FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: BAS 765 00 F

Product name(s): Daxur

Chemical active substance(s):

Mefentriflucoanzole, 100 g/L
Kresoxim-methyl, 150 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: BASF

Submission date: December 2020

MS Finalisation date: 03/11/2021

Version history

When	What
12/2020	Initial dRR – BASF DocID 2020/2096199
02/2021	Dossier sent for evaluation to Merit Mark (PL)
08/2021	zRMS finalised evaluation
11/2021	Evaluation after commenting period - RR

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7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

The text of the applicant was not rewritten. The evaluator text and corrections are on grey background. The assessment details of the submitted by the applicant data are included in the Appendix 2. The submitted data are sufficient for the evaluation.

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 765 00 F are presented in Table 7.1-1. They have been selected from the individual GAPs in the Central Zone for wheat, triticale, barley and rye. A list of all intended uses within the Central Zone is given in Part B, Section 0.
Review report for the renewal of active substance kresoxim-methyl SANCO/11029/2011 Rev 3 and review report for the active substance mefentrifluconazole SANTE/11612/2018 Rev. 3 (2021) in list of uses supported by available data shows cereal GAPs covering the intended GAP.

Overall conclusion

The product can be approved for use consistent with the intended GAP (table 7.1-1).
The data available are considered sufficient for risk assessment. An exceedance of the current MRLs of 0.6 mg/kg (barley) and 0.05 mg/kg (wheat, rye and triticale) for mefentrifluconazole and 0.15 mg/kg (barley) and 0.08 mg/kg (wheat, rye and triticale) for kresoxim-methyl as laid down in Reg (EU) 396/2005 is not expected.
The processing studies available for BAS 750 F are sufficient to cover the intended use of BAS 765 00 F. For kresoxim-methyl the processing investigation is not required.
Regarding the dietary burden for parent BAS 750 F and TDMs, all calculated maximum dietary burdens are comparable to the recent EFSA calculations (EFSA Journal 2020;18(7):6193). The calculations demonstrated that the livestock exposure to the residues of TA, TLA and TAA (exceeded trigger) resulting from the existing and intended uses of mefentrifluconazole are lower than or identical to the burdens that were calculated in context of EFSA (2018, 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. Regarding kresoxim-methyl, 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.
Due to the large amount of data, details of the input values for risk assessment the applicant provided in the supplemental document BASF DocID 2020/2106123.
Following SCoPAFF agreements of 6 December 2019 on active substances belonging to the triazole class of fungicides, the applicant applied the EFSA risk assessment approach, i.e. considered relevant reference values and performed a separate risk assessment. Triazole toxicological reference values have been established for each derivative during the EU peer review of confirmatory data for TDMs (EFSA Journal 2018;16(7):5376; see also SANTE/11612/2018 Rev. 3 2021). Dietary risk assessments for mefentrifluconazole (BAS 750 F) and the TDMs 1,2,4-T, TA, TLA and TAA as well as kresoxim-methyl were carried out based on the EFSA PRIMo model vers. 3.1. The estimated chronic and the short-term residue intakes after the use of the evaluated product are unlikely to present a public health concern.
As far as consumer health protection is concerned, PL agrees with the authorization of the intended uses. 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)

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.

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	Crop and/ or situation **	Zone	Product	F, Fn, Fpn G, Gn, Gpn or I***	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Conclusion
						Type	Conc. of as	method kind	growth stage & season	number min max	interval between applications (min) (days)	kg as/hL min max	water L/ha min max	kg as/ha min max		
1	wheat TRZAW, TRZAS TRZDU, TRZSP	CZ	BAS 765 00 F	F	B. graminis - ERYSGR Zymoseptoria tritici - SEPTTR Puccinia triticina - PUCCRT Fusarium sp. - FUSASP Oculimacula spp.- PSDCHE	SC	a) 100 g/L b) 150 g/L	Spraying	30 - 69	a) 1 b) 1	-	a) 0.60 - 1.00 b) 0.60 - 1.00	100 - 300	a) 0.100 / 0.150 b) 0.100 / 0.150	35	For Fusarium Head Blight control, only one application at BBCH 61-69.
2	barley HORVW HORVS	CZ	BAS 765 00 F	F	Pyrenophora teres - PYRNTE P. hordei - PUCCHD	SC	a) 100 g/L b) 150 g/L	Spraying	30 - 49	a) 1 b) 1	-	a) 0.60 - 1.00 b) 0.60 - 1.00	100 - 300	a) 0.100 / 0.150 b) 0.100 / 0.150	35	
3	rye SECCW SECCS SECCE	CZ	BAS 765 00 F	F	Puccinia recondita - PUCCRE	SC	a) 100 g/L b) 150 g/L	Spraying	30 - 69	a) 1 b) 1	-	a) 0.60 - 1.00 b) 0.60 - 1.00	100 - 300	a) 0.100 / 0.150 b) 0.100 / 0.150	35	

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min) (days)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		
4	triticale TTLWI TTLSO	CZ	BAS 765 00 F	F	Septoria spp. - SEPTSP Puccinia recondita - PUCCRE	SC	a) 100 g/L b) 150 g/L	Spraying	30 - 69	a) 1 b) 1	-	a) 0.60 - 1.00 b) 0.60 - 1.00	100 - 300	a) 0.100 / 0.150 b) 0.100 / 0.150	35	For Fusarium Head Blight control, only one application at BBCH 61-69.
5	**wheat TRZAW, TRZAS TRZDU, TRZSP**	**HU**	**BAS 765 00 F**	**F**	**B. graminis - ERYSGR Zymoseptoria tritici - SEPTTR Puccinia triticina - PUCCRT Fusarium sp. - FUSASP Oculimacula spp.- PSDCHE**	**SC**	**a) 100 g/L** **b) 150 g/L**	**Spraying**	**30 - 69**	**a) 2** **b) 2**	**14***	**a) 0.60 - 1.00** **b) 0.60 - 2.00**	**100 - 300**	**a) 0.100 / 0.150** **b) 0.200 / 0.300**	**35**	***if first application after BBCH 49; min. 21 days spray interval. For Fusarium Head Blight control, only one application at BBCH 61-69.**
6	barley HORVW HORVS	HU	BAS 765 00 F	F	Pyrenophora teres - PYRNTE P. hordei - PUCCHD	SC	a) 100 g/L b) 150 g/L	Spraying	30 - 49	a) 1 b) 1	14	a) 0.60 - 1.00 b) 0.60 - 2.00	100 - 300	a) 0.100 / 0.150 b) 0.200 / 0.300	35	

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min) (days)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		
7	rye SECCW SECCS SECCE	HU	BAS 765 00 F		B. graminis - ERYSGR R. secalis - RHYNSE Puccinia recondita - PUCCRE	SC	a) 100 g/L b) 150 g/L	Spraying	30 - 49	a) 1 b) 1	14*	a) 0.60 - 1.00 b) 0.60 - 2.00	100 - 300	a) 0.100 / 0.150 b) 0.200 / 0.300	35	*if first application after BBCH 49; min. 21 days spray interval.
8	triticale TTLWI TTLSO	HU	BAS 765 00 F		B. graminis - ERYSGR Septoria spp. - SEPTSP Puccinia recondita - PUCCRE	SC	a) 100 g/L b) 150 g/L	Spraying	30 - 49	a) 1 b) 1	14*	a) 0.60 - 1.00 b) 0.60 - 2.00	100 - 300	a) 0.100 / 0.150 b) 0.200 / 0.300	35	*if first application after BBCH 49; min. 21 days spray interval. For Fusarium Head Blight control, only one application at BBCH 61-69.

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	Crop and/ or situation **	Zone	Product	F, Fn, Fpn G, Gn, Gpn or I***	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Conclusion
						Type	Conc. of as	method kind	growth stage & season	number min max	interval between applications (min) (days)	kg as/hL min max	water L/ha min max	kg as/ha min max		
9	**wheat TRZAW, TRZAS TRZDU, TRZSP**	**PL**	**BAS 765 00 F**	**F**	**B. graminis - ERYSGR Zymoseptoria tritici - SEPTTR Puccinia triticina - PUCCRT Fusarium sp. - FUSASP Oculimacula spp.- PSDCHE**	**SC**	**a) 100 g/L b) 150 g/L**	**Spraying**	**30 - 69**	**a) 2 b) 2**	**14***	**a) 1.00 b) 2.00**	**100 - 300**	**a) 0.100 / 0.150 b) 0.200 / 0.300**	**35**	***if first application after BBCH 49; min. 21 days spray interval. For Fusarium Head Blight control, only one application at BBCH 61-69.**
10	**barley HORVW HORVS**	**PL**	**BAS 765 00 F**	**F**	**Pyrenophora teres - PYRNTE P. hordei - PUCCHD**	**SC**	**a) 100 g/L b) 150 g/L**	**Spraying**	**30 - 69**	**a) 2 b) 2**	**14**	**a) 1.00 b) 2.00**	**100 - 300**	**a) 0.100 / 0.150 b) 0.200 / 0.300**	**35**	
11	**rye SECCW SECCS SECCE**	**PL**	**BAS 765 00 F**	**F**	**Puccinia recondita - PUCCRE**	**SC**	**a) 100 g/L b) 150 g/L**	**Spraying**	**30 - 69**	**a) 2 b) 2**	**14***	**a) 1.00 b) 2.00**	**100 - 300**	**a) 0.100 / 0.150 b) 0.200 / 0.300**	**35**	***if first application after BBCH 49; min. 21 days spray interval.**

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min) (days)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		
12	**triticale TTLWI TTLSO**	**PL**	**BAS 765 00 F**	**F**	**Septoria spp. - SEPTSP Puccinia recondita - PUCCRE**	**SC**	**a) 100 g/L b) 150 g/L**	**Spraying**	**30 - 69**	**a) 2 b) 2**	**14***	**a) 1.00 b) 2.00**	**100 - 300**	**a) 0.100 / 0.150 b) 0.200 / 0.300**	**35**	***if first application after BBCH 49; min. 21 days spray interval.**
13	**wheat TRZAW, TRZAS TRZDU, TRZSP**	**RO**	**BAS 765 00 F**	**F**	**B. graminis - ERYSGR Zymoseptoria tritici - SEPTTR Puccinia triticina - PUCCRT Fusarium sp. - FUSASP Oculimacula spp.- PSDCHE**	**SC**	**a) 100 g/L b) 150 g/L**	**Spraying**	**30 - 69**	**a) 2 b) 2**	**14***	**a) 0.60 - 1.00 b) 0.60 - 2.00**	**100 - 300**	**a) 0.100 / 0.150 b) 0.200 / 0.300**	**35**	***if first application after BBCH 49; min. 21 days spray interval. For Fusarium Head Blight control, only one application at BBCH 61-69.**
14	barley HORVW HORVS	RO	BAS 765 00 F	F	Pyrenophora teres - PYRNTE P. hordei - PUCCHD	SC	a) 100 g/L b) 150 g/L	Spraying	30 - 49	a) 1 b) 1	14	a) 0.60 - 1.00 b) 0.60 - 2.00	100 - 300	a) 0.100 / 0.150 b) 0.200 / 0.300	35	

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min) (days)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		
15	rye SECCW SECCS SECCE	RO	BAS 765 00 F		B. graminis - ERYSGR R. secalis - RHYNSE Puccinia recondita - PUCCRE	SC	a) 100 g/L b) 150 g/L	Spraying	30 - 49	a) 1 b) 1	14*	a) 0.60 - 1.00 b) 0.60 - 2.00	100 - 300	a) 0.100 / 0.150 b) 0.200 / 0.300	35	*if first application after BBCH 49; min. 21 days spray interval.
16	triticale TTLWI TTLSO	RO	BAS 765 00 F		B. graminis - ERYSGR Septoria spp. - SEPTSP Puccinia recondita - PUCCRE	SC	a) 100 g/L b) 150 g/L	Spraying	30 - 49	a) 1 b) 1	14*	a) 0.60 - 1.00 b) 0.60 - 2.00	100 - 300	a) 0.100 / 0.150 b) 0.200 / 0.300	35	*if first application after BBCH 49; min. 21 days spray interval. For Fusarium Head Blight control, only one application at BBCH 61-69.

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min) (days)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		
17	**wheat TRZAW, TRZAS TRZDU, TRZSP**	**SI**	**BAS 765 00 F**	**F**	**B. graminis - ERYSGR Zymoseptoria tritici - SEPTTR Puccinia triticina - PUCCRT Fusarium sp. - FUSASP Oculimacula spp.- PSDCHE**	**SC**	**a) 100 g/L b) 150 g/L**	**Spraying**	**30 - 69**	**a) 2 b) 2**	**14***	**a) 0.60 - 1.00 b) 0.60 - 2.00**	100 - 300	**a) 0.100 / 0.150 b) 0.200 / 0.300**	**35**	***if first application after BBCH 49; min. 21 days spray interval. For Fusarium Head Blight control, only one application at BBCH 61-69.**
18	barley HORVW HORVS	SI	BAS 765 00 F	F	Pyrenophora teres - PYRNTE P. hordei - PUCCHD	SC	a) 100 g/L b) 150 g/L	Spraying	30 - 49	a) 1 b) 1	14	a) 0.60 - 1.00 b) 0.60 - 2.00	100 - 300	a) 0.100 / 0.150 b) 0.200 / 0.300	35	
19	rye SECCW SECCS SECCE	SI	BAS 765 00 F		B. graminis - ERYSGR R. secalis - RHYNSE Puccinia recondita - PUCCRE	SC	a) 100 g/L b) 150 g/L	Spraying	30 - 49	a) 1 b) 1	14*	a) 0.60 - 1.00 b) 0.60 - 2.00	100 - 300	a) 0.100 / 0.150 b) 0.200 / 0.300	35	*if first application after BBCH 49; min. 21 days spray interval.

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min) (days)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		
20	triticale TTLWI TTLSO	SI	BAS 765 00 F		B. graminis - ERYSGR Septoria spp. - SEPTSP Puccinia recondita - PUCCRE	SC	a) 100 g/L b) 150 g/L	Spraying	30 - 49	a) 1 b) 1	14*	a) 0.60 - 1.00 b) 0.60 - 2.00	100 - 300	a) 0.100 / 0.150 b) 0.200 / 0.300	35	*if first application after BBCH 49; min. 21 days spray interval. For Fusarium Head Blight control, only one application at BBCH 61-69.
21	**wheat TRZAW, TRZAS TRZDU, TRZSP**	**SK**	**BAS 765 00 F**	**F**	**B. graminis - ERYSGR Zymoseptoria tritici - SEPTTR Puccinia triticina - PUCCRT Fusarium sp. - FUSASP Oculimacula spp.- PSDCHE**	**SC**	**a) 100 g/L** **b) 150 g/L**	**Spraying**	**30 - 69**	**a) 2** **b) 2**	**14***	**a) 0.60 - 1.00** **b) 0.60 - 2.00**	**100 - 300**	**a) 0.100 / 0.150** **b) 0.200 / 0.300**	**35**	***if first application after BBCH 49; min. 21 days spray interval. For Fusarium Head Blight control, only one application at BBCH 61-69.**
22	barley HORVW HORVS	SK	BAS 765 00 F	F	Pyrenophora teres - PYRNTE P. hordei - PUCCHD	SC	a) 100 g/L b) 150 g/L	Spraying	30 - 49	a) 1 b) 1	14	a) 0.60 - 1.00 b) 0.60 - 2.00	100 - 300	a) 0.100 / 0.150 b) 0.200 / 0.300	35	

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min) (days)**	**kg as/hL min max**	**water L/ha min max**	**kg as/ha min max**		
23	rye SECCW SECCS SECCE	SK	BAS 765 00 F		B. graminis - ERYSGR R. secalis - RHYNSE Puccinia recondita - PUCCRE	SC	a) 100 g/L b) 150 g/L	Spraying	30 - 49	a) 1 b) 1	14*	a) 0.60 - 1.00 b) 0.60 - 2.00	100 - 300	a) 0.100 / 0.150 b) 0.200 / 0.300	35	*if first application after BBCH 49; min. 21 days spray interval.
24	triticale TTLWI TTLSO	SK	BAS 765 00 F		B. graminis - ERYSGR Septoria spp. - SEPTSP Puccinia recondita - PUCCRE	SC	a) 100 g/L b) 150 g/L	Spraying	30 - 49	a) 1 b) 1	14*	a) 0.60 - 1.00 b) 0.60 - 2.00	100 - 300	a) 0.100 / 0.150 b) 0.200 / 0.300	35	*if first application after BBCH 49; min. 21 days spray interval. For Fusarium Head Blight control, only one application at BBCH 61-69.

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

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

critical GAPs are highlighted in **bold**

a) Mefentrifluconazole

b) Kresoxim-methyl

Explanation for Column 11 “Conclusion”

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

7.1.2 Summary of the evaluation

The formulated product BAS 765 00 F contains the active ingredients mefentrifluconazole (BAS 750 F) and kresoxim-methyl (BAS 490 F). Their toxicological endpoints are summarized below. As also being relevant, the set endpoints for the triazole derivative metabolites (TDMs) are shown in the table.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of BAS 750 F, TDMs and BAS 490 F

Reference value	Source	Year	Value	Study relied upon	Safety factor
Mefentrifluconazole - Parent compound					
ADI*	EFSA, 2018a	2018	0.035 mg/kg bw per day	18-month carcinogenicity study in mice	100
ARfD*	EFSA, 2018a	2018	0.15 mg/kg bw	Developmental toxicity study in rabbits	100
1,2,4-Triazole (1,2,4-T) - TDM					
ADI	EFSA, 2018b	2018	0.023 mg/kg bw per day	Newly submitted rat 12-month study	300
ARfD	EFSA, 2018b	2018	0.1 mg/kg bw	Rabbit developmental study	300
Triazole alanine (TA) - TDM					
ADI	EFSA, 2018b	2018	0.3 mg/kg bw per day	Newly submitted rabbit developmental study	100
ARfD	EFSA, 2018b	2018	0.3 mg/kg bw	Newly submitted rabbit developmental study	100
Triazole acetic acid (TAA) - TDM					
ADI	EFSA, 2018b	2018	1 mg/kg bw per day	Newly submitted rat 2-generation and rabbit developmental studies	100
ARfD	EFSA, 2018b	2018	1 mg/kg bw	Newly submitted rat 2-generation and rabbit developmental studies	100
Triazole lactic acid (TLA) - TDM					
ADI	EFSA, 2018b	2018	0.3 mg/kg bw per day	Newly submitted rabbit developmental study	100
ARfD	EFSA, 2018b	2018	0.3 mg/kg bw	Newly submitted rabbit developmental study	100
Kresoxim-methyl - Parent compound					
ADI	EFSA	2010	0.4 mg/kg bw per day	Rat 2-year oral toxicity study	100
ARfD	EFSA	2010	Not allocated	Not necessary	Not applicable

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

7.1.2.1 Summary for Mefentrifluconazole (BAS 750 F)

Table 7.1-3: Summary for mefentrifluconazole

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
5, 9, 13, 17, 21	wheat	Yes	Yes (12 NEU#/ 13 SEU#)	Yes	Yes	Yes	No	No
10	barley	Yes	Yes (13 NEU#/ 13 SEU#)	Yes	Yes	Yes		No
11	rye (extrapolation from wheat)	Yes	Yes (12 NEU#/ 13 SEU#)	Yes	Yes	Yes		No
12	triticale (covered by wheat according to EU Reg. 2018/62)	Yes	Yes (12 NEU#/ 13 SEU#)	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
\# 4 trials per zone and crop result from new studies
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 Kresoxim-methyl

Table 7.1-4: Summary for kresoxim-methyl

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?
5, 9, 13, 17, 21	wheat	Yes	Yes (17 NEU#/ 19 SEU#)	Yes	Yes	Yes	No	No
10	barley	Yes	Yes (20 NEU#/ 23 SEU#)	Yes	Yes	Yes	No	No
11	rye (extrapolation from wheat)	Yes	Yes (17 NEU#/ 19 SEU#)	Yes	Yes	Yes	No	No
12	triticale (covered by wheat according to EU Reg. 2018/62)	Yes	Yes (17 NEU#/ 19 SEU#)	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
\# 4 trials per zone and crop result from new studies
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

As residues of kresoxim-methyl do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of processing on the magnitude of the residues.

Residues in succeeding crops have been sufficiently investigated. Based on the available data it can be concluded, that for the intended uses of kresoxim-methyl in the product BAS 765 00 F on cereals no residues of parent and the relevant metabolites above 0.01 mg/kg are expected in rotational crops. Further investigation of residues in rotational crops is therefore not required.

Considering dietary burden, 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 new MRLs or mitigation measures have been proposed.

7.1.2.3 Summary for active substance 3

Not relevant.

7.1.2.4 Summary for BAS 765 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 765 00 F is directed to the crop only. Withholding period/PHI is detailed in the following table.

Table 7.1-5: Information on BAS 765 00 F (KCA 6.8)

Crop	PHI for BAS 765 00 F proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for BAS 765 00 F proposed by zRMS	zRMS Comments (if different PHI proposed)
		mefentrifluconazole	kresoxim-methyl		
Wheat	35 days**	Yes	Yes	35	
Barley	35 days**	Yes	Yes	35	
Rye	35 days**	Yes	Yes	35	
Triticale	35 days**	Yes	Yes	35	

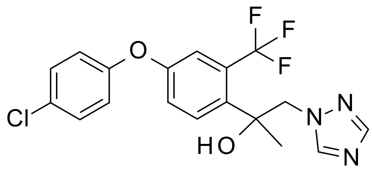
NR: not relevant
* Purpose of withholding period to be specified
** PHI may vary due to geographical and climatic conditions, please refer to comment at the beginning of Table 7.1-1

Assessment

7.2 Mefentrifluconazole

General data on mefentrifluconazole are summarized in the table below (last updated 2020/10/16).

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) No 2019/977
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 2018
EFSA Journal: conclusion on article 12	No
Current MRL applications on intended uses	No

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

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

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

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

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

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

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

Conclusion on stability of residues during storage (EFSA, 2018)

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 considered that sufficient data is available to support the storage stability of BAS 750 F in all plant commodities for at least 730 days. Additionally, as there is no observed decline in residues across these commodities, specific storage stability data is not required for processed commodities.

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

Metabolites

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

Triazole derivative metabolites (TDMs) are formed during the metabolism of BAS 750 F in plant and animal commodities. The TDMs are 1,2,4-triazole, triazole alanine, triazole acetic acid and triazole lactic acid. Frozen storage stability of these metabolites was considered as part of the 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. L0076/01 (BASF DocID 2015/3001681). Stability tests were conducted in six representative matrices (tomato whole fruit, citrus whole fruit, dry beans seed, wheat grain, soybean grain and coffee grain). BAS 750 F showed to be stable for up to 8 days.

For animal matrices, stability tests for BAS 750 F were done during the validation study of BASF analytical Method No. L0272/01 (BASF DocID: 2015/1106707). Stability tests for extracts and final volumes were conducted in seven representative animal matrices (bovine meat, bovine milk, bovine cream, bovine fat, bovine liver, bovine kidney, hen egg). BAS 750 F 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 was submitted in the framework of this application. In the context of the Annex I inclusion process three plant metabolism studies have been submitted by the applicant. These studies are summarized in the table below. For a detailed assessment refer to the EFSA conclusion (2018a).

Table 7.2-3: Summary of plant metabolism studies

<table>
<tr><th rowspan="2">Crop Group</th><th rowspan="2">Crop</th><th rowspan="2">Label position</th><th colspan="5">Application and sampling details</th><th rowspan="2">Reference</th></tr>
<tr><th>Method, F or G (a)</th><th>Rate (kg a.s./ha)</th><th>No</th><th>Sampling (DAT)</th><th>Remarks</th></tr>
<tr><td colspan="9">EU data</td></tr>
<tr><td rowspan="2">Fruit crops</td><td rowspan="2">Grape</td><td>Chlorophenyl-ring (C-ring)</td><td rowspan="2">Foliar spray applications, F*</td><td rowspan="2">0.150</td><td rowspan="2">3</td><td rowspan="2">Leaf, stalk and grape fruits: “-0” (21 DAT)¹⁾, 12</td><td rowspan="2">10 day interval</td><td rowspan="2">EFSA, 2018a BASF DocID 2015/1073822</td></tr>
<tr><td>Triazole-ring (T-ring)</td></tr>
<tr><td rowspan="2">Cereals/grass crops</td><td rowspan="2">Wheat</td><td>Chlorophenyl-ring (C-ring)</td><td rowspan="2">Foliar spray applications, G**</td><td rowspan="2">0.150</td><td rowspan="2">2</td><td rowspan="2">Forage: -6 (=15)³⁾
Grain: 35
Straw: 35</td><td rowspan="2">application: BBCH 49 and 69, 21 day interval</td><td rowspan="2">EFSA, 2018a BASF DocID 2015/1001872</td></tr>
<tr><td>Triazole-ring (T-ring)</td></tr>
<tr><td rowspan="2">Pulses/Oilseeds</td><td rowspan="2">Soybean</td><td>Chlorophenyl-ring (C-ring)</td><td rowspan="2">Foliar spray applications, G**</td><td rowspan="2">0.125</td><td rowspan="2">3</td><td rowspan="2">Forage: -17 (=19 DAT)²⁾
Seed: 47/48
Hull: 47/48
Rest of plant: 47/48
Green pods: 47/48</td><td rowspan="2">application: BBCH 60, 72 and 77, 18 day interval</td><td rowspan="2">EFSA, 2018a, BASF DocID 2014/1224012</td></tr>
<tr><td>Triazole-ring (T-ring)</td></tr>
<tr><td colspan="9">New data</td></tr>
<tr><td>No new data</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
</table>

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

DAT = days after last treatment

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

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

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

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

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

Summary of plant metabolism studies reported in the EU (EFSA, 2018a)

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

Other metabolites were formed via two main pathways:

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

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

Conclusion on metabolism in primary crops

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

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

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

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

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)**	Harvest Intervals (DAP)Δ	Remarks	
EU data								
Root/tuber crops	White radish	Chlorophenyl-ring (C-ring)	G	0.300	30 120 365	68 57 61	One application to bare soil	EFSA, 2018a BASF DocID 2015/1001871
		Triazole-ring (T-ring)			31 122 364	70 59 61	One application to bare soil	
Leafy crops	Spinach	Chlorophenyl-ring (C-ring)	G	0.300	30 120 365	28-41 33-41 27-40	One application to bare soil	
		Triazole-ring (T-ring)			31 122 364	25-44 32-43 33-46	One application to bare soil	
Cereal (small grain)	Wheat	Chlorophenyl-ring (C-ring)	G	0.300	30 120 365	49-105 50-144 55-137	One application to bare soil	
		Triazole-ring (T-ring)			31 122 364	53-105 52-148 54-138	One application to bare soil	
New data								
No new data								

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

Summary of plant metabolism studies reported in the EU (EFSA, 2018a)

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

Conclusion on metabolism in rotational crops

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

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

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

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

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

Conclusion on nature of residues in processed commodities (EFSA, 2018a,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 was submitted in the framework of this application. In the context of the Annex I inclusion process three animal metabolism studies (hen, goat, trout) have been submitted by the applicant. These studies are summarized in the table below. For a detailed assessment refer to the EFSA conclusion (2018a).

Table 7.2-7: Summary of animal metabolism studies

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

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	
						Excreta	24 h prior to first dose administration, once daily	
						Tissues	at sacrifice	
Lactating ruminants	Goat	Chlorophenyl ring (C-ring)	2	0.36	14	Milk	twice daily	EFSA, 2018a BASF DocID 2015/1078841
						Urine and faeces	daily	
						Tissues	at sacrifice	
		Trifluoromethyl-phenyl ring (TFMP-ring)	1	0.40	12	Milk	twice daily	
						Urine and faeces	daily	
						Tissues	at sacrifice	
		Triazole ring (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 765 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: BAS 750 F RA = according to risk assessment residue definition: a) BAS 750 F b) triazole derivative metabolites (TDMs) with a separate assessment of 1) TA, 2) TLA, 3) TAA, 4) 1,2,4-T	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Wheat grain (and extrapolation to rye and triticale grain)	EFSA, 2018a BASF DocIDs 2014/1010809 and 2015/1099704 and 2017/1141927		GAP: 2 x 0.15 kg as/ha, BBCH 49-69, PHI 35d***, outdoor	0.01**	0.026**	-	0.05	yes
		N-EU	E/RA a): 4x <0.01, 0.011, 0.014, 0.016, 0.024					
		S-EU	E/RA a): 7x <0.01, 0.018, 0.026					
		N-EU	RA b) 1)[#] 0.10, 0.12, 0.20, 0.22, 0.26, 0.26, 0.54, 1.21 2) 3) 0.016, 0.019, 0.022, 0.023, 0.063, 0.1, 0.16, 0.42 4) 8x <0.01	1) 0.26** 2) 3) 0.06** 4) 0.01**	1) 1.21** 2) 3) 0.42** 4) 0.01**	-	-	-
		S-EU	RA b) 1)[#] 0.02, 0.13, 0.23, 0.26, 0.32, 0.33, 0.36, 0.37, 0.85 2) 3) <0.01, 0.015, 0.023, 0.046, 0.068, 0.081, 0.091, 0.11, 0.2 4) 9x <0.01					

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of BAS 765 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: BAS 750 F RA = according to risk assessment residue definition: a) BAS 750 F b) triazole derivative metabolites (TDMs) with a separate assessment of 1) TA, 2) TLA, 3) TAA, 4) 1,2,4-T	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
	New trials BASF DocID 2020/2093149 (CA 6.3.2/1)		GAP: 2 x 0.1 kg as/ha, BBCH 49-69, PHI 35d, outdoor	0.01**	0.036**	Highest residue covered by MRL 0.05 mg/kg. No further considerations needed.		yes
		N-EU	E/RA a): 3x <0.01, 0.012					
		S-EU	E/RA a): <0.01, 0.021, 0.032, 0.036					
		N-EU	RA b) 1) 0.11, 0.13, 2x 0.23 2) 4x <0.01 3) 0.031, 0.05, 2x 0.12 4) 4x <0.01	1) 0.15** 2) 0.01** 3) 0.09** 4) 0.01**	1) 0.35** 2) 0.01** 3) 0.18** 4) 0.01**	-	-	-
		S-EU	RA b) 1) 0.050, 0.052, 0.17, 0.35 2) 4x <0.01 3) <0.01, 0.014, 0.17, 0.18 4) 4x <0.01			-	-	-

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of BAS 765 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: BAS 750 F RA = according to risk assessment residue definition: a) BAS 750 F b) triazole derivative metabolites (TDMs) with a separate assessment of 1) TA, 2) TLA, 3) TAA, 4) 1,2,4-T	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Wheat straw (and extrapolation to rye and triticale straw)	EFSA, 2018a BASF DocIDs 2014/1010809 and 2015/1099704 and 2017/1141927		GAP: 2 x 0.15 kg as/ha, BBCH 49-69, PHI 35d, outdoor	3.6**	18.0**	-	30	yes
		N-EU	E/RA a): 1.9, 2.3, 3.4, 3.6, 3.9, 4.9, 5.5, 10					
		S-EU	E/RA a): 0.5, 0.56, 1.6, 2.9, 3.1, 3.8, 4.6, 9.0, 18.0					
		N-EU	RA b) 1)[#] 0.117, 0.118, 0.152, 0.161, 0.355, 0.483, 0.511, 0.642 2) 3) 3x <0.01, 0.014, 0.029, 0.086, 0.088, 0.16 4) 8x <0.01	1) 0.25** 2) 3) 0.03** 4) 0.01**	1) 1.51** 2) 3) 0.16** 4) 0.01**	-	-	-
		S-EU	RA b) 1)[#] 0.157, 0.164, 0.198, 0.23, 0.245, 0.37, 0.55, 0.705, 1.51 2) 3) 3x <0.01, 0.013, 0.031, 0.032, 0.054, 0.06, 0.081 4) 9x <0.01					
	New trials BASF DocID 2020/2093149 (CA 6.3.2/1)		GAP: 2 x 0.1 kg as/ha, BBCH 49-69, PHI 35d, outdoor	1.9	3.8	Highest residue covered by pseudo MRL 30 mg/kg. No further considerations needed.		yes
		N-EU	E/RA a): 0.95, 1.3, 1.5, 3.8					
		S-EU	E/RA a): 1.0, 2.3, 2.5, 3.6					
		N-EU	RA b) 1) <0.01, 0.012, 0.016, 0.027 2) 0.016, 0.043, 0.084, 0.094 3) 0.022, 0.036, 0.057, 0.059 4) 4x <0.01	1) 0.01** 2) 0.06** 3) 0.05** 4) 0.01**	1) 0.057** 2) 0.112** 3) 0.089** 4) 0.01**	-	-	-

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of BAS 765 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: BAS 750 F RA = according to risk assessment residue definition: a) BAS 750 F b) triazole derivative metabolites (TDMs) with a separate assessment of 1) TA, 2) TLA, 3) TAA, 4) 1,2,4-T	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
		S-EU	RA b) 1) 2x <0.01, 0.031, 0.057 2) <0.01, 0.014, 0.11, 0.112 3) <0.01, 0.012, 0.062, 0.089 4) 4x <0.01					
Barley grain	EFSA, 2018a BASF DocIDs 2014/1010808 and 2015/1099703 and 2017/1101701		GAP: 2 x 0.15 kg as/ha, BBCH 49-69, PHI 35d, outdoor	0.1**	0.41**	-	0.6	yes
		N-EU	E/RA a): 0.014, 0.06, 0.071, 0.087, 0.1, 0.15, 0.15, 0.19, 0.28					
		S-EU	E/RA a): 0.03, 0.033, 0.07, 0.1, 0.1, 0.14, 0.16, 0.29, 0.41					
		N-EU	RA b) 1)[#] 0.159, 0.187, 0.397, 0.514, 0.844, 1.186, 1.32, 2.6, 3.8 2) 3) 0.019, 0.021, 0.025, 0.096, 0.11, 0.3, 0.34, 0.37, 0.5 4) 9x <0.01	1) 0.33** 2) 3) 0.09** 4) 0.01**	1) 3.8** 2) 3) 0.5** 4) 0.01**	-	-	-
		S-EU	RA b) 1)[#] 0.078, 0.09, 0.12, 0.126, 0.233, 0.24, 0.27, 0.701, 0.92 2) 3) 3x <0.01, 0.02, 0.081, 0.091, 0.011, 0.18, 0.2 4) 9x <0.01					
			GAP: 2 x 0.1 kg as/ha, BBCH 49-69, PHI 35d, outdoor	0.12**	0.32**			yes
		N-EU	E/RA a): 0.038, 0.068, 0.13, 0.15					

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of BAS 765 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: BAS 750 F RA = according to risk assessment residue definition: a) BAS 750 F b) triazole derivative metabolites (TDMs) with a separate assessment of 1) TA, 2) TLA, 3) TAA, 4) 1,2,4-T	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
	New trials BASF DocID 2020/2100869 (CA 6.3.1/1)	S-EU	E/RA a): 0.055, 0.10, 0.26, 0.32			Highest residue covered by MRL 0.6 mg/kg. No further considerations needed.		
		N-EU	RA b) 1) 0.07, 0.12, 0.21, 0.34 2) <0.01, 0.013, 0.017, 0.074 3) 0.037, 0.055, 0.24, 0.37 4) 4x < 0.01	1) 0.15** 2) 0.01** 3) 0.1** 4) 0.01**	1) 0.77** 2) 0.074** 3) 0.43** 4) 0.01**	-	-	-
		S-EU	RA b) 1) 0.037, 0.13, 0.16, 0.77 2) 3x < 0.01, 0.012 3) < 0.01, 0.079, 0.13, 0.43 4) 4x < 0.01					
Barley straw	EFSA, 2018a BASF DocIDs 2014/1010808 and 2015/1099703 and 2017/1101701		GAP: 2 x 0.15 kg as/ha, BBCH 49-69, PHI 35d, outdoor	4.25**	18.0**	-	30	yes
		N-EU	E/RA a): 1.0, 1.7, 3.1, 3.9, 4.3, 4.3, 5.6, 6.8, 15.0					
		S-EU	E/RA a): 0.39, 2.1, 2.2, 3.3, 4.2, 4.6, 6.4, 11.0, 18.0					
		N-EU	RA b) 1) # 0.27, 0.423, 0.458, 0.57, 0.598, 0.897, 0.94, 1.171, 10.67 2) 3) <0.01, 0.025, 0.026, 0.027, 0.035, 0.11, 0.12, 0.2, 0.33 4) 9x <0.01	1) 0.33** 2) 3) 0.04** 4) 0.01**	1) 10.67** 2) 3) 0.33** 4) 0.01**	-	-	-

Table 7.2-9: Summary of EU reported and new data supporting the intended uses of BAS 765 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: BAS 750 F RA = according to risk assessment residue definition: a) BAS 750 F b) triazole derivative metabolites (TDMs) with a separate assessment of 1) TA, 2) TLA, 3) TAA, 4) 1,2,4-T	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
		S-EU	RA b) 1)[#] 0.427, 0.413, 0.465, 0.54, 0.544, 0.584, 0.688, 0.842, 4.51 2) 3) 4x <0.01, 0.035, 0.045, 0.05, 0.095, 0.11 4) 9x <0.01					
	New trials		GAP: 2 x 0.1 kg as/ha, BBCH 49-69, PHI 35d, outdoor	2.35**	4.8**	Highest residue covered by pseudo MRL 30 mg/kg. No further considerations needed.		yes
	BASF DocID 2020/2100869 (CA 6.3.1/1)	N-EU	E/RA a): 0.8, 3.0, 4.4, 4.8,					
		S-EU	E/RA a): 0.50, 1.2, 1.7, 3.5					
		N-EU	RA b) 1) 0.015, 0.018, 0.056, 0.17 2) 0.010, 0.015, 0.27, 0.31, 3) 0.019, 0.039, 0.14, 0.45 4) 3x <0.01, 0.059	1) 0.04** 2) 0.03** 3) 0.05** 4) 0.01**	1) 0.26** 2) 0.34** 3) 0.45** 4) 0.059**	-	-	-
		S-EU	RA b) 1) <0.01, 0.032, 0.088, 0.26 2) 0.017, 0.028, 0.04, 0.34 3) <0.01, 0.053, 0.054, 0.28 4) 4x <0.01					

[#] EFSA 2018a: residues are reported as the sum of TA and TLA measurements
* Source of EU MRL: Reg. (EU) 2019/977
** U-test confirms that the NEU and SEU data sets are not statistically different, hence they are combined in each case to provide overall STMR and HR values. (test was performed for parent residues only)
*** PHI may vary due to geographical and climatic conditions, please refer to comment at the beginning of Table 7.1-1
General note: in context of EFSA (2018a), for TA, TLA, TAA and 1,2,4-T only the residue values from treated plots were reported. In context of the new trials, untreated values were considered for further calculations if they were higher than the values from the treated plots.

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on cereals are considered acceptable, for outdoor uses. The extrapolation rules have been applied according to SANCO 7525/VI/95 Rev. 10.3. The data submitted show that no exceedance of the current mefentrifluconazole MRLs for the intended uses (barley, wheat, rye, triticale) 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*				
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	-	-

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment/ Source	Input value (mg/kg)	Comment/ Source
Corn, field, hominy meal	0.02	$STMR_P$ (STMR 0.01 x PF 1.70)[(c)] / EFSA, 2020	-	-
Corn, field, gluten feed	0.03	$STMR_P$ (STMR 0.01 x PF 2.70)[(c)] / EFSA, 2020	-	-
Corn, field, gluten meal	0.03	$STMR_P$ (STMR 0.01 x PF 2.70)[(c)] / EFSA, 2020	-	-
Potato, culls (= roots)	0.01	STMR / EFSA, 2020	0.01	HR / EFSA, 2020
Potato, process waste	0.005	$STMR_P$ (STMR 0.01 x PF 0.45) / EFSA, 2020	-	-
Potato, dried pulp	0.02	$STMR_P$ (STMR 0.01 x PF 2.43) / EFSA, 2020	-	-
Canola (rape seed), meal	0.02	$STMR_P$ (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	-	-
Sunflower, meal	0.02	$STMR_P$ (STMR 0.01 x PF 2.0)[(a)] / EFSA, 2020	-	-
Wheat grain	0.01[1]	STMR / EFSA, 2018a	0.01[1]	STMR / EFSA, 2018a
Wheat straw	3.6[1]	STMR / EFSA, 2018a	18.0[1]	HR / EFSA, 2018a
Wheat gluten meal	0.003[1]	$STMR_P$ (STMR 0.01 x PF 0.3) / EFSA, 2018a	-	-
Wheat milled byproducts	0.01[1]	$STMR_P$ (STMR 0.01 x PF 0.6) / EFSA, 2018a	-	-
Wheat distiller's grain (dried)	0.03[1]	$STMR_P$ (STMR 0.01 x PF 2.7) / EFSA, 2018a	-	-
Rye grain	0.01[1]	STMR / EFSA, 2018a	0.01[1]	STMR / EFSA, 2018a
Rye straw	3.6[1]	STMR / EFSA, 2018a	18.0[1]	HR / EFSA, 2018a
Triticale grain	0.01[1]	STMR / EFSA, 2018a	0.01[1]	STMR / EFSA, 2018a
Triticale straw	3.6[1]	STMR / EFSA, 2018a	18.0[1]	HR / EFSA, 2018a
Barley grain	0.12	STMR / Table 7.2-9	0.12	STMR / Table 7.2-9
Barley straw	4.25[1]	STMR / EFSA, 2018a	18.0[1]	HR / EFSA, 2018a
Barley brewers grain (dried)	0.29	$STMR_P$ (STMR 0.12 x PF 2.4) / Table 7.2-9	-	-
Oat grain	0.12[2]	STMR / Table 7.2-9	0.12[2]	STMR / Table 7.2-9
Oat straw	4.25[1]	STMR / EFSA, 2018a	18.0[1]	HR / EFSA, 2018a

HR = highest residue
STMR = Supervised Trials Median Residue
(a): In the absence of specific processing factors supported by data, default processing factors of 2 (oilseed meal), 18 and 3 (sugar

beet dried and ensiled pulp, respectively) were included in the calculation to consider the potential concentration of residues in these commodities.
(b): Since residues in RAC and in processed products were below the LOQ (please refer to EFSA, 2020), a processing factor was not applied. Concentration of residues is not expected.
(c): Tentative processing factor derived based on a limited dataset.
[1] STMRs and HRs of EFSA, 2018a cover also data from new trials submitted in this dossier
[2] *according to SANCO 7525/VI/95 Rev. 10.3. extrapolation from barley to oat is possible. No use for oat is intended in this submission. But to be consistent with previous submissions and to cover future uses in oat, STMR and HR of barley was used also for oat.*

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*	0.039	0.150	barley straw	6.26	yes
Dairy cattle*	0.060	0.238	barley straw	6.19	yes
Ram/Ewe	0.099	0.408	barley straw	12.24	yes
Lamb	0.126	0.520	barley straw	12.24	yes
Breeding swine	0.006	0.014	beet, sugar, tops	0.62	yes
Finishing swine*	0.004	0.004	barley, grain	0.15	no
Broiler poultry	0.009	0.009	barley, grain	0.13	yes
Layer poultry*	0.036	0.148	wheat straw	2.17	yes
Turkey	0.009	0.009	barley, grain	0.12	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 comparable to 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 (except barley being relevant for brewers grain dried: non-significant increase with a STMR 0.12 mg/kg instead of 0.10 mg/kg), no further considerations are considered appropriate.

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

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

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

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

7.2.4.3 Dietary burden calculation in Triazole derived metabolites

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

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

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

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

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

For the input values, please refer to Table 7.2-13 and the supplemental document, in which a detailed derivation of input values is presented (BASF DocID 2020/2106123).
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 wheat, rye, triticale and barley 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 (input 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 (input values in brackets are based on calculations with residue values from* Table 7.2-9*)*				
Wheat grain	0.01	STMR	0.01	STMR
Wheat straw	0.01	STMR	0.01	HR
Wheat gluten meal	0.01	STMR	-	-
Wheat milled byproducts	0.01	STMR	-	-
Wheat distiller's grain (dried)	0.01	STMR	-	-
Rye grain	0.01	STMR	0.01	STMR
Rye straw	0.01	STMR	0.01	HR
Triticale grain	0.01	STMR	0.01	STMR
Triticale straw	0.01	STMR	0.01	HR
Barley grain	0.01	STMR	0.01	STMR
Barley straw	0.01	STMR	0.06 (0.06)	HR
Barley brewers grain (dried)	0.01	STMR	0.01	HR
Oat grain	0.01	STMR	0.01	STMR
Oat straw	0.01	STMR	0.06 (0.06)	HR
Risk assessment residue definition: *TA (input values in brackets are based on calculations with residue values from* Table 7.2-9*)*				
Wheat grain	0.28 (0.15)	STMR	0.28 (0.15)	STMR
Wheat straw	0.035 (0.01)	STMR	0.83 (0.057)	HR
Wheat gluten meal	0.05	$STMR_P$ (STMR 0.28 x PF 0.19)	-	-
Wheat milled byproducts	0.16	$STMR_P$ (STMR 0.28 x PF 0.58)	-	-
Wheat distiller's grain (dried)	0.92	$STMR_P$ (STMR 0.28 x PF 3.3)	-	-
Rye grain	0.28 (0.15)	STMR	0.28 (0.15)	STMR
Rye straw	0.035 (0.01)	STMR	0.83 (0.057)	HR
Triticale grain	0.28 (0.15)	STMR	0.28 (0.15)	STMR

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment/ Source[1]	Input value (mg/kg)	Comment/ Source[1]
Triticale straw	0.035 (0.01)	STMR	0.83 (0.057)	HR
Barley grain	0.25 (0.15)	STMR	0.25 (0.15)	STMR
Barley straw	0.09 (0.04)	STMR	0.71 (0.26)	HR
Barley brewers grain (dried)	0.01	$STMR_P$ (STMR 0.25 x PF 0.04)	-	-
Oat grain	0.25 (0.15)	STMR	0.25 (0.15)	STMR
Oat straw	0.09 (0.04)	STMR	0.71 (0.26)	HR
Risk assessment residue definition: *TAA (input values in brackets are based on calculations with residue values from* Table 7.2-9*)*				
Wheat grain	0.09 (0.09)	STMR	0.09 (0.09)	STMR
Wheat straw	0.05 (0.05)	STMR	0.17 (0.09)	HR
Wheat gluten meal	0.08 (0.08)	$STMR_P$ (STMR 0.09 x PF 0.95)	-	-
Wheat milled byproducts	0.05 (0.05)	$STMR_P$ (STMR 0.09 x PF 0.63)	-	-
Wheat distiller's grain (dried)	0.28 (0.28)	$STMR_P$ (STMR 0.09 x PF 3.3)	-	-
Rye grain	0.09 (0.09)	STMR	0.09 (0.09)	STMR
Rye straw	0.05 (0.05)	STMR	0.17 (0.09)	HR
Triticale grain	0.09 (0.09)	STMR	0.09 (0.09)	STMR
Triticale straw	0.05 (0.05)	STMR	0.17 (0.09)	HR
Barley grain	0.1 (0.1)	STMR	0.1 (0.1)	STMR
Barley straw	0.05 (0.05)	STMR	0.45 (0.45)	HR
Barley brewers grain (dried)	0.01	$STMR_P$ (STMR 0.1 x PF 0.08)	-	-
Oat grain	0.1 (0.1)	STMR	0.1 (0.1)	STMR
Oat straw	0.05 (0.05)	STMR	0.45 (0.45)	HR
Risk assessment residue definition: *TLA (input values in brackets are based on calculations with residue values from* Table 7.2-9*)*				

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	**Comment/ Source[1]**	**Input value (mg/kg)**	**Comment/ Source[1]**
Wheat grain	0.01 (0.01)	STMR	0.01 (0.01)	STMR
Wheat straw	0.077 (0.06)	STMR	1.50 (0.112)	HR
Wheat gluten meal	0.02	$STMR_P$ (STMR 0.01 x PF 1.8)	-	-
Wheat milled byproducts	0.07	$STMR_P$ (STMR 0.01 x PF 7)	-	-
Wheat distiller's grain (dried)	0.03	$STMR_P$ (STMR 0.01 x PF 3.3)	-	-
Rye grain	0.01 (0.01)	STMR	0.01 (0.01)	STMR
Rye straw	0.077 (0.06)	STMR	1.50 (0.112)	HR
Triticale grain	0.01 (0.01)	STMR	0.01 (0.01)	STMR
Triticale straw	0.077 (0.06)	STMR	1.50 (0.112)	HR
Barley grain	0.079 (0.01)	STMR	0.079 (0.01)	STMR
Barley straw	0.55 (0.03)	STMR	11.0 (0.34)	HR
Barley brewers grain (dried)	0.006	$STMR_P$ (STMR 0.079 x PF 0.07)	-	-
Oat grain	0.079 (0.01)	STMR	0.079 (0.01)	STMR
Oat straw	0.55 (0.03)	STMR	11.0 (0.34)	HR

HR = highest residue
STMR = Supervised Trials Median Residue
1 For Source, please refer to the supplemental document (BASF DocID 2020/2106123)

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	0.04	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*	0.007	0.015	potato culls	0.62	yes
Dairy cattle*	0.012	0.024	potato culls	0.63	yes
Ram/Ewe	0.010	0.028	potato culls	0.80	yes
Lamb	0.014	0.033	potato culls	0.78	yes
Breeding swine	0.010	0.017	distiller's grain	0.72	yes
Finishing swine*	0.013	0.022	distiller's grain	0.72	no
Broiler poultry	0.024	0.029	distiller's grain	0.41	yes
Layer poultry*	0.024	0.034	distiller's grain	0.50	yes
Turkey	0.023	0.033	distiller's grain	0.46	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	0.010	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	0.009	0.009	distiller’s grain	0.12	yes
Layer poultry*	0.010	0.011	barley straw	0.16	yes
Turkey	0.007	0.007	distiller’s grain	0.10	yes

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

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

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

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
TLA					
Beef cattle*	0.007	0.091	barley straw	3.80	yes
Dairy cattle*	0.011	0.147	barley straw	3.81	yes
Ram/Ewe	0.015	0.250	barley straw	7.50	yes
Lamb	0.0019	0.319	barley straw	7.50	yes
Breeding swine	0.003	0.004	beet, sugar, tops	0.16	no
Finishing swine*	0.003	0.003	beet, sugar, dried pulp	0.11	no
Broiler poultry	0.006	0.006	barley, grain	0.09	yes
Layer poultry*	0.008	0.048	barley, straw	0.70	yes
Turkey	0.005	0.005	barley, grain	0.07	yes

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

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

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

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

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 also in the table below. For a detailed assessment refer to the EFSA conclusion (2018a).

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.	No comments.	EFSA, 2018a BASF DocID 2014/1315283 (study submitted as part of the Annex I inclusion)
		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.		
		<0.29 (BAS 750 F)	n.a.		

Processed commodity	Number of studies	Median PF *	Median CF **(a)	Comments	Reference
wheat/starch		<0.03 (TA)	n.a.		
		<0.05 (TAA)	n.a.		
wheat/whole meal flour		0.79 (BAS 750 F)	n.a.		
		1.0 (TA)	n.a.		
		0.90 (TAA)	n.a.		
wheat/whole grain bread		0.56 (BAS 750 F)	n.a.		
		0.86 (TA)	n.a.		
		1.19 (TAA)	n.a.		
wheat/milled by products		0.62 (BAS 750 F)	n.a.		
		0.58 (TA)	n.a.		
		0.65 (TAA)	n.a.		
wheat/aspirated grain fraction		38.46 (BAS 750 F)	n.a.		
		0.69 (TA)	n.a.		
		0.63 (TAA)	n.a.		
wheat/silage, wet		1.19 (BAS 750 F)	n.a.		
wheat/silage, wilted		1.88 (BAS 750 F)	n.a.		
barley/pearled, pot barley	1 (3 trials)	0.12 (BAS 750 F)	n.a.		EFSA, 2018a BASF DocID 2014/1315282 (study submitted as part of the Annex I inclusion)
		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.		
		1.09 (BAS 750 F)	n.a.		

Processed commodity	Number of studies	Median PF *	Median CF **(a)	Comments	Reference
barley/malt sprouts		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

1) based on the residues of one trial

2) based on the residues of two trials

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 765 00 F.

7.2.6 Magnitude of residues in representative succeeding crops

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

7.2.6.1 Field rotational crop studies (KCA 6.6.2)

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 BAS 750 F sufficiently addresses aspects of the residue situation that might arise from the use of BAS 765 00 F. Therefore, other special studies are not needed.

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

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

7.2.8.1 Input values for the consumer risk assessment

For sake of being comprehensive, residue data from all previous submissions were taken into account as a worst-case scenario of the chronic risk assessment.
In context of TMDI calculations, the (default) MRLs as reported in EU Reg 2019/977 were used as input values as well as the MRLs proposed by EFSA (EFSA, 2020).
The following table summarizes the input values from plant and animal commodities used for the chronic (IEDI) and acute (IESTI) dietary risk assessment (according to EFSA PRIMo model vers. 3.1).
The PRIMo 3.1 xls-spreadsheets used are attached to this submission to facilitate evaluation (TMDI: BASF DocID 2020/2106108, IEDI: BASF DocID 2020/2106110 and IESTI: BASF DocID 2020/2106112).

Table 7.2-20: Input values for the consumer risk assessment for BAS 750 F

Commodity	Chronic risk assessment (normal mode)		Acute risk assessment (refined calculation mode)	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment residue definition plant and animal except poultry: parent BAS 750 F *Risk assessment residue definition poultry: sum of parent BAS 750 F, metabolite M750F022 and fatty acid conjugates of M750F022, expressed as parent equivalents*				
Products of plant origin				
Pome fruits	0.08	STMR, extrapolation from apple and pear	-	
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 immature corn (EFSA 2020)	-	
Sunflower seeds	0.01	STMR (EFSA, 2020)	-	
Rapeseeds / canola seeds	0.01	STMR (EFSA, 2020)	-	
Barley	0.12	STMR (Table 7.2-9)	0.12	STMR (Table 7.2-9)*
Maize/corn	0.01	STMR (EFSA, 2020)	-	
Oats	0.12[1]	STMR (Table 7.2-9)	-	
Rye	0.01	STMR (EFSA, 2018a)	0.01	STMR (EFSA, 2018a)*
Wheat	0.01	STMR (EFSA, 2018a)	0.01	STMR (EFSA, 2018a)*

Table 7.2-20: Input values for the consumer risk assessment for BAS 750 F

Commodity	Chronic risk assessment (normal mode)		Acute risk assessment (refined calculation mode)	
	Input (mg/kg)	**Comment**	**Input** (mg/kg)	**Comment**
Sugar beet roots	0.02	STMR (EFSA, 2020)	-	
Products of animal origin				
Risk assessment residue definition plant and animal except poultry: parent BAS 750 F				
Swine: Meat	0.01	STMR (EFSA, 2018a)	-	
Swine: Fat free of lean meat	0.01	STMR (EFSA, 2018a)	-	
Swine: Liver	0.01	STMR (EFSA, 2018a)	-	
Swine: Kidney	0.01	STMR (EFSA, 2018a)	-	
Swine: Edible offal	0.01	STMR (EFSA, 2018a)	-	
Bovine: Meat	0.024	STMR (EFSA, 2018a)	-	
Bovine: Fat	0.06	STMR (EFSA, 2018a)	-	
Bovine: Liver	0.09	STMR (EFSA, 2018a)	-	
Bovine: Kidney	0.02	STMR (EFSA, 2018a)	-	
Bovine: Edible offal	0.02	STMR (EFSA, 2018a)	-	
Sheep: Meat	0.032	STMR (EFSA, 2018a)	-	
Sheep: Fat	0.09	STMR (EFSA, 2018a)	-	
Sheep: Liver	0.14	STMR (EFSA, 2018a)	-	
Sheep: Kidney	0.03	STMR (EFSA, 2018a)	-	
Sheep: Edible offal	0.03	STMR (EFSA, 2018a)	-	
Goat: Meat	0.032	STMR (EFSA, 2018a)	-	
Goat: Fat	0.09	STMR (EFSA, 2018a)	-	
Goat: Liver	0.14	STMR (EFSA, 2018a)	-	
Goat: Kidney	0.03	STMR (EFSA, 2018a)	-	
Goat: Edible offal	0.03	STMR (EFSA, 2018a)	-	
Horse: Meat	0.024	STMR (EFSA, 2018a)	-	
Horse: Fat	0.06	STMR (EFSA, 2018a)	-	
Horse: Liver	0.09	STMR (EFSA, 2018a)	-	
Horse: Kidney	0.02	STMR (EFSA, 2018a)	-	
Horse: Edible offal	0.02	STMR (EFSA, 2018a)	-	
Poultry: Meat	0.062	STMR (EFSA, 2018a)	-	
Poultry: Fat	0.163	STMR (EFSA, 2018a)	-	
Poultry: Liver	0.05	STMR (EFSA, 2018a)	-	
Poultry: Kidney	0.05	STMR (EFSA, 2018a)	-	
Poultry: Edible offal	0.05	STMR (EFSA, 2018a)	-	
Milk and milk products: Cattle	0.01	STMR (EFSA, 2018a)	-	

Table 7.2-20: Input values for the consumer risk assessment for BAS 750 F

Commodity	Chronic risk assessment (normal mode)		Acute risk assessment (refined calculation mode)	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Milk and milk products: Sheep	0.01	STMR (EFSA, 2018a)	-	
Milk and milk products: Goat	0.01	STMR (EFSA, 2018a)	-	
Milk and milk products: Horse	0.01	STMR (EFSA, 2018a)	-	
Birds' eggs	0.05	STMR (EFSA, 2018a)	-	
Eggs: Chicken	0.05	STMR (EFSA, 2018a)	-	
Eggs: Duck	0.05	STMR (EFSA, 2018a)	-	
Eggs: Goose	0.05	STMR (EFSA, 2018a)	-	
Eggs: Quail	0.05	STMR (EFSA, 2018a)	-	
Other eggs	0.05	STMR (EFSA, 2018a)	-	
Processed products of plant origin				
Barley / beer	-	HR RAC	0.016	HR_p (HR 0.41 x PF 0.04)
Barley / milling (flour)	-	HR RAC	1.50	HR_p (HR 0.41 x PF 3.67)
Barley / cooked	-	HR RAC	0.41	HR
Oat / milling (flakes)	-	HR RAC	0.41	HR
Oat / boiled	-	HR RAC	0.41	HR
Rye / milling (wholemeal)-baking	-	HR RAC	0.028	HR_p (HR 0.036 x PF 0.79)
Rye / boiled	-	HR RAC	0.036	HR
Wheat / bread (wholemeal)	-	HR RAC	0.020	HR_p (HR 0.036 x PF 0.56)
Wheat / bread/pizza	-	HR RAC	0.036	HR
Wheat / pasta	-	HR RAC	0.036	HR
Wheat / milling (wholemeal)-baking	-	HR RAC	0.028	HR_p (HR 0.036 x PF 0.79)
Wheat / milling (flour)	-	HR RAC	0.010	HR_p (HR 0.036 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)*
[1] *according to SANCO 7525/VI/95 Rev. 10.3. extrapolation from barley to oat is possible. No use for oat is intended in this submission. But to be consistent with previous submissions and to cover future uses in oat, STMR and HR of barley was used also for oat.*

Separate consumer risk assessments are performed for triazole derivative metabolites (TDMs) 1,2,4-T, TA, TAA and TLA. Toxicological reference values have been established for each triazole derivative metabolites during the EU peer review of confirmatory data for TDMs (EFSA, 2018b). The set endpoints for the TDMs are shown in the table Table 7.1-2. The PRIMo 3.1 xls-spreadsheets used are attached to this submission to facilitate evaluation (1,2,4-T: BASF DocID 2020/2106118, TA: BASF DocID 2020/2106113, TLA: BASF DocID 2020/2106117 and TAA: BASF DocID 2020/2106116).

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 2020/2106123. 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, grain for TLA).

The acute consumer risk assessment was performed considering the intended uses for barley, wheat, rye and triticale. 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 2020/2106123. 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 apricots, peaches (for TA) and barley, grain (for TA and TLA).

An overview of the input values is presented in the table below, details are provided in the supplemental document with BASF DocID 2020/2106123.

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

<table>
<tr><th rowspan="2">Commodity</th><th colspan="2">Chronic risk assessment
(normal mode)</th><th colspan="2">Acute risk assessment
(refined calculation mode)</th></tr>
<tr><th>Input
(mg/kg)</th><th>Comment</th><th>Input
(mg/kg)</th><th>Comment</th></tr>
<tr><td colspan="5">Risk assessment residue definition plant and animal: 1,2,4-T</td></tr>
<tr><td>Products of plant and animal origin</td><td colspan="4">Derived in context of the TDM review, for details please refer to the supplemental document with BASF DocID 2020/2106123</td></tr>
<tr><td colspan="5">Risk assessment residue definition plant and animal: TA</td></tr>
<tr><td colspan="5">Products of plant origin</td></tr>
<tr><td>Apricots, peaches, cherries</td><td>0.32</td><td>STMR / TDM review</td><td>1.10</td><td>HR / EFSA, 2020</td></tr>
<tr><td>Barley, grain
Oat, grain</td><td>0.62</td><td>STMR / TDM review</td><td>2.6</td><td>HR*
Table 7.2-9</td></tr>
<tr><td>Products of animal origin and all other products of plant origin</td><td colspan="4">Derived in context of the TDM review, for details please refer to the supplemental document with BASF DocID 2020/2106123</td></tr>
<tr><td colspan="5">Risk assessment residue definition plant and animal: TAA</td></tr>
<tr><td>Products of plant and animal origin</td><td colspan="4">Derived in context of the TDM review, for details please refer to the supplemental document with BASF DocID 2020/2106123</td></tr>
<tr><td colspan="5">Risk assessment residue definition plant and animal TLA</td></tr>
<tr><td colspan="5">Products of plant origin</td></tr>
<tr><td>Barley, grain
Oat, grain</td><td>0.079</td><td>STMR / combined dataset of TDM review and new trials</td><td>1.2</td><td>HR*
Table 7.2-9</td></tr>
<tr><td>Products of animal origin and all other products of plant origin</td><td colspan="4">Derived in context of the TDM review, for details please refer to the supplemental document with BASF DocID 2020/2106123</td></tr>
</table>

** 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.

<u>Mefentrifluconazole</u>

TMDI Calculation

BAS 750 F
The TMDI calculation was performed with the current EFSA model (version 3.1) using an ADI of 0.035 mg/kg bw/day applying default and established MRLs of EU Reg 2019/977.

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 deviating from TDM review (United Kingdom, 2018b) 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 2020/2106208.

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 TLA and TAA of the ADI. The highest contributor is milk (cattle) (42%) for 1,2,4-T, maize, corn (1%) for TA, milk (cattle) (0.6%) for TLA, and maize, corn (0.6%) for TAA.

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

IESTI Calculation

BAS 750 F
A refined IESTI calculation was performed with the current EFSA model (version 3.1) using an ARfD of 0.15 mg/kg bw/day and HRs as listed in Table 7.2-20.

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 for children was 2% for consumption of barley/milling (flour). For adults, the highest ARfD utilization was 0.4% for consumption of barley/beer.

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 deviating from TDM review (United Kingdom, 2018b) 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. Highest ARfD utilization for TLA was for consumption of barley: 0.1%. For adults, the highest ARfD utilization was for consumption of wheat: 0.4% for 1,2,4-T, 2% for TA and 0.7% for TAA. Highest ARfD utilization for TLA was for consumption of barley: 0.1%.

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

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: 2% (children, barley / milling (flour)) 0.4% (adults, barley / beer)
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) 0.06% (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

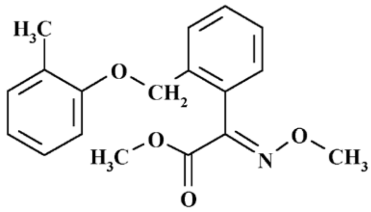
* includes raw and processed commodities if both values are required for PRIMo
** if national model is available

The proposed uses of mefentrifluconazole (BAS 750 F) in the formulation BAS 765 00 F do not represent unacceptable acute and chronic risks for the consumer.

7.3 Kresoxim-methyl

General data on kresoxim-methyl are summarized in the table below (last updated 2020/10/19)

Table 7.3-1: General information on kresoxim-methyl

Active substance (ISO Common Name)	Kresoxim-methyl
IUPAC	methyl (E)-methoxyimino[α-(o-tolyloxy)-o-tolyl]acetate
Chemical structure	
Molecular formula	$C_{18}H_{19}NO_4$
Molar mass	313.3 g/mol
Chemical group	Kresoxim-methyl belongs to the group of strobilurin compounds which are used as fungicides and which are structurally related to strobilurin A, a natural product of the wood-decaying fungus *Strobilurus tenacellus*.
Mode of action (if available)	Kresoxim-methyl is absorbed through the roots and translocated in the xylem to the stems and leaves, or through leaf surfaces to the leaf tips and growing edges. It affects the mitochondrial respiration in fungi at the level of complex III, leading to the inhibition of spore germination, mycelia growth, and spore production. The ester linkage in kresoxim-methyl is essential for its activity.
Systemic	Yes
Company (ies)	BASF SE*
Rapporteur Member State (RMS)	Sweden/Belgium**
Approval status	Approved [99/01/EC, 2007/21/EC, Reg. (EU). No 810/2011, Reg. (EU) No 540/2011, Reg. (EU) No 2019/291]
Restriction	Approval is restricted to uses as fungicide only
Review Report	SANCO/11029/2011 – Rev. 5 12 December 2014
Current MRL regulation	Regulation (EC) No 2020/856
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, 2010 - see list of references)
EFSA Journal: conclusion on article 12	Yes (EFSA, 2014 & EFSA, 2018 - see list of references)
Current MRL applications on intended uses	None

* Notifier in the EU process to whom the a.s. belong(s)
** RMS in AI renewal process

7.3.1 Stability of Residues (KCA 6.1)

7.3.1.1 Stability of residues during storage of samples

Available data

A new study on the storage stability of kresoxim-methyl residues in animal matrices 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
EU data			
Plant products			
Apple and processed products	High water content	Up to 12 months(1)	Belgium, 2010a EFSA, 2010 BASF DocID 1994/11097, 1999/5006
Grape	High acid content	Up to 26 months(1)	Belgium, 2010a EFSA, 2010 BASF DocID 1999/5006
Dried pea	Dry commodity/ High protein content	Up to 24 months(1)	Belgium, 2010a EFSA, 2010 BASF DocID 2009/1120208
Soy bean	High oil content	Up to 24 months(2)	Belgium, 2010a EFSA, 2014 BASF DocID 2009/1120208
Cucumber	High water content	Up to 6 months(1)	Belgium, 2010a BASF DocID 1998/5189
Pecan, nutmeat	High oil content	Up to 6 months(1)	Belgium, 2010a EFSA, 2014 BASF DocID 1997/5339
Wheat grain	Dry commodity/ High starch content	Up to 24 months(1)	Belgium, 2010a EFSA, 2010 BASF DocID 2009/1018683, 2009/1120208
Wheat straw	Others	Up to 3 months(1)	Belgium, 2010a EFSA, 2010 BASF DocID 2009/1120208
Wheat green matter	High water content	Up to 5 months(1)	Belgium, 2010a EFSA, 2010 BASF DocID 2009/1120208
Animal Products			
Ruminant	Liver Kidney	Up to 15 months(3)	Belgium 2018, EFSA, 2018

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
	Muscle Fat Milk		BASF DocID 2016/1235729
New data			
No new data			

(1) Kresoxim-methyl and its metabolites BF 490-2 and BF 490-9.
(2) Metabolite BF 490-2 is stable in soya bean for up to two years. However, parent kresoxim-methyl and metabolite BF 490-9 seem to degrade in soya bean specimens when stored frozen.
(3) BF 490-1: liver, kidney, muscle and fat; BF 490-2: milk, kidney, muscle and fat; BF 490-9: milk, liver, kidney and fat.

Summary of storage stability studies reported in the EU

Regarding plant matrices, EFSA (2014) concluded: "In the framework of the peer review, storage stability of kresoxim-methyl and metabolites BF 490-2 and BF 490-9 (glycoside conjugates) was demonstrated for periods of 12 and 26 months at -10 °C in commodities with high water content (apple, apple processed products) and high acid content (grape), respectively. In dry commodities (wheat grain, dried pea), wheat green matter and wheat straw, kresoxim-methyl and metabolites BF 490-2 and BF 490-9 were shown to be stable for periods of 24, 5 and 3 months at -20 °C, respectively (EFSA, 2010a, 2010b). Finally, according to RMS, kresoxim-methyl and metabolites BF 490-2 and BF 490-9 were shown to be stable for 6 months at -10°C in high oil content commodities (pecans). Besides, BF 490-2 was also shown to be stable for 24 months at -20°C in soya bean."

Regarding animal matrices, EFSA (2018) concluded: "A study investigating the storage stability of the metabolites of kresoxim-methyl (BF 490-1, BF 490-2 and BF 490-9) has been submitted in order to fulfil the identified confirmatory data requirement for kresoxim-methyl and was assessed by the RMS. […]
According to the RMS, the data provided by the applicant are not complete, since the storage stability was not tested for all matrix/metabolite combinations: no data were provided for storage stability of BF 490-9 in muscle, BF 490-2 in liver and BF 490-1 in milk. However, considering that according to the metabolism study assessed in the MRL review […] residues in the matrix/metabolite combinations mentioned are not expected, EFSA is of the opinion that the submitted storage stability study is sufficient to address the data gap. It concluded that the metabolites BF 490-1, BF 490-2 and BF 490-9 are stable for 15 months under frozen conditions in commodities of animal origin. Therefore, the feeding study used to derive the MRL proposals and the risk assessment values are valid."

Conclusion on stability of residues during storage

Grain samples of wheat and barley were stored between 110 and 221 days in the submitted residue studies (BASF DocIDs 2020/2100869 and 2020/2093149), which is well covered by existing stability data for cereal grain (24 months). Cereal straw samples of the new residue studies were analysed within 3 months, which is identical to EU agreed data, please refer to Table 7.3-2.
Therefore, residues in the analysed stored plant and animal commodities, which were used to support the intended uses of kresoxim-methyl in the product BAS 765 00 F on cereals, are considered stable during the respective time of storage.

7.3.1.2 Stability of residues in sample extracts (KCA 6.1)

Available data

No new data submitted in the framework of this application.

The storage stability of four fungicidal active substances epoxiconazole, kresoxim-methyl, dimoxystrobin and boscalid was investigated in methanol, methanol/water, iso-octane and acetonitrile at 4°C in the dark and at room temperature in daylight (BASF DocID 2000/1014856). Analysis of mixing solutions at a starting concentration of 10 µg/mL, were performed after several time-intervals for up to 118 days by HPLC-UV.
The study demonstrates that the kresoxim-methyl (BAS 490 F) in the solvents investigated is stable for at least 30 days.

Besides, the stability of metabolites in organic solvents was adequately demonstrated in the available metabolism studies on primary crops.

Conclusion on stability of residues in sample extracts

Residues in the analysed sample extracts, which were used to support the intended uses of kresoxim-methyl in the product BAS 765 00 F on cereals, is considered stable during the respective time of storage.

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 (1)	**Rate (kg a.s./ha)**	**No**	**Sampling (DAT)**	**Remarks**	
EU data								
Fruits and fruiting vegetables	Apples	^{14}C-phenyl	Foliar spray, F	0.4	6	14	1^{st} application at BBCH 61	Belgium, 1997 and 2010a EFSA, 2014 BASF DocID 1992/11332, 1992/11618, 1992/11760, 1994/10265, 1994/10466
			Foliar spray, F	0.4	2	149	application at BBCH 59 and 69	
		^{14}C-phenyl:^{13}C-methoxyimino (2:1)	Direct fruit application	0.8 (spray solution containing 0.054% a.s.)	2	14	at application leaves and branches were protected with a foil	
	Grapes	^{14}C-phenyl	Foliar spray, F	0.5	5	14	--	Belgium, 1997 and 2010a EFSA, 2014 BASF DocID 1995/5001
		^{14}C-phenoxy	Foliar spray, F	0.5	5	14	--	
Cereals	Wheat	^{14}C-phenyl	Foliar spray, G	0.25	2	$55^{(2)}$;$64^{(3)}$	application at BBCH 41 and 51	Belgium, 1997 and 2010a EFSA, 2014 BASF DocID 1991/10607, 1991/10608, 1994/10685
		^{14}C-phenyl:^{13}C-methoxyimino (1:1)	Foliar spray, G	1.25	2	63	--	
Root and tuber vegetables	Sugar beets	^{14}C-phenyl	Foliar spray, F	0.15	2	before the 2^{nd} application, 0, 28 (harvest) (roots, leaves)	1^{st} application at BBCH 39	Belgium, 2010a EFSA, 2014 BASF DocID 1999/10740

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

(2) Sampling of forage after 1 application
(3) Sampling of grain and straw after 2 applications

Summary of plant metabolism studies reported in the EU

EFSA (2014) concluded: "The metabolism of kresoxim-methyl was investigated for foliar application on fruits and fruiting vegetables (apples, grapes), root and tuber vegetables (sugar beet) and cereals (spring wheat), using ^{14}C-labelled kresoxim-methyl on the phenoxy or on the phenyl ring or a mixture with ^{13}C-labelled kresoxim-methyl on the methoxyimino chain […].

In fruits, higher TRR levels were recovered in grapes (4.72 mg eq./kg) than in apples, where they amounted to 0.84 mg eq./kg. On wheat, TRR levels recovered in grain were low (0.06 mg eq./kg), while they reached 1.31 mg eq./kg and 9.21 mg eq./kg in forage and straw, respectively. Finally, in sugar beet, only small amounts of the applied radioactivity were translocated from the leaves (TRR = 1.26 mg eq./kg) to the roots (TRR = 0.009 mg eq./kg). In all studies, extraction rates were acceptable: unextracted residues were most of the time below 10% TRR, ranging from 1.8% TRR (or 0.015 mg eq./kg, in apples) to 8.9% TRR (or 0.11 mg eq./kg, in sugar beet leaves). In wheat grain, unextracted residues levels reached 38.8% TRR (0.035 mg eq./kg) but were incorporated into polysaccharides (starch, lignin, cellulose) or proteins. Finally, in sugar beet roots, 36.6% TRR was unextracted but corresponded to 0.003 mg eq./kg and it was therefore considered negligible. […]

The metabolic pathway of kresoxim-methyl in plants was shown to be similar in all tested crops and proceeds first by the cleavage of the methyl ester bond to generate the metabolite BF 490-1 (acid of kresoxim-methyl), which can be regarded as an intermediate that is hydroxylated to form the metabolites BF 490-2 and BF 490-9 with further glucoside conjugations. Most of the identified metabolites, BF 490-1, BF 490-2 and BF 490-9, were also observed in the rat metabolism and it was concluded that their toxicity was covered by the toxicological reference value derived for the parent compound […].

Based on the above findings, EFSA already concluded that, following foliar application, the residue definition proposed for enforcement in all plant commodities is defined as parent kresoxim-methyl only. For risk assessment, the residue is defined as the sum of kresoxim-methyl and the metabolites BF 490-2 and BF 490-9, free and conjugated, expressed as parent (EFSA, 2010a, 2010b). The inclusion of the metabolites BF 490-2 and BF 490-9, observed in limited proportions and levels in the metabolism studies, is supported by the residue trials on grapes, where these metabolites were present at the same level as the parent compound at a 35 days PHI. Validated analytical methods for enforcement of the proposed residue definition are available […]. These methods distinguish kresoxim-methyl from its Z-isomer, hereby allowing the specific enforcement of the proposed residue definition."

Summary of new plant metabolism studies

Not applicable, as no new data are submitted.

Conclusion on metabolism in primary crops

No new studies were conducted since the metabolism of kresoxim-methyl was sufficiently investigated in the studies presented in the DAR (Belgium, 1997) and in its revision (Belgium, 2010a). Therefore, the residue definitions for primary crops for enforcement and the residue definition for risk assessment is also applicable for the intended uses of kresoxim-methyl in the product BAS 765 00 F on cereals.

7.3.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

A new confined rotational crop study has been submitted by the applicant in the framework of this application. This study is summarized in the Table below. The detailed assessment of these studies is presented in Appendix 2.

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 [(1)]	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Lettuce	^{14}C-phenyl	Bare soil	0.3[(2)]	30	56-60 (immature plant), 79-96 (head)	-	Belgium, 1997 and 2010a EFSA, 2014 BASF DocID 1993/10500, 1993/11533, 1994/10860
Root and tuber vegetables	Carrots	^{14}C-phenyl	Bare soil	0.3[(2)]	30	80-82 (immature plant), 119-120 (tops, root), 141 (root)	-	
Pulses and oilseeds	Beans	^{14}C-phenyl	Bare soil n.r.	0.3[(2)]	30	56 (immature plant), 105-107 (green bean, mature plant)	-	
Cereals	Spring wheat	^{14}C-phenyl	Bare soil	0.3[(2)]	30	72-91 (immature plant), 154-155 (grain, straw)	-	
New data								
Leafy vegetables	Lettuce	benzyl-U-C^{14}	Bare soil	1.5	30, 120, 365	28 (immature plant), 53-59 (head)	-	CA 6.6.1/1 Kampke-Thiel K., Deppermann N., 2013 BASF DocID 2011/1110200
Root and tuber vegetables	White radish	benzyl-U-C^{14}	Bare soil	1.5	30, 120, 365	14 (immature plant), 77-84 (tops), 77-84 (root)	-	

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (1)	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
Cereals	Spring wheat	benzyl-U-C^{14}	Bare soil	1.5	30, 120, 365	50-61 (forage), 123-158 (chaff), 123-158 (straw), 123-158 (grain)	-	

(1) Not reported if studies were performed with outdoor/field application (F) or glasshouse/protected/indoor application (G).

(2) The active ingredient had been aerobically aged in the soil for 29 days. The aged soil was then mixed with untreated soil in a ratio of 1:9 in order to simulate ploughing. Seeding and planting were done on the following day, 30 days after soil treatment.

Summary of metabolism studies in rotational crops reported in the EU

EFSA (2014) concluded: "TRR levels in plants sown 30 days after application were low in mature consumable parts (lettuce head, carrot root, green bean, wheat grain), ranging from 0.003 (carrot root) to 0.028 mg eq./kg (lettuce head). In wheat forage and wheat straw, TRR levels reached up to 0.232 and 0.119 mg eq./kg respectively. Finally, in immature bean, carrot, lettuce or mature plants foliage, TRR ranged from 0.010 mg eq./kg (carrot mature foliage) to 0.361 mg eq./kg (bean immature plant).

The nature of the radioactivity in wheat straw, immature bean, immature carrot and lettuce (head) was examined. In extracts of immature bean, immature carrot and lettuce, the conjugated fraction was the predominant radioactive residue. This conjugated fraction accounted for 36.7% TRR in immature bean, 43.6% TRR in immature carrot and 41.5% TRR in lettuce. Enzymatic cleavage of these conjugates afforded mainly the aglycone metabolites BF 490-2 and BF 490-9. The rest of extractable radioactivity in these samples was composed of several radioactive peaks. Lettuce contained 9.4% TRR of unchanged parent and carrot forage 12.7% TRR of BF 490-1. The extract of wheat straw contained an unknown peak representing 12.5 - 26.5% TRR, more polar than the conjugated fraction (representing 8.9 - 11.6% TRR and yielding aglycone metabolites BF 490-2 and BF 490-9 after cleavage). This unknown peak was further characterized: cleavage with acid did not change its polarity and diazomethane formed an unpolar derivative. The rest of extractable radioactivity consisted of several polar peaks and of the free hydroxy metabolites BF 490-2 and BF 490-9 (together representing 3.4 - 8.5% TRR). Unchanged parent was present in very small amounts.
Consequently, metabolism in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary (EFSA, 2010a)."

Summary of new metabolism studies in rotational crops

The metabolism of radiolabelled kresoxim-methyl (BAS 490 F) in confined rotational crops was investigated after spray application of the test item to bare soil at a nominal rate of 1x 1500 g a.s./ha (approximately 1.34 lb/A).

A fast translocation of radioactive residues from soil into the plants was observed. Relatively high total radioactive residues were thus determined in the samples from crops planted or sown 30 DAT. The highest residue levels were measured in spring wheat straw (1.629 mg/kg). In samples from crops planted or sown 365 DAT, the TRRs declined significantly and ranged between 0.012 (mature lettuce) and 0.163 mg/kg (spring wheat straw).

Kresoxim-methyl was readily metabolized and was detected only in very minor amounts in lettuce, white radish top and in spring wheat straw (30 DAT). After a plant back interval of 30 DAT, the main metabolite in lettuce, white radish as well as in spring wheat forage was the hydroxylated derivative 490M78 at concentrations of 0.006 mg/kg in lettuce and of 0.073 mg/kg in radish roots. Residues of parent BAS 490 F in edible portions were 0.003 mg/kg in lettuce, which is below the analytical LOQ of enforcement methods of 0.01 mg/kg. The hydroxylated derivatives 490M02 and 490M09 which are part of the residue definition for data generation and risk assessment were not detected. In spring wheat straw (30 DAT), glycoside conjugates and metabolites formed from cleavage at the benzyl position and further oxidation were identified. The solubilization and characterization of considerable parts of the non-extractable residues by enzymatic cleavage of natural macromolecules indicate an incorporation of ^{14}C labeled C1 or C2 units into plant polysaccharides. Moreover, the residues in the macerozyme solubilizate of the residues after solvent extraction of wheat grain (30 DAT) were identified as carbohydrates by fermentation with yeast. After a plant back interval of 365 DAT, kresoxim-methyl was evidently extensively degraded in soil and the radioactive residues in plants were mainly recovered as polar components and non-extractable residues.

Overall, it can be concluded that kresoxim-methyl was extensively metabolized, conjugated with carbohydrates or incorporated in natural macromolecules like e.g. polysaccharides.

Conclusion on metabolism in rotational crops

The metabolism of kresoxim-methyl in rotational crops was already investigated in the studies presented in the DAR (Belgium, 1997) and in its revision (Belgium, 2010a). In addition, a new confined rotational crop study was submitted by the applicant covering a higher application rate and sowing intervals of 30 DAT and more.
Since the metabolism in rotational crops is similar to the metabolism in primary crops, there is no need for a different residue definition for rotational crops.
It can be concluded, that for the intended uses of kresoxim-methyl in the product BAS 765 00 F on cereals no residues of parent and the relevant metabolites above 0.01 mg/kg are expected in rotational crops. Further investigation of residues in rotational crops is therefore not required.
Please refer to Chapter 7.3.6. for a more detailed conclusion on the magnitude of residues in rotational crops.

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)	Kresoxim-methyl (99.2) BF 490-1 (n.d.) BF 490-2 (n.d.)	Belgium, 2010a BASF DocID 2008/1014942
Baking, boiling, brewing (60 minutes, 100°C, pH 5)	Kresoxim-methyl (89.6) BF 490-1 (7.9) BF 490-2 (2.4)	
Sterilisation (20 minutes, 120°C, pH 6)	Kresoxim-methyl (23.5) BF 490-1 (70.8) BF 490-2 (4.6)	

EFSA (2014) concluded: “Studies were conducted simulating representative hydrolytic conditions for pasteurisation (20 minutes at 90°C, pH 4), boiling/brewing/baking (60 minutes at 100°C, pH 5) and sterilisation (20 minutes at 120°C, pH 6). From these studies, it was concluded that processing by pasteurisation and baking/brewing/boiling is not expected to have a significant impact on the composition of residues in matrices of plant origin. Nevertheless, kresoxim-methyl was almost totally degraded to the acid metabolite (BF 490-1) under sterilisation conditions (71% TRR). Unfortunately, the possible presence of the metabolite BF 490-1 in the processed commodities could not be confirmed by the processing studies, since samples were analysed for BF 490-1 after alkaline hydrolysis. Consequently, the actual ratio “parent/BF 490-1” in processed commodities is not known and the residue definition for enforcement in processed commodities is therefore proposed as the sum of kresoxim-methyl and the metabolite BF 490-1, expressed as parent. For risk assessment and considering that BF 490-2 and BF 490-9 were detected at significant levels in some processed fractions (wine), and that the presence of BF 490-1 cannot be excluded, EFSA proposes to define the residue for risk assessment in processed products as the sum of kresoxim-methyl and the metabolites BF 490-1, BF 490-2 and BF 490-9, free and conjugated, expressed as parent.”

Conclusion on nature of residues in processed commodities

No new studies were conducted because the stability of kresoxim-methyl during pasteurisation, baking, boiling, brewing and sterilisation was sufficiently investigated in the study presented in the revision of the DAR (Belgium, 2010a). Since the residue pattern in processed commodities is not similar to the residue pattern in raw commodities, a different residue definition for processed commodities is required.
The residue definition for processed commodities for enforcement is defined as kresoxim-methyl and BF 490-1, expressed as parent and for risk assessment it is the sum of kresoxim-methyl and the metabolites BF 490-1, BF 490-2 and BF 490-9, free and conjugated, expressed as parent.
This is also applicable for the intended uses of kresoxim-methyl in the product BAS 765 00 F on cereals.

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 crops (grape, apple) Cereals (wheat) Root and tuber crops (sugar beet)
Rotational crops covered	Spring wheat, lettuce, carrot, green bean, white radish
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Kresoxim-methyl was shown to be stable during the simulation of pasteurisation and baking, brewing and boiling processes, but it was almost totally degraded to the acid metabolite (BF 490-1) under sterilisation conditions (71% TRR)
Residue pattern in processed commodities similar to pattern in raw commodities?	No Monitoring residue definition for processed commodities: Kresoxim-methyl and BF 490-1, expressed as parent (EFSA 2014) Risk assessment residue definition for processed commodities: Sum of kresoxim-methyl and the metabolites BF 490-1, BF 490-2 and BF 490-9, free and conjugated, expressed as parent (EFSA 2014)
Plant residue definition for monitoring	Kresoxim-methyl (EFSA 2014)
Plant residue definition for risk assessment	Sum of kresoxim-methyl and the metabolites BF 490-2 and BF 490-9, free and conjugated, expressed as parent (EFSA 2014)
Conversion factor from enforcement to RA	Barley grain, Oats grain(1): 2 Rye grain, Wheat grain(1): 2.4 Pecan(2): 1 Pome Fruits(2): 1.4 Grapes(2): 1.5 Strawberries(2): 1.4 Blueberries, Cranberries, Currants, Gooseberries, Azarole(2): 1.6 Table olives, Olives for oil production(2): 2 Turnips(2): 1 Garlic, Onions, Shallots(2): 2.3 Tomatoes, Aubergines(2): 1.5 Peppers(2): 1.4 Cucurbits with edible peel(2): 1 Cucurbits with inedible peel(2): 2.2 Vine leaves (grape leaves) (2): 1.1 Asparagus(2): 1 Leek(2): 1.1 Sunflower seed(2): 1 Beetroot, Sugar beet (root) (2): 1 (EFSA 2014)

(1) Commodity for which uses are intended in this application.
(2) All other commodities from authorized GAPs in Europe and which were evaluated by EFSA (2015) . These conversion factors were used in the risk assessment.

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

Available data

No new data submitted in the framework of this application.

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	^{14}C-phenyl; ^{13}C-kresoxim-methyl(1)	3	by intubation Goat A: 0.25 Goat B: 25 Goat C: 25	Goat A: 5 Goat B: 8 Goat C: 8	Milk	Daily	Belgium, 1997 and 2010a EFSA, 2014 BASF DocID 1992/10545, 1992/10883, 1994/11104
						Urine and faeces	Daily	
						Tissues	At sacrifice(2): muscle, liver, kidney, fat	
	Goat	^{14}C-phenoxy	1	by oral gavage, once per day: 13.9 mg/kg in the diet	5	Milk	Twice per day(4)	Belgium, 2010a EFSA, 2014 BASF DocID 1996/10074
						Urine and faeces	Daily	
						Tissues	At sacrifice(3): liver, kidney, bile, rumen, gastrointestinal tract, muscle, fat	
Laying poultry	Hens	^{14}C-phenyl; ^{13}C-kresoxim-methyl(5)	Group 1: 5 hens Group 2: 10 hens	by oral gavage, once per day: 1 (group 1); 19 (group 2)	6	Eggs	Daily	Belgium, 1997 and 2010a EFSA, 2014 BASF DocID 1994/11102, 1994/11103
						Excreta	Daily	
						Tissues	At sacrifice(6): muscle, liver, kidney, fat, skin, gastrointestinal tract	
Fish	Bioaccumulation and metabolism study in rainbow trout: The bioconcentration factor for whole fish was 220 and elimination was rapid. Due to the rapid excretion of the active substance from fish it is concluded that there is no risk of bioaccumulation in food chains.							Belgium, 2010a EFSA, 2010 BASF DocID 1994/10725

(1) Different ratios according to the goats: goat A, $^{14}C/^{13}C$/unlabelled: 3/0/1; goat B, $^{14}C/^{13}C$/unlabelled: 1/4/10; goat C, $^{14}C/^{13}C$/unlabelled: 1/0/20.
(2) Sacrifice occurred within 24 hours of the last administration (23 h for goat A, 4 h for goats B and C).
(3) Sacrifice occurred 23 hours after the final dose.
(4) Milking occurred twice daily, in the morning just prior to dosing and in the afternoon.
(5) Different ratios according to the poultry groups: ratio ^{14}C/unlabelled: 1/1 (group 1), ratio $^{14}C/^{13}C$/unlabelled: 1/4/3 (group 2).
(6) Sacrifice occurred 23 hours after the final dose for the low dose group and 3h after the final dose for the high dose group.

Summary of livestock metabolism studies reported in the EU

EFSA (2018) pointed out, that "the residue definition in the Commission database does not correspond to the residue definitions specify for kresoxim-methyl in Commission Regulation (EU) 2016/486." For the current Commission Regulation (EU) 2020/856 this is also the case. In the SCoPAFF Meeting (February 2019), it was decided to refer for monitoring purposes to the residue definition including metabolite BF 490-9 expressed as parent (products of animal origin, except honey).

EFSA (2014) concluded on ruminants and pigs: "In the first goat study, parent compound was extensively metabolized and was recovered only in fat at a low level (6.6% TRR, 0.023 mg eq./kg). Major metabolites were BF 490-1, BF 490-2 and BF 490-9, in proportions varying according to the tissue. In milk, the major metabolite was BF 490-9 (63% TRR, 0.119 mg eq./kg). In liver, major metabolites were BF 490-1 (13% TRR, 0.85 mg eq./kg) and BF 490-9 (29% TRR, 1.93 mg eq./kg). In kidney, major metabolites were BF 490-1 (22% TRR, 2.94 mg eq./kg), BF 490-2 (34% TRR, 4.59 mg eq./kg) and BF 490-9 (30% TRR, 4.02 mg eq./kg). In muscle and fat, major metabolites were BF 490-1 (respectively 24% TRR, 0.054 mg eq./kg and 23% TRR, 0.083 mg eq./kg) and BF 490-2 (respectively 14% TRR, 0.032 mg eq./kg and 24% TRR, 0.086 mg eq./kg). Some minor metabolites were not present in the rat metabolism: one of them is a conjugated form of BF 490-1 with glycine and two others reflecting different combinations of the reactions observed in the rat. Therefore, they were considered of no concern. In the second goat study, identification could only be performed in kidney and liver samples, but the metabolic profile of kresoxim-methyl was qualitatively and quantitatively similar to the one observed in the first study.

Therefore, the main degradation pathway of kresoxim-methyl in lactating goats involves cleavage of the methyl ester bond to form the free acid metabolite BF 490-1, hydroxylation of the phenoxy-methyl group to form BF 490-2 and hydroxylation of the aromatic ring to generate the metabolite BF 490-9. Nevertheless, this metabolic profile is not totally consistent with the results of the feeding study […], where BF 490-1 is shown to be present in significantly higher amounts than BF 490-2 and BF 490-9. The highly overdosed levels used in the metabolism study may explain these differences. EFSA therefore proposes to rely on the feeding study defining the residue for enforcement as metabolite BF 490-1 only, expressed as parent. Validated analytical methods for enforcement of the proposed residue definition are available. For risk assessment, it is proposed to define the residue as sum of the metabolites BF 490-1, BF 490-2 and BF 490-9, expressed as parent.
In the metabolism study, BF 490-1 was recovered at trace level in milk, while BF 490-9 represented the major metabolite. Since BF 490-9 was not detected in the feeding study at the highest dose rate, no residues are expected to be transferred in milk and it was decided, by default, to set for milk the same residue definition for enforcement and risk assessment as for the other ruminant matrices. As the general metabolic pathways in rodents and ruminants were found to be comparable, the proposed residue definition in ruminants can be extrapolated to pigs."

EFSA (2014) concluded on poultry: "Residue levels in eggs were stable in the low dose group, while they increased over the study duration from 0.10 to 0.22 mg eq./kg in the high dose group. In the low dose group, TRR levels were very low (0.012 mg eq./kg (eggs) to 0.082 mg eq./kg (liver)). In the high dose group, TRR levels recovered were higher in liver and kidney (6.99 mg eq./kg and 6.36 mg eq./kg respectively) than in the other matrices (0.20 mg eq./kg in muscle, 0.76 mg eq./kg in fat). Parent compound was extensively metabolized to a great number of degradation products but was still present in all tissues except liver. In fat, parent compound was the major compound identified (41.2% TRR) while BF 490-9 was the major metabolite in liver (20.1% TRR). Other metabolites, which were not identified as major in goat, were found to be major in poultry muscle, liver, fat and in eggs. Several metabolites were not recovered in the rat metabolism but generally reflected different combinations of the reactions observed in the rat. […]
EFSA concludes that there is no need to define a residue in commodities of poultry origin and MRLs are not required for poultry. "

Summary of new livestock metabolism studies

Not applicable, as no new data are submitted.

Conclusion on metabolism in livestock

The current dossier is submitted before the date of renewal of the approval of the active substance kresoxim-methyl. Hence, the old active substance data requirements still apply (trigger value of 0.1 mg/kg DM).

According to the dietary burden calculation, presented in Chapter 7.3.4.1, the trigger of 0.1 mg/kg DM is exceeded for ruminants, poultry and pigs. Hence, investigation on the fate of residues in these animals is necessary.
No new studies were conducted since the metabolism of kresoxim-methyl in livestock was sufficiently investigated in the studies presented in the DAR (Belgium, 1997) and in its revision (Belgium, 2010a). The residue definition for animals for enforcement and risk assessment (see table below) is also applicable for the intended uses of kresoxim-methyl in the product BAS 765 00 F on cereals.
The available metabolism studies indicate that residues >0.01 mg/kg at 1x dose rate need to be expected in edible commodities of sheep and cattle. Thus, a feeding study in ruminants is required which is presented in the revised DAR (Belgium, 2010a).

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	3 days in milk
	In eggs, residue levels were stable in the low dose group, while they increased over the study duration from 0.10 to 0.22 mg/kg equiv. in the high dose group.
Animal residue definition for monitoring	New: Metabolite BF 490-9 expressed as parent (products of animal origin, except honey). (According to Reg. (EU) 2020/856) Previous: Metabolite BF 490-1 for meat, fat, liver, kidney, expressed as kresoxim-methyl. Metabolite BF 490-9 for milk, expressed as kresoxim-methyl. Parent kresoxim-methyl for eggs. (Regulation (EC) No 2016/486) Proposed: Metabolite BF 490-1, expressed as parent. (EFSA 2014)
Animal residue definition for risk assessment	Sum of the metabolites BF 490-1, BF 490-2 and BF 490-9, expressed as parent (EFSA 2014)
Conversion factor	Ruminant and pig meat: 1[(1)] (see 7.3.4.2) Ruminant and pig fat: 10.9[(1)] (see 7.3.4.2) Ruminant and pig liver: 4.31[(1)] (see 7.3.4.2) Ruminant and pig kidney: 5.0[(1)] (see 7.3.4.2) Milk: 1.0 (EFSA 2014)
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	Kresoxim-methyl (fat soluble: log $P_{o/w}$ = 3.4) is almost totally degraded in goat to BF 490-1 which is non fat soluble

(1) New calculated conversion factors for ruminant and pig meat, fat, liver and kidney based on the monitoring residue definition of metabolite BF 490-9 expressed as parent (products of animal origin, except honey).

7.3.3 Magnitude of residues in plants (KCA 6.3)

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

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

Table 7.3-9: Summary of EU reported and new data supporting the intended uses of BAS 765 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)	Rounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) [(1)]	MRL compliance
Wheat grain → extrapolated to triticale and rye grain	EFSA, 2014	N-EU	GAP on which EU a.s. assessment is based: *Barley, oat, rye, wheat:* 2x 0.13 kg as/ha, BBCH 69, PHI 35d, outdoor *Wheat, rye (grain):* E: 13x <0.05 RA: 13x <0.05[(2)]	E: 0.05	E: 0.05	0.05	0.08	yes
	EFSA, 2014	S-EU	GAP on which EU a.s. assessment is based: *Barley, oat, rye, wheat:* 2x 0.13 kg as/ha, BBCH 69, PHI 35d, outdoor *Wheat, rye (grain):* E[(3)]: 9x <0.01, <0.05, 2x 0.01, 2x 0.02, 0.06 RA: 6x <0.03, 0.07, 5x 0.03, 2x 0.04, 0.08	E: 0.01 RA: 0.03	E: 0.06 RA: 0.08	0.08	0.08	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)	Rounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) (1)	MRL compliance
	EFSA, 2010 Belgium, 2010a	N-EU	GAP on which EU a.s. assessment is based: *Wheat, barley, rye, triticale*: 2x 0.125 kg as/ha, BBCH 25-69, PHI 35d, outdoor *Wheat (grain):* E: 13x <0.05 RA: 13x <0.05(2) *Rye (grain):* E: <0.05 RA: <0.05(2)	E: 0.05	E: 0.05	0.05	0.08	yes
	EFSA, 2010 Belgium, 2010a	S-EU	GAP on which EU a.s. assessment is based: *Wheat, barley, rye, triticale*: 2x 0.125 kg as/ha, BBCH 25-69, PHI 35d, outdoor *Wheat (grain):* E: 9x <0.01, 2x 0.01, 2x 0.02, <0.05, 0.06 RA: 6x <0.03, 0.07, 5x 0.03, 2x 0.04, 0.08	E: 0.01 RA: 0.03	E: 0.06 RA: 0.08	0.08	0.08	yes
	Belgium, 1997	N-EU	GAP on which EU a.s. assessment is based: *Cereals:* 2x 0.125 kg as/ha, BBCH n.r., PHI determined by the stage of application, outdoor *Wheat (grain):* E: 13x <0.05 RA: 13x <0.05(2)	E: 0.05	E: 0.05	0.05	0.08	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)	Rounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) (1)	MRL compliance
	New trials BASF DocID 2020/2093149 (CA 6.3.2/1) **Combining NEU with SEU data from EFSA 2014 and new trials not possible according to Mann-Whitney U test**	N-EU	Trials GAP: 2x 0.15 kg as/ha; BBCH 49-69; PHI 35d, outdoor E: 4x <0.01 RA: 4x <0.03	E: 0.01 RA: 0.03	E: 0.01 RA: 0.03	Highest residue covered by MRL 0.08 mg/kg. No further considerations needed.		Yes
		S-EU	Trials GAP: 2x 0.15 kg as/ha; BBCH 49-69; PHI 35d, outdoor E: 3x < 0.01, 0.012 RA: 3x <0.03, 0.032	E: 0.01 RA: 0.03	E: 0.012 RA: 0.032	Highest residue covered by MRL 0.08 mg/kg. No further considerations needed.		Yes
Wheat straw → extrapolated to trticale and rye straw	EFSA, 2014	N-EU	GAP on which EU a.s. assessment is based: 2x 0.13 kg as/ha, BBCH 69, PHI 35d, outdoor *Wheat, rye (straw):* E: 2x <0.05, 0.06, 0.09, 0.17, 0.23, 0.24, 0.36, 0.47, 0.48, 0.56, 0.57, 0.58, 0.59, 0.65, 0.74, 1.16, 1.51, 2x 2.42, 2.62, 4.00 RA: <0.15, 0.17, 0.18, 0.19, 0.23, 0.30, 0.35, 0.82, 0.57, 0.62, 0.68, 1.02, 0.95, 1.00, 0.94, 0.93, 1.52, 2.60, 2.56, 3.51, 3.21, 4.76	E: 0.57 RA: 0.81	E: 4.00 RA: 4.76	5.10	5 (tentative)	Yes
	EFSA, 2014	S-EU	GAP on which EU a.s. assessment is based: 2x 0.13 kg as/ha, BBCH 69, PHI 35d, outdoor *Wheat, rye (straw):* E: <0.01; 0.04; 0.07; 2x 0.10; 0.11; 0.21; 0.22; 0.25; 0.38; 0.45; 0.48; 0.51; 0.52; 1.50 RA: <0.03; 0.06; 0.09; 0.14; 0.16; 0.18; 0.31; 0.24; 0.36; 0.40; 0.50; 0.58; 0.59; 0.58; 1.59	E: 0.22 RA: 0.31	E: 1.50 RA: 1.59	1.81	5 (tentative)	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)	Rounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) (1)	MRL compliance
	EFSA, 2010 Belgium, 2010a	N-EU	GAP on which EU a.s. assessment is based: *Wheat, rye, triticale*: 2x 0.125 kg as/ha, BBCH 25-69, PHI 35d, outdoor *Wheat (straw):* E: 2x <0.05, 0.06, 0.09, 0.24, 0.36, 0.58, 0.59, 0.65, 0.74, 1.16, 1.51, 2.42 RA: 0.17, <0.15, 0.18, 0.19, 0.35, 0.82, 0.95, 0.96, 0.94, 0.93, 1.52, 1.6, 2.56 *Rye (straw):* E: <0.05 RA: 0.23	E: 0.47 RA: 0.88	E: 2.42 RA: 2.56	-	5 (tentative)	Yes
	EFSA, 2010 Belgium, 2010a	S-EU	GAP on which EU a.s. assessment is based: *Wheat, rye, triticale*: 2x 0.125 kg as/ha, BBCH 25-69, PHI 35d, outdoor *Wheat (straw):* E: <0.01, 0.04, 0.07, 2x 0.10, 0.11, 0.21, 0.22, 0.25, 0.38, 0.45, 0.48, 0.51, 0.52, 1.50 RA: <0.03; 0.06; 0.09; 0.14; 0.16; 0.18; 0.31; 0.24; 0.36; 0.40; 0.50; 0.58; 0.59; 0.58; 1.59	E: 0.21 RA: 0.24	E: 1.50 RA: 1.59	-	5 (tentative)	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)	Rounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) (1)	MRL compliance
	Belgium, 1997	N-EU	GAP on which EU a.s. assessment is based: *Cereals:* 2x 0.125 kg as/ha, BBCH n.r., PHI determined by the stage of application, outdoor *Wheat (straw):* E: 2x <0.05, 0.06, 0.09, 0.24, 0.36, 0.58, 0.59, 0.65, 0.74, 1.16, 1.51, 2.42 RA: 0.17, <0.15, 0.18, 0.19, 0.35, 0.82, 0.95, 0.96, 0.94, 0.93, 1.52, 1.6, 2.56	E: 0.58 RA: 0.93	E: 2.42 RA: 2.56	-	5 (tentative)	Yes
	New trials BASF DocID 2020/2093149 (CA 6.3.2/1) **Combining NEU with SEU data from EFSA 2014 and new trials is possible according to Mann-Whitney U test (resulting unrounded OECD calculator MRL: 4.04 mg/kg)**	N-EU	Trials GAP: 2x 0.15 kg as/ha; BBCH 49-69; PHI 35d, outdoor E: 0.12, 0.5, 0.89, 1.2 RA: 0.18, 0.62, 0.99, 1.3	E: 0.70 RA: 0.81	E: 1.2 RA: 1.3	Highest residue covered by pseudo MRL 5 mg/kg. No further considerations needed.		Yes
		S-EU	Trials GAP: 2x 0.15 kg as/ha; BBCH 49-69; PHI 35d, outdoor E: <0.01, 0.98, 1.2, 1.8 RA: 0.12, 1.3, 1.5, 2.0	E: 1.09 RA: 1.40	E: 1.8 RA: 2.0	Highest residue covered by pseudo MRL 5 mg/kg. No further considerations needed.		Yes

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Rounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) (1)	MRL compliance
Barley grain	Commission Regulation 2020/856 with referral to FAO/WHO Report 2018 "Pesticide residues in food 2018"	Outside EU (CXL)	Adoption of CXL 0.15 mg/kg including extrapolation to buckwheat and oat European cGAP on which CXL is based: 2x 0.125 kg as/ha, BBCH 69, PHI 35d, outdoor *Barley (grain):* E(3): 0.01, 4x 0.02, 2x 0.03, 0.04, 0.06, 0.08	E: 0.025	E: 0.08	-	0.15	yes
	EFSA, 2014	N-EU	GAP on which EU a.s. assessment is based: *Barley, oat:* 2x 0.13 kg as/ha, BBCH 69, PHI 35d, outdoor *Barley, oat (grain):* E: 16x <0.05 RA: 16x <0.05(2)	E: 0.05	E: 0.05	0.05	0.15	yes
	EFSA, 2014	S-EU	GAP on which EU a.s. assessment is based: *Barley, oat:* 2x 0.13 kg as/ha, BBCH 69, PHI 35d, outdoor *Barley, oat (grain):* E: <0.01, 8x 0.01, 4x 0.02, 3x 0.03, 0.04, 0.05, 0.08 RA: <0.03, 8x 0.03, 4x 0.04, 3x 0.05, 0.06, 0.07, 0.10	E: 0.02 RA: 0.03	E: 0.08 RA: 0.10	0.10	0.15	yes
	EFSA, 2010 Belgium, 2010a	N-EU	GAP on which EU a.s. assessment is based: *Barley*: 2x 0.125 kg as/ha, BBCH 25-69, PHI 35d, outdoor *Barley (grain):* E: 16x <0.05 RA: 16x <0.05(2)	E: 0.05	E: 0.05	0.05	0.15	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)	Rounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) [1]	MRL compliance
	EFSA, 2010 Belgium, 2010a	S-EU	GAP on which EU a.s. assessment is based: *Barley*: 2x 0.125 kg as/ha, BBCH 25-69, PHI 35d, outdoor *Barley (grain):* E: <0.01, 8x 0.01, 4x 0.02, 3x 0.03, 0.04, 0.05, 0.08 RA: <0.03, 8x 0.03, 4x 0.04, 3x 0.05, 0.06, 0.07, 0.10	E: 0.02 RA: 0.03	E: 0.08 RA: 0.10	0.10	0.15	yes
	Belgium, 1997	N-EU	GAP on which EU a.s. assessment is based: *Cereals:* 2x 0.125 kg as/ha, BBCH n.r., PHI determined by the stage of application, outdoor *Barley (grain):* E: 16x <0.05 RA: 16x <0.05[2]	E: 0.05	E: 0.05	0.05	0.15	yes
	New trials BASF DocID 2020/2100869 (CA 6.3.1/1)	N-EU	Trials GAP: 2x 0.15 kg as/ha; BBCH 49-69; PHI 35d, outdoor E: 0.01, 0.011, 0.021, 0.022 RA: <0.03, 0.031, 0.041, 0.044	E: 0.016 RA: 0.036	E: 0.022 RA: 0.044	Highest residue covered by MRL 0.15 mg/kg. No further considerations needed.		Yes

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Rounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) (1)	MRL compliance
	Combining NEU with SEU data from EFSA 2014 and new trials is not possible according to Mann-Whitney U test. **Combining NEU EFSA 2014 data with NEU new trials leads to unrounded OECD calculator MRL: 0.10 mg/kg.** **Combining SEU EFSA 2014 data with SEU new trials leads to unrounded OECD calculator MRL: 0.12 mg/kg.**	S-EU	Trials GAP: 2x 0.15 kg as/ha; BBCH 49-69; PHI 35d, outdoor E: <0.01, 0.013, 0.036, 0.093 RA: <0.03, 0.044, 0.097, 0.13	E: 0.025 RA: 0.071	E: 0.093 RA: 0.13	Highest residue covered by MRL 0.15 mg/kg. No further considerations needed.		No
Barley straw	EFSA, 2014	N-EU	GAP on which EU a.s. assessment is based: 2x 0.13 kg as/ha, BBCH 69, PHI 35d, outdoor *Barley, oat (straw):* E: 4x <0.05, 0.07, 0.13, 0.15, 0.26, 0.28, 0.36, 0.52, 0.55, 0.61, 0.63, 0.66, 0.75 RA: 2x <0.15, 2x 0.16, 0.17, 0.33, 0.36, 0.48, 0.41, 0.55, 0.71, 0.74, 0.82, 0.81, 1.14, 1.01	E: 0.27 RA: 0.44	E: 0.75 RA: 1.01	1.36	3 (tentative)	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)	Rounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) (1)	MRL compliance
	EFSA, 2014	S-EU	GAP on which EU a.s. assessment is based: 2x 0.13 kg as/ha, BBCH 69, PHI 35d, outdoor *Barley, oat (straw):* E: 0.04; 2x 0.09; 0.13; 0.15; 0.17; 0.22; 0.32; 0.36; 0.41; 2x 0.43; 0.44; 0.57; 0.87; 0.89; 1.06; 1.24; 2.14 RA: 0.06; 0.12; 0.11; 0.15; 0.17; 0.26; 0.24; 0.36; 0.46; 0.67; 2x 0.53; 0.46; 0.61; 0.92; 0.99; 1.08; 1.33; 2.48	E: 0.41 RA: 0.46	E: 2.14 RA: 2.48	2.62	3 (tentative)	Yes
	EFSA, 2010 Belgium, 2010a	N-EU	GAP on which EU a.s. assessment is based: *Barley*: 2x 0.125 kg as/ha, BBCH 25-69, PHI 35d, outdoor *Barley (straw):* E: 4x <0.05, 0.07, 0.13, 0.15, 0.26, 0.28, 0.36, 0.52, 0.55, 0.61, 0.63, 0.66, 0.75 RA: 2x <0.15, 2x 0.16, 0.17, 0.33, 0.36, 0.48, 0.41, 0.55, 0.71, 0.74, 0.82, 0.81, 1.14, 1.01	E: 0.27 RA: 0.44	E: 0.75 RA: 1.01	1.36	3 (tentative)	Yes
	EFSA, 2010 Belgium, 2010a	S-EU	GAP on which EU a.s. assessment is based: *Barley*: 2x 0.125 kg as/ha, BBCH 25-69, PHI 35d, outdoor *Barley (straw)*: E: 0.04, 2x 0.09, 0.13, 0.15, 0.17, 0.22, 0.32, 0.41, 2x 0.43, 0.44, 0.57, 0.87,0.89, 1.06, 1.24, 2.14 RA: 0.06; 0.12; 0.11; 0.15; 0.17; 0.26; 0.24; 0.36; 0.46; 0.67; 2x 0.53; 0.46; 0.61; 0.92; 0.99; 1.08; 1.33; 2.48	E: 0.41 RA: 0.46	E: 2.14 RA: 2.48	2.62	3 (tentative)	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)	Rounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) (1)	MRL compliance
	Belgium, 1997	N-EU	GAP on which EU a.s. assessment is based: *Cereals:* 2x 0.125 kg as/ha, BBCH n.r., PHI determined by the stage of application, outdoor *Barley (straw):* E: 4x <0.05, 0.07, 0.13, 0.15, 0.26, 0.28, 0.36, 0.52, 0.55, 0.61, 0.63, 0.66, 0.75 RA: 2x <0.15, 2x 0.16, 0.17, 0.33, 0.36, 0.48, 0.41, 0.55, 0.71, 0.74, 0.82, 0.81, 1.14, 1.01	E: 0.27 RA: 0.44	E: 0.75 RA: 1.01	1.36	3 (tentative)	Yes
	New trials BASF DocID 2020/2100869 (CA 6.3.1/1)	NEU	Trials GAP: 2x 0.15 kg as/ha; BBCH 49-69; PHI 35d, outdoor E: 0.23, 0.5, 1.9, 2.3 RA: 0.3, 0.55, 2.2, 2.6	E: 1.2 RA: 1.38	E: 2.3 RA: 2.6	Highest residue covered by pseudo MRL 3 mg/kg. No further considerations needed.		Yes
	Combining NEU with SEU data from EFSA 2014 and new trials is possible according to Mann-Whitney U test (resulting unrounded OECD calculator MRL: 2.85 mg/kg)	SEU	Trials GAP: 2x 0.15 kg as/ha; BBCH 49-69; PHI 35d, outdoor E: 0.099, 0.48, 1.2, 1.8 RA: 0.17, 0.59, 1.6, 2.1	E: 0.84 RA: 1.1	E: 1.8 RA: 2.1	Highest residue covered by pseudo MRL 3 mg/kg. No further considerations needed.		yes

n.r.: Not reported
(1) Source of EU MRL: Regulation (EC) No 2020/856
(2) Metabolites BF 490-2 and BF 490-9 were not analyzed; therefore, results according to the residue definition for RA are not available and no conversion factor could be derived. Nevertheless, as all trials results were below the LOQ, no conversion factor is necessary.
(3) Dataset on which current MRL is based on.

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 extrapolation rules have been applied according to SANCO 7525/VI/95 Rev. 10.3. The data submitted show that no exceedance of the current kresoxim-methyl MRLs for the intended uses (barley, wheat, rye, triticale) is expected.

7.3.4 Magnitude of residues in livestock

7.3.4.1 Dietary burden calculation

7.3.4.2 Dietary burden calculation

Table 7.3-10: Input values for the dietary burden calculation (considering the uses evaluated in Art. 12 procedure and the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition in RAC: Sum of kresoxim-methyl and the metabolites BF 490-2 and BF 490-9, free and conjugated, expressed as parent. **Risk assessment residue definition in processed commodities:** Sum of kresoxim-methyl and the metabolites BF 490-1, BF 490-2 and BF 490-9, free and conjugated, expressed as parent.				
Sugar and fodder beet leaves	0.37	STMR x CF [0.17 x 2.2] (EFSA, 2014)	0.77	HR x CF [0.35 x 2.2] (EFSA, 2014)
Apple pomace	0.04	STMR x PF x CF [0.05 x 0.77 x 1.0] (EFSA, 2014)	0.04	STMR x PF x CF [0.05 x 0.77 x 1.0] (EFSA, 2014)
Wheat and rye grain	0.12	STMR x CF [0.05 x 2.4] (EFSA, 2014)	0.12	STMR x CF [0.05 x 2.4] (EFSA, 2014)
Barley and oats grain	0.10	STMR x CF [0.05 x 2.0] (EFSA, 2014)	0.10	STMR x CF [0.05 x 2.0] (EFSA, 2014)
Wheat and rye straw	0.80	STMR x CF [0.57 x 1.4] (EFSA, 2014)	5.60	HR x CF [4.0 x 1.4] (EFSA, 2014)
Barley and oats straw	0.53	STMR x CF [0.41 x 1.3] (EFSA, 2014)	2.78	HR x CF [2.14 x 1.3] (EFSA, 2014)
Turnip roots(1)	0.05*	STMR x CF [0.05 x 1.0] (EFSA, 2014)	0.05*	HR x CF [0.05 x 1.0] (EFSA, 2014)
Sugar and fodder beet roots	0.05*	STMR x CF [0.05 x 1.0] (EFSA, 2014)	0.05*	HR x CF [0.05 x 1.0] (EFSA, 2014)
Sunflower seed meal	0.10	STMR x 2 x CF [0.05 x 2 x 1.0] (EFSA, 2014)	0.10	STMR x 2 x CF [0.05 x 2 x 1.0] (EFSA, 2014)

(1): Extrapolated from sugar beet roots

Table 7.3-11: Results of the dietary burden calculation[(1)]

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Most critical diet[(2)]	Most critical commodity[(3)]	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: Sum of kresoxim-methyl and the metabolites BF 490-2 and BF 490-9, free and conjugated, expressed as parent						
Cattle (all diets)	**0.037**	**0.068**	**Dairy cattle**	**Rye straw**	**1.77**	**Yes**
Cattle (dairy only)	0.037	0.068	Dairy cattle	Rye straw	1.77	Yes
Sheep (all diets)	**0.036**	**0.128**	**Lamb**	**Rye straw**	**3.02**	**Yes**
Sheep (ewe only)	0.020	0.101	Ram/Ewe	Rye straw	3.0	Yes
Swine (all diets)	**0.012**	**0.016**	**Swine (breeding)**	**Sugarbeet tops**	**0.71**	**Yes**
Poultry (all diets)	**0.019**	**0.057**	**Poultry layer**	**Wheat straw**	**0.83**	**Yes**
Poultry (layer only)	0.019	0.057	Poultry layer	Wheat straw	0.83	Yes

Values in **bold** were considered for the calculation of the overdosing factor and therefore for the comparison with livestock feeding results.

(1) Performed according to "OECD Guidance Document, series on testing and assessment number 64, series on pesticides 32" and "OECD Guidance 73 on residues in livestock", calculated with Animal model 2017.xls.

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

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

7.3.4.3 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

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

Table 7.3-12: 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 (Belgium, 1997, 2010a; EFSA, 2014) BASF DocID 1994/10960, 1996/10146												
Enforcement residue definition: Metabolite BF 490-9 expressed as parent (products of animal origin, except honey). **Risk assessment residue definition:** Sum of the metabolites BF 490-1, BF 490-2 and BF 490-9, expressed as parent.												
Pig meat	0.011	0.015	0.23	1	<0.01[f]	n.r.	<0.03	n.r.	<0.01	<0.01	0.01*	1.00
			0.65	1	<0.01[f]	n.r.	<0.03	n.r.				
			2.19	1	<0.01[f]	n.r.	<0.03	n.r.				
Pig fat			0.23	1	<0.01	n.r.	<0.03	n.r.	<0.01	<0.01	0.01*	10.9
			0.65	1	<0.01	n.r.	0.048	n.r.				
			2.19	1	<0.01	n.r.	0.109	n.r.				
Pig liver			0.23	1	<0.01	n.r.	<0.03	n.r.	<0.01	<0.01	0.01*	4.31
			0.65	1	0.013	n.r.	0.050	n.r.				
			2.19	1	0.013	n.r.	0.056	n.r.				
Pig kidney			0.23	1	<0.01	n.r.	0.050	n.r.	<0.01	<0.01	0.01*	5.00
			0.65	1	0.014	n.r.	0.126	n.r.				
			2.19	1	0.030	n.r.	0.304	n.r.				

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)				
Ruminant meat	0.037(g)	0.128(g)	0.23	1	<0.01(f)	n.r.	<0.03	n.r.	<0.01	<0.01	0.01*	1.00
			0.65	1	<0.01(f)	n.r.	<0.03	n.r.				
			2.19	1	<0.01(f)	n.r.	<0.03	n.r.				
Ruminant fat			0.23	1	<0.01	n.r.	<0.03	n.r.	<0.01	<0.01	0.01*	10.9
			0.65	1	<0.01	n.r.	0.048	n.r.				
			2.19	1	<0.01	n.r.	0.109	n.r.				
Ruminant liver			0.23	1	<0.01	n.r.	<0.03	n.r.	<0.01	<0.01	0.01*	4.31
			0.65	1	0.013	n.r.	0.050	n.r.				
			2.19	1	0.013	n.r.	0.056	n.r.				
Ruminant kidney			0.23	1	<0.01	n.r.	0.050	n.r.	<0.01	<0.01	0.01*	5.00
			0.65	1	0.014	n.r.	0.126	n.r.				
			2.19	1	0.030	n.r.	0.304	n.r.				
Milk	0.036	0.066	0.23	1	<0.002 (e)	N/A	<0.006	N/A	<0.01	<0.01	0.01*	1.00
			0.65	1	<0.002	N/A	<0.006	N/A				
			2.19	1	<0.002	N/A	<0.006	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.
(**) According to EU Reg. 2020/845 the current MRLs for all animal matrices are 0.05 mg/kg, except milk: 0.02 mg/kg
(a): Based on a 485-671 kg animal (day 1) consuming 10-16 kg/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 1 until day 28 (14 cows, 9 sampling days).
(f): Since according to the metabolism study in lactating goat residues of BF 490-9 are not expected in meat, residue values <LOQ (0.01 mg/kg) were considererd for MRL calculation.
(g): To cover the worst case for ruminants, the med. dietary burden of catlle (dairy) and the max. dietary burden of sheep (lamb) were indcluded.

Conclusion on feeding studies

Metabolism studies in ruminants presented in the revision of the DAR (Belgium, 2010a) indicate that residues >0.01 mg/kg have to be expected at 1x dose rate in edible commodities of sheep and cattle. Therefore, a feeding study in ruminants is required, which is provided in the revised DAR (Belgium, 2010a). Since a pig feeding study is not triggered, the data on pigs is only presented as supplemental information.
With the results of this study and the results of the dietary burden calculation (see Chapter 7.3.4.1), MRLs for animal commodities have been calculated based on the enforcement residue definition including metabolite BF 490-9 expressed as parent (products of animal origin, except honey).
The intended uses of kresoxim-methyl in BAS 765 00 F do not lead to an exceedance of the existing EU MRL for animal commodities.

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

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

7.3.5.2 Conclusion on processing studies

As residues of kresoxim-methyl exceeding 0.1 mg/kg are not expected in the treated crops and as the chronic exposure does not exceed 10% of the ADI (see Chapter 7.3.8), the investigation of the effect of processing on the magnitude of the residues is not required.

7.3.6 Magnitude of residues in representative succeeding crops

The confined rotational crop studies presented in the DAR (which were conducted in accordance with the intended total application rate of 0.3 kg as/ha), resulted in residues >0.01 mg/kg.
In spring wheat straw and grains, residue levels of kresoxim-methyl equivalents were 0.119 mg/kg eq. and 0.006 mg/kg eq., respectively 124 days after sowing. In the beans plants and green beans the residues were 0.210 mg/kg eq. and 0.009 mg/kg eq., respectively 77 days after sowing. In the carrots tap roots the residues were 0.006 mg/kg eq. 111 days after sowing. In the lettuce head the residues were 0.028 mg/kg eq. after 56 days after sowing and 0.010 mg/kg eq. 66 days after sowing.
But the residues in commodities intended as livestock feed (such as wheat straw, beans plants) are already covered by the livestock feeding studies.
For commodities intended for human consumption, no relevant residues are expected, except in lettuce, (0.028 mg/kg eq.). Total residue in lettuce consisted for 41.5% of conjugate fractions (mainly 490M02 (alcohol acid) and 490M09 (phenol acid) and 9.4% unchanged parent.

The new confined rotational crop study was performed with a remarkably exaggerated application rate of 1.5 kg as/ha (5 times higher than the intended total application rate of 0.3 kg as/ha) and replant intervals of 30, 120 and 365 days. Hydroxylated derivatives 490M02 and 490M09 were not detected. Besides, residues of kresoxim-methyl in lettuce were only up to 0.003 mg/kg at 30 DAT.
Taken these results into account, residues of the parent and its relevant metabolites in lettuce are not expected to exceed 0.01 mg/kg.
Furthermore, since the new confined rotational crop study is highly overdosed, recalculations (to match the intended total application rate of 0.3 kg as/ha) of the residues of kresoxim-methyl in wheat straw and radish top resulted in residues below 0.01 mg/kg.

Therefore, it can be concluded, that for the intended uses of kresoxim-methyl in the product BAS 765 00 F on cereals no residues of parent and the relevant metabolites above 0.01 mg/kg are expected in rotational crops. Further investigation of residues in rotational crops is therefore not required.

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

The current dossier is submitted before the date of renewal of the approval of the active substance kresoxim-methyl. Hence, the old active substance data requirements still apply. Therefore, no studies concerning the effect on the residue level in pollen and bee products are required.
The available data for the active substance sufficiently addresses aspects of the residue situation that might arise from the use of BAS 765 00 F. Therefore, other special studies are not needed.

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

7.3.8.1 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 Chapter 7.1.2).
Assessments of the potential chronic dietary consumer risk resulting from exposure to residues kresoxim-methyl were performed using revision 3.1 (18.04.2019) of the EFSA Pesticide Residues Intake Model (PRIMo). The risk assessment was based on the current EU MRLs laid down in Regulation (EC) 2020/856 multiplied by the conversion factors given in the EFSA RO (2014), except for ruminants and pigs, where the new calculated conversion factors (see chapter 7.3.4.2) for meat, fat, liver and kidney were used.
As an ARfD was not deemed necessary, the conduction of an acute risk assessment is not relevant.

The following table summarizes the input values from plant and animal commodities used for the TMDI dietary risk assessment (according to EFSA PRIMO model vers. 3.1).
The PRIMo 3.1 xls-spreadsheets used are attached to this submission to facilitate evaluation (TMDI: BASF DocID 2020/2106122).

7.3.8.2 Input values for the consumer risk assessment

Table 7.3-13: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Risk assessment residue definition for plants: Sum of kresoxim-methyl and the metabolites BF 490-2 and BF 490-9, free and conjugated, expressed as parent. **Risk assessment residue definition for animals:** Sum of the metabolites BF 490-1, BF 490-2 and BF 490-9, expressed as parent.				
Barley grain, Oats grain	0.30	EU MRL(1) x CF(2) [0.15 x 2]	-	-
Rye grain, Wheat grain	0.19	EU MRL(1) x CF(2) [0.08 x 2.4]	-	-
Grapefruits	1.2	EU MRL(1) x CF(2) [0.5 x 2.4]#		
Oranges	1.2	EU MRL(1) x CF(2) [0.5 x 2.4]#		
Pecan	0.05	EU MRL(1) x CF(2) [0.05 x 1(3)]	-	-
Pome Fruits	0.28	EU MRL(1) x CF(2) [0.2 x 1.4]	-	-
Peaches	3.6	EU MRL(1) x CF(2) [1.5 x 2.4]#		
Table & wine grapes	2.25	EU MRL(1) x CF(2) [1.5 x 1.5]	-	-
Strawberries	2.10	EU MRL(1) x CF(2) [1.5 x 1.4]	-	-

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Blueberries, Cranberries, Currants (red, black and white), Gooseberries, Azarole	1.44	EU MRL(1) x CF(2) [0.9 x 1.6]	-	-
Mango	0.24	EU MRL(1) x CF(2) [0.1 x 2.4]#		
Table olives, Olives for oil production	0.40	EU MRL(1) x CF(2) [0.2 x 2]	-	-
Turnips	0.05	EU MRL(1) x CF(2) [0.05 x 1(3)]	-	-
Garlic, Onions, Shallots	0.69	EU MRL(1) x CF(2) [0.3 x 2.3]	-	-
Tomatoes, Aubergines (egg plants)	0.90	EU MRL(1) x CF(2) [0.6 x 1.5]	-	-
Peppers	1.12	EU MRL(1) x CF(2) [0.8 x 1.4]	-	-
Cucumbers, Gherkins, Courgettes (Cucurbits with edible peel)	0.5	EU MRL(1) x CF(2) [0.5 x 1(3)]	-	-
Melons, Pumpkins, Watermelons (Cucurbits with inedible peel)	1.10	EU MRL(1) x CF(2) [0.5 x 2.2]	-	-
Vine leaves (grape leaves)	16.5	EU MRL(1) x CF(2) [15 x 1.1]	-	-
Asparagus	0.05	EU MRL(1) x CF(2) [0.05* x 1(3)]	-	-
Leek	11.0	EU MRL(1) x CF(2) [10 x 1.1]	-	-
Buckwheat	2.55	EU MRL(1) x CF(2) [0.15 x 2.4]#		
Sunflower seed	0.05	EU MRL(1) x CF(2) [0.05* x 1(3)]	-	-
Beetroot, Sugar beet (root)	0.05	EU MRL(1) x CF(2) [0.05 x 1(3)]	-	-
Ruminant and pig meat	0.05	Calculated MRL(4) x CF(4) [0.05* x 1.0]	-	-
Ruminant and pig fat	0.55	Calculated MRL(4) x CF(4) [0.05* x 10.9]	-	-
Ruminant and pig liver	0.22	Calculated MRL(4) x CF(4) [0.05 x 4.31]	-	-
Ruminant and pig kidney	0.25	Calculated MRL(4) x CF(4) [0.05 x 5.0]	-	-

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Milk	0.02	EU MRL(1) x CF(2) [0.02* x 1]	-	-
All other commodities	-	EU MRLs(1)	-	-

CF: Conversion Factor for enforcement residue definition to risk assessment definition

* Indicates lower limit of analytical determination.

\# For grapefruits, oranges, peaches, mango and buckwheat, no CF is given in -EFSA 2014. Therefore, the highest CF available for plant commodities (2.4) was chosen.

(1) According to EU Pesticides Database, Regulation (EU) 2020/856

(2) Conversion factor values as given in EFSA (2014)

(3) The conversion factors for risk assessment were calculated considering only the residue data above the LOQ. Therefore, where all trials results were below the LOQ, a CF of 1 applies.

(4) New calculated conversion factors and MRLs (see Chapter 7.3.4.2) for ruminant meat, fat, liver and kidney, according to the monitoring residue definition of metabolite BF 490-9 expressed as parent (products of animal origin, except honey).

7.3.8.3 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.3-14: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo	5% (based on DE child)
IEDI (% ADI) according to EFSA PRIMo	Not necessary
IESTI (% ARfD) according to EFSA PRIMo	Not necessary
NTMDI (% ADI)	Not necessary
NEDI (% ADI)	Not necessary
NESTI (% ARfD)	Not necessary

The proposed uses of kresoxim-methyl in the formulation BAS 765 00 F do not represent unacceptable chronic risks for the consumer.

7.4 Active substance 3

Not applicable

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

For kresoxim-methyl no ARfD has been established. Therefore, conduction of an acute risk assessment from combined exposure is not relevant.

However, as Triazole alanine and Triazole lactic acid share the same residue definition a combined risk assessment has been performed

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) is very low. For the present estimation, dose-addition of both TDMs is assumed. Such an approach most likely results in an overestimating of the exposure and risk, i.e. for cases where both 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. For each TDM, 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 765 00 F in cereals. 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	Triazole alanine	0.0117 (0.0035/0.3)
	Triazole lactic acid	0.0015 (0.00044/0.3)
	Cumulative risk barley (HI)	**0.0121**
Wheat	Triazole alanine	0.0300 (0.009/0.3)
	Triazole lactic acid	0.00107 (0.00032/0.3)
	Cumulative risk wheat (HI)	**0.0311**
Rye	Triazole alanine	0.0130 (0.0039/0.3)
	Triazole lactic acid	0.0005 (0.00014/0.3)
	Cumulative risk rye (HI)	**0.0135**

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 (cereals) 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 765 00 F in cereals. 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 765 00 F (barley, wheat including triticale, rye)

Diet	Active Ingredient	HQ (based on IEDI according to EFSA PRIMo 3.1)
DE child	Triazole alanine	0.010
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.011**
DK child	Triazole alanine	0.021
	Triazole lactic acid	0.001
	Cumulative risk (HI)	**0.021**
ES child	Triazole alanine	0.009
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.010**
FR infant	Triazole alanine	0.002
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.002**

Table 7.5-2: Assessment of combined exposure of TA and TLA as a result of the intended use of BAS 765 00 F (barley, wheat including triticale, rye)

Diet	Active Ingredient	HQ (based on IEDI according to EFSA PRIMo 3.1)
FR toddler 2 - 3 yr	Triazole alanine	0.006
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.007**
FR child 3 - 15 yr	Triazole alanine	0.010
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.010**
IT toddler	Triazole alanine	0.014
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.014**
NL toddler	Triazole alanine	0.009
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.010**
NL child	Triazole alanine	0.009
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.009**
UK infant	Triazole alanine	0.005
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.006**
UK toddler	Triazole alanine	0.008
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.008**
DK adult	Triazole alanine	0.003
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.004**
ES adult	Triazole alanine	0.006
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.006**

Table 7.5-2: Assessment of combined exposure of TA and TLA as a result of the intended use of BAS 765 00 F (barley, wheat including triticale, rye)

Diet	Active Ingredient	HQ (based on IEDI according to EFSA PRIMo 3.1)
FI adult	Triazole alanine	0.002
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.002**
FR adult	Triazole alanine	0.005
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.005**
IE adult	Triazole alanine	0.005
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.005**
IT adult	Triazole alanine	0.009
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.009**
LT adult	Triazole alanine	0.005
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.005**
NL general	Triazole alanine	0.005
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.005**
PL general	Triazole alanine	0.000
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.000**
PT general	Triazole alanine	0.008
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.009**
RO general	Triazole alanine	0.010
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.011**

Table 7.5-2: Assessment of combined exposure of TA and TLA as a result of the intended use of BAS 765 00 F (barley, wheat including triticale, rye)

Diet	Active Ingredient	HQ (based on IEDI according to EFSA PRIMo 3.1)
SE general	Triazole alanine	0.007
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.007**
UK adult	Triazole alanine	0.004
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.004**
UK vegetarian	Triazole alanine	0.004
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.004**
GEMS/Food G06	Triazole alanine	0.015
	Triazole lactic acid	0.001
	Cumulative risk (HI)	**0.016**
GEMS/Food G07	Triazole alanine	0.010
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.011**
GEMS/Food G08	Triazole alanine	0.012
	Triazole lactic acid	0.001
	Cumulative risk (HI)	**0.012**
GEMS/Food G10	Triazole alanine	0.010
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.010**
GEMS/Food G11	Triazole alanine	0.009
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.010**
GEMS/Food G15	Triazole alanine	0.011
	Triazole lactic acid	0.001
	Cumulative risk (HI)	**0.012**

Table 7.5-2: Assessment of combined exposure of TA and TLA as a result of the intended use of BAS 765 00 F (barley, wheat including triticale, rye)

Diet	Active Ingredient	HQ (based on IEDI according to EFSA PRIMo 3.1)
DE general	Triazole alanine	0.006
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.006**
DE women 14 - 50 yr	Triazole alanine	0.006
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.006**
IE child	Triazole alanine	0.002
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.003**
FI 3 yr	Triazole alanine	0.004
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.004**
FI 6 yr	Triazole alanine	0.003
	Triazole lactic acid	0.000
	Cumulative risk (HI)	**0.003**

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

7.6 References

Mefentrifluconazole

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

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

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

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

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

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

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

Kresoxim-methyl

Commission Directive 1999/1/EC of 21 January 1999 including an active substance (kresoxim-methyl) in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market

Commission Directive No 2007/21/EC of 10 April 2007 amending Council Directive 91/414/EEC as regards the expiry dates for inclusion in Annex I of the active substances azoxystrobin, imazalil, kresoxim-methyl, spiroxamin, azimsulfuron, prohexadion-calcium and fluroxypyr

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances

Commission Implementing Regulation (EU) No 810/2011 of 11 August 2011 approving the active substance kresoxim-methyl, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

Commission Implementing Regulation (EU) 2019/291 of 19 February 2019 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-naphthylacetamide, 1-naphthylacetic acid, acrinathrin, azoxystrobin, fluazifop p, fluroxypyr, imazalil, kresoxim-methyl, oxyfluorfen, prochloraz, prohexadione, spiroxamine, tefluthrin and terbuthylazine

Commission Regulation (EU) 2020/856 of 9 June 2020 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyantraniliprole, cyazofamid, cyprodinil, fenpyroximate, fludioxonil, fluxapyroxad, imazalil, isofetamid, kresoxim-methyl, lufenuron, mandipropamid, propamocarb, pyraclostrobin, pyriofenone, pyriproxyfen and spinetoram in or on certain products

EC (European Commission), 2011. Review report for the renewal of active substance kresoxim-methyl. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 17 June 2011 in view of the approval of kresoxim-methyl as active substance in accordance with Regulation (EC) No 1107/2009. SANCO/11029/2011-rev.5, 12 December 2014.

Belgium, 1997. Draft assessment report on the active substance kresoxim-methyl prepared by the rapporteur Member State Belgium in the framework of Council Directive 91/414/EEC, January 1997.

Belgium, 2010a. Assessment Report on the active substance kresoxim-methyl prepared by the rapporteur Member State Belgium in consultation with Lithuania in the framework of Commission Regulation (EC) No 737/2007, March 2010.

Belgium, 2010b. Final Addendum to the Assessment Report on the active substance kresoxim-methyl, prepared by the rapporteur Member State Belgium in the framework of Commission Regulation (EC) No 737/2007, compiled by EFSA, September 2010.

EFSA (European Food Safety Authority), 2010. Conclusion on the peer review of the pesticide risk assessment of the active substance kresoxim-methyl. EFSA Journal 2010;8(11):1891, October 2010.

EFSA, 2014. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for kresoxim-methyl according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(1):3549, January 2014.

EFSA (European Food Safety Authority), 2015. Residues trials and MRL calculations Proposals for a harmonised approach for the selection of the trials and data used for the estimation of MRL, STMR and HR. September 2015. Available online:
http://ec.europa.eu/food/plant/docs/pesticides_mrl_guidelines_plant_mrl_calculations_2015_en.pdf

EFSA (European Food Safety Authority), 2018. Evaluation of confirmatory data following the Article 12 MRL review for kresoxim-methyl. EFSA Journal 2018;16(11):5471.

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

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3.1/1	Meyer, M.	2020	Residues of Mefentrifluconazole and Kresoxim-methyl in barley after treatment with either BAS 765 00 F, BAS 750 01 F or BAS 494 04 F under field conditions in Northern and Southern Europe, 2019 2020/2100869 SGS Institut Fresenius GmbH, Taunusstein, Germany Fed.Rep. yes Unpublished	No	BASF
KCA 6.3.2/1	Ziske, J.	2020	Residues of Mefentrifluconazole and Kresoxim-methyl in Wheat after Treatment with either BAS 765 00 F, BAS 750 01 F or BAS 494 04 F under Field Conditions in Northern and Southern Europe, 2019 2020/2093149 SGS Institut Fresenius GmbH, Taunusstein, Germany Fed.Rep. yes Unpublished	No	BASF
KCA 6.6.1/1	Deppermann, N., Kampke-Thiel, K.	2013	Confined rotational crop study with 14C-BAS 490 F 2011/1110200 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCA 6.9/1	Anonymous	2020	TMDI calculations 750F 2020/2106108 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.9/2	Anonymous	2020	IEDI calculations 750F 2020/2106110 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCA 6.9/3	Anonymous	2020	IESTI calculations 750F 2020/2106112 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCA 6.9/4	Anonymous	2020	IEDI/IESTI calculations TA 2020/2106113 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCA 6.9/5	Anonymous	2020	IEDI/IESTI calculations TAA 2020/2106116 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCA 6.9/6	Anonymous	2020	IEDI/IESTI calculations TLA 2020/2106117 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCA 6.9/7	Anonymous	2020	IEDI/IESTI calculations 1,2,4-T 2020/2106118 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.9/8	Anonymous	2020	TMDI calculations 490F 2020/2106122 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCA 6.9/9	Guedez Orozco, A.	2020	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 765 00 F 2020/2106123 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 765 00 F is a new product, no already evaluated product studies are available.

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 studies (goat, hen) have been submitted by the applicant. These studies are summarized in chapter 7.2. For a detailed assessment refer to the EFSA conclusion (2018a) and the DAR (UK, 2018).

A 2.1.3 Magnitude of residues in plants

A 2.1.3.1 Cereals

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 (days)	Growth stage at last application	PHI (days)
Barley					
cGAP N-EU/S-EU (EFSA, 2018a)	2	0.150	14	BBCH 69	35
Intended cGAP (10*)	2	0.100	14 (21 if first application after BBCH 49)	BBCH 69	35
Wheat, triticale, rye					
cGAP N-EU/S-EU (EFSA, 2018a)	2	0.150	14	BBCH 69	35
Intended cGAP (5, 9, 11, 12, 13, 17, 21*)	2	0.100	14 (21 if first application after BBCH 49)	BBCH 69	35

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

A 2.1.3.1.1 Study 1 – BASF DocID 2020/2100869

Comments of zRMS:	The study is acceptable. During the growing season of 2019 8 field trials (4 NEU and 4 SEU where 4 of them were bridging trials, 2 per zone) in barley were conducted in order to determine the magnitude of the residues of BAS 750 F (Mefentrifluconazole) and its metabolites 1,2,4-Triazole (T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) as well as BAS 490 F (Kresoxim-methyl) and its metabolites BF 490-2 and BF 490-9 after treatment with either BAS 765 00 F (the evaluation subject), BAS 750 01 F (Mefentrifluconazole only, 100.0 g/L) or BAS 494 04 F (BAS 480 F – Epoxiconazole 125 g/L, BAS 490 F - Kresoxim-methyl 125 g/L). The applications took place at BBCH 49 and BBCH 69 according to the GAP consistent with the proposed GAP (max. 2 applications of 0.1 kg/ha BAS 750 F and 0,15 kg/ha of BAS 490 F up to BBCH 69 with PHI 35). In the study maximal total treatment was 0,3 kg/ha of BAS 750 F as well as of BAS 490 F. Samples of barley were collected at 0 DALA, (on plot 1 before the application, 0 DBLA), on 27-29 DALA, 35-36 DALA and 41- 43 DALA. The employed in the study methods were as follows: BASF Method **L0076/09** was adapted for Mefentrifluconazole using LC-MS/MS to achieve a limit of quantification (LOQ) of 0.010 mg/kg. BASF Method **L0095/01** was adapted for Kresoxim-methyl (BAS 490 F, determined as its acid BF 490-1) and its metabolites (OH-metabolites BF 490-2 and BF 490-9, free and glycosylated forms) using LC-MS/MS to achieve an LOQ of 0.010 mg/kg per analyte except of BF 490-9 in straw where the limit of quantitation (LOQ) is 0.050 mg/kg. For 1,2,4-T, TA, TAA and TLA BASF Method **L0170/02** was adapted using LC-DMS-MS/MS to achieve a limit of quantification (LOQ) of 0.010 mg/kg per analyte. Validation of the analytical methods was performed in separate studies. For all analytical methods concurrent procedural recoveries, performed with fortified untreated specimens at levels covering the working range from LOQ to 10xLOQ, were analysed together with the field samples. 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 %. No residues of mefentrifluconazole, kresoxim-methyl, kresoxim-methyl metabolites were found in any of the control samples above the LOQ. No residues of 1,2,4-T above the LOQ were found in most of the control samples. Residues of TAA, TLA and TA above the LOQ were detected in most of the untreated samples suggesting the use of triazole pesticide actives and/or fertilizers in previous seasons. In barley grain mefentrifluconazole residues were up to 0,32 mg/kg (BBCH 87-89; MRL 0.6 mg/kg). Kresoxim-methyl and its metabolites residues were up to 0.13 mg/kg (MRL 0.15 mg/kg).

Reference:	CA 6.3.1/1
Report	Residues of Mefentrifluconazole and Kresoxim-methyl in barley after treatment with either BAS 765 00 F, BAS 750 01 F or BAS 494 04 F under field conditions in Northern and Southern Europe, 2019, Meyer, M., 2020 report No 871102, IF19-04892284 BASF DocID 2020/2100869 Authority registration No
Guideline(s):	EEC 7525/VI/95 rev. 10.3, EC 7029/VI/95 Rev.5, OECD 509 (2009)

Deviations: No

GLP: yes

(certified by Hessisches Ministerium fuer Umwelt, Klimaschutz, Landwirtschaft und Verbraucherschutz, Wiesbaden)

Acceptability: Yes

Table A 2: Summary of recoveries of BAS 750 F in barley matrices

Matrix	Fortification Levels [mg/kg]	Summary Recoveries BAS 750 F			
Method No. L0076/09*		**Mean [%]**	**SD [±]**	**RSD [%]**	**n**
Whole plant without roots	0.01, 0.10 and 10	91.8	4.8	5.2	7
Ears	0.01, 0.10 and 10	95.2	4.2	4.4	7
Rest of plant without roots	0.01, 0.10 and 10	86.3	3.0	3.5	7
Grain	0.01, 0.10 and 10	87.7	7.2	8.2	7
Straw	0.01, 0.10 and 10	86.6	8.1	9.4	7
	Overall:	**89.5**	**6.5**	**7.2**	**35**

SD = standard deviation, RSD = coefficient of variation, n = number of recoveries
* LOQ 0.01 mg/kg

Table A 3: Summary of recoveries of metabolites 1,2,4-triazole, TA, TAA and TLA in barley matrices

Matrix	Fortification Level [mg/kg]	Summary Recoveries															
		1, 2, 4-Triazole				TA				TAA				TLA			
Method No. L0170/02*		**Mean [%]**	**SD [±]**	**RSD [%]**	**n**	**Mean [%]**	**SD [±]**	**RSD [%]**	**n**	**Mean [%]**	**SD [±]**	**RSD [%]**	**n**	**Mean [%]**	**SD [±]**	**RSD [%]**	**n**
Whole plant without roots	0.01, 0.1, 1.0	91.3	11	12	24	95.6	7.9	8.2	24	103	6.2	6.1	24	91.8	13	14	24
Ears	0.01, 0.1, 1.0	91.6	7.9	8.6	26	85.0	12	14	26	91.6	8.8	9.6	26	90.8	10	11	26
Rest of plant without roots	0.01, 0.1, 1.0	86.4	8.8	10	27	87.2	12	13	27	93.5	10	11	27	94.3	9.7	10	27
Grain	0.01, 0.1, 1.0	94.5	6.0	6.3	13	85.4	14	17	13	91.4	12	13	13	75.9	5.7	7.5	13
Straw	0.01, 0.1, 1.0	84.6	10	12	41	84.2	10	12	41	88.1	8.6	9.8	41	90.3	10	12	41
	Overall:	**88.6**	**9.8**	**11**	**131**	**87.2**	**12**	**13**	**131**	**92.9**	**10**	**11**	**131**	**90.1**	**11**	**13**	**131**

TA = triazole alanine, TAA = triazole acetic acid, TLA = triazole lactic acid, SD = standard deviation, RSD = coefficient of variation, n = number of recoveries
* LOQ 0.01 mg/kg

Table A 4: Summary of residues of BAS 750 F and TDMs on barley in Northern and Southern Europe 2019 (treated samples)

Study No./ Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment: g a.s./ ha	Application rate per treatment: Water (L/ha)	Application rate per treatment: g a.s./hL	Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	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)
2020/2100869 L190195 Germany 67294 Mauchenheim Northern Europe 2019	Barley/ GC 0640 Avalon	1. 23.02.2019 2. 04.06 - 13.06.2019 3. 24.07.2019	100 (plot 2)	200	50	2 13.06.2019	69	Whole plant(f)	2.4	<0.01	0.052	0.043	0.18	0	Analytical method. BASF Method No. L0076/09 for BAS 750 F and L0170/02 for TDMs, LOQ = 0.01 mg/kg Plot 2: BAS 765 00 F (SC) Plot 3: BAS 750 01 F (EC) Treatment: Boom Sprayer Max. storage interval between sampling and extraction: 227 days (BAS 750 F) and 298 days (TDMs)
								Grain	0.20	<0.01	0.15	0.17	<0.01	27	
								Straw	2.7	<0.01	<0.01	0.067	0.30	27	
								Grain	0.15	<0.01	0.16	0.16	<0.01	35	
								Straw	4.8	<0.01	<0.01	0.075	0.22	35	
								Grain	0.14	<0.01	0.19	0.17	<0.01	42	
								Straw	4.7	<0.01	0.015	0.11	0.23	42	
			150 (plot 3)	200	75		69	Whole plant(f)	4.7	<0.01	0.036	0.029	0.12	0	
								Grain	0.21	<0.01	0.16	0.16	0.015	27	
								Straw	5.0	<0.01	0.011	0.082	0.20	27	
								Grain	0.21	<0.01	0.19	0.17	0.012	35	
								Straw	12	<0.01	<0.01	0.067	0.13	35	
								Grain	0.18	<0.01	0.19	0.15	<0.01	42	
								Straw	11	<0.01	0.017	0.089	0.14	42	
2020/2100869 L190196 Poland 89-665 Ogorzeliny Northern Europe 2019	Barley/ GC 0640 Bla	1. 04.05.2019 2. 25.06. - 05.07.2019 3. 14.08.2019	100 (plot 2)	200	50	2 03.07.2019	69	Whole plant(f)	3.8	<0.01	0.026	0.018	0.033	0	
								Ears	0.69	<0.01	0.058	0.039	0.013	28	
								Rest of plant(f)	2.8	<0.01	0.14	0.015	0.033	28	
								Grain	0.060	<0.01	0.095	0.060	<0.01	35	
								Straw	3.8	<0.01	0.024	0.035	0.044	35	
								Grain	0.068	<0.01	0.14	0.066	0.013	42	
								Straw	4.4	<0.01	0.029	0.051	0.045	42	
			150 (plot 3)	200	75		69	Whole plant(f)	5.9	<0.01	0.050	0.030	0.043	0	
								Ears	2.2	<0.01	0.13	0.091	0.026	28	
								Rest of plant(f)	6.9	<0.01	0.027	0.024	0.058	28	
								Grain	0.044	<0.01	0.20	0.12	<0.01	35	
								Straw	5.4	<0.01	0.039	0.064	0.068	35	
								Grain	0.024	<0.01	0.25	0.18	0.013	42	
								Straw	5.9	<0.01	0.041	0.081	0.070	42	

Study No./ 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)
			g a.s./ ha	Water (L/ha)	g a.s./hL				BAS 750 F	1,2,4-T	TA	TAA	TLA		
2020/2100869 L190197 Hungary 4440 Tiszavasvári Northern Europe 2019	Barley/ GC 0640 Scarlet	1. 01.03.2019 2. 10.06. - 16.06.2019 3. 24.07.2019	100 (plot 2)	200	50	2 13.06.2019	69	Whole plant(f) Grain Straw Grain Straw Grain Straw	2.0 0.072 3.1 0.084 2.9 0.13 3.0	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 0.060 0.010 0.042 0.018 0.065 0.017	<0.01 0.036 0.021 0.018 <0.01 0.014 0.010	0.018 <0.01 0.039 <0.01 <0.01 <0.01 0.010	0 27 27 35 35 41 41	Analytical method. BASF Method No. L0076/09 for BAS 750 F and L0170/02 for TDMs, LOQ = 0.01 mg/kg Plot 2: BAS 765 00 F (SC) Plot 3: BAS 750 01 F (EC) Treatment: Boom Sprayer Max. storage interval between sampling and extraction: 227 days (BAS 750 F) and 298 days (TDMs)
2020/2100869 L190198 Denmark 6200 Rollum Northern Europe 2019	Barley/ GC 0640 Fairway	1. 28.04.2019 2. 02.07. - 03.07.2019 3. 15.08.2019	100 (plot 2)	200	50	2 03.07.2019	69	Whole plant(f) Ears Rest of plant(f) Grain Straw Grain Straw	3.5 0.46 1.3 0.038 0.80 0.026 0.60	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.020 0.071 0.014 0.076 0.056 0.079 0.024	0.019 0.047 0.012 0.040 0.039 0.038 0.017	0.031 0.010 0.022 <0.01 0.013 <0.01 <0.01	0 28 28 36 36 43 43	
2020/2100869 L190199 France 47700 Antagnac Southern Europe 2019	Barley/ GC 0640 Memento	1. 05.10.2018 2. 13.05. - 20.05.2019 3. 01.07. - 03.07.2019	100 (plot 2)	200	50	2 20.05.2019	69	Whole plant(f) Ears Rest of plant(f) Ears Rest of plant(f) Grain Straw	0.071 0.62 0.59 0.66 0.61 0.10 1.2	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.069 0.14 <0.01 0.10 <0.01 0.15 0.032	0.030 0.11 0.016 0.076 0.014 0.11 0.050	0.11 0.018 0.027 0.011 0.020 <0.01 0.036	0 28 28 35 35 42 42	
			150 (plot 3)	200	75		69	Whole plant(f) Ears Rest of plant(f) Ears Rest of plant(f) Grain Straw	4.5 1.0 1.6 1.2 1.6 0.043 2.5	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.17 0.27 <0.01 0.32 0.020 0.30 0.086	0.081 0.25 0.039 0.28 0.051 0.26 0.16	0.23 0.045 0.097 0.048 0.10 0.023 0.11	0 28 28 35 35 42 42	

Study No./ 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)
			g a.s./ ha	Water (L/ha)	g a.s./hL				BAS 750 F	1,2,4-T	TA	TAA	TLA		
2020/2100869 L190200 Italy 13040 Borgo D´ale Southern Europe 2019	Barley/ GC 0640 Idra	1. 02.12.2018 2. 20.05. - 28.05.2019 3. 09.07.2019	100 (plot 2)	200	50	2 27.05.2019	69	Whole plant[f] Grain Straw Grain Straw Grain Straw	1.9 0.020 0.57 0.053 0.46 0.055 0.50	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 0.099 0.085 0.12 0.088 0.11 0.066	<0.01 0.041 0.049 0.060 0.054 0.061 0.041	<0.01 <0.01 0.022 <0.01 0.023 <0.01 0.028	0 29 29 36 36 43 43	Analytical method. BASF Method No. L0076/09 for BAS 750 F and L0170/02 for TDMs, LOQ = 0.01 mg/kg Plot 2: BAS 765 00 F (SC) Plot 3: BAS 750 01 F (EC) Treatment: Boom Sprayer Max. storage interval between sampling and extraction: 227 days (BAS 750 F) and 298 days (TDMs)
			150 (plot 3)	200	75		69	Whole plant[f] Grain Straw Grain Straw Grain Straw	6.3 0.057 0.85 0.043 1.1 0.24 1.4	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.013 0.13 0.087 0.13 0.041 0.11 0.067	<0.01 0.045 0.044 0.044 0.040 0.044 0.040	0.018 <0.01 0.014 <0.01 0.033 <0.01 0.032	0 29 29 36 36 43 43	
2020/2100869 L190201 Greece 57006 Lakia Southern Europe 2019	Barley/ GC 0640 Thessaloniki	1. 14.12.2018 2. 25.04. - 05.05.2019 3. 12.06.2019	100 (plot 2)	200	50	2 03.05.2019	69	Whole plant[f] Ears Rest of plant[f] Grain Straw Grain Straw	3.3 3.1 5.3 0.32 3.5 0.20 3.0	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.30 0.49 0.11 0.61 0.13 0.77 0.26	0.13 0.31 0.18 0.37 0.22 0.43 0.28	0.18 0.059 0.48 0.012 0.34 0.011 0.26	0 28 28 35 35 42 42	
2020/2100869 L190202 Spain 18128 Zafarraya Southern Europe 2019	Barley/ GC 0640 Yuriko	1. 07.01.2019 2. 02.05. - 08.05.2019 3. 19.06.2019	100 (plot 2)	200	50	2 08.05.2019	69	Whole plant[f] Ears Rest of plant[f] Ears Rest of plant[f] Grain Straw	1.9 0.92 1.3 1.6 1.9 0.26 1.7	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 0.022 <0.01 0.023 <0.01 0.037 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 0.010 0.012 <0.01 0.017	0 28 28 35 35 42 42	

(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
(f) without root
1,2,4-T = 1,2,4-triazole, TA = triazole alanine, TAA = triazole acetic acid, TLA = triazole lactic acid. The underlined values (e.g. 0.018) are used for MRL calculation.

Table A 5: Summary of residues of BAS 750 F and TDMs on barley in Northern and Southern Europe 2019 (untreated samples)

Study No./ 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)
			g a.s./ ha	Water (L/ha)	g a.s./hL				BAS 750 F	1,2,4-T	TA	TAA	TLA		
2020/2100869 L190195 Germany 67294 Mauchenheim Northern Europe 2019	Barley/ GC 0640 Avalon	1. 23.02.2019 2. 04.06 - 13.06.2019 3. 24.07.2019	-	-	-	-	-	Whole plant[f]	<0.01	<0.01	0.041	0.036	0.13	0	Analytical method. BASF Method No. L0076/09 for BAS 750 F and L0170/02 for TDMs, LOQ = 0.01 mg/kg Plot 1: untreated Max. storage interval between sampling and extraction: 227 days (BAS 750 F) and 298 days (TDMs)
								Ears	<0.01	<0.01	0.16	0.24	0.027	28	
								Rest of plant[f]	<0.01	<0.01	<0.01	0.11	0.29	28	
								Ears	<0.01	<0.01	0.21	0.24	0.017	35	
								Rest of plant[f]	<0.01	<0.01	<0.01	0.12	0.27	35	
								Grain	<0.01	<0.01	0.21	0.21	0.015	42	
								Straw	<0.01	<0.01	0.013	0.14	0.22	42	
2020/2100869 L190196 Poland 89-665 Ogorzeliny Northern Europe 2019	Barley/ GC 0640 Bla	1. 04.05.2019 2. 25.06. - 05.07.2019 3. 14.08.2019	-	-	-	-	-	Whole plant[f]	<0.01	<0.01	0.15	0.082	0.15	0	
								Ears	<0.01	<0.01	0.33	0.32	0.074	28	
								Rest of plant[f]	<0.01	<0.01	0.049	0.12	0.22	28	
								Grain	<0.01	<0.01	0.34	0.26	0.019	35	
								Straw	<0.01	0.059	0.17	0.45	0.31	35	
								Grain	<0.01	<0.01	0.31	0.24	0.018	42	
								Straw	<0.01	<0.01	0.068	0.13	0.10	42	
2020/2100869 L190197 Hungary 4440 Tiszavasvári Northern Europe 2019	Barley/ GC 0640 Scarlet	1. 01.03.2019 2. 10.06. - 16.06.2019 3. 24.07.2019	-	-	-	-	-	Whole plant[f]	<0.01	<0.01	0.014	0.012	0.022	0	
								Grain	<0.01	<0.01	0.035	0.039	<0.01	27	
								Straw	<0.01	<0.01	<0.01	0.025	0.025	27	
								Grain	<0.01	<0.01	0.056	0.042	<0.01	35	
								Straw	<0.01	<0.01	0.015	0.030	0.030	35	
								Grain	<0.01	<0.01	0.070	0.037	<0.01	41	
								Straw	<0.01	<0.01	<0.01	0.019	<0.01	41	
2020/2100869 L190198 Denmark 6200 Rollum Northern Europe 2019	Barley/ GC 0640 Fairway	1. 28.04.2019 2. 02.07. - 03.07.2019 3. 15.08.2019	-	-	-	-	-	Whole plant[f]	<0.01	<0.01	0.051	0.039	0.053	0	
								Ears	<0.01	<0.01	0.080	0.073	0.012	28	
								Rest of plant[f]	<0.01	<0.01	0.020	0.029	0.029	28	
								Grain	<0.01	<0.01	0.11	0.055	0.013	36	
								Straw	<0.01	<0.01	0.033	0.033	0.015	36	
								Grain	<0.01	<0.01	0.12	0.053	<0.01	43	
								Straw	<0.01	<0.01	0.034	0.025	0.014	43	

Study No./ 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)
			g a.s./ ha	**Water (L/ha)**	**g a.s./hL**				**BAS 750 F**	**1,2,4-T**	**TA**	**TAA**	**TLA**		
2020/2100869 L190199 France 47700 Antagnac Southern Europe 2019	Barley/ GC 0640 Memento	1. 05.10.2018 2. 13.05. - 20.05.2019 3. 01.07. - 03.07.2019	-	-	-	-	-	Whole plant[f] Ears Rest of plant[f] Ears Rest of plant[f] Grain Straw	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	0.10 0.20 <0.01 0.18 <0.01 0.16 0.016	0.048 0.19 0.028 0.15 0.024 0.13 0.053	0.15 0.026 0.039 0.015 0.036 <0.01 0.040	0 28 28 35 35 42 42	Analytical method. BASF Method No. L0076/09 for BAS 750 F and L0170/02 for TDMs, LOQ = 0.01 mg/kg Plot 1: untreated Max. storage interval between sampling and extraction: 227 days (BAS 750 F) and 298 days (TDMs)
2020/2100869 L190200 Italy 13040 Borgo D´ale Southern Europe 2019	Barley/ GC 0640 Idra	1. 02.12.2018 2. 20.05. - 28.05.2019 3. 09.07.2019	-	-	-	-	-	Whole plant[f] Grain Straw Grain Straw Grain Straw	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 0.013 <0.01 <0.01	<0.01 0.058 0.021 0.11 <0.01 0.13 0.014	<0.01 0.016 0.020 0.070 <0.01 0.079 0.019	0.012 <0.01 0.016 <0.01 <0.01 <0.01 0.021	0 29 29 36 36 43 43	
2020/2100869 L190201 Greece 57006 Lakia Southern Europe 2019	Barley/ GC 0640 Thessaloniki	1. 14.12.2018 2. 25.04. - 05.05.2019 3. 12.06.2019	-	-	-	-	-	Whole plant[f] Ears Rest of plant[f] Grain Straw Grain Straw	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 0.012 0.011 0.043 <0.01 0.039 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 0.020 <0.01 0.028 <0.01 0.024	0 28 28 35 35 42 42	
2020/2100869 L190202 Spain 18128 Zafarraya Southern Europe 2019	Barley/ GC 0640 Yuriko	1. 07.01.2019 2. 02.05. - 08.05.2019 3. 19.06.2019	-	-	-	-	-	Whole plant[f] Ears Rest of plant[f] Ears Rest of plant[f] Grain Straw	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 0.010 <0.01 <0.01 <0.01 0.028 <0.01	<0.01 <0.01 <0.01 <0.01 <0.01 <0.01 <0.01	<0.01 <0.01 <0.01 <0.01 0.012 <0.01 0.011	0 28 28 35 35 42 42	

(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
(f) without root
1,2,4-T = 1,2,4-triazole, TA = triazole alanine, TAA = triazole acetic acid, TLA = triazole lactic acid.

A 2.1.3.1.2 Study 2 – BASF DocID 2020/2093149

Comments of zRMS:	The study is acceptable. 8 residue field trials in wheat were conducted in EU (4 NEU, 4 SEU; four of them were bridging trials; 2 per zone). The objective of this study was to determine residues of Mefentrifluconazole (BAS 750 F), Kresoxim-methyl (BAS 490 F), and its metabolites (OH metabolites BF 490-2 and BF 490-9, free and glycosylated forms), 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in wheat from the trials after two applications of either BAS 765 00 F, BAS 750 01 F or BAS 494 04 F. The applications took place at BBCH 49 and BBCH 69 according to the GAP consistent with the proposed GAP (max. 2 applications of 0.1 kg/ha BAS 750 F and 0,15 kg/ha of BAS 490 F up to BBCH 69 with PHI 35). In the study maximal total treatment was 0,3 kg/ha of BAS 750 F as well as of BAS 490 F. Samples of barley were collected at 0 DALA, (on plot 1 before the application, 0 DBLA), on 34-36 DALA, 41-42 DALA and 47- 49 DALA. For the analysis of Mefentrifluconazole (BAS 750 F) BASF method no. L0076/09 was used. For the analysis of Kresoxim-methyl (BAS 490 F, determined as its acid BF 490-1) and its metabolites (OH-metabolites BF 490-2 and BF 490-9, free and glycosilated forms) BASF method no. L0095/01 was used. For the analysis of 1,2,4-T, TA, TAA TLA BASF method no. L0170/02 was used. All the methods were LC-MS/MS methods. Validation of the analytical methods was performed in separate studies. The methods LOQ was set at 0,01. 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 samples. 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 %. No residues of mefentrifluconazole, kresoxim-methyl, kresoxim-methyl metabolites were found in any of the control samples above the LOQ. No residues of 1,2,4-T above the LOQ were found in any of the control samples. Residues of TAA, TLA and TA above the LOQ were detected in most of the untreated samples suggesting the use of triazole pesticide actives and/or fertilizers in previous seasons. Residues of mefentrifluconazole found in wheat grain were up to 0.036 mg/kg (MRL 0,05). Residues of kresoxim-methyl in wheat grain (MRL 0,08) were always <0.010 mg/kg except of specimens sampled at DALA 41-42 where residues between < 0.010 and 0.012 mg/kg were found. Residues of kresoxim-methyl metabolites BF 490-2 and BF 490-9 in wheat grain were always <0.010 mg/kg.

Reference:	CA 6.3.2/1
Report	Residues of Mefentrifluconazole and Kresoxim-methyl in Wheat after Treatment with either BAS 765 00 F, BAS 750 01 F or BAS 494 04 F under Field Conditions in Northern and Southern Europe, 2019, Ziske, J., 2020 report No 871100, IF19-04889508 BASF DocID 2020/2093149 Authority registration No
Guideline(s):	7029/VI/95 rev. 5-22/07/97, EEC 7525/VI/95 rev. 10.3, OECD 509

	(2009)
Deviations:	No
GLP:	yes (certified by Hessisches Ministerium fuer Umwelt, Energie, Landwirtschaft und Verbraucherschutz, Wiesbaden)
Acceptability:	Yes

Table A 6: Summary of recoveries of BAS 750 F in wheat matrices

Matrix	**Fortification Levels [mg/kg]**	**Summary Recoveries**			
		BAS 750 F			
Method No. L0076/09*		**Mean [%]**	**SD [±]**	**RSD [%]**	**n**
Whole plant without roots	0.01, 0.10 and 10	88.1	5.3	6.1	8
Ears	0.01, 0.10 and 10	76.4	4.5	5.9	7
Rest of plant without roots	0.01, 0.10 and 10	85.9	2.9	3.4	7
Grain	0.01, 0.10 and 10	92.4	9.5	10	7
Straw	0.01, 0.10 and 10	80.7	4.3	5.3	7
	Overall:	**84.8**	**7.8**	**9.2**	**36**

SD = standard deviation, RSD = coefficient of variation, n = number of recoveries
* LOQ 0.01 mg/kg

Table A 7: Summary of recoveries of metabolites 1,2,4-Triazole, TA, TAA and TLA in wheat matrices

Matrix	**Fortification Level [mg/kg]**	**Summary Recoveries**															
		1, 2, 4-Triazole				**TA**				**TAA**				**TLA**			
Method No. L0170/02*		**Mean [%]**	**SD [±]**	**RSD [%]**	**n**	**Mean [%]**	**SD [±]**	**RSD [%]**	**n**	**Mean [%]**	**SD [±]**	**RSD [%]**	**n**	**Mean [%]**	**SD [±]**	**RSD [%]**	**n**
Whole plant without roots	0.01, 0.1, 1.0	94.8	11	12	21	90.3	11	12	21	97.0	12	13	21	90.8	14	16	21
Ears	0.01, 0.1, 1.0	91.2	11	12	24	90.2	13	14	24	93.3	11	12	24	88.5	12	13	24
Rest of plant without roots	0.01, 0.1, 1.0	90.9	12	13	24	91.6	12	13	24	95.6	11	11	24	95.0	9.3	9.8	24
Grain	0.01, 0.1, 1.0	94.2	9.1	9.7	9	85.9	12	14	9	88.0	13	15	9	75.9	5.9	7.7	9
Straw	0.01, 0.1, 1.0	81.0	9.2	11	34	82.2	10	12	34	90.2	9.7	11	34	88.2	8.5	9.7	34
	Overall:	**88.9**	**12**	**13**	**112**	**87.7**	**12**	**13**	**112**	**93.1**	**11**	**12**	**112**	**89.2**	**11**	**13**	**112**

TA = triazole alanine, TAA = triazole acetic acid, TLA = triazole lactic acid, SD = standard deviation, RSD = coefficient of variation, n = number of recoveries
* LOQ 0.01 mg/kg

Table A 8: Summary of residues of BAS 750 F and TDMs on wheat in Northern and Southern Europe 2019 (treated samples)

Study No./ Trial No./ Location/ EU zone/ Year	Commodity / Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment: g a.s./ ha	Water (L/ha)	g a.s./hL	Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg): BAS 750 F	1,2,4-T	TA	TAA	TLA	PHI (days) (d)	Details on trial (e)
2020/2093149 L190187 Germany 74193 Stetten a. H. Northern Europe 2019	Wheat/ GC 0654 Ponticus	1. 10.11.2018 2. 03.06.-11.06.2019 3. 25.07.2019	100 (plot 2)	200	50	2 11.06.2019	69	Whole plant[f] Ears Rest of plant[f] Grain Straw Grain Straw	2.0 0.12 0.93 <0.010 0.95 <0.010 0.90	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0.034 0.22 0.014 0.23 0.016 0.20 0.027	0.02 0.097 0.021 0.087 0.038 0.073 0.041	0.022 <0.010 0.085 <0.010 0.069 <0.010 0.046	0 35 35 42 42 49 49	Analytical method. BASF Method No. L0076/09 for BAS 750 F and L0170/02 for TDMs, LOQ = 0.01 mg/kg Plot 2: BAS 765 00 F (SC) Plot 3: BAS 750 01 F (EC) Treatment: Boom Sprayer Max. storage interval between sampling and extraction: 208 days (BAS 750 F) and 291 days (TDMs)
			150 (plot 3)	200	75		69	Whole plant[f] Ears Rest of plant[f] Grain Straw Grain Straw	3.1 0.23 0.70 <0.010 0.84 <0.010 0.80	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0.032 0.26 0.011 0.28 0.018 0.27 0.031	0.018 0.10 0.021 0.086 0.030 0.09 0.044	0.027 <0.010 0.094 <0.010 0.061 <0.010 0.037	0 35 35 42 42 49 49	
2020/2093149 L190188 Hungary H-4461 Nyírtelek-Ferenctanya Northern Europe 2019	Wheat/ GC 0654 GK Szilárd	1. 17.10.2018 2. 25.05. - 05.06.2019 3. 17.07. - 18.07.2019	100 (plot 2)	200	50	2 30.05.2019	69	Whole plant[f] Grain Straw Grain Straw Grain Straw	1.6 <0.010 1.1 <0.010 1.3 <0.010 1.3	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0.046 0.21 0.011 0.20 <0.010 0.22 <0.010	0.045 0.086 0.043 0.084 0.047 0.090 0.042	0.038 <0.010 0.043 <0.010 0.043 <0.010 0.028	0 36 36 42 42 48 48	
			150 (plot 3)	200	75		69	Whole plant[f] Grain Straw Grain Straw Grain Straw	4.4 <0.010 4.2 <0.010 4.1 <0.010 4.6	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0.035 0.27 0.019 0.28 0.016 0.28 0.020	0.032 0.10 0.055 0.11 0.067 0.11 0.0524	0.035 <0.010 0.052 <0.010 0.064 <0.010 0.031	0 36 36 42 42 48 48	

Study No./ 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)
			g a.s./ ha	Water (L/ha)	g a.s./hL				BAS 750 F	1,2,4-T	TA	TAA	TLA		
2020/2093149 L190189 Denmark 6200 Varnæs Northern Europe 2019	Wheat/ GC 0654 Julius	1. 18.09.2018 2. 11.06. - 13.06.2019 3. 30.07.2019	100 (plot 2)	200	50	2 13.06.2019	69	Whole plant(f) Ears Rest of plant(f) Ears Rest of plant(f) Grain Straw	2.1 0.29 1.2 0.39 1.5 <0.010 1.5	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0.021 0.12 <0.010 0.11 0.016 0.13 0.016	0.013 0.038 0.017 0.040 0.031 0.050 0.036	0.032 <0.010 0.022 <0.010 0.017 <0.010 0.016	0 34 34 41 41 47 47	Analytical method. BASF Method No. L0076/09 for BAS 750 F and L0170/02 for TDMs, LOQ = 0.01 mg/kg Plot 2: BAS 765 00 F (SC) Plot 3: BAS 750 01 F (EC) Treatment: Boom Sprayer Max. storage interval between sampling and extraction: 208 days (BAS 750 F) and 291 days (TDMs)
2020/2093149 L190190 Belgium 6211 Mellet Northern Europe 2019	Wheat/ GC 0654 KWS Mistral	1. 21.03.2019 2. 15.06. - 22.06.2019 3. 05.08. – 12.08.2019	100 (plot 2)	200	50	2 21.06.2019	69	Whole plant(f) Ears Rest of plant(f) Grain Straw Grain Straw	3.1 0.37 3.2 0.012 3.8 0.012 3.7	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0.021 0.096 <0.010 0.11 <0.010 0.11 <0.010	0.012 0.035 <0.010 0.031 0.016 0.030 0.020	0.012 <0.010 0.032 <0.010 0.023 <0.010 0.018	0 34 34 42 42 48 48	
2020/2093149 L190191 France 47200 Meilhan sur Garonne Southern Europe 2019	Wheat/ GC 0654 Oregrain	1. 22.11.2018 2. 20.05. - 25.05.2019 3. 15.07. - 20.07.2019	100 (plot 2)	200	50	2 31.05.2019	69	Whole plant(f) Ears Rest of plant(f) Ears Rest of plant(f) Grain Straw	2.2 0.34 0.73 0.34 1.3 <0.010 1.0	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	<0.010 0.042 <0.010 0.067 <0.010 0.050 <0.010	<0.010 <0.010 <0.010 0.017 0.010 <0.010 0.012	0.011 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0 35 35 42 42 47 47	
			150 (plot 3)	200	75		69	Whole plant(f) Ears Rest of plant(f) Ears Rest of plant(f) Grain Straw	3.8 0.77 2.2 0.80 3.2 <0.010 2.7	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0.015 0.087 <0.010 0.12 0.011 0.090 <0.010	<0.010 0.023 0.012 0.036 0.016 0.021 0.018	0.015 <0.010 0.021 <0.010 0.023 <0.010 0.022	0 35 35 42 42 47 47	

Study No./ 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)
			g a.s./ ha	Water (L/ha)	g a.s./hL				BAS 750 F	1,2,4-T	TA	TAA	TLA		
2020/2093149 L190192 Spain 18128 Zafarraya, Granada Southern Europe 2019	Wheat/ GC 0654 Marius	1. 02.01.2019 2. 14.05. - 21.05.2019 3. 09.07.2019	100 (plot 2)	200	50	2 21.05.2019	69	Whole plant[f]	3.0	<0.010	<0.010	<0.010	0.023	0	Analytical method. BASF Method No. L0076/09 for BAS 750 F and L0170/02 for TDMs, LOQ = 0.01 mg/kg Plot 2: BAS 765 00 F (SC) Plot 3: BAS 750 01 F (EC) Treatment: Boom Sprayer Max. storage interval between sampling and extraction: 208 days (BAS 750 F) and 291 days (TDMs)
								Ears	0.32	<0.010	0.040	<0.010	<0.010	34	
								Rest of plant[f]	3.4	<0.010	<0.010	<0.010	0.012	34	
								Ears	0.24	<0.010	0.042	0.014	<0.010	41	
								Rest of plant[f]	2.9	<0.010	<0.010	<0.010	0.014	41	
								Grain	0.021	<0.010	0.052	0.014	<0.010	49	
								Straw	2.3	<0.010	<0.010	<0.010	0.014	49	
			150 (plot 3)	200	75		69	Whole plant[f]	3.6	<0.010	0.017	<0.010	0.018	0	
								Ears	0.39	<0.010	0.12	0.023	<0.010	34	
								Rest of plant[f]	3.3	<0.010	<0.010	<0.010	0.027	34	
								Ears	0.41	<0.010	0.12	0.030	<0.010	41	
								Rest of plant[f]	4.1	<0.010	0.011	<0.010	0.043	41	
								Grain	0.023	<0.010	0.15	0.046	<0.010	49	
								Straw	3.4	<0.010	0.010	<0.010	0.037	49	
2020/2093149 L190193 Italy 20090 Caleppio di Settala Southern Europe 2019	Wheat/ GC 0654 Arabia	1. 20.11.2018 2. 14.05. - 29.05.2019 3. 08.07.2019	100 (plot 2)	200	50	2 21.05.2019	69	Whole plant[f]	2.5	<0.010	0.020	0.018	0.066	0	
								Grain	0.036	<0.010	0.34	0.082	<0.010	36	
								Straw	2.1	<0.010	0.055	0.056	0.087	36	
								Grain	0.035	<0.010	0.33	0.087	<0.010	41	
								Straw	2.3	<0.010	0.055	0.061	0.103	41	
								Grain	0.036	<0.010	0.35	0.086	<0.010	48	
								Straw	2.5	<0.010	0.057	0.062	0.112	48	
2020/2093149 L190194 Greece 57006 Lakia Southern Europe 2019	Wheat/ GC 0654 Yecora	1. 14.12.2018 2. 25.04. - 05.05.2019 3. 18.06.2019	100 (plot 2)	200	50	2 03.05.2019	69	Whole plant[f]	2.9	<0.010	0.039	0.033	0.024	0	
								Grain	0.032	<0.010	0.099	0.080	<0.010	35	
								Straw	3.2	<0.010	<0.010	0.017	0.066	35	
								Grain	0.027	<0.010	0.12	0.09	<0.010	42	
								Straw	3.6	<0.010	0.023	0.042	0.059	42	
								Grain	0.021	<0.010	0.12	0.10	<0.010	48	
								Straw	2.5	<0.010	0.021	0.041	0.059	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
(f) without root
1,2,4-T = 1,2,4-triazole, TA = triazole alanine, TAA = triazole acetic acid, TLA = triazole lactic acid. The underlined values (e.g. 0.018) are used for MRL calculation.

Table A 9: Summary of residues of BAS 750 F and TDMs on wheat in Northern and Southern Europe 2019 (untreated samples)

Study No./ 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)
			g a.s./ ha	Water (L/ha)	g a.s./hL				BAS 750 F	1,2,4-T	TA	TAA	TLA		
2020/2093149 L190187 Germany 74193 Stetten a. H. Northern Europe 2019	Wheat/ GC 0654 Ponticus	1. 10.11.2018 2. 03.06.-11.06.2019 3. 25.07.2019	- (plot 1)	-	-	-	-	Whole plant[f]	<0.010	<0.010	0.040	0.028	0.025	0	Analytical method. BASF Method No. L0076/09 for BAS 750 F and L0170/02 for TDMs, LOQ = 0.01 mg/kg Plot 1: untreated Max. storage interval between sampling and extraction: 208 days (BAS 750 F) and 291 days (TDMs)
								Ears	<0.010	<0.010	0.12	0.11	<0.010	35	
								Rest of plant[f]	<0.010	<0.010	<0.010	0.029	0.063	35	
								Grain	<0.010	<0.010	0.138	0.12	<0.010	42	
								Straw	<0.010	<0.010	<0.010	0.057	0.084	42	
								Grain	<0.010	<0.010	0.16	0.088	<0.010	49	
								Straw	<0.010	<0.010	0.012	0.056	0.068	49	
2020/2093149 L190188 Hungary H-4461 Nyírtelek-Ferenctanya Northern Europe 2019	Wheat/ GC 0654 GK Szilárd	1. 17.10.2018 2. 25.05. - 05.06.2019 3. 17.07. - 18.07.2019	- (plot 1)	-	-	-	-	Whole plant[f]	<0.010	<0.010	0.035	0.034	0.039	0	
								Grain	<0.010	<0.010	0.18	0.11	<0.010	36	
								Straw	<0.010	<0.010	0.012	0.059	<0.010	36	
								Grain	<0.010	<0.010	0.23	0.12	<0.010	42	
								Straw	<0.010	<0.010	0.011	0.052	0.031	42	
								Grain	<0.010	<0.010	0.20	0.12	<0.010	48	
								Straw	<0.010	<0.010	0.010	0.058	0.024	48	
2020/2093149 L190189 Denmark 6200 Varnæs Northern Europe 2019	Wheat/ GC 0654 Julius	1. 18.09.2018 2. 11.06. - 13.06.2019 3. 30.07.2019	- (plot 1)	-	-	-	-	Whole plant[f]	<0.010	<0.010	0.022	0.016	0.029	0	
								Ears	<0.010	<0.010	0.11	0.064	<0.010	34	
								Rest of plant[f]	<0.010	<0.010	<0.010	0.024	0.021	34	
								Ears	<0.010	<0.010	0.13	0.070	<0.010	41	
								Rest of plant[f]	<0.010	<0.010	<0.010	0.043	0.027	41	
								Grain	<0.010	<0.010	0.075	0.045	<0.010	47	
								Straw	<0.010	<0.010	<0.010	0.032	<0.010	47	
2020/2093149 L190190 Belgium 6211 Mellet Northern Europe 2019	Wheat/ GC 0654 KWS Mistral	1. 21.03.2019 2. 15.06. - 22.06.2019 3. 05.08. – 12.08.2019	- (plot 1)	-	-	-	-	Whole plant[f]	<0.010	<0.010	0.014	<0.010	<0.010	0	
								Ears	<0.010	<0.010	0.039	0.016	<0.010	34	
								Rest of plant[f]	<0.010	<0.010	<0.010	<0.010	0.017	34	
								Grain	<0.010	<0.010	0.042	0.014	<0.010	42	
								Straw	<0.010	<0.010	<0.010	0.022	0.094	42	
								Grain	<0.010	<0.010	0.038	0.011	<0.010	48	
								Straw	<0.010	<0.010	<0.010	0.011	<0.010	48	

Study No./ 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)
			g a.s./ ha	Water (L/ha)	g a.s./hL				BAS 750 F	1,2,4-T	TA	TAA	TLA		
2020/2093149 L190191 France 47200 Meilhan sur Garonne Southern Europe 2019	Wheat/ GC 0654 Oregrain	1. 22.11.2018 2. 20.05. - 25.05.2019 3. 15.07. - 20.07.2019	- (plot 1)	-	-	-	-	Whole plant(f) Ears Rest of plant(f) Ears Rest of plant(f) Grain Straw	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	<0.010 0.012 <0.010 0.016 <0.010 <0.010 <0.010	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0.014 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0 35 35 42 42 47 47	Analytical method. BASF Method No. L0076/09 for BAS 750 F and L0170/02 for TDMs, LOQ = 0.01 mg/kg Plot 1: untreated Max. storage interval between sampling and extraction: 208 days (BAS 750 F) and 291 days (TDMs)
2020/2093149 L190192 Spain 18128 Zafarraya, Granada Southern Europe 2019	Wheat/ GC 0654 Marius	1. 02.01.2019 2. 14.05. - 21.05.2019 3. 09.07.2019	- (plot 1)	-	-	-	-	Whole plant(f) Ears Rest of plant(f) Ears Rest of plant(f) Grain Straw	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	<0.010 <0.010 <0.010 0.011 <0.010 0.010 <0.010	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0.020 <0.010 <0.010 <0.010 0.011 <0.010 <0.010	0 34 34 41 41 49 49	
2020/2093149 L190193 Italy 20090 Caleppio di Settala Southern Europe 2019	Wheat/ GC 0654 Arabia	1. 20.11.2018 2. 14.05. - 29.05.2019 3. 08.07.2019	- (plot 1)	-	-	-	-	Whole plant(f) Grain Straw Grain Straw Grain Straw	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0.023 0.16 0.023 0.34 0.016 0.21 0.018	0.022 0.037 0.031 0.18 0.030 0.043 0.029	0.083 <0.010 0.028 <0.010 0.029 <0.010 0.030	0 36 36 41 41 48 48	
2020/2093149 L190194 Greece 57006 Lakia Southern Europe 2019	Wheat/ GC 0654 Yecora	1. 14.12.2018 2. 25.04. - 05.05.2019 3. 18.06.2019	- (plot 1)	-	-	-	-	Whole plant(f) Grain Straw Grain Straw Grain Straw	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	<0.010 <0.010 <0.010 <0.010 <0.010 <0.010 <0.010	0.065 0.14 <0.010 0.17 0.024 0.17 0.031	0.075 0.12 0.042 0.16 0.059 0.17 0.089	0.044 <0.010 0.11 <0.010 0.072 <0.010 0.083	0 35 35 42 42 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
(f) without root
1,2,4-T = 1,2,4-triazole, TA = triazole alanine, TAA = triazole acetic acid, TLA = triazole lactic acid.

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. These studies are summarized in chapter 7.2. For a detailed assessment refer to the EFSA conclusion (2018a) and the DAR (UK, 2018).

A 2.1.6 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 765 00 F are intended to be used in cereals. No “other study” is provided.

A 2.2 Kresoxim-methyl

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

No new data.

A 2.2.1.1.2 Storage stability of residues in animal products

No new data.

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 data.

A 2.2.2.1.2 Nature of residue in rotational crops

A 2.2.2.1.2.1 Study 1 – BASF DocID 2011/1110200

Comments of zRMS:	The study is acceptable. Also, the investigated after application to bare soil of 1 x 1500 g a.s./ha, metabolic pathway in rotational crops proposal of ^{14}C-labelled kresoxim-methyl is accepted. After application, the soil was aged for 30 days (simulating an emergency plant back), 120 days (a fall plant back) and 365 days (annual plant back). Afterwards, lettuce was planted, and white radish and spring wheat were sown. The analytical determinations were done by HPLC-MS/MS. The extractability of kresoxim-methyl radioactive residues from the plant samples and the extracts over the period of investigation has remained similar. The storage stability of residues in the relevant matrices was demonstrated to be sufficient. As readily metabolized, kresoxim-methyl was detected only in very minor amounts (0,003) in immature and mature lettuce, immature white radish, white radish top and in spring wheat straw of crops planted or sown 30 DAT and in lettuce planted 120 DAT. In crops sown or planted 30 DAT, the main metabolic pathway is the hydroxylation of the methylphenyl moiety. The hydroxylated derivatives 490M02 and 490M09 which are part of the residue definition for data generation and risk assessment were not detected. The hydroxylated moiety then can be conjugated with carbohydrates or incorporated into e.g. polysaccharides. After a plant back interval of 365 DAT, kresoxim-methyl was evidently extensively degraded in soil and the radioactive residues in plants were mainly recovered as polar components and non-extractable residues. It can be concluded, that for the intended uses of kresoxim-methyl in the product BAS 765 00 F on cereals no residues of parent and the relevant metabolites above 0.01 mg/kg are expected in rotational crops.

Reference:	CA 6.6.1/1
Report	Confined rotational crop study with 14C-BAS 490 F, Deppermann, N., Kampke-Thiel, K., 2013 report No 290005 BASF DocID 2011/1110200 Authority registration No
Guideline(s):	BBA IV 3-10, PMRA Residue Chemistry Guidelines Section 97.13 Confined Accumulation in Rotational Crops (Canada), EPA 860.1000: EPA Residue Chemistry Test Guidelines, EPA 860.1850: Confined Accumulation in Rotational Crops, Lundehn III: 7524/VI/95 Rev. 2 Appendix C (EU) Testing of plant protection products in rotational crops (draft)
Deviations:	No
GLP:	yes (certified by Landesamt fuer Umwelt, Wasserwirtschaft und Gewerbeaufsicht, Mainz, Germany)
Acceptability:	Yes

Materials and methods

A. MATERIALS

1. Test Material:

Description:	benzyl-ring-U-C^{14} kresoxim-methyl Unlabeled kresoxim-methyl
Lot/Batch #:	613-2019 (benzyl label) COD-000225 (unlabeled)
Purity:	Radiochemical purity: 99.6 % (benzyl label) Chemical purity: 97.8 % (unlabeled)
Specific activity:	14.4 MBq/mg (benzyl label)
CAS#:	143390-89-0

2. Test Commodity:

Crop:	lettuce		white radish	s pring wheat
Type:	leafy vegetables	v	root egetables	cereals
Variety:	Matilda, Lucan		April Cross	Thassos
Botanical name:	*Lactuca sativa*		*Raphanus sativus*	*Triticum aestivum*

Crop part / processed commodity: Lettuce; white radish tops and roots; spring wheat forage, straw, chaff and grain; soil samples after ploughing and after harvest of individual crops

Sample size: not reported

3. Soil: A sandy loam soil (USDA) was used. The soil physicochemical properties are described below.

Table A 10: Soil Physicochemical Properties

Soil Series	Soil Type	pH	OC %	Sand %	Silt %	Clay %	Maximal water holding capacity g/100 g dry soil	CEC(1) $cmol^+/kg$
Li 33 b	Sandy loam(2)	7.3(3)	0.71	71.7(2)	23.8(2)	4.5(2)	22.2	6.7

(1) Cation Exchange Capacity
(2) USDA scheme
(3) Water suspension

B. STUDY DESIGN

The study was conducted during the period August, 2007 to July, 2013 by BASF SE in Limburgerhof, Germany.

1. Test procedure

A confined rotational crop study was conducted with ^{14}C BAS 490 F (kresoxim-methyl). The active substance was applied to sandy loam soil (USDA scheme) in 12 plastic containers at a nominal application rate of 1 x 1500 g a.s./ha (approximately 1.34 lb/A). Uniformly ^{14}C-labeled kresoxim-methyl (benzyl ring) was mixed with unlabelled active substance in a ratio of 2:1 and applied to the bare soil using an automatic spray track. The nature and the level of radioactive residues were investigated in lettuce, white radish (root and top) and spring wheat (forage, chaff, straw and grain) after plant back intervals of 30, 120 and 365 days. Before planting or sowing of the following crops, the soil was mixed to simulate ploughing. The lettuce varieties planted were “Matilda” and “Lucan”, the white radish variety “April Cross” and the spring wheat variety “Thassos” were sown.

2. Sampling

Plant samples were harvested at maturity. Lettuce heads were cut above the soil line and cut into pieces. White radishes were pulled from the soil, separated into the edible parts (root) and the remaining green tops and cut into pieces. For wheat forage, immature green plants were sampled and cut into pieces. Mature wheat was harvested by cutting the ears. Afterwards straw was harvested by cutting the remaining plant parts just above the soil line. Straw was chopped, and the ears were separated into grain and chaff. After the individual plant back intervals, soil samples (top soil, mixed samples from the respective containers) were taken after ploughing and after harvest of the crops. All samples were stored in a freezer at -18 °C or below immediately after sampling.

3. Description of analytical procedures

Prior to extraction and determination of the TRR, sample material was homogenized with a laboratory mill.

Combustion: Appropriate aliquots of solid plant and soil samples were combusted with a sample oxidizer to determine the Total Radioactive Residue (TRR combusted). In order to determine the background radioactivity, aliquots of untreated samples (lettuce, straw and grain) were combusted under the same conditions.

LSC: For the quantitation of radioactivity in liquid samples, a Liquid Scintillation Counter (LSC) was used. Aliquots of liquid samples were mixed with an appropriate volume of a suitable scintillator prior to LSC measurement.

Extraction: Aliquots of homogenized plant material were extracted three times with methanol and twice with water. The radioactivity in each extract was determined by LSC. The combined results of methanol extractions and water extractions are referred to as extractable radioactive residues (ERR). The residue after solvent extraction of each sample was dried, homogenized and combusted for the determination of the residual radioactive residue (RRR). The total radioactive residues were obtained by calculating the sum of ERR and RRR values (TRR calculated).

Partition: Subsamples of the methanol extracts of plant matrices from the plant back interval 30 DAT were evaporated to the water phase and partitioned three times with equal volumes of dichloromethane. Afterwards, the remaining water phases were partitioned three times with equal volumes of ethyl acetate.

Solubilization: The residual radioactive residues after extraction with methanol and water (RRR) with a sufficient level of radioactivity were extracted twice with ammonia. After ammonia extraction, the residues were dried and subsequently solubilized with different enzymes (macerozyme R-10 and cellulase; β-glucosidase and hesperidinase; α-amylase, β-amylase and amyloglucosidase; or tyrosinase and laccase). The residues after tyrosinase / laccase incubation of wheat chaff and straw samples were additionally subjected to non-enzymatic solubilization procedures using microwave and acidic / alkaline hydrolysis.

HPLC: Extracts and solubilizates with a sufficient level of radioactivity were analyzed by HPLC.

MS: Identification of metabolites was based on the HPLC-MS and MS/MS analyses of fractions from the methanol extract of radish root (30 DAT) and from the methanol extract of spring wheat straw (30 DAT).

Results and discussion

A. TOTAL RADIOACTIVE RESIDUES (TRRs)

The TRR was measured by direct combustion analysis of solid plant and soil samples followed by

LSC. Additionally, the TRR of plant samples was calculated by addition of the extractable (ERR) and non-extractable radioactive residues (RRR). The measured TRR showed generally no major difference to the calculated TRR values. The results of the analysis of plant samples in the present study are based on the TRR calculated. The measured TRR showed generally comparable results to the calculated TRR values. The highest residue levels were determined in spring wheat straw with 1.629 mg/kg (30 DAT) and 0.163 mg/kg (365 DAT). In general, the TRRs in crops sown or planted declined significantly with growing plant back intervals.

Table A 11: Total radioactive residues in soil and crops samples after treatment with ^{14}C-kresoxim-methyl

Matrix (Days After Sowing / Planting)	TRR Combusted [mg/kg]	TRR Calculated [mg/kg]
Plant back interval: 30 DAT		
Soil after ploughing	0.361	n.a.
Lettuce (56 DAP)	0.098	0.049
Soil after harvest of lettuce (56 DAP)	0.117	n.a.
White radish top (84 DAP)	0.538	0.507
White radish root (84 DAP)	0.178	0.211
Soil after harvest of radish (84 DAP)	0.178	n.a.
Spring wheat forage (50 DAP)	0.334	0.303
Spring wheat chaff (123 DAP)	0.629	0.636
Spring wheat straw (123 DAP)	1.987	1.629
Spring wheat grain (123 DAP)	0.413	0.377
Soil after harvest of wheat (123 DAP)	0.134	n.a.
Plant back interval: 120 DAT		
Soil after ploughing	0.144	n.a.
Lettuce (59 DAP)	0.096	0.094
Soil after harvest of lettuce (59 DAP)	0.102	n.a.
White radish top (81 DAP)	0.095	0.092
White radish root (81 DAP)	0.040	0.038
Soil after harvest of radish (81 DAP)	0.127	n.a.
Spring wheat forage (61 DAP)	0.062	0.056
Spring wheat chaff (145 DAP)	0.163	0.169
Spring wheat straw (145 DAP)	0.360	0.330
Spring wheat grain (145 DAP)	0.103	0.103
Soil after harvest of wheat (123 DAP)	0.092	n.a.
Plant back interval: 365 DAT		
Soil after ploughing	0.124	n.a.
Lettuce (53 DAP)	0.012	0.012
Soil after harvest of lettuce (53 DAP)	0.107	n.a.
White radish top (77 DAP)	0.046	0.042
White radish root (77 DAP)	0.011	0.012
Soil after harvest of radish (77 DAP)	0.107	n.a.
Spring wheat forage (61 DAP)	0.022	0.021
Spring wheat chaff (158 DAP)	0.099	0.099
Spring wheat straw (158 DAP)	0.169	0.163
Spring wheat grain (158 DAP)	0.066	0.066
Soil after harvest of wheat (158 DAP)	0.056	n.a.

DAT: Days after treatment
n.a. not applied

B. EXTRACTION AND CHARACTERIZATION OF RESIDUES

1. Extraction and characterization of residues in rotational crops

The residues found in lettuce, white radish, spring wheat forage and straw planted or sown 30 DAT were highly extractable with methanol and water (>70 % ERR). The predominant portion of residues was extracted with methanol and significantly smaller portions with water. In spring wheat forage and straw the extractability of the residues declined significantly with a longer plant back interval and was less than 40 % ERR after 365 DAT. In spring wheat chaff the extractability of residues was 55.7 % TRR after 30 DAT and declined to 25.2 % TRR after 365 DAT, while in grain the extractability was constantly low with approximately 16 % TRR after all plant back intervals.

The methanol extracts from rotational crop matrices planted or sown 30 DAT were partitioned between water, ethyl acetate and water. The predominant portion of the radioactive residues in all matrices remained in the water phase.

2. Identification, characterization and quantification of radioactive residues in rotational crops

Kresoxim-methyl metabolites were identified by HPLC-MS analysis of fractions derived from the methanol extracts of white radish root and spring wheat straw. Metabolites in other extracts or solubilizates were assigned by comparison of the retention times with those of the identified metabolites.

<u>Extractable radioactive residues (ERR):</u> Kresoxim-methyl was detected only in very minor amounts in lettuce, white radish top and in spring wheat straw (30 DAT). The main metabolite in lettuce, white radish and spring wheat forage was the hydroxylated derivative 490M78 (lettuce: up to 0.013 mg/kg or 14.6 % TRR; white radish: up to 0.192 mg/kg or 43.7 % TRR and spring wheat forage: up to 0.033 mg/kg or 11.1 % TRR). Further considerable portions of the methanol and water extracts eluted as a polar fraction. In spring wheat straw (30 DAT) the following metabolites were identified: a mixture of the isomeric carboxylic acids 490M68 / 490M69 (0.261 mg/kg or 16.0 % TRR), a mixture of the isomeric glucose-conjugates 490M76 / 490M77 (0.154 mg/kg) and the de-methylphenylated derivative 490M06 (0.142 mg/kg).

<u>Residues after solvent extraction (RRR):</u> Significant portions of the residues after solvent extraction of lettuce (30 and 120 DAT), white radish top and root (120 DAT) and spring wheat forage and grain (30 and 120 DAT) were solubilized with a macerozyme / cellulase mixture (7.0 % to 36.1 % TRR) and from spring wheat grain 30 DAT also with an amylase / amyloglucosidase mixture (18.6 % TRR). The residues after solvent extraction from spring wheat chaff and straw (30 and 120 DAT) were poorly soluble upon enzymatic treatment. HPLC analysis of selected solubilizates resulted in a predominant polar fraction. The residues in the macerozyme solubilizate of the bound residues after solvent extraction of wheat grain (30 DAT) were identified as carbohydrates by fermentation with yeast.

Table A 12: Extractability of residues in rotational crop samples following treatment with ^{14}C-kresoxim-methyl

Crop Matrix (Days After Sowing / Planting)	TRR calculated	Methanol extract	Water extract	ERR	RRR
	[mg/kg]	[% TRR]	[% TRR]	[% TRR]	[% TRR]
30 DAT					
Lettuce (56 DAP)	0.049	67.3	5.5	72.8	27.2
Radish top (84 DAP)	0.507	75.6	11.5	87.1	12.9
Radish root (84 DAP)	0.211	71.3	1.9	73.2	26.8
Wheat forage (50 DAP)	0.303	73.9	4.9	78.7	21.3
Wheat chaff (123 DAP)	0.636	35.7	20.0	55.7	44.3
Wheat straw (123 DAP)	1.629	59.7	15.3	75.0	25.0
Wheat grain (123 DAP)	0.377	8.3	7.8	16.1	83.9
120 DAT					
Lettuce (59 DAP)	0.094	43.9	4.8	48.7	51.3
Radish top (81 DAP)	0.092	58.2	9.3	67.6	32.4
Radish root (81 DAP)	0.038	61.9	4.2	66.2	33.8
Wheat forage (61 DAP)	0.056	43.3	3.4	46.7	53.3
Wheat chaff (145 DAP)	0.169	27.0	11.0	37.9	62.1
Wheat straw (145 DAP)	0.330	38.0	12.9	50.8	49.2
Wheat grain (145 DAP)	0.103	7.4	8.2	15.6	84.4
365 DAT					
Lettuce (53 DAP)	0.012	43.9	5.3	49.3	50.7
Radish top (77 DAP)	0.042	63.6	8.2	71.8	28.2
Radish root (77 DAP)	0.012	58.9	2.7	61.7	38.3
Wheat forage (61 DAP)	0.021	32.7	4.6	37.3	62.7
Wheat chaff (158 DAP)	0.099	12.2	13.1	25.2	74.8
Wheat straw (158 DAP)	0.043	26.1	12.9	39.0	61.0
Wheat grain (158 DAP)	0.066	7.7	8.8	16.5	83.5

ERR = Extractable Radioactive Residues
RRR = Residual Radioactive Residues
DAP = Days after Planting
DAT = Days after Treatment

Table A 13: Solubilization of residues after solvent extraction of rotational crop samples following treatment with ^{14}C-kresoxim

Crop Matrix (Days After Sowing / Planting)	RRR	Ammonia	Macerozyme / cellulase	Amylase / amylo-glucosidase	Tyrosinase / laccase
	[mg/kg]	[% TRR]	[% TRR]	[% TRR]	[% TRR]
30 DAT					
Lettuce (56 DAP)	0.013	1.4	9.2	n.a.	n.a.
Radish top(84 DAP)	0.065	3.3	0.8	n.a.	n.a.
Radish root (84 DAP)	0.056	1.0	1.4	n.a.	n.a.
Wheat forage (50 DAP)	0.064	1.8	7.0	0.6	0.3
Wheat chaff (123 DAP)(1)	0.282	3.6	5.6	2.5	0.6
Wheat straw (123 DAP)(2)	0.407	4.4	2.5	0.7	0.8
Wheat grain (123 DAP)(4)	0.316	6.9	34.4	18.6	2.8
120 DAT					
Lettuce (59 DAP)	0.049	2.8	12.8	n.a.	n.a.
Radish top (81 DAP)	0.030	2.4	11.8	n.a.	n.a.
Radish root (81 DAP)	0.013	4.0	8.8	n.a.	n.a.
Wheat forage (61 DAP)	0.030	1.3	16.7	n.a.	n.a.
Wheat chaff (145 DAP)(3)	0.105	4.5	7.1	3.8	n.a.
Wheat straw (145 DAP)[3]	0.162	4.3	6.1	1.7	n.a.
Wheat grain (145 DAP)[4]	0.087	3.5	36.1	n.a.	n.a.

RRR = Residual Radioactive Residues
DAP = Days after Planting
DAT = Days after Treatment
n.a. = not applied

(1) The residue after tyrosinase / laccase incubation was further worked up with non-enzymatic solubilization steps including microwave heating and acidic / alkaline hydrolysis
(2) The residue after tyrosinase / laccase incubation was further worked up with acidic and alkaline hydrolysis
(3) The residue after amylase / amyloglucosidase incubation was further worked up with alkaline hydrolysis
(4) Additional glucosidase / hesperidinase incubation released 5.2% TRR (30 DAT) and 6.4% TRR (120 DAT).

Table A 14: Total identified residues in rotational crop samples following treatment with ^{14}C-kresoxim-methyl

Crop Matrix (Days After Sowing / Planting)	BAS 490 F	490M06	490M68 / 490M69	490M78 1)	490M76 / 490M77	Carbohydrates
	[mg/kg] [% TRR]	[mg/kg] [% TRR]	[mg/kg] [% TRR]	[mg/kg] [% TRR]	[mg/kg] [% TRR]	[mg/kg] [% TRR]
30 DAT						
Lettuce (56 DAP)	0.003 6.1	n.d.	n.d.	0.006 12.0	n.d.	n.d.
Radish top (84 DAP)	0.018 3.5	n.d.	n.d.	0.142 27.9	n.d.	n.d.
Radish root (84 DAP)	n.d.	n.d.	n.d.	0.073 34.8	n.d.	n.d.
Wheat forage (50 DAP)	n.d.	n.d.	n.d.	0.033 11.1	n.d.	n.d.
Wheat straw (123 DAP)	0.035 2.2	0.142 8.7	0.261 16.0	0.114 7.0	0.154 9.4	n.d.
Wheat grain (123 DAP)	n.d.	n.d.	n.d.	n.d.	n.d.	0.129 34.4
120 DAT						
Lettuce (59 DAP)	0.001 1.1	n.d.	n.d.	0.003 3.0	n.d.	n.d.
Radish top (81 DAP)	n.d.	n.d.	n.d.	0.007 17.4	n.d.	n.d.
Radish root (81 DAP)	n.d.	n.d.	n.d.	0.007 18.8	n.d.	n.d.
Wheat forage (61 DAP)	n.d.	n.d.	n.d.	0.002 3.0	n.d.	n.d.
365 DAT						
Lettuce (53 DAP)	n.d.	n.d.	n.d.	0.001 4.5	n.d.	n.d.
Radish top (77 DAP)	n.d.	n.d.	n.d.	0.009 21.6	n.d.	n.d.
Radish root (77 DAP)	n.d.	n.d.	n.d.	0.001 10.5	n.d.	n.d.
Wheat forage (61 DAP)	n.d.	n.d.	n.d.	0.001 6.2	n.d.	n.d.

DAP = Days after Planting
DAT = Days after Treatment
n.d. not detected
(1) Concentration including further hydroxylated derivatives detected in wheat straw

3. Proposed metabolic pathway

The proposed metabolic pathway of kresoxim-methyl in rotational crops is shown in Figure A 1. Kresoxim-methyl is extensively metabolized. In crops sown or planted 30 DAT, the main metabolic pathway is the hydroxylation of the methylphenyl moiety. The resulting alcohol 490M78 was detected as the main metabolite in lettuce and white radish samples and in spring wheat forage. In spring wheat straw (30 DAT), metabolites resulting from glycosylation of the hydroxygroup on the methylphenyl moiety (490M76 and 490M77) and from cleavage of the methylphenyl group (490M06) and oxidation of the emerging hydroxymethyl group (490M68 and 490M69) were identified. In crops sown or planted 365 DAT, the radioactive residues were mainly recovered as polar components and non-extractable residues that were solubilized with macerozyme / cellulase and amylase / amyloglucosidase. The solubilization and characterization of considerable parts of these bound residues by enzymatic cleavage of natural macromolecules indicate an incorporation of ^{14}C labeled C1 or C2 units into plant polysaccharides.

4. Storage stability

A comparison of the extractabilities and of the metabolite patterns obtained at the beginning and at the end of the investigation period from samples stored frozen and from stored extracts showed that there was no relevant change in the nature of the radioactive residues of kresoxim-methyl during storage of the plant samples and of the extracts over the period of investigation.

The storage stability of residues in the relevant matrices mature lettuce, white radish root, spring wheat straw and grain sown or planted after soil ageing of 30 DAT was demonstrated for a time interval of approximately three years in extracts and for five years in matrix.

Conclusions

A confined rotational crop study was conducted with ^{14}C BAS 490 F (kresoxim-methyl) at a nominal application rate of 1 x 1500 g a.s./ha (approximately 1.34 lb/A).

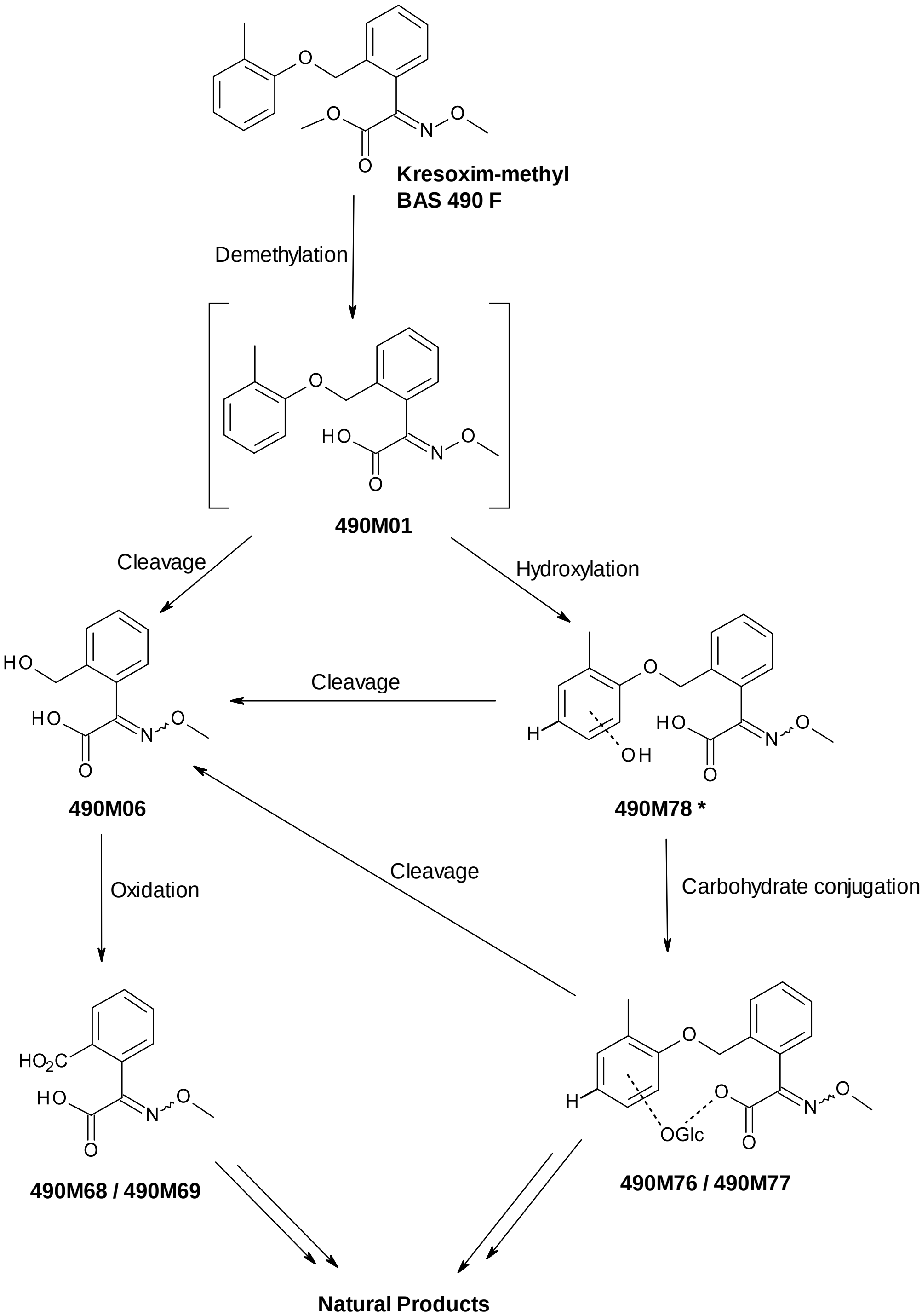
A fast translocation of radioactive residues from soil into the plants was observed. Relatively high total radioactive residues were thus determined in the samples from crops planted or sown 30 DAT. The highest residue levels were measured in spring wheat straw (1.629 mg/kg). In samples from crops planted or sown 365 DAT, the TRRs declined significantly and ranged between 0.012 (mature lettuce) and 0.163 mg/kg (spring wheat straw).

The residues in lettuce, white radish, spring wheat forage and straw grown after a plant back interval of 30 DAT were highly extractable (>70 % ERR). The predominant portions of residues were extracted with methanol and significantly smaller portions with water. The residues in the methanol extracts of all crop matrices planted or sown 30 DAT were predominantly water soluble upon partition between water, ethyl acetate and dichloromethane.

Kresoxim-methyl was readily metabolized and was detected only in very minor amounts in lettuce, white radish top and in spring wheat straw (30 DAT). After a plant back interval of 30 DAT, the main metabolite in lettuce, white radish as well as in spring wheat forage was the hydroxylated derivative 490M78 at concentrations of 0.006 mg/kg in lettuce and of 0.073 mg/kg in radish roots. Residues of parent BAS 490 F in edible portions were 0.003 mg/kg in lettuce, which is below the analytical LOQ of enforcement methods of 0.01 mg/kg. The hydroxylated derivatives 490M02 and 490M09 which are part of the residue definition for data generation and risk assessment were not detected. In spring wheat straw (30 DAT), glycoside conjugates and metabolites formed from cleavage at the benzyl position and further oxidation were identified. The solubilization and characterization of considerable parts of the non-extractable residues by enzymatic cleavage of natural macromolecules indicate an incorporation of ^{14}C labeled C1 or C2 units into plant polysaccharides. Moreover, the residues in the macerozyme solubilizate of the residues after solvent extraction of wheat grain (30 DAT) were identified as carbohydrates by fermentation with yeast. After a plant back interval of 365 DAT, kresoxim-methyl was evidently extensively degraded in soil and the radioactive residues in plants were mainly recovered as polar components and non-extractable residues.

Overall, it can be concluded that kresoxim-methyl was extensively metabolised, conjugated with carbohydrates or incorporated in natural macromolecules like e.g. polysaccharides.

Figure A 1: Metabolic pathway in rotational crops of ^{14}C-labelled kresoxim-methyl on the benzyl-ring



A 2.2.2.1.3 Nature of residues in processed commodities

No new data.

A 2.2.2.2 Nature of residues in livestock

No new data.

A 2.2.3 Magnitude of residues in plants

A 2.2.3.1 Cereals

Table A 15: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (kg a.s./ha)	Interval between application (days)	Growth stage at last application	PHI (days)
Barley					
cGAP N-EU/S-EU (Belgium, 2010a, EFSA, 2010)	2	0.125	21 days	BBCH 25-69	35
cGAP N-EU/S-EU (Art. 12, EFSA, 2014)	2	0.130	21 days	BBCH 69	35
Intended cGAP (10*)	2	0.150	14 (21 if first application after BBCH 49)	BBCH 69	35
Wheat, tritical, rye					
cGAP N-EU/S-EU (Belgium, 2010a, EFSA, 2010)	2	0.125	21 days	BBCH 25-69	35
cGAP N-EU/S-EU (Art. 12, EFSA, 2014)	2	0.130	21 days	BBCH 69	35
Intended cGAP (5, 9, 11, 12, 13, 17, 21*)	2	0.150	14 (21 if first application after BBCH 49)	BBCH 69	35

n.r. not reported
* 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 – BASF DocID 2020/2100869

Comments of zRMS:	The study is acceptable. During the growing season of 2019 8 field trials (4 NEU and 4 SEU where 4 of them were bridging trials, 2 per zone) in barley were conducted in order to determine the magnitude of the residues of BAS 750 F (Mefentrifluconazole) and its metabolites 1,2,4-Triazole (T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) as well as BAS 490 F (Kresoxim-methyl) and its metabolites BF 490-2 and BF 490-9 after treatment with either BAS 765 00 F (the evaluation subject), BAS 750 01 F (Mefentrifluconazole only, 100.0 g/L) or BAS 494 04 F (BAS 480 F – Epoxiconazole 125 g/L, BAS 490 F - Kresoxim-methyl 125 g/L). The applications took place at BBCH 49 and BBCH 69 according to the GAP consistent with the proposed GAP (max. 2 applications of 0.1 kg/ha BAS 750 F and 0,15 kg/ha of BAS 490 F up to BBCH 69 with PHI 35). In the study maximal total treatment was 0,3 kg/ha of BAS 750 F as well as of BAS 490 F. Samples of barley were collected at 0 DALA, (on plot 1 before the application, 0 DBLA), on 27-29 DALA, 35-36 DALA and 41- 43 DALA. The employed in the study methods were as follows: BASF Method **L0076/09** was adapted for Mefentrifluconazole using LC-MS/MS to achieve a limit of quantification (LOQ) of 0.010 mg/kg. BASF Method L0095/01 was adapted for Kresoxim-methyl (BAS 490 F, determined as its acid BF 490-1) and its metabolites (OH-metabolites BF 490-2 and BF 490-9, free and glycosylated forms) using LC-MS/MS to achieve an LOQ of 0.010 mg/kg per analyte except of BF 490-9 in straw where the limit of quantitation (LOQ) is 0.050 mg/kg. For 1,2,4-T, TA, TAA and TLA BASF Method L0170/02 was adapted using LC-DMS-MS/MS to achieve a limit of quantification (LOQ) of 0.010 mg/kg per analyte. 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 samples. 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 %. No residues of mefentrifluconazole, kresoxim-methyl, kresoxim-methyl metabolites were found in any of the control samples above the LOQ. No residues of 1,2,4-T above the LOQ were found in most of the control samples. Residues of TAA, TLA and TA above the LOQ were detected in most of the untreated samples suggesting the use of triazole pesticide actives and/or fertilizers in previous seasons. In barley grain Mefentrifluconazole residues were up to 0,32 mg/kg (BBCH 87-89; MRL 0.6 mg/kg). Kresoxim-methyl and its metabolites residues were up to 0.13 mg/kg (MRL 0.15 mg/kg).

Reference:	CA 6.3.1/1
Report	Residues of Mefentrifluconazole and Kresoxim-methyl in barley after treatment with either BAS 765 00 F, BAS 750 01 F or BAS 494 04 F under field conditions in Northern and Southern Europe, 2019, Meyer, M., 2020 report No 871102, IF19-04892284 BASF DocID 2020/2100869 Authority registration No
Guideline(s):	EEC 7525/VI/95 rev. 10.3, EC 7029/VI/95 Rev.5, OECD 509 (2009)

Deviations: No

GLP: yes

(certified by Hessisches Ministerium fuer Umwelt, Klimaschutz, Landwirtschaft und Verbraucherschutz, Wiesbaden)

Acceptability: Yes

Table A 16: Summary of recoveries of BAS 490 F (barley)

Matrix	Fortification Level [mg/kg]	BAS 490 F (determined as BF 490-1)				
		n	Mean [%]	Range [%]	SD [±]	RSD [%]
Barley (whole plant no roots)	0.010, 0.10 and 4.0	10	96.8	87.4 - 104	5.1	5.3
Barley (rest of plant without roots)	0.010, 0.10 and 4.0	13	91.1	75.8 - 109	9.0	9.9
Barley (ears)	0.010, 0.10 and 4.0	7	94.7	84.0 - 106	6.6	7.0
Barley (grain)	0.010, 0.10 and 4.0	16	95.8	81.6 - 109	8.0	8.4
Barley (straw)	0.010, 0.10, 2.0 and 4.0	19	89.6	72.9 - 108	12	13
Overall matrices		65	93.1	72.9 - 109	9.4	10

Table A 17: Summary of recoveries of BF 490-2 (barley)

Matrix	Fortification Level [mg/kg]	BF 490-2				
		n	Mean [%]	Range [%]	SD [±]	RSD [%]
Barley (whole plant no roots)	0.010, 0.10 and 4.0	10	89.3	78.8 – 98.0	6.2	6.9
Barley (rest of plant without roots)	0.010, 0.10 and 4.0	13	82.5	72.8 – 108	9.4	11
Barley (ears)	0.010, 0.10 and 4.0	7	78.8	71.6 – 85.6	4.1	5.2
Barley (grain)	0.010, 0.10 and 4.0	16	85.1	74.4 – 99.2	8.4	9.8
Barley (straw)	0.010, 0.10, 2.0 and 4.0	19	80.1	70.8 – 92.8	7.2	9.0
Overall matrices		65	83.1	70.8 - 108	8.2	9.8

Table A 18: Summary of recoveries of BF 490-9 (barley)

Matrix	Fortification Level [mg/kg]	BF 490-9				
		n	Mean [%]	Range [%]	SD [±]	RSD [%]
Barley (whole plant no roots)	0.010, 0.10 and 4.0	10	98.3	82.4 - 110	9.8	9.9
Barley (rest of plant without roots)	0.010, 0.10 and 4.0	13	91.1	75.6 - 107	11	12
Barley (ears)	0.010, 0.10 and 4.0	7	99.7	90.0 - 104	5.6	5.6
Barley (grain)	0.010, 0.10 and 4.0	16	101	76.2 - 109	9.4	9.3
Barley (straw)	0.050, 0.50, 10 and 20	19	84.6	71.8 – 98.4	8.4	9.9
Overall matrices		65	93.7	71.8 - 110	11	12

Table A 19: **Summary of residues of kresoxim-methyl on barley in Northern and Southern Europe 2019**

Study No./ 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)
			g a.s./ ha	Water (L/ha)	g a.s./hL				BAS 490 F	BF 490-2	BF 490-9 (f)	BAS 490 F total (g)		
2020/2100869 L190195 Germany 67294 Mauchenheim Northern Europe 2019	Barley/ GC 0640 Avalon	1. 23.02.2019 2. 04.06 - 13.06.2019 3. 24.07.2019	150 (plot 2)	200	75	2 13.06.2019	69	Whole plant[f] Grain Straw Grain Straw Grain Straw	2.5 0.037 1.7 0.022 2.3 0.013 1.8	0.054 0.011 0.13 0.010 0.14 <0.01 0.091	0.25 0.054 0.36 0.012 0.17 <0.01 0.085	2.8 0.10 2.2 0.044 2.6 0.033 1.9	0 27 27 35 35 42 42	Analytical method. BASF Method No. L0095/01 Validation: Mean recovery 70%-110%, RSD ≤ 20% LOQ = 0.01 mg/kg, except 0.05 mg/kg for BF 490-9 in straw LOD = 0.002, except 0.01 mg/kg for BF 490-9 in straw Plot 2: BAS 765 00 F (SC) Plot 4: BAS 494 04 F (SC) Treatment: Boom Sprayer Max. storage interval between sampling and extraction: 205 days
			125 (plot 4)	200	63		69	Whole plant[f] Grain Straw Grain Straw Grain Straw	2.6 0.066 1.6 0.019 2.4 0.017 2.2	0.035 <0.01 0.11 <0.01 0.075 <0.01 0.068	0.17 0.047 0.35 <0.01 0.085 <0.01 0.050	2.8 0.12 2.1 0.039 2.6 0.037 2.3	0 27 27 35 35 42 42	
2020/2100869 L190196 Poland 89-665 Ogorzeliny Northern Europe 2019	Barley/ GC 0640 Bla	1. 04.05.2019 2. 25.06. - 05.07.2019 3. 14.08.2019	150 (plot 2)	200	75	2 03.07.2019	69	Whole plant[f] Ears Rest of plant[f] Grain Straw Grain Straw	4.3 0.15 1.4 0.011 1.9 0.011 1.8	0.065 0.021 0.11 <0.01 0.14 <0.01 0.16	0.26 0.028 0.21 <0.01 0.19 <0.01 0.14	4.6 0.20 1.7 0.031 2.2 0.031 2.1	0 28 28 35 35 42 42	
			125 (plot 4)	200	63		69	Whole plant[f] Ears Rest of plant[f] Grain Straw Grain Straw	4.5 0.23 1.7 <0.01 0.72 <0.01 2.0	0.093 0.029 0.13 <0.01 0.057 <0.01 0.14	0.35 0.048 0.21 <0.01 0.055 <0.01 0.11	4.9 0.3 2.0 <0.03 0.84 <0.03 2.3	0 28 28 35 35 42 42	

Study No./ 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)
			g a.s./ ha	Water (L/ha)	g a.s./hL				BAS 490 F	BF 490-2	BF 490-9 (f)	BAS 490 F total (g)		
2020/2100869 L190197 Hungary 4440 Tiszavasvári Northern Europe 2019	Barley/ GC 0640 Scarlet	1. 01.03.2019 2. 10.06. - 16.06.2019 3. 24.07.2019	150 (plot 2)	200	75	2 13.06.2019	69	Whole plant[f] Grain Straw Grain Straw Grain Straw	2.1 <0.01 1.2 0.012 0.5 0.021 0.36	0.059 <0.01 0.11 <0.01 0.032 <0.01 0.024	0.30 0.013 0.13 0.010 <0.05 <0.01 <0.05	2.4 0.033 1.4 0.032 0.55 0.041 0.44	0 27 27 35 35 41 41	Analytical method. BASF Method No. L0095/01 Validation: Mean recovery 70%-110%, RSD ≤ 20% LOQ = 0.01 mg/kg, except 0.05 mg/kg for BF 490-9 in straw LOD = 0.002, except 0.01 mg/kg for BF 490-9 in straw Plot 2: BAS 765 00 F (SC) Plot 4: BAS 494 04 F (SC) Treatment: Boom Sprayer Max. storage interval between sampling and extraction: 205 days.
2020/2100869 L190198 Denmark 6200 Rollum Northern Europe 2019	Barley/ GC 0640 Fairway	1. 28.04.2019 2. 02.07. - 03.07.2019 3. 15.08.2019	150 (plot 2)	200	75	2 03.07.2019	69	Whole plant[f] Ears Rest of plant[f] Grain Straw Grain Straw	5.6 0.048 0.58 0.010 0.23 <0.01 0.13	0.042 0.016 0.049 <0.01 0.020 <0.01 0.012	0.13 <0.01 0.063 <0.01 <0.05 <0.01 <0.05	5.8 0.073 0.70 <0.03 0.30 <0.03 0.19	0 28 28 36 36 43 43	
2020/2100869 L190199 France 47700 Antagnac Southern Europe 2019	Barley/ GC 0640 Memento	1. 05.10.2018 2. 13.05. - 20.05.2019 3. 01.07. - 03.07.2019	150 (plot 2)	200	75	2 20.05.2019	69	Whole plant[f] Ears Rest of plant[f] Ears Rest of plant[f] Grain Straw	2.2 0.078 0.46 0.064 0.43 0.013 0.48	0.026 0.050 0.060 0.026 0.037 0.013 0.067	0.095 0.097 0.089 0.027 0.041 0.018 <0.05	2.3 0.22 0.61 0.12 0.51 0.044 0.59	0 28 28 35 35 42 42	
			125 (plot 4)	200	63		69	Whole plant[f] Ears Rest of plant[f] Ears Rest of plant[f] Grain Straw	2.3 0.036 0.58 0.052 0.79 <0.01 0.36	0.015 0.026 0.052 0.015 0.039 <0.01 0.049	0.063 0.058 0.089 0.018 0.028 <0.01 <0.05	2.4 0.12 0.72 0.085 0.86 <0.03 0.45	0 28 28 35 35 42 42	

Study No./ 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
			g a.s./ ha	Water (L/ha)	g a.s./hL				BAS 490 F	BF 490-2	BF 490-9	BAS 490 F total		
	(a)	(b)				(c)					(f)	(g)	(d)	(e)
2020/2100869 L190200 Italy 13040 Borgo D´ale Southern Europe 2019	Barley/ GC 0640 Idra	1. 02.12.2018 2. 20.05. - 28.05.2019 3. 09.07.2019	150 (plot 2)	200	75	2 27.05.2019	69	Whole plant[f]	2.7	0.071	0.23	3.0	0	Analytical method. BASF Method No. L0095/01 Validation: Mean recovery 70%-110%, RSD ≤ 20% LOQ = 0.01 mg/kg, except 0.05 mg/kg for BF 490-9 in straw LOD = 0.002, except 0.01 mg/kg for BF 490-9 in straw Plot 2: BAS 765 00 F (SC) Plot 4: BAS 494 04 F (SC) Treatment: Boom Sprayer Max. storage interval between sampling and extraction: 205 days.
								Grain	<0.01	<0.01	<0.01	<0.03	29	
								Straw	0.10	0.025	<0.05	0.18	29	
								Grain	<0.01	<0.01	<0.01	<0.03	36	
								Straw	0.088	0.023	<0.05	0.16	36	
								Grain	<0.01	<0.01	<0.01	<0.03	43	
								Straw	0.099	0.025	<0.05	0.17	43	
			125 (plot 4)	200	63		69	Whole plant[f]	2.0	0.067	0.22	2.3	0	
								Grain	<0.01	<0.01	0.012	0.032	29	
								Straw	0.47	0.042	<0.05	0.56	29	
								Grain	<0.01	<0.01	<0.01	<0.03	36	
								Straw	0.18	0.025	<0.05	0.25	36	
								Grain	<0.01	<0.01	<0.01	<0.03	43	
								Straw	0.24	0.031	<0.05	0.32	43	
2020/2100869 L190201 Greece 57006 Lakia Southern Europe 2019	Barley/ GC 0640 Thessaloniki	1. 14.12.2018 2. 25.04. - 05.05.2019 3. 12.06.2019	150 (plot 2)	200	75	2 03.05.2019	69	Whole plant[f]	5.2	0.056	0.15	5.4	0	
								Ears	0.30	0.025	0.11	0.44	28	
								Rest of plant[f]	4.7	0.12	0.33	5.2	28	
								Grain	0.036	0.010	0.025	0.097	35	
								Straw	1.8	0.086	0.18	2.1	35	
								Grain	0.016	<0.01	0.016	0.043	42	
								Straw	1.1	0.046	0.083	1.2	42	
2020/2100869 L190202 Spain 18128 Zafarraya Southern Europe 2019	Barley/ GC 0640 Yuriko	1. 07.01.2019 2. 02.05. - 08.05.2019 3. 19.06.2019	150 (plot 2)	200	75	2 08.05.2019	69	Whole plant[f]	3.0	0.020	0.060	3.03	0	
								Ears	0.28	0.018	0.088	0.39	28	
								Rest of plant[f]	1.1	0.078	0.31	1.5	28	
								Ears	0.31	0.016	0.096	0.42	35	
								Rest of plant[f]	1.3	0.085	0.30	1.7	35	
								Grain	0.093	<0.01	0.029	0.13	42	
								Straw	1.2	0.11	0.32	1.6	42	

(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
(f) BAS 490 F, detected as BF 490-1 (acid, conversion factor: 0.9550)
(g) For calculation of the sum of BAS 490 F, BF 490-2 (conversion factor: 1.0061) and BF 490-9 (conversion factor: 1.0061) residues of < 0.01 mg/kg were taken as 0.01 mg/kg (except for straw w here the LOQ for BF 490-9 is 0.05 mg/kg). For this calculation the values of BF 490-2 and BF 490-9 were taken into account as parent equivalents (conversion factor: 1.0061, each).
(h) without root

A 2.2.3.1.2 Study 2 – BASF DocID 2020/2093149

Comments of zRMS:	The study is acceptable. 8 residue field trials in wheat were conducted in EU (4 NEU, 4 SEU; four of them were bridging trials; 2 per zone). The objective of this study was to determine residues of Mefentrifluconazole (BAS 750 F), Kresoxim-methyl (BAS 490 F), and its metabolites (OH metabolites BF 490-2 and BF 490-9, free and glycosylated forms), 1,2,4-Triazole (1,2,4-T), Triazole alanine (TA), Triazole acetic acid (TAA) and Triazole lactic acid (TLA) in wheat from the trials after two applications of either BAS 765 00 F, BAS 750 01 F or BAS 494 04 F. The applications took place at BBCH 49 and BBCH 69 according to the GAP consistent with the proposed GAP (max. 2 applications of 0.1 kg/ha BAS 750 F and 0,15 kg/ha of BAS 490 F up to BBCH 69 with PHI 35). In the study maximal total treatment was 0,3 kg/ha of BAS 750 F as well as of BAS 490 F. Samples of barley were collected at 0 DALA, (on plot 1 before the application, 0 DBLA), on 34-36 DALA, 41-42 DALA and 47- 49 DALA. For the analysis of Mefentrifluconazole (BAS 750 F) BASF method no. L0076/09 was used. For the analysis of Kresoxim-methyl (BAS 490 F, determined as its acid BF 490-1) and its metabolites (OH-metabolites BF 490-2 and BF 490-9, free and glycosilated forms) BASF method no. L0095/01 was used. For the analysis of 1,2,4-T, TA, TAA TLA BASF method no. L0170/02 was used. All the methods were LC-MS/MS methods. Validation of the analytical methods was performed in separate studies. The methods LOQ was set at 0,01. 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 samples. 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 %. No residues of mefentrifluconazole, kresoxim-methyl, kresoxim-methyl metabolites were found in any of the control samples above the LOQ. No residues of 1,2,4-T above the LOQ were found in any of the control samples. Residues of TAA, TLA and TA above the LOQ were detected in most of the untreated samples suggesting the use of triazole pesticide actives and/or fertilizers in previous seasons. Residues of mefentrifluconazole found in wheat grain were up to 0.036 mg/kg (MRL 0,05). Residues of kresoxim-methyl in wheat grain (MRL 0,08) were always <0.010 mg/kg except of specimens sampled at DALA 41-42 where residues between < 0.010 and 0.012 mg/kg were found. Residues of kresoxim-methyl metabolites BF 490-2 and BF 490-9 in wheat grain were always <0.010 mg/kg.

Reference:	CA 6.3.2/1
Report	Residues of Mefentrifluconazole and Kresoxim-methyl in Wheat after Treatment with either BAS 765 00 F, BAS 750 01 F or BAS 494 04 F under Field Conditions in Northern and Southern Europe, 2019, Ziske, J., 2020 report No 871100, IF19-04889508 BASF DocID 2020/2093149 Authority registration No
Guideline(s):	7029/VI/95 rev. 5-22/07/97, EEC 7525/VI/95 rev. 10.3, OECD 509 (2009)

Deviations: No

GLP: yes

(certified by Hessisches Ministerium fuer Umwelt, Energie, Landwirtschaft und Verbraucherschutz, Wiesbaden)

Acceptability: Yes

Table A 20: Summary of procedural recoveries of BAS 490 F (wheat)

Matrix	Fortification Level [mg/kg]	BAS 490 F (determined as BF 490-1)				
		n	Mean [%]	Range [%]	SD [±]	RSD [%]
Wheat (whole plant no roots)	0.010, 0.10 and 4.0	9	99.7	94.8-108	5.3	5.3
Wheat (rest of plant without roots)	0.010, 0.10 and 4.0	12	93.2	77.2-105	8.5	9.1
Wheat (ears)	0.010, 0.10 and 4.0	11	83.7	72.8-96.6	8.2	9.7
Wheat (grain)	0.010, 0.10 and 4.0	11	100	88.0-110	7.2	7.2
Wheat (straw)	0.010, 0.10, 2.0 and 4.0	19	94.4	80.0-107	8.2	8.7
	Overall matrices	62	94.1	72.2-110	9.3	10

Table A 21: Summary of recoveries of BF 490-2 (wheat)

Matrix	Fortification Level [mg/kg]	BF 490-2				
		n	Mean [%]	Range [%]	SD [±]	RSD [%]
Wheat (whole plant no roots)	0.010, 0.10 and 4.0	9	92.0	84.8-103	5.6	6.0
Wheat (rest of plant without roots)	0.010, 0.10 and 4.0	12	85.1	70.8-102	9.4	11
Wheat (ears)	0.010, 0.10 and 4.0	11	83.4	74.0-97.0	7.3	8.8
Wheat (grain)	0.010, 0.10 and 4.0	11	81.0	74.6-90.5	4.9	6.1
Wheat (straw)	0.010, 0.10, 2.0 and 4.0	19	79.8	70.5-102	8.2	10
	Overall matrices	62	83.4	70.5-103	8.2	9.9

Table A 22: Summary of recoveries of BF 490-9 (wheat)

Matrix	Fortification Level [mg/kg]	BF 490-9				
		n	Mean [%]	Range [%]	SD [±]	RSD [%]
Wheat (whole plant no roots)	0.010, 0.10 and 4.0	9	99.1	92.8-108	5.1	5.2
Wheat (rest of plant without roots)	0.010, 0.10 and 4.0	12	92.3	76.4-106	9.5	10
Wheat (ears)	0.010, 0.10 and 4.0	11	89.9	80.4-100	6.4	7.1
Wheat (grain)	0.010, 0.10 and 4.0	11	96.4	71.4-110	14	15
Wheat (straw)	0.050, 0.50, 10 and 20	20	87.5	71.2-102	8.8	10
	Overall matrices	63	92.0	71.2-110	10	11

Table A 23: Summary of residues of kresoxim-methyl on wheat in Northern and Southern Europe 2019

Study No./ 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)
			g a.s./ ha	Water (L/ha)	g a.s./hL				BAS 490 F	BF 490-2	BF 490-9 (f)	BAS 490 F total (g)		
2020/2093149 L190187 Germany 74193 Stetten a. H. Northern Europe 2019	Wheat/ GC 0654 Ponticus	1. 10.11.2018 2. 03.06.-11.06.2019 3. 25.07.2019	150 (plot 2)	200	75	2 11.06.2019	69	Whole plant[h] Ears Rest of plant[h] Grain Straw Grain Straw	2.7 0.029 0.68 <0.010 0.5 <0.010 0.23	0.037 <0.010 0.080 <0.010 0.062 <0.010 0.057	0.19 <0.010 0.12 <0.010 <0.050 <0.010 <0.050	2.9 0.049 0.89 <0.030 0.62 <0.030 0.34	0 35 35 42 42 49 49	Analytical method. BASF Method No. L0095/01 Validation: Mean recovery 70%-110%, RSD ≤ 20% LOQ = 0.010 mg/kg, except 0.050 mg/kg for BF 490-9 in straw LOD = 0.002 mg/kg, except 0.01 mg/kg for BF 490-9 in straw Plot 2: BAS 765 00 F (SC) Plot 4: BAS 494 04 F (SC) Treatment: Boom Sprayer Max. storage interval between sampling and extraction: 221 days.
			125 (plot 4)	200	63		69	Whole plant[h] Ears Rest of plant[h] Grain Straw Grain Straw	1.7 0.028 0.68 <0.010 0.34 <0.010 0.33	0.025 <0.010 0.052 <0.010 0.049 <0.010 0.041	0.092 0.019 0.058 <0.010 <0.050 <0.010 <0.050	1.9 0.057 0.79 <0.030 0.44 <0.030 0.42	0 35 35 42 42 49 49	
2020/2093149 L190188 Hungary H-4461 Nyírtelek-Ferenctanya Northern Europe 2019	Wheat/ GC 0654 GK Szilárd	1. 17.10.2018 2. 25.05. - 05.06.2019 3. 17.07. - 18.07.2019	150 (plot 2)	200	75	2 30.05.2019	69	Whole plant[h] Grain Straw Grain Straw Grain Straw	2.0 <0.010 0.071 <0.010 0.12 <0.010 0.043	0.023 <0.010 0.027 <0.010 0.036 <0.010 0.028	0.10 <0.010 <0.050 <0.010 <0.050 <0.010 <0.050	2.1 <0.030 0.15 <0.030 0.18 <0.030 0.121	0 36 36 42 42 48 48	
			125 (plot 4)	200	63		69	Whole plant[h] Grain Straw Grain Straw Grain Straw	1.8 <0.010 0.13 <0.010 0.14 <0.010 0.14	0.024 <0.010 0.056 <0.010 0.064 <0.010 0.044	0.14 <0.010 <0.050 <0.010 <0.050 <0.010 <0.050	2.0 <0.030 0.24 <0.030 0.26 <0.030 0.24	0 36 36 42 42 48 48	

Study No./ Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment g a.s./ ha	 Water (L/ha)	 g a.s./hL	Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg) BAS 490 F	 BF 490-2	 BF 490-9 (f)	 BAS 490 F total (g)	PHI (days) (d)	Details on trial (e)
2020/2093149 L190189 Denmark 6200 Varnæs Northern Europe 2019	Wheat/ GC 0654 Julius	1. 18.09.2018 2. 11.06. - 13.06.2019 3. 30.07.2019	150 (plot 2)	200	75	2 13.06.2019	69	Whole plant(h) Ears Rest of plant(h) Ears Rest of plant(h) Grain Straw	2.2 0.086 1.1 0.13 1.2 <0.010 0.89	0.041 0.012 0.064 0.014 0.049 <0.010 0.052	0.16 0.039 0.040 <0.010 0.017 <0.010 <0.050	2.4 0.14 1.2 0.15 1.2 <0.030 0.99	0 34 34 41 41 47 47	Analytical method. BASF Method No. L0095/01 Validation: Mean recovery 70%-110%, RSD ≤ 20% LOQ = 0.010 mg/kg, except 0.050 mg/kg for BF 490-9 in straw LOD = 0.002 mg/kg, except 0.01 mg/kg for BF 490-9 in straw Plot 2: BAS 765 00 F (SC) Plot 4: BAS 494 04 F (SC) Treatment: Boom Sprayer Max. storage interval between sampling and extraction: 221 days.
2020/2093149 L190190 Belgium 6211 Mellet Northern Europe 2019	Wheat/ GC 0654 KWS Mistral	1. 21.03.2019 2. 15.06. - 22.06.2019 3. 05.08. – 12.08.2019	150 (plot 2)	200	75	2 21.06.2019	69	Whole plant(h) Ears Rest of plant(h) Grain Straw Grain Straw	4.3 0.073 1.1 <0.010 1.2 <0.010 0.52	0.036 0.012 0.11 <0.010 0.10 <0.010 0.071	0.57 <0.010 0.18 <0.010 <0.050 <0.010 <0.050	4.9 0.095 1.4 <0.030 1.3 <0.030 0.64	0 34 34 42 42 48 48	
2020/2093149 L190191 France 47200 Meilhan sur Garonne Southern Europe 2019	Wheat/ GC 0654 Oregrain	1. 22.11.2018 2. 20.05. - 25.05.2019 3. 15.07. - 20.07.2019	150 (plot 2)	200	75	2 31.05.2019	69	Whole plant(h) Ears Rest of plant(h) Ears Rest of plant(h) Grain Straw	2.9 0.055 0.42 0.031 0.41 <0.010 <0.010	0.029 0.014 0.074 0.011 0.070 <0.010 0.070	0.10 0.019 0.028 0.015 0.045 <0.010 <0.050	3.1 0.088 0.52 0.057 0.53 <0.030 0.12	0 35 35 42 42 47 47	
			125 (plot 4)	200	63		69	Whole plant(h) Ears Rest of plant(h) Ears Rest of plant(h) Grain Straw	1.9 0.034 0.48 0.034 0.56 <0.010 0.30	0.017 <0.010 0.051 <0.010 0.034 <0.010 0.047	0.063 0.016 0.020 0.010 0.031 <0.010 <0.050	2.0 0.059 0.550 0.055 0.63 <0.030 0.40	0 35 35 42 42 47 47	

Study No./ Trial No./ Location/ EU zone/ Year	Commodity/ Variety (a)	Date of 1.Sowing or planting 2.Flowering 3. Harvest (b)	Application rate per treatment g a.s./ ha	Water (L/ha)	g a.s./hL	Dates of treatment or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analyzed	Residues (mg/kg) BAS 490 F	BF 490-2	BF 490-9 (f)	BAS 490 F total (g)	PHI (days) (d)	Details on trial (e)
2020/2093149 L190192 Spain 18128 Zafarraya, Granada Southern Europe 2019	Wheat/ GC 0654 Marius	1. 02.01.2019 2. 14.05. - 21.05.2019 3. 09.07.2019	150 (plot 2)	200	75	2 21.05.2019	69	Whole plant(h)	3.6	0.042	0.18	3.8	0	Analytical method. BASF Method No. L0095/01 Validation: Mean recovery 70%-110%, RSD ≤ 20% LOQ = 0.010 mg/kg, except 0.050 mg/kg for BF 490-9 in straw LOD = 0.002 mg/kg, except 0.01 mg/kg for BF 490-9 in straw Plot 2: BAS 765 00 F (SC) Plot 4: BAS 494 04 F (SC) Treatment: Boom Sprayer Max. storage interval between sampling and extraction: 221 days.
								Ears	0.094	0.013	<0.010	0.11	34	
								Rest of plant(h)	1.4	0.11	0.28	1.8	34	
								Ears	0.060	<0.01	0.028	0.098	41	
								Rest of plant(h)	1.4	0.13	0.33	1.8	41	
								Grain	<0.010	<0.010	<0.010	<0.03	49	
								Straw	0.98	0.091	0.27	1.3	49	
			125 (plot 4)	200	63		69	Whole plant(h)	1.8	0.022	0.095	1.9	0	
								Ears	0.091	0.010	0.012	0.11	34	
								Rest of plant(h)	1.2	0.089	0.33	1.6	34	
								Ears	0.051	0.005	0.019	0.079	41	
								Rest of plant(h)	0.93	0.093	0.25	1.3	41	
								Grain	<0.010	<0.010	<0.010	<0.030	49	
								Straw	0.84	0.066	0.21	1.1	49	
2020/2093149 L190193 Italy 20090 Caleppio di Settala Southern Europe 2019	Wheat/ GC 0654 Arabia	1. 20.11.2018 2. 14.05. - 29.05.2019 3. 08.07.2019	150 (plot 2)	200	75	2 21.05.2019	69	Whole plant(h)	2.9	0.046	0.13	3.0	0	
								Grain	0.010	<0.010	<0.010	<0.030	36	
								Straw	0.96	0.14	0.13	1.2	36	
								Grain	0.012	<0.010	<0.010	0.032	41	
								Straw	1.2	0.15	0.11	1.5	41	
								Grain	<0.010	<0.010	<0.010	<0.030	48	
								Straw	1.0	0.13	0.13	1.3	48	
2020/2093149 L190194 Greece 57006 Lakia Southern Europe 2019	Wheat/ GC 0654 Yecora	1. 14.12.2018 2. 25.04. - 05.05.2019 3. 18.06.2019	150 (plot 2)	200	75	2 03.05.2019	69	Whole plant(h)	4.0	0.041	0.16	4.2	0	
								Grain	<0.010	<0.010	<0.010	<0.030	35	
								Straw	1.8	0.054	0.12	2.0	35	
								Grain	<0.010	<0.010	<0.010	<0.030	42	
								Straw	1.6	0.035	0.072	1.8	42	
								Grain	<0.010	<0.010	<0.010	<0.030	48	
								Straw	1.3	0.026	0.057	1.4	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
(f) BAS 490 F, detected as BF 490-1 (acid, conversion factor: 0.9550).
(g) BF 490-2 conversion factor: 1.0061, BF 490-9 conversion factor: 1.0061. For sum residue of <0.010 mg/kg and <0.050 mg/kg w ere taken as 0.010 mg/kg and 0.050 mg/kg, if the residues are below LOQ for all

analytes the sum is reported as <sum of LOQs.

(h) without root

A 2.2.4 Magnitude of residues in livestock

A 2.2.4.1 Livestock feeding studies

No new data.

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 data.

A 2.2.5.2 Processing studies on a core set of representative processes

No new data.

A 2.2.6 Magnitude of residues in representative succeeding crops

No new data.

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

No new data.

Appendix 3 Pesticide Residue Intake Model (PRIMo)

Mefentrifluconazole

A 3.1 Mefentrifluconazole TMDI calculations

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	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)
32%	NL toddler	11.04	12%	Apples	5%	Milk: Cattle	5%	Pears	1.0%	6%
26%	DE child	9.01	14%	Apples	4%	Table grapes	2%	Cherries (sweet)	0.6%	2%
17%	NL child	6.00	7%	Apples	3%	Table grapes	2%	Milk: Cattle	0.5%	3%
11%	PT general	3.77	6%	Wine grapes	1%	Apples	0.7%	Table grapes	0.3%	0.6%
11%	RO general	3.68	4%	Wine grapes	2%	Apples	1.0%	Milk: Cattle	0.4%	2%
10%	DE women 14-50 yr	3.66	3%	Apples	2%	Wine grapes	1%	Milk: Cattle	0.3%	2%
10%	DE general	3.65	3%	Apples	2%	Wine grapes	1%	Milk: Cattle	0.3%	2%
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%	3%
10%	GEMS/Food G08	3.47	3%	Wine grapes	2%	Barley	1%	Apples	0.6%	3%
10%	GEMS/Food G11	3.38	3%	Wine grapes	2%	Apples	1%	Barley	0.6%	3%
9%	FR child 3 15 yr	3.25	2%	Milk: Cattle	2%	Apples	0.9%	Wine grapes	0.5%	3%
9%	FR adult	3.20	6%	Wine grapes	0.9%	Apples	0.4%	Milk: Cattle	0.2%	0.7%
9%	FR toddler 2 3 yr	3.18	4%	Apples	3%	Milk: Cattle	0.6%	Wine grapes	0.4%	3%
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%	4%
7%	NL general	2.50	2%	Apples	2%	Wine grapes	0.7%	Milk: Cattle	0.3%	2%
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%	2%
6%	ES child	1.98	1%	Apples	1%	Milk: Cattle	0.6%	Wheat	0.4%	2%
6%	DK adult	1.97	2%	Wine grapes	1%	Apples	0.5%	Milk: Cattle	0.2%	0.6%
6%	ES adult	1.94	1%	Wine grapes	0.9%	Apples	0.8%	Barley	0.2%	2%
5%	SE general	1.76	1%	Apples	1%	Milk: Cattle	0.9%	Bovine: Muscle/meat	0.4%	2%
5%	UK adult	1.62	3%	Wine grapes	0.5%	Apples	0.3%	Milk: Cattle	0.1%	0.5%
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%	2%
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%	0.6%
4%	FI 3 yr	1.42	1%	Apples	1.0%	Oat	0.6%	Table grapes	0.4%	0.3%
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%	0.2%
3%	FI adult	0.88	0.8%	Wine grapes	0.7%	Apples	0.2%	Oat	0.3%	0.1%
1%	IE child	0.43	0.4%	Apples	0.3%	Milk: Cattle	0.2%	Wheat	0.1%	0.5%

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 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	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)
7%	NL toddler	2.60	2%	Apples	2%	Milk: Cattle	1.0%	Pears		0.2%
6%	DE child	2.01	3%	Apples	0.7%	Table grapes	0.6%	Milk: Cattle		0.1%
4%	NL child	1.45	1%	Apples	0.7%	Milk: Cattle	0.5%	Table grapes		0.1%
3%	RO general	0.91	0.9%	Wine grapes	0.3%	Milk: Cattle	0.3%	Apples		0.1%
2%	FR child 3 15 yr	0.87	0.7%	Milk: Cattle	0.4%	Apples	0.2%	Sugar beet roots		0.1%
2%	DE women 14-50 yr	0.86	0.6%	Apples	0.4%	Wine grapes	0.4%	Milk: Cattle		0.1%
2%	DE general	0.86	0.6%	Apples	0.4%	Wine grapes	0.4%	Milk: Cattle		0.2%
2%	GEMS/Food G07	0.85	0.8%	Wine grapes	0.2%	Apples	0.2%	Poultry: Muscle/meat		0.3%
2%	UK infant	0.85	1%	Milk: Cattle	0.4%	Apples	0.2%	Eggs: Chicken		0.1%
2%	FR toddler 2 3 yr	0.84	0.8%	Milk: Cattle	0.7%	Apples	0.2%	Sugar beet roots		0.1%
2%	GEMS/Food G15	0.82	0.5%	Wine grapes	0.3%	Barley	0.3%	Apples		0.4%
2%	GEMS/Food G08	0.80	0.5%	Wine grapes	0.3%	Barley	0.3%	Apples		0.4%
2%	PT general	0.80	1%	Wine grapes	0.2%	Apples	0.2%	Peaches		0.1%
2%	GEMS/Food G11	0.77	0.5%	Wine grapes	0.4%	Apples	0.3%	Barley		0.4%
2%	DK child	0.72	0.5%	Apples	0.4%	Milk: Cattle	0.2%	Rye		0.3%
2%	FR adult	0.71	1%	Wine grapes	0.2%	Apples	0.1%	Milk: Cattle		0.1%
2%	IE adult	0.67	0.6%	Wine grapes	0.2%	Apples	0.1%	Peaches		0.1%
2%	UK toddler	0.67	0.6%	Milk: Cattle	0.4%	Apples	0.2%	Sugar beet roots		0.1%
2%	GEMS/Food G06	0.63	0.5%	Table grapes	0.2%	Apples	0.2%	Wheat		0.2%
2%	GEMS/Food G10	0.61	0.3%	Poultry: Muscle/meat	0.2%	Wine grapes	0.2%	Barley		0.3%
2%	NL general	0.61	0.3%	Apples	0.3%	Wine grapes	0.2%	Milk: Cattle		0.2%
2%	ES child	0.57	0.4%	Milk: Cattle	0.3%	Apples	0.2%	Poultry: Muscle/meat		0.1%
1%	ES adult	0.47	0.2%	Wine grapes	0.2%	Apples	0.2%	Barley		0.2%
1%	DK adult	0.46	0.5%	Wine grapes	0.2%	Apples	0.2%	Milk: Cattle		0.0%
1%	SE general	0.44	0.4%	Milk: Cattle	0.2%	Apples	0.1%	Eggs: Chicken		0.1%
1%	FR infant	0.42	0.5%	Milk: Cattle	0.4%	Apples	0.1%	Sugar beet roots		0.0%
1%	UK adult	0.38	0.6%	Wine grapes	0.1%	Apples	0.1%	Milk: Cattle		0.1%
1.0%	PL general	0.35	0.5%	Apples	0.2%	Table grapes	0.1%	Cherries (sweet)		
1.0%	LT adult	0.34	0.4%	Apples	0.1%	Milk: Cattle	0.1%	Potatoes		0.1%
1.0%	UK vegetarian	0.34	0.4%	Wine grapes	0.1%	Apples	0.1%	Milk: Cattle		0.1%
0.9%	IT toddler	0.31	0.2%	Apples	0.2%	Wheat	0.1%	Peaches		0.2%
0.9%	FI 3 yr	0.31	0.2%	Apples	0.2%	Oat	0.1%	Potatoes		0.1%
0.8%	IT adult	0.27	0.2%	Apples	0.2%	Peaches	0.1%	Wheat		0.1%
0.6%	FI 6 yr	0.22	0.1%	Apples	0.1%	Potatoes	0.1%	Oat		0.1%
0.5%	FI adult	0.17	0.2%	Wine grapes	0.1%	Apples	0.0%	Oat		0.0%
0.4%	IE child	0.13	0.1%	Milk: Cattle	0.1%	Apples	0.0%	Wheat		0.0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Mefentrifluconazole BAS 750 F (F) is unlikely to present a public health concern.

A 3.3 IESTI calculations - Raw commodities

Acute risk assessment /children	Acute risk assessment / adults / general population	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)
0.4%	Barley	0.6 / 0.12	0.67
0.10%	Wheat	0.05 / 0.01	0.14
0.04%	Rye	0.05 / 0.01	0.06

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%	Barley	0.6 / 0.12	0.58
0.06%	Wheat	0.05 / 0.01	0.08
0.03%	Rye	0.05 / 0.01	0.05

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)
2%	Barley	0.6 / 0.6	3.4
0.5%	Wheat	0.05 / 0.05	0.72
0.2%	Rye	0.05 / 0.05	0.32

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)
2%	Barley	0.6 / 0.6	2.9
0.3%	Wheat	0.05 / 0.05	0.42
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 IESTI calculations - Processed commodities

Processed commodities

Results for children				Results for adults			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Barley / milling (flour)	0.6 / 1.47	2.7	0.4%	Barley / beer	0.6 / 0.02	0.58
1.0%	Barley / cooked	0.6 / 0.4	1.5	0.1%	Wheat / bread/pizza	0.05 / 0.04	0.16
0.1%	Rye / boiled	0.05 / 0.04	0.13	0.09%	Wheat / pasta	0.05 / 0.04	0.14
0.1%	Wheat / milling (flour)	0.05 / 0.01	0.13	0.05%	Wheat / bread	0.05 / 0.02	0.07
0.1%	Wheat / milling (wholeme:	0.05 / 0.02	0.11	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0.1%	Rye / milling (wholemeal)-	0.05 / 0.03	0.10	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
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Expand/collapse list							

Results for children				Results for adults			
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 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%	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
0.1%	Rye / boiled	0.05 / 0.05	0.18	0.1%	Wheat / pasta	0.05 / 0.05	0.19
0.1%	Wheat / milling (flour)	0.05 / 0.01	0.18	0.07%	Wheat / bread (wholemeal)	0.05 / 0.03	0.10
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!
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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 Mefentrifluconazole BAS 750 F (F) is unlikely to present a public health risk.

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

1, 2, 4, Triazole

A 3.5 1, 2, 4, Triazole TMDI calculations

not applicable

A 3.6 IEDI calculations

European Food Safety Authority

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	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
48%	NL toddler	11,05	42%	Milk: Cattle	2%	Maize/corn	1%	Sugar beet roots		1,0%
30%	UK infant	6,80	27%	Milk: Cattle	0,9%	Bovine: Muscle/meat	0,6%	Wheat		0,6%
24%	FR toddler 2 3 yr	5,52	20%	Milk: Cattle	0,8%	Bovine: Muscle/meat	0,7%	Wheat		0,7%
22%	NL child	5,10	17%	Milk: Cattle	2%	Sugar beet roots	0,9%	Wheat		0,9%
20%	FR child 3 15 yr	4,71	16%	Milk: Cattle	1%	Bovine: Muscle/meat	1,0%	Wheat		1%
17%	UK toddler	4,00	14%	Milk: Cattle	0,9%	Bovine: Muscle/meat	0,9%	Wheat		0,9%
17%	DE child	3,82	14%	Milk: Cattle	0,9%	Wheat	0,5%	Apples		1%
14%	DK child	3,16	9%	Milk: Cattle	1%	Rye	1%	Swine: Muscle/meat		2%
13%	FR infant	2,96	12%	Milk: Cattle	0,3%	Sugar beet roots	0,2%	Bovine: Muscle/meat		0,2%
13%	SE general	2,95	9%	Milk: Cattle	3%	Bovine: Muscle/meat	0,7%	Wheat		0,8%
12%	ES child	2,80	9%	Milk: Cattle	1,0%	Bovine: Muscle/meat	1,0%	Wheat		1,0%
12%	DE general	2,66	9%	Milk: Cattle	0,9%	Sugar beet roots	0,6%	Swine: Muscle/meat		0,6%
12%	DE women 14-50 yr	2,65	9%	Milk: Cattle	1,0%	Sugar beet roots	0,5%	Wheat		0,6%
11%	RO general	2,59	8%	Milk: Cattle	1%	Wheat	0,6%	Swine: Muscle/meat		1%
9%	NL general	1,97	6%	Milk: Cattle	0,6%	Sugar beet roots	0,5%	Bovine: Muscle/meat		0,5%
8%	GEMS/Food G15	1,94	5%	Milk: Cattle	1,0%	Wheat	0,7%	Swine: Muscle/meat		1%
8%	GEMS/Food G11	1,91	5%	Milk: Cattle	0,8%	Wheat	0,6%	Swine: Muscle/meat		1,0%
8%	GEMS/Food G07	1,85	4%	Milk: Cattle	0,9%	Wheat	0,6%	Bovine: Muscle/meat		1%
7%	GEMS/Food G08	1,70	4%	Milk: Cattle	1%	Swine: Muscle/meat	0,9%	Wheat		1%
7%	GEMS/Food G10	1,58	4%	Milk: Cattle	0,9%	Wheat	0,6%	Bovine: Muscle/meat		1%
6%	ES adult	1,27	3%	Milk: Cattle	0,5%	Bovine: Muscle/meat	0,5%	Wheat		0,6%
5%	DK adult	1,23	4%	Milk: Cattle	0,5%	Swine: Muscle/meat	0,4%	Bovine: Muscle/meat		0,4%
5%	FR adult	1,17	3%	Milk: Cattle	0,5%	Wheat	0,4%	Bovine: Muscle/meat		0,5%
5%	IE adult	1,15	3%	Milk: Cattle	0,5%	Wheat	0,3%	Bovine: Muscle/meat		0,5%
5%	GEMS/Food G06	1,14	2%	Milk: Cattle	2%	Wheat	0,3%	Sugar beet roots		2%
4%	LT adult	1,00	3%	Milk: Cattle	0,5%	Swine: Muscle/meat	0,2%	Rye		0,5%
3%	UK adult	0,77	2%	Milk: Cattle	0,5%	Bovine: Muscle/meat	0,4%	Wheat		0,4%
3%	UK vegetarian	0,70	2%	Milk: Cattle	0,4%	Wheat	0,1%	Sugar beet roots		0,5%
3%	IE child	0,70	2%	Milk: Cattle	0,3%	Wheat	0,1%	Swine: Muscle/meat		0,3%
2%	IT toddler	0,36	1%	Wheat	0,0%	Potatoes	0,0%	Apples		1%
1%	PT general	0,34	0,9%	Wheat	0,2%	Potatoes	0,1%	Wine grapes		0,9%
1%	IT adult	0,23	0,9%	Wheat	0,0%	Apples	0,0%	Potatoes		0,9%
0,8%	FI 3 yr	0,19	0,3%	Wheat	0,2%	Potatoes	0,1%	Rye		0,4%
0,7%	FI 6 yr	0,15	0,2%	Wheat	0,2%	Potatoes	0,1%	Rye		0,4%
0,4%	FI adult	0,08	0,2%	Rye	0,1%	Wheat	0,1%	Potatoes		0,2%
0,3%	PL general	0,06	0,1%	Potatoes	0,1%	Apples	0,0%	Table grapes		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of 1,2,4-T is unlikely to present a public health concern.

A 3.7 IESTI calculations - Raw commodities

Show results for all crops

Unprocessed commodities

Results for children				Results for adults			
No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,7%	Wheat	0 / 0,05	0,72	0,4%	Wheat	0 / 0,05	0,42
0,3%	Rye	0 / 0,05	0,32	0,2%	Rye	0 / 0,05	0,24
0,3%	Barley	0 / 0,05	0,28	0,2%	Barley	0 / 0,05	0,24
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

A 3.8 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)
0,6%	Wheat / milling (flour)	0 / 0,05	0,60	0,4%	Barley / beer	0 / 0,01	0,36
0,3%	Wheat / milling (wholemea	0 / 0,05	0,28	0,2%	Wheat / bread/pizza	0 / 0,05	0,22
0,2%	Rye / boiled	0 / 0,05	0,18	0,2%	Wheat / pasta	0 / 0,05	0,19
0,2%	Barley / cooked	0 / 0,05	0,18	0,2%	Wheat / bread	0 / 0,05	0,17
0,2%	Rye / milling (wholemeal)-l	0 / 0,05	0,18	#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!
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Expand/collapse list							

Triazole alanine

A 3.9 Triazole alanine TMDI calculations

not applicable

A 3.10 IEDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

TA

LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	0,3	ARfD (mg/kg bw):	0,3
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
4%	NL toddler	12,40	1%	Maize/corn	0,8%	Wheat	0,4%	Milk: Cattle		0,9%
3%	DK child	7,67	1%	Rye	0,9%	Wheat	0,1%	Potatoes		2%
2%	GEMS/Food G06	6,50	1%	Wheat	0,3%	Maize/corn	0,1%	Potatoes		2%
2%	NL child	6,17	0,9%	Wheat	0,2%	Potatoes	0,2%	Milk: Cattle		0,9%
2%	GEMS/Food G15	6,01	0,9%	Wheat	0,2%	Potatoes	0,2%	Sunflower seeds		1%
2%	GEMS/Food G08	6,00	0,8%	Wheat	0,2%	Potatoes	0,2%	Barley		1%
2%	RO general	5,94	1%	Wheat	0,2%	Sunflower seeds	0,2%	Potatoes		1%
2%	DE child	5,80	0,9%	Wheat	0,3%	Apples	0,2%	Rye		1%
2%	GEMS/Food G07	5,65	0,9%	Wheat	0,2%	Potatoes	0,2%	Rapeseeds/canola seeds		1%
2%	GEMS/Food G10	4,95	0,8%	Wheat	0,2%	Potatoes	0,1%	Maize/corn		1,0%
2%	FR child 3 15 yr	4,90	1,0%	Wheat	0,2%	Milk: Cattle	0,1%	Potatoes		1,0%
2%	IT toddler	4,62	1%	Wheat	0,1%	Potatoes	0,0%	Peaches		1%
2%	PT general	4,53	0,8%	Wheat	0,3%	Potatoes	0,1%	Sunflower seeds		0,8%
1%	GEMS/Food G11	4,28	0,7%	Wheat	0,2%	Potatoes	0,2%	Barley		0,9%
1%	UK infant	4,21	0,5%	Wheat	0,3%	Milk: Cattle	0,2%	Maize/corn		0,5%
1%	ES child	4,13	0,9%	Wheat	0,1%	Potatoes	0,1%	Milk: Cattle		0,9%
1%	UK toddler	4,02	0,8%	Wheat	0,2%	Potatoes	0,1%	Milk: Cattle		0,8%
1%	FR toddler 2 3 yr	3,71	0,6%	Wheat	0,2%	Milk: Cattle	0,1%	Potatoes		0,6%
1%	SE general	3,66	0,7%	Wheat	0,3%	Potatoes	0,1%	Bovine: Muscle/meat		0,7%
1%	DE general	3,19	0,4%	Wheat	0,1%	Rye	0,1%	Barley		0,6%
1%	NL general	3,11	0,4%	Wheat	0,1%	Potatoes	0,1%	Rapeseeds/canola seeds		0,5%
1%	DE women 14-50 yr	3,11	0,4%	Wheat	0,1%	Rye	0,1%	Milk: Cattle		0,6%
1%	IE adult	3,03	0,5%	Wheat	0,1%	Potatoes	0,1%	Sunflower seeds		0,5%
1,0%	IT adult	2,99	0,9%	Wheat	0,0%	Peaches	0,0%	Potatoes		0,9%
0,9%	FI 3 yr	2,69	0,3%	Potatoes	0,2%	Wheat	0,1%	Rye		0,4%
0,8%	ES adult	2,55	0,5%	Wheat	0,1%	Barley	0,1%	Potatoes		0,6%
0,8%	LT adult	2,39	0,2%	Rye	0,2%	Wheat	0,2%	Potatoes		0,5%
0,7%	FR adult	2,21	0,5%	Wheat	0,0%	Wine grapes	0,0%	Potatoes		0,5%
0,7%	FI 6 yr	2,13	0,2%	Potatoes	0,2%	Wheat	0,1%	Rye		0,3%
0,6%	UK vegetarian	1,83	0,4%	Wheat	0,1%	Potatoes	0,0%	Milk: Cattle		0,4%
0,6%	DK adult	1,68	0,2%	Wheat	0,1%	Rye	0,1%	Potatoes		0,3%
0,5%	UK adult	1,62	0,3%	Wheat	0,1%	Potatoes	0,0%	Wine grapes		0,4%
0,5%	FR infant	1,49	0,2%	Wheat	0,1%	Potatoes	0,1%	Milk: Cattle		0,2%
0,4%	FI adult	1,05	0,1%	Rye	0,1%	Potatoes	0,1%	Wheat		0,2%
0,3%	IE child	0,99	0,2%	Wheat	0,0%	Potatoes	0,0%	Milk: Cattle		0,2%
0,3%	PL general	0,93	0,2%	Potatoes	0,0%	Apples	0,0%	Plums		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of TA is unlikely to present a public health concern.

A 3.11 IESTI calculations - Raw commodities

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
3%	Wheat	0 / 0,62	9,0
1%	Rye	0 / 0,62	3,9
1%	Barley	0 / 0,62	3,5

Expand/collapse list

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Wheat	0 / 0,62	5,2
1%	Rye	0 / 0,62	3,0
1%	Barley	0 / 0,62	3,0

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

A 3.12 IESTI calculations - Processed commodities

Processed commodities

Results for children				**Results for adults**			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Wheat / milling (flour)	0 / 0,32	3,8	0,9%	Wheat / bread/pizza	0 / 0,62	2,7
1,0%	Wheat / milling (wholemea	0 / 0,53	3,0	0,8%	Wheat / pasta	0 / 0,62	2,4
0,8%	Rye / boiled	0 / 0,62	2,3	0,6%	Wheat / bread	0 / 0,53	1,9
0,8%	Barley / cooked	0 / 0,62	2,3	0,3%	Barley / beer	0 / 0,02	0,89
0,7%	Rye / milling (wholemeal)-l	0 / 0,62	2,2	#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!
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Expand/collapse list							

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of TA is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

Triazole acetic acid

A 3.13 Triazole acetic acid TMDI calculations

not applicable

A 3.14 IEDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

TAA			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	1	ARfD (mg/kg bw):	1
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	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		0,3%
0,4%	UK toddler	4,13	0,3%	Wheat	0,1%	Milk: Cattle	0,0%	Sugar beet roots		0,3%
0,4%	PT general	3,90	0,3%	Wheat	0,0%	Maize/corn	0,0%	Wine grapes		0,3%
0,4%	FR toddler 2 3 yr	3,85	0,2%	Wheat	0,1%	Milk: Cattle	0,0%	Sugar beet roots		0,2%
0,3%	SE general	3,38	0,3%	Wheat	0,0%	Milk: Cattle	0,0%	Rye		0,3%
0,3%	IT adult	3,35	0,3%	Wheat	0,0%	Apples	0,0%	Maize/corn		0,3%
0,3%	DE general	3,29	0,1%	Wheat	0,0%	Rye	0,0%	Barley		0,2%
0,3%	DE women 14-50 yr	3,19	0,2%	Wheat	0,0%	Rye	0,0%	Milk: Cattle		0,2%
0,3%	ES adult	2,63	0,2%	Wheat	0,0%	Barley	0,0%	Milk: Cattle		0,2%
0,3%	IE adult	2,62	0,2%	Wheat	0,0%	Maize/corn	0,0%	Oat		0,2%
0,3%	NL general	2,57	0,2%	Wheat	0,0%	Milk: Cattle	0,0%	Barley		0,2%
0,2%	FR adult	2,24	0,2%	Wheat	0,0%	Milk: Cattle	0,0%	Wine grapes		0,2%
0,2%	LT adult	2,09	0,1%	Rye	0,1%	Wheat	0,0%	Milk: Cattle		0,2%
0,2%	FI 3 yr	2,08	0,1%	Wheat	0,1%	Rye	0,0%	Oat		0,2%
0,2%	UK vegetarian	1,91	0,2%	Wheat	0,0%	Milk: Cattle	0,0%	Wine grapes		0,2%
0,2%	FI 6 yr	1,65	0,1%	Wheat	0,0%	Rye	0,0%	Oat		0,1%
0,2%	DK adult	1,64	0,1%	Wheat	0,0%	Rye	0,0%	Milk: Cattle		0,1%
0,2%	UK adult	1,61	0,1%	Wheat	0,0%	Milk: Cattle	0,0%	Wine grapes		0,1%
0,1%	FR infant	1,33	0,1%	Wheat	0,1%	Milk: Cattle	0,0%	Sugar beet roots		0,1%
0,1%	IE child	1,08	0,1%	Wheat	0,0%	Milk: Cattle	0,0%	Apples		0,1%
0,1%	FI adult	0,99	0,1%	Rye	0,0%	Wheat	0,0%	Oat		0,1%
0,0%	PL general	0,13	0,0%	Apples	0,0%	Potatoes	0,0%	Table grapes		

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of TAA is unlikely to present a public health concern.

A 3.15 IESTI calculations - Raw commodities

Show results for all crops

Unprocessed commodities

Results for children				Results for adults			
No. of commodities for which ARfD/ADI is exceeded (IESTI):			---	No. of commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Wheat	0 / 0,79	11	0,7%	Wheat	0 / 0,79	6,6
0,5%	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
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							

A 3.16 IESTI calculations - Processed commodities

Processed commodities

Results for children				**Results for adults**			
No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---	No of processed commodities for which ARfD/ADI is exceeded (IESTI):			---
IESTI				**IESTI**			
Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,8%	Wheat / milling (flour)	0 / 0,64	7,7	0,4%	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%	Barley / cooked	0 / 0,79	2,9	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
0,3%	Rye / milling (wholemeal)-l	0 / 0,79	2,8	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
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#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
Expand/collapse list							

Triazole lactic acid

A 3.17 Triazole lactic acid TMDI calculations

not applicable

A 3.18 IEDI calculations

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

TLA			
LOQs (mg/kg) range from:		to:	
Toxicological reference values			
ADI (mg/kg bw/day):	**0,3**	ARfD (mg/kg bw):	**0,3**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2018**	Year of evaluation:	**2018**

Input values

Details - chronic risk assessment

Supplementary results - chronic risk assessment

Details - acute risk assessment/children

Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	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)
TMDI/NEDI/IEDI calculation (based on average food consumption)	1,0%	NL toddler	2,93	0,6%	Milk: Cattle	0,1%	Apples	0,1%	Maize/corn		0,0%
	0,5%	UK infant	1,50	0,4%	Milk: Cattle	0,0%	Potatoes	0,0%	Wheat		0,0%
	0,5%	NL child	1,42	0,2%	Milk: Cattle	0,1%	Apples	0,0%	Wheat		0,0%
	0,5%	DE child	1,36	0,2%	Milk: Cattle	0,1%	Apples	0,0%	Wheat		0,0%
	0,4%	FR toddler 2 3 yr	1,27	0,3%	Milk: Cattle	0,0%	Apples	0,0%	Wheat		0,0%
	0,4%	FR child 3 15 yr	1,15	0,2%	Milk: Cattle	0,0%	Wheat	0,0%	Apples		0,0%
	0,3%	UK toddler	0,98	0,2%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes		0,0%
	0,3%	DK child	0,94	0,1%	Milk: Cattle	0,0%	Rye	0,0%	Wheat		0,1%
	0,3%	RO general	0,84	0,1%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes		0,0%
	0,3%	DE general	0,75	0,1%	Milk: Cattle	0,0%	Apples	0,0%	Sugar beet roots		0,0%
	0,3%	GEMS/Food G15	0,75	0,1%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes		0,1%
	0,2%	SE general	0,75	0,1%	Milk: Cattle	0,0%	Bovine: Muscle/meat	0,0%	Potatoes		0,0%
	0,2%	ES child	0,74	0,1%	Milk: Cattle	0,0%	Wheat	0,0%	Bovine: Muscle/meat		0,0%
	0,2%	GEMS/Food G07	0,74	0,1%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes		0,0%
	0,2%	DE women 14-50 yr	0,74	0,1%	Milk: Cattle	0,0%	Apples	0,0%	Wheat		0,0%
	0,2%	GEMS/Food G08	0,72	0,1%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes		0,1%
	0,2%	GEMS/Food G11	0,69	0,1%	Milk: Cattle	0,0%	Potatoes	0,0%	Wheat		0,0%
	0,2%	FR infant	0,67	0,2%	Milk: Cattle	0,0%	Apples	0,0%	Potatoes		0,0%
	0,2%	NL general	0,60	0,1%	Milk: Cattle	0,0%	Potatoes	0,0%	Apples		0,0%
	0,2%	GEMS/Food G10	0,60	0,1%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes		0,0%
	0,2%	GEMS/Food G06	0,49	0,1%	Wheat	0,0%	Milk: Cattle	0,0%	Table grapes		0,1%
	0,2%	IE adult	0,45	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Wine grapes		0,0%
	0,1%	FR adult	0,42	0,0%	Milk: Cattle	0,0%	Wine grapes	0,0%	Wheat		0,0%
	0,1%	ES adult	0,42	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Barley		0,0%
	0,1%	PT general	0,40	0,0%	Potatoes	0,0%	Wine grapes	0,0%	Wheat		0,0%
	0,1%	DK adult	0,38	0,1%	Milk: Cattle	0,0%	Wine grapes	0,0%	Apples		0,0%
	0,1%	LT adult	0,37	0,0%	Milk: Cattle	0,0%	Potatoes	0,0%	Apples		0,0%
	0,1%	UK adult	0,27	0,0%	Milk: Cattle	0,0%	Wine grapes	0,0%	Wheat		0,0%
	0,1%	UK vegetarian	0,26	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Wine grapes		0,0%
	0,1%	FI 3 yr	0,25	0,0%	Potatoes	0,0%	Oat	0,0%	Apples		0,0%
	0,1%	IT toddler	0,23	0,0%	Wheat	0,0%	Apples	0,0%	Potatoes		0,0%
	0,1%	FI 6 yr	0,19	0,0%	Potatoes	0,0%	Oat	0,0%	Wheat		0,0%
	0,1%	IE child	0,18	0,0%	Milk: Cattle	0,0%	Wheat	0,0%	Potatoes		0,0%
	0,1%	PL general	0,17	0,0%	Potatoes	0,0%	Apples	0,0%	Table grapes		
	0,1%	IT adult	0,17	0,0%	Wheat	0,0%	Apples	0,0%	Peaches		0,0%
	0,0%	FI adult	0,10	0,0%	Potatoes	0,0%	Apples	0,0%	Rye		0,0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of TLA is unlikely to present a public health concern.

A 3.19 IESTI calculations - Raw commodities

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,1%	Barley	0 / 0,08	0,44
0,1%	Wheat	0 / 0,02	0,32
0,05%	Rye	0 / 0,02	0,14

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)
0,1%	Barley	0 / 0,08	0,38
0,06%	Wheat	0 / 0,02	0,18
0,04%	Rye	0 / 0,02	0,11

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

A 3.20 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)
	0,2%	Barley / milling (flour)	0 / 0,3	0,55	2%	Barley / beer	0 / 0,14	4,9
	0,1%	Barley / cooked	0 / 0,08	0,29	0,03%	Wheat / bread/pizza	0 / 0,02	0,10
	0,1%	Wheat / milling (flour)	0 / 0,02	0,27	0,03%	Wheat / pasta	0 / 0,02	0,08
	0,0%	Wheat / milling (wholemea	0 / 0,02	0,12	0,03%	Wheat / bread	0 / 0,02	0,08
	0,0%	Rye / boiled	0 / 0,02	0,08	#ZAHL!	#ZAHL!	#ZAHL!	#ZAHL!
	0,0%	Rye / milling (wholemeal)-l	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!
	Expand/collapse list							

Kresoxim-methyl

A 3.21 Kresoxim-methyl TMDI calculations

European Food Safety Authority
EFSA PRIMo revision 3.1; 2019/03/19

Kresoxim-methyl			
LOQs (mg/kg) range from: 0.01	to: 0.05		
Toxicological reference values			
ADI (mg/kg bw/day):	0.4	ARfD (mg/kg bw):	insert valid entry
Source of ADI:	EFSA	Source of ARfD:	
Year of evaluation:	2014	Year of evaluation:	

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)
5%	DE child	18.75	1%	Oranges	0.9%	Apples	0.8%	Table grapes	0.1%	
5%	NL toddler	18.31	0.9%	Table grapes	0.8%	Apples	0.7%	Oranges	0.1%	
4%	GEMS/Food G06	14.69	0.8%	Tomatoes	0.6%	Table grapes	0.3%	Wheat	0.0%	
3%	FR child 3 15 yr	12.99	1%	Oranges	0.5%	Leeks	0.2%	Wheat	0.1%	
3%	NL child	11.75	0.6%	Table grapes	0.4%	Oranges	0.4%	Apples	0.1%	
3%	GEMS/Food G11	11.63	0.8%	Leeks	0.6%	Wine grapes	0.2%	Table grapes	0.1%	
3%	IE adult	11.43	0.7%	Wine grapes	0.3%	Oranges	0.3%	Peaches	0.1%	
3%	GEMS/Food G07	11.29	0.8%	Wine grapes	0.4%	Oranges	0.2%	Tomatoes	0.1%	
3%	PT general	11.16	1%	Wine grapes	0.3%	Peaches	0.2%	Tomatoes	0.0%	
3%	RO general	10.73	0.9%	Wine grapes	0.4%	Tomatoes	0.2%	Wheat	0.0%	
3%	GEMS/Food G08	10.54	0.6%	Wine grapes	0.3%	Tomatoes	0.2%	Leeks	0.1%	
3%	FR adult	10.24	1%	Wine grapes	0.3%	Leeks	0.2%	Oranges	0.0%	
2%	GEMS/Food G15	9.99	0.6%	Wine grapes	0.3%	Tomatoes	0.2%	Wheat	0.1%	
2%	DE women 14-50 yr	9.85	0.6%	Oranges	0.5%	Wine grapes	0.2%	Leeks	0.0%	
2%	DE general	9.10	0.5%	Oranges	0.5%	Wine grapes	0.2%	Leeks	0.0%	
2%	FR toddler 2 3 yr	9.09	0.7%	Leeks	0.4%	Oranges	0.2%	Apples	0.0%	
2%	GEMS/Food G10	8.79	0.3%	Oranges	0.3%	Tomatoes	0.2%	Wine grapes	0.1%	
2%	ES child	7.74	0.7%	Oranges	0.2%	Tomatoes	0.2%	Wheat	0.0%	
2%	DK child	7.43	0.3%	Rye	0.2%	Wheat	0.2%	Cucumbers	0.0%	
2%	NL general	7.28	0.4%	Leeks	0.3%	Wine grapes	0.3%	Oranges	0.0%	
2%	UK toddler	7.04	0.6%	Oranges	0.2%	Wheat	0.1%	Table grapes	0.0%	
2%	ES adult	6.61	0.4%	Oranges	0.2%	Wine grapes	0.2%	Peaches	0.0%	
2%	SE general	6.04	0.2%	Oranges	0.2%	Tomatoes	0.2%	Wheat	0.0%	
1%	IT toddler	5.88	0.3%	Tomatoes	0.3%	Wheat	0.3%	Peaches	0.0%	
1%	UK vegetarian	5.57	0.5%	Wine grapes	0.3%	Oranges	0.1%	Tomatoes	0.0%	
1%	FR infant	5.53	0.7%	Leeks	0.1%	Apples	0.1%	Strawberries	0.0%	
1%	DK adult	5.51	0.5%	Wine grapes	0.1%	Tomatoes	0.1%	Table grapes	0.0%	
1%	UK infant	5.14	0.4%	Oranges	0.2%	Milk: Cattle	0.1%	Wheat	0.0%	
1%	FI 3 yr	5.10	0.2%	Strawberries	0.1%	Cucumbers	0.1%	Table grapes	0.0%	
1%	IT adult	5.10	0.3%	Peaches	0.3%	Tomatoes	0.2%	Wheat	0.0%	
1%	UK adult	5.05	0.6%	Wine grapes	0.2%	Oranges	0.1%	Tomatoes	0.0%	
1.0%	FI 6 yr	3.99	0.1%	Strawberries	0.1%	Tomatoes	0.1%	Table grapes	0.0%	
0.9%	FI adult	3.58	0.2%	Wine grapes	0.1%	Tomatoes	0.1%	Oranges	0.1%	
0.9%	PL general	3.45	0.2%	Tomatoes	0.2%	Table grapes	0.1%	Apples	0.0%	
0.6%	LT adult	2.46	0.1%	Tomatoes	0.1%	Apples	0.1%	Rye	0.0%	
0.3%	IE child	1.05	0.1%	Wheat	0.0%	Table grapes	0.0%	Oranges	0.0%	

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Kresoxim-methyl is unlikely to present a public health concern.

A 3.22 IEDI calculations

Not applicable

A 3.23 IESTI calculations - Raw commodities

Not applicable

A 3.24 IESTI calculations - Processed commodities

Not applicable

A 3.25 Further considerations on combined toxicity (chronic)

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
Triazole alanine																				
Barley	0,621	STMR																		
Wheat	0,621	STMR																		
Rye	0,621	STMR																		
			µg/kg bw/day	3,11	6,16	2,76	0,49	1,92	2,86	4,13	2,81	2,67	1,63	2,45	1,03	1,76	0,65	1,38	1,52	2,57
			mg/kg bw/day	0,0031	0,0062	0,0028	0,0005	0,0019	0,0029	0,0041	0,0028	0,0027	0,0016	0,0024	0,0010	0,0018	0,0006	0,0014	0,0015	0,0026
			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
			HQ	**0,010**	**0,021**	**0,009**	**0,002**	**0,006**	**0,010**	**0,014**	**0,009**	**0,009**	**0,005**	**0,008**	**0,003**	**0,006**	**0,002**	**0,005**	**0,005**	**0,009**
Triazole lactic acid																				
Barley	0,022	STMR																		
Wheat	0,022	STMR																		
Rye	0,022	STMR																		
			µg/kg bw/day	0,1108	0,2183	0,0977	0,0173	0,0681	0,1020	0,1471	0,1093	0,0952	0,0577	0,0874	0,0363	0,0905	0,0241	0,0491	0,0547	0,0917
			mg/kg bw/day	1E-04	2E-04	1E-04	2E-05	7E-05	1E-04	1E-04	1E-04	1E-04	6E-05	9E-05	4E-05	9E-05	2E-05	5E-05	5E-05	9E-05
			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
			HQ	**0,000**	**0,001**	**0,000**	**0,000**	**0,000**	**0,000**	**0,000**	**0,000**	**0,000**	**0,000**	**0,000**	**0,000**	**0,000**	**0,000**	**0,000**	**0,000**	**0,000**
Cummulative risk HI				**0,011**	**0,021**	**0,010**	**0,002**	**0,007**	**0,010**	**0,014**	**0,010**	**0,009**	**0,006**	**0,008**	**0,004**	**0,006**	**0,002**	**0,005**	**0,005**	**0,009**

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	LT adult	NL general	PL general	PT general	RO general	SE general	UK adult	UK vegetarian	GEMS/Food G06	GEMS/Food G07	GEMS/Food G08	GEMS/Food G10	GEMS/Food G11	GEMS/Food G15	DE general	DE women 14-50 yr	IE child	FI 3 yr	FI 6 yr
Triazole alanine																						
Barley	0,621	STMR																				
Wheat	0,621	STMR																				
Rye	0,621	STMR																				
			µg/kg bw/day	1,36	1,43	0,00	2,54	3,15	2,17	1,06	1,30	4,56	3,03	3,45	2,87	2,74	3,45	1,85	1,75	0,72	1,19	1,02
			mg/kg bw/day	0,0014	0,0014	0,0000	0,0025	0,0031	0,0022	0,0011	0,0013	0,0046	0,0030	0,0035	0,0029	0,0027	0,0034	0,0018	0,0017	0,0007	0,0012	0,0010
			ADI	0,300	0,300	0,300	0,300	0,300	0,300	0,300	0,300	0,300	0,300	0,300	0,300	0,300	0,300	0,300	0,300	0,300	0,300	0,300
			HQ	**0,005**	**0,005**	**0,000**	**0,008**	**0,010**	**0,007**	**0,004**	**0,004**	**0,015**	**0,010**	**0,012**	**0,010**	**0,009**	**0,011**	**0,006**	**0,006**	**0,002**	**0,004**	**0,003**
Triazole lactic acid																						
Barley	0,022	STMR																				
Wheat	0,022	STMR																				
Rye	0,022	STMR																				
			µg/kg bw/day	0,0516	0,0672	0,0000	0,0916	0,1115	0,0769	0,0391	0,0470	0,1656	0,1416	0,1731	0,1350	0,1414	0,1666	0,0944	0,0726	0,0259	0,0457	0,0395
			mg/kg bw/day	5E-05	7E-05	0E+00	9E-05	1E-04	8E-05	4E-05	5E-05	2E-04	1E-04	2E-04	1E-04	1E-04	2E-04	9E-05	7E-05	3E-05	5E-05	4E-05
			ADI	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	0,3	1,3
			HQ	**0,000**	**0,000**	**0,000**	**0,000**	**0,000**	**0,000**	**0,000**	**0,000**	**0,001**	**0,000**	**0,001**	**0,000**	**0,000**	**0,001**	**0,000**	**0,000**	**0,000**	**0,000**	**0,000**
Cummulative risk HI				**0,005**	**0,005**	**0,000**	**0,009**	**0,011**	**0,007**	**0,004**	**0,004**	**0,016**	**0,011**	**0,012**	**0,010**	**0,010**	**0,012**	**0,006**	**0,006**	**0,003**	**0,004**	**0,003**

Appendix 4 Additional information provided by the applicant

Not applicable