yes	Yes	Yes		

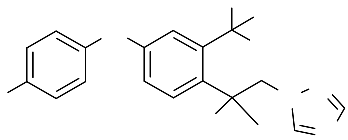
NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Assessment

7.2 Mefentrifluconazole

General data on mefentrifluconazole are summarized in the table below (last updated 2021/10/27).

Table 7.2-1: General information on mefentrifluconazole

Active substance (ISO Common Name)	Mefentrifluconazole (ISO provisionally approved) (BAS 750 F)
IUPAC	(2RS)-2-[4-(4-chlorophenoxy)-α,α,α-trifluoro-o-tolyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol
Chemical structure	
Molecular formula	$C_{18}H_{15}ClF_3N_3O_2$
Molar mass	397.8 g/mol
Chemical group	Azole
Mode of action (if available)	Blocking of ergosterol biosynthesis through inhibition of cytochrome P450 sterol 14α-demethylase (CYP51). The depletion of ergosterol and accumulation of non-functional 14α-methyl sterols results in inhibition of growth and cell membrane disruption.
Systemic	Yes
Company (ies)	BASF SE*
Rapporteur Member State (RMS)	ES Original RMS: United Kingdom Co-RMS: FR/AT
Approval status	Approved 20/03/2019 Reg. (EU) No 2019/337
Restriction (e.g. is restricted to use as "...")	N.A.
Review Report	SANTE/11612/2018 Rev.2 25 January 2019
Current MRL regulation	Reg. (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 2018a
EFSA Journal: conclusion on article 12	No
Current MRL applications on intended uses	No

* Notifier in the EU process to whom the a.s. belong(s)
** If yes: EFSA, YYYY - see list of references

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application. In the context of the Annex I inclusion process three storage stability studies have been submitted by the applicant. These studies are summarized in the table below. For a detailed assessment refer to the EFSA Conclusion (2018a and b).

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

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

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

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

Conclusion on stability of residues during storage

BAS 750 F

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

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

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

Metabolites

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

Triazole derivative metabolites (TDMs) are formed during the metabolism of BAS 750 F in plant and animal commodities. The TDMs are 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid. Frozen storage stability of these metabolites was considered as part of the TDM peer review (EFSA, 2018b) for which BASF was one of the members of the TDM group who submitted the studies. These studies were considered acceptable in the TDM review. This table includes the studies in which the longest storage period was considered (other studies covering shorter time scales were also presented in the review).

During the initial TDM review in 2015 only an interim storage stability study was available for triazole lactic acid (TLA). To support the duration of sample storage in studies considered for BAS 750 F, the full study for TLA has been submitted, and is evaluated in the EFSA conclusions 2018a and 2018b. This study demonstrates that TLA is stable in wheat grain, navy bean, orange, canola seed, and lettuce matrices for at least 48 months when stored under deep frozen conditions. As at least one crop has been considered in all five crop groups, it can be considered that sufficient data is available to support the storage stability of TLA in all plant commodities for at least 48 months.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

No new data was submitted in the framework of this application. In the context of the Annex I inclusion process sufficient information has been submitted by the applicant. For a detailed assessment refer to the EFSA conclusion (2018a).

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

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

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

Conclusion on stability of residues in sample extracts

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

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 three plant metabolism studies have been submitted by the applicant. These studies are summarized in the table below. For a detailed assessment refer to the EFSA conclusion (2018a).

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruit crops	Grape	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 interval	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/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 interval	EFSA, 2018a, BASF DocID 2014/1224012
New data								
No new data								

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

DAT = days after last treatment

* cultivated on outdoor test plots, test area 0.4 m^2, under natural climatic conditions

** cultivated indoor (plastic containers located in vegetation hall/greenhouse/pythotron)

[1] immediately prior to the last (=third) application (DALA"-0") corresponding to 21 after the first application

[2] 19 days after the first application (19 DAT) corresponding to directly prior to the second application, and 17 days prior to last application (-17 DALA).

[3] only one application: 15 days after the first application (= 15 DAT) corresponding to 6 days prior to last application (DALA= -6)

Summary of plant metabolism studies reported in the EU

EFSA, 2018a: Metabolism was investigated using two radiolabels (BAS 750 F labelled in the C-ring or in the T-ring). Results obtained with both labels show a consistent picture of BAS 750 F metabolism. Investigations were done in three plant species, wheat (cereal crop group), soybean (pulses and oilseed crop group), and grapevine (fruits/fruiting vegetable crop group), foliar applied with BAS 750 F and reflecting the cGAP (critical GAP). Comparable results were obtained for all three crop groups.
In most matrices the unchanged parent is the predominant component of the residue (>60% of the radioactive residue), notably in forage (wheat, soybean), leaf/stalk (grapevine), straw/hull/chaff (wheat, soybean), green pod (soybean) and grape (grapevine). The enantiomer ratio of the two BAS 750 F isomers remains unchanged (racemic mixture).
In wheat grain and soybean seed, the predominant component of the residue is the group of TDM, with triazole alanine as the most abundant compound (formed via cleavage of the T-bridge). In these matrices unchanged parent is present at very low levels if at all.

Other metabolites were formed via two main pathways:

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

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

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

For processed commodities and rotational crops, the same residue definitions were proposed.
EFSA concludes that the above-mentioned residue definitions are appropriate for the current assessment.

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 has been submitted by the applicant. This study is summarized in the table below. For a detailed assessment refer to the EFSA conclusion (2018a).

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)**	Harvest Intervals (DAP)Δ	Remarks	
EU data								
Root/tuber crops	White radish	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	
Cereal (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 rotational crop metabolism studies reported in the EU

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

Conclusion on metabolism in rotational crops

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

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

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

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

Conclusion on nature of residues in processed commodities

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

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

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

Table 7.2-6: Summary of the nature of residues in commodities of plant origin (EFSA, 2018a)

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

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

Available data

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

Table 7.2-7: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Laying poultry	Hens	Chlorophenyl ring (C-ring)	10	1.11	14	Eggs	24 h prior to first dose administration, twice daily, additionally, whole eggs still in oviduct after termination	EFSA, 2018a BASF DocID 2015/1001001
						Excreta	24 h prior to first dose administration, once daily	
						Tissues	at sacrifice	
		Trifluoromethyl-phenyl ring (TFMP-ring)	10	1.15	14	Eggs	24 h prior to first dose administration, twice daily, additionally, whole eggs still in oviduct after termination	
						Excreta	24 h prior to first dose administration, once daily	
						Tissues	at sacrifice	
		Triazole ring (T-ring)	10	1.11	14	Eggs	24 h prior to first dose administration, twice daily, additionally, whole eggs still in oviduct after termination	
						Excreta	24 h prior to first dose	

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	
							administration, once daily	
						Tissues	at sacrifice	
Lactating ruminants	Goat	Chlorophenyl ring (C-ring)	2	0.36	14	Milk	twice daily	EFSA, 2018a BASF DocID 2015/1078841
						Urine and faeces	daily	
						Tissues	at sacrifice	
		Trifluoromethyl-phenyl ring (TFMP-ring)	1	0.40	12	Milk	twice daily	
						Urine and faeces	daily	
						Tissues	at sacrifice	
		Triazole ring (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	Feces	daily prior to and after feeding	EFSA, 2018a (study submitted as part of EU AI dossier) BASF DocID 2015/1106141
						Filet, filet with skin and liver	6 hours after the last dose	
		Triazole ring (T-ring)	5	5.4 mg/kg DM	10-14	Feces	daily prior to and after feeding	
						Filet, filet with skin and liver	6 hours after the last dose	
New data								
No new data								

Summary of animal metabolism studies reported in the EU

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

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

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

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

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

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

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

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

Conclusion on metabolism in livestock

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

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

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

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

Table 7.2-8: Summary on the nature of residues in commodities of animal origin (EFSA, 2018a)

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

7.2.3 Magnitude of residues in plants (KCA 6.3)

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

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

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of BAS 758 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 750F b) triazole derivative metabolites (TDMs) with a separate assessment of 1) TA, 2) TLA, 3) TAA, 4) 1,2,4-T**	**STMR (mg/kg)**	**HR (mg/kg)**	**Unrounded OECD calculator MRL (mg/kg)**	**Current EU MRL (mg/kg) ***	**MRL compliance**
Wheat grain (and extrapolation to rye and triticale grain)	EFSA, 2018a BASF DocIDs 2014/1010809 and 2015/1099704 and 2017/1141927	N-EU	GAP on which EU a.s. assessment is based: 2x 0.15 kg as/ha, BBCH 49-69, PHI 35d***, outdoor E/RA a): 4x <0.01, 0.011, 0.014, 0.016, 0.024	0.01**	0.026**	-	0.05	Yes
		S-EU	GAP on which EU a.s. assessment is based: 2x 0.15 kg as/ha, BBCH 49-69, PHI 35d***, outdoor E/RA a): 7x <0.01, 0.018, 0.026					
		N-EU	GAP on which EU a.s. assessment is based: 2x 0.15 kg as/ha, BBCH 49-69, PHI 35d***, outdoor RA b):	1)+2) 0.26** 3) 0.06**	1)+2) 1.21** 3) 0.42** 4) 0.01**	-	-	-

			1)+2)[#] 0.10, 0.12, 0.20, 0.22, 0.26, 0.26, 0.54, 1.21 3) 0.016, 0.019, 0.022, 0.023, 0.063, 0.1, 0.16, 0.42 4) 8x <0.01	4) 0.01**				
		S-EU	GAP on which EU a.s. assessment is based: 2x 0.15 kg as/ha, BBCH 49-69, PHI 35d***, outdoor RA b): 1)+2)[#] 0.02, 0.13, 0.23, 0.26, 0.32, 0.33, 0.36, 0.37, 0.85 3) <0.01, 0.015, 0.023, 0.046, 0.068, 0.081, 0.091, 0.11, 0.2 4) 9x <0.01					
	New trials BASF DocID 2021/2000402	N-EU	GAP: 2x 0.1 kg as/ha, BBCH 30-59, PHI 56d, outdoor (less critical GAP) E/RA a): 4x <0.010	0.010	0.010	Highest residue covered by current MRL 0.05 mg/kg. No further considerations needed.		Yes
			GAP: 2x 0.1 kg as/ha, BBCH 30-59, PHI 56d, outdoor (less critical GAP) RA b): 1) 0.10, 0.15, 0.16, 0.19 2) 4x <0.010 3) 0.038, 0.080, *0.094*, *0.14* 4) 4x <0.010	1) 0.155 2) 0.010 3) 0.087 4) 0.010	1) 0.190 2) 0.010 3) 0.140 4) 0.010	-	-	-
	Overall supporting data for cGAP	N-EU	GAP on which EU a.s. assessment is based: 2x 0.15 kg as/ha, BBCH 49-69, PHI 35d***, outdoor E/RA a): 4x <0.01, 0.011, 0.014, 0.016, 0.024	0.011	0.024	0.033	0.05 (based on N-EU and S-EU data)	yes
			RA b): 1)+2)[#] 0.10, 0.12, 0.20, 0.22, 0.26, 0.26, 0.54, 1.21 3) 0.016, 0.019, 0.022, 0.023, 0.063, 0.1, 0.16, 0.42 4) 8x <0.01	1)+2) 0.24 3) 0.043 4) 0.01	1)+2) 1.21 3) 0.42 4) 0.01	-	-	-

Wheat straw (and extrapolation to rye and triticale straw)	EFSA, 2018a BASF DocIDs 2014/1010809 and 2015/1099704 and 2017/1141927	N-EU	GAP on which EU a.s. assessment is based: 2x 0.15 kg as/ha, BBCH 49-69, PHI 35d***, outdoor E/RA a): 1.9, 2.3, 3.4, 3.6, 3.9, 4.9, 5.5, 10	3.6**	18.0**	-	30	Yes
		S-EU	GAP on which EU a.s. assessment is based: 2x 0.15 kg as/ha, BBCH 49-69, PHI 35d***, outdoor E/RA a): 0.5, 0.56, 1.6, 2.9, 3.1, 3.8, 4.6, 9.0, 18.0					
		N-EU	GAP on which EU a.s. assessment is based: 2x 0.15 kg as/ha, BBCH 49-69, PHI 35d***, outdoor RA b): 1)+2) # 0.117, 0.118, 0.152, 0.161, 0.355, 0.483, 0.511, 0.642 3) 3x <0.01, 0.014, 0.029, 0.086, 0.088, 0.16 4) 8x <0.01	1)+2) 0.25** 3) 0.03** 4) 0.01**	1)+2) 1.51** 3) 0.16** 4) 0.01**	-	-	-
		S-EU	GAP on which EU a.s. assessment is based: 2x 01.5 kg as/ha, BBCH 49-69, PHI 35d***, outdoor RA b): 1)+2) # 0.157, 0.164, 0.198, 0.23, 0.245, 0.37, 0.55, 0.705, 1.51 3) 3x <0.01, 0.013, 0.031, 0.032, 0.054, 0.06, 0.081 4) 9x <0.01					
	New trials BASF DocID 2021/2000402	N-EU	GAP: 2x 0.1 kg as/ha, BBCH 39-59, PHI 56 d, outdoor (less critical GAP) 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
		N-EU	GAP: 2x 0.1 kg as/ha, BBCH 39-59, PHI 56 d, outdoor (less critical GAP) RA b): 1) 3x <0.010, *0.010* 2) 0.010, *0.033*, 0.046, 0.064 3) 0.012, *0.048*, *0.060*, *0.110*	1) 0.010 2) 0.040 3) 0.054 4) 0.010	1) 0.010 2) 0.064 3) 0.110 4) 0.010	-	-	-

			4) 4x <0.010						
	Overall supporting data for cGAP	N-EU	GAP on which EU a.s. assessment is based: 2x 0.15 kg as/ha, BBCH 49-69, PHI 35d***, outdoor E/RA a): 1.9, 2.3, 3.4, 3.6, 3.9, 4.9, 5.5, 10	3.75	10	14.62	30 (based on N-EU and S-EU data)	Yes	
			RA b): 1)+2)[#] 0.117, 0.118, 0.152, 0.161, 0.355, 0.483, 0.511, 0.642 3) 3x <0.01, 0.014, 0.029, 0.086, 0.088, 0.16 4) 8x <0.01	1)+2) 0.26 3) 0.022 4) 0.01	1)+2) 0.64 3) 0.16 4) 0.01	-	-	-	
Barley grain (and extrapolation to oat grain)	EFSA, 2018a BASF DocIDs 2014/1010808 and 2015/1099703 and 2017/1101701	N-EU	GAP on which EU a.s. assessment is based: 2x 0.15 kg as/ha, BBCH 49-69, PHI 35d***, outdoor E/RA a): 0.014, 0.06, 0.071, 0.087, 0.1, 0.15, 0.15, 0.19, 0.28	0.1**	0.41**	-	0.6	yes	
		S-EU	GAP on which EU a.s. assessment is based: 2x 0.15 kg as/ha, BBCH 49-69, PHI 35d***, outdoor E/RA a): 0.03, 0.033, 0.07, 0.1, 0.1, 0.14, 0.16, 0.29, 0.41						
		N-EU	GAP on which EU a.s. assessment is based: 2x 0.15 kg as/ha, BBCH 49-69, PHI 35d***, outdoor RA b) 1)+2)[#] 0.159, 0.187, 0.397, 0.514, 0.844, 1.186, 1.32, 2.6, 3.8 3) 0.019, 0.021, 0.025, 0.096, 0.11, 0.3, 0.34, 0.37, 0.5 4) 9x <0.01	1)+2) 0.33** 3) 0.09** 4) 0.01**	1)+2) 3.8** 3) 0.5** 4) 0.01**	-	-	-	
		S-EU	GAP on which EU a.s. assessment is based: 2x 0.15 kg as/ha, BBCH 49-69, PHI 35d***, outdoor RA b) 1)+2)[#] 0.078, 0.09, 0.12, 0.126, 0.233, 0.24, 0.27,						

			0.701, 0.92 3) 3x <0.01, 0.02, 0.081, 0.091, 0.011, 0.18, 0.2 4) 9x <0.01					
	New trials BASF DocID 2021/2000401	N-EU	Trials GAP: 2x 0.1 kg as/ha, BBCH 30-59, PHI 56d, outdoor (less critical GAP) E/RA a): 0.026, 0.029, 0.058, , 0.10	0.044	0.100	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 (less critical GAP) RA b) 1) 0.11, 0.15, 0.18, 0.20 2) 4x <0.010 3) 0.029, 0.088, 0.096, 0.12 4) 4x <0.010	1) 0.165 2) 0.010 3) 0.092 4) 0.010	1) 0.200 2) 0.010 3) 0.120 4) 0.010	-	-	-
	Overall supporting data for cGAP	N-EU	GAP on which EU a.s. assessment is based: 2x 0.15 kg as/ha, BBCH 49-69, PHI 35d***, outdoor E/RA a): 0.014, 0.06, 0.071, 0.087, 0.1, 0.15, 0.15, 0.19, 0.28	0.10	0.28	0.442	0.6 (based on N-EU and S-EU data)	yes
			RA b): 1)+2) # 0.159, 0.187, 0.397, 0.514, 0.844, 1.186, 1.32, 2.6, 3.8 3) 0.019, 0.021, 0.025, 0.096, 0.11, 0.3, 0.34, 0.37, 0.5 4) 9x <0.01	1)+2) 0.84 3) 0.11 4) 0.01	1)+2) 3.8 3) 0.5 4) 0.01	-	-	-
Barley straw (and extrapolation to oat straw)	EFSA, 2018a BASF DocIDs 2014/1010808 and 2015/1099703 and 2017/1101701	N-EU	GAP on which EU a.s. assessment is based: 2x 0.15 kg as/ha, BBCH 49-69, PHI 35d***, outdoor E/RA a): 1.0, 1.7, 3.1, 3.9, 4.3, 4.3, 5.6, 6.8, 15.0	4.25**	18.0**	-	30	yes
		S-EU	GAP on which EU a.s. assessment is based: 2x 0.15 kg as/ha, BBCH 49-69, PHI 35d***, outdoor E/RA a): 0.39, 2.1, 2.2, 3.3, 4.2, 4.6, 6.4, 11.0, 18.0					
		N-EU	GAP on which EU a.s. assessment is based: 2x	1)+2)	1)+2)	-	-	-

			0.15 kg as/ha, BBCH 49-69, PHI 35d***, outdoor RA b) 1)+2)[#] 0.27, 0.423, 0.458, 0.57, 0.598, 0.897, 0.94, 1.171, 10.67 3) <0.01, 0.025, 0.026, 0.027, 0.035, 0.11, 0.12, 0.2, 0.33 4) 9x <0.01	0.33** 3) 0.04** 4) 0.01**	10.67** 3) 0.33** 4) 0.01**			
		S-EU	GAP on which EU a.s. assessment is based: 2x 0.15 kg as/ha, BBCH 49-69, PHI 35d***, outdoor RA b) 1)+2)[#] 0.427, 0.413, 0.465, 0.54, 0.544, 0.584, 0.688, 0.842, 4.51 3) 4x <0.01, 0.035, 0.045, 0.05, 0.095, 0.11 4) 9x <0.01					
	New trials BASF DocID 2021/2000401	N-EU	Trials GAP: 2x 0.1 kg as/ha, BBCH 30-59, PHI 56d, outdoor (less critical GAP) E/RA a): 1.1, 1.2, 1.4, 3.7	1.300	3.700	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 (less critical GAP) RA b) 1) *0.011*, 0.014, *0.022*, 0.024 2) 0.014, 0.047, 0.056, 0.082 3) 0.016, 0.032, 0.036, *0.040* 4) 4x <0.010	1) 0.018 2) 0.052 3) 0.034 4) 0.010	1) 0.024 2) 0.082 3) 0.040 4) 0.010	-	-	-
	Overall supporting data for cGAP	N-EU	GAP on which EU a.s. assessment is based: 2x 0.15 kg as/ha, BBCH 49-69, PHI 35d***, outdoor E/RA a): 1.0, 1.7, 3.1, 3.9, 4.3, 4.3, 5.6, 6.8, 15.0	4.3	15	21.58	30 (based on N-EU and S-EU data)	yes
			RA b): 1)+2)[#] 0.27, 0.423, 0.458, 0.57, 0.598, 0.897, 0.94, 1.171, 10.67 3) <0.01, 0.025, 0.026, 0.027, 0.035, 0.11, 0.12,	1)+2) 0.598 3) 0.035 4) 0.01	1)+2) 10.67 3) 0.33 4) 0.01	-	-	-

			0.2, 0.33 4) 9x <0.01					

[#] EFSA 2018a: residues are reported as the sum of TA and TLA measurements
* Source of EU MRL: Reg. (EU) 2021/590
** U-test confirms that the NEU and SEU data sets are not statistically different, hence they are combined in each case to provide overall STMR and HR values. (test was performed for parent residues only)
*** general note regarding the intended PHI of 35 days: the time interval between the second application and harvest may vary depending on geographical and weather conditions. As soon the last application is made at the latest BBCH stage foreseen in the cGAP (BBCH 69), residue trials are considered valid even if the PHI of 35 days is not met.
General note: in context of EFSA (2018a and 2020), for TA, TLA, TAA and 1,2,4-T only the residue values from treated plots were reported. In context of the new trials, untreated values (*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

According to the available data, the intended uses on cereals are considered acceptable, for outdoor uses. The extrapolation rules have been applied according to SANTE/2019/12752. The data submitted show that no exceedance of the current mefentrifluconazole MRLs for the intended uses (barley, wheat, rye, triticale and oat) is expected.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

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

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

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment/ Source	Input value (mg/kg)	Comment/ Source
Enforcement residue definition: *parent BAS 750 F* Risk assessment residue definition: *animal except poultry: parent BAS 750 F, poultry: sum of parent BAS 750 F, metabolite M750F022 and fatty acid conjugates of M750F022, expressed as parent equivalents.* (Values in brackets are based on calculations with residue values from Table 7.2-9)				
Apple, wet pomace	0.25	$STMR_P$ (STMR 0.08 x PF 3.10) / EFSA, 2020	0.25	$STMR_P$ (STMR 0.08 x PF 3.10) / EFSA, 2020
Beet, sugar, tops	0.24	STMR/ EFSA, 2020	1.10	HR/ EFSA, 2020
Beet, sugar, dried pulp	0.10	$STMR_P$ (STMR 0.02 x PF 4.75) / EFSA, 2020	0.10	$STMR_P$ (STMR 0.02 x PF 4.75) / EFSA, 2020
Beet, sugar, ensiled pulp	0.02	$STMR_P$ (STMR 0.02 x PF 0.88) / EFSA, 2020	0.02	$STMR_P$ (STMR 0.02 x PF 0.88) / EFSA, 2020
Beet, sugar, molasses	0.02	$STMR_P$ (STMR 0.02 x PF 0.88) / EFSA, 2020	0.02	$STMR_P$ (STMR 0.02 x PF 0.88) / EFSA, 2020
Corn, field (maize), grain	0.01	STMR/ EFSA, 2020	0.01	STMR/ EFSA, 2020
Corn, pop, grain	0.01	STMR/ EFSA, 2020	0.01	STMR/ EFSA, 2020
Corn, field, stover (fodder)	0.13	STMR/ EFSA, 2020	0.61	HR / EFSA, 2020
Corn, pop, stover (fodder)	0.13	STMR/ EFSA, 2020	0.61	HR / EFSA, 2020
Corn, field, milled byproducts	0.09	$STMR_P$ (STMR 0.01 x PF 8.8) / EFSA, 2020	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	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	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	0.03	$STMR_P$ (STMR 0.01 x PF 2.70)[(c)] / EFSA, 2020
Potato, culls (= roots)	0.01	STMR / EFSA, 2020	0.01	HR / EFSA, 2020
Potato, process waste	0.005	$STMR_P$ (STMR 0.01 x PF 0.45) / EFSA, 2020	0.005	$STMR_P$ (STMR 0.01 x PF 0.45) / EFSA, 2020

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment/ Source	Input value (mg/kg)	Comment/ Source
Potato, dried pulp	0.02	STMR$_P$ (STMR 0.01 x PF 2.43) / EFSA, 2020	0.02	STMR$_P$ (STMR 0.01 x PF 2.43) / EFSA, 2020
Canola (rape seed), meal	0.02	STMR$_P$ (STMR 0.01 x PF 2.0)[(a)] / EFSA, 2020	0.02	STMR$_P$ (STMR 0.01 x PF 2.0)[(a)] / EFSA, 2020
Rape, meal	0.02	STMR$_P$ (STMR 0.01 x PF 2.0)[(a)] / EFSA, 2020	0.02	STMR$_P$ (STMR 0.01 x PF 2.0)[(a)] / EFSA, 2020
Sunflower, meal	0.02	STMR$_P$ (STMR 0.01 x PF 2.0)[(a)] / EFSA, 2020	0.02	STMR$_P$ (STMR 0.01 x PF 2.0)[(a)] / EFSA, 2020
Wheat grain	0.01[1] (0.01)	STMR / EFSA, 2018a (STMR in this submission)	0.01[1] (0.01)	STMR / EFSA, 2018a (STMR in this submission)
Wheat straw	3.6[1] (1.45)	STMR / EFSA, 2018a (STMR in this submission)	18.0[1] (2.1)	HR / EFSA, 2018a (HR in this submission)
Wheat gluten meal	0.003[1] (0.003)	STMR$_P$ (STMR 0.01 x PF 0.3) / EFSA, 2018a (STMR in this submission 0.01 x PF 0.3)	0.003[1] (0.003)	STMR$_P$ (STMR 0.01 x PF 0.3) / EFSA, 2018a (STMR in this submission 0.01 x PF 0.3)
Wheat milled byproducts	0.01[1] (0.006)	STMR$_P$ (STMR 0.01 x PF 0.6) / EFSA, 2018a (STMR in this submission 0.01 x PF 0.6)	0.01[1] (0.006)	STMR$_P$ (STMR 0.01 x PF 0.6) / EFSA, 2018a (STMR in this submission 0.01 x PF 0.6)
Wheat distiller's grain (dried)	0.03[1] (0.027)	STMR$_P$ (STMR 0.01 x PF 2.7) / EFSA, 2018a (STMR in this submission 0.01 x PF 2.7)	0.03[1] (0.027)	STMR$_P$ (STMR 0.01 x PF 2.7) / EFSA, 2018a (STMR in this submission 0.01 x PF 2.7)
Rye grain	0.01[1] (0.01)	STMR / EFSA, 2018a (extrapolation from wheat, STMR in this submission)	0.01[1] (0.01)	STMR / EFSA, 2018a (extrapolation from wheat, STMR in this submission)
Rye straw	3.6[1] (1.45)	STMR / EFSA, 2018a (extrapolation from wheat, STMR in this submission)	18.0[1] (2.1)	HR / EFSA, 2018a (extrapolation from wheat, HR in this submission)
Triticale grain	0.01[1] (0.01)	STMR / EFSA, 2018a (extrapolation from wheat, STMR in this submission)	0.01[1] (0.01)	STMR / EFSA, 2018a (extrapolation from wheat, STMR in this submission)
Triticale straw	3.6[1] (1.45)	STMR / EFSA, 2018a (extrapolation from wheat, STMR in this submission)	18.0[1] (2.1)	HR / EFSA, 2018a (extrapolation from wheat, HR in this submission)
Barley grain	0.1[1] (0.044)	STMR / EFSA, 2018a (STMR in this submission)	0.1[1] (0.044)	STMR / EFSA, 2018a (STMR in this submission)

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment/ Source	Input value (mg/kg)	Comment/ Source
Barley straw	4.25[1] (1.30)	STMR / EFSA, 2018a (STMR in this submission)	18.0[1] (3.70)	HR / EFSA, 2018a (HR in this submission)
Barley brewers grain (dried)	0.24[1] (0.106)	$STMR_P$ (STMR 0.1 x PF 2.4) / EFSA, 2018a (STMR in this submission 0.044 x PF 2.4)	0.24[1] (0.106)	$STMR_P$ (STMR 0.1 x PF 2.4) / EFSA, 2018a (STMR in this submission 0.044 x PF 2.4)
Oat grain	0.1[1] (0.044)	STMR / EFSA, 2018a (extrapolation from barley, STMR in this submission)	0.1[1] (0.044)	STMR / EFSA, 2018a (extrapolation from barley, STMR in this submission)
Oat straw	4.25[1] (1.30)	STMR / EFSA, 2018a (extrapolation from barley, STMR in this submission)	18.0[1] (3.70)	HR / EFSA, 2018a (extrapolation from barley, HR in this submission)

HR = highest residue
STMR = Supervised Trials Median Residue
(a): 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.
(b): Since residues in RAC and in processed products were below the LOQ (please refer to EFSA, 2020), a processing factor was not applied. Concentration of residues is not expected.
(c): Tentative processing factor derived based on a limited dataset.
[1] STMRs and HRs of EFSA, 2018a and 2020 cover also data from new trials submitted in this dossier

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

Table 7.2-11: Results of the dietary burden calculation

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

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

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

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

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

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

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

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

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

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[(b)]	Highest residue (mg/kg)[(c)]	Calculated MRL (mg/kg)	CF for RA[(d)]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)[(a)]	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
	cattle)		1.042	3	0.291	0.505	0.291	0.505				
			3.740	3	1.295	1.880	1.295	1.880				
Bovine milk	0.060 (Dairy cattle)	0.238 (Dairy cattle)	0.035	3	0.01*[(e)]	N/A	0.01*[(e)]	N/A	0.01	0.02	0.03	1.0
			0.193	3	0.01* [(e)]	N/A	0.01* [(e)]	N/A				
			1.042	3	0.08 [(e)]	N/A	0.08 [(e)]	N/A				
			3.740	3	0.216 [(e)]	N/A	0.216 [(e)]	N/A				
Sheep meat	0.126 (Lamb)	0.520 (Lamb)	0.035	3	0.01*	0.01*	0.01*	0.01*	0.02	0.05	0.06	1.0
			0.193	3	0.01*	0.01*	0.01*	0.01*				
			1.042	3	0.073	0.105	0.073	0.105				
			3.740	3	0.163	0.221	0.163	0.221				
Sheep fat	0.126 (Lamb)	0.520 (Lamb)	0.035	3	0.017	0.018	0.017	0.018	0.09	0.38	0.4	1.0
			0.193	3	0.049	0.059	0.049	0.059				
			1.042	3	0.649	0.900	0.649	0.900				
			3.740	3	1.711	2.290	1.711	2.290				
Sheep liver	0.126 (Lamb)	0.520 (Lamb)	0.035	3	0.031	0.034	0.031	0.034	0.14	0.65	0.7	1.0
			0.193	3	0.150	0.182	0.150	0.182				
			1.042	3	0.993	1.400	0.993	1.400				
			3.740	3	3.030	3.580	3.030	3.580				
Sheep kidney	0.126	0.520	0.035	3	0.012	0.014	0.012	0.014	0.03	0.25	0.3	1.0

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

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[(b)]	Highest residue (mg/kg)[(c)]	Calculated MRL (mg/kg)	CF for RA[(d)]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)[(a)]	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
	(Lamb)	(Lamb)	0.193	3	0.048	0.074	0.048	0.074				
			1.042	3	0.291	0.505	0.291	0.505				
			3.740	3	1.295	1.880	1.295	1.880				
Sheep milk	0.099 (Ram/Ewe)	0.407 (Ram/Ewe)	0.035	3	0.01*[(e)]	N/A	0.01*[(e)]	N/A	0.01	0.03	0.04	1.0
			0.193	3	0.01* [(e)]	N/A	0.01* [(e)]	N/A				
			1.042	3	0.08 [(e)]	N/A	0.08 [(e)]	N/A				
			3.740	3	0.216 [(e)]	N/A	0.216 [(e)]	N/A				
Pig meat	0.005 (Breeding)	0.014 (Breeding)	0.035	3	0.01*	0.01*	0.01*	0.01*	0.01	0.01	0.01*	1.0
			0.193	3	0.01*	0.01*	0.01*	0.01*				
			1.042	3	0.073	0.105	0.073	0.105				
			3.740	3	0.163	0.221	0.163	0.221				
Pig fat	0.005 (Breeding)	0.014 (Breeding)	0.035	3	0.017	0.018	0.017	0.018	0.002	0.01	0.01*	1.0
			0.193	3	0.049	0.059	0.049	0.059				
			1.042	3	0.649	0.900	0.649	0.900				
			3.740	3	1.711	2.290	1.711	2.290				
Pig liver	0.005 (Breeding)	0.014 (Breeding)	0.035	3	0.031	0.034	0.031	0.034	0.005	0.013	0.015	1.0
			0.193	3	0.150	0.182	0.150	0.182				
			1.042	3	0.993	1.400	0.993	1.400				
			3.740	3	3.030	3.580	3.030	3.580				

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

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[(b)]	Highest residue (mg/kg)[(c)]	Calculated MRL (mg/kg)	CF for RA[(d)]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)[(a)]	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Pig kidney	0.005 (Breeding)	0.014 (Breeding)	0.035	3	0.012	0.014	0.012	0.014	0.002	0.01	0.01*	1.0
			0.193	3	0.048	0.074	0.048	0.074				
			1.042	3	0.291	0.505	0.291	0.505				
			3.740	3	1.295	1.880	1.295	1.880				
Poultry meat	0.035 (Layer)	0.147 (Layer)	0.010	3	0.01*	0.01*	0.062	0.062	0.06	0.07	0.015	6.2
			0.096	3	0.01*	0.01*	0.062	0.062				
			0.296	3	0.01*	0.01*	0.062	0.062				
			0.984	3	0.016	0.027	0.099	0.167				
Poultry fat	0.035 (Layer)	0.147 (Layer)	0.010	3	0.01*	0.01*	0.163	0.163	0.16	0.36	0.03	16.3
			0.096	3	0.01*	0.01*	0.163	0.163				
			0.296	3	0.022	0.025	0.359	0.408				
			0.984	3	0.167	0.250	2.722	4.075				
Poultry liver	0.035 (Layer)	0.147 (Layer)	0.010	3	0.01*	0.01*	0.049	0.049	0.05	0.13	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)	0.147 (Layer)	0.010	3	0.01*	0.01*	0.049	0.049	0.05	0.05	0.015	4.9
			0.096	3	0.01*	0.01*	0.049	0.049				
			0.296	3	0.01*	0.01*	0.049	0.049				

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

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[b]	Highest residue (mg/kg)[c]	Calculated MRL (mg/kg)	CF for RA[d]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)[a]	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
			0.984	3	0.035	0.042	0.172	0.206				
New data												
No new data												

N/A: Not applicable – only the mean values are considered for calculating MRLs in milk.
n.r.: Not reported
(*): Indicates that the MRL is set at the limit of analytical quantification.
(F): MRL is expressed as mg/kg of fat contained in the whole product.
(a): Based on a xx kg animal consuming xx kg feed DM/day.
(b): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).
(c): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).
(d): The median conversion factor for enforcement to risk assessment.
(e): Mean residue level from day 3 until day 28 (3 cows, 9 sampling days).

Conclusion on feeding studies

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

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

Accepted by the zRMS.

7.2.4.1 Dietary burden calculation in Triazole derived metabolites

Austria 2019:

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

All feed items, which might be treated with the active substance have been considered. In this calculation the registered as well as the proposed uses of BAS 750 F are considered. A separate calculation has been made for each TDM (1,2,4-T, TA, TAA and TLA).

Even in the absence of maintenance treatments with triazole-containing plant protection products, many residue trials showed measurable residues of TDMs in the control samples. These residues are attributed to the use of triazole-containing plant products on the test plots during previous seasons. Therefore, the levels of TDM residues measured in the treated samples are considered to properly reflect the residues that result from the test item and from the use of triazole-containing plant protection products during previous growing seasons. Whenever the residues measured in the control samples exceeded the levels found in the corresponding treated samples, the residues in the control samples were taken into account (instead of the residues in the corresponding treated samples) for the calculation of the median and highest residue levels (STMR and HR).

In summary, the available data package is considered to adequately reflect the residue levels in crops because it covers:

- Treatment programmes involving several triazole-containing plant protection products.
- Residues that may result from the use of triazole-containing plant protection products during previous seasons.

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

For the input values, please refer to Table 7.2-13 and the supplemental document, in which a detailed derivation of input values is presented (BASF DocID 2021/2047472).

The results of the total maximum dietary burden calculations are reported in the tables below (Table 7.2-14 to Table 7.2-17).

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

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

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment/ Source[1]	Input value (mg/kg)	Comment/ Source[1]
Risk assessment residue definition: 1,2,4-T[2]				
Wheat grain	0.01	STMR[1]	0.01	STMR[1]
Wheat straw	0.01	STMR[1]	0.01	HR[1]
Wheat gluten meal	0.01	STMR[1]	0.01	STMR[1]
Wheat milled byproducts	0.01	STMR[1]	0.01	STMR[1]
Wheat distiller's grain (dried)	0.01	STMR[1]	0.01	STMR[1]
Rye grain	0.01	STMR[1], extrapolation from wheat	0.01	STMR[1], extrapolation from wheat
Rye straw	0.01	STMR[1], extrapolation from wheat	0.01	HR[1], extrapolation from wheat
Triticale grain	0.01	STMR[1], extrapolation from wheat	0.01	STMR[1], extrapolation from wheat
Triticale straw	0.01	STMR[1], extrapolation from wheat	0.01	HR[1], extrapolation from wheat
Barley grain	0.01	STMR[1]	0.01	STMR[1]
Barley straw	0.01	STMR[1]	0.059	HR[1]
Barley brewers grain (dried)	0.01	STMR[1]	0.01	STMR[1]
Oat grain	0.01	STMR[1] , extrapolation from barley	0.01	STMR[1], extrapolation from barley
Oat straw	0.01	STMR[1], extrapolation from barley	0.059	HR[1], extrapolation from barley
Risk assessment residue definition: *TA* (values in brackets are based on calculations with residue values from **Fehler! Verweisquelle konnte nicht gefunden werden.**)				
Wheat grain	0.25 (0.155)	STMR[1] (STMR in this submission)	0.25 (0.155)	STMR[1] (STMR in this submission)
Wheat straw	0.035 (0.01)	STMR[1] (STMR in this submission)	0.83 (0.01)	HR[1] (HR in this submission)
Wheat gluten meal	0.05 (0.03)	$STMR_P$ (STMR 0.25 x PF 0.19)[1] (STMR in this submission 0.155 x PF 0.19)[1]	0.05 (0.03)	$STMR_P$ (STMR 0.25 x PF 0.19)[1] (STMR in this submission 0.155 x PF 0.19)[1]
Wheat milled byproducts	0.15 (0.09)	$STMR_P$ (STMR 0.25 x PF 0.58)[1] (STMR in this submission 0.155 x PF 0.58)[1]	0.15 (0.09)	$STMR_P$ (STMR 0.25 x PF 0.58)[1] (STMR in this submission 0.155 x PF 0.58)[1]

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	**Comment/ Source[1]**	**Input value (mg/kg)**	**Comment/ Source[1]**
Wheat distiller's grain (dried)	0.83 (0.51)	STMR$_P$ (STMR 0.25 x PF 3.3)[1] (STMR in this submission 0.155 x PF 3.3)[1]	0.83 (0.51)	STMR$_P$ (STMR 0.25 x PF 3.3)[1] (STMR in this submission 0.155 x PF 3.3)[1]
Rye grain	0.25 (0.155)	STMR[1] (STMR in this submission, extrapolation from wheat)	0.25 (0.155)	STMR[1] (STMR in this submission, extrapolation from wheat)
Rye straw	0.035 (0.01)	STMR[1] (STMR in this submission, extrapolation from wheat)	0.83 (0.01)	HR[1] (HR in this submission, extrapolation from wheat)
Triticale grain	0.25 (0.155)	STMR[1] (STMR in this submission, extrapolation from wheat)	0.25 (0.155)	STMR[1] (STMR in this submission, extrapolation from wheat)
Triticale straw	0.035 (0.01)	STMR[1] (STMR in this submission, extrapolation from wheat)	0.83 (0.01)	HR[1] (HR in this submission, extrapolation from wheat)
Barley grain	0.25 (0.165)	STMR[1] (STMR in this submission)	0.25 (0.165)	STMR[1] (STMR in this submission)
Barley straw	0.087 (0.018)	STMR[1] (STMR in this submission)	0.71 (0.024)	HR[1] (HR in this submission)
Barley brewers grain (dried)	0.01 (0.007)	STMR$_P$ (STMR 0.25 x PF 0.04)[1] (STMR in this submission 0.165 x PF 0.04)[1]	0.01 (0.007)	STMR$_P$ (STMR 0.25 x PF 0.04)[1] (STMR in this submission 0.165 x PF 0.04)[1]
Oat grain	0.25 (0.165)	STMR[1] (STMR in this submission, extrapolation from barley)	0.25 (0.165)	STMR[1] (STMR in this submission, extrapolation from barley)
Oat straw	0.087 (0.018)	STMR[1] (STMR in this submission, extrapolation from barley)	0.71 (0.024)	HR[1] (HR in this submission, extrapolation from barley)
Risk assessment residue definition: *TAA* (values in brackets are based on calculations with residue values from **Fehler! Verweisquelle konnte nicht gefunden werden.**)				
Wheat grain	0.087 (0.087)	STMR[1] (STMR in this submission)	0.087 (0.087)	STMR[1] (STMR in this submission)
Wheat straw	0.054 (0.054)	STMR[1] (STMR in this submission)	0.17 (0.11)	HR[1] (HR in this submission)
Wheat gluten meal	0.08 (0.08)	STMR$_P$ (STMR 0.087 x PF 0.95)[1] (STMR in this submission 0.087 x PF 0.95)[1]	0.08 (0.08)	STMR$_P$ (STMR 0.087 x PF 0.95)[1] (STMR in this submission 0.087 x PF 0.95)[1]
Wheat milled byproducts	0.05 (0.05)	STMR$_P$ (STMR 0.087 x PF 0.63)[1] (STMR in this submission 0.087 x PF 0.63)[1]	0.05 (0.05)	STMR$_P$ (STMR 0.087 x PF 0.63)[1] (STMR in this submission 0.087 x PF 0.63)[1]

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	**Comment/ Source[1]**	**Input value (mg/kg)**	**Comment/ Source[1]**
Wheat distiller's grain (dried)	0.29 (0.29)	STMR$_P$ (STMR 0.087 x PF 3.3)[1] (STMR in this submission 0.087 x PF 3.3)[1]	0.29 (0.29)	STMR$_P$ (STMR 0.087 x PF 3.3)[1] (STMR in this submission 0.087 x PF 3.3)[1]
Rye grain	0.087 (0.087)	STMR[1] (STMR in this submission, extrapolation from wheat)	0.087 (0.087)	STMR[1] (STMR in this submission, extrapolation from wheat)
Rye straw	0.054 (0.054)	STMR[1] (STMR in this submission, extrapolation from wheat)	0.17 (0.11)	HR[1] (HR in this submission, extrapolation from wheat)
Triticale grain	0.087 (0.087)	STMR[1] (STMR in this submission, extrapolation from wheat)	0.087 (0.087)	STMR[1] (STMR in this submission, extrapolation from wheat)
Triticale straw	0.054 (0.054)	STMR[1] (STMR in this submission, extrapolation from wheat)	0.17 (0.11)	HR[1] (HR in this submission, extrapolation from wheat)
Barley grain	0.11 (0.092)	STMR[1] (STMR in this submission)	0.11 (0.092)	STMR[1] (STMR in this submission)
Barley straw	0.054 (0.034)	STMR[1] (STMR in this submission)	0.45 (0.04)	HR[1] (HR in this submission)
Barley brewers grain (dried)	0.01 (0.009)	STMR$_P$ (STMR 0.11 x PF 0.1)[1] (STMR in this submission 0.092 x PF 0.1)[1]	0.01 (0.009)	STMR$_P$ (STMR 0.11 x PF 0.1)[1] (STMR in this submission 0.092 x PF 0.1)[1]
Oat grain	0.11 (0.092)	STMR[1] (STMR in this submission, extrapolation from barley)	0.11 (0.092)	STMR[1] (STMR in this submission, extrapolation from barley)
Oat straw	0.054 (0.034)	STMR[1] (STMR in this submission, extrapolation from barley)	0.45 (0.04)	HR[1] (HR in this submission, extrapolation from barley)
Risk assessment residue definition: *TLA* (values in brackets are based on calculations with residue values from **Fehler! Verweisquelle konnte nicht gefunden werden.**)				
Wheat grain	0.01 (0.01)	STMR[1] (STMR in this submission)	0.01 (0.01)	STMR[1] (STMR in this submission)
Wheat straw	0.077 (0.04)	STMR[1] (STMR in this submission)	1.50 (0.064)	HR[1] (STMR in this submission)
Wheat gluten meal	0.02 (0.02)	STMR$_P$ (STMR 0.01 x PF 1.8)[1] (STMR in this submission 0.01 x PF 1.8)[1]	0.02 (0.02)	STMR$_P$ (STMR 0.01 x PF 1.8)[1] (STMR in this submission 0.01 x PF 1.8)[1]
Wheat milled byproducts	0.07 (0.07)	STMR$_P$ (STMR 0.01 x PF 7.0)[1] (STMR in this submission 0.01 x PF 7.0)[1]	0.07 (0.07)	STMR$_P$ (STMR 0.01 x PF 7.0)[1] (STMR in this submission 0.01 x PF 7.0)[1]

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	**Comment/ Source[1]**	**Input value (mg/kg)**	**Comment/ Source[1]**
Wheat distiller's grain (dried)	0.03 (0.03)	$STMR_P$ (STMR 0.01 x PF 3.3) [1] (STMR in this submission 0.01 x PF 3.3)[1]	0.03 (0.03)	$STMR_P$ (STMR 0.01 x PF 3.3) [1] (STMR in this submission 0.01 x PF 3.3)[1]
Rye grain	0.01 (0.01)	STMR[1] (STMR in this submission, extrapolation from wheat)	0.01 (0.01)	STMR[1] (STMR in this submission, extrapolation from wheat)
Rye straw	0.077 (0.04)	STMR[1] (STMR in this submission, extrapolation from wheat)	1.50 (0.064)	HR[1] (STMR in this submission, extrapolation from wheat)
Triticale grain	0.01 (0.01)	STMR[1] (STMR in this submission, extrapolation from wheat)	0.01 (0.01)	STMR[1] (STMR in this submission, extrapolation from wheat)
Triticale straw	0.077 (0.04)	STMR[1] (STMR in this submission, extrapolation from wheat)	1.50 (0.064)	HR[1] (STMR in this submission, extrapolation from wheat)
Barley grain	0.076 (0.01)	STMR[1] (STMR in this submission)	0.076 (0.01)	STMR[1] (STMR in this submission)
Barley straw	0.495 (0.052)	STMR[1] (STMR in this submission)	11.0 (0.082)	HR[1] (STMR in this submission)
Barley brewers grain (dried)	0.01 (0.007)	$STMR_P$ (STMR 0.076 x PF 0.07)[1] (STMR in this submission 0.01 x PF 0.07)[1]	0.01 (0.007)	$STMR_P$ (STMR 0.076 x PF 0.07)[1] (STMR in this submission 0.01 x PF 0.07)[1]
Oat grain	0.076 (0.01)	STMR[1] (STMR in this submission, extrapolation from barley)	0.076 (0.01)	STMR[1] (STMR in this submission, extrapolation from barley)
Oat straw	0.495 (0.052)	STMR[1] (STMR in this submission, extrapolation from barley)	11.0 (0.082)	HR[1] (HR in this submission, extrapolation from barley)

HR = highest residue, STMR = Supervised Trials Median Residue

1 For Source, please refer to the supplemental document (BASF DocID 2021/2047472)

2 For 1,2,4-T, STMR and HR calculations are based on residue values from Table 7.2-9 and are 0.01 mg/kg for all matrices in this submission

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

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

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

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

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

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
TA					
Beef cattle*	0.012	0.020	rape meal	0.81	yes
Dairy cattle*	0.011	0.024	potato culls	0.63	yes
Ram/Ewe	0.013	0.030	rape meal	0.90	yes
Lamb	0.018	0.037	rape meal	0.86	yes
Breeding swine	0.011	0.018	canola meal	0.78	yes
Finishing swine*	0.015	0.023	canola meal	0.77	yes
Broiler poultry	0.032	0.037	canola meal	0.52	yes
Layer poultry*	0.027	0.035	canola meal	0.51	yes
Turkey	0.033	0.043	canola meal	0.60	yes

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

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

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

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

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

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

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

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
TLA					
Beef cattle*	0.006	0.091	barley straw	3.80	yes
Dairy cattle*	0.011	0.147	barley straw	3.81	yes
Ram/Ewe	0.014	0.250	barley straw	7.50	yes
Lamb	0.018	0.319	barley straw	7.50	yes
Breeding swine	0.003	0.004	beet, sugar, tops	0.16	no
Finishing swine*	0.003	0.003	beet, sugar, dried pulp	0.11	no
Broiler poultry	0.006	0.006	barley, grain	0.08	yes
Layer poultry*	0.008	0.048	barley, straw	0.70	yes
Turkey	0.005	0.005	barley, grain	0.07	yes

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

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

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

Accepted by the zRMS.

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

7.2.5.1 Available data for all crops under consideration

No new data were submitted in the framework of this application. In the context of the Annex I inclusion process two processing studies in wheat and barley have been submitted by the applicant. These studies are summarized in the table below. For a detailed assessment refer to the EFSA conclusion (2018a) and to EFSA, 2020.

Table 7.2-18: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **(a)	Comments	Reference
EU data					
Enforcement residue definition: *parent BAS 750 F* *Risk assessment residue definition:* *a) BAS 750 F* *b) triazole derivative metabolites (TDMs) with a separate assessment of: 1) TA and TLA, 2) TAA, 3) 1,2,4-T*					
wheat/bran	1 (3 trials)	2.94 (BAS 750 F)	n.a.	-	EFSA, 2018a BASF DocID 2014/1315283
		2.86 (TA)	n.a.		
		1.35 (TAA)	n.a.		
wheat/flour		<0.29 (BAS 750 F)	n.a.		
		0.51 (TA)	n.a.		
		0.81 (TAA)	n.a.		
wheat/germ		1.12 (BAS 750 F)	n.a.		
		0.97 (TA)	n.a.		
		0.70 (TAA)	n.a.		
wheat/middlings		2.26 (BAS 750 F)	n.a.		
		2.74 (TA)	n.a.		
		1.42 (TAA)	n.a.		
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.		
wheat/starch		<0.29 (BAS 750 F)	n.a.		
		<0.03 (TA)	n.a.		
		<0.05 (TAA)	n.a.		
wheat/whole meal flour		0.79 (BAS 750 F)	n.a.		
		1.0 (TA)	n.a.		
		0.90 (TAA)	n.a.		
wheat/whole grain bread		0.56 (BAS 750 F)	n.a.		
		0.86 (TA)	n.a.		
		1.19 (TAA)	n.a.		
wheat/milled byproducts		0.62 (BAS 750 F)	n.a.		
		0.58 (TA)	n.a.		
		0.65 (TAA)	n.a.		
wheat/aspirated grain fraction		38.46 (BAS 750 F)	n.a.		
		0.69 (TA)	n.a.		
		0.63 (TAA)	n.a.		
wheat/silage, wet		1.19 (BAS 750 F)	n.a.		
wheat/silage, wilted		1.88 (BAS 750 F)	n.a.		
barley/pearled, pot barley	1 (3 trials)	0.12 (BAS 750 F)	n.a.	-	EFSA, 2018a 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.		
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

* The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
** The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.
(a): n.a. not applicable, since residue definitions for risk assessment and for monitoring do NOT differ
1,2,4-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 758 00 F.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation. Data dealing with magnitude of residues in succeeding crops are available/have been 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. This study is summarized in the table below. For a detailed assessment refer to the EFSA conclusion (2018a).

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

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

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

Conclusion on rotational crops studies

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

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

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

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

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 758 00 F. Therefore, other special studies are not needed.

For the intended uses on cereals no further studies regarding honey are necessary. According SANTE/11956/2016 rev. 9, cereals (barley, oat, wheat, triticale and rye) does not have melliferous capacity. However, in the context of the MRL application (EFSA-Q-2021-00692) two new studies of residues in bee products for human consumption resulting from residues taken up by honeybees from oilseed rape/rapeseed inflorescences, pollen and honey and buckwheat inflorescences and honey have been submitted by the applicant. Results indicated that no residues of BAS 750 F are expected in honey. For details please refer to the MRL application (EFSA-Q-2021-00692).

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 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 7.2-20: Input values for the consumer risk assessment

Commodity	Chronic risk assessment (normal mode)		Acute risk assessment (refined calculation mode)	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment residue definition plant and animal except poultry: parent BAS 750 F *Risk assessment residue definition poultry: sum of parent BAS 750 F, metabolite M750F022 and fatty acid conjugates of M750F022, expressed as parent equivalents* (Values in brackets are based on calculations with residue values from Table 7.2-9)				
Products of plant origin				

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

Commodity	Chronic risk assessment (normal mode)		Acute risk assessment (refined calculation mode)	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Pome fruits	0.08	STMR, extrapolation from apple and pear (EFSA, 2020)	-	
Apricots	0.15	STMR (EFSA, 2020)	-	
Cherries	0.48	STMR (EFSA, 2020)	-	
Peaches	0.15	STMR (EFSA, 2020)	-	
Plums	0.11	STMR (EFSA, 2020)	-	
Table grapes	0.18	STMR, extrapolation from wine grapes (EFSA, 2020)	-	
Wine grapes	0.18	STMR (EFSA, 2020)	-	
Potatoes	0.01	STMR (EFSA, 2020)	-	
Sweet corn	0.01	STMR, extrapolation from corn (EFSA, 2020)	-	
Sunflower seeds	0.01	STMR (EFSA, 2020)	-	
Rapeseeds / canola seeds	0.01	STMR (EFSA, 2020)	-	
Barley	0.10 (0.044)	STMR (EFSA, 2018a) (STMR in this submission)	0.10 (0.044)	STMR (EFSA, 2018a) (STMR* in this submission)
Maize/corn	0.01	STMR (EFSA, 2020)	-	
Oats	0.10 (0.044)	STMR, extrapolation from barley (EFSA, 2018a) (STMR in this submission)	0.10 (0.044)	STMR (EFSA, 2018a)* (STMR* in this submission)
Rye	0.01 (0.01)	STMR, extrapolation from wheat (EFSA, 2018a) (STMR in this submission)	0.01 (0.01)	STMR (EFSA, 2018a)* (STMR* in this submission)
Wheat	0.01 (0.01)	STMR (EFSA, 2018a) (STMR in this submission)	0.01 (0.01)	STMR (EFSA, 2018a)* (STMR* in this submission)
Sugar beet roots	0.02	STMR (EFSA, 2020)	-	
Products of animal origin				
Risk assessment residue definition plant and animal except poultry: parent BAS 750 F				
Swine: Meat	0.01	STMR (EFSA, 2018a)	-	
Swine: Fat free of lean meat	0.01	STMR (EFSA, 2018a)	-	
Swine: Liver	0.01	STMR (EFSA, 2018a)	-	
Swine: Kidney	0.01	STMR (EFSA, 2018a)	-	
Swine: Edible offal	0.01	STMR (EFSA, 2018a)	-	
Swine: Others	0.01	STMR (EFSA, 2018a)	-	
Bovine: Meat	0.024	STMR (EFSA, 2018a)	-	
Bovine: Fat	0.06	STMR (EFSA, 2018a)	-	

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

Commodity	Chronic risk assessment (normal mode)		Acute risk assessment (refined calculation mode)	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
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)	-	
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)	-	

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

Commodity	Chronic risk assessment (normal mode)		Acute risk assessment (refined calculation mode)	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
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)	-	
Processed products of plant origin				
Barley / beer	-		0.004 (0.002)	$STMR_p$ (STMR* 0.1 x PF 0.04) (STMR* in this submission 0.044 x PF 0.04)
Barley / milling (flour)	-		0.367 (0.162)	$STMR_p$ (STMR* 0.1 x PF 3.67) (STMR* in this submission 0.044 x PF 3.67)
Barley / cooked	-		0.1 (0.044)	STMR* (STMR* in this submission)
Oat / milling (flakes)	-		0.1 (0.044)	STMR* (STMR* in this submission, , extrapolation from barley)
Oat / boiled	-		0.1 (0.044)	STMR* (STMR* in this submission, extrapolation from barley)
Rye / milling (wholemeal)-baking			0.0079 (0.0079)	$STMR_p$ (STMR* 0.01 x x PF 0.79) (STMR* in this submission 0.01 x PF 0.79, extrapolation from wheat)
Rye / boiled			0.01 (0.01)	STMR* (STMR* in this submission, extrapolation from wheat)
Wheat / bread (wholemeal)	-		0.0056 (0.0056)	$STMR_p$ (STMR* 0.01 x x PF 0.56) (STMR* in this submission 0.01 x PF 0.56)

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

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

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

Separate consumer risk assessments are performed for triazole derivative metabolites (TDMs) 1,2,4-T, TA, TAA and TLA. Toxicological reference values have been established for each triazole derivative metabolites during the EU peer review of confirmatory data for TDMs (EFSA, 2018b). The set endpoints for the TDMs are shown in the table Table 7.1-2.

For the chronic consumer risk assessment, the STMR values for 1,2,4-T, TA, TAA and TLA derived during the TDM risk assessment (United Kingdom, 2018b Appendix E) were compared to STMRs after use of BAS 750 F, please refer to the supplemental document with BASF DocID 2021/2047472. In general, all STMR values derived from residues following BAS 750 F treatment resulted in lower values than those used in the TDM review with one exception (barley/oat, grain for TLA).

The acute consumer risk assessment was performed considering the intended use for wheat (with extrapolation to rye) and barley (with extrapolation to oat). STMR and HR values derived in the TDM review (United Kingdom, 2018b Appendix E) were compared to the residue values following application of BAS 750 F, please refer to the supplemental document with BASF DocID 2021/2047472. In general, STMR/HR values derived from residues following BAS 750 F treatment resulted in higher values compared to those used in TDM review for barley/oats, grain (HR for TA and STMR/HR for TLA).

An overview of the input values (intended uses only) is presented in the table below, details are provided in the supplemental document with BASF DocID 2021/2047472. Note: for processing factors please refer to Table 7.2-18).

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

Commodity	Chronic risk assessment (normal mode)		Acute risk assessment (refined calculation mode)	
	Input (mg/kg)	**Comment**	**Input** (mg/kg)	**Comment**
Risk assessment residue definition plant and animal: 1,2,4-T (Values in brackets are based on calculations with residue values from Table 7.2-9)				
Products of plant origin				
Wheat	0.05 (0.01)	STMR / TDM review (STMR in this submission)	0.05 (0.01)	STMR* / TDM review (STMR* in this submission)
Rye	0.05 (0.01)	STMR / TDM review (STMR in this submission), extrapolation from wheat	0.05 (0.01)	STMR* / TDM review (STMR* in this submission), extrapolation from wheat
Barley	0.05 (0.01)	STMR / TDM review (STMR in this submission)	0.05 (0.01)	STMR* / TDM review (STMR* in this submission)
Oat	0.05 (0.01)	STMR / TDM review (STMR in this submission), extrapolation from barley	0.05 (0.01)	STMR* / TDM review (STMR* in this submission), extrapolation from barley
Wheat / bread (whole-meal)	-		0.05 (0.01)	STMR* / TDM review (STMR* in this submission)
Wheat / bread/pizza	-		0.05 (0.01)	STMR* / TDM review (STMR* in this submission)
Wheat / pasta	-		0.05 (0.01)	STMR* / TDM review (STMR* in this submission)
Wheat / milling (who-lemeal)-baking	-		0.05 (0.01)	STMR* / TDM review (STMR* in this submission)
Wheat / milling (flour)	-		0.05 (0.01)	STMR* / TDM review (STMR* in this submission)
Barley / beer	-		0.01 (0.002)	STMRp (STMR*/ TDM review 0.05 x default PF 0.2) (STMR* 0.01 in this submission x default PF 0.2)
Barley / milling (flour)	-		0.05 (0.01)	STMR* / TDM review (STMR* in this submission)
Barley / cooked	-		0.05 (0.01)	STMR* / TDM review (STMR* in this submission)
Oat / milling (flakes)	-		0.05 (0.01)	STMR* / TDM review (STMR* in this submission), extrapolation from barley
Oat / boiled	-		0.05 (0.01)	STMR* / TDM review (STMR* in this submission), extrapolation from barley
Rye / milling (whole-meal)-baking			0.05 (0.01)	STMR* / TDM review (STMR* in this submission), extrapolation from wheat
Rye / boiled			0.05 (0.01)	STMR* / TDM review (STMR* in this submission), extrapolation from wheat

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

Commodity	**Chronic risk assessment (normal mode)**		**Acute risk assessment (refined calculation mode)**	
	Input (mg/kg)	**Comment**	**Input** (mg/kg)	**Comment**
Products of animal origin and all other products of plant origin	Derived in context of the TDM review, for details please refer to the supplemental document with BASF DocID 2021/2047472			
Risk assessment residue definition plant and animal: TA (Values in brackets are based on calculations with residue values from Table 7.2-9)				
Products of plant origin				
Wheat	0.621 (0.155)	STMR / TDM review (STMR in this submission)	0.621 (0.155)	STMR* / TDM review (STMR* in this submission)
Rye	0.621 (0.155)	STMR / TDM review (STMR in this submission), extrapolation from wheat	0.621 (0.155)	STMR* / TDM review (STMR* in this submission), extrapolation from wheat
Barley	0.621 (0.165)	STMR / TDM review (STMR in this submission)	0.621 (0.165)	STMR* / TDM review (STMR* in this submission)
Oat	0.621 (0.165)	STMR / TDM review (STMR in this submission), extrapolation from barley	0.621 (0.165)	STMR* / TDM review (STMR* in this submission), extrapolation from barley
Wheat / bread (wholemeal)	-		0.534 (0.133)	STMR$_p$ (STMR* 0.621 x PF 0.86) (STMR* 0.155 in this submission x PF 0.86)
Wheat / bread/pizza	-		0.621 (0.155)	STMR* / TDM review (STMR* in this submission)
Wheat / pasta	-		0.621 (0.155)	STMR* / TDM review (STMR* in this submission)
Wheat / milling (wholemeal)-baking	-		0.621 (0.155)	STMR* / TDM review (STMR* in this submission)
Wheat / milling (flour)	-		0.317 (0.096)	STMR$_p$ (STMR* 0.621 x PF 0.51) (STMR* 0.155 in this submission x PF 0.621)
Barley / beer	-		0.025 (0.007)	STMRp (STMR*/ TDM review 0.621 x PF 0.04) (STMR* 0.165 in this submission x PF 0.04)
Barley / milling (flour)	-		0.745 (0.198)	STMRp (STMR*/ TDM review 0.621 x PF 1.2) (STMR* 0.165 in this submission x PF 1.2)
Barley / cooked	-		0.621 (0.165)	STMR* / TDM review (STMR* in this submission)
Oat / milling (flakes)	-		0.621 (0.165)	STMR* / TDM review (STMR* in this submission), extrapolation from barley

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

Commodity	Chronic risk assessment (normal mode)		Acute risk assessment (refined calculation mode)	
	Input (mg/kg)	**Comment**	**Input** (mg/kg)	**Comment**
Oat / boiled	-		0.621 (0.165)	STMR* / TDM review (STMR* in this submission), extrapolation from barley
Rye / milling (whole-meal)-baking			0.621 (0.155)	STMR* / TDM review (STMR* in this submission), extrapolation from wheat
Rye / boiled			0.621 (0.155)	STMR* / TDM review (STMR* in this submission), 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 2021/2047472			
Risk assessment residue definition plant and animal TAA (Values in brackets are based on calculations with residue values from Table 7.2-9)				
Products of plant origin				
Wheat	0.79 (0.087)	STMR / TDM review (STMR in this submission)	0.79 (0.087)	STMR* / TDM review (STMR* in this submission)
Rye	0.79 (0.087)	STMR / TDM review (STMR in this submission), extrapolation from wheat	0.79 (0.087)	STMR* / TDM review (STMR* in this submission), extrapolation from wheat
Barley	0.79 (0.092)	STMR / TDM review (STMR in this submission)	0.79 (0.092)	STMR* / TDM review (STMR* in this submission)
Oat	0.79 (0.092)	STMR / TDM review (STMR in this submission), extrapolation from barley	0.79 (0.092)	STMR* / TDM review (STMR* in this submission), extrapolation from barley
Wheat / bread (whole-meal)	-		0.94 (0.104)	$STMR_p$ (STMR* 0.79 x PF 1.19) (STMR* 0.087 in this submission x PF 1.19)
Wheat / bread/pizza	-		0.79 (0.087)	STMR* / TDM review (STMR* in this submission)
Wheat / pasta	-		0.79 (0.087)	STMR* / TDM review (STMR* in this submission)
Wheat / milling (wholemeal)-baking	-		0.79 (0.087)	STMR* / TDM review (STMR* in this submission)
Wheat / milling (flour)	-		0.64 (0.07)	$STMR_p$ (STMR* 0.79 x PF 0.81) (STMR* 0.087 in this submission x PF 0.81)
Barley / beer	-		0.119 (0.014)	STMRp (STMR*/ TDM review 0.79 x PF 0.15) (STMR* 0.092 in this submission x PF 0.15)

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

Commodity	Chronic risk assessment (normal mode)		Acute risk assessment (refined calculation mode)	
	Input (mg/kg)	**Comment**	**Input** (mg/kg)	**Comment**
Barley / milling (flour)	-		1.67 (0.194)	STMRp (STMR*/ TDM review 0.79 x PF 2.11) (STMR* 0.092 in this submission x PF 2.11)
Barley / cooked	-		0.79 (0.092)	STMR* / TDM review (STMR* in this submission)
Oat / milling (flakes)	-		0.79 (0.092)	STMR* / TDM review (STMR* in this submission), extrapolation from barley
Oat / boiled	-		0.79 (0.092)	STMR* / TDM review (STMR* in this submission), extrapolation from barley
Rye / milling (wholemeal)-baking			0.79 (0.087)	STMR* / TDM review (STMR* in this submission), extrapolation from wheat
Rye / boiled			0.79 (0.087)	STMR* / TDM review (STMR* in this submission), 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 2021/2047472			
Risk assessment residue definition plant and animal TLA (Values in brackets are based on calculations with residue values from Table 7.2-9)				
Products of plant origin				
Wheat	0.022 (0.01)	STMR / TDM review (STMR in this submission)	0.022 (0.01)	STMR* / TDM review (STMR* in this submission)
Rye	0.022 (0.01)	STMR / TDM review (STMR in this submission), extrapolation from wheat	0.022 (0.01)	STMR* / TDM review (STMR* in this submission), extrapolation from wheat
Barley	0.076 (0.01)	STMR (STMR in this submission)	0.076 (0.01)	STMR* (STM*R in this submission)
Oat	0.076 (0.01)	STMR (STMR in this submission), extrapolation from barley	0.076 (0.01)	STMR* (STMR* in this submission), extrapolation from barley
Wheat / bread (wholemeal)	-		0.022 (0.01)	STMR* / TDM review (STMR* in this submission)
Wheat / bread/pizza	-		0.022 (0.01)	STMR* / TDM review (STMR* in this submission)
Wheat / pasta	-		0.022 (0.01)	STMR* / TDM review (STMR* in this submission)
Wheat / milling (wholemeal)-baking	-		0.022 (0.01)	STMR* / TDM review (STMR* in this submission)
Wheat / milling (flour)	-		0.022 (0.01)	STMR* / TDM review (STMR* in this submission)

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

Commodity	Chronic risk assessment (normal mode)		Acute risk assessment (refined calculation mode)	
	Input (mg/kg)	**Comment**	**Input** (mg/kg)	**Comment**
Barley / beer	-		0.123 (0.017)	STMRp (STMR* 0.076 x PF 1.71) (STMR* 0.01 in this submission x PF 1.71)
Barley / milling (flour)	-		0.293 (0.039)	STMRp (STMR* 0.076 x PF 3.86) (STMR* 0.01 in this submission x PF 3.86)
Barley / cooked	-		0.076 (0.01)	STMR* (STMR* in this submission)
Oat / milling (flakes)	-		0.076 (0.01)	STMR* (STMR* in this submission), extrapolation from barley
Oat / boiled	-		0.076 (0.01)	STMR* (STMR* in this submission), extrapolation from barley
Rye / milling (wholemeal)-baking			0.022 (0.01)	STMR* / TDM review (STMR* in this submission), extrapolation from wheat
Rye / boiled			0.022 (0.01)	STMR* / TDM review (STMR* in this submission), 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 2021/2047472			

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

7.2.8.2 Conclusion on consumer risk assessment

Results of the extensive calculations are presented in Appendix 3.

TMDI Calculation

BAS 750 F
The TMDI calculation was performed with the current EFSA model (version 3.1) using an ADI of 0.035 mg/kg bw/day applying default and established MRLs of Reg. (EU) 2021/590.

The summary of the chronic assessment is presented in Appendix 3. The ADI utilization ranges from 1 to 32% ADI. The highest TMDI was 32% ADI for the “NL toddler”, the highest contributor are apples (12% ADI).
The TMDI is well below the ADI for all European sub-population groups, therefore no health effects due to chronic exposure are expected.

IEDI Calculation

BAS 750 F
The IEDI calculation was performed with the current EFSA model (version 3.1) using an ADI of 0.035 mg/kg bw/day and STMRs as listed in Table 7.2-20.

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

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

TDMs
The IEDI calculation was performed with the current EFSA model (version 3.1) using an ADI of 0.023 mg/kg bw/day for 1,2,4-T, 0.3 mg/kg bw/day for TA and TLA and 1 mg/kg bw/day for TAA. Input values (intended uses) are listed in Table 7.2-21. A complete list of input values and their derivation can be found in the supplemental document with BASF DocID 2021/2047472.
The summary of the chronic assessment is presented in Appendix 3. The maximum ADI utilization is 48% (NL toddler) for 1,2,4-T, 4% (NL toddler) for TA and 1% (NL toddler) for TAA and TLA of the ADI. The highest contributor is milk (cattle) (42%) for 1,2,4 T, maize, corn (1%) for TA, maize, corn (0.6%) for TAA and milk (cattle) (0.6%) for TLA.

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

Accepted by the zRMS

IESTI Calculation

BAS 750 F
A refined IESTI calculation was performed with the current EFSA model (version 3.1) using an ARfD of 0.15 mg/kg bw/day and STMRs as listed in Table 7.2-20 for 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 (0.1%). For adults, the highest ARfD utilization was 0.3% for consumption of barley.
For processed commodities, the highest ARfD utilization was 0.4% for consumption of barley/milling (flour) for children and 0.1% for adults for consumption of oat / boiled.

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

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

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

For processed commodities, the highest ARfD utilization was for consumption of wheat / milling (flour): 0.6% for 1,2,4-T, 1% for TA, 0.8% for TAA and for consumption of barley / milling (flour): 0.2% for TLA for children. For adults, the highest ARfD utilization was for 1,2,4-T 0.4% for consumption of barley / beer, for TA 0.9% for consumption of wheat / bread/pizza, 0.4% for TAA for consumption of barley / beer and 2% for 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 7.2-22: Consumer risk assessment

BAS 750 F	
TMDI (% ADI) according to EFSA PRIMo	Highest TMDI: 32% (NL toddler)
IEDI (% ADI) according to EFSA PRIMo	Highest IEDI: 7% (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: 48% (NL toddler)
IESTI (% ARfD) according to EFSA PRIMo*	unprocessed Highest IESTI: 0.7% (children, wheat) 0.4% (adults, wheat) processed Highest IESTI: 0.6% (children, wheat / milling (flour)) 0.4% (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: 4% (NL toddler)
IESTI (% ARfD) according to EFSA PRIMo*	unprocessed Highest IESTI: 3% (children, wheat) 2% (adults, wheat) processed Highest IESTI: 1% (children, wheat / milling (flour)) 0.9% (adults, wheat / bread/pizza)
NTMDI (% ADI) **	not applicable
NEDI (% ADI)**	not applicable
NESTI (% ARfD) **	not applicable
TAA	
TMDI (% ADI) according to EFSA PRIMo	not applicable
IEDI (% ADI) according to EFSA PRIMo	Highest IEDI: 1% (NL toddler)
IESTI (% ARfD) according to EFSA PRIMo*	unprocessed Highest IESTI: 1% (children, wheat) 0.7% (adults, wheat)

	processed Highest IESTI: 0.8% (children, wheat / milling (flour)) 0.4% (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: 0.1% (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

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

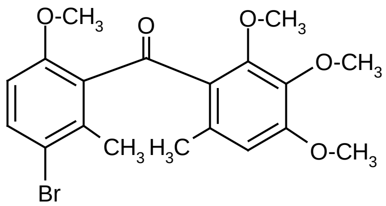
The proposed uses of mefentrifluconazole (BAS 750 F) in the formulation BAS 758 00 F do not represent unacceptable acute and chronic risks for the consumer.

Accepted by the zRMS

7.3 Metrafenone

General data on metrafeneone are summarized in the table below (last updated 2017/12/21)
All information reported in this table can be found in the EFSA Conclusion of the peer review of metrafenone (EFSA Scientific Report (2006) 58, 1- 72).

Table 7.3-1: General information on metrafenone

Active substance (ISO Common Name)	Metrafenone
IUPAC	3'-bromo-2,3,4,6'-tetramethoxy-2',6-dimethylbenzophenone
Chemical structure	
Molecular formula	$C_{19}H_{21}BrO_5$
Molar mass	409.27 g/mol
Chemical group	Benzophenone
Mode of action (if available)	The available data suggest that metrafenone interferes with hyphal morphogenesis, polarized hyphal growth, and establishment and maintenance of cell polarity. Metrafenone likely disturbs a pathway regulating organization of the actin cytoskeleton.
Systemic	Yes
Company (ies)	BASF SE*
Rapporteur Member State (RMS)	UK was the RMS for first review. Latvia is the RMS for the renewal of approval.
Approval status	Approved. Submission for approval renewal made on 19/10/2015 Date of first approval (14/02/2007) and reference to decision (COMMISSION DIRECTIVE 2007/6/EC) Extension of approval,-REGULATION (EU) 2018/524). Regulation (EU) 2022/378
Restriction	Only to be used as a fungicide.
Review Report	SANCO/10280/06 – rev. final, 14/07/2006
Current MRL regulation	Regulation (EU) No 2018/687
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal: Conclusion on the peer review	Yes (EFSA Scientific Report (2006) 58, 1- 72)
EFSA Journal: conclusion on article 12	Yes (EFSA Journal 2013;11(12):3498)
Current MRL applications on intended uses	None

* Notifier in the EU process to whom the a.s. belong(s)
** If yes: EFSA, YYYY - 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

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

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

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Cereal (grain and straw)	High starch content	24 months	UK, 2005 EFSA, 2006 BASF DocID 2002/7004653
Animal Products			
Not relevant since no animal feeding studies were required.			UK, 2005 EFSA, 2006
New data (Submitted to support the renewal of active substance approval for metrafenone)			
Plant products			
Wheat (whole plant)	High starch content	24 months	Lehmann and Mackenroth, 2012, report No. 2012/1166088
Wheat (grain)	High starch content	24 months	Lehmann and Mackenroth, 2012, report No. 2012/1166088
Wheat straw	Dry commodity	24 months	Lehmann and Mackenroth, 2012, report No. 2012/1166088

Conclusion on stability of residues during storage

Residues of metrafenone are stable for at least 24 months in wheat whole plants, grain and straw. These data are sufficient to support the intended use on cereals. Additional data are presented which confirm the earlier studies and also show stability for 24 months in whole cereal plants. No studies assessing the stability of residues in products of animal origin were carried out since livestock feeding studies were not required. No further data are required in the framework of this application.

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								
Fruits and fruiting vegetable	Grape	Bromophenyl-6-^{14}C] and [Trimethoxyphenyl-U-^{14}C]	foliar treatment, F	0.2	5	0 ,19, 35		UK, 2005 EFSA, 2006 BASF DocID 2001/7000342
	Cucumber	[Trimethoxyphenyl-U-^{14}C]	foliar treatment, F	0.2	2	0 (leaf), 14,17$^{(b)}$		EFSA, 2013 BASF DocID 2010/1054630
Cereals	wheat	Bromophenyl-6-^{14}C] and [Trimethoxyphenyl-U-^{14}C]	foliar treatment, F	2x 0.3 + 1x 0.2	3	Immature plant: 0$^{(c)}$, Forage: 3, Hay: 14, Grain & straw: 35		UK, 2005 EFSA, 2006 BASF DocID 2002/7005253

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)
(b): DAT are calculated from the date of first application
(c): 0 DAT after each individual application

Summary of plant metabolism studies reported in the EU

According to the Article 12 review for metrafenone (EFSA Journal 2013;11(12):3498):

"Parent metrafenone is the most important compound in the residue for all crops. The metabolites identified in treated plants (grape leaves only) were oxidation products of the parent compound. In several crop parts, a significant degradation to polar components was also observed and the available metabolism studies did not indicate any evidence of a molecular cleavage of the parent compound. It is concluded that similar metabolism of metrafenone can be assumed in the two crop categories investigated (cereals and fruits and fruiting vegetables).

Based on the above finding, EFSA already concluded that the residue definition for enforcement and risk assessment can be set as metrafenone only (EFSA, 2006). Validated analytical methods for enforcement of the proposed residue definition are available (see also section 1.1). However, the proposed residue definition is restricted to cereals and fruits and fruiting vegetables and no general residue definition for commodities of plant origin can be proposed. It is also noted that metrafenone is authorised for application on cultivated fungi. Although, according to the current guidance documents, the metabolism study on fruits and fruiting vegetables is considered acceptable for cultivated fungi, this extrapolation is uncertain from a scientific point of view. A metabolism study on a third crop group is therefore considered desirable (minor deficiency) as this would provide more certainty on the expectation that the metabolic pattern will not differ in fungi."

Summary of new plant metabolism studies

No new data submitted in the framework of this application.

Conclusion on metabolism in primary crops

Metabolism was investigated in fruit, fruiting vegetables and cereals and has been previously reported in the DAR (UK, 2005; EFSA, 2006). A study using bromophenyl or trimethoxyphenyl 14C-metrafenone in wheat was carried out at exaggerated rates compared to GAP. Based on this study, the residues definition for enforcement and risk assessment was proposed as 'metrafenone only' for cereals.

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing inter-vals (DAT)	Harvest Intervals (DAT)	Re-marks	
EU data								
Fruits and fruiting vege-table	none							
Leafy vegeta-bles	Lettuce	Bromophenyl-6-^{14}C] and [Tri-methoxyphenyl-U-^{14}C]	Bare soil application, F	0.625	30, 60, 90, 365	Immature** and mature plants	Leaves	UK, 2005 EFSA, 2006 BASF DocID 2002/7005187
Root and tu-ber vegeta-bles	Radish	Bromophenyl-6-^{14}C] and [Tri-methoxyphenyl-U-^{14}C]	Bare soil application, F	0.625	30, 60, 90, 365	Mature plants	Roots and leaves	UK, 2005 EFSA, 2006 BASF DocID 2002/7005187
Pulses and oilseeds	Oilseed rape	Bromophenyl-6-^{14}C] and [Tri-methoxyphenyl-U-^{14}C]	Bare soil application, F	0.625	30, 60, 90, 365	Mature plants	Straw, pods, seeds	UK, 2005 EFSA, 2006 BASF DocID 2002/7005187
Cereals	none							

* Outdoor/field application (F) or glasshouse/protected/indoor application (G)
** For the 90 days plant-back interval only

Summary of rotational crop metabolism studies reported in the EU

The metabolism of metrafenone in rotational crops has been previously reported in the DAR (UK, 2005; EFSA, 2006). A study using bromophenyl or trimethoxyphenyl ^{14}C-metrafenone with lettuce, radish and oilseed rape as rotational crops indicated that there is no accumulation of metrafenone or its degradation products in the parts of plants used for human food or animal feed consumption expected. The levels of individual metabolites were below 0.01 mg/kg and therefore a separate residues definition for rotational crops was not required. Since the metabolism in rotational crops study shows that no detectable residues would be expected, field data are not required.

Summary of new plant metabolism studies

No new data in the framework of this application.

Conclusion on metabolism in rotational crops

The available data show that when lettuce, radish and oilseed rape are sown as rotational crops, there is no accumulation of metrafenone or its degradation products in the parts of plants used for human food or animal feed consumption expected. The levels of metrafenone and individual metabolites were below 0.01 mg/kg therefore a separate residues definition for rotational crops is not required. Since the data show that no detectable residues would be expected, field data are not required.

7.3.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

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

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	98.0-105.0% metrafenone	UK, 2005 EFSA, 2006 BASF DocID 2000/7000137
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	94.7-109.9% metrafenone	UK, 2005 EFSA, 2006 BASF DocID 2000/7000137
Sterilisation (20 minutes, 120°C, pH 6)	95.6-96.8% metrafenone	UK, 2005 EFSA, 2006 BASF DocID 2000/7000137
Other conditions	**Identified compound(s) (%)**	
Winemaking …	None	

Conclusion on nature of residues in processed commodities

In a standard nature of the residues study (OECD 507), metrafenone was not degraded during the simulation of pasteurisation (pH 4, 90°C), baking, boiling, brewing (pH 5, 100°C) or sterilisation (pH 6, 120°C).

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

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

Endpoints	
Plant groups covered	Fruit and fruiting vegetables (grapes and cucumber) Cereals (wheat)
Rotational crops covered	Leafy vegetables (lettuce) Root and tuber vegetables (radish) Pulses and oilseeds (oilseed rape)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	a.s. is stable under standard hydrolysis conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Metrafenone (EFSA, 2013)
Plant residue definition for risk assessment	Metrafenone (EFSA, 2006)
Conversion factor from enforcement to RA	Not required (UK, 2005, EFSA, 2006)

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

Available data

A study on lactating goats has previously been submitted. One new metabolism study in hens (a final version of an interim study previously submitted) has been submitted by the applicant in the framework of this application. A detailed assessment of this study is presented in Appendix 2. All available studies are summarized in the table below.

Table 7.3-7: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	Bromophenyl-6-^{14}C] and [Trimethoxyphenyl-U-^{14}C]	5	8 or 13 and 60 or 87 ppm diet (0.39 or 0.36 and 2.87 or 2.52 mg/kg bw/day)	5	Milk	twice daily	UK, 2005; EFSA, 2006 BASF DocID 2002/7005114
						Urine and faeces	daily	
						Tissues	at sacrifice	
Laying poultry	Hens	Bromophenyl-6-^{14}C] and [Trimethoxyphenyl-U-14C]	16	14 ppm diet (0.95-1 mg/kg bw/day)	12	Eggs	daily	UK, 2005; EFSA, 2006 (interim report) BASF DocID 2005/1026047
						Excreta	daily	
						Tissues	at sacrifice	
New data								
Laying poultry	Hens	Bromophenyl-6-^{14}C] and [Trimethoxyphenyl-U-^{14}C]	16	14 ppm diet (0.95-1 mg/kg bw/day)	12	Eggs	daily	Hoefs, 2008, report No 2005/1026047
						Excreta	daily	
						Tissues	at sacrifice	

Summary of animal metabolism studies reported in the EU

Metabolism was investigated in goats. Dosing levels were well above the predicted livestock dietary burden levels and the plateau in milk was seen after 2 days. The majority of radioactivity (76-86%) was excreted in faeces and urine. Parent metrafenone levels were low in all ruminant tissues and no detectable residues of parent or metabolites were seen in fat or milk. Metabolites were detectable liver and kidney which led to a discussion of the residues definition for these commodities under the Article 12 review (EFSA, 2013). However the subsequent risk management decision confirmed the residues definition for monitoring and risk assessment as metrafenone only. An interim study on hen metabolism was reviewed and the final study report has been provided in the context of this submission.

Summary of new animal metabolism studies

In hens dosed for 12 days at *ca.* 14 ppm diet, there was rapid absorption and almost complete excretion within 24 hours. Levels of TRR were low in muscle (0.01 mg/kg), skin with fat (0.07-0.10 mg/kg) and eggs (0.10-0.12 mg/kg) but higher in liver (0.35-0.57 mg/kg). There was no indication of any accumulation in edible tissues or eggs (maximum daily TRR *ca.* 0.12 mg/kg). TRR plateaued in eggs around day 9. Little or no parent compound was detected in eggs or edible tissues. Any metabolites present were at very low levels (<0.01 mg/kg).
In the newly submitted metabolism study for metrafenone in hens, an unknown major metabolite was identified (14% TRR and 0.015 mg eq./kg) in eggs as reported in the detailed study evaluation in Appendix 2.

Conclusion on metabolism in livestock

Metabolism studies were carried out in hens (poultry) and goats (ruminants). Metabolism studies were not necessary in pigs since the metabolite patterns in rodents (rats) and ruminants (goats) did not differ significantly and intakes by pigs are not expected to be significantly higher than other livestock. Metabolism studies in fish were not necessary since intakes did not exceed 0.1 mg/kg total diet (dry matter). Based on dietary burden calculations, residues of parent or any of the low level metabolites would occur at <0.01 mg/kg. This is in line with the Article 12 review for metrafenone (EFSA Journal 2013;11(12):3498) resulting in MRLs under Regulation (EU) 2016/1 and consequently under Regulation (EU) 2018/687.

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

Table 7.3-8: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	2 days in milk
	9 days in eggs
Animal residue definition for monitoring	metrafenone (EFSA 2013; RO 3498)*
Animal residue definition for risk assessment	metrafenone (EFSA 2013)*
Conversion factor	Not relevant
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes

* agreed as subsequent risk management decision (refer to Regulation (EU) 2015/1040)

Since metabolism was similar in rats and goats and intakes in pigs are not expected to be significantly different to other livestock, a metabolism study in pigs is not required.

Intakes by fish are predicted to be below 0.1 ppm diet DM and therefore a metabolism study in fish is not required.

7.3.3 Magnitude of residues in plants (KCA 6.3)

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

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. These studies are summarized in the Table below. The detailed assessment of these studies is presented in Appendix 2. Other residues data are taken from the review of MRLs under article 12 (EFSA, 2013) and the DAR (EFSA, 2006)

Table 7.3-9: Summary of EU reported and new data supporting the intended uses of BAS 758 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	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Wheat and rye grain	EFSA, 2013 UK, 2012 BASF DocID 2002/7004680, 2002/7004745, 2002/7004672, 2001/7000487, 2001/7001658	N-EU	cGAP on which EU a.s. assessment is based: 2 x 0.15 kg as/ha, 21d interval, BBCH 30-79, PHI 35d, outdoor E/RA 6 x < 0.01, 2 x 0.01, 2 x 0.03, 3 x 0.04.	N/A				
	New trials	N-EU	Trials GAP: 2 x 0.15 kg as/ha, 14d interval, LTOA GS59, PHI 56d, outdoor E/RA: 4x <0.01. (less critical GAP)					
	Overall supporting data for cGAP	N-EU	cGAP on which EU a.s. assessment is based: 2 x 0.15 kg as/ha, 21d interval, BBCH 30-79, PHI 35d, outdoor E/RA 6 x < 0.01, 2 x 0.01, 2 x 0.03, 3 x 0.04.	E/RA: 0.01	E/RA: 0.04	N/R	0.07	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	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Wheat straw	EFSA, 2013, UK, 2012 BASF DocID 2002/7004672, 2002/7004680, 2001/7000487, 2002/7004745, 2001/7001658, 2001/7001675	N-EU	cGAP on which EU a.s. assessment is based: 2 x 0.15 kg as/ha, 21d interval, BBCH 30-79, PHI 35d, outdoor E/RA: 0.40, 0.58, 2 x 0.61, 0.67, 0.93, 0.98, 1.43, 1.72, 1.80, 1.85, 2.04, 2.32, 3.86	N/A				
	New trials	N-EU	Trials GAP: 2 x 0.15 kg as/ha, 14d interval, LTOA GS59, PHI 56d, outdoor E/RA: 0.034 ~~0.039,~~ 0.039, 0.04, 0.07 (less critical GAP)					
	Overall supporting data for cGAP	EU	cGAP on which EU a.s. assessment is based: 2 x 0.15 kg as/ha, 21d interval, BBCH 30-79, PHI 35d, outdoor E/RA: 0.40, 0.58, 2 x 0.61, 0.67, 0.93, 0.98, 1.43, 1.72, 1.80, 1.85, 2.04, 2.32, 3.86	E/RA: 1.58	E/RA: 3.86	N/R	N/R (Art.12 HR: 3.86; STMR: 1.21)	N/R
Barley and oat grain	EFSA, 2013 UK, 2012 BASF DocID 2002/7004745, 2002/7004681, 2001/7001660, 2001/7001659, 2001/7001676, 2002/7004445, 2002/7004922	N-EU	cGAP on which EU a.s. assessment is based: 2 x 0.15 kg as/ha, 21d interval, BBCH 30-79, PHI 35d, outdoor E/RA 0.01, 0.02, 0.03, 0.04, 0.06, 0.07, 0.09, 0.11, 0.14, 0.15, 0.15, 0.16, 0.40	N/A				

Commodity	**Source**	**Residue zone (N-EU, S-EU, EU, outside EU)**	**Evaluation** **GAP** **Residue levels (mg/kg)** **E = according to enforcement residue definition** **RA = according to risk assessment residue definition**	**STMR (mg/kg)**	**HR (mg/kg)**	**Unrounded OECD calculator MRL (mg/kg)**	**Current EU MRL (mg/kg) ***	**MRL compliance**
	New trials	N-EU	Trials GAP: 2 x 0.15 kg as/ha, 14d interval, LTOA GS59, PHI 56d, outdoor E/RA: 3x <0.01 0.023 ~~0.018.~~ (less critical GAP)					
	Overall supporting data for cGAP	N-EU	cGAP on which EU a.s. assessment is based: 2 x 0.15 kg as/ha, 21d interval, BBCH 30-79, PHI 35d, outdoor E/RA 0.01, 0.02, 0.03, 0.04, 0.06, 0.07, 0.09, 0.11, 0.14, 0.15, 0.15, 0.16, 0.40	E/RA: 0.09	E/RA: 0.40	N/R	0.6	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	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Barley straw	EFSA, 2013, UK, 2012 BASF DocID 2002/7004681, 2001/7001659, 2002/7004745, 2001/7001676, 2001/7001660, 2002/7004445, 2002/7004922	N-EU	cGAP on which EU a.s. assessment is based: 2 x 0.15 kg as/ha, 21d interval, BBCH 30-79, PHI 35d, outdoor E/RA: 0.54, 0.64, 0.78,1.08, 1.10, 1.11, 1.12, 1.15, 1.28, 1.6, 1.7, 2.01	N/A				
	New trials	N-EU	Trials GAP: 2 x 0.15 kg as/ha, 14d interval, LTOA GS59, PHI 56d, outdoor E/RA: ~~0.039, 0.039, 0.04, 0.07~~ 0.085, 0.087, 0.12, 0.14 (less critical GAP)					
	Overall supporting data for cGAP	EU	cGAP on which EU a.s. assessment is based: 2 x 0.15 kg as/ha, 21d interval, BBCH 30-79, PHI 35d, outdoor E/RA: 0.54, 0.64, 0.78,1.08, 1.10, 1.11, 1.12, 1.15, 1.28, 1.6, 1.7, 2.01	E/RA: 1.12	E/RA: 2.01	N/R	N/R (Art.12 HR: 2.01; STMR: 1.21)	N/R

7.3.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on cereals are considered acceptable, for outdoor uses.
The shorter application interval has no effect on the residue levels in grain and straw.
The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

Since the GAP for BAS 758 00 F is less critical than that considered under the Article 12 review, and additional data show that residues in wheat and braley grain and straw are low compared to the cGAP, no additional dietary burden calculations have been carried out.

7.3.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

An assessment of the transfer of residues into products of animal origin has been previously reported in the DAR (UK, 2005).

The agreed end points from the first EU assessment of metrafenone were set out in the EFSA Conclusion on the peer review of metrafenone (EFSA Scientific Report (2006) 58, 1- 72) and are reproduced below:

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

Intakes by livestock ≥ 0.1 mg/kg diet/day:	Ruminant: yes	Poultry: yes	Pig: yes
Muscle Liver Kidney Fat Milk Eggs	No ruminant feeding study conducted. Metabolism results indicated that residues will not be of significance at N rate.	No hen feeding study conducted. Metabolism results indicated that residues will not be of significance.	No pig feeding study conducted. Metabolism in rat and ruminant similar, ruminant metabolism indicated that residues will not be of significance

This conclusion was subsequently confirmed in EFSA's Reasoned Opinion on metrafenone MRLs following its review under Article 12 (EFSA Journal 2013;11(12):3498).

> "According to the above mentioned metabolism studies in lactating goats, highest residues according to the residue definition were found in liver (0.27 mg/kg at a 38N dosing rate and 0.11 mg/kg at an 8N dosing rate). It is therefore concluded that significant residues in edible matrices of ruminants are not expected based on the calculated dietary burden (see section 3.2.1). Nevertheless, as there are no validated analytical methods to enforce the residue in food of animal origin, EFSA is not in position to derive MRL proposals at LOQ. For pigs and poultry products however, MRLs are not required because these groups of livestock are not expected to be exposed to significant levels of metrafenone residues."

According to the Pesticides Steering Committee notes from their meeting on 19-20 June 2014,

> "New feed items such as wheat forage, hay… have been introduced in the feedstuff tables. After discussion the meeting agreed that, by default, intended uses on cereals should be understood as "on cereal for grain production" and therefore, only residues in grains and straw considered for the animal burden calculation. Residue data at forage, silage growth stages have therefore not to be requested for uses intended on cereal grain. It was agreed that, when grown for forage, silage, the GAPs are different, and therefore, the GAPs proposed for cereal grains would not be relevant to derive residues in forage or silage."

Therefore, livestock dietary burdens have been calculated taking account of residues in cereal grain and straw only.

In the metabolism study in ruminants, goats were fed for 5 days at *ca.* 8 or 60 and 13 or 87 ppm diet (trimethoxyphenyl or bromophenyl labels, respectively). The TRR in muscle was low (<0.01 mg/kg in all dose groups) and therefore it was not characterized. Levels of metrafenone in milk and relevant tissues were as shown below:

Tissue	**Maximum mg/kg metrafenone**		**Dose (ppm diet/mg/kg bw/day, label)**		~~**mg/kg metrafenone based on an intake of *ca.* 3.1 ppm diet (DM) or 1.58 ppm diet (DM) for milk**~~
	Trimethyl oxyphenyl	bromophenyl	Trimethyl oxyphenyl	bromophenyl	
Milk	-	<0.005	60/2.87	87/2.52	~~0.0001~~
Adipose tissue	0.019	0.009	60/2.87	87/2.52	~~0.0003-0.001~~
Liver	0.025	0.035	60/2.87	87/2.52	~~0.001~~
Kidney	0.005	0.014	60/2.87	87/2.52	~~0.0002-0.0005~~

In the metabolism study in poultry, hens were fed for 12 days at *ca.* 14 ppm diet (refer to Appendix 2). mg/kg metrafenone or TRR in eggs and tissues was as shown below:

Tissue	**Maximum mg/kg metrafenone (*ca.* 14 ppm/*ca.* 1 mg/kg bw/day)**	~~**mg/kg TRR based on an intake of 0.84 ppm diet (DM)**~~
Eggs	0.002	~~0.0001~~
Muscle	0.013 (TRR)	~~0.0008~~
Skin with fat	0.001	~~0.00006~~
Liver	<0.001	~~<0.00006~~

Livestock dietary burdens have been calculated using the EFSA 2017 model. When comparing the dietary burden to the TRR from livestock metabolism studies, it can be clearly seen that residues will not exceed the current MRLs of 0.01* mg/kg metrafenone. The exception is sheep liver where an MRL of 0.02 mg/kg is calculated based on TRR levels. However when the calculation is carried out based on metrafenone rather than TRR (metrafenone is 3.5% of TRR in ruminant liver) the current MRL of 0.01* mg/kg is shown to be sufficient.

Animal burden calculation	metrafenone
According to:	"OECD Guidance Document, Series on testing and assessment No 64 and Series on pesticides No 32" and "OECD Guidance Document on Residues in livestock, Series on Pesticides No 73"

Maximum Intake	Cattle						Sheep					
	Beef	500 kg 12 kg		Dairy	650 kg 25 kg		Ram/Ewe	75 kg 2.5 kg		Lamb	40 kg 1.7 kg	
(mg/kg bw/d)	0.011	mg/kg bw/d	%	0.016	mg/kg bw/d	%	0.026	mg/kg bw/d	%	0.033	mg/kg bw/d	%
Contributor 1	Barley	straw	30	Barley	straw	30	Barley	straw	60	Barley	straw	60
Contributor 2	Barley	grain	70	Barley	grain	40	Barley	grain	40	Barley	grain	40
Contributor 3			0	Wheat	milled bypdt	30			0			0
Contributor 4												
Median intake	0.0106	mg/kg bw/d		0.0162	mg/kg bw/d		0.0261	mg/kg bw/d		0.0333	mg/kg bw/d	

Maximum Intake	Swine					
	Breeding	260 kg 6 kg		Finishing	100 kg 3 kg	
(mg/kg bw/d)	0.002	mg/kg bw/d	%	0.003	mg/kg bw/d	%
Contributor 1	Barley	grain	80	Barley	grain	80
Contributor 2	Distiller's grain	dried	20	Distiller's grain	dried	20
Contributor 3						
Contributor 4						
Median intake	0.002	mg/kg bw/d		0.003	mg/kg bw/d	

Intakes >0.004 mg/kg bw/d are highlighted

Maximum Intake	Poultry								
	Broiler	1.7 kg 0.12 kg		Layer	1.9 kg 0.13 kg		Turkey	7 kg 0.5 kg	
(mg/kg bw/d)	0.006	mg/kg bw/d	%	0.016	mg/kg bw/d	%	0.004	mg/kg bw/d	%
Contributor 1	Barley	grain	70	Wheat	straw	10	Barley	grain	50
Contributor 2	Wheat	milled bypdt	20	Barley	grain	90	Wheat	milled bypdt	20
Contributor 3						0			
Contributor 4									
Median intake	0.006	mg/kg bw		0.016	mg/kg bw		0.004	mg/kg bw	

Intakes expressed on the dry mater basis (mg/kg DM)						
mg/kg DM	Cattle		Sheep		Swine	
	Beef	Dairy	Ram/Ewe	Lamb	Breeding	Finishing
Maximum	0.44	0.42	0.8	0.78	0.09	0.09
Median	0.44	0.42	0.78	0.78	0.09	0.09
	Poultry					
	Broiler	Layer	Turkey	Intake >0.1 mg/kg DM in red characters		
Maximum	0.08	0.23	0.06			
Median	0.08	0.23	0.06			

Animal commodity	Residues at the closet feeding level (mg/kg)		Estimated value at 1N level		MRL proposal (mg/kg)	CF	STMR (mg/kg)	HR (mg/kg)
	Mean	Highest	$STMR_{Mo}$ (mg/kg)	HR_{Mo} (mg/kg)				
Cattle (all diets)								
Closest feeding level[(a)]:	0.39	mg/kg bw	24.1 N Dairy cattle (highest diet)					
Muscle	0.01	0.01	0.01	0.01	**0.005**	n.c.	0.01	0.01
Fat	0.01	0.01	0.01	0.01	**0.005**	n.c.	0.01	0.01
Liver	0.21	0.21	0.01	0.01	**0.009**	n.c.	0.01	0.01
Kidney	0.05	0.05	0.00	0.00	**0.002**	n.c.	0.00	0.00
Cattle (dairy only)								
Closest feeding level[(a)]:	0.39	mg/kg bw	24.1 N Dairy cattle					
Milk[(b)]	0.01	0.01	0.01	0.01	**0.005**	n.c.	0.01	0.01
Sheep (all diets)								
Closest feeding level[(a)]:	0.39	mg/kg bw	11.7 N Lamb (highest diet)					
Muscle	0.01	0.01	0.01	0.01	**0.005**	n.c.	0.01	0.01
Fat	0.01	0.01	0.01	0.01	**0.005**	n.c.	0.01	0.01
Liver	0.21	0.21	0.02	0.02	**0.02**	n.c.	0.02	0.02
Kidney	0.05	0.05	0.00	0.00	**0.004**	n.c.	0.00	0.00
Sheep (dairy only)								
Closest feeding level[(a)]:	0.39	mg/kg bw	15.0 N Ewe					
Milk[(b)]	0.01	0.01	0.01	0.01	**0.005**	n.c.	0.01	0.01
Swine								
Closest feeding level[(a)]:	0.39	mg/kg bw	146.1 N Finishing (highest diet)					
Muscle	0.01	0.01	0.01	0.01	**0.005**	n.c.	0.01	0.01
Fat	0.01	0.01	0.01	0.01	**0.005**	n.c.	0.01	0.01
Liver	0.21	0.21	0.00	0.00	**0.0015**	n.c.	0.00	0.00
Kidney	0.05	0.05	0.00	0.00	**0.001**	n.c.	0.00	0.00
Poultry (all diets)								
Closest feeding level[(a)]:	0.95	mg/kg bw	60.8 N Layer (highest diet)					
Muscle	0.01	0.01	0.00	0.00	**0.001**			
Fat	0.10	0.10	0.00	0.00	**0.002**			
Liver	0.35	0.35	0.01	0.01	**0.006**			
Poultry (layer only)								
Closest feeding level[(a)]:	0.95	mg/kg bw	60.8 N Layer					
Eggs[(c)]	0.12	0.12	0.00	0.00	**0.002**			

Available data

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

Conclusion on feeding studies

The requested uses (and the new mode of calculation) modify the livestock dietary burden for animals, but regarding available feeding data, there is no risk for the current MRLs for products of animal origin (0.01* mg/kg) to be exceeded.

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

7.3.5.1 Available data for all crops under consideration

The effects of processing on residues of metrafenone have been previously reported in the DAR (UK, July 2005) and the EFSA Conclusion on the peer review of metrafenone (EFSA Scientific Report (2006) 58, 1-72).

This conclusion was subsequently confirmed in EFSA's Reasoned Opinion on metrafenone MRLs following its review under Article 12 (EFSA Journal 2013;11(12):3498).

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

Table 7.3-10: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
Enforcement residue definition: metrafenone					
Barley/ Pearl barley	1	0.14	N/A		UK, 2003 EFSA, 2006 BASF DocID 2002/1004080
Barley/ Bran	1	2.9	N/A	-	UK, 2003 EFSA, 2006 BASF DocID 2002/1004080
Barley/ Beer	1	0.14	N/A	-	UK, 2003 EFSA, 2006 BASF DocID 2002/1004080

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

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

7.3.5.2 Conclusion on processing studies

No additional data are provided. Available data show that residues of metrafenone are reduced when barley is processed into pearl barley or beer but are concentrated into the bran fraction. A processing factor of 2.9 was derived. EFSA considered these processing factors as indicative only due to a limited dataset (only 1 processing study). Nevertheless, further processing studies are not required in this case as they are not expected to affect the outcome of the risk assessment (EFSA Journal 2013;11(12):3498.

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 7.2.2.2), 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.

Data/information on residues in succeeding crops (Annex II Section 4 Point 6.6.1) was assessed for the first EU approval of metrafenone and was considered to be acceptable. The metabolism of metrafenone in rotational crops has been previously reported in the DAR (UK, July 2005). The agreed end points from the first EU assessment of metrafenone were set out in the EFSA Conclusion on the peer review of metrafenone (EFSA Scientific Report (2006) 58, 1- 72) and are reproduced below:

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)	Not required. Based on rotational crops metabolism data residues in succeeding crops are unlikely if metrafenone is used according to GAP.

This conclusion was subsequently confirmed in EFSA's Reasoned Opinion on metrafenone MRLs following its review under Article 12 (EFSA Journal 2013;11(12):3498).

Conclusion on rotational crops studies

No data from field rotational crop studies are required. Based on rotational crops metabolism data, residues in succeeding crops are unlikely when metrafenone is used in accordance with the intended GAP.

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 758 00 F. Therefore, other special studies are not needed.

For the intended uses on cereals no further studies regarding honey are necessary. According SANTE/11956/2016 rev. 9, cereals (barley, oat, wheat, triticale and rye) does not have melliferous capacity. However, in the context of the approval renewal of metrafenone additional data were submitted and the results indicated that no residues of BAS 750 F are expected in honey.

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

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

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

7.3.8.1 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) 2018/687 were used as input values.
The following table summarizes the input values from plant and animal commodities used for the chronic (IEDI) and dietary risk assessment (according to EFSA PRIMO model vers. 3.1).

Table 7.3-11: 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 plants and animals: metrafenone)				
Grapefruits	0.01	MRL Reg. (EU) 2018/687	-	
Oranges	0.01	MRL Reg. (EU) 2018/687	-	
Lemons	0.01	MRL Reg. (EU) 2018/687	-	
Limes	0.01	MRL Reg. (EU) 2018/687	-	
Mandarins	0.01	MRL Reg. (EU) 2018/687	-	
Other citrus fruit	0.01	MRL Reg. (EU) 2018/687	-	
Almonds	0.01	MRL Reg. (EU) 2018/687	-	
Brazil nuts	0.01	MRL Reg. (EU) 2018/687	-	
Cashew nuts	0.01	MRL Reg. (EU) 2018/687	-	
Chestnuts	0.01	MRL Reg. (EU) 2018/687	-	
Coconuts	0.01	MRL Reg. (EU) 2018/687	-	
Hazelnuts/cobnuts	0.01	MRL Reg. (EU) 2018/687	-	
Macadamia	0.01	MRL Reg. (EU) 2018/687	-	
Pecans	0.01	MRL Reg. (EU) 2018/687	-	
Pine nut kernels	0.01	MRL Reg. (EU) 2018/687	-	
Pistachios	0.01	MRL Reg. (EU) 2018/687	-	
Walnuts	0.01	MRL Reg. (EU) 2018/687	-	
Other tree nuts	0.01	MRL Reg. (EU) 2018/687	-	
Apples	0.23	STMR-RAC (EFSA, 2015)	-	
Pears	0.23	STMR-RAC (EFSA, 2015)	-	
Quinces	0.23	STMR-RAC (EFSA, 2015)	-	
Medlar	0.23	STMR-RAC (EFSA, 2015)	-	
Loquats/Japanese medlars	0.23	STMR-RAC (EFSA, 2015)	-	
Other pome fruit	0.23	STMR-RAC (EFSA, 2015)	-	
Apricots	0.21	STMR-RAC (EFSA, 2015)	-	
Cherries (sweet)	0.52	STMR-RAC (EFSA, 2015)	-	
Peaches	0.21	STMR-RAC (EFSA, 2015)	-	
Plums	0.01	MRL Reg. (EU) 2018/687	-	
Other stone fruit	0.01	MRL Reg. (EU) 2018/687	-	
Table grapes	1.08	STMR-RAC (EFSA, 2013)	-	

Commodity	Chronic risk assessment (normal mode)		Acute risk assessment (refined calculation mode)	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Wine grapes	0.24	STMR-RAC (EFSA, 2013)	-	
Strawberries	0.13	STMR-RAC (EFSA, 2013)	-	
Blackberries	0.01	MRL Reg. (EU) 2018/687	-	
Dewberries	0.01	MRL Reg. (EU) 2018/687	-	
Raspberries (red and yellow)	0.01	MRL Reg. (EU) 2018/687	-	
Other cane fruit	0.01	MRL Reg. (EU) 2018/687	-	
Blueberries	0.01	MRL Reg. (EU) 2018/687	-	
Cranberries	0.01	MRL Reg. (EU) 2018/687	-	
Currants (red, black and white)	0.01	MRL Reg. (EU) 2018/687	-	
Gooseberries (green, red and yellow)	0.01	MRL Reg. (EU) 2018/687	-	
Rose hips	0.01	MRL Reg. (EU) 2018/687	-	
Mulberries (black and white)	0.01	MRL Reg. (EU) 2018/687	-	
Azarole/Mediteranean medlar	0.23	STMR-RAC (EFSA, 2017)	-	
Elderberries	0.01	MRL Reg. (EU) 2018/687	-	
Other small fruit & berries	0.01	MRL Reg. (EU) 2018/687	-	
Dates	0.01	MRL Reg. (EU) 2018/687	-	
Figs	0.01	MRL Reg. (EU) 2018/687	-	
Table olives	0.01	MRL Reg. (EU) 2018/687	-	
Kumquats	0.01	MRL Reg. (EU) 2018/687	-	
Carambolas	0.01	MRL Reg. (EU) 2018/687	-	
Kaki/Japanese persimmons	0.23	STMR-RAC (EFSA, 2017)	-	
Jambuls/jambolans	0.01	MRL Reg. (EU) 2018/687	-	
Other miscellaneous fruit (edible peel)	0.01	MRL Reg. (EU) 2018/687	-	
Kiwi fruits (green, red, yellow)	0.01	MRL Reg. (EU) 2018/687	-	
Litchis/lychees	0.01	MRL Reg. (EU) 2018/687	-	
Passionfruits/maracujas	0.01	MRL Reg. (EU) 2018/687	-	
Prickly pears/cactus fruits	0.01	MRL Reg. (EU) 2018/687	-	
Star apples/cainitos	0.01	MRL Reg. (EU) 2018/687	-	
American persimmon/Virginia kaki	0.01	MRL Reg. (EU) 2018/687	-	
Other miscellaneous fruit (inedible peel, small)	0.01	MRL Reg. (EU) 2018/687	-	
Avocados	0.01	MRL Reg. (EU) 2018/687	-	
Bananas	0.01	MRL Reg. (EU) 2018/687	-	
Mangoes	0.01	MRL Reg. (EU) 2018/687	-	
Papayas	0.01	MRL Reg. (EU) 2018/687	-	
Granate apples/pomegranates	0.01	MRL Reg. (EU) 2018/687	-	
Cherimoyas	0.01	MRL Reg. (EU) 2018/687	-	
Guavas	0.01	MRL Reg. (EU) 2018/687	-	
Pineapples	0.01	MRL Reg. (EU) 2018/687	-	
Breadfruits	0.01	MRL Reg. (EU) 2018/687	-	
Durians	0.01	MRL Reg. (EU) 2018/687	-	
Soursops/guanabanas	0.01	MRL Reg. (EU) 2018/687	-	
Other miscallaneous fruit (inedible peel, large)	0.01	MRL Reg. (EU) 2018/687	-	
Potatoes	0.01	MRL Reg. (EU) 2018/687	-	
Cassava roots/manioc	0.01	MRL Reg. (EU) 2018/687	-	
Sweet potatoes	0.01	MRL Reg. (EU) 2018/687	-	

Commodity	Chronic risk assessment (normal mode)		Acute risk assessment (refined calculation mode)	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Yams	0.01	MRL Reg. (EU) 2018/687	-	
Arrowroots	0.01	MRL Reg. (EU) 2018/687	-	
Other tropical root and tuber vegetables	0.01	MRL Reg. (EU) 2018/687	-	
Beetroots	0.01	MRL Reg. (EU) 2018/687	-	
Carrots	0.01	MRL Reg. (EU) 2018/687	-	
Celeriacs/turnip rooted celer-ies	0.01	MRL Reg. (EU) 2018/687	-	
Horseradishes	0.01	MRL Reg. (EU) 2018/687	-	
Jerusalem artichokes	0.01	MRL Reg. (EU) 2018/687	-	
Parsnips	0.01	MRL Reg. (EU) 2018/687	-	
Parsley roots/Hamburg roots parsley	0.01	MRL Reg. (EU) 2018/687	-	
Radishes	0.01	MRL Reg. (EU) 2018/687	-	
Salsifies	0.01	MRL Reg. (EU) 2018/687	-	
Swedes/rutabagas	0.01	MRL Reg. (EU) 2018/687	-	
Turnips	0.01	MRL Reg. (EU) 2018/687	-	
Other other root and tuber vegetables	0.01	MRL Reg. (EU) 2018/687	-	
Garlic	0.01	MRL Reg. (EU) 2018/687	-	
Onions	0.01	MRL Reg. (EU) 2018/687	-	
Shallots	0.01	MRL Reg. (EU) 2018/687	-	
Spring onions/green onions and Welsh onions	0.01	MRL Reg. (EU) 2018/687	-	
Other bulb vegetables	0.01	MRL Reg. (EU) 2018/687	-	
Tomatoes	0.11	STMR-RAC (EFSA, 2017)	-	
Sweet peppers/bell peppers	0.35	STMR-RAC (EFSA, 2017)	-	
Aubergines/egg plants	0.11	STMR-RAC (EFSA, 2017)	-	
Okra/lady’s fingers	0.01	MRL Reg. (EU) 2018/687	-	
Other solanacea	0.01	MRL Reg. (EU) 2018/687	-	
Cucumbers	0.13	STMR-RAC (EFSA, 2017)	-	
Gherkins	0.13	STMR-RAC (EFSA, 2017)	-	
Courgettes	0.13	STMR-RAC (EFSA, 2017)	-	
Other cucurbits - edible peel	0.13	STMR-RAC (EFSA, 2017)	-	
Melons	0.13	STMR-RAC (EFSA, 2017)	-	
Pumpkins	0.13	STMR-RAC (EFSA, 2017)	-	
Watermelons	0.13	STMR-RAC (EFSA, 2017)	-	
Other cucurbits - inedible peel	0.13	STMR-RAC (EFSA, 2017)	-	
Sweet corn	0.01	MRL Reg. (EU) 2018/687	-	
Broccoli	0.01	MRL Reg. (EU) 2018/687	-	
Cauliflowers	0.01	MRL Reg. (EU) 2018/687	-	
Other flowering brassica	0.01	MRL Reg. (EU) 2018/687	-	
Brussels sprouts	0.01	MRL Reg. (EU) 2018/687	-	
Head cabbages	0.01	MRL Reg. (EU) 2018/687	-	
Other head brassica	0.01	MRL Reg. (EU) 2018/687	-	
Chinese cabbages/pe-tsai	0.01	MRL Reg. (EU) 2018/687	-	
Kales	0.01	MRL Reg. (EU) 2018/687	-	
Other leafy brassica	0.01	MRL Reg. (EU) 2018/687	-	
Kohlrabies	0.01	MRL Reg. (EU) 2018/687	-	
Lamb's lettuce/corn salads	0.01	MRL Reg. (EU) 2018/687	-	
Lettuces	0.01	MRL Reg. (EU) 2018/687	-	

Commodity	Chronic risk assessment (normal mode)		Acute risk assessment (refined calculation mode)	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Escaroles/broad-leaved endives	0.01	MRL Reg. (EU) 2018/687	-	
Cress and other sprouts and shoots	0.01	MRL Reg. (EU) 2018/687	-	
Land cress	0.01	MRL Reg. (EU) 2018/687	-	
Roman rocket/rucola	0.01	MRL Reg. (EU) 2018/687	-	
Red mustards	0.01	MRL Reg. (EU) 2018/687	-	
Baby leaf crops (including brassica species)	0.01	MRL Reg. (EU) 2018/687	-	
Other lettuce and other salad plants	0.01	MRL Reg. (EU) 2018/687	-	
Spinaches	0.01	MRL Reg. (EU) 2018/687	-	
Purslanes	0.01	MRL Reg. (EU) 2018/687	-	
Chards/beet leaves	0.01	MRL Reg. (EU) 2018/687	-	
Other spinach and similar	0.01	MRL Reg. (EU) 2018/687	-	
Grape leaves and similar species	0.01	MRL Reg. (EU) 2018/687	-	
Watercress	0.01	MRL Reg. (EU) 2018/687	-	
Witloofs/Belgian endives	0.01	MRL Reg. (EU) 2018/687	-	
Chervil	0.02	MRL Reg. (EU) 2018/687	-	
Chives	0.02	MRL Reg. (EU) 2018/687	-	
Celery leaves	0.02	MRL Reg. (EU) 2018/687	-	
Parsley	0.02	MRL Reg. (EU) 2018/687	-	
Sage	0.02	MRL Reg. (EU) 2018/687	-	
Rosemary	0.02	MRL Reg. (EU) 2018/687	-	
Thyme	0.02	MRL Reg. (EU) 2018/687	-	
Basil and edible flowers	0.02	MRL Reg. (EU) 2018/687	-	
Laurel/bay leaves	0.02	MRL Reg. (EU) 2018/687	-	
Tarragon	0.02	MRL Reg. (EU) 2018/687	-	
Other herbs	0.02	MRL Reg. (EU) 2018/687	-	
Beans (with pods)	0.01	MRL Reg. (EU) 2018/687	-	
Beans (without pods)	0.01	MRL Reg. (EU) 2018/687	-	
Peas (with pods)	0.01	MRL Reg. (EU) 2018/687	-	
Peas (without pods)	0.01	MRL Reg. (EU) 2018/687	-	
Lentils (fresh)	0.01	MRL Reg. (EU) 2018/687	-	
Other legume vegetables (fresh)	0.01	MRL Reg. (EU) 2018/687	-	
Asparagus	0.01	MRL Reg. (EU) 2018/687	-	
Cardoons	0.01	MRL Reg. (EU) 2018/687	-	
Celeries	0.01	MRL Reg. (EU) 2018/687	-	
Florence fennels	0.01	MRL Reg. (EU) 2018/687	-	
Globe artichokes	0.01	MRL Reg. (EU) 2018/687	-	
Leeks	0.01	MRL Reg. (EU) 2018/687	-	
Rhubarbs	0.01	MRL Reg. (EU) 2018/687	-	
Bamboo shoots	0.01	MRL Reg. (EU) 2018/687	-	
Palm hearts	0.01	MRL Reg. (EU) 2018/687	-	
Other stem vegetables	0.01	MRL Reg. (EU) 2018/687	-	
Cultivated fungi	0.11	STMR-RAC (EFSA, 2013)	-	
Wild fungi	0.01	MRL Reg. (EU) 2018/687	-	
Mosses and lichens	0.01	MRL Reg. (EU) 2018/687	-	
Algae and prokaryotes organisms	0.01	MRL Reg. (EU) 2018/687	-	

Commodity	Chronic risk assessment (normal mode)		Acute risk assessment (refined calculation mode)	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Beans	0.01	MRL Reg. (EU) 2018/687	-	
Lentils	0.01	MRL Reg. (EU) 2018/687	-	
Peas	0.01	MRL Reg. (EU) 2018/687	-	
Lupins/lupini beans	0.01	MRL Reg. (EU) 2018/687	-	
Other pulses	0.01	MRL Reg. (EU) 2018/687	-	
Linseeds	0.01	MRL Reg. (EU) 2018/687	-	
Peanuts/groundnuts	0.01	MRL Reg. (EU) 2018/687	-	
Poppy seeds	0.01	MRL Reg. (EU) 2018/687	-	
Sesame seeds	0.01	MRL Reg. (EU) 2018/687	-	
Sunflower seeds	0.01	MRL Reg. (EU) 2018/687	-	
Rapeseeds/canola seeds	0.01	MRL Reg. (EU) 2018/687	-	
Soyabeans	0.01	MRL Reg. (EU) 2018/687	-	
Mustard seeds	0.01	MRL Reg. (EU) 2018/687	-	
Cotton seeds	0.01	MRL Reg. (EU) 2018/687	-	
Pumpkin seeds	0.01	MRL Reg. (EU) 2018/687	-	
Safflower seeds	0.01	MRL Reg. (EU) 2018/687	-	
Borage seeds	0.01	MRL Reg. (EU) 2018/687	-	
Gold of pleasure seeds	0.01	MRL Reg. (EU) 2018/687	-	
Hemp seeds	0.01	MRL Reg. (EU) 2018/687	-	
Castor beans	0.01	MRL Reg. (EU) 2018/687	-	
Other oilseeds	0.01	MRL Reg. (EU) 2018/687	-	
Olives for oil production	0.01	MRL Reg. (EU) 2018/687	-	
Oil palm kernels	0.01	MRL Reg. (EU) 2018/687	-	
Oil palm fruits	0.01	MRL Reg. (EU) 2018/687	-	
Kapok	0.01	MRL Reg. (EU) 2018/687	-	
Other oilfruit	0.01	MRL Reg. (EU) 2018/687	-	
Barley	0.09	This assessment	-	
Buckwheat and other pseudo-cereals	0.01	MRL Reg. (EU) 2018/687	-	
Maize/corn	0.01	MRL Reg. (EU) 2018/687	-	
Common millet/proso millet	0.01	MRL Reg. (EU) 2018/687	-	
Oat	0.09	This assessment	-	
Rice	0.01	MRL Reg. (EU) 2018/687	-	
Rye	0.04	STMR-RAC (EFSA, 2013)	-	
Sorghum	0.01	MRL Reg. (EU) 2018/687	-	
Wheat	0.04	STMR-RAC (EFSA, 2013)	-	
Other cereals	0.01	MRL Reg. (EU) 2018/687	-	
Tea (dried leaves of Camellia sinensis)	0.05	MRL Reg. (EU) 2018/687	-	
Coffee beans	0.05	MRL Reg. (EU) 2018/687	-	
Chamomille	0.05	MRL Reg. (EU) 2018/687	-	
Hybiscus/roselle	0.05	MRL Reg. (EU) 2018/687	-	
Rose	0.05	MRL Reg. (EU) 2018/687	-	
Jasmine	0.05	MRL Reg. (EU) 2018/687	-	
Lime/linden	0.05	MRL Reg. (EU) 2018/687	-	
Other herbal infusions (dried flowers)	0.05	MRL Reg. (EU) 2018/687	-	
Strawberry leaves	0.05	MRL Reg. (EU) 2018/687	-	
Rooibos	0.05	MRL Reg. (EU) 2018/687	-	
Mate/maté	0.05	MRL Reg. (EU) 2018/687	-	

Commodity	Chronic risk assessment (normal mode)		Acute risk assessment (refined calculation mode)	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Other herbal infusions (dried leaves)	0.05	MRL Reg. (EU) 2018/687	-	
Valerian root	0.05	MRL Reg. (EU) 2018/687	-	
Ginseng root	0.05	MRL Reg. (EU) 2018/687	-	
Other herbal infusions (dried roots)	0.05	MRL Reg. (EU) 2018/687	-	
Cocoa beans	0.05	MRL Reg. (EU) 2018/687	-	
Carobs/Staint John's bread	0.05	MRL Reg. (EU) 2018/687	-	
HOPS (dried)	22.05	STMR-RAC (EFSA, 2013)	-	
Anise/aniseed	0.05	MRL Reg. (EU) 2018/687	-	
Black caraway/black cumin	0.05	MRL Reg. (EU) 2018/687	-	
Celery seed	0.05	MRL Reg. (EU) 2018/687	-	
Coriander seed	0.05	MRL Reg. (EU) 2018/687	-	
Cumin seed	0.05	MRL Reg. (EU) 2018/687	-	
Dill seed	0.05	MRL Reg. (EU) 2018/687	-	
Fennel seed	0.05	MRL Reg. (EU) 2018/687	-	
Fenugreek	0.05	MRL Reg. (EU) 2018/687	-	
Nutmeg	0.05	MRL Reg. (EU) 2018/687	-	
Other spices (seeds)	0.05	MRL Reg. (EU) 2018/687	-	
Allspice/pimento	0.05	MRL Reg. (EU) 2018/687	-	
Sichuan pepper	0.05	MRL Reg. (EU) 2018/687	-	
Caraway	0.05	MRL Reg. (EU) 2018/687	-	
Cardamom	0.05	MRL Reg. (EU) 2018/687	-	
Juniper berry	0.05	MRL Reg. (EU) 2018/687	-	
Peppercorn (black, green and white)	0.05	MRL Reg. (EU) 2018/687	-	
Vanilla pods	0.05	MRL Reg. (EU) 2018/687	-	
Tamarind	0.05	MRL Reg. (EU) 2018/687	-	
Other spices (fruits)	0.05	MRL Reg. (EU) 2018/687	-	
Cinnamon	0.05	MRL Reg. (EU) 2018/687	-	
Other spices (bark)	0.05	MRL Reg. (EU) 2018/687	-	
Liquorice	0.05	MRL Reg. (EU) 2018/687	-	
Ginger	0.05	MRL Reg. (EU) 2018/687	-	
Turmeric/curcuma	0.05	MRL Reg. (EU) 2018/687	-	
Horseradish, root spices	0.01	MRL Reg. (EU) 2018/687	-	
Other spices (roots)	0.05	MRL Reg. (EU) 2018/687	-	
Cloves	0.05	MRL Reg. (EU) 2018/687	-	
Capers	0.05	MRL Reg. (EU) 2018/687	-	
Other spices (buds)	0.05	MRL Reg. (EU) 2018/687	-	
Saffron	0.05	MRL Reg. (EU) 2018/687	-	
Other spices (flower stigma)	0.05	MRL Reg. (EU) 2018/687	-	
Mace	0.05	MRL Reg. (EU) 2018/687	-	
Other spices (aril)	0.05	MRL Reg. (EU) 2018/687	-	
Sugar beet roots	0.01	MRL Reg. (EU) 2018/687	-	
Sugar canes	0.01	MRL Reg. (EU) 2018/687	-	
Chicory roots	0.01	MRL Reg. (EU) 2018/687	-	
Other sugar plants	0.01	MRL Reg. (EU) 2018/687	-	
Swine: Muscle/meat	0.01	MRL Reg. (EU) 2018/687	-	
Swine: Fat tissue	0.01	MRL Reg. (EU) 2018/687	-	
Swine: Liver	0.01	MRL Reg. (EU) 2018/687	-	

Commodity	Chronic risk assessment (normal mode)		Acute risk assessment (refined calculation mode)	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Swine: Kidney	0.01	MRL Reg. (EU) 2018/687	-	
Swine: Edible offals (other than liver and kidney)	0.01	MRL Reg. (EU) 2018/687	-	
Swine: Other products	0.01	MRL Reg. (EU) 2018/687	-	
Bovine: Muscle/meat	0.01	MRL Reg. (EU) 2018/687	-	
Bovine: Fat tissue	0.01	MRL Reg. (EU) 2018/687	-	
Bovine: Liver	0.01	MRL Reg. (EU) 2018/687	-	
Bovine: Kidney	0.01	MRL Reg. (EU) 2018/687	-	
Bovine: Edible offals (other than liver and kidney)	0.01	MRL Reg. (EU) 2018/687	-	
Bovine: Other products	0.01	MRL Reg. (EU) 2018/687	-	
Sheep: Muscle/meat	0.01	MRL Reg. (EU) 2018/687	-	
Sheep: Fat tissue	0.01	MRL Reg. (EU) 2018/687	-	
Sheep: Liver	0.01	MRL Reg. (EU) 2018/687	-	
Sheep: Kidney	0.01	MRL Reg. (EU) 2018/687	-	
Sheep: Edible offals (other than liver and kidney)	0.01	MRL Reg. (EU) 2018/687	-	
Sheep: other products	0.01	MRL Reg. (EU) 2018/687	-	
Goat: Muscle/meat	0.01	MRL Reg. (EU) 2018/687	-	
Goat: Fat tissue	0.01	MRL Reg. (EU) 2018/687	-	
Goat: Liver	0.01	MRL Reg. (EU) 2018/687	-	
Goat: Kidney	0.01	MRL Reg. (EU) 2018/687	-	
Goat: Edible offals (other tha liver and kindey)	0.01	MRL Reg. (EU) 2018/687	-	
Goat: other products	0.01	MRL Reg. (EU) 2018/687	-	
Equine: Muscle/meat	0.01	MRL Reg. (EU) 2018/687	-	
Equine: Fat tissue	0.01	MRL Reg. (EU) 2018/687	-	
Equine: Liver	0.01	MRL Reg. (EU) 2018/687	-	
Equine: Kidney	0.01	MRL Reg. (EU) 2018/687	-	
Equine: Edible offals (other than liver and kidney)	0.01	MRL Reg. (EU) 2018/687	-	
Equine: Other products	0.01	MRL Reg. (EU) 2018/687	-	
Poultry: Muscle/meat	0.01	MRL Reg. (EU) 2018/687	-	
Poultry: Fat tissue	0.01	MRL Reg. (EU) 2018/687	-	
Poultry: Liver	0.01	MRL Reg. (EU) 2018/687	-	
Poultry: Kidney	0.01	MRL Reg. (EU) 2018/687	-	
Poultry: Edible offals (other than liver and kideny)	0.01	MRL Reg. (EU) 2018/687	-	
Poultry: Other products	0.01	MRL Reg. (EU) 2018/687	-	
Other farmed animals: Mus-cle/meat	0.01	MRL Reg. (EU) 2018/687	-	
Other farmed animals: Fat tissue	0.01	MRL Reg. (EU) 2018/687	-	
Other farmed animals: Liver	0.01	MRL Reg. (EU) 2018/687	-	
Other farmed animals: Kid-ney	0.01	MRL Reg. (EU) 2018/687	-	
Other farmed animals: Edible offals (other than liver and kidney)	0.01	MRL Reg. (EU) 2018/687	-	
Other farmed animals: Other products	0.01	MRL Reg. (EU) 2018/687	-	
Milk: Cattle	0.01	MRL Reg. (EU) 2018/687	-	
Milk: Sheep	0.01	MRL Reg. (EU) 2018/687	-	
Milk: Goat	0.01	MRL Reg. (EU) 2018/687	-	

Commodity	Chronic risk assessment (normal mode)		Acute risk assessment (refined calculation mode)	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Milk: Horse	0.01	MRL Reg. (EU) 2018/687	-	
Milk: Others	0.01	MRL Reg. (EU) 2018/687	-	
Eggs: Chicken	0.01	MRL Reg. (EU) 2018/687	-	
Eggs: Duck	0.01	MRL Reg. (EU) 2018/687	-	
Eggs: Goose	0.01	MRL Reg. (EU) 2018/687	-	
Eggs: Quail	0.01	MRL Reg. (EU) 2018/687	-	
Eggs: Others	0.01	MRL Reg. (EU) 2018/687	-	
Honey and other apiculture products	0.05	MRL Reg. (EU) 2018/687	-	
Amphibians and reptiles	0.01	MRL Reg. (EU) 2018/687	-	
Terrestrial invertebrate animals	0.01	MRL Reg. (EU) 2018/687	-	
Wild terrestrial vertebrate animals	0.01	MRL Reg. (EU) 2018/687	-	

7.3.8.2 Conclusion on consumer risk assessment

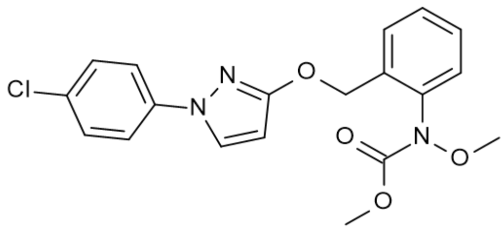
~~Since the GAP for BAS 758 00 F does not lead to higher residues in cereals than have already been assessed, no additional consumer exposure assessments have been conducted.~~
Chronic consumer exposure resulting from the authorised uses reported in the EFSA Article 12 review (EFSA Journal 2013; 11(12); 3498), EFSA MRL review for hops (EFSA Journal 2015;13(4):4078) and the scientific support for the 47th and 49th Codex Committee on Pesticide Residues (CCPR) meetings (EFSA Journal 2015;13(7):4208 and EFSA Journal 2017;15(7):4929) ~~(was calculated using revision 2 of the EFSA PRIMo. The highest chronic exposure represented 1.8% of the ADI (French all population).~~ were calculated using the PRiMo version 3.1 model. The highest chronic exposure represented 3.0% of the ADI (NL toddler). Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

The proposed uses of metrafenone in the formulation BAS 758 00 F do not represent unacceptable chronic risks for the consumer.

7.4 Pyraclostrobin

General data on pyraclostrobin are summarized in the table below (last updated March 2021)

Table 7.4-1: General information on pyraclostrobin

Active substance (ISO Common Name)	Pyraclostrobin
IUPAC	methyl N-(2-{[1-(4-chlorophenyl)-1H-pyrazol-3-yl] oxymethyl}phenyl)-(N-methoxy)carbamate
Chemical structure	
Molecular formula	$C_{19}H_{18}ClN_3O_4$
Molar mass	387.8 g/mol
Chemical group	Strobilurines
Mode of action (if available)	Inhibition of mitochondrial respiration resulting from a blockage of the mitochondrial electron transport chain, thus blocking phosphorylation further down in the respiratory chain. In consequence, this leads to a reduction of energy-rich ATP which is required to support a range of essential processes in the fungal cell. In the end, the various fungal development processes of spore germination, formation of infection structures, mycelium growth and sporulation are permanently disrupted.
Systemic	No (with local systemic activity)
Company (ies)	BASF*
Rapporteur Member State (RMS)	Germany
Approval status	Approved 01.06.2004 Commission Directive 2004/30/EC amended by Commission Directive 2009/25/EC; Implementing Regulation (EU) 540/2011 amended by Regulation (EU) No. 823/2012, Regulation (EU) 2016/2016, Regulation (EU) 2018/84, Regulation (EU) 2018/1796, Regulation (EU) 2019/2094, (EU) 2021/52 Regulation (EU) 2021/2068
Restriction (e.g. is restricted to use as "...")	No
Review Report	SANCO/1420/2001-Final 08/09/2004
Current MRL regulation	Regulation (EC) No ~~2020/1633~~ 2022/1324
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes

EFSA Journal : Conclusion on the peer review	No**
EFSA Journal: conclusion on article 12	Yes***
Current MRL applications on intended uses	No

* Notifier in the EU process to whom the a.s. belong(s)
** not officially peer-reviewed by EFSA
*** EFSA, 2011a - see list of references

7.4.1 Stability of Residues (KCA 6.1)

7.4.1.1 Stability of residues during storage of samples

Available data

The storage stability of pyraclostrobin in plant and animal matrices was already evaluated and is summarized in the table below. For pyraclostrobin in plant matrices, only data of an interim report was available at the time point of evaluation. The final stability study was submitted in context of the AIR3 submission to RMS Germany; the results of the study are summarized in the table below.

Table 7.4-2: 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 pyraclostrobin & metabolite 500M07)			
Peanut nutmeat	High oil content	18 months	*2000/5248* Germany, 2001 The interim report was already peer-reviewed. The final report is presented below as ‘data submitted in context of AIR3 submission’ (Abdel-Baky S., 2001).
Peanut oil	High oil content	18 months	
Wheat grain	High starch content	18 months	
Wheat straw	Dry matrix	18 months	
Sugar beet tops	High water content	18 months	
Sugar beet roots	High starch content	18 months	
Tomatoes	High water content	18 months	
Grape juice	High acid content	18 months	
Animal products (parent pyraclostrobin & metabolite 500M07)			
Ruminant	Liver	8 months	*2000/1017116* Germany, 2001
Ruminant	Muscle	8 months	*2000/1017116* Germany, 2001
Ruminant	Milk	8 months	*2000/1017116* Germany, 2001
Data submitted in context of AIR3 submission (to RMS Germany) **(already included in draft RAR)**			
Plant products (parent pyraclostrobin & metabolite 500M07)			
Peanut nutmeat	High oil content	19 months	Abdel-Baky S., 2001) (study already included in publicly available draft RAR) *2001/5000232*
Peanut oil	High oil content	19 months	
Wheat grain	High starch content	25 months	
Wheat straw	Dry commodity	25 months	
Sugar beet tops	High water content	25 months	
Sugar beet roots	High water content	25 months	
Tomatoes	High water content	25 months	

Matrix	Characteristics of the matrix	Acceptable maximum storage duration	Reference
Grape juice	High acid content	25 months	
Animal products (parent pyraclostrobin & metabolite 500M07)			
No new data	--	--	--

Conclusion on stability of residues during storage

Storage stability of pyraclostrobin and of its metabolite 500M07 was demonstrated for a period of 19 months at ≤ -18°C for high oil content commodities such as peanut oil and nutmeat, and 25 months at ≤ -18°C in high starch (wheat grain, sugar beets), high water (tomato), high acid (grape juice) commodities and dry matrix (wheat straw) (for details see the table above). As all the residues trial samples were stored in accordance with these conditions, degradation of residues during storage of the trial samples is not expected.
The storage stability of pyraclostrobin (BAS 500 F) in samples of animal origin under deep freeze conditions is proven over a period of 8 months. Metabolite 500M35 (model compound) shows slow degradation but is stable enough to evaluate the submitted feeding study (analysed within 6 months) (Germany 2001).

7.4.1.2 Stability of residues in sample extracts (KCA 6.1)

No new study on the stability of residues in sample extracts was conducted.
For the active substance pyraclostrobin, investigations were performed using sample extracts out of ^{14}C-metabolism studies and fortified samples during the validation of the residue analytical methods. In none of the extracts investigated any degradation was observed. Further details are provided within the method studies in section 5. From the data available it can be concluded that pyraclostrobin is stable in sample extracts or solutions when stored during residue analysis.

7.4.2 Nature of residues in plants, livestock and processed commodities

7.4.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

New metabolism studies have been submitted by the applicant in the framework of the AIR3 submission to RMS Germany and are referenced here for completion purposes. These studies are summarized in the table below.

No new data submitted in the framework of this application.

Table 7.4-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								
Fruits and fruiting vegetable	Grapes	[tolyl-U-14C]-Pyraclostrobin and [chloro-phenyl-U-14C]-Pyra-clostrobin	Foliar, F	0.48, 0.24, 0.18, 0.13, 0.24; 0.24	6	40	Applications: BBCH 53-55 (1st appli.); BBCH 81 (last applica-tion)	*1998/10988* *2000/1000201* EFSA, 2011a
Root and tuber vege-tables	Potatoes	[tolyl-U-14C]-Pyraclostrobin and [chloro-phenyl-U-14C]-Pyra-clostrobin	Foliar, F	0.30, 0.30, 0.30, 0.40 0.30; 0.30	7	7 days af-ter the 3rd application and 7 days after last application (maturity)	Applications: BBCH 31 (1st appli.) then applica-tion every 9 days	*1999/11419* *2000/1000048* EFSA, 2011a
Cereals	Wheat	[tolyl-U-14C]-Pyraclostrobin and [chloro-phenyl-U-14C]-Pyra-clostrobin	Foliar, F	0.30	2	0, 31, 41	Applications: BBCH 32 (1st appli.); BBCH 61 (2nd appli.)	*1999/11137* *2001/1000966* EFSA, 2011a
Data submitted in context of AIR3 submission (to RMS Germany) (already included in publicly available draft RAR)								
Fruits and fruiting vegetable	Grape (leaves)	[tolyl-U-14C]-Pyraclostrobin and [chloro-phenyl-U-14C]-Pyra-clostrobin	Foliar, F	0.48, 0.24, 0.18, 0.13, 0.24; 0.24	6	40	Applications: BBCH 53-55 (1st appli.); BBCH 81 (last applica-tion)	*2004/1000758*
Leafy vege-tables	Chinese cabbage	[tolyl-U-14C]-Pyraclostrobin and [chloro-phenyl-U-14C]-Pyra-clostrobin	Foliar, F	0.13	3	3	Applications: 17, 10 and 3 before sam-pling (sam-pling at BBCH 49)	*2000/1018512*

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
Cereals	Rice (paddy)	[tolyl-U-14C]-Pyraclostrobin, [chlorophenyl-U-14C]-Pyraclostrobin and [pyrazole-3-13C]-Pyraclostrobin	Foliar, F	0.100	2	1 day before 2nd appl. (forage), BBCH 89 (straw, grain, spelts)	Applications: BBCH 39 (1st appli.); BBCH 69 (2nd appli.)	*2013/1134958*
Cereals	Wheat (seed treatment)	[tolyl-U-14C]-Pyraclostrobin and [chlorophenyl-U-14C]-Pyraclostrobin	Seed Treatment, G	0.010 (0.005 kg /100 kg seeds)	1	63-65 (BBCH 59, forage), 74-76 (BBCH 73-75, whole plants for further processing into hay), 103-104 (BBCH 89, ears, straw)	Application: BBCH 00	*2012/1158148*

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

Summary of plant metabolism studies reported in the EU

The following summary of the grape, potato and wheat metabolism study is taken from the EFSA MRL review according to article 12 (EFSA, 2011a):
The relevant residue in grapes consisted of parent pyraclostrobin (55.7 - 66% TRR) and its desmethoxy metabolite 500M07 (11.2 - 15.3% TRR). In potatoes, the highest TRR was identified in green matter (41.2 - 57.9 mg/kg) in both studies. Parent pyraclostrobin was the main component of the TRR in green matter and potato tubers in studies with [chlorophenyl-U-^{14}C]-pyraclostrobin, amounting for 55% and 29.4% of the TRR, respectively. In the green matter, desmethoxy metabolite 500M07 was identified in levels >20% of the TRR in both studies. In the tolyl study, the major component of the TRR in potato tubers was identified as natural amino acid L-tryptophan (29.2% TRR). In cereals, the lowest TRR was found in grains, varying between 0.098 mg/kg in the chlorophenyl-labelled and 0.441 mg/kg in the tolyl-labelled matrix. The highest TRR was identified in wheat straw, accounting for up to 37.76 mg/kg (chlorophenyl study) and 40.46 mg/kg (tolyl study). The major component of the TRR in straw and grain in the chlorophenyl study was parent pyraclostrobin and its desmethoxy metabolite (500M07). In the tolyl study, the major component of the TRR in grain was L-tryptophan (23% TRR), any other components being below 10% of the TRR. L-tryptophan is an essential natural amino acid; therefore, it is of no toxicological relevance.

Generally, it was concluded in the peer review that the metabolic pathway is similar in all crop groups investigated. Results from the supervised residue trials indicated that desmethoxy metabolite 500M07 occurs in crops in small amounts compared to parent pyraclostrobin; therefore, in the peer review it was concluded that a general residue definition for risk assessment and enforcement should be set as parent pyraclostrobin only.

Summary of plant metabolism studies available in draft RAR (AIR3 submission)

For covering a broader use spectrum and a different application type, two new crop metabolism studies have been conducted. New crop metabolism studies were performed in wheat (seed treatment application) and in paddy rice. Besides these new studies, a cabbage metabolism study is newly submitted in the EU. This study was performed for achieving the Japanese registration. Furthermore, a supplementary document (non-GLP) to the grape metabolism study was prepared upon request of Japan. Purpose of the document was to clarify the way of metabolite identification which is based on extracts from grape leaves.

Grapes (fruits and leaves):
The investigation of the metabolism of pyraclostrobin in grapes, using material labelled either in the tolyl or the chlorophenyl ring, leads to the conclusion that the predominant residue in grapes consists of the parent compound pyraclostrobin and its desmethoxy metabolite 500M07 (BF 500-3). Some other compounds were identified as products formed by cleavage of the molecule. The cleavage reaction resulting in the metabolites 500M04 (BF 500-5) and 500M55 is more expressed in leaves than in fruits. The metabolization by O-glucosylation or methoxylation is a minor degradation pathway; the metabolites 500M54, 500M56 and 500M71 are present in amounts clearly below 10% of the TRR.

Chinese cabbage:
The investigation of the metabolism of BAS 500 F in Chinese cabbage using material labelled in either the tolyl or the chlorophenyl ring leads to the conclusion that the predominant residue in outer leaves and leaf ball consists of the parent compound pyraclostrobin and its metabolite 500M07. Some other components which were identified as products formed by cleavage of the molecule, O-glucosylation or methoxylation turned out to be of minor importance, because their respective amount was far below 10% of the TRR (amounts ranged between <0.16 and 3.65 % of the TRR).

Paddy rice:
The highest levels of total radioactive residues (TRR) were found in rice straw (8.564 mg/kg chlorophenyl label and 10.503 mg/kg tolyl label). In rice grain, lower levels were detected for both labels (1.948 mg/kg chlorophenyl label, 2.112 mg/kg tolyl label). The lowest values were found in rice forage, sampled one day before the second application, amounting to 1.921 mg/kg (chlorophenyl label) and 1.622 mg/kg (tolyl label). The predominant residues of ^{14}C-pyraclostrobin in rice consisted of the unchanged parent compound and its desmethoxy metabolite 500M07 (BF 500-3). In rice forage, straw and grain of both labels, pyraclostrobin was the main component identified, ranging from 41.5 % to 73.3 % TRR. Metabolite 500M07 was found in all matrices as the second most prominent compound (from 8.0% to 17.3% TRR). Some further polar and medium polar components were characterized by their HPLC elution behaviour and were all clearly below 10% TRR.

Wheat (seed treatment):

The levels of total radioactive residues (TRR) were very low (<0.010 mg/kg) in all wheat matrices. The highest levels of total radioactive residues (TRR) were found in wheat straw (0.0051 mg/kg and 0.0045 mg/kg, chlorophenyl and tolyl label, respectively) followed by hay (0.0015 mg/kg and 0.0014 mg/kg, chlorophenyl and tolyl label). In wheat forage, the TRR amounted to 0.0008 mg/kg (chlorophenyl label) and 0.0005 mg/kg (tolyl label). The TRR values of grain were 0.0008 mg/kg (chlorophenyl label) and 0.0011 mg/kg (tolyl label).

Retention time comparison with authentic reference compounds suggest that the only significant peak detected, most probably represents the parent compound pyraclostrobin and/or its desmethoxylated metabolite 500M07, which are co-eluting using the applied HPLC methods.

Summary of new plant metabolism studies

No new studies submitted.

Conclusion on metabolism in primary crops

Generally, it can be concluded that the metabolic pathway is similar in all crop groups investigated (grape fruits and leaves, potatoes, Chinese cabbage, paddy rice and wheat). Results from the supervised residue trials indicated that desmethoxy metabolite 500M07 occurs in crops in small amounts compared to parent pyraclostrobin; therefore, it can be concluded that a general residue definition for risk assessment and enforcement should be set as parent pyraclostrobin only.

7.4.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

A new metabolism study has been submitted by the applicant in the framework of the AIR3 submission to RMS Germany and is referenced here for completion purposes. This study is summarized in the table below.

No new data submitted in the framework of this application.

Table 7.4-4: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Lettuce	[tolyl-U-14C]-Pyraclostrobin and [chlorophenyl-U-14C]-Pyraclostrobin	Foliar, F	0.9	30, 120, 365	60-61, 75-76, 61-62	One application to bare soil	*1999/11829* EFSA, 2011a
Root and tuber vegetables	Radish	[tolyl-U-14C]-Pyraclostrobin and [chlorophenyl-U-14C]-Pyraclostrobin	Foliar, F	0.9	30, 120, 365	47-48, 64-65, 47-48	One application to bare soil	*1999/11829* EFSA, 2011a
Cereals	Wheat	[tolyl-U-14C]-Pyraclostrobin and [chlorophenyl-U-14C]-Pyraclostrobin	Foliar, F	0.9	30, 120, 365	166-167, 156-157, 152-153	One application to bare soil	*1999/11829* EFSA, 2011a
Data submitted in context of AIR3 submission (to RMS Germany) (already included in publicly available draft RAR)								
Leafy vegetables	Lettuce	[pyrazole-3-14C]-Pyraclostrobin	Foliar, F	0.5	30	74	One application to bare soil	*2014/1001761*
Root and tuber vegetables	Radish	pyrazole-3-14C]-Pyraclostrobin	Foliar, F	0.5	30	74	One application to bare soil	*2014/1001761*
Cereals	Wheat	pyrazole-3-14C]-Pyraclostrobin	Foliar, F	0.5	30	74	One application to bare soil	*2014/1001761*

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

Summary of plant metabolism studies reported in the EU

The following summary of the rotational crop study conducted in lettuce, radish and wheat is taken from the EFSA MRL review according to article 12 (EFSA, 2011a):
In the peer review, the metabolism of pyraclostrobin in rotational crops was studied in lettuce, radish and wheat with [tolyl-U-^{14}C]-pyraclostrobin and [chlorophenyl-U-^{14}C]-pyraclostrobin (Germany, 2001). The radiolabelled active substance was applied on bare soil once at an application rate of 0.9 kg as/ha and respective crops were sown or planted at 30, 120 and 365 DAT. The peer review concluded that the metabolic pathway of pyraclostrobin in rotational crops is similar to that in primary crops and no formation of new metabolites was observed. There is no accumulation of pyraclostrobin or its degradation products (including 500M07) in the parts of plants used for human or animal consumption. The relevant residue in rotational crops therefore should be defined as parent pyraclostrobin.

The total radioactive residues in the edible parts of succeeding crops were very low for all plant back intervals: radish roots, lettuce ≤0.04 mg/kg and wheat grain ≤0.089 mg/kg. No accumulation of pyraclostrobin or its residues was observed in rotational crops. Application rates supported in the framework of this review range between 0.05 and 0.67 kg as/ha.
Considering the overdosing factor of the above study and the fact that pyraclostrobin was applied to bare soil (interception of pyraclostrobin by the plants is expected in practice), it is expected that residues of pyraclostrobin resulting from soil uptake will not exceed 0.01 mg/kg. Specific plant back restrictions related to the use of pyraclostrobin are therefore not required, provided that pyraclostrobin is applied in compliance with the GAPs evaluated in the framework of this review.

Summary of metabolism studies in rotational crops available in draft RAR (AIR3 submission)

In order to prove that no metabolite consisting solely of the pyrazole moiety is formed in soil and taken up by plants, preliminary investigations with the ^{14}C-pyrazole-labelled pyraclostrobin were performed. ^{14}C-pyrazole-labelled pyraclostrobin was applied at the maximum seasonal rate of 500 g as/ha to bare soil. After an aging period of 30 DAT, crops were planted / sown. The use rate of 500 g as/ha corresponds to a realistic worst-case GAP for Europe (2 x 250 g as/ha in cereals).

In all rotational crop matrices (radish, wheat, lettuce), low levels of radioactive residues were determined. The calculated total radioactive residues (TRR) in radish leaf accounted for 0.010 mg/kg, for radish root 0.003 mg/kg, for wheat forage 0.014 mg/kg and for lettuce plant 0.016 mg/kg. The measured TRR of the top soil layer after aging and ploughing was 0.140 mg/kg.
An assignment of the peaks to structures was not possible due to the low levels of radioactive residues. All peaks were below the trigger of 0.01 mg/kg.
The results indicate that there was no significant translocation of pyraclostrobin and / or its degradation products from the soil.

Summary of new metabolism studies in rotational crops

No new studies submitted.

Conclusion on metabolism in rotational crops

Considering the overdosing factor of the already peer-reviewed study and the application rate of the new study (representing a worst-case scenario for cereal crops) and the fact that pyraclostrobin was applied to bare soil (interception of pyraclostrobin by the plants is expected in practice), it is expected that residues of pyraclostrobin resulting from soil uptake will not exceed 0.01 mg/kg. Specific plant back restrictions related to the use of pyraclostrobin are furthermore not required, provided that pyraclostrobin is applied in compliance with the critical GAPs registered in Europe.

7.4.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

A new oil hydrolysis study has been submitted by the applicant in the framework of the AIR3 submission to RMS Germany and is referenced here for completion purposes but is not considered relevant for the intended uses. The study results are summarized in the table below.

No new data submitted in the framework of this application.

Table 7.4-5: Nature of the residues in processed commodities

Conditions (Duration, Temperature, pH)	Identified compound(s) (%)	Reference
EU data		
Pasteurisation (20 minutes, 90°C, pH 4)	Parent (98.1%) [Chlorophenyl label] Parent (103.9%) [Tolyl label]	*1998/10840* Germany, 2001
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Parent (110.9%) [Chlorophenyl label] Parent (98.1%) [Tolyl label]	*1998/10840* Germany, 2001
Sterilisation (20 minutes, 120°C, pH 6)	Parent (97.4%) [Chlorophenyl label] Parent (96.1%) [Tolyl label]	*1998/10840* Germany, 2001
Data submitted in context of AIR3 submission (to RMS Germany) **(already included in publicly available draft RAR)**		
Other conditions	**Identified compound(s) (%)**	
Oil refining (deodorization step from raw oil to refined oil)	<u>190°C (30 min):</u> Parent (23.3%) [Chlorophenyl label] (34.8%) [Tolyl label] 500M07 (41.3%) [Chlorophenyl label] (35.7%) [Tolyl label] 500M04 (19.0%) [Chlorophenyl label] (not detected) [Tolyl label] 500M49 (not detected) [Chlorophenyl label] (8.0%) [Tolyl label] <u>240°C (30 min):</u> Parent (not detected) [Chlorophenyl label] (2.5%) [Tolyl label] 500M07 (6.3%) [Chlorophenyl label] (15.9%) [Tolyl label] 500M04 (76.1%) [Chlorophenyl label] (not detected) [Tolyl label] 500M49 (not detected) [Chlorophenyl label] (2.3%) [Tolyl label]	*2014/1136542*

Conclusion on nature of residues in processed commodities

Regarding the intended use in celeals, the effect of processing on the nature of pyraclostrobin residues was investigated in the framework of the peer review. A study was conducted simulating representative hydrolytic conditions for pasteurization (20 minutes at 90°C, pH 4), boiling/brewing/baking (60 minutes at 100°C, pH 5) and sterilization (20 minutes at 120°C, pH 6). This study demonstrates that food processes, such as brewing, cooking, sterilization or pasteurization, will not impact the nature of pyraclostrobin residues. The relevant residue for enforcement and risk assessment in processed commodities is therefore expected to be the same as for primary crops (Germany, 2001).

Beyond the conclusions of representative food processing effects, a supplemental oil processing study was designed to investigate the degradation of [^{14}C]-pyraclostrobin during the process of olive oil refining. During the deodorization process oil / water mixtures will be heated up to 190°C and 240°C. Thus, in the present study, the transformation of [^{14}C]-pyraclostrobin in an olive oil / water mixture was determined. Pyraclostrobin (BAS 500 F, Reg. No. 304428) was incubated in an olive oil / water mixture (2:1) at 190°C and 240°C for 30 minutes. In the study, an extensive degradation of the test item was observed. At a temperature of 240°C, only trace amounts of the parent test item could be detected after 30 min. As a major degradation product, the metabolite 500M07 was identified at 190°C.

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

Table 7.4-6: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Fruits and fruiting vegetable (Grapes) Leafy vegetables (Chinese cabbage) Root and tuber vegetables (Potatoes) Cereals (Wheat, Paddy rice)
Rotational crops covered	Leafy vegetables (Lettuce) Root and tuber vegetables (Radish) Cereals (Wheat)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	is stable under standard hydrolysis conditions
Residue pattern in processed commodities similar to pattern in raw commodities?	Yes
Plant residue definition for monitoring	Pyraclostrobin (parent) (EC, 2004)
Plant residue definition for risk assessment	Pyraclostrobin (parent) (EC, 2004)
Conversion factor from enforcement to RA	Not applicable

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

Available data

The nature of pyraclostrobin residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (Germany, 2001). Reported metabolism studies include 4 studies, two in lactating goats and two in laying hens using ^{14}C-chlorophenyl-labelled pyraclostrobin and ^{14}C-tolyl-labelled pyraclostrobin. The studies are summarized below. These studies were also considered by the 2004 JMPR (FAO, 2004).

Submitted data in the evaluation process (AIR3)

New metabolism studies have been submitted by the applicant in context of the AIR3 submission to the RMS Germany. In the meantime, they have been included in the publicly available draft RAR. For completion purposes and to facilitate evaluation, those studies are also addressed in context of this dRR submission.
Upon request of the Australian authority, an *in vitro* comparison study was performed for goat and cow cell cultures. In order to allow a comprehensive overview, the study summary of these supplemental investigations is provided. Goat and cow microsomes and hepatocytes were incubated with the chlorophenyl-^{14}C-labelled test substance.
A bioaccumulation study was performed in 1999. The study has already been submitted in context of the previous Annex I inclusion process. However, in the previous evaluation at EU level, it has not been assessed within the residue section. In the study, the tolyl-^{14}C and chlorophenyl-^{14}C-labelled test substance was applied to water. The study includes the identification of metabolites in edible and inedible portions of bluegill sunfish.
As a new data requirement according to Regulation 283/2013, metabolism studies on fish may be required where the plant protection product is used in crops whose parts or products, also after processing, are fed to fish and where residues in feed may occur from the intended applications. Pyraclostrobin is registered in the majority of crops being intended as fish feed item. In most of these crops, residue levels above LOQ occur. The working document on the study conduct was published in II/2013. In order to meet these new data requirements, a fish metabolism study (dosing via diet) has been performed.
These studies are summarized in the table below.

No new data submitted in the framework of this application.

Table 7.4-7: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Goat	^{14}C-chlorophenyl	2 (low dose (a)) 1 (high dose (b))	0.9 – 1.0 2.72	5	Milk	Twice daily	*1998/10636* Germany, 2001
						Urine and faeces	Daily	
		^{14}C-tolyl	2 (low dose (a)) 1 (high dose (b))	0.65 – 0.75 1.37	5	Tissues	After sacrifice	
Laying poultry	Hens	^{14}C-chlorophenyl	11(a)	0.70	7	Eggs	Twice daily	*1998/10637* Germany, 2001
						Excreta	Daily	
		^{14}C-tolyl	11(a)	0.88	7	Tissues	After sacrifice	
Data submitted in context of AIR3 submission (to RMS Germany) (already included in publicly available draft RAR)								
Lactating ruminants	Goat and Cow (liver microsomes, in-vitro)	^{14}C-chlorophenyl	1 mg microsomal protein per incubation mixture	10 µM (low dose) 100 µM (high dose)	3h at 37°C	Incubation mixture	After incubation	*2009/1067176*
Fish (Bio-accumulation study)	Bluegill sunfish	^{14}C-chlorophenyl	ca. 150	305 ng as/L water	14	Edible (muscle)	At Days 0, 1, 4, 7, 14, 21, 28 and 35	*1999/11348*
		^{14}C-tolyl	ca. 150	300 ng as/L water	21	Viscera		
Fish	Rainbow trout	^{14}C-chlorophenyl	5	11.07 mg/kg food	10	Faeces	Daily	*2014/1001601*
						Filet	After sacrifice	
		^{14}C-tolyl	5	10.54 mg/kg food	10	Filet skin		
						Liver		

(a): dose corresponding to 12 mg/kg DM feed
(b): dose corresponding to 50 mg/kg DM feed

Summary of animal metabolism studies reported in the EU

The following summary of pyraclostrobin metabolism studies in livestock is taken from the EFSA MRL review according to article 12 (EFSA, 2011a):
The metabolic patterns identified for goats and hens were consistent with the rat metabolism and a specific metabolism study in pigs is not considered necessary. pyraclostrobin was identified as the major indicator compound in commodities of animal origin except in ruminant liver and milk fat. Based on these findings, the JMPR defined the parent compound as the only relevant residue for enforcement and risk assessment, but EFSA is of the opinion that consideration should be given to the presence of the desmethoxy metabolite (500M07). An ideal residue definition for ruminant products would therefore include parent and at least metabolite 500M07 (and possibly also metabolite 500M04); however, the difficulty is that a method of analysis specific to individual metabolites is not available (EC, 2002). Moreover, based on the available livestock feeding study in cows, it is expected that relevant metabolites will only be present in ruminant liver and that residues will decline quickly after the end of dosing. Hence, the relevant residue for enforcement is defined as the parent compound pyraclostrobin in commodities of animal origin. The relevant residue for risk assessment is defined as the sum of pyraclostrobin and its metabolites containing the 1-(4-chlorophenyl)-1H-pyrazole moiety or the 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazole moiety, expressed as pyraclostrobin.
EFSA proposes to set different levels of conversion factors from enforcement to risk assessment. Conversion factors will be set at 4 for ruminant liver and at 1 for all other commodities. In the framework of the peer review, the proposed residue definition was considered to be fat-soluble based on the fact that the log Po/w of pyraclostrobin is higher than 3 (Germany, 2001). Validated analytical methods for enforcement of the proposed residue definition are available.

Summary of animal metabolism studies available in draft RAR (AIR3 submission)

The investigation of the *in vitro* metabolism of pyraclostrobin in goat and cow was conducted by incubation experiments of the test item (mix of unlabelled and ^{14}C-labelled pyraclostrobin) at 100 µM (high dose) or 10 µM (low dose) with the corresponding microsomes, followed by qualitative and quantitative analysis of the residues. Pyraclostrobin was similarly metabolized by goat and cow microsomes. All metabolites identified in samples from incubations with cow microsomes were also found in the experiments with goat microsomes. The appearance of the main metabolite 500M04 was independent from the microsome‘s origin and resulted from cleavage of the ether bond. It was already identified in a previous *in vivo* goat study as one of the key degradation products of pyraclostrobin. The metabolite 500M88 (demethylation of the N-methoxycarbamate group) and 500M34 (desmethoxylation of the N-methoxycarbamate group and hydroxylation of the benzylic ring) are further common metabolites found after the incubation of pyraclostrobin with goat or cow microsomes. Both are putative precursors of the main metabolite 500M04. Hydroxylation of the chlorophenyl moiety played only a minor role in the *in vitro* biotransformation route of pyraclostrobin. In samples from the control experiments with heat-inactivated microsomes, only the unmodified parent compound pyraclostrobin was detected, demonstrating that the transformation of pyraclostrobin was dependent on the presence of active microsomal enzymes.
In context of the bioaccumulation study in fish after exposure of fish to pyraclostrobin at a nominal exposure level of 300 ng/L, apparent steady state was reached after 2 - 4 days. After termination of the exposure, radioactivity levels in fish tissues decreased rapidly with a half-life of ca. 0.7 - 1.0 days. Bioconcentration factors (BCF) based on total radioactivity were relatively low in edibles (232 - 262) and relatively high in inedibles (1169 - 1221). For the unchanged parent compound, the BCF values were considerably lower in all tissues. This is an indication for an intensive metabolic clearance of pyraclostrobin. Only minor differences were observed between the two labelled forms of the test compound with regard to the kinetic parameters. In the edible tissues, pyraclostrobin formed the major part of the residue, followed by 500M07. Cleavage of the ether bond resulting in the formation of the metabolite 500M04 occurred to a minor extent and mainly in the inedible portion of fish.

In context of the fish metabolism study, in all matrices (filet, filet skin, liver) and in both labels (chlorophenyl and tolyl) most of the extracted residues consisted mainly of unchanged parent (70.4 - 93.1% TRR). Only minor amounts of the metabolite 500M89 (Reg. No. 334089) were detected in extracted residue (1 - 4 % TRR). Taking the actual feed burden and the overdosing factor (8 x) into account, no significant residues of 500M89 will occur when fish are fed with commodities being treated with pyraclostrobin. Only one metabolic transformation could be identified: Cleavage of the amide residue yielding metabolite 500M89 (Reg. No. 334089). Reactions leading to a cleavage of the molecule between the ring systems did not occur. Therefore, both labels are comparable with respect to the overall result regarding metabolite formation of both studies. A degradation to polar residues occurred in a range of 1 - 7% TRR, as characterized by TLC. In liver, ca. 8 - 11% TRR were incorporated in the tissue and were only releasable with digestive enzymes. The results achieved in analysis of the chlorophenyl and tolyl label were very well comparable. The amounts of residues in the same tissues of both labels were very similar and in both labels the main identified residue consisted of unchanged pyraclostrobin. The results are in accordance with those obtained during the BCF study.

Summary of new animal metabolism studies

No new studies submitted.

Conclusion on metabolism in livestock

The outcome of the new metabolism studies reinforces the established residue definitions for animal matrices (enforcement and risk assessment).

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

Table 7.4-8: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats
	Laying hens
Time needed to reach a plateau concentration	3 days in milk
	Not reached in eggs after 7 days of dosing
Animal residue definition for monitoring	Pyraclostrobin (parent)
Animal residue definition for risk assessment	Pyraclostrobin (parent) except: Liver (except poultry liver) and milk fat only: Pyraclostrobin and its metabolites analysed as the hydroxypyrazoles BF 500-5 (500M04) and BF 500-8 (500M85), sum expressed as Pyraclostrobin
Conversion factor	Liver (w/o poultry): 4 All other: 1
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Yes

7.4.3 Magnitude of residues in plants (KCA 6.3)

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

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

Table 7.4-9: Summary of EU reported and new data supporting the intended uses of BAS 758 00 F and conformity to existing MRL

<table>
<tr><th>Commodity</th><th>Source</th><th>Residue zone (N-EU, S-EU, EU, outside EU)</th><th>Evaluation
GAP
Residue levels (mg/kg)
E = according to enforcement residue definition
RA = according to risk assessment residue definition</th><th>STMR (mg/kg)</th><th>HR (mg/kg)</th><th>Un-rounded OECD calculator MRL (mg/kg)</th><th>Current EU MRL (mg/kg)
*</th><th>MRL compliance</th></tr>
<tr><td rowspan="4">Wheat grain

(and extrapolation to rye and triticale grain)</td><td>EU Reg 293/2013</td><td>EU and Outside EU</td><td>Adoption of CXL</td><td>0.02</td><td>0.09</td><td>-</td><td>0.2</td><td></td></tr>
<tr><td>EFSA, 2011</td><td>N-EU</td><td>cGAP on which EU assessment is based: 2x 0.25 kg as/ha, PHI 35d, outdoor
E/RA: 12x<0.02; 0.02; 0.03; 2x0.04; 2x0.05</td><td>0.02</td><td>0.05</td><td>0.07</td><td>0.2
(based on adoption of CXL)</td><td>yes</td></tr>
<tr><td>New trials BASF DocID 2021/2000402</td><td>N-EU</td><td>Trials GAP: 2 x 0.12 kg as/ha, PHI 56d, outdoor
(less critical GAP)
E/RA: 4x <0.010</td><td>0.010</td><td>0.010</td><td>0.01</td><td colspan="2">Highest residue covered by current MRL 0.2 mg/kg. No further considerations needed.</td></tr>
<tr><td>Overall supporting data for cGAP</td><td>N-EU</td><td>cGAP on which EU a.s. assessment is based: 2x 0.25 kg as/ha, PHI 35d, outdoor
E/RA: 12x<0.02; 0.02; 0.03; 2x0.04; 2x0.05</td><td>0.02</td><td>0.05</td><td>0.07</td><td>0.2
(based on adoption of CXL)</td><td>yes</td></tr>
</table>

Commodity	Source	Resi-due zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Un-rounded OECD cal-culator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compli-ance
Wheat straw (and extrapolation to rye and triticale straw)	EFSA,2011	S-EU	cGAP on which EU assessment is based: 2x 0.25 kg as/ha, PHI 35d, outdoor E/RA: 0.75; 1.44; 1.53; 2x1.67; 1.85; 2.07; 2.20; 4.59; 4.95; 5.68	1.85	5.68	-	10 (pseudo MRL)	
	New trials BASF DocID 2021/2000402	N-EU	Trials GAP: 2 x 0.12 kg as/ha, PHI 56d, outdoor (less critical GAP) E/RA: 0.40, 0.51, 0.70, 1.1	0.605	1.1	2.033	Highest residue covered by pseudo MRL 10 mg/kg. No further considerations needed.	
	Overall supporting data for cGAP	N-EU	cGAP on which EU a.s. assessment is based: 2 x 0.12 kg as/ha, PHI 56d, outdoor E/RA: 0.40, 0.51, 0.70, 1.1	0.605	1.1	2.033	10 (pseudo MRL, based on S-EU data)	
Barley grain (and extrapolation to oat grain)	EU Reg 293/2013	EU and Outside EU	Adoption of CXL	0.345	0.62	-	1.0	
	EFSA, 2011	N-EU	cGAP on which EU assessment is based: 2x 0.25 kg as/ha, PHI 35d, outdoor E/RA: 4x<0.02; 4x0.03; 3x0.04; 2x0.05; 0.06; 4x0.07; 0.09; 2x0.1; 2x0.11; 2x0.12; 2x0.13; 0.14; 0.29	0.07	0.29	0.303	1.0 (based on adoption of CXL)	yes
	New trials BASF DocID 2021/2000401	N-EU	Trials GAP: 2 x 0.12 kg as/ha, PHI 56d, outdoor (less critical GAP) E/RA: 0.017, 0.020, 0.027, 0.047	0.024	0.047	0.083	Highest residue covered by current MRL 1.0 mg/kg. No further considerations needed	
	Overall supporting data for cGAP	N-EU	cGAP on which EU a.s. assessment is based: 2x 0.25 kg as/ha, PHI 35d, outdoor E/RA: 4x<0.02; 4x0.03; 3x0.04; 2x0.05; 0.06; 4x0.07; 0.09; 2x0.1; 2x0.11; 2x0.12; 2x0.13; 0.14; 0.29	0.07	0.29	0.303	1.0 (based on adoption of CXL)	yes
Barley straw	EFSA, 2011	S-EU	cGAP on which EU assessment is based: 2x 0.25 kg as/ha, PHI 35d, outdoor	3.38	6.92	-	15 (pseudo MRL)	

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Un-rounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
(and extrapolation to oat grain)			E/RA: 0.66; 1.17; 1.69; 2.84; 3.91; 4.87; 6.59; 6.92					
	New trials BASF DocID 2021/2000401	N-EU	Trials GAP: 2 x 0.12 kg as/ha, PHI 56d, outdoor (less critical GAP) E/RA: 0.29, 0.40, 0.48, 1.0	0.440	1.0	1.802	Highest residue covered by pseudo MRL 15 mg/kg. No further considerations needed.	
	Overall supporting data for cGAP	N-EU	cGAP on which EU a.s. assessment is based: 2 x 0.12 kg as/ha, PHI 56d, outdoor E/RA: 0.29, 0.40, 0.48, 1.0	0.440	1.0	1.802	15 (pseudo MRL, based on S-EU data)	

* Source of EU MRL: Reg. ~~(EU) 2020/1633~~ Reg. (EU) 2022/1324 amending MRL Reg. (EC) No 396/2005

7.4.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on cereals are considered acceptable, for outdoor uses. The extrapolation rules have been applied according to SANTE/2019/12752. The data submitted show that no exceedance of the current pyraclostrobin MRLs for the intended uses (barley, wheat, rye, triticale and oat) is expected.

7.4.4 Magnitude of residues in livestock

7.4.4.1 Dietary burden calculation

The dietary burden was calculated for all uses evaluated in the Article 12 process (EFSA, 2011a) and additional uses since then (see footnotes). The intended use of BAS 758 00 F on cereals (wheat, rye, triticale, barley and oat) does contribute to the overall dietary burden, but input values are covered by the already evaluated values.

Table 7.4-10: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure [including additional uses since that] and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: pyraclostrobin (parent)				
Barley, straw	**3.38**	**STMR (derived in context of the AIR3 submission to RMS Germany)**	**8.73**	**HR (derived in context of the AIR3 submission to RMS Germany)**
Beet, sugar, tops	0.07	STMR (EFSA, 2011a)	0.18	HR (EFSA, 2011a)
Cabbage, heads	0.02	STMR (EFSA, 2018a)	0.22	HR (EFSA, 2018a)
Corn, field, forage/silage	0.51	STMR x 1.43 (EFSA, 2018a)	1.09	HR x 1.43 (EFSA, 2018a)
Kale	0.18	STMR (EFSA, 2012)	0.70	HR (EFSA, 2012)
Oat, straw	**3.38**	**STMR (derived in context of the AIR3 submission to RMS Germany)**	**8.73**	**HR (derived in context of the AIR3 submission to RMS Germany)**
Rye, straw	**1.85**	**STMR (derived in context of the AIR3 submission to RMS Germany)**	**6.96**	**HR (derived in context of the AIR3 submission to RMS Germany)**
Triticale, straw	**1.85**	**STMR (derived in context of the AIR3 submission to RMS Germany)**	**6.96**	**HR (derived in context of the AIR3 submission to RMS Germany)**
Wheat, straw	**1.85**	**STMR (derived in context of the AIR3 submission to RMS Germany)**	**6.96**	**HR (derived in context of the AIR3 submission to RMS Germany)**
Carrot, culls	0.12	STMR (HR/STMR in context of a JMPR submission leading to CODEX MRL, which was later adopted by EFSA)	0.24	HR (HR/STMR in context of a JMPR submission leading to CODEX MRL, which was later adopted by EFSA)
Potatoes, culls	0.02	STMR (EFSA, 2011a)	0.02	HR (EFSA, 2011a)
Swede, roots	0.02	STMR (EFSA, 2014a)	0.06	HR (EFSA, 2014a)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Turnip, roots	0.02	STMR (EFSA, 2014a)	0.06	HR (EFSA, 2014a)
Barley, grain	**0.35**	**STMR (EFSA, 2014b)**	**0.35**	**HR (EFSA, 2014b)**
Bean, seed	0.04	STMR (EFSA, 2011a)	0.04	STMR (EFSA, 2011a)
Corn, field, grain	0.02	STMR (EFSA, 2011a)	0.02	STMR (EFSA, 2011a)
Corn, pop, grain	0.02	STMR (EFSA, 2011a)	0.02	STMR (EFSA, 2011a)
Cotton, undelinted seed	0.03	STMR (EFSA, 2011b)	0.03	STMR (EFSA, 2011b)
Lupin, seed	0.02	STMR (EFSA, 2011b)	0.02	STMR (EFSA, 2011b)
Oat, grain	**0.35**	**STMR (EFSA, 2014b)**	**0.35**	**STMR (EFSA, 2014b)**
Pea, seed	0.04	STMR (EFSA, 2011a)	0.04	STMR (EFSA, 2011a)
Rye, grain	**0.02**	**STMR (EFSA, 2011a)**	**0.02**	**STMR (EFSA, 2011a)**
Sorghum, grain	0.025	STMR (HR/STMR in context of a JMPR submission leading to CODEX MRL, which was later adopted by EFSA)	0.025	STMR (HR/STMR in context of a JMPR submission leading to CODEX MRL, which was later adopted by EFSA)
Soybean, seed	0.02	STMR (EFSA 2011b, 2018c)	0.02	STMR (EFSA 2011b, 2018c)
Triticale, grain	**0.02**	**STMR (EFSA, 2011a)**	**0.02**	**STMR (EFSA, 2011a)**
Wheat, grain	**0.02**	**STMR (EFSA, 2011a)**	**0.02**	**STMR (EFSA, 2011a)**
Apples pomace	0.35	STMR (EFSA, 2011a)	0.35	STMR (EFSA, 2011a)
Beet, sugar, dried pulp	0.10	STMR x PF 2.5 (EFSA, 2011a) for dehydration step extrapolated from apple processing study (pomace) and citrus processing study (dried pulp)	0.10	STMR x PF 2.5 (EFSA, 2011a) for dehydration step extrapolated from apple processing study (pomace) and citrus processing study (dried pulp)
Beet, sugar, ensiled pulp	0.12	STMR x 3 (EFSA, 2011a) filled in by the model automatically applying default processing factors (pf)	0.12	STMR x 3 (EFSA, 2011a) filled in by the model automatically applying default processing factors (pf)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Beet, sugar, molasses [1,8]	1.12	STMR x 28 (EFSA, 2011a) filled in by the model automatically applying default processing factors (pf)	1.12	STMR x 28 (EFSA, 2011a) filled in by the model automatically applying default processing factors (pf)
Brewer`s grain, dried	**1.16**	**STMR x 3.3 (EFSA, 2014b) filled in by the model automatically applying default processing factors (pf)**	**1.16**	**STMR x 3.3 (EFSA, 2014b) filled in by the model automatically applying default processing factors (pf)**
Canola, meal	0.07	STMR x 2 (EFSA, 2011b) filled in by the model automatically applying default processing factors (pf)	0.07	STMR x 2 (EFSA, 2011b) filled in by the model automatically applying default processing factors (pf)
Citrus, dried pulp	3.73	STMR x 6.9 (EFSA, 2018a)	3.73	STMR x 6.9 (EFSA, 2018a)
Corn, field, milled byproducts	0.02	STMR x 1 (EFSA, 2011a) residues in RAC <LOQ	0.02	STMR x 1 (EFSA, 2011a) residues in RAC <LOQ
Corn, field, hominy meal	0.02	STMR x 1 (EFSA, 2011a) residues in RAC <LOQ	0.02	STMR x 1 (EFSA, 2011a) residues in RAC <LOQ
Corn, field, gluten feed	0.02	STMR x 1 (EFSA, 2011a) residues in RAC <LOQ	0.02	STMR x 1 (EFSA, 2011a) residues in RAC <LOQ
Corn, field, gluten, meal	0.02	STMR x 1 (EFSA, 2011a) residues in RAC <LOQ	0.02	STMR x 1 (EFSA, 2011a) residues in RAC <LOQ
Cotton, meal	0.006	STMR x 0.19 (EFSA, 2011b) filled in by the model automatically applying default processing factors (pf)	0.006	STMR x 0.19 (EFSA, 2011b) filled in by the model automatically applying default processing factors (pf)
Distiller´s grain, dried	**0.066**	**STMR x 3.3 (EFSA, 2011a) filled in by the model automatically applying default processing factors (pf)**	**0.066**	**STMR x 3.3 (EFSA, 2011a) filled in by the model automatically applying default processing factors (pf)**
Flaxseed/Linseed, meal	0.052	STMR x 1.3 (EFSA, 2011b)	0.052	STMR x 1.3 (EFSA, 2011b)
Lupin seed, meal [8]	0.022	STMR x 1.1. (EFSA, 2011a) filled in by the model automatically applying default processing factors (pf)	0.022	STMR x 1.1. (EFSA, 2011a) filled in by the model automatically applying default processing factors (pf)
Peanut, meal	0.02	STMR x 1 (EFSA, 2011a) residues in RAC <LOQ	0.02	STMR x 1 (EFSA, 2011a) residues in RAC <LOQ

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Potato, process waste	0.02	STMR x 1 (EFSA, 2011a) residues in RAC <LOQ	0.02	STMR x 1 (EFSA, 2011a) residues in RAC <LOQ
Potato, dried pulp	0.02	STMR x 1 (EFSA, 2011a) residues in RAC <LOQ	0.02	STMR x 1 (EFSA, 2011a) residues in RAC <LOQ
Rape, meal	0.07	STMR x 2 (EFSA, 2011b)	0.07	STMR x 2 (EFSA, 2011b)
Rice, bran/pollard	0.106	STMR x 5.3 (EFSA, 2018b)	0.106	STMR x 5.3 (EFSA, 2018b)
Safflower, meal	0.052	STMR x 1.3 (EFSA, 2011b)	0.052	STMR x 1.3 (EFSA, 2011b)
Soybean, meal	0.02	STMR x 1 (EFSA, 2011b) residues in RAC <LOQ	0.02	STMR x 1 (EFSA, 2011b) residues in RAC <LOQ
Soybean, hulls	0.02	STMR x 1 (EFSA, 2011b) residues in RAC <LOQ	0.02	STMR x 1 (EFSA, 2011b) residues in RAC <LOQ
Sunflower, meal	0.106	STMR x 2 (EFSA, 2011b)	0.106	STMR x 2 (EFSA, 2011b)
Wheat gluten, meal	**0.036**	**STMR x 1.8 (EFSA, 2011a) filled in by the model automatically applying default processing factors (pf)**	**0.036**	**STMR x 1.8 (EFSA, 2011a) filled in by the model automatically applying default processing factors (pf)**
Wheat, milled byproducts	**0.054**	**STMR x 2.7 (STMR: EFSA, 2011a, pf: derived in context of the AIR3 submission to RMS Germany)**	**0.054**	**STMR x 2.7 (STMR: EFSA, 2011a, pf: derived in context of the AIR3 submission to RMS Germany)**

Target crops are marked in **bold**

Table 7.4-11: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: pyraclostrobin (parent)					
Beef cattle*	0.0406	0.088	Barley, straw	3.65	Yes
Dairy cattle*	0.0864	0.162	Barley, straw	4.20	Yes
Ram/ewe	0.0853	0.218	Barley, straw	6.5	Yes
Lamb	0.1124	0.274	Barley, straw	6.45	Yes
Breeding swine	0.029	0.042	Citrus, dried pulp	1.82	Yes
Finishing swine*	0.019	0.027	Carrot, culls	0.88	Yes
Broiler poultry	0.036	0.043	Carrot, culls	0.60	Yes
Layer poultry*	0.049	0.095	Wheat, straw	1.39	Yes
Turkey	0.030	0.037	Carrot, culls	0.52	Yes

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

The calculated dietary burden values (derived by using the Animal model 2017) are very comparable with the results of the overall dietary burden calculations, which were submitted to RMS Germany in context of the renewal process of the active substance pyraclostrobin (AIR3). As can be seen from those results (see below) and the results of the related feeding studies, there is no need for an adjustment of MRLs in animal matrices.

Table 7.4-12: Results of the dietary burden calculation (RWCFL, AIR3 submission)

Animal species	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: pyraclostrobin (parent)				
Beef cattle*	0.083	Barley straw	3.461	Yes
Dairy cattle*	0.134	Barley straw	3.483	Yes
Ram/ewe	0.212	Barley straw	6.365	Yes
Lamb	0.271	Barley straw	6.365	Yes
Breeding swine	0.028	Carrot culls	1.225	Yes
Finishing swine*	0.024	Carrot culls	0.798	Yes
Broiler poultry	0.036	Barley grain	0.515	Yes
Layer poultry*	0.079	Wheat straw	1.149	Yes
Turkey	0.031	Carrot culls	0.435	Yes

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

7.4.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Data/information on poultry and lactating ruminant feeding studies for pyraclostrobin were reviewed during the Annex I inclusion process and were considered to be acceptable. The following section was copied from the Draft Assessment Report, which was prepared by RMS Germany.

Table 7.4-13: Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

Intakes by livestock ≥ 0.1 mg/kg diet/day:	Ruminant: yes/~~no~~	Poultry: yes/~~no~~	Pig: yes/~~no~~
Muscle	< 0.05	< 0.05	< 0.05
Liver	< 0.05	< 0.05	< 0.05
Kidney	< 0.05	< 0.05	< 0.05
Fat	< 0.05	< 0.05	< 0.05
Milk	< 0.01	Not applicable	Not applicable
Eggs	Not applicable	< 0.05	Not applicable

Available data

Data/information on poultry (no study needed based on the intended uses) and ruminant (BASF DocID *1999/11895* & *2000/1000003*) feeding studies for pyraclostrobin were reviewed during the Annex I inclusion process and were considered to be acceptable.
For the Annex I inclusion process, data were submitted covering the safe uses in cereals, grapes and banana (import tolerance). Due to the favourable residue behaviour of pyraclostrobin, where even at the 10 x dose level no residues above the LOQ were found, the revised feed burden covering the use in cereals did not result in any new MRL proposal. This was re-confirmed by the RMS Germany and in the EFSA publication from February 2012 (EFSA, 2012).

One new feeding study on poultry (BASF DocID *2000/5005*) has been submitted by the applicant in context of the AIR3 submission in 2014 and is included in the publicly available draft RAR. This study was performed for registration purposes in the US using the common moiety approach, is considered as supplemental information, and is summarized in the table below.

Table 7.4-14: Overview of the values derived from livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) [(a)]	Highest residue (mg/kg) [(b)]	Calculated MRL (mg/kg)	CF for RA [(c)]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (EFSA, 2011a)												
Enforcement residue definition: *Pyraclostrobin (parent)* and risk assessment: *Pyraclostrobin (parent) except liver (except poultry liver) and milk fat only: Pyraclostrobin and its metabolites analysed as the hydroxypyrazoles BF 500-5 (500M04) and BF 500-8 (500M85), sum expressed as Pyraclostrobin*												
Pig meat	0.011	0.021	0.22	3	<0.05	N/A	<0.05	N/A	0.05	0.05	0.05+(F)	1.00
			0.67	3	<0.05	N/A	<0.05	N/A				
			2.40	3	<0.05	N/A	<0.05	N/A				
Pig fat			0.22	3	<0.05	N/A	<0.05	N/A	0.05	0.05	0.05+	1.00
			0.67	3	<0.05	N/A	<0.05	N/A				
			2.40	3	<0.05	N/A	<0.05	N/A				
Pig liver			0.22	3	<0.05	n.r.	0.20	n.r.	0.05	0.05	0.05+	4.00
			0.67	3	<0.05	n.r.	0.52	n.r.				
			2.40	3	<0.05	n.r.	2.48	n.r.				
Pig kidney			0.22	3	<0.05	N/A	<0.05	N/A	0.05	0.05	0.05+	1.00
			0.67	3	<0.05	N/A	<0.05	N/A				
			2.40	3	<0.05	N/A	<0.05	N/A				
Ruminant meat	0.035	0.066	0.22	3	<0.05	N/A	<0.05	N/A	0.05	0.05	0.05+(F)	1.00
			0.67	3	<0.05	N/A	<0.05	N/A				
			2.40	3	<0.05	N/A	<0.05	N/A				
Ruminant fat			0.22	3	<0.05	N/A	<0.05	N/A	0.05	0.05	0.05+	1.00
			0.67	3	<0.05	N/A	<0.05	N/A				
			2.40	3	<0.05	N/A	<0.05	N/A				

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg) [(a)]	Highest residue (mg/kg) [(b)]	Calculated MRL (mg/kg)	CF for RA [(c)]
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)	No	Result for enforcement		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
EU data (EFSA, 2011a)												
Enforcement residue definition: *Pyraclostrobin (parent)* and risk assessment: *Pyraclostrobin (parent) except liver (except poultry liver) and milk fat only: Pyraclostrobin and its metabolites analysed as the hydroxypyrazoles BF 500-5 (500M04) and BF 500-8 (500M85), sum expressed as Pyraclostrobin*												
Ruminant liver			0.22	3	<0.05	n.r.	0.20	n.r.	0.05	0.05	0.05^{+}	4.00
			0.67	3	<0.05	n.r.	0.52	n.r.				
			2.40	3	<0.05	n.r.	2.48	n.r.				
Ruminant kidney			0.22	3	<0.05	N/A	<0.05	N/A	0.05	0.05	0.05^{+}	1.00
			0.67	3	<0.05	N/A	<0.05	N/A				
			2.40	3	<0.05	N/A	<0.05	N/A				
Milk	0.054	0.103	0.22	3	<0.05	N/A	<0.05	N/A	0.01	0.01	0.01^{+}	1.00
			0.67	3	<0.05	N/A	<0.05	N/A				
			2.40	3	<0.05	N/A	<0.05	N/A				
Data submitted (xxxxxxxxxxxxxxxxx, 2000, Doc ID *2000/5005*) in context of AIR3 submission (to RMS Germany), included in the publicly available draft RAR												
Poultry meat	0.039	0.070	0.18*	11	<0.05	N/A	<0.05	N/A	0.05	0.05	0.05^{+}	1.00
			0.58**	12	<0.05	N/A	<0.05	N/A				
			1.93***	20	<0.05	N/A	<0.05	N/A				
Poultry fat			0.18*	11	<0.05	N/A	<0.05	N/A	0.05	0.05	0.05^{+}	1.00
			0.58**	12	<0.05	N/A	<0.05	N/A				
			1.93***	20	<0.05	N/A	<0.05	N/A				
Poultry liver			0.18*	11	<0.05	N/A	<0.05	N/A	0.05	0.05	0.05^{+}	1.00
			0.58**	12	<0.05	N/A	<0.05	N/A				
			1.93***	20	<0.05	N/A	<0.05	N/A				
Eggs	0.039	0.070	0.18*	11	<0.05	N/A	<0.05	N/A	0.05	0.05	0.05^{+}	1.00
			0.58**	12	<0.05	N/A	<0.05	N/A				
			1.93***	20	<0.05	N/A	<0.05	N/A				

N/A: Not applicable – only the mean values are considered for calculating MRLs in milk.
n.r.: Not reported
+ Indicates that the MRL is set at the limit of analytical quantification.
(F): MRL is expressed as mg/kg of fat contained in the whole product.
(a): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).
(b): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).
(c): The median conversion factor for enforcement to risk assessment.
* not specified in the study report, calculated by the actual dose rate 0.28 mg/d/animal and the average body weight of this group at the beginning of the study (1.55787 kg)
** not specified in the study report, calculated by the actual dose rate 0.88 mg/d/animal and the average body weight of this group at the beginning of the study (1.5293 kg)
*** not specified in the study report, calculated by the actual dose rate 3.01 mg/d/animal and the average body weight of this group at the beginning of the study (1.5573 kg)

Conclusion on feeding studies

Considering the requested uses (and the animal model 2017) the theoretical maximum daily intake for animals was modified only slightly compared to previous evaluations; however, no risk for animal MRLs to be exceeded is expected based on available feeding data.

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

7.4.5.1 Available data for all crops under consideration

No new data were submitted in the framework of this application. Data/information on processing studies was reviewed during the approval of active substance pyraclostrobin and/or MRL setting and were considered acceptable and is summarized in the table below.

Table 7.4-15: Overview of the available processing studies

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
EU data					
Processing factors recommended for enforcement and risk assessment (sufficiently supported by data)					
Barley, brewing malt	2 (4 trials)	1.20	1.00		Germany, 2001, EFSA, 2011 BASF DocID 1999/11826, 1999/11827
Barley, beer	2 (4 trials)	0.70	1.00		
Indicative processing factors (limited data sets)					
Barley, pot/pearl	1 (1 trial)	0.70	1.00		Germany, 2001, EFSA, 2011 BASF DocID 1999/11826
Wheat and rye, white flour	1 (1 trial)	0.06	1.00		Germany, 2001, EFSA, 2011 BASF DocID 1999/5122
Data submitted in context of AIR3 submission (to RMS Germany) (already included in publicly available draft RAR)					
Processing factors recommended for enforcement and risk assessment (sufficiently supported by data)					
Wheat, bran Wheat, white flour Wheat, starch Wheat, wholemeal flour	1 (4 trials)	2.67 0.31 0.24 0.92	1.00	Submitted to RMS Germany in context of the AIR3 submission, already included in publicly available draft RAR	Plier S. (2012) BASF DocID 2012/1067586

Processed commodity	Number of studies	Median PF *	Median CF **	Comments	Reference
Oat, bran Oat, flour Oat, groats/rolled oats	1 (4 trials)	0.31 0.11 0.06	1.00	Submitted to RMS Germany in context of the AIR3 submission, already included in publicly available draft RAR	Plier S. (2012) BASF DocID 2013/1037950
Corn, refined oil Corn, flour Corn, meal Corn, bran Corn, gluten feed meal	1 (4 trials)	1 1 1 1 1	1.00	Submitted to RMS Germany in context of the AIR3 submission, already included in publicly available draft RAR	Braun D. (2010) BASF DocID 2010/1144336
Indicative processing factors (limited data sets)					
Rice, bran Rice, flour	1 (3 trials)	5.29 0.16	1.00	Submitted to RMS Germany in context of an ongoing import tolerance petition for rice	Woodard, D. L. (2015) BASF DocID 2015/7000583
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.

7.4.5.1 Conclusion on processing studies

For the intended use in cereals several processing studies are available, which were already peer-reviewed by EFSA. For beer robust processing factors were derived, for pot barley and wheat/rye flour only indicative processing factors are available.
According to EFSA (EFSA, 2011), "further processing studies are not required as they are not ex-pected to affect the outcome of the risk assessment. However, if there would be the intention to derive more robust processing factors, in particular for enforcement purposes, additional processing studies would be required."
The existing processing studies and the derived processing factors are considered appropriate to support the use of formulation BAS 758 00 F in cereals. No risk to consumers is expected to arise from processed cereals, which have been previously treated with the plant protection product of concern.

7.4.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Data dealing with magnitude of residues in succeeding crops have been submitted and are summarized hereafter.

In context of the MRL review according to article 12 (EFSA, 2011a) it was concluded, "that the metabolic pathway of pyraclostrobin in rotational crops is similar to that in primary crops and no formation of new metabolites was observed. There is no accumulation of pyraclostrobin or its degradation products (including 500M07) in the parts of plants used for human or animal consumption. The relevant residue in rotational crops therefore should be defined as parent pyraclostrobin."

7.4.6.1 Field rotational crop studies (KCA 6.6.2)

Available data

As concluded in chapter 7.2.2.2 and confirmed by EFSA (EFSA, 2011a) the total radioactive residues in the edible parts of succeeding crops were very low for all plant back intervals: radish roots, lettuce ≤0.04 mg/kg and wheat grain ≤0.089 mg/kg. No accumulation of pyraclostrobin or its residues was observed in rotational crops.
Application rates supported in the framework of the MRL review according to article 12 (EFSA, 2011a) ranged between 0.05 and 0.67 kg as/ha. The maximum single application rate foreseen for product BAS 758 00 F is 0.120 kg as/ha and is therefore well in the range, which has already been considered by EFSA.
No new data submitted in the framework of this application.

Conclusion on rotational crops studies

Considering the overdosing factor of the rotational crop metabolism study (0.9 kg as/ha, see 7.4.2.2) and the fact that pyraclostrobin was applied to a bare soil (interception of pyraclostrobin by the plants is expected in practice), it is expected that residues of pyraclostrobin resulting from soil uptake will not exceed 0.01 mg/kg. Specific plant-back restrictions related to the use of pyraclostrobin are therefore not required, provided that pyraclostrobin is applied in compliance with the GAPs.

7.4.7 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 758 00 F. Therefore, other special studies are not needed.

For the intended uses on cereals no further studies regarding honey are necessary. According SANTE/11956/2016 rev. 9, cereals (barley, oat, wheat, triticale and rye) does not have melliferous capacity. However, during the AIR process of pyraclostrobin, a honey study was submitted, evaluated and accepted. No residues of pyraclostrobin were found in honey.

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

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see Table 7.1-2). For this assessment, an ADI (Acceptable Daily Intake) of 0.03 mg/kg bw/day was used for the chronic dietary assessment, and an ARfD (Acute Reference Dose) of 0.03 mg/kg bw/day was used for the acute dietary assessment.

7.4.8.1 Input values for the consumer risk assessment

In context of the TMDI calculations only the existing MRLs (Reg. (EU) 2020/1633) as shown below were used without further refinement. In context of the IEDI and IESTI calculations the input values as specified in Table 7.4-16 were applied.

Table 7.4-16: Input values for the consumer risk assessment

Code	Commodity	TMDI		Chronic risk assessment (IEDI)[1]		Acute risk assessment (IESTI)[2]	
		existing/ proposed MRL	Source/type of MRL	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Pyraclostrobin (BAS 500 F)							
110010	Grapefruits	2	Existing EU MRL	0.054 (0.54 x 0.1)	STMR-RAC*PeF	-	
110020	Oranges	2	Existing EU MRL	0.084 (0.6 x 0.14)	STMR-RAC*PeF	-	
110030	Lemons	2	Existing EU MRL	0.054 (0.54 x 0.1)	STMR-RAC*PeF	-	
110040	Limes	2	Existing EU MRL	0.054 (0.54 x 0.1)	STMR-RAC*PeF	-	
110050	Mandarins	2	Existing EU MRL	0.0689 (0.53 x 0.13)	STMR-RAC*PeF	-	
110990	Other citrus fruit	2	Existing EU MRL	0.054	STMR-RAC*PeF	-	
120100	Pistachios	1	Existing EU MRL	0.22	STMR-RAC	-	
130010	Apples	0.5	Existing EU MRL	0.14	STMR-RAC	-	
130020	Pears	0.5	Existing EU MRL	0.14	STMR-RAC	-	
130030	Quinces	0.5	Existing EU MRL	0.14	STMR-RAC	-	
130040	Medlar	0.5	Existing EU MRL	0.14	STMR-RAC	-	
130050	Loquats/Japanese medlars	0.5	Existing EU MRL	0.14	STMR-RAC	-	

Code	Commodity	TMDI		Chronic risk assessment (IEDI)[1)]		Acute risk assessment (IESTI)[2)]	
		existing/ proposed MRL	Source/type of MRL	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
130990	Other pome fruit	0.5	Existing EU MRL	0.14	STMR-RAC	-	
140010	Apricots	1	Existing EU MRL	0.43	STMR-RAC	-	
140020	Cherries (sweet)	3	Existing EU MRL	0.51	STMR-RAC	-	
140030	Peaches	0.3	Existing EU MRL	0.07	STMR-RAC	-	
140040	Plums	0.8	Existing EU MRL	0.09	STMR-RAC	-	
151010	Table grapes	0.3	Existing EU MRL	0.061	STMR-RAC	-	
151020	Wine grapes	2	Existing EU MRL	0.48	STMR-RAC	-	
152000	Strawberries	1.5	Existing EU MRL	0.2	STMR-RAC	-	
153010	Blackberries	3	Existing EU MRL	0.87	STMR-RAC	-	
153020	Dewberries	2	Existing EU MRL	0.87	STMR-RAC	-	
153030	Raspberries (red and yellow)	3	Existing EU MRL	0.87	STMR-RAC	-	
153990	Other cane fruit	2	Existing EU MRL	0.87	STMR-RAC	-	
154010	Blueberries	4	Existing EU MRL	0.78	STMR-RAC	-	
154020	Cranberries	3	Existing EU MRL	0.94	STMR-RAC	-	
154030	Currants (red, black and white)	3	Existing EU MRL	0.94	STMR-RAC	-	
154040	Gooseberries (green, red and yellow)	3	Existing EU MRL	0.94	STMR-RAC	-	
154050	Rose hips	3	Existing EU MRL	0.94	STMR-RAC	-	
154060	Mulberries (black and white)	3	Existing EU MRL	0.94	STMR-RAC	-	
154070	Azarole/Mediteranean medlar	3	Existing EU MRL	0.94	STMR-RAC	-	
154080	Elderberries	3	Existing EU MRL	0.94	STMR-RAC	-	
154990	Other other small fruit & berries	3	Existing EU MRL	0.94	STMR-RAC	-	
162030	Passion-fruits/maracujas	0.2	Existing EU MRL	0.05	STMR-RAC	-	
163010	Avocados	0.2	Existing EU MRL	0.053	STMR-RAC	-	
163030	Mangoes	0.6	Existing EU MRL	0.110	STMR-RAC	-	
163040	Papayas	0.07	Existing EU MRL	0.05	STMR-RAC	-	
163080	Pineapples	0.3	Existing EU MRL	0.0135 (0.05*0.27)	STMR-RAC*PeF	-	
211000	Potatoes	0.02	Existing EU MRL	0.02	STMR-RAC	-	

Code	Commodity	TMDI		Chronic risk assessment (IEDI)[1)]		Acute risk assessment (IESTI)[2)]	
		existing/ proposed MRL	Source/type of MRL	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
213010	Beetroots	0.1	Existing EU MRL	0.03	STMR-RAC	-	
213020	Carrots	0.5	Existing EU MRL	0.12	STMR-RAC	-	
213030	Celeriacs/turnip rooted celeries	0.5	Existing EU MRL	0.16	STMR-RAC	-	
213040	Horseradishes	0.3	Existing EU MRL	0.08	STMR-RAC	-	
213050	Jerusalem artichokes	0.06	Existing EU MRL	0.02	STMR-RAC	-	
213060	Parsnips	0.3	Existing EU MRL	0.08	STMR-RAC	-	
213070	Parsley roots/Hamburg roots parsley	0.1	Existing EU MRL	0.03	STMR-RAC	-	
213080	Radishes	0.5	Existing EU MRL	0.08	STMR-RAC	-	
213090	Salsifies	0.1	Existing EU MRL	0.03	STMR-RAC	-	
213100	Swedes/rutabagas	0.09	Existing EU MRL	0.02	STMR-RAC	-	
213110	Turnips	0.09	Existing EU MRL	0.02	STMR-RAC	-	
220010	Garlic	0.3	Existing EU MRL	0.02	STMR-RAC	-	
220020	Onions	1.5	Existing EU MRL	0.06	STMR-RAC	-	
220030	Shallots	0.3	Existing EU MRL	0.02	STMR-RAC	-	
220040	Spring onions/green onions and Welsh onions	1.5	Existing EU MRL	0.42	STMR-RAC	-	
231010	Tomatoes	0.3	Existing EU MRL	0.10	STMR-RAC	-	
231020	Sweet peppers/bell peppers	0.5	Existing EU MRL	0.08	STMR-RAC	-	
231030	Aubergines/egg plants	0.3	Existing EU MRL	0.10	STMR-RAC	-	
232010	Cucumbers	0.5	Existing EU MRL	0.06	STMR-RAC	-	
232020	Gherkins	0.5	Existing EU MRL	0.06	STMR-RAC	-	
232030	Courgettes	0.5	Existing EU MRL	0.06	STMR-RAC	-	
232990	Other cucurbits - edible peel	0.5	Existing EU MRL	0.06	STMR-RAC	-	
233010	Melons	0.5	Existing EU MRL	0.055 (0.11*0.5)	STMR-RAC*PeF	-	
233020	Pumpkins	0.5	Existing EU MRL	0.055 (0.11*0.5)	STMR-RAC*PeF	-	
233030	Watermelons	0.5	Existing EU MRL	0.055 (0.11*0.5)	STMR-RAC*PeF	-	
233990	Other cucurbits - inedible peel	0.5	Existing EU MRL	0.055 (0.11*0.5)	STMR-RAC*PeF	-	

Code	Commodity	TMDI		Chronic risk assessment (IEDI)[1]		Acute risk assessment (IESTI)[2]	
		existing/ proposed MRL	Source/type of MRL	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
234000	Sweet corn	0.04	Existing EU MRL	0.016	STMR-RAC	-	
241010	Broccoli	0.5	Existing EU MRL	0.05	STMR-RAC	-	
241020	Cauliflowers	0.5	Existing EU MRL	0.05	STMR-RAC	-	
241990	Other flowering brassica	0.5	Existing EU MRL	0.05	STMR-RAC	-	
242010	Brussels sprouts	0.3	Existing EU MRL	0.03	STMR-RAC	-	
242020	Head cabbages	0.4	Existing EU MRL	0.01	STMR-RAC	-	
243010	Chinese cabbages/ petsai	1.5	Existing EU MRL	0.18	STMR-RAC	-	
243020	Kales	1.5	Existing EU MRL	0.18	STMR-RAC	-	
243990	Other leafy brassica	1.5	Existing EU MRL	0.18	STMR-RAC	-	
251010	Lamb's lettuce/corn salads	10	Existing EU MRL	2.5	STMR-RAC	-	
251020	Lettuces	2	Existing EU MRL	0.26	STMR-RAC	-	
251030	Escaroles/broad-leaved endives	0.4	Existing EU MRL	0.04	STMR-RAC	-	
251040	Cress and other sprouts and shoots	10	Existing EU MRL	2.5	STMR-RAC	-	
251050	Land cress	10	Existing EU MRL	2.5	STMR-RAC	-	
251060	Roman rocket/ rucola	10	Existing EU MRL	2.5	STMR-RAC	-	
251070	Red mustards	10	Existing EU MRL	2.5	STMR-RAC	-	
251080	Baby leaf crops (including brassica species)	10	Existing EU MRL	2.5	STMR-RAC	-	
251990	Other lettuce and other salad plants	10	Existing EU MRL	2.5	STMR-RAC	-	
252010	Spinaches	0.6	Existing EU MRL	0.05	STMR-RAC	-	
252030	Chards/beet leaves	1.5	Existing EU MRL	0.26	STMR-RAC	-	
255000	Witloofs/Belgian endives	0.09	Existing EU MRL	0.03	STMR-RAC	-	
256010	Chervil	2	Existing EU MRL	0.26	STMR-RAC	-	
256020	Chives	2	Existing EU MRL	0.26	STMR-RAC	-	
256030	Celery leaves	2	Existing EU MRL	0.26	STMR-RAC	-	
256040	Parsley	2	Existing EU MRL	0.26	STMR-RAC	-	
256050	Sage	2	Existing EU MRL	0.26	STMR-RAC	-	

Code	Commodity	TMDI		Chronic risk assessment (IEDI)[1)]		Acute risk assessment (IESTI)[2)]	
		existing/ proposed MRL	Source/type of MRL	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
256060	Rosemary	2	Existing EU MRL	0.26	STMR-RAC	-	
256070	Thyme	2	Existing EU MRL	0.26	STMR-RAC	-	
256080	Basil and edible flowers	2	Existing EU MRL	0.26	STMR-RAC	-	
256090	Laurel/bay leaves	2	Existing EU MRL	0.26	STMR-RAC	-	
256100	Tarragon	2	Existing EU MRL	0.26	STMR-RAC	-	
256990	Other herbs	2	Existing EU MRL	0.26	STMR-RAC	-	
260010	Beans (with pods)	0.6	Existing EU MRL	0.13	STMR-RAC	-	
260020	Beans (without pods)	0.3	Existing EU MRL	0.01	STMR-RAC	-	
260030	Peas (with pods)	0.6	Existing EU MRL	0.13	STMR-RAC	-	
260040	Peas (without pods)	0.15	Existing EU MRL	0.01	STMR-RAC	-	
270030	Celeries	1.5	Existing EU MRL	0.4	STMR-RAC	-	
270040	Florence fennels	1.5	Existing EU MRL	0.4	STMR-RAC	-	
270050	Globe arti-chokes	3	Existing EU MRL	0.25	STMR-RAC		
270060	Leeks	0.8	Existing EU MRL	0.26	STMR-RAC		
300010	Beans	0.3	Existing EU MRL	0.04	STMR-RAC	-	
300020	Lentils	0.5	Existing EU MRL	0.13	STMR-RAC	-	
300030	Peas	0.3	Existing EU MRL	0.04	STMR-RAC	-	
300040	Lupins/lupini beans	0.05	Existing EU MRL	0.02	STMR-RAC	-	
300990	Other pulses	0.3	Existing EU MRL	0.04	STMR-RAC	-	
401010	Linseeds	0.2	Existing EU MRL	0.04	STMR-RAC	-	
401020	Peanuts/ground-nuts	0.04	Existing EU MRL	0.02	STMR-RAC	-	
401030	Poppy seeds	0.2	Existing EU MRL	0.04	STMR-RAC	-	
401040	Sesame seeds	0.2	Existing EU MRL	0.04	STMR-RAC	-	
401050	Sunflower seeds	0.3	Existing EU MRL	0.053	STMR-RAC	-	
401060	Rapeseeds/can-ola seeds	0.2	Existing EU MRL	0.035	STMR-RAC	-	
401070	Soyabeans	0.2	Existing EU MRL	0.02	STMR-RAC	-	
401080	Mustard seeds	0.2	Existing EU MRL	0.04	STMR-RAC	-	

Code	Commodity	TMDI		Chronic risk assessment (IEDI)[1)]		Acute risk assessment (IESTI)[2)]	
		existing/ proposed MRL	Source/type of MRL	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
401090	Cotton seeds	0.3	Existing EU MRL	0.03	STMR-RAC	-	
401110	Safflower seeds	0.2	Existing EU MRL	0.04	STMR-RAC	-	
401120	Borage seeds	0.2	Existing EU MRL	0.04	STMR-RAC	-	
401130	Gold of pleasure seeds	0.2	Existing EU MRL	0.04	STMR-RAC	-	
401150	Castor beans	0.2	Existing EU MRL	0.04	STMR-RAC	-	
500010	**Barley**	**1**	**Existing EU MRL**	**0.345 (0.024)**	**STMR-RAC**	**0.345 (0.024)**	**STMR-RAC***
500050	**Oat**	**1**	**Existing EU MRL**	**0.345 (0.024)**	**STMR-RAC**	**0.345 (0.024)**	**STMR-RAC***
500060	Rice	0.09	Existing EU MRL	0.02	STMR-RAC	-	
500070	**Rye**	**0.2**	**Existing EU MRL**	**0.02 (0.01)**	**STMR-RAC**	**0.02 (0.01)**	**STMR-RAC***
500080	Sorghum	0.5	Existing EU MRL	0.025	STMR-RAC	-	
500090	**Wheat**	**0.2**	**Existing EU MRL**	**0.02 (0.01)**	**STMR-RAC**	**0.02 (0.01)**	**STMR-RAC***
620000	Coffee beans	0.3	Existing EU MRL	0.025	STMR-RAC	-	
700000	Hops (dried)	15	Existing EU MRL	3.45	STMR-RAC	-	
840040	Horseradish, root spices	0.3	Existing EU MRL	0.08	STMR-RAC	-	
900010	Sugar beet roots	0.2	Existing EU MRL	0.04	STMR-RAC	-	
900020	Sugar canes	0.08	Existing EU MRL	0.027	STMR-RAC	-	
900030	Chicory roots	0.08	Existing EU MRL	0.03	STMR-RAC	-	
1012030	Bovine: Liver	0.05	Existing EU MRL	0.2	MRL*CF	-	
1013030	Sheep: Liver	0.05	Existing EU MRL	0.2	MRL*CF	-	
1014030	Goat: Liver	0.05	Existing EU MRL	0.2	MRL*CF	-	
1015030	Equine: Liver	0.05	Existing EU MRL	0.2	MRL*CF	-	
1020010	Milk: Cattle	0.01	Existing EU MRL	0.068	MRL*CF	-	
1020020	Milk: Sheep	0.01	Existing EU MRL	0.068	MRL*CF	-	
…	Other crops/commodities		MRL/LOQ according to EU Reg 2020/1633			-	
	Barley / beer					**0.2415 (0.0168)**	**STMRp (STMR* 0.345 x PF 0.70) (0.024 x 0.70)**
	Barley / milling (flour)					**0.345 (0.024)**	**STMR***

Code	Commodity	TMDI		Chronic risk assessment (IEDI)1)		Acute risk assessment (IESTI)2)	
		existing/ proposed MRL	Source/type of MRL	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
	Barley / cooked					**0.345 (0.024)**	**STMR***
	Oat / milling (flakes)					**0.345 (0.024)**	**STMR***
	Oat / boiled					**0.345 (0.024)**	**STMR***
	Rye / milling (wholemeal)-baking					**0.02 (0.01)**	**STMR***
	Rye / boiled					**0.02 (0.01)**	**STMR***
	Wheat / bread (wholemeal)					**0.02 (0.01)**	**STMR***
	Wheat / bread/pizza					**0.02 (0.01)**	**STMR***
	Wheat / pasta					**0.02 (0.01)**	**STMR***
	Wheat / milling (wholemeal)-baking					**0.02 (0.01)**	**STMR***
	Wheat / milling (flour)					**0.0012 (0.0006)**	**STMRp (STMR* 0.02 x PF 0.06) (0.01 x 0.06)**

(1) Normal mode
(2) Refined calculation mode, but only the target crops (marked in bold) were chosen as “GAP under assessment (‘yes’)”
** 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)*
Target crops are marked in **bold**
(Values in brackets are based on calculations with residue values from Table 7.4-9)

7.4.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3. A summary of the results is given below.

Table 7.4-17: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	83 % (based on DE child)
IEDI (% ADI) according to EFSA PRIMo	31 % (based on NL toddler)
IESTI (% ARfD) according to EFSA PRIMo*	Unprocessed commodities Barley 6% (based on children and adults) Oat 1 % (based on children) and 0.7% (based on adults) Processed commodities Oat / boiled and barley / cooked 4 % (based on children) Barley / beer 29 % (based on adults)
NTMDI (% ADI) **	Not necessary
NEDI (% ADI)**	Not necessary
NESTI (% ARfD) **	Not necessary

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

The proposed uses of pyraclostrobin in the formulation BAS 758 00 F do not represent unacceptable acute and chronic risks for the consumer.

7.5 Combined exposure and risk assessment

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

7.5.1 Acute consumer risk assessment from combined exposure

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

A combined risk assessment has been performed for parent mefentrifluconazole (BAS 750 F), parent pyraclostrobin (BAS 500 F) and the triazole derivative metabolites (TDMs: 1,2,4-Triazole, Triazole alanine, Triazole acetic acid and Triazole lactic acid).

In the absence of agreed guidance on estimating combined acute exposure, an indicative Hazard Index (HI) can be derived in order to show specifically for the intended use, that the combined exposure from ~~both triazole derivative metabolites (TDMs)~~ parent BAS 750 F, BAS 500 F and the triazole derivative metabolites (TDMs) is very low. For the present estimation, dose-addition of ~~both TDMs~~ parent BAS 750 F, BAS 500 F and the TDMs is assumed. Such an approach most likely results in an overestimating of the exposure and risk, i.e. for cases where ~~both TDMs~~ BAS 750 F, BAS 500 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 ~~both TDMs~~ BAS 750 F, BAS 500 F and the TDMs. ~~For each TDM, the~~ The HQ ~~of~~ 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 758 00 F in barley (with extrapolation to oat) and wheat (with extrapolation to rye and covering triticale according to EU Reg. 2018/62). A HI <1 indicates absence of a health concern even if dose-addition of active ingredients is assumed.

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

Crop	Active Ingredient	HQ (based on IESTI according to EFSA PRIMo)
Barley	Mefentrifluconazole (BAS 750 F)	0.0040 (0.0006/0.15)
	1,2,4-Triazole (1,2,4-T)	0.0030 (0.0003/0.1)
	Triazole alanine (TA)	0.0117 (0.0035/0.3)
	Triazole acetic acid (TAA)	0.0044 (0.0044/1.0)
	Triazole lactic acid (TLA)	0.0013 (0.0004/0.3)
	Pyraclostrobin (BAS 500 F)	0.063 (0.0019/0.03)
	Cumulative risk barley (HI)	**~~0.013~~ 0.087**
Oat	Mefentrifluconazole (BAS 750 F)	0.0007 (0.0001/0.15)

Crop	Active Ingredient	HQ (based on IESTI according to EFSA PRIMo)
	1,2,4-Triazole (1,2,4-T)	0.0010 (0.0001/0.1)
	Triazole alanine (TA)	0.0023 (0.0007/0.3)
	Triazole acetic acid (TAA)	0.0009 (0.0009/1.0)
	Triazole lactic acid (TLA)	0.0003 (0.0001/0.3)
	Pyraclostrobin (BAS 500 F)	0.013 (0.0004/0.03)
	Cumulative risk oat (HI)	**~~0.0026~~ 0.0182**
Rye	Mefentrifluconazole (BAS 750 F)	0.0007 (0.0001/0.15)
	1,2,4-Triazole (1,2,4-T)	0.0030 (0.0003/0.1)
	Triazole alanine (TA)	0.0130 (0.0039/0.3)
	Triazole acetic acid (TAA)	0.0050 (0.0050/1.0)
	Triazole lactic acid (TLA)	0.0003 (0.0001/0.3)
	Pyraclostrobin (BAS 500 F)	0.0033 (0.0001/0.03)
	Cumulative risk rye (HI)	**~~0.0133~~ 0.0253**
Wheat (including 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)
	Pyraclostrobin (BAS 500 F)	0.010 (0.0003/0.03)
	Cumulative risk wheat (HI)	**~~0.0310~~ 0.0601**

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)

7.5.2 Chronic consumer risk assessment from combined exposure

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

Using the EFSA PRIMo model (version 3.1) the combined chronic risk for triazole alanine and triazole lactic acid was assessed. Calculations for estimated worst-case chronic exposure based on STMRs in target crops (barley with extrapolation to oat and wheat with extrapolation to rye) was calculated in section 7.3.8.

Briefly, the Hazard Quotient (HQ) is calculated for TA and TLA in the formulated product which are chronically toxic. For TA and TLA, the HQ of is defined as the chronic exposure (IEDI) divided by the chronic toxicological reference value (ADI). Summation of these HQ (irrespective of having in fact a common toxicological target) yields the (indicative) Hazard Index (HI) for the intended use of BAS 758 00 F in barley, oat, wheat and rye grain. A HI <1 indicates absence of a health concern even if dose-addition of active ingredients is assumed.

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

Table 7.5-2: Assessment of combined exposure of TA and TLA as a result of the intended use of BAS 758 00 F (barley, oat, wheat and rye)

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 758 00 F (barley, oat, wheat and rye)

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 758 00 F (barley, oat, wheat and rye)

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 758 00 F (barley, oat, wheat and rye)

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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Pyraclostrobin

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Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.1/1	Lehmann, A., Macken-roth, C.	2012	Investigation of the storage stability of BAS 560 F in plant matrices 2012/1166088 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCA 6.2.2/1	xxxxxxxx	2008	BAS 560 F (AC 375839): Metabolism in laying hens 2005/1026047 xxxxxxxxxxxxxxxxxx yes Unpublished	Yes	BASF
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 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

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 6.3.1/2	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 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 6.3.2/2	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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.9/1	Guedez Orozco, A.	2021	Supplemental document, 1,2,4-T, TA, TAA, TLA: Derivation of input values for the livestock dietary burden and the risk assessments for formulation BAS 758 00 F 2021/2047472 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review (BAS 750 F)

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.1/1	Eilers, B., Guedez Orozco, A.	2016	Storage Stability of BAS 750 F in plant matrices 2016/1112644 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCA 6.1/2	Perez, R.	2015	Freezer storage stability of Triazolyl lactic acid in plant samples 2015/7005764 ADPEN Laboratories Inc., Jacksonville FL, United States of America yes Unpublished	No	Yes	Data protection started with Dagonis (BAS 717 00F), Reg. No. R-36/2019, approved: 12.02.2019	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.1/3	Guedez Orozco, A., Heger, N.	2015	Storage stability of BAS 750 F in animal matrices 2015/1106711 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCA 6.1/4	Heger, N., Taraschewski, I.	2015	Storage stability of Reg.No. 6011210 in animal matrices 2015/1106710 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCA 6.2.1/1	Birk, B.	2015	Metabolism of 14C-BAS 750 F in grape 2015/1073822 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCA 6.2.1/2	Rabe, U.	2015	Metabolism of 14C LS 5834378 in wheat 2015/1001872 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.2.1/3	Thiaener, J.	2015	Metabolism of 14C-BAS 750 F in soybean 2014/1224012 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCA 6.2.2/1	xxxxxxxxxxxx	2015	The metabolism of 14C-Reg. No 5834378 (BAS 750 F) in laying hens 2015/1001001 xxxxxxxxxxxxxxxxxxx yes Unpublished	Yes	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCA 6.2.3/1	xxxxxxxxxxx	2015	The metabolism of [14C]-Reg. No. 5834378 (BAS 750 F) in lactating goats 2015/1078841 xxxxxxxxxxxxxxxxxxx yes Unpublished	Yes	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCA 6.2.5/1	xxxxxxxxxxx	2015	The metabolism of 14C-BAS 750 F in rainbow trout (Oncorhynchus mykiss) 2015/1106141 xxxxxxxxxxxxxxxxxxx yes Unpublished	Yes	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.3/1	Erdmann, H.	2015	Study on the residue behaviour of Reg.No. 5834378 (BAS 750 F) in wheat after application of EXP 5834378 F-AV (BAS 750 00 F) under field condition in Germany, The Netherlands, United Kingdom, Southern France, Greece, Italy and Spain, 2013 2014/1010809 Agro-Check Dr. Teresiak & Erdmann GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCA 6.3.3/2	Ale, E.	2015	Residue study (Decline) with BAS 750 01 F, BAS 750 00 F and BAS 750 BU F applied to wheat in Northern and Southern Europe in 2014 2015/1099704 Envigo CRS Ltd. Sucursal en Espana, Valencia, Spain yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCA 6.3.3/3	Ale, E.	2017	Report Amendment 1: Residue study (Decline) with BAS 750 01 F, BAS 750 00 F and BAS 750 BU F applied to wheat in Northern and Southern Europe in 2014 2017/1141927 Envigo CRS Ltd. Sucursal en Espana, Valencia, Spain yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.4/1	Erdmann, H.	2015	Study on the residue behaviour of Reg.No. 5834378 (BAS 750 F) in barley after application of EXP 5834378 F-AV (BAS 750 00 F) under field condition in Germany, The Netherlands, United Kingdom, Southern France, Greece, Italy and Spain, 2013 2014/1010808 Agro-Check Dr. Teresiak & Erdmann GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCA 6.3.4/2	Ale, E.	2015	Residue study (Decline) with BAS 750 01 F, BAS 750 00 F and BAS 750 BU F applied to barley in Northern and Southern Europe in 2014 2015/1099703 Envigo CRS Ltd. Sucursal en Espana, Valencia, Spain yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCA 6.3.4/3	Ale, E.	2017	Amendment No. 1 - Residue study (decline) with BAS 750 01 F, BAS 750 00 F and BAS 750 BU F applied to barley in Northern and Southern Europe in 2014 2017/1101701 Envigo CRS Ltd. Sucursal en Espana, Valencia, Spain yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.5.1/1	Hassink, J.	2014	BAS 750 F: Hydrolysis at 90°C, 100°C and 120°C 2014/1170665 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCA 6.5.3/1	Plier, S.	2015	Determination of residues of BAS 750 F (Reg.No. 5834378) in wheat and its processed products after two applications of BAS 750 01 F in Germany, 2014 2014/1315283 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCA 6.5.3/2	Plier, S.	2015	Determination of residues of BAS 750 F (Reg.No. 5834378) in barley and its processed products after two applications of BAS 750 01 F in Germany, 2014 2014/1315282 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF
KCA 6.6.1/1	Glaessgen, W., Rabe, U.	2015	Confined rotational crop study with 14C LS 5834378 2015/1001871 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.6.2/1	Martin, T.	2015	Study on the residue behavior of BAS 750 F on the rotational crops: wheat, carrots or radish, broccoli or cauliflower and spinach or lettuce after one application of BAS 750 01 F to bare soil under field conditions, 2014-2015 2015/1106682 Agrologia SLU, Utrera, Spain yes Unpublished	No	Yes	Data/study submitted before in the context of Mefentrifluconazole first approval	BASF

BAS 560 F

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.1/1	Class, T.	2002	BAS 560 F (AC 375839): Storage stability of BAS 560 F residues at less than or equal to 18°C in cereal grain and straw 2002/7004653 PTRL Europe GmbH, Ulm, Germany Fed.Rep. yes Unpublished	No	No	Not applicable (Data protection expired; EC 91/414)	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.2.1/1	Class, T., Schlueter, H.	2001	AC 375839: Metabolism of carbon14 labeled AC 375839 in grapevines 2001/7000342 PTRL Europe GmbH, Ulm, Germany Fed.Rep. yes Unpublished	No	No	Not applicable (Data protection expired; EC 91/414)	BASF
KCA 6.2.1/2	Grosshans, F.	2010	Metabolism of 14C-BAS 560 F in cucumber 2010/1054630 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection starts with BAS 560 02 F (Vivando) Reg.-Nr. R-27/2017wu; approved 17.05.2017	BASF
KCA 6.2.1/3	Zulalian, J.	2002	BAS 560 F : Metabolism of carbon14 labeled AC 375839 in wheat under field conditions 2002/7005253 BASF Corp. Agro Research, Princeton NJ, United States of America yes Unpublished	No	No	Not applicable (Data protection expired; EC 91/414)	BASF
KCA 6.2.3/1	xxxxxxxxxxx	2002	BAS 560 F (AC 375839) - Metabolism of 14C BAS 560 F in the lactating goat 2002/7005114 xxxxxxxxxxxxxxxxxxxxxx yes Unpublished	Yes	No	Not applicable (Data protection expired; EC 91/414)	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.1/1	Smalley, R.	2002	AC 375839 300g a.s./L SC (SF 09957): Decline curve residue study on AC 375839 in winter wheat - United Kingdom 1999 2002/7004680 BASF plc, Gosport Hampshire PO13 0AU, United Kingdom yes Unpublished	No	No	Not applicable (Data protection expired; EC 91/414)	BASF
KCA 6.3.1/2	Smalley, R.	2002	AC 375839 300g a.s./L SC (SF 09957): Decline curve residue study on AC 375839 in winter wheat - Netherlands 1999 2002/7004745 BASF plc, Gosport Hampshire PO13 0AU, United Kingdom yes Unpublished	No	No	Not applicable (Data protection expired; EC 91/414)	BASF
KCA 6.3.1/3		2002	BAS 560 F (AC 375839) 300 g a.s./L SC (SF10358) and BAS 560 F 300 g a.s./L SC (SF09957): At harvest residue study on BAS 560 F in winter wheat, Germany, 2000 2002/7004672 CEMAS - CEM Analytical Services Ltd., North Ascot Berkshire SL5 8JB, United Kingdom yes Unpublished	No	No	Not applicable (Data protection expired; EC 91/414)	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.1/4	Trewhitt, J.	2001	AC 375839 300 g a.s./L SC (SF10358 (BAS 560 00 F) and SF09957): At harvest residues study on AC 375839 (BAS 560 F) in winter wheat - The Netherlands, 2000 2001/7000487 BASF plc, Gosport Hampshire PO13 0AU, United Kingdom yes Unpublished	No	No	Not applicable (Data protection expired; EC 91/414)	BASF
KCA 6.3.1/5	Smalley, R.	2001	BAS 560 F (AC 375839) 300g a.s./L SC (SF10358) and BAS 560 F (AC 375839) 300g a.s./L SC (SF09957): At harvest residue study on BAS 560 F in winter wheat - United Kingdom 2000 2001/7001658 BASF plc, Gosport Hampshire PO13 0AU, United Kingdom yes Unpublished	No	No	Not applicable (Data protection expired; EC 91/414)	BASF
KCA 6.3.2/1	Smalley, R.	2001	AC 375839 300g a.s./L SC (SF 09957): Decline curve residue study on AC 375839 in winter wheat - Germany 1999 2001/7001675 BASF plc, Gosport Hampshire PO13 0AU, United Kingdom yes Unpublished	No	No	Not applicable (Data protection expired; EC 91/414)	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.3/1	Trewhitt, J.	2002	AC 375839 300 g a.s./L SC (SF09957): Decline curve residue study on AC 375839 (BAS 560 F) in winter barley - UK, 1999 2002/7004681 BASF plc, Gosport Hampshire PO13 0AU, United Kingdom yes Unpublished	No	No	Not applicable (Data protection expired; EC 91/414)	BASF
KCA 6.3.3/2	Smalley, R.	2001	BAS 560 F (AC 375839) 300g a.s./L SC (SF 10358): Decline curve residue study on BAS 560 F in winter wheat - North France 2000 2001/7001660 BASF plc, Gosport Hampshire PO13 0AU, United Kingdom yes Unpublished	No	No	Not applicable (Data protection expired; EC 91/414)	BASF
KCA 6.3.3/3	Smalley, R.	2001	AC 375839 300g a.s./L SC (SF 09957): Decline curve residue study on AC 375839 in winter barley - Germany 1999 2001/7001659 BASF plc, Gosport Hampshire PO13 0AU, United Kingdom yes Unpublished	No	No	Not applicable (Data protection expired; EC 91/414)	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.3/4	Smalley, R.	2001	BAS 560 F (AC 375839) 300g a.s./L SC (SF 10358): Decline curve residue study on BAS 560 F in winter wheat - South France 2000 2001/7001676 BASF plc, Gosport Hampshire PO13 0AU, United Kingdom yes Unpublished	No	No	Not applicable (Data protection expired; EC 91/414)	BASF
KCA 6.3.3/5	Smalley, R.	2002	BAS 560 F (AC 375839) 300g a.s./L SC (SF10358) and BAS 560 F (AC 375839) 300g a.s./L SC (SF09957): At harvest residue study on BAS 560 F in winter barley - North France 2000 2002/7004445 BASF plc, Gosport Hampshire PO13 0AU, United Kingdom yes Unpublished	No	No	Not applicable (Data protection expired; EC 91/414)	BASF
KCA 6.3.3/6	Smalley, R.	2002	BAS 560 F (AC 375839) 300g a.s./L SC (SF 10358): Decline curve residue study on BAS 560 F in winter barley - North France 2000 2002/7004922 BASF plc, Gosport Hampshire PO13 0AU, United Kingdom yes Unpublished	No	No	Not applicable (Data protection expired; EC 91/414)	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.5.1/1		2000	AC 375839: Effects of processing on the nature of the residues due to hydrolysis 2000/7000137 BASF Corp., Ewing NJ, United States of America yes Unpublished	No	No	Not applicable (Data protection expired; EC 91/414)	BASF
KCA 6.5.2/1		2002	Determination of residues of BAS 560 F in field samples and in processed goods after application of BAS 560 00 F in summer barley at 4 sites in Germany in 2001 2002/1004080 GAB Biotechnologie GmbH & IFU Umweltanalytik GmbH, Niefern-Oeschelbronn, Germany Fed.Rep. yes Unpublished	No	No	Not applicable (Data protection expired; EC 91/414)	BASF
KCA 6.5.3/1	Jordan, J., Kasiri, A.	2006	Magnitude of BAS 560 F residues in grapes and grape processed fractions following applications of BAS 560 00 F (amended final report) 2006/7007012 BASF Corp., Research Triangle Park NC, United States of America yes Unpublished	No	Yes	Data/study report submitted before in the context of Metrafenone AIR 3	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.6.1/1	Zulalian, J.	2002	BAS 560 F (AC 375839): Confined rotational crop study with carbon-14 labeled AC 375839 2002/7005187 BASF Corp., Princeton NJ, United States of America yes Unpublished	No	No	Not applicable (Data protection expired; EC 91/414)	BASF

BAS 500 F

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	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.1/1	Abdel-Baky, S.	2000	Storage stability of BAS 500 F and BF 500-3 in various plant matrices including processed commodities for up to 19 months of frozen storage 2000/5248 BASF Corporation Agricultural Products Center, Research Triangle Park, NC 27709-3528, United States of America yes Unpublished	No	No	Not applicable (DP expired submitted under 91/414)	BASF
KCA 6.1/2	xxxxxxxxxxxxx	2000	Investigation of the stability of residues of BAS 500 F (Reg. No. 304428) in sample material of animal origin under usual storage conditions 2000/1017116 xxxxxxxxxxxxxxxxxxxxxxxxxx yes Unpublished	Yes	No	Not applicable (DP expired submitted under 91/414)	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.1/3	Abdel-Baky, S.	2001	Freezer storage stability of BAS 500 F and BF 500-3 in plant matrices including processed commodities 2001/5000232 BASF Agro Research, Research Triangle Park NC, United States of America yes Unpublished	No	No	Not applicable (DP expired submitted under 91/414)	BASF
KCA 6.2.1/1	Hamm, R.	1998	Metabolism of BAS 500 F in grapes 1998/10988 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable (DP expired submitted under 91/414)	BASF
KCA 6.2.1/2	Hamm, R.	2000	Amendment No. 1: Metabolism of BAS 500 F in grapes 2000/1000201 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable (DP expired submitted under 91/414)	BASF
KCA 6.2.1/3	Bross, M., Mackenroth, C.	1999	The metabolism of 14C-BAS 500 F (14C-Reg.No. 304428) in potato 1999/11419 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable (DP expired submitted under 91/414)	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.2.1/4	Bross, M., Mackenroth, C.	2000	Report amendment No. 1: The metabolism of 14C-BAS 500 F (14C-Reg.No. 304428) in potato 2000/1000048 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable (DP expired submitted under 91/414)	BASF
KCA 6.2.1/5	Reinhard, K.	1999	Metabolism of 14C-BAS 500 F in wheat 1999/11137 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable (DP expired submitted under 91/414)	BASF
KCA 6.2.1/6	Reinhard, K.	2001	Amendment no. 1: Metabolism of 14C BAS 500 F in wheat 2001/1000966 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable (DP expired submitted under 91/414)	BASF
KCA 6.2.1/7	Bross, M.	2004	Pyraclostrobin (BAS 500 F) - Grape metabolism: Additional information on the investigations of grape leaves 2004/1000758 BASF AG, Limburgerhof, Germany Fed.Rep. no Unpublished	No	Yes	Data protection starts with BAS 734 00 F (Inovor) Reg.-Nr. R-233/2017; approved 21.11.2017	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.2.1/8	Satoh, K.	2000	Metabolic fate of BAS 500 F in Chinese cabbage 2000/1018512 The Institute of Environmental Toxicology, Mitsukaido-shi Ibaraki 303-0043, Japan yes Unpublished	No	Yes	Data protection starts with BAS 734 00 F (Inovor) Reg.-Nr. R-233/2017; approved 21.11.2017	BASF
KCA 6.2.1/9	Kloeppner, U., Rabe, U.	2014	Metabolism of 14C-Pyraclostrobin in rice 2013/1134958 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection starts with BAS 734 00 F (Inovor) Reg.-Nr. R-233/2017; approved 21.11.2017	BASF
KCA 6.2.1/10	Birk, B., Kloeppner, U.	2013	Metabolism of 14 C-Pyraclostrobin (14C-BAS 500 F) in wheat after seed treatment 2012/1158148 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection starts with BAS 734 00 F (Inovor) Reg.-Nr. R-233/2017; approved 21.11.2017	BASF
KCA 6.2.2/1	xxxxxxxxxxx	1998	14C-BAS 500 F - Study of the absorption, distribution and excretion after repeated oral administration to laying hens 1998/10637 xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx yes Unpublished	Yes	No	Not applicable (DP expired submitted under 91/414)	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.2.2/2	xxxxxxxxxx	1999	Metabolism of [14C]BAS 500 F in laying hens 1999/11480 xxxxxxxxxxxxxxxxxxxxxxxx yes Unpublished	Yes	No	Not applicable (DP expired submitted under 91/414)	BASF
KCA 6.2.3/1	xxxxxxxxxxxxx	1998	14C-BAS 500 F - Absorption, distribution and excretion after repeated oral administration in lactating goats 1998/10636 xxxxxxxxxxxxxxxxxxxxxxxxxxxx yes Unpublished	Yes	No	Not applicable (DP expired submitted under 91/414)	BASF
KCA 6.2.3/2	Bross, M., Lutz, T.	2009	In vitro investigations of the metabolism of BAS 500 F in goat and cow 2009/1067176 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection starts with BAS 734 00 F (Inovor) Reg.-Nr. R-233/2017; approved 21.11.2017	BASF
KCA 6.2.3/3	xxxxxxxxxxxx	2000	Investigation of the metabolism of 14C-BAS 500 F in the goat 2000/1000004 xxxxxxxxxxxxxxxxxxxxxxxxxxx yes Unpublished	Yes	No	Not applicable (DP expired submitted under 91/414)	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.2.5/1	xxxxxxxxxxxxxx	1999	Bioaccumulation and metabolism of (14C)-BAS 500F in bluegill sunfish 1999/11348 xxxxxxxxxxxxxxxxxxxx yes Unpublished	Yes	No	Not applicable (DP expired submitted under 91/414)	BASF
KCA 6.2.5/2	xxxxxxxxxxxxxxx	2014	The metabolism of 14C-BAS 500 F in rainbow trout (Oncorhynchus mykiss) 2014/1001601 xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx yes Unpublished	Yes	Yes	Data protection starts with BAS 734 00 F (Inovor) Reg.-Nr. R-233/2017; approved 21.11.2017	BASF
KCA 6.3.1/1	Beck, J.	1999	Study on the residue behavior of BAS 500 F, Epoxiconazole and Kresoxim-methyl in cereals after treatment with BAS 500 01 F, BAS 512 00 F and BAS 513 00 F under field conditions in Belgium, France, Germany, Great Britain, Spain, Sweden and the Netherlands, 1998 1999/11509 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable (DP expired submitted under 91/414)	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.1/2	Beck, J.	1999	Study on the residue behavior of BAS 500 F in cereals after treatment with BAS 500 01 F under field conditions in Denmark, France, Germany, Great Britain, Spain and Sweden, 1999 1999/11824 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable (DP expired submitted under 91/414)	BASF
KCA 6.3.1/3	Benz-Birck, A., Meumann, H., Mackenroth, C.	1999	Evaluation of the residue behavior of BAS 500 F after application of BAS 500 01 F in cereals under field conditions in Germany, France and Sweden, 1998 1999/11825 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable (DP expired submitted under 91/414)	BASF
KCA 6.3.1/4	Riley, M., Versoi, P.	1999	Magnitude of BAS 500 F residues in wheat 1999/5096 BASF Corp., Research Triangle Park NC, United States of America yes Unpublished	No	Yes	Data/study report never submitted before	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.1/5	Wyatt, D.	2009	Magnitude of the residue of Pyraclostrobin in or on wheat raw agricultural commodities following applications of BAS 500 00 F with various application spray volumes 2009/7000170 The Carringers Inc., Apex NC, United States of America yes Unpublished	No	Yes	Data/study report never submitted before	BASF
KCA 6.3.1/6	Abdel-Baky, S.	2000	Analysis of BAS 500 F residues in barley, wheat, oats, corn, soybeans, and peanuts after treatment with BAS 512 00 F in Brazil (2000 season) 2000/5236 BASF Corp., Research Triangle Park NC, United States of America no Unpublished	No	No	Not applicable	BASF
KCA 6.3.1/7	Abdel-Baky, S.	2003	Amended final report: Analysis of BAS 500 F residues in barley, wheat, oats, corn, soybeans, and peanuts after treatment with BAS 512 00 F in Brazil (2000 season) 2003/5000120 BASF Corp., Research Triangle Park NC, United States of America no Unpublished	No	No	Not applicable	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.1/8	Regenstein, H.	2003	Report amendment No. 1: Analysis of BAS 500 F residues in barley, wheat, oats, corn, soybeans, and peanuts after treatment with BAS 512 F in Brazil (2000 season) 2003/1013067 BASF AG, Limburgerhof, Germany Fed.Rep. no Unpublished	No	No	Not applicable	BASF
KCA 6.3.1/9	Plier, S.	2011	Determination of residues of BAS 500 F in wheat after two applications of BAS 500 06 F in Germany, United Kingdom, France (North), Denmark, France (South), Greece, Italy and Spain, 2010 2011/1135915 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data/study report submitted before in the context of Pyraclostrobin AIR 3	BASF
KCA 6.3.1/10	Plier, S.	2013	Determination of residues of BAS 500 F in wheat after two applications of BAS 500 06 F in Germany, United Kingdom, Netherlands, France (South), Greece, Italy and Spain, 2011 2012/1067588 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection starts with BAS 751 00 F (Balaya, Selytor, Revycare, Felyco) Reg.-Nr. R-174/2019, R-175/2019, R-176/2019, R-177/2019; approved 30.10.2019	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.1/11	Tandy, R.	2012	Study on the residue behaviour of Pyraclostrobin (BAS 500 F) and Metconazole (BAS 555 F) in winter wheat after treatment with either BAS 556 03 F, BAS 500 06 F or BAS 555 00 F in Northern andSouthern Europe during 2011 2012/1194991 Eurofins Agroscience Services Ltd., Melbourne Derbyshire DE73 8AG, United Kingdom yes Unpublished	No	Yes	Data protection starts with BAS 751 00 F (Balaya, Selytor, Revycare, Felyco) Reg.-Nr. R-174/2019, R-175/2019, R-176/2019, R-177/2019; approved 30.10.2019	BASF
KCA 6.3.1/12	Tandy, R.	2014	Amendment No. 1: Study on the residue behaviour of Pyraclostrobin (BAS 500 F) and Metconazole (BAS 555 F) in winter wheat after treatment with either BAS 556 03 F, BAS 500 06 F or BAS 555 00 F in Northern and Southern Europe during 2011 2014/1090810 Eurofins Agroscience Services Ltd., Melbourne Derbyshire DE73 8AG, United Kingdom yes Unpublished	No	Yes	Data protection starts with BAS 751 00 F (Balaya, Selytor, Revycare, Felyco) Reg.-Nr. R-174/2019, R-175/2019, R-176/2019, R-177/2019; approved 30.10.2019	BASF
KCA 6.3.1/13	Meyer, M.	2013	Study on residue behaviour of Fluxapyroxad (BAS 700 F), Pyraclostrobin (BAS 500 f) in wheat after treatment with either BAS 703 04 F, BAS 700 00 F or BAS 500 06 F under field conditions, Germany, United Kingdom, Spain, Southern France, 2012 2013/1336790 SGS Institut Fresenius GmbH, Taunusstein, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection starts with BAS 703 07 F (Priaxor) Reg.-Nr. R-46/2016; approved 29.02.2016	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.3.2/1	Jordan, J., Saha, M.	2006	The magnitude of residues of Metconazole (BAS 555 F) and its metabolites in sugar beet 2006/7006726 BASF Corp., Research Triangle Park NC, United States of America yes Unpublished	No	Yes	Data/study report submitted before in the context of Metconazole AIR 3	BASF
KCA 6.4.1/1	xxxxxxxxxxxxxxxx	2000	A meat and egg magnitude of the residue study with BAS 500 F in laying hens 2000/5005 xxxxxxxxxxxxxxxxxxxxxxxxxxxxx yes Unpublished	Yes	Yes	Data protection starts with BAS 734 00 F (Inovor) Reg.-Nr. R-233/2017; approved 21.11.2017	BASF
KCA 6.5.1/1	Scharf-Ehrenberg, J.	1998	Hydrolysis of BAS 500 F at 90°C, 100°C, and 120°C 1998/10840 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable (DP expired submitted under 91/414)	BASF
KCA 6.5.1/2	Hueben, M.	2014	High temperature hydrolysis - Simulated processing of 14C-Pyraclostrobin (14C-BAS 500 F) 2014/1136542 Fraunhofer-Institute for Molecular Biology and Applied Ecology, Schmallenberg, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection starts with BAS 734 00 F (Inovor) Reg.-Nr. R-233/2017; approved 21.11.2017	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.5.2/1	Schulz, H.	2000	Determination of the residues of BAS 500 F in barley and processed products following treatment with BAS 500 01 F under field conditions in Germany 1999 1999/11826 Institut Fresenius Chemische und Biologische Laboratorien GmbH, Taunusstein, Germany Fed.Rep. yes Unpublished	No	No	Not applicable (DP expired submitted under 91/414)	BASF
KCA 6.5.2/2	Schulz, H.	2000	Determination of the residues of BAS 500 F in barley and processed products following treatment with BAS 500 01 F under field conditions in Germany 1999 - Follow up study 1999/11827 Institut Fresenius Chemische und Biologische Laboratorien GmbH, Taunusstein, Germany Fed.Rep. yes Unpublished	No	No	Not applicable (DP expired submitted under 91/414)	BASF
KCA 6.5.2/3	Abdel-Baky, S., Riley, M., Versoi, P.	1999	Magnitude of BAS 500 F residues in wheat processed fractions and aspirated grain fraction 1999/5122 BASF Corporation Agricultural Products Center, Research Triangle Park, NC 27709-3528, United States of America yes Unpublished	No	No	Not applicable (DP expired submitted under 91/414)	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.5.2/4	Plier, S.	2013	Determination of residues of BAS 500 F (Pyraclostrobin) in wheat and its processed products after two applications of BAS 500 06 F in Germany 2012/1067586 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection starts with BAS 734 00 F (Inovor) Reg.-Nr. R-233/2017; approved 21.11.2017	BASF
KCA 6.5.2/5	Plier, S.	2013	Determination of residues of BAS 700 F (Fluxapyroxad) and BAS 500 F (Pyraclostrobin) in oat and its processed products after two applications of BAS 703 04 F in Germany, 2012 2013/1037950 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection starts with BAS 703 07 F (Priaxor) Reg.-Nr. R-46/2016; approved 29.02.2016	BASF
KCA 6.5.3/1	Braun, D.	2011	Determination of residues of BAS 500 F (Pyraclostrobin) and BAS 480 F (Epoxiconazole) in maize and its processed products after one application of BAS 512 04 F in Germany 2010/1144336 BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection starts with BAS 512 16 F (Retengo Plus 183 SE) Reg.-Nr. R-38-2014; approved 13.03.2014	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 6.5.3/2	Woodard, D.	2015	Study on the residue behavior of BAS 500 F (Pyraclostrobin) and its metabolites in paddy rice processed fractions after treatment with BAS 500 23 F under field conditions 2014 2015/7000583 SynTech Research Laboratory Services LLC, Stilwell KS, United States of America yes Unpublished	No	Yes	Data protection starts with BAS 734 00 F (Inovor) Reg.-Nr. R-233/2017; approved 21.11.2017	BASF
KCA 6.6.1/1	Veit, P.	2000	Confined rotational crop study with 14C-BAS 500 F 1999/11829 BASF AG, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	No	Not applicable (DP expired submitted under 91/414)	BASF
KCA 6.6.1/2	Rabe, U.	2014	Confined indicator rotational crop study with 14C-Pyraclostrobin 2014/1001761 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	Yes	Data protection starts with BAS 734 00 F (Inovor) Reg.-Nr. R-233/2017; approved 21.11.2017	BASF

Please also refer to Part A

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Mefentrifluconazole

A 2.1.1 Stability of residues

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

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

No new data submitted in the framework of this application. In the context of the Annex I inclusion process three plant metabolism studies (grapes, soybeans, wheat), one metabolism study in rotational crops (spinach, white radish, wheat), one hydrolysis study and two animal metabolism stud-ies (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 Wheat

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)	2	0.150 kg as/ha	14	BBCH 49- 69	35**
Intended cGAP (1*)	2	0.100	14	BBCH 30 - 59	56

* 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.

A 2.1.3.1.1 Study 1 – wheat – BASF DocID 2021/2000402

Comments of zRMS:	The study has been accepted. The objective of the study was to determine the magnitude of residues of BAS 750 F (Mefentrifluconazole) and its triazole metabolites, BAS 500 F (Pyraclostrobin), its metabolite M500F007 and BAS 560 F (Metrafenone) in wheat after treatment with either BAS 758 00 F, BAS 750 01 F, BAS 500 06 F or BAS 560 00 F. The selected application rates, frequency and spray interval cover the Good Agriculture Practice (critical GAP), which will be defined by the label directions. 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. Furthermore, due to high residue found, additional fortifications were performed to cover the highest residue. Overall and average recoveries were all in the range of 70 – 110 % and relative standard deviations (RSD) were < 20 %. During the 2020 growing season, 4 trials in wheat were conducted in different representative growing areas in Northern Europe to determine the residue level of BAS 750 F (Mefentrifluconazole), BAS 500 F (Pyraclostrobin) and BAS 560 F (Metrafenone) after application of either BAS75800F, BAS75001F, BAS50006F or BAS56000F in or on RAC. All trials consisted of five plots: plot 1 (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). **Plot 2:** In all trials the first application was made 13-14 days before application no. 2 (except of trial L200225: 19 days before application no. 2, see deviation). The second application was performed at BBCH 59. **Plots 3 to 5:** The first application was made at BBCH 49. The second applications were made at BBCH 69. **BAS 758 00 F** (66.6 g BAS 750 F/L, 80.0 g BAS 500 F/L, 100.0 g BAS 560 F/L, EC) was applied in all trials twice at a single rate of 1.5 L/ha formulated product, equals to 0.10 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 on plot 2 with a water volume of 200 L/ha. **BAS 750 01 F** (100.0 g BAS 750 F/L, EC) was applied in all trials twice at a single rate of 1.5 L/ha formulated product, equals to 0.15 kg a.i./ha of BAS 750 F on plot 3 with a water volume of 200 L/ha. **BAS 500 06 F** (200.0 g BAS 500 F/L, EC) was applied in all trials twice at a single rate of 1.25 L/ha formulated product, equals to 0.25 kg a.i./ha of BAS 500 F on plot 4 with a water volume of 200 L/ha. **BAS 560 00 F** (300.0 g BAS 560 F/L, SC) was applied in all trials twice at a single rate of 0.5 L/ha formulated product, equals to 0.15 kg a.i./ha of BAS 560 F on plot 5 with a water volume of 200 L/ha. **Plots 1 and 2:** Wheat specimens 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. At 48-50 DALA the specimens were sampled as grain and straw on plot 2. At 55-57 DALA wheat specimens were collected as grain and straw on plots 1 and 2. At 63-64 DALA specimens were sampled as grain and straw on plot 2. **Plots 1, 3, 4 and 5:** Wheat specimens were collected at BBCH 69 on plot 1 immediately before application no. 2 and directly after application no. 2 on plots 3 to 5 as whole plant no roots. At 34-35 DALA the specimens were sampled as ears and rest of plant without roots or as grain and straw on plot 1 and plots 3 to 5. At 41-42 DALA wheat specimens were collected as grain and straw on plots 3 to 5. At 48-49 DALA specimens were sampled

as grain and straw on plots 3 to 5.

All wheat specimens of plots 1 and 2 were analysed for BAS 750 F (Mefentrifluconazole), BAS 500 F (Pyraclostrobin) and its metabolite M500F007, BAS 560 F (Metrafenone) using the BASF Method L0076/09. The method has a limit of quantitation of 0.010 mg/kg.
All wheat specimens of plot 3 were analysed for BAS 750 F (Mefentrifluconazole) using the BASF Method L0076/09. The method has a limit of quantitation of 0.010 mg/kg.
All treated wheat specimens of plot 4 were analysed for BAS 500 F (Pyraclostrobin) and its metabolite M500F007 using the BASF Method L0076/09. The method has a limit of quantitation of 0.010 mg/kg.
All treated wheat specimens of plot 5 were analysed for BAS 560 F (Metrafenone) using the BASF Method L0076/09. The method has a limit of quantitation of 0.010 mg/kg.
The results of the average procedural recoveries in wheat matrices at fortification levels between 0.010 and 10 mg/kg were at 90.4 % for BAS 750 F, at 92.8 % for BAS 500 F, at 95.7 % for M500F007 and at 99.1 % for BAS 560 F. Results are summarized in the tables below.

Table S- 1: Procedural Recoveries for BAS 750 F (Mefentrifluconazole)

Matrix		Fortification Level [mg/kg]	BAS 750 F 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

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

Table S- 2: Procedural Recoveries for BAS 500 F (Pyraclostrobin) and its Metabolite M500F007

Matrix		Fortification Level [mg/kg]	BAS 500 F Mean [%]	SD [±]	RSD [%]	n
Wheat	Whole plant no roots	0.010, 0.10 and 10	84.7	7.8	9.2	9
	Ears	0.010, 0.10 and 10	97.5	4.8	4.9	7
	Rest of plant without roots	0.010, 0.10 and 10	96.3	5.5	5.7	7
	Grain	0.010, 0.10 and 1.0	96.8	3.5	3.6	7
	Straw	0.010, 0.10 and 10	91.7	8.8	9.6	11
Overall:			92.8	8.1	8.7	41
Matrix		**Fortification Level [mg/kg]**	**M500F007 Mean [%]**	**SD [±]**	**RSD [%]**	**n**
Wheat	Whole plant no roots	0.010, 0.10 and 10	88.6	7.0	7.9	9
	Ears	0.010, 0.10 and 10	101	6.2	6.1	7
	Rest of plant without roots	0.010, 0.10 and 10	101	5.5	5.4	7

	Grain	0.010, 0.10 and 1.0	97.1	4.6	4.8	7
	Straw	0.010, 0.10 and 10	93.7	6.8	7.3	11
		Overall:	95.7	7.7	8.0	41

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

Table S- 3: Procedural Recoveries for BAS 560 F (Metrafenone)

Matrix		**Fortification Level [mg/kg]**	**BAS 560 F**			
			Mean [%]	**SD [±]**	**RSD [%]**	**n**
Wheat	Whole plant no roots	0.010, 0.10 and 10	90.8	9.4	10	9
	Ears	0.010, 0.10 and 10	106	4.6	4.4	7
	Rest of plant without roots	0.010, 0.10 and 10	103	4.7	4.6	7
	Grain	0.010, 0.10 and 1.0	99.7	4.0	4.1	7
	Straw	0.010, 0.10 and 10	98.4	4.9	4.9	11
		Overall:	99.1	7.8	7.8	41

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

Further all wheat specimens of plot 1, 2 and 3 were analysed for 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) using the adapted BASF method no. L0170/02. The method has a limit of quantitation of 0.010 mg/kg for each analyte.

The results of the average procedural recoveries in plant matrices
- at fortification levels between 0.010 and 1.0 mg/kg were 89.4 % for 1,2,4-Triazole,
- at fortification levels between 0.010 and 1.0 mg/kg were 88.7 % for Triazole alanine,
- at fortification levels between 0.010 and 1.0 mg/kg were 97.2 % for Triazole acetic acid,
- at fortification levels between 0.010 and 1.0 mg/kg were 85.5 % for Triazole lactic acid.

Results are summarized in the table below.

Table S- 4: Procedural Recoveries for 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)

Matrix		**Recoveries of**	**Fortification Level [mg/kg]**	**Mean [%]**	**SD [±]**	**RSD [%]**	**n**
Wheat	Whole plant no roots	1,2,4-Triazole (1,2,4-T)	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
Wheat	Whole plant no roots	Triazole alanine (TA)	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
Wheat	Whole plant no roots	Triazole acetic acid (TAA)	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
Wheat	Whole plant no roots	Triazole lactic acid (TLA)	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

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

Table S- 5: Summary of Residues of BAS 750 F (Mefentrifluconazole) in Wheat

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	1.5 - 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 with BAS 750 01 F (2x 1.5 L/ha)					
1	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

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

<u>**Residues of BAS 750 F (Mefentrifluconazole)**</u>

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.

Table S- 6: Summary of Residues of BAS 500 F (Pyraclostrobin) and its Metabolite M500F007 in Wheat

Sampl. No.	Portion analyzed	Timing DALA	Growth Stage (BBCH)	n	Range of Residues [mg/kg]		
					BAS 500 F	expressed as parent equivalents M500F007 [1)]	Sum [2)]
Plot 2: treated with BAS 758 00 F (2x 1.5 L/ha)							
1	Whole plant no roots	0	59	4	1.7 - 3.3	0.029 - 0.085	1.7 - 3.3
2	Grain	48 - 50	87 - 89	4	< 0.010	< 0.011	< 0.021
	Straw			4	0.35 - 1.2	0.16 - 0.49	0.50 - 1.7
3	Grain	55 - 57	87 - 89	4	< 0.010	< 0.011	< 0.021
	Straw			4	0.34 - 1.1	0.19 - 0.48	0.53 - 1.6
4	Grain	63 - 64	89	4	< 0.010	< 0.011	< 0.021
	Straw			4	0.40 - 0.58	0.22 - 0.32	0.62 - 0.89
Plot 4: treated with BAS 500 06 F (2x 1.25 L/ha)							
1	Whole plant no roots	0	69	4	2.5 - 5.3	0.11 - 0.36	2.6 - 5.6
2	Ears	34	83	1	0.20	0.12	0.32
	Rest of plant without roots			1	0.77	0.47	1.2
	Grain	34 - 35	85 - 89	3	< 0.010 - 0.014	< 0.011	< 0.021 - 0.025
	Straw			3	1.7 - 3.3	0.82 - 1.3	2.6 - 4.6
3	Grain	41 - 42	87 - 89	4	< 0.010 - 0.016	< 0.011	< 0.021 - 0.027
	Straw			4	0.81 - 4.6	0.51 - 2.0	1.3 - 6.6
4	Grain	48 - 49	89	4	< 0.010 - 0.022	< 0.011	< 0.021 - 0.033
	Straw			4	0.98 - 4.5	0.64 - 1.7	1.6 - 6.2

DALA = days after last application n = Number of specimens
General: The limit of quantification (LOQ) is 0.010 mg/kg for BAS 500 F and 0.011 mg/kg for M500F007 (expressed as parent equivalent).

1) Conversion factor for calculation of M500F007 to parent BAS 500 F is 1.084
2) for residues of BAS 500 F < 0.010 mg/kg, value was set to 0.010 mg/kg for calculation of sum and for residues of M500F007, expressed as parent equivalent < 0.011 mg/kg, value was set to 0.011 mg/kg for calculation of sum; if both values are below LOQ the sum is <0.021 mg/kg

Residues of BAS 500 F (Pyraclostrobin)

Plot 2: The residues of **BAS 500 F** analyzed in wheat whole plant no roots specimens sampled immediately after the last application (59 BBCH) ranged from 1.7 to 3.3 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 500 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 500 F were analyzed between 0.35 and 1.2 mg/kg. At 55-57 DALA (87-89 BBCH) and 63-64 DALA (89 BBCH) residues of BAS 500 F were in a range from 0.34 to 1.1 mg/kg and from 0.40 to 0.58 mg/kg, respectively.
Plot 4: The residues of **BAS 500 F** analyzed in wheat whole plant no roots specimens sampled immediately after the last application (69 BBCH) ranged from 2.5 to 5.3 mg/kg.
In ears specimens collected at 34 DALA (83 BBCH) a residue of BAS 500 F was found at 0.20 mg/kg. Rest of plant without roots specimens taken at the same sampling event showed a residue of BAS 500 F of 0.77 mg/kg.
In grain specimens sampled at 34-35 DALA (85-89 BBCH) residues of BAS 500 F were found between < 0.010 and 0.014 mg/kg. At 41-42 DALA (87-89 BBCH) and 48-49 DALA (89 BBCH) residues were analyzed from < 0.010 to 0.016 mg/kg and from < 0.010 to 0.022 mg/kg, respectively.
In straw specimens sampled at 34-35 DALA (85-89 BBCH) residues of BAS 500 F ranged from 1.7 to 3.3 mg/kg. At 41-42 DALA (87-89 BBCH) and 48-49 DALA (89 BBCH) residues were analyzed from 0.81 to 4.6 mg/kg and from 0.98 to 4.5 mg/kg, respectively.

Plot 2: The residues of **M500F007 (expressed as parent equivalent)** analyzed in wheat whole plant no roots specimens sampled immediately after the last application (59 BBCH) ranged from 0.029 to 0.085 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 M500F007 were found at or above the LOQ (0.011 mg/kg).

In straw specimens sampled at 48-50 DALA (87-89 BBCH) residues of M500F007 were analyzed between 0.16 and 0.49 mg/kg. At 55-57 DALA (87-89 BBCH) and 63-64 DALA (89 BBCH) residues of M500F007 were in a range from 0.19 to 0.48 mg/kg and from 0.22 to 0.32 mg/kg, respectively.

Plot 4: The residues of **M500F007 (expressed as parent equivalent)** analyzed in wheat whole plant no roots specimens sampled immediately after the last application (69 BBCH) ranged from 0.11 to 0.36 mg/kg.

In ears specimens collected at 34 DALA (83 BBCH) a residue of M500F007 was found at 0.12 mg/kg. Rest of plant without roots specimens taken at the same sampling event showed a residue of M500F007 of 0.47 mg/kg.

In grain specimens sampled at 34-35 DALA (85-89 BBCH), 41-42 DALA (87-89 BBCH) and 48-49 DALA (89 BBCH) no residues of M500F007 were found at or above the LOQ (0.011 mg/kg).

In straw specimens sampled at 34-35 DALA (85-89 BBCH) residues of M500F007 ranged from 0.82 to 1.3 mg/kg. At 41-42 DALA (87-89 BBCH) and 48-49 DALA (89 BBCH) residues were analyzed from 0.51 to 2.0 mg/kg and from 0.64 to 1.7 mg/kg, respectively.

No residues of BAS 500 F and its metabolite M500F007 were detected at or above the LOQ in any of the untreated control samples.

Bridging showed, that the new formulation BAS 758 00 F does not lead to higher residues than the respective solo formulation BAS 500 06 F

Table S- 7: Summary of Residues of BAS 560 F (Metrafenone) in Wheat

Sampl. No.	Portion analyzed	Timing DALA	Timing Growth stage (BBCH)	n	Range of Residues (mg/kg) BAS 560 F
Plot 2: treated with BAS 758 00 F (2x 1.5 L/ha)					
1	Whole plant no roots	0	59	4	1.7 - 3.2
2	Grain	48 - 50	87 - 89	4	< 0.010
	Straw			4	0.033 - 0.086
3	Grain	55 - 57	87 - 89	4	< 0.010
	Straw			4	0.034 - 0.070
4	Grain	63 - 64	89	4	< 0.010
	Straw			4	0.026 - 0.040
Plot 5: treated with BAS 560 00 F (2x 0.5 L/ha)					
1	Whole plant no roots	0	69	4	2.1 - 3.1
2	Ears	34	83	1	0.060
	Rest of plant without roots			1	0.85
	Grain	34 - 35	85 - 89	3	< 0.010
	Straw			3	0.78 - 2.9
3	Grain	41 - 42	87 - 89	4	< 0.010
	Straw			4	0.69 - 3.8
4	Grain	48 - 49	89	4	< 0.010
	Straw			4	1.1 - 3.1

DALA = days after last application n = Number of specimens
General: The limit of quantification (LOQ) is 0.010 mg/kg for BAS 560 F.

Residues of BAS 560 F (Metrafenone)

Plot 2: The residues of **BAS 560 F** analyzed in wheat whole plant no roots specimens sampled
immediately after the last application (59 BBCH) ranged from 1.7 to 3.2 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 560 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 560 F were analyzed between 0.033 and 0.086 mg/kg. At 55-57 DALA (87-89 BBCH) and 63-64 DALA (89 BBCH) residues of BAS 560 F were in a range from 0.034 to 0.070 mg/kg and from 0.026 to 0.040 mg/kg, respectively.
Plot 5: The residues of **BAS 560 F** analyzed in wheat whole plant no roots specimens sampled immediately after the last application (69 BBCH) ranged from 2.1 to 3.1 mg/kg.
In ears specimens collected at 34 DALA (83 BBCH) a residue of BAS 560 F was found at 0.060 mg/kg. Rest of plant without roots specimens taken at the same sampling event showed a residue of BAS 560 F of 0.85 mg/kg.
In grain specimens sampled at 34-35 DALA (85-89 BBCH), 41-42 DALA (87-89 BBCH) and 48-49DALA (89BBCH) no residues of BAS560F were found at or above the LOQ (0.010 mg/kg).
In straw specimens sampled at 34-35 DALA (85-89 BBCH) residues of BAS 560 F ranged from 0.78 to 2.9 mg/kg. At 41-42 DALA (87-89 BBCH) and 48-49 DALA (89 BBCH) residues were analyzed from 0.69 to 3.8 mg/kg and from 1.1 to 3.1 mg/kg, respectively.

In the untreated control specimens, no residues of BAS 560 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 560 00 F.

Table S- 8: Summary of residues in the untreated Wheat Specimens for 1,2,4-Triazole (1,2,4-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 (1,2,4-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	< 0.010 – 0.040	< 0.010 – 0.058	< 0.010 – 0.045
3	Grain	55 – 57	87-89	4	< 0.010	0.045 – 0.14	0.021 – 0.14	< 0.010
	Straw			4	< 0.010	< 0.010 – 0.010	< 0.010 – 0.11	< 0.010 – 0.041
Plot 1 – untreated (in regard to plot 3)								
1	Whole plant no roots	0 DBLA	69	4	< 0.010	< 0.010 – 0.042	< 0.010 – 0.057	< 0.010 – 0.034
2	Ears	34	83	1	< 0.010	0.075	0.038	< 0.010
	Rest of plant without roots			1	< 0.010	< 0.010	0.016	0.023
2	Grain	34-35	85-89	3	< 0.010	0.038 – 0.13	0.019 – 0.11	< 0.010
	Straw			3	< 0.010	< 0.010 – 0.017	< 0.010 – 0.098	< 0.010 – 0.040

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

Table S- 9: Summary of residues in the treated Wheat Specimens for 1,2,4-Triazole (1,2,4-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 (1,2,4-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	0.010 - 0.034	< 0.010 - 0.042	< 0.010 - 0.029
2	Grain	49-50	85-89	4	< 0.010	0.10 - 0.17	0.035 - 0.10	< 0.010
	Straw			4	< 0.010	< 0.010 - 0.011	< 0.010 - 0.077	0.010 - 0.050
3	Grain	56-57	87-89	4	< 0.010	0.10 - 0.19	0.038 - 0.10	< 0.010
	Straw			4	< 0.010	< 0.010	0.012 - 0.078	0.010 - 0.064
4	Grain	63-64	89	4	< 0.010	0.086 - 0.16	0.036 - 0.097	< 0.010
	Straw			4	< 0.010	< 0.010	< 0.010 - 0.078	< 0.010 - 0.042
Plot 3: treated with BAS 750 01 F (2x 1.5 L/ha)								
1	Whole plant no roots	0	69	4	< 0.010	0.014 - 0.056	< 0.010 - 0.047	< 0.010 - 0.029

2	Ears	34	83	1	< 0.010	0.15	0.055	< 0.010
	Rest of plant without roots			1	< 0.010	< 0.010	0.019	0.044
	Grain	34 - 35	85-89	3	< 0.010	0.15 - 0.21	0.041 - 0.14	< 0.010
	Straw			3	< 0.010	< 0.010 - 0.013	< 0.010 - 0.10	0.014 - 0.068
3	Grain	41 - 42	87-89	4	< 0.010	0.16 - 0.22	0.040 - 0.10	< 0.010
	Straw			4	< 0.010	< 0.010 - 0.015	0.016 - 0.076	0.016 - 0.048
4	Grain	48 - 49	89	4	< 0.010	0.15 - 0.22	0.041 - 0.14	< 0.010
	Straw			4	< 0.010	< 0.010 - 0.016	0.014 - 0.10	0.010 - 0.066

DALA = days after last application n = Number of specimens

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 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 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: 13-14 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 3: 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 4: 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 5: 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 (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment: kg a.s./ha	Application rate per treatment: Water (l/ha)	Application rate per treatment: kg a.s./hl	Dates of treatment or no. of treatments and last date* (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg): BAS 750 F	Residues (mg/kg): 1,2,4-T	Residues (mg/kg): TA	Residues (mg/kg): TAA	Residues (mg/kg): TLA	PHI (days) (d)	Details on trial (e)
2021/2000402	Wheat	1. 21.10.2019	0.10	200	0.05	**Plot 2**	59	whole plant no roots	1.7	<0.010	0.034	0.042	0.029	0	2021/2000402
L200223	GC 0654	2. 02.06-16.06.2020				18.05.2020		grain	<0.010	<0.010	0.16	0.10	<0.010	49	Plot 2: BAS 758 00 F EC
16833 Lentzke	/ Linus	3. 20.07-03.08.2020				01.06.2020		straw	2.0	<0.010	0.011	0.077	0.040	49	Mefentrifluconazole 66.6 g/L
Brandenburg								grain	<0.010	<0.010	0.16	0.10	<0.010	56	
Germany								straw	1.6	<0.010	<0.010	0.078	0.046	56	
EU-North								grain	<0.010	<0.010	0.16	0.097	<0.010	63	
2020								straw	1.3	<0.010	<0.010	0.078	0.040	63	Plot 3: BAS 750 01 F EC
			0.15	200	0.075	**Plot 3**	69	whole plant no roots	2.8	<0.010	0.039	0.047	0.029	0	Mefentrifluconazole 100 g/L
						25.05.2020		grain	<0.010	<0.010	0.19	0.14	<0.010	35	
						16.06.2020		straw	5.3	<0.010	<0.010	0.10	0.068	35	BASF method L0076/09
								graiw	0.012	<0.010	0.18	0.10	<0.010	41	for Mefentrifluconazole
								straw	7.8	<0.010	<0.010	0.076	0.044	41	and L0170/02 for Triazole Metabolites
								grain	0.011	<0.010	0.22	0.14	<0.010	48	
								straw	5.6	<0.010	0.010	0.10	0.061	48	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Application rate per treatment			Dates of treatment or no. of treatments and last date*	Growth stage at last treatment or date	Portion analyzed	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 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	1.5	<0.010	0.030	0.019	0.018	0	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)
								grain	<0.01	<0.010	0.15	0.061	<0.010	50	
								straw	0.80	<0.010	0.010	0.029	0.026	50	
								grain	<0.010	<0.010	0.15	0.066	<0.010	57	
								straw	1.3	<0.010	<0.010	0.034	0.025	57	
								grain	<0.010	<0.010	0.13	0.061	<0.010	64	
								straw	1.2	<0.010	<0.010	0.033	0.031	64	
			0.15	200	0.075	**Plot 3** 20.05.2020 12.06.2020	69	whole plant no roots	3.5	<0.010	0.056	0.031	0.025	0	
								grain	<0.010	<0.010	0.21	0.093	<0.010	35	
								straw	3.6	<0.010	0.013	0.043	0.041	35	
								grain	<0.010	<0.010	0.22	0.093	<0.010	42	
								straw	4.5	<0.010	0.015	0.045	0.039	42	
								grain	<0.010	<0.010	0.21	0.097	<0.010	49	
								straw	3.8	<0.010	0.016	0.049	0.041	49	
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	2.0	<0.010	0.010	<0.010	<0.010	0	
								grain	<0.010	<0.010	0.10	0.035	<0.010	49	
								straw	2.1	<0.010	<0.010	<0.010	0.010	49	
								grain	<0.010	<0.010	0.10	0.038	<0.010	56	
								straw	2.1	<0.010	<0.010	0.012	0.010	56	
								grain	<0.010	<0.010	0.086	0.036	<0.010	64	
								straw	1.2	<0.010	<0.010	<0.010	<0.010	64	
			0.15	200	0.075	**Plot 3** 26.05.2020 10.06.2020	69	whole plant no roots	3.4	<0.010	0.014	<0.010	<0.010	0	
								grain	<0.010	<0.010	0.15	0.041	<0.010	34	
								straw	4.5	<0.010	<0.010	<0.010	0.014	34	
								grain	<0.010	<0.010	0.16	0.040	<0.010	42	
								straw	5.9	<0.010	<0.010	0.016	0.016	42	
								grain	<0.010	<0.010	0.15	0.041	<0.010	49	
								straw	5.2	<0.010	<0.010	0.014	0.010	49	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment kg a.s./ ha	Application rate per treatment Water (l/ha)	Application rate per treatment kg a.s./hl	Dates of treatment or no. of treatments and last date* (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg) BAS 750 F	Residues (mg/kg) 1,2,4-T	Residues (mg/kg) TA	Residues (mg/kg) TAA	Residues (mg/kg) TLA	PHI (days) (d)	Details on trial (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	0.10	200	0.05	**Plot 2** 30.04.2020 13.05.2020	59	whole plant no roots	2.5	<0.010	0.031	0.027	0.018	0	
								grain	<0.010	<0.010	0.17	0.069	<0.010	48	
								straw	0.75	<0.010	<0.010	0.025	0.050	48	
								grain	<0.010	<0.010	0.19	0.080	<0.010	55	
								straw	0.77	<0.010	<0.010	0.039	0.064	55	
								grain	<0.010	<0.010	0.14	0.063	<0.010	64	
								straw	0.98	<0.010	<0.010	0.034	0.042	64	
			0.15	200	0.075	**Plot 3** 05.05.2020 20.05.2020	69	whole plant no roots	2.2	<0.010	0.045	0.043	0.026	0	
								grain	0.35	<0.010	0.15	0.055	<0.010	34	
								straw	3.1	<0.010	<0.010	0.019	0.044	34	
								graiw	<0.010	<0.010	0.19	0.082	<0.010	41	
								straw	2.7	<0.010	<0.010	0.024	0.048	41	
								grain	<0.010	<0.010	0.21	0.080	<0.010	48	
								straw	4.1	<0.010	0.011	0.040	0.066	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 6: 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 (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment kg a.s./ ha	Application rate per treatment Water (l/ha)	Application rate per treatment kg a.s./hl	Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg) BAS 750 F	Residues (mg/kg) 1,2,4-T	Residues (mg/kg) TA	Residues (mg/kg) TAA	Residues (mg/kg) TLA	PHI (days) (d)	Details on trial (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	<0.010	<0.010	0.040	0.058	0.045	0 DBLA	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)
								grain	<0.010	<0.010	0.14	0.14	<0.010	56	
								straw	<0.010	<0.010	<0.010	0.11	0.041	56	
						Plot 1[2)]	-	whole plant no roots	<0.010	<0.010	0.042	0.057	0.034	0 DBLA	
								grain	<0.010	<0.010	0.12	0.11	<0.010	35	
								straw	<0.010	<0.010	<0.010	0.098	0.040	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	<0.010	<0.010	0.030	0.020	0.023	0 DBLA	
								grain	<0.010	<0.010	0.13	0.094	<0.010	57	
								straw	<0.010	<0.010	<0.010	0.060	0.033	57	
						Plot 1[2)]	-	whole plant no roots	<0.010	<0.010	0.036	0.028	0.026	0 DBLA	
								grain	<0.010	<0.010	0.13	0.080	<0.010	35	
								straw	<0.010	<0.010	0.017	0.038	0.024	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	<0.010	<0.010	<0.010	<0.010	<0.010	0 DBLA	
								grain	<0.010	<0.010	0.045	0.021	<0.010	56	
								straw	<0.010	<0.010	<0.010	<0.010	<0.010	56	
						Plot 1[2)]	-	whole plant no roots	<0.010	<0.010	<0.010	<0.010	<0.010	0 DBLA 34	
								grain	<0.010	<0.010	0.038	0.019	<0.010	34	
								straw	<0.010	<0.010	<0.010	<0.010	<0.010		

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)					PHI (days) (d)	Details on trial (e)
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				BAS 750 F	1,2,4-T	TA	TAA	TLA		
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 2.1.3.2 Barley

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)	2	0.150 kg as/ha	14	BBCH 49- 69	35**
Intended cGAP (2*)	2	0.100	14	BBCH 30 - 59	56

* 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.

A 2.1.3.2.1 Study 2 – barley – BASF DocID 2021/2000401

Comments of zRMS:	The study has been accepted. The objective of the study was to determine the magnitude of residues of BAS 750 F (Mefentrifluconazole) and its triazole metabolites, BAS 500 F (Pyraclostrobin), its metabolite M500F007 and BAS 560 F (Metrafenone) in barley after treatment with either BAS 758 00 F, BAS 750 01 F, BAS 500 06 F or BAS 560 00 F. The selected application rates, frequency and spray interval cover the Good Agriculture Practice (critical GAP), which will be defined by the label directions. During the 2020 growing season, 4 trials in barley were conducted in different representative growing areas in Northern Europe to determine the residue level of BAS750F (Mefentrifluconazole), BAS 500 F (Pyraclostrobin) and BAS 560 F (Metrafenone) after application of either BAS75800F, BAS75001F, BAS50006F or BAS56000F in or on Raw Agricultural Commodities (RAC). All trials consisted of five plots: plot 1 (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). **BAS 758 00 F** (66.6 g BAS 750 F/L, 80.0 g BAS 500 F/L, 100.0 g BAS 560 F/L, EC) was applied in all trials twice at a single rate of 1.5 L/ha formulated product, equals to 0.10 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 on plot 2 with a water volume of 200 L/ha. **BAS 750 01 F** (100.0 g BAS 750 F/L, EC) was applied in all trials twice at a single rate of 1.5 L/ha formulated product, equals to 0.15 kg a.i./ha of BAS 750 F on plot 3 with a water volume of 200 L/ha. **BAS 500 06 F** (200.0 g BAS 500 F/L, EC) was applied in all trials twice at a single rate of 1.25 L/ha formulated product, equals to 0.25 kg a.i./ha of BAS 500 F on plot 4 with a water volume of 200 L/ha. **BAS 560 00 F** (300.0 g BAS 560 F/L, SC) was applied in all trials twice at a single rate of 0.5 L/ha formulated product, equals to 0.15 kg a.i./ha of BAS 560 F on plot 5 with a water volume of 200 L/ha.

Plot 2: In all trials the first application was made 13-15 days before application no. 2 (except of trial L200230: 11 days before application no. 2, see deviation). The second application was performed at BBCH 59.
Plot 3 to 5: The first application was made at BBCH 49. The second application was made at BBCH 69.
Plot 1 and 2: Barley specimens 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.
At 48-49 DALA the specimens were sampled as grain and straw on plot 2.
At 55-56 DALA barley specimens were collected as grain and straw on plot 1 and 2.
At 62-63 specimens were sampled as grain and straw on plot 2 (except of trial L200230: sampling no. 4 could not be performed, see deviation).
Plot 1, 3, 4 and 5: Barley specimens were collected at BBCH 69 on plot 1 immediately before application no. 2 and directly after application no. 2 on plot 3 to 5 as whole plant no roots.
At 27-28 DALA specimens were collected as ears and rest of plant without roots or as grain and straw on plot 3 to 5.
At 34-35 DALA the specimens were sampled as grain and straw on plot 1 and 3 to 5. At 41-43 DALA barley specimens were collected as grain and straw on plot 3 to 5.
All barley specimens of plot 1 and 2 were analysed for BAS 750 F (Mefentrifluconazole), BAS 500 F (Pyraclostrobin) and its metabolite M500F007, BAS 560 F (Metrafenone) using the BASF Method L0076/09. The method has a limit of quantitation of 0.010 mg/kg.
All barley specimens of plot 3 were analysed for BAS 750 F (Mefentrifluconazole) using the BASF Method L0076/09. The method has a limit of quantitation of 0.010 mg/kg.
All treated barley specimens of plot 4 were analysed for BAS 500 F (Pyraclostrobin) and its metabolite M500F007 using the BASF Method L0076/09. The method has a limit of quantitation of 0.010 mg/kg.
All treated barley specimens of plot 5 were analysed for BAS 560 F (Metrafenone) using the BASF Method L0076/09. The method has a limit of quantitation of 0.010 mg/kg.
The results of the average procedural recoveries in barley matrices at fortification levels between 0.010 and 10 mg/kg were at 78.7 % for BAS 750 F, at 83.3 % for BAS 500 F, at 83.7 % for M500F007 and at 88.8 % for BAS 560 F. Results are summarized in the tables below.

Table S- 1: Procedural Recoveries for BAS 750 F (Mefentrifluconazole)

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

Table S- 2: Procedural Recoveries for BAS 500 F (Pyraclostrobin) and its Metabolite M500F007

Matrix		Fortification Level [mg/kg]	BAS 500 F			
			Mean [%]	**SD [±]**	**RSD [%]**	**n**
Barley	Whole plant no roots	0.010, 0.10 and 10	92.3	4.7	5.1	7
	Ears	0.010, 0.10 and 10	74.2	2.5	3.4	8
	Rest of plant without roots	0.010, 0.10 and 10	73.5	3.7	5.0	7
	Grain	0.010, 0.10 and 10	86.6	3.5	4.0	7
	Straw	0.010, 0.10 and 10	91.3	4.6	5.0	7
Overall:			83.3	9.1	11	36
Matrix		**Fortification Level [mg/kg]**	**Mean [%]**	**M500 SD [±]**	**007 RSD [%]**	**n**
Barley	Whole plant no roots	0.010, 0.10 and 10	88.6	5.4	6.1	7
	Ears	0.010, 0.10 and 10	78.4	3.5	4.5	8
	Rest of plant without roots	0.010, 0.10 and 10	78.3	7.0	8.9	7
	Grain	0.010, 0.10 and 10	85.9	4.3	5.0	7
	Straw	0.010, 0.10 and 10	87.9	2.5	2.8	7
Overall:			83.7	6.4	7.7	36

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

Table S- 3: Procedural Recoveries for BAS 560 F (Metrafenone)

Matrix		Fortification Level [mg/kg]	BAS 560 F			
			Mean [%]	**SD [±]**	**RSD [%]**	**n**
Barley	Whole plant no roots	0.010, 0.10 and 10	94.4	6.9	7.3	7
	Ears	0.010, 0.10 and 10	81.2	3.5	4.4	8
	Rest of plant without roots	0.010, 0.10 and 10	79.4	4.6	5.8	7
	Grain	0.010, 0.10 and 10	92.4	6.2	6.7	7
	Straw	0.010, 0.10 and 10	98.0	7.7	7.8	7
Overall:			88.8	9.4	11	36

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

Further all barley specimens of plot 1, 2 and 3 were analysed for 1,2,4-Triazole (T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) using the adapted BASF method no. L0170/02. The method has a limit of quantitation of 0.010 mg/kg for each analyte.

The results of the average procedural recoveries in plant matrices
- at fortification levels between 0.010 and 1.0 mg/kg were 89.2 % for 1,2,4-Triazole,
- at fortification levels between 0.010 and 1.0 mg/kg were 89.0 % for Triazole alanine,
- at fortification levels between 0.010 and 1.0 mg/kg were 97.5 % for Triazole acetic acid, – at fortification levels between 0.010 and 1.0 mg/kg were 92.1 % for Triazole lactic acid.

Results are summarized in the table below.

Table S- 4: Procedural Recoveries for 1,2,4-Triazole (T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (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

Table S- 5: Summary of Residues of BAS 750 F (Mefentrifluconazole) in Barley

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.

<u>**Residues of BAS 750 F (Mefentrifluconazole)**</u>

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 0.026to 0.10mg/kg and from 0.021 to 0.040mg/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 0.056mg/kg. At 34-35 DALA (85-87BBCH) and 41-43 DALA (89BBCH) 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.

Table S- 6: Summary of Residues of BAS 500 F (Pyraclostrobin) and its Metabolite M500F007 in Barley

Sampl. No.	Portion analyzed	Timing DALA	Growth Stage (BBCH)	n	Range of Residues [mg/kg] BAS 500 F	expressed as parent equivalent M500F007 1)	Sum 2)
Plot 2: treated with BAS 758 00 F (2x 1.5 L/ha)							
1	Whole plant no roots	0	59	4	1.8 - 4.4	0.027 - 0.11	1.8 - 4.5
2	Grain	48-49	87-89	4	0.013 - 0.044	0.014 - 0.016	0.026 - 0.060
	Straw			4	0.17 - 0.69	0.092 - 0.47	0.26 - 1.2
3	Grain	55-56	89	4	0.017 - 0.047	0.012 - 0.018	0.031 - 0.064
	Straw			4	0.29 - 1.0	0.16 - 0.38	0.44 - 1.4
4	Grain	62-63	89	3	0.019 - 0.036	< 0.011 - 0.014	0.030 - 0.050
	Straw			3	0.40 - 0.86	0.24 - 0.29	0.63 - 1.1
Plot 4: treated with BAS 500 06 F (2x 1.25 L/ha)							
1	Whole plant no roots	0	69	4	2.7 - 5.8	0.089 - 0.25	2.8 - 6.0
2	Ears	27-28	77-83	3	0.052 - 0.23	0.097 - 0.18	0.15 - 0.41
	Rest of plant without roots			3	0.46 - 2.7	0.22 - 0.81	0.68 - 3.5
	Grain	27	85	1	0.047	0.026	0.073
	Straw			1	0.33	0.16	0.50
3	Grain	34-35	85-87	4	0.029 - 0.13	0.032 - 0.079	0.080 - 0.21
	Straw			4	0.40 - 2.0	0.20 - 0.68	0.60 - 2.7
4	Grain	41-43	89	4	0.039 - 0.13	0.029 - 0.080	0.072 - 0.21
	Straw			4	0.37 - 2.4	0.25 - 0.83	0.62 - 3.2

DALA = days after last application n = Number of specimens
General: The limit of quantification (LOQ) is 0.010 mg/kg for BAS 500 F and 0.011 mg/kg for M500F007 (expressed as parent equivalent).
1) Conversion factor for calculation of M500F007 to parent BAS 500 F is 1.084
2) for residues of BAS 500 F < 0.010 mg/kg, value was set to 0.010 mg/kg for calculation of sum and for residues
of M500F007, expressed as parent equivalent < 0.011 mg/kg, value was set to 0.011 mg/kg for calculation of sum; if both values are below LOQ the sum is <0.021 mg/k

<u>Residues of BAS 500 F (Pyraclostrobin) and its metabolite M500F007</u>

Plot 2: The residues of **BAS 500 F** analyzed in barley whole plant no roots specimens sampled
immediately after the last application (59 BBCH) ranged from 1.8 to 4.4 mg/kg.

In grain specimens collected at 48-49 DALA (87-89 BBCH) residues of BAS 500 F were found between 0.013 and 0.044 mg/kg. At 55-56 DALA (89 BBCH) and 62-63 DALA (89 BBCH) the residues were in a range from 0.017 to 0.047 mg/kg and from 0.019 to 0.036 mg/kg,
respectively.

In straw specimens sampled at 48-49 DALA (87-89 BBCH) residues of BAS 500 F were analyzed between 0.17 and 0.69 mg/kg. At 55-56 DALA (89 BBCH) and 62-63 DALA (89 BBCH) residues of BAS 500 F were in a range from 0.29 to 1.0 mg/kg and from 0.40 to 0.86 mg/kg, respectively.

Plot 4: The residues of **BAS 500 F** analyzed in barley whole plant no roots specimens sampled immediately after the last application (69 BBCH) ranged from 2.7 to 5.8 mg/kg.

In ears specimens collected at 27-28 DALA (77-83 BBCH) residues of BAS 500 F were analyzed between 0.052 and 0.23 mg/kg. Rest of plant without roots specimens taken at the same sampling event showed residues from 0.46 to 2.7 mg/kg.

In grain specimens collected at 27 DALA (85 BBCH) a residue of BAS 500 F was found at 0.047 mg/kg. At 34-35 DALA (85-87 BBCH) and 41-43 DALA (89 BBCH) residues of BAS 500 F were analyzed in grain specimens from 0.029 to 0.13 mg/kg and from 0.039 to 0.13 mg/kg, respectively.

In straw specimens collected at 27 DALA (85 BBCH) a residue of BAS 500 F was found at 0.33 mg/kg. At 34-35 DALA (85-87 BBCH) and 41-43 DALA (89 BBCH) residues of BAS 500 F were analyzed in straw specimens in a range from 0.40 to 2.0 mg/kg and from 0.37 to 2.4 mg/kg, respectively.

In the untreated control specimens, no residues of BAS 500 F were detected at or above the limit of quantitation (LOQ, 0.010 mg/kg).

Plot 2: The residues of **M500F007 (expressed as parent equivalent)** analyzed in barley whole plant no roots specimens sampled immediately after the last application (59 BBCH) ranged from 0.027 to 0.11 mg/kg.

In grain specimens collected at 48-49 DALA (87-89 BBCH) residues of M500F007 were found between 0.014 and 0.016 mg/kg. At 55-56 DALA (89 BBCH) and 62-63 DALA (89 BBCH) the residues were in a range from 0.012 to 0.018 mg/kg and from < 0.011 to 0.014 mg/kg, respectively.

In straw specimens sampled at 48-49 DALA (87-89 BBCH) residues of M500F007 were analyzed between 0.092 and 0.47 mg/kg. At 55-56 DALA (89 BBCH) and 62-63 DALA (89 BBCH) residues of M500F007 were in a range from 0.16 to 0.38 mg/kg and from 0.24 to 0.29 mg/kg, respectively.

Plot 4: The residues of **M500F007 (expressed as parent equivalent)** analyzed in barley whole plant no roots specimens sampled immediately after the last application (69 BBCH) ranged from 0.089 to 0.25 mg/kg.

In ears specimens collected at 27-28 DALA (77-83 BBCH) residues of M500F007 were analyzed between 0.097 and 0.18 mg/kg. Rest of plant without roots specimens taken at the same sampling event showed residues from 0.22 to 0.81 mg/kg.

In grain specimens collected at 27 DALA (85 BBCH) a residue of M500F007 was found at 0.026 mg/kg. At 34-35 DALA (85-87 BBCH) and 41-43 DALA (89 BBCH) residues of M500F007 were analyzed in grain specimens from 0.032 to 0.079 mg/kg and from 0.029 to 0.080 mg/kg, respectively.

In straw specimens collected at 27 DALA (85 BBCH) a residue of M500F007 was found at 0.16 mg/kg. At 34-35 DALA (85-87 BBCH) and 41-43 DALA (89 BBCH) residues of M500F007 were analyzed in straw specimens in a range from 0.20 to 0.68 mg/kg and from 0.25 to
0.83 mg/kg, respectively.

In the untreated control specimens, no residues of M500F007 were detected at or above the
limit of quantitation (LOQ, 0.011 mg/kg, expressed as parent equivalent).

Bridging showed, that the new formulation BAS 758 00 F does not lead to higher residues than the respective solo formulation BAS 500 06 F.

Table S- 7: Summary of Residues of BAS 560 F (Metrafenone) in Barley

Sampl. No.	**Portion analyzed**	**Timing**		**n**	**Range of Residues (mg/kg) BAS 560 F**
		DALA	**Growth stage (BBCH)**		
Plot 2: treated with BAS 758 00 F (2x 1.5 L/ha)					
1	Whole plant no roots	0	59	4	2.1 - 3.6
2	Grain	48-49	87-89	4	< 0.010 - 0.021
	Straw			4	0.031 - 0.13
3	Grain	55-56	89	4	< 0.010 - 0.023
	Straw			4	0.057 - 0.12
4	Grain	62-63	89	3	< 0.010 - 0.018
	Straw			3	0.085 - 0.14
Plot 5: treated with BAS 560 00 F (2x 0.5 L/ha)					
1	Whole plant no roots	0	69	4	1.9 - 3.2
2	Ears	27-28	77-83	3	0.051 – 0.071
	Rest of plant without roots			3	0.73 - 2.2
	Grain	27	85	1	0.051
	Straw			1	0.30
3	Grain	34-35	85-87	4	0.020 - 0.064
	Straw			4	0.29 - 1.5
4	Grain	41-43	89	4	0.026 - 0.052
	Straw			4	0.34 - 1.2

DALA = days after last application n = Number of specimens General: The limit of quantification (LOQ) is 0.010 mg/kg for BAS 560 F.

Residues of BAS 560 F (Metrafenone)

Plot 2: The residues of **BAS 560 F** analyzed in barley whole plant no roots specimens sampled
immediately after the last application (59 BBCH) ranged from 2.1 to 3.6 mg/kg.

In grain specimens collected at 48-49 DALA (87-89 BBCH) residues of BAS 560 F were found between < 0.010 and 0.021 mg/kg. At 55-56 DALA (BBCH) and 62-63 DALA (89 BBCH) the residues were in a range from < 0.010 to 0.023 mg/kg and from < 0.010 to 0.018 mg/kg,

respectively.

In straw specimens sampled at 48-49 DALA (87-89 BBCH) residues of BAS 560 F were analyzed between 0.031 and 0.13 mg/kg. At 55-56 DALA (89 BBCH) and 62-63 DALA (89 BBCH) residues of BAS 560 F were in a range from 0.057 to 0.12 mg/kg and from 0.085 to 0.14 mg/kg, respectively.

Plot 5: The residues of **BAS 560 F** analyzed in barley whole plant no roots specimens sampled
immediately after the last application (69 BBCH) ranged from 1.9 to 3.2 mg/kg.

In ears specimens collected at 27-28 DALA (77-83 BBCH) residues of BAS 560 F were analyzed between 0.051 and 0.071 mg/kg. Rest of plant without roots specimens taken at the
same sampling event showed residues from 0.73 to 2.2 mg/kg.

In grain specimens collected at 27 DALA (85 BBCH) a residue of BAS 560 F was found at 0.051 mg/kg. At 34-35 DALA (85-87 BBCH) and 41-43 DALA (89 BBCH) residues of BAS 560 F were analyzed in grain specimens from 0.020 to 0.064 mg/kg and from 0.026 to
0.052 mg/kg, respectively.

In straw specimens collected at 27 DALA (85 BBCH) a residue of BAS 560 F was found at 0.30 mg/kg. At 34-35 DALA (85-87 BBCH) and 41-43 DALA (89 BBCH) residues of BAS 560 F were analyzed in straw specimens in a range from 0.29 to 1.5 mg/kg and from 0.34 to
1.2 mg/kg, respectively.

In the untreated control specimens, no residues of BAS 560 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 560 00 F.

Table S- 8: Summary of residues in the untreated Barley Specimens for 1,2,4-Triazole (T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)

Sampl. No.	Portion analyzed	Timing		n	Range of Triazole residues and related analytes [mg/kg]			
		DALA	Growth Stage (BBCH)		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.

Table S- 9: Summary of residues in the treated Barley Specimens 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

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. Furthermore, due to high residue found, additional fortifications were performed to cover the highest residue. Overall and average recoveries were all in the range of 70 - 110 % and relative standard deviations (RSD) were < 20 %.

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 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

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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 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 Rate (kg a.s./ha)	Application Water vol. (L/ha)	Target Timing Appl.	Target Timing 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 9: 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 10: 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 11: 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 (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment: kg a.s./ha	Application rate per treatment: Water (l/ha)	Application rate per treatment: kg a.s./hl	Dates of treatment or no. of treatments and last date* (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg): BAS 750 F	Residues (mg/kg): 1,2,4-T	Residues (mg/kg): TA	Residues (mg/kg): TAA	Residues (mg/kg): TLA	PHI (days) (d)	Details on trial (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	1.4	<0.010	0.043	0.015	0.055	0	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)
								grain	0.025	<0.010	0.22	0.11	<0.010	49	
								straw	0.60	<0.010	<0.010	0.019	0.049	49	
								grain	0.026	<0.010	0.20	0.095	<0.010	56	
								straw	0.86	<0.010	<0.010	0.027	0.056	56	
								grain	0.024	<0.010	0.19	0.096	<0.010	62	
								straw	1.1	<0.010	<0.010	0.030	0.042	62	
			0.15	200	0.075	**Plot 3** 03.05.2020 21.05.2020	69	whole plant no roots	1.5	<0.010	0.062	0.024	0.061	0	
								grain	0.056	<0.010	0.19	0.091	<0.010	27	
								straw	1.6	<0.010	<0.010	0.025	0.062	27	
								grain	0.049	<0.010	0.21	0.11	<0.010	34	
								straw	1.3	<0.010	<0.010	0.023	0.049	34	
								grain	0.054	<0.010	0.23	0.13	<0.010	43	
								straw	2.0	<0.010	0.012	0.035	0.068	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	2.4	<0.010	0.039	0.015	0.069	0	
								grain	0.052	<0.010	0.15	0.088	<0.010	49	
								straw	2.4	<0.010	<0.010	0.024	0.059	49	
								grain	0.058	<0.010	0.15	0.088	<0.010	56	
								straw	3.7	<0.010	0.014	0.032	0.082	56	
								grain	0.040	<0.010	0.14	0.072	<0.010	62	
								straw	2.8	<0.010	0.014	0.032	0.068	62	
			0.15	200	0.075	**Plot 3** 27.04.2020 18.05.2020	69	whole plant no roots	4.4	<0.010	0.043	0.019	0.063	0	
								ears	0.65	<0.010	0.11	0.055	<0.010	28	
								rest of plant w/o roots	4.2	<0.010	<0.010	0.012	0.057	28	
								grain	0.13	<0.010	0.17	0.086	<0.010	35	
								straw	7.4	<0.010	<0.010	0.019	0.064	35	
								grain	0.18	<0.010	0.15	0.087	<0.010	43	
								straw	8.8	<0.010	0.014	0.035	0.073	43	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date* (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)					PHI (days) (d)	Details on trial (e)
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				BAS 750 F	1,2,4-T	TA	TAA	TLA		
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 0.029 1.1 0.021 1.4	<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 (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date* (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)					PHI (days) (d)	Details on trial (e)
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				BAS 750 F	1,2,4-T	TA	TAA	TLA		
2021/2000401 L200230 64-000 Ko-korzyn 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	2.5	<0.010	0.033	0.027	0.058	0	
								grain	0.038	<0.010	0.18	0.097	<0.010	48	
								straw	0.71	<0.010	0.012	0.40	0.063	48	
								grain	0.10	<0.010	0.18	0.12	<0.010	55	
								straw	1.2	<0.010	0.013	0.036	0.047	55	
			0.15	200	0.075	**Plot 3** 29.04.2020 15.05.2020	69	whole plant no roots	3.6	<0.010	0.043	0.038	0.061	0	
								ears	0.54	<0.010	0.17	0.054	<0.010	28	
								rest of plant w/o roots	1.6	<0.010	0.012	0.024	0.071	28	
								grain	0.12	<0.010	0.22	0.11	<0.010	34	
								straw	2.8	<0.010	0.011	0.031	0.10	34	
								grain	0.11	<0.010	0.25	0.14	<0.010	41	
								straw	4.2	<0.010	0.040	0.066	0.072	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 12: 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 (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date* (c)	Growth stage at last treat-ment or date	Portion an-alyzed	Residues (mg/kg)					PHI (days) (d)	Details on trial (e)
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				BAS 750 F	1,2,4-T	TA	TAA	TLA		
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	<0.010	<0.010	0.046	0.019	0.079	0 DBLA	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)
								grain	<0.010	<0.010	0.17	0.091	<0.010	56	
								straw	<0.010	<0.010	0.011	0.040	0.039	56	
						Plot 1[2]		whole plant no roots	<0.010	<0.010	0.051	0.019	0.055	0 DBLA	
								grain	<0.010	<0.010	0.16	0.078	<0.010	34	
								straw	<0.010	<0.010	<0.010	0.026	0.044	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	<0.010	<0.010	0.031	<0.010	0.053	0 DBLA	
								grain	<0.010	<0.010	0.095	0.057	<0.010	56	
								straw	<0.010	<0.010	<0.010	0.023	0.056	56	
						Plot 1[2]		whole plant no roots	<0.010	<0.010	0.038	0.015	0.065	0 DBLA	
								grain	<0.010	<0.010	0.096	0.058	<0.010	35	
								straw	<0.010	<0.010	<0.010	0.014	0.050	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	<0.010	<0.010	0.019	<0.010	<0.010	0 DBLA	
								grain	<0.010	<0.010	0.050	0.013	<0.010	55	
								straw	<0.010	<0.010	0.012	<0.010	<0.010	55	
						Plot 1[2]		whole plant no roots	<0.010	<0.010	0.014	<0.010	<0.010	0 DBLA	
								grain	<0.010	<0.010	0.035	0.011	<0.010	34	
								straw	<0.010	<0.010	<0.010	<0.010	0.015	34	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date* (c)	Growth stage at last treat-ment or date	Portion an-alyzed	Residues (mg/kg)					PHI (days) (d)	Details on trial (e)
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				BAS 750 F	1,2,4-T	TA	TAA	TLA		
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 2.1.4 Magnitude of residues in livestock

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

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

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

A 2.1.6 Magnitude of residues in representative succeeding crops

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

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

The active substance BAS 750 F and its formulation BAS 758 00 F are intended to be used in wheat and barley. No “other study” is provided.

A 2.2 Metrafenone

A 2.2.1 Stability of residues

A 2.2.1.1 Stability of residues during storage of samples

A 2.2.1.1.1 Storage stability of residues in plant products

A 2.2.1.1.1.1 Study 1

Comments of zRMS:	The study has been accepted. The deep freeze stability of BAS 560 F in plant matrices was investigated over a period of two years. Samples were analysed with BASF method no. L0076/01 (also referred to as 535/1) which allows the quantitation of BAS 560 F residues to a limit of 0.01 mg/kg in different matrices. Procedural recoveries averaged at 93 %. The results are expressed as average percentage of the nominal fortification level. The sufficient metrafenone stability was shown in wheat (whole plant, grain and straw), grape, tomato, dried pea and soybean seeds.

Reference:	CA 6.1/1
Report	Investigation of the storage stability of BAS 560 F in plant matrices, Lehmann A., Mackenroth C., 2012 report No EU-360859 2012/1166088 Authority registration No
Guideline(s):	EEC 7032/VI/97 rev. 5, EEC 1607/VI/97 rev. 2 10.06.1999, EEC 91/414 Annex II (Part A Section 6), EEC 91/414 Annex III (Part A Section 8), EPA 860.1380
Deviations:	No
GLP:	yes (certified by Landesamt fuer Umwelt, Wasserwirtschaft und Gewerbe-aufsicht, Mainz, Germany),
Acceptability:	Yes

The deep freeze stability of metrafenone in plant matrices was investigated over a period of two years. Samples were spiked with the test item at concentration levels of 0.1 mg/kg. The spiked samples were stored under the usual storage conditions for field samples (polyethylene containers, about -20°C) and analysed after different intervals. Samples were analysed with BASF method no. L0076/01 (also referred to as 535/1) with a limit of quantitation of 0.01 mg/kg. Procedural recoveries averaged at 93%. After a storage time of about two years, metrafenone was shown to be stable in the matrices investigated wheat (whole plant, grain and straw), grape, tomato, dried pea and soya bean seed.

I. Materials and Methods

A. Materials

1. **Test Material:** Metrafenone
Description: Active substance
Lot/Batch #: 01814-189
Purity: 99.7%
CAS#: 220899-03-6
Development code: BAS 560 F
Spiking levels: 0.1 mg/kg

2. **Test Commodity:**
Crop: Wheat, grapes, tomato, pea, soybean
Type: not specified
Variety: not specified (not relevant)
Botanical name: *Triticum spp., Vitis vinifera, Solanum lycopersicum, Pisum sativum, Glycine max*
Crop parts(s) or processed commodity: Wheat: whole plant, grain, straw
Grape: fruit
Tomato: fruit
Pea: dried pea seed
Soybean: soybean seed
Sample size: 5g (stored sample)

B. Study Design and Methods

1. Test procedure

Plant materials were spiked with a concentration equivalent to 10 x of the limit of quantitation (LOQ = 0.01 mg/kg) and stored at about -20°C in the dark. According to the Guidelines, storage stability studies can either be performed with treated field samples or with control samples fortified with the compound of interest. Samples of respective materials with residue concentrations high enough to monitor a potential decline of the analyte were not available, therefore spiked samples were used in this study.

2. Description of analytical procedures

The specimens were analysed using BASF method L0076/01 (Validation of BASF Method No. 535/1 in plant matrices; A Lehmann, Ch Mackenroth BASF Doc ID 2006/1039426) which had a limit of quantification of 0.01 mg/kg for metrafenone. Samples of each matrix were fortified at 0.1 mg/kg (10X LOQ). Mean procedural recoveries were 85.1, 97.3, 88.0, 89.8, 90.3, 98.9 and 99.8% for wheat (whole plant), wheat grain, wheat grain, wheat straw, grape, tomato, dried peas and soybean, respectively. The overall mean procedural recovery for all matrices was 93.2% (RSD 9.0%).

II. Results and Discussion

Results from the analysis of samples stored for two years showed recoveries of residues for all matrices investigated ranged from 72 to 107% compared to 77 to 107% for freshly spiked samples.

Table A 13: Storage stability of metrafenone in range of plant samples

Mean recovery (%)														
Days	A: mean in stored samples, % nominal							B: mean procedural, in freshly spiked samples						
	A	B	A	B	A	B	A	B	A	B	A	B	A	B
	Wheat wh. plant		Wheat grain		Wheat straw		Grape fruit		Tomato fruit		Dried pea seed		Soyabean seed	
0	86	83	107	107	91	89	89	88	89	85	104	99	98	100
28-32	73	78	78	91	90	90	77	81	88	90	90	96	72	96
55													78	93
84													89	106
85													82	102
174-178	83	86	83	97	84	89	97	99	101	101	96	104	60	99
358-360	80	80	85	102	91	95	106	96	75	97	90	100	72	100
455									76	77				
726-739	85	99	77	90	78	78	83	84	96	91	83	96	98	103

Table A 14: Mean storage stability of metrafenone in range of plant samples (mean % recovery corrected for procedural recovery)

Months (approx.)	Wheat wh. plant	Wheat grain	Wheat straw	Grape fruit	Tomato fruit	Dried pea seed	Soybean seed
0	104	100	102	101	105	105	98
1	94	86	100	95	98	94	75
2							84
3							80-84
6	97	86	94	98	100	92	61
12	100	83	96	110	77	90	72
15					99		
24	86	86	100	99	105	86	95

As soyabean seed showed degradation near 70% after 28 days, additional samples were analysed at 55, 84 and 85 days. Stability was confirmed using these additional samples.

III. Conclusion

After storage of about two years metrafenone was shown to be stable in all matrices investigated, wheat (whole plant, grain and straw), grape, tomato, dried pea and soybean seeds.

A 2.2.1.1.2 Storage stability of residues in animal products

No new studies are submitted or required.

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

A 2.2.2.1 Nature of residue in plants

A 2.2.2.1.1 Nature of residue in primary crops

No new studies are submitted or required.

A 2.2.2.1.2 Nature of residue in rotational crops

No new studies are submitted or required.

A 2.2.2.1.3 Nature of residues in processed commodities

No new studies are submitted or required.

A 2.2.2.2 Nature of residues in livestock

A 2.2.2.2.1 Study 1

Comments of zRMS:	The study has been accepted. A final version of an interim study (previously submitted) has been submitted by the applicant in the framework of this application for completeness (in ruminants were already done; in pigs were not necessary). The relevant residue definition is in force. Thus, metabolism studies were carried out in poultry. There was no indication of any accumulation in edible tissues or eggs. Any metabolites present were at very low levels (<0.01 mg/kg). In the context of the authorisation request the study is not necessary.

Reference:	CA 6.2.2/1
Report	BAS 560 F (AC 375839): Metabolism in laying hens, Hoefs R. et al., 2008 report No EU-M01A839PT1 2005/1026047 Authority registration No
Guideline(s):	EPA 860.1300, EEC 91/414 (7030(VI/95 Rev. 3)
Deviations:	No
GLP:	yes (certified by Landesamt fuer Umwelt, Wasserwirtschaft und Gewerbeaufsicht, Mainz, Germany),
Acceptability:	Yes
Duplication (if vertebrate study)	No

Note: An interim report of this study was previously reported in the DAR (UK, July 2005).

Executive Summary

The metabolism of metrafenone was investigated in laying hens following repeated oral administration of ^{14}C-metrafenone. The test compound was ^{14}C or ^{13}C-labelled either on the trimethyoxyphenyl ring moiety (trimethoxyphenyl label) or on the bromophenyl ring moiety (bromophenyl label). After 12 consecutive daily oral administrations of ^{14}C-metrafenone at ca. 14 ppm diet to laying hens, there was rapid absorption and almost complete excretion within 24 hours. There was no indication of any accumulation in edible tissues or eggs. At sacrifice, 22 hours after the final dose, the total radioactive residues in edible tissues and organs were 0.108 mg/kg or 0.117 mg/kg in eggs, 10.214 mg/kg or 10.641 mg/kg in bile, 0.566 mg/kg or 0.346 mg/kg in the liver, 0.010 mg/kg or 0.013 mg/kg in muscle, and 0.070 mg/kg or 0.096 mg/kg in skin with adhering fat for the trimethoxyphenyl or bromophenyl label, respectively. The total identified and characterized radioactive residue accounted for 89.4% or 81.3% of the TRR for the trimethoxyphenyl or bromophenyl label, respectively, in eggs; 80.8% or 78.4% of TRR in excreta; 100% TRR in bile (both labels); 91.4% or 101.4% TRR in liver and 86.7% or 81.5% TRR in skin with fat, including residues released by protease digestion or characterized by hydrolysis.

The parent compound metrafenone was metabolized *via* three routes: hydroxylation of the active substance at the bromophenyl ring or the attached methyl group resulted in the formation of M560F05, which was demethylated and conjugated with glucuronic acid in bile to form the metabolite M560F07. Demethylation of the parent compound at the trimethoxyphenyl ring formed the metabolite M560F06 which was also conjugated with glucuronic acid in bile to form the metabolites M560F08 and M560F09. Full oxidation of the methyl group on the bromomethoxytoluene ring to the carboxylic acid (*via* the respective isomer of M560F05) led to the metabolite M560F03. M560F03 and M560F06 are possible intermediates for the formation of the oxidized and demethylated metabolites M560F01 and M560F02 which are further converted to the methyl ester M560F04.

I. MATERIAL AND METHODS

A. MATERIALS

1. **Test Material:** Metrafenone
Description: Active substance
Lot/Batch #: AC 12102-57 (Trimethoxyphenyl-U-^{14}C)
AC 12102-58 (Bromophenyl-6-^{14}C)
Purity: AC 12102-57: radiochemical purity: 99.2%
chemical purity: 108.8%
specific radioactivity 38.5 µCi/mg (1.42 MBq/mg)
AC 12102-58: radiochemical purity: 99.6%
chemical purity: 99.8%
specific radioactivity 39.8 µCi/mg (1.47 MBq/mg)
CAS#: 220899-03-6
Development code: BAS 560 F

3. **Animals:** Hens
Species: white leghorn
Gender: female
Age: not specified (mature)
Weight at dosing: 1.0-2.5 kg
Number of animals: 16
Acclimation period: 7 days
Housing: stainless steel cages
Husbandry: 8 hens/group, eggs collected twice daily, excreta collected daily
Diet: layer crumble
Water: ad libitum
Environmental Conditions: room lights on continuously
Temperature: 70° ± 4°F
Humidity: 20 and 70%

B. STUDY DESIGN AND METHODS

1. Test procedure

Two groups of laying hens, eight hens per group, were treated daily for 12 consecutive days with gelatin capsules containing test substance at a nominal dose rate of 12 ppm in the feed based on an average feed consumption of 120 g per hen per day. The actual doses corrected for actual feed consumption were 14.19 ppm (trimethoxyphenyl label) and 13.87 ppm (bromophenyl label).

Excreta from each group were collected daily and composited per group. Eggs were collected daily during the dosing period with two collections (composited) per sampling interval (the afternoon collection of the previous day plus the morning collection of the sampling day). Approximately 22 hours after administration of the final dose, the animals were sacrificed. Tissue samples (skin with adhering fat, muscle and liver) and bile from the gall bladder were collected.

Details of the study design are summarised below:

Dose group	**A** **Trimethoxyphenyl-U-^{14}C**	**B** **Bromophenyl-6-^{14}C**
Number of animals	8	8
Specific Activity (µCi/mg)	38.5	39.8
Nominal dose (ppm feed)	12	12
Actual dose (ppm feed)	14.19	13.87
Actual dose (mg/animal/day)	1.55	1.56
Actual dose (mg/kg body weight)	1.00	0.95
Number of doses	12	12
Sacrifice time (hours post last dose)	22	22

2. Description of analytical procedures

All measurements of radioactivity in liquid samples were analysed directly by liquid scintillation counting (LSC). Solid samples were combusted prior to analysis by LSC. Extractions were performed using methanol and water.

II. RESULTS AND DISCUSSION

Absorption, Distribution and Excretion

Following oral administration of ^{14}C-metrafenone to laying hens, the overall recoveries of radioactivity were approximately 96 and 86% of the total applied dose for the trimethyoxyphenyl and bromophenyl labels, respectively. Radioactivity was rapidly eliminated within 24 hours with 95.1% (trimethyoxyphenyl label) and 85.9% (bromophenyl label) of the administered dosed recovered in the excreta. The percentage of radioactivity in eggs ranged from 0.236 to 0.251%, followed by liver from 0.066 to 0.102%. The lowest levels of radioactivity were found in skin with fat followed by muscle. Bile from the gall bladder contained 0.027 to 0.028% of the applied dose. There was no indication of accumulation of metrafenone related residues in eggs or tissues.

The material balance has been summarised below.

Table A 15: Material Balance after administration of ^{14}C -metrafenone to laying hens

Matrix	**Material balance in % of total applied dose**	
	Dose Group A trimethyoxyphenyl label	**Dose Group B bromophenyl label**
Eggs	0.236	0.251
Organs and Tissues		
Muscle	0.003	0.003
Skin with fat	0.006	0.010
Liver	0.102	0.066
Bile	0.027	0.028
Excreta	95.1	85.9
Total	**95.5**	**86.3**

Total radioactive residues

Total radioactive residues (TRR) in all matrices are given below. Reported values are based either on direct analysis by liquid scintillation counting (LSC) or on extraction data. In the case of the latter, the TRR values are calculated as the sum of extractable radioactivity and residual radioactivity remaining in the post extraction solid.

Table A 16: Total Radioactive Residues (TRRs) in Eggs, Tissue and Excreta

Matrix		**Dose Group A trimethyoxyphenyl label**	**Dose Group B bromophenyl label**
		[mg/kg]	**[mg/kg]**
Eggs	Day 1	<0.001	<0.001
	Day 2	0.016	0.018
	Day 3	0.026	0039
	Day 4	0.054	0.055
	Day 5	0.072	0.064
	Day 6	0.086	0.102
	Day 7	0.095	0.094
	Day 8	0.097	0.106
	Day 9	0.107	0.115
	Day 10	0.109	0.117
	Day 11	0.106	0.118
	Day 12	0.110	0.118
	Days 9-12 pooled	0.108	0.117
Muscle		0.010	0.013
Skin with fat		0.070	0.096
Liver		0.566	0.346
Bile		10.214	10.641
Excreta (Days 6-12 pooled)		15.370	14.089

Extractability

Extraction of the incurred radioactivity in all matrices derived from each label are summarised below. All matrices were sequentially extracted with methanol (3x) and water (2x).

Table A 17: Extractability of Residues of Metrafenone in Hen Matrices (Trimethyoxy-phenyl Label and Bromophenyl Label)

Matrix	TRR[1)]	Methanol	Water	ERR [2)]	PES [3)]	TRR[4)] Recovery
	[mg/kg]	[mg/kg] (% TRR)	[mg/kg] (% TRR)	[mg/kg] (% TRR)	[mg/kg] (% TRR)	[mg/kg] [%]
Trimethyoxyphenyl Label						
Eggs pooled (days 9-12)	0.108	0.043 (39.7)	0.009 (8.3)	0.052 (48.0)	0.056 (52.0)	0.108 (100)
Muscle	0.010	0.003 (26.8)	0.0001 (1.0)	0.003 (27.8)	0.007 (72.2)	0.010 (100)
Skin with fat	0.070	0.034 (48.6)	n.a.	0.034 (48.6)	0.036 (51.4)	0.070 (100)
Liver	0.566	0.048 (8.5)	0.035 (6.2)	0.083 (14.7)	0.483 (85.3)	0.566 (100)
Excreta pool (days 6-12)	15.370	12.418 (80.8)	n.a.	12.418 (80.8)	2.952 (19.2)	15.370 (100)
Bromophenyl Label						
Eggs pooled (days 9-12)	0.117	0.043 (36.9)	0.009 (8.3)	0.53 (44.9)	0.065 (55.1)	0.117 (100)
Muscle	0.013	0.004 (30.7)	0.0002 (1.8)	0.004 (32.5)	0.009 (67.5)	0.013 (100)
Skin with fat	0.096	0.041 (42.9)	n.a.	0.041 (42.9)	0.055 (57.1)	0.096 (100)
Liver	0.346	0.037 (10.8)	0.029 (8.2)	0.066 (19.0)	0.280 (81.0)	0.346 (100)
Excreta pool (days 6-12)	14.089	11.051 (78.4)	n.a.	11.051 (78.4)	3.039 (21.6)	14.089 (100)

[1)] TRR values reported as sum of radioactivity on methanol and water extract measured directly by LSC and in post extraction solids after combustion
[2)] ERR – extractable radioactive residues (sum of methanol and water extracts)
[3)] PES – Post extraction solids remaining after extraction with methanol and water
[4)] Sum of all extracts and post extraction solids
n.a. = not applied

Table A 18: Summary of Released Radioactivity of Residues of Metrafenone in Hen Matrices (Trimethyoxy-phenyl Label and Bromophenyl Label)

Trimethyoxyphenyl Label					
Matrix	RRR [1)]	Protease treatment	Final residue	Hydrolysis	Recovery [2)]
	[mg/kg] (% TRR)	[mg/kg] (% TRR)	[mg/kg] (% TRR)	[mg/kg] (% TRR)	[%]
Eggs pooled (days 9-12)	0.056 (52.0)	0.044 (41.1)	0.010 (9.6)	n.a.	96.4
Liver	0.483 (85.3)	0.356 (63.0)	0.091 (16.1)	0.069 (12.2)	92.5
Skin with ad-hering fat	0.036 (51.4)	0.030 (42.9)	0.005 (7.3)	n.a.	97.2
Bromophenyl Label					
Matrix	RRR [5)]	Protease treatment	Final residue	Hydrolysis	Recovery [6)]
	[mg/kg] (% TRR)	[mg/kg] (% TRR)	[mg/kg] (% TRR)	[mg/kg] (% TRR)	[%]
Eggs pooled (days 9-12)	0.065 (55.1)	0.052 (44.2)	0.013 (10.9)	n.a.	100.0
Liver	0.280 (81.0)	0.197 (56.8)	0.050 (14.5)	0.046 (13.2)	88.2
Skin with ad-hering fat	0.055 (57.1)	0.045 (47.1)	0.011 (11.0)	n.a.	101.8

[1)] Residual radioactive residue after solvent extraction

[2)] Recovery calculated as (Protease Supernatant + Final residue * 100/RRR

Excreta
Excreta were efficiently extracted with methanol releasing 78.4 to 80.8% TRR (11.051 to 12.418 mg/kg). Unextractable residues accounted for 19.2 to 21.6% TRR.

Eggs
Extraction of pooled eggs (days 9-12) yielded 36.9 to 39.7% TRR (0.043 mg/kg) in the methanol extract and a further 8.0 to 8.3% (0.009 mg/kg) in water, giving a total of 44.9 to 48.0% TRR (0.052 to 0.053 mg/kg) as extractable residues. Protease treatment released a further 41.1 to 44.2% TRR (0.044 to 0.052 mg/kg).

Muscle
Low levels of radioactivity were found in muscle, with 0.010 mg/kg and 0.013 mg/kg in the trimethyoxy-phenyl and bromophenyl labels, respectively. Extraction with methanol released 26.8 to 30.7% TRR, 1 to 1.8% TRR was extracted in water. Unextractable residues accounted for 67.5 to 72.2% TRR (0.007 to 0.009 mg/kg) in the PES.

Skin with adhering fat
Extraction of the skin led to 42.9 to 48.6% TRR (0.034 to 0.041 mg/kg) being extracted with methanol and 42.9 to 47.1% TRR (0.030 to 0.045 mg/kg) being solubilised with protease.

Liver
Extraction of liver yielded 8.5 to 10.8% TRR (0.037 to 0.048 mg/kg) in the methanol extract and a further 6.2 to 8.2% TRR (0.029 to 0.035 mg/kg) in water. Further extractions sing protease released 56.8 to 63.0% TRR (0.197 to 0.356 mg/kg).

Characterisation and identification of metabolites

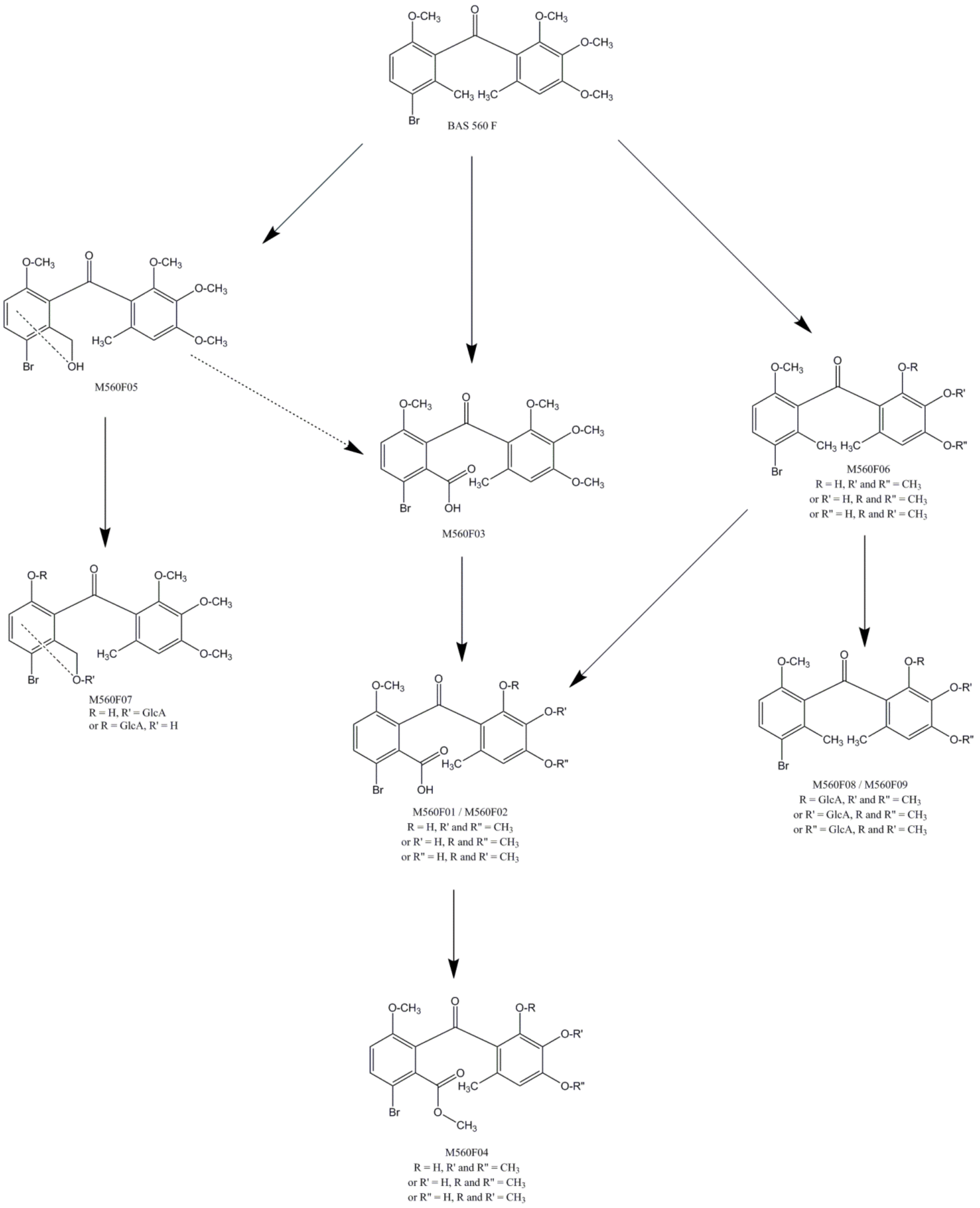
Characterisation of metabolites was performed by LC-MS and LC-MS/MS analysis. Metrafenone was found only in eggs (1.8–2.2% TRR) and in skin + fat (1.9% TRR). A comparison with the retention times and metabolite patterns for the components in the methanol extract of excreta (bromophenol-label), allowed the assignment of the metabolite M560F06 in the skin + fat extracts (at about 6–11% TRR) and tentatively in eggs (unquantifiable). With the exception of one unknown component in eggs (found at about 14% TRR and 0.015 mg eq./kg) all other components were below 10% TRR (< 0.01 mg eq./kg) in all tissues and eggs.

Table A 19: Residues of metrafenone and other characterised components in hen matrices after 12 daily oral administrations of [^{14}C] metrafenone.

Matrix	Metrafenone		Characterised (ERR)		Characterised (Released from RRR)		Total characterised	
	mg/kg	% TRR	mg eq./kg	% TRR	mg eq./kg	% TRR	mg eq./kg	% TRR
	Trimethoxyphenyl Label							
Eggs pooled (days 9–12)	0.002	2.2	0.052[a, b]	48.0	0.045	41.4	0.097	89.4
Muscle	n.a.	n.a.	0.0031	27.8	n.a	n.a.	0.0031	27.8
Skin with fat	0.001	1.9	0.026[i]	37.2	0.027	38.1	0.061	86.7
Liver			0.084[e, f]	15.1	0.356	63.0	0.516	91.4
	Bromophenyl Label							
Eggs pooled (days 9–12)	0.002	1.8	0.053[c, d]	44.9	0.043	36.4	0.096	81.3
Muscle	n.a.	n.a.	0.0042	32.5	n.a.	n.a.	0.0042	32.5
Skin with fat	<0.001	<0.001	0.036[j]	37.1	0.037	38.6	0.079	81.5
Liver	<0.001	<0.001	0.088[g,h]	25.4	0.218	63.0	0.351	101.4

a methanol phase includes nine peaks (one assigned to parent), each < 0.01 mg eq/kg or ≤ 4.6% TRR, except 1 peak tentatively identified as M560F06 (0.01 mg eq./kg or 9.0% TRR)
b aqueous phase includes eight peaks, each << 0.01 mg eq/kg or ≤ 1.3% TRR
c methanol phase includes seven peaks, each ≤ 4.5% TRR, except one peak tentatively identified as M560F06 (0.008 mg eq/kg, 7.0% TRR)
d aqueous phase includes eight peaks, each <<0.01 mg eq./kg ≤ 2.7% TRR
e methanol/aqueous phase of methanol extract includes 10 peaks, each <<0.01 mg eq./kg or ≤ 3.7% TRR except for one at 0.02 mg eq./kg
f aqueous phase includes twelve peaks, each <<0.01 mg/kg or ≤ 1.6% TRR
g methanol/aqueous phase of methanol extract includes six peaks, each ≤0.016 mg eq./kg or ≤ 4.5% TRR
h aqueous phase includes five peaks, each ≤0.014 mg/kg or ≤ 4.1% TRR
i methanol phase includes thirteen peaks, each < 0.01 mg eq/kg or < 6.7% TRR, except for one peak identified as M560F06 (11.4% TRR)
j methanol phase includes thirteen peaks, each < 0.01 mg eq/kg or < 9.2% TRR, including one peak identified as M560F06 (5.8% TRR)

Figure A 1: Proposed metabolic pathway of metrafenone in hens



III. CONCLUSION

After 12 consecutive daily oral administrations of ^{14}C-metrafenone to laying hens, there was rapid absorption and almost complete excretion within 24 hours. Levels of TRR were low in all tissues. There was no indication of any accumulation in edible tissues or eggs. The parent compound metrafenone was metabolized *via* three routes: hydroxylation of the active substance at the bromophenyl ring or the attached methyl group resulted in the formation of M560F05, which was demethylated and conjugated with glucuronic acid in bile to form the metabolite M560F07. Demethylation of the parent compound at the trimethoxyphenyl ring formed the metabolite M560F06 which was also conjugated with glucuronic acid in bile to form the metabolites M560F08 and M560F09. Full oxidation of the methyl group on the bromomethoxytoluene ring to the carboxylic acid (*via* the respective isomer of M560F05) led to the metabolite M560F03. M560F03 and M560F06 are possible intermediates for the formation of the oxidized and demethylated metabolites M560F01 and M560F02 which are further converted to the methyl ester M560F04.

A 2.2.3 Magnitude of residues in plants

A 2.2.3.1 Cereals

Table A 20: 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 Conclusion,)	2	0.15 kg/ha	21	BBCH 79	35
cGAP EU (Renewal dossier, 2015)	2	0.15 kg/ha	21	BBCH 69	35
cGAP EU (Art. 12, EFSA, 2013) Rye	2	0.15 kg/ha	21	BBCH 82	35
cGAP EU (Art. 12, EFSA, 2013) Barley	2	0.15 kg/ha	21	BBCH 79	35
Intended cGAP (number 1-5; 16-22)*	2	0.15 kg/ha	14	BBCH 59	56

Data show that application interval has no impact on residues in grain and straw.

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

A 2.2.3.1.1 Study 1 (Cereals, Barley)

Comments of zRMS:	The study has been accepted (see also page 161) The objective of the study was to determine the magnitude of residues of BAS 750 F (Mefentrifluconazole) and its triazole metabolites, BAS 500 F (Pyraclostrobin), its metabolite M500F007 and BAS 560 F (Metrafenone) in barley after treatment with either BAS 758 00 F, BAS 750 01 F, BAS 500 06 F or BAS 560 00 F. The selected application rates, frequency and spray interval cover the Good Agriculture Practice (critical GAP), which will be defined by the label directions. During the 2020 growing season, 4 trials in barley were conducted in different representative growing areas in Northern Europe to determine the residue level of BAS750F (Mefentrifluconazole), BAS 500 F (Pyraclostrobin) and BAS 560 F (Metrafenone) after application of either BAS75800F, BAS75001F, BAS50006F or BAS56000F in or on Raw Agricultural Commodities (RAC). All trials consisted of five plots: plot 1 (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). **BAS 758 00 F** (66.6 g BAS 750 F/L, 80.0 g BAS 500 F/L, 100.0 g BAS 560 F/L, EC) was applied in all trials twice at a single rate of 1.5 L/ha formulated product, equals to 0.10 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 on plot 2 with a water volume of 200 L/ha. **BAS 750 01 F** (100.0 g BAS 750 F/L, EC) was applied in all trials twice at a single rate of 1.5 L/ha formulated product, equals to 0.15 kg a.i./ha of BAS 750 F on plot 3 with a water volume of 200 L/ha. **BAS 500 06 F** (200.0 g BAS 500 F/L, EC) was applied in all trials twice at a single rate of 1.25 L/ha formulated product, equals to 0.25 kg a.i./ha of BAS 500 F on plot 4 with a water volume of 200 L/ha. **BAS 560 00 F** (300.0 g BAS 560 F/L, SC) was applied in all trials twice at a single rate of 0.5 L/ha formulated product, equals to 0.15 kg a.i./ha of BAS 560 F on plot 5 with a water volume of 200 L/ha. Plot 2: In all trials the first application was made 13-15 days before application no. 2 (except of trial L200230: 11 days before application no. 2, see deviation). The second application was performed at BBCH 59. Plot 3 to 5: The first application was made at BBCH 49. The second application was made at BBCH 69. Plot 1 and 2: Barley specimens 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. At 48-49 DALA the specimens were sampled as grain and straw on plot 2. At 55-56 DALA barley specimens were collected as grain and straw on plot 1 and 2. At 62-63 specimens were sampled as grain and straw on plot 2 (except of trial L200230: sampling no. 4 could not be performed, see deviation). Plot 1, 3, 4 and 5: Barley specimens were collected at BBCH 69 on plot 1 immediately before application no. 2 and directly after application no. 2 on plot 3 to 5 as whole plant no roots. At 27-28 DALA specimens were collected as ears and rest of plant without roots or as grain and straw on plot 3 to 5. At 34-35 DALA the specimens were sampled as grain and straw on plot 1 and 3 to 5. At 41-43 DALA barley specimens were collected as grain and straw on plot 3 to 5.

All barley specimens of plot 1 and 2 were analysed for BAS 750 F (Mefentrifluconazole), BAS 500 F (Pyraclostrobin) and its metabolite M500F007, BAS 560 F (Metrafenone) using the BASF Method L0076/09. The method has a limit of quantitation of 0.010 mg/kg.
All barley specimens of plot 3 were analysed for BAS 750 F (Mefentrifluconazole) using the BASF Method L0076/09. The method has a limit of quantitation of 0.010 mg/kg.
All treated barley specimens of plot 4 were analysed for BAS 500 F (Pyraclostrobin) and its metabolite M500F007 using the BASF Method L0076/09. The method has a limit of quantitation of 0.010 mg/kg.
All treated barley specimens of plot 5 were analysed for BAS 560 F (Metrafenone) using the BASF Method L0076/09. The method has a limit of quantitation of 0.010 mg/kg.
The results of the average procedural recoveries in barley matrices at fortification levels between 0.010 and 10 mg/kg were at 78.7 % for BAS 750 F, at 83.3 % for BAS 500 F, at 83.7 % for M500F007 and at 88.8 % for BAS 560 F. Results are summarized in the tables below.

Table S- 1: Procedural Recoveries for BAS 750 F (Mefentrifluconazole)

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

Table S- 2: Procedural Recoveries for BAS 500 F (Pyraclostrobin) and its Metabolite M500F007

Matrix		Fortification Level [mg/kg]	BAS 500 F			
			Mean [%]	SD [±]	RSD [%]	n
Barley	Whole plant no roots	0.010, 0.10 and 10	92.3	4.7	5.1	7
	Ears	0.010, 0.10 and 10	74.2	2.5	3.4	8
	Rest of plant without roots	0.010, 0.10 and 10	73.5	3.7	5.0	7
	Grain	0.010, 0.10 and 10	86.6	3.5	4.0	7
	Straw	0.010, 0.10 and 10	91.3	4.6	5.0	7
Overall:			83.3	9.1	11	36

Matrix		Fortification Level [mg/kg]	Mean [%]	M500 007 SD [±]	RSD [%]	n
Barley	Whole plant no roots	0.010, 0.10 and 10	88.6	5.4	6.1	7
	Ears	0.010, 0.10 and 10	78.4	3.5	4.5	8
	Rest of plant without roots	0.010, 0.10 and 10	78.3	7.0	8.9	7
	Grain	0.010, 0.10 and 10	85.9	4.3	5.0	7
	Straw	0.010, 0.10 and 10	87.9	2.5	2.8	7
		Overall:	83.7	6.4	7.7	36

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

Table S- 3: Procedural Recoveries for BAS 560 F (Metrafenone)

Matrix		Fortification Level [mg/kg]	BAS 560 F			
			Mean [%]	SD [±]	RSD [%]	n
Barley	Whole plant no roots	0.010, 0.10 and 10	94.4	6.9	7.3	7
	Ears	0.010, 0.10 and 10	81.2	3.5	4.4	8
	Rest of plant without roots	0.010, 0.10 and 10	79.4	4.6	5.8	7
	Grain	0.010, 0.10 and 10	92.4	6.2	6.7	7
	Straw	0.010, 0.10 and 10	98.0	7.7	7.8	7
		Overall:	88.8	9.4	11	36

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

Further all barley specimens of plot 1, 2 and 3 were analysed for 1,2,4-Triazole (T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) using the adapted BASF
method no. L0170/02. The method has a limit of quantitation of 0.010 mg/kg for each analyte.

The results of the average procedural recoveries in plant matrices
- at fortification levels between 0.010 and 1.0 mg/kg were 89.2 % for 1,2,4-Triazole,
- at fortification levels between 0.010 and 1.0 mg/kg were 89.0 % for Triazole alanine,
- at fortification levels between 0.010 and 1.0 mg/kg were 97.5 % for Triazole acetic acid, – at fortification levels between 0.010 and 1.0 mg/kg were 92.1 % for Triazole lactic acid.

Results are summarized in the table below.

Table S- 4: Procedural Recoveries for 1,2,4-Triazole (T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (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

Table S- 5: Summary of Residues of BAS 750 F (Mefentrifluconazole) in Barley

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.

<u>Residues of BAS 750 F (Mefentrifluconazole)</u>

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 0.026to 0.10mg/kg and from 0.021 to 0.040mg/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 0.056mg/kg. At 34-35 DALA (85-87BBCH) and 41-43 DALA (89BBCH) 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.

Table S- 6: Summary of Residues of BAS 500 F (Pyraclostrobin) and its Metabolite M500F007 in Barley

Sampl. No.	Portion analyzed	Timing DALA	Growth Stage (BBCH)	n	Range of Residues [mg/kg]		
					BAS 500 F	expressed as parent equivalent M500F007 1)	Sum 2)
Plot 2: treated with BAS 758 00 F (2x 1.5 L/ha)							
1	Whole plant no roots	0	59	4	1.8 - 4.4	0.027 - 0.11	1.8 - 4.5
2	Grain	48-49	87-89	4	0.013 - 0.044	0.014 - 0.016	0.026 - 0.060
	Straw			4	0.17 - 0.69	0.092 - 0.47	0.26 - 1.2
3	Grain	55-56	89	4	0.017 - 0.047	0.012 - 0.018	0.031 - 0.064
	Straw			4	0.29 - 1.0	0.16 - 0.38	0.44 - 1.4
4	Grain	62-63	89	3	0.019 - 0.036	< 0.011 - 0.014	0.030 - 0.050
	Straw			3	0.40 - 0.86	0.24 - 0.29	0.63 - 1.1
Plot 4: treated with BAS 500 06 F (2x 1.25 L/ha)							
1	Whole plant no roots	0	69	4	2.7 - 5.8	0.089 - 0.25	2.8 - 6.0
2	Ears	27-28	77-83	3	0.052 - 0.23	0.097 - 0.18	0.15 - 0.41
	Rest of plant without roots			3	0.46 - 2.7	0.22 - 0.81	0.68 - 3.5
	Grain	27	85	1	0.047	0.026	0.073
	Straw			1	0.33	0.16	0.50
3	Grain	34-35	85-87	4	0.029 - 0.13	0.032 - 0.079	0.080 - 0.21
	Straw			4	0.40 - 2.0	0.20 - 0.68	0.60 - 2.7
4	Grain	41-43	89	4	0.039 - 0.13	0.029 - 0.080	0.072 - 0.21
	Straw			4	0.37 - 2.4	0.25 - 0.83	0.62 - 3.2

DALA = days after last application n = Number of specimens
General: The limit of quantification (LOQ) is 0.010 mg/kg for BAS 500 F and 0.011 mg/kg for M500F007 (expressed as parent equivalent).
1) Conversion factor for calculation of M500F007 to parent BAS 500 F is 1.084
2) for residues of BAS 500 F < 0.010 mg/kg, value was set to 0.010 mg/kg for calculation of sum and for residues
of M500F007, expressed as parent equivalent < 0.011 mg/kg, value was set to 0.011 mg/kg for calculation of sum; if both values are below LOQ the sum is <0.021 mg/k

Residues of BAS 500 F (Pyraclostrobin) and its metabolite M500F007

Plot 2: The residues of **BAS 500 F** analyzed in barley whole plant no roots specimens sampled
immediately after the last application (59 BBCH) ranged from 1.8 to 4.4 mg/kg.

In grain specimens collected at 48-49 DALA (87-89 BBCH) residues of BAS 500 F were found between 0.013 and 0.044 mg/kg. At 55-56 DALA (89 BBCH) and 62-63 DALA (89 BBCH) the residues were in a range from 0.017 to 0.047 mg/kg and from 0.019 to 0.036 mg/kg,
respectively.

In straw specimens sampled at 48-49 DALA (87-89 BBCH) residues of BAS 500 F were analyzed between 0.17 and 0.69 mg/kg. At 55-56 DALA (89 BBCH) and 62-63 DALA (89 BBCH) residues of BAS 500 F were in a range from 0.29 to 1.0 mg/kg and from 0.40 to 0.86 mg/kg, respectively.

Plot 4: The residues of **BAS 500 F** analyzed in barley whole plant no roots specimens sampled immediately after the last application (69 BBCH) ranged from 2.7 to 5.8 mg/kg.

In ears specimens collected at 27-28 DALA (77-83 BBCH) residues of BAS 500 F were analyzed between 0.052 and 0.23 mg/kg. Rest of plant without roots specimens taken at the same sampling event showed residues from 0.46 to 2.7 mg/kg.

In grain specimens collected at 27 DALA (85 BBCH) a residue of BAS 500 F was found at 0.047 mg/kg. At 34-35 DALA (85-87 BBCH) and 41-43 DALA (89 BBCH) residues of BAS 500 F were analyzed in grain specimens from 0.029 to 0.13 mg/kg and from 0.039 to 0.13 mg/kg, respectively.

In straw specimens collected at 27 DALA (85 BBCH) a residue of BAS 500 F was found at 0.33 mg/kg. At 34-35 DALA (85-87 BBCH) and 41-43 DALA (89 BBCH) residues of BAS 500 F were analyzed in straw specimens in a range from 0.40 to 2.0 mg/kg and from 0.37 to 2.4 mg/kg, respectively.

In the untreated control specimens, no residues of BAS 500 F were detected at or above the limit of quantitation (LOQ, 0.010 mg/kg).

Plot 2: The residues of **M500F007 (expressed as parent equivalent)** analyzed in barley whole plant no roots specimens sampled immediately after the last application (59 BBCH) ranged from 0.027 to 0.11 mg/kg.

In grain specimens collected at 48-49 DALA (87-89 BBCH) residues of M500F007 were found between 0.014 and 0.016 mg/kg. At 55-56 DALA (89 BBCH) and 62-63 DALA (89 BBCH) the residues were in a range from 0.012 to 0.018 mg/kg and from < 0.011 to 0.014 mg/kg, respectively.

In straw specimens sampled at 48-49 DALA (87-89 BBCH) residues of M500F007 were analyzed between 0.092 and 0.47 mg/kg. At 55-56 DALA (89 BBCH) and 62-63 DALA (89 BBCH) residues of M500F007 were in a range from 0.16 to 0.38 mg/kg and from 0.24 to 0.29 mg/kg, respectively.

Plot 4: The residues of **M500F007 (expressed as parent equivalent)** analyzed in barley whole plant no roots specimens sampled immediately after the last application (69 BBCH) ranged from 0.089 to 0.25 mg/kg.

In ears specimens collected at 27-28 DALA (77-83 BBCH) residues of M500F007 were analyzed between 0.097 and 0.18 mg/kg. Rest of plant without roots specimens taken at the same sampling event showed residues from 0.22 to 0.81 mg/kg.

In grain specimens collected at 27 DALA (85 BBCH) a residue of M500F007 was found at 0.026 mg/kg. At 34-35 DALA (85-87 BBCH) and 41-43 DALA (89 BBCH) residues of M500F007 were analyzed in grain specimens from 0.032 to 0.079 mg/kg and from 0.029 to 0.080 mg/kg, respectively.

In straw specimens collected at 27 DALA (85 BBCH) a residue of M500F007 was found at 0.16 mg/kg. At 34-35 DALA (85-87 BBCH) and 41-43 DALA (89 BBCH) residues of M500F007 were analyzed in straw specimens in a range from 0.20 to 0.68 mg/kg and from 0.25 to 0.83 mg/kg, respectively.

In the untreated control specimens, no residues of M500F007 were detected at or above the limit of quantitation (LOQ, 0.011 mg/kg, expressed as parent equivalent).

Bridging showed, that the new formulation BAS 758 00 F does not lead to higher residues than the respective solo formulation BAS 500 06 F.

Table S- 7: Summary of Residues of BAS 560 F (Metrafenone) in Barley

Sampl. No.	Portion analyzed	Timing DALA	Timing Growth stage (BBCH)	n	Range of Residues (mg/kg) BAS 560 F
Plot 2: treated with BAS 758 00 F (2x 1.5 L/ha)					
1	Whole plant no roots	0	59	4	2.1 - 3.6
2	Grain	48-49	87-89	4	< 0.010 - 0.021
	Straw			4	0.031 - 0.13
3	Grain	55-56	89	4	< 0.010 - 0.023
	Straw			4	0.057 - 0.12
4	Grain	62-63	89	3	< 0.010 - 0.018
	Straw			3	0.085 - 0.14
Plot 5: treated with BAS 560 00 F (2x 0.5 L/ha)					
1	Whole plant no roots	0	69	4	1.9 - 3.2
2	Ears	27-28	77-83	3	0.051 – 0.071
	Rest of plant without roots			3	0.73 - 2.2
	Grain	27	85	1	0.051
	Straw			1	0.30
3	Grain	34-35	85-87	4	0.020 - 0.064
	Straw			4	0.29 - 1.5
4	Grain	41-43	89	4	0.026 - 0.052
	Straw			4	0.34 - 1.2

DALA = days after last application n = Number of specimens General: The limit of quantification (LOQ) is 0.010 mg/kg for BAS 560 F.

<u>Residues of BAS 560 F (Metrafenone)</u>

Plot 2: The residues of **BAS 560 F** analyzed in barley whole plant no roots specimens sampled immediately after the last application (59 BBCH) ranged from 2.1 to 3.6 mg/kg.

In grain specimens collected at 48-49 DALA (87-89 BBCH) residues of BAS 560 F were found between < 0.010 and 0.021 mg/kg. At 55-56 DALA (BBCH) and 62-63 DALA (89 BBCH) the residues were in a range from < 0.010 to 0.023 mg/kg and from < 0.010 to 0.018 mg/kg,

respectively.

In straw specimens sampled at 48-49 DALA (87-89 BBCH) residues of BAS 560 F were analyzed between 0.031 and 0.13 mg/kg. At 55-56 DALA (89 BBCH) and 62-63 DALA (89 BBCH) residues of BAS 560 F were in a range from 0.057 to 0.12 mg/kg and from 0.085 to 0.14 mg/kg, respectively.

Plot 5: The residues of **BAS 560 F** analyzed in barley whole plant no roots specimens sampled
immediately after the last application (69 BBCH) ranged from 1.9 to 3.2 mg/kg.

In ears specimens collected at 27-28 DALA (77-83 BBCH) residues of BAS 560 F were analyzed between 0.051 and 0.071 mg/kg. Rest of plant without roots specimens taken at the
same sampling event showed residues from 0.73 to 2.2 mg/kg.

In grain specimens collected at 27 DALA (85 BBCH) a residue of BAS 560 F was found at 0.051 mg/kg. At 34-35 DALA (85-87 BBCH) and 41-43 DALA (89 BBCH) residues of BAS 560 F were analyzed in grain specimens from 0.020 to 0.064 mg/kg and from 0.026 to
0.052 mg/kg, respectively.

In straw specimens collected at 27 DALA (85 BBCH) a residue of BAS 560 F was found at 0.30 mg/kg. At 34-35 DALA (85-87 BBCH) and 41-43 DALA (89 BBCH) residues of BAS 560 F were analyzed in straw specimens in a range from 0.29 to 1.5 mg/kg and from 0.34 to
1.2 mg/kg, respectively.

In the untreated control specimens, no residues of BAS 560 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 560 00 F.

Table S- 8: Summary of residues in the untreated Barley Specimens for 1,2,4-Triazole (T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)

Sampl. No.	Portion analyzed	Timing		n	Range of Triazole residues and related analytes [mg/kg]			
		DALA	Growth Stage (BBCH)		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.

Table S- 9: Summary of residues in the treated Barley Specimens 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

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. Furthermore, due to high residue found, additional fortifications were performed to cover the highest residue. Overall and average recoveries were all in the range of 70 - 110 % and relative standard deviations (RSD) were < 20 %.

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 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):	Regulation (EC) No. 1107/2009 of the European Parliament and of the Council of 21 Oct 2009 7029/VI/95 rev. 5 (July 22 1997) SANCO 7525/VI/95 rev. 10.3 (13 June 2017) OECD 509 Crop Field Trial (2009)
Deviations:	No
GLP:	Yes (certified by Land Brandenburg Ministerium der Justiz und für Europa und Verbraucherschutz, Potsdam, Germany)
Acceptability:	Yes

Table A 21: Application and sampling details for trials conducted in 2019/2020

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)	Mefentriflu-conazole Pyraclostrobin Metrafenone	0.10 0.12 0.15	200	1st application 14 ± 1 Days before application no. 2 2nd application BBCH 59	0, 49, 56, 63 DALA, BBCH 89
		3	2	F	foliar	BAS 750 01 F (EC)	Mefentriflu-conazole	0.15	200	1st application BBCH 49 2nd application BBCH 69	0, 28, 35, 42 DALA, BBCH 89
		4	2	F	foliar	BAS 500 06 F (EC)	Pyraclostrobin	0.25	200	1st application BBCH 49 2nd application BBCH 69	0, 28, 35, 42 DALA, BBCH 89
		5	2	F	foliar	BAS 560 00 F (SC)	Metrafenone	0.15	200	1st application BBCH 49 2nd application BBCH 69	0, 28, 35, 42 DALA, BBCH 89

1) days after last application, 2) Field, Glasshouse or Indoor

Table A 22: Summary of recoveries of Metrafenone in barley specimens

Matrix	Fortification Level (mg/kg)	Summary Recoveries			
		n	Mean (%)	SD (+/-)	RSD (%)
Method No. L0076/09		**Metrafenone**			
Whole plant no roots	0.010, 0.10, 10	7	94.4	6.9	7.3

Ears	0.010, 0.10, 10	8	81.2	3.5	4.4
Rest of plant without roots	0.010, 0.10, 10	7	79.4	4.6	5.8
Grain	0.010, 0.10, 10	7	92.4	6.2	6.7
Straw	0.010, 0.10, 10	7	98.0	7.7	7.8
Overall	0.010 - 10	**36**	**88.8**	**9.4**	**11**

Table A 23: Summary of the study 1 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Growing stage at sampling (BBCH)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metrafenone (BAS 560 F)			
Trial No: L200227 Location: 16833 Lentzke, Germany (N) Year: 2020	Barley (GC 0640)/ Infinity	1. 04.10.2019 2. 13.05.-21.05.2020 3. 13.07.-14.07.2020	150	200	75	2 12.05.2020	59	whole plant no roots grain straw grain straw grain straw	2.1 <0.010 0.042 <0.010 0.057 <0.010 0.085	0 49 49 56 56 62 62	59 87-89 87-89 89 89 89 89	BASF method L0076/09 LOQ: 0.010 mg/kg 2x BAS 758 00 F (EC) (plot 2) Treatment: foliar application Storage: barley whole plant no roots 293 days, barley ears 260 days, barley rest of plant without roots 260 days, barley grain 230 days, barley straw 254 days
			150	200	75	2 21.05.2020	69	whole plant no roots grain straw grain straw grain straw	1.9 0.051 0.30 0.048 0.29 0.048 0.34	0 27 27 34 34 43 43	69 85 85 87 87 89 89	BASF method L0076/09 LOQ: 0.010 mg/kg 2x BAS 560 00 F (SC) (plot 5) Treatment: foliar application Storage: barley whole plant no roots 293 days, barley ears 260 days, barley rest of plant without roots 260 days, barley grain 230 days, barley straw 254 days

Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date** (c)	**Growth stage at last treatment or date**	**Portion analyzed**	**Residues (mg/kg)**	**PHI (days)** (d)	**Growing stage at sampling (BBCH)**	**Details on trial** (e)
			g a.s./ ha	**Water (l/ha)**	**g a.s./hl**				**Metrafenone (BAS 560 F)**			
Trial No: L200228 Location: 6562 KC Groesbeek, The Netherlands (N) Year: 2020	Barley (GC 0640)/ Rafaela	1. 14.10.2019 2. 09.05.-18.05.2020 3. 30.06.-08.07.2020	150	200	75	2 07.05.2020	59	whole plant no roots grain straw grain straw grain straw	2.6 0.021 0.095 0.023 0.12 0.018 0.11	0 49 49 56 56 62 62	59 87-89 87-89 89 89 89 89	BASF method L0076/09 LOQ: 0.010 mg/kg 2x BAS 758 00 F (EC) (plot 2) Treatment: foliar application Storage: barley whole plant no roots 293 days, barley ears 260 days, barley rest of plant without roots 260 days, barley grain 230 days, barley straw 254 days
			150	200	75	2 18.05.2020	69	whole plant no roots ears rest of plant without roots grain straw grain straw	3.2 0.069 2.0 0.064 0.89 0.052 1.0	0 28 28 35 35 43 43	69 81-83 81-83 87 87 89 89	BASF method L0076/09 LOQ: 0.010 mg/kg 2x BAS 560 00 F (SC) (plot 5) Treatment: foliar application Storage: barley whole plant no roots 293 days, barley ears 260 days, barley rest of plant without roots 260 days, barley grain 230 days, barley straw 254 days

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)**	**Growing stage at sampling (BBCH)**	**Details on trial**
			g a.s./ ha	**Water (l/ha)**	**g a.s./hl**				**Metrafenone (BAS 560 F)**			
	(a)	(b)				(c)				(d)		(e)
Trial No: L200229 Location: 57810 Donnelay, France (N) Year: 2020	Barley (GC 0640)/ Pixel	1. 10.10.2019 2. 07.05.-13.05.2020 3. 30.06.2020	150	200	75	2 07.05.2020	59	whole plant no roots grain straw grain straw grain straw	3.6 <0.010 0.13 <0.010 0.074 <0.010 0.14	0 48 48 55 55 63 63	59 89 89 89 89 89 89	BASF method L0076/09 LOQ: 0.010 mg/kg 2x BAS 758 00 F (EC) (plot 2) Treatment: foliar application Storage: barley whole plant no roots 293 days, barley ears 260 days, barley rest of plant without roots 260 days, barley grain 230 days, barley straw 254 days
			150	200	75	2 13.05.2020	69	whole plant no roots ears rest of plant without roots grain straw grain straw	3.1 0.071 2.2 0.037 1.5 0.040 1.2	0 27 27 34 34 41 41	69 83 83 85 85 89 89	BASF method L0076/09 LOQ: 0.010 mg/kg 2x BAS 560 00 F (SC) (plot 5) Treatment: foliar application Storage: barley whole plant no roots 293 days, barley ears 260 days, barley rest of plant without roots 260 days, barley grain 230 days, barley straw 254 days

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Growing stage at sampling (BBCH)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metrafenone (BAS 560 F)			
Trial No: L200230 Location: 64-000 Kokorzyn Poland (N) Year: 2020	Barley (GC 0640)/ Sandra	1. 24.09.2019 2. 08.05.-15.05.2020 3. 08.07.2020	150	200	75	2 08.05.2020	59	whole plant no roots grain straw grain straw	2.7 <0.010 0.031 <0.010 0.087	0 48 48 55 55	59 89 89 89 89	BASF method L0076/09 LOQ: 0.010 mg/kg 2x BAS 758 00 F (EC) (plot 2) Treatment: foliar application Storage: barley whole plant no roots 293 days, barley ears 260 days, barley rest of plant without roots 260 days, barley grain 230 days, barley straw 254 days
			150	200	75	2 15.05.2020	69	whole plant no roots ears rest of plant without roots grain straw grain straw	3.1 0.051 0.73 0.020 0.45 0.026 0.56	0 28 28 34 34 41 41	69 77 77 85 85 89 89	BASF method L0076/09 LOQ: 0.010 mg/kg 2x BAS 560 00 F (SC) (plot 5) Treatment: foliar application Storage: barley whole plant no roots 293 days, barley ears 260 days, barley rest of plant without roots 260 days, barley grain 230 days, barley straw 254 days

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

A 2.2.3.1.2 Study 2 (Cereals, Wheat)

Comments of zRMS:	The study has been accepted. (See also page 144). The objective of the study was to determine the magnitude of residues of BAS 750 F (Mefentrifluconazole) and its triazole metabolites, BAS 500 F (Pyraclostrobin), its metabolite M500F007 and BAS 560 F (Metrafenone) in wheat after treatment with either BAS 758 00 F, BAS 750 01 F, BAS 500 06 F or BAS 560 00 F. The selected application rates, frequency and spray interval cover the Good Agriculture Practice (critical GAP), which will be defined by the label directions. During the 2020 growing season, 4 trials in wheat were conducted in different representative growing areas in Northern Europe to determine the residue level of BAS 750 F (Mefentrifluconazole), BAS 500 F (Pyraclostrobin) and BAS 560 F (Metrafenone) after application of either BAS75800F, BAS75001F, BAS50006F or BAS56000F in or on RAC. All trials consisted of five plots: plot 1 (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). **Plot 2:** In all trials the first application was made 13-14 days before application no. 2 (except of trial L200225: 19 days before application no. 2, see deviation). The second application was performed at BBCH 59. **Plots 3 to 5:** The first application was made at BBCH 49. The second applications were made at BBCH 69. **BAS 758 00 F** (66.6 g BAS 750 F/L, 80.0 g BAS 500 F/L, 100.0 g BAS 560 F/L, EC) was applied in all trials twice at a single rate of 1.5 L/ha formulated product, equals to 0.10 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 on plot 2 with a water volume of 200 L/ha. **BAS 750 01 F** (100.0 g BAS 750 F/L, EC) was applied in all trials twice at a single rate of 1.5 L/ha formulated product, equals to 0.15 kg a.i./ha of BAS 750 F on plot 3 with a water volume of 200 L/ha. **BAS 500 06 F** (200.0 g BAS 500 F/L, EC) was applied in all trials twice at a single rate of 1.25 L/ha formulated product, equals to 0.25 kg a.i./ha of BAS 500 F on plot 4 with a water volume of 200 L/ha. **BAS 560 00 F** (300.0 g BAS 560 F/L, SC) was applied in all trials twice at a single rate of 0.5 L/ha formulated product, equals to 0.15 kg a.i./ha of BAS 560 F on plot 5 with a water volume of 200 L/ha. **Plots 1 and 2:** Wheat specimens 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. At 48-50 DALA the specimens were sampled as grain and straw on plot 2. At 55-57 DALA wheat specimens were collected as grain and straw on plots 1 and 2. At 63-64 DALA specimens were sampled as grain and straw on plot 2. **Plots 1, 3, 4 and 5:** Wheat specimens were collected at BBCH 69 on plot 1 immediately before application no. 2 and directly after application no. 2 on plots 3 to 5 as whole plant no roots. At 34-35 DALA the specimens were sampled as ears and rest of plant without roots or as grain and straw on plot 1 and plots 3 to

5. At 41-42 DALA wheat specimens were collected as grain and straw on plots 3 to 5. At 48-49 DALA specimens were sampled as grain and straw on plots 3 to 5.

All wheat specimens of plots 1 and 2 were analysed for BAS 750 F (Mefentrifluconazole), BAS 500 F (Pyraclostrobin) and its metabolite M500F007, BAS 560 F (Metrafenone) using the BASF Method L0076/09. The method has a limit of quantitation of 0.010 mg/kg.
All wheat specimens of plot 3 were analysed for BAS 750 F (Mefentrifluconazole) using the BASF Method L0076/09. The method has a limit of quantitation of 0.010 mg/kg.
All treated wheat specimens of plot 4 were analysed for BAS 500 F (Pyraclostrobin) and its metabolite M500F007 using the BASF Method L0076/09. The method has a limit of quantitation of 0.010 mg/kg.
All treated wheat specimens of plot 5 were analysed for BAS 560 F (Metrafenone) using the BASF Method L0076/09. The method has a limit of quantitation of 0.010 mg/kg.
The results of the average procedural recoveries in wheat matrices at fortification levels between 0.010 and 10 mg/kg were at 90.4 % for BAS 750 F, at 92.8 % for BAS 500 F, at 95.7 % for M500F007 and at 99.1 % for BAS 560 F. Results are summarized in the tables below.

Table S- 1: Procedural Recoveries for BAS 750 F (Mefentrifluconazole)

Matrix		Fortification Level [mg/kg]	BAS 750 F 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

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

Table S- 2: Procedural Recoveries for BAS 500 F (Pyraclostrobin) and its Metabolite M500F007

Matrix		Fortification Level [mg/kg]	BAS 500 F Mean [%]	SD [±]	RSD [%]	n
Wheat	Whole plant no roots	0.010, 0.10 and 10	84.7	7.8	9.2	9
	Ears	0.010, 0.10 and 10	97.5	4.8	4.9	7
	Rest of plant without roots	0.010, 0.10 and 10	96.3	5.5	5.7	7
	Grain	0.010, 0.10 and 1.0	96.8	3.5	3.6	7
	Straw	0.010, 0.10 and 10	91.7	8.8	9.6	11
		Overall:	92.8	8.1	8.7	41

Matrix		Fortification Level [mg/kg]	Mean [%]	M500 007 SD [±]	RSD [%]	n
Wheat	Whole plant no roots	0.010, 0.10 and 10	88.6	7.0	7.9	9
	Ears	0.010, 0.10 and 10	101	6.2	6.1	7
	Rest of plant without roots	0.010, 0.10 and 10	101	5.5	5.4	7
	Grain	0.010, 0.10 and 1.0	97.1	4.6	4.8	7
	Straw	0.010, 0.10 and 10	93.7	6.8	7.3	11
		Overall:	95.7	7.7	8.0	41

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

Table S- 3: Procedural Recoveries for BAS 560 F (Metrafenone)

Matrix		Fortification Level [mg/kg]	BAS 560 F			
			Mean [%]	SD [±]	RSD [%]	n
Wheat	Whole plant no roots	0.010, 0.10 and 10	90.8	9.4	10	9
	Ears	0.010, 0.10 and 10	106	4.6	4.4	7
	Rest of plant without roots	0.010, 0.10 and 10	103	4.7	4.6	7
	Grain	0.010, 0.10 and 1.0	99.7	4.0	4.1	7
	Straw	0.010, 0.10 and 10	98.4	4.9	4.9	11
		Overall:	99.1	7.8	7.8	41

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

Further all wheat specimens of plot 1, 2 and 3 were analysed for 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) using the adapted BASF method no. L0170/02. The method has a limit of quantitation of 0.010 mg/kg
for each analyte.

The results of the average procedural recoveries in plant matrices
- at fortification levels between 0.010 and 1.0 mg/kg were 89.4 % for 1,2,4-Triazole,
- at fortification levels between 0.010 and 1.0 mg/kg were 88.7 % for Triazole alanine,
- at fortification levels between 0.010 and 1.0 mg/kg were 97.2 % for Triazole acetic acid,
- at fortification levels between 0.010 and 1.0 mg/kg were 85.5 % for Triazole lactic acid.

Results are summarized in the table below

Table S- 4: Procedural Recoveries for 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)

Matrix		Recoveries of	Fortification Level [mg/kg]	Mean [%]	SD [±]	RSD [%]	n
Wheat	Whole plant no roots		0.010, 0.10 and 1.0	95.5	7.1	7.5	8

	Ears	1,2,4-Triazole (1,2,4-T)	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
Wheat	Whole plant no roots	Triazole alanine (TA)	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
Wheat	Whole plant no roots	Triazole acetic acid (TAA)	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
Wheat	Whole plant no roots	Triazole lactic acid (TLA)	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

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

Table S- 5: Summary of Residues of BAS 750 F (Mefentrifluconazole) in Wheat

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	1.5 - 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 with BAS 750 01 F (2x 1.5 L/ha)					
1	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

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

<u>Residues of BAS 750 F (Mefentrifluconazole)</u>

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.

Table S- 6: Summary of Residues of BAS 500 F (Pyraclostrobin) and its Metabolite M500F007 in Wheat

Sampl. No.	Portion analyzed	Timing DALA	Growth Stage (BBCH)	n	Range of Residues [mg/kg] BAS 500 F	expressed as p M500F007 1)	rent equivalents Sum 2)
Plot 2: treated with BAS 758 00 F (2x 1.5 L/ha)							
1	Whole plant no roots	0	59	4	1.7 - 3.3	0.029 - 0.085	1.7 - 3.3
2	Grain	48 - 50	87 - 89	4	< 0.010	< 0.011	< 0.021
	Straw			4	0.35 - 1.2	0.16 - 0.49	0.50 - 1.7
3	Grain	55 - 57	87 - 89	4	< 0.010	< 0.011	< 0.021
	Straw			4	0.34 - 1.1	0.19 - 0.48	0.53 - 1.6
4	Grain	63 - 64	89	4	< 0.010	< 0.011	< 0.021
	Straw			4	0.40 - 0.58	0.22 - 0.32	0.62 - 0.89
Plot 4: treated with BAS 500 06 F (2x 1.25 L/ha)							
1	Whole plant no roots	0	69	4	2.5 - 5.3	0.11 - 0.36	2.6 - 5.6
2	Ears	34	83	1	0.20	0.12	0.32
	Rest of plant without roots			1	0.77	0.47	1.2
	Grain	34 - 35	85 - 89	3	< 0.010 - 0.014	< 0.011	< 0.021 - 0.025
	Straw			3	1.7 - 3.3	0.82 - 1.3	2.6 - 4.6
3	Grain	41 - 42	87 - 89	4	< 0.010 - 0.016	< 0.011	< 0.021 - 0.027
	Straw			4	0.81 - 4.6	0.51 - 2.0	1.3 - 6.6
4	Grain	48 - 49	89	4	< 0.010 - 0.022	< 0.011	< 0.021 - 0.033
	Straw			4	0.98 - 4.5	0.64 - 1.7	1.6 - 6.2

DALA = days after last application n = Number of specimens
General: The limit of quantification (LOQ) is 0.010 mg/kg for BAS 500 F and 0.011 mg/kg for M500F007 (expressed as parent equivalent).
1) Conversion factor for calculation of M500F007 to parent BAS 500 F is 1.084
2) for residues of BAS 500 F < 0.010 mg/kg, value was set to 0.010 mg/kg for calculation of sum and for residues of M500F007, expressed as parent equivalent < 0.011 mg/kg, value was set to 0.011 mg/kg for calculation of sum; if both values are below LOQ the sum is <0.021 mg/kg

Residues of BAS 500 F (Pyraclostrobin)

Plot 2: The residues of **BAS 500 F** analyzed in wheat whole plant no roots specimens sampled immediately after the last application (59 BBCH) ranged from 1.7 to 3.3 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 500 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 500 F were analyzed between 0.35 and 1.2 mg/kg. At 55-57 DALA (87-89 BBCH) and 63-64 DALA (89 BBCH) residues of BAS 500 F were in a range from 0.34 to 1.1 mg/kg and from 0.40 to 0.58 mg/kg, respectively.

Plot 4: The residues of **BAS 500 F** analyzed in wheat whole plant no roots specimens sampled immediately after the last application (69 BBCH) ranged from 2.5 to 5.3 mg/kg.

In ears specimens collected at 34 DALA (83 BBCH) a residue of BAS 500 F was found at 0.20 mg/kg. Rest of plant without roots specimens taken at the same sampling event showed a residue of BAS 500 F of 0.77 mg/kg.

In grain specimens sampled at 34-35 DALA (85-89 BBCH) residues of BAS 500 F were found between < 0.010 and 0.014 mg/kg. At 41-42 DALA (87-89 BBCH) and 48-49 DALA (89 BBCH) residues were analyzed from < 0.010 to 0.016 mg/kg and from < 0.010 to 0.022 mg/kg, respectively.

In straw specimens sampled at 34-35 DALA (85-89 BBCH) residues of BAS 500 F ranged from 1.7 to 3.3 mg/kg. At 41-42 DALA (87-89 BBCH) and 48-49 DALA (89 BBCH) residues were analyzed from 0.81 to 4.6 mg/kg and from 0.98 to 4.5 mg/kg, respectively.

Plot 2: The residues of **M500F007 (expressed as parent equivalent)** analyzed in wheat whole plant no roots specimens sampled immediately after the last application (59 BBCH) ranged from 0.029 to 0.085 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 M500F007 were found at or above the LOQ (0.011 mg/kg).

In straw specimens sampled at 48-50 DALA (87-89 BBCH) residues of M500F007 were analyzed between 0.16 and 0.49 mg/kg. At 55-57 DALA (87-89 BBCH) and 63-64 DALA (89 BBCH) residues of M500F007 were in a range from 0.19 to 0.48 mg/kg and from 0.22 to 0.32 mg/kg, respectively.

Plot 4: The residues of **M500F007 (expressed as parent equivalent)** analyzed in wheat whole plant no roots specimens sampled immediately after the last application (69 BBCH) ranged from 0.11 to 0.36 mg/kg.

In ears specimens collected at 34 DALA (83 BBCH) a residue of M500F007 was found at 0.12 mg/kg. Rest of plant without roots specimens taken at the same sampling event showed a residue of M500F007 of 0.47 mg/kg.

In grain specimens sampled at 34-35 DALA (85-89 BBCH), 41-42 DALA (87-89 BBCH) and 48-49 DALA (89 BBCH) no residues of M500F007 were found at or above the LOQ (0.011 mg/kg).

In straw specimens sampled at 34-35 DALA (85-89 BBCH) residues of M500F007 ranged from 0.82 to 1.3 mg/kg. At 41-42 DALA (87-89 BBCH) and 48-49 DALA (89 BBCH) residues were analyzed from 0.51 to 2.0 mg/kg and from 0.64 to 1.7 mg/kg, respectively.

No residues of BAS 500 F and its metabolite M500F007 were detected at or above the LOQ in any of the untreated control samples.

Bridging showed, that the new formulation BAS 758 00 F does not lead to higher residues than the respective solo formulation BAS 500 06 F

Table S- 7: Summary of Residues of BAS 560 F (Metrafenone) in Wheat

Sampl. No.	Portion analyzed	Timing DALA	Timing Growth stage (BBCH)	n	Range of Residues (mg/kg) BAS 560 F
Plot 2: treated with BAS 758 00 F (2x 1.5 L/ha)					
1	Whole plant no roots	0	59	4	1.7 - 3.2
2	Grain	48 - 50	87 - 89	4	< 0.010
	Straw			4	0.033 - 0.086
3	Grain	55 - 57	87 - 89	4	< 0.010
	Straw			4	0.034 - 0.070
4	Grain	63 - 64	89	4	< 0.010
	Straw			4	0.026 - 0.040
Plot 5: treated with BAS 560 00 F (2x 0.5 L/ha)					
1	Whole plant no roots	0	69	4	2.1 - 3.1
2	Ears	34	83	1	0.060
	Rest of plant without roots			1	0.85
	Grain	34 - 35	85 - 89	3	< 0.010
	Straw			3	0.78 - 2.9
3	Grain	41 - 42	87 - 89	4	< 0.010
	Straw			4	0.69 - 3.8
4	Grain	48 - 49	89	4	< 0.010
	Straw			4	1.1 - 3.1

DALA = days after last application n = Number of specimens
General: The limit of quantification (LOQ) is 0.010 mg/kg for BAS 560 F.

Residues of BAS 560 F (Metrafenone)

Plot 2: The residues of **BAS 560 F** analyzed in wheat whole plant no roots specimens sampled
immediately after the last application (59 BBCH) ranged from 1.7 to 3.2 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 560 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 560 F were analyzed between 0.033 and 0.086 mg/kg. At 55-57 DALA (87-89 BBCH) and 63-64 DALA (89 BBCH) residues of BAS 560 F were in a range from 0.034 to 0.070 mg/kg and from 0.026 to 0.040 mg/kg, respectively.
Plot 5: The residues of **BAS 560 F** analyzed in wheat whole plant no roots specimens sampled immediately after the last application (69 BBCH) ranged from 2.1 to 3.1 mg/kg.
In ears specimens collected at 34 DALA (83 BBCH) a residue of BAS 560 F was found at 0.060 mg/kg. Rest of plant without roots specimens taken at the same sampling event showed a residue of BAS 560 F of 0.85 mg/kg.
In grain specimens sampled at 34-35 DALA (85-89 BBCH), 41-42 DALA (87-89 BBCH) and 48-49DALA (89BBCH) no residues of BAS560F were found at or above

the LOQ (0.010 mg/kg).
In straw specimens sampled at 34-35 DALA (85-89 BBCH) residues of BAS 560 F ranged from 0.78 to 2.9 mg/kg. At 41-42 DALA (87-89 BBCH) and 48-49 DALA (89 BBCH) residues were analyzed from 0.69 to 3.8 mg/kg and from 1.1 to 3.1 mg/kg, respectively.
In the untreated control specimens, no residues of BAS 560 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 560 00 F.

Table S- 8: Summary of residues in the untreated Wheat Specimens for 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)

Sampl. No.	Portion analyzed	Timing DALA	Growth Stage (BBCH)	n	Range of Triazole residues and related analytes [mg/kg] 1,2,4-Triazole (1,2,4-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	< 0.010 – 0.040	< 0.010 – 0.058	< 0.010 – 0.045
3	Grain	55 – 57	87-89	4	< 0.010	0.045 – 0.14	0.021 – 0.14	< 0.010
	Straw			4	< 0.010	< 0.010 – 0.010	< 0.010 – 0.11	< 0.010 – 0.041
Plot 1 – untreated (in regard to plot 3)								
1	Whole plant no roots	0 DBLA	69	4	< 0.010	< 0.010 – 0.042	< 0.010 – 0.057	< 0.010 – 0.034
2	Ears	34	83	1	< 0.010	0.075	0.038	< 0.010
	Rest of plant without roots			1	< 0.010	< 0.010	0.016	0.023
2	Grain	34-35	85-89	3	< 0.010	0.038 – 0.13	0.019 – 0.11	< 0.010
	Straw			3	< 0.010	< 0.010 – 0.017	< 0.010 – 0.098	< 0.010 – 0.040

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

Table S- 9: Summary of residues in the treated Wheat Specimens for 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)

Sampl. No.	Portion analyzed	Timing DALA	Growth Stage (BBCH)	n	Range of Triazole residues and related analytes [mg/kg] 1,2,4-Triazole (1,2,4-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	0.010 - 0.034	< 0.010 - 0.042	< 0.010 - 0.029
2	Grain	49-50	85-89	4	< 0.010	0.10 - 0.17	0.035 - 0.10	< 0.010
	Straw			4	< 0.010	< 0.010 - 0.011	< 0.010 - 0.077	0.010 - 0.050
3	Grain	56-57	87-89	4	< 0.010	0.10 - 0.19	0.038 - 0.10	< 0.010

	Straw			4	< 0.010	< 0.010	0.012 - 0.078	0.010 - 0.064
4	Grain	63-64	89	4	< 0.010	0.086 - 0.16	0.036 - 0.097	< 0.010
	Straw			4	< 0.010	< 0.010	< 0.010 - 0.078	< 0.010 - 0.042
Plot 3: treated with BAS 750 01 F (2x 1.5 L/ha)								
1	Whole plant no roots	0	69	4	< 0.010	0.014 - 0.056	< 0.010 - 0.047	< 0.010 - 0.029
2	Ears	34	83	1	< 0.010	0.15	0.055	< 0.010
	Rest of plant without roots			1	< 0.010	< 0.010	0.019	0.044
	Grain	34 - 35	85-89	3	< 0.010	0.15 - 0.21	0.041 - 0.14	< 0.010
	Straw			3	< 0.010	< 0.010 - 0.013	< 0.010 - 0.10	0.014 - 0.068
3	Grain	41 - 42	87-89	4	< 0.010	0.16 - 0.22	0.040 - 0.10	< 0.010
	Straw			4	< 0.010	< 0.010 - 0.015	0.016 - 0.076	0.016 - 0.048
4	Grain	48 - 49	89	4	< 0.010	0.15 - 0.22	0.041 - 0.14	< 0.010
	Straw			4	< 0.010	< 0.010 - 0.016	0.014 - 0.10	0.010 - 0.066

DALA = days after last application   n = Number of specimens

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. Furthermore, due to high residue found, additional fortifications were performed to cover the highest residue. Overall and average recoveries were all in the range of 70 – 110 % and relative standard deviations (RSD) were < 20 %.

Reference:	CA 6.3.2/2
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):	Regulation (EC) No. 1107/2009 of the European Parliament and of the Council of 21 Oct 2009 7029/VI/95 rev. 5 (July 22 1997) SANCO 7525/VI/95 rev. 9 (March 2011) OECD 509 Crop Field Trial (2009)
Deviations:	No
GLP:	Yes (certified by Land Brandenburg Ministerium der Justiz und für Europa und Verbraucherschutz, Potsdam, Germany)
Acceptability:	Yes

Table A 24: Application and sampling details for trials conducted in 2019/2020

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)	Mefentriflu-co-nazole Pyraclostrobin Metrafenone	0.10 0.12 0.15	200	1st application 14 ± 1 Days be-fore application no. 2 2nd application BBCH 59	0, 49, 56, 63 DALA, BBCH 89
		3	2	F	foliar	BAS 750 01 F (EC)	Mefentriflu-co-nazole	0.15	200	1st application BBCH 49 2nd application BBCH 69	0, 35, 42, 49 DALA, BBCH 89
		4	2	F	foliar	BAS 500 06 F (EC)	Pyraclostrobin	0.25	200	1st application BBCH 49 2nd application BBCH 69	0, 35, 42, 49 BBCH 89
		5	2	F	foliar	BAS 560 00 F (SC)	Metrafenone	0.15	200	1st application BBCH 49 2nd application BBCH 69	0, 35, 42, 49 DALA, BBCH 89

1) days after last application, 2) Field, Glasshouse or Indoor

Table A 25: Summary of recoveries of Metrafenone in wheat specimen

Matrix	Fortification Level (mg/kg)	Summary Recoveries			
		n	Mean (%)	SD (+/-)	RSD (%)
Method No. L0076/09		**Metrafenone**			
Whole plant no roots	0.010, 0.10, 10	9	90.8	9.4	10
Ears	0.010, 0.10, 10	7	106	4.6	4.4
Rest of plant without roots	0.010, 0.10, 10	7	103	4.7	4.6
Grain	0.010, 0.10, 10	7	99.7	4.0	4.1
Straw	0.010, 0.10, 10	11	98.4	4.9	4.9
Overall	0.010 - 10	**41**	**99.1**	**7.8**	**7.8**

Table A 26: Summary of the study 2 trials

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)	PHI (days) (d)	Growing stage at sampling (BBCH)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metrafenone (BAS 560 F)			
Trial No: L200223 Location: 16833 Lentzke, Germany (N) Year: 2020	Wheat (GC 0654)/ Linus	1. 21.10.2019 2. 02.06.-16.06.2020 3. 20.07.-03.08.2020	150	200	75	2 01.06.2020	59	whole plant no roots grain straw grain straw grain straw	1.7 <0.010 0.083 <0.010 0.036 <0.010 0.040	0 49 49 56 56 63 63	59 87-89 87-89 89 89 89 89	BASF method L0076/09 LOQ: 0.010 mg/kg 2x BAS 758 00 F (EC) (plot 2) Treatment: foliar application Storage: wheat whole plant no roots 257 days, wheat ears 227 days, wheat rest of plant without roots 224 days, wheat grain 199 days, wheat straw 203 days
			150	200	75	2 16.06.2020	69	whole plant no roots grain straw grain straw grain straw	2.1 <0.010 1.5 <0.010 1.2 <0.010 1.4	0 35 35 41 41 48 48	69 87-89 87-89 89 89 89 89	BASF method L0076/09 LOQ: 0.010 mg/kg 2x BAS 560 00 F (SC) (plot 5) Treatment: foliar application Storage: wheat whole plant no roots 257 days, wheat ears 227 days, wheat rest of plant without roots 224 days, wheat grain 199 days, wheat straw 203 days

Trial No./ Location/ EU zone/ Year	Commod-ity/ Variety (a)	Date of 1.Sowing or plant-ing 2.Flowering 3. Harvest (b)	Application rate per treat-ment			Dates of treat-ment or no. of treatments and last date (c)	Growth stage at last treat-ment or date	Portion ana-lyzed	Residues (mg/kg)	PHI (days) (d)	Growing stage at sampling (BBCH)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metrafenone (BAS 560 F)			
Trial No: L200224 Location: 6599 AV Ven-Zelder-heide, The Netherlands (N) Year: 2020	Wheat (GC 0654)/ Bennington	1. 25.11.2019 2. 02.06.-12.06.2020 3. 31.07.-03.08.2020	150	200	75	2 31.05.2020	59	whole plant no roots grain straw grain straw grain straw	1.7 <0.010 0.033 <0.010 0.034 <0.010 0.026	0 50 50 57 57 64 64	59 87 87 87-89 87-89 89 89	BASF method L0076/09 LOQ: 0.010 mg/kg 2x BAS 758 00 F (EC) (plot 2) Treatment: foliar application Storage: wheat whole plant no roots 257 days, wheat ears 227 days, wheat rest of plant without roots 224 days, wheat grain 199 days, wheat straw 203 days
			150	200	75	2 12.06.2020	69	whole plant no roots grain straw grain straw grain straw	2.4 <0.010 0.78 <0.010 1.1 <0.010 1.1	0 35 35 42 42 49 49	69 85-87 85-87 87-89 87-89 89 89	BASF method L0076/09 LOQ: 0.010 mg/kg 2x BAS 560 00 F (SC) (plot 5) Treatment: foliar application Storage: wheat whole plant no roots 257 days, wheat ears 227 days, wheat rest of plant without roots 224 days, wheat grain 199 days, wheat straw 203 days

Trial No./ Location/ EU zone/ Year	Commod-ity/ Variety (a)	Date of 1.Sowing or plant-ing 2.Flowering 3. Harvest (b)	Application rate per treat-ment g a.s./ ha	Water (l/ha)	g a.s./hl	Dates of treat-ment or no. of treatments and last date (c)	Growth stage at last treat-ment or date	Portion ana-lyzed	Residues (mg/kg) Metrafenone (BAS 560 F)	PHI (days) (d)	Growing stage at sampling (BBCH)	Details on trial (e)
Trial No: L200225 Location: 64-020 Jasień, Poland (N) Year: 2020	Wheat (GC 0654)/ Arkadia	1. 15.10.2019 2. 03.06.-10.06.2020 3. 04.08.2020	150	200	75	2 01.06.2020	59	whole plant no roots grain straw grain straw grain straw	2.5 <0.010 0.086 <0.010 0.070 <0.010 0.033	0 49 49 56 56 64 64	59 89 89 89 89 89 89	BASF method L0076/09 LOQ: 0.010 mg/kg 2x BAS 758 00 F (EC) (plot 2) Treatment: foliar application Storage: wheat whole plant no roots 257 days, wheat ears 227 days, wheat rest of plant without roots 224 days, wheat grain 199 days, wheat straw 203 days
			150	200	75	2 10.06.2020	69	whole plant no roots grain straw grain straw grain straw	3.1 <0.010 2.9 <0.010 3.8 <0.010 3.1	0 34 34 42 42 49 49	69 87 87 89 89 89 89	BASF method L0076/09 LOQ: 0.010 mg/kg 2x BAS 560 00 F (SC) (plot 5) Treatment: foliar application Storage: wheat whole plant no roots 257 days, wheat ears 227 days, wheat rest of plant without roots 224 days, wheat grain 199 days, wheat straw 203 days

Trial No./ Location/ EU zone/ Year	Commod-ity/ Variety (a)	Date of 1.Sowing or plant-ing 2.Flowering 3. Harvest (b)	Application rate per treat-ment			Dates of treat-ment or no. of treatments and last date (c)	Growth stage at last treat-ment or date	Portion ana-lyzed	Residues (mg/kg)	PHI (days) (d)	Growing stage at sampling (BBCH)	Details on trial (e)
			g a.s./ ha	Water (l/ha)	g a.s./hl				Metrafenone (BAS 560 F)			
Trial No: L200226 Location: 67170 Kriegsheim, France (N) Year: 2020	Wheat (GC 0654)/ Absalon	1. 18.10.2019 2. 13.05.-20.05.2020 3. 06.07.2020	150	200	75	2 13.05.2020	59	whole plant no roots grain straw grain straw grain straw	3.2 <0.010 0.042 <0.010 0.039 <0.010 0.037	0 48 48 55 55 64 64	59 87 87 89 89 89 89	BASF method L0076/09 LOQ: 0.010 mg/kg 2x BAS 758 00 F (EC) (plot 2) Treatment: foliar application Storage: wheat whole plant no roots 257 days, wheat ears 227 days, wheat rest of plant without roots 224 days, wheat grain 199 days, wheat straw 203 days
			150	200	75	2 20.05.2020	69	whole plant no roots ears rest of plant without roots grain straw grain straw	2.2 0.060 0.85 <0.010 0.69 <0.010 1.2	0 34 34 41 41 48 48	69 83 83 87 87 89 89	BASF method L0076/09 LOQ: 0.010 mg/kg 2x BAS 560 00 F (SC) (plot 5) Treatment: foliar application Storage: wheat whole plant no roots 257 days, wheat ears 227 days, wheat rest of plant without roots 224 days, wheat grain 199 days, wheat straw 203 days

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

A 2.2.4 Magnitude of residues in livestock

A 2.2.4.1 Livestock feeding studies

No new studies are submitted or required.

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

A 2.2.5.1 Distribution of the residue in peel/pulp

No new studies are submitted or required.

A 2.2.5.2 Processing studies on a core set of representative processes

No new studies are submitted or required.

A 2.2.6 Magnitude of residues in representative succeeding crops

No new studies are submitted or required.

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

No new studies are submitted or required.

A 2.3 Pyraclostrobin

In the following, only relevant data is reported being relevant for the uses of concern (cereals). Beyond that, additional new studies (e.g. metabolism studies) were generated and submitted to RMS Germany in context of the AIR3-process. Those studies and related summaries should therefore be available to all EU member states and are in the meantime also included in the publicly available draft RAR. They are not presented in this Appendix 2.

A 2.3.1 Stability of residues

A 2.3.1.1 Stability of residues during storage of samples

A 2.3.1.1.1 Storage stability of residues in plant products

No further studies are submitted.

A 2.3.1.1.2 Storage stability of residues in animal products

No further studies are submitted.

A 2.3.2 Nature of residues in plants, livestock and processed commodities

A 2.3.2.1 Nature of residue in plants

A 2.3.2.1.1 Nature of residue in primary crops

No further studies are submitted.

A 2.3.2.1.2 Nature of residue in rotational crops

No further studies are submitted.

A 2.3.2.1.3 Nature of residues in processed commodities

No further studies are submitted.

A 2.3.2.2 Nature of residues in livestock

No further studies are submitted.

A 2.3.3 Magnitude of residues in plants

A 2.3.3.1 Wheat

Table A 27: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (EFSA, 2018a)	2	0.250 kg as/ha	14	BBCH 49 - 69	35**
Intended cGAP (1*)	2	0.120 kg as/ha	14	BBCH 30 - 59	56

* 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.

A 2.3.3.1.1 Study 1 – wheat – BAS DocID 2021/2000402

Comments of zRMS:	The study has been accepted. (See also page 144). The objective of the study was to determine the magnitude of residues of BAS 750 F (Mefentrifluconazole) and its triazole metabolites, BAS 500 F (Pyraclostrobin), its metabolite M500F007 and BAS 560 F (Metrafenone) in wheat after treatment with either BAS 758 00 F, BAS 750 01 F, BAS 500 06 F or BAS 560 00 F. The selected application rates, frequency and spray interval cover the Good Agriculture Practice (critical GAP), which will be defined by the label directions. During the 2020 growing season, 4 trials in wheat were conducted in different representative growing areas in Northern Europe to determine the residue level of BAS 750 F (Mefentrifluconazole), BAS 500 F (Pyraclostrobin) and BAS 560 F (Metrafenone) after application of either BAS75800F, BAS75001F, BAS50006F or BAS56000F in or on RAC. All trials consisted of five plots: plot 1 (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). **Plot 2:** In all trials the first application was made 13-14 days before application no. 2 (except of trial L200225: 19 days before application no. 2, see deviation). The second application was performed at BBCH 59. **Plots 3 to 5:** The first application was made at BBCH 49. The second applications were made at BBCH 69. **BAS 758 00 F** (66.6 g BAS 750 F/L, 80.0 g BAS 500 F/L, 100.0 g BAS 560 F/L, EC) was applied in all trials twice at a single rate of 1.5 L/ha formulated product, equals to 0.10 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 on plot 2 with a water volume of 200 L/ha. **BAS 750 01 F** (100.0 g BAS 750 F/L, EC) was applied in all trials twice at a single rate of 1.5 L/ha formulated product, equals to 0.15 kg a.i./ha of BAS 750 F on plot 3 with a water volume of 200 L/ha. **BAS 500 06 F** (200.0 g BAS 500 F/L, EC) was applied in all trials twice at a single rate of 1.25 L/ha formulated product, equals to 0.25 kg a.i./ha of BAS 500 F on plot 4 with a water volume of 200 L/ha. **BAS 560 00 F** (300.0 g BAS 560 F/L, SC) was applied in all trials twice at a single rate of 0.5 L/ha formulated product, equals to 0.15 kg a.i./ha of BAS 560 F on plot 5 with a water volume of 200 L/ha. **Plots 1 and 2:** Wheat specimens 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. At 48-50 DALA the specimens were sampled as grain and straw on plot 2. At 55-57 DALA wheat specimens were collected as grain and straw on plots 1 and 2. At 63-64 DALA specimens were sampled as grain and straw on plot 2. **Plots 1, 3, 4 and 5:** Wheat specimens were collected at BBCH 69 on plot 1 immediately before application no. 2 and directly after application no. 2 on plots 3 to 5 as whole plant no roots. At 34-35 DALA the specimens were sampled as ears and rest of plant without roots or as grain and straw on plot 1 and plots 3 to

5. At 41-42 DALA wheat specimens were collected as grain and straw on plots 3 to 5. At 48-49 DALA specimens were sampled as grain and straw on plots 3 to 5.

All wheat specimens of plots 1 and 2 were analysed for BAS 750 F (Mefentrifluconazole), BAS 500 F (Pyraclostrobin) and its metabolite M500F007, BAS 560 F (Metrafenone) using the BASF Method L0076/09. The method has a limit of quantitation of 0.010 mg/kg.
All wheat specimens of plot 3 were analysed for BAS 750 F (Mefentrifluconazole) using the BASF Method L0076/09. The method has a limit of quantitation of 0.010 mg/kg.
All treated wheat specimens of plot 4 were analysed for BAS 500 F (Pyraclostrobin) and its metabolite M500F007 using the BASF Method L0076/09. The method has a limit of quantitation of 0.010 mg/kg.
All treated wheat specimens of plot 5 were analysed for BAS 560 F (Metrafenone) using the BASF Method L0076/09. The method has a limit of quantitation of 0.010 mg/kg.
The results of the average procedural recoveries in wheat matrices at fortification levels between 0.010 and 10 mg/kg were at 90.4 % for BAS 750 F, at 92.8 % for BAS 500 F, at 95.7 % for M500F007 and at 99.1 % for BAS 560 F. Results are summarized in the tables below.

Table S- 1: Procedural Recoveries for BAS 750 F (Mefentrifluconazole)

Matrix		Fortification Level [mg/kg]	BAS 750 F			
			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

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

Table S- 2: Procedural Recoveries for BAS 500 F (Pyraclostrobin) and its Metabolite M500F007

Matrix		Fortification Level [mg/kg]	BAS 500 F			
			Mean [%]	SD [±]	RSD [%]	n
Wheat	Whole plant no roots	0.010, 0.10 and 10	84.7	7.8	9.2	9
	Ears	0.010, 0.10 and 10	97.5	4.8	4.9	7
	Rest of plant without roots	0.010, 0.10 and 10	96.3	5.5	5.7	7
	Grain	0.010, 0.10 and 1.0	96.8	3.5	3.6	7
	Straw	0.010, 0.10 and 10	91.7	8.8	9.6	11
Overall:			92.8	8.1	8.7	41

Matrix		Fortification Level [mg/kg]	Mean [%]	M500 SD [±]	007 RSD [%]	n
Wheat	Whole plant no roots	0.010, 0.10 and 10	88.6	7.0	7.9	9
	Ears	0.010, 0.10 and 10	101	6.2	6.1	7
	Rest of plant without roots	0.010, 0.10 and 10	101	5.5	5.4	7
	Grain	0.010, 0.10 and 1.0	97.1	4.6	4.8	7
	Straw	0.010, 0.10 and 10	93.7	6.8	7.3	11
		Overall:	95.7	7.7	8.0	41

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

Table S- 3: Procedural Recoveries for BAS 560 F (Metrafenone)

Matrix		Fortification Level [mg/kg]	BAS 560 F			
			Mean [%]	SD [±]	RSD [%]	n
Wheat	Whole plant no roots	0.010, 0.10 and 10	90.8	9.4	10	9
	Ears	0.010, 0.10 and 10	106	4.6	4.4	7
	Rest of plant without roots	0.010, 0.10 and 10	103	4.7	4.6	7
	Grain	0.010, 0.10 and 1.0	99.7	4.0	4.1	7
	Straw	0.010, 0.10 and 10	98.4	4.9	4.9	11
		Overall:	99.1	7.8	7.8	41

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

Further all wheat specimens of plot 1, 2 and 3 were analysed for 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) using the adapted BASF method no. L0170/02. The method has a limit of quantitation of 0.010 mg/kg
for each analyte.

The results of the average procedural recoveries in plant matrices

- at fortification levels between 0.010 and 1.0 mg/kg were 89.4 % for 1,2,4-Triazole,
- at fortification levels between 0.010 and 1.0 mg/kg were 88.7 % for Triazole alanine,
- at fortification levels between 0.010 and 1.0 mg/kg were 97.2 % for Triazole acetic acid,
- at fortification levels between 0.010 and 1.0 mg/kg were 85.5 % for Triazole lactic acid.

Results are summarized in the table below.

Table S- 4: Procedural Recoveries for 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)

Matrix		Recoveries of	Fortification Level [mg/kg]	Mean [%]	SD [±]	RSD [%]	n
Wheat	Whole plant no roots		0.010, 0.10 and 1.0	95.5	7.1	7.5	8

	Ears	1,2,4-Triazole (1,2,4-T)	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
Wheat	Whole plant no roots	Triazole alanine (TA)	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
Wheat	Whole plant no roots	Triazole acetic acid (TAA)	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
Wheat	Whole plant no roots	Triazole lactic acid (TLA)	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

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

Table S- 5: Summary of Residues of BAS 750 F (Mefentrifluconazole) in Wheat

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	1.5 - 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 with BAS 750 01 F (2x 1.5 L/ha)					
1	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

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

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.

Table S- 6: Summary of Residues of BAS 500 F (Pyraclostrobin) and its Metabolite M500F007 in Wheat

Sampl. No.	Portion analyzed	Timing DALA	Growth Stage (BBCH)	n	Range of Residues [mg/kg] BAS 500 F	expressed as parent equivalents M500F007 1)	Sum 2)
Plot 2: treated with BAS 758 00 F (2x 1.5 L/ha)							
1	Whole plant no roots	0	59	4	1.7 - 3.3	0.029 - 0.085	1.7 - 3.3
2	Grain	48 - 50	87 - 89	4	< 0.010	< 0.011	< 0.021
	Straw			4	0.35 - 1.2	0.16 - 0.49	0.50 - 1.7
3	Grain	55 - 57	87 - 89	4	< 0.010	< 0.011	< 0.021
	Straw			4	0.34 - 1.1	0.19 - 0.48	0.53 - 1.6
4	Grain	63 - 64	89	4	< 0.010	< 0.011	< 0.021
	Straw			4	0.40 - 0.58	0.22 - 0.32	0.62 - 0.89
Plot 4: treated with BAS 500 06 F (2x 1.25 L/ha)							
1	Whole plant no roots	0	69	4	2.5 - 5.3	0.11 - 0.36	2.6 - 5.6
2	Ears	34	83	1	0.20	0.12	0.32
	Rest of plant without roots			1	0.77	0.47	1.2
	Grain	34 - 35	85 - 89	3	< 0.010 - 0.014	< 0.011	< 0.021 - 0.025
	Straw			3	1.7 - 3.3	0.82 - 1.3	2.6 - 4.6
3	Grain	41 - 42	87 - 89	4	< 0.010 - 0.016	< 0.011	< 0.021 - 0.027
	Straw			4	0.81 - 4.6	0.51 - 2.0	1.3 - 6.6
4	Grain	48 - 49	89	4	< 0.010 - 0.022	< 0.011	< 0.021 - 0.033
	Straw			4	0.98 - 4.5	0.64 - 1.7	1.6 - 6.2

DALA = days after last application n = Number of specimens
General: The limit of quantification (LOQ) is 0.010 mg/kg for BAS 500 F and 0.011 mg/kg for M500F007 (expressed as parent equivalent).
1) Conversion factor for calculation of M500F007 to parent BAS 500 F is 1.084
2) for residues of BAS 500 F < 0.010 mg/kg, value was set to 0.010 mg/kg for calculation of sum and for residues of M500F007, expressed as parent equivalent < 0.011 mg/kg, value was set to 0.011 mg/kg for calculation of sum; if both values are below LOQ the sum is <0.021 mg/kg

<u>Residues of BAS 500 F (Pyraclostrobin)</u>

Plot 2: The residues of **BAS 500 F** analyzed in wheat whole plant no roots specimens sampled immediately after the last application (59 BBCH) ranged from 1.7 to 3.3 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 500 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 500 F were analyzed between 0.35 and 1.2 mg/kg. At 55-57 DALA (87-89 BBCH) and 63-64 DALA (89 BBCH) residues of BAS 500 F were in a range from 0.34 to 1.1 mg/kg and from 0.40 to 0.58 mg/kg, respectively.

Plot 4: The residues of **BAS 500 F** analyzed in wheat whole plant no roots specimens sampled immediately after the last application (69 BBCH) ranged from 2.5 to 5.3 mg/kg.

In ears specimens collected at 34 DALA (83 BBCH) a residue of BAS 500 F was found at 0.20 mg/kg. Rest of plant without roots specimens taken at the same sampling event showed a residue of BAS 500 F of 0.77 mg/kg.

In grain specimens sampled at 34-35 DALA (85-89 BBCH) residues of BAS 500 F were found between < 0.010 and 0.014 mg/kg. At 41-42 DALA (87-89 BBCH) and 48-49 DALA (89 BBCH) residues were analyzed from < 0.010 to 0.016 mg/kg and from < 0.010 to 0.022 mg/kg, respectively.

In straw specimens sampled at 34-35 DALA (85-89 BBCH) residues of BAS 500 F ranged from 1.7 to 3.3 mg/kg. At 41-42 DALA (87-89 BBCH) and 48-49 DALA (89 BBCH) residues were analyzed from 0.81 to 4.6 mg/kg and from 0.98 to 4.5 mg/kg, respectively.

Plot 2: The residues of **M500F007 (expressed as parent equivalent)** analyzed in wheat whole plant no roots specimens sampled immediately after the last application (59 BBCH) ranged from 0.029 to 0.085 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 M500F007 were found at or above the LOQ (0.011 mg/kg).

In straw specimens sampled at 48-50 DALA (87-89 BBCH) residues of M500F007 were analyzed between 0.16 and 0.49 mg/kg. At 55-57 DALA (87-89 BBCH) and 63-64 DALA (89 BBCH) residues of M500F007 were in a range from 0.19 to 0.48 mg/kg and from 0.22 to 0.32 mg/kg, respectively.

Plot 4: The residues of **M500F007 (expressed as parent equivalent)** analyzed in wheat whole plant no roots specimens sampled immediately after the last application (69 BBCH) ranged from 0.11 to 0.36 mg/kg.

In ears specimens collected at 34 DALA (83 BBCH) a residue of M500F007 was found at 0.12 mg/kg. Rest of plant without roots specimens taken at the same sampling event showed a residue of M500F007 of 0.47 mg/kg.

In grain specimens sampled at 34-35 DALA (85-89 BBCH), 41-42 DALA (87-89 BBCH) and 48-49 DALA (89 BBCH) no residues of M500F007 were found at or above the LOQ (0.011 mg/kg).

In straw specimens sampled at 34-35 DALA (85-89 BBCH) residues of M500F007 ranged from 0.82 to 1.3 mg/kg. At 41-42 DALA (87-89 BBCH) and 48-49 DALA (89 BBCH) residues were analyzed from 0.51 to 2.0 mg/kg and from 0.64 to 1.7 mg/kg, respectively.

No residues of BAS 500 F and its metabolite M500F007 were detected at or above the LOQ in any of the untreated control samples.

Bridging showed, that the new formulation BAS 758 00 F does not lead to higher residues than the respective solo formulation BAS 500 06 F

Table S- 7: Summary of Residues of BAS 560 F (Metrafenone) in Wheat

Sampl. No.	Portion analyzed	Timing DALA	Timing Growth stage (BBCH)	n	Range of Residues (mg/kg) BAS 560 F
Plot 2: treated with BAS 758 00 F (2x 1.5 L/ha)					
1	Whole plant no roots	0	59	4	1.7 - 3.2
2	Grain	48 - 50	87 - 89	4	< 0.010
	Straw			4	0.033 - 0.086
3	Grain	55 - 57	87 - 89	4	< 0.010
	Straw			4	0.034 - 0.070
4	Grain	63 - 64	89	4	< 0.010
	Straw			4	0.026 - 0.040
Plot 5: treated with BAS 560 00 F (2x 0.5 L/ha)					
1	Whole plant no roots	0	69	4	2.1 - 3.1
2	Ears	34	83	1	0.060
	Rest of plant without roots			1	0.85
	Grain	34 - 35	85 - 89	3	< 0.010
	Straw			3	0.78 - 2.9
3	Grain	41 - 42	87 - 89	4	< 0.010
	Straw			4	0.69 - 3.8
4	Grain	48 - 49	89	4	< 0.010
	Straw			4	1.1 - 3.1

DALA = days after last application n = Number of specimens
General: The limit of quantification (LOQ) is 0.010 mg/kg for BAS 560 F.

Residues of BAS 560 F (Metrafenone)

Plot 2: The residues of **BAS 560 F** analyzed in wheat whole plant no roots specimens sampled
immediately after the last application (59 BBCH) ranged from 1.7 to 3.2 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 560 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 560 F were analyzed between 0.033 and 0.086 mg/kg. At 55-57 DALA (87-89 BBCH) and 63-64 DALA (89 BBCH) residues of BAS 560 F were in a range from 0.034 to 0.070 mg/kg and from 0.026 to 0.040 mg/kg, respectively.
Plot 5: The residues of **BAS 560 F** analyzed in wheat whole plant no roots specimens sampled immediately after the last application (69 BBCH) ranged from 2.1 to 3.1 mg/kg.
In ears specimens collected at 34 DALA (83 BBCH) a residue of BAS 560 F was found at 0.060 mg/kg. Rest of plant without roots specimens taken at the same sampling event showed a residue of BAS 560 F of 0.85 mg/kg.
In grain specimens sampled at 34-35 DALA (85-89 BBCH), 41-42 DALA (87-89 BBCH) and 48-49DALA (89BBCH) no residues of BAS560F were found at or above

the LOQ (0.010 mg/kg).
In straw specimens sampled at 34-35 DALA (85-89 BBCH) residues of BAS 560 F ranged from 0.78 to 2.9 mg/kg. At 41-42 DALA (87-89 BBCH) and 48-49 DALA (89 BBCH) residues were analyzed from 0.69 to 3.8 mg/kg and from 1.1 to 3.1 mg/kg, respectively.
In the untreated control specimens, no residues of BAS 560 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 560 00 F.

Table S- 8: Summary of residues in the untreated Wheat Specimens for 1,2,4-Triazole (1,2,4-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 (1,2,4-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	< 0.010 – 0.040	< 0.010 – 0.058	< 0.010 – 0.045
3	Grain	55 – 57	87-89	4	< 0.010	0.045 – 0.14	0.021 – 0.14	< 0.010
	Straw			4	< 0.010	< 0.010 – 0.010	< 0.010 – 0.11	< 0.010 – 0.041
Plot 1 – untreated (in regard to plot 3)								
1	Whole plant no roots	0 DBLA	69	4	< 0.010	< 0.010 – 0.042	< 0.010 – 0.057	< 0.010 – 0.034
2	Ears	34	83	1	< 0.010	0.075	0.038	< 0.010
	Rest of plant without roots			1	< 0.010	< 0.010	0.016	0.023
2	Grain	34-35	85-89	3	< 0.010	0.038 – 0.13	0.019 – 0.11	< 0.010
	Straw			3	< 0.010	< 0.010 – 0.017	< 0.010 – 0.098	< 0.010 – 0.040

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

Table S- 9: Summary of residues in the treated Wheat Specimens for 1,2,4-Triazole (1,2,4-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 (1,2,4-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	0.010 - 0.034	< 0.010 - 0.042	< 0.010 - 0.029
2	Grain	49-50	85-89	4	< 0.010	0.10 - 0.17	0.035 - 0.10	< 0.010
	Straw			4	< 0.010	< 0.010 - 0.011	< 0.010 - 0.077	0.010 - 0.050
3	Grain	56-57	87-89	4	< 0.010	0.10 - 0.19	0.038 - 0.10	< 0.010

	Straw			4	< 0.010	< 0.010	0.012 - 0.078	0.010 - 0.064
4	Grain	63-64	89	4	< 0.010	0.086 - 0.16	0.036 - 0.097	< 0.010
	Straw			4	< 0.010	< 0.010	< 0.010 - 0.078	< 0.010 - 0.042
Plot 3: treated with BAS 750 01 F (2x 1.5 L/ha)								
1	Whole plant no roots	0	69	4	< 0.010	0.014 - 0.056	< 0.010 - 0.047	< 0.010 - 0.029
2	Ears	34	83	1	< 0.010	0.15	0.055	< 0.010
	Rest of plant without roots			1	< 0.010	< 0.010	0.019	0.044
	Grain	34 - 35	85-89	3	< 0.010	0.15 - 0.21	0.041 - 0.14	< 0.010
	Straw			3	< 0.010	< 0.010 - 0.013	< 0.010 - 0.10	0.014 - 0.068
3	Grain	41 - 42	87-89	4	< 0.010	0.16 - 0.22	0.040 - 0.10	< 0.010
	Straw			4	< 0.010	< 0.010 - 0.015	0.016 - 0.076	0.016 - 0.048
4	Grain	48 - 49	89	4	< 0.010	0.15 - 0.22	0.041 - 0.14	< 0.010
	Straw			4	< 0.010	< 0.010 - 0.016	0.014 - 0.10	0.010 - 0.066

DALA = days after last application n = Number of specimens

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. Furthermore, due to high residue found, additional fortifications were performed to cover the highest residue. Overall and average recoveries were all in the range of 70 – 110 % and relative standard deviations (RSD) were < 20 %.

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 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 28: 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 29: Summary of recoveries of BAS 500 F in wheat matrices

Matrix		Fortification level [mg/kg]	BAS 500 F			
			n	Mean [%]	SD [±]	RSD [%]
Wheat	Whole plant no roots	0.010, 0.10 and 10	9	84.7	7.8	9.2
	Ears	0.010, 0.10 and 10	7	97.5	4.8	4.9
	Rest of plant without roots	0.010, 0.10 and 10	7	96.3	5.5	5.7
	Grain	0.010, 0.10 and 1.0	7	96.8	3.5	3.6
	Straw	0.010, 0.10 and 10	11	91.7	8.8	9.6
	Overall		**41**	**92.8**	**8.1**	**8.7**

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

Table A 30: **Summary of recoveries of M500F007 in wheat matrices**

Matrix		Fortification level [mg/kg]	M500F007			
			n	Mean [%]	SD [±]	RSD [%]
Wheat	Whole plant no roots	0.010, 0.10 and 10	9	88.6	7.0	7.9
	Ears	0.010, 0.10 and 10	7	101	6.2	6.1
	Rest of plant without roots	0.010, 0.10 and 10	7	101	5.5	5.4
	Grain	0.010, 0.10 and 1.0	7	97.1	4.6	4.8
	Straw	0.010, 0.10 and 10	11	93.7	6.8	7.3
	Overall		41	95.7	7.7	8.0

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

Table A 31: Summary of residues of BAS 500 F and M500F007 on wheat in Northern Europe 2020 (treated)

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 500 F	M500F007[1)]	sum[2)]		
	(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	0.12	200	0.06	**Plot 2** 18.05.2020 01.06.2020	59	whole plant no roots grain straw grain straw grain straw	1.9 <0.010 0.94 <0.010 0.51 <0.010 0.51	0.080 <0.011 0.41 <0.011 0.28 <0.011 0.23	1.9 <0.021 1.3 <0.021 0.78 <0.021 0.74	0 49 49 56 56 63 63	2021/2000402 Plot 2: BAS 758 00 F EC Mefentrifluconazole 66.6 g/L Pyraclostrobin 80.0 g/L Plot 4: BAS 500 06 F EC Pyraclostrobin 200 g/L BASF method L0076/09 for Pyraclostrobin and M500F007 LOQ: 0.010 mg/kg for BAS 500 F LOQ: 0.011 mg/kg for M500F007 as parent equivalent Storage time for all commodities ≤264 days (Pyraclostrobin and M500F007) None of the untreated samples examined had any residue of BAS 500 F (Pyraclostrobin) exceeding the respective LOQ (0.010 mg/kg). None of the untreated samples examined had any residue of M500F007 exceeding the respective LOQ (0.011 mg/kg, expressed as
			0.25	200	0.125	**Plot 4** 25.05.2020 16.06.2020	69	whole plant no roots grain straw grain straw grain straw	2.5 0.014 1.7 0.016 2.4 0.022 2.3	0.11 <0.011 0.89 <0.011 1.1 <0.011 1.1	2.6 0.025 2.6 0.027 3.5 0.033 3.4	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	0.12	200	0.06	**Plot 2** 18.05.2020 31.05.2020	59	whole plant no roots grain straw grain straw grain straw	1.7 <0.010 0.55 <0.010 0.70 <0.010 0.58	0.029 <0.011 0.21 <0.011 0.29 <0.011 0.24	1.7 <0.021 0.76 <0.021 0.99 <0.021 0.82	0 50 50 57 57 64 64	
			0.25	200	0.125	**Plot 4** 20.05.2020 12.06.2020	69	whole plant no roots grain straw grain straw grain straw	4.0 <0.010 2.0 <0.010 2.3 <0.010 2.8	0.19 <0.011 0.82 <0.011 0.92 <0.011 1.1	4.2 <0.021 2.8 <0.021 3.2 <0.021 3.9	0 35 35 42 42 49 49	

Trial No./ Location/ EU zone/ Year	**Commodity/ Variety** (a)	**Date of 1.Sowing or planting 2.Flowering 3. Harvest** (b)	**Application rate per treatment**			**Dates of treatment or no. of treatments and last date*** (c)	**Growth stage at last treatment or date**	**Portion analyzed**	**Residues (mg/kg)**			**PHI (days)** (d)	**Details on trial** (e)
			kg a.s./ ha	**Water (l/ha)**	**kg a.s./hl**				**BAS 500 F**	**M500F007[1)]**	**sum[2)]**		
2021/2000402 L200225 64-020 Jasien Wielkopolska Poland EU-North 2020	Wheat GC 0654 / Arkadia	1. 15.10.2019 2. 03.06-10.06.2020 3. 04.08.2020	0.12	200	0.06	**Plot 2** 13.05.2020 01.06.2020	59	whole plant no roots grain straw grain straw grain straw	2.3 <0.010 1.2 <0.010 1.1 <0.010 0.57	0.085 <0.011 0.49 <0.011 0.48 <0.011 0.32	2.3 <0.021 1.7 <0.021 1.6 <0.021 0.89	0 49 49 56 56 64 64	parent equivalent).
			0.25	200	0.125	**Plot 4** 26.05.2020 10.06.2020	69	whole plant no roots grain straw grain straw grain straw	5.3 <0.010 3.3 <0.010 4.6 <0.010 4.5	0.31 <0.011 1.3 <0.011 2.0 <0.011 1.7	5.6 <0.021 4.6 <0.021 6.6 <0.021 6.2	0 34 34 42 42 49 49	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date* (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)			PHI (days) (d)	Details on trial (e)
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				BAS 500 F	M500F007[1)]	sum[2)]		
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	0.12	200	0.06	**Plot 2** 30.04.2020 13.05.2020	59	whole plant no roots grain straw grain straw grain straw	3.3 <0.010 0.35 <0.010 0.34 <0.010 0.40	0.064 <0.011 0.16 <0.011 0.19 <0.011 0.22	3.3 <0.021 0.50 <0.021 0.53 <0.021 0.62	0 48 48 55 55 64 64	
			0.25	200	0.125	**Plot 4** 05.05.2020 20.05.2020	69	whole plant no roots ears rest of plant w/o grain straw grain straw	5.1 0.20 0.77 <0.010 0.81 <0.010 0.98	0.36 0.12 0.47 <0.011 0.51 <0.011 0.64	5.4 0.32 1.2 <0.021 1.3 <0.021 1.6	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
1) Conversion factor for calculation of M500F007 to parent BAS 500 F is 1.084
2) for residues of BAS 500 F < 0.010 mg/kg, value was set to 0.010 mg/kg for calculation of sum and for residues of M500F007, expressed as parent equivalent < 0.011 mg/kg, value was set to 0.011 mg/kg for calculation of sum; if both values are below LOQ the sum is <0.021 mg/kg
* Plot 2 was treated with formulation BAS 758 00 F and plot 4 was treated with formulation BAS 500 06 F
In the untreated control specimens, no residues of BAS 500 F were detected at or above the limit of quantitation (LOQ, 0.010 mg/kg).
In the untreated control specimens, no residues of M500F007 were detected at or above the limit of quantitation (LOQ, 0.011 mg/kg, expressed as parent equivalent).

A 2.3.3.2 Barley

Table A 32: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (EFSA, 2018a)	2	0.250 kg as/ha	14	BBCH 49 - 69	35**
Intended cGAP (2*)	2	0.120 kg as/ha	14	BBCH 30 - 59	56

* 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.

A 2.3.3.2.1 Study 2 – barley – BAS DocID 2021/2000401

Comments of zRMS:	The study has been accepted (see also page 161) The objective of the study was to determine the magnitude of residues of BAS 750 F (Mefentrifluconazole) and its triazole metabolites, BAS 500 F (Pyraclostrobin), its metabolite M500F007 and BAS 560 F (Metrafenone) in barley after treatment with either BAS 758 00 F, BAS 750 01 F, BAS 500 06 F or BAS 560 00 F. The selected application rates, frequency and spray interval cover the Good Agriculture Practice (critical GAP), which will be defined by the label directions. During the 2020 growing season, 4 trials in barley were conducted in different representative growing areas in Northern Europe to determine the residue level of BAS750F (Mefentrifluconazole), BAS 500 F (Pyraclostrobin) and BAS 560 F (Metrafenone) after application of either BAS75800F, BAS75001F, BAS50006F or BAS56000F in or on Raw Agricultural Commodities (RAC). All trials consisted of five plots: plot 1 (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). **BAS 758 00 F** (66.6 g BAS 750 F/L, 80.0 g BAS 500 F/L, 100.0 g BAS 560 F/L, EC) was applied in all trials twice at a single rate of 1.5 L/ha formulated product, equals to 0.10 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 on plot 2 with a water volume of 200 L/ha. **BAS 750 01 F** (100.0 g BAS 750 F/L, EC) was applied in all trials twice at a single rate of 1.5 L/ha formulated product, equals to 0.15 kg a.i./ha of BAS 750 F on plot 3 with a water volume of 200 L/ha. **BAS 500 06 F** (200.0 g BAS 500 F/L, EC) was applied in all trials twice at a single rate of 1.25 L/ha formulated product, equals to 0.25 kg a.i./ha of BAS 500 F on plot 4 with a water volume of 200 L/ha. **BAS 560 00 F** (300.0 g BAS 560 F/L, SC) was applied in all trials twice at a single rate of 0.5 L/ha formulated product, equals to 0.15 kg a.i./ha of BAS 560 F on plot 5 with a water volume of 200 L/ha.

Plot 2: In all trials the first application was made 13-15 days before application no. 2 (except of trial L200230: 11 days before application no. 2, see deviation). The second application was performed at BBCH 59.
Plot 3 to 5: The first application was made at BBCH 49. The second application was made at BBCH 69.
Plot 1 and 2: Barley specimens 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.
At 48-49 DALA the specimens were sampled as grain and straw on plot 2.
At 55-56 DALA barley specimens were collected as grain and straw on plot 1 and 2.
At 62-63 specimens were sampled as grain and straw on plot 2 (except of trial L200230: sampling no. 4 could not be performed, see deviation).
Plot 1, 3, 4 and 5: Barley specimens were collected at BBCH 69 on plot 1 immediately before application no. 2 and directly after application no. 2 on plot 3 to 5 as whole plant no roots.
At 27-28 DALA specimens were collected as ears and rest of plant without roots or as grain and straw on plot 3 to 5.
At 34-35 DALA the specimens were sampled as grain and straw on plot 1 and 3 to 5. At 41-43 DALA barley specimens were collected as grain and straw on plot 3 to 5.
All barley specimens of plot 1 and 2 were analysed for BAS 750 F (Mefentrifluconazole), BAS 500 F (Pyraclostrobin) and its metabolite M500F007, BAS 560 F (Metrafenone) using the BASF Method L0076/09. The method has a limit of quantitation of 0.010 mg/kg.
All barley specimens of plot 3 were analysed for BAS 750 F (Mefentrifluconazole) using the BASF Method L0076/09. The method has a limit of quantitation of 0.010 mg/kg.
All treated barley specimens of plot 4 were analysed for BAS 500 F (Pyraclostrobin) and its metabolite M500F007 using the BASF Method L0076/09. The method has a limit of quantitation of 0.010 mg/kg.
All treated barley specimens of plot 5 were analysed for BAS 560 F (Metrafenone) using the BASF Method L0076/09. The method has a limit of quantitation of 0.010 mg/kg.
The results of the average procedural recoveries in barley matrices at fortification levels between 0.010 and 10 mg/kg were at 78.7 % for BAS 750 F, at 83.3 % for BAS 500 F, at 83.7 % for M500F007 and at 88.8 % for BAS 560 F. Results are summarized in the tables below.

Table S- 1: Procedural Recoveries for BAS 750 F (Mefentrifluconazole)

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

Table S- 2: Procedural Recoveries for BAS 500 F (Pyraclostrobin) and its Metabolite M500F007

Matrix		**Fortification Level [mg/kg]**	**BAS 500 F**			
			Mean [%]	**SD [±]**	**RSD [%]**	**n**
Barley	Whole plant no roots	0.010, 0.10 and 10	92.3	4.7	5.1	7
	Ears	0.010, 0.10 and 10	74.2	2.5	3.4	8
	Rest of plant without roots	0.010, 0.10 and 10	73.5	3.7	5.0	7
	Grain	0.010, 0.10 and 10	86.6	3.5	4.0	7
	Straw	0.010, 0.10 and 10	91.3	4.6	5.0	7
Overall:			83.3	9.1	11	36
Matrix		**Fortification Level [mg/kg]**	**Mean [%]**	**M500 SD [±]**	**007 RSD [%]**	**n**
Barley	Whole plant no roots	0.010, 0.10 and 10	88.6	5.4	6.1	7
	Ears	0.010, 0.10 and 10	78.4	3.5	4.5	8
	Rest of plant without roots	0.010, 0.10 and 10	78.3	7.0	8.9	7
	Grain	0.010, 0.10 and 10	85.9	4.3	5.0	7
	Straw	0.010, 0.10 and 10	87.9	2.5	2.8	7
Overall:			83.7	6.4	7.7	36

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

Table S- 3: Procedural Recoveries for BAS 560 F (Metrafenone)

Matrix		**Fortification Level [mg/kg]**	**BAS 560 F**			
			Mean [%]	**SD [±]**	**RSD [%]**	**n**
Barley	Whole plant no roots	0.010, 0.10 and 10	94.4	6.9	7.3	7
	Ears	0.010, 0.10 and 10	81.2	3.5	4.4	8
	Rest of plant without roots	0.010, 0.10 and 10	79.4	4.6	5.8	7
	Grain	0.010, 0.10 and 10	92.4	6.2	6.7	7
	Straw	0.010, 0.10 and 10	98.0	7.7	7.8	7
Overall:			88.8	9.4	11	36

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

Further all barley specimens of plot 1, 2 and 3 were analysed for 1,2,4-Triazole (T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) using the adapted BASF method no. L0170/02. The method has a limit of quantitation of 0.010 mg/kg for each analyte.

The results of the average procedural recoveries in plant matrices
- at fortification levels between 0.010 and 1.0 mg/kg were 89.2 % for 1,2,4-Triazole,
- at fortification levels between 0.010 and 1.0 mg/kg were 89.0 % for Triazole alanine,
- at fortification levels between 0.010 and 1.0 mg/kg were 97.5 % for Triazole acetic acid, – at fortification levels between 0.010 and 1.0 mg/kg were 92.1 % for Triazole lactic acid.

Results are summarized in the table below.

Table S- 4: Procedural Recoveries for 1,2,4-Triazole (T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (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

Table S- 5: Summary of Residues of BAS 750 F (Mefentrifluconazole) in Barley

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.

<u>**Residues of BAS 750 F (Mefentrifluconazole)**</u>

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 0.026to 0.10mg/kg and from 0.021 to 0.040mg/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 0.056mg/kg. At 34-35 DALA (85-87BBCH) and 41-43 DALA (89BBCH) 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.

Table S- 6: Summary of Residues of BAS 500 F (Pyraclostrobin) and its Metabolite M500F007 in Barley

Sampl. No.	Portion analyzed	Timing DALA	Growth Stage (BBCH)	n	Range of Residues [mg/kg] BAS 500 F	expressed as parent equivalent M500F007 1)	Sum 2)
Plot 2: treated with BAS 758 00 F (2x 1.5 L/ha)							
1	Whole plant no roots	0	59	4	1.8 - 4.4	0.027 - 0.11	1.8 - 4.5
2	Grain	48-49	87-89	4	0.013 - 0.044	0.014 - 0.016	0.026 - 0.060
	Straw			4	0.17 - 0.69	0.092 - 0.47	0.26 - 1.2
3	Grain	55-56	89	4	0.017 - 0.047	0.012 - 0.018	0.031 - 0.064
	Straw			4	0.29 - 1.0	0.16 - 0.38	0.44 - 1.4
4	Grain	62-63	89	3	0.019 - 0.036	< 0.011 - 0.014	0.030 - 0.050
	Straw			3	0.40 - 0.86	0.24 - 0.29	0.63 - 1.1
Plot 4: treated with BAS 500 06 F (2x 1.25 L/ha)							
1	Whole plant no roots	0	69	4	2.7 - 5.8	0.089 - 0.25	2.8 - 6.0
2	Ears	27-28	77-83	3	0.052 - 0.23	0.097 - 0.18	0.15 - 0.41
	Rest of plant without roots			3	0.46 - 2.7	0.22 - 0.81	0.68 - 3.5
	Grain	27	85	1	0.047	0.026	0.073
	Straw			1	0.33	0.16	0.50
3	Grain	34-35	85-87	4	0.029 - 0.13	0.032 - 0.079	0.080 - 0.21
	Straw			4	0.40 - 2.0	0.20 - 0.68	0.60 - 2.7
4	Grain	41-43	89	4	0.039 - 0.13	0.029 - 0.080	0.072 - 0.21
	Straw			4	0.37 - 2.4	0.25 - 0.83	0.62 - 3.2

DALA = days after last application n = Number of specimens
General: The limit of quantification (LOQ) is 0.010 mg/kg for BAS 500 F and 0.011 mg/kg for M500F007 (expressed as parent equivalent).
1) Conversion factor for calculation of M500F007 to parent BAS 500 F is 1.084
2) for residues of BAS 500 F < 0.010 mg/kg, value was set to 0.010 mg/kg for calculation of sum and for residues
of M500F007, expressed as parent equivalent < 0.011 mg/kg, value was set to 0.011 mg/kg for calculation of sum; if both values are below LOQ the sum is <0.021 mg/kg

Residues of BAS 500 F (Pyraclostrobin) and its metabolite M500F007

Plot 2: The residues of **BAS 500 F** analyzed in barley whole plant no roots specimens sampled
immediately after the last application (59 BBCH) ranged from 1.8 to 4.4 mg/kg.

In grain specimens collected at 48-49 DALA (87-89 BBCH) residues of BAS 500 F were found between 0.013 and 0.044 mg/kg. At 55-56 DALA (89 BBCH) and 62-63 DALA (89 BBCH) the residues were in a range from 0.017 to 0.047 mg/kg and from 0.019 to 0.036 mg/kg,
respectively.

In straw specimens sampled at 48-49 DALA (87-89 BBCH) residues of BAS 500 F were analyzed between 0.17 and 0.69 mg/kg. At 55-56 DALA (89 BBCH) and 62-63 DALA (89 BBCH) residues of BAS 500 F were in a range from 0.29 to 1.0 mg/kg and from 0.40 to 0.86 mg/kg, respectively.

Plot 4: The residues of **BAS 500 F** analyzed in barley whole plant no roots specimens sampled immediately after the last application (69 BBCH) ranged from 2.7 to 5.8 mg/kg.

In ears specimens collected at 27-28 DALA (77-83 BBCH) residues of BAS 500 F were analyzed between 0.052 and 0.23 mg/kg. Rest of plant without roots specimens taken at the same sampling event showed residues from 0.46 to 2.7 mg/kg.

In grain specimens collected at 27 DALA (85 BBCH) a residue of BAS 500 F was found at 0.047 mg/kg. At 34-35 DALA (85-87 BBCH) and 41-43 DALA (89 BBCH) residues of BAS 500 F were analyzed in grain specimens from 0.029 to 0.13 mg/kg and from 0.039 to 0.13 mg/kg, respectively.

In straw specimens collected at 27 DALA (85 BBCH) a residue of BAS 500 F was found at 0.33 mg/kg. At 34-35 DALA (85-87 BBCH) and 41-43 DALA (89 BBCH) residues of BAS 500 F were analyzed in straw specimens in a range from 0.40 to 2.0 mg/kg and from 0.37 to 2.4 mg/kg, respectively.

In the untreated control specimens, no residues of BAS 500 F were detected at or above the limit of quantitation (LOQ, 0.010 mg/kg).

Plot 2: The residues of **M500F007 (expressed as parent equivalent)** analyzed in barley whole plant no roots specimens sampled immediately after the last application (59 BBCH) ranged from 0.027 to 0.11 mg/kg.

In grain specimens collected at 48-49 DALA (87-89 BBCH) residues of M500F007 were found between 0.014 and 0.016 mg/kg. At 55-56 DALA (89 BBCH) and 62-63 DALA (89 BBCH) the residues were in a range from 0.012 to 0.018 mg/kg and from < 0.011 to 0.014 mg/kg, respectively.

In straw specimens sampled at 48-49 DALA (87-89 BBCH) residues of M500F007 were analyzed between 0.092 and 0.47 mg/kg. At 55-56 DALA (89 BBCH) and 62-63 DALA (89 BBCH) residues of M500F007 were in a range from 0.16 to 0.38 mg/kg and from 0.24 to 0.29 mg/kg, respectively.

Plot 4: The residues of **M500F007 (expressed as parent equivalent)** analyzed in barley whole plant no roots specimens sampled immediately after the last application (69 BBCH) ranged from 0.089 to 0.25 mg/kg.

In ears specimens collected at 27-28 DALA (77-83 BBCH) residues of M500F007 were analyzed between 0.097 and 0.18 mg/kg. Rest of plant without roots specimens taken at the same sampling event showed residues from 0.22 to 0.81 mg/kg.

In grain specimens collected at 27 DALA (85 BBCH) a residue of M500F007 was found at 0.026 mg/kg. At 34-35 DALA (85-87 BBCH) and 41-43 DALA (89 BBCH) residues of M500F007 were analyzed in grain specimens from 0.032 to 0.079 mg/kg and from 0.029 to 0.080 mg/kg, respectively.

In straw specimens collected at 27 DALA (85 BBCH) a residue of M500F007 was found at 0.16 mg/kg. At 34-35 DALA (85-87 BBCH) and 41-43 DALA (89 BBCH) residues of M500F007 were analyzed in straw specimens in a range from 0.20 to 0.68 mg/kg and from 0.25 to 0.83 mg/kg, respectively.

In the untreated control specimens, no residues of M500F007 were detected at or above the limit of quantitation (LOQ, 0.011 mg/kg, expressed as parent equivalent).

Bridging showed, that the new formulation BAS 758 00 F does not lead to higher residues than the respective solo formulation BAS 500 06 F.

Table S- 7: Summary of Residues of BAS 560 F (Metrafenone) in Barley

Sampl. No.	Portion analyzed	Timing DALA	Timing Growth stage (BBCH)	n	Range of Residues (mg/kg) BAS 560 F
Plot 2: treated with BAS 758 00 F (2x 1.5 L/ha)					
1	Whole plant no roots	0	59	4	2.1 - 3.6
2	Grain	48-49	87-89	4	< 0.010 - 0.021
	Straw			4	0.031 - 0.13
3	Grain	55-56	89	4	< 0.010 - 0.023
	Straw			4	0.057 - 0.12
4	Grain	62-63	89	3	< 0.010 - 0.018
	Straw			3	0.085 - 0.14
Plot 5: treated with BAS 560 00 F (2x 0.5 L/ha)					
1	Whole plant no roots	0	69	4	1.9 - 3.2
2	Ears	27-28	77-83	3	0.051 – 0.071
	Rest of plant without roots			3	0.73 - 2.2
	Grain	27	85	1	0.051
	Straw			1	0.30
3	Grain	34-35	85-87	4	0.020 - 0.064
	Straw			4	0.29 - 1.5
4	Grain	41-43	89	4	0.026 - 0.052
	Straw			4	0.34 - 1.2

DALA = days after last application n = Number of specimens General: The limit of quantification (LOQ) is 0.010 mg/kg for BAS 560 F.

<u>Residues of BAS 560 F (Metrafenone)</u>

Plot 2: The residues of **BAS 560 F** analyzed in barley whole plant no roots specimens sampled immediately after the last application (59 BBCH) ranged from 2.1 to 3.6 mg/kg.

In grain specimens collected at 48-49 DALA (87-89 BBCH) residues of BAS 560 F were found between < 0.010 and 0.021 mg/kg. At 55-56 DALA (BBCH) and 62-63 DALA (89 BBCH) the residues were in a range from < 0.010 to 0.023 mg/kg and from < 0.010 to 0.018 mg/kg,

respectively.

In straw specimens sampled at 48-49 DALA (87-89 BBCH) residues of BAS 560 F were analyzed between 0.031 and 0.13 mg/kg. At 55-56 DALA (89 BBCH) and 62-63 DALA (89 BBCH) residues of BAS 560 F were in a range from 0.057 to 0.12 mg/kg and from 0.085 to 0.14 mg/kg, respectively.

Plot 5: The residues of **BAS 560 F** analyzed in barley whole plant no roots specimens sampled
immediately after the last application (69 BBCH) ranged from 1.9 to 3.2 mg/kg.

In ears specimens collected at 27-28 DALA (77-83 BBCH) residues of BAS 560 F were analyzed between 0.051 and 0.071 mg/kg. Rest of plant without roots specimens taken at the
same sampling event showed residues from 0.73 to 2.2 mg/kg.

In grain specimens collected at 27 DALA (85 BBCH) a residue of BAS 560 F was found at 0.051 mg/kg. At 34-35 DALA (85-87 BBCH) and 41-43 DALA (89 BBCH) residues of BAS 560 F were analyzed in grain specimens from 0.020 to 0.064 mg/kg and from 0.026 to
0.052 mg/kg, respectively.

In straw specimens collected at 27 DALA (85 BBCH) a residue of BAS 560 F was found at 0.30 mg/kg. At 34-35 DALA (85-87 BBCH) and 41-43 DALA (89 BBCH) residues of BAS 560 F were analyzed in straw specimens in a range from 0.29 to 1.5 mg/kg and from 0.34 to
1.2 mg/kg, respectively.

In the untreated control specimens, no residues of BAS 560 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 560 00 F.

Table S- 8: Summary of residues in the untreated Barley Specimens for 1,2,4-Triazole (T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA)

Sampl. No.	Portion analyzed	Timing		n	Range of Triazole residues and related analytes [mg/kg]			
		DALA	Growth Stage (BBCH)		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.

Table S- 9: Summary of residues in the treated Barley Specimens 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

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. Furthermore, due to high residue found, additional fortifications were performed to cover the highest residue. Overall and average recoveries were all in the range of 70 - 110 % and relative standard deviations (RSD) were < 20 %.

Reference: CA 6.3.1/2

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

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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 33: 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 Rate (kg a.s./ha)	Application Water vol. (L/ha)	Target Timing Appl.	Target Timing 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 34: Summary of recoveries of BAS 500 F in barley matrices

Matrix		Fortification level [mg/kg]	BAS 500 F			
			n	Mean [%]	SD [±]	RSD [%]
Barley	Whole plant no roots	0.010, 0.10 and 10	7	92.3	4.7	5.1
	Ears	0.010, 0.10 and 10	8	74.2	2.5	3.4
	Rest of plant without roots	0.010, 0.10 and 10	7	73.5	3.7	5.0
	Grain	0.010, 0.10 and 1.0	7	86.6	3.5	4.0
	Straw	0.010, 0.10 and 10	7	91.3	4.6	5.0
	Overall		**36**	**83.3**	**9.1**	**11**

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

Table A 35: Summary of recoveries of M500F007 in barley matrices

Matrix		Fortification level [mg/kg]	M500F007			
			n	Mean [%]	SD [±]	RSD [%]
Barley	Whole plant no roots	0.010, 0.10 and 10	7	88.6	5.4	6.1
	Ears	0.010, 0.10 and 10	8	78.4	3.5	4.5
	Rest of plant without roots	0.010, 0.10 and 10	7	78.3	7.0	8.9
	Grain	0.010, 0.10 and 1.0	7	85.9	4.3	5.0
	Straw	0.010, 0.10 and 10	7	87.9	2.5	2.8
	Overall		**36**	**83.7**	**6.4**	**7.7**

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

Table A 36: Summary of residues of BAS 500 F and M500F007 on barley in Northern Europe 2020 (treated)

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment: kg a.s./ ha	Application rate per treatment: Water (l/ha)	Application rate per treatment: kg a.s./hl	Dates of treatment or no. of treatments and last date* (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg): BAS 500 F	Residues (mg/kg): M500F007[1)]	Residues (mg/kg): sum[2)]	PHI (days) (d)	Details on trial (e)
2021/2000401 L200227 16833 Lentzke Brandenburg Germany EU-N 2020	Barley AS 0640 / Infinity	1. 04.10.2019 2. 13.05.-21.05.2020 3. 13.07.-14.07.2020	0.12	200	0.06	**Plot 2** 28.04.2020 12.05.2020	59	whole plant no roots grain straw grain straw grain straw	1.8 0.020 0.39 0.019 0.29 0.020 0.40	0.027 0.014 0.11 0.012 0.16 0.013 0.24	1.8 0.034 0.50 0.031 0.44 0.033 0.63	0 49 49 56 56 62 62	2021/2000401 Plot 2: BAS 758 00 F EC Mefentrifluconazole 66.6 g/L Pyraclostrobin 80.0 g/L Plot 4: BAS 500 06 F EC Pyraclostrobin 200 g/L BASF method L0076/09 for Pyraclostrobin and M500F007 LOQ: 0.010 mg/kg for BAS 500 F LOQ: 0.011 mg/kg for M500F007 as parent equivalent None of the untreated samples examined had any residue of BAS 500 F (Pyraclostrobin) exceeding the respective LOQ (0.010 mg/kg). None of the untreated samples examined had any residue of M500F007 exceeding the respective LOQ (0.011 mg/kg, expressed as parent equivalent).
			0.25	200	0.125	**Plot 4** 03.05.2020 21.05.2020	69	whole plant no roots grain straw grain straw grain straw	2.7 0.047 0.33 0.050 0.40 0.043 0.56	0.089 0.026 0.16 0.032 0.20 0.029 0.27	2.8 0.073 0.50 0.082 0.60 0.072 0.83	0 27 27 34 34 43 43	
2021/2000401 L200228 6562 KC Groesbeck Gelderland / Groesbeck The Netherlands EU-N 2020	Barley AS 0640 / Rafaela	1. 14.10.2019 2. 09.05.-18.05.2020 3. 30.06.-08.07.2020	0.12	200	0.06	**Plot 2** 24.04.2020 07.05.2020	59	whole plant no roots grain straw grain straw grain straw	3.0 0.044 0.69 0.047 1.0 0.036 0.86	0.11 0.016 0.47 0.017 0.38 0.014 0.29	3.1 0.060 1.2 0.064 1.4 0.050 1.1	0 49 49 56 56 62 62	
			0.25	200	0.125	**Plot 4** 27.04.2020 18.05.2020	69	whole plant no roots ears rest of plant w/o roots grain straw grain straw	5.1 0.19 2.7 0.11 2.0 0.094 2.4	0.25 0.11 0.81 0.047 0.68 0.041 0.83	5.3 0.29 3.5 0.16 2.7 0.13 3.2	0 28 28 35 35 43 43	
2021/2000401 L200229 57810	Barley AS 0640 / Pixel	1. 10.10.2019 2. 07.05.-13.05.2020	0.12	200	0.06	**Plot 2** 22.04.2020	59	whole plant no roots grain straw	4.4 0.030 0.44	0.061 0.015 0.19	4.5 0.045 0.63	0 48 48	

Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment			Dates of treatment or no. of treatments and last date* (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg)			PHI (days) (d)	Details on trial (e)
			kg a.s./ ha	Water (l/ha)	kg a.s./hl				BAS 500 F	M500F007[1)]	sum[2)]		
Donnelay Grand Est / Moselle France EU-N 2020		3. 30.06.2020				07.05.2020		grain straw grain straw	0.027 0.35 0.019 0.48	0.014 0.19 <0.011 0.27	0.040 0.54 0.030 0.75	55 55 63 63	
			0.25	200	0.125	**Plot 4** 27.04.2020 13.05.2020	69	whole plant no roots ears rest of plant w/o roots grain straw grain straw	5.8 0.23 2.5 0.13 1.8 0.13 1.9	0.24 0.18 0.67 0.079 0.46 0.080 0.54	6.0 0.41 3.2 0.21 2.3 0.21 2.5	0 27 27 34 34 41 41	
2021/2000401 L200230 64-000 Ko-korzyn Wielkopolska Poland EU-N 2020	Barley AS 0640 / Sandra	1. 24.09.2019 2. 08.05.-15.05.2020 3. 08.07.2020	0.12	200	0.06	**Plot 2** 27.04.2020 08.05.2020	59	whole plant no roots grain straw grain straw	2.9 0.013 0.17 0.017 0.29	0.091 0.014 0.092 0.018 0.23	3.0 0.026 0.26 0.035 0.51	0 48 48 55 55	
			0.25	200	0.125	**Plot 4** 29.04.2020 15.05.2020	69	whole plant no roots ears rest of plant w/o roots grain straw grain straw	3.8 0.052 0.46 0.029 0.42 0.039 0.37	0.20 0.097 0.22 0.051 0.39 0.062 0.25	4.0 0.15 0.68 0.080 0.81 0.10 0.62	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
1) expressed as parent equivalent, conversion factor for calculation of M500F007 to parent BAS 500 F is 1.084
2) for residues of BAS 500 F < 0.010 mg/kg, value was set to 0.010 mg/kg for calculation of sum and for residues of M500F007, expressed as parent equivalent < 0.011 mg/kg, value was set to 0.011 mg/kg for calculation of sum; if both valuesare below LOQ the sum is <0.021 mg/kg
* Plot 2 was treated with formulation BAS 758 00 F and plot 4 was treated with formulation BAS 500 06 F.
In the untreated control specimens, no residues of BAS 500 F were detected at or above the limit of quantitation (LOQ, 0.010 mg/kg).
In the untreated control specimens, no residues of M500F007 were detected at or above the limit of quantitation (LOQ, 0.011 mg/kg, expressed as parent equivalent).

A 2.3.4 Magnitude of residues in livestock

A 2.3.4.1 Livestock feeding studies

A 2.3.4.1.1 Livestock feeding study 1

No further studies are submitted.

A 2.3.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

A 2.3.5.1 Distribution of the residue in peel/pulp

No further studies are submitted.

A 2.3.5.2 Processing studies on a core set of representative processes

No further studies are submitted.

A 2.3.6 Magnitude of residues in representative succeeding crops

No further studies are submitted.

A 2.3.7 Other/Special Studies (KCA 6.10, KCA 6.10.1)

No further studies are submitted.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

Mefentrifluconazole (BAS 750 F)

A 3.1 BAS 750 F - TMDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Mefentrifluconazole BAS 750 F (F)

LOQs (mg/kg) range from:	0.01	to:	0.05
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)
32%	NL toddler	11.04	12%	Apples	5%	Milk: Cattle	5%	Pears	1.0%	1%
26%	DE child	9.01	14%	Apples	4%	Table grapes	2%	Cherries (sweet)	0.6%	1%
17%	NL child	6.00	7%	Apples	3%	Table grapes	2%	Milk: Cattle	0.5%	0.7%
11%	PT general	3.77	6%	Wine grapes	1%	Apples	0.7%	Table grapes	0.3%	0.7%
11%	RO general	3.68	4%	Wine grapes	2%	Apples	1.0%	Milk: Cattle	0.4%	0.7%
10%	DE women 14-50 yr	3.66	3%	Apples	2%	Wine grapes	1%	Milk: Cattle	0.3%	0.9%
10%	DE general	3.65	3%	Apples	2%	Wine grapes	1%	Milk: Cattle	0.3%	1%
10%	GEMS/Food G07	3.65	4%	Wine grapes	1%	Apples	1%	Barley	0.5%	2%
10%	GEMS/Food G15	3.49	3%	Wine grapes	1%	Barley	1%	Apples	0.5%	2%
10%	GEMS/Food G08	3.47	3%	Wine grapes	2%	Barley	1%	Apples	0.6%	2%
10%	GEMS/Food G11	3.38	3%	Wine grapes	2%	Apples	1%	Barley	0.6%	2%
9%	FR child 3 15 yr	3.25	2%	Milk: Cattle	2%	Apples	0.9%	Wine grapes	0.5%	0.8%
9%	FR adult	3.20	6%	Wine grapes	0.9%	Apples	0.4%	Milk: Cattle	0.2%	0.3%
9%	FR toddler 2 3 yr	3.18	4%	Apples	3%	Milk: Cattle	0.6%	Wine grapes	0.4%	0.5%
9%	IE adult	3.15	3%	Wine grapes	0.8%	Apples	0.7%	Table grapes	0.6%	0.7%
8%	DK child	2.87	3%	Apples	1%	Milk: Cattle	0.8%	Rye	0.3%	2%
8%	GEMS/Food G06	2.87	3%	Table grapes	1%	Apples	1%	Wheat	0.6%	1%
8%	UK infant	2.86	3%	Milk: Cattle	2%	Apples	0.4%	Oat	0.4%	0.8%
7%	NL general	2.50	2%	Apples	2%	Wine grapes	0.7%	Milk: Cattle	0.3%	0.9%
7%	GEMS/Food G10	2.46	1%	Wine grapes	1%	Barley	0.9%	Apples	0.6%	2%
7%	UK toddler	2.41	2%	Apples	2%	Milk: Cattle	0.6%	Table grapes	0.3%	0.7%
6%	ES child	1.98	1%	Apples	1%	Milk: Cattle	0.6%	Wheat	0.4%	0.6%
6%	DK adult	1.97	2%	Wine grapes	1%	Apples	0.5%	Milk: Cattle	0.2%	0.2%
6%	ES adult	1.94	1%	Wine grapes	0.9%	Apples	0.8%	Barley	0.2%	1%
5%	SE general	1.76	1%	Apples	1%	Milk: Cattle	0.9%	Bovine: Muscle/meat	0.4%	0.5%
5%	UK adult	1.63	3%	Wine grapes	0.5%	Apples	0.3%	Milk: Cattle	0.1%	0.3%
5%	PL general	1.59	2%	Apples	0.8%	Table grapes	0.5%	Cherries (sweet)	0.2%	
4%	FR infant	1.56	2%	Apples	1%	Milk: Cattle	0.2%	Sugar beet roots	0.2%	0.1%
4%	IT toddler	1.53	1%	Apples	0.9%	Wheat	0.7%	Peaches	0.2%	1.0%
4%	UK vegetarian	1.49	2%	Wine grapes	0.7%	Apples	0.3%	Wheat	0.2%	0.4%
4%	FI 3 yr	1.42	1%	Apples	1.0%	Oat	0.6%	Table grapes	0.4%	1%
4%	LT adult	1.31	2%	Apples	0.3%	Milk: Cattle	0.2%	Pears	0.2%	0.6%
4%	IT adult	1.31	0.9%	Apples	0.8%	Peaches	0.6%	Wheat	0.2%	0.6%
3%	FI 6 yr	0.99	0.7%	Apples	0.5%	Oat	0.4%	Table grapes	0.3%	0.9%
3%	FI adult	0.88	0.8%	Wine grapes	0.7%	Apples	0.2%	Oat	0.3%	0.4%
1%	IE child	0.43	0.4%	Apples	0.3%	Milk: Cattle	0.2%	Wheat	0.1%	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 (F) is unlikely to present a public health concern.

A 3.2 BAS 750 F - IEDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Mefentrifluconazole BAS 750 F (F)			
LOQs (mg/kg) range from:	0.01	to:	0.01
Toxicological reference values			
ADI (mg/kg bw/day):	0.035	ARfD (mg/kg bw):	0.15
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
7%	NL toddler	2.60	2%	Apples	2%	Milk: Cattle	1.0%	Pears		0.2%
6%	DE child	2.01	3%	Apples	0.7%	Table grapes	0.6%	Milk: Cattle		0.2%
4%	NL child	1.46	1%	Apples	0.7%	Milk: Cattle	0.5%	Table grapes		0.1%
3%	RO general	0.92	0.9%	Wine grapes	0.3%	Milk: Cattle	0.3%	Apples		0.1%
3%	FR child 3 15 yr	0.89	0.7%	Milk: Cattle	0.4%	Apples	0.2%	Sugar beet roots		0.2%
2%	DE women 14-50 yr	0.86	0.6%	Apples	0.4%	Wine grapes	0.4%	Milk: Cattle		0.2%
2%	UK infant	0.86	1%	Milk: Cattle	0.4%	Apples	0.2%	Eggs: Chicken		0.1%
2%	FR toddler 2 3 yr	0.86	0.8%	Milk: Cattle	0.7%	Apples	0.2%	Sugar beet roots		0.1%
2%	DE general	0.85	0.6%	Apples	0.4%	Wine grapes	0.4%	Milk: Cattle		0.2%
2%	GEMS/Food G07	0.85	0.8%	Wine grapes	0.2%	Apples	0.2%	Poultry: Muscle/meat		0.3%
2%	GEMS/Food G15	0.81	0.5%	Wine grapes	0.3%	Apples	0.2%	Barley		0.4%
2%	PT general	0.79	1%	Wine grapes	0.2%	Apples	0.2%	Peaches		0.1%
2%	GEMS/Food G08	0.79	0.5%	Wine grapes	0.3%	Apples	0.3%	Barley		0.4%
2%	GEMS/Food G11	0.77	0.5%	Wine grapes	0.4%	Apples	0.2%	Milk: Cattle		0.3%
2%	DK child	0.73	0.5%	Apples	0.4%	Milk: Cattle	0.2%	Rye		0.4%
2%	FR adult	0.72	1%	Wine grapes	0.2%	Apples	0.1%	Milk: Cattle		0.1%
2%	UK toddler	0.69	0.6%	Milk: Cattle	0.4%	Apples	0.2%	Sugar beet roots		0.1%
2%	IE adult	0.68	0.6%	Wine grapes	0.2%	Apples	0.1%	Peaches		0.1%
2%	GEMS/Food G06	0.64	0.5%	Table grapes	0.2%	Apples	0.2%	Wheat		0.2%
2%	NL general	0.61	0.3%	Apples	0.3%	Wine grapes	0.2%	Milk: Cattle		0.2%
2%	GEMS/Food G10	0.61	0.3%	Poultry: Muscle/meat	0.2%	Wine grapes	0.2%	Apples		0.3%
2%	ES child	0.59	0.4%	Milk: Cattle	0.3%	Apples	0.2%	Poultry: Muscle/meat		0.1%
1%	SE general	0.50	0.4%	Milk: Cattle	0.3%	Bovine: Muscle/meat	0.2%	Apples		0.1%
1%	ES adult	0.47	0.2%	Wine grapes	0.2%	Apples	0.1%	Milk: Cattle		0.2%
1%	DK adult	0.47	0.5%	Wine grapes	0.2%	Apples	0.2%	Milk: Cattle		0.0%
1%	FR infant	0.42	0.5%	Milk: Cattle	0.4%	Apples	0.1%	Sugar beet roots		0.0%
1%	UK adult	0.39	0.6%	Wine grapes	0.1%	Apples	0.1%	Milk: Cattle		0.1%
1.0%	PL general	0.35	0.5%	Apples	0.2%	Table grapes	0.1%	Cherries (sweet)		
1.0%	LT adult	0.34	0.4%	Apples	0.1%	Milk: Cattle	0.1%	Potatoes		0.1%
1.0%	UK vegetarian	0.34	0.4%	Wine grapes	0.1%	Apples	0.1%	Milk: Cattle		0.1%
0.9%	IT toddler	0.31	0.2%	Apples	0.2%	Wheat	0.1%	Peaches		0.2%
0.8%	FI 3 yr	0.29	0.2%	Apples	0.2%	Oat	0.1%	Potatoes		0.2%
0.8%	IT adult	0.27	0.2%	Apples	0.2%	Peaches	0.1%	Wheat		0.1%
0.6%	FI 6 yr	0.21	0.1%	Apples	0.1%	Potatoes	0.1%	Oat		0.2%
0.5%	FI adult	0.16	0.2%	Wine grapes	0.1%	Apples	0.0%	Table grapes		0.1%
0.4%	IE child	0.13	0.1%	Milk: Cattle	0.1%	Apples	0.0%	Wheat		0.0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Mefentrifluconazole BAS 750 F (F) is unlikely to present a public health concern.

A 3.3 BAS 750 F - IESTI calculations - Raw commodities

Acute risk assessment /children	Acute risk assessment / adults / general population	Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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 new
Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new
Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.4%	Barley	0.6 / 0.1	0.56
0.10%	Wheat	0.05 / 0.01	0.14
0.07%	Oat	0.6 / 0.1	0.11
0.04%	Rye	0.05 / 0.01	0.06

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.3%	Barley	0.6 / 0.1	0.48
0.06%	Wheat	0.05 / 0.01	0.08
0.04%	Oat	0.6 / 0.1	0.06
0.03%	Rye	0.05 / 0.01	0.05

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Barley	0.6 / 0.6	3.4
0.5%	Wheat	0.05 / 0.05	0.72
0.4%	Oat	0.6 / 0.6	0.67
0.2%	Rye	0.05 / 0.05	0.32

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Barley	0.6 / 0.6	2.9
0.3%	Wheat	0.05 / 0.05	0.42
0.3%	Oat	0.6 / 0.6	0.38
0.2%	Rye	0.05 / 0.05	0.24

Expand/collapse list

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

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

A 3.4 BAS 750 F - IESTI calculations - Processed commodities

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				Results for adults 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%	Oat / boiled	0.6 / 0.1	0.15
0.2%	Oat / boiled	0.6 / 0.1	0.36	0.10%	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
0.2%	Oat / milling (flakes)	0.6 / 0.1	0.30	0.03%	Wheat / pasta	0.05 / 0.01	0.04
0.0%	Rye / boiled	0.05 / 0.01	0.04	0.01%	Wheat / bread (wholemeal)	0.05 / 0.01	0.02
0.0%	Wheat / milling (flour)	0.05 / 0	0.04	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.0%	Wheat / milling (wholemeal)-	0.05 / 0.01	0.03	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.0%	Rye / milling (wholemeal)-	0.05 / 0.01	0.03	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
Expand/collapse list							

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI new				**IESTI new**			
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)
3%	Barley / milling (flour)	0.6 / 2.2	4.0	0.6%	Oat / boiled	0.6 / 0.6	0.91
1%	Oat / boiled	0.6 / 0.6	2.2	0.6%	Barley / beer	0.6 / 0.02	0.86
1%	Barley / cooked	0.6 / 0.6	2.2	0.1%	Wheat / bread/pizza	0.05 / 0.05	0.22
1%	Oat / milling (flakes)	0.6 / 0.6	1.8	0.1%	Wheat / pasta	0.05 / 0.05	0.19
0.1%	Rye / boiled	0.05 / 0.05	0.18	0.07%	Wheat / bread (wholemeal)	0.05 / 0.03	0.10
0.1%	Wheat / milling (flour)	0.05 / 0.01	0.18	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.1%	Wheat / milling	0.05 / 0.03	0.16	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.09%	Rye / milling (wholemeal)-	0.05 / 0.04	0.14	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!

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.

A 3.5 1,2,4-T - IEDI calculations

European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

1,2,4-T			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	**0.023**	ARfD (mg/kg bw):	**0.1**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2018**	Year of evaluation:	**2018**

Input values | Details - chronic risk assessment | Supplementary results - chronic risk assessment | Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
48%	NL toddler	11.05	42%	Milk: Cattle	2%	Maize/corn	1%	Sugar beet roots		1%
30%	UK infant	6.80	27%	Milk: Cattle	0.9%	Bovine: Muscle/meat	0.6%	Wheat		0.6%
24%	FR toddler 2 3 yr	5.52	20%	Milk: Cattle	0.8%	Bovine: Muscle/meat	0.7%	Wheat		0.7%
22%	NL child	5.10	17%	Milk: Cattle	2%	Sugar beet roots	0.9%	Wheat		0.9%
20%	FR child 3 15 yr	4.71	16%	Milk: Cattle	1%	Bovine: Muscle/meat	1.0%	Wheat		1%
17%	UK toddler	4.00	14%	Milk: Cattle	0.9%	Bovine: Muscle/meat	0.9%	Wheat		0.9%
17%	DE child	3.82	14%	Milk: Cattle	0.9%	Wheat	0.5%	Apples		1%
14%	DK child	3.16	9%	Milk: Cattle	1%	Rye	1%	Swine: Muscle/meat		2%
13%	FR infant	2.96	12%	Milk: Cattle	0.3%	Sugar beet roots	0.2%	Bovine: Muscle/meat		0.2%
13%	SE general	2.95	9%	Milk: Cattle	3%	Bovine: Muscle/meat	0.7%	Wheat		0.8%
12%	ES child	2.80	9%	Milk: Cattle	1.0%	Bovine: Muscle/meat	1.0%	Wheat		1.0%
12%	DE general	2.66	9%	Milk: Cattle	0.9%	Sugar beet roots	0.6%	Swine: Muscle/meat		0.7%
12%	DE women 14-50 yr	2.65	9%	Milk: Cattle	1.0%	Sugar beet roots	0.5%	Wheat		0.6%
11%	RO general	2.59	8%	Milk: Cattle	1%	Wheat	0.6%	Swine: Muscle/meat		1%
9%	NL general	1.97	6%	Milk: Cattle	0.6%	Sugar beet roots	0.5%	Bovine: Muscle/meat		0.5%
8%	GEMS/Food G15	1.94	5%	Milk: Cattle	1.0%	Wheat	0.7%	Swine: Muscle/meat		1%
8%	GEMS/Food G11	1.91	5%	Milk: Cattle	0.8%	Wheat	0.6%	Swine: Muscle/meat		1.0%
8%	GEMS/Food G07	1.85	4%	Milk: Cattle	0.9%	Wheat	0.6%	Bovine: Muscle/meat		1%
7%	GEMS/Food G08	1.70	4%	Milk: Cattle	1%	Swine: Muscle/meat	0.9%	Wheat		1%
7%	GEMS/Food G10	1.58	4%	Milk: Cattle	0.9%	Wheat	0.6%	Bovine: Muscle/meat		1%
6%	ES adult	1.27	3%	Milk: Cattle	0.5%	Bovine: Muscle/meat	0.5%	Wheat		0.6%
5%	DK adult	1.23	4%	Milk: Cattle	0.5%	Swine: Muscle/meat	0.4%	Bovine: Muscle/meat		0.4%
5%	FR adult	1.17	3%	Milk: Cattle	0.5%	Wheat	0.4%	Bovine: Muscle/meat		0.5%
5%	IE adult	1.15	3%	Milk: Cattle	0.5%	Wheat	0.3%	Bovine: Muscle/meat		0.6%
5%	GEMS/Food G06	1.14	2%	Milk: Cattle	2%	Wheat	0.3%	Sugar beet roots		2%
4%	LT adult	1.00	3%	Milk: Cattle	0.5%	Swine: Muscle/meat	0.2%	Rye		0.5%
3%	UK adult	0.77	2%	Milk: Cattle	0.5%	Bovine: Muscle/meat	0.4%	Wheat		0.4%
3%	UK vegetarian	0.70	2%	Milk: Cattle	0.4%	Wheat	0.1%	Sugar beet roots		0.5%
3%	IE child	0.70	2%	Milk: Cattle	0.3%	Wheat	0.1%	Swine: Muscle/meat		0.3%
2%	IT toddler	0.36	1%	Wheat	0.0%	Potatoes	0.0%	Apples		1%
1%	PT general	0.34	0.9%	Wheat	0.2%	Potatoes	0.1%	Wine grapes		0.9%
1%	IT adult	0.23	0.9%	Wheat	0.0%	Apples	0.0%	Potatoes		0.9%
0.8%	FI 3 yr	0.19	0.3%	Wheat	0.2%	Potatoes	0.1%	Rye		0.5%
0.7%	FI 6 yr	0.15	0.2%	Wheat	0.2%	Potatoes	0.1%	Rye		0.4%
0.4%	FI adult	0.08	0.2%	Rye	0.1%	Wheat	0.1%	Potatoes		0.3%
0.3%	PL general	0.06	0.1%	Potatoes	0.1%	Apples	0.0%	Table grapes		

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

A 3.6 1,2,4-T - IESTI calculations - Raw commodities

Acute risk assessment /children	Acute risk assessment / adults / general population	Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.7%	Wheat	0 / 0.05	0.72
0.3%	Rye	0 / 0.05	0.32
0.3%	Barley	0 / 0.05	0.28
0.06%	Oat	0 / 0.05	0.06

Expand/collapse list

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.4%	Wheat	0 / 0.05	0.42
0.2%	Rye	0 / 0.05	0.24
0.2%	Barley	0 / 0.05	0.24
0.03%	Oat	0 / 0.05	0.03

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

IESTI new
Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)

IESTI new
Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)

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

A 3.7 1,2,4-T - IESTI calculations - Processed commodities

Processed commodities

Results for children				Results for adults				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):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI new):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI new):			---
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
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)	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	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.3%	Wheat / milling (wholeme:	0 / 0.05	0.28	0.2%	Wheat / bread/pizza	0 / 0.05	0.22	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.2%	Rye / boiled	0 / 0.05	0.18	0.2%	Wheat / pasta	0 / 0.05	0.19	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.2%	Oat / boiled	0 / 0.05	0.18	0.2%	Wheat / bread	0 / 0.05	0.17	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.2%	Barley / cooked	0 / 0.05	0.18	0.08%	Oat / boiled	0 / 0.05	0.08	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.2%	Rye / milling (wholemeal)-	0 / 0.05	0.18	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.2%	Oat / milling (flakes)	0 / 0.05	0.15	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.1%	Barley / milling (flour)	0 / 0.05	0.09	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
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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.

A 3.8 TA - IEDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

TA			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	**0.3**	ARfD (mg/kg bw):	**0.3**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2018**	Year of evaluation:	**2018**

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
4%	NL toddler	12.40	1%	Maize/corn	0.8%	Wheat	0.4%	Milk: Cattle		1.0%
3%	DK child	7.67	1%	Rye	0.9%	Wheat	0.1%	Potatoes		2%
2%	GEMS/Food G06	6.50	1%	Wheat	0.3%	Maize/corn	0.1%	Potatoes		2%
2%	NL child	6.17	0.9%	Wheat	0.2%	Potatoes	0.2%	Milk: Cattle		0.9%
2%	GEMS/Food G15	6.01	0.9%	Wheat	0.2%	Potatoes	0.2%	Sunflower seeds		1%
2%	GEMS/Food G08	6.00	0.8%	Wheat	0.2%	Potatoes	0.2%	Barley		1%
2%	RO general	5.94	1%	Wheat	0.2%	Sunflower seeds	0.2%	Potatoes		1%
2%	DE child	5.80	0.9%	Wheat	0.3%	Apples	0.2%	Rye		1%
2%	GEMS/Food G07	5.65	0.9%	Wheat	0.2%	Potatoes	0.2%	Rapeseeds/canola seeds		1%
2%	GEMS/Food G10	4.95	0.8%	Wheat	0.2%	Potatoes	0.1%	Maize/corn		1.0%
2%	FR child 3 15 yr	4.90	1.0%	Wheat	0.2%	Milk: Cattle	0.1%	Potatoes		1.0%
2%	IT toddler	4.62	1%	Wheat	0.1%	Potatoes	0.0%	Peaches		1%
2%	PT general	4.53	0.8%	Wheat	0.3%	Potatoes	0.1%	Sunflower seeds		0.9%
1%	GEMS/Food G11	4.28	0.7%	Wheat	0.2%	Potatoes	0.2%	Barley		0.9%
1%	UK infant	4.21	0.5%	Wheat	0.3%	Milk: Cattle	0.2%	Maize/corn		0.6%
1%	ES child	4.13	0.9%	Wheat	0.1%	Potatoes	0.1%	Milk: Cattle		0.9%
1%	UK toddler	4.02	0.8%	Wheat	0.2%	Potatoes	0.1%	Milk: Cattle		0.8%
1%	FR toddler 2 3 yr	3.71	0.6%	Wheat	0.2%	Milk: Cattle	0.1%	Potatoes		0.7%
1%	SE general	3.66	0.7%	Wheat	0.3%	Potatoes	0.1%	Bovine: Muscle/meat		0.7%
1%	DE general	3.19	0.4%	Wheat	0.1%	Rye	0.1%	Barley		0.6%
1%	NL general	3.11	0.4%	Wheat	0.1%	Potatoes	0.1%	Rapeseeds/canola seeds		0.5%
1%	DE women 14-50 yr	3.11	0.4%	Wheat	0.1%	Rye	0.1%	Milk: Cattle		0.6%
1%	IE adult	3.03	0.5%	Wheat	0.1%	Potatoes	0.1%	Sunflower seeds		0.5%
1.0%	IT adult	2.99	0.9%	Wheat	0.0%	Peaches	0.0%	Potatoes		0.9%
0.9%	FI 3 yr	2.69	0.3%	Potatoes	0.2%	Wheat	0.1%	Rye		0.5%
0.8%	ES adult	2.55	0.5%	Wheat	0.1%	Barley	0.1%	Potatoes		0.6%
0.8%	LT adult	2.39	0.2%	Rye	0.2%	Wheat	0.2%	Potatoes		0.5%
0.7%	FR adult	2.21	0.5%	Wheat	0.0%	Wine grapes	0.0%	Potatoes		0.5%
0.7%	FI 6 yr	2.13	0.2%	Potatoes	0.2%	Wheat	0.1%	Rye		0.4%
0.6%	UK vegetarian	1.83	0.4%	Wheat	0.1%	Potatoes	0.0%	Milk: Cattle		0.4%
0.6%	DK adult	1.68	0.2%	Wheat	0.1%	Rye	0.1%	Potatoes		0.3%
0.5%	UK adult	1.62	0.3%	Wheat	0.1%	Potatoes	0.0%	Wine grapes		0.4%
0.5%	FR infant	1.49	0.2%	Wheat	0.1%	Potatoes	0.1%	Milk: Cattle		0.2%
0.4%	FI adult	1.05	0.1%	Rye	0.1%	Potatoes	0.1%	Wheat		0.2%
0.3%	IE child	0.99	0.2%	Wheat	0.0%	Potatoes	0.0%	Milk: Cattle		0.2%
0.3%	PL general	0.93	0.2%	Potatoes	0.0%	Apples	0.0%	Plums		

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

A 3.9 TA - IESTI calculations - Raw commodities

Acute risk assessment /children	Acute risk assessment / adults / general population	Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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 new** **Results for children** No. of commodities for which ARfD/ADI is exceeded (IESTI new):	---	**IESTI new** **Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI new):	---

IESTI (children)

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
3%	Wheat	0 / 0.62	9.0
1%	Rye	0 / 0.62	3.9
1%	Barley	0 / 0.62	3.5
0.2%	Oat	0 / 0.62	0.69

IESTI (adults)

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Wheat	0 / 0.62	5.2
1%	Rye	0 / 0.62	3.0
1%	Barley	0 / 0.62	3.0
0.1%	Oat	0 / 0.62	0.40

IESTI new (children)

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)

IESTI new (adults)

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)

Expand/collapse list

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

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

A 3.10 TA - IESTI calculations - Processed commodities

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	**Results for children** No of processed commodities for which ARfD/ADI is exceeded (IESTI new):			---	**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new):			---
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
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)	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	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
1.0%	Wheat / milling (wholeme:	0 / 0.53	3.0	0.8%	Wheat / pasta	0 / 0.62	2.4	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.8%	Rye / boiled	0 / 0.62	2.3	0.6%	Wheat / bread	0 / 0.53	1.9	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.8%	Oat / boiled	0 / 0.62	2.3	0.3%	Oat / boiled	0 / 0.62	0.94	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.8%	Barley / cooked	0 / 0.62	2.3	0.3%	Barley / beer	0 / 0.02	0.89	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.7%	Rye / milling (wholemeal)-	0 / 0.62	2.2	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.6%	Oat / milling (flakes)	0 / 0.62	1.9	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.4%	Barley / milling (flour)	0 / 0.75	1.3	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
Expand/collapse list															

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of TA is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

A 3.11 TAA - IEDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

TAA

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	1	ARfD (mg/kg bw):	1
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
1%	NL toddler	12.18	0.6%	Maize/corn	0.3%	Wheat	0.2%	Milk: Cattle		0.4%
0.9%	DK child	8.81	0.4%	Rye	0.3%	Wheat	0.0%	Milk: Cattle		0.8%
0.7%	GEMS/Food G06	7.14	0.6%	Wheat	0.1%	Maize/corn	0.0%	Milk: Cattle		0.6%
0.6%	RO general	5.54	0.4%	Wheat	0.1%	Maize/corn	0.0%	Milk: Cattle		0.4%
0.5%	GEMS/Food G15	5.50	0.4%	Wheat	0.1%	Barley	0.1%	Maize/corn		0.4%
0.5%	DE child	5.44	0.3%	Wheat	0.1%	Rye	0.1%	Milk: Cattle		0.4%
0.5%	GEMS/Food G08	5.36	0.3%	Wheat	0.1%	Barley	0.0%	Rye		0.4%
0.5%	IT toddler	5.35	0.5%	Wheat	0.0%	Apples	0.0%	Maize/corn		0.5%
0.5%	NL child	5.32	0.3%	Wheat	0.1%	Milk: Cattle	0.0%	Sugar beet roots		0.3%
0.5%	FR child 3 15 yr	5.22	0.4%	Wheat	0.1%	Milk: Cattle	0.0%	Maize/corn		0.4%
0.5%	GEMS/Food G07	4.79	0.3%	Wheat	0.0%	Barley	0.0%	Maize/corn		0.4%
0.5%	GEMS/Food G10	4.67	0.3%	Wheat	0.1%	Maize/corn	0.0%	Barley		0.4%
0.5%	UK infant	4.50	0.2%	Wheat	0.1%	Milk: Cattle	0.1%	Maize/corn		0.2%
0.4%	ES child	4.36	0.4%	Wheat	0.0%	Milk: Cattle	0.0%	Maize/corn		0.4%
0.4%	GEMS/Food G11	4.13	0.3%	Wheat	0.1%	Barley	0.0%	Milk: Cattle		0.4%
0.4%	UK toddler	4.13	0.3%	Wheat	0.1%	Milk: Cattle	0.0%	Sugar beet roots		0.3%
0.4%	PT general	3.90	0.3%	Wheat	0.0%	Maize/corn	0.0%	Wine grapes		0.3%
0.4%	FR toddler 2 3 yr	3.85	0.2%	Wheat	0.1%	Milk: Cattle	0.0%	Sugar beet roots		0.2%
0.3%	SE general	3.38	0.3%	Wheat	0.0%	Milk: Cattle	0.0%	Rye		0.3%
0.3%	IT adult	3.35	0.3%	Wheat	0.0%	Apples	0.0%	Maize/corn		0.3%
0.3%	DE general	3.29	0.1%	Wheat	0.0%	Rye	0.0%	Barley		0.2%
0.3%	DE women 14-50 yr	3.19	0.2%	Wheat	0.0%	Rye	0.0%	Milk: Cattle		0.2%
0.3%	ES adult	2.63	0.2%	Wheat	0.0%	Barley	0.0%	Milk: Cattle		0.2%
0.3%	IE adult	2.62	0.2%	Wheat	0.0%	Maize/corn	0.0%	Oat		0.2%
0.3%	NL general	2.57	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Barley		0.2%
0.2%	FR adult	2.24	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Wine grapes		0.2%
0.2%	LT adult	2.09	0.1%	Rye	0.1%	Wheat	0.0%	Milk: Cattle		0.2%
0.2%	FI 3 yr	2.08	0.1%	Wheat	0.1%	Rye	0.0%	Oat		0.2%
0.2%	UK vegetarian	1.91	0.2%	Wheat	0.0%	Milk: Cattle	0.0%	Wine grapes		0.2%
0.2%	FI 6 yr	1.65	0.1%	Wheat	0.0%	Rye	0.0%	Oat		0.2%
0.2%	DK adult	1.64	0.1%	Wheat	0.0%	Rye	0.0%	Milk: Cattle		0.1%
0.2%	UK adult	1.61	0.1%	Wheat	0.0%	Milk: Cattle	0.0%	Wine grapes		0.1%
0.1%	FR infant	1.33	0.1%	Wheat	0.1%	Milk: Cattle	0.0%	Sugar beet roots		0.1%
0.1%	IE child	1.08	0.1%	Wheat	0.0%	Milk: Cattle	0.0%	Apples		0.1%
0.1%	FI adult	0.99	0.1%	Rye	0.0%	Wheat	0.0%	Oat		0.1%
0.0%	PL general	0.13	0.0%	Apples	0.0%	Potatoes	0.0%	Table grapes		

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

A 3.12 TAA - IESTI calculations - Raw commodities

Acute risk assessment /children	Acute risk assessment / adults / general population	Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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 new** **Results for children** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---				**IESTI new** **Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI				**IESTI**				IESTI new				IESTI new			
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)	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								
0.5%	Rye	0 / 0.79	5.0	0.4%	Rye	0 / 0.79	3.8								
0.4%	Barley	0 / 0.79	4.4	0.4%	Barley	0 / 0.79	3.8								
0.09%	Oat	0 / 0.79	0.88	0.05%	Oat	0 / 0.79	0.51								
Expand/collapse list															
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)								**Total number of commodities found exceeding the ARfD/ADI in children and adult diets (IESTI new calculation)**							

A 3.13 TAA - IESTI calculations - Processed commodities

Processed commodities

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** 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 (wholemea	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	0 / 0.94	3.3
0.3%	Rye / boiled	0 / 0.79	2.9	0.3%	Wheat / pasta	0 / 0.79	3.0
0.3%	Oat / boiled	0 / 0.79	2.9	0.1%	Oat / boiled	0 / 0.79	1.2
0.3%	Barley / cooked	0 / 0.79	2.9	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.3%	Rye / milling (wholemeal)-	0 / 0.79	2.8	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.2%	Oat / milling (flakes)	0 / 0.79	2.4	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
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Expand/collapse list							

Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---				**Results for adults** No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---			
IESTI new				**IESTI new**			
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)
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
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#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!

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.

A 3.14 TLA - IEDI calculations

efsa
European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

Input values | Details - chronic risk assessment | Supplementary results - chronic risk assessment | Details - acute risk assessment/children | Details - acute risk assessment/adults

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

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	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
1.0%	NL toddler	2.93	0.6%	Milk: Cattle	0.1%	Apples	0.1%	Maize/corn		0.0%
0.5%	UK infant	1.50	0.4%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat		0.0%
0.5%	NL child	1.42	0.2%	Milk: Cattle	0.1%	Apples	0.0%	Wheat		0.0%
0.5%	DE child	1.36	0.2%	Milk: Cattle	0.1%	Apples	0.0%	Wheat		0.0%
0.4%	FR toddler 2 3 yr	1.27	0.3%	Milk: Cattle	0.0%	Apples	0.0%	Wheat		0.0%
0.4%	FR child 3 15 yr	1.15	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Apples		0.0%
0.3%	UK toddler	0.98	0.2%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes		0.0%
0.3%	DK child	0.94	0.1%	Milk: Cattle	0.0%	Rye	0.0%	Wheat		0.1%
0.3%	RO general	0.84	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes		0.0%
0.3%	DE general	0.75	0.1%	Milk: Cattle	0.0%	Apples	0.0%	Sugar beet roots		0.0%
0.2%	GEMS/Food G15	0.75	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes		0.1%
0.2%	SE general	0.75	0.1%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Potatoes		0.0%
0.2%	ES child	0.74	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Bovine: Muscle/meat		0.0%
0.2%	GEMS/Food G07	0.74	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes		0.0%
0.2%	DE women 14-50 yr	0.74	0.1%	Milk: Cattle	0.0%	Apples	0.0%	Wheat		0.0%
0.2%	GEMS/Food G08	0.72	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes		0.1%
0.2%	GEMS/Food G11	0.69	0.1%	Milk: Cattle	0.0%	Potatoes	0.0%	Wheat		0.0%
0.2%	FR infant	0.67	0.2%	Milk: Cattle	0.0%	Apples	0.0%	Potatoes		0.0%
0.2%	NL general	0.60	0.1%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples		0.0%
0.2%	GEMS/Food G10	0.60	0.1%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes		0.0%
0.2%	GEMS/Food G06	0.49	0.1%	Wheat	0.0%	Milk: Cattle	0.0%	Table grapes		0.1%
0.2%	IE adult	0.45	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Wine grapes		0.0%
0.1%	FR adult	0.42	0.0%	Milk: Cattle	0.0%	Wine grapes	0.0%	Wheat		0.0%
0.1%	ES adult	0.42	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Barley		0.0%
0.1%	PT general	0.40	0.0%	Potatoes	0.0%	Wine grapes	0.0%	Wheat		0.0%
0.1%	DK adult	0.38	0.1%	Milk: Cattle	0.0%	Wine grapes	0.0%	Apples		0.0%
0.1%	LT adult	0.37	0.0%	Milk: Cattle	0.0%	Potatoes	0.0%	Apples		0.0%
0.1%	UK adult	0.27	0.0%	Milk: Cattle	0.0%	Wine grapes	0.0%	Wheat		0.0%
0.1%	UK vegetarian	0.26	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Wine grapes		0.0%
0.1%	FI 3 yr	0.25	0.0%	Potatoes	0.0%	Oat	0.0%	Apples		0.0%
0.1%	IT toddler	0.23	0.0%	Wheat	0.0%	Apples	0.0%	Potatoes		0.0%
0.1%	FI 6 yr	0.19	0.0%	Potatoes	0.0%	Oat	0.0%	Wheat		0.0%
0.1%	IE child	0.18	0.0%	Milk: Cattle	0.0%	Wheat	0.0%	Potatoes		0.0%
0.1%	PL general	0.17	0.0%	Potatoes	0.0%	Apples	0.0%	Table grapes		
0.1%	IT adult	0.17	0.0%	Wheat	0.0%	Apples	0.0%	Peaches		0.0%
0.0%	FI adult	0.10	0.0%	Potatoes	0.0%	Apples	0.0%	Rye		0.0%

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

A 3.15 TLA - IESTI calculations - Raw commodities

Acute risk assessment /children	Acute risk assessment / adults / general population	Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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 new
Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new
Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Barley	0 / 0.08	0.43
0.1%	Wheat	0 / 0.02	0.32
0.05%	Rye	0 / 0.02	0.14
0.03%	Oat	0 / 0.08	0.08

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0.1%	Barley	0 / 0.08	0.37
0.06%	Wheat	0 / 0.02	0.18
0.04%	Rye	0 / 0.02	0.11
0.02%	Oat	0 / 0.08	0.05

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)

Expand/collapse list

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

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

A 3.16 TLA - IESTI calculations - Processed commodities

Processed commodities

Results for children				Results for adults				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):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI new):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI new):			---
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
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)	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	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.1%	Oat / boiled	0 / 0.08	0.28	0.04%	Oat / boiled	0 / 0.08	0.12	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.1%	Barley / cooked	0 / 0.08	0.28	0.03%	Wheat / bread/pizza	0 / 0.02	0.10	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.1%	Wheat / milling (flour)	0 / 0.02	0.27	0.03%	Wheat / pasta	0 / 0.02	0.08	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.1%	Oat / milling (flakes)	0 / 0.08	0.23	0.03%	Wheat / bread	0 / 0.02	0.08	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.0%	Wheat / milling (wholeme:	0 / 0.02	0.12	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.0%	Rye / boiled	0 / 0.02	0.08	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.0%	Rye / milling (wholemeal)-	0 / 0.02	0.08	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
Expand/collapse list															

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of TLA is unlikely to present a public health risk.

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

A 3.17 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																			
Oat	0.621	STMR																			
Rye	0.621	STMR																			
Wheat	0.621	STMR																			
			µg/kg bw/day	3.2416	6.4017	2.7557	0.4890	1.9518	2.9156	4.1343	2.9330	2.6989	1.7845	2.4755	1.0251	1.7636	0.7308	1.3943	1.6367	2.5740	1.4153
			mg/kg bw/day	0.0032	0.0064	0.0028	0.0005	0.0020	0.0029	0.0041	0.0029	0.0027	0.0018	0.0025	0.0010	0.0018	0.0007	0.0014	0.0016	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	**0.0108**	**0.0213**	**0.0092**	**0.0016**	**0.0065**	**0.0097**	**0.0138**	**0.0098**	**0.0090**	**0.0059**	**0.0083**	**0.0034**	**0.0059**	**0.0024**	**0.0046**	**0.0055**	**0.0086**	**0.0047**
Triazole lactic acid																					
Barley	0.076	STMR																			
Oat	0.076	STMR																			
Rye	0.022	STMR																			
Wheat	0.022	STMR																			
			µg/kg bw/day	0.1267	0.2475	0.0977	0.0174	0.0724	0.1082	0.1471	0.1236	0.0989	0.0769	0.0910	0.0363	0.0891	0.0341	0.0504	0.0685	0.0917	0.0583
			mg/kg bw/day	1E-04	2E-04	1E-04	2E-05	7E-05	1E-04	1E-04	1E-04	1E-04	8E-05	9E-05	4E-05	9E-05	3E-05	5E-05	7E-05	9E-05	6E-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**	**0.0008**	**0.0003**	**0.0001**	**0.0002**	**0.0004**	**0.0005**	**0.0004**	**0.0003**	**0.0003**	**0.0003**	**0.0001**	**0.0003**	**0.0001**	**0.0002**	**0.0002**	**0.0003**	**0.0002**
Cummulative risk HI				**0.0112**	**0.0222**	**0.0095**	**0.0017**	**0.0067**	**0.0101**	**0.0143**	**0.0102**	**0.0093**	**0.0062**	**0.0086**	**0.0035**	**0.0062**	**0.0025**	**0.0048**	**0.0057**	**0.0089**	**0.0049**

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 y	IE child	FI 3 yr	FI 6 yr
Triazole alanine																					
Barley	0.621	STMR																			
Oat	0.621	STMR																			
Rye	0.621	STMR																			
Wheat	0.621	STMR																			
			µg/kg bw/day	1.4507	0.0000	2.5554	3.1464	2.1714	1.0720	1.3258	4.5605	3.1056	3.5189	2.9168	2.7709	3.4783	1.9112	1.8095	0.7314	1.5444	1.2178
			mg/kg bw/day	0.0015	0.0000	0.0026	0.0031	0.0022	0.0011	0.0013	0.0046	0.0031	0.0035	0.0029	0.0028	0.0035	0.0019	0.0018	0.0007	0.0015	0.0012
			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	**0.0048**	**0.0000**	**0.0085**	**0.0105**	**0.0072**	**0.0036**	**0.0044**	**0.0152**	**0.0104**	**0.0117**	**0.0097**	**0.0092**	**0.0116**	**0.0064**	**0.0060**	**0.0024**	**0.0051**	**0.0041**
Triazole lactic acid																					
Barley	0.076	STMR																			
Oat	0.076	STMR																			
Rye	0.022	STMR																			
Wheat	0.022	STMR																			
			µg/kg bw/day	0.0694	0.0000	0.0938	0.1115	0.0769	0.0403	0.0506	0.1655	0.1493	0.1784	0.1394	0.1430	0.1678	0.1007	0.0796	0.0267	0.0895	0.0635
			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	1E-04	8E-05	3E-05	9E-05	6E-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	**0.0002**	**0.0000**	**0.0003**	**0.0004**	**0.0003**	**0.0001**	**0.0002**	**0.0006**	**0.0005**	**0.0006**	**0.0005**	**0.0005**	**0.0006**	**0.0003**	**0.0003**	**0.0001**	**0.0003**	**0.0000**
Cummulative risk HI				**0.0051**	**0.0000**	**0.0088**	**0.0109**	**0.0075**	**0.0037**	**0.0046**	**0.0158**	**0.0108**	**0.0123**	**0.0102**	**0.0097**	**0.0122**	**0.0067**	**0.0063**	**0.0025**	**0.0054**	**0.0041**

Metrafenone

A 3.18 Metrafenone TMDI calculations

~~Since residues of metrafenone in wheat and barley grain and straw are below those previously considered in the EFSA Article 12 review of metrafenone (EFSA, 2013) which showed acceptable consumer exposure, no further assessments of consumer exposure are required.~~ Since the IEDI only represents 3% of the ADI, TMDI calculations have not been presented.

A 3.19 IEDI calculations

~~Since residues of metrafenone in wheat and barley grain and straw are below those previously considered in the EFSA Article 12 review of metrafenone (EFSA, 2013) which showed acceptable consumer exposure, no further assessments of consumer exposure are required..~~

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

metrafenone

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	**0.25**	ARfD (mg/kg bw):	**not necessary**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2006**	Year of evaluation:	**2006**

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	Expsoure (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)
3%	NL toddler	6.93	1.0%	Apples	0.7%	Table grapes	0.4%	Pears		
2%	DE child	5.87	1%	Apples	0.6%	Table grapes	0.1%	Milk: Cattle		
2%	NL child	4.05	0.5%	Apples	0.4%	Table grapes	0.2%	Sugar beet roots		
1%	GEMS/Food G06	3.14	0.5%	Table grapes	0.2%	Tomatoes	0.1%	Wheat		
0.8%	DE women 14-50 yr	2.10	0.2%	Apples	0.1%	Table grapes	0.1%	Sugar beet roots		
0.8%	GEMS/Food G15	2.07	0.1%	Table grapes	0.1%	Apples	0.1%	Wine grapes		
0.8%	DE general	2.07	0.2%	Apples	0.1%	Table grapes	0.1%	Sugar beet roots		
0.8%	RO general	2.07	0.2%	Wine grapes	0.1%	Apples	0.1%	Tomatoes		
0.8%	FR child 3 15 yr	2.02	0.2%	Apples	0.2%	Table grapes	0.1%	Milk: Cattle		
0.8%	DK child	2.01	0.2%	Apples	0.1%	Rye	0.1%	Cucumbers		
0.8%	GEMS/Food G11	1.95	0.2%	Table grapes	0.1%	Apples	0.1%	Wine grapes		
0.8%	GEMS/Food G08	1.95	0.1%	Table grapes	0.1%	Apples	0.1%	Wine grapes		
0.7%	GEMS/Food G07	1.85	0.1%	Table grapes	0.1%	Wine grapes	0.1%	Apples		
0.7%	PT general	1.78	0.2%	Wine grapes	0.1%	Table grapes	0.1%	Apples		
0.7%	FR toddler 2 3 yr	1.72	0.3%	Apples	0.1%	Milk: Cattle	0.1%	Sugar beet roots		
0.7%	GEMS/Food G10	1.64	0.1%	Table grapes	0.1%	Apples	0.1%	Wheat		
0.6%	IE adult	1.62	0.1%	Wine grapes	0.1%	Table grapes	0.1%	Apples		
0.6%	UK toddler	1.52	0.2%	Apples	0.1%	Table grapes	0.1%	Milk: Cattle		
0.6%	NL general	1.39	0.1%	Apples	0.1%	Table grapes	0.1%	Sugar beet roots		
0.5%	UK infant	1.33	0.2%	Milk: Cattle	0.1%	Apples	0.0%	Wheat		
0.5%	FR adult	1.32	0.2%	Wine grapes	0.1%	Apples	0.0%	Table grapes		
0.5%	ES child	1.21	0.1%	Apples	0.1%	Wheat	0.0%	Milk: Cattle		
0.5%	PL general	1.15	0.2%	Apples	0.1%	Table grapes	0.0%	Tomatoes		
0.4%	IT toddler	1.12	0.1%	Wheat	0.1%	Apples	0.1%	Tomatoes		
0.4%	SE general	1.12	0.1%	Apples	0.1%	Wheat	0.0%	Milk: Cattle		
0.4%	FI 3 yr	1.10	0.1%	Table grapes	0.1%	Apples	0.1%	Cucumbers		
0.4%	DK adult	1.07	0.1%	Wine grapes	0.1%	Apples	0.1%	Table grapes		
0.4%	ES adult	0.98	0.1%	Apples	0.0%	Wine grapes	0.0%	Wheat		
0.4%	IT adult	0.96	0.1%	Apples	0.1%	Wheat	0.1%	Table grapes		
0.4%	FR infant	0.91	0.2%	Apples	0.1%	Milk: Cattle	0.0%	Sugar beet roots		
0.3%	UK vegetarian	0.87	0.1%	Wine grapes	0.1%	Apples	0.0%	Table grapes		
0.3%	UK adult	0.86	0.1%	Wine grapes	0.1%	HOPS (dried)	0.0%	Apples		
0.3%	LT adult	0.84	0.2%	Apples	0.0%	Tomatoes	0.0%	Cucumbers		
0.3%	FI 6 yr	0.83	0.1%	Table grapes	0.1%	Apples	0.0%	Cucumbers		
0.2%	FI adult	0.61	0.1%	Apples	0.0%	Table grapes	0.0%	Wine grapes		
0.1%	IE child	0.28	0.0%	Apples	0.0%	Table grapes	0.0%	Wheat		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of metrafenone is unlikely to present a public health concern.

A 3.20 IESTI calculations - Raw commodities

Not required. It was not necessary to establish an ARfD for metrafenone.

A 3.21 IESTI calculations - Processed commodities

Not required. It was not necessary to establish an ARfD for metrafenone.

Pyraclostrobin

A 3.22 Pyraclostrobin TMDI calculations

European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

Pyraclostrobin

LOQs (mg/kg) range from:	0.01	to:	0.10
Toxicological reference values			
ADI (mg/kg bw/day):	0.03	ARfD (mg/kg bw):	0.03
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2004	Year of evaluation:	2004

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	Expsoure (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)
83%	DE child	24.78	27%	Oranges	21%	Apples	4%	Cherries (sweet)	2%	
83%	NL toddler	24.76	18%	Apples	15%	Oranges	7%	Pears	4%	
55%	NL child	16.59	10%	Apples	9%	Oranges	6%	Sugar beet roots	2%	
53%	FR child 3 15 yr	15.76	23%	Oranges	4%	Other lettuce and other salad plants	3%	Wheat	2%	
48%	GEMS/Food G07	14.29	10%	Wine grapes	9%	Oranges	3%	Wheat	1%	
47%	IE adult	14.25	8%	Wine grapes	7%	Oranges	5%	Grapefruits	1%	
45%	GEMS/Food G11	13.49	7%	Wine grapes	5%	Oranges	3%	Lamb's lettuce/corn salads	1%	
45%	GEMS/Food G06	13.37	7%	Oranges	5%	Wheat	4%	Onions	0.7%	
43%	GEMS/Food G10	12.99	8%	Oranges	3%	Onions	3%	Wine grapes	1%	
43%	GEMS/Food G08	12.94	7%	Wine grapes	3%	Oranges	3%	Barley	1%	
43%	DE women 14-50 yr	12.86	13%	Oranges	6%	Wine grapes	4%	Apples	0.9%	
40%	GEMS/Food G15	12.04	7%	Wine grapes	4%	Oranges	3%	Wheat	1%	
40%	DE general	12.00	10%	Oranges	6%	Wine grapes	4%	Apples	1.0%	
39%	FR toddler 2 3 yr	11.77	10%	Oranges	5%	Apples	5%	Mandarins	2%	
37%	FR adult	11.00	15%	Wine grapes	5%	Other lettuce and other salad plants	4%	Oranges	0.7%	
37%	RO general	10.96	11%	Wine grapes	4%	Onions	3%	Wheat	1%	
36%	PT general	10.80	17%	Wine grapes	4%	Oranges	3%	Wheat	0.4%	
35%	UK toddler	10.37	13%	Oranges	3%	Apples	3%	Wheat	1%	
33%	ES child	10.03	14%	Oranges	3%	Wheat	3%	Lettuces	2%	
31%	SE general	9.36	5%	Oranges	3%	Mandarins	3%	Lettuces	2%	
29%	NL general	8.81	7%	Oranges	4%	Wine grapes	2%	Apples	1.0%	
29%	ES adult	8.58	9%	Oranges	4%	Lettuces	3%	Wine grapes	0.8%	
27%	DK child	8.23	4%	Apples	4%	Rye	3%	Wheat	2%	
27%	UK infant	8.09	9%	Oranges	3%	Apples	2%	Carrots	2%	
25%	IT toddler	7.53	4%	Wheat	4%	Other lettuce and other salad plants	3%	Oranges	0.2%	
24%	IT adult	7.18	5%	Other lettuce and other salad plants	3%	Wheat	3%	Lettuces	0.1%	
23%	FI 3 yr	6.89	3%	Mandarins	2%	Onions	2%	Oat	0.5%	
23%	UK vegetarian	6.76	6%	Oranges	5%	Wine grapes	1%	Wheat	0.3%	
20%	FI adult	5.90	6%	Coffee beans	3%	Oranges	2%	Wine grapes	0.1%	
20%	UK adult	5.87	7%	Wine grapes	4%	Oranges	1%	Wheat	0.5%	
18%	FI 6 yr	5.28	2%	Mandarins	1%	Onions	1%	Strawberries	0.4%	
17%	FR infant	5.18	3%	Apples	2%	Carrots	2%	Oranges	0.9%	
17%	DK adult	5.16	6%	Wine grapes	2%	Apples	1.0%	Oranges	0.7%	
12%	PL general	3.62	3%	Apples	2%	Onions	0.9%	Cherries (sweet)	0.3%	
10%	LT adult	3.10	3%	Apples	0.7%	Rye	0.7%	Wheat	0.7%	
4%	IE child	1.26	0.8%	Wheat	0.6%	Oranges	0.5%	Apples	0.3%	

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Pyraclostrobin is unlikely to present a public health concern.

A 3.23 IEDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Pyraclostrobin			
LOQs (mg/kg) range from:	0.01	to:	0.10
Toxicological reference values			
ADI (mg/kg bw/day):	0.03	ARfD (mg/kg bw):	0.03
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2004	Year of evaluation:	2004

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	Expsoure (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)
31%	NL toddler	9.17	14%	Milk: Cattle	5%	Apples	2%	Pears	1%	0.7%
18%	DE child	5.42	6%	Apples	4%	Milk: Cattle	1%	Oranges	0.7%	0.6%
16%	NL child	4.76	6%	Milk: Cattle	3%	Apples	1%	Sugar beet roots	0.7%	0.4%
13%	UK infant	4.03	9%	Milk: Cattle	0.7%	Apples	0.5%	Carrots	0.7%	0.5%
13%	FR toddler 2 3 yr	3.87	7%	Milk: Cattle	1%	Apples	0.4%	Oranges	0.5%	0.3%
13%	FR child 3 15 yr	3.86	5%	Milk: Cattle	1.0%	Oranges	0.9%	Other lettuce and other salad pla	0.6%	0.4%
10%	GEMS/Food G11	3.10	2%	Milk: Cattle	2%	Wine grapes	0.9%	Barley	0.5%	1%
10%	GEMS/Food G07	3.08	2%	Wine grapes	1%	Milk: Cattle	0.7%	Barley	0.4%	1%
10%	DE women 14-50 yr	2.92	3%	Milk: Cattle	1%	Wine grapes	1%	Apples	0.3%	0.5%
10%	DE general	2.91	3%	Milk: Cattle	1%	Wine grapes	1%	Apples	0.2%	0.9%
10%	GEMS/Food G08	2.90	2%	Wine grapes	1%	Milk: Cattle	1%	Barley	0.5%	1%
10%	UK toddler	2.90	5%	Milk: Cattle	0.8%	Apples	0.6%	Oranges	0.5%	0.3%
10%	RO general	2.86	3%	Wine grapes	3%	Milk: Cattle	0.7%	Apples	0.4%	0.3%
9%	GEMS/Food G15	2.77	2%	Wine grapes	2%	Milk: Cattle	0.9%	Barley	0.4%	1%
9%	IE adult	2.68	2%	Wine grapes	1.0%	Milk: Cattle	0.4%	Other other small fruit & berries	0.7%	0.4%
9%	FR adult	2.62	4%	Wine grapes	1%	Other lettuce and other salad plants	1%	Milk: Cattle	0.3%	0.2%
8%	GEMS/Food G10	2.52	1%	Milk: Cattle	0.7%	Barley	0.7%	Wine grapes	0.4%	1%
8%	DK child	2.49	3%	Milk: Cattle	1%	Apples	0.5%	Carrots	0.4%	1%
8%	SE general	2.32	3%	Milk: Cattle	0.7%	Bovine: Muscle/meat	0.5%	Apples	0.6%	0.2%
8%	ES child	2.27	3%	Milk: Cattle	0.6%	Oranges	0.5%	Apples	0.6%	0.3%
7%	GEMS/Food G06	2.23	1%	Tomatoes	0.6%	Milk: Cattle	0.5%	Wheat	0.4%	0.6%
7%	NL general	2.14	2%	Milk: Cattle	0.9%	Wine grapes	0.7%	Apples	0.4%	0.5%
7%	FR infant	2.11	4%	Milk: Cattle	0.8%	Apples	0.4%	Carrots	0.2%	0.1%
7%	PT general	2.09	4%	Wine grapes	0.5%	Apples	0.4%	Potatoes	0.4%	0.3%
6%	ES adult	1.71	1%	Milk: Cattle	0.7%	Wine grapes	0.6%	Barley	0.3%	0.7%
5%	DK adult	1.46	2%	Wine grapes	1%	Milk: Cattle	0.4%	Apples	0.2%	0.1%
4%	FI 3 yr	1.34	0.7%	Oat	0.5%	Raspberries (red and yellow)	0.4%	Apples	0.5%	0.9%
4%	UK adult	1.28	2%	Wine grapes	0.7%	Milk: Cattle	0.2%	Apples	0.2%	0.2%
4%	UK vegetarian	1.27	1%	Wine grapes	0.7%	Milk: Cattle	0.3%	Apples	0.2%	0.2%
4%	IT adult	1.26	1%	Other lettuce and other salad plants	0.4%	Tomatoes	0.4%	Apples	0.1%	0.3%
4%	IT toddler	1.26	0.9%	Other lettuce and other salad plants	0.5%	Tomatoes	0.4%	Wheat	0.2%	0.5%
3%	LT adult	1.03	0.9%	Milk: Cattle	0.9%	Apples	0.2%	Potatoes	0.3%	0.3%
3%	FI 6 yr	0.95	0.4%	Raspberries (red and yellow)	0.4%	Oat	0.3%	Apples	0.4%	0.5%
3%	FI adult	0.84	0.5%	Wine grapes	0.5%	Coffee beans	0.3%	Apples	0.1%	0.2%
3%	PL general	0.76	1.0%	Apples	0.3%	Tomatoes	0.2%	Potatoes	0.3%	
2%	IE child	0.48	0.8%	Milk: Cattle	0.2%	Apples	0.1%	Currants (red, black and white)	0.1%	0.1%

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

A 3.24 IESTI calculations - Raw commodities

Acute risk assessment /children	Acute risk assessment / adults / general population	Acute risk assessment /children	Acute risk assessment / adults / general population
Details - acute risk assessment /children	Details - acute risk assessment/adults	Hide IESTI new calculations	Show IESTI new calculations

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

IESTI new calculations:
The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.
Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

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)
6%	Barley	1 / 0.35	1.9
1%	Oat	1 / 0.35	0.38
1.0%	Wheat	0.2 / 0.02	0.29
0.4%	Rye	0.2 / 0.02	0.13

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)
6%	Barley	1 / 0.35	1.7
0.7%	Oat	1 / 0.35	0.22
0.6%	Wheat	0.2 / 0.02	0.17
0.3%	Rye	0.2 / 0.02	0.10

IESTI new
Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
19%	Barley	1 / 1	5.6
10%	Wheat	0.2 / 0.2	2.9
4%	Rye	0.2 / 0.2	1.3
4%	Oat	1 / 1	1.1

IESTI new
Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
16%	Barley	1 / 1	4.8
6%	Wheat	0.2 / 0.2	1.7
3%	Rye	0.2 / 0.2	0.97
2%	Oat	1 / 1	0.64

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

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

A 3.25 IESTI calculations - Processed commodities

Processed commodities

Results for children				Results for adults				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):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI new):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI new):			---
IESTI				**IESTI**				**IESTI new**				**IESTI new**			
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)	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)
4%	Oat / boiled	1 / 0.35	1.3	29%	Barley / beer	1 / 0.24	8.7	12%	Oat / boiled	1 / 1	3.6	84%	Barley / beer	1 / 0.7	25
4%	Barley / cooked	1 / 0.35	1.3	2%	Oat / boiled	1 / 0.35	0.52	12%	Barley / cooked	1 / 1	3.6	5%	Oat / boiled	1 / 1	1.5
3%	Oat / milling (flakes)	1 / 0.35	1.0	0.3%	Wheat / bread/pizza	0.2 / 0.02	0.09	10%	Oat / milling (flakes)	1 / 1	3.0	3%	Wheat / bread/pizza	0.2 / 0.2	0.88
2%	Barley / milling (flour)	1 / 0.35	0.62	0.3%	Wheat / pasta	0.2 / 0.02	0.08	6%	Barley / milling (flour)	1 / 1	1.8	3%	Wheat / pasta	0.2 / 0.2	0.76
0.4%	Wheat / milling (wholeme:	0.2 / 0.02	0.11	0.2%	Wheat / bread	0.2 / 0.02	0.07	4%	Wheat / milling	0.2 / 0.2	1.1	2%	Wheat / bread (wholemeal)	0.2 / 0.2	0.70
0.2%	Rye / boiled	0.2 / 0.02	0.07	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	2%	Rye / boiled	0.2 / 0.2	0.73	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.2%	Rye / milling (wholemeal)-	0.2 / 0.02	0.07	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	2%	Rye / milling (wholemeal)-	0.2 / 0.2	0.70	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.0%	Wheat / milling (flour)	0.2 / 0	0.01	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	0.5%	Wheat / milling (flour)	0.2 / 0.01	0.15	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
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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 Pyraclostrobin is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.